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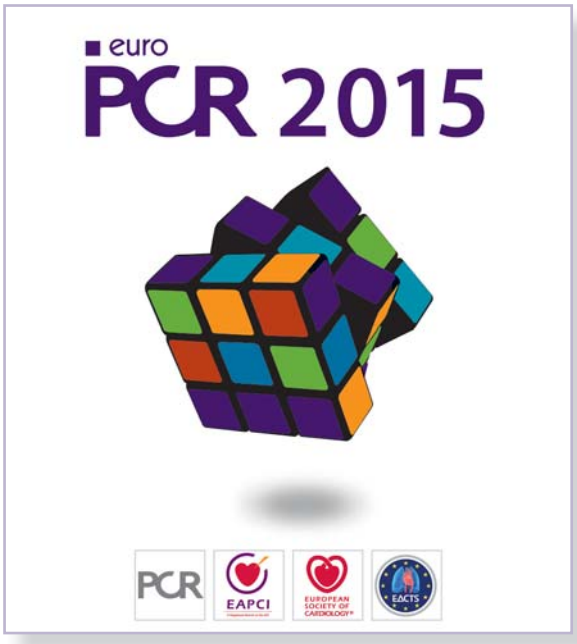

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FOREWORD

CORONARY INTERVENTIONS

INTERVENTIONS FOR HYPERTENSION & HEART FAILURE

INTERVENTIONS FOR STRUCTURAL HEART DISEASE

NURSES & TECHNICIANS

PERIPHERAL INTERVENTIONS

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Introduction to the scientific abstract presentations at EuroPCR 2015

Alberto Cremonesi, Jean Fajadet, William Wijns, Stephan Windecker, *EuroPCR Course Directors*

Please allow us to start by extending our deepest thanks to our interventional peers from around the world, who choose EuroPCR as the forum to share with us the results of their scientific research. It pleases us to see, year after year, the growing interest in presenting at EuroPCR reflected in the number of submissions received: a record 1,183 abstracts were submitted this year. EuroPCR functions today as the leading forum for learning and exchange between peers, to further one's education and enrich one's scientific knowledge.

The annual Abstracts Book, comprising a selection of the best abstracts being presented during this year's Course, is a valuable companion tool in the EuroPCR experience. Your scientific contributions are the foundation of this publication, created "by and for" you as an abstract submitter, much like the Course itself.

The PCR's got talent initiative was launched this year. The best graded 24 abstract presenters agreed to take part in a friendly competition by presenting 3 times, in different formats. They will receive coached advice and professional feedback on their communication skills, their ability to use presentation tools effectively and to deliver memorable key messages. Do not hesitate to attend these sessions taking place on the following dates :

First round: Wednesday 20th May 2015 - 10:30 am to 12:15 pm
Second round: Thursday 21st May 2015 - 16:50 pm to 18:20 pm
Third round: Friday 22nd May 2015 - 9:00 am to 10:00 am

The Best Presentation Award will be announced in the Main arena on Friday 22nd May during the closing ceremony.

This year's submission numbers, seen in **Table 1**, show a jump in the number of Coronary intervention abstracts received. After all, the case is not closed at all: there is need for continued research aiming at improving outcomes of coronary patients.

Table 1. Abstract submissions in categories and yearly comparisons.

Submissions	2013	2014	2015
Total abstracts	963	1,052	1,183
Coronary interventions	664	680	777
Interventions for structural heart disease	183	226	254
Peripheral interventions	84	76	78
Interventions for hypertension and heart failure	32	51	49
Nurses and technicians	0	19	25

The Nurses and technicians abstract submissions, introduced last year, are showing an encouraging growth from last year as well. It is promising to see that the EuroPCR community, bringing together a team of clinicians, nurses and technicians who deliver patient-centred interventional care, has been receptive to the initiative.

We would also like to draw your attention to the 317 posters, which are published online at http://www.pcronline.com/eurointervention/AbstractsEuroPCR2015. These posters will be displayed in the dedicated Poster area of the Palais des Congrès.

Before we conclude this introduction, let's have a look at how the geographical origin of the submissions has evolved this year, **Table 2**. It is no surprise that countries with an established submission track record are leading the top 10. It can be noted, however, that this year again, a great surge in submissions was sent from India. This confirms the growing interest coming from our Indian friends and colleagues and from other emerging nations, whom we encourage to keep submitting in the years to come.

Table 2. The geographical origins of the submissions.

	Country	Number of submissions	Number of authors
1	Japan	147	108
2	Italy	138	82
3	Germany	114	63
4	Spain	66	38
5	South Korea	64	40
6	United States	60	34
7	United Kingdom	54	43
8	The Netherlands	51	27
9	India	47	24
10	Switzerland	37	23

Getting such a great response to the call for submissions greatly pleases the Board of EuroPCR and the Programme Committee Members. Of course we could not close this introduction without mentioning the tireless work of our 122 esteemed graders and 16 Selection Committee Members, who not only gave up their valuable time to review and assess the submissions within a tight deadline, but also continuously uphold and protect the integrity of the scientific peer review. You will find a list of these esteemed colleagues in our acknowledgement.

In conclusion, we wish to welcome you, the readers, participants and contributors to another edition of EuroPCR 2015. We hope you enjoy the Course.

euro PCR Coronary interventions Euro15A-MA001

Advanced age and high-residual platelet reactivity in patients receiving dual antiplatelet therapy with clopidogrel or ticagrelor

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Aims: Elderly patients still represent a challenging subset of patients for the management of antithrombotic strategies, due to the complex balance between an increased frailty and risk of bleedings and an enhanced platelet reactivity. Therefore, controversies still exist on the optimisation of dual antiplatelet therapy after percutaneous coronary interventions or acute coronary syndromes in advanced age. The aim of present study was to evaluate the impact of age on platelet function and the occurrence of high-residual on treatment platelet reactivity (HRPR) in patients treated with dual antiplatelet therapy with ASA and clopidogrel or ticagrelor.

Methods and results: Patients treated with DAPT (ASA+clopidogrel or ticagrelor) for an ACS or elective PCI were scheduled for platelet function assessment at 30-90 days post-discharge. Platelet function was assessed by whole blood impedance aggregometry (Multiplate®-Roche Diagnostics AG), HRPR was considered for ASPI test >862 AU*min (for ASA) and ADP test values >417AU*min (for ADP-antagonists). Elderly were defined for age ≥70 years old. Among 494 patients on DAPT, 224 (45.3%) were ≥70 years old. Advanced age was associated with female gender (p=0.003), hypertension (p=0.001), previous myocardial infarction (p=0.005), surgical coronary revascularisation (p<0.001), renal failure (p<0.001), therapy with nitrates (p=0.02) and diuretics (p<0.001), while inversely with body mass index (p<0.001), smoking (p<0.001) and statins therapy (p<0.001). Age was directly related to C-reactive protein levels (p=0.02), fibrinogen and creatinine levels (p<0.001), and inversely to haemoglobin (p<0.001), and LDL cholesterol levels (p=0.01). Elderly had higher values of ADP-mediated platelet aggregation (341.8±185 vs. 298.7±168.8, p=0.006) and a reduced effectiveness of ADP-antagonists, while no difference was observed for other aggregation tests and for ASA response. In fact, among the 117 patients displaying HRPR (23.7%), a higher prevalence was observed among patients above 70-years-old (30.4%vs 18.1%, p=0.002, adjusted OR [95% CI]=2.14 [1.26-3.63], p=0.005). Similar results were obtained among the 266 clopidogrel treated patients (HRPR prevalence: 38.5% vs. 27.9%, p=0.09, adjusted OR [95% CI]=2.85 [1.42-5.7], p=0.003) and in the 228 patients receiving ticagrelor (HRPR rate: 19.1% vs. 8.1%, p=0.03, adjusted OR [95% CI]=2.93 [0.91-9.45], p=0.07).

Conclusions: In patients receiving dual antiplatelet therapy, advanced age is independently associated with a reduced effectiveness of ADP-antagonists and a higher rate of high-on treatment platelet reactivity with both clopidogrel and ticagrelor.

euro PCR Coronary interventions Euro15A-MA002

The role of thrombus aspiration for primary angioplasty in patients >75 years with ST elevated myocardial infarction: the ESTROFA-MI-elderly study

De La Torre Hernandez J.M.[1], Gomez Hospital J.A.[2], Brugaletta S.[3], Perez De Prado A.[4], Lopez Palop R.[5], Cid B.[6], Garcia Camarero T.[1], Diego A.[7], Gimeno De Carlos F.[8], Fernandez Diaz J.A.[9], Navarro Cuartero J.[10], Sanchis J.[11], Botas J.[12], Elizaga J.[13], Linares J.A.[14], Hernandez F.[15], Arrebola A.L.[16], Gomez Jaume A.[17], Salvatella N.[18], Rumoroso J.R.[19], Andraka L.[20], Monteagudo M.[21]

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Aims: Primary angioplasty is the best reperfusion treatment in ST-elevated myocardial infarction. The prevalence of very elderly patients (>75 years) undergoing primary angioplasty is progressively increasing as population is ageing. The benefit of thrombus aspiration is unknown for this important subgroup of patients.

Methods and results: Retrospective consecutive registry conducted in 21 centres. A total of 2,146 pts have been included and, among these,1,064 (49.5%) underwent thrombus aspiration and 1,082 (50.5%) did not. A propensity score matching was performed yielding two comparable groups of 432 patients each without significant differences in baseline clinical or angiographic characteristics. All patients had completed one-year follow-up. Outcomes at 12 months were: cumulative incidence of cardiac death, MI and TLR 22.2% without aspiration vs. 16.5% with aspiration (p=0.03), TLR 3.9% vs. 1.8% (p=0.1) and definite or probable stent thrombosis 3.6% vs. 1.1% (p=0.08) respectively.

Conclusions: In this registry, half of patients over 75 years underwent thrombus aspiration during primary angioplasty. In a propensity score-matching analysis the use of thrombus aspiration was associated to a significant improvement in clinical outcomes at 12 months.

Coronary interventions

Euro15A-MA003

Primary PCI in nonagenarian patients with STEMI: in-hospital mortality and outcomes at one year follow-up from a single centre registry

Muraglia S., Braito G., Dallago M., Menotti A., Casavecchia M., Bonmassari R.

S. Chiara Hospital, Trento, Italy

Aims: Limited information is available about the efficacy and outcomes after primary PCI in very elderly patients with STEMI.

Methods and results: We evaluated in-hospital, 6-months and 1-year mortality in a retrospective analysis of nonagenarian patients admitted in our department with STEMI and treated with primary PCI from November 2004 and December 2013. In this period 22 non-agenarian patients were treated (1% of the total STEMI population underwent PCI). All patients received aspirin and 300 mg clopidogrel loading dose. Mean age was 91.2 years (range 90-96). Sixty-four percent were women. Mean left ventricular ejection fraction (LVEF) at the admission was: 39% (23% of the cases with <LVEF 35%).Ten patients (41%) were in advanced Killip class (3-4) at presentation. Baseline characteristic were as follows: 13.6% of patients with prior myocardial revascularisation, 13.6% prior stroke, 22.7% diabetes, 40.9% hypertension, 4.5% atrial fibrillation. All patients presented a good mental status. Renal function was evaluated by creatinine clearance as measured by the Cockcroft–Gault equation: the mean value was 38.7 mL/min (range 16.8-72.9). The radial approach was performed in 68% (100% of cases from 2012). The percentage of radial to femoral shift was 6%. The mean number of vessels treated per patients was 1.04, showing a strategy of treating the culprit vessel only (3 left main, 8 left anterior descending coronary, 4 circumflex coronary artery, seven right coronary artery). An average of 1.18 stents per patients were implanted (100% were BMS). In four patients, we performed PCI without stent. No glycoprotein IIb/IIIa inhibitors were used. Intra-aortic balloon pump was implanted in one patient. The TIMI flow 2-3 post-PCI was achieved in 81.8% of cases. One patient developed acute renal failure post PCI and in one patient occurred major bleeding; no cases of stroke. The overall in-hospital mortality rate was 36.3% (one patient died during the procedure). Cumulative mortality at six months was 14% and at one year was 28.5%.

Conclusions: Our data suggest that primary PCI in nonagenarian can be performed with an acceptable bleeding risk. The radial approach is feasible and safe. The in-hospital mortality is significant but the cumulative mortality at 6-months and 1-year showed a good success rate of the PCI strategy. The invasive strategy in a select very elderly population can be offered.

Coronary interventions

Euro15A-MA004

ST elevation myocardial infarction in the elderly (>75 yrs): is PPCI for all ages?

Gifford J., Arri S., Corbo B., Gerber R.T.

East Sussex Healthcare NHS Trust, Hastings, United Kingdom

Aims: Patients in their eighth and ninth decade are grossly under-represented in randomised studies, in particular in relation to primary PCI (PPCI), and there is limited data on long-term outcomes following this procedure in the very elderly. We compare here, PPCI outcomes of very elderly patients (>80 yrs) to a cohort traditionally reported in the literature (75-80 yrs).

Methods and results: All consecutive patients aged 80 and over undergoing PPCI were selected from the institutional database and outcomes were compared to a younger cohort (75-80 yrs.). The primary endpoint was MACCE (major adverse cardiac and cerebrovascular events), defined as a composite of cardiac death, MI, stroke, target vessel (TVR) and target lesion revascularisation (TLR). The secondary endpoint was stent thrombosis (ST). One hundred and nine (109) consecutive patients undergoing PPCI were identified from the start of the heart attack programme and follow-up curtailed at 2013 to allow 12 months follow-up. The baseline characteristics of the two groups were similar: 53% male, 15% diabetic, 45% positive smoking history. In hospital periprocedural mortality was higher in the elderly cohort 11% (75-80 yrs.) vs. 21% (>80 yrs.). At 12-month follow-up MACCE was non-significantly higher in the more elderly cohort 33% vs. 19% as was cardiac mortality 13% vs. 11%. If in-hospital events are excluded, the long-term follow-up between the two groups is comparable (9% vs. 12%; p=ns). Stent thrombosis was slightly higher in the older group 3.85% vs 1.75% (p=0.6)

Conclusions: This study demonstrates an acceptable MACCE in a high-risk group following discharge from hospital. Periprocedural events in the very elderly group drive the higher MACCE rates. Further work is required to determine which elderly patient cohort should be offered PPCI and frailty scores may be of use in this context.

Percutaneous coronary angioplasty in elderly patients: net benefit from drug-eluting stents versus bare metal stents

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Aims: Limited data are available on long-term efficacy and safety of drug-eluting stents (DES) in elderly patients undergoing PCI.

Methods and results: A total of 635 consecutive elderly patients (aged ≥75 years) undergoing PCI were enrolled at two European centres. Of these, 170 patients received at least one DES, whereas 465 patients received bare metal stent (BMS) only. The primary endpoint was the incidence of net adverse clinical events, defined as the occurrence of ischaemic events or bleeding events, and was compared at a median follow-up of 31.2 months. Clinical follow-up information was available in 593 patients (93.4%). The duration of dual antiplatelet therapy was 12.3±5.1 months in the DES group, and 3.8±7.4 months in the BMS group. The Kaplan–Meier estimate of net adverse clinical events at 5 years were significantly lower in DES-treated patients (40.5%) than in BMS-treated patients (55.7%; p=0.009). This benefit was driven by a significant reduction in myocardial infarction (8.6 vs. 16.6%; p=0.038) and target vessel revascularisation rates (7.9 vs. 21.9%; p=0.003) in the DES group, with no significant increase in the incidence of bleeding events (13.8 vs. 12.2%; p=0.882). These results were confirmed at propensity score-adjusted Cox proportional hazard analysis.

Conclusions: In elderly patients, the use of DES compared with BMS seems to reduce myocardial infarction and repeat revascularisation rates at long-term follow-up, without an increase in bleeding despite longer duration of dual antiplatelet therapy. This net clinical benefit, resulting from persistent efficacy and safety over time, supports the use of DES as a reasonable option in elderly patients.

Index of microcirculatory resistance in patients with STEMI treated with primary angioplasty: relation with other indicators of microvascular reperfusion, infarct size and regional systolic function improvement

Baptista S., Faustino M., Loureiro J., Brizida L., Alves P., Nedio M., Monteiro C., Lourenço E., Leal P., Farto E Abreu P., Gil V., Morais C.

Hospital Fernando Fonseca, Amadora, Portugal

Aims: The index of microcirculatory resistance (IMR) was recently showed to have a prognostic value in patients with acute ST-elevation myocardial infarction (STEMI) treated with primary angioplasty (P-PCI). Probably, this new index reflects the microvascular involvement in the setting of myocardial infarction, but its relation with other measurements of microvascular reperfusion was not cleared showed. The purpose of this study was to compare IMR with other indirect measurements of microvascular reperfusion, with the extension of myocardial necrosis and with the regional systolic function improvement.

Methods and results: IMR was measured with a pressure-wire, in maximal hyperaemia obtained with adenosine, after successful P-PCI. Microvascular compromise was defined as an IMR≥40. TIMI frame count (TIMIfc) and TIMI myocardial perfusion grade (TMPG–Blush) were evaluated at the end of the procedure. ECGs were recorded before, immediately after, and at 90 and 180 min after P-PCI, for ST resolution evaluation. Troponin I (TnI) was measured at admission and every 6 hours after P-PCI, for the first 48 h. The area under the curve (AUC) of TnI release was calculated and this value was adjusted to the area at risk (APPROACH score). An echo was performed in the first 24 hours after P-PCI and again at 3 months, to measure the wall motion score index (WMSI) improvement. Fifty-two (52) patients were included (59.0±12.5 years, 42 males); 34 (65.4%) had an IMR<40 (group 1) and 18 (34.6%) had an IMR IMR≥40 (group 2). IMR correlated with TIMIfc (r=0.64, p<0.0001). Patients in group 1 had lower TIMIfc (15.3±4.2 vs. 23.3±7.9, p>0.0001) and more frequently TMPG≥2 (97.1% vs. 72.2%, p=0.015). The AUC of TnI release adjusted to the area at risk (452±277 vs. 701±539 ng/dl, p=0.032) and the TnI peak values (27.3±18.0 vs. 41.3±32.8, p=0.05) were both significantly lower in group 1. AUC of TnI release and peak TnI values correlated with IMR (r=0.48, p<0.0001 and 0.51, p<0.0001, respectively). There were no significant differences in ST resolution scores (ST-elevation and ST-deviation 180 min >70%) but these were very high in both groups (ST-elevation resolution: 85.3% vs. 83.3%, p=0.57; ST deviation resolution: 79.4% vs. 83.3%, p=0.52). The improvement in the WMSI was significantly higher in group 1 (-14.6±15.6 vs. –6.9±5.4, p=0.028).

Conclusions: IMR correlated with other indirect measurements of microvascular reperfusion in patients with STEMI treated with P-PCI. Patients with an IMR<40 (suggesting better microvascular reperfusion) had smaller infarctions and better WMSI improvement at three months. IMR can be considered as useful tool to evaluate microvascular reperfusion after STEMI, and can eventually be used as a surrogate endpoint for the evaluation of future treatments targeting the coronary microcirculation in this setting.

euroPCR Coronary interventions

Euro15A-MA007

Predictive role of serial assessment of coronary microvascular dysfunction in STEMI for left ventricular functional recovery

Lee M-J., Park S-D., Baek Y-S., Kwon S-W., Shin S-H., Woo S-I., Kim D-H., Kwan J.
Inha University Hospital, Incheon, South Korea

Aims: We assessed serial change of coronary microvascular dysfunction using the coronary flow reserve (CFR) and the index of microcirculatory resistance (IMR) in patients with ST–segment elevation myocardial infarction (STEMI). This study was performed to evaluate the relationship between serial change of coronary microcirculation and left ventricular functional recovery in patients with STEMI undergoing primary percutaneous coronary intervention (PCI).

Methods and results: Twenty STEMI patients who underwent successful primary PCI were enrolled. The CFR and IMR were assessed immediately after primary PCI and at the 9-months follow-up by using a coronary pressure-temperature sensor tip. To evaluate the left ventricular functional recovery, 2-dimensional transthoracic echocardiography (2D TTE) were obtained within 24 hours and at 9-months after primary PCI. Left ventricular ejection fraction (LVEF) and wall motion score index (WMSI) was assessed. The mean age of the study population was 53±11 years; 16 patients (80%) were men. The CFR and IMR measured immediately after primary PCI were 1.68±0.89 and 25.41±18.54 U. The baseline LVEF and WMSI were 49.3±5.7% and 1.4±0.2. At 9-month follow-up, the CFR significantly increased (1.68±0.89 vs. 3.93±1.43, p=0.002) and IMR decreased (25.41±18.54 vs. 18.97±8.31 U, p=0.480) as compared with baseline assessment. In correlation analysis, the change of CFR was strongly correlated with change of LVEF (r=0.704, p=0.005). However, the change of IMR did not show significant correlation with change of LVEF (r=0.014, p=0.962). In patients with LV functional recovery defined by LVEF ≥ 5%, the CFR more significantly increased than in the patients without LV functional improvement (3.35±1.1 vs. 0.76±0.51%, p<0.001). But, there was no significant difference in change of IMR between patients with or without LV functional recovery (–2.80±20.2 vs. –3.92±9.66 U, p=0.9).

Conclusions: On long-term serial assessment of coronary microcirculation, improvement in CFR is significantly associated with myocardial recovery after successful primary PCI in patients with STEMI.

euroPCR Coronary interventions

Euro15A-MA008

Quantitative assessment of microcirculatory resistance in infarct-related and non-infarct-related coronary arteries in patients with ST-segment elevation myocardial infarction treated with primary percutaneous coronary intervention

Orlic D., Ostojic M., Beleslin B., Zivkovic M., Dedovic V., Stojkovic S., Nedeljkovic M., Stankovic G.
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Aims: It has been shown that index of microcirculatory resistance (IMR) in infarct-related artery is an predictor of infarct size and recovery of left ventricular function in patients with ST-segment elevation myocardial infarction (STEMI) treated by primary percutaneous coronary intervention (PCI). However, microcirculatory resistance in non-infarct-related arteries remains unknown in patients with STEMI.

Methods and results: In 70 patients where the first STEMI was treated with primary PCI we determined IMR in infarct-related and non-infarct-related coronary arteries with no critical stenosis (diameter stenosis <70% in non-infarct-related arteries) in order to quantitatively assess microcirculatory resistance in infarcted and non-infarcted territories. Coronary wedge pressure was measured in the infarct-related artery and used for the calculation of corrected IMR. The IMR in infarct-related artery was significantly increased as compared with IMR in non-infarct-related arteries: median 32.5 U (range 7.4 to 162.1) vs. 20.3 U (range 7.9 to 49.9; p<0.001) in an adjacent vessel and 32.5 vs. 22.6 (range 5.9 to 105.1; p=0.0022) in artery giving collateral blood supply to the infarct-related artery. Corrected IMR was also increased compared to IMR in non-infarct-related arteries: 29.9 U (range 10.3 to 112.2) vs. 20.3 U, p<0.001 and 29.9 vs. 22.6 U, p=0.0047. The IMR values in the adjacent vessel and vessel giving collateral blood supply to infarct-related artery were similar (20.3 vs. 22.6 U, p=0.32).

Conclusions: Microcirculatory resistance is elevated in the territory of the infarct-related artery as compared with the non-infarct-related arteries in patients with STEMI. There is no difference in the microcirculatory resistance between vessels adjacent to infarct-related artery and vessel giving collateral blood supply to infarct-related artery.

Predictors of microcirculatory dysfunction in STEMI patients treated with primary angioplasty

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Aims: Despite normalisation of epicardial coronary flow after primary angioplasty (P-PCI) in patients with ST-elevation acute myocardial infarction (STEMI), many patients have a worse evolution due to microcirculatory dysfunction. The index of microcirculatory resistance (IMR) can be used to evaluate the coronary microcirculation and its prognostic value in STEMI patient was recently established. The purpose of this study was to identify predictors of IMR in patients with STEMI treated with P-PCI.

Methods and results: IMR was measured with a pressure-wire at maximal hyperaemia obtained with adenosine after successful P-PCI. The impact of main epidemiological, clinical and procedure variables in IMR values was evaluated. Fifty-two (52) patients were included (59.0±12.5 years, 42 males). The infarct related artery was the LAD, LCX and RCA respectively in 23 (44.2%), 11 (21.2%) and 18 (34.6%) patients. Median pain-to-balloon time was 195 min (IQR 122 min) and median first medical contact (FMC)-to-balloon time was 80 min (IQR 37 min). Mechanical thrombus aspiration was performed in 26 (50%) patients and abciximab was administered in 11 (21.2%). Median IMR value was 24 (IQR 33). On univariate analysis, glucose admission values was the only continuous variable related with IMR (r=0.42, p=0.003). Other variables, including age, pain-to-balloon time, FMC-to-balloon time and proBNP admission values were not related with IMR (p=ns). Among categorical variables, significant lower values of IMR were observed in patients treated with abciximab (median IMR 14.5; IQR 5.8 vs. 27.0; IQR 33; p=0.001). There was also a trend to higher values of IMR in patients with balloon pre-dilatation of the culprit lesion (median IMR 25.5; IQR 35.5 vs. 22.0; IQR 27.0, p=0.079). There were no significant differences in other variables, including gender, cardiovascular risk factors or other treatments, including the use of mechanical thrombus aspiration. On multivariable analysis, including variables identified as significant in the univariate analysis and also other clinically relevant variables (age, diabetes, pain-to-balloon time), glucose admission values (ß=0.472, p=0.001), treatment with abciximab (ß=-0.279, p=0.034) and age (ß=0.280, p=0.034) were showed to have and independent impact on the IMR values.

Conclusions: As reported in previous studies, age is positively related with IMR values in patients with STEMI treated with P-PCI. Abciximab treatment was associated with significant lower values of IMR, suggesting that it is useful in reducing microvascular lesion. Glucose admission values (a well-known risk marker in STEMI patients) were a strong predictor of IMR, suggesting that acute hyperglycaemia may also have a role in microvascular dysfunction in this setting. Mechanical thrombus aspiration was not related with better IMR values. These results should be confirmed in randomised trials.

Residual intra-stent thrombus and microcirculatory indexes during primary angioplasty: insights from the COCKTAIL II study

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Aims: Recent FD-OCT studies showed that, even with the use of aggressive technical solutions, a complete removal of thrombotic materials is rarely achieved after percutaneous coronary interventions for ST-segment elevation myocardial infarction (STEMI). Residual intra-stent thrombus can result in distal embolisation leading to microcirculatory injury. The aim of this study was to find a possible correlation between residual intra-stent thrombus and angiographic indexes of myocardial reperfusion.

Methods and results: The study population consisted of 128 STEMI patients which underwent primary PCI within 6 hours from onset of chest pain and randomised to one of the following four treatments: local infusion of abciximab delivered by the ClearWay with (group 1) or without thrombectomy (group 2), intracoronary abciximab with (group 3) or without thrombectomy (group 4). Intra-stent thrombus at OCT assessment was defined as the maximum % value of thrombus area (thrombus area/stent area x 100 in the cross section with largest thrombus). A thrombus area >16% (median value) was considered indicative of high residual intra-stent thrombus. By study design, the following angiographic indexes of myocardial reperfusion were evaluated: TIMI value, corrected TIMI frame count (cTFC) and myocardial blush grade (MBG). The study population consisted of 119 patients: 64 had a maximum % value of thrombus area <16%, whilst the remaining 55 had a residual intra-stent thrombus >16%. No differences were found between the two groups regarding the microcirculatory indexes at baseline angiogram. After intervention patients with intra-stent thrombus <16% showed a significant improvement in the final TIMI value (2.87±0.33 vs. 2.67±0.54; p=0.014) and final cTFC (11.71±4.58 vs. 17.44±17.44; p=0.012) and a non-significant improvement in the final MBG value (2.58±0.59 vs. 2.43±0.76; p=0.254).

Conclusions: Data obtained from the COCTAIL II study suggest that the presence of high residual intra-stent thrombus in patients undergoing primary angioplasty is associated with worsened final microcirculatory indexes.

EuroPCR Coronary interventions

Euro15A-MA011

Comparison of radiation exposure between left radial and femoral access in CABG patients

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Aims: Access for coronary angiography (CAG) and/or PCI (CAG+PCI) in CABG patients is usually restricted to the left radial (LRA) or either femoral artery (FA). To our knowledge, the radiation doses between these routes has not been compared in this specific setting. The aim of this study was to compare the radiation exposure between LRA and FA in CABG patients.

Methods and results: This was a single-centre study from a prospective database performed in the period 2009-2014. To reduce bias related to the use of different angiographic systems, we use data from a single cathlab suite. From a total of 5,339 procedures, we selected consecutive CABG patients submitted to CAG (n=217) or CAG+PCI (n=189) through LRA or FA. Radiation was measured by an angiographic systems with an integrated collimator and data was collected on fluoroscopy time (FT, in minutes) and dose-area product (DAP, in Gy·cm^2). Statistical analysis was performed with Mann-Whitney and Fisher's exact test. In the CAG group, there were no significant differences between LRA and FA in median (interquartile range) of DAP or FT: 16.5 (76) vs. 10.9 (30) (p=ns) and 8.7 (14) vs. 9.2 (10) (p=ns). In the CAG+PCI group there was a non-significant trend towards higher DAP in LRA but not in FT: 98.6 (198) vs. 22.7 (78) (p=0.061) and 21.3 (30) vs. 18.4 (13) (p=ns). The median number of grafts did not differ between LRA vs. FA groups in both CAG and CAG+PCI. The need for a second arterial access was higher with LRA than FA (16% vs. 1.7%, p<0.0001).

Conclusions: The radiation exposure does not differ significantly with the use of femoral vs. left radial artery access for coronary angiography or angiography in CABG patients, although it was numerically higher in the latter group. There was a significantly higher need for an alternative access with LRA. These data suggest that even in CABG patients, the current trend towards radial access should be maintained.

EuroPCR Coronary interventions

Euro15A-MA012

The influence of the access sites on procedure time, fluoroscopy time and contrast volume in PCI

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Aims: Procedure time (PT) and fluoroscopy time (FT) not only are indicators of radiation hazards but also are associated with periprocedural complications and early mortality. The amount of contrast media (CM) used during percutaneous coronary intervention (PCI) is also a predictor of post-procedural renal dysfunctions. As different access sites using different procedural techniques, we investigated the influence of the access sites during PCI on the PT, the FT and the amount of CM.

Methods and results: From February to October 2013, patients undergoing coronary angiography in 20 centres of South Korea were enrolled in Korean TRI Prospective Registry. Among the patients, 1,805 patients who had undergone at least one coronary artery stent implantation were selected for analysis. A definition of complex PCI includes PCIs for two or more vessel CAD, heavy calcifications, a lesion with severe tortuousness, a lesion length >20 mm, a CTO lesion, a bifurcation lesion and a left main disease. TFIs were performed in 395 patients and TRIs were performed in 1,410 patients. The complex PCI was noted in 903 patients (50.1%). Diabetes, renal dysfunction, peripheral artery diseases, acute coronary syndrome, prior PCI and prior bypass surgery were more frequent in the TFI group than in the TRI group. The sheath size was larger in the TFI group. However, the numbers of significant coronary lesions, the frequency of the complex PCI and the implanted stent length did not differ between the two groups. The procedure time was marginally longer in the TFI group than in the TRI group (28/45/70 minutes vs. 29/42/60 minutes as the first quartile/median/the third quartile values, p=0.087), while the FT (8/14.7/24.3 minutes vs. 8/12/19 minutes, p<0.001) was significantly longer and the CM volume (240.5±120.4 ml vs.218.7±105.4 ml, p=0.002) was significantly larger in the TFI group. In patients undergoing a simple PCI, the PT, the FT and the contrast volume did not differ between the TFI group and the TRI group. By contrast, the PT and FT were longer, and the contrast volume was larger in the TFI group in patients undergoing complex PCI. After age, gender, comorbidities, PCI indications and the sheath sizes were adjusted, a multiple linear regression analysis showed that the complex PCI and performing TFI were significantly associated with longer PT and FT, whereas the access sites was not significantly associated with the CM volume.

Conclusions: TFIs were associated with longer PT and FT and use of larger amount of CM, compare to TRIs. Although these results should be interpreted carefully because there were differences in comorbidities between the TFI group and the TRI group, TRIs would be non-inferior to TFIs in terms of radiation hazards and contrast-associated renal dysfunctions.

Comparison of success rate, procedural factors, and radiation exposure for coronary angiography between the right and left radial approach: Korean Transradial Coronary Intervention Prospective Registry (KOTRI)

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Aims: We aimed to compare the success rate, procedural factors and radiation exposure according to radial access site in patients in which coronary angiography (CAG) was performed.

Methods and results: The study population was from a TRI prospective registry from 20 institutes in Korea. Exclusion criteria were patients with over 30% of data missing, invalid data, less than 19-year-olds, patients who received interventional treatment and patients who received CAG via the femoral approach. Among 5,779 patients, a total of 3,496 were assessed for data analysis. Success rate for CAG, crossover rate, procedural factors, fluoroscopic time and fluoroscopic dose were compared between the right radial (RR) and left radial (LR) approaches. The mean age was 62.9±11.6 years and 1,974 patients (56.5%) were male. The use of EMLA cream was higher in the LR group (29.2% vs. 14.0%, p<0.001). CAG with single catheter was similar between the RR and LR group (14.5% vs. 15.1%, p=0.652). Success rate for CAG was higher in the RR group (99.4% vs. 98.1%, p=0.001). Crossover rates were higher in the LR group (1.9% vs. 0.6%, p<0.001). The most common cause for crossover was puncture failure (0.3% vs. 1.2%, p=0.002). Puncture time and CAG time were faster in the LR group (2.1±2.7 min vs. 2.5±3.0 min, p<0.001; 10.4±7.4 min vs. 11.3±8.7 min, p=0.003). The LR group showed lower fluoroscopic time, dose (3.5±3.6 min vs. 4.9±6.6 min, p<0.001; 37.5±47.8 Gycm^2 vs. 41.1±42.2 Gycm^2, p<0.001) and higher total contrast volume (84.8±41.1 mL vs. 77.4±33.9 mL, p<0.001).

Conclusions: In the KOTRI analysis, the success rate for CAG was higher in the RR group, but radiation time and dose were lower in the LR group. The most common cause of crossover was puncture failure.

Radiation exposure of the operator during coronary interventions: comparison of right radial, left radial and right femoral approach

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Aims: Because of a presumably increased incidence of long-term malignancy in interventional cardiologists, radiation exposure of the operator during coronary interventions is of rising concern. A few studies concerning the operator radiation exposure comparing femoral to radial or radial right to radial left access have previously been published, but no data comparing the three access sites are available to our knowledge. We therefore sought to compare the operator radiation exposure by right femoral (RFA), right radial (RRA) and left radial (LRA) access during percutaneous catheterisation for diagnostic coronary angiography (CA) with or without coronary angioplasty (PCI).

Methods and results: From September 2014 to January 2015, all consecutive patients (n=510) undergoing elective or emergency CA±PCI, performed by five interventional cardiologists in our catheterisation laboratory at Fribourg Hospital, Switzerland, were prospectively included. The selection of the percutaneous access site was left to the discretion of the interventional cardiologist. Operator radiation was measured using individual electronic radiation dosimeter badges positioned externally on the sternum. Radioprotection materials and equipment was similar for all procedures. The primary endpoint was operator radiation exposure, quantified as cumulative dose (CD) per dose-area product (DAP), in order to adjust for the administered radiation dose. A total of 510 consecutive procedures (278 CA and 232 PCI) were performed, of which 276 were realised via the RFA, 171 via the RRA and 63 via the LRA. The cumulative dose of radiation received by the operator was significantly lower in the RFA compared to the RRA or the LRA group (RFA 7.0±10.7 µSv vs. RRA 28.6±61.1 µSv, p<0.001, vs. LRA 9.6±18.3 µSv, p=0.003). The latter approach showed a significantly lower cumulative dose compared to RRA (p<0.001). There was no difference in the DAP between the LRA and RRA group (LRA 3,594±2,472 Gycm^2 vs. RRA 4,338±2,912 Gycm^2, p=0.07). The RFA group, however, demonstrated higher levels (RFA 6,012±6,680 Gycm^2) compared to both RRA (p=0.049) and LRA (p=0.002), probably due to procedural complexity and/or operator's procedural technique. The adjusted operator radiation exposure defined as CD/DAP was significantly lower in the RFA compared to the RRA or the LRA group (RFA 0.15±0.21 Sv/Gycm^2 vs. RRA 0.62±0.73 Sv/Gycm^2, p<0.001, vs. LRA 0.28±0.26 Sv/Gycm^2, p<0.001). Operator radiation exposure was equally lower in the LRA compared to the RRA group (p<0.001).

Conclusions: The RFA in percutaneous coronary angiography and percutaneous coronary intervention is associated with significantly lower operator radiation exposure when compared to the RRA or LRA. The LRA is associated with significantly lower operator radiation exposure when compared to the RRA.

Coronary interventions

Euro15A-MA015

Reduction in operator radiation exposure during transradial coronary procedures using a simple lead rectangle

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Aims: Transradial access for cardiac catheterisation and intervention is a recognised method for reducing complications and improving patient comfort. However, there are concerns over possible increased operator radiation exposure. A lead attenuator was shown in preclinical studies to reduce operator radiation dose. This study sought to determine the efficacy of lead attenuator shielding for the reduction of operator radiation exposure during percutaneous coronary procedures via the radial access.

Methods and results: Patients undergoing either diagnostic or interventional procedures using transradial access were assigned in a consecutive manner to the use of a 0.5 mm lead rectangle (60 cm×100 cm) across the patient's abdomen and pelvis from the umbilicus down, in addition to standard operator protection. Patients were divided into 2 groups: enhanced shielding vs. standard shielding. Dosimeters were taped to the patient's umbilicus site underneath and over the lead rectangle and primary operator outside the thyroid guard. Dosimeters were read after 10 -16 consecutive patients have been recruited. All data was normalised to the same dose-area product. The operator exposure was measured for each site in millisievert (mSv). The same operator performed all procedures, to reduce variability in radiation absorption. Fifty-two (52) consecutive patients undergoing coronary angiography and angioplasty by radial approach were recruited to pelvic attenuator use versus no radiation shield protection (26 with attenuator, 26 control). No difference was found in baseline characteristics. Despite similar average fluoroscopy time (12.3±9.8 min vs. 9.3±5.4 min, p=0.175) and average examination dose (111,866±80,790 vs. 91,268±47,916 Gycm^2, p=0.2688), the mean total radiation exposure to the operator at the thyroid level was significantly lower when pelvic attenuator was utilised (20.2% p<0.0001). At the umbilical level, readings showed significant radiation dose reduction of 94.5% p<0.0001 with the attenuator compare to control.

Conclusions: The use of a lead rectangle reduces significantly the rate of operator radiation exposure at the thyroid and umbilical measurement sites. A lead attenuator is a highly effective novel solution to reduce operator's radiation exposure during radial procedures and a lead rectangle should be regarded as a standard and mandatory tool in the catheterisation laboratory.

Coronary interventions

Euro15A-MA016

Clinical impact of various types of stents on midterm prognosis of patients with vasospastic angina

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Aims: DES, especially first generation DES, implantation may be associated with endothelial dysfunction. However, the clinical impact of various types of stents on patients with vasospastic angina (VSA) had been poorly understood. The purpose of the present study was to evaluate whether the implantation of BMS, sirolimus-eluting stent (SES) or newer generation DES (N-DES) affects the midterm prognosis of VSA patients.

Methods and results: From May 1997 to January 2014, 3,522 patients with chest pain had undergone an ergonovine provocation test for the first time in our hospital. The patients were divided into two groups based on the test results: 650 patients with positive results (VSA) and 2,872 patients with negative results (non-VSA). Due to the progression of coronary artery stenosis, the implantation of BMS, SES, or N-DES, including biolimus-, everolimus- and zotarolimus-eluting stents was performed in 115 VSA patients and 191 non-VSA patients: BMS for VSA patients (BMS-V), n=68; BMS for non-VSA patients (BMS-NV), n=78; SES for VSA patients (SES-V), n=21; SES for non-VSA patients (SES-NV), n=51; N-DES for VSA patients (N-DES-V), n=26, and N-DES for non-VSA patients (N-DES-NV), n=62. Angiographic follow-up was performed on all patients within 8 months after stent implantation. A composite of cardiovascular events which included target lesion revascularisation, target vessel revascularisation, emergency coronary angiography due to unstable angina or acute myocardial infarction and cardiac death within 12 months after stent implantation was evaluated in three stent groups. The composite event rate was significantly higher in SES-V than in SES-NV (38.1% vs. 11.8%, p=0.02). In contrast, it showed no significant difference between BMS-V and BMS-NV (30.9% vs. 30.7%, p=1.00) and between N-DES-V and N-DES-NV (15.4% vs. 12.9%, p=0.74).

Conclusions: The implantation of BMS or N-DES does not affect the midterm prognosis of VSA patients. In contrast, the implantation of SES may increase cardiovascular events in VSA patients.

Preliminary experience with drug-coated balloon angioplasty as primary therapy in primary PCI for STEMI

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Aims: Primary PCI (PPCI) is the preferred reperfusion therapy for STEMI. Stent implantation (whether with BMS or DES) is considered as routine during PPCI as it is associated with reduction of early ischaemia, restenosis and reocclusion of the culprit artery in comparison with pure old balloon angioplasty (POBA). Drug-coated balloon (DCB) has emerged as a new therapeutic option to treat coronary artery disease as stent technology has certain limitations. There is, however, limited data on the feasibility of using DCB as primary therapy in PPCI. Previous clinical studies had shown no difference in the mortality rates between those who received stents or POBA during PPCI with the main difference driven largely by lower rate of target vessel revascularisation (TVR) in the stenting group. It is possible that DCB could close this gap for the POBA group, and we therefore evaluated the clinical feasibility (i.e., safety and efficacy) of using paclitaxel-coated balloons in our cohort of Southeast Asian patients undergoing PPCI for STEMI.
Methods and results: Between January 2010 to September 2014, 89 STEMI patients (83% male, mean age 59±14 years) with a total of 89 coronary lesions were treated with SeQuent Please DCB during PPCI. The PPCI strategy was to perform thrombus aspiration (for visible thrombus) followed by predilatation of lesion site before treatment with DCB. Bailout stenting was performed only when there was significant vessel recoil/coronary dissection (>type B dissection). Clinical outcomes are reported at 30 days follow-up. The majority of patients presented with inferior STEMI (55%) with the left anterior descending artery (LAD) being the most common target vessel for PCI (37%) followed by right coronary artery (33%), left circumflex (13.5%) and others (17%); 28% of the patients had underlying diabetes mellitus. Mean left ventricular ejection fraction was 44±11%. Thrombus aspiration was performed in 50 patients (56%) with glycoprotein IIb/IIIa inhibitors administered in 71 patients (80%). Preprocedural Thrombolysis in Myocardial Infarction (TIMI) flow was 0 in 70% of patients. At the end of PPCI, TIMI 3 flow was successfully restored in 98% of patients with residual stenosis of 29%. DCB-only PCI was the predominant approach (96% of patients) with the remaining 4% of patients receiving bailout stenting for significant recoil/dissection after treatment with DCB. An average of 1.2±0.5 DCB were used per patient, with mean DCB diameter of 2.6±0.5 mm and average length of 23.2±10.2 mm. The mean inflation pressure for DCB was 10±3 atm and mean inflation time was 54±22 seconds. At 30-day follow-up, there were four deaths (4.5%). Three patients succumbed due to cardiogenic shock and one died of sepsis. No patients experienced abrupt closure of the infarct-related artery and there was no reported target-lesion failure, target vessel MI or target lesion thrombosis.
Conclusions: Our preliminary experience showed that the use of DCB as primary therapy for STEMI patients in PPCI was feasible and associated with a high rate of final TIMI 3 flow and low 30-day major adverse cardiac event. Further studies with longer follow-up are required to confirm our initial observation.

First-in-man (FIM) evaluation of a novel balloon delivery system for the self-apposing coronary artery stent: 30-day results

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Aims: To evaluate the safety and feasibility of a novel balloon delivery system for the STENTYS® sirolimus eluting stent based on the clinical and angiographic results of a multicentre, single-arm first-in-man study of 25 all-comer patients.
Methods and results: The novel balloon delivery system (BDS) developed for the self-apposing STENTYS® sirolimus-eluting stent (SES) consists of inflating a balloon at low pressures to split the covering delivery sheath longitudinally, which releases the self-apposing STENTYS SES. The stent deploys and apposes to the vessel wall where after the "jailed" sheath is retracted. This system aims for easy delivery and a highly precise longitudinal placement of the STENTYS SES. This first-in-man, prospective, non-randomised, single-arm study included 25 patients (mean age 66.1±10.7 years) with *de novo* coronary lesions in two European centres. Indication for PCI was in seven patients (28%) ST-segment elevation myocardial infarction (STEMI), 1 patient (4%) Non-STEMI, 3 (12%) stabilised STEMI, 8 (32%) stabilised Non-STEMI, and six (24%) stable angina. Patients with lesions ≤ 25 mm in length and with a reference vessel diameter of >2.5 mm and <6.0 mm were eligible. All patients underwent PCI using the STENTYS SES-BDS. Optical coherence tomography (OCT) was performed post-procedurally to evaluate acute stent strut malapposition. Off-line two-dimensional quantitative coronary angiography (QCA) analyses were used to measure acute gain and longitudinal geographical miss (LGM) which was defined as uncovered diseased target vessel segment by the SES. In all patients, stent crossing of the lesion and deployment of the STENTYS SES-BDS was successful, without any periprocedural complications. As assessed by QCA, mean stenosis MLD was 1.30±0.74 mm, 2.71±0.30 mm direct post-stenting, and 2.74±0.44 mm after post-dilatation. The post-procedural MLD after post-dilatation was not significantly larger as compared to the MLD immediate post-stenting (p=0.277) using the Wilcoxon test. Post-procedural acute gain was 1.44±0.70 mm and LGM was not observed (0%). At 30-day clinical follow-up, 2 (8%) major adverse cardiac events (MACE; defined as the composite of cardiac death, myocardial infarction [MI] and target vessel revascularisation) were observed. The events observed were; one acute stent thrombosis direct post-procedural, as result of inadequate preprocedural antithrombotic therapy, the second non-fatal MI was in a non-target vessel.
Conclusions: This first-in-man experience demonstrates that intracoronary deployment of the self-apposing STENTYS® SES-BDS is feasible with a high procedural success rate and no LGM. This novel delivery system represents an improvement as compared to the manually retractable delivery sheath for self-apposing devices in terms of ease of use and stent placement accuracy. Our angiographic data shows that the final MLD did not significantly improve after balloon post-dilatation, which suggests that expansion of the self-apposing STENTYS® SES-BDS may be optimal immediately after stent placement and deployment. OCT results to confirm our findings will be presented at EuroPCR2015.

euroPCR Coronary interventions

Euro15A-MA019

Seven-year outcomes from a single centre registry of excimer laser coronary atherectomy performed for degenerate saphenous vein graft stenosis

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Aims: Excimer coronary laser angioplasty (ELCA) as an adjunctive to coronary angioplasty can be utilised in specific subsets of percutaneous coronary intervention. The major drawbacks of perforation, major dissection and abrupt vessel closure discourage widespread uptake. We demonstrate a UK single centre outcome data of ELCA as compared to conventional balloon angioplasty over a seven-year period in the treatment of SVG lesions.

Methods and results: Data collection was prospective. Four hundred and eight (408) patients underwent saphenous vein graft PCI between January 2007 and December 2014 in a single UK centre. Fifty-one (51) patients underwent 0.9, 1.7 or 2 mm laser angioplasty using the concentric ELCA™ coronary laser atherectomy catheter (Spectranetics, Colorado Springs, CO, USA) and 357 underwent conventional angioplasty. Data was extracted from the British Cardiovascular Intervention Society dataset under the auspices of the Central Cardiac Audit database and mortality tracking was 100% using unique NHS patient identifier. Procedural outcome and survival data was obtained to 4 years. Data analysis was performed using chi-squared analysis and Mann-Whitney U test for categorical and continuous variables respectively. There was no difference in baseline patient characteristics between the two groups, although acute coronary syndrome was the more common presentation in conventional SVG PCI when compared to ELCA cohort. There were no significant differences in total MACCE (7% conventional vs. 4% ELCA; p=0.44); however, there was absolute reduction in-hospital mortality in laser cohort (0/51 vs. 11/357; p=0.3). No CK rise was observed with ELCA. ELCA was associated with high procedural success (50/51; 98%); with all patients achieving TIMI III (90%) or TIMI II (10%) flow grade. ELCA facilitated the use of distal protection device in 67% with adjunctive GPIIB/IIIA necessitated in 47% due to high thrombus burden.

Conclusions: This single centre experience demonstrates the safety and feasibility of ELCA performed with minimal procedural risks or complication in degenerate SVGs that comprise a lesion subset at high risk for periprocedural complications in an experienced centre. We noted a trend toward early outcome benefit in appropriately selected patient groups.

euroPCR Coronary interventions

Euro15A-MA020

Percutaneous coronary intervention of complex calcified lesions with rotational atherectomy followed by drug-eluting balloon treatment

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Aims: Drug-eluting balloon (DEB) has been shown to be effective for the treatment of in-stent restenosis. The feasibility of DEB in other types of percutaneous coronary interventions (PCI) is less well established. Complex calcified coronary artery lesions may need preparation with rotational atherectomy (rotablation) before angioplasty, usually followed by implantation of a drug-eluting stent. In a retrospective single-centre study, we investigated the efficacy and safety of DEB after rotablation in patients with a high risk of bleeding.

Methods and results: Eighty-two (82) PCIs using rotablation followed by DEB treatment were performed in 65 patients (mean age 72±10 years, 68% male) between March 2011 and December 2013. Major cardiovascular adverse effects (MACE, the composite of death, non-fatal myocardial infarction and target lesion revascularisation) and bleeding events were studied. The median follow-up time was 18 months. Of the study patients, 37% were diabetic, 25% had suffered prior myocardial infarction, 47% of patients had reduced ejection fraction (<50%) and 31% had moderate to severe renal failure. Prior bleeding events counted for 25% of the patients and 40% used an oral anticoagulant, with 32% having had an acute coronary syndrome. Only one PCI (1.5%) was done for in-stent restenosis and the rest for *de novo* lesions. Rotablation followed by DEB treatment was used in 12 left main lesions (11% of the population). The 12 and 24 month MACE rate was 13% and 23%, respectively, mainly driven by death (6% at 12 months and 17% at 24 months). The rate of ischaemia-driven target lesion revascularisation was only 1.5% by 12 months and 3% by 24 months. No acute closure of the treated vessel occurred. The 12-month rate of significant bleeding was 8%. The median duration of DAPT was one month. Bailout stenting was needed only in 10% of the cases after DEB treatment. Control angiograms showed positive remodelling of the treated lesion.

Conclusions: This is the first study to show that PCI using DEB treatment after the preparation of complex calcified lesions with rotablation is safe and efficient including in patients with the left main disease. The rate of target lesion revascularisation was low. DEB requires a short term DAPT (1 month), which is beneficial in patients who have a significant bleeding risk such as those using an oral anticoagulant.

Clinical characteristics and 12-month outcomes of patients treated with warfarin undergoing PCI

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Aims: Patients treated with warfarin who undergo PCI present a difficult therapeutic problem. Their baseline demographics, procedural characteristics and 12-month outcomes are poorly defined.
Methods and results: We conducted a retrospective analysis of all patients who underwent PCI at a UK cardiac centre between 2012 and 2013 and used internal and national databases to source study data. Of the 2,678 patients who underwent PCI, 158 were on long-term warfarin (5.9%). Patients on warfarin were older (73.0±11.3 vs. 65.6±11.8 years, p<0.0001), more likely to have a previous history of CABG (14.1 vs. 5.8%, p<0.0001), MI (35.4 vs. 28.7%, p<0.05) or severe LV dysfunction (15.0 vs. 5.8%, p=0.078), and more likely to have significant comorbidity including hypertension (73.4 vs. 63.4%, p<0.01), diabetes (21.1 vs. 17.4%, p<0.05), chronic kidney disease (5.2 vs. 3.2%, p<0.05) peripheral vascular disease (7.0 vs. 2.6%, p<0.001) or history of stroke (5.1 vs. 1.6%, p<0.001) than patients not on warfarin. The modified Mehran bleed score was higher in patients treated with warfarin vs. those not treated (19.0±5.8 vs. 15.4±8.0, p=0.004) with high or very high scores also more common (78.7 vs. 43.8%, p<0.001). Baseline SYNTAX scores were higher in the patients treated with warfarin (18.5±9.1 vs. 12.4±3.8, p=0.0006). During PCI patients treated with warfarin were more likely to undergo left main (4.6 vs. 3.6%, p<0.05) or graft intervention (5.9 vs. 3.6%, p<0.05) and require atherectomy (12.1 vs. 6.6%, p=0.0002) or distal protection use (1.3 vs. 0.6%, p<0.05). Despite the higher SYNTAX scores and more complex PCI the number of vessels and number of lesions treated were similar between cohorts. Bare metal stents (BMS) were more frequently utilised in warfarin patients than non-warfarin patients (44.8 vs. 26.3%, p<0.0001), whilst procedural success was lower (92.9 vs. 95.0%, p<0.05) and an intra-procedural complication (3.3 vs. 2.5%, p<0.05) and TIMI 3 flow <3 (6.7 vs. 3.2%, p=0.008) were more common. Residual SYNTAX score was also significantly higher in patients treated with warfarin (8.3±1.1 vs. 3.8±5.9, p=0.001). Antiplatelet mono-therapy was prescribed after PCI in 14.4% of warfarin patients and 0.7% of non-warfarin (p<0.0001) whilst average DAPT duration was also significantly shorter (4.3 vs. 10.7 months, p<0.0001). At 1-year follow-up TVR (6.5 vs. 3.3%, p<0.05), stent thrombosis (5.0 vs. 2.6%, p=0.14), death (10.1 vs. 4.6%, p<0.01) and TVR/ST/death (21.6% vs. 10.5%, p=0.004) were all more common in the warfarin cohort.
Conclusions: Patients treated with warfarin who need PCI are a more complex cohort with higher pre- and post-Syntax scores. Furthermore, they are more likely to receive less intense and shorter durations of antiplatelet therapy and have adverse 1-year outcomes. This data suggests the need for more trials of both current DES and newer DES technologies in warfarin-treated patients.

Early healing after treatment of coronary lesions by everolimus or biolimus-eluting bioresorbable polymer stents: one-month results in the SORT-OUT VIII optical coherence tomography study

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Aims: Improved early healing may reduce the risk of early stent thrombosis in patients treated with drug-eluting stents. We aimed to compare healing at one month (Cohort A) and at three months (Cohort B) after treatment by an everolimus-eluting biodegradable polymer stent (SYNERGY™; Boston Scientific, Marlborough, MA, USA) or a biolimus-eluting biodegradable polymer stent (BioMatrix NeoFlex™; Biosensors, Morges, Switzerland). Here we present the results of Cohort A.
Methods and results: The study was a prospective, randomised dual-centre trial with one-month follow-up (Cohort A). Patients were randomised 1:1 to SYNERGY or BioMatrix NeoFlex. Cohort A was powered to include 80 patients. Inclusion criteria were stable angina pectoris, non-ST or ST-elevation myocardial infarction. Exclusion criteria were impaired renal function, severe vessel tortuosity or severe systemic disease. Clinical follow-up was performed at one-month and will be continued for five years. Optical frequency domain imaging (OFDI, LUNAWAVE; Terumo, Tokyo, Japan) was performed at baseline and at follow-up or earlier in case of a target vessel event. Frame level matched analysis of baseline and follow-up OFDI was performed using semi-automated analysis software (QCU-CMS Research, Leiden University Medical Center, Leiden, The Netherlands). The primary endpoint is the coronary stent healing index, a weighted index of uncovered apposed and malapposed struts, excess neointimal hyperplasia, acquired- and persisting malapposition and size of the extra-stent lumen. A total of 80 patients were enrolled in Cohort A. Indications for STEMI was 25% of patients in both groups. Two cardiac deaths and one stent thrombosis occurred in the BioMatrix group, no clinical events occurred in the SYNERGY group. A total of 64 patients completed one-month OFDI follow-up, 33 patients in the BioMatrix group and 31 patients in the SYNERGY group.
Conclusions: OFDI results including the primary one-month OFDI endpoint, the coronary stent healing index, will be presented at EuroPCR 2015. Clinical trials identifier: NCT02253108.

Coronary interventions

Euro15A-MA028

Evaluation of PCI with everolimus-eluting versus novolimus-eluting bioresorbable scaffolds in an all-comers-population: a matched analysis

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Aims: Bioresorbable scaffolds (BRS) are a reasonable alternative to metallic drug-eluting stents for the treatment of coronary lesions. Various techniques are under investigation with PLLA being the most common used basic material. However only two BRS have gained CE mark for commercial use, both PLLA-based, and differences in their performance have not yet been investigated.

Methods and results: Both study devices are manufactured from PLLA, have a strut thickness of approximately 160 µm and radiopaque markers on both ends. One is eluted with anti-inflammatory everolimus (e-BRS) and the other with novolimus (n-BRS). All patients treated between April 2013 and September 2014 at the University Hospital of Gießen, Germany were analysed. Of 225 patients treated with e-BRS and 56 patients treated with n-BRS, 54 patients in each group were found to be eligible for a matched comparison. The primary endpoint was the 12-month major adverse cardiac event (MACE) rate, a composite endpoint of cardiac death, any myocardial infarction and clinically driven target lesion revascularisation. Secondary endpoint was target vessel failure (TVF), which included cardiac death, target-vessel myocardial infarction and clinically driven target vessel revascularisation (TVR). After matching, cardiovascular risk factors, clinical presentation and lesion characteristics did not statistically differ in a significant way. Furthermore, procedural parameters were matched and thus no significant differences found. During a median follow-up time of 178 days, 3 MACE were noted in the e-BRS group and in the n-BRS group 1 event was observed. Resulting MACE rates were 3.7% and 1.9% and did not differ in a statistically significant fashion. All MACE were also categorised as TVF and thus the TVF rate did not differ between both groups as well.

Conclusions: Both BRS offer equal clinical outcomes without any differences in performance and thus are both appropriate for routine clinical use. However, large-scale randomised controlled trials will be required to confirm these findings.

Coronary interventions

Euro15A-MA029

A new novolimus-eluting bioresorbable scaffold with a strut thickness of 100 µm, first clinical experience: an OCT evaluation in an all-comers population

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Aims: Limitations of current bioresorbable scaffolds (BRS) are mostly related to their strut thickness, which is approximately 150 µm for most of the existing BRS. This results in limited deliverability, vessel injury and non-laminar blood flow with increased risk for adverse events. The aim was to evaluate procedural parameters and short-term outcome after implantation of a novolimus-eluting bioresorbable scaffold with a strut thickness of 100 µm.

Methods and results: Patients with any evidence of ischaemia who were treated with the latest generation of a novolimus-eluting BRS were included. Exclusion criteria were cardiogenic shock, contraindications against dual antiplatelet therapy or scaffold components and age under 18 years of age. Patient enrolment is still ongoing. This BRS consists of a poly-L-lactic acid backbone with a strut thickness of 100 µm. Further features are a self-correction property, which can resolve minor malapposition, and the possibility of a larger range of overexpansion compared with other BRS. Periprocedural optical coherence tomography (OCT) measurements were repeated offline and analysis was performed in 1 mm increments. Follow-up data for this study were gathered by telephone. A total of 7 patients with a mean age of 64.9±7.7 years were included in this investigation and 85.7% of them were male. Cardiovascular risk factors noted were hypertension in 100%, diabetes in 42.9%, dyslipidaemia in 85.7%, and 71.4% were current or present smokers. A total of 7 lesions were treated with a total of 10 BRS. Stable coronary artery disease was an indication for catheterisation in 42.9% of the patients and acute coronary syndrome in 57.1%. Pre-dilatation was performed with a non-compliant balloon in all cases, and an additional scoring balloon was required in 1 patient. Post-dilatation was performed in 85.7% of the cases with a mean pressure of 14.6±3.4 atm. Mean procedure time, mean fluoroscopic time, and mean contrast agent use were 83.4±47.5 min, 16.1±13.6 min, and 190.0±72.7 mL, respectively. Additional optical coherence tomography (OCT) was performed 71.4% of the cases. OCT evaluation of 7 BRS shows a mean scaffold diameter of 2.8±0.3 mm, a mean scaffold area of 6.1±1.5 mm^2, a mean eccentricity index of 0.78±0.05% and incomplete strut apposition in 2.8% of all struts. No procedure-related complications occurred during the hospital stay. No MACE were noted and there was also no evidence of scaffold thrombosis during the 30-day follow-up.

Conclusions: Preliminary results in a small cohort demonstrated the technical feasibility of the implantation of this new bioresorbable scaffold with 100 µm strut thickness that might be able to overcome some drawbacks of 150 µm scaffolds. However, data derived from larger patient series with a longer follow-up as well as from randomised-controlled trials will be required.

Short- and midterm outcomes of PCI with bioresorbable vascular scaffolds for STEMI treatment

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Aims: Studies demonstrate favourable clinical outcomes for the everolimus-eluting bioresorbable vascular scaffolds (BVS) in patients with stable coronary artery disease. But current data on the use of everolimus-eluting bioresorbable vascular scaffolds in patients with ST-segment elevation myocardial infarction are still very limited. We evaluated feasibility, short-term and midterm outcomes of STEMI treatment with PCI using bioresorbable vascular scaffolds.

Methods and results: The prospective single-centre registry was initiated to evaluate feasibility and performance of everolimus-eluting bioresorbable vascular scaffolds in STEMI setting. Within the ongoing registry, 94 STEMI patients underwent PCI with BVS implantation from 1 October 2013 to 1 November 2014 and the results were analysed. The mean age of patients was 51.2±6.3 (range 27-66) years, 76.6% were males. The primary endpoints of the study were the device success defined as BVS implantation in the culprit lesion without intraprocedural complications and the major adverse cardiac events (MACE) defined as all-cause death, myocardial infarction, repeat target vessel revascularisation and the composite of these at 30 days and at a median 197 (range 51-411) days of follow-up. Five (5.3%) patients presented with Killip class III-IV at admission. Multivessel PCI with BVS in acute phase was performed in 2 (2.1%) patients due to unstable haemodynamics after infarct-related artery intervention; 26.6% of patients received multiple scaffolds in the infarct-related artery; 38.3% of BVS implantations were IVUS-guided. All patients had successful scaffold implantation with TIMI-3 flow achieved in 94.7% of cases. The MACE rate at 30 days was 0%. At a median 197 (range 51-411) days of follow-up, there was 1 (1.1%) non-cardiac death. No scaffold thrombosis was recorded. The overall rate of major adverse cardiac events at follow-up was 1.1%.

Conclusions: The study demonstrates that PCI with bioresorbable vascular scaffolds is technically feasible and safe for STEMI treatment. PCI with bioresorbable vascular scaffolds for STEMI treatment has favourable short-term and midterm outcomes.

Usefulness of platelet-to-lymphocyte ratio and neutrophil-to-lymphocyte ratio in predicting the long-term adverse events among patients undergoing drug-eluting stent implantation for coronary artery disease

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Aims: The usefulness of platelet-to-lymphocyte ratio (PLR) and neutrophil-to-lymphocyte ratio (NLR) in predicting the long-term adverse events of coronary artery disease (CAD) has not been sufficiently evaluated. The aim of the present study was to investigate the PLR and NLR in predicting the long-term clinical outcomes in patients undergoing percutaneous coronary intervention (PCI) with drug-eluting stent (DES).

Methods and results: A total of 798 patients who underwent successful PCI with DES were consecutively enrolled. The patients were classified into four groups according to the optimal cutoff value of PLR and NLR for the discriminating adverse events by a receiver operating characteristic (ROC) curve (group I; low PLR and low NLR, group II; low PLR and high NLR, group III; high PLR and low NLR, group IV; high PLR and high NLR). The efficacy of the PLR and NLR in predicting the adverse events, the correlations between these markers and the adverse events (all-cause mortality, cardiac death, and non-fatal myocardial infarction) were analysed. The follow-up period was 5.1±2.4 years. On ROC analysis, the PLR and NLR were found to have the largest area under the curve (AUC=0.605, 95% confidence interval, CI 0.570 to 0.639, p=0.018 and AUC=0.633, 95% CI: 0.599 to 0.667, p=0.003, respectively) with an optimal PLR cutoff value of 128 (sensitivity 56%, specificity 65%) and a NLR value of 2.6 (sensitivity 52%, specificity 75%) for predicting adverse events. On logistic regression analysis, a high PLR (odds ratio, OR: 1.961, 95% CI: 1.158 to 3.321, p=0.012) and high NLR (OR: 3.045, 95% CI: 1.691 to 5.484, p<0.001) were found to be independent predictors of long-term adverse events after adjustments of traditional cardiovascular risk factors.

Conclusions: High pre-intervention PLR and NLR are independent predictors of long-term adverse clinical outcomes such as all-cause mortality, cardiac deaths and myocardial infarction in patients undergoing PCI with DES.

euroPCR Coronary interventions

Euro15A-MA037

Acute and long-term effect of PCI on serially-measured oxidative, inflammatory, and coagulation biomarkers in patients with stable angina

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Aims: To derive insights into the temporal changes in oxidative, inflammatory and coagulation biomarkers in patients with stable angina undergoing percutaneous coronary intervention (PCI), and in particular in oxidised phospholipids present on plasminogen (OxPL-PLG).

Methods and results: Plasma samples were collected before, immediately after, 6 and 24 hours, 3 and 7 days, and 1, 3, and 6 months after PCI in 125 patients with stable angina undergoing uncomplicated PCI. Plasminogen levels, OxPL-PLG, and array of 16 oxidative, inflammatory and coagulation biomarkers were measured with established assays. OxPL-PLG and plasminogen declined significantly immediately post-PCI, rebounded to baseline, peaked at 3 days and slowly returned to baseline by 6 months ($p<0.0001$ by ANOVA). The temporal trends to maximal peak in biomarkers were as follows: immediately post-PCI: OxPL/apoB and lipoprotein (a); day 1- the inflammatory biomarkers IL-6 and hsCRP; day 3- coagulation biomarkers OxPL-PLG, plasminogen, urokinase and tissue plasminogen activators and complement factor H binding to malondialdehyde-LDL; day 3-7- plasminogen activator inhibitor; and Day 7-30- autoantibodies to OxLDL. Most of the biomarkers trended to baseline by 6 months.

Conclusions: PCI results in a specific, temporal sequence of changes in plasma biomarkers. These observations provide insights into the effects of PCI on iatrogenic plaque disruption and suggest avenues of investigation to explain complications of PCI and development of targeted therapies to enhance procedural success.

euroPCR Coronary interventions

Euro15A-MA038

Neutrophil-to-lymphocyte ratio in patients undergoing elective percutaneous coronary intervention: periprocedural variations and association with myocardial necrosis

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Aims: The neutrophil-to-lymphocyte ratio is an independent predictor of clinical outcomes in patients with coronary artery disease. However, no data are available on potential periprocedural variations in NLR and its association with periprocedural myocardial necrosis in patients undergoing PCI.

Methods and results: We enrolled a total of 502 consecutive patients undergoing elective PCI after exclusion of those with: chronic kidney disease (glomerular filtration rate<60 ml/min), severe left ventricular dysfunction (ejection fraction <30%), acute coronary syndrome, thrombocytopenia, sepsis, severe pulmonary disease, or neoplasm. Blood samples collected at baseline, 6 and 24 hours post-PCI in order to estimate neutrophil-to-lymphocyte ratio from blood cell count and to measure troponin-T and creatine kinase MB levels. Periprocedural myocardial infarction was defined according to the 2012 Universal Definition of Myocardial infarction. In the whole population, a significant increase in neutrophil-to-lymphocyte ratio was observed from baseline (median 3.25 [interquartile range 2.75-4.00]) to post-PCI values (6 hours: 4.42 [3.39-6.02], $p<0.001$ vs. baseline; 24 hours: 4.72 [3.94-5.75], $p<0.001$ vs. baseline). A total of 33 (6.6%) patients developed periprocedural myocardial infarction. No significant difference in baseline neutrophil-to-lymphocyte ratio was observed between patients with and without periprocedural myocardial infarction (3.25 [2.86-3.85] vs. 3.25 [2.75-4.00]; $p=0.887$). However, patients who developed periprocedural myocardial infarction presented higher neutrophil-to-lymphocyte ratio both at 6 hours (5.75 [4.52-8.93] vs. 4.37 [3.37-5.95]; $p<0.001$) and 24 hours post-PCI (5.18 [4.57-7.87] vs. 4.67 [3.92-5.68]; $p=0.003$). A significant correlation was found between post-PCI increase of neutrophil-to-lymphocyte ratio and post-PCI increase of both troponin-T (Spearman rho=0.115, $p=0.013$) and creatine kinase MB (Spearman rho=0.099, $p=0.048$).

Conclusions: Coronary interventions induce alterations in inflammatory cells patterns with a significant increase of neutrophil-to-lymphocyte ratio. Such increase is higher in patients who develop periprocedural myocardial infarction and is proportional to the magnitude of myocardial necrosis.

An increased concentration of matrix metalloproteinase-9 in the blood after coronary stenting lasts much longer than the increase of other markers of inflammation

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Aims: Coronary stenting induces an inflammatory response and leads to increase of concentration of inflammatory markers in the blood of patients. Matrix metalloproteinases (MMP) are involved in inflammation and remodelling of the vessel wall. Changes in the level of MMP in blood may reflect both these process.
Methods and results: We measured the concentrations of high-sensitive C-reactive protein (hs-CRP), fibrinogen, MMP-9 and tissue inhibitor of matrix metalloproteinase (TIMP-1) in the blood of 104 patients with stable angina before the implantation of sirolimus-eluting coronary stents and on the first, second and seventh day, and then the 1st, 3rd, 6th month as well as 1 year after stenting. Restenosis was revealed by angiography in 12 patients, 1 year after stenting. Concentration of hs-CRP and fibrinogen in the blood of patients increased during the first week after stenting and later dropped below baseline. We observed maximal concentration of hs-CRP on the second day after stenting: 4.8 [2.2-10.1] mg/l (here and thereafter data presented as median [25th-75th percentiles]) vs. initial 1.7 [0.9-3.3] mg/dl, p<0.05. Minimal concentration of hs-CRP: 0.9 [0.5-1.6] mg/l was observed 12 months after stenting. The concentration of fibrinogen reached its maximal level in the first week after stenting: 4.0 [3.6-4.5] g/l vs. initial 3.6 [3.3-4.2] g/l, p<0.05 with subsequent fall to minimal level 3.3 [3.1-3.7] g/l at 6 months after the stenting. The concentration of MMP-9 in the blood increased on day 2 after stenting (428 [256-625] ng/ml versus the initial 347 [215-518] ng/ml, p <0.05), and reached its maximum level at 1 month after the intervention (466 [269-608] ng/ mL). An increase of concentration of MMP-9 was observed until the sixth month (416 [318-595] ng/ml) after stenting. The concentration of TIMP-1 in blood decreased one month after stenting from baseline 153 [124-187] till 134 [124-164] ng/ml, p<0.05. We did not find significant differences in the concentrations of inflammatory markers in the blood of patients with and without restenosis in any time points, but patients with subsequent development of restenosis tended to have lower concentration of MMP-9 before stenting in comparison to patients without restenosis: 229 [171-377] vs. 367 [222-516] ng/ml, p=0.08.
Conclusions: An increase of the concentration of MMP-9 in the blood after coronary stenting lasts much longer than the increase of the concentration of other inflammatory markers. This phenomenon may be a reflection of a long process of vascular remodelling after coronary stenting.

Biochemical risk factors for coronary in-stent restenosis

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Aims: We sought to identify biochemical risk factors that indicate susceptibility to in-stent restenosis (ISR) after coronary artery bare-metal stenting.
Methods and results: A total of 111 consecutive patients with post-percutaneous coronary intervention (PCI) in-stent restenosis of a target lesion within 12 months were matched for age, sex, vessel diameter and diabetes with 111 controls without post-PCI in-stent restenosis. Levels of biochemical markers were measured: matrix metalloproteinase (MMP) 2, 3, 9; myeloperoxidase (MPO); asymmetric dimethylarginine (ADMA); lipoprotein (a) (Lp[a]); apolipoproteins E and D (ApoE and D); and lecitin-cholesterol acyltransferase (LCAT). Multivariable logistic regression association tests were performed. Results: Increased plasma MMP-3 (OR: 1.013; 95% CI: 1.004-1.023; p=0.005), MMP-9 (OR: 1.014; 95% CI: 1.008-1.020; p<0.0001) or MPO (OR: 1,003; 95% CI: 1.001-1.005; p=0.002) was significantly associated with increased risk of ISR. Increased levels of ADMA (OR: 0.212; 95% CI: 0.054-0.827; p=0.026), ApoE (OR: 0.924; 95% CI: 0.899-0.951; p<0,0001), ApoD (OR: 0.919; 95% CI: 0.880-0.959; p=0.0001), or LCAT (OR: 0.927; 95% CI: 0.902-0.952; p<0.0001) was associated with risk reduction. No correlation was found between plasma MMP-2 or Lp (a) and in-stent restenosis risk.
Conclusions: Increased levels of MMP-3, MMP-9 and MPO represent risk factors for in-stent restenosis after bare-metal stent implantation. In contrast, increased ADMA, LCAT, and Apo E and D indicate decreased risk.

EuroPCR Coronary interventions

Euro15A-MA041

Predictors and results of selective thrombus aspiration in real-world practice

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Aims: Systematic thrombus aspiration has failed to show a consistent benefit in clinical trials. We sought to analyse the associated factors and the results of selective thrombus aspiration use.

Methods and results: We conducted a prospective observational study of all consecutive STEMI patients treated by primary PCI in a tertiary hospital during a 3-year period (2008-2011). Thrombus aspiration was performed at operator´s discretion, in all cases with 6 Fr compatible catheters. Angiograms were evaluated by an investigator unaware of clinical data. Large thrombus burden was defined as angiographic thrombus length ≥2 vessel diameters. Four hundred and sixty-four (464) patients were included (64±13 years, 74% male, 34% anterior location). Thrombus aspiration was performed in 76 (16%), obtaining macroscopic solid material in 59 (78%). Younger age (OR 0.74 per decade, p=0.006), reference diameter ≥3.0 mm (OR 3.9, p=0.003), large thrombus burden (OR 2.1, p=0.013) and pre-interventional TIMI flow grade 0/1 (OR 3.5, p=0.048) were independent predictors of catheter thrombus aspiration use. Thrombus removal allowed more frequently direct stenting (64% vs. 44%, p=0.002), and despite worse preprocedural flow it was associated with similar post-interventional TIMI flow grade 3 (72% vs. 74%, p=0.721). One-year unadjusted rates of death or reinfarction were 6.9% in thrombus aspiration and 11.1% in conventional PCI group (RR 0.63, 95% CI: 0.26-1.53, p=0.293).

Conclusions: Selective thrombus aspiration in patients with large thrombus burden characteristics is associated with favourable procedural results and midterm outcomes.

EuroPCR Coronary interventions

Euro15A-MA042

Comparison of the 48-month clinical outcomes between patients with non-ST-elevation myocardial infarction who had an occluded culprit artery and those with ST-elevation myocardial infarction

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Aims: Recent studies have suggested that a subset of patients with non-ST-elevation myocardial infarction (NSTEMI) with an occluded culprit artery had worse outcomes compared to those with a non-occluded culprit artery. Therefore, they have been regarded as "STEMI-equivalents". We aimed to compare the clinical characteristics and the long-term prognosis between these "STEMI-equivalents" and patients with true STEMI.

Methods and results: A total of 5,025 patients with acute MI from 9 cardiovascular centres were retrospectively registered in COREA-AMI (Convergent REgistry of catholic and chonnAm university for Acute MI) registry. Out of these, patients whom had a total occlusion (TIMI 0 or 1) of the "culprit" left anterior descending artery (LAD) on the baseline angiography were selected as study subjects. They were classified into two groups by the initial electrocardiographic findings: the "NSTEMI" group (n=253) and the "STEMI" group (n=800). The clinical, angiographic findings and the incidences of adverse events including in-hospital death (IHD), cardiac death (CD), recurrent nonfatal MI (RMI) and target vessel revascularisation (TVR) were compared between two groups. The median follow-up duration was 47.3 months (IQR: 32.7-66.2). The patients in the STEMI group were younger and had lower left ventricular ejection fraction (LVEF). The peak level of cardiac troponin was significantly higher in the STEMI group. Meanwhile, the NSTEMI group had more complex angiographic lesion (B2/C), multivessel disease, and smaller stent-diameter. The incidence of IHD was significantly higher in the STEMI group than in the NSTEMI group (4.1% vs. 1.2%, p=0.027). In the multivariate Cox regression, age (adjusted HR: 1.161, 95% CI: [1.104-1.221], p=0.035), LVEF (0.938 [0.894-0.985], p=0.010), and peak level of troponin (1.102 [1.100-1.104], p=0.016) were revealed as the independent predictors for IHD. During the 48-month follow-up, however, CD (10.6% vs. 9.1%), RMI (6.3% vs. 7.9%), and TVR (4.5% vs. 3.2%) occurred at similar rates in both groups (all p>0.05). Furthermore, in the 12-month landmark analysis, the risk of all adverse events were not significantly different between both groups beyond 12 months (p>0.05).

Conclusions: Although patients with NSTEMI with an occluded "culprit" LAD demonstrated a lower incidence of IHD, they showed similar rates of adverse cardiovascular events during 48 months, compared to those with STEMI. These patients in the NSTEMI group may represent true "STEMI-equivalents". Thus, the precise early risk stratification followed by an early intervention should be considered for these high-risk patients.

Health system delays for primary angioplasty: are we adhering to the guidelines?

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Aims: The European Society of Cardiology (ESC) recommends that the health system delay (HSD) for primary angioplasty (PPCI) must be less than 90 minutes, except in patients with less than 2 hours of symptoms, which should be less than 60 minutes. The aim of this study was to assess the degree of adherence to the ESC guidelines regarding HSD for PCI and the impact of the "Stent for Life" (SFL) programme.

Methods and results: We studied 638 consecutive patients referred for primary PCI between 2009 and 2013 from the pre-hospital emergency (EMS) and 2 centres without catheterisation laboratory (A and B). We calculated the proportions of patients with HSD, defined as the time from the first contact medical until the opening of the artery responsible for the infarction, within the limits recommended by ESC. We analysed the impact of the SFL programme comparing the DHS pre-SFL (2009-2011) with the post-SFL (2012-2013). The population had a mean age of 62±13 years and 25% were female. The proportion of patients with HSD within the limits recommended by ESC was 21.2% and increased significantly post-SFL (26% vs. 18% pre-SFL, $p < 0.05$). In patients within the HSD limits recommended by ESC, total mortality during a mean follow-up of 34 months was 13.6%, versus 17.8% in the remaining patients. Patients referred by EMS presented more often DHS within the limits recommended by ESC (62.7% vs. 7.7% and 10.6% for A and B, respectively; $p<0.001$).

Conclusions: In a population of patients referred for primary angioplasty, adherence to ESC guidelines regarding the health system delay was generally low. The pre-hospital emergency had the best performance and the impact of the Stent for Life programme was significant.

Prognosis is similar for STEMI patients treated with primary PCI during office hours and during off-hours: a report from SCAAR

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Aims: Timely PCI improves prognosis in STEMI. However, recent reports indicate that patients with STEMI who present during off-hours have worse prognosis. The aim of this study was to compare outcome between patients with STEMI who underwent primary PCI during off-hours and regular hours.

Methods and results: We retrieved data from the Swedish Coronary Angiography and Angioplasty Registry (SCAAR) for all patients who underwent primary PCI in Västra Götaland County due to STEMI between January 2004 and May 2013. We fitted unadjusted and adjusted Cox proportional hazards regression and logistic regression models for the outcomes death, cardiogenic shock, stent thrombosis and in-stent restenosis. A propensity scores adjusted Cox proportional hazards model which adjusted for traditional cardiovascular risk factors was pre-defined as the primary statistical model. Death at any time during the study period was pre-specified as primary endpoint. During the study period, 7,144 patients (29% women) underwent acute coronary angiography due to STEMI. Approximately 1/3 of the patients underwent angiography off-hours. There was a small but statistically significant yearly trend towards a greater proportion of patients undergoing angiography off-hours. Acute mortality was similar in both groups with no apparent yearly trends. The hazard ratio was near 1.0 in all models. Subgroup analyses did not reveal any significant interactions between age, gender, diabetes mellitus, smoking or calendar year and the risk of undergoing acute coronary angiography during off-hours relative to undergoing acute coronary angiography on office-hours.

Conclusions: In our region, short- and long-term prognosis for patients with STEMI who undergo primary PCI for patients presenting during off-hours and regular office hours is similar.

EuroPCR Coronary interventions Euro15A-MA045

OCT assessment of the midterm vascular healing after bioresorbable scaffold implantation in STEMI (BVS-STEMI-FIRST): a comparison with metal stents

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Aims: Bioresorbable vascular scaffolds are a novel treatment for obstructive coronary lesions. Despite reports of favourable healing response in stable patients, the vascular healing response after everolimus-eluting bioresorbable scaffold implantation (Absorb; Abbott Vascular, Santa Clara, CA, USA) in myocardial infarction has not been studied yet. We assessed the vascular healing response by OCT 6 months after bioresorbable scaffold implantation in patients with ST-elevation myocardial infarction (STEMI), and compared it to the vascular response of a cohort of STEMI patients treated with a metal drug-eluting stent (DES) with biodegradable polymer.

Methods and results: The BVS-STEMI–FIRST is a single-centre investigator-driven pilot cohort study. A total of 39 consecutive patients previously admitted with STEMI and treated with bioresorbable scaffold(s) at the index procedure, that consented to undergo invasive follow-up at 6 months including OCT study of the treated culprit lesion, were included in the study. The OCT findings were compared to findings from a historic cohort from the TROFI study. The TROFI study comprised STEMI patients randomised to primary PCI with thrombectomy vs. primary PCI without thrombectomy, subsequently treated with a metal DES with biodegradable polymer (Nobori; Terumo Corp, Tokyo, Japan). Forty-nine (49) patients from this study underwent 6-month follow-up OCT. Morphometric OCT measurements and markers of vascular healing, i.e., coverage and apposition were compared between the two groups. In the group of bioresorbable scaffolds, no binary restenosis was observed and OCT was successfully performed in all 39 cases. There were no significant differences between the bioresorbable scaffold and the metal DES groups in stent diameter (3.15±0.37 mm vs. 3.10±0.39; p=0.55), length (23.74±11.32 mm vs.23.29±10.08 mm; p=0.842), or treated vessel (p=0.49). Patients in the bioresorbable scaffold group had undergone thrombus aspiration more often (82% vs. 51%, p<0.01). The mean and minimal lumen area was non-significantly lower in the bioresorbable scaffold group (mean: 6.63±1.80 mm vs. 7.36±2.23 mm, p=0.10; minimal: 5.04±1.81 mm vs. 5.83±2.11 mm, p=0.07). There was no significant difference in the percentage of malapposed struts (0.6±8.0% vs. 0.4±6.2%, p=0.60), while the percentage of uncovered struts was significantly lower in the bioresorbable scaffold group (0.6±7.8% vs. 6.3±24.3%, p<0.01). The percentage of frames with thrombus or malapposed struts did not differ significantly between the two groups (thrombus: 2.3±4.4% vs. 2.4±4.0%, p=0.93; malapposition: 0.7±1.7% vs. 0.4±0.9%, p=0.26) whereas the percentage of frames with uncovered struts was lower in the bioresorbable scaffold group (5.3±6.4% vs. 21.5±18.9%, p<0.01).

Conclusions: The implantation of bioresorbable scaffolds in STEMI is associated with a healing response comparable to the healing response of a metal DES with biodegradable polymer, demonstrating absence of lumen compromise, an overall low rate of malapposed struts and a lower rate of uncovered struts compared to metal DES.

EuroPCR Coronary interventions Euro15A-MA052

TriGuard™HD embolic deflection device for cerebral protection during transcatheter aortic valve replacement: the results of the DEFLECT II Trial

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Aims: To evaluate the safety and performance of the embolic deflection device TriGuard™HD in patients undergoing transcatheter aortic valve replacement (TAVR).

Methods and results: This prospective, single-arm feasibility pilot study included 15 patients with severe symptomatic aortic stenosis scheduled for TAVR. Cerebral diffusion weighted magnetic resonance imaging (DWI) was planned in all patients one day before and at day 4 (±2) after the procedure. Major adverse cerebral and cardiac events (MACCE) and neurological status, including NIH Stroke Scale (NIHSS) and the modified Rankin Scale (mRS) scores, were recorded for all patients. Primary endpoints of this study were: I) device performance success defined as complete coverage of the three aortic arch take-offs throughout the entire TAVR procedure and II) MACCE occurrence. Secondary endpoints included the number and the volume of new cerebral ischaemic lesions on DWI. Fourteen patients underwent transfemoral TAVR and one patient a transapical procedure. Edwards SAPIEN valve prosthesis was implanted in 9 (60%) patients and Medtronic CoreValve prosthesis in the remaining 6 (40%). Predefined performance success of the TriGuard™HD device was achieved in 10 (67%) patients. The composite endpoint MACCE occurred in none of the patients. NIH Stroke Scale scores were 0 in all patients on admission and remained unchanged during hospital stay. Modified Rankin Scale scores ranged from 0 to 3 (average 2.1) on admission and remained unchanged during hospitalisation. Post-procedural DWI was performed in 12 patients. Comparing the DWI of these patients to a historical control group showed no reduction in number [median 5.5 vs. 5.5, p=0.96], however a trend towards a decrease in mean lesion volume per patient [median 12.4 vs. 25.1, p=0.11] and total ischaemic volume [median 98.9 vs. 129.4, p=0.16].

Conclusions: The use of the TriGuard™HD for cerebral protection during TAVR is safe. Device performance success was achieved in 67% of all cases. Our data indicate that the use of this protection device might decrease cerebral ischaemic burden during TAVR.

Effect on clinical outcomes of short- or long-duration dual antiplatelet therapy after drug-eluting stents: a meta-analysis of randomised trials

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Aims: Current guidelines recommend 12-month dual antiplatelet therapy (DAPT) after drug-eluting stent implantation. Recent randomised controlled trials comparing different DAPT durations have yielded conflicting findings. We aimed to assess benefits and risks of shorter (i.e., <12 months) DAPT and of prolonged (i.e., >12 months) DAPT duration.

Methods and results: PubMed, EMBASE, the Cochrane Central Register of Controlled Trials, ClinicalTrials.gov databases were searched from inception through December 2014 for randomised trials comparing 1) shorter than 12-month DAPT vs. at least 12-month DAPT, or 2) longer than 12-month DAPT vs. 12-month DAPT, after drug-eluting stenting. No language restrictions were applied. Two reviewers independently extracted study data. Ten trials (31,643 participants) were included. Data were pooled by meta-analysis using a fixed-effects or a random-effects model, as appropriate. Compared to at least 12-month DAPT, patients receiving shorter than 12-month DAPT (7 trials, 15,378 participants) had a comparable risk of all-cause death (odds ratio [OR] 0.89; 95% CI: 0.68 to 1.15; p=0.37), cardiovascular death (OR 0.92; 95% CI: 0.66 to 1.28; p=0.63), myocardial infarction (OR 1.14; 95% CI: 0.89 to 1.47; p=0·30), definite or probable stent thrombosis (OR 1.36; 95% CI: 0.85 to 2.16; p=0.19), stroke (OR 0.84; 95% CI: 0.53 to 1.31; p=0.30), and a lower risk of major bleeding (OR 0.53; 95% CI: 0.34 to 0.84; p=0.007). Compared to 12-month DAPT, patients receiving longer DAPT (3 trials, 16,265 participants) had a higher risk of all-cause death (OR 1.30; 95% CI: 1.02 to 1.66, p=0.035), and of major bleeding (OR 1.54; 95% CI: 1.08 to 2.19; p=0.017), a lower risk of myocardial infarction (OR 0.58, 95% CI: 0.40 to 0.84; p=0.004), and of definite stent thrombosis (0.34, 95% CI: 0.17 to 0.69; p=0.003), similar risk of cardiovascular death (OR 1.12; 95% CI: 0.73 to 1.71; p=0.61) and stroke (OR 0.93, 95% CI: 0.66 to 1.31, p=0.67).

Conclusions: After drug-eluting stent implantation, shorter than 12-month DAPT is associated with a lower risk of major bleeding, while maintaining comparable anti-ischaemic efficacy. By contrast, DAPT continuation beyond 12 months, as compared to 12-month DAPT, is associated with increased risk of all-cause death and major bleeding while it reduces the risk of myocardial infarction and stent thrombosis.

Duration of dual antiplatelet therapy following drug-eluting stent implantation: a systematic review and meta-analysis of randomised controlled trials

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Aims: The optimal duration of DAPT after DES implantation is unclear, and its risks and benefits may vary according to the DES type. Therefore, we sought to evaluate efficacy and safety of extended dual antiplatelet therapy (DAPT) after drug-eluting stent (DES) implantation.

Methods and results: We included randomised controlled trials (RCTs) evaluating the safety and efficacy of different duration of DAPT after DES implantation. Study groups were classified as: shorter DAPT (S-DAPT), defined as the per-protocol minimum duration of DAPT after DES implantation and longer DAPT (L-DAPT), defined as the per-protocol period of prolonged DAPT beyond the S-DAPT period. Primary efficacy and safety outcomes were definite/probable stent thrombosis (ST) and clinically significant bleeding (CSB) respectively. Following systematic review of literature, a total of 10 RCTs (n=32,135) were included. As compared to L-DAPT, S-DAPT was associated with higher rate of ST (odds ratio [OR]: 1.71; 95% confidence interval [CI]: 1.26-2.32; p=0.001). The effect on ST with S-DAPT was attenuated with use of the 2nd-generation DES (OR: 1.67; 95% CI: 0.99-2.80) compared with use of 1st-generation DES (OR: 4.55, 95% CI: 2.32-8.92; p for interaction =0.018). S-DAPT had significantly lower risk of CSB (OR: 0.61; 95% CI: 0.51-0.73; p<0.001). L-DAPT was also associated with a lower risk of myocardial infarction (MI; OR: 1.39; 95% CI: 1.20-1.62; p<0.0001); however, no differences were observed in cardiac mortality between S-DAPT and L-DAPT (OR: 0.94; 95% CI: 0.76-1.15, p=0.563). Finally, a trend towards lower all-cause mortality was observed in the S-DAPT group (OR: 0.87; 95% CI: 0.74-1.01; p=0.07).

Conclusions: L-DAPT was associated with lower rates of ST and MI compared with S-DAPT. However, the antithrombotic efficacy of L-DAPT was significantly attenuated with use of 2nd-generation DES. The benefits of L-DAPT were counterbalanced by higher rate of bleeding and possibly all-cause mortality. Given the risk and benefits of L-DAPT, the results of the present study underscore that prolongation of DAPT after a mandatory period should be applied carefully after an individualised evaluation of the trade-off between ischaemic and bleeding risk.

euroPCR Coronary interventions

Euro15A-OP003

Risk and benefits of a "triple" antithrombotic regimen in patients undergoing percutaneous coronary stent implantation requiring chronic oral anticoagulation: a meta-analysis of 12 trials

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Aims: Patients with coronary artery disease who undergo stent implantation with concomitant indications for long-term oral anticoagulation represent a considerable percentage of the overall population. To date, there is still no consensus about the optimal antithrombotic strategy to choose in this kind of patient, due to the difficult balance between an increased risk of bleeding and thromboembolic complications. The aim of this meta-analysis was to evaluate risk and benefits of triple antithrombotic therapy versus dual antiplatelet therapy in patients undergoing coronary stent implantation requiring long-term oral anticoagulation.

Methods and results: We performed formal searches of PubMed, EMBASE, Cochrane central register of controlled trials and major international scientific session abstracts from January 1990 to September 2014 regarding the use of triple antithrombotic therapy versus dual antiplatelet therapy in patients undergoing percutaneous coronary stent implantation that required chronic oral anticoagulation. Data regarding study design, inclusion/exclusion criteria, number of patients, and selected endpoints was extracted by 2 investigators. Disagreements were resolved by consensus. Twelve trials, with a total of 7,838 patients undergoing stent implantation were finally included. A total of 2,686 patients were treated with triple therapy whereas 5,152 patients received dual antiplatelet therapy alone. The follow-up period ranged from 270 to 2,000 days. Mortality occurred in 10.8% of patients receiving triple therapy versus 16.7% of patients in dual antiplatelet therapy (OR [95% CI]=0.80 [0.69-0.94], p=0.005; p_{het}=0.0003). No relationship was observed between reduction in mortality and the risk of bleedings (p=0.10). Data regarding secondary endpoints showed a significant association between triple therapy and an increased risk of bleedings (12.3% versus 9.9%) (OR [95% CI]=1.37 [1.16-1.62], p=0.0002; p_{het}=0.20), while we did not find any significant difference in terms of the recurrence of myocardial infarction (p=0.39), stent thrombosis (p=0.46) or stroke (p=0.15). Finally, the total occurrence of major adverse cardiac event (MACE-defined as per protocol) was 539 out of 2,686 (20%) versus 1,323 out of 5,113 (25.9%) (OR [95% CI]=0.86 [0.76-0.97], p=0.02; p_{het}<0.00001).

Conclusions: This meta-analysis showed that among patients undergoing coronary stent implantation who require chronic oral anticoagulation, the use of a triple antithrombotic therapy is associated with a significant reduction in mortality that largely outweighs the higher risk of major bleeding complications associated with triple therapy.

euroPCR Coronary interventions

Euro15A-OP004

The optimal duration of dual antiplatelet therapy after drug-eluting stent: a risk-benefit analysis using Bayesian Network meta-analysis of randomised controlled trials

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Aims: Dual antiplatelet therapy (DAPT) for 12 months is recommended by professional societies after placement of a drug-eluting stent (DES), although recent studies comparing shorter (3-6 months) and longer (>24 months) DAPT have cast doubts on the optimal duration of DAPT after DES. We aimed to compare different DAPT durations for risk and benefits after DES placement.

Methods and results: We systematically searched electronic databases for randomised trials comparing various duration of dual antiplatelet therapy after drug-eluting stent placement. The DAPT duration were characterised as ≤6 months, 12 months and 24 months or longer. A network meta-analysis using a Bayesian method was conducted to compare three DAPT durations on the risk of stent thrombosis (ST) and major bleeding. Stochastic Multi-criteria Acceptability Analysis was conducted for the risk and benefit of the above endpoints. Ten studies meeting the inclusion criteria were included in the analysis. DAPT for ≥24 months was associated with significantly lower risk of ST compared to ≤6 months (odds ratio [OR]=0.33, 95% CI: 0.09-0.82) and 12 months (OR=0.39, 95% CI: 0.14-0.87). DAPT for ≥24 months was associated with higher risk of Thrombolysis in Myocardial Infarction (TIMI) major bleeding compared to ≤6 months (OR=3.30, 95% CI: 1.45-9.76) but similar risk compared to 12 months (OR=1.67 95% CI: 0.86-3.74). However, when the study focussed on major bleeding, DAPT use for ≥24 months was associated with higher bleeding compared to both ≤6 months (OR=2.98, 95% CI: 1.65-6.45) and 12 months (OR=1.72, 95% CI: 1.14-3.17). Consequently, DAPT for ≥24 months is the best option if prevention of ST is preferred 3 times over the prevention of TIMI major bleeding (central weights 75:25, respectively). Whereas, DAPT ≤6 months is the best option if prevention of TIMI major bleeding is preferred almost twice over the prevention of ST (central weights 66:34 respectively). DAPT for 12 months could be used if both are equally preferred (central weights 0.47:0.53 for ST and TIMI major bleeding, respectively). There was no difference in DAPT durations in terms of all-cause death, cardiac death, stroke or myocardial infarction.

Conclusions: The duration of DAPT could be changed to <6 months, 12 months or ≥24 months after DES placement based on the relative priority of ST versus major bleeding prevention. More research is required to accurately predict the risk of these endpoints in an individual patient.

Dual antiplatelet therapy duration following drug-eluting stent implantation: insights from a network meta-analysis of randomised trials

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Aims: Dual antiplatelet therapy is the standard of care following percutaneous coronary intervention (PCI) with drug-eluting stent (DES). However, the safest and most effective dual antiplatelet therapy duration still remains controversial. We sought to define the optimal dual antiplatelet therapy duration performing a hierarchical Bayesian network meta-analysis of randomised trials comparing different dual antiplatelet therapy regimens.
Methods and results: The search was performed in PubMed, Embase, Scopus, Cochrane Library and Web of Science electronic databases. Inclusion criteria were the following: 1) randomised trials comparing two or more dual antiplatelet therapy durations; 2) patients of any age, ischaemic risk profile and clinical presentation, with or without documented pre-existing coronary artery disease, undergoing PCI with implantation of one or more DESs. Exclusion criteria were the following: 1) trials comparing a dual antiplatelet therapy regimen with acetylsalicylic acid as control; 2) trials with primary clinical setting different from coronary artery disease or including patients with coronary artery disease undergoing medical therapy or surgical coronary artery revascularisation. The primary efficacy endpoint was all-cause death, while the primary safety endpoint was major bleeding. A Bayesian network meta-analysis was carried out for each endpoint using a consistency random-effect model computed with Markov Chain Monte Carlo simulation. Convergence was confirmed using the Brooks-Gelman-Rubin diagnostic after a 50,000-iteration "burn-in" phase, and direct probability statements were based on a further 100,000-iteration phase. Inferences were calculated by sampling from the posterior distribution of the parameters and reported as mean odds ratio with corresponding 95% credible interval. Heterogeneity was explored using I^2 statistic. Dual antiplatelet therapy durations were ranked attempting to define the probability of each treatment to be the best. A total of 7 randomised trials (15,870 patients) were identified: 2 trials compared 3-month dual antiplatelet therapy with 12-month, 3 trials compared 6-month dual antiplatelet therapy with 12-month, and 2 trials compared 6-month dual antiplatelet therapy with 24-months. Although the observed differences in the risk of all-cause death between the different dual antiplatelet therapy durations were not statically significant, we observed a trend toward a low-to-moderate risk reduction with 24-month duration, which was associated with a probability of 44% to be the best treatment. Conversely, we observed a progressive increase in the risk of major bleeding from shorter to longer dual antiplatelet therapy duration: 3-month duration was associated with a probability of 59% to be the best treatment.
Conclusions: Long-term dual antiplatelet therapy was associated with a reduced risk of all-cause death but also with a higher risk of major bleeding.

Myocardial blush and microvascular reperfusion following manual thrombectomy during PCI for STEMI: insights from the TOTAL trial

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Aims: Myocardial blush grade has been shown to predict mortality after primary percutaneous coronary intervention (PPCI). Small trials have shown improvement in myocardial blush grade with manual thrombectomy. Larger trials have shown conflicting results for clinical outcomes with manual thrombectomy.
Methods and results: The TOTAL trial is an international, prospective randomised (multicentre) trial of manual thrombus aspiration (using the Export® catheter, Medtronic CardioVascular, Santa Rosa, CA, USA) in STEMI patients versus PPCI alone that has enrolled 10,732 patients. The angiographic substudy will determine if manual thrombectomy can reduce the incidence of myocardial blush grade (MBG) 0 or 1 compared to PCI alone. The substudy will randomly select 1,610 patients and will have 80% power to detect a 25% relative risk reduction in MBG 0 or 1. All angiographic outcomes will be assessed blinded to treatment assignment at the Peter Munk Cardiac Care Centre, Toronto, Canada. In addition to MBG, the following outcomes will be assessed: i) post-PCI TIMI flow grade, ii) Distal embolisation, iii) TIMI thrombus grade, iv) PPCI complications, v) severity of infarct related artery (IRA) and non IRA- related disease. The full results of angiographic substudy will be available for presentation in May 2015 at EuroPCR.
Conclusions: The TOTAL trial is the largest trial to examine the impact of thrombectomy during PPCI for STEMI. This important substudy will provide detailed angiographic outcomes and provide insights on the findings observed in the overall trial for clinical outcomes.

euroPCR Coronary interventions

Euro15A-OP007

In-hospital and long-term outcomes of mesh covered MGUARD stent implantation for treatment of ST-segment elevation myocardial infarction with high thrombus burden despite manual aspiration

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Aims: The MGUARD (MG) is a dedicated steel stent with closed cells coated with Dacron which has been designed to ensure a reduced distal embolisation of thrombotic material and consequently lower risk of no-reflow phenomenon. As of today, few data have been reported to evaluate the usefulness of the MG stent in patients with STEMI with a high thrombus burden.

Methods and results: We prospectively collected data of patients presenting with STEMI and high thrombotic burden (thrombus burden grade 4 or 5 according to the TIMI score) who underwent primary PCI (PPCI) with MG stent implantation in our centre. Lesions involving a bifurcation or very calcified and tortuous vessels were not included. Final TIMI 3 flow, normal myocardial blush (MB), and complete ST-segment resolution were defined as short-term endpoints while MACE were evaluated during follow-up. From August 2008 to June 2013, the MG stent was implanted in 104 (9.3%) of 1,108 patients who underwent PPCI. Cardiogenic shock was present in 4 patients (3.8%). Final TIMI-3 flow was achieved in 97% patients, myocardial blush grade 3 in 57% while a regression of ST-segment elevation ≥70% within 90 minutes was recorded in 64% of patients. In-hospital mortality was 2.9% (3 patients) while, at mean follow-up of 455±430 days; there were 9 (8.6%) MACE reported, 5 (4.9%) cardiac deaths and 2 (1.9%) instances of stent thrombosis occurred.

Conclusions: In selected patients with STEMI undergoing PPCI, the use of the mesh-covered stent MGUARD was effective and safe in vessels presenting with large thrombotic burden despite thrombus aspiration both immediately and at mid- to long-term follow-up.

euroPCR Coronary interventions

Euro15A-OP008

Impact of percutaneous coronary interventions for culprit vessels versus complete staged revascularisation in ST-elevation myocardial infarction patients with multivessel coronary artery disease

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Aims: Our aim was to determine and compare the major adverse cardiac and cerebrovascular events (MACCE: cardiac death, reinfarction and stroke, the need for revascularisation and major bleeding) in those STEMI patients with angiographic patterns of multivessel coronary artery disease with clinical indications to undergo either PCI of the culprit lesion alone versus complete staged revascularisation.

Methods and results: We prospectively studied 120 patients presenting with STEMI and multivessel coronary artery disease, 60 patients were enrolled in culprit vessel only PCI group, 60 patients were enrolled in staged PCI group. Both groups were well matched in terms of incidence of cardiovascular risk factors. Baseline syntax score and grace risk score at admission were similar in the two groups. The residual SYNTAX score was significantly higher in the culprit vessel PCR group $p<0.001$. The composite MACCE endpoint at 6 months was higher in the culprit vessel PCI group (13.3%) than in the staged PCI group, $p=0.038$. Also, there was a statistically significant relationship between the residual SYNTAX score and MACCE at six months.

Conclusions: In patients with STEMI presenting with multivessel coronary artery disease, primary PCI of the culprit vessel followed by complete staged revascularisation was associated with better short- and midterm outcomes compared to PCI of the culprit vessel alone. The residual SYNTAX score, the Grace Risk score at discharge and smoking are independent predictors of MACCE at 6 months in the culprit vessel PCI group.

Primary angioplasty in bifurcations lesions: comparison of a complex versus simple strategy and its impact on myocardial reperfusion

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Aims: It is not uncommon to find bifurcation lesions during primary angioplasty (AP) in patients presenting with an acute myocardial infarction with ST-segment elevation (STEMI). Although the literature supports a simple strategy in patients with stable coronary heart disease and bifurcations, there is little evidence which is the best strategy for interventional treatment in bifurcation lesions during the AP. We evaluate the effectiveness and safety of AP in patients with bifurcation lesions in STEMI, comparing a simple strategy (one stent, 1 guide) vs. a complex strategy (provisional stent (SP) and/or 2 stents technique).
Methods and results: An observational retrospective cohort analytical study. We selected patients with bifurcation lesions in the culprit vessel. We reviewed the clinical characteristics, peri- and post-procedural angiographic data, and the presence of major adverse cardiac events (MACE; mortality, stroke, reinfarction, revascularisation of the culprit vessel) and follow-up mortality. Final angiographic results were compared using a simple strategy (controls) vs. complex (cases). Of a total of 853 patients with STEMI in the period analysed, 125 (14.6%) had bifurcation lesions in the culprit vessel. groups (32 cases, 93 controls) were comparable for baseline clinical and angiographic characteristics with a group of cases which used more contrast (213 mL vs. 269 mL, p=0.01) and radiation (2,432 vs. 4,342 mGy; p=0.005). A better final microvascular flow in the main epicardial vessel measured by TIMI frame count (cTFC) in certain cases vs. controls was obtained (20.8 vs. 26.8, p=<0.001, cTFC <23 84% vs. 49%, p=0.001). When analysing subgroups of complex strategy according to the technique of bifurcation (SP and 2 stents) vs. the control group (CG), better cTFC was observed in both groups vs. the CG (21±5.8 vs. 26.8±11.5; p=0.004; 2 stents: 20.1±5GC vs. 26.8±11.5 p=0.03), finding no differences between subgroups of patients (SP stents vs. 2 vs. 21±5.8±20.1 5; p=0.97). There were no differences in MACE (31.2% vs. 28.7%; p=0.83) or overall mortality (6.25 vs. 6%; p=0.2), with a mean of 2.4 years (13-44 months).
Conclusions: AP in bifurcation using a complex strategy vs. a simple one allows for better myocardial reperfusion in the main vessel, although there is more radiation exposure and a slight increase in use of contrast without deterioration of renal function. No differences in the presentation of MACE or follow-up mortality were observed.

Impact of complete revascularisation in a real-world population of patients presenting with ST-elevation myocardial infarction and multivessel disease

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Aims: Complete revascularisation during primary percutaneous coronary intervention (PCI) in patients with multivessel disease is associated with better outcome in highly selected cohorts. We evaluated this subject in an all-comers ST-elevation myocardial infarction (STEMI) population.
Methods and results: A retrospective analysis was performed of 2,078 consecutive patients with STEMI admitted to the cathlab who were prospectively included in a tertiary centre registry between January 2004 and January 2014. We assessed the evolution of complete revascularisation over the study time-frame and evaluated the absolute differences in 1-year major adverse cardiac events (MACE) according to the completeness of the revascularisation. One thousand, one hundred and nine (1,109) patients had multivessel disease, 25.2% underwent complete revascularisation. The rate of complete revascularisation showed a progressive and significant increase over time (8%, 19%, 22%, 22%, 28% per biennium, p=0.03). Complete revascularisation was associated with a lower rate of 1- and 2-year MACE (11.4% vs. 21%, p=0.01 and 15.5% vs. 27%, p=0.001, respectively) reflecting a lower rate in non-urgent revascularisation and myocardial infarction. There was no difference regarding all-cause mortality at 1 year (8.1% vs. 10.6%, p=0.316) and 2 years (9% vs. 13%, p=0.107).
Conclusions: In patients with STEMI and multivessel coronary artery disease undergoing culprit lesion PCI, preventive PCI in non-infarct coronary arteries with significant stenosis significantly reduced the risk of adverse cardiovascular events, as compared with incomplete revascularisation, even in a real-world population.

EuroPCR Coronary interventions

Euro15A-OP011

Thrombogenicity and early vascular healing response in metallic biodegradable polymer based and fully bioabsorbable drug-eluting stents

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Aims: Acute thrombogenicity and re-endothelialisation of coronary stents represent clinically relevant endpoints pertaining to safety of contemporary percutaneous coronary intervention. We aimed to assess comparative acute thrombogenicity and other components of vascular healing in contemporary biodegradable polymer based drug-eluting stents and fully bioabsorbable stents.

Methods and results: We investigated the comparative outcomes with respect to acute thrombogenicity and re-endothelialisation among thin-strut biodegradable polymer metallic everolimus eluting stents, thick-strut bioabsorbable everolimus eluting stents, thick-strut biodegradable polymer metallic biolimus-eluting stents and control bare metal stents. An *ex vivo* porcine arterio-venous shunt model was used to assess platelet aggregation, while a healthy rabbit model of ileofemoral stent implantation was used to assess re-endothelialisation and inflammation. The analysis involved scanning electron and confocal microscopy of immunofluorescent markers for thrombocytes (CD61/CD42b), inflammatory cells (CD14/PM-1 and RAM-11), and endothelium (CD31/PECAM-1). Thin-strut biodegradable polymer metallic everolimus-eluting stents demonstrated significantly less acute thrombogenicity and inflammatory cell adhesion compared to thick-strut bioabsorbable everolimus-eluting stents and thick-strut biodegradable polymer metallic biolimus-eluting stents. Thin-strut biodegradable polymer metallic everolimus-eluting stents also exhibited superior results with respect to re-endothelialisation and reduced adhesion of monocytes/macrophages when compared to thick-strut bioabsorbable everolimus-eluting stents and thick-strut biodegradable polymer metallic biolimus-eluting stents.

Conclusions: In comparison to thick-strut bioabsorbable everolimus-eluting stents and thick-strut biodegradable polymer metallic biolimus-eluting stents, thin-strut biodegradable polymer metallic everolimus-eluting stents showed decreased acute thrombogenicity and advanced re-endothelialisation in established animal models. These outcomes indicate differential trends in vascular healing among contemporary stents used in clinical practice and may have implication for adjunct anti-thrombotic pharmacotherapy.

EuroPCR Coronary interventions

Euro15A-OP012

Impact of wall shear stress on long-term vascular healing of bioresorbable vascular scaffold

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Aims: We aimed to explore the association between wall shear stress 2 years after bioresorbable scaffold implantation and the 5-year scaffolded segment morphology.

Methods and results: Seven patients underwent invasive 5-year follow-up including IVUS, virtual histology and OCT. Multi-slice computed tomography study had been performed 18 months post-bioresorbable scaffold implantation, and invasive imaging follow-up at 24 months. Thus, ECG-gated IVUS pullbacks at 2 years were available for 7/8 patients. Fusion of the 3D vessel centreline derived from the 18-month computed tomography study with lumen information derived from the 24-month IVUS studies was performed, in order to create a three-dimensional reconstruction of the scaffolded segment. Thereby, seven 3D reconstructions were generated by fusion of computed tomography and IVUS, in which computational fluid dynamics was performed. Computational fluid dynamics calculations were performed based on these meshes and wall shear stress was calculated. Shear stress values were then evaluated with relation to plaque morphology and morphometric measurements by OCT and IVUS. These possible associations were evaluated in two levels: a) segment level and b) plaque level. For the segment-level analysis, the scaffolded region was divided in two equal segments (proximal and distal segment). The relative differences in shear stress were calculated as the difference of shear stress in the distal versus proximal segment divided by the average shear stress of the entire scaffolded segment. All the variables derived by the OCT, IVUS and virtual histology analysis were assessed separately for the distal and the proximal segment and differences were calculated. Within a scaffold, relative shear stress differences in distal versus proximal segments were positively correlated to differences in minimum cap thickness (r^2=0.76, p=0.03), with a trend for negative correlation with differences in maximum necrotic core arc by OCT (r^2=0.51; p=0.07). There was no significant correlation between shear stress and changes in lumen, vessel, or plaque area from 2 to 5 years. Change of dense calcium area from 2 to 5 years was the only virtual histology variable showing a positive correlation with relative shear stress differences (r^2=0.73; p=0.03). For the plaque-level analysis, the lumen and cap contours at areas of necrotic core were segmented in the OCT images and co-registered with the 3D shear stress map, using the same landmarks used for IVUS-computed tomography fusion. Shear stress values were numerically lower in regions with OCT necrotic core versus regions without OCT necrotic core, albeit not reaching significance (1.49±1.27 Pa vs. 1.83±1.72 Pa; p=0.21).

Conclusions: Wall shear stress 2 years after bioresorbable scaffold implantation is associated with the vascular healing response by OCT at 5 years. Specifically, within a scaffold, regions with lower shear stress are associated with thinner fibrous cap.

Clinical outcome of acute recoil after everolimus-eluting bioresorbable vascular scaffolds implantation

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Aims: To assess the clinical outcome of acute recoil in patients who underwent percutaneous coronary interventions with everolimus-eluting bioresorbable vascular scaffolds (BVS) implantation.

Methods and results: All consecutive patients who underwent percutaneous coronary intervention (PCI) with BVS implantation in our Institution between April 2012 and September 2014 were enrolled. Device implantation was performed according to standard procedure techniques; pre-dilatation, post-dilatation and usage of intracoronary imaging were led to operator's discretion. Prior to scaffold implantation, patients received a loading dose of 600 mg of clopidogrel and 300 mg of aspirin, and this regimen was followed by aspirin 100 mg and 75 mg of clopidogrel daily for 12 months. Mean follow-up was 317±198 days. Acute recoil was measured by the difference between mean diameter of the scaffold delivery balloon at highest pressure at and luminal diameter of scaffold segment after implantation. We classified the patients according to acute scaffold recoil tertiles. We included 93 patients (mean age 59±11 y, 78 [84%] males), 35 presenting with ST segment elevation myocardial infarction (38%), 18 with stable angina (19%) and 40 with non-ST segment elevation acute coronary syndrome (43%). A higher stent thrombosis rate was observed in patients in the highest tertile of acute recoil (>0.20 mm) (0% vs. 12%, p=0.01). No other clinical events were different between the two groups.

Conclusions: Our data suggest that high acute recoil after BVS implantation can infer prognostic implications as it has been associated with higher rates of stent thrombosis.

Predictors of acute scaffold recoil after implantation of the everolimus-eluting bioresorbable scaffold: an optical coherence tomography assessment in native coronary arteries

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Aims: Initial reports have suggested slightly higher acute recoil of the everolimus-eluting bioresorbable scaffold (BRS) compared to its metallic counterpart. In this study, we aimed to assess the magnitude of acute scaffold recoil in unselected patient population treated with BRS, and to investigate its prediction based on optical coherence tomography (OCT) findings.

Methods and results: Of 191 patients treated with BRS at a single institution, 39 patients (56 lesions) were examined by OCT during the initial procedure and represent the population of the current analysis. For each treated lesions, off-line quantitative coronary angiography (QCA) and OCT recordings were retrospectively analysed. OCT images were analysed at 1 mm intervals for quantitative measurements. Acute absolute recoil as assessed by QCA was defined as the difference between the mean diameter of the last inflated balloon at the highest pressure (X) and the mean lumen diameter of the scaffold immediately after last balloon deflation (Y). Acute percent recoil was defined as (X-Y)/X and expressed as a percentage. Plaque and scaffold eccentricity (PE and SE) as assessed by OCT were defined as follows: PE=(lumen diameter [LD]+the maximum thickness of plaque [Pmax] – minimum thickness of plaque [Pmin]) / (LD – Pmax+Pmin); SE=(maximum diameter – minimum diameter) /maximum diameter. Coronary plaques were classified into 3 different types according to their OCT characteristics: calcific (score=2), fibrous (score=1), or fibro-fatty (score=0). The mean age of the study population was 60±8 years, and 15 (38%) were males. All target lesions were treated with balloon predilatation and scaffold deployment at a pressure not exceeding the rated burst pressure. Post-dilatation with a balloon shorter than the implanted scaffold was done at the operator's discretion (49/56 lesions, 87.5%). The mean diameter and length of the implanted scaffold were 2.95±0.36 and 22.0±5.8 mm, respectively. Mean acute recoil was 6.4±3.0%. Based on the previously reported average acute recoil value for BRS of 6.7% (Absorb cohort B study), lesions were divided into two groups: the no acute recoil group (NAR, N=34) and the acute recoil group (AR, N=22). There were no significant differences between both groups with respect to baseline clinical characteristics, ACC/AHA lesion type, scaffold diameter and frequency of post-dilatation. However, PE (1.59±0.27 vs. 1.41±0.18, p=0.01), SE (18.1±5.1 vs. 14.6±2.7%, p=0.01), plaque composition score (1.13±0.12 vs. 1.04±0.09, p=0.01) were all significantly higher in the AR compared to the NAR group. A significant positive correlation was observed between PE and SE (R=0.35, p=0.02). Multivariate logistic regression analysis revealed that PE >1.49 (odds ratio [OR] 5.08, 95% confidence interval [CI]: 1.23-20.3, p=0.02), plaque composition score >1.25 (OR 4.84, 95% CI: 1.1-19.7, p=0.03), and scaffold/artery ratio >1.07 (OR 4.99, 95% CI: 1.3-19.4, p=0.02) were significant positive predictors for the occurrence of acute recoil.

Conclusions: Acute recoil of the everolimus-eluting BRS seems to be influenced by procedural as well as OCT-derived plaque characteristics, particularly plaque eccentricity and fibro-calcific plaque composition.

EuroPCR Coronary interventions Euro15A-OP015

Differences in stent/scaffold expansion between everolimus-eluting bioresorbable scaffolds and metallic drug-eluting stents in calcified lesions: an optical coherence tomography study

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Aims: We compared the acute expansion and apposition pattern of BVS (ABSORB, Abbott Vascular, Santa Clara, CA, USA) compared with MPS in noncalcified and calcified coronary artery lesions by optical coherence tomography (OCT).

Methods and results: We selected discrete lesions of patients included in the BVS Expand registry that have optical coherence tomography (OCT) data post-device-implantation. These lesions were then grouped according to the angiographic degree of calcification in a 2:2:1 fashion (No/mild; Moderate; Heavy). An equal number of matched lesions treated with MPS with data from an imaging database were studied. Pre- and post-dilation were performed with short balloons of similar diameter in most of the procedures. The following stent performance indexes were assessed with OCT: mean scaffold area, % malapposed struts, eccentricity index (EI) and symmetry index (SI). The EI was defined as ratio between minimal and maximal scaffold diameter in each analysed frame. SI was defined as: (maximal scaffold diameter- minimal scaffold diameter)/(maximal scaffold diameter) in each analysed frame. For each scaffold, both the mean EI and SI were computed. One hundred (100: BVS/MPS; 50/50) discrete lesions from 85 (BVS/MPS; 37/48) patients were analysed. Baseline clinical and demographic variables were similar between the BVS and MPS groups. Lesion complexity was similar in the 2 groups (AHA B2/C lesion was 62% in BVS vs. 64% in MPS, p=0.836). Pre-dilation was performed more frequently in BVS (96.0% vs. 58.0%, p<0.001). Most of the BVS and MPS were post-dilated with short noncompliant (NC) balloons of similar diameter. There was no significant differences in mean scaffold area between BVS and MPS groups in the none/mild, moderately and heavily calcified lesions (BVS vs. MPS; 7.06±1.75 vs. 8.41±3.64 mm^2, p=0.147 and 6.94 ±1.70 vs. 7.84±2.44, p=0.184 and 7.02±1.96 vs. 7.72±1.69 mm^2, p=0.403 correspondingly). Compared to MPS, the BVS group showed a marginal smaller EI in the none/mild calcified group (0.85±0.04 vs. 0.88±0.03, p=0.008) but was similar in the moderate (0.84±0.05 vs. 0.87±0.03, p=0.078) and heavily calcified (0.83±0.04 vs. 0.86±0.02, p=0.110) groups. Compared to MPS, BVS showed significantly lower strut malapposition in the moderate calcified groups (% malapposed struts; 3.65±2.17 vs. 7.70±5.32, p=0.004) and lower malapposition which trends towards significance in the heavily calcified group (2.23±2.17 vs. 8.84±9.26, p=0.053). There was no significant difference in strut malapposition between BVS and MPS in the none/mild calcified (3.17±4.09 vs. 4.05±4.37, p=0.515). There were no significant differences in the SI between the BVS and MPS in the 3 calcified groups. No cases of strut fractures were observed in our cohort.

Conclusions: In our selected cohort the degree of lesion calcification did not severely limit the uniform expansion of polymeric BVS compared to MPS as measured by the mean scaffold area and EI. Strut malapposition was lower in the BVS compared to MPS in more calcified lesions.

EuroPCR Coronary interventions Euro15A-OP016

Long coronary lesions treated with thin strut bioresorbable polymer DES: experience from multicentre randomised CENTURY II study

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Aims: Long coronary lesions (LL) have been generally associated with worse clinical outcomes in percutaneous coronary interventions (PCI) with use of drug-eluting stents (DES). However, the exact impact of lesion length on the short- and long-term outcomes of DES implantations is not as clear. Our aim was to assess safety and efficacy of new, bioresorbable polymer sirolimus-eluting stent Ultimaster (BP-SES) in patients with LL and to compare it to permanent polymer everolimus-eluting stent XIENCE (PP-EES).

Methods and results: In the frame of a single-blind, randomised, multicentre CENTURY II study, out of 1,119 patients enrolled, 182 patients had LL (defined as ≥25 mm) treated and assigned randomly to treatment with BP-SES (101) or PP-EES (81). The primary endpoint of the study was TLF at 9 months and 2-year follow-up is currently ongoing. All data were monitored and adverse events were adjudicated by an independent clinical event committee. There was no significant difference noted in baseline patient characteristics such as age, gender, presence of IDDM and NIDDM, hypertension, smoking, previous MI and previous PCI in BP-SES and PP-EES groups. LAD was the most frequent target vessel in both groups and lesions were accessed most frequently using the transradial approach (68.3% vs. 69.1%; p=0.93), without any significant difference. Multivessel disease was present with similar frequency (51.5% vs. 65.4%; p=0.06), as well as bifurcation lesions (17.5% vs. 14.5%; p=0.50) in BP-SES and PP-EES groups respectively, with lesions presence mostly in smaller vessels (preprocedural RVD - 2.6±0.6 mm vs. 2.6±0.5 mm; p=0.86) and no difference in lesion length (29.4±12.5 mm vs. 29.1±11.4 mm; p=0.76). Thrombus burden was numerically higher in BP-SES group, but not reaching statistical significance (2.9% vs. 0.0%; p=0.07). There was no difference in number of treated lesions (1.58±0.78 vs. 1.53±0.76; p=0.65) and stents implanted per lesion (1.5±0.6 vs. 1.6±0.7; p=0.23). At 1 year, there was no difference noted in rate of cardiac death (2.0% vs. 2.5%; p=0.82), MI (4.0% vs. 4.9%; p=0.75), clinically driven TVR (6.9% vs. 7.4%; p=0.90) and TLR (3.0% vs. 6.2%; p=0.30), for BP-SES and PP-EES respectively. Composite endpoints such as TLF (8.9% vs. 9.9%; p=0.82), TVF (12.9% vs. 11.1%; p=0.72) and POCE (16.8% vs. 22.2%; p=0.36) were following the same trend. There was no stent thrombosis (ST) recorded in BP-SES group up to 1 year, while 1 case of subacute ST was recorded in PP-EES group, resulting in very low and similar ST rates (0.0% vs. 1.2%; p=0.26).

Conclusions: Patients with long coronary lesions showed favourable and similar clinical outcomes when treated with Ultimaster BP-SES and XIENCE PP-EES. Absence of stent thrombosis in BP-SES group up to 9 months is encouraging and long-term follow-up data are needed to show whether it reflects clearly potential advantages of bioresorbable polymer.

Clinical outcomes from unselected real-world patients with long coronary lesion receiving 40 mm bioabsorbable polymer coated sirolimus-eluting stent

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Aims: Long lesions remain a lesion subset in which drug-eluting stents (DES) are still associated with relatively high restenosis rates, especially in real-world patients and registries. We aimed to examine the safety and efficacy of the long (40 mm), thin-strut (60 µm) and bioabsorbable polymer coated Indolimus sirolimus-eluting stent (SES) in real-world patients with long coronary lesions.

Methods and results: This observational, non-randomised, real-world study was carried out in four different clinical centres of India. A total of 258 patients treated for long coronary lesion, with 40 mm Indolimus SES (Sahajanand Medical Technologies Pvt. Ltd, Gujarat, India), between April 2012 and June 2014 were included in this study. The incidence of major adverse cardiac events (MACE), a composite of cardiac death, myocardial infarction (MI), target lesion revascularisation (TLR) or target vessel revascularisation (TVR), at 6-month follow-up was the primary endpoint of this study. Adverse events, including ST according to Academic Resource Consortium, were also analysed. Long-term follow-up of this study is ongoing. The study population was predominantly male (n=192; 74.4%) and average age was 53.2±11.0 years. The study included high-risk patients among whom 99 (38.4%) were hypertensive and 83 (32.2%) were diabetics. A total of 278 lesions were intervened with a total of 280 study stents (1.1±0.3 stent per patient). Modified American College of Cardiology/American Heart Association type B2 and C lesions accounted for 163 (58.6%) lesions and 61 (21.9%) patients presented with chronic total occlusion. Clinical follow-up was completed in 256 (99.2%) patients at the end of 6-month. The observed MACE at 6-month follow-up was 2.0% (5/256), which included 0.8% (2/256) cardiac death and 1.2% MI (3/256). Despite the long lesion length and unfavourable lesion characteristics, there were no TLR or TVR observed in this study. Also, there was no any ST during 6-month follow-up.

Conclusions: The long (40 mm) Indolimus, a thin-strut, bioabsorbable polymer coated SES, demonstrated low MACE rate as well as acceptable safety outcomes for the treatment of long lesions in real-world patients.

Three-year clinical outcomes of patients with DES in diffuse long lesions: comparison of first-generation sirolimus-eluting stent versus second generation everolimus-eluting stent

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Aims: The aim of this study is to compare clinical outcomes between first-generation sirolimus-eluting stent and second-generation everolimus-eluting stent in patients with diffuse long lesions for 3 years.

Methods and results: A total of 370 consecutive patients with diffuse long lesion treated with ≥ 50 mm stent segment in *de novo* lesions from January 2006 to December 2010 were enrolled. The patients were divided into two groups as sirolimus-eluting stent (SES, n=340) group and everolimus-eluting stent (EES, n=215) group. Study endpoints were major adverse cardiac events (MACE) including all death, myocardial infarction (MI), and ischaemic-driven target vessel revascularisation (Id-TVR). Baseline characteristics were similar between the two groups. Stent length was 61.93±11.68 mm in SES and 62.63±13.69 mm in EES (p=0.639). For 3-year clinical follow-up, the rate of cumulative MACE was 11.3% in SES and 6.2% in EES (p=0.128). The rate of Id-TVR was observed 5.4% in SES and 1.8% in EES (p=0.164). The rate of MI was observed 1.2% in SES and 0.9% in EES (p=1.000). The rate of all death was observed 6.6% in SES and 5.3% in EES group (p=0.632).

Conclusions: The clinical outcomes between SES and EES in patients with diffuse long lesions were not different for 3 years. Further longer-term follow-up and larger population study will be needed for better evaluation.

euroPCR Coronary interventions

Euro15A-OP020

Treatment of long lesions with overlapping drug-eluting stents: comparative analysis between second-generation everolimus-eluting stents and first-generation drug-eluting stents

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Aims: First-generation drug-eluting stents (DES) have demonstrated better results for the treatment of long lesions (>30 mm) requiring two or more overlapped DES compared with bare metal stents. However, there is still insufficient evidence regarding the long-term safety and efficacy of overlapping two or more DES either first- or second-generation devices. We sought to compare the long-term clinical outcomes between second-generation everolimus-eluting stents and the first-generation sirolimus- and paclitaxel-eluting stents for the treatment of long lesions with overlapped stents.

Methods and results: This single centre retrospective study included 215 consecutive patients treated with two or more overlapping DES. Everolimus-eluting stents were used in 117 patients, 212 lesions; sirolimus-eluting stents in 48 patients, 81 lesions; paclitaxel-eluting stents 50 patients, 94 lesions. In-hospital and long-term outcomes were analysed. Endpoints were major adverse cardiovascular events defined as the composite of death, myocardial infarction or target lesion revascularisation, and definite stent thrombosis. Baseline clinical and angiographic characteristics were similar between groups. Of the study population, 84% were male, age 61±9 years, 31% diabetics; target vessel left anterior descending accounted for 54%, acute coronary syndrome 51%. Stent length was 49±13 mm in everolimus, 51±11 mm in paclitaxel and 51±8 in sirolimus (p=0.37). Periprocedural myocardial infarction (creatine kinase above three times) was observed in 2.5%, 8.0% and 0% of each group respectively (p=0.07). All patients completed a two-year clinical follow-up. Major adverse cardiovascular events occurred in 2.6% of everolimus group, 8% of paclitaxel group and 4.2% of sirolimus group (p=0.27). All-cause mortality (0.46%) and definite stent thrombosis (0.92%) at two years were low, and without significant differences between groups. Survival, free of major adverse cardiovascular events, was 97% for everolimus group, 92% for paclitaxel group and 96% for sirolimus group treated patients (p log-rank=0.27).

Conclusions: In this single centre study of patients with long coronary lesions that requiring treatment with two or more overlapping DES, there were no significant differences in long-term outcomes between the second-generation and first-generation DES, each with similar safety and efficacy outcomes.

euroPCR Coronary interventions

Euro15A-OP021

FFR grey zone and clinical outcome

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Aims: Fractional flow reserve (FFR) invasively assesses the ischaemic potential of coronary stenosis and predicts the expected improvement by revascularisation. An FFR value of 0.75 has been validated against ischaemic testing, while an FFR value of 0.80 has been widely accepted to guide clinical-decision-making. Whether revascularisation should be proposed when the FFR is between 0.75-0.80 ("grey zone") is still debatable. Therefore, we studied the clinical outcome of patients with an isolated stenosis and an FFR value in the grey zone.

Methods and results: From February 1997 to June 2013, all consecutive patients presenting with single segment disease at coronary angiography and FFR between 0.70-0.85 were included. Patients with previous bypass surgery, in-stent restenosis, myocardial bridge or heart transplantation were excluded. According to FFR values, patients were divided into the following strata: a) 0.70-0.75; b) 0.76-0.80; c) 0.81-0.85. Study endpoints consisted of major adverse cardiovascular events (MACE: death, myocardial infarction and any revascularisation) up to 5 years. Data were also analysed according to lesion location (proximal and mid versus distal coronary segments). Out of 17,380 patients undergoing FFR measurement: a) 2,781 (16%) patients presented lesions with FFR in the grey zone; b) 1,459 fulfilled the inclusion/exclusion criteria and were included in the present analysis: 449 treated with percutaneous revascularisation (PCI) and 1,010 with medical therapy (MT). Clinical characteristics were similar among patients treated with PCI or MT, except for male gender (more frequent in PCI group [p=0.002]). Diameter stenosis, minimum lumen diameter, and FFR values were lower in PCI group (p<0.0001). In patients with an FFR between 0.70 and 0.75, MACE's were more frequent after MT than after PCI (11 [2%] vs. 53 [12%], respectively, p=0.026). In patients with an FFR between 0.81 and 0.85, MACE tended to be less frequent after MT than after PCI (58 [8%] vs. 53 [12%], respectively, p=0.057). Among patients treated with MT alone, a progressive increase in MACE was observed in the 3 FFR strata (FFR, 0.81-0.85: 58 [8%] vs. FFR, 0.76-0.80: 35 [13%] vs. FFR, 0.70-0.75: n=11 [21%], p<0.0001). In patients treated with MT alone and a stenosis located in proximal or mid segments, decreasing FFR values were paralleled by an increase in overall mortality (p=0.032).

Conclusions: The present study which focus on lesions in and around the FFR "grey zone", confirms the value of the 0.80 threshold for clinical-decision-making: patients with lesions with an FFR<0.75 benefit from PCI, while in lesions with an FFR >0.80, PCI can safely be deferred.

Instantaneous wave-free ratio (iFR) provides the most robust measure of any resting physiological index: assessment of the effects of pressure drift and biological variability on stenosis misclassification in 447 stenoses

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Aims: Pressure drift and biological variability (real-time fluctuations in value during measurement) can result in stenosis misclassification if values cross treatment thresholds. We assessed these variables and investigated their effect on stenosis misclassification with FFR, iFR and whole cycle Pd/Pa indices.

Methods and results: Four hundred and forty-seven (447) stenoses were assessed (mean age 62.7 years [±10 years], 79% male). Intracoronary pressure was measured distal to the stenosis at rest and under pharmacologic vasodilation with adenosine. Data were analysed offline using a custom software package designed with Matlab (Mathworks, Inc., Natick, MA, USA) to calculate physiological stenosis severity by FFR, iFR and whole cycle Pd/Pa indices. Cutoff thresholds to define a positive result for FFR, iFR and whole cycle Pd/Pa were ≤0.8, <0.90 and <0.93, respectively. The effect of drift was analysed by offsetting the distal intracoronary pressure trace by ±1 mmHg across the range –3 mmHg to +3 mmHg. FFR, iFR and whole cycle Pd/Pa values were recalculated according to the degree of drift and compared to their respective cutoff threshold values to quantify stenosis misclassification. Biological variability was analysed by recalculating values with an offset of ±0.01 units, across a range from –0.03 to +0.03 units. Values were compared to cutoff thresholds as previously described. All analyses were performed in a fully automated manner, eliminating the need for manual selection of data time points. Drift and biological variability were plotted against stenosis misclassification (% of total cohort) across a range of –3 mmHg to +3 mmHg and –0.03 to +0.03 units, respectively. The area under the curve was calculated to compare the diagnostic performance of indices. Stenosis misclassification with iFR and whole cycle Pd/Pa indices were compared to the current gold standard method (FFR). The misclassification rates across the three techniques were compared using the Chi squared test, and p-values for *post hoc* comparisons were adjusted using the Bonferroni method. Mean FFR, iFR and whole cycle Pd/Pa values for the cohort were 0.78 (±0.14), 0.85 (±0.16), and 0.90 (±0.12), with 48%, 47% and 45% of stenoses below the cutoff thresholds to define a positive result respectively. Pressure drift across the range of ±3 mmHg resulted in 43% (192/447), 55% (246/447) and 72% (322/447) of stenoses being reclassified with FFR, iFR and whole cycle Pd/Pa respectively (p<0.001 for each group). Biological variability across the range of ±0.03 units resulted in 35% (156/447), 47% (210/447) and 67% (299/447) of all stenoses being reclassified with iFR and whole cycle Pd/Pa respectively. All three groups were significantly different from each other (p<0.001). iFR was proportionally more resilient to the effects of drift and biological variability than whole cycle Pd/Pa by 233% and 254%, respectively, when compared to the current gold standard method (FFR) (p<0.001).

Conclusions: iFR is more resistant to drift and biological variability than whole cycle Pd/Pa. This results in less stenosis misclassification using iFR than whole cycle PdPa, making iFR a far more clinically robust tool in the catheter laboratory.

Japan study of distal evaluation of functional significance of intra-arterial stenosis narrowing effect (J-DEFINE)

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Aims: Hybrid instantaneous wave-free ratio (IFR) and fractional flow reserve (FFR) decision-making strategy has been proposed. Proposed strategy of IFR cutoff is >0.93 and <0.80. If IFR is 0.8-0.93 of grey zone, FFR measurement is recommended. However, the feasibility of this decision-making strategy remains unclear. To assess the feasibility of hybrid IFR and FFR making decision strategy in daily practice, classification agreement was evaluated. Hybrid instantaneous wave-free ratio (IFR) and fractional flow reserve (FFR) decision-making strategy has been proposed. Proposed strategy of IFR cutoff is >0.93 and <0.80. If IFR is 0.8-0.93 of grey zone, FFR measurement is recommended. However, the feasibility of this decision-making strategy remains unclear. To assess the feasibility of hybrid IFR and FFR making decision strategy in daily practice, classification agreement was evaluated.

Methods and results: A total of 412 patients with angiographically intermediate stenosis was prospectively enrolled from 29 sites in Japan. Both iFR and FFR was measured in a total of 579 lesions. Mean iFR was 0.84±0.16 and FFR was 0.77±0.13. The iFR was correlated well with FFR (correlation r was 0.77, 0.75, 0.79, and 0.59 in all, LAD, LCx, and RCA, respectively p<0.001). Patients was classified into 3 groups according to iFR value. group â'<0.86 (n=112), group â'¡0.86-0.93 (n=126), group â'¢>0.93 (n=133). Diagnostic agreement between iFR and FFR was 89.3%, 53.2%, and 91.7% in group â', â'¡, â'¢, respectively. Diagnostic agreement in groups â' and â'¢ was better in LAD compared with RCA (LAD 92% vs. RCA 84.3ï'). When hybrid decision-making strategy is applied in this series, 64.2% of the population is spared from vasodilator while maintaining a 91% overall agreement with FFR lesion classification. After iFR-FFR hybrid measurement, medical treatment was changed to revascularisation in 13.7%, while PCI was switched to medical treatment in 27.8%.

Conclusions: When measured in daily practice, iFR maintained close relationship with FFR. This study may confirm the feasibility of hybrid iFR and FFR decision-making-strategy.

euroPCR Coronary interventions

Euro15A-OP024

FFR guidance during primary PCI in multivessel STEMI patients: insights from the ongoing COMPARE-ACUTE trial

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Aims: Current guidelines deem percutaneous coronary intervention (PCI) of a non-infarct related artery (n-IRA) at the time of primary PCI (pPCI). This approach is being challenged by recent studies, which show benefits of complete rather than culprit vessel-only revascularisation at the time of pPCI. However, these studies assessed grade of stenosis in the n-IRA by visual estimate. The impact of fractional-flow reserve (FFR) measurements during pPCI of n-IRA has not been assessed.

Methods and results: COMPARE ACUTE is an ongoing prospective, randomised strategy trial carried out at 22 sites across Europe and Asia. Patients are randomly allocated (2:1) to receive either FFR guided multivessel (MV) PCI vs. culprit vessel-only PCI with blinded FFR measurements of n-IRA lesions in the setting of STEMI. The primary study endpoint is MACCE defined as death, myocardial infarction, any revascularisation or cerebral accident at 12 months. FFR measurements were done directly after completion of pPCI in all n-IRA with visual estimate of ≥50% stenosis. Positive FFR measurement was defined as ≤0.80 under maximal hyperaemia. From July 2011 to January 2015, 614 STEMI patients undergoing primary PCI with multivessel disease were enrolled. Mean age was 61.3±11.5 (78.2% male) with Killip class I at presentation in 95.3%. In 38.2% the pPCI was performed in the LAD, 42.8% in the RCA and 19.0% in the RCX. Successful pPCI defined as TIMI 3 flow was achieved in 95.6%. FFR-measurements of 867 n-IRA vessels (888 lesions) were performed in the LAD in 43.3%, RCA 24.3% and RCX 32.4%. In 59.0% the FFR measurement of an n-IRA lesion was negative and in 41.0% positive. On a patient level, 50% of the STEMI patients with angiographic multivessel disease had no haemodynamic significant lesions in the n-IRA.

Conclusions: This preliminary data from the COMPARE ACUTE trial indicates that a high portion of lesions found in non-infarct related arteries with visual estimated stenosis of >50% are FFR negative. This aspect should be taken into account during the debate on multivessel primary PCI in STEMI patients.

euroPCR Coronary interventions

Euro15A-OP025

Impact of the distribution of haemodynamically significant coronary stenosis assessed by fractional flow reserve on the patency of bypass graft

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Aims: Fractional flow reserve (FFR) has been reported to be associated with the graft patency in patients receiving coronary artery bypass graft. The aim of this study was to investigate the impact of the distribution of hemodynamically significant coronary stenosis on bypass graft patency.

Methods and results: We retrospectively investigated 72 patients who underwent coronary bypass surgery including internal mammary artery (IMA) to left anterior descending artery (LAD) graft after FFR measurement in our institution between 2008 and 2014. The graft patency was assessed within one year after bypass surgery. All patients had haemodynamically significant stenosis with FFR <0.80 at distal LAD. Based on the FFR pullback recording, we divided the patients into two groups, proximal lesion group (n=52) and distal lesion group (n=20), according to whether FFR at mid LAD was <0.80 or ≥0.80. The distal lesion group had higher FFR value both in distal and mid LAD than the proximal lesion group (FFR in distal LAD: 0.71±0.07 vs. 0.64±0.07, p<0.001; FFR in mid LAD: 0.83±0.03 vs. 0.71±0.05, p<0.001, respectively). The patency of bypass graft was lower in the distal lesion group than in the proximal lesion group (65% vs. 90%, p=0.016).

Conclusions: The distribution of the pressure gradient in a coronary artery affected the patency of bypass grafts even on haemodynamically significant lesions.

Evaluation of physiological improvement after PCI using instantaneous wave-free ratio (iFR): the potential of iFR to detect and predict post-PCI residual ischaemia

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Aims: To determine whether the instantaneous wave-free ratio (iFR) can be used for the diagnosis of residual ischaemia and prediction of physiological improvement after PCI, by comparing fractional flow reserve (FFR).

Methods and results: A total of 104 lesions from 101 patients scheduled for elective PCI were analysed. Both indices were recorded from far distal, just distal and just proximal of the lesion, before and after PCI. Step-up value across lesion was defined as iFR and FFR. iFR and FFR after PCI were predicted by the addition of ΔiFR, ΔFFR to pre-iFR, pre-FFR. These were defined as predicted-iFR and predicted-FFR, respectively. Both indices improved significantly (FFR 0.64±0.14 → 0.86±0.10, p<0.001; iFR 0.72±0.23→ 0.93±0.07, p<0.001). The improvement in iFR after intervention (0.22±0.22) was similar to FFR (0.22±0.16) and correlated well (R^2=0.71 p<0.001). Sensitivity, specificity, positive predictive value, negative predictive value, accuracy of iFR-cutoff of 0.89 to detect the residual ischaemia defined by FFRâ'0.8 after PCI was 68%, 92%, 76%, 87% and 86%. Linear regression analysis showed better correlation between predicted-iFR and post-iFR (R^2=0.50; p<0.001), than that of predicted-FFR and post-FFR (R^2=0.25; p<0.001).

Conclusions: The changes in coronary haemodynamics can be detected by iFR elicited by PCI. iFR might be useful to objectively document improvement in coronary haemodynamics and diagnose the presence of residual ischaemia following PCI as well as the prediction of recovery more accurately than FFR.

Long-term outcome of FFR-guided PCI for stable coronary artery disease in daily clinical practice: a propensity score-matched landmark analysis

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Aims: Fractional flow reserve (FFR) has a key role in the latest guidelines on myocardial revascularisation. This study aimed to investigate long-term outcome of FFR-guided PCI in routine clinical practice based on a propensity score (PS)-matched landmark analysis.

Methods and results: In this retrospective study, 3,512 patients with stable angina and at least one intermediate coronary stenosis were identified. In order to compare FFR-guided with angiography (XA)-guided PCI, all patients considered for PCI after XA examination (n=1,716) were selected for further analysis. Of these, 962 (56%) were treated based on XA alone, whereas 754 patients (44%) had an FFR-guided treatment. In the latter group, 321 patients (43%) were reallocated to another therapeutic option, predominantly medical treatment. After PS-matching, the number of indicated lesions was 957 in the XA-guided and 947 in the FFR-guided group. FFR-guidance resulted in deferral from PCI in 462 lesions (48.8%). In a 7-day landmark analysis, the rate of periprocedural myocardial infarction (MI) was less than half in the FFR-guided group; however, statistical significance was not achieved. For the 8-days to 4-year follow-up period, FFR-guidance resulted in a significantly lower rate of the combined endpoint death or MI (37% relative risk [RR] reduction) and MI-driven target lesion revascularisation (65% RR reduction); stratified analysis showed that this favourable outcome was maintained across all subgroups (p-for-interaction >0.05).

Conclusions: This study shows that performing FFR has a large impact on therapeutic strategy and demonstrates the favourable outcome of FFR-guided PCI in daily clinical practice.

EuroPCR Coronary interventions

Euro15A-OP028

Impact of device sizing on outcome in patients undergoing percutaneous coronary intervention with bioresorbable scaffolds: insights from the GHOST-EU registry

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Aims: Routine clinical practice data on percutaneous coronary intervention (PCI) performed with bioresorbable vascular scaffolds (BVS) from the GHOST-EU registry showed higher major adverse cardiovascular events (MACE) rates in comparison to small, randomised studies. In this setting, the role of device sizing in routine clinical practice has not been previously addressed.

Methods and results: Between November 2011 and January 2014, 1,189 patients underwent percutaneous coronary intervention with one or more BVS at 10 European centres. Quantitative coronary angiography (QCA) data at baseline were available for 904 patients. This latter cohort has been divided according to the presence or absence of possible BVS undersizing (defined as: proximal reference vessel diameter – BVS diameter >0 mm). Patients with possible BVS undersizing had more MACE during a mean follow-up of 211±136 days (7.9% vs. 4.6%; p=0.015). In the multivariate Cox regression, independent predictors of MACE were undersizing (HR 2.65, 95% CI: 1.27-5.53, p=0.009) and number of implanted scaffolds (HR 1.33, 95% CI: 1.04-1.70, p=0.024), while a significant trend emerged also for diabetes mellitus (HR 1.93, 95% CI: 0.98-3.79, p=0.056).

Conclusions: Scaffold undersizing is associated with a worse long-term outcome. Scaffold undersizing and number of implanted scaffolds were both independent predictors of worse long-term outcome in patients treated with BVS.

EuroPCR Coronary interventions

Euro15A-OP029

Six-month clinical outcomes of patients with calcified lesions treated with BVS bioresorbable scaffold

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Aims: Bioresorbable vascular scaffolds (BVS) are the newest interventional treatment for CAD. However, of BVS usage for complex lesions such as calcified lesions is still considered limited. Therefore, we examined the performance and feasibility of BVS in patients with moderate and severe calcified lesions.

Methods and results: Between September 2012 and October 2013, 93 patients with 127 lesions were investigated: 92 (72.4%) moderate calcified lesions and 35 (27.6%) severely calcified lesions as assessed by angiography. The mean age was 63.3±9.4 years; 76.3% were male; 22.6% were diabetic; 51.6% presented with multivessel disease. One hundred and fourteen (114) lesions (89.8%) were implanted with a total of 189 BVS devices. Bail-out stenting using DES was performed in one patient (1.1%). In 2 patients (2.2%) both metal and bioresorbable devices were implanted. BVS clinical device success/lesion was 113/124 (91.1%). Pre-dilatation was performed in 94.5% of the lesions and post-dilatation in 57.5%. A scoring or cutting balloon was used in 9.3% of the patients. Mean % diameter stenosis post-procedure was 18.4±8.5. Pre- and post-procedural quantitative coronary angiography (QCA) analyses showed an acute lumen gain of 1.44 mm. Six-month clinical outcomes were available in 81 patients (87%) and revealed four cases of cardiac death (4.8%), three cases of myocardial infarction (3.6%), three cases of target lesion revascularisation (3.6%), three cases of target vessel revascularisation (3.6%) and two cases of non-target vessel revascularisation (2.4%). All target lesion revascularisation/ target vessel revascularisation were for definite scaffold thrombosis; no other target lesion revascularisation/ target vessel revascularisation were observed. In two cases of scaffold thrombosis, no post-dilatation was performed. Three of the cardiac death cases were classified as probable scaffold thrombosis. Rate of major adverse cardiac events at six months was 6.3%.

Conclusions: BVS implantation in moderate and severe calcified lesions resulted in good acute outcome. Follow-up showed an important number of scaffold thrombosis driving the search for an optimal implantation technique and technical improvements in scaffold design.

Provisional versus systemic double stenting strategy in coronary bifurcation lesions treated with bioresorbable scaffold

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Aims: The use of bioresorbable scaffolds (BRS) in percutaneous coronary intervention (PCI) has been restricted to simple lesions. However, in experienced centres indications are being expanded to complex lesions, including bifurcations. The aim of this study was to investigate clinical outcomes of patients treated with a provisional stenting (PS) versus systemic double stenting (SDS) strategy in coronary bifurcation lesions with BRS.
Methods and results: We evaluated patients treated with BRS for bifurcation lesions between May 2012 and November 2014. Absorb (Abbott Vascular, Santa Clara, CA, USA) BRS were used in all patients. A total of 122 consecutive bifurcation lesions were identified (PS strategy 99 lesions [89 patients] and SDS strategy 23 lesions [22 patients]). Median follow-up period was 398 (interquartile range 216–556) days. The SDS group consisted of patients with a higher prevalence of insulin-dependent diabetes mellitus (PS 7.6% vs. SDS 18.2%, p=0.05), a higher SYNTAX score (PS 17.1±8.0 vs. SDS 21.2±8.8, p=0.04) and a greater number of true bifurcation lesions (PS 52.0% vs. SDS 91.3%, p<0.001). The main bifurcation site was the left anterior descending artery/diagonal branch (69.7%). Intracoronary vascular ultrasound was used in 82.7% with no difference between groups. In the provisional stenting group, 7 lesions (7.1%) were crossed-over to side branch T-stenting with BVS in 2 lesions and DES in 5 lesions. In the SDS group, 13 lesions (56.5%) were treated with BRS implantation to the side branch (T-stenting 9 lesions, Mini-crush stenting 3 lesions, and V-stenting 1 lesion). A hybrid stenting technique (BRS implantation to the main branch, and drug-eluting metal stent to the side branch) was utilised in 10 lesions (T-stenting 2 lesions, Mini-crush 7 lesions, and crush stenting 1 lesion). There were no significant differences in major adverse cardiac events (MACE; defined as all-cause death, follow-up myocardial infarction, and target vessel revascularisation) between the two groups at 1-year follow-up (MACE: PS 9.5% vs. SDS 11.2%, p=0.91). Definite scaffold thrombosis occurred in 1 patient in the PS group but the thrombosis occurred in a BRS implanted distal to the bifurcation. This patient prematurely stopped clopidogrel 2 months following BRS implantation. At a median follow-up time of 398 days (IQR 216-556 days), TLR rates were 5.5% for provisional and 11.2% for double stenting (p=0.49).
Conclusions: These preliminary results suggest that bifurcation lesions can be successfully treated with BRS. The rates of TLR tended to be higher in the SDS group compared to when a PS strategy was employed. Considering the worse lesion and baseline characteristics, the use of a systematic double stenting strategy with BVS to the main branch and BVS/DES to the side branch is both safe and feasible.

Bioresorbable vascular scaffold for the percutaneous treatment of chronic total occlusion lesions: clinical outcomes and computed tomography scan follow-up

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Aims: Percutaneous coronary intervention (PCI) for chronic total occlusion (CTO) is becoming associated with high rates of failure. Everolimus-eluting bioresorbable vascular scaffold (BVS) implantation in this subset of lesion has to be considered. The reabsorption of the device could provide theoretical advantages at long-term follow-up as compared with metallic drug-eluting stents (DES). The aim of this study was to assess the feasibility of BVS for the CTO percutaneous treatment as well as to analyse clinical outcomes and patency of BVS by computed tomography scan at midterm follow-up.
Methods and results: From February 2013 to June 2014, 121 CTO in 116 patients were recanalised and treated percutaneously in our centre. From them, 42 patients with 46 CTO were successfully treated by BVS implantation and they constitute the study group. The decision of an antegrade or retrograde approach was taken by the operator after a thorough study of the CTO anatomy. Once the guidewire reached the distal lumen, all occluded segment was predilated with balloons of increasing diameter testing the uniform expansion of them. After BVS implantation, post-dilation using non-compliant balloons with a maximum diameter 0.5 mm more than BVS diameter was performed. A computed tomography scan was scheduled for all patients at 6 months after treatment. The mean age was 58±9 years and 41 (98%) were male. Diabetes mellitus was present in 14 (33%) and 15 (36%) had a previous PCI. The target vessel was predominantly the left anterior descending artery (22, 48%). According to the Japanese-CTO score of complexity, 25 (54%) CTO were classified as easy or intermediate while 21 (46%) were difficult or very difficult. An antegrade approach was the strategy used to cross 34 (74%) CTO while in 12 (26%) a retrograde approach was needed. Only BVS were implanted in 39 (85%) CTO and in the remaining 7 (15%) a hybrid procedure, with a DES at the distal segment, was the applied treatment. Twenty-two recanalised CTO (48%) were treated with 1 single BVS, 18 (39%) with 2 and 6 (13%) with 3 BVS. Post-dilation with high-pressure balloons was performed in 100% of the lesions. In 11 (24%) CTO, a bifurcation lesion was also treated by a simple approach. Technical success was achieved in 45 of 46 lesions (98%). One patient (2.4%) presented with significant troponin elevations in the range associated with a non-Q periprocedural myocardial infarction. No other in-hospital adverse clinical events were recorded and all patients were discharged free of symptoms under dual antiplatelet treatment for one year. Re-evaluation by coronary computed tomography scan (angiography in case of clinical recurrence) was obtained in all patients at 6±1 months after the treatment. Two scaffold reocclusions and a focal restenosis were identified. After 13±5 months of follow-up, the events rate was 4.3 due to 2 repeat revascularisation. Neither death nor myocardial infarction were documented.
Conclusions: Percutaneous treatment with BVS for CTO seems to be an interesting strategy, with a high rate of technical success and low rate of cardiac events at midterm follow-up. However, future validations of our findings at long-term follow-up are required in order to clearly establish the indication of this treatment.

EuroPCR Coronary interventions Euro15A-OP032

Everolimus-eluting bioresorbable scaffold as a treatment option for patients with in-stent restenosis: insights from the multicentre GHOST-EU registry

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Aims: Drug-eluting balloons or drug-eluting metallic stents are the most common treatment options for patients with in-stent restenosis (ISR). Everolimus-eluting bioresorbable scaffolds (BRS) may be a treatment option, since they potentially ensure adequate drug delivery capacity and do not affect lumen diameter after resorption.

Methods and results: All patients from the retrospective, non-randomised multicentre GHOST-EU (Gauging coronary Healing with bioresorbable Scaffolding plaTforms in EUrope) registry with an ISR of a previously implanted metallic stent who had been treated with BRS were evaluated. The composite endpoint was target lesion failure (TLF) including clinically driven percutaneous or surgical target lesion revascularisation, target vessel myocardial infarction, or cardiac death. Out of 1,189 patients, a total of 41 (3.4%) patients with ISR were identified. The median age was 64.0(56.0-72.0) years, 87.8% were male, 90.2% suffered from hypertension and 34.1 from diabetes. Stable coronary artery disease was present in 73.25% and 26.8% were admitted due to acute coronary syndrome. Femoral vascular access was used in 72.5% and radial access in 27.5%. Pre-dilatation was performed in 97.7%, an additional rotational atherectomy was utilised in 2.3%, a cutting balloon was required in 11.4%, and a scoring balloon in 13.6%. Post-dilation was performed in 61.4% of the cases. More than 1 BRS was needed in 26.8% and a hybrid strategy with a metallic stent was required in 14.6%. During a median follow-up of 200.0 (183.0-229.0) days, TLF occurred in 9.7%, target vessel myocardial infarction in 2.4% and neither scaffold thrombosis nor any deaths were noted.

Conclusions: With their beneficial attributes, BRS might be considered as an alternative approach for the treatment of ISR. The present results suggest that BRS implantation in ISR is technically feasible with reasonable midterm outcomes. Prospective, randomised long-term data is needed.

EuroPCR Coronary interventions Euro15A-OP033

Bioresorbable vascular scaffold implantation for the treatment of coronary in-stent restenosis: results from a multicentre Italian experience

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Aims: The aim of this multicentre registry was to investigate the feasibility of bioresorbable vascular scaffold (BVS) use in in-stent restenosis (ISR) lesions.

Methods and results: A prospective cohort analysis was performed on all patients that underwent percutaneous coronary intervention (PCI) with BVS implantation for ISR at 6 Italian centres. Primary endpoints were procedural success defined as the successful delivery and deployment of the BVS at the target lesion with less than 30% final residual stenosis without in-hospital major adverse cardiac and/or cerebrovascular events (MACCE) defined as a composite of cardiac death, Q-wave myocardial infarction, stroke, or any repeat target lesion revascularisation (surgical or percutaneous). From April 2012 to June 2014, a total of 315 patients (334 lesions) underwent PCI for ISR at the participating centres. Of those, 83 patients (90 lesions) received BVS. Among the ISR lesions, the majority were DES-ISR (55, 61%); 33 (36%) recurrent-ISR and according to the angiographic pattern 58 (64%) were defined as diffuse-ISR. The mean patient age was 65±10 years and 70 patients (84.3%) were male. Type 2 diabetes mellitus was present in 28 (34%) patients while chronic kidney disease in 11 (13%). PCI procedures were performed in 44 (53%) patients presenting with stable CAD, 34 (41%) with UA/NSTEMI and 5 (6%) with STEMI. Intracoronary imaging evaluation was performed in 23 (26%) lesions before and in 30 (33%) lesions post-BVS implantation. Target lesion length was 29±15 mm requiring the use of 1.4±0.6 BVS per lesion, with a mean BVS length of 36±18.2 mm per lesion. Lesion pre-dilatation was mandatory, and post dilatation was needed in 84% of cases. Procedural success was achieved in all patients. No in-hospital and 30-day MACCE occurred. At a median of 7 months (IQR 3–18) follow-up, MACCE rate was 12%. TLR per patient was 8.4%, TLR per lesion 7.7%, while all-cause death 2.4%. Definite BVS-in-stent thrombosis was reported in 1 patient (1.1%).

Conclusions: To the best of our knowledge, we report the largest registry of complex ISR lesions treated with BVS. The results of our registry suggest that BVS implantation for the treatment of ISR is technically feasible and associated with favourable midterm clinical outcomes. These data could be considered hypothesis generating for a future randomised clinical trial.

A novel approach to treat in-stent-restenosis: 6-months results using the Absorb bioresorbable vascular scaffold

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Aims: Treatment of in-stent-restenosis (ISR) remains challenging in 2014. Few case reports have described successful use of bioresorbable vascular scaffolds (BVS) to treat ISR. The aim of this report is to report our experience with this novel approach.
Methods and results: Patients with ISR undergoing percutaneous coronary intervention (PCI) for ISR in the Luzerner Kantonsspital were eligible to be treated using BVS. BVS ISR and BVS thrombosis rates at 6 months post-procedure are reported. A total of 53 ISR lesions were treated in 36 patients. The mean age was 68±10 years, one third of the patients had ACS, 28% had diabetes mellitus and 7 (19%) had previous coronary artery bypass grafting (CABG). PCI was successful in all patients and all scaffolds were delivered and deployed successfully in the target lesion. No scaffold thrombosis or repeat revascularisation occurred during the hospitalisation or at 30 days. At six months BVS ISR was observed in 3/53 lesions (5.7%). All scaffolds with ISR had a diameter of 2.5 mm and only one of them was post-dilated. One patient (2.8%) had a probable stent thrombosis with unexplained death 1-week post-procedure and 1 patient had a stent thrombosis in a metallic stent proximal to the BVS.
Conclusions: ISR treatment using BVS is feasible and has acceptable target lesion failure rates at 6 months. With increased understanding of optimal implanting techniques, this rate can even be improved in the future.

Results of 13 years of the DESIRE (Drug-Eluting Stents In the Real-world) registry: the longest available clinical follow-up of a cohort of "real-world" patients treated exclusively with drug-eluting stents

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Aims: There is still uncertainty about the durability of the results of drug-eluting stents (DES) in real-world complex patients (pts). We sought to provide the longest clinical follow-up data on outcomes of unselected patients treated solely with DES.
Methods and results: The DESIRE registry is a prospective, single-centre registry encompassing all consecutive patients treated solely with DES since May 2002. The primary goal is the very long-term occurrence of MACE and stent thrombosis (ST). Patients were clinically followed at 1, 6 and 12 months and then annually. A multivariate model was built to determine independent predictors of MACE and ST. A total of 5,614 pts (8,825 lesions/9,980 DES) were included. The mean age was 64±11 years. DM was detected in 31.5% and 41.8% presented with acute coronary syndrome (STEMI represented 16.8% of the cohort). Follow-up was obtained in 98.4% of the patients (median 5.9 years). Currently, 78.9% of the population is free of any MACE. Ischaemia-driven TVR was performed in 7.3% of the patients. Q-wave MI rate was only 1.7% while cumulative incidence of definite/probable ST was 4.1%. Independent predictors of MACE were initial presentation as ACS (HR 1.4; 95% CI: 1.1 to 1.7, p=0.001), lesion length >20 mm (HR 1.4; 95% CI: 1.2 to 1.6, p<0.001), residual stenosis (HR 1.02; 95% CI: 1.01 to 1.03, p<0.001), DM (HR 1.6; 95% CI: 1.1 to 2.2, p=0.006) and severe coronary calcification (HR 1.4; 95% CI: 1.1 to 1.8, p=0.004) while use of second-generation DES was protective (HR 0.7; 95% CI: 0.5 to 0.9, p=0.007). Independent predictors of ST were PCI for STEMI (HR 2.6; 95% CI: 1.6 to 4.3, p<0.001) and treatment of small vessels (HR 2.0; 95% CI: 1.3 to 3.3, p=0.002).
Conclusions: In our single centre experience, the use of DES was associated with very long-term safety and effectiveness with acceptable low rates of adverse clinical events, including ST. Treatment of patients with ACS, in particular STEMI, increase the risk of adverse events while use of second-generation DES might be protective.

EuroPCR Coronary interventions

Euro15A-OP036

Five-year follow-up of safety and efficacy of the Resolute zotarolimus-eluting stent: insights from the RESOLUTE global clinical trial program in approximately 8,000 patients

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Aims: To assess the long-term (five-year) safety of the Resolute™ zotarolimus- eluting stent (R-ZES) in nearly 8,000 patients enrolled in the RESOLUTE Global clinical trial programme.

Methods and results: The RESOLUTE global clinical trial programme enrolled 7,618 patients from the following studies: RESOLUTE (N=139; 5 -year follow-up), RESOLUTE all-comers (N=1,140 R-ZES arm; 5-year follow-up), RESOLUTE international (N=2,349; 3-year follow-up), RESOLUTE US (R-US, N=1,402; 4-year follow-up) and R-US 38 mm substudy (N=114; 3-year follow-up), RESOLUTE Japan trial (N=100; 4-year follow-up) and RESOLUTE Japan small vessel study (N=65; 3-year follow-up), RESOLUTE-Asia dual vessel cohort (N=202; 2-year follow-up) and RESOLUTE Asia 38 mm cohort (N=109; 3-year follow-up), RESOLUTE China randomised controlled trial (R-China RCT, N=198 R-ZES; 2-year follow-up), RESOLUTE China registry (N=1,800; 2-year follow-up). Most patients (72%) were enrolled in "all-comer" trials and were men (75.4%), 30.4% had diabetes mellitus, 29.2% prior myocardial infarction, 64.0% presented with an acute coronary syndrome, and 46.7% were complex. The five-year cumulative incidence of target lesion failure was 13.3% and was comprised of 6.1% clinically driven target lesion revascularisation, 4.9% cardiac death, and 4.3% target vessel myocardial infarction. Usage of dual antiplatelet therapy was 91% at 12 months, 38% at 3 years, and 14% at 5 years. The five-year cumulative incidence of Academic Research Consortium definite and definite/probable stent thrombosis was 0.8% and 1.2%, respectively. By the time of PCR presentation, R-US and R-Japan Trial will have 5-year outcomes and R-China RCT will have 3-year outcomes, and therefore the majority of patients (5,616) will have 3-year follow-up, and 2,781 patients will have 5-year follow-up.

Conclusions: Excellent long-term outcomes were observed with use of the R-ZES during long-term follow-up, supporting its safety and efficacy in a broad spectrum of patients and lesions.

EuroPCR Coronary interventions

Euro15A-OP037

Three-year results from the multicentre PROMUS Element European post-approval (PE-Prove) registry: outcomes in 1,010 unselected patients treated with a platinum-chromium, everolimus-eluting stent

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Aims: The objective of the PROMUS Element™ European post-approval (PE-Prove) registry is to collect outcomes from an unselected patient population treated with the platinum-chromium, everolimus-eluting PROMUS Element stent. We report 3-year outcomes.

Methods and results: PE-PROVE is a prospective, open-label, multicentre observational study that enrolled 1,010 patients at 40 European sites who were candidates for coronary artery stenting with the PROMUS Element stent and who provided informed consent. At baseline, 75.4% of patients were male, 24.9% had medically treated diabetes, 17.8% had a myocardial infarction within 24 hours prior to the index procedure, and 20.1% had unstable angina. Exactly half (50.0%) of the patients had AHA/ACC Type B2 or C lesions, 6.9% had chronic total occlusions, and 14.5% required overlapping stents. We have previously reported that the 1-year primary endpoint of overall and PROMUS Element-stent-related target vessel failure rates (defined as death related to the target vessel, myocardial infarction related to the target vessel, and target vessel revascularisation) were 6.2% (60/975) and 3.4% (33/976), respectively. At 3 years, 955 patients were eligible for clinical follow-up, and data were available on 948 (99.3%).By Kaplan-Meier analysis, the overall 3-year rate of target vessel failure was 10.1% (n=99) and study stent-related target vessel failure was 5.0% (n=49). Three-year cardiac and overall death rates were 2.9% (n=28) and 5.6% (n=55), respectively. Myocardial infarction was defined according to the historical definition used in the Platinum trial, and occurred in 4.8% (n=47) of patients; of these, 2.5% (n=25) were considered related to the study stent. A total of 6.4% (n=62) patients underwent target vessel revascularisation, and 3.7% (n=36) of those were target lesion revascularisation. ARC definite/probable stent thrombosis was reported for 0.9% (n=9) patients at 3 years, all of which were considered related to the PROMUS Element stent. Additional results in high-risk subgroups (e.g., diabetes, small vessels, long lesions) will be available at the time of the meeting.

Conclusions: The PROMUS Element stent continues to provide favourable outcomes with extended clinical follow-up, demonstrating low rates of adverse events at 3 years in routine clinical practice.

BIOFLOW-III an all comers registry with a sirolimus-eluting stent: presentation of one-year target lesion failure data in patients with complex lesions

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Aims: The aim of this registry is to evaluate the clinical performance of a new generation sirolimus-eluting stent system (Orsiro) in a large patient population in standard clinical care. The Orsiro is a unique hybrid solution that combines passive and active components. PROBIO passive coating encapsulates the stent and minimises interaction between the metal stent and surrounding tissue. BIOlute active coating contains a highly biocompatible and biodegradable polymer.

Methods and results: Between August 2011 and March 2012, 1,356 subjects were enrolled consecutively in this international, multicentre BIOFLOW-III all-comers registry using the Orsiro Sirolimus eluting stent. Primary endpoint is target lesion failure (TLF) at twelve months follow-up. A subgroup analysis has been conducted in patients with complex lesions like diabetics, acute STEMI, CTO, small vessels, B2/C lesions and multivessel disease which have a higher risk of experiencing an adverse event. Nine hundred seventy-one men (72%) and three hundred eighty-five women were enrolled at 43 sites in 14 countries. The mean age was 66.1±10.7, ranging from 29-91 years. The majority of subjects presented with hypertension 76%, hypercholesterolemia 60%, smoker 55%, and diabetes 30%. Of all stented vessels, 48% had a diameter ≤2.75 mm, 4% presented with chronic total occlusion, 10.6% with STEMI, 77.5% with multivessel disease and 52% with B2/C lesions. In this all-comers setting, a TLF rate of 5.1% was observed within the first 12 months for the overall cohort. The low TLF rate was also confirmed for the subgroups: diabetics (7.7%), acute STEMI (5.0%), small vessel (5.8%), CTO (1.8%) and multivessel disease (6.7%).

Conclusions: The results observed in this "real-world" population demonstrate a low TLF rate comparable to other state of the art DES at 12-months, not only in the overall cohort but also in patients with complex lesions which have a higher risk of experiencing an adverse event.

Comparative evaluation of high-risk acute coronary syndrome and stable patients treated with bioresorbable polymer DES

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Aims: The use of DES to treat patients with high-risk acute coronary syndromes, HR-ACS (STEMI/NSTEMI) is increasing. However, controversies still exist related to their safety in this complex patient population. Therefore, the aim of this study was to analyse 1-year clinical outcomes of HR-ACS patients and compare it with stable patients (SP) presenting with stable angina or silent ischaemia when treated with one type of DES.

Methods and results: In the frame of large, prospective, single-arm, multicentre, observational e-NOBORI registry, total of 3,449 HR-ACS patients and 5,149 SP patients were treated with bioresorbable polymer Nobori® DES. The primary endpoint of the study was target lesion failure (TLF) defined as composite of cardiac death (CD), target vessel related myocardial infarction (TV-MI) and target lesion revascularisation (TLR). An independent clinical event committee adjudicated all, endpoints related events. Baseline characteristics revealed that patients with HR-ACS were younger (62.8±12.5 vs. 63.5±12.0 years; p=0.01), were less frequently diagnosed with diabetes (29.0% vs. 33.8%; p<0.01), hypertension (61.2% vs. 77.5%; p<0.01), hyperlipidaemia (54.1% vs. 68.4%; p<0.01) peripheral vascular disease (6.4% vs. 9.5%; p<0.01), but more frequently current smokers (20.5% vs. 36.4%; p<0.01). Additionally, fewer patients with HR-ACS had history of previous MI (18.0% vs. 32.3%; p<0.01), previous PCI (16.0% vs. 36.0%; p<0.01) and CABG (4.0% vs. 7.9%; p<0.01). LAD was the most frequent target vessel in both groups (44.8% vs. 42.9%; p=0.85) and radial access was the most frequent in both groups, being significantly more frequent in HR-ACS patients (64.9% vs. 52.4%; p<0.01). Patients in HR-ACS group had more B2 type of lesions (35.2% vs. 31.6%; p<0.01) while C type was more frequent in SP group (21.0% vs. 22.5%; p=0.04). As expected, thrombus burden was higher in HR-ACS group (26.5% vs. 2.1%l p<0.01), while lesions were less frequently ostial (9.8% vs. 12.0%; p<0.01), at bifurcation (5.0% vs. 6.9%; p<0.01) and calcified (28.4% vs. 33.4%; p<0.01). Up to 1-year significantly more patients in HR-ACS group died for any or cardiac causes (2.6% vs. 1.3% and 1.8% vs 0.9%; p<0.01 for both) or suffered MI (1.8% vs. 1.1%; p<0.01). The frequency of target lesion (1.6% vs. 1.3%; p=0.24) and target vessel revascularisation (2.1% vs. 1.9%; p=0.47) showed no significant difference between the two groups. Composite rate of TLF (4.2% vs. 3.0%; p<0.01), TVF (4.6% vs. 3.4%; p<0.01) and definite and probable stent thrombosis (0.9% vs. 0.4%; p<0.01), were all higher in HR-ACS group.

Conclusions: The rate of adverse events was low in both groups of patients in this unselected all-comer population, but as expected, higher rates of adverse events occurred in HR-ACS compared to patients with stable coronary disease. Based on our data the use of DES with bioresorbable polymer seems to be appropriate for both, HR-ACS and stable patients, providing very good safety and efficacy profile.

euroPCR Coronary interventions Euro15A-OP040

Primary clinical outcomes of the EVOLVE II diabetes substudy evaluating a novel bioabsorbable polymer-coated, everolimus-eluting coronary stent in diabetic patients

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Aims: We report the results of apre-specified analysis of all medically treated diabetic subjects enrolled into the EVOLVE II randomised trial (RCT) and the diabetes substudy who received treatment with the SYNERGY stent.

Methods and results: Enrolled diabetic subjects could have up to 3 native coronary artery lesions in up to 2 major epicardial vessels with reference vessel diameter ≥2.25 mm to ≤4.00 mm, and lesion length ≤34 mm. Exclusion criteria included recent (<72 hours) STEMI, left main, vein graft or ostial stenosis, in stent restenosis, chronic total occlusion, or thrombus. The trial primary endpoint is TLF (composite occurrence of ischaemia-driven target lesion revascularisation, target-vessel myocardial infarction, or cardiac death) to 12 months among diabetic patients treated with the SYNERGY stent. The primary endpoint was tested against a pre-specified performance goal based on TLF rates derived from diabetic patient cohorts treated with durable polymer everolimus-eluting stents in prior studies (PLATINUM, SPIRIT IV, COMPARE, EVOLVE). Enrolled diabetic subjects were either randomised to SYNERGY in the EVOLVE II RCT (263 patients from 125 centres in 11 countries between November, 2012 and August, 2013) or following EVOLVE II RCT completion were enrolled in the diabetes substudy (203 patients from 48 sites from August to December, 2013) for a total of 466 diabetic patients treated with SYNERGY stent. All endpoint component events were independently adjudicated. Dual antiplatelet therapy (aspirin plus a $P2Y_{12}$ inhibitor) was recommended for ≥6 months or longer, as tolerated and aspirin was prescribed indefinitely. Patients will be followed for 5 years. Primary endpoint and component events to 1 year will be presented and compared with the performance goal to determine the relative safety and efficacy of SYNERGY stent in patients with diabetes.

Conclusions: The EVOLVE II Diabetes substudy will establish the relative safety and efficacy of the novel SYNERGY stent in patients with medically treated diabetes compared with durable polymer everolimus-eluting stents. The primary endpoint and major secondary endpoint results through 12 months will be available for presentation at EuroPCR 2015.

euroPCR Coronary interventions Euro15A-OP041

Biolimus-eluting stent versus everolimus-eluting stent use in patients undergoing PCI: the 12-months outcome

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Aims: To compare the incidence rate of major adverse cardiac events (MACE) in 12-month follow-up between patients undergoing percutaneous coronary intervention (PCI) with EES (XIENCE V; Abbott Vascular, Santa Clara, CA,USA and PROMUS Element™ Plus; Boston Scientific, Marlborough, MA, USA) or BES (BioMatrix; Biosensors, Morges, Switzerland and Nobori; Terumo Europe N.V, Leuven, Belgium) and evaluating associated factors.

Methods and results: From January 2007 until December 2011, 3,270 consecutive patients with coronary artery disease undergoing PCI with BES or EES in Tehran Heart Centre (THC) were enrolled in our study. All patients were followed up in 1, 6 and 12 month(s) intervals after the procedure. The primary endpoint of our study was MACE, which was the composite of death, non-fatal myocardial infarction (MI), target vessel and target lesion revascularisation (by PCI or CABG). Of the study population, 2,648 were assigned to receive EES and 622 to BES. 163 of Nobori, 551 of BioMatrix, 1,160 of Promus and 2,007 of XIENCE stents were implanted overall. In the BES group, the incidence of MACE during the 12-month follow-up was not higher than EES group (2.7% vs. 2.7%, p=0.984). After adjustment by multivariate analysis, cumulative probability of survival in BES group was not inferior compared to EES group (Hazard ratio: 0.768, CI 95%: 0.421-1.44, p=0.388).

Conclusions: The novel BES (BioMatrix; Biosensors and Nobori; Terumo Europe N.V.) are as efficient and safe as EES (XIENCE V; Abbott Vascular and PROMUS Element™ Plus; Boston Scientific) in patients with coronary artery disease after 12-month follow-up and could be appropriate alternative to EES containing durable polymer.

Four-year clinical outcomes in the EVOLVE trial: a randomised evaluation of a novel bioabsorbable polymer-coated, everolimus-eluting stent

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Aims: The EVOLVE study compared the performance of the SYNERGY stent (2 dose formulations) to the durable polymer PROMUS Element everolimus-eluting stent (EES).

Methods and results: The EVOLVE trial was a prospective, multicentre, randomised, controlled first human use trial enrolling patients with a *de novo* lesion ≤28 mm in length in a coronary artery ≥2.25 and ≤3.5 mm in diameter. Patients were randomised 1:1:1 to treatment with one of three stents: PROMUS Element (N=98), SYNERGY stents releasing everolimus at an equivalent dose to PROMUS Element ('SYNERGY' group; N=92) and SYNERGY stents releasing everolimus at half that dose ('SYNERGY Dose' group; N=99). The primary clinical endpoint was 30-day target lesion failure (defined as target vessel-related cardiac death, target vessel-related myocardial infarction (MI), or target lesion revascularisation). At 30 days, the rate of TLF was not significantly different among groups; 0% in the PROMUS Element arm, 1.1% with SYNERGY, and 3.1% in the SYNERGY dose group (PROMUS Element: vs. SYNERGY p=0.49; vs. SYNERGY Dose p=0.25). The primary angiographic endpoint of 6-month in-stent late loss was non-inferior between the control and SYNERGY groups (0.15±0.34 mm for PROMUS Element, 0.10±0.25 mm for SYNERGY, and 0.13±0.26 mm for SYNERGY dose; PROMUS Element: vs. SYNERGY p=0.19; vs. SYNERGY dose p=0.56). Three-year clinical event rates including TLF, death, MI and revascularisation were low and not significantly different between groups. At 3 years, the rate of TLF was 6.1% in the PROMUS Element group, 5.5% in the SYNERGY group and 5.2% in the SYNERGY Dose group (PROMUS Element: vs. SYNERGY $p_{noninferiority}$<0.0001; vs. SYNERGY Dose, $p_{noninferiority}$<0.001) with no additional TLF events after 2 years. No stent thromboses were found in any group at 3 years.

Conclusions: Results to 3 years in the EVOLVE trial have demonstrated comparable clinical outcomes with the PROMUS Element and SYNERGY platforms. This will be the first presentation of any 4-year clinical results with the SYNERGY stent comprising an ultra-thin abluminal bioabsorbable polymer (eluting everolimus at 2 dose levels).

Clinical outcomes of patients with multivessel coronary artery disease after treatment with thin strut DES with bioresorbable polymer: results from CENTURY II trial

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Aims: Newer-generations of drug-eluting stents (DES) have been continually developed in order to improve the safety and efficacy of percutaneous coronary intervention (PCI), especially in higher risks patient populations such as patients with multivessel coronary artery disease (MVD). Our aim was to assess safety and efficacy of new, bioresorbable polymer sirolimus-eluting stent Ultimaster (BP-SES) in patients with MVD and to compare it to permanent polymer everolimus-eluting stent XIENCE (PP-EES).

Methods and results: In the frame of a single-blind, randomised, multicentre CENTURY II study, out of 1,119 patients enrolled, 546 patients were diagnosed with MVD and assigned randomly to treatment with BP-SES (275) or PP-EES (271). The primary endpoint of the study was TLF at 9 months and 2-year follow-up is currently ongoing. All data were 100% monitored and adverse events were adjudicated by an independent clinical event committee. Concerning the baseline patient characteristics, no significant differences were found in patient age, gender, presence of IDDM and NIDDM, hypertension, smoking, previous MI and previous PCI in BP-SES and PP-EES groups. Lesions were located mainly in LAD in both groups (37.8% vs. 37.1%; p=0.89), and accessed most frequently via radial artery (69.8% vs. 67.9%; p=0.64). Concerning the lesion characteristics, similar rate of bifurcation (14.6% vs. 11.2%; p=0.15) and ostial (7.2% vs. 10.0%; p=0.16) lesions were recorded, with similar presence of moderate/severe calcifications (25.2% vs. 19.8%; p=0.29) and similar thrombus burden (3.2% vs. 3.0%; p=0.84) in BP-SES and PP-EES, respectively. There was no difference noted in a lesion length (16.8±9.7 mm vs. 16.4±9.1 mm; p=0.59), number of treated lesions (1.5±0.7 vs. 1.5±0.7; p=0.60) and number of stents implanted per lesion (1.1±0.4 vs. 1.1±0.5; p=0.09). At 12 months, there was no difference noted in rate of cardiac death (1.8% vs. 2.2%; p=0.74), MI (2.6% vs. 3.3%; p=0.59), clinically driven TVR (5.1% vs. 5.2%; p=0.97) and TLR (3.3% vs. 4.1%; p=0.63). Composite endpoints such as TLF (5.8% vs. 7.8%; p=0.37) and TVF (7.6% vs. 8.9%; p=0.60), although being numerically lower in BP-SES group did not reach statistical significance. Rate of definite and probable stent thrombosis (ST) was following the same trend (1.1% vs. 1.8%; p=0.46) with 3 cases recorded in BP-SES and 5 cases in PP-EES groups.

Conclusions: Treatment of patients with MVD, using BP-SES and PP-SES resulted in favourable and similar clinical outcomes up to 12 months. Further follow-up will give valuable information about long-term safety and efficacy of the new DES, Ultimaster. Two years data will be presented.

EuroPCR Coronary interventions

Euro15A-OP044

In-hospital, thirty-day and six-month result of biodegradable polymer coated sirolimus eluting stent in coronary artery lesions (i-TRIAL study)

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Aims: The i-TRIAL study assess the safety, efficacy and clinical performance of the Indolimus (Sahajanand Medical Technologies Pvt. Ltd.), a low-profile, thin-strut, biodegradable polymer coated sirolimus eluting cobalt chromium stent, in real-world of interventional cardiology.

Methods and results: The i-TRIAL study was a multicentre, retrospective, non-randomised, single-arm study, which enrolled 1,008 consecutive patients treated with Indolimus, between April 2012 and June 2014.The only exclusion criteria was patient's refusal to provide written informed consent. The primary endpoint of the study was major adverse cardiac events (MACE), which is an aggregate of cardiac death, target lesion revascularisation (TLR), target vessel revascularisation (TVR), myocardial infarction (MI) and stent thrombosis (ST).The clinical follow-ups were scheduled at 30-day and 6-month. The mean age of enrolled patients was 52.6±11.0 years. A total of 1,137 lesions were intervened successfully with 1,242 stents (1.09±0.30 stent per lesion).The average stent length and diameter was 27.42±9.01 mm and 3.12±0.36 mm respectively. There were 740 (73.40%) male patients, indicating their high prevalence. Diabetes, hypertension and chronic totally occluded lesions were found in 372 (36.90%), 408 (40.47%) and 170 (16.86%) patients, respectively. These shows that study also included high-risk complex lesions and not ideal recruited lesions. The incidence of MACE at in-hospital, 30-day and 6-month was 3 (0.30%), 3 (0.30%) and 18 (1.80%) respectively. At 6-month, TLR was found in 5 (0.50%) patients. There were 2 (0.20%) cases of ST and 7 (0.70%) cases of MI at 6-month follow-up.

Conclusions: The use of Indolimus is associated with lower incidence of TLR, ST and consequent MACE. Thus, the i-TRIAL study gives an idea about favourable safety, efficacy and clinical performance of the Indolimus in the real world of interventional cardiology.

EuroPCR Coronary interventions

Euro15A-OP045

Bioabsorbable polymer-coated thin strut everolimus-eluting SYNERGY stent for coronary revascularisation in daily clinical practice: one-year results of the SWEET registry (SWiss Evaluation of bioabsorbable polymer-coated Everolimus-eluting coronary sTent)

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Aims: Bioresorbable polymer drug-eluting stents (DES) represent an indisputable improvement over first-generation DES with promising results on long-term adverse events. We sought to determine the 1-year clinical follow-up in patients treated with the bioabsorbable polymer-coated Everolimus-eluting SYNERGY stent in daily clinical routine.

Methods and results: All consecutive patients treated with the SYNERGY stent at University and Hospital Fribourg, La Tour Hospital in Geneva and the University Hospital of Bern between December 2012 and June 2014 were prospectively included in the SWEET registry (SWiss Evaluation of bioabsorbable polymer-coated Everolimus-eluting coronary sTent). Clinical follow-up was performed at 1 year. The primary endpoint was the Academic Research Consortium (ARC) device-oriented composite of cardiac death (CD), myocardial infarction of the target vessel (TV-MI) and clinically indicated target lesion revascularisation (CI-TLR) at 1 year. Descriptive statistical analysis was performed. Binary logistic regression was performed to identify predictors associated with the primary endpoint. Nine hundred forty-seven patients were included in the SWEET registry. Intermediate analysis was performed in the first 414 patients (638 lesions) in whom 1-year follow-up was available. Mean age was 68±12 years and 70% (n=289) of patients were men. Diabetes mellitus was present in 23% (n=95) and a history of previous myocardial infarction in 18% (n=76) of patients. Acute coronary syndrome was the indication for stent implantation in 57% (n=235) of cases of which 23% (n=97) presented with STEMI. Mean SYNTAX score was 17±12. Left main treatment was performed in 3% (n=17) and saphenous vein graft interventions in 2% (n=13) of patients. The primary endpoint occurred in 11% (n=45) of patients at 1 year. The rate of CD was 6% (n=23) and TV-MI occurred in 4% (n=16) of patients. CI-TLR was performed in 4% (n=18) of patients. ARC defined definitive stent thrombosis occurred in 10 patients (2.4%) within the first year after stent implantation (early: 2.2% [n=9], late 0.2% [n=1]). In multivariate analysis, a diminished left ventricular ejection fraction (per 5% decrease; OR 1.03; 95% CI: 1.01-1.05, p=0.02) and an increasing number of treated lesions per patient (per 1 additionally treated lesion; OR 1.47; 95% CI: 1.04-2.08, p=0.03) were significantly associated with worse clinical outcome.

Conclusions: The bioabsorbable polymer-coated thin strut everolimus-eluting SYNERGY stent yields a favourable safety and efficacy in daily clinical practice.

Long-term safety and efficacy of biolimus-eluting coronary stents in an unselected patient population: final 3-year report of the large, multicentre e-BioMatrix registry

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Aims: We present the final, 3-year results of the prospective e-BioMatrix registry with either the BioMatrix™ or BioMatrix Flex™ stents.

Methods and results: Between April 2008 and August 2011, 5,653 patients were enrolled in this study in 57 centres in Europe, the Middle East, Russia and North Africa. The design of this registry uses the same all-comers principle as was applied in the randomised LEADERS trial. There were no limitations to the number, type and length of treated lesions, nor to the number of treated vessels. Dual antiplatelet therapy (DAPT) with aspirin and a $P2Y_{12}$ blocker was recommended for 6 to 12 months. The primary endpoint was defined as the rate of major adverse cardiac events (MACE), a composite of cardiac death, myocardial infarction (Q-wave and non-Q-wave), or clinically indicated target vessel revascularisation (ci-TVR) at 12 months. Major secondary endpoints included the incidence of definite/probable stent thrombosis (ST) and major bleeding (MB). One hundred and eighty-two (182) patients were excluded, usually due to implantation of non-study stents. Finally, 5,471 patients were therefore available for follow-up. Mean patient age was 63±11 years. Of these, 24% were diabetic; 28% had a prior history of PCI or CABG. Concerning ACS, 50% of the patients presented with ACS, among which 34.5% were with STEMI, 43.7% with NSTEMI and 21.8% with unstable angina. A total of 18% of patients had a multivessel procedure; 3.3% were for left main stem lesions. A small diameter stent (≤2.75 mm) was implanted in 48.8% of patients, and a long stent (≥20 mm) was implanted in 51% of the patients. At three-year follow-up, the incidence of the primary endpoint (MACE) was 9.1% (cardiac death 2.1%, myocardial infarction 3.2%, ci-TVR 5.7%). Definite or probable ST was seen in 0.88% of the patients (0.42% early, 0.17% late and 0.29% very late). Other endpoints as well as results of the landmark analysis at 12 months are in the process of being adjudicated by the clinical events committee and will be reported at the time of presentation.

Conclusions: This study demonstrates a low 36-month MACE rate and a very low ST-incidence in an unselected patient population undergoing BES implantation. The complete final 3-year follow-up analysis will be available at the time of the meeting.

Three years clinical outcomes of the Ultimaster drug-eluting stent: results of the CENTURY study

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Aims: The aim of CENTURY study is to assess the safety and performance of Ultimaster, a thin-strut cobalt-chromium sirolimus-eluting stent with an innovative abluminally gradient-coated bioresorbable polymer. Drug-eluting stents with bioresorbable polymers are expected to offer long-term safety benefits as they might reduce permanent polymers associated adverse effects.

Methods and results: The CENTURY is a multicentre, single-arm, prospective, controlled study that enrolled 105 patients with previously untreated lesions in up to two epicardial vessels. The primary endpoint was superiority in 6-month late-lumen loss of Ultimaster DES versus its bare metal platform, the Kaname stent (historical control). At 6 months angiography, 45 and 20 patients respectively underwent IVUS and OCT assessments. Clinical follow-up is available up to 2 years and will continue up to 5 years. The Ultimaster proved superior to the Kaname stent with in-stent late loss at 6 months of 0.04±0.35 mm versus 0.75±0.43 mm, respectively ($p<0.0001$), also reflected in a significantly lower binary restenosis rate of 0.9% versus 16.9% ($p<0.001$) and confirmed by IVUS assessed neointimal volume obstruction of 1.2±1.9% vs. 26.0±11.6% ($p<0.0001$). The mean struts coverage assessed by OCT was 96.2% with 1.66±4.02 malapposed stent struts. Overall target lesion failure at 2-year was 5.7% in Ultimaster with TLR of 2.9%. There were no late or very late stent thromboses. Three-year follow-up is currently ongoing and data will be available at the time of presentation.

Conclusions: Long-term clinical outcomes after treatment with the Ultimaster DES appears to be beneficial for the patient in terms of safety and efficacy. Longer follow-up data might further confirm the potential benefit of the combined stent characteristics of thin struts and bioresorbable abluminal gradient polymer coating.

euroPCR Coronary interventions

Euro15A-OP048

Multicentre, prospective, randomised, single blind, consecutive enrolment evaluation of a novolimus-eluting coronary stent system with bioabsorbable polymer compared to a zotarolimus-eluting coronary stent system: long-term (48-month) clinical follow-up from the EXCELLA BD study

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Aims: To evaluate the long-term safety and efficacy of the Elixir DESyne BD novolimus-eluting coronary stent system (CSS) with a biodegradable polymer compared to the Endeavor zotarolimus-eluting CSS.

Methods and results: A total of 149 patients were randomised 3:1 either to the Elixir DESyne BD novolimus-eluting CSS loaded with 5 mcg per mm of stent length of novolimus, a sirolimus metabolite, eluted via a biodegradable polylactide-based polymer, or to the Endeavor zotarolimus-eluting CSS loaded with 10 mcg per mm of stent length of zotarolimus eluted via a durable phosphoryl choline polymer. All patients were analysed for the primary endpoint of in-stent late lumen loss (LLL) assessed by quantitative coronary angiography (QCA) at 6 months. Moreover, all patients underwent evaluation for the secondary endpoints at 1, 6, 9 and 12 months and annually through 5 years, including the device-oriented composite endpoint (DoCE) defined as: cardiac death, target vessel myocardial infarction (MI) and clinically-indicated target lesion revascularisation (CI-TLR); clinically-indicated target vessel revascularisation (TVR) and stent thrombosis. Lesions were also evaluated for angiographic endpoints at 6 months including: in-segement LLL, percent diameter stenosis, minimal lumen diameter post-procedure and angiographic binary restenosis (ABR) (≥ 50%). A subset of patients underwent IVUS evaluation including percent (%) neointimal obstruction at 6 months. The study met the primary endpoint demonstrating both non-inferiority and superiority of the DESyne BD CSS compared to the control (0.12±0.15 mm vs. 0.67±0.47 mm, p<0.001), additionally, in-stent ABR was significantly lower for the DESyne BD (0% vs. 7.9%, p=0.003). Excellent clinical results at 6 months were demonstrated for both devices (DoCE 2.7% vs. 3.2%, p=1.0, DEsyne BD and Endeavor, respectively), as well as through 36 months (DoCE 5.4% vs. 6.5%, p=0.68). Clinical results through 48 months and complete angiographic and IVUS results will be presented.

Conclusions: In this first report, the long-term 48-month clinical results and complete angiographic and IVUS results of the DESyne BD Novolimus eluting CSS will be presented.

euroPCR Coronary interventions

Euro15A-OP049

Comparison of middle-term outcomes between an everolimus-eluting stent and a biolimus A9-eluting stent implantation for unprotected left main coronary artery bifurcations

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Aims: To investigate the outcomes of second generation drug-eluting stent (DES) implantation for unprotected left main coronary artery (ULMCA) bifurcation lesions.

Methods and results: This is a single centre, retrospective study. Between April 2007 and March 2013, a total of 10,755 percutaneous coronary intervention were performed in our hospital. Among them, we performed elective DES implantation for 241 stable angina patients with ULMCA bifurcation lesions. Eighty-four (84) everolimus-eluting stents (EES) and 41 Biolimus A9-eluting stents (BES) were implanted. We evaluated their backgrounds and clinical outcomes of the EES group and the BES group. The endpoints were the occurrence of major adverse cardiac events (MACE) and target lesion revascularisation (TLR). Patients were followed up for 609±371 days. Backgrounds are similar in both groups. Kaplan-Meier survival curves showed that freedom from MACE at 2 years was 90.1% in the EES group compared with 94.3% in the BES group (p=0.86). Freedom from TLR at 2 years was 91.3% in the EES group compared with 94.3% in the BES group (p=0.63).

Conclusions: Middle-term clinical outcomes after ULMCA bifurcation stenting with EES and BES are similar.

EuroPCR Coronary interventions

Euro15A-OP050

Satisfactory neointimal healing after second-generation drug-eluting stent implantation in the left main trunk: an evaluation by optical coherence tomography

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Aims: Recently, percutaneous coronary intervention (PCI) of the unprotected left main trunk (LMT) with a second, second-generation drug-eluting stent (2nd DES) is increasingly performed. The objective of this study is to examine the neointimal response after LMT-PCI with a 2nd DES by OCT and to evaluate the safety of the procedure.

Methods and results: Fifty patients who underwent PCI for LMT with a 2nd DES and were analysed by OCT 6-8 months after PCI were included in this study. Single stenting was performed in 39 patients (biolimus-eluting stent [BES]=16, everolimus-eluting stent [EES]=23), and double stenting (culotte stenting) in 11. First, in the single stenting group, the struts were well covered irrespective of the stent (93.2% with BES, 94.2% with EES). The rate of malapposed struts was extremely low (2.9% with BES, 1.0% with EES). The neointima on the strut was thicker with EES than BES (87±73 μm vs. 72±59 μm, p<0.0001). Secondly, in the double stenting group and contrary to expectations, the percentage of uncovered struts was significantly lower at overlapping sites than non-overlapping sites (4.9% vs. 7.7%, p=0.04), and the frequency of malapposed struts and the neointimal thickness were similar at both sites.

Conclusions: At 6-8 months after LMT-PCI with the 2nd DES, stents were well covered by the neointima, even at the overlapping site of culotte stenting. Satisfactory neointimal healing after LMT-PCI with a 2nd DES was observed in our study.

EuroPCR Coronary interventions

Euro15A-OP051

Two-year clinical outcome of patients treated with the Nobori biolimus-eluting stent and XIENCE everolimus-eluting stent for unprotected left main disease

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Aims: Percutaneous coronary intervention (PCI) is increasingly used as a treatment option for unprotected left main disease (ULMD) lesions. However, there is little data regarding clinical outcome of patients treated with new-generation drug-eluting stents. The aim of this study was to evaluate two-year clinical outcome of patients treated with the Nobori biolimus-eluting stent (BES) compared to those with the XIENCE everolimus-eluting stent (EES) for ULMD.

Methods and results: Between February 2010 and July 2012, a total of 153 patients undergoing PCI for ULMD (63 BES and 90 EES) were analysed. We assessed the rates of major adverse cardiac events (MACE), defined as a composite of cardiac death, non-fatal myocardial infarction (MI), definite stent thrombosis (ST), and clinically driven target lesion revascularisation (TLR) within 2-year. Baseline patients and lesion characteristics were similar between BES and EES groups. No significant differences were observed with regard to lesion location (distal bifurcation lesion; 77.1% vs. 72.2%, p=0.48) and number of stent strategy (single stent strategy; 84.8% vs. 76.2%, p=0.28) between the two groups. The 2-year MACE rate was not significantly different between BES and EES groups (14.9% vs. 17.5%, p=0.76). The cumulative incidence of cardiac death, MI, ST, and clinically driven TLR rate were similar between the two groups (6.4% vs. 4.7%, p=0.57; 3.4% vs. 2.3%, p=0.70; 1.6% vs. 1.1%, p=0.79; 8.8% vs. 14.2%, p=0.35, respectively).

Conclusions: Two-year clinical outcome after BES implantation was not different from that after EES implantation for ULMD. Two-year clinical outcomes after both BES and EES use were excellent with a low rate of ST for ULMD.

euroPCR Coronary interventions

Euro15A-OP052

Long-term clinical outcomes after Nobori biolimus-eluting stent implantation for unprotected left main coronary artery disease compared with coronary artery bypass grafting

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Aims: We aimed to assess the long-term clinical outcomes of Nobori biolimus-eluting stent (BES) in patients with unprotected left main coronary artery (ULMCA) disease compared with coronary artery bypass grafting (CABG).

Methods and results: From 2011 to 2013, 393 patients were treated for ULMCA disease with percutaneous coronary intervention (PCI) (239 patients) or CABG (154 patients). In the PCI group, we excluded 68 patients with non-BES treatment for ULMCA. We also excluded 65 patients in the PCI group and 101 patients in the CABG group with previous PCI or CABG, and acute myocardial infarction (MI) within 24 hours from onset. A retrospective analysis was conducted in 159 patients with ULMCA disease undergoing PCI with BES (106 patients) or CABG (53 patients). We assessed the clinical outcomes such as all-cause death, cardiac death, target vessel revascularisation (TVR), major adverse cardiac and cerebrovascular events (MACCE: all-cause death, MI, stroke, and TVR), and the composite endpoint including death, MI, and stroke. The mean age was 70.6 years, and 85% were men. The median follow-up duration of the survived patients was 743 days (interquartile range 525 to 1,099 days). Between the PCI and CABG groups, there were no significant differences in baseline patient characteristics such as sex, hypertension, diabetes mellitus, dyslipidaemia, peripheral artery disease, renal failure, and left ventricular ejection fraction. On another front, the CABG group had significantly younger age (67.8±11.5 vs. 72.0±9.3, p=0.01), mo*re previous cerebrovascular events (34% vs. 17%, p=0.03), and more three-vessel diseases (62% vs. 22%, p<0.001) compared with the PCI group. The mean SYNTAX score showed no significant differences between the PCI and CABG groups (32.2±9.7 vs. 30.0±7.5, p=0.15). The clinical outcomes at 3 years showed no significant differences between the PCI and CABG groups (all-cause death: 11.5% vs. 11.2%, p=0.91; cardiac death: 2.0% vs. 0%, p=0.32; TVR: 12.4% vs. 3.9%, p=0.22; MACCE: 24.5% vs. 17.0%, p=0.77; and a composite of death/MI/stroke: 15.3% vs. 13.1%, p=0.87). Whether the SYNTAX score is low/intermediate (<33) or high (≥33), the 3-year cumulative rate of the composite of death/MI/stroke also showed no significant differences between the PCI and CABG groups (14.6% vs. 14.8%, p=0.72; 16.0% vs. 10.8%, p=0.87). The 3-year cumulative rate of TVR showed no significant differences between the two groups when the SYNTAX score was low or intermediate (4.9% vs. 6.3%, p=0.58), but tended to be higher in the PCI group when it was high (20.0% vs. 0%, p=0.068).

Conclusions: The risk of serious adverse events after PCI with BES for ULMCA disease appears to be comparable to that after CABG regardless of the SYNTAX score.

euroPCR Coronary interventions

Euro15A-OP053

Clinical outcomes in patients with left main disease treated with bioresorbable polymer drug-eluting stent

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Aims: Percutaneous coronary intervention (PCI) in patients with left main disease was shown to be associated with higher risk of adverse events. Our aim was to compare in-hospital and one-year clinical outcomes in real-world patients with and without left main stenting with bioresorbable polymer drug-eluting stent (DES).

Methods and results: We analysed data of unselected patients who received Nobori® biolimus A9 eluting stent within the large, prospective, single-arm, multicentre, observational e-NOBORI registry. The primary endpoint was target lesion failure (TLF) defined as composite of cardiac death (CD), target vessel related myocardial infarction (TV-MI) and clinically driven target lesion revascularisation (TLR). An independent clinical events committee adjudicated all endpoint related adverse events. A total of 10,112 patients were included in the analysis, of which 288 (2.85%) underwent PCI for left main disease. Protected left main PCI was performed in 33.8% of the cases. Patients in the left main group were older (67±13 vs. 63±12, p<0.01), had more often hypertension (79% vs. 72%, p=0.02), previous cardiac surgery (25% vs. 6%, p<0.01) and multivessel PCI (57% vs. 22%, p<0.01). In the group with no left main PCI, rate of patients presenting with ST-segment elevation (STEMI) was higher (6% vs. 10%, p=0.02). Treatment of bifurcation and ostial lesions was more prevalent in patients with left main PCI (16% vs. 6%, p<0.01 and 41% vs. 11%; p<0.01, respectively). Isolated left main was treated in 43% of patients, while LM with at least two other vessels was treated in 19%. Radial access was less frequently used in LM group (48% vs. 57%; p=0.02). Up to one year, overall and cardiac mortality were significantly higher in LM group (4.5% vs. 1.6%; and 2.8% vs. 1.1%; p<0.01 for both). The rate of MI was similar (1.4% vs. 1.1%) while target vessel (3.8% vs. 2.0%; p=0.02) and target lesion revascularisation (2.8% vs. 1.2%; p=0.04) were more frequent in LM group. TLF rate was significantly higher in LM group in hospital at 1- and 12-months (1.7% vs. 0.7%, p=0.03; 2.8% vs. 1.2%, p=0.01 and 6.3% vs. 3.0%, p<0.01). Target vessel failure was also higher in LM group reaching 6.6% vs. 3.4% (p=0.003) at 1-year. Stent thrombosis rate (definite and probable) was similar in both groups (0.69% vs. 0.51%, p=0.67).

Conclusions: Implantation of the Nobori® bioresorbable polymer DES in patients undergoing PCI for left main disease is associated with low rates of adverse events at one-year follow-up.

Vascular response to everolimus- and biolimus-eluting coronary stents vs. everolimus-eluting bioresorbable scaffolds: an optical coherence tomography substudy of the EVERBIO II trial

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Aims: Head-to-head OCT data comparing metallic stents to bioresorbable vascular scaffolds (BVS) is lacking. This study assesses vascular healing at 9-month follow-up after implantation of everolimus- and biolimus-eluting stents (EES; BES) and everolimus-eluting BVS.

Methods and results: Optical coherence tomography (OCT) was performed in 74 (34%) of the 216 patients who underwent 9-month follow-up angiography in the EVERBIO II (NCT01711931) trial (23 with EES - 26 lesions, 7,625 struts, 23 with BES - 26 lesions, 6,140 struts and 28 with BVS - 33 lesions, 10,891 struts). OCT images were acquired using the pullback and non-occlusive flushing technique and analysed offline. Lesions were analysed at cross sectional level with an interval of 0.5 mm and assessed for strut coverage, malapposition, protrusion and peri-strut intensity. Struts were considered uncovered in case of a partial or complete absence of tissue coverage (<10 µm, minimal axial resolution of OCT). Strut malapposition was defined as a distance ≥163 µm for BVS (strut thickness 153 µm), ≥ 122 µm for BES (strut thickness 112 µm) and ≥91 µm for EES (strut thickness 81 µm) based on the consensus derived from the strut thickness plus the minimal axial resolution of OCT. Peri-strut intensity was assessed and reported as % decrease of intensity units of the "key" component of the CMYK colour model. Analyses were carried out at strut- and lesion-level. There were no significant differences in baseline and angiographic characteristics between patients included in the sub-study and the patient population of the main trial. EES&BES-treated patients were older (67±8 yrs. vs. BVS: 62±11 yrs.; p<0.05) and more frequently presented arterial hypertension (76% [n=35] vs. BVS: 36% [n=10], p<0.01). Total stent length was longer in BVS- (26±12 mm) than in EES&BES-treated patients (23±15 mm, p=0.04). At strut-level analysis, BVS demonstrated a higher "capping" effect with less uncovered struts (366/10,891 struts versus 3,039/13,765 in the EES&BES group, p<0.001). Malapposed struts were seen less frequently with BVS (213/10,891) than with EES&BES (583/13,765, p<0.001). At lesion-level analysis, BVS (4±8%) showed a significantly lower percentage of uncovered struts per lesion compared to EES&BES (22±14%, p<0.001). The percentage of malapposed struts did not significantly differ between the 2 treatment groups (BVS: 2.1±3.3% vs. EES&BES: 4.1±8.5%, p=0.60). BVS showed thicker neointimal hyperplasia (100±45 µm) than EES&BES (65±38 µm, p<0.001). In a predefined signal intensity scale, quantitative analysis of the "Key component" (black) revealed lower intensity in BVS than EES&BES (14±23% versus 13±12%, p=0.007). Intensity was lower in polylactide-containing stents (BVS&BES) versus EES (15±19% vs. 10±10%, p<0.001).

Conclusions: BVS has higher lesion capping and decreased incomplete apposition compared with EES&BES. It is not known whether this improved capping correlates with superior vascular healing. Polylactide-containing stents (BVS and BES) demonstrate lower peri-strut intensity compared to EES.

Endothelialisation and inflammation after implantation of biostable versus biodegradable polymer DES

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Aims: Vascular injury following percutaneous coronary intervention results in activation of endothelial cells and leukocytes, which is known to impact on clinical outcome. We aimed to assess the relationship of endothelial maturation (VE-cadherin: vascular endothelial cadherin) and inflammatory marker (ICAM-1: intercellurar adhesion molecul-1, VCAM-1: vascular adhesion molecul-1) expression after implantatin of biostable polymer based everolimus-eluting stents (bs EES) and biodegradable polymer based sirolimus-eluting stents (bd SES), respectively.

Methods and results: Twelve New Zealand white rabbits were included in the study. Endothelial denudation was performed prior to stent delivery. A single stent was then deployed into each artery to include either bs EES or bd SES (n=12 each). Animals were terminated at 28 days (n=6) and 45 days (n=6), respectively. Bisected stented segments underwent immunofluorescent staining using ICAM-1, VCAM-1 and VE-cadherin. The overall extent of re-endothelialisation was confirmed by scanning electron microscopy (SEM). Endothelial coverage by SEM above stent struts was significantly higher in bd SES than bs EES at both time points (bd SES 76.5±10.2% vs. bs EES 52.8±15.6%, p=0.025 at 28 days; bd SES 95.6±2.8% vs. bs EES 78.2±13.8%, p=0.037 at 45 days). Endothelial junctions were assessed by VE-cadherin staining above stent struts and at 28 days there was higher expression in bd SES than bs EES (bd SES 36.9±13.0% vs. bs EES 24.5±14.9%, p=0.34). On the other hand, ICAM-1 expression was significantly greater in bd SES than bs EES at 28-days (bd SES 20.3±23.7% vs. bs EES 4.3±4.5%, p=0.025) however, although the ICAM-1 expression remained higher at 45 days, though the differences were not significant (bd SES 12.7±9.6% vs. bs EES 4.5±4.6, p=0.078). Similarly, VCAM expression was greater in bd SES than bs EES at 28 days (bd SES 7.7±7.6 vs. bs EES 2.4±3.3%, p=0.34), but was not statistically significant and at 45 days, both groups showed similar VCAM-1 expression (bd SES 2.3±1.4 vs. bs EES 2.3±2.6, p=0.97). ICAM-1/VCAM-1 areas of positivity showed an absence of VE cadherin expression.

Conclusions: Overall endothelial coverage was greater in bd SES compared to bs EES. Regenerating endothelium was accompanied by greater expression of ICAM-1/VCAM-1 in bd SES as compared to bs EES. The relative absence of ICAM-1/VCAM-1 in VE-cadherin positive endothelium suggests a dynamic regulation of inflammatory markers during endothelial regeneration post-stenting.

euroPCR Coronary interventions

Euro15A-OP056

The first establishment of early healing profile and 9-month outcomes of a new polymer-free Biolimus-A9 drug-coated-stent by longitudinal sequential OCT follow-ups: the EGO-BioFreedom study

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Aims: The new polymer-free Biolimus-A9 (BA9) coated BioFreedom stent (Biosensors Europe SA, Morges, Switzerland) have been studied using longitudinal sequential OCT follow-ups (FU).

Methods and results: The primary endpoint of the study is the percentage of strut coverage from one to 9 months by OCT. Using three longitudinal sequential OCT examinations in this prospective, single-centre study, 100 patients (29% DM) received 128 BioFreedom (BF) stents, 12 months DAPT was mandated. All had baseline OCT during PCI (for best stent apposition), a second OCT FU divided into 5 monthly groups (1-5 months), each randomly assigned 20 patients (for early healing profile [% strut coverage] using 6 categories), and a third OCT FU at 9 months (for total stent coverage and neointima growth). Clinical FU and MACE to 12 months were also documented as secondary endpoints. OCT analyses were performed in a blinded fashion by CRF Core Laboratory, NY, NY, USA. Mean stent length was 26.6 mm and the diameter 3.05 mm. In the first 5-month groups, 100% OCT FU was obtained. Early strut coverage was classified into six categories: early coverage (Cat. D to F) increased progressively from a minimum of 74% at 1 month to 97.43% [IQR 95.31-99.01; min 88.58, max 99.93] at 5 months. In each group of 20 patients, the range variations of coverage % were much wider in the earlier (1-2 months) groups; such variations were largely replaced by near complete coverage in the later months. Nine-month OCT FU is still ongoing; 55 patients have been studied with OCT results analysed to date, reaching a coverage of 99.07% [IQR 96.64-99.72; min. 85.41, max. 100]. In addition to progressive increase in coverage over time, more mature neointimal tissue (brighter intensity and more homogenous in appearance) was observed. Neointimal thickness (NIT) increased progressively from 1 month to 5 months at 0.04 (IQR 0.03-0.06), 0.04 (0.03-0.06), 0.04 (0.03-0.07), 0.05 (0.03-0.10), and 0.06 (0.04-0.11) mm, overall p=0.0028, respectively. Nine-month NIT remained very low at 0.10 mm (0.05-0.16) to date (55 patients). In-stent neointimal volume percentage increased from 4.3% (IQR 2.1-7.5) in the first 5 months to 12.2% (9.4-15.9) at 9 months. The mean FU duration is 448±172 days to date; three patients had in-stent restenosis requiring treatment (TLR rate 3%); no other target vessel related infarct or cardiac death recorded. Angiographic binary restenosis is still pending core lab analyses. No ARC (definite or probable) late stent thrombosis was recorded. Complete data will be available at presentation.

Conclusions: The BA9 BF Stent is the first polymer-free drug-coated-stent studied with the early healing profile and 9-month neointimal changes established via OCT.) 12-month clinical outcomes are favourable without occurrence of late stent thrombosis to date.

euroPCR Coronary interventions

Euro15A-OP057

Incidence and characteristics of late catch-up phenomenon between sirolimus-eluting stents and everolimus-eluting stents: a propensity matched study

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Aims: Late catch-up phenomenon after everolimus-eluting stent (EES) implantation has not been evaluated sufficiently. We evaluated and compared the incidence and characteristics of late catch-up phenomenon between EES and sirolimus-eluting stent (SES) implantations.

Methods and results: Between April 2007 and May 2011, 1,234 patients with coronary artery disease were treated with SES and 502 patients with EES. Following propensity score matching, we evaluated 495 SES-treated patients and 495 ESS-treated patients. The incidences of late catch-up phenomenon (i.e., late target lesion revascularisation [TLR] [1-3 years]) were compared. Angiographic characteristics and intravascular ultrasound (IVUS) findings of restenosis lesions were compared. After propensity matching, no significant difference in the baseline characteristics was found between the two groups. The cumulative incidence of TLR at 3 years was 11.9% in the SES group and 6.1% in the EES group (p=0.001, log-rank test). The incidence of late TLR was 7.5% in the SES group and 3.4% in the EES group (p=0.004, log-rank test). IVUS showed a higher rate of stent fracture (SF) in late restenosis lesions in the SES group than in the EES group (37.0% vs. 7.7%). The SF rate increased in late restenosis compared with early restenosis (within 1 year) in the SES group (37.0% vs. 22.2%), but was not significantly different in the EES group (7.7% vs. 10.0%).

Conclusions: EES was significantly superior to SES with respect to the incidence of late catch-up phenomenon. SF, particularly late acquired SF, may be associated with late catch-up phenomenon after SES implantation.

Coverage and apposition of bioabsorbable scaffolds assessed by optical coherence tomography: the ALSTER-OCT ABSORB registry

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Aims: Dual antiplatelet therapy is currently recommended for 6-12 months after scaffold implantation. However, dual antiplatelet therapy is associated with a high risk of bleeding events comparable to oral anticoagulation. Complete stent coverage by tissue as newly analysable by optical coherence tomography (OCT) may allow reducing the duration of dual antiplatelet therapy. This registry analysed scaffold strut coverage six-seven months after ABSORB scaffold implantation. It will test the hypothesis that the ABSORB will have complete strut coverage as measured by OCT allowing for early termination of dual antiplatelet therapy. Furthermore, 12-month clinical follow-up will be assessed.

Methods and results: Clinically-induced angiography with OCT was performed in 14 patients (13/14 male, mean age 51.7±1.8 years) after PCI with ABSORB scaffolds at follow-up (205.7±21.9 days). Scaffold strut coverage was classified according to published criteria (mean±standard error of the mean). Embedded covered struts: 80.6±3.9%; protruding covered struts:16.2±3.6%; apposed uncovered struts: 2.5±0.7%; malapposed uncovered struts: 0.7±0.4%. Mean neointimal thickness was measured as 96.6±7.5 µm. Up to the present date no clinically relevant events occurred. The OCT measurements of 25 patients, as well as one-year clinical follow-up, will be completed within the next months.

Conclusions: The ABSORB scaffold achieved nearly complete strut coverage as measured by OCT after r.a. seven months. An earlier termination of dual antiplatelet therapy could be an option to prevent major bleeding events possibly without increasing the risk of stent thrombosis.

Coronary evaginations and peri-stent aneurysms following implantation of bioresorbable scaffolds: incidence and optical coherence tomography analysis of possible mechanisms.

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Aims: Peri-stent aneurysms, malapposition or evaginations have been proposed as possible risk factors for late stent thrombosis. We set out to assess the incidence, predictors, and possible mechanisms of coronary evaginations detected by optical coherence tomography (OCT) at 12 months following implantation of bioresorbable vascular scaffolds.

Methods and results: A total of 103 scaffolds implanted in 96 patients (age 62±13 years, 76 males, 16 diabetics) were analysed with angiography and OCT 12 months after implantation. Evaginations were identified as any hollow in the luminal vessel contour between well-apposed struts and were classified as major when extending ≥3 mm with a depth ≥10% of the stent diameter; 50.5% of the scaffolds had at least one evagination (in average 5.5±5.5 evaginations per scaffold), with a mean volume of 1.7±1.7 mm^2. Major evaginations were only found in one patient. The presence of evaginations was strongly associated with that of malapposition ($p=0.005$). No association could be shown between the presence and volume of the evaginations and any clinical variable, and there was no association between evaginations and the presence of uncovered struts ($p>0.5$). In addition, inappropriate sizing did not appear to be a predictor of evaginations. Peri-strut low intensity areas (a marker suggestive of inflammatory reactions to the scaffold) were present in 10 of the patients with evaginations (19.6%), and their presence was strongly associated with the total evagination volume in single and multivariate analysis ($p<0.0001$).

Conclusions: OCT-detected evaginations are relatively common after scaffold implantation, but the incidence of major evaginations, as for modern drug-eluting metallic stents, is very low. Evaginations appear to be unrelated to clinical variables, undersizing and were not associated with the presence of uncovered struts. Inflammatory reactions to one of the components of the device might have a pathophysiological role in about 20% of the cases, in which this phenomenon appears to be particularly severe.

euroPCR Coronary interventions

Euro15A-OP060

Comparative study with optical coherence tomography at 6 and 12 months between drug-eluting stents of resorbable polymer and drug-eluting scaffolds with completely bioresorbable platforms implanted simultaneously in different lesions of the same patient.

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Aims: Bioresorbable everolimus-eluting scaffolds (BVS) and metallic drug-eluting stents with bioerodable polymers (MBP-DES) have shown positive clinical results in studies. Direct comparative evaluation between both for the process of endothelisation is lacking and could be relevant to define their safety profile and subsequently estimate the appropriate duration of dual antiplatelet therapy.

Methods and results: This was a multicentre (15 centres), prospective study. Patients were recruited when requiring stent implantation (without overlapping) in at least two separate lesions of similar morphologic characteristics. Each lesion was randomised to be treated with either a BVS or a MBP-DES (Synergy, Orsiro or BioMatrix). After the procedure, patients were scheduled alternatively for 6 or 12 months evaluation with optical coherence tomography. Primary endpoint was the % of uncovered struts at 6 months. As of now, 74 patients have been included (32 with BVS+Synergy, 25 with BVS+Orsiro and 17 with BVS+BioMatrix). Of these, 14 patients have been examined at present with OCT at 6 months. Of those examined, in 9 patients the stents were Synergy+BVS, in 3 Orsiro+BVS and in 2 BioMatrix+BVS. The % of uncovered struts was 3.9% with MBP-DES and 4.7% with BVS (p=0.4).

Conclusions: Pending final follow-up and analysis of the whole cohort, at 6 months the proportion of uncovered struts is low and comparable between bioresorbable everolimus-eluting scaffolds and metallic drug-eluting stents with bioabsorbable polymers.

euroPCR Coronary interventions

Euro15A-OP061

Percutaneous coronary intervention with everolimus-eluting bioabsorbable vascular scaffolds: implantation failure, application of intravascular imaging, lesion preparation and non-compliant balloon post-dilatation in a single centre registry with 231 consecutive patients

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Aims: PCI with implantation of everolimus-eluting bioabsorbable scaffolds (BVS) requires a more detailed planning, including intravascular imaging, as well as lesion preparation and non-compliant balloon post-dilatation due to mechanical limitations of the polylactic polymer. We were interested whether the application of these technical aspects as well as the incidence of implantation failures (i.e., inability of lesion crossing) changes with increasing operator experience.

Methods and results: A single-centre registry with comparison of the first 50 (cohort A) versus the following 181 consecutive patients (cohort B) with intention of BVS implantation (from October 2012 to October 2014) was compiled. Clinical baseline characteristics were statistically not different including age (54±9 vs. 55±8 years), female gender (24% vs. 15%) and diabetes (32% vs. 27%). Patients with STEMI (4% vs. 8%) and stable angina (42% vs. 54%) were numerically lower present in cohort A (p=ns for both). Distribution of target vessels (left anterior descending artery: 62% vs. 61%, left circumflex artery: 28% vs. 7%; right coronary artery: 38% vs.45%; left main artery: 4% vs1%) and type b2/c lesions (85% vs. 83%) were statistically not different. Multivessel- (23% vs.39%) and bifurcation PCI (51% vs.59%), thrombus aspiration (4% vs.13%), as well as number and length of BVS implanted (2.0±1.4 vs. 2.2±1.4 mm; 43±33 vs.. 49±35 mm) showed a non-significant trend for increase in cohort B. Failure of BVS implantation (n=8; 3%) was numerically lower in cohort B (6% vs.3%, p=ns) and associated with higher age (62±7 vs. 54±8 years; p=0.006) and presence of type C lesion (100% vs. 33%; p=0.001). Intravascular imaging was performed in 37% of all patients (96% OCT, 4% IVUS) with a highly significant decrease from cohort A to B (74% vs. 27%; p<0.001). Lesion preparation was performed in 100% of patients. Predilatation with a balloon-to-scaffold ratio of 0.9±0.1 was performed in 99% (non-significantly increasing from 0.8±0.1 to 0.9±0.1 in cohort B) and thrombus aspiration alone in 1%. Usage of scoring balloons or rotational atherectomy significantly increased from 11 % in cohort A to 35% in cohort B (p=0.002). Rate of non-compliant balloon post-dilatation was high (77%) with a non-significant increase in cohort B (72% vs. 78%).

Conclusions: While the application of intravascular imaging during BVS implantation decreased with increasing operator experience in our registry, lesion preparation with scoring balloons significantly increased, resulting in a numerical higher implantation success. The rate of non-compliant balloon post-dilatation remained high, underlining its importance in BVS implantation.

EuroPCR Coronary interventions Euro15A-OP062

A hybrid strategy with bioresorbable scaffold and drug coated balloon for complex coronary artery lesions in the same vessel: the "No More Metallic Cages" Multicenter Experience

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Aims: The length of a permanent metal stent (PMS) is a well-known predictor of in-stent restenosis (ISR) and stent thrombosis (ST). Both bioresorbable scaffold (BRS) and drug-coated balloon (DCB) emerged as an attractive alternative to PMS for the treatment of coronary artery disease. The aim of this study was to assess feasibility and results of an innovative hybrid approach with BRS plus DCB for the treatment of complex coronary lesions in the same vessel.

Methods and results: A retrospective, multicentre cohort analysis was performed on all consecutive patients that underwent BRS (ABSORB, Abbott Vascular, Santa Clara, CA, USA) implantation for a *de novo* lesion (proximal or middle segment) and DCB inflation for associated small vessel disease (distal segment or side branch) or in-stent restenosis (ISR) in the same vessel. The study objective was procedural success defined as residual stenosis less than 30% in the BVS or DCB treated segments without in-hospital clinical adverse events (cardiac death, target vessel myocardial infarction [TV-MI] and/or emergent target lesion revascularisation [TLR]). Furthermore, we evaluated the TLR and BRS/DCB segment thrombosis rates at follow-up. Between May 2012 and July 2014, 41 consecutive patients were treated with the combined BRS/DCB strategy. Hybrid approach was mainly performed in the presence of diffuse or tandem coronary disease (28, 68.2%), bifurcations (9, 22.0%) and ISR (4, 9.8%). Mean patient age was 62±10.2 years while 11 (26.8%) patients were diabetics. The predominant clinical presentation was stable angina (25, 61%). Intracoronary imaging was performed in 22 (53.7%) cases. Mean BRS and DCB length were 36.8±18.7 mm and 25.7±8.6 mm respectively. Regarding DCB type, IN.PACT Falcon (Medtronic, Minneapolis, MN, USA) was used in 22 (53.7%) patients, Pantera Lux (Biotronik AG, Bulach, Switzerland) in 12 (29.2%) and Sequent Please (BE Braun Melsungen AG, Melsungen, Germany) in 7 (17.1%). Procedural success was obtained in all patients and 3 (7.3%) patients required bail-out stenting for DCB-related dissection. At a median follow-up period of 12 months (IQR: 6-18) there were no cases of cardiac death, TV-MI, BRS/DCB segment thrombosis. TLR occurred in 4 (9.7%) BRS and 1 (2.4%) DCB treated segments. All TLR cases were successfully managed with re-PCI.

Conclusions: This experience suggests that long/complex lesions can be treated with a hybrid strategy using BVS for a *de novo* lesion and DCB for a concomitant small vessel disease or ISR in the same vessel. These preliminary results support a favourable clinical outcome.

EuroPCR Coronary interventions Euro15A-OP063

Applicability and procedural success rate of bioresorbable vascular scaffolds for percutaneous coronary intervention in an all-comer cohort of 383 patients

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Aims: Bioresorbable vascular scaffolds can be used for PCI of coronary artery stenoses. Limitations include a larger crossing profile as compared to new generation drug-eluting stents (DES), a limited size matrix, and treatment of bifurcation lesions is not recommended. Given these restrictions, we analysed the applicability and procedural success rate of PCI using a commercially available poly-L-lactic acid based bioresorbable vascular scaffold (Absorb®; Abbott Vascular, Santa Clara, CA, USA) in an all-comer patient cohort.

Methods and results: A cohort of 383 consecutive patients (mean age 86±10 years, 274 male, 109 female) who underwent PCI for haemodynamically relevant coronary stenoses was analysed. A bioresorbable vascular scaffold (Absorb®) was used as the first line device unless any of the following contraindications were present: Bifurcation lesion with side branch >2.0 mm, reference vessel diameter <2.5 mm or >4.0 mm, lesion length <8.0 mm, in-stent stenosis or inability to prescribe 12 months of dual antiplatelet therapy. Patients and coronary lesions were evaluated regarding suitability for treatment with a bioresorbable vascular scaffold and, if scaffold placement was attempted, regarding procedural success (successful device placement and residual stenosis <30%). In 383 consecutive patients (acute coronary syndrome: 124, stable coronary disease 259), 588 lesions were treated. The mean number of vessels treated per patient was 1.18±0.44, the mean number of treated lesions per patient was 1.48±0.82. Of all 588 lesions, 303 lesions (51%) were deemed unsuitable for placement of a bioresorbable vascular scaffold, while treatment with scaffold was attempted for all others (n=285). Reasons for inability to use a scaffold were presence of a bifurcation (30% of unsuitable lesions), diameter >4.0 mm (13%), diameter <2.5 mm (12%), inability to prescribe dual antiplatelet therapy for 12 months (13%), in-stent stenosis (14%) and desired device length <12 mm (4%). Lesions not intended for scaffold treatment were treated with DES (32% of all lesions), BMS (8%), plain balloon angioplasty (3%) and drug-eluting balloon (8%). If use of the Absorb® bioresorbable vascular scaffold was attempted, procedural success with a scaffold was achieved in 271/285 (95%). Crossing failure occurred in 14 cases (5%). Lesions with crossing failure were significantly more calcified than lesions with successful scaffold placement. The mean number of scaffolds placed per lesion was 1.2±0.7, mean diameter was 3.1 mm, mean length was 20.0 mm.

Conclusions: Even with a conservative approach, approximately one-half of lesions in an all-comer population of 383 consecutive patients could be treated with current poly-L-lactic acid based bioresorbable vascular scaffolds. Most frequent reasons requiring alternative approaches were bifurcations and unsuitable vessel size. Crossing failure was extremely rare.

euroPCR Coronary interventions

Euro15A-OP064

Expansion of bioresorbable vascular scaffold use to coronary bifurcation lesions: a substudy of the European multicentre GHOST-EU registry

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Aims: The aim of this study was to evaluate early and midterm outcomes of bioresorbable vascular scaffolds (BVS) implanted in coronary bifurcation lesions.

Methods and results: Between November 2011 and January 2014, 1,189 patients underwent PCI with BVS at 10 European centres (GHOST-EU registry). Of these, we evaluated 289 consecutive patients (302 bifurcation lesions) treated with either provisional single-stenting in 86% (n=260) or elective double-stenting in 14% (n=42). Mean age was 61.6 years. Regarding clinical presentation, 34% of the cases presented with an ACS. True bifurcation (Medina 1,1,1/1,0,1/0,1,1) were observed in 45%. Pre-dilation and post-dilation of the main branch were performed in 96% and 61%, respectively. Final kissing inflation with small protrusion of a side branch balloon into main branch was performed in 19%. Median follow-up period of this study was 186 (IQR 118 to 276) days. Estimated rates of target lesion failure (TLF) defined as the composite endpoint of cardiac death, target vessel myocardial infarction or clinically driven target lesion revascularisation (TLR) were 3.8% and 5.7% at 90 days and 180 days, respectively. TLR rates were 2.3% and 4.2% at 90 and 180 days, respectively. The rate of definite and probable scaffold thrombosis in this complex cohort was 2.6% at 90 days and 3.2% at 180 days. In patients who experienced a scaffold thrombosis, majority (75%) occurred within 35 days from the index PCI, did not have intravascular imaging guidance, and did not discontinue dual antiplatelet therapy at the time of the event. Independent predictors of TLF were presentation of ACS and diabetes.

Conclusions: These results suggest that the treatment with BVS for coronary bifurcation lesions is associated with acceptable clinical outcomes in our "real-world" practice. However, the high scaffold thrombosis rate warrants further investigation and underlies the importance of meticulous implantation technique when implanting BVS.

euroPCR Coronary interventions

Euro15A-OP065

One-year clinical outcomes after full-plastic jacket bioresorbable scaffold implantation

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Aims: In cases of percutaneous coronary intervention (PCI) for long-diffuse lesions, the best management strategy is unclear with options including treating most of the vessel length as opposed to a more focal approach. A common option is to implant a "full-metal jacket" (FMJ) which remains associated with higher rates of in-stent restenosis and stent thrombosis and may preclude future surgical revascularisation. The use of bioresorbable scaffolds (BRS) is therefore very attractive by virtue of their full reabsorption 2 to 3 years after implantation. We therefore sought to investigate the feasibility and short-term clinical outcomes following BRS implantation for very long lesions ("full-plastic jacket").

Methods and results: A retrospective analysis in two high volume centres in Milan was performed on consecutive patients who underwent PCI with BRS (ABSORB; Abbott Vascular, Santa Clara, CA, USA) between May 2012 and November 2014. Procedural "full-plastic jacket" (FPJ) was defined as a continuous segment of BRS measuring 60 mm or more. During the study period, 233 lesions (171 patients) treated with BRS (total length <60) and 31 lesions (28 patients) treated with FPJ were identified. Patients treated with FPJ had a higher prevalence of diabetes (43% vs. 24%) and higher SYNTAX scores (20.6 vs.16.5) compared to those with BRS total length <60 mm. The main target vessel in the FPJ group was the LAD (80.6%). The incidence of periprocedural MI (as defined by a creatinine kinase [CK] >2 times the upper limit of normal in addition to a CK-MB elevation) was higher in the FPJ group (FPJ 17.9% vs. BRS length <60 mm 8.8%: p=0.17). The incidence of major adverse cardiac events (defined as a combination of all-cause death, myocardial infarction and target vessel revascularisation) tended to be higher in the FPJ group (FPJ 18.5% vs. BRS length <60 mm 7.5%: p=0.14) at 1-year follow-up. In the FPJ group, there was one case of definite stent thrombosis in a patient who stopped clopidogrel 2 months after BRS implantation. The incidence of TVR tended to be higher in the FPJ group (FPJ 18.3% vs. BRS length <60 mm 6.5%: p=0.10).

Conclusions: FPJ treatment for diffuse long lesions is feasible and safe. One-year outcomes are acceptable when compared to BRS use in shorter lesions when accounting for the greater comorbidity and lesion complexity in this group.

Small vessel treatment during PCI: clinical outcomes after use of DES with bioresorbable polymer gradient coating

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Aims: Treating coronary artery disease in small vessels (RVD≤2.5 mm) is critically important, as it is often associated in woman with heart disease and in diabetic patients who may have long diffuse disease. Our aim was to analyse clinical outcomes in this complex population when treated with an innovative thin strut DES, Ultimaster, coated abluminaly with bioresorbable gradient polymer. We performed a subanalysis on patients with small vessel treatment within the CENTURY II trial.

Methods and results: CENTURY II is a single-blinded, randomised, multicentre study comparing sirolimus-eluting, bioresorbable polymer, Ultimaster stent (BP-SES) and an everolimus-eluting, permanent polymer, XIENCE stent (PP-EES). Out of 1,119 patients enrolled, 525 patients had small vessels and were assigned randomly to BP-SES (277) or PP-EES (248). The primary endpoint of the CENTURY II study is target lesion failure rate (TLF) at 9 months, composite of cardiac death, target vessel related MI and clinically driven TLR. Clinical outcomes up to 1 year are evaluated in this substudy and 2-year follow-up is currently ongoing. All data are monitored and adverse events are adjudicated by an independent clinical event committee. Baseline clinical characteristics are similar in both study arms for age (66±11 for both), male gender (75% vs. 81%), diabetes mellitus (32% vs. 34%), hypertension (75% vs. 69%), previous MI (34% vs. 30%), previous PCI (43% vs. 39%) and previous CABG (5% for both), for BP-SES and PP-EES respectively. Neither were there significant differences in baseline lesion characteristics concerning lesion length (17.18±10.32 mm vs. 15.74±8.51 mm), RVD (2.30±0.40 mm vs. 2.31±0.42 mm), and diameter stenosis pre-procedure (66.91±11.95% vs. 66.24±12.58%) for both BP-SES and PP-EES, respectively. The TLF rate at 1 year was 6.9% and 7.7% (p=0.72), with similar rates for cardiac death (1.1% vs. 1.2%; p=0.89), target vessel related MI (1.8% vs. 3.2%; p=0.30) and clinically driven TLR (3.6% vs. 4.4%; p=0.63), for BP-SES and PP-EES respectively. Stent thrombosis rate at 1 year was 0.7% for BP-SES and 1.2% for PP-EES (p=0.57).

Conclusions: In a complex patient population, treatment of small vessels with the BP-SES Ultimaster stent showed good and similar outcomes to the PP-EES XIENCE stent at 9 months. The combination of stent characteristics such as small strut thickness and bioresorbable abluminal gradient polymer coating, delivering drug only to the surface of the vessel wall, may favourably enhance treatment in this patient subset.

Predictors of midterm restenosis in very small vessel lesions after treatment with 2.25 mm DES

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Aims: To evaluate the predictors of midterm restenosis in very small vessel lesions after treatment with a 2.25 mm DES and the impact of implanted stent type.

Methods and results: Between January 2010 and April 2014, we treated 311 very small vessel lesions using three types of 2.25 mm DES: a platinum chromium everolimus-eluting stent (PtCr-EES) in 202 lesions; a cobalt chromium everolimus-eluting stent (CoCr-EES) in 59 lesions; and a zotarolimus-eluting stent (ZES) in 50 lesions. Angiographic follow-up was scheduled at 8 months after procedure (midterm). The follow-up rate was 75.9%. By multivariate adjustment analysis, an independent positive predictor of restenosis was insulin-treated diabetes mellitus (OR 4.94; 95% CI: 1.16-19.1; p=0.03). The use of PtCr-EES was a negative predictor of restenosis (OR 0.24; 95% CI: 0.06-0.81; p=0.02). Among PtCr-EES, CoCr-EES and ZES, PtCr-EES had significantly lower values in the restenosis rate (2.6% vs. 6.4% vs. 17.7%, p=0.002), target lesion revascularisation rate (0.65% vs. 6.4% vs. 8.8%, p=0.01), and late lumen loss (0.23±0.4 mm vs. 0.21±0.4 mm vs. 0.43±0.4 mm, p=0.03).

Conclusions: The predictors of midterm restenosis in very small vessel lesions after treatment with 2.25 mm DES were insulin-treated diabetes mellitus and the implanted stent type. Using PtCr-EES may bring better outcomes.

euro PCR Coronary interventions

Euro15A-OP068

Two-years results of second-generation drug-eluting stents for the treatment of left main and/or three-vessel disease as compared to first-generation drug-eluting stents: propensity matched analysis

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Aims: The efficacy of second-generation drug-eluting stent (DES) for the treatment of left main disease (LM) and/or three-vessel disease (3VD) remains unclear. We thus investigated the efficacy of second-generation DES for the treatment of left main disease (LM) and/or three-vessel disease (3VD).

Methods and results: Between April 2008 and September 2012, 326 patients with LM and/or 3VD were treated by percutaneous coronary intervention. Of these, 154 patients were treated with first-generation DES and 137 patients were treated with second-generation DES. We performed propensity matching to minimise the impact of baseline confounding factors. Target lesion revascularisation (TLR) and major adverse cardiac events (MACE) at 2 years were compared between the two groups. After propensity matching, there were 101 patients in each group. TLR and MACE at 2 years were higher in first-generation DES compared with second-generation DES (TLR: 23.8% vs. 7.9%; p=0.003, MACE: 31.7% vs. 12.9%; p=0.002). TLR and MACE in low and intermediate SYNTAX scores were tend to be high in first-generation DES group, but there were no statistical significance (low score, TLR: 14.6% vs. 5.9%; p=0.258, MACE: 18.8% vs. 11.8%; p=0.481, intermediate score, TLR: 27.3% vs. 6.5%; p=0.116, MACE: 40.9% vs. 9.7%; p=0.052). On the other hand, in high SYNTAX scores TLR and MACE were significantly higher in first-generation DES group (TLR: 35.5% vs. 11.1%; p=0.020, MACE: 45.2% vs. 16.7%; p=0.048).

Conclusions: Second-generation DES significantly improved TLR and MACE in patients with LM and/or 3VD compared with first-generation DES.

euro PCR Coronary interventions

Euro15A-OP069

Comparison of first- and second-generation drug-eluting stent implantation for ostial right coronary artery lesions

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Aims: The aim of this study was to compare clinical outcomes 1-year after first- or second-generation drug-eluting stent implantation for ostial right coronary artery lesions.

Methods and results: Ostial right coronary artery (RCA) lesions were defined as lesions within 3 mm of the aorto-ostium. The study subjects were 114 patients with ostial RCA lesions treated with drug-eluting stent (DES) (65 first generation and 49 second generation) between January 2005 and December 2012. Study endpoints were major adverse cardiac events (MACE), defined as all cause death, target lesion revascularisation (TLR) or myocardial infarction (MI) within 1 year after percutaneous coronary intervention. The incidence of cardiac death was also evaluated. Patient characteristics were similar between the two groups. MACE were significantly lower in the second-generation DES group (adjusted hazard ratio [HR]: 0.29; 95% confidence interval [CI]: 0.13 to 0.64; p=0.002) because of a lower TLR rate (adjusted HR: 0.25; 95% CI: 0.10 to 0.60; p=0.002). No cardiac death or MI occurred in either group. Cox regression analysis identified haemodialysis as an independent predictor of MACE (HR:4.57; 95% CI: 2.05 to 10.18; p<0.001).

Conclusions: The rate of MACE after second-generation DES implantation for ostial RCA lesions was significantly lower compared with first-generation DES implantation because of a significantly lower TLR rate. However, PCI for ostial RCA lesions, even with second generation DES, may be contraindicated in haemodialysis patients.

Impact of coronary artery calcification severity on outcome after percutaneous coronary intervention with everolimus-eluting stents in patients with a long coronary lesions

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Aims: Research on the effectiveness of percutaneous coronary intervention (PCI) with an everolimus-eluting stent in a calcified lesion is lacking. It is unclear whether coronary artery calcification affects the outcome after PCI with everolimus-eluting stent and we hypothesised that coronary artery calcification does not affect the outcome after PCI with everolimus-eluting stent in patients with a long coronary lesion.
Methods and results: The angiographic eligibility for inclusion required a lesion length of more than 28 mm. We identified 298 consecutive patients who underwent successful PCI with everolimus-eluting stent. Our study sample included 344 lesions that were more than 28 mm in length. The calcium arc was measured by intravascular ultrasound. Calcified lesions were grouped according to the calcium arc, which ranged from 0 to 180 (mild to moderate coronary artery calcification) and 181 to 360 (severe coronary artery calcification). The incidence of target lesion revascularisation, target vessel revascularisation, myocardial infarction, all cause death, and major adverse cardiac events were not significantly different between the mild to moderate coronary artery calcification and severe coronary artery calcification groups. The target lesion revascularisation-free rate and the major adverse cardiac events-free rate were not significantly different between the two groups.
Conclusions: We showed that coronary artery calcification does not affect the outcome after PCI with everolimus-eluting stent in patients with a long coronary lesion. This result suggests that in these patients with long coronary lesions, everolimus-eluting stents might be safe and effective in calcified lesions as well as non-calcified lesions.

Evaluation of a thin-strut bioresorbable polymer DES in patients with high risk ACS: data from CENTURY II trial

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Aims: The PCI with implantation of DES has increased in patients with high-risk acute coronary syndromes (STEMI/NSTEMI). However, long-term safety in this complex patient population is still controversial. Therefore, in the CENTURY II study, safety and efficacy of new, sirolimus-eluting stent coated with bioresorbable polymer, Ultimaster (BP-SES), in high-risk acute coronary syndrome (ACS) patients was evaluated.
Methods and results: In the frame of a single-blind, randomised, multicentre CENTURY II study, randomisation was stratified for high risk ACS. Out of 1,119 patients enrolled, 264 have been diagnosed with high risk ACS and assigned randomly to treatment with Ultimaster BP-SES (126) or durable polymer everolimus-eluting stent XIENCE (138) (DP-EES). The primary endpoint of the study was TLF at 9 months and 2-year follow-up is currently ongoing. All data were 100% monitored and an independent clinical event committee adjudicated all adverse events. Baseline patient characteristics such as age, gender, presence of diabetes, hypertension, dyslipidaemia, family history of CAD, smoking, previous MI and previous PCI were similar in both study arms. Besides, there were no differences noted in pre-procedure thrombus presence (10.1% vs. 11.8%, p=0.61) or lesion complexity (lesion type B2 and C 81.1% vs. 79.5%) in BP-SES and PP-EES arms respectively. LAD was the most frequent target vessel and radial access was used in >70% of cases, without difference between treatment arms. At 1-year, there was no significant difference noted in target lesion failure (4.8% vs. 5.1%; p=0.90) and clinically driven target vessel revascularisation (3.2% vs. 4.4%; p=0.62) for BP-SES and DP-EES, respectively. Numerically, lower rates of cardiac death (0% vs. 1.5%; p=0.18), MI (2.4% vs. 3.6%; p=0.56), and target vessel failure (4.8% vs. 7.3%; p=0.40) were recorded in the BP-SES group, without reaching statistical significance. Two cases of stent thrombosis (ST) were reported in the BP-SES arm whereas three ST in one patient occurred in the DP-EES arm, resulting in similar rate in both arms (1.6% vs. 0.7; p=0.51). All reported cases of ST were subacute. There were no late ST in any study arm. At 12 months, 66% of patients in both arms were on dual antiplatelet therapy. Bleeding and angina complaints were observed in 8.7% and 10.9% and in 2.4% and 1.5% of the patients in BP-SES and DP-EES arms, respectively.
Conclusions: One-year safety and efficacy of new Ultimaster DES was very good and similar to the XIENCE DES in patients with high-risk ACS. Two-year clinical outcomes will be available at the time of presentation.

EuroPCR Coronary interventions

Euro15A-OP072

enABL e-registry: 2 year clinical investigation of novel abluminal coated sirolimus-eluting stent

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Aims: An innovative delivery of sirolimus was tested with the drug and polymer matrix being abluminally coated on the stent and the exposed part of the balloon in pre-crimped condition. The aim of enABL e-registry is to capture long-term clinical data of the DES by evaluation of safety and efficacy in large population in routine clinical practice.

Methods and results: The study is designed for all-comers by the prospective method in 3,000 Indian patients. The data was divided in 3 subsets of patients; diabetic (n=300), MVD (n=200) and long lesion (n=200) subsets. We evaluated 491 prospective patients. The primary endpoint was MACE rate defined as composite cardiac death, Q-wave and non-Q-wave MI or TLR at 12 months. Major secondary endpoints were stent thrombosis (definite and probable according to ARC conditions) at 3, 9, 12 months, 2 and 3 years. Mean age of the population was 59.01±10.43%, 34.01 patients were diabetic, 5.49% had prior PCI or CABG, 11.20% had a STEMI <72 hours, and 14.05% had MVD. An average of 1.34 stent per patient had been implanted.

Conclusions: Interim analysis has revealed a MACE rate 1.42% at 9-month follow-up and 0 ST which remains unchanged at 2-year follow-up. The data suggests safety and efficacy of DES in routine clinical practice. QCA data will be presented during the meeting.

EuroPCR Coronary interventions

Euro15A-OP073

Novel core wire technology on a zotarolimus-eluting stent provides improved acute performance, including deliverability and radiopacity

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Aims: To evaluate the acute performance of the Resolute Onyx™ zotarolimus-eluting stent (ZES; Medtronic, Inc., Santa Rosa, CA, USA) that utilises a continuous sinusoidal technology and novel core wire technology through bench testing, a patient case with tortuous anatomy, and computational fluid dynamics.

Methods and results: The Resolute Onyx™ SES is composed of a composite wire material consisting of a platinum iridium alloy core, resulting in improved radiopacity as compared with Resolute Integrity™ ZES (RI-ZES, Medtronic, Inc.), and a shell composed of the same cobalt alloy material as RI-ZES. Utilisation of this novel, core wire technology enables the Resolute Onyx ZES to improve radiopacity, despite being composed of thinner stent struts as compared with Resolute Integrity ZES (81 µm vs. 91 µm, respectively). These changes result in a lower crossing profile (1.04 mm vs. 1.12 mm) and facilitate improved tracking and lesion crossing. Resolute Onyx ZES showed to be 20% more trackable than RI-ZES based on a lower mean maximum force required to pass through a simulated tortuosity model. To negate any compromise in radial strength, the Resolute Onyx ZES adopts an increased strut width to thickness ratio. Radial strength was measured by applying a load of 200 mmHg to a small diameter (worst case) 2.25 mm (and 8 mm length) stent. A total of 10 devices of each stent platform were tested. The diameter of RI-ZES was reduced by 1.0±0.16% while that of Resolute Onyx ZES reduced by 0.4±0.11%, $p<0.001$. Additionally, a patient case will highlight the device deliverability and radiopacity, as well as stent apposition using optical coherence tomography (OCT). Furthermore, a patient-specific case created from OCT and computed tomography will undergo computational fluid dynamics modelling to quantify haemodynamic alterations from stenting, including distributions of wall shear stress. The results will be compared to the calculated haemodynamic alterations with other manufactured stents after virtual implantation within the same patient. The Resolute Onyx ZES retains the key features of drug coating formulation, drug dose density, coating process, outer stent material, and use of continuous sinusoid technology as RI-ZES, intended to maintain the long-term effectiveness and safety demonstrated by the RESOLUTE Global Clinical Trial Program.

Conclusions: The Resolute Onyx ZES utilises a novel, stent design approach that improves acute performance via application of core wire technology, allowing for thinner stent struts, lower crossing profile, enhanced deliverability, and improved radiopacity, while maintaining similar or even improved radial strength as compared with the RI-ZES. The acute procedural performance improvements, without compromise to other key attributes, of core wire technology and the Resolute Onyx ZES stent design is demonstrated through the bench testing, clinical evaluation, and computational modelling presented here.

Direct implantation of rapamycin-eluting stents with bioresorbable drug carrier technology utilising a drug-eluting coronary stent integrated delivery system (IDS): the DIRECT II study

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Aims: The Svelte sirolimus-eluting coronary stent Integrated delivery system (IDS) is designed to facilitate transradial interventions (TRI) / "Slender" PCI and direct stenting. The DIRECT II study was undertaken to demonstrate the feasibility of the Svelte IDS in a randomised, controlled setting.

Methods and results: The Svelte IDS utilizes an 81 µ thick CoCr stent with bioresorbable amino acid-based (PEA) drug carrier eluting sirolimus mounted on a novel Integrated delivery system (IDS), which consists of a low-compliant balloon with balloon control bands (BCBs) affixed to a 0.014" integrated wire with shapeable tip. The DIRECT I First-In-Man study (n=30) reported 0% clinically driven MACE through 30-months. DIRECT II, a prospective, randomised study designed to establish non-inferiority of the Svelte IDS compared with the Resolute Integrity™ DES, was undertaken at 18 clinical sites in Europe; 159 patients with symptomatic ischaemic heart disease due to *de novo* lesions in arteries with RVD 2.5-3.5 mm and lesion length <20 mm were enrolled. Clinical and angiographic follow-up was performed at 6-months to assess TVF and LLL as well as multiple secondary endpoints, with clinical follow-up continuing through 5-years. Stent evaluation post-procedure and at 6-months via OCT was also performed in 30 patients. All events and imaging were reviewed and adjudicated by an independent core lab and DSMB. The transradial approach was used in 67% of interventions; approximately 40% of the investigators were first-time users of the Svelte IDS. At 6-months, in-stent LL was 0.09±0.31 mm with the Svelte IDS compared to 0.13±0.27 with Resolute Integrity ($p<0.001$ for non-inferiority). Also at 6-months, OCT revealed good stent coverage (94.2±9.0%) and low stent strut malapposition (0.7±1.9%). Six-month and 1-year rates of target vessel failure (TVF) were similar (4.6% vs. 7.8%; $p=0.469$ at 6 months and 6.5% vs. 9.8%; $p=0.524$ at 12 months) in the Svelte IDS and Resolute Integrity arms, respectively. No patients in either arm experienced stent thrombosis through 1-year. A subanalysis of the top 5 enrolling sites demonstrated reduced procedural times with the Svelte IDS, with 22 minutes (n=23) and 31 minutes (n=26) reported in the Svelte IDS and Resolute Integrity arms, respectively ($p=0.039$). In addition, device times were 4 minutes in the Svelte IDS group vs. 11 minutes in the Resolute Integrity group ($p=.005$). Trends toward reduction in fluoroscopy time and contrast use with the Svelte IDS were also observed.

Conclusions: DIRECT II demonstrated at 1 year non-inferiority of the Svelte IDS to the Resolute Integrity DES with respect to LLL at 6-months and TVF at 6- and 12-month follow-up. Procedure and device times were reduced with the Svelte IDS, with trends toward reduction in fluoroscopy time and contrast use.

Proactively biocompatible plasma-activated stents

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Aims: We have developed a robust, haemocompatible plasma-activated coating to covalently bind biomolecules in their bioactive state to metallic surfaces, including stents. We then immobilised human tropoelastin, a major regulator of vascular cells *in vivo*. We aim to investigate the biocompatibility of this novel platform in established pre-clinical models of stenting.

Methods and results: Our plasma-activated coating is an integrated carbon and nitrogen-based polymer layer which has a hydrophilic contact angle of 63°, is extremely smooth (1-2 nm rms roughness) and wear resistant using a 3 week pulsed flow of 500 ml/min, 100 pulses/min. Covalent binding of tropoelastin by the plasma-activated coating was confirmed using enzyme-linked immunosorbent assay after rigorous detergent washing at 90°C. Tropoelastin functionalised stainless steel surfaces dramatically enhanced endothelial cell attachment by 86.3±10.5% ($p<0.01$) and cell proliferation by 36.3±12.2% at day 5 ($p<0.05$) and 76.9±6.4% at day 7 ($p<0.001$). In a smooth muscle cell proliferation assay, tropoelastin surfaces inhibited growth to the same degree as the rapamycin positive control and showed no significant cell growth from day 1 to day 4. Moreover, in a modified Chandler loop containing flowing whole blood, thrombus weight was reduced by 93±1.2% ($p<0.001$ vs stainless steel), while serum soluble P-selectin was also reduced by 24.5±8.7% ($p<0.01$). Our plasma-activated coating was subsequently applied to custom laser-cut 316L stainless steel stents. Scanning electron microscopy confirmed that a smooth, uninterrupted coating was successfully applied which was resistant to delamination following crimping and expansion. Stents were implanted in an established rabbit model of bilateral iliac artery stenting. Stents were crimped onto a 3.25 mm balloon catheter, advanced to the common iliac artery and expanded at 6 atmospheres to a diameter of 3.1 mm, giving a stent to artery ratio of 1.2:1. The location and patency of the stented iliac arteries and surrounding vasculature was confirmed by angiography. After 7 days, stents were explanted, fixed and embedded in methyl methacrylate resin. Haematoxylin and eosin staining showed a significant reduction in neointimal thickness (33.3±3.3%, $p<0.05$) and area (11.6±1.2%, $p<0.05$) relative to control BMS. The amount of fibrin was also significantly reduced in tropoelastin functionalised stents (27.3±2.6%, $p<0.05$). In a baboon *ex vivo* shunt model of acute thrombogenicity, the plasma-activated coating significantly reduced radiolabelled platelet adhesion by 51.1±5.8% relative to BMS, demonstrating a striking improvement in haemocompatibility in a primate. Twenty-eight-day rabbit iliac implants are underway and will employ OCT for high-resolution surface imaging of graft re-endothelialisation and IVUS to provide complimentary information on neointimal hyperplasia.

Conclusions: We have developed a novel coating technology to covalently bind bioactive proteins to metallic stents. Using this technology, immobilised human tropoelastin reduces neointimal thickness and area in a rabbit iliac model, while reducing thrombogenicity in primates. This has profound potential to improve the efficacy of all metallic vascular implants, and particularly endovascular stents.

EuroPCR Coronary interventions

Euro15A-OP076

Diabetes mellitus, glucose control parameters and platelet reactivity in ticagrelor treated patients

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Aims: Advances in percutaneous coronary revascularisation strategies and antithrombotic therapies have not filled the prognostic gap between diabetic and non-diabetic patients after an acute cardiovascular event. In fact, diabetes mellitus and poor glycaemic control represent well-established pro-thrombotic conditions that have been associated with a reduced effectiveness of antiplatelet therapies and an increased risk of high-residual platelet reactivity (HRPR) and recurrent ischaemic events. New antiplatelet agents, as ticagrelor, have provided a more potent and predictable platelet inhibition, potentially offering larger benefits in those patients with enhanced thrombotic status. However, no study has so far investigated the relationship between diabetes mellitus and platelet reactivity in patients treated with ticagrelor for a recent acute coronary syndrome (ACS).

Methods and results: Two hundred and twenty-four (224) post-ACS patients, treated with a dual antiplatelet therapy with ASA (100-160 mg) and ticagrelor (90 mg twice a day) were scheduled for platelet reactivity assessment at 30-90 days post-discharge. Diabetic status was defined as a history of diabetes treated with or without drug therapies, fasting glucose >126 g/dl or HbA1c >6.5% at the moment of admission. Aggregation was assessed by multiple-electrode aggregometry. HRPR during ticagrelor treatment was defined as ADP test results >417 AU*min. Eighty-six (86) out of 224 patients (38.4%) were diabetic. Diabetic status related to older age (p=0.05), higher BMI (p=0.009), renal failure (p=0.016), hypertension (p=0.02), treatment with diuretics (p=0.02), higher levels of WBC, glycaemia, HbA1c and lower levels of HDL-cholesterol (p<0.001, respectively). Platelet reactivity was higher in diabetics as compared to non-diabetics (p=0.046 for ASPI test, p=0.013 for COL test, p=0.04 for TRAP test and p=0.002 for ADP test). Twenty-nine patients (12.9%) displayed HRPR with ticagrelor with an almost double rate in diabetics as compared to non-diabetics (18.8% vs 9.4%, p=0.06; adjusted OR [95% CI]=2.12[1.1-4.1], p=0.025). A direct linear relationship was observed between ADP-mediated platelet reactivity and glycosylated haemoglobin, as a parameter of chronic glycaemic control, (r=0.15, p=0.029), but not with fasting glycaemia (r=0.08, p=0.20).

Conclusions: The present study shows among post-ACS patients, that diabetic status is associated with a higher platelet reactivity despite dual antiplatelet therapy with ASA and ticagrelor, and especially in those patients with poor chronic glycaemic control. In fact, diabetes emerged as independent predictor of HRPR with ticagrelor.

EuroPCR Coronary interventions

Euro15A-OP077

Effects of cigarette smoking on platelet reactivity in patients receiving $P2Y_{12}$ inhibitors after myocardial infarction and DES implantation

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Aims: To evaluate the effects of cigarette smoking on platelet reactivity in patients receiving oral $P2Y_{12}$ inhibition after myocardial infarction and DES implantation.

Methods and results: Two-hundred-five consecutive current smokers receiving DES implantation after ST-segment elevation MI were enrolled. Mean time from MI was 8±3 months. All patients were aspirin-treated and on chronic therapy with clopidogrel (N=59), prasugrel (N=71) or ticagrelor (N=75); by protocol, all patients had no high on-treatment platelet reactivity by the VerifyNow $P2Y_{12}$ assay at baseline. Platelet reactivity, expressed by $P2Y_{12}$ reaction units (PRU), was measured at baseline (T0), after a 15-day period of smoking cessation (T1) and after further 15 days of smoking resumption (T2). In the overall population there was a significant reduction of PRU values from T0 to T1 (from 173±14 to 165±17, p<0.0001); resumption of cigarette smoking was associated with a re-increase of platelet reactivity (from 165±17 at T1 to 170±17 at T2, p=0.0001). These variations were consistent in the subgroups receiving clopidogrel, prasugrel or ticagrelor and were irrespective of the number of cigarettes smoked.

Conclusions: Cigarette smoking reduces antiplatelet effects of oral $P2Y_{12}$ inhibitors and this was irrespective of the type of antiplatelet agent. These results should be kept in mind in the clinical management of patients with DES implantation. (NCT02026713)

Body mass index has no impact on platelet inhibition induced by ticagrelor after ACS, conversely to prasugrel

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Aims: In recent years, obesity has become a major public health problem and coronary artery disease is the primary cause of death in obese patients. Studies investigating platelet reactivity in patients treated with thienopyridines identified obesity as an important modulator of response to both clopidogrel and prasugrel, suggesting that antiplatelet therapy in this growing subgroup of patients should be optimised. We evaluated the impact of BMI on platelet inhibition induced by ticagrelor, in comparison with prasugrel, after an ACS.

Methods and results: All consecutive patients admitted for ACS with successful stent implantation in our institution were eligible. Patients were randomised and received a loading dose of ticagrelor 180 mg or prasugrel 60 mg and were treated at discharge with ticagrelor 90 mg twice a day or prasugrel 10 mg once. Antiplatelet response was assessed one month after ACS with platelet reactivity index VASP (PRI VASP). Patients were classified as obese depending on body mass index (BMI) (BMI ≥30 kg/m^2). Overweight was defined by 25≤BMI<30 kg/m^2. High on treatment platelet reactivity (HTPR) was defined as PRI VASP>50%, very low on treatment platelet reactivity (VLTPR) as PRI VASP≤10%. The Bleeding Academic Research Consensus (BARC) definitions of bleeding were used. Primary endpoints of the present study were defined as correlation of degree of platelet inhibition and BMI in patients treated with ticagrelor and prasugrel, one month after an ACS. Secondary endpoint consisted in the comparison between prasugrel and ticagrelor in obese patients. Between March and December 2013; 186 patients were included, 93 patients assigned to ticagrelor and 93 to prasugrel. No significant difference on basal characteristics was observed between the two cohorts. Mean BMI was 26.5±4.2 kg/m. Twenty-seven patients (15%) were defined as obese and 77 (41%) as overweight. All these patients received aspirin 75 mg in association to $P2Y_{12}$ inhibitor. We observed 13% of bleeding complications (n=24 patients). A majority of BARC1 bleedings were reported (83%). At one month, PRI VASP was 18.7±11.5% on ticagrelor versus 34.0±15.3% on prasugrel (p<0.0001). Interestingly, only one patient was defined as HTPR (BMI=24.6 kg/m), 27 (29%) were classified as VLTPR on ticagrelor. On prasugrel we observed 13 HTPR patients (BMI=28.9 kg/m), four (4%) were classified as VLTPR. No significant correlation between BMI and platelet inhibition was observed (r=0.04; p=0.72) on ticagrelor unlike prasugrel (r=0.32; p<0.01). On ticagrelor, no difference is observed on PR between obese and non-obese patients (p=0.20) and between overweight and non-overweight patients (p=0.49). Inversely on prasugrel we reported significantly higher levels of PRI VASP in overweight patients (p<0.001 compared with others) and obese patients (p<0.01 compared with others). PRI VASP comparison in obese patients reported significantly lower levels in ticagrelor treated patients (20.9±2.8% vs. 45.9±3.6%; p<0.001).

Conclusions: The present study suggests that platelet inhibition induced by ticagrelor is not correlated with BMI, unlike prasugrel. Ticagrelor induces higher platelet inhibition than prasugrel in obese patients. This highlights the potential value of ticagrelor in obese patients and suggests benefits of tailored therapy based on BMI in these high-risk patients.

Morphine is associated with delayed platelet inhibition in patients with STEMI undergoing primary PCI with prasugrel and bivalirudin

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Aims: Opiate use in the acute treatment of ST-elevation myocardial infarction (STEMI) has been observed to delay the effect of oral adenosine diphosphate (ADP) receptor platelet inhibitors. Previous small cohort studies have focused specifically on ADP receptor function. Multiplate platelet function testing offers a broader assessment of platelet function, including arachidonic acid pathway (ASPI), thrombin receptor (TRAP) and ADP receptor (ADP) activity, providing a greater understanding of the relationship between opiate use and platelet reactivity.

Methods and results: One hundred and six patients presenting with STEMI, treated with preloading of prasugrel and procedural bivalirudin underwent Multiplate platelet function testing at baseline, immediately post-procedure and 1, 2 and 24 hours post-procedure. Of these, 36/106 (34.0%) patients received morphine alone, 44/106 (41.5%) received morphine plus anti-emetics and 26/106 (24.5%) patients received no morphine. The effect of morphine on platelet activity as measured by ADP response significantly differed across the five time points (morphine group by time interaction p<0.001). The strongest effect was observed at the end of primary PCI (p<0.001); patients who received morphine before the procedure had significantly higher levels of ADP (median 901 AU*min, interquartile range [IQR] 668, 1,108) compared to those who received morphine plus anti-emetics (median 759 AU*min, IQR 611, 894) or those who did not receive morphine (median 435 AU*min, IQR 193, 721). High residual platelet reactivity (HRPR) has previously been defined as ADP response >468 AU*min indicating incomplete platelet $P2Y_{12}$ blockade. A significant morphine effect was also observed at 1 and 2 hours post-primary PCI (p=0.035 and p=0.007, respectively); importantly no morphine effect was observed at baseline or 24 hours post-primary PCI (p=0.56 and p=0.16, respectively). No significant effect was seen when investigating the effect of morphine on TRAP or ASPI. Four patients (3.8%) developed acute stent thrombosis within two hours of completion of the procedure, all demonstrating HRPR. All four patients had preprocedural morphine.

Conclusions: Upstream opiate administration does not appear to affect baseline ADP function in oral ADP receptor inhibitor-naïve patients. However, opiate use significantly influences ADP platelet function following administration of prasugrel, with a delayed inhibition observed in the early phase. Use of anti-emetics appears to partially negate this effect. Interestingly, aspirin pre-treatment is not influenced by opiate administration, and this is likely to reflect the early administration (upstream or in parallel with opiate) and rapid bioavailability of the drug. Use of intravenous ADP inhibitors, such as cangrelor, may negate the observed opiate effect and merit testing in the acute STEMI setting.

EuroPCR Coronary interventions

Euro15A-OP080

Efficacy of platelet inhibition with prasugrel in patients with acute myocardial infarction undergoing therapeutic hypothermia after cardiopulmonary resuscitation

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Aims: Acute ST-elevation myocardial infarction (STEMI) is the leading cause for out-of-hospital cardiac arrest. Therapeutic hypothermia improves neurological outcome in combination with early revascularisation, but reduces clopidogrel responsiveness. The more potent thienopyridine, prasugrel has not yet been sufficiently evaluated during therapeutic hypothermia.

Methods and results: We investigated 23 consecutive STEMI patients (61±11 years) following out-of-hospital resuscitation undergoing revascularisation and therapeutic hypothermia. Prasugrel efficacy was assessed by the platelet-reactivity-index (PRI) before and 2, 4, 6, 12, 24, 48, and 72 hours following a loading dose of 60 mg via a gastric tube. As reference, prasugrel efficacy was assessed in 10 consecutive stable AMI patients (56±13 years). Prasugrel significantly reduced PRI despite hypothermia (p=0.0002). Mean PRI (±SD) was 70±12% before (vs. control) and 60±16% (2 h, ns), 52±21% (4 h, p<0.05), 42±26% (6 h, p<0.01), 37±21% (12 h, p<0.01), 27±23% (24 h, p<0.01), 18±14% (48 h, p<0.01), and 13±10% (72 h, p<0.01) after loading. Sufficient platelet inhibition occurred later compared to stable AMI patients, however, high on-treatment platelet reactivity significantly decreased over time and was non-existent after 72 hours (PRI>50%: 2 h: 72%, 4 h: 52%, 6 h: 43%, 12 h: 29%, 24 h: 17%, 48 h: 5%, 72 h: 0%). There was no relation between 30 d mortality rate (31%) and PRI values.

Conclusions: Prasugrel significantly reduced platelet reactivity even during vasopressor use, analgosedation and therapeutic hypothermia. Despite a significant delay compared to stable STEMI patients, sufficient platelet inhibition was reached in 83% of patients within 24 hours. Therefore, prasugrel administration via gastric tube might be a useful therapeutic strategy in these patients at high risk, providing potent and effective $P2Y_{12}$ inhibition.

EuroPCR Coronary interventions

Euro15A-OP081

Clopidogrel loading before or after the start of PCI: impact on periprocedural outcomes in the CHAMPION PHOENIX trial

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Aims: The CHAMPION PHOENIX trial was a double-blind randomised trial comparing cangrelor to control in the prevention of periprocedural complications. The trial enrolled 11,145 patients who had not had $P2Y_{12}$ inhibition, and demonstrated a reduction in the primary composite outcome of death, myocardial infarction, ischaemia-driven revascularisation, or stent thrombosis at 48 hours after randomisation (adjusted odds ratio with cangrelor, 0.78; 95% confidence interval, 0.66 to 0.93; p=0.005). A loading dose of clopidogrel (or dummy) was to be given as soon as possible after the decision to proceed with PCI, at the investigator's discretion. Therefore, it could have occurred before the start of PCI, defined by guidewire insertion (early load), or after the start of PCI (late load). We examined whether early load or late load impacted the rate of periprocedural complications and the effects of cangrelor.

Methods and results: There were 6,902 early load and 3,979 late load patients. The median time was –5 and 20 minutes from PCI, respectively. Early load was more frequently used among STEMI patients (83.8%) and NSTE-ACS (72.1%) than in stable patients (54.0%). Within the clopidogrel arm (n=5438), 3,442 patients had early load and 1,996 late load. Rates of the primary outcome were similar (6.0 vs. 5.4% for early load vs. late load, respectively, p=0.41) as were rates for stent thrombosis (1.5 vs. 1.0%, p=0.11). Results were similar after adjusting for potential confounders, including clinical presentation. Compared with clopidogrel, cangrelor consistently reduced the primary outcome in both early load and late load (4.8 vs. 6.0%, odds ratio (OR): 0.80, 95% confidence interval (95% CI): 0.64-0.98 for early load and 4.3 vs. 5.4%, OR: 0.79 and 95% CI: 0.59-1.06 for late load, interaction p=0.99). Likewise, the reduction in stent thrombosis was consistent for early load (1.0 vs. 1.5%,OR: 0.63 and 95% CI: 0.40-0.97) and late load (0.7 vs. 1.0%, OR 0.65 and 95% CI: 0.32-1.32) (interaction p=0.93). GUSTO severe/moderate bleeding rates were similar between treatment arms for both early load (OR: 1.2) and in late load (OR: 2.5) (interaction p-value=0.25).

Conclusions: The timing of clopidogrel loading did not appear to affect the rate of periprocedural PCI complications (in a non-randomised comparison). The benefits of cangrelor in reducing PCI complications compared to clopidogrel alone were consistent regardless of the timing of clopidogrel administration.

Coronary interventions

Euro15A-OP082

Time related effect of antiplatelet therapy and time related advantage of the new antiplatelet drugs

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Aims: The major goal in the treatment of ST-segment elevation myocardial infarction (STEMI) is early reperfusion. $P2Y_{12}$ inhibitors demonstrated to improve angiographic results of primary PCI and patients' clinical prognosis. The new antiplatelet drugs prasugrel and ticagrelor showed better clinical outcomes over clopidogrel, but to date comparison data are missing. The aim of our observational study was to establish if the benefit of the $P2Y_{12}$ inhibitors loading dose administration is time related and to find out any difference between antiplatelet drugs.

Methods and results: A total of 119 consecutive patients with STEMI (83% males, 63.6±12.8 years old, 32% diabetics) addressed to primary PCI were enrolled. Exclusion criteria was cardiogenic shock at presentation. We detected a mean "first medical contact to balloon" time of 111.8±88 minutes; the great variability is due to the inclusion of both patients presenting directly at our HUB Hospital Emergency Room and patients transferred to our centre from elsewhere. We divided our population into three groups depending of the time interval from "$P2Y_{12}$ inhibitors loading dose administration to balloon": the first group included patients receiving $P2Y_{12}$ inhibitors loading dose at least 60 minutes before primary PCI, the second group between 30 and 60 minutes before primary PCI, the third group less than 30 minutes to primary PCI. Angiographic, clinical and biochemical parameters were evaluated. Post-primary PCI TIMI flow grade was significantly different in the three groups ($p<0.001$); it improved throughout the groups proportionally to the increasing "$P2Y_{12}$ inhibitors loading dose administration to balloon" time. We found the following rates of post-PCI TIMI flow grade 3: 93.5% in the first group, 91.4% in the second group, 86.2% in the third group. When we compared patients treated with prasugrel versus ticagrelor, no significant difference between groups in terms of post-primary PCI TIMI flow grade was detected. Conversely we found that post-primary PCI TIMI flow grade 3 rates were higher in new antiplatelet drugs groups than in clopidogrel group, nevertheless this difference was statistically significant (90% versus 55%, $p=0.023$) only in the third group, so when the $P2Y_{12}$ inhibitors loading dose was administrated immediately before or at the time of angiography.

Conclusions: Current guidelines recommend rapid initiation of antiplatelet therapy; our findings support a time-related benefit of $P2Y_{12}$ inhibitors administration: a longer time window between $P2Y_{12}$ inhibitors administration and primary PCI significantly improves coronary reperfusion in terms of post-primary PCI TIMI flow grade; known to be related to mid- to long-term prognosis. Moreover, we found no difference between the two new antiplatelet drugs. Conversely, new antiplatelet drugs showed better angiographic outcomes than clopidogrel; this benefit is evident when drug administration is periprocedural, while it seems to vanish when the antiplatelet drugs are administrated more than 30 minutes before the procedure.

Coronary interventions

Euro15A-OP083

Is platelet inhibition correlated with time from last $P2Y_{12}$ blockers intake after an acute coronary syndrome? A pilot study

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Aims: Delay from the last intake of drug could be an important and unexplored variable in the biological response to antiplatelet agent after an ACS. The objective of this study is to define the impact of delay from $P2Y_{12}$ blocker intake and variation in platelet inhibition level. We aim to compare ticagrelor, prasugrel and clopidogrel treated patients.

Methods and results: All consecutive patients who had been addressed between 2013 and 2015 to our centre for ACS involving PCI and stent implantation, treated with combination of aspirin and $P2Y_{12}$ blocker were eligible for this study. One month after discharge patients had fasting blood sample. Before the blood sample, a nurse blinded to the protocol proposed a questionnaire to the patient. On this questionnaire three questions about the name of the drug, the regularity of the intakes and the hour of the last intake were collected. The response to antiplatelet therapy was assessed using the platelet reactivity index vasodilator-stimulated phosphoprotein (PRI VASP) and % of ADP induced aggregation (%ADP). The primary objective of this study was to evaluate the correlation between platelet inhibition and delay from drug intake. We compared correlations on clopidogrel, prasugrel and ticagrelor. Between January 2013 and 2015 we enrolled 476 patients discharged from our centre on dual antiplatelet therapy including 152 STEMI (32%), 324 NSTEMI (68%). All were on a dual antiplatelet therapy with aspirin in association with clopidogrel 75 mg in 184 cases (39% patients), prasugrel in 193 cases (41%) or ticagrelor in 99 patients (21%). We observed a significant correlation between delay from intake and PRI VASP and %ADP for ticagrelor only (PRI VASP: $r=0.26$; $p=0.01$; %ADP: $r=0.22$; $p=0.03$). On clopidogrel (PRI VASP: $r=0.08$; $p=0.27$; %ADP: $r=0.01$; $p=0.85$) and prasugrel (PRI VASP: $r=0.02$; $p=0.83$; %ADP: $r=0.11$; $p=0.13$) no correlation exists between the hour of last intake and platelet inhibition.

Conclusions: In conclusion we observed that ticagrelor, unlike thienopyridines, is associated with a significant correlation between delay from the last intake and platelet inhibition. These results highlight the importance of standardisation concerning delays in studies exploring platelet inhibition induced by ticagrelor to afford extrapolation. Education about drug observance and regularity of intakes is crucial during management of stented ACS patients, moreover when ticagrelor is prescribed.

EuroPCR Coronary interventions

Euro15A-OP084

Prehospital administration of $P2Y_{12}$ inhibitors and early coronary reperfusion in primary PCI: a comparative study

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Aims: The newer oral $P2Y_{12}$ inhibitors prasugrel and ticagrelor have been reported to be more potent and faster-acting antiplatelet agents than clopidogrel. This study aimed to investigate whether prehospital administration of prasugrel or ticagrelor improves early coronary reperfusion as compared to prehospital loading with clopidogrel in a real-world STEMI setting.

Methods and results: Over a 70-month period, 3,497 patients with on-going STEMI <6 hours and without cardiac arrest or cardiogenic shock underwent primary percutaneous coronary intervention (PCI) at our centre. The primary endpoint of this study was the proportion of patients who did not meet the criteria for TIMI (Thrombolysis In Myocardial Infarction) flow grade 3 in the infarct-related artery at initial angiography before PCI. Prehospital administration of prasugrel (n=883) or ticagrelor (n=491) did not result in a higher rate of early coronary reperfusion as compared to prehospital loading with clopidogrel (n=1,532) – a TIMI flow grade 3 at initial angiography was absent in, respectively, 71.7%, 69.0% and 71.5% (p>0.05). At 30-days follow-up, rates of all-cause death, myocardial infarction and urgent revascularisation were low and no difference was evident between the different $P2Y_{12}$ inhibitors; nor was there statistical difference for definite stent thrombosis at 24 hours and 30 days and the safety endpoint major bleeding at 30 days.

Conclusions: Prehospital loading with the newer and faster-acting oral $P2Y_{12}$ inhibitors does not result in a higher rate of early coronary reperfusion as compared to prehospital loading with clopidogrel in STEMI patients.

EuroPCR Coronary interventions

Euro15A-OP085

A subgroup analysis of the CHAMPION PHOENIX trial assessing the effect of cangrelor to prevent PCI periprocedural complications in stable and ACS patients

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Aims: The CHAMPION PHOENIX trial was a double-blind randomised trial comparing cangrelor with placebo in the prevention of periprocedural complications. It enrolled 11,145 patients and demonstrated a reduction with cangrelor in the primary composite outcome of death, myocardial infarction, ischaemia-driven revascularisation, or stent thrombosis at 48 hours after randomisation with an adjusted odds ratio [OR], of 0.78 (95% confidence interval [CI]: 0.66 to 0.93; p=0.005). Cangrelor also reduced the key secondary endpoint of stent thrombosis (OR 0.62; 95% CI: 0.43 to 0.90; p=0.01), without a significant increase in GUSTO severe/moderate bleeding. We examined whether the effects of cangrelor were consistent across patients with or without ACS (patients who presented with acute coronary syndrome, with or without ST-segment elevation).

Methods and results: Patients were categorised by the site as stable angina (n=6,358) or ACS (n=4,584) at the time of randomisation. Cangrelor reduced the primary outcome in both stable angina and ACS consistently (OR 0.83; 95% CI: 0.67 to 1.01 for stable angina and OR 0.71; 95% CI: 0.52 to 0.96 for ACS, interaction p=0.41). Likewise, the reduction in stent thrombosis was consistent for stable angina (odds ratio, 0.55; 95% CI: 0.30 to 1.01) and ACS (OR 0.67; 95% CI: 0.42 to 1.06), interaction p=0.62. Similar results were observed in consistency analyses performed in which ACS patients were defined using final diagnosis rather than diagnosis at the time of randomisation. The rates of GUSTO severe/moderate bleeding were similar between treatment arms in both stable angina (odds ratio 1.49 95% CI: 0.67 to 3.33) and in ACS (OR 1.79, 95% CI: 0.79 to 4.07), interaction p=0.754.

Conclusions: The benefits of cangrelor in reducing PCI periprocedural complications are consistent for stable angina and ACS patients.

Randomised evaluation of intra-lesion vs. intra-coronary abciximab and aspiration thrombectomy in patients with STEMI: the COCKTAIL II trial

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Aims: We sought to compare the efficacy of pharmacological and catheter-based strategies for thrombus in patients with acute ST-elevation myocardial infarction (STEMI) and high thrombus burden.

Methods and results: One-hundred-twenty-eight STEMI patients undergoing primary percutaneous coronary intervention (PCI) at 5 centres were randomly assigned in a 2×2 factorial design to intracoronary abciximab bolus (via the guide catheter) vs. intra-lesion abciximab bolus, each with vs. without aspiration thrombectomy. Study endpoints were residual intra-stent thrombus burden, defined as the number of cross sections with residual thrombus area >10% as assessed by optical coherence tomography (OCT), and indices of angiographic and myocardial reperfusion. Residual intra-stent thrombus burden did not significantly differ with intra-lesion vs. intracoronary abciximab (median [interquartile range] 6.0 [1-15] vs. 6.0 [2-11], p=0.806) and with aspiration thrombectomy vs. no aspiration (6.0 [1-13] vs. 6.0 [2-12], p=0.775). Intra-lesion abciximab administration was associated with improved angiographic myocardial reperfusion in terms of TIMI flow (3 [3-3] vs. 3 [2-3], p=0.040), corrected TIMI Frame Count (12±5 vs. 17±16, p=0.021) and myocardial blush grade (3 [2-3] vs. 3 [2-3], p=0.035). Aspiration thrombectomy had no significant effect on indices of angiographic or myocardial reperfusion.

Conclusions: In patients with STEMI and high thrombotic burden, neither intra-lesion vs. intracoronary abciximab nor aspiration thrombectomy versus no aspiration reduced post-procedure intra-stent thrombus burden in patients with STEMI undergoing primary PCI. However, intra-lesion abciximab improved indices of angiographic and myocardial reperfusion compared to intracoronary abciximab, benefits not apparent with aspiration thrombectomy.

Post-procedural bivalirudin infusion duration and acute stent thrombosis rates from a large United Kingdom primary angioplasty programme: how long is long enough?

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Aims: Recent trials of bivalirudin treatment during PCI have yielded conflicting data with respect to the rates of early stent thrombosis (ST). Prolonging post-PCI infusions may abrogate this signal but at an increased cost. We hypothesised that continuing the bivalirudin infusion commenced during the procedure at the PCI recommended dose until infusion end would be sufficient to prevent excess early stent thrombosis.

Methods and results: Baseline demographics, procedural data and outcomes were gathered prospectively on all patients undergoing primary PCI at a large UK PCI centre. Data was retrieved from analysis of internal hospital and external national databases. The definition of ST was ARC definite stent thrombosis. Pharmacology choice was as the discretion of the responsible physician's discretion. Local protocol recommended continuation of the procedural bivalirudin at the PCI dose until infusion end. To calculate post-PCI duration the weight and procedural duration were recorded for each individual patient. Between 2012 and 2014, 1,395 patients underwent primary PCI at our institution. Mean age of the patients was 62.8±13.1 years with 11.4% presenting with shock. Patients were preloaded with clopidogrel (12.9%), prasugrel (86.4%) or ticagrelor (0.9%) at a median time of 25±12 minutes prior to balloon time. During the procedure, aspiration (60.7%) and drug-eluting stents (63.8%) were frequently used. Mean door-to-balloon time was 40±22 minutes and mean call-to-balloon time was 123±78 minutes. The majority of patients underwent PCI using bivalirudin with fewer using heparin (87.7 vs. 12.3%, p<0.0001). Glycoprotein inhibitor bailout rates were 6.1% with bivalirudin and 36.3% with heparin (p<0.0001). The mean weight of the patients was 81.7 kg and the mean procedure duration was 44±21 minutes. Calculated on an individual patient basis the mean post-procedure duration of the bivalirudin infusion was 49±12 minutes. An extra procedural vial of bivalirudin was required in 3.9% of cases. The acute (<24-hours) ST rates were 4/1224 with bivalirudin±GPI (0.3%) and 0/171 with heparin±GPI (0%, p=0.41). The subacute (24-hours to 30-days) ST rates were 3/1224 for bivalirudin±GPI (0.3%) and 2/171 with heparin±GPI (1.2%, p=0.11). In total the early (<30-days) ST rates were 7/1224 for bivalirudin±GPI (0.6%) and 2/171 with heparin±GPI (1.2%, p=0.31).

Conclusions: In a large primary PCI programme continuing the bivalirudin infusion commenced during the procedure at the PCI recommended dose until infusion end appears to be sufficient to completely abrogate excess early stent thrombosis. Whether bivalirudin infusion prolongation maintains the previously observed bleeding reduction when compared to glycoprotein inhibitors is the subject ongoing study.

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Euro15A-OP088

Clinical outcomes between eptifibatide and abciximab remain similar during primary percutaneous coronary intervention for ST-elevation myocardial infarction

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Aims: Glycoprotein IIb/IIIa inhibitors are recommended for patients with ST- segment elevation myocardial infarction (STEMI) undergoing primary percutaneous coronary intervention (PCI). Few large-scale studies directly compare these agents. The aim of this study was to evaluate the clinical effectiveness of the use of eptifibatide compared with abciximab in STEMI patients treated with primary PCI.
Methods and results: We retrospectively evaluated the outcomes of 2,463 patients with STEMI undergoing primary PCI from 2006 to 2013. Patients who did not receive a GPIIb/IIIa inhibitor were excluded. The primary endpoint was the first major adverse cardiac event (MACE) defined as death, non-fatal myocardial infarction, stroke or target vessel revascularisation. Other outcomes recorded include net adverse clinical events (major and minor bleeding). Unadjusted Kaplan-Meier analysis revealed no significant difference in the 1-year event rates between patients given eptifibatide (n=1,522) versus abciximab (n=941; p=0.201). Similarly, no significant difference was observed in 1 year outcomes between abciximab and eptifibatide using the age-adjusted Cox analysis (HR 0.83 [95% CI: 0.73-1.39]), and the multivariate adjustment (HR 0.92 [95% CI: 0.79-1.56]). Patients who received eptifibatide had higher rates of previous PCI and hypercholesterolemia and were more likely to undergo a procedure from the radial route. However, after regression adjustment incorporating a propensity score (age, gender, ethnicity, previous MI, PCI or coronary artery bypass grafting (CABG), diabetes, hypertension, hypercholesterolemia, smoking status, presence or absence of shock, and ejection fraction) into the hazards model as a covariate, no difference in outcome emerged (HR 0.88 [95% CI: 0.71-1.44]). Similar rates of adverse bleeding events were noted between the two groups.
Conclusions: In conclusion, similar outcomes are observed between abciximab and eptifibatide in patients with STEMI undergoing primary PCI. This supports the current use of eptifibatide as an adjunctive antiplatelet agent in majority of patients undergoing primary PCI.

EuroPCR Coronary interventions

Euro15A-OP089

Meta-analysis of safety and efficacy of bivalirudin vs heparin with or without routine GPIIb/IIIa inhibitor in patients with acute coronary syndrome

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Aims: Bivalirudin has been a mainstay of anticoagulation in patients with acute coronary syndrome (ACS) as compared to heparin. The extent to which trial results have been affected by the co-administration of heparin with a GPIIb/IIIa inhibitor (GPI), however, remains unclear. The aim of this meta-analysis was to compare the 30-day safety and efficacy of bivalirudin against heparin with or without routine GPI in patients with ACS.
Methods and results: A total of 13 randomised controlled trials involving 24,605 patients were included. There was no significant difference in 30-day mortality or myocardial infarction rate with bivalirudin vs. heparin with or without routine GPI. A reduction of 30-day major bleeding was observed with bivalirudin vs. heparin, that was significant when heparin was administered with routine (OR 0.52 [95% CI: 0.45-0.60], p<0.001) but not with provisional GPI (OR 0.66 [CI: 0.33-1.32]; p=0.24). The occurrence of stent thrombosis (ST) at 30 days was significantly increased with bivalirudin vs. heparin plus routine GPI (OR 1.67 [CI: 1.13-2.45], p=0.02), but not vs. heparin plus provisional GPI (OR 2.08 [CI: 0.35-12.32], p=0.42). Acute ST (≤24 hours), however, was almost 4.5-fold higher with bivalirudin vs. heparin with or without GPI, whereas the rate of subacute ST (24 hours to 30 days) did not differ significantly.
Conclusions: Overall, bivalirudin in ACS patients is associated with a significant reduction of major bleeding compared to heparin plus routine GPI, but with a marked increase of ST rates compared to heparin with or without GPI.

Intracoronary bolus-only versus intracoronary-bolus plus infusion administration of glycoprotein IIb/IIIa inhibitors in patients with ST-elevation myocardial infarction undergoing primary PCI: one-year clinical outcome

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Aims: The aim of the present study is to compare intracoronary (IC) bolus-only with IC- bolus plus maintenance intravenous (IV) infusion of GP IIb/IIIa inhibitors with respect to the one-year major adverse cardiac events (MACE) including mortality, target vessel or target lesion revascularisation, coronary bypass graft surgery and non-fatal myocardial infarction after primary percutaneous coronary intervention (PCI).

Methods and results: This is an observational cohort of 233 consecutive patients who presented with ST-segment elevation myocardial infarction (STEMI) and underwent primary PCI between April 2009 and December 2012. Patients were grouped into: (1) patients who received IC bolus-only of GP IIb/IIIa (n=102), (2) patients who received IC bolus plus maintenance IV infusion (n=131). In-hospital post-procedural MI occurred in 4 (1.7) patients. Mortality occurred in one patient who was treated with IV GP IIb/IIIa. Major bleeding occurred in only 5 patients, among whom 4 patients had received GP IIb/IIIa IV infusion. However, the difference was not statistically significant (p-value=0.389). Both univariate analysis and the adjusted model for the potential confounders (all variables with a univariate p-value≤0.2), revealed no significant association between the way of GP IIb/IIIa administration (IC-only vs. IC+IV infusion) and one-year MACE.

Conclusions: Our findings suggest that IV infusion of GP IIb/IIIa inhibitors after the bolus dose is not associated with better one-year outcome after adjustment for confounding variables. Moreover, IV infusions may increase the risk of major bleedings after primary PCI. This finding implies that the necessity of IV infusion of GP IIb/IIIa in patients undergoing primary PCI is under question. Further randomised studies are necessary to clarify the role of GP IIb/IIIa IV infusions on in-hospital events and long-term outcome.

Coronary computer tomography for systematic screening of coronary stent fractures in patients at high risk

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Aims: This study prospectively evaluated the incidence of stent fractures in high-risk patients using coronary computer tomography (CCT) and assessed the clinical relevance of this finding using catheter coronary angiography (CCA).

Methods and results: Patients with two or more risk factors for a stent fracture defined as (1) stent length ≥28 mm, (2) overlapping stents, (3) stent localisation in the right coronary artery or saphenous vein graft and (4) vessel angulation ≥75° before implantation or stent angulation ≥45° after implantation were invited to undergo a CCT 6 months after the procedure. To differentiate between stent fracture and overlap failure all stents were identified on the CCT image by measuring the distance between edges and comparing these measurements with the known stent lengths. A coronary angiography including optical coherence tomography (OCT) was recommended in patients with a partial or total stent gap. Patients without stent gaps but with pathological findings in the CCT who underwent coronary angiography served as controls. In 27 out of 102 patients (27%), coronary computer tomography revealed a stent gap including 17 patients with a stent fracture (17%) and 10 patients with an overlap failure (10%). In the following coronary angiography, all stent gaps were confirmed by optical coherence tomography. A clinically relevant stent-related pathology could be detected in 8 out of 27 patients (30%) with stent gaps (in-stent restenosis in four patients, chronic total occlusion in two patients, coronary aneurysm and thrombus in one patient, respectively) including 6 out of 17 patients (35%) with a stent fracture and 2 out of 10 patients (20%) with an overlap failure. Compared to the 8 out of 27 patients with stent gaps (30%) and a clinically relevant pathology, only 2 out of 26 controls (8%) had a clinically relevant pathology (chi-square p=0.041). Compared to the 6 out of 17 stent fracture patients (35%) with a clinically relevant pathology, only 2 out of 26 controls (8%) had a clinically relevant pathology (chi-square p=0.023).

Conclusions: Stent gaps are frequent in high-risk patients. The majority of these gaps result from a stent fracture, which is often associated with a clinically relevant pathology. Therefore, screening for stent fractures using coronary computer tomography in high-risk patients might be beneficial.

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Incidence and clinical impact of longitudinal stent deformation after the PROMUS Element platinum chromium-everolimus eluting stent implantation

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Aims: The PROMUS Element platinum-chromium everolimus-eluting stent (PtCr-EES) has a novel metal and stent design intended to improve deliverability, comformability and radial strength, whereas such features might have the trade-off of reducing longitudinal stent strength, which would account for the occurrence of longitudinal stent deformation (LSD) as reported previously. However, the incidence and clinical impact of LSD after PtCr-EES implantation in clinical practice have not been fully evaluated.
Methods and results: A total of 803 patients with 1,050 lesions undergoing PtCr-EES implantation between March 2012 and August 2013 were analysed. LSD was defined as the distortion or shortening and elongation of a stent in the longitudinal axis following successful stent deployment. We assessed the incidence of longitudinal stent deformation and cumulative incidence of major adverse cardiac events (MACE), defined as a composite of cardiac death, non-fatal myocardial infarction, definite stent thrombosis, and clinically driven target lesion revascularisation within 1-year. Of 803 patients with 1,050 lesions, we performed an intravascular ultrasound (IVUS) and post-dilatation in 752 patients (93.6%) with 992 lesions (94.5%) and in 408 patients (50.8%) with 538 lesions (51.2%). In the LSD group, IVUS and post-dilatation were performed in all patients. LSD was observed in 12 patients (1.5%) with 12 lesions (1.1%). The mechanism of LSD was due to the following reasons: compression by post-dilatation balloons (n=1, 8.3%), entrapped IVUS (n=8, 66.7%) and pull backed jailed guidewire (n=3, 25%). At 1-year, the cumulative incidence of MACE, cardiac death, myocardial infarction, stent thrombosis and clinically driven target lesion revascularisation were not significantly different between the LSD and non-LSD groups (9.1% vs. 2.8%, p=0.19; 0% vs. 0%, p=1.00; 0% vs. 0.1%, p=0.92; 0% vs. 0.14%, p=0.88; 9.1% vs. 2.8%, p=0.19, respectively).
Conclusions: LSD after PtCr-EES implantation occurs in 1.1% of lesions. However, LSD is not associated with MACE within 1-year.

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Thienopyridine therapy beyond one year after sirolimus-eluting stent implantation: impact of stent fracture and peri-stent contrast staining

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Aims: The efficacy of thienopyridine therapy beyond one year after sirolimus-eluting stent (SES) implantation is controversial.
Methods and results: We identified consecutive 1,962 patients who had undergone their first SES implantation between November 2002 and October 2007 and the subsequent follow-up angiography within 1 year. The data of discontinuation of thienopyridine therapy at 1 year after the index procedure were collected retrospectively and the relation between discontinuation of thienopyridine therapy and clinical outcomes including cardiac death, myocardial infarction, composite incidence of cardiac death and myocardial infarction and definite very late stent thrombosis (VLST) with a landmark analysis at 1 year after SES implantation were examined. Of the 1,962 patients, 558 (28.4%) discontinued thienopyridine therapy before the 1-year landmark point. Complete follow-up data were available in 98.7% and 96.7% at 5 years and 6 years after SES implantations. During the 6-year follow-up period, the definite VLST developed in 16 patients (0.82% [0.16%/year]) and the incidence of definite VLST in patients discontinued thienopyridine therapy within 1 year was significantly higher than that in patients continuing thienopyridine therapy (1.8% vs. 0.56%; HR [95% CI]: 3.28 [1.22 to 8.80], p=0.018). On the other hand, the rates of cardiac death and myocardial infarction in patients discontinued thienopyridine therapy within 1 year were comparable to those in continuing thienopyridine therapy beyond 1 year (5.7% vs. 4.6%, p=0.37 and 2.7% vs. 2.1%, p=0.50, respectively). The rate of composite incidence of cardiac death and myocardial infarction also did not differ significantly whether they discontinued or continued thienopyridine (8.1% vs. 6.1%, p=0.13). Moreover, stent fracture (SF) and peri-stent contrast staining (PSS) were evaluated by the follow-up angiography within 1 year and the impact of thienopyridine therapy beyond 1 year on clinical events were assessed in patients with SF or PSS, or both (SF/PSS group: N=256) and those with neither SF nor PSS (Non-SF/PSS group: N=1706). Of 16 patients with VLST, 10 patients belonged to SF/PSS group and 6 belonged to non-SF/PSS group. The incidence of VLST differed significantly in SF/PSS group whether they discontinued or continued thienopyridine (10.1% vs. 1.9%; HR [95% CI]: 6.01 [1.56 to 23.27], p=0.009). Furthermore, the rates of myocardial infarction and the composite incidence of cardiac death and myocardial infarction in patients discontinued thienopyridine therapy within 1 year were higher than those in patients continuing thienopyridine therapy (9.3% vs. 2.8%, p=0.04 and 13.3% vs. 5.5%, p=0.06, respectively), whereas the rate of cardiac death was similar between groups (4.0% vs. 3.3%, p=0.72). In contrast, no significant difference of incidence of VLST was observed in non-SF/PSS group between the groups (0.45% vs. 0.36%; HR [95% CI]: 1.28 [0.23 to 6.96], p=0.78) and the rates of cardiac death, myocardial infarction and composite incidence of cardiac death and myocardial infarction were similar between groups (6.0% vs. 4.8%, p=0.38; 1.7% vs. 2.0%, p=0.82; 7.2% vs. 6.1%, p=0.46, respectively).
Conclusions: The discontinuation of thienopyridine therapy within 1 year is reasonable strategy in patients with neither SF nor PSS. However, the continuation of thienopyridine therapy beyond 1 year could be acceptable strategy to prevent the development of VLST and myocardial infarction in patients with SF or PSS after SES implantation.

Impact of angiographically visible stent malapposition (peri-stent contrast staining [PSS]) on 5-year clinical and angiographic outcome in consecutive 807 patients with drug-eluting stents

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Aims: While peri-stent contrast staining (PSS) is thought to represent angiographically-visible incomplete stent apposition, previous IVUS/OCT studies revealed that incomplete stent apposition plays a role in thrombus formation following drug-eluting stent implantation. However, previous studies have provided conflicting circumstantial evidence concerning the role of PSS in very late stent thrombosis (VLST).

Methods and results: Consecutive patients undergoing sirolimus-eluting stent (SES) implantation with follow-up angiography (n=807, 644 male, mean age 66.0 years) at >6 months were studied. The primary endpoint was major adverse cardiac events (MACE), defined as a composite of death, myocardial infarction, stent thrombosis, and target lesion revascularisation. Twenty patients (2.48%) exhibited PSS at follow-up angiography. After a median of five years (3,744 patient-years) of follow-up, seven (35.0%) in the PSS group reached the primary endpoint versus 117 (14.9%) in the non-PSS group (p=0.013). Together with diabetes, renal failure, unstable angina, saphenous vein graft and longer total stent length, PSS independently predicted the primary endpoint (HR: 2.94, 95% confidence interval 1.36 to 6.35, p=0.006). PSS was also significantly associated with VLST, which occurred in three (15.0%) patients with PSS versus 13 (1.7%) patients without PSS (p=0.006).

Conclusions: Our study clearly and statistically demonstrated for the first time that PSS is an uncommon but significant angiographic finding in patients treated with SES implantation, which independently predicts MACE, and may contribute to an increased risk of VLST.

Comparison between two- and three-dimensional quantitative coronary angiography bifurcation analyses for the assessment of bifurcation lesions

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Aims: Three-dimensional (3D) quantitative coronary angiography (QCA) provides more accurate measurements by minimising inherent limitations of two-dimensional (2D) QCA. The aim of this study was to compare the measurements between 2D and 3D QCA analyses in bifurcation lesions.

Methods and results: A total of 114 cases with non-left main bifurcation lesions in the TRYTON pivotal IDE Coronary Bifurcation Trial (ClinicalTrials.gov: NCT01258972) were analysed using a validated bifurcation QCA software (CAAS 5.10; Pie Medical Imaging, Maastricht, The Netherlands). All cases were analysed in matched projections between pre- and post-procedure. The 2D analysis was performed using one of two angiographic images used for 3D reconstruction showing a larger distal bifurcation angle. In the treated segments (stent and balloon), there were no differences in minimal luminal diameter (MLD) between 2D and 3D, while diameter stenosis (DS) was significantly larger in 2D compared to 3D both pre-procedure and post-procedure (53.9% for 2D vs. 52.1% for 3D pre-procedure, p<0.01; 23.2% for 2D vs. 20.9% for 3D post-procedure, p=0.01). In the sub-segment level analysis, lengths of proximal main branch, distal main branch, and side branch were consistently shorter in 2D compared to 3D both pre-procedure and post-procedure. Using 3D QCA, the anatomic location of the smallest MLD or the largest DS was relocated to a different bifurcation sub-segment in a considerable proportion of the patients compared to when 2D-QCA was used (kappa values: 0.50 for MLD, 0.55 for DS).

Conclusions: Our data showed differences in addressing anatomical severity and location of coronary bifurcation lesions between *in vivo* 2D and 3D QCA analyses. More studies are needed to investigate potential clinical benefits in using 3D approach over 2D QCA for the assessment of bifurcation lesions.

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Acute performance of second generation everolimus-eluting bioresorbable vascular scaffolds for percutaneous treatment of chronic total coronary occlusions

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Aims: There is a lack of knowledge regarding the use of bioresorbable scaffold (BRS) in chronic total occlusions (CTO). Early isolated clinical experiences suggest that using BRS in this setting is feasible. The aim of the present study was to evaluate the acute performance of systematic BRS use in CTO lesions.

Methods and results: Device and procedural success rate of BRS use in percutaneous coronary intervention (PCI) of CTO lesions performed at a single centre were prospectively evaluated. Patients with reference vessel diameter (RVD) ≤2.25 mm and ≥3.8 mm, heavy calcification within the CTO segment and target lesion in bifurcation involving a side branch ≥2 mm in diameter were intentionally excluded. Device acute success was defined as 1) successful BRS delivery and implantation 2) post-procedural residual diameter stenosis <30% within the treated segment; 3) restoration of Thrombolysis in Myocardial Infarction (TIMI) grade 3 antegrade flow. Procedural success was defined as device success with no in-hospital major adverse cardiac events (MACE). Between May 2013 and May 2014, 51 patients underwent intended CTO-PCI with BRS. Wire crossing of the CTO lesion was achieved successfully in 42 cases and the Absorb BRS (Abbott Vascular, Santa Clara, CA, USA) implanted in 32 of them. At least one exclusion criteria was encountered in 10 patients. Most of the procedures (30/32) were performed via the default antegrade approach, whereas switching to a retrograde approach was needed in two cases (6.2%). A total of 90 BRS were successfully implanted with a mean number per patient of 2.81±1.28 and a mean scaffold length of 54.92±28.38. Eight of 32 patients (25%) received both BRSs and drug-eluting stents (due to shelf unavailability in seven cases and delivery failure in one case). Intravascular ultrasound evaluation was carried out in 21/32 patients (65.6%). Device and procedural success were 78.1% and 78.1% respectively. In 7 of 32 patients (21.9%) a maximum residual stenosis >30% persisted. In-hospital stay was uneventful in all cases. Optical coherence tomography assessment was performed post-PCI in 26 of 32 patients (81.2%). Among 63 scaffold analysed, under-expansion was noted in 14 (22%) while both sub-medial dissection and BRS fracture were observed in 2 cases (3% respectively). Mean scaffold area was 8.25±2.52 and 9.52±2.54 in overlapping and non-overlapping segments respectively. No case of incomplete scaffold apposition was detected.

Conclusions: BRS use for CTOs recanalisation appears to be affected by a non-negligible rate of technical failure. Adequate lesion preparation together with expected device ameliorations will be key to enable routine use of BRS in the CTO setting.

EuroPCR Coronary interventions

Euro15A-OP097

Efficiency of biolimus-eluting stents with biodegradable polymers for the treatment of chronically occluded coronary arteries

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Aims: Due to low success rates, periprocedural complications and higher risk for restenosis, the recanalisation of chronic total occlusions of coronary arteries (CTO) remain a challenging task in interventional cardiology. Furthermore, several studies have revealed that restenosis and late stent thrombosis are linked to the polymer layer of drug-eluting stents. We therefore tested whether drug-eluting stents with completely biodegradable polymers are applicable for the treatment of CTOs.

Methods and results: In order to test this hypothesis we retrospectively examined in a monocentric analysis data of 161 CTO patients who were exclusively treated with biolimus-eluting stents with fully biodegradable polymers in the past 36 months. CTO was defined as total occlusion of a coronary artery for more than 3 months and TIMI 0 flow in the occluded segment. The primary study endpoint was late loss at the initial occlusion site after 6 months. Secondary clinical endpoints included a composite of cardiac death, myocardial infarction and target vessel revascularisation after 6 months (MACE). Two hundred and ten (210) CTO procedures were performed in the past 24 months. One hundred and seventy-two (172) were successfully recanalised, corresponding to a success rate of 82%. An antegrade approach was chosen in 145 patients (84%), while 27 patients were recanalised with the help of retrograde techniques. The mean occlusion length of 32±16 mm was treated with an average stent length of 71±35 mm. The J-CTO score was 2.1±1.0. One hundred and sixty-one (161) of the successfully recanalised CTO patients exclusively received biolimus-eluting stents with biodegradable polymers. Meanwhile, 113 patients have concluded angiographic and clinical 6-month follow-up. Late loss at the initial occlusion site was 0.29±0.68 mm. Binary restenosis with the need for reintervention occurred in 9 patients (7.9%). Cardiac death was documented in 1 patient. In addition to that, one patient suffered from a stent thrombosis with a consecutive myocardial infarction during follow-up. Therefore, the MACE rate was calculated with 9.7%.

Conclusions: First results of our monocentric analysis indicate that biolimus-eluting stents with fully biodegradable polymers are associated with little late loss and low MACE rates in complex CTO lesions. Future studies in larger, independent patient cohorts are necessary to confirm our study results.

Angiographic and clinical results after recanalisation of true coronary chronic total occlusions with the sirolimus-eluting stent with an absorbable polymer

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Aims: Chronic total occlusion (CTO) defined by Thrombolysis in Myocardial Infarction 0 flow and duration of occlusion of more than 3 months are associated with a higher risk of restenosis compared to other lesion types. We evaluated angiographic and clinical results of the sirolimus-eluting Orsiro hybrid stent with bioresorbable polymer coating after recanalisation of CTOs. The Orsiro stent is a cobalt chromium stents with an absorbable polymer and thin struts of 60 µm. The Orsiro stent was available in diameters from 2.25 to 4.0 mm and in length from 9 mm up to 40 mm.
Methods and results: We enrolled a total of 70 patients after successful recanalisation of a true CTO in a native coronary artery in our prospective registry (clinical trials.gov NCT02162082). CTO recanalisation was performed by antegrade approach in 63% or retrograde approach in 37%. After pre-dilatation a mean of 3.0±1.1 (range 1-6), Orsiro stents were implanted with a mean length of 80.2±30.3 mm (range 15-149 mm). Dual antiplatelet therapy was recommended for 12 months. Patients were scheduled for angiographic control after 9 months and clinical follow-up after 12 months. The primary angiographic outcome measure was in-stent late lumen loss. Secondary angiographic endpoints include minimal luminal diameter, percentage of diameter stenosis, binary restenosis. Primary clinical outcome measures were target lesion revascularisation rate (TLR) and major adverse cardiac events (MACE) defined a composite of cardiac death, myocardial infarction related to the target vessel and target vessel revascularisation. Patients suffered from diabetes mellitus in 31.5% (N=21/68) of cases. CTO was located in right coronary artery (66.7%), circumflex artery (18.5%) or left anterior descending artery (14.8%). Reference diameter post-PCI was 3.07±0.51 mm, minimum lumen diameter 2.87±0.51 mm and percent diameter stenosis 6.1±10.8 mm. After 9 months, in-stent late lumen loss (primary endpoint) was 0.22±0.48 mm, minimum lumen diameter 1.99±0.63 mm, percent diameter stenosis 24.0±18.5. Target vessel revascularisation was 11.1% resulting in a total MACE rate of 11.1%, including one myocardial infarction. There was no definite or probable stent thrombosis according to Academic Research Consortium criteria. In-stent late lumen loss was 0.13±0.24 mm for patients treated with one Orsiro stent and 0.23±50 mm for patients treated with multiple stents (p=0.98).
Conclusions: Treatment of true CTO lesions with the sirolimus-eluting Orsiro stent resulted in a low in-stent late lumen loss, low rate of binary restenosis and no occurrence of stent thrombosis with a 12-month dual antiplatelet therapy.

Everolimus-eluting vascular scaffold for treatment of either totally occluded or non-totally occluded coronary vessels

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Aims: Limited data are currently available on the performance of everolimus eluting bioresorbable vascular scaffold for treatment of coronary total occlusions. Therefore, we evaluated results after implantation of such device in this particular setting.
Methods and results: The present analysis is part of EXPAND registry, evaluating data after the expanded clinical use of the everolimus eluting bioresorbable vascular scaffold. Patients presenting with clinical indicated revascularisation of a coronary vessel with total occlusion were considered for inclusion in the present study after successful wiring of the true coronary lumen. Operators were encouraged to perform adequate lesion preparation and post-dilatation. Angiographic results in vessel with total occlusion were compared with those in vessel with non-occlusive stenosis enrolled in the EXPAND registry. Quantitative coronary angiography measurements we performed pre- and post-scaffold implantation. The 37 µm platinum radio-markers located at each end of the scaffold aided in the localisation of the non-radio-opaque scaffold. Analysed parameters included reference vessel diameter, calculated with interpolate method, percentage diameter stenosis and minimal lumen diameter. Acute gain was defined as post-procedural minus preprocedural minimal lumen diameter. The angiographic analysis were performed by three investigators who were extensively trained in an experienced core lab. All potential events were adjudicated by a local independent Clinical Events Committee (CEC). A total of 29 vessels showing a total occlusion were treated with bioresorbable scaffolds. After the vessel was cleared, the total occluded vessels were treated achieving a final minimal lumen diameter (2.51±0.53 mm vs. 2.40±0.39; p=0.163) and a percentage diameter stenosis (17.2±9.4% vs. 17.7±8.6%; p=0.780) not different from other lesion types, with a high rate of final device success (96.6% vs. 98.2%; p=0.465) and procedure success (96.6% vs. 98.6%; p=0.393) also not particularly different compared with other lesion types. To reach these results, supportive wires were used much more frequently in occluded vessels (54.2% vs. 2.1%; p<0.001). At the time of the presentation, 1-year clinical follow-up will be available.
Conclusions: The use of bioresorbable vascular scaffolds for treatment of totally occluded coronary vessels could be associated with acute angiographic results comparable to those achieved in vessels with non-occlusive stenotic lesions.

EuroPCR Coronary interventions

Euro15A-OP100

Performance of everolimus-eluting stents and predictors of clinical outcome after chronic total occlusion (CTO) intervention in 1,509 patients from the Korean national registry of CTO interventions

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Aims: There are limited data comparing clinical outcomes between everolimus-eluting stents (EES) and sirolimus-eluting stents (SES) or paclitaxel-eluting stents (PES), as well as limited data of the predictors for outcome after chronic total occlusion (CTO) interventions. The purpose of this study was to compare clinical outcomes of EES with first generation drug-eluting stents (DES) in CTO interventions and to analyse the predictors for clinical outcome.

Methods and results: The Korean National Registry of CTO interventions is a retrospective cohort from 26 centres in South Korea for 5 years (January 2007-December 2011). The primary endpoint was major adverse cardiovascular events (MACE) defined as a composite of cardiac death, nonfatal myocardial infarction, and target lesion revascularisation. Among all-comer 1,754 patients, 1,509 patients (EES: 311, SES: 642, PES: 556) were finally analysed after excluding 245 patients (mixed DESs in 46 and follow-up loss in 199). In the inverse, probability weighted adjusted population, one year MACE rates of EES were comparable to that of SES (5.8% vs. 3.4%, p=0.796) and PES (5.8%, vs. 6.9%, p=0.740). The individual components of MACE were also comparable among the three stents with an insignificantly higher incidence in PES. Importantly, the independent predictors of MACE were diabetes mellitus, previous congestive heart failure (CHF) and left circumflex artery (LCX) CTO.

Conclusions: EES, for the first time in the largest CTO cohort, showed good 1-year clinical outcomes that were comparable to SES. Independent predictors of MACE after CTO intervention were clinical factors (diabetes, CHF), and lesion location (LCX).

EuroPCR Coronary interventions

Euro15A-OP101

Bleeding and stent thrombosis with $P2Y_{12}$-inhibitors: a collaborative analysis on the role of platelet reactivity for risk stratification after PCI

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Aims: Balancing bleeding events and thrombotic complications are crucial in patients undergoing PCI and receiving dual antiplatelet therapy. The potential role of platelet function testing in risk stratification after PCI is unknown. We sought to determine the prognostic value of low (LPR), optimal (OPR), or high platelet reactivity (HPR) during $P2Y_{12}$-inhibitor treatment by applying standardised cutoff criteria for recommended platelet function assays (VerifyNOW, Multiplate and VASP) in patients undergoing PCI.

Methods and results: Authors of studies published before December 2014, reporting associations between platelet reactivity, ST and major bleeding were contacted for a collaborative analysis using *a priori* defined, uniform cutoff values for standardised platelet function assays. Based on recommendations of prior consensus documents and the best evidence available (exploratory studies), LPR-OPR-HPR categories were defined as <95, 95-208 and >208 PRU for VerifyNow, <19, 19-46, and >46 U for the Multiplate analyser and <16, 16-50 and >50% for VASP assay, respectively. Seventeen studies including 20,841 patients were pooled for the analysis; 97% were treated with clopidogrel and 3% with prasugrel. Patients with HPR had a significantly higher risk for ST (RR: 2.73, 95% CI: 2.03-3.69, p<0.00001) yet a slightly lower risk for bleeding (RR: 0.84, 95% CI: 0.71-0.99, p=0.04) compared to those with OPR. In contrast, patients with LPR had a significantly higher risk for bleeding (RR: 1.74, 95% CI: 1.47-2.06, p<0.0001), but identical risk for ST (RR: 1.06 95% CI: 0.68-1.05, p=0.85) as those with OPR. Mortality was significantly higher in patients with HPR (RR: 1.54 95% CI: 1.22-1.94, p<0.0002), but was similar between LPR and OPR patients (RR: 1.03 95% CI: 0.76-1.40 p=0.85). Validation cohorts confirmed the results suggested by exploratory studies.

Conclusions: Assessing platelet reactivity during $P2Y_{12}$-inhibitor treatment with the herein-validated cutoff values may help stratifying PCI-treated patients to higher risk for mortality and ST (HPR) or an elevated risk for bleeding (LPR).

Correlation between residual platelet reactivity after clopidogrel loading and long-term major adverse outcome among STEMI patients undergoing delayed primary percutaneous coronary intervention.

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Aims: It has been shown that higher residual platelet reactivity (RPR) ($P2Y_{12}$-Reaction-Units, PRU>251.5) after clopidogrel loading is associated with larger intracoronary thrombus burden, as well as with impaired myocardial perfusion after revascularisation. We investigated whether RPR is further correlated with long-term major adverse clinical events among ST-elevation myocardial infarction (STEMI) patients undergoing an unexpectedly delayed primary PCI.

Methods and results: A retrospective observational study was conducted, including patients with STEMI, who were either transferred from a referring hospital or presented directly to our hospital and unexpectedly failed to achieve the goal of a first medical contact-to-balloon time of less than 2 h. VerifyNow assay was used to determine RPR after clopidogrel loading. Study population was divided into Low and High RPR groups (PRU<251.5 and PRU>251.5, respectively) according to the previously published study. Major adverse clinical events (MACE) (cardiovascular death, stroke, myocardial infarction, revascularisation) were recorded in long-term follow-up. A total of 61 consecutive STEMI patients (mean age 62.13±12 years, 48 males) were enrolled in the study. Low RPR group included 38 patients (62.3%), while high RPR group included 23 patients (37.7%). In long-term follow-up (mean follow-up period 33± 19 months), it was found that among patients with high RPR, MACE were more frequent in comparison with the low RPR group (p=0.043, phi coefficient=0.3). After adjustment for age, diabetes mellitus and ejection fraction at hospital exit, high RPR group remained an independent predictor of MACE (OR: 4.478, CI: 1.001-20.096; p=0.05). To further investigate the prognostic value of high RPR in clinical outcomes, by Cox proportional hazards regression model, it was shown that high RPR levels, is an independent prognostic factor for MACE-free survival among STEMI patients undergoing primary PCI (hazard ratio: 0.282, 95% CI: [0.093-0.854], p=0.025).

Conclusions: Among STEMI patients undergoing primary PCI, those with initial PRU levels above the cutoff point of 251.1, have a higher incidence of major adverse cardiac events during long-term follow-up.

Predictors of early and late bleeding events after drug-eluting stent implantation

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Aims: Patients who underwent drug-eluting-stent (DES) implantation need antiplatelet therapy and bleeding event often happen unexpectedly. Our aim in this study was to clarify the predictors of bleeding events after DES implantation.

Methods and results: We studied 1,669 consecutive patients who underwent DES implantation in our hospital (70±10 years, 26% woman). Bleeding events were recorded as early (within 1 year) and late (more than 1 year) bleeding events. Bleeding event was defined as a composite of type 5, 3, or 2 bleeding in Bleeding Academic Research Consortium (BARC) criteria. Predictors were assessed using Cox proportional hazard model. Patients backgrounds were as follows, age>80 (17%), hypertension (75%), diabetes mellitus (43%), severe renal dysfunction (defined as estimated glomerular filtration rate <40 mL/min/1.73 m) (12%), haemodialysis (6.2%), past history of gastrointestinal ulcer (GI) (6.2%). Percentage of warfarin use was 6.6%. Overall bleeding events were happened in 82 patients (4.9%). Early and late bleeding events were observed in 48 (2.8%) and 35 (2.2%) patients during follow-up duration (23.1±16.3 months). Bleeding events related with stent implantation were observed only in early bleeding events and other cause of bleeding events were similar between early and late bleeding events (p=0.67). The incidence of fatal bleeding defined as type 5 bleeding was similar between early and late bleeding events (8.3% vs 20%, p=0.12). Warfarin use, past history of GI were independent predictors of early bleeding events (adjusted HR: 3.93, 3.6, p=0.001, 0.005). All patients who used warfarin and suffered from early bleeding events kept dual antiplatelet therapy. Age >80, severe renal dysfunction, hypertension were independent predictors of late bleeding events (adjusted HR: 3.2, 5.1, 3.6, p=0.01, 0.001, 0.04).

Conclusions: Predictors of bleeding events after DES implantation differ depending on the time period. Triple antithrombotic therapy included highly risk of early bleeding events.

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Euro15A-OP104

Incremental value of platelet reactivity over a risk score of clinical and procedural variables in predicting bleeding after percutaneous coronary intervention via the femoral approach: development and validation of a new bleeding risk score

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Aims: Bleeding after percutaneous coronary intervention (PCI) is associated with increased risk of death, while growing evidence suggests that platelet reactivity may predict bleeding. We investigate the incremental value of platelet reactivity in predicting bleeding after PCI via the femoral approach over a validated bleeding risk score of clinical and procedural variables.

Methods and results: A total of 800 patients undergoing elective PCI via the femoral approach were included. Platelet reactivity was measured before PCI with the VerifyNow $P2Y_{12}$ Assay and low platelet reactivity was defined as a $P2Y_{12}$ reaction units value ≤178. Calculation of the bleeding risk score included the following: age, gender, intra-aortic balloon pump, glycoprotein IIb/IIIa inhibitors, chronic kidney disease, anaemia, low-molecular-weight heparin within 48 hours pre-PCI. A new risk score including low platelet reactivity (BRS-PR) was developed and validated in an independent cohort of patients (n=310). Bleeding events at 30 days after PCI were defined according to the TIMI, REPLACE-2 and BARC criteria. Both bleeding risk score and platelet reactivity showed high discriminatory power for bleeding (area under the curve >0.7 for all definitions). Discriminatory power of BRS-PR (area under the curve=0.809 for TIMI bleeding; area under the curve=0.814 for BARC class ≥2 bleeding; area under the curve=0.708 for BARC class ≥3 bleeding; area under the curve=0.813 for REPLACE-2 bleeding) was significantly higher than that of bleeding risk score alone ($p<0.001$ for all bleeding definitions). In the validation set, BRS-PR showed higher discriminatory power for TIMI bleeding than bleeding risk score alone (area under the curve=0.788 vs. 0.709, p=0.036).

Conclusions: Platelet reactivity has incremental predictive value on bleeding events after elective PCI via the femoral approach over a validated risk score of clinical and procedural variables. A risk score including platelet reactivity yields significantly better prognostic performance compared with the original bleeding risk score.

EuroPCR Coronary interventions

Euro15A-OP105

Randomised comparisons of the platelet Inhibitory effect of clopidogrel and low dose of ticagrelor in patients receiving antiplatelet therapy after coronary stent implantation

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Aims: Ticagrelor is the first orally active reversible $P2Y_{12}$ receptor antagonist and acts by blocking the $P2Y_{12}$ receptor, to inhibit ADP-induced platelet activation and aggregation. But, ticagrelor was associated with a higher rate of TIMI major non-CABG related bleeding in the PLATO trial and the standard dose of ticagrelor might not be suitable for patients of East Asian ethnicity. Therefore, we sought to compare the platelet inhibitory efficacy determined by the VerifyNow $P2Y_{12}$ point-of-care assay between low dose ticagrelor 90 mg once daily, 45 mg twice a day and clopidogrel 75 mg once daily on maintenance phase of dual antiplatelet therapy after percutaneous coronary stent implantation.

Methods and results: This study was an open label, single-centre, prospective randomised controlled trial. All patients have received open-label clopidogrel 75 mg taken daily with 100 mg aspirin after coronary stent implantation and they randomly assigned clopidogrel 75 mg, ticagrelor 90 mg once daily and 45 mg twice a day with aspirin for 28 days. Platelet function testing was performed at baseline and 28 days after receiving assigned drugs using VerifyNow $P2Y_{12}$ point-of-care assay. The primary endpoint was the comparison of $P2Y_{12}$ reaction units (PRU) determined by VerifyNow $P2Y_{12}$ at 28 days between study groups. A total of 69 patients were randomised, 62 patients were included in the final analysis. There were no differences in baseline PRU between three groups (clopidogrel vs. ticagrelor 90 mg qd vs. ticagrelor 45 mg bid; 215.8±50.7 vs. 193.1±31.4 vs. 215.8±50.7, p=0.168). The ticagrelor 90 mg once daily and 45 mg twice a day had significantly lower PRU compared with clopidogrel 75 mg at 28 days (clopidogrel vs. ticagrelor 90 mg qd vs. ticagrelor 45 mg bid; 221.2±50.1 vs. 98.6±73.4 vs. 65.5±58.8, $p<0.001$). Comparing ticagrelor 90 mg once daily and 45 mg twice a day, there was no significant difference in PRU (98.6±73.4 vs. 65.5±58.8, p=0.123).

Conclusions: Two different regimens of low dose ticagrelor, 90 mg qd once daily and 45 mg twice a day, were associated with a more potent platelet inhibitory effect than the standard dose of clopidogrel in patient undergoing PCI.

Prasugrel versus adjusted high-dose clopidogrel in patients with high-on-clopidogrel platelet reactivity: the PECS-HPR randomised, multicentre study

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Aims: Repeated loading doses (LD) of clopidogrel were shown to effectively overcome high-on-clopidogrel platelet reactivity (HPR); however, comparison to potent $P2Y_{12}$-inhibitors is lacking. We sought to compare the antiplatelet effect of high-dose clopidogrel versus prasugrel at both short- and long-term in acute coronary syndrome patients (ACS) with HPR (NCT01493999).

Methods and results: ACS patients receiving 600 mg clopidogrel pre-treatment were randomised to prasugrel or high-dose clopidogrel in a multicentre, controlled trial if platelet function testing revealed HPR (>46 U) after PCI. In the prasugrel group, patients received an immediate 60 mg LD followed by 10 mg for three days. After day 3, patients were randomised to either standard (10 mg) or reduced (5 mg) maintenance doses (MD-s) up to 30 days. Patients randomised to high dose clopidogrel received repeated LDs of 600 mg clopidogrel based on controlled platelet function testing for three days, and then were randomised to 75 mg or 150 mg MDs for 30 days. ADP-induced platelet reactivity was measured with the Multiplate assay at day 0 (randomisation), 1, 2, 3 and 25. Between May 2011 and March 2013, 147 patients were randomised. Although baseline platelet reactivity did not differ between groups (p=0.22), prasugrel provided significantly more rapid and more potent platelet inhibition compared to repeated LDs of clopidogrel through all three days after randomisation (p<0.0001). During the maintenance phase, there was a dose-dependent increase in platelet reactivity from prasugrel 10 mg to clopidogrel 75 mg (p for trend <0.0001), demonstrating the superiority of both doses of prasugrel over 75 and 150 mg clopidogrel. No difference was observed between clopidogrel groups at day 25 (p=0.35), leading to a rebound in HPR and returning to the level of baseline platelet reactivity with both 75 and 150 mg clopidogrel (p=0.66 vs. day 0).

Conclusions: Prasugrel provides significantly more rapid and more potent platelet reactivity inhibition compared to repeated loading doses of clopidogrel. The observed differences persisted with maintenance dosing, leading to rebound in HPR with both standard and high-dose clopidogrel.

Randomised trial to compare a protective effect of clopidogrel versus ticagrelor on coronary microvascular injury in ST-segment elevation myocardial infarction (CV-TIME) trial

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Aims: Ticagrelor has shown greater, more rapid and more consistent platelet inhibition than clopidogrel. However, the superiority of ticagrelor for preventing ischaemic damage in ST-elevation myocardial infarction (STEMI) patients has not been proven. Then this trial is to assess whether a 180 mg loading dose (LD) of ticagrelor is superior to a 600 mg LD of clopidogrel in preventing the microvascular injury in STEMI.

Methods and results: The CV-TIME trial is a single-centre, randomised designed to compare the effectiveness of a LD of ticagrelor with an LD of clopidogrel in preventing microvascular injury in STEMI patients. Patients with STEMI underwent prospective random assignment to receive an LD of clopidogrel 600 mg or ticagrelor 180 mg (1:1 ratio) before primary percutaneous intervention (PCI). As the primary endpoint, the index of microcirculatory resistance (IMR), a standard method of evaluating microvascular injury, was measured immediately after primary PCI. The secondary endpoint was the infarct size estimated from the wall motion score index (WMSI), by transthoracic echocardiography (TTE) at baseline and at three months on. A total of 76 patients were enrolled (clopidogrel group=38, ticagrelor group=38). The IMR in the ticagrelor group was significantly lower than that in the clopidogrel group (22.2±18.0 vs. 34.4±18.8 U, p=0.005). Cardiac enzymes were less elevated in the ticagrelor group than in the clopidogrel group (CK peak; 2,651±1,710 vs. 3,139±2,698 ng/ml, p=0.06). Infarct size, estimated by WMSI, was not different between ticagrelor and clopidogrel group at baseline (1.55±0.30 vs. 1.61±0.29, p=0.41) or after three months (1.42±0.33 vs. 1.47±0.33, p=0.57).

Conclusions: In patients with STEMI treated by primary PCI, a 180 mg LD of ticagrelor is more effective at reducing microvascular injury than a 600 mg LD of clopidogrel, as demonstrated by IMR immediately after primary PCI.

EuroPCR Coronary interventions

Euro15A-OP108

Clinical outcome of rotational atherectomy in complex calcified coronary lesions: data from the multicentre international ROTATE registry

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Aims: Rotational atherectomy (RA) is widely used for treating calcified coronary lesions. The ROTATE (ROTational AThEerectomy) multicentre international registry was developed to assess the short- and long-term outcome after RA in a large real-world population.

Methods and results: From April 2002 to December 2014 a total of 1,079 consecutive patients, treated with RA in ten different high volume centres worldwide, were collected in the ROTATE registry. Their mean age was 70.6±9.5 years, 65% being male, and about half with diabetes mellitus, renal impairment or a previous PCI. More than a quarter of patients (26.1%) were treated with RA during the hospitalisation for an acute coronary syndrome, exploiting the radial approach in 28.6%. The most frequently treated coronary artery was the left anterior descending (47.1%) followed by the right coronary (24.9%); protected and unprotected left main stem lesions were respectively faced in 1.3% and 7.4%. Chronic total occlusions were 8.2% of total and 31.2% of procedures were IVUS-guided with a burr/artery ratio ≥ 0.6 in 32.5%. Second-generation DES were implanted in 63.1%. Serious procedural complications (perforations and no-flow/slow-flow), occurred rarely (respectively 0.6% and 1.3%). In-hospital death occurred in 0.7%, myocardial infarction in 6.9% (6.4% non-Q-wave and 0.5% Q wave) and stroke in 0.4%; the cumulative incidence of in-hospital major adverse events showed no differences between gender and clinical presentation, with a trend of being lower in those with radial access. The 1- and 3-year overall survival (Kaplan Meier estimate) was 96.1% and 87.7%. Multivariate analysis using the Cox proportional hazards model showed that age>75 (OR 1.98; CI 95%: 1.23-3.17; p=0.005), diabetes (OR 1.6; CI 95%: 0.99-2.59; p=0.05) and left ventricular ejection fraction <35 (OR 3.51; CI 95%: 2.08-5.93; p<0.001) were independent predictors of death at follow-up.

Conclusions: ROTATE registry represents the largest international registry data set of patients treated with RA in the DES era. RA appears to be feasible and effective, with a high rate of success and favourable short and long-term outcome even in this very complex real-world population.

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Euro15A-OP109

Rotational atherectomy in ACS: is it still contraindicated? Clinical data from the multicentre International ROTATE registry

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Aims: Length of life and hence comorbidities are increasing in general population leading us to observe a growing number of patients with acute coronary syndrome (ACS) and severe calcified lesions. Historically, the rotational atherectomy (RA) was considered contraindicated in patients with ACS due to its pro-thrombotic state. The aim of our study was to compare RA safety and long-term efficacy in NSTE-ACS versus stable angina patients (SA).

Methods and results: We evaluated retrospectively 845 consecutive patients who underwent to RA from April 2002 to August 2014 in 8 cathlab centres collected in the observational ROTATE multicentre registry. The primary endpoint of safety was evaluated as incidence of intraprocedural complications, TIMI bleeding, periprocedural myocardial infarction and in hospital death. A secondary endpoint of long-term efficacy was evaluated as the incidence of all-cause death and major adverse cardiovascular events (MACE) during follow-up. Our population was composed by 274 NSTE-ACS (32.5%) and 571 SA (67.5%) patients. Baseline clinical and angiographic characteristics were similar in both groups. In terms of procedural complications (perforations, slow-flow/no-flow) we observed 6.2% of total events in NSTE-ACS group, almost superimposable to those of patients with SD (5.8%, p=0.78). The incidence of in-hospital death (p=0.25) and periprocedural myocardial infarction (p=0.34) was not significantly different between the two groups. At the mean follow-up of 24 months (IR: 10.7-47.6) overall survival was 88.1% in NSTE-ACS group and 91.4% in SD group (log rank=0.35), while MACE-free survival was respectively 69.5% and 77.0% in the two groups (log rank=0.26).

Conclusions: RA has a similar safety in NSTE-ACS and SA patients, moreover it shows similar long-term efficacy.

Percutaneous coronary intervention using rotational atherectomy: a multicentre comparison of the radial versus the femoral approach

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Aims: Rotational atherectomy (RA) is a well-established adjuvant device for use during percutaneous coronary intervention (PCI). The femoral artery has historically been the arterial access of choice for RA, facilitating the use of large-bore guide catheters. Transradial access has become a default for many European centres, but radial access RA has been considered limited by smaller arterial size. We present a large, contemporary, multicentre comparison of RA-PCI utilising radial and femoral access.

Methods and results: Patients from four regional cardiology centres from the United Kingdom undergoing RA-PCI from 2008 to 2013 were included in the study. Patients were separated into access site used with both procedural and clinical outcomes compared. Major adverse clinical events (MACE) were reported at 30 days and at 1 year. Six hundred and thirty-five (635) patients underwent RA-PCI (radial n=357 and femoral n=278). Baseline demographics were similar between groups, except for notable differences in male sex (radial 73.7% vs. femoral 62.6% p<0.001), weight (80.7 kg vs. 77.3 kg, p=0.02) and left ventricular impairment (30.6% vs. 40.7%, p<0.001). Procedural success was high in both cohorts (98.5% vs. 97.6%, p=0.39). Guide catheter diameter was smaller in the radial group (6 Fr vs. 7 Fr, p<0.001), but average burr size was similar. Left main PCI was more common in the femoral group (9.8% vs. 18.0%, p=0.002) as was use of adjuvant devices (30.6% vs. 44.4%, p<0.001) whereas the radial group had a higher percentage of DES usage (91.5% vs. 85.2%, p=0.01). Procedural time (90 min vs. 114 min, p<0.001) and screening time (28 min vs. 32 min, p=0.006) were significantly lower in the radial cohort. Bleeding rates, procedural and vascular complications were similar as was 30-day MACE. One-year MACE was less in the radial cohort (10.1% vs. 15.5%, p=0.04) with death significantly lower in the radial group (4.2% vs. 10.1%, p=0.003). No differences in stroke, myocardial infarction or target vessel revascularisation were noted.

Conclusions: This large, multicentre comparative study demonstrates that radial artery RA-PCI can be performed safely with similar success, bleeding and complication rates as the femoral approach. Procedural and screening times were less in the radial cohort as was 1-year MACE, with a significant reduction in death.

Usefulness and success of rotational atherectomy for the treatment of coronary bifurcations

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Aims: Coronary bifurcation is a challenging setting for performing PCI. We aim to identify the role, safety and feasibility as well as the parameters for a successful rotational atherectomy for the treatment of bifurcation lesions.

Methods and results: We conducted a prospective single-centre registry at a hospital with onsite cardiac surgery. Analysis included 64 prospective patients in which rotational atherectomy was performed for the treatment of 87 bifurcations lesions. Mean age was 78(9) years with a very high-cardiovascular risk profile. Prior myocardial infarction and PCI were present in 57.8% respectively. Moderate LVEF dysfunction (≤44%) was present in 26.2%. A majority of the procedures were performed in unstable patients (65.7%). The prevalence of multivessel disease was 81.2%. The left anterior descending artery was the most diseased (98.4%, p=0.002). The most treated bifurcation affecting the LAD and first diagonal branch: 50.6%. Bivalirudin was the most used antithrombotic regime (p=0.017). Clinical and angiographic success were 98.6% and 98% respectively. Cardiovascular death during hospitalisation was 4.6% (3 patients), being related with the procedure, 1 (1.5%) and related with rotational atherectomy, 1 (1.5%). The third death was due to cardiac rupture nine days after primary PCI. Regarding angiographic success, we recorded only one coronary dissection (1.1%), which was solved with a new stent, and 1 slow-flow phenomenon (1.1%). We failed to implant stents in 2 stenoses after rotational atherectomy. We did not recorded side branch closures, burr entrapment or coronary perforations. No stent thrombosis was recorded. Moreover, overall MACCE was 23.4% during a median follow-up 494 days (range 0-1148). The global death rate was 20.3% (13 patients, median 560 day, ICA 484 days). Cardiovascular death during all follow-up was 7.8% (5 patients). Non-cardiovascular death (12.5%, 8 patients) was mainly due to sepsis (5) or oncological status (3). Furthermore, during follow-up we observed two cardio-embolic strokes (3.1%) where both patients were under antithrombotic treatment. As far as we know at present, there were no threatened bleeding nor bleeding requiring transfusion reported.

Conclusions: Rotational atherectomy is a safe and feasible technique for complex PCI. Rotational atherectomy should be considered a promising coadjutant therapy for the management of bifurcation lesions despite very high cardiovascular risk profile with its very low complication rate. Left main and proximal LAD bifurcations should be treated with this technique.

EuroPCR Coronary interventions Euro15A-OP112

The impact of coronary plaque components observed by preprocedural iMap-IVUS on superficial coronary calcification in patients treated with rotational atherectomy

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Aims: The aim of this study was to evaluate the morphology of coronary calcification using a serial 40 MHs intravascular ultrasound (iMap-IVUS) imaging system.

Methods and results: From January 2011 to March 2014, a total of 49 patients were treated with percutaneous coronary intervention (PCI) following rotational atherectomy (RA), with a pre-procedural analysis using IVUS imaging. This study consisted of 27 superficial coronary calcified segments of 9 of these patients which could be analysed using IVUS before RA. The serial iMap-IVUS system analysed coronary segments as fibrotic, lipidic, necrotic or calcified tissues based on the radiofrequency spectrum at 1 mm interval. A positive correlation was found between the values of calcification, thickness and the percentage of calcified tissues ($r=0.29$, $p<0.0001$). No correlation was found between the values of calcification thickness and the percentage of other tissues.

Conclusions: In the vessel with superficial coronary calcification before RA, a positive correlation was observed between the percentage of calcified tissues determined by iMap-IVUS and the values of calcification thickness detected by grey-scale IVUS.

EuroPCR Coronary interventions Euro15A-OP113

Coronary autoregulation preserves resting flow velocity in the presence of stenoses: a phasic analysis of human coronary physiology

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Aims: The majority of our understanding of coronary physiology is based upon animal studies with external constrictors used to model a stenosis. We sought to use combined intracoronary pressure and flow velocity measurements to elucidate of the behaviour of the human coronary circulation in response to a native stenosis.

Methods and results: Five hundred and sixty-seven (567) coronary vessels underwent simultaneous intracoronary pressure and flow velocity assessments, from which coronary flow velocity, transtenotic gradient (TG) and microvascular resistance (MVR) were computed. Measurements were made during rest over the whole cardiac cycle and the diastolic wave-free period (wfp), and also during adenosine-mediated hyperaemia. Stenoses was stratified according to severity as objectively determined by fractional flow reserve (FFR). Data is mean±SEM. Linear regression analysis estimated trends and p-values. As stenosis severity increases, from reference angiographically normal vessels to those with FFR≤0.50, resting flow velocity changed little (whole cycle, 18±0.5 cm/s; $p=0.40$, wfp, 25±0.7 cm/s, $p=0.30$). In contrast, hyperaemic flow falls from 45 to 19 cm/s ($p<0.01$). With increasing stenosis severity, distal pressure falls such that the TG increases from 1.5 to 46 mmHg at rest (whole cycle) and 1.6 to 56 mmHg for wfp; hyperaemic TG similarly falls from 3.5 to 55 mmHg ($p<0.01$ for all). Resting MVR declines as stenoses increase in severity, from 6.2 to 4.2 mmHg/cm/s at rest ($p<0.01$), over the wfp from 4.4 to 2.0 mmHg/cm/s ($p<0.01$); overall hyperaemic resistance was consistent across stenoses (2.3±1.1; $p=0.19$) but with a trend to suggest paradoxical vasoconstriction in severe stenoses.

Conclusions: With progressive stenosis severity, distal coronary pressure falls and transtenotic gradients enlarge but resting coronary flow is preserved and maintained by a compensatory reduction of microvascular resistance. This confirms coronary auto-regulation under resting conditions in humans and explains why resting pressure gradients can detect the haemodynamic stenosis significance. Resting gradients are therefore an assessment of the natural physiological response of a given coronary bed to the presence of a stenosis. This work is also pertinent for non-invasive approaches that attempt to model physiology using anatomy since we describe all three physiological parameters across a large dataset from real-world patients. Finally, the stability of resting flow across a wide-spectrum of stenoses suggests that it should be feasible to predict the change in a resting pressure index or gradient before stenting a given stenosis.

Relation between fractional flow reserve and the intracoronary pressure waveform

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Aims: The determination of the coronary fractional flow reserve (FFR) is the gold standard of the assessment of the functional consequence of coronary artery stenosis. For the FFR measurement, the difference of the simultaneously recorded continuous pressure trace of the aorta and of the intracoronary pressure sensor distal to coronary lesion is evaluated during vasodilatation. According to some publications the change of the distal pressure waveform during the resting state can have clinical importance. Our aim was to analyse the intracoronary pressure waveforms in relation to the distal to proximal pressure ratios.

Methods and results: FFR measurements in 33 coronary arteries of 23 patients were analysed. During resting condition and maximal hyperaemia, the proximal and distal pressure curves were continuously recorded and exported to our JAVA software to calculate the derivative curves. The local minimal and maximal values and the differences were determined from the distal derivative curves around the dicrotic notch (delta dPn/dt). The correlation was tested between these values and the pressure gradients in the resting state and during hyperaemia (FFR). The FFR and the distal dPn/dt from hyperaemic distal pressure curves showed significant correlation ($r=0.82$, $p<0,001$). On the other hand, there was no correlation between the resting dPn/dt, and neither the resting pressure ratios nor the FFR ($r=0.19$, $p=0.33$ and $r=0.19$ $p=0.58$, respectively).

Conclusions: During hyperaemia, the change of the distal pressure waveform is related with the actual pressure gradient. The dPn/dt is a useful parameter for the quantitation of the waveform. Regarding the tight correlation between this parameter and the FFR, the discordance between the FFR and the dPn/dt can be a good indicator of such a pitfall of the intracoronary pressure measurements like wedging of the catheter or drift of the trace.

Combining baseline distal-to-aortic pressure ratio and fractional flow reserve in the assessment of coronary stenosis severity: a pressure, coronary flow velocity and thermodilution study

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Aims: Baseline distal-to-aortic pressure ratio (Pd/Pa) is always available before fractional flow reserve (FFR) assessment, and cumulative evidence supports the notion that hyperaemia-free indices can determine the ischaemic potential of coronary stenosis in selected subsets. We sought to explore 1) if adding baseline Pd/Pa to FFR conveys important information; and 2) the physiological basis of Pd/Pa and FFR agreement and discordance using coronary flow reserve (CFR), stenosis resistance (SR) and microcirculatory resistance (MR) measurements.

Methods and results: Three hundred and sixty-three (363) patients with 467 stenosed vessels were investigated with pressure and flow sensors, during baseline and hyperaemia: 135 patients (168 vessels) with thermodilution-derived flow and 228 patients (299 vessels) with Doppler-derived flow. Pd/Pa was significantly correlated with FFR (=0.798, $p<0.001$). Pd/Pa correlated more strongly with CFR than FFR (difference=0.129; p for comparison<0.001). The optimal Pd/Pa cutoff (ROC analysis) against FFR≤0.80 was 0.91, and classified correctly 80.7% of stenoses. Discordant Pd/Pa>0.91 and FFR≤0.80 vessels (n=59, 12.6%) were more prevalent in younger patients, and characterised by high (+140%) flow increases, high (+72%) SR increases to intermediate hyperaemic values and the largest (-68%) drops in MR. Discordant Pd/Pa≤0.91 and FFR>0.80 vessels (n=35, 7.5%) were more frequent in elderly and hypertensive patients and characterised by moderate (+97%) flow increases, moderate SR decreases (–33%) to low hyperaemic values, and relatively low (–54%) drops in MR.

Conclusions: The combination of baseline Pd/Pa with FFR seems to provide a more comprehensive physiological examination of the vessel under examination, and a closer pressure-based appraisal of the flow reserve of the downstream myocardial bed.

EuroPCR Coronary interventions

Euro15A-OP116

Diagnostic accuracy of contrast-induced fractional flow reserve (cFFR) measurement in stable lesions depends on the observed value: what about the grey zone?

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Aims: Recent work reported the feasibility and efficiency of contrast-induced fractional flow reserve (cFFR) to assess the severity of stable coronary artery stenosis as compared with adenosine induced FFR (aFFR). Although there are some convergences supporting the routine use of cFFR as a first line assessment in current practice, there are also some concerns about the best cFFR threshold to apply. We previously showed that a cutoff value of 0.85 was efficient to predict lesion severity in a cohort of patients with clinical indication of FFR measurement. The aim of the present study was to analyse the ability of cFFR to accurately classify lesions severity as a function of the observed values.

Methods and results: This multicentre prospective study included patients with suspicion of stable coronary disease for whom an elective coronary angiography and haemodynamic assessment of stenosis severity by FFR was indicated. Patients with acute coronary syndrome, chronic renal failure and contra-indication to adenosine use were excluded. FFR measurements were made at baseline, after contrast injection (Iomeprol or iodinaxol, 10 ml intracoronary [IC] for left coronary artery [LCA] and 6 ml IC for right coronary artery [RCA]) and after adenosine (150 µg IC for LCA, 100 µg IC for RCA). An aFFR value ≤0.8 defined a significant lesion. This cohort included n=104 patients (mean age=68.4 years, 76% male) and a total of n=129 lesions evaluated by cFFR and aFFR (54% left anterior descending, 17% RCA, 29% circumflex lesions, mean QCA: 51±8%). There was an excellent correlation between cFFR and aFFR values in the whole population (Pearson's r=0.92, p<0.0001). Using a threshold value of 0.85, cFFR correctly identified 89% of the lesions, with a positive predictive value (PPV) of 82% and negative predictive value (NPV) of 95%. We then stratified the cohort in 3 subgroups, according to the cFFR value. In the first (cFFR<0.82/ n=49 lesions) and second (cFFR>0.85/ n=62 lesions) groups, cFFR and aFFR were highly correlated (respectively r=0.82 and r=0.77, p<0.001) and lesions were correctly classified in respectively 94% and 95 of the cases. However, in the third group (0.82≤ cFFR ≤ 0.85 / n=18 lesions, i.e., 14% of the initial population), there was no significant correlation (r=0.36, p=0.15) between aFFR and cFFR values and lesions were only correctly classified in 50% of the cases, suggesting that these values range could be considered as a "grey zone", requiring the use of adenosine to obtain a valid classification of patients.

Conclusions: Contrast-induced FFR measurement is a reliable method for assessing coronary artery stenosis severity with cFFR <0.82 or >0.85, which represents 86% of a non-selected all-comers population with an indication of FFR measurement. This method is not accurate enough in case of intermediate cFFR values ranging between 0.82 and 0.85: in this "grey zone", subsequent aFFR measurement is required for accurate patients' classification.

EuroPCR Coronary interventions

Euro15A-OP117

Comprehensive physiologic assessment of ischaemic heart disease patients to define the mechanism and prognosis using fractional flow reserve, coronary flow reserve and index of microcirculatory resistance

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Aims: Microvascular disease with or without epicardial coronary stenosis can induce ischaemic heart disease (IHD). The clinical manifestation and prevalence of this form of IHD, and its prognostic implication in patients undergoing interrogation of fractional flow reserve (FFR), has not yet been clearly defined.

Methods and results: Three hundred and thirty-four (334) patients with 663 vessels with available FFR, coronary flow reserve (CFR) and index of microcirculatory resistance (IMR) were classified into 4 quadrants according to the cutoff value of FFR<0.80 and CFR≤2. Angiographic severity and surrogate markers of atherosclerotic burden (Gensini and SYNTAX score) and clinical outcomes were evaluated. The patient-oriented composite outcome (POCO, a composite of any death, any myocardial infarction, and any revascularisation) was the primary outcome. The distribution of patients in each quadrant was as follows; low-FFR and high-CFR (group A, 12.6%), high FFR and high CFR (group B; adequate and concordant, 62.6%), low FFR and low CFR (group C; reduced and concordant, 9.0%), and high-FFR and low-CFR (group D, 15.9%). Angiographic lesion severity and both Gensini and SYNTAX scores were significantly higher in the low FFR groups (A and C) than in the high FFR groups (B and D). Among patients with low FFR, group A had lower IMR values than group C, suggesting that group A had predominantly macrovascular disease. In the high FFR groups, IMR value was higher in group D than in group B, suggesting that group D had predominantly microvascular disease with minimal macrovascular disease. Patients with high-FFR and low-CFR showed a higher rate of POCO than those with high-CFR (9.4% versus 2.4%, log rank p=0.021). Among patients with FFR-guided deferral of revascularisation, low-CFR (HR 4.753, 95% CI: 1.254-18.006, p=0.022) and multivessel disease (4.596, 95% CI: 1.149-18.380, p=0.031) were independent predictors for POCO.

Conclusions: Integration of microvascular assessment using CFR and IMR to FFR can provide additional information on the mechanism of myocardial ischaemia and improve risk stratification of patients with IHD.

Multicentre evaluation of the novolimus-eluting, fully bioresorbable coronary scaffold: two-year clinical and longer-term imaging endpoints

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Aims: Bioresorbable vascular scaffolds represent an exciting advance in percutaneous coronary interventions (PCI) providing initial coronary support, which is eventually resorbed by the body. The DESolve Nx study is a prospective, multicentre evaluation of the safety and efficacy of the DESolve novolimus-eluting bioresorbvable coronary scaffold (BCSS) in patients with single, *de novo*, native coronary artery lesions through clinical endpoints and multiple imaging modalities.

Methods and results: The DESolve BSCC is a novel drug-eluting bioresorbable vascular scaffold that combines a poly-L-lactide (PLLA-based) scaffold coated with a biodegradable PLLA-based polymer and the drug novolimus, a macrocyclic lactone, mammalian target of rapamycin (mTOR) inhibitor which has demonstrated potent antiproliferative properties in previous clinical trials using Elixir's metallic novolimus eluting coronary stents. The drug dose is 5 mcg per mm of scaffold length and is available in multiple diameters (2.5, 3.0, 3.25, and 3.5 mm) and lengths (14, 18, and 28 mm). A total of 126 patients with single, *de novo*, coronary artery lesions were enrolled in this prospective, multicentre, single-arm study. Those patients receiving the study device are being analysed for multiple clinical endpoints including: device and procedure success; major adverse cardiac events (MACE) which is a composite endpoint of cardiac death, target-vessel MI or clinically-indicated target lesion revascularisation (CL-TLR); CI-TLR and clinically-indicated target vessel revascularisation (CI-TVR) and stent thrombosis all assessed at 1, 6 and 12 months and annually up to 5 years. All patients underwent angiographic assessment at 6 months and a subset of patients underwent IVUS and OCT assessment, also at 6 months. Imaging was conducted in the subset of patients at 12 months using multislice computed tomography (MSCT), which demonstrated similar luminal results to those see by angiography at 6 months. Additionally, at a single centre, imaging was completed at 18 months. At 12 months, MACE was 5.69% with no definite stent thrombosis, and the 6-month in-scaffold late lumen loss was 0.20±0.32 mm demonstrating the safety and effectiveness of this novel device. Clinical results at 2-years, as well as longer-term (18 month) imaging, will be presented.

Conclusions: The DESolve novolimus-eluting BCSS demonstrated safety and efficacy in this study through to 24 months. A report of the clinical results and longer-term imaging will be presented.

ABSORB vs. DESolve: an OCT study comparision of the acute mechanical performances

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Aims: The bioresorbable scaffold (BRS) is a novel approach to treat coronary artery lesions. The mechanical properties of the polymer based ABSORB scaffold (Abbott Vascular, Santa Clara, CA, USA) have already been compared to those of second-generation metallic DES. Lately, the novolimus-eluting DESolve® (Elixir Medical Corporation, Sunnyvale, California, USA) gained permission for clinical use in Europe. The aim of our study was to compare with OCT the acute performance of the ABSORB scaffold vs. the DESolve scaffold and to evaluate appropriate deployment.

Methods and results: Very-final, post-deployment OCT pullbacks of consecutive patients treated with either ABSORB or DESolve were reviewed. The following parameters were calculated: mean and minimal lumen area (MLA), residual in scaffold area stenosis (RAS), incomplete strut apposition (ISA), tissue prolapse area, eccentricity index, symmetry index, strut fracture and edge dissection. A total of 54 patients were included. The ABSORB group consisted of 33 patients treated with 61 ABSORB® scaffolds and the DESolve group of 21 patients treated with 28 DESolve® scaffolds. Baseline characteristics did not differ significantly between the two groups. Angiographic and QCA lesion characteristics were similar, except for bifurcation involvement, which was more common in the ABSORB group (34.7% vs. 0%; p<0.01). OCT analysis showed similar MLA (5.9±1.9 mm^2 vs. 5.9±1.6 mm^2, p=0.97) and mean lumen area (7.2±2.2 mm^2 vs. 7.5±1.7 mm^2). There was a trend towards a larger maximum scaffold diameter (3.2±0.5 mm vs. 3.5±0.4 mm, p=0.04) and a lower degree of RAS (20±7.5% vs. 16.7±14.8, p=0.16) with DESolve®. The eccentricity index was 0.85±0.05 with ABSORB and 0.80±0.07 with DESolve, p<0.01. DESolve® showed higher frequency of distal edge ISA (9.8% vs. 39.3%; p<0.01) and a larger prolapse area (1.1 vs. 5.0 mm^2; p<0.01) in comparison to ABSORB. Procedural characteristics were different with respect to scaffold deployment and post-dilatation balloon inflation pressure.

Conclusions: The two scaffolds showed similar MLA, while there was a trend towards a lower RAS and a larger maximum scaffold diameter with DESsolve. The DESolve scaffold was more eccentric compared to the ABSORB. These results might be related to the unique expansion capabilities and self-correction properties of the DESolve scaffold. Indeed, the question of whether OCT parameters might result in different clinical outcomes is something that needs to be evaluated.

EuroPCR Coronary interventions

Euro15A-OP120

Optical coherence tomography-guided BVS implantation in complex coronary lesions

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Aims: To investigate the impact of optical coherence tomography (OCT) in guiding coronary angioplasty with bioresorbable vascular scaffold (BVS) implantation in complex coronary lesions.

Methods and results: Optical coherence tomography was used at different stages during BVS implantation to assess lesion severity, characteristics of the lesions and/or to optimise scaffold expansion/apposition. A total of 108 BVS were implanted in 107 lesions of 62 patients. The mean age was 59±12 years and 38.7% of patients had diabetes. Eighty-six (80.4%) coronary lesions were complex (b2-c AHA-ACC-type). The decision whether or not to perform an OCT imaging was left to operator's discretion, however the PCI strategy changed in 23.5% of the OCT pullbacks performed. After full lesion preparation by balloon dilation, 16 (13.9%) OCT pullbacks were performed suggesting further pre-dilatation in 15 (93.7%) cases. Interestingly, after obtaining a good angiographic result (BVS implantation followed by post-dilatation at high atmospheres with non-compliant balloons), 83 (72.2%) pullbacks were performed suggesting further post-dilatation in 29 (34.9%) cases. Also of interest, 10.5% of pullbacks performed before stenting suggested a different scaffold size compared to the one chosen after angiography. Six out of 115 (5.2%) pullbacks demonstrated the need for further stenting because of dissections or the presence of severe residual stenosis. Overall, 53 out of 115 (43.1%) OCT pullbacks performed at any procedural step changed the strategy or indicated the need for further intervention. Moreover, in order to evaluate the possible improvement of BVS periprocedural performance overtime in our centre, we divided our population into two groups according to the time of the procedure: group 1 ("implementation phase"), including the first 20 consecutive patients treated with a BVS and group 2 ("consolidation phase") including 25 patients treated after the "implementation phase" with the same device. Patients and procedural characteristics didn't show any significant difference between the groups except for balloon diameter used for further post-dilatations, which was significantly higher in group 2 (3.3±0.2 in group 1 vs. 3.8±0.6 in group 2, p=0.019). At OCT analysis, a lower distal edge malapposition rate was reported in group 2 (11.1% in group 1 vs. null in group 2). However, minimal scaffold area was similar in both groups (p=0,778) as well as proximal edge area (p=0.653) and distal edge area (p=0.638). Not surprisingly, further post-dilatation rate was higher in complex lesions (29% in b2/c vs. 5.9% in a/b1; p=0.048). Interestingly, the number of post-dilations was not related with the occurrence of local complications, such as dissections (p=0.091) or stent fractures (p=n.s.). Similarly, neither post-dilatation pressure (p=0.971) nor post-dilatation balloon diameter (p=0.476) were related to the occurrence of dissections.

Conclusions: The present study from a real-world cohort confirms that OCT imaging can play a pivotal role in guiding coronary angioplasty with bioresorbable vascular scaffold (BVS) implantation in complex coronary lesions and could therefore represent a useful tool to improve the procedural outcomes.

EuroPCR Coronary interventions

Euro15A-OP121

Twelve-month clinical results following bioresorbable vascular scaffold implantation in STEMI patients: insights from the multicentre Italian ABSORB registry

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Aims: To evaluate the 12-month clinical outcomes following single or multiple overlapping bioresorbable vascular scaffold (BVS ABSORB) implantation in STEMI patients enrolled in the multicentre Italian ABSORB registry (RAI).

Methods and results: The BVS RAI registry is a spontaneous, ongoing multicentre Italian data collection and is not recipient of funding or benefits originating from the BVS manufacturer. This prospective registry includes all consecutive patients who have undergone unrestricted (including bifurcations, lesions longer than 28 mm, in-stent restenosis, chronic total occlusions, left mains, acute coronary syndromes) successful implantation of one or more BVS. As a part of this registry, a cohort analysis was performed on all STEMI patients that underwent primary PCI with BVS implantation. Between December 2012 and February 2014, 1,232 STEMI patients underwent primary PCI at the participating centres. Of those, 74 (6.0%) received a BVS, 18 (24.3%) of them were multiple and overlapping. Diabetics accounted for 10.8% (8/74) of the patients. Procedural success was obtained in 72 (97.3%) cases without differences between the groups (overlapping BVS 100% vs. single-BVS 96.4%, p=0.5). One patient experienced an in-hospital, non-fatal, reinfarction due to subacute BVS thrombosis, while the other patient had a "slow-flow" phenomenon (final TIMI flow 2). From discharge to 12-month follow-up there was 1 (1.3%) non-cardiac death, 2 (2.7%) non-fatal MIs (of which 1 was a target-vessel MI), 3 (4.1%) TLR and 1 (1.3%) subacute BVS thrombosis (on dual antiplatelet therapy) were reported. In 4 patients (1 [5.6%] overlapping BVS vs. 3 [5.1%] single BVS group, p=0.5) BVS restenosis and BVS thrombosis occurred within 2 months after device implantation, while no events were reported from 2 to 12 months follow-up. All these events were successfully managed with re-PCI.

Conclusions: Single or multiple overlapping BVS implantation in STEMI patients is associated with encouraging 12-month outcomes. Clustering of events within the early period after index procedure suggests the need for careful lesion evaluation and meticulous PCI techniques when implanting BVS in the STEMI setting.

Angiographic and optical coherence tomography insights into bioresorbable scaffold thrombosis: a single-centre experience

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Aims: As bioresorbable vascular scaffolds are being increasingly used in complex "real-world" lesions and populations, bioresorbable scaffold thrombosis cases have been reported. We present angiographic and OCT findings in a series of patients treated in our centre for definite bioresorbable scaffold thrombosis.

Methods and results: Up to 1/6/2014, fourteen patients presented with definite bioresorbable scaffold thrombosis in our centre. Identification of scaffold thrombosis required both angiographic evidence of thrombosis (including 5 mm edge segments) and clinical evidence of acute coronary syndrome, and was classified as acute, subacute, late or very late. OCT was performed in 9 patients at the operator's discretion. Time interval from index procedure to scaffold thrombosis ranged from 0 to 675 days. There were 4 cases with acute, 2 cases with subacute, 5 cases with late and 3 cases with very late thrombosis. Three patients had discontinued both antiplatelet therapies (one before completing one year), while two had discontinued only $P2Y_{12}$ inhibitor. In three of them antiplatelet therapy discontinuation had occurred the week preceding the event. Incomplete lesion coverage by angiography was identified in 4/14 cases, while in two cases with ostial LAD stent implantation there was scaffold protrusion into left main. By OCT, thrombus was visualised in 8/9 patients, incomplete scaffold apposition in 5/9 patients with a malapposition distance of 348 µm (214-482 µm), underexpansion in 2/9 cases and scaffold discontinuity in 2/9 patients. In late and very-late thrombosis, the incidence of malapposed struts was 2.2% (0.9%-3.6%), and the malapposition distance was 520 µm (369-672 µm). Overall, frames with thrombus had lower lumen (4.35 mm [2.61-6.08 mm] versus 5.84 mm [4.11-7.58 mm]; p<0.001) and scaffold area (7.63 mm [6.32-8.95 mm] versus 8.14 mm [6.83-9.46 mm]; p<0.001) compared to frames without thrombus. No difference was found in the incidence of frame-level malapposition (p=0.75), with the malapposition area being non-significantly higher in frames with thrombus (1.54 mm [0-3.44 mm] versus 0.44 mm [0.00-6.70 mm]; p=0.18). In acute and subacute scaffold thrombosis, suboptimal implantation was the main mechanism with the main contributing factors being incomplete lesion coverage, scaffold protrusion in left main and extensive strut overlap. Findings in late and very-late scaffold thrombosis were also suggestive of suboptimal flow conditions, often in combination with antiplatelet therapy discontinuation. In three cases, imaging gave only hints as to the possible substrate, without clear identification.

Conclusions: In a series of 14 patients with bioresorbable scaffold thrombosis, 0-675 days after implantation, suboptimal implantation with malapposition, underexpansion and incomplete lesion coverage emerged as the main substrate both for early and late events. Dual antiplatelet therapy discontinuation was also identified as a contributor in several late events. Our observations suggest that a number of potential triggers for bioresorbable scaffold thrombosis could be avoided and might warrant prospective validation.

Periprocedural myocardial injury and predictors of small side branches occlusion in coronary bifurcation intervention

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Aims: Occlusion of SB may result in significant adverse clinical events. We aim to characterise periprocedural myocardial injury (PMI) and predictors of small side branch (SB) occlusion in coronary bifurcation intervention.

Methods and results: In this study, 925 patients with 949 bifurcation lesions (SB≤2.0 mm) treated with percutaneous coronary intervention (PCI) were studied. All clinical characteristics, coronary angiography findings, PCI procedural factors and quantitative coronary angiographic analysis data were collected. Creatine kinase-myocardial band activity was determined by using an immune-inhibition assay and confirmed by mass spectrometry. We compared the incidence of PMI between no SB occlusion group and SB occlusion group. Multivariate logistic regression analysis was performed to identify independent predictors of small SB occlusion. SB occlusion occurred in 86 (9.1%) of 949 bifurcation lesions. Of SB occlusion, total occlusion occurred in 64 (74.4%) lesions and a decrease in Thrombolysis in Myocardial Infarction (TIMI) flow occurred in 22 (25.6%) lesions. We observed a significantly higher incidence of PMI in each cutoff level in patients with SB occlusion compared with those without SB occlusion. True bifurcation lesion, irregular plaque, pre-dilation in SB, preprocedural SB TIMI flow grade, preprocedural diameter stenosis of distal MV, preprocedural diameter stenosis of bifurcation core, bifurcation angle, diameter ratio between MV/SB, diameter stenosis of SB before MV stenting and MV lesion length were independent risk factors of SB branch occlusion.

Conclusions: Small SB occlusion was significantly associated with PMI. True bifurcation lesion, irregular plaque and 8 other predictors were independent predictors of SB occlusion.

euroPCR Coronary interventions

Euro15A-OP124

Influences of vessel curve and bifurcation around plaque on the plaque progression and rupture risk in coronary artery disease

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Aims: To reveal the influence of geometrical features of coronary arteries such as vessel curve or bifurcation on atherosclerotic plaque rupture and progression risk, we performed a systematic evaluation of the coronary arterial disease haemodynamics and to reveal types of plaque with high progression and rupture risk.

Methods and results: The present study was based on computational fluid dynamics models with idealised geometries and patient specific geometries to examine the details of the patients haemodynamics with four different types of coronary artery disease. To do this we created 3D idealised coronary artery geometries. The geometrical features of coronary arteries were determined by the average value of coronary computed tomography angiography data from 100 patients. Two types of 75% stenosis disease were placed at the left anterior descending artery-diagonal branch bifurcation site of the idealised model: the "contralateral" and "ipsilateral" sites. Fractional flow reserve (FFR) was predominately 0.68 and 0.51 at the "contralateral" and "ipsilateral" plaque, respectively. The maximum wall shear stress and its fluctuation: oscillatory shear index demonstrated 386.1 Pa and 0.91 at the "ipsilateral" plaque, and these values were 315.6 Pa and 0.92 at the "contralateral" plaque. The stream lines went through the bifurcation area without severe flow acceleration or flow detachment in the "contralateral" model, but the flow of the bifurcation area in the "ipsilateral" model demonstrated flow disturbance, resulting in the extremely low FFR value and extremely fluctuating high-wall shear stress value. Next, two types of 75% stenosis disease were placed at the proximal portion of the idealised right coronary artery: "convex" and "concave" sites. Moreover, two patient-specific 50% stenosis geometries created from the computed tomography angiogram were used for analysis, which were named the "patient specific convex" model and "patient specific concave" model. In idealised models, even though FFR showed no difference irrespective of the plaque sites, the maximum wall shear stress and oscillatory shear index in the "convex" site were 149.9 Pa and 0.46, and these values in the "concave" site were 128.1 Pa and 0.33. In patient specific models, even though FFR had also showed no differences irrespective of the plaque site, the maximum wall shear stress and oscillatory shear index in the "convex" site was 62.6 Pa and 0.33, and these values in the "concave" site were 52.1 Pa and 0.20.

Conclusions: Coronary disease at the convex site of a curved lesion has a higher plaque rupture risk than that at the concave site of a curved lesion. In the bifurcation area, the "ipsilateral" model had more severe ischaemic disease present and had a higher plaque rupture risk, resulting in a high-risk patient with acute coronary syndrome. Treatment strategy decisions for coronary disease at the curved lesion and bifurcation area, one should consider not only the degree of the lumen stenosis and the severity of the coronary ischaemia, but also the risks of the plaque rupture and plaque progression.

euroPCR Coronary interventions

Euro15A-OP125

How the bifurcation angle impacts the fate of the side branch after main vessel stenting: a retrospective analysis of 1,200 consecutive bifurcation lesions in a single centre

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Aims: The bifurcation angle (BA) was thought to impact the risk of side branch (SB) occlusion in coronary bifurcation patients undergoing percutaneous coronary intervention (PCI). We aim to investigate the effect of BA on SB occlusion after main vessel (MV) stenting.

Methods and results: One thousand, one hundred and seventy-one (1,171) consecutive patients with 1,200 bifurcation lesions undergoing the one stent or provisional two-stent technique were studied. Lesions were divided into low-angle and high-angle groups using the median BA (52°). Multivariate logistic regression analysis was performed to identify independent predictors of SB occlusion. SB occlusion occurred in 88 (7.33%) of 1,200 bifurcation lesions treated with one stent technique or MV stenting as first strategy. The rate of SB occlusion was significantly higher in high-angle group (63/600, 10.5%) than the low-angle group (25/600, 4.2%) ($p<0.001$). The rate of SB occlusion increased significantly across quartiles of BA: from 3.63% in the first quartile of BA, to 4.71% in quartile II, to 8.14% in quartile III to 12.97% in quartile IV ($p<0.001$). Multivariable analysis showed that a high angle was an independent predictor of SB occlusion (odds ratio: 1.026, 95% confidence intervals: 1.014-1.037, $p<0.001$). Plaque distribution at the same side of SB, MV TIMI flow grade before stenting, preprocedural diameter stenosis of bifurcation core, diameter ratio between MV/SB and diameter stenosis of SB before MV stenting were also independent predictors of SB occlusion.

Conclusions: High BA was an independent predictor of SB occlusion after MV stenting. The occlusion risk of SB with high BA should not be ignored.

Impact of side branch remodelling in coronary bifurcation lesions on clinical the outcome of provisional stenting

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Aims: We assessed the impact of SB constrictive remodelling on the clinical outcome of provisional bifurcation stenting.

Methods and results: In a prospective multicentre registry of provisional stenting in 300 non-left main coronary bifurcation lesions, we analysed 151 lesions in which the IVUS examination was completed in both main vessel (MV) and SB before and after coronary intervention. The SB remodelling index was defined as an external elastic membrane (EEM) area in the minimal lumen site / EEM area in the distal reference in the IVUS analysis. The lesions were divided into the three groups according to SB remodelling index (NEG: index <0.95, n=75, NOR: 0.95-1.05, n=34, POS: >1.05, n=41). The patient background did not differ among the groups. In the geographic characteristics, significantly narrower bifurcation angles were noted in both NEG (56.0±18.3°) and POS groups (56.1±23.6°) compared to the NOR (67.4±27.2°) group. The frequency of true bifurcation lesion was 38% in the NEG, 33% in the NOR and 63% in the POS group, respectively ($p<0.01$). Consecutive lower remodelling index was observed in the proximal MV in the NEG group and higher index was in the distal MV in the POS group. The quantitative angiography analysis (QCA) and the IVUS before the intervention showed smaller minimal lumen diameter and area in the proximal MV in the NEG group. Although MV stent size and length were similar, in the additional MV stenting, longer stent was required in the NEG (21.5±5.6 mm vs. 16.4±5.8 mm in NOR, 12.7±5.0 mm in POS, $p<0.05$) and it occurred less frequently in the POS group (7% vs. 27% in NEG, 32% in NOR, $p<0.05$). Smaller balloons were used for the kissing balloon inflation in the MV in the NEG and in the SB in the POS group. SB-related complications, which included myocardial infarction, SB dissection, SB occlusion, and SB stenting, were numerically frequent in both NEG (12.0%) and POS (7.3%) groups compared to the NOR group (5.9%), which was not statistically significant. The lumen size or stenosis after the intervention in each branch did not differ significantly in the QCA or the IVUS analysis. Major adverse cardiac events up to 9-month follow-up including myocardial infarction, cardiac death, stent thrombosis, and target vessel revascularisation were 4.0%, 8.8%, and 7.3%, respectively (not significant). No significant differences were observed in the diameter stenosis of each branch among the groups.

Conclusions: Negative SB remodelling is likely to coexist with a diffuse proximal MV lesion, which requires a longer additional MV stent, while the positive SB remodelling is likely to coexist with a true bifurcation lesion with tight SB lesion and consecutive positive remodelling in the distal MV. The SB remodelling with specific changes is likely to lead to SB-related complications; however, a similar midterm outcome is obtainable under the IVUS-guidance.

An angiographic tool for risk prediction of side branch occlusion in coronary bifurcation intervention: the RESOLVE score system

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Aims: The risk of side branch (SB) occlusion is the most important consideration affecting the selection of an optimal intervention strategy. We aim to establish a scoring system to evaluate the risk of SB occlusion in patients undergoing coronary bifurcation intervention.

Methods and results: We studied 1,545 consecutive patients undergoing percutaneous coronary intervention for bifurcation lesions (1,601 lesions treated with a single stent technique or main vessel (MV) stenting first strategy). Of these, 1,200 lesions were used for the construction of the risk model and score system, 401 lesions were used for validating the model. A multivariable risk score was constructed with incremental weights attributed to each component variable according to their estimated coefficients. SB occlusion after MV stenting was defined as any decrease in TIMI flow grade or absence of flow in SB after MV stenting. SB occlusion occurred in 118 (7.37%) of 1,601 bifurcation lesions. In multivariable analyses, six variables were independently associated with the risk of SB occlusion (model C-statistic=0.80 (95% confidence interval [CI]: 0.75 to 0.85) with good calibration. For the 401 lesions included in the validation cohort, the RESOLVE score had a C-statistic=0.77 (95% CI: 0.69 to 0.86), with good calibration. SB occlusion rates in the validation cohort increased significantly across different risk groups from 0.0% in the low-risk group to 3.8% in the intermediate risk group, to 19.8% in the high-risk group ($p<0.001$).

Conclusions: The RESOLVE score, a novel angiographic risk stratification tool, can help identify patients at risk for SB occlusion during bifurcation intervention.

EuroPCR Coronary interventions

Euro15A-OP128

Predictors for crossover from the one stent to the two stent technique while treating coronary bifurcation lesions

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Aims: To investigate the predictors for crossover from one to two stents in the treatment of coronary bifurcation lesions.

Methods and results: We analysed 923 consecutive patients who underwent PCI involving a bifurcation lesion. We evaluated the clinical setting they presented with to the catheterisation laboratory and the type of their bifurcation according to the Medina classification. We than performed univariate and multivariate analysis to predict crossover from one to two stents. Of these, 38% of the patients presented with stable angina, 47% with acute coronary syndrome, 15% with ST-elevation myocardial infarction; 58% presented with acute angle (<70) bifurcation. One stent was planned in 644 patients (70%), crossover to two stents was observed in 83 patients (13%). In a univariate analysis predictors for crossover were: Medina 1,1,1 (p=0.004) and side branch dilatation (p=0.001). In a multivariate analysis side branch predilatation was associated with OR 1.5, CI:1.1-2.3, p=0.002 for crossover to two stents.

Conclusions: Side branch predilatation was the strongest predictor for crossover from one to two stents in a coronary bifurcation lesion and should be avoided.

EuroPCR Coronary interventions

Euro15A-OP129

The single string technique for complex coronary bifurcation stenting

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Aims: Double-stent techniques may be required for complex bifurcation lesions. Currently, applied methods all have their morphologic or structural limitations with respect to wall coverage, multiple strut layers or apposition rate. The study aims to evaluate the adequacy and feasibility of the "single string" bifurcation stenting technique.

Methods and results: "Single string" is a novel stenting technique for complex bifurcation lesions, where first the side branch (SB) stent is deployed with one single proximal stent-cell protruding into the main branch (MB). Second, the MB is wired through that protruding stent-cell and a stent is deployed into the MB across it. Procedure is completed by final kissing balloon dilation. "Single string" was first tested *in vitro* (n=20) using silicone bifurcation phantoms and next applied in patients (n=11) with complex bifurcation stenoses. All *in vitro* procedures were performed successfully, crossing the most proximal stent-cell in 100% of cases. Duration of the procedure was 23.0±7.9 minutes, fluoroscopy time was 9.4±3.5 minutes. Result was evaluated by OCT, showing fully apposed struts in 83.0±9.2% in the bifurcation area. Residual area obstruction in the MB was 6.4±5.6% and 25.0±16.9% in the SB, evaluated by micro-computed tomography. No strut fracture was identified. *In vitro* data suggest that the "single string" technique can be performed with most of the current stent platforms having an open cell design. All the human cases were performed successfully with excellent angiographic result. Residual area stenosis was 27±8% in MB and 29±10% in SB by 3-dimensional quantitative coronary angiography. No relevant periprocedural enzyme rise was observed. During follow-up (14±5 months) no adverse clinical events (death, myocardial infarction, target vessel revascularisation) were noted.

Conclusions: The "single string" technique for complex bifurcation lesions is shown to be adequate *in vitro* and feasible in humans with favourable results in terms of stent overlap, malapposition rate and low residual obstruction in both MB and SB.

Microscopic assessment of the jailed guidewire in the treatment of coronary bifurcation lesions

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Aims: The jailed wire technique is a useful strategy in the treatment of bifurcation lesions by provisional stenting. However, these wires can be damaged or even be broken during its removal. The aim of our study was to evaluate the induced damage in polymeric and non-polymeric jailed wires.

Methods and results: Between January 2011 and December 2012, we performed an observational study evaluating by stereoscopic microscopy 135 jailed guidewires (45 non-polymeric and 90 polymeric) that were used in the treatment of bifurcation lesions. We assessed the distal 40 mm in every guidewire using zoom lenses. The induced damage in the guidewires was classified as mild, moderate or severe. The clinical characteristics were similar in groups of patients treated with polymeric or non-polymeric wires. However, operators selected polymeric wires more frequently in complex bifurcations and in diabetic patients. Some degree of microscopic damage was evidenced in 25 (18%) of the analysed wires. There was not any complete rupture of the wire, and severe damage was induced only in two cases (1.5%). Paradoxically, we observed more frequent damage in the non-polymeric than in polymeric wires (53% vs. 1.1%; p<0.001).

Conclusions: Jailed wires during interventional procedures of bifurcation lesions commonly have microscopic damage. Although polymeric wires were used in more complex bifurcations lesions, they presented less damage than the non-polymeric wires.

Intracoronary electrocardiography based strategy for treatment of coronary bifurcation lesions: a method for reduction of periprocedural myonecrosis and major cardiac adverse events at 12-months

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Aims: To evaluate influence of icECG-guided strategy for treatment of side branch after stenting main vessel (in provisional T-stenting strategy) on periprocedural myonecrosis (troponin elevation) and one-year major adverse cardiac events rates (death, MI, TVF).

Methods and results: One hundred and thirty-two (132) patients with stable or unstable angina followed at least 12 months. Inclusion criteria: coronary bifurcation lesions, RVD≥2.5-4.5 mm; SB RVD ≥2.0 mm. Exclusion criteria: STEMI; LM stenosis; CTOs; lesion of interest located at infarct-related artery; LVEF<30%; moderate/severe degree valvular disease; primary cardiomyopathy; L/RBBB, atrial fibrillation/flutter with no identifiable isoelectric line. Intracoronary ECG-guided strategy was followed: after stenting main vessel, icECG from SB was recorded; if ST-segment elevation was recorded then balloon dilatation±kissing balloon inflation was performed. Depending on results from icECG (occurrence of ST-segment elevation, STE) six groups were formed: group 1 - SB%DS>50% after stenting, with icECG STE in side branch region, no further intervention on SB. group 2 - SB%DS>50% after stenting, no icECG STE; no additional treatment of side branch. group 3 - SB%DS>50% after stenting, icECG STE in side branch region, balloon dilatation of side branch ostium and icECG STE was eliminated afterwards. group 4 - SB%DS>50% after stenting, icECG STE in side branch, ballooning of SB ostium, but sustained icECG STE on final record from side branch. group 5 - icECG STE in side branch region after stenting, but ostial stenosis was less than 50% and no treatment performed. group 0 - SB%DS<50% after stenting and no icECG STE. The rates of periprocedural myonecrosis and cumulative MACE rates at 12 months are categorised as follows {No Tn increase / Tn increase / p /MACE (-) / MACE (+) /p] Group 0 10 (48%) 11 (52%) p <.001 21 (100%) 0 (0%) p=.003; Group 1 2 (10%) 10 (91%) 8 (67%) 4 (33%); Group 2 19 (54%) 16 (46%) 28 (85%) 5 (15%); Group 3 24 (69%) 11 (31%) 29 (83%) 6 (17%); Group 4 1 (5%) 20 (95%) 12 (57%) 9 (43%); Group 5 5 (50%) 5 (50%) 5 (50%) 5 (50%)

Conclusions: Intracoronary ECG guided treatment of SB after main vessel stenting is a simple and no-cost strategy for identification of side branches requiring treatment. icECG guided strategy for treatment of side branches after stenting main vessel reduces periprocedural myonecrosis and MACE at 12 months.

EuroPCR Coronary interventions

Euro15A-OP132

Clinical benefit of a combined enhanced stent and vessel imaging technology in bifurcation stenting

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Aims: Combined enhanced stent and vessel imaging technology (CESVI) enables us to visualise the stent in relation to the vessel lumen by processing the conventional post-deployment angiogram. In this new generation of the enhanced stent imaging tool (ESI), the balloon markers are used as a reference to combine the ESI image with the injected vessel image. The result is displayed as a dynamic sequence fading in and out between the stent and the vessel allowing us to optimally see their relative position. We hypothesised about whether this imaging technology could help in assessing the stent position when a bifurcation is involved.

Methods and results: We collected 68 conventional post-deployment angiograms from 37 consecutive patients who underwent PCI in our facility from November 2013 to January 2014, on an Innova 2100-IQ cardiovascular system (GE Healthcare, Pontoise, France). Out of these 68 angiograms, 29 bifurcation lesions were identified and treated with the provisional approach (1 stent in the main branch). Related angiogram images were retrospectively processed with the CESVI technology. The perceived image quality of CESVI, a combination of both the rendered injected vessel and the enhanced stent image quality, was rated for each case. Clinical benefit of CESVI was independently assessed for each bifurcation by three experienced interventional cardiologists who retrospectively rated the position of the stent at the bifurcation level, first with the conventional post-deployment angiogram alone and then using in addition the CESVI image. The increasing level of confidence when evaluating the stent position was also graded, from 0 to 3 by the reviewers. The perceived image quality of CESVI, was rated poor, sub-optimal and optimal in respectively 10%, 28% and 62% of the cases. In 10 cases out of 29 (34%), at least 2 of the 3 reviewers found their assessment of the stent position changed by the CESVI result, either by strengthening the level of confidence in their initial assessment or by changing their assessment. In average, the level of confidence was significantly higher when adding CESVI to the conventional angiogram (1.66 vs. 1.91, $p<0.05$). Among these 10 cases, seven lesions only covered the proximal or the distal part of the main branch; in that specific configuration CESVI proved to better help assess if the stent covered the lesion without overlapping the side branch ostium.

Conclusions: In lesions located at a bifurcation, combined enhanced stent and vessel imaging (CESVI) helps in assessing the stent position in relation to the side branch. This may be particularly useful when the lesion of the main vessel is extending up to the ostia of the side branch and as such requires a precise positioning of the stent. In further studies, we will evaluate prospectively the interest of this technique in guiding stent deployment by getting this image at the time of the stent placement right before its deployment.

EuroPCR Coronary interventions

Euro15A-OP133

OCT evidence of stent distortion in bifurcation lesions

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Aims: Anecdotal cases of bifurcation lesion stenting performed with final kissing balloon (FKB) inflation, and imaged with optical coherence tomography (OCT) at the end of procedure, indicated that a wrong FKB technique can lead to marked stent malapposition with stent distortion. The aim of this study was to quantify the occurrence of this OCT-defined stent distortion, despite the achievement of acceptable angiographic results.

Methods and results: Fifty-one *de novo* bifurcation lesions were included in this study, 28 in the left main/left anterior descending artery (54.9%) and 23 in the left anterior descending artery-diagonal (45.1%). The FKB technique was done in all cases with good final angiographic results. OCT was obtained immediately after FKB to assess in-stent minimal lumen area (MLA), stent expansion, stent eccentricity index (SEI), and malapposition (mainly in the stented segment proximal to side branch (SB) take-off). Based on OCT findings, the stented bifurcation lesions were classified into 2 groups: group with stent distortion (malapposition distance ≥1 mm and in-stent minimal cross sectional area [CSA] <70% of nominal CSA) and control group (malapposition distance <1 mm and/or in-stent CSA >70% of the nominal CSA). We observed 4 cases of stent distortion (7.8%) characterised by a mean stent malapposition distance of 1.49±0.3 mm and severe underexpansion (48.38±9.67%). Stent distortion was due to the wrong passage of guidewires, while performing wire exchange during the FKB technique: in fact, in all 4 cases at least one guidewire entered the stent laterally through a non-apposed stent cell instead of entering from the natural inflow.

Conclusions: OCT has a great value during the FKB technique to ensure the correct passage of guidewires through the target main vessel and side branch ostium and avoid stent distortion.

Concept and practice of 5 Fr transradial percutaneous treatment of coronary bifurcations with conventional devices

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Aims: To explore how to extend the advantages of slender transradial intervention to the treatment of lesions simultaneously involving two coronary branches using the non-dedicated devices normally available in every catheterisation laboratory.
Methods and results: Overall, 40 patients (mean age 64±9 years, 28 men) with bifurcations lesions of increasing complexity were enrolled in this study. Only conventional devices were used for treatment (workhorse 0.014 inch coronary guidewires, regular balloons, market leader drug-eluting stents, etc.). True bifurcations accounted for 70% of cases, with the left anterior descending artery/diagonal branch being the most frequent bifurcation site (n=19, 47.5%), followed by left circumflex/obtuse marginal branch (n=11, 27.5%), right coronary artery bifurcation (n=7, 17.5%) and left main coronary artery bifurcation (n=3, 7.5%). Procedural success was achieved in 39 (97.5%) patients through a 5 Fr guiding catheter whereas in one case, a 5 Fr to 6 Fr guiding catheter upgrade was required to optimise side branch treatment after the main bifurcation vessel have been secured. Main vessel stenting with single balloon dilation towards the side branch followed by proximal optimisation technique was the most frequently implemented strategy. No major procedural complication was recorded. Notably, each bifurcation intervention provided a valuable piece of knowledge for a more confidant approach for the next procedure, thus allowing an outlining of relevant tips and tricks.
Conclusions: This concept series demonstrates the feasibility of 5 Fr bifurcation intervention with non-dedicated devices and, in a preliminary fashion, supports its efficacy and safety over a wide range of bifurcation anatomy and complexity. Undoubtedly, careful methodology is of paramount importance to increase success and avoid complications.

Treatment of bifurcation lesions with a thin-strut DES with bioresorbable polymer: clinical outcomes of the CENTURY II trial

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Aims: Clinical outcomes of PCI in coronary bifurcation lesions are in general inferior when compared to non-bifurcation lesions even when treated by drug-eluting stents (DES). Comparison of the performance of the new Ultimaster sirolimus-eluting stent with bioresorbable polymer (BP-SES) and an open cell design with the XIENCE everolimus-eluting stent featuring durable polymer coating (DP-EES), was performed in this complex clinical setting.
Methods and results: CENTURY II is a large, randomised, single-blind, intercontinental study comparing Ultimaster BP-SES and XIENCE DP-EES. Out of 1,119 enrolled patients, 194 patients (269 lesions) had at least one bifurcation lesion treated and were randomly assigned to either BP-SES (95) or DP-EES (99) group. The study had 100% on-site source data verification and an independent clinical event committee adjudicated all events. The primary endpoint was target lesion failure (TLF), a composite of cardiac death, target vessel related MI and clinically driven target lesion revascularisation (TLR). Two-year follow-up is currently ongoing. There were no significant differences in demographic characteristics, approximately 28% of the patients were female, 31% of the patients had diabetes mellitus, 74% hypertension and 32% had previous MI. Most of the patients were admitted with stable angina (50%). Patients treated with BP-SES had significantly more multivessel disease (57.9% vs. 43.4%; p=0.04) and, consequently, significantly more multivessel treatment (34.7% vs. 20.2%; p=0.02). Most of the bifurcation lesions were classified as 1,1,0 (29%), followed by 1,1,1 (22%) and 0,1,1 (10%) according to the Medina classification and the vessel most frequently treated was LAD (48%), with no significant differences between the study arms. The number of stent implanted and the total stent length per patient were significantly higher in BP-SES group: 1.7±0.8 stents vs.1.6±0.9 (p=0.05) and 35.7±17.0 mm vs. 31.8±21.8 (p<0.01), respectively. Clinical outcomes reported at 12-months were as follows: for patients treated with BP-SES, numerically lower rates for TLF, (5.3% vs. 8.1%, p=0.43), Following rates of target vessel failure (6.3% vs. 9.1%; p=0.47), cardiac death (0% vs. 3%; p=0.09), and MI (3.2% vs. 3.0%; p=0.96) were reported, without reaching statistical significance. There was one stent thrombosis in each arm.
Conclusions: Both stents showed good clinical outcomes up to 12-months and long-term follow-up is expected to give further evidence about the potential benefit of Ultimaster stent design for the treatment of bifurcation lesions. Two-year follow-up data will be available at the time of presentation.

euroPCR Coronary interventions

Euro15A-OP136

Five-year clinical follow-up after treatment of bifurcation lesions with a biodegradable polymer-coated biolimus-eluting stent or durable polymer-coated sirolimus-eluting stent: a substudy of the LEADERS all-comers randomised trial

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Aims: The aim to compare the 5-year clinical outcomes after the treatment of bifurcation lesions using sirolimus-eluting stents (SES) and Biolimus A9™-eluting stents (BES).

Methods and results: The LEADERS trial was a 10-centre, assessor-blind, non-inferiority, all-comers trial, randomising 1,707 patients to treatment with either a BES or a SES. In total there were 497 (29%) patients with at least one bifurcation lesion (BES=258; SES=239). There were no differences in baseline clinical characteristics between the two treatment groups, except that in the BES group more patients presented with silent ischaemia (14.7% vs. 7.1%, p=0.007). There were 233 patients (47% of the total bifurcation group) with a "true'" bifurcation lesion (i.e., with significant side branch involvement). Patients with a true bifurcation were treated more often with a two-stent strategy compared to patients with a "partial" bifurcation (i.e., bifurcation without side branch involvement), although patients were treated with a single-stent strategy in the vast majority of both bifurcation subtypes (BES in true bifurcations: 71.8%, SES in true bifurcations: 73.5%, BES in partial bifurcations: 85.4%, and SES in partial bifurcations: 90.0%). At 5-year follow-up, within the total bifurcation group there were no differences in death (13.6% in BES vs. 12.1% in SES, p=0.648), cardiac death (9.3% vs. 7.5%, p=0.494) or myocardial infarction (12.8% vs. 10.9%, p=0.495). However, the following efficacy endpoints were significantly lower in the BES group than in the SES group: clinically-indicated target lesion revascularisation (TLR) rate (10.1% vs. 15.9%, p=0.0495), any TLR (11.2% vs. 18.8%, p=0.017), clinically-indicated target vessel revascularisation (TVR) (12.0% vs.19.2%, p=0.023), any TVR (14.7% vs. 22.6%, p=0.021), and any revascularisation (21.7% vs. 29.3%, p=0.042). ARC defined definite ST rate (2.3% vs. 4.6%, p=0.177) as well as definite/probable ST rate (3.1% vs. 5.9%, p=0.148) were only numerically lower in the BES group. Very late definite/probable ST rate between 1 and 5 years was also lower with BES, and this difference almost reached statistical significance (0.4% vs. 3.1%, p=0.057), as shown with a landmark analysis with the landmark set at 12 months.

Conclusions: For the treatment of bifurcation lesions, the use of BES lead to superior long-term efficacy compared to SES. Safety outcomes were comparable, with an observed trend towards a lower very late definite/probable ST rate between 1 and 5 years with BES.

euroPCR Coronary interventions

Euro15A-OP137

Comparison of efficacy between first- and second-generation DES in the single-stent approach with final kissing balloon technique for coronary bifurcation

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Aims: In the present study, we compare the clinical outcomes between first-generation drug-eluting stents (1st Gen-DES) and second-generation drug-eluting stents (2nd Gen-DES) for coronary bifurcations treated by single, crossover stenting with final kissing balloon technique (FKB).

Methods and results: We analysed clinical data from 910 consecutive patients (995 lesions) who underwent percutaneous coronary intervention (PCI) with DES. PCI for bifurcated lesion was performed for 134 patients (135 lesions) using first- or second-generation DES between January 2007 and October 2011 (1st Gen-DES: 63 patients/63 lesions vs. 2nd Gen-DES: 71 patients/72 lesions). In all cases, lesions were treated by single stent implantation with FKB. The primary endpoint was MACE (major adverse cardiac events), defined as cardiac death, myocardial infarction and target lesion revascularisation at three years. There were no significant differences in patient characteristics between two groups. There were no significant differences in lesion location, stent size, stent length and other lesions and procedure characteristics. Higher binary restenosis and late loss were observed in 1st Gen-DES group. At three years, MACE was significantly higher in 1st Gen-DES group (1st Gen-DES: 14.2% vs. 2nd Gen-DES: 1.4% p=0.017).

Conclusions: In comparison to first-generation DES, the use of second-generation DES is more beneficial for coronary bifurcated lesions treated with FKB after a single-stent approach.

EuroPCR Coronary interventions Euro15A-OP138

Myocardial infarction rates in bifurcation lesions: are they still elevated after the use of contemporary, highly deliverable drug-eluting stents with novel, flexible designs?

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Aims: In bifurcated target lesions (BL), percutaneous coronary interventions (PCI) with second-generation drug-eluting stents (DES) showed higher rates of myocardial infarction (MI) and periprocedural MI. The use of flexible, highly deliverable novel generation DES with thinner struts and/or novel stents designs, which accommodate well to vessel tapering, was recently associated with particularly low MI rates in all-comers; but it is unknown whether such modern DES still have a higher risk of periprocedural MI when being implanted in BL.

Methods and results: We compared in the data of the DUTCH PEERS trial the 2-year clinical outcome of patients with at least one BL versus patients with non-BL only. All patients were treated with novel generation Resolute Integrity (Medtronic) or Promus Element stents (Boston Scientific). Among patients treated for BL, we also assessed the potential impact on clinical outcome of single versus two-stent strategies, final kissing-balloon inflations and the size of the side branch. Target vessel failure (TVF), the primary endpoint of the DUTCH PEERS, is a composite of cardiac death, target-vessel related MI and clinically driven target-vessel revascularisation. Two-year follow-up was available in 1,810 of all 1,811 patients (99.9%). The TVF rate (9.2% vs. 7.9%; p log-rank=0.33) was similar for patients with BL vs. non-BL. Patients with BL had a higher rate of target vessel-related MI (3.4% vs. 1.6%; p=0.02), due to a significantly higher incidence of periprocedural MI (3.2% vs. 1.0%; p<0.01). The rate of definite stent thrombosis was similar and low after treatment of patients with BL and non-BL only (0.4% vs. 1.0%; p=0.38). Among patients with BL, there was no significant difference in target vessel-related MI between lesions with side branches ≥2.0 mm versus <2.0 mm (3.8% vs. 2.4%; p=0.58) and the use of final kissing-balloon inflations or not (4.3% vs. 3.1%; p=0.50). PCI of BL with a two-stent technique resulted in a higher periprocedural MI rate than with a single stent approach (9.0% vs. 2.1%; p<0.01).

Conclusions: Despite an overall low incidence of periprocedural MI following the implantation of novel, highly deliverable DES, patients with BL still had a significantly higher risk of periprocedural MI. Nevertheless, the similar and low rates of the composite clinical endpoint target vessel failure in patients with and without BL imply a high safety and efficacy of the DES used.

EuroPCR Coronary interventions Euro15A-OP139

Bifurcation stenting failure rates determined from the CVPath Institute Autopsy Registry on BMS and 1st- and 2nd-generation DES

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Aims: To determine the prevalence and mechanism of stent failure in coronary bifurcation cases at autopsy.

Methods and results: We evaluated 572 patients with 780 stented lesions and identified 85 lesions as involving bifurcations (11.9%), treated with BMS (n=18, 21%), 1st-gen DES (n=53, 62.3%) and 2nd-gen DES (n=14, 16.5%). The mean age was 63±13 years and the duration of implant was 379±422 days. Bifurcation lesions were treated with an average of 1.7±1.16 stents. Prevalence of stent thrombosis was 39.6% for 1st-gen DES, 28.5% for 2nd-gen DES and 11.1 for BMS, reaching a borderline significance (p=0.07). Restenosis was seen in 7.5% of 1st-gen DES and 7.1% of 2nd-gen DES, respectively, as compared to 16.6% in BMS (p=0.5). Stent fracture was significantly more frequent in 1st-gen DES (37.7%) compared to 2nd-gen DES (7.1%) and BMS (0%) (P<0.001). One stent was used in 49 cases (57.6%), two stents in 23 cases (38.8%) and 3 or more stents in 13 cases (15.3%). The overall stent thrombosis rate was 22.5% when single stents were used, 39.1% when 2 stents were used and 53.8% when ≥3 stents were used.

Conclusions: The key pathological finding after treatment of bifurcated coronary lesions with BMS was restenosis (16.6%), while thrombosis was predominant in 1st- and 2nd-gen DES (39.6 and 28.5%, respectively). Fracture of stent struts was increased in 1st-gen DES. Overall stent thrombosis rate increased with the number of stents used.

euroPCR Coronary interventions

Euro15A-OP140

Immediate results and one-year follow-up of patients with bifurcation coronary lesions treated with everolimus-eluting bioabsorbable scaffold

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Aims: To analyse the feasibility and midterm results of everolimus-eluting bioabsorbable vascular scaffold (BVS) for the percutaneous treatment of bifurcation coronary lesions.

Methods and results: Our study includes a group of 203 patients with 221 bifurcation coronary lesions treated with BVS. Baseline ultrasound study (IVUS) was conducted in 77 (49) lesions. After BVS implantation the geometry of the scaffold was evaluated by IVUS in 75 bifurcations (34%) and by optical coherence tomography (OCT) in 81 (37%). Creatine kinase and troponin were serially measured in all patients after the procedure. Myocardial infarction and stent thrombosis were defined according to the Academic Research Consortium criteria. Clinical follow-up was achieved by medical visits or telephone calls in all patients. In 150 patients (74%), an angio-CT scan was conducted at 6-months follow-up. The mean age was 58±9 years. Most of the patients were male (85%) and an acute coronary syndrome was the main clinical presentation (55%). The most frequent location was at the left anterior descending – diagonal artery (139, 63%). The demography of the bifurcation following the Medina classification was as follows: (1,1,1) in 76 (34%); (1,1,0) in 49 (22%); (0,1,1) in 17 (8%); (0,1,0) in 41(18%); (1,0,1,) in 10 (4%),(1,0,0) in 24 (11%) and (0,0,1) in 4 (2%). In 209 lesions (95%) the bifurcation was treated with a single BVS. In 92 lesions, the BVS was implanted in the main branch (MB), without further intervention on the side branch (SB). In 29 lesions, the BVS was implanted in the MB after SB angioplasty and in 88 the SB was post-dilated through the cells of the BVS after MB scaffolding. SB post-dilation was conducted with single balloon in 48 instances, with modified kissing balloon in 31 and with sequential dilation SB-MB-SB in nine. The mean balloon diameter used for the SB was 2.3±0.3 mm and was inflated at nominal pressure. In three instances, focal fracture of the BVS was observed by OCT after balloon dilation of SB. In these cases the geometry of the BVS was restored after balloon post-dilation of the MB. In 12 lesion (5%), complex stent repair of the bifurcation was needed (T-stenting in 6, culotte technique in 4 and V-stenting in 2). Angiographic success was obtained in all lesions. Four (2%) patients had a periprocedural myocardial infarction. Two patients (1%) had a subacute thrombosis and one of them (0.5%) died. After a mean clinical follow-up of 13±6 months, 150 patients with 156-scaffolded bifurcations (70%) were evaluated with angio-CT scan. Patency of the SB was observed in all cases. Restenosis of the scaffold was documented in six cases by CT and in three by angiography. In all nine, restenosis (4%) target lesion revascularisation was conducted. One patient died at 4 months follow-up due to late thrombosis. The remaining patients are symptoms-free.

Conclusions: Treatment of bifurcation coronary lesions with BVS is feasible and safe, with a low rate of adverse cardiac events at one-year follow-up.

euroPCR Coronary interventions

Euro15A-OP141

Everolimus-eluting bioresorbable vascular scaffold for treatment of coronary bifurcation lesions

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Aims: The present study is aiming to evaluate the feasibility, safety and performance of the everolimus-eluting bioresorbable vascular scaffold for treatment of patients with coronary artery bifurcation lesions in routine clinical practice.

Methods and results: This is an investigator initiated, prospective, single-centre, single-arm, post-market study. Enrolled patients were subjects presenting with silent ischaemia, stable, unstable angina, or non-ST-segment elevation myocardial infarction caused by *de novo* stenotic lesions located in a coronary artery bifurcation with side branch ≥2.0 mm. No restrictions were applied to lesion complexity. Due to the device size availability, a proximal and distal mean lumen diameter within the upper limit of 3.8 mm and the lower limit of 2.0 mm by online QCA was required. Exclusion criteria were minimal and comprised allergies or contraindications to antiplatelet medication, female patient with childbearing potential or currently breastfeeding, acute ST-segment elevation myocardial infarction and post-CABG patients. To provide insights on the coronary bifurcation treatment we performed a full analysis of techniques and material used and we reported the occurrence of the composite endpoint "side branch impairment", previously described in the literature and defined as at least one of the following procedural parameters: 1) side branch TIMI flow grade <3 after main vessel stenting; 2) need of guidewire(s) different from the workhorse wire to rewire side branch after main vessel scaffolding; 3) failure to rewire the side branch after main vessel scaffolding; or 4) failure to dilate the side branch after main vessel scaffolding and side branch rewiring. A total of 54 lesions located at the site of a bifurcation with a side- branch ≥ 2.0 mm were treated. Involvement of both side branch and main vessel (Medina 1,1,1; 1,0,1; 0,1,1) was present in 15 cases (27.8%). In 51 cases, a provisional T-stenting technique was used, in addition 1 T-stenting, 1 culotte and 1 T-stenting and small protrusion techniques were performed. In 18 cases side branch wire protection was used, pre-dilatation and post-dilatation of the main vessel was performed in 44 (81.4%) and 26 (44.4%) cases respectively. An approach with side branch predilatation was adopted in 6 (11.1%) cases mainly when a 2-scaffold technique was used. Side branch dilatation post-main vessel scaffolding was necessary in 18 lesions (33.3%). Final kissing balloon was rarely performed (3 cases) as a sequential ballooning or proximal optimisation technique was preferred in 26 (44.4%) cases. A final TIMI flow <3 in the main vessels was observed in only one case, at the side branch this was reported in 3 lesions. Failure to rewire the side branch was never reported but in one case the operator was unable to recross the scaffold with a small balloon of 1.5 mm in diameter. The overall rate of the composite endpoint of side branch impairment was low as compared with previous reports with metal stents 9.3% (5/54).

Conclusions: The data reported in our investigation are supportive of the concept that BVS could be used safely in bifurcation lesions with side branch ≥ 2.0 mm especially with a single scaffold approach and could provide results similar to metallic stents.

Self-expanding drug-eluting stents in coronary bifurcation lesions at 24-month follow-up: results from the OPEN II trial

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Aims: Results of PCI in coronary bifurcation lesions with balloon expandable stents are often impaired by lack of support at carina, strut deformation, malapposition or excessive metallic burden when treated with 2 stents. The self-expanding STENTYS DES (STENTYS, Paris), designed for a provisional approach, has shown high procedural success and low short-term major adverse cardiac events rate in the OPEN I study. We assessed the long-term efficacy of the STENTYS DES in a real-world population.

Methods and results: In the OPEN II non-randomised study, 207 patients who received the STENTYS paclitaxel-eluting stent in routine coronary bifurcation stenosis were enrolled in 21 European centres between 2011 and 2013. They were followed-up prospectively at 6, 12 and 24 months. Main exclusion criteria included Medina class 0,0,1 chronic total occlusion, unprotected left main artery and STEMI. Mean age was 66±11 years, 78% of the patients were male. Diabetes was present in 30% of patients; 39% of them presented with unstable angina. Medina class 1,1,1 was found in 36% of the patients. Stenting in the side branch was performed in 13% of the procedures. Revascularisation was successful in 99% in the main branch, and 91% in the side branch. Major adverse cardiac events at 6 and 12 months (resp. 10.1% and 13.0%) confirmed that the STENTYS stent is a true alternative to balloon expandable DES for the provisional approach. Final kissing balloon technique appeared not to be required.

Conclusions: The OPEN II study is the largest study assessing the self-expanding STENTYS DES in bifurcation lesions in a routine clinical setting. Long-term rate of major adverse cardiac events at 24-month follow-up and population subgroup analysis will be presented at EuroPCR 2015.

Regular drug-eluting stent versus dedicated bifurcation sirolimus-eluting stent in the coronary bifurcation treatment: the randomised, multicentre, open-label, controlled POLBOS II trial

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Aims: The POLBOS II (POLish Bifurcation Optimisation Strategy) is a randomised trial, in which a sirolimus-eluting stent BiOSS® LIM (Balton, Poland) has been compared with regular DES (rDES).

Methods and results: In five centres in Poland and Spain patients with stable coronary artery disease or NSTE-ACS were assigned 1:1 to one of two treatment strategies: dedicated bifurcation sirolimus-eluting BiOSS LIM® stent versus rDES implantation. Patients with STEMI or Medina type 0,0,1 bifurcation lesions were excluded from the study. Provisional T-stenting was the obligatory strategy. The primary endpoint was the composite of cardiac death, myocardial infarction (MI), and target lesion revascularisation (TLR) at 12 months. Here, we present data (complete in 95%) from the 12-month follow-up. At the time of EuroPCR 2015 final data will be ready. The BiOSS® LIM stent was implanted in 102 patients (50.5%) and rDES was deployed in 100 patients with bifurcation lesions (according to Medina classification true bifurcations were present in 65%). In the BiOSS group there were significantly more patients with diabetes (44.1% vs. 32%, p=0.02), whereas in the rDES group there were significantly more patients with peripheral artery disease (9% vs. 3.9%, p=0.02). The dominant vessel was LAD (BiOSS vs. DES: 41.2% vs 43%) followed by LMS (38.2% vs. 38%, respectively). In the rDES group, there were 24% of sirolimus-eluting stents, 22% of paclitaxel-eluting stents and 46% of everolimus-eluting stents. There were following nominal stent parameters: in BiOSS group 3.74±0.45 mm (proximal diameter) x 3.03±0.43 mm (distal diameter) x 17.83±2.69 mm (length) and in DES group: 3.26±0.48 mm x 19.94±6.32 mm. Except for 1 (1%) case in rDES group and 1 (0.9%) in BiOSS group, all stents were implanted successfully (avg. pressure 14 atm) without any serious periprocedural complications. Side branch treatment with rDES in the BiOSS group and in rDES group was required in 8.8% and 7% of cases, respectively. Final kissing balloon was applied in 32.7% (BiOSS) and 49% (rDES) of cases (p=0.03) and proximal optimisation technique in 37.3% (BiOSS) and 68% (rDES) (p<0.01), respectively. At 30 days in both groups, there was one case of stent thrombosis and subsequent MI. At 12 months (follow-up complete in 95%) the composed primary endpoint was 13.5% in the BiOSS group and 17.9% in rDES group. In BiOSS group there was no cardiac death, and in rDES group, there were three cases. The rates of MI, TLR and TVR were as follows: 2.2%, 11.5%, 14.5% (BiOSS) and 3.4%, 11.2%, 13.5% (rDES), respectively. The rate of clinically driven TLR was 5.2% and 3.4%, respectively.

Conclusions: BiOSS LIM® is a safe and effective device. The cumulative rate of major cardiovascular events was comparable between the BiOSS and rDES groups.

Coronary interventions

Euro15A-OP144

The DEBSIDE study: systematic treatment of the side branch in a bifurcation lesion with a new drug-eluting balloon, one-year results

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Aims: The optimal treatment of the side branch (SB) in a bifurcation coronary lesion is still a debate. Very few studies have evaluated the role of drug-eluting balloon SB inflation after placement of a drug-eluting stent in the main branch (MB). The DANUBIO balloon integrates Speed Pax technology combining an excipient (BTCH) with paclitaxel (2.5 µg/mm). The DEBSIDE study is a prospective non-randomised multicentre study evaluating the DANUBIO balloon for the treatment of SB lesion (SB>2 mm diameter) after placement of a dedicated paclitaxel stent (Nile PAX) in the MB. The DEBSIDE clinical trial was registered at the United States National institute of Health website (NCT01485081).

Methods and results: From 8 French centres, 50 patients (male 78%, diabetic 26%, acute coronary syndrome 28%) with bifurcation lesion were enrolled. After balloon pre-dilatation, placement of the Nile PAX dedicated stent and kissing inflation (80%) without significant residual dissection, a DANUBIO balloon according to the SB size was inflated for 30 s at 9.4±2.2 atm. Coronary angiography pre-procedure, before and after DANUBIO inflation and at 6 months were recorded and analysed by an independent core laboratory. Clinical follow-up was scheduled at 1, 6 and 12 months. The primary endpoint involved 6-month late loss (LL) at the ostium of the SB and secondary endpoints MB L, binary restenosis rate of SB and MB and clinically driven revascularisation rates for main and secondary branches. Bifurcation lesions reached LAD/diag 74%, circumflex/marginal 18% and distal right coronary in 8%. Significant SB lesion (Medina 1,1,1; 1,0,1; 0,1,1) was noted in 64% of the patients. Procedural success rate reached 98% after two additional stents in the main branch. No additional stents were placed in the SB. Two patients without cardiac events did not accept the angiographic control. For the 48 others (96%), the minimal luminal diameter at 6 months of the SB (1.55±0.35 mm) was identical to the post-procedure one (1.52+/60;31 mm) resulting in a very low LL of -0.04±0.33 mm. Accordingly, the SB target lesion revascularisation (TLR) rate reached only 2% at 6 months and did not change at 12 months. For the MB specifically, the TLR reached 6% and 10% at 6 and 12 months, respectively.

Conclusions: Systematic final inflation of a DANUBIO balloon in the side branch after placement of a Nile PAX stent in the main branch for the treatment of a bifurcation lesion results in very low LLL and restenosis rates at the side branch ostium with sustained clinical improvement at one year.

Coronary interventions

Euro15A-OP145

Evaluation of "real-world" bifurcation PCI with dedicated side branch stents

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Aims: Cappella Sideguard, a self-expanding nitinol dedicated side branch bare metal stent, has been introduced for treatment of complex bifurcation lesions. The aim of this paper is to report the clinical effectiveness and safety of this stent when used in *de novo* bifurcation lesions.

Methods and results: The data of all Sideguard cases in our institution (March 2011 to June 2013) was collected from our local PCI database, registry database and discharge summaries. The parameters included demographics, access sites, clinical syndrome, contrast use, fluoroscopy time and total procedural time. The vessels involved, Medina classification, dimensions of main vessel(MV) and side-branch(SB), post-procedural stenosis, success and TIMI flow as well as Major adverse cardiovascular and cerebrovascular events (MACCE) at 6,12 and 24 months were recorded. MACCE was defined as myocardial infarction, death, target lesion revascularisation and stroke (neurological deficit lasting for more than 24 hours). Patients with more than one event were reported by the single most significant event. Lesion success was defined as device success and residual stenosis in the target lesion of more than or equal to 30% and procedural success was defined as lesion success without any MACCE during index admission. A total of 83 patients underwent Sideguard implantation (74 in the European Cappella Registry). Demographics: 62 (74%) males, mean age of 68 years, with the risk factors of smoking (82%), hypertension (58%), previous cardiac procedures (50%), high cholesterol (31%) and diabetes (15%). Of these, 66% were elective cases, 20% NSTEMI and 14% STEMI. 87% of cases were performed radially. All patients received dual antiplatelet agents. Medina classification was 1,1,1 in 79%, reflecting a highly complex population; 79% of the lesions involved the left anterior descending artery/first diagonal. The mean dimensions of MV were 3 (2.25-4) mm by 31.6 (8-56) mm and SB was 2.85 (2.5-3.5) mm by 12.6 (8-40) mm. DES was used in majority of the cases (n=88, MV: 76; SB: 12) followed by drug-eluting balloons (8) and BMS(1). Post-procedural kissing was performed in only14 (16.8%) for significant residual side branch stenosis. The mean contrast used was 189 mls (50-320) fluoroscopy time was18.9 minutes (5.5-62.5) and the total procedural time was 82.8 minutes (44-197). Post-procedural stenosis in 93% of cases was between 0% to 30%. Procedural success was reported in 89.2% of cases with no device failures. Post-procedure TIMI flow was III in 98.7% of cases. MACCE was 6.3% at 6 months, 7.6% at12 months and 15% at 24 months. Sixteen other events were recorded in total. There were 4 deaths during the study period (2 non-cardiac).

Conclusions: This study demonstrates over 85% procedural success with the use of the Sideguard stent in patients with complex bifurcation lesions. The MACCE rate at 1 year appears lower than the recently reported standard two-stent DES approach. Therefore, we conclude that dedicated side branch stents have a role in treating complex bifurcation lesions with a high procedural success rates.

Treatment of bifurcation lesions with a novel dedicated drug-eluting self-expanding stent (AXXESS): single centre first experience

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Aims: The AXXESS stent is a nitinol self-expanding Biolimus A9™ eluting stent that deploys at the carina, providing easy access to the distal branches. The aim of this study was to evaluate the acute performance of the device and the type of strategy intended.

Methods and results: A total of 24 consecutive patients (67±9 years, 70% men, 45% diabetic and 25% with previous revascularisation procedures) were included in our centre. The clinical presentation was ACS all cases (37.5% NSTEMI, 16.8% STEMI). The access was 95.8% by radial approach (7 Fr). The bifurcation treated was: 75% LAD-diagonal; 4.2% CX-marginal; 4.2% RCA-PDA; 16.7% LM-LAD-CX. There were 83.4% of true bifurcations lesions. The most frequent type was Medina 1,1,1 (79.2%), followed by 1,0,0 (12.5%), 0,1,1 (4.2%), 0,1,0 (4.2%). The bifurcation angle was less than 70º in 79.2% of patients. In 37.5% only an AXXESS was implanted, 29.2% AXXESS +MB stent, 20.8% AXXESS +SB stent and in only 12.5% were necessary implant AXXESS +MB+SB stents. Sixteen (16) patients had multivessel disease (66.6%) and complete revascularisation was performed in 95.8% of patients. Antiplatelet therapy was 79.2% clopidogrel, 16.7% ticagrelor and 4.2% prasugrel. Most of the lesions were (70.8%) highly calcified and 45.8% (n=11) long lesions. Only a 4.2% (n=1) of CTOs were treated with AXXESS s. We passed a wire to protect the SB in 91.7% of cases. Differently from what is recommended in the IFU's, we implanted the device over the MB, irrespective of the angulation. Predilatation was done in all cases (25% MB only; 4.2% SB only; 70.8% MB+SB), and the most frequently diameter used was 2.5 and 3 mm (mean 2.6 mm) by 10 mm of length. Balloon PTCA on SB was done in 91% and SB stenting was needed in 25% of cases using a mean stent diameter of 2.79 with a mean length of 16.5 mm. MB distal stent was performed in 50% of cases with a mean diameter of 2.8 mm and with a length of 21.1 mm. All stents used were biolimus eluting stents. Post-dilatation was done in 95.8% (50% MB+SB; 45.8% MB only), and the mean diameter was 3.2 mm, using pressures higher than 16 atm in most lesions (86%). Final kissing was performed in 41.7% of patients. Intracoronary imaging techniques were performed pre-PCI in 4.2% and post PCI in 45.8% (25% OCT vs. 20.8% IVUS). The most frequent diameter used for AXXESS was 3.5 mm (62.5%) and the most frequent length was 14 mm (70.8%). Implant success was achieved in 93.1% of patients. At the end of procedure in 8.3% the SB remain with dissection, but with TIMI 3 flow. In two cases of LMCA bifurcation, the stent was not implanted because the excessive angle prevented it from stabilising, and finally we needed to retrieve them. During a mean follow-up of 203±113 days there was a MACE rate of 8.4% (1 non-CV death and 1 restenosis of SB).

Conclusions: In our series, the AXXESS stent performed well, offering a unique approach to bifurcation treatment. Those with angles wider than 70º should be avoided, as stabilising the stent is far more difficult.

First-in-man real-time assessment of coronary plaque birefringence by polarisation-sensitive OCT

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Aims: We aimed to evaluate the safety and feasibility of a real-time polarisation-sensitive OCT imaging system in human subjects.

Methods and results: Seven patients (5 male and 2 female, mean age 67±6 years) scheduled to undergo PCI on the grounds of stable or unstable angina were included in the study. Two consecutive OCT pullbacks were performed aiming to visualise at least a 20 mm long segment of a native coronary artery. OCT images were acquired using a commercially available OCT catheter (Fastview, Terumo Corporation, Tokyo, Japan), and a custom-made optical frequency-domain imaging system (Wellman Centre for Photomedicine) (centre wavelength: 1.290 nm; bandwidth: 130 nm; axial resolution 8.5 μm; lateral resolution in tissue: 25 μm). This system has the ability to simultaneously record birefringence information during image acquisition and project it over the traditional OCT intensity image in the form of a colour map. Images were acquired with a frame rate of 100 frames/sec and a pullback speed of 20 mm/sec during simultaneous contrast infusion by a power injector with a flow rate of 3 ml/sec. All studies were reviewed offline and reproducibility was examined by the visual assessment of the birefringence colour maps in matched sites of the consecutive pullbacks. Image acquisition was successfully performed in all seven cases, resulting in the visualisation of a mean native coronary artery length of 69.3 mm±8.1 mm with simultaneous recording of the birefringence information. The imaged vessel was the LAD in 1 case, the LCx in 1 case and the RCA in 5 cases. No adverse events were noted during the imaging. The birefringence information could be identified in a variety of plaque types, including normal vessel, fibrous plaque, fibroatheroma, and fibrocalcific plaque and also in two cases with intracoronary thrombi. Visual assessment of the repeatability of birefringence measurements showed good agreement between matched frames of consecutive pullbacks. Although distinct plaques could share the same morphological classification in the traditional OCT intensity images (e.g., fibroatheroma morphology), the patterns of birefringence between them could differ significantly, thus defining potential morphological subtypes (e.g., fibroatheroma with highly-birefringent cap or with lowly-birefringent cap). This finding suggests a potential for a further discrimination of plaque types based on the birefringence signal.

Conclusions: Polarisation-sensitive OCT is a novel imaging modality assessing microstructural features of the plaque in real time, and could potentially provide a more advanced tissue characterisation compared to traditional intensity OCT. This first-in-man application showed the safety and feasibility of this imaging modality in human subjects. Further studies are warranted to evaluate the potential significance of PS-OCT findings.

euroPCR Coronary interventions

Euro15A-OP148

Intracoronary near-infrared spectroscopy assessment of coronary artery remodelling and lipid core burden index in patients with non-ST-segment elevation myocardial infarction

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Aims: Positive remodelling of coronary artery lesions is associated with unstable clinical presentation. Patients with acute coronary syndrome may have a higher incidence of lesions composed of vulnerable lipid-core plaque (LCP), compared to patients with stable angina pectoris. Near-infrared spectroscopy (NIRS) is a validated method to identify LCP. The aim of the present study was to assess coronary artery remodelling and lipid-core plaque with NIRS in patients with non-ST-segment elevation myocardial infarction (NSTEMI).

Methods and results: We studied 25 NSTEMI patients treated with PCI and a single bioabsorbable polymer SYNERGY stent. NIRS acquisition was performed (1) after pre-dilation with a 2.0 mm balloon and (2) after high-pressure stent implantation. The intravascular ultrasound (IVUS) measures included volumes of external elastic membrane (EEM), lumen, plaque+media; and plaque burden. The remodelling index was defined as a ratio of (lesion/average reference) EEM area. Positive remodelling was defined as a remodelling index >1.05 and negative remodelling as a remodelling index <0.95. The NIRS measures included lipid core burden index (LCBI) and $maxLCBI_{4mm}$ (maximum value of LCBI for any of the 4 mm segment). The study population was divided into two groups: culprit lesions with $maxLCBI_{4mm}\geq500$ and $maxLCBI_{4mm}<500$. Among 25 NSTEMI patients (age 60.8±10.1 years; 80% male) $maxLCBI_{4mm}\geq500$ was detected in 13 patients (52%) and $maxLCBI_{4mm}<500$ was seen in 12 patients (48%). The remodelling index was higher in patients with $maxLCBI_{4mm}\geq500$ compared to patients with $maxLCBI_{4mm}<500$: 1.3±0.3 vs. 1.1±0.3, p=0.10. Maximum plaque burden at minimum lumen area site was similar in the two groups: 0.86±0.04 vs. 0.84±0.03, p=0.18. Lesion plaque volume tended to be higher in patients with $maxLCBI_{4mm}\geq500$ compared to patients with $maxLCBI_{4mm}<500$: 248±76 mm^3 vs. 201±88 mm^3, p=0.17. The reduction in plaque volume after stent implantation was reduced by 16±8% in patients with $maxLCBI_{4mm}\geq500$ compared to 15±9% (p=0.82) in patients with $maxLCBI_{4mm}<500$ which was accompanied by an increase in EEM volume of 360±108 mm^3 vs. 424±122 mm^3, p<0.001 and 315±137 mm^3 vs. 372±163 mm^3, p<0.001, respectively.

Conclusions: In NSTEMI patients, $maxLCBI_{4mm}\geq500$ was seen in half of the patients accompanied by a higher positive remodelling index compared to patients with $maxLCBI_{4mm}<500$.

euroPCR Coronary interventions

Euro15A-OP149

Clinical implications of coronary plaque features assessed by optical coherence tomography in patients with stable coronary artery disease

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Aims: Stable coronary artery disease (SCAD) may precede the development of acute coronary syndrome (ACS). Some coronary atherosclerotic plaque characteristics like calcium or lipid core width and thin cap fibro atheroma (TCFA) have been observed by frequency-domain optical coherence tomography (FD-OCT) and linked to adverse prognosis in patients with ACS. We sought to assess the presence and the clinical associations of such adverse plaque features in the setting of SCAD.

Methods and results: We selected consecutive SCAD patients admitted for elective coronary diagnostic or interventional procedures who underwent FD-OCT. Clinical history and risk profile was prospectively assessed. The presence of TCFA, the lipid volume index (LVI) (averaged lipid arc multiplied by lipid length), calcium volume index (CVI) (averaged calcium arc multiplied by calcium length) were (blind to clinical status) evaluated in each plaque. A total of 75 coronary plaques from 55 patients were considered. All adverse features were significantly associated with advanced age. TCFA was more frequent in the presence of smoking habit (50% vs. 40%; p=0.022) and with history of previous myocardial infarction (50% vs. 41%; p=0.022). LVI was significantly greater in the presence of renal failure (768±1502 vs. 627±1,273 μm^2; p=0.003) and diabetes (719±1,352 vs. 658±1,298 μm^2; p=0.005). CVI was significantly greater in plaques from patients with smoking habit (179±742 vs. 137±593 μm^2; p=0.049) and renal failure (174±716 vs. 134±597 μm^2; p=0.027). The presence of plaque micro-vessels was associated to a wider LVI (503±569 vs. 607±1,189 μm^2; p=0.005).

Conclusions: Within the setting of SCAD, coronary plaque FD-OCT features with established adverse impact in ACS are often found and are associated with specific clinical risk pattern (age, diabetes, renal failure).

Optical coherence tomography features of plaque rupture with or without evidence of systemic inflammation

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Aims: To assess coronary plaque rupture features by optical coherence tomography (OCT), according to levels of C-reactive protein as marker of systemic inflammation in patients with acute coronary syndrome (ACS).

Methods and results: We enrolled consecutive patients admitted to our coronary care unit with diagnosis of ST-elevation myocardial infarction (STEMI) or Non-ST-elevation myocardial infarction (NSTEMI) undergoing coronary angiography followed by OCT. Plaque rupture was defined as presence of fibrous cap discontinuity leading to a communication between the inner (necrotic) core of the plaque and the lumen. Serum high-sensitivity C-reactive protein was measured on admission by latex-enhanced immunophelometric assay. Seventy-nine patients (mean age 65± 1.2 years, 60 [76%] males) were included, 26 (33%) with STEMI and 53 (67%) with NSTEMI. Out of these, 44 (56%) exhibit a C-reactive protein value <3 mg/dl, whereas 35 (44%) had a C-reactive protein value ≥3 mg/dl. Patients with low C-reactive protein have more likely hypertension (82% vs. 54%, p=0.008), while those with high C-reactive protein have a higher incidence of familiar history of cardiovascular disease than those with low C-reactive protein (48% vs. 18% p=0.036). By angiography, patients with low C-reactive protein have coronary plaques with a diameter stenosis %>70% more frequently than those with high C-reactive protein (98% vs. 71%; p=0.001). By OCT, patients with low C-reactive protein have smaller minimal lumen area (1.5± 0.7 vs. 2.6± 2.3, p=0.002), a higher number of lipid quadrants (3.3 ±1.1 vs. 2.6±1.3, p=0.011) and higher lipid arc degree (276±103 vs. 212±114, p=0.01) compared to those with high C-reactive protein.

Conclusions: Plaque rupture and low C-reactive protein levels identify a subset of ACS patients with a peculiar mechanism of coronary instability, possibly related to more severe stenosis and stress induced plaque destabilisation, as suggested by the higher rate of hypertension in this patient group.

Frequency domain optical coherence tomography assessment of left main coronary artery bifurcation disease

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Aims: Left main coronary artery (LM) bifurcation lesions are associated with adverse prognosis and may benefit from additional information obtained by intravascular imaging. Frequency domain (FD)-OCT is a high resolution imaging technique that allows careful identification of both severity and morphology of coronary plaques. According to the clinical practice of our centre, FD-OCT is used to evaluate patients with ambiguous non-ostial LM disease. The aim of the present study was to evaluate the distribution and the clinical implications of atherosclerotic plaques at LM bifurcation using FD-OCT.

Methods and results: We retrospectively identified consecutive patients who underwent FD-OCT assessment to guide management of angiographically ambiguous non-ostial LM lesions. Off-line, blind to clinical outcome, FD-OCT plaque analysis was performed by dividing the scanned area in three segments: 1) LM proximal to bifurcation; 2) LM bifurcation; 3) "proximal LAD or LCX". Cross-section images were divided into four quadrants for plaque localisation and atherosclerotic plaques were classified in fibrotic, fibrocalcific, fibroatheroma and thin cap fibroatheroma (TCFA). Clinical follow-up was obtained by telephone interview and/or outpatient visit to evaluate the occurrence of target vessel failure (TVF=death+acute myocardial infarction not related to other vessel+repeat target vessel revascularisation). A total of 74 patients were selected. In 32 (43%) patients, the LM disease was considered not significant on the basis of FD-OCT leading to conservative medical management, while 32 (43%) underwent LM PCI and 10 (14%) underwent CABG. At FD-OCT analysis, a significant difference in the distribution of atherosclerotic plaques and TCFA was observed across the 4 quadrants (p<0.0001) (due to worse features in the opposite to side-branch quadrants). Moreover, the LM proximal to bifurcation segment has been identified as a region with thinner fibrous cap in comparison with LM bifurcation and proximal LAD/LCX segment (85.4±60.1 vs. 111.1±84.3 vs. 115.5±83.9, p=0.008). A medium follow-up of 22 months was available for 69 patients (93%). Only three patients (4%) had TVF (1 cardiovascular death and 2 target vessel revascularisation). Kaplan-Meyer survival curves free from TVF according to the conservative management versus revascularisation did not reveal significant difference in events risk (p=0.07).

Conclusions: FD-OCT analysis of LM bifurcation revealed significant differences in plaque distribution and type. An FD-OCT-based management of patients with angiographically ambiguous LM lesions is feasible.

Coronary interventions

Euro15A-OP152

Comparison of strategies to treat restenosis of second-generation drug-eluting stents

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Aims: The optimal strategy to treat restenosis of second-generation DES has not been adequately evaluated. The aim of this study is to compare the outcomes of plain old balloon angioplasty (POBA) with another DES implantation to treat restenosis of second generation DES.
Methods and results: Among patients who received *de novo* PCI using second-generation DES between August 2011 and August 2013 in our institute, there were 71 patients (90 lesions) who encountered in-stent restenosis and then were revascularised and in which, one year later, received follow-up coronary angiography. We analysed the outcome. Among the 90 lesions, 47% were focal in-stent restenosis, 28% were diffuse in-stent restenosis and 26% were stent-edge restenosis. At these lesions, POBA was applied to 38%, while another DES was implanted in 62% of them. The strategies were at the operator's discretion. Concerning focal in-stent restenosis, another DES implantation significantly reduced re-restenosis rates compared with POBA (0.22 vs. 0.58, p=0.04). On the other hand, for diffuse in-stent restenosis, another DES implantation and POBA did not differ significantly (0.45 vs. 0.71). Concerning the other lesions which were treated previously with small stents (diameter=2.5 mm, 41ï' of all lesions), both another DES implantation and POBA resulted in higher re-restenosis rates, and did not differ significantly (0.44 vs. 0.76). Multivariable analysis found less than 2.5 mm of prior stent diameter to be the predictor of re-restenosis (OR 3.15, 95% CI: 1.19-8.30, p=0.02).
Conclusions: Another DES implantation is still favourable to reduce re-restenosis rates in second-generation DES restenosis, especially for focal in-stent restenosis. POBA therapy could be justified in diffuse in-stent restenosis or restenosis of small stent (diameter=2.5 mm), to which another DES implantation also results in higher re-restenosis rate.

Coronary interventions

Euro15A-OP153

Searching for the best treatment for coronary in-stent restenosis: results from a network meta-analysis

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Aims: The treatment of patients with coronary in-stent restenosis is challenging and currently the best therapeutic strategy is still not clear. We sought to compare different therapeutic strategies for coronary in-stent restenosis in a hierarchical Bayesian network meta-analysis.
Methods and results: The search was performed in PubMed, Embase, Scopus, Cochrane Library, and Web of Science electronic databases. We included only randomised trials of patients with coronary in-stent restenosis. Patients of any age, ischaemic risk profile and clinical presentation were considered. Drug-eluting stents (DES), drug-coated balloons and plain balloons were the treatments allowed. Trials including cutting balloons and rotational ablation were excluded since these strategies could not be considered as definitive but generally requiring subsequent stent implantation. The primary efficacy endpoint was target lesion revascularisation at 12 months. A Bayesian NMA was carried out for each endpoint using consistency random-effect model computed with Markov Chain Monte Carlo simulation. Convergence was confirmed using the Brooks-Gelman-Rubin diagnostic after a 50,000-iteration "burn-in" phase and direct probability statements were based on a further 100,000-iteration phase. Inferences were calculated by sampling from the posterior distribution of the parameters and reported as mean odds ratio with corresponding 95% credible interval. Heterogeneity was explored using I^2 statistic. Consistency of the network was assessed by node-splitting and p-value for the difference between direct and indirect evidence was estimated. Finally, the three treatments were ranked attempting to define the probability of each treatment to be the best. A total of 12 randomised trials were identified through search process: 11 were 2-arm trials and 1 was 3-arm trial. Both DES and drug-coated balloon resulted to be associated with a significant and consistent reduction in the risk of TLR (0.19 [0.08-0.38] and 0.22 (0.10-0.45], respectively). However, drug-coated balloon compared with DES resulted to slightly reduce the risk of target-lesion revascularisation (1.10 [0.34-1.80]). Although node-splitting did not identify a significant inconsistency (p=0.074), the result of the comparison between drug-coated balloon and DES was driven by indirect evidence (1.10 [0.54-2.60]), since direct comparison tended to favour non-significantly DES (0.77 [0.34-1.80]). Heterogeneity was moderate (I^2=51.3%).
Conclusions: Plain balloons should not be used for in-stent restenosis treatment since DES and drug-coated balloons appear to be associated with a lower risk of target-lesion revascularisation at 12 months. Larger trials comparing drug-coated balloons with DES are required to define which treatment is more effective.

Paclitaxel-coated balloon for the treatment of in-stent restenosis in high-risk patients: a single-centre prospective observational study with angiographic follow-up

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Aims: In-stent restenosis is a major cause of failure of percutaneous coronary intervention (PCI). The efficacy and safety of drug-coated balloon in patients with high-risk clinical features are largely unknown. We aimed to assess the efficacy and safety of drug-coated balloon for the treatment of in-stent restenosis in high-risk patients.
Methods and results: We enrolled 82 consecutive high-risk patients with angiographically significant (diameter stenosis ≥50%) in-stent restenosis of bare metal stent (BMS) or drug-eluting stent (DES), treated with paclitaxel-coated balloon. All patients presented at least one of the following criteria: high bleeding risk, neoplasm, chronic inflammatory disease, need for non-cardiac surgery. Dual antiplatelet therapy was indicated for 4 weeks after the procedure. At angiographic follow-up, overall late lumen loss was 0.24±0.32 mm, with no significant difference between BMS in-stent restenosis and DES in-stent restenosis (0.25±0.35 vs. 0.22±0.30 mm, p=0.714). The Kaplan-Meier estimate for major adverse clinical events-free survival at 3 years was 81.4% (82.3% in BMS in-stent restenosis vs. 79.4% in DES in-stent restenosis, log-rank p=0.866).
Conclusions: The use of paclitaxel-coated balloon seems to be associated with favourable outcomes after PCI for BMS- or DES- in-stent restenosis in patients with high-risk clinical features and could be considered as a reasonable option in the presence of systemic comorbidities and contraindications to long-term dual antiplatelet therapy.

Late restenosis following paclitaxel-coated balloon angioplasty occurs in patients with drug-eluting stent restenosis

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Aims: There are currently inadequate data on whether "late restenosis" occurs after paclitaxel-coated balloon (PCB) angioplasty for in-stent restenosis (ISR) lesions. To evaluate the long-term efficacy of PCB angioplasty, we investigated serial angiographic outcomes after PCB angioplasty for ISR lesions.
Methods and results: Between September 2008 and December 2012, PCB angioplasty was performed in 468 patients with 550 ISR lesions (bare-metal stent restenosis [BMS-ISR]: 101 lesions, drug-eluting stent restenosis [DES-ISR]: 436 lesions). Two serial angiographic follow-ups were routinely planned for the patients (at 6 and 18 months after the procedure). Early follow-up (at 6 months) angiography was performed for 488 lesions (89%), and recurrent restenosis occurred in 13 lesions (14.9%) in the BMS-ISR group and in 82 lesions (21.1%) in the DES-ISR group. Target lesion revascularisation (TLR) was performed for 7 lesions (7.0%) in the BMS-ISR group and 54 lesions (13.9%) in the DES-ISR group. Late follow-up (18 months) angiography was performed for 377 (88%) of the remaining 427 lesions (excluding TLR lesions), and late restenosis was found in 2 lesions (2.5%) in the BMS-ISR group and 50 lesions (16.8%) in the DES-ISR group (p<0.001). Delayed late loss was significantly larger in the DES-ISR group (0.09 ±0.29 mm vs. 0.22 ±0.50 mm, p=0.004).
Conclusions: "Late restenosis" occurs after PCB angioplasty for DES-ISR lesions.

Coronary interventions

Euro15A-OP156

Comparison of outcomes between repeat PCI for in-stent or edge DES restenosis lesions

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Aims: Stent edge restenosis can occur after implantation of a drug-eluting stent (DES). Previous studies have suggested that stent-edge plaque burden is a predictor of stent edge restenosis but the data comparing the outcomes between repeat PCI for in-stent or edge restenosis lesions are missing.
Methods and results: From April 2007 to March 2014, 7,971 lesions implanted DES at our institution for ischaemic coronary artery disease. Of those, 686 lesions 8.6% detected restenosis in follow-up angiogram. Subject of the study was serial 105 *de novo* in-stent DES restenosis lesions in the ISR group and serial 60 *de novo* edge DES restenosis lesions in ER group. A TLR procedure was performed with repeat DES implantation. Outcomes were compared between the two groups retrospectively. Edge restenosis was defined as restenosis occurring only at the 5 mm segment adjacent to the stent. Restenosis and re-restenosis were defined as % diameter stenosis >50% in follow-up angiogram. Baseline characteristics were similar. One-year cumulative incidence of re-restenosis after the TLR procedure calculated by the Kaplan-Meier method was ISR group 41% and ER group 19% (p=0.0273 by log-rank test), respectively.
Conclusions: Repeat DES implantation for DES restenosis lesion was more effective in edge restenosis lesions.

Coronary interventions

Euro15A-OP157

Lipid-core burden response to stent implantation assessed with near-infrared spectroscopy in patients with myocardial infarction

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Aims: Patients with acute coronary syndrome have a higher incidence of lesions composed of vulnerable lipid-core plaque (LCP), compared to patients with stable angina pectoris. LCP at the stent edge may increase the risk for later stent related complications. Near-infrared spectroscopy (NIRS) is a validated method to identify LCP. The LCP and vascular response were assessed with NIRS after nominal and high-pressure stent implantation in patients with non-ST segment elevation myocardial infarction (NSTEMI). Further, it was examined if the LCP was compressed or redistributed during percutaneous coronary intervention (PCI).
Methods and results: We studied 25 NSTEMI patients treated with PCI and a single bioabsorbable polymer SYNERGY stent. NIRS acquisition was performed (1) after predilation with a 2.0 mm balloon, (2) after stent implantation with nominal pressure and (3) after post-dilation with a non-compliant balloon+0.5 mm. The intravascular ultrasound (IVUS) measures included volumes of external elastic membrane (EEM), lumen and plaque+media. The NIRS measures included lipid core burden index (LCBI) and max$LCBI_{4mm}$(maximum value of LCBI for any of the 4-mm long segment). From predilation to stent implantation EEM increased significantly from 337±124 mm^3 to 369±136 mm^3, p<0.001. Plaque+media volume decreased significantly from 225±84 mm^3 to 202±85 mm^3, p<0.001. After post-dilation with a non-compliant balloon, EEM volume further increased significantly to 397±144 mm^3, p<0.001 and plaque+media volume further decreased significantly to 192±81 mm^3, p<0.001. In the 5 mm proximal and distal reference segments, only EEM and not plaque+media volumes increased significantly in the distal reference segment. The max$LCBI_{4mm}$ decreased significantly from predilation to stent implantation: 492±235 to 208±193, p<0.001, whereas post-dilation did not cause any further significant reduction 187±187, p=ns. The same pattern was seen in the entire lesion (corresponding to the stent covered segment) as the LCBI decreased significantly from predilation to stent implantation: 173±103 to 68±67, p<0.001, whereas post-dilation did not cause any further significant reduction 59±57, p=ns. Neither in the proximal nor in the distal reference segments did the LCBI change significantly during stent implantation or post-dilation.
Conclusions: During stent implantation, both plaque+media volume and LCBI were compressed and not redistributed longitudinally. Following high-pressure deployment, vessel volume increased, plaque+media volume decreased without further reduction in LCBI.

The time course of stent malapposition, thrombus, tissue prolapse and dissection detected by optical coherence tomography after primary percutaneous coronary intervention for ST-segment elevation myocardial infarction

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Aims: We investigated the natural consequences of stent malapposition, thrombus, tissue prolapse and dissection detected by optical coherence tomography (OCT) after primary percutaneous coronary intervention (PCI) for ST-segment elevation myocardial infarction (STEMI).

Methods and results: Thirty patients with 30 lesions underwent primary PCI for STEMI. We analysed the OCT images immediately after primary PCI (acute phase), 7-14 days follow-up (early phase) and 8-12 months follow-up (chronic phase). At the early phase, early persistent stent malapposition was observed in 43% of lesions, thrombus and tissue prolapse was observed in 33% of the lesions, dissection was observed in 3% of lesions. At the chronic phase, late-acquired stent malapposition was observed in 17% of lesions, thrombus and tissue prolapse was observed in 0% of lesions.

Conclusions: Most cases of minor stent malapposition, thrombus, tissue prolapse and edge dissection improved after the early phase. Most of the late-acquired stent malapposition occurred during the early phase due to thrombus resolution.

Clinical impact of coronary calcium fracture by percutaneous coronary intervention on the outcomes after everolimus-eluting stent implantation: an optical coherence tomography study

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Aims: Heavily calcified lesions in coronary arteries have been known to be a cause of stent underexpansion, which increases the risk of in-stent restenosis. The aim of the present optical coherence tomography (OCT) study was to investigate clinical impact of coronary calcium fracture by percutaneous coronary intervention (PCI) on the outcomes after drug-eluting stent implantation.

Methods and results: We enrolled 61 patients with chronic stable angina who had heavily calcified lesions on coronary angiography. Everolimus-eluting stents were used for PCI. OCT was performed before and immediately after PCI. In OCT, calcium fracture by PCI was characterised by a gap of calcium and direct exposure of calcium to the lumen at the gap. Follow-up angiography was conducted 10 months after PCI. Calcium fracture was seen in 48% of patients by OCT. The median calcium fracture thickness was 450 micrometres (interquartile range 300 to 660 micrometres). The maximum calcium fracture thickness was 770 micrometres. Maximum stent area was significantly greater in the group with calcium fracture compared with the group without calcium fracture (5.02±1.43 mm^2 vs. 4.33±1.22 mm^2, p=0.047). Stent expansion index was significantly greater in the group with calcium fracture compared with the group without calcium fracture (0.88±0.17 vs. 0.78±0.18, p=0.030). At 10-month follow-up, percent diameter stenosis was significantly smaller in the group with calcium fracture compared with the group without calcium fracture (19±27% vs. 38±38%, p=0.030). The frequency of binary restenosis (14% vs. 41%, p=0.024) and target lesion revascularisation (7% vs. 28%, p=0.046) was significantly lower in the group with calcium fracture compared with the group without calcium fracture.

Conclusions: Coronary calcium fracture by PCI was associated with adequate stent expansion and favourable late outcomes.

euroPCR Coronary interventions

Euro15A-OP160

Impact of jailing configuration and bifurcation angle on incomplete stent apposition after single crossover stenting with final kissing balloon dilatation, assessed by three-dimensional OCT

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Aims: We have reported that the achievement of both distal re-wiring and favourable stent configuration of jailing struts could reduce incomplete stent apposition (ISA) after side branch dilatation. Several reports suggest that the bifurcation angle (BA) could be also an important viewpoint in left main (LM) bifurcation stenting. But the relation between ISA and BA remains unclear. We examined the effect of LM-BA and jailing configuration on ISA of biolimus-eluting stent (BES) that was deployed on LM-LAD followed by final kissing balloon dilatation (FKBD).

Methods and results: Eighteen patients who were deployed BES on LM-LAD and underwent OCT were enrolled in this study. After stent deployment on LM-LAD across the left circumflex artery (LCx), the coronary guidewire was re-crossed to the LCx through the jailing strut under fluoroscopic guidance. Frequency domain (FD)-OCT (SJM ILUMIEN OPTIS FD-OCT system) was performed before FKBD. Images were obtained from the distal portion of LM-LAD at the pullback speed of 10 mm/s. 3D stent images was reconstructed using the in-house software which detected stent strut automatically. The configuration of jailing strut and the re-wiring position were assessed on the 3D-OCT image. The configuration of jailing strut was classified as follows: 1) free carina (FC) type, there is no longitudinal link bridging from the carina; 2) connecting to carina (CC) type, there is a longitudinal link connecting to the carina. Favourable distal re-wiring was achieved in all cases by 3D-OCT, and final OCT was performed after FKBD. Bifurcation angles were measured by validated QAngio XA 3D bifurcation version 1.1.9 (Medis Specials bv, Leiden, The Netherlands) using coronary angiographic images. The pre-stented angle of LM-LCx and the ISA at the side branch ostium after FKBD have a negative correlation (R^2=0.487, P=0.0038), whereas LM-LAD angle and LAD-LCx angle were not significantly correlated with ISA in this study. The median angle of LM-LCx was 140 degrees. The cases were divided into two groups according to the angle of LM-LCx: wide-angle group (>140 degree, n=10) and narrow angle group (<140 degree, n=8). The percentages of ISA (%ISA) at the side branch ostium in the wide angle group were significantly smaller than those in the narrow angle group (2.8±2.2% vs. 9.6±8.2%, p<0.05). Moreover, only in cases of the CC type, any bifurcation parameter had no significant correlation with the %ISA. The %ISA at the side branch ostium in the CC type were significantly higher than those in the FC type (CC 21.7±15.2% vs. FC 9.4±14.4%, p<0.05).

Conclusions: 3D-OCT analysis has revealed that steep LM-LCx angle could bring down ISA of BES that was deployed on LM-LAD, even after FKBD. In each angle group, ISA of FC type configuration tended to be smaller than that of CC type. Both jailing configuration and bifurcation angle could be important factors to be taken into account in LM bifurcation stenting.

euroPCR Coronary interventions

Euro15A-OP161

Rationale and design of the randomised OCT study comparing two second generation drug-eluting stents on the degree of early stent healing and late neointima progression: the OCT-ORION study

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Aims: We aimed to evaluate the differences and outcomes of two second-generation DES (a) by longitudinal sequential OCTs which enable high resolution images for robust quantification of the early stent strut coverage (healing) and subsequent neo-intimal progression, and (b) in order to minimise any confounding factors, each patient would be receiving both of the study stents, each in one of the 2 target vessels with critical stenoses requiring PCI, in a randomised manner; only patients with 2- to 3-vessels disease were enrolled.

Methods and results: In this single-centre, randomised, assessor-blinded, prospective study, 60 symptomatic patients with 2- or 3-vessel disease were treated with both of the study stents with 3 longitudinal sequential OCT assessment follow-ups (FU). Two second-generation DES were compared, the Resolute Integrity zotarolimus-eluting stent (RI-ZES; Medtronic, Inc., Minneapolis, MN, USA) versus the BioMatrix Biolimus-A9 eluting stent (BioMatrix BES; Biosensors, Singapore). BioMatrix BES has a luminal bare metal stainless steel surface, an abluminal biodegradable polymer (poly-lactic acid) which will fully break down to lactic acid in 6 months converting the DES to a BMS, and an eluting biolimus-A9 drug. The RI-ZES is composed of cobalt alloy with a durable biocompatible BioLinx polymer which allows continuous elution of zotarolimus for 180 days. The primary endpoint was the differences of the OCT percentage strut coverage by nine months. All patients enrolled (presenting with at least with 2-vessel disease) would receive both study stents after randomisation at the same index procedure; the remaining 3rd vessel (if 3-vessel disease) would be treated during the first OCT FU. Baseline OCT right after stenting was to ensure maximal stent optimisation and apposition. The patients were than randomly assigned to 5 monthly groups, each 15 patients, for first OCT FU assessment at 2, 3, 4, 5 or 6 months (the 1st month was omitted because good healing in DES was not expected and most of the "coverage" could just be fibrin) and targeted to establish the healing profile curves (degree of early stent strut coverage) comparing the 2 stents. At 9 months, another FU OCT assessment would be performed to assess the differences in total coverage and neointimal progression. Core lab results are pending and more data will be available at presentation.

Conclusions: Longitudinal sequential OCT assessments could provide maximal information on the safety, efficacy and *in vivo* biological behaviour as well as neointimal changes of any stents, benefiting better patient treatment. Comparing two stents in each individual patient simultaneously could minimise any confounding factors providing better information on the benefits of various stent designs.

EuroPCR Coronary interventions Euro15A-OP162

Drug-eluting balloon: a real-world two-centre experience

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Aims: To report on a two-centre "all-comers" registry concerning the safety and efficacy of drug-eluting balloons (DEB) in the treatment of in-stent restenosis (ISR) and *de novo* coronary artery disease.

Methods and results: Consecutive patients treated with the In.Pact Falcon™ (Medtronic Inc., Minneapolis, MN, USA) paclitaxel-eluting balloon between January 2012 and November 2014 were retrospectively enrolled in our registry. The measured clinical endpoints were cardiac death, myocardial infarction (MI), target lesion revascularisation (TLR), target vessel revascularisation (TVR) and major adverse cardiac events (MACE) defined as combination of cardiac death, MI, and TLR, while procedural success was defined as the ability to reach, cross and dilate a lesion with the study device. The primary endpoint of the study was the occurrence of MACE at follow-up. A total of 100 lesions were successfully treated in 86 patients. The mean age was 65.1±15.8 years, and 83.7% were males. The main risk factors were represented by hypertension and dyslipidaemia while 32.9% of patients were diabetics. The 81% of the population had a prior-PCI and the main indication for PCI was because of ACS (75% while 25% of patients suffered from stable angina).The predominant indication for DEB use was ISR (72.9%), mainly of type III (32.4%), involving a DES in the 74.1% of cases. Procedural success was achieved in 97.6%. A mean of 1.2±0.5 DEB were used per patient. Bailout stenting was required in two lesions. No events were recorded at 30-day follow-up. Medium-term follow-up was available for 82.5% of the study population (median 223 days [IQR 160-415]). The overall rates of MACE was 7% with an event free survival of 86.5%.

Conclusions: Our results confirm the safety and efficacy at short- and medium-term follow-up of DEBs in patients presented mainly with ACS.

EuroPCR Coronary interventions Euro15A-OP163

Percutaneous coronary intervention of left main stem restenosis with drug-eluting balloon

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Aims: Drug-eluting balloons (DEB) are mainly used for in-stent restenosis (ISR) and the safety and efficacy of DEB for ISR has been demonstrated in a number of published data. However, there are limited published data on the use of DEB in left main stem restenosis (LMS ISR). The objectives of this study were to evaluate the rationale, safety, feasibility and medium term outcome of the use of DEB for LMS ISR.

Methods and results: From our hospital database we identified all DEB coronary intervention cases up to June 2014 and then those for LMS ISR. The procedural details, images, equipment used, complications and follow-up details were recorded and analysed. DEB was used in 265 cases and 29 were for LMS ISR. Mean age of these 29 was 73.7±12.4 years, 22 (76%) were males and 7 had previous CABG. A single stent was used in the initial LMS PCI in 12 patients (41.3%), while 17 (58.7%) had bifurcating stenting (6 culotte, 6 crush, 2 Tryton, 2 TAP and 1 SKS). Stents used were: 3 BMS (9.7%), 12 1st-generation DES (42%) and 14, 2nd-generation DES (48.3%). IVUS was used in 22 cases (76%) and final kissing balloon inflation was performed in all 17 (100%) of the 2 stent cases. DEB PCI for LMS ISR was performed at a mean of 16.7±19 months (range 2-78) after the initial PCI. The clinical presentation of these cases was 18 stable angina (62%), 4 unstable angina (14%), 5 NSTEMI (17%) and 2 pulmonary oedema (7%). Site of LMS ISR was 1 LMS ostium (3%), 4 LMS body (14%), 5 LMS and LAD (17%), 11 LMS and circumflex (38%), and 8 bifurcation involving LMS, LAD and circumflex (28%). During this intervention, IVUS was used in 18 cases and in total IVUS was used in 27 cases (93%) either during the initial PCI or DEB intervention. LMS ISR preparation was with NC balloon alone in 19 (65%), cutting balloon alone in 2 (7%) and both in 8 (28%), mean balloon size was 3.33±0.9 mm. Mean size of DEB balloon was 3.55±0.37 mm, Kissing inflation following DEB inflation was performed in 7 (87%) of bifurcation LMS ISR. The DEB balloon size was same as original stent size in 14 (48%), less than 0.25-0.5 mm in 7 (24%), and greater than 0.25-0.75 mm in 8 (28%). No complication occurred during DEB intervention procedure. Mean follow-up was for 34±22 months (range 7-75) with clinical events in 9 patients (31%). Six (20%) developed further severe ISR at a mean of 5.1±1.9 months. Five of the 6 (83%) had DEB for LMS bifurcation ISR and 1 for LMS and ostial LAD ISR. Four patients (1 with ISR following DEB) died after 11±10.7 months. Two patients died (age 91 and 86 years) at home and cardiac death could not be ruled out. One patient died due to severe aortic stenosis (82 years) and 1 patient morbidly obese (BMI 46.7) with previous CABG died due to ACS in hospital (66 years). A further 10 (34%) had undergone angiogram for various clinical reasons during the follow-up period with no significant ISR. The only parameter indicating further ISR following DEB use was intervention for bifurcation LM ISR 5/8 (63%) versus single DEB 1/21 (5%)(p=0.002).

Conclusions: In this, the largest reported study of DEB in LMS ISR, 69% of patients had good medium-term outcome, increasing to 95% in those requiring a single DEB. However, clinical events appear high (63%) in those with LMS bifurcation ISR and perhaps an alternative revascularisation strategy may be more appropriate in these patients. Further data is required.

Coronary interventions

Euro15A-OP164

Outcomes of a drug-eluting balloon-only strategy in native coronary arteries and venous grafts in stable coronary artery disease and in acute coronary syndromes registry study

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Aims: The drug-eluting balloon (DEB) has been found efficient for the treatment of in-stent restenosis but little is known about the performance of DEB-only strategy in other types of PCI including *de novo* lesions of large native coronary arteries or in venous grafts. The aim of this registry-based study was to assess the efficacy and safety of PCI using DEB in this real life patient population.

Methods and results: Five hundred and twenty-four (524) PCIs was performed in 500 patients having either stable coronary artery disease or acute coronary syndrome (unstable angina, NSTEMI or STEMI) using a paclitaxel-coated DEB (SeQuent Please) between September 2009 and December 2013. Major cardiovascular adverse effects (MACE, the composite of death, non-fatal myocardial infarction and target lesion revascularisation) and bleeding events were studied. The median follow-up time was 18.5 months. Mean age of the patients was 68 years, 29% had diabetes and 26% had suffered prior myocardial infarction; 16% of the patients used an oral anticoagulant; 55% of the patients had an acute coronary syndrome (6% STEMI); 92% of the treated lesions were *de novo*. Ten left main lesions and 29 venous grafts were treated with DEB. Bailout stenting (81% BMS or 19% DES) was needed in 17% of the PCIs. The 12 and 24 month MACE rate for the whole study population was 12% and 15%, respectively. Acute vessel closure rate was 1.0%. Three of four of them were associated with bailout BMS. The rate of target lesion revascularisation was 2.5% by 12 months and 3.2% by 24 months. Both the 12- and 24-month MACE rate for the in-venous graft subgroup was 21% and the target lesion revascularisation rate was 7% by 12 and 24 months. Median duration of the dual antiplatelet therapy after DEB was 1 month. The 12-month rate for significant bleeding was 5.7%.

Conclusions: The results of this all-comers registry suggest that PCI using a DEB-only strategy is an efficient alternative to stenting in *de novo* lesions including large vessels, venous grafts and left main lesions. A DEB-only strategy is feasible both in stable coronary artery disease and acute coronary syndromes.

Coronary interventions

Euro15A-OP165

Paclitaxel-eluting balloon versus conventional balloon predilatation in acute myocardial infarction undergoing endothelial progenitor cell-capture stent implantation: the DEBORA 2 randomised multicentre trial

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Aims: To assess the angiographic and clinical outcomes in STEMI patients after PCI with the Genous stent after pre-dilatation with either a paclitaxel drug coated balloon or a non-drug-eluting balloon

Methods and results: We conducted a multicentre, randomised, open trial, in STEMI patients undergoing primary PCI. They were randomly assigned to predilatation with a paclitaxel-coated drug-eluting balloon (DEB group) or conventional balloon (non-DEB group), followed by implantation of a Genous endothelial progenitor cell (EPC)-capture stent. Dual antiplatelet therapy was continued for 12 months and the choice of $P2Y_{12}$ inhibitor was at the discretion of the physician. The primary endpoint was minimal lumen late loss at nine-month follow-up angiography assessed by quantitative coronary analysis. The secondary endpoint was major adverse cardiac events (MACE: death, re-infarction and target vessel revascularisation) at 1, 9 and 12 months after treatment. A total of 130 patients were randomised. Follow-up angiography was performed in 102 patients (78%), 55 in the DEB group and 47 in the non-DEB group. The mean minimal lumen late loss was 0.13±0.51 mm in the DEB group and 0.51±0.47 mm in the non-DEB group ($p<0.01$). The angiographic in stent late loss in the DEB group was 0.15±0.44 mm compared to 0.43±0.41 mm in the non-DEB group ($p=0.001$). Clinical follow-up to 12 months was available for 126 of 130 patients. No significant difference with regard to MACE was observed between groups (8.1% vs. 9.5%, $p=0.773$) at any time interval of clinical follow-up.

Conclusions: In patients undergoing primary PCI for STEMI, predilatation with a paclitaxel-eluting balloon followed by EPC-capture stent implantation significantly reduces minimal lumen late loss. There were no differences in MACE after 12 months of follow-up

Long-term (3-year) follow-up of the balloon elution and late loss optimisation (BELLO) study

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Aims: We aimed to assess the treatment of *de novo* small-vessel coronary artery disease with drug-eluting balloons (DEB).

Methods and results: The BELLO study was an investigator-initiated, prospective, multicentre, single-blinded, active-treatment controlled trial. Patients undergoing percutaneous revascularisation with small coronary vessels (<2.8 mm by visual estimation) were randomly assigned in a 1:1 ratio to treatment with: 1) IN.PACT Falcon paclitaxel DEB (Medtronic, Santa Rosa, CA, USA) dilatation and provisional bare-metal stenting (BMS); or 2) paclitaxel-eluting stent (PES), the TAXUS Liberte (Boston Scientific, MA, USA), implantation as per standard clinical practice. A total of 182 patients were enrolled from 15 Italian centres and randomised to treatment with DEB (n=90) in 94 lesions or PES (n=92) in 98 lesions. One hundred and sixty-six patients (91.2%) completed 3-year follow-up (83 patients in each group) and were included in the final analysis. Nine patients (4.9%) were lost to follow-up and 7 patients died: 2 patients in the DEB group (1 sudden cardiac death, 1 following coronary artery bypass graft surgery) and 5 patients in the PES group (5 cancer, 1 respiratory failure, 1 following a stroke) (p=0.28). Major adverse cardiac events (MACE) were defined as the composite of death, Q- or non-Q-wave myocardial infarction, and target vessel revascularisation (TVR). All events that occurred up to 1,100 days from the index procedure were included in the final analysis. The occurrence of the first event of the MACE composite analysed using the Kaplan-Meier method showed a statistically significant difference between groups (n=13 [14.4%], DEB group and n=28 [30.4%], PES group, p=0.015). Six patients (7.2%) underwent TLR in the DEB group and 12 patients (14.4%) in the PES group (p=0.17). There were no differences between the groups with regards to any of the other secondary endpoints. Of note, there was a high incidence of diabetes mellitus in both groups (43.3% in DEB and 38% in PES) and 67 patients completed 3-year follow-up (n=35, DEB group, n=32 PES group). In the diabetic patients, 6 MACE occurred in the DEB group and 14 events occurred in the PES group. There was a trend favouring DEB treatment with regards to overall MACE in this subgroup of patients (p=0.04).

Conclusions: We have demonstrated here that the treatment of small vessels with DEB has good efficacy in comparison to PES at 3-year follow-up in support of our observations at 1-year. There was a statistically significant benefit with regards to MACE at 3 years with DEB in comparison to PES. Whilst this study was not adequately powered for this endpoint, it does raise the interesting hypothesis that treatment of small vessels with DEB maybe associated with an outcome benefit.

Risk of scaffold thrombosis after bioresorbable vascular scaffold implantation

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Aims: Since publication of the data from a European international registry (GHOST-EU) suggesting the high risk of scaffold thrombosis (ST) with bioresorbable vascular scaffolds (BVS) the safety of BVS has been debated.

Methods and results: A systematic literature search was performed to identify published data regarding BVS safety. Data of definite and probable ST frequency were extracted and analysed in random effect models. Linear meta-regression analyses and hyperbolic curve fit to the patient number weighted data were performed to estimate time-risk relations after BVS implantation. Twenty-two studies including 4,864 BVS treated patients were identified. Fifty-eight cases of ST were reported (1.0% 95% confidence interval [CI]: 0.6-1.3%). Controlled studies found numerically higher but not significantly higher risk compared to patients with metallic stents (1.29 vs. 0.54%, odds ratio 1.8, CI: 0.83-3.93, p=0.138). The proportion of patients in the cohort with myocardial infarction was in significant correlation with the frequency of ST (p=0.029). The non-linear curve fit estimated a 1.67% (95% CI: 1.24-2.09%) long-term ST frequency.

Conclusions: The available data do not support that BVS implantation would expose patients to significantly increased risk of device thrombosis.

euroPCR Coronary interventions

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Comparison of predictors of stent thrombosis between 1st-generation and 2nd-generation drug-eluting stents after primary percutaneous coronary intervention

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Aims: Although drug-eluting stents (DES) markedly reduced the incidence of in-stent restenosis (ISR), the risk of the stent thrombosis (ST) cannot be ignored. In previous studies, the comparison of predictors of ST between bare-metal stents and DES was the primary subject of the studies. The aim of this study was to evaluate the differences of predictors of ST between 1st-generation and 2nd-generation DES after primary percutaneous coronary intervention (PPCI).

Methods and results: From January 2006 to December 2013, 2,117 patients who underwent PPCI due to acute myocardial infarction were enrolled. The 1st-generation drug-eluting stents (DES) included the Cypher and TAXUS. The 2nd-generation DES included Resolute, XIENCE and Promus. ST was shown in 39 patients (1.84%). 1st-generation DES was used in 30 patients (30/1,084=2.8%) and 2nd-generation DES was used in 9 patients (9/1,033=0.9%). Patients who used 1st-generation DES showed significantly higher ST rates compared with patients who used 2nd-generation DES. In patients treated with 1st-generation DES, younger age (RR 0.956, CI: 0.926-0.987, p=0.006) and hypertension (2.494, 1.136-5.478, 0.023) were associated with the increased risk of stent thrombosis. In patients treated with 2nd-generation DES, younger age (0.888, 0.828-0.952, 0.001), lower ejection fraction (0.904, 0.842-0.970, 0.005), multi-stents (5.676, 1.255-25.671, 0.024) were associated with the increased risk of ST.

Conclusions: Patients who treated with 1st-generation DES showed higher incidence rate of ST compared with 2nd-generation DES. Although there were similar independent predictors of ST for both DES such as younger age, there were also different predictors as hypertension for 1st-generation DES and lower ejection fraction for 2nd-generation DES.

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Predictive factors of one-year stent thrombosis in patients with STEMI treated with titanium-nitro-oxide-coated stent implantation: insights from TITAN-AMI study

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Aims: Stent thrombosis (ST) is a complication of PCI procedures that has a bad prognosis. STEMI is a predictive factor associated with an increase rate of ST during follow-up. The aim of this analysis was to detect the independent predictive factors of cumulative one-year definite or probable stent thrombosis in patients admitted by an STEMI and treated with TITAN stent during a PPCI.

Methods and results: TITAN-AMI study was a multicentre prospective registry made in 23 tertiary centres in Spain that includes patients with acute coronary syndrome. For this analysis, we selected those patients presented with ST-segment elevation MI (STEMI). Stent thrombosis was defined following the recommendations of ARC. For the analysis, we selected definite or probable stent thrombosis as a primary endpoint. We collected demographic, previous history, medical treatment, angio- and procedural factors in an electronic database. Cox regression analysis including variables with p-value <0.1 in the univariate analysis was performed. All data were prospectively introduced in a web-data base and an external CRO (Clinical Research Organisation) was responsible for controlling the data entered. An external clinical event committee adjudicated the events. Eight hundred seventy-nine patients presented with ST-segment elevation, and they were the population analysed in this study. Primary PCI was the most common indication for the procedure 773 (86.6%), facilitated PCI was performed in 45 (5.0%) and rescue PCI for a failed thrombolytic therapy was performed in 75 (8.4%). All lesions were treated with TITAN2 stent implantation. Mean age was 61-years-old and diabetes was present in 16%. The most frequent ECG localisation was inferior (54.8%) and anterior (36.6%). Twenty-five patients (2.8%) presented one-year ST, and were strongly related with one-year mortality. In the univariate analysis, variables related with ST were: previous MI, Previous PCI, treatment with aspirin or clopidogrel one month after PCI, residual left ventricular ejection fraction (LVEF), final TIMI flow and ST-segment resolution >70%. After Cox regression analysis, residual LVEF (HR 0.94; 95% CI: 0.89-0.99) and ST-segment resolution >70% (HR 0.17; 95% CI: 0.05-0.56) were independently related with one-year ST.

Conclusions: In patients with STEMI treated with titanium-nitro-oxide-coated stent implantation during PPCI one-year stent thrombosis was 2.8% and is independently related with residual LVEF and ST-segment resolution >70%.

Clinical parameters do not predict thrombosis after implantation of bioresorbable vascular scaffolds, but introduction of a specific implantation strategy is associated with a significant reduction in its incidence

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Aims: In recent multicentre registries on the use of bioresorbable vascular scaffolds, an elevated incidence of in-scaffold thrombosis was reported. The mechanisms and possible associations with clinical or procedural parameters have not been investigated yet. Most importantly, it is also unknown whether this incidence can be modified by the operator at the time of implantation. We describe the incidence of in-scaffold thrombosis and its associations with clinical presentation and procedural characteristics in a real-world multicentre registry.

Methods and results: One thousand three hundred and two (1,302) patients (age 64±12 years, 68% males) underwent percutaneous coronary intervention and received one or more scaffolds in one of the 4 participating centres in Germany and Switzerland between May 2012 and December 2014. Following the findings previously reported in the GHOST-EU registry, a specific scaffold-implantation strategy consisting of: 1) predilation with balloons of the same size as the scaffold to be implanted; 2) systematic post-dilation with non-compliant balloons and 3) implantation of scaffolds exclusively in the presence of an effective predilation was mandatorily implemented in Mainz since Janurary 1, 2014. In the whole patient cohort, the prevalence of hypertension, diabetes, smoking and hyperlipidaemia were respectively 72%, 23%, 37% and 49%. A total of 1,751 (1.34/patient) scaffolds were implanted, in 49% of the cases for the treatment of acute coronary syndromes (19% STEMI) and in 11% of the cases in bifurcation lesions. Post-dilation was performed in 44% of the lesions. In-scaffold thrombosis was recorded in 35 patients (2.7%). In multivariate analysis, none of the clinical or procedural characteristics was associated with the incidence of in-scaffold thrombosis. Until December 31, 2015, 440 patients received a scaffold in Mainz, and 18 in-scaffold thromboses (4%, including definite, probable and possible thromboses) were recorded. Since January 1, 2014, 330 patients were treated with scaffolds, and only 3 cases of thrombosis (1%) were reported. There was no difference across time periods in the clinical characteristics of the patients. The Fisher´s exact two-tailed probability for the difference determined by the implantation strategy demonstrated a significant effect (P=0.007).

Conclusions: In this large, "real-world" registry, none of the traditional clinical parameters was associated with in-scaffold thrombosis. In contrast, introduction of a specific implantation strategy drastically reduced the incidence of this ominous complication.

The comparison between plain old balloon angioplasty vs. stent implantation for stent thrombosis: the New Tokyo registry

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Aims: Stent thrombosis (ST) is an infrequent but potentially fatal complication of percutaneous coronary intervention (PCI). There is little data on comparison of clinical data between plain old balloon angioplasty (POBA) and stent implantation in ST patients. This study aimed to compare strategies between POBA and stent implantation in patients treated for ST.

Methods and results: Between January 2005 and December 2014, 78 consecutive patients who were detected definite ST were included (12 acute ST, 33 sub-acute ST, 5 late ST and 28 very late ST). Of these, 38 patients were treated with POBA and 40 patients were treated with stent. Study endpoints included cardiac death and recurrent ST. Mean age was 67.6±9.1 years, male gender in 75.6%, diabetes mellitus in 46.2%, and haemodialysis in 5.1%. Intra-aortic balloon pump was used in 47.4% and mean CPK elevation was 2906+-2769. There was no significant difference of patient and lesion characteristics between the two groups. Cardiac death occurred in a total of 15.4% at 5-years (26.3% in the POBA group vs. 5.0% in the stent group). The occurrence of cardiac death was significantly higher in the POBA group as compared to the stent group (HR, 5.44 [95% CI: 1.19-24.84], p=0.03). On the other hand, the occurrence of recurrent ST occurred in a total of 7 patients (2 patients in the POBA group and 5 patients in the stent group). There was no significant difference in the occurrence of recurrent ST (HR, 0.43 [95% CI: 0.08-2.20], p=0.31). When final TIMI grade 3 was obtained even in the POBA group, cardiac death occurred less as compared to those with TIMI grade 1 and 2 (13% in TIMI 3, 40.7% in TIMI 2 and 100% in TIMI 1 at 5-years, p=0.001).

Conclusions: Stent implantation might be a better treatment than POBA in patients with ST. However, when TIMI grade 3 were obtained, POBA for ST might be feasible.

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Real-world incidence of early definite stent thrombosis after primary PCI in bivalirudin-treated STEMI patients

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Aims: In recent studies of primary PCI (PPCI), bivalirudin compared to heparin has been associated with an increased risk of stent thrombosis (ST). Our aim was to describe real-life incidence of definite, angiographically proven ST in a large contemporary population of bivalirudin treated patients undergoing PPCI.

Methods and results: We conducted a prospective, observational cohort study of 16,860 bivalirudin treated PPCI patients who received a stent in Sweden from January 2007 to July 2014, in the nationwide complete SWEDEHEART registry. The primary outcome measure was incidence of definite, angiographically proven ST within 30 days of PCI (early ST). Secondary outcomes included all-cause mortality and descriptive variables of ST patients. Early ST was found in 0.84% (n=142) of the patient population. ST at day 0-1 occurred in 0.34% (n=55). Patients with early ST had higher all-cause mortality than patients without ST (n=16,718) (12.7% vs. 5.5% at 30 days [p<0.001], 22.6% vs. 9.8% at one year [p<0.001]). Patients with ST at day 2-30 had numerically higher all-cause mortality at one year compared to patients with ST day 0-1 (25.9% vs. 17.3%, p=0.246).

Conclusions: In this large, contemporary, real-world observational study of bivalirudin-treated PPCI patients, the incidence of early ST was low (0.84%). Early ST was associated with markedly increased mortality. Numerically higher all-cause mortality at one year was noted with ST at day 2-30 compared to ST at day 0-1.

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Consistent reduction in stent thrombosis risk at 5 years with a zotarolimus-eluting stent versus a sirolimus-eluting stent in men and women

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Aims: We studied whether gender may potentially modify the relationship between stent type and the incidence of stent thrombosis during long-term follow-up.

Methods and results: 2,062 women and 6,648 men who underwent PCI for various indications were enrolled in the PROTECT trial of the Endeavor zotarolimus-eluting stenting versus Cypher sirolimus-eluting stenting with 5 year follow-up. Women were older (66 vs. 61 years), more often had insulin dependent diabetes mellitus (9.7% vs. 6.1%), had a lower glomerular filtration rate (79 vs. 96 ml/min), and on average had a smaller stent diameter (2.9 vs. 3.0 mm) than men. These factors increased their stent thrombosis risk relative to men. In contrast, women were less often smokers (38% vs. 64%), less often had a previous myocardial infarction (17% vs. 22%), and had a smaller total stent length (29.5 vs. 31.8 mm) than men, which reduced their ST risk relative to men. In PROTECT, dual antiplatelet therapy, the combination of aspirin and clopidogrel or ticlopidine was to be given for the period of at least 1 year, in accordance with the guidelines of the European Society of Cardiology. At 2-year follow-up, 36% of women versus 33% of men still used dual antiplatelet therapy. At 5 years, the gender gap was increased to 4%: 25% of women and 21% of men were on dual antiplatelet therapy. At 5 years, the primary endpoint of definite or probable stent thrombosis was reached in 36 (1.8%) of women and 152 (2.4%) of men (p-value 0.15). Vascular healing in younger women might be influenced by (variations in) oestrogen levels. Therefore, we also studied the primary endpoint in the 294 women and 1,837 men below the age of 55, and women appeared to have a slightly lower incidence (0.7% vs. 2.9%; p-value 0.033). In a multivariate Cox regression model (adjusting for all relevant confounders) to predict the endpoint of definite or probable stent thrombosis, the gender treatment (Endeavor zotarolimus-eluting stenting versus Cypher sirolimus-eluting stenting) interaction was non-significant. Thus, we found no evidence for a differential effect on the incidence of definite or probable stent thrombosis of Endeavor zotarolimus-eluting stenting compared to Cypher sirolimus-eluting stenting between women and men at 5-year follow-up. The point estimates were 0.52 (women) and 0.58 (men), respectively, in favour of Endeavor zotarolimus-eluting stenting, with largely overlapping 95% confidence intervals, and irrespective of (young) age.

Conclusions: In PROTECT, despite differences in baseline characteristics and dual antiplatelet therapy treatment during follow-up, women and men had similar incidence of stent thrombosis at 5-year follow-up. The favourable effect of the study stent Endeavor zotarolimus-eluting stenting over Cypher sirolimus-eluting stenting was not gender-specific.

Incidence, predictors and correlates of stent thrombosis following drug-eluting stent implantation up to 12 years in daily practice

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Aims: The occurrence of stent thrombosis has being described as a relatively rare event in current era of DES; however, such an event is associated with significant morbidity and mortality. Importantly, several predictors of early- and late-stent thrombosis, especially in complex conditions and procedures, have being reported after DES, even though the overall incidence and correlates of very-late events (>1 year) in daily clinical practice are still not fully understood. Thus, our objective was to report occurrence of stent thrombosis up to 12 years after DES implantation in daily PCI.
Methods and results: A total of 5,614 patients with 9,045 coronary lesions were consecutively enrolled (since DES became commercially available locally in May/2002) in the large, prospective, non-randomised, single arm drug-eluting stent in the real-world (DESIRE) trial, which included patients from daily clinical practice with coronary artery disease, with at least one significant coronary lesion (>50% stenosis by visual estimation) with clinical indication for percutaneous revascularisation, treated solely with DES as default PCI strategy at a single institution. The main objective of the DESIRE trial was to assess the long-term clinical outcomes of patients treated with DES in real-world practice. The only exclusion criteria was PCI treatment with BMS (alone or in combination with any DES) at the time of the index procedure. Stent thrombosis was classified according to the Academic Research Consortium criteria. Overall, mean age was 64.6 years, 32% had diabetes, 29% smoking, 21% previous myocardial infarction, 24% previous CABG, 8.3% renal insufficiency, and 42% presented with ACS. Fifty-seven % had multivessel disease, type C lesion was found in 49% and 7.4% were bifurcations. During procedure, a total of 9,680 DES were implanted (mean 1.8 stents per patient) including 34% second-generation DES, given that mean nominal (total) stent length and diameter were 35.31 mm and 2.89 mm, respectively. There were 133 stent thromboses reported up to 12 years (follow-up in 96%, median duration 4.9 years), representing 2.4% incidence rate. Of these, approximately 60% of events were definite events; also, the majority of events were reported >1 year. In the multivariate model, significant predictors of overall stent thrombosis were recent myocardial infarction <72 hours (hazard ratio [HR] 2.61, 95% confidence interval [CI]: 1.58-4.34), recent myocardial infarction between 3 and 30 days (HR 2.03, 95% CI: 1.25-3.29), saphenous vein grafts (HR 2.24, 95% CI: 1.37-3.68), residual stenosis as assessed by quantitative coronary angiography (HR per % unit 1.03, 95% CI: 1.01-1.06), total stent length (HR 1.01, 95% CI: 1.01-1.02), and the use second-generation DES (HR 0.56, 95% CI: 0.31-1.00). Considering only definite/probable stent thrombosis, predictors were recent myocardial infarction <72 hours (HR 3.03, 95% CI: 1.47-6.24), saphenous vein grafts (HR 3.03, 95% CI: 1.55-5.94), and residual stenosis (HR 1.04, 95% CI: 1.01-1.07). As for very late events, predictors were recent myocardial infarction <72 hours (HR 1.63, 95% CI: 1.01-2.63), recent myocardial infarction between 3 and 30 days (HR 2.25, 95% CI: 1.19-4.23), and total stent length (HR1.02, 95% CI: 1.00-1.03).
Conclusions: The overall incidence of stent thrombosis up to 12 years was relatively low (2.4%) and significantly associated to clinical presentation of recent myocardial infarction, saphenous vein grafts, stent underexpansion, total stent length, and the use of first-generation DES.

Stent thrombosis in 2,424 Middle Eastern patients undergoing PCI for acute and stable coronary syndromes is associated with low mortality; the first Jordanian PCI registry (JoPCR1)

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Aims: To evaluate the incidence and impact on prognosis of stent thrombosis in Middle Eastern patients undergoing PCI for acute coronary syndrome (ACS) and stable angina.
Methods and results: We report interim results (in-hospital, N=2,286 and at 1 month, N=1,866 patients) of patients who underwent PCI in this registry that enrolled 2,424 patients (2013-2014). PCI was indicated for ACS in 82% (STEMI 30% and NSTEACS 52%) and stable angina in 18%. Dual antiplatelet therapy was prescribed for 99% of patients. In-hospital stent thrombosis occurred in 9 patients (0.4%) and in 24 (1.3%) from the time of discharge to 1 month. Of those 24 patients; 7 (29%) were admitted with STEMI and 9 (38%) with NSTEACS. None reported discontinuation of antiplatelet agents. Death occurred in two of the nine in-hospital stent thrombosis (22%), and 3 of the 24 stent thrombosis that occurred later (12.5%). Mortality at 1 month was 15% for stent thrombosis patients compared with 1.3% of patients who did not have stent thrombosis (p<0.001). Compared with patients who did not have stent thrombosis; those who had stent thrombosis were more likely to have diabetes (61% vs. 48%), past CVD (45% vs. 26%), ST-segment deviation (70% vs. 48%), LV EF<45% (36% vs. 13%), heart failure (30% vs. 11%) and ACS (100% vs. 82%) (all p-values <0.01). Other factors were not different among patients with or without stent thrombosis, including age, gender, smoking status, prior use of antiplatelet agents, PCI (including primary) for STEMI, or number of treated coronary arteries.
Conclusions: In this Middle Eastern registry, the incidence of stent thrombosis at 1 month was not different from other regions. Certain risk factors were more prevalent in patients who had stent thrombosis; however, the majority of them did not present with STEMI and had a mortality rate much lower than reported from other regions.

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Incidence and clinical features of early stent thrombosis in the era of new $P2Y_{12}$ inhibitors (PLATIS-2)

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Aims: Early stent thrombosis (EST) (i.e., ≤ 30 days after stent implantation) is a relatively rare but deleterious complication of percutaneous coronary intervention (PCI). Administration of the newer $P2Y_{12}$ inhibitors (i.e., prasugrel and ticagrelor) in conjugation with aspirin has demonstrated a decrement in the incidence of subacute and late stent thrombosis in comparison to clopidogrel. The aim of the current study was to investigate the "real life" incidence of EST in large national registry in a setting where newer $P2Y_{12}$ inhibitors are widely used.

Methods and results: Patients were derived from the acute coronary syndromes Israeli survey (ACSIS), conducted during 2006, 2008, 2010, 2013. Major adverse cardiac events (MACE) at 30-days were defined as all cause death, recurrent ACS, EST and stroke. Of the 4,717 patients with ACS who underwent PCI and stenting, 83% were treated with clopidogrel, 11% with prasugrel and 7% with ticagrelor. The MACE rate was 10.4% in the clopidogrel group compared with 7% and 8% in the prasugrel and ticagrelor group, respectively (p=0.03). Nevertheless, the EST rate was similar in all groups (1.4% for clopidogrel; 1.6% for prasugrel and 2% of ticagrelor group, p=0.6). Moreover, the EST rate (1%, 2.5%, 1.1%, 1.5%) did not differ significantly between the years 2006, 2008, 2010, 2013, respectively.

Conclusions: The incidence of EST following PCI in ACS was similar between patients who had received newer antiplatelet agents and clopidogrel. Nevertheless, MACE rate was lower in patients who had received newer antiplatelets agents.

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Long-term clinical outcomes of patients treated with rheolytic thrombectomy for acute myocardial infarction complicated by cardiogenic shock

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Aims: Since data is lacking, the main aim of this study was to evaluate the effects of rheolytic thrombectomy on long-term major adverse cardiac and cerebrovascular events and survival in patients treated with primary-PCI for acute myocardial infarction complicated by cardiogenic shock.

Methods and results: From a registry of 3,809 consecutive patients treated in a high-volume single centre with primary PCI for acute myocardial infarction from 1995 to 2012, we focused on 371 patients presented with cardiogenic shock at admission. Of these, a comparison was made between 63 patients treated with rheolytic thrombectomy (RT) vs. the remaining 308 treated without RT (Not-RT). The primary endpoint was the long-term (median 3.3 years) of all major cardiac and cerebrovascular events (All-MACCE), including cardiac and all-cause death. The results showed that although RT did not significantly reduce cardiac (52,2% RT vs. 56,5% Not-RT, p=0.579) and all-cause death (54.0% RT vs 58.8% Not-RT, p=0.487); a significant All-MACCE reduction was seen in the RT-group patients (57.1% vs. 71.4%, p=0.036); mainly due to re-infarction (1.6% vs 9.4%, p=0.04) and ischaemia-driven target vessel revascularisation (3.2% vs 13.6%, p=0.017). In a multivariate analysis, advanced age, not DES use, and Not-RT treatment were independents predictors of worse All-MACCE.

Conclusions: In the setting of real-world patients treated for acute myocardial infarction complicated by cardiogenic shock who are at high-risk of complications even after many years, rheolytic thrombectomy during primary PCI improves long-term major adverse cardiac and cerebrovascular events.

Intra-thrombus delivery of thrombolytics before thrombectomy in patients with ST-elevation myocardial infarction undergoing primary percutaneous coronary intervention: the DISSOLUTION randomised trial

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Aims: To evaluate the hypothesis that intra-thrombus delivery of thrombolytics can enhance the efficacy of thrombus aspiration in STEMI patients undergoing primary PCI.

Methods and results: A total of 102 patients with STEMI and angiographic evidence of massive thrombosis in the culprit artery were randomly assigned to receive local intra-thrombus bolus of 200,000 units urokinase (group A; N=51) or saline solution (group B; N=51) via an infusion microcatheter followed by manual aspiration thrombectomy and PCI. Both groups received abciximab (i.v. bolus+12-h infusion). Endpoints included final thrombolysis in myocardial infarction flow grade and frame count, myocardial blush grade, 60 min ST-segment resolution >70% and major adverse cardiac and cerebrovascular events, defined as the death, reinfarction, stroke, or clinically driven target vessel revascularisation at 6 months. All patients had echocardiography at 6 months and left ventricular ejection fraction and wall motion score were obtained. Baseline clinical and angiographic characteristics of both groups were similar. Local urokinase was associated with post-PCI evidence of higher TIMI flow grade 3 (96%vs. 68%; p=0.027), lower TIMI frame count (18±11 vs. 25±13; p=0.045) and fewer TIMI thrombus grade >2 (myocardial blush grade 20% vs. 52%; p=0.039). Histopathological evaluation performed in 11 group A and 11 group B patients showed that aspirated thrombi after urokinase were greater in amount, softer and less organised than after a saline solution. Post-PCI myocardial perfusion was slightly increased with urokinase (2/3: 88% vs. 64%; p=0.09), with significantly more patients showing 60 min ST-segment resolution>70% (80% vs. 56%, p=0.001). No differences between the two groups were subsequently seen in clinical outcomes and EF, whereas the 6-month wall motion score was significantly lower in patients receiving local urokinase than saline solution (1.21±0.29 vs. 1.45±0.32, p=0,008).

Conclusions: Intra-thrombus delivery of low-dose thrombolytics before thrombectomy in STEMI patients undergoing primary PCI is associated with improved coronary flow, myocardial perfusion and 6-months regional myocardial function. Delivery of low-dose thrombolytic agents directly to the site of thrombus might be an effective strategy to enhance efficacy of thrombus aspiration in primary PCI. (ClinicalTrials.gov Identifier: NCT01568931)

The optical coherence tomography substudy of the routine thrombectomy versus PCI alone (TOTAL) randomised trial: evaluation of residual thrombus burden after manual aspiration thrombectomy versus PCI alone

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Aims: Manual aspiration thrombectomy has been proposed as a strategy to reduce thrombus burden and thus distal embolisation during primary PCI in STEMI patients. However, the effectiveness of thrombectomy in reducing thrombus burden at the lesion site is uncertain. In this substudy of the TOTAL trial, we quantified culprit lesion thrombus burden with optical coherence tomography in patients treated with thrombectomy versus PCI alone.

Methods and results: The TOTAL trial is an international, multicentre, randomised trial of manual aspiration (using the Export catheter, Medtronic Cardiovascular, Santa Rosa, CA, USA) in STEMI patients treated with primary PCI (N=10,723). The OCT substudy prospectively enrolled 214 patients at 13 sites in 5 countries. Thrombus quantification was performed by an independent core laboratory (Tampere University, Finland) blinded to the treatment assignment. OCT was performed immediately after thrombectomy or angioplasty and prior to stent deployment and then repeated after stent deployment. The primary outcome was pre-stent thrombus burden (%) defined as the average of the thrombus area divided by the lumen area over the length of the analysed segment. In a 29 patient pilot assessment of feasibility and reliability, this outcome was assessable in 86% of cases and had excellent inter-observer reliability (limits of agreement –2.6 to 2.2). A sample size of 200 patients provided 84% power to detect a 30% reduction in thrombus burden. Key secondary outcomes were pre-stent quadrants of thrombus (mean number/mm) and post-stent atherothrombotic burden (%). The results of the OCT substudy will be available for presentation at EuroPCR, 2015.

Conclusions: The OCT substudy will document differences in residual thrombus burden after manual aspiration thrombectomy versus PCI alone and provide important mechanistic insights into the results of the TOTAL trial.

euroPCR Coronary interventions Euro15A-OP180

OCT evaluation of culprit lesions in STEMI after manual thrombus aspiration

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Aims: Thrombus aspiration is a well-established technique in the setting of primary coronary angioplasty for STEMI. We conducted a prospective OCT study evaluating the effect of intensive thrombo-aspiration in STEMI. We present here a part of this study: the characteristics of the underlying culprit lesion as seen by OCT.

Methods and results: In a prospective non-randomised single centre study, 40 consecutive patients with STEMI were treated by manual thrombus aspiration guided by OCT. Once a TIMI 3 flow is obtained after a mean of 4 aspirations (standard care), a first OCT run was done to assess residual thrombus. Then aspiration was continued with an OCT run every 4 catheter passages until no further decrease in thrombus burden was observed by OCT (intensive aspiration). A mean of ten aspirations were done in order to obtain the smallest final thrombus volume which was halved as compared to thrombus burden after standard care. The OCT characteristics of the underlying lesion were studied on the last run before stenting. We evaluated the continuity of the fibrous cap and the presence of a disruption defined a plaque rupture, a thrombus attached to an intact cap characterised an OCT plaque erosion. We also studied the thickness of the fibrous cap, the presence of macrophages and the extent of the lipid pool. Plaque rupture was found as culprit lesion in 34 patients (85%) and plaque erosion in 6 patients (15%). Plaque rupture was associated with a larger thrombus burden (8.24 vs. 1.62 mm^3), a larger lipid pool (+45%), and greater macrophages accumulation (+400%). A larger thrombus burden was associated with the presence of plaque rupture and a longer total ischaemic time. There was no correlation between thrombus volume and vessel size nor with distance between the lesion and the first collateral.

Conclusions: In the setting of STEMI, 85% of culprit lesions are plaque rupture. Thrombus burden is greater in the presence of a plaque rupture when compared to a plaque erosion and is correlated to a longer total ischaemic time. This data emphasise the utility of an effective thrombus aspiration.

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Dose-response study of endovascular moderate versus mild therapeutic hypothermia on infarct size reduction

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Aims: Previous evaluations of endovascular cooling during primary PCI for acute anterior myocardial infarction in human trials and animal studies suggest a treatment effect on infarct size reduction related to core temperature at the time of reperfusion. These indications of reduced infarct size have not translated into results seen in recent randomised trials. The objective of our study was to investigate a comparative dose response relationship between myocardial salvage and the depth of cooling.

Methods and results: Twenty-four pigs were randomly assigned to three groups: normothermia (38°C), mild hypothermia 35°C and moderate hypothermia 32°C. Infarct was induced by 1-hour balloon occlusion of the mid left anterior descending artery followed by reperfusion. A heat-exchange balloon catheter was placed in the inferior vena cava and the core left ventricle temperature was controlled to either 32°C or 35°C. Cooling was initiated after occlusion, but 30 minutes before reperfusion and maintained for 1 hour followed by rewarming (1.2°C/h) to normothermia. On the 6^{th} day post-intervention, infarct size was assessed with magnetic resonance imaging and pathological analysis (Evans Blue and Triphenyl Tetrazolium Chloride staining), followed by histomorphometric analysis. Groupwise comparison of continuous variables was done using one-way ANOVA with Tukey's *post hoc* test. Target temperature was reached in 9±5 and 29±8 minutes for 35°C and 32°C, respectively. Area-at-risk from tissue staining was equivalent in all groups (38°C 30±6, 35°C: 28±7, 32°C: 26±6, p=0.473. Both the 32°C and 35°C groups showed significant infarct size reduction relative to area-at-risk (38°C: 45±12, 35°C: 17±10, 32°C: 4±4, 62% and 91% reduction respectively, p<0.001) and a similar reduction relative to left ventricle mass (38°C: 14±5, 35°C: 5±3, 32°C: 1±1, p<0.001). Further, the 32°C group showed a significant 76% infarct to area-at-risk reduction compared to the 35°C group (p=0.033) suggesting better outcomes from deeper cooling on tissue salvage. Additionally, a higher reproducibility was observed in the 32°C group compared to 35°C in reducing infarct size (standard deviation 4 vs.10 relative to area-at-risk and 3 vs 1 relative to left ventricle). Histological (Mason's Trichrome and Haematoxylin/Eosin) and immunohistochemistry staining (Macrophages, angiogenesis and fibroblasts) confirms the significant infarct size reduction in the 35°C and 32°C groups (55% and 74% reductions relative to area-at-risk, p<0.002, respectively). *In vivo* magnetic resonance imaging evaluation of infarct size as percent left ventricle also supported the results of significant infarct reduction in the 32°C group (38°C: 10±4, 35°C: 8±3, 32°C: 3±2, p<0.001). Cardiac output relative to baseline was significantly preserved in the 32°C group only (38°C: -30%±16, 35°C: -24%±7, 32°C: -17%±18, p=0.037). In the linear regression model, target temperature was a significant predictor of infarct size reduction from tissue staining both relative to area-at-risk and left ventricle (goodness-of-fit residual R^2=0.746 and 0.685, respectively, p<0.001 for both). The predicted infarct reduction is 10% of area-at-risk and 3.6% of the left ventricle per 1°C drop of target cooling at reperfusion.

Conclusions: Pre-reperfusion therapeutic hypothermia shows dose-response infarct size reduction as well as favourable haemodynamic outcome for moderate 32°C cooling more consistently than mild hypothermia.

Measurement of microvascular function during coronary angiography: comparison of thermodilution and Doppler techniques

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Aims: Coronary microvascular function is increasingly measured after myocardial infarction, both as an index of prognosis and to compare peri-reperfusion adjunctive therapies. Currently there is no accepted gold-standard invasive measure of coronary microvascular function. We compared two novel measurements of coronary microvascular function recorded in the cardiac catheter laboratory: Doppler-derived hyperaemic microvascular resistance and a thermodilution-derived index of microvascular resistance, against myocardial perfusion reserve index using high-resolution cardiac magnetic resonance imaging.

Methods and results: Thrirty-seven patients (61±10 yrs) were recruited, 63% following an ACS. Simultaneous intracoronary pressure, Doppler flow velocity and cold-bolus transit time were measured in 45 coronary arteries, using a Volcano Combowire and St Jude Pressure Wire, at rest and during intravenous adenosine hyperaemia. Measurements were taken post-PCI in patients with significant coronary artery stenoses (stable angina and ACS patients). In some patients, when clinically feasible, a second set of measurements was taken in a normal reference vessel. We calculated, using standard definitions: mean coronary flow reserve from thermodilution and Doppler, hyperaemic microvascular resistance and the index of microvascular resistance. Three tesla cardiac magnetic resonance imaging scans were carried out and myocardial perfusion reserve index (the ratio of semi-quantitative perfusion assessed at rest and during hyperaemia) was calculated in the corresponding segments. In ACS patients, regional wall motion in corresponding segments and overall left ventricular ejection fraction (both from cine images), and infarct size (from late gadolinium enhancement images) were also calculated. Hyperaemic microvascular resistance correlated with the index of microvascular resistance($r=0.67$, $p<0.001$). In ACS patients, both were univariate predictors of left ventricular ejection fraction, infarct size and regional wall motion. However, hyperaemic microvascular resistance was the only independent predictor of regional wall motion. Delong receiver operating characteristic comparison analysis demonstrated that hyperaemic microvascular resistance had superior diagnostic accuracy over the index of microvascular resistance to predict mean coronary flow reserve (area under curve 0.79 versus 0.59, $p<0.01$) and separately to predict myocardial perfusion reserve index (area under curve 0.97 versus 0.84, $p=0.09$).

Conclusions: In patients presenting with an ACS, accurate assessment of coronary microvascular function on the cardiac catheter laboratory table is feasible, safe and rapid. This study, for the first time, simultaneously assessed the diagnostic accuracy of two such measures of coronary microvascular function. We demonstrated Doppler-derived hyperaemic microvascular resistance had superior diagnostic accuracy at predicting established invasive and non-invasive reference standards of microvascular function; in coronary flow reserve and myocardial perfusion reserve index, respectively.

Effect of ageing on microvascular function in non-obstructed reference coronary arteries

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Aims: Physiology-guided coronary revascularisation using fractional flow reserve (FFR) has shown to improve clinical outcomes in stable ischaemic heart disease compared with angiographic guidance. Nonetheless, it should be born in mind that the clinical benefit of FFR-guided decision-making documented in large randomised clinical trials did not investigate the validity of these findings in specific patient subsets. This is particularly important for advanced age, because physiological changes of the coronary vasculature and alterations in myocardial function associated with ageing may theoretically interfere with the reliability of FFR. This consideration is essential in an era when, as a result of changing demographics, an increasing number of older patients is being referred for percutaneous coronary intervention (PCI), while our understanding of the influence of ageing on coronary physiology parameters remains limited. Accordingly, in this study, we sought to document the changes in coronary physiology associated with ageing.

Methods and results: In patients scheduled for physiological lesion assessment, coronary flow was assessed in a non-obstructed reference coronary artery (n=172) using the Doppler-technique. Hyperaemia was induced by intracoronary bolus injection (40 µg) of adenosine. Coronary flow reserve (CFR) was defined as the ratio of maximal to resting flow velocity, representing microvascular function in absence of significant epicardial disease. Baseline and hyperaemic microvascular resistance (BMR, HMR), were defined as the distal pressure divided by distal flow velocity under baseline and hyperaemic conditions, respectively. In the 172 angiographically normal reference coronary arteries in patients evaluated with Doppler flow velocity, mean CFR was 2.9±0.7. We found that reference vessel CFR was negatively associated with advancing age ($rho=-0.31$, $p<0.001$; $R^2=0.07$, $p<0.001$). This occurred in the presence of a decrease in hyperaemic flow ($rho=-0.22$, $p=0.006$; $R^2=0.05$, $p=0.004$), in concomitance with an increase in hyperaemic microvascular resistance ($rho=0.25$, $p=0.002$; $R^2=0.06$, $p=0.002$), while no pertinent changes in basal flow ($rho=0.013$, $p=0.87$, $R^2=0.00$, $p=0.98$) or basal microvascular resistance ($rho=-0.01$, $p=0.93$, $R^2=0.00$, $p=0.70$) were documented.

Conclusions: Ageing of the non-obstructed coronary vasculature is associated with a reduction of the microvascular vasodilator response to pharmacological vasodilation, associated with an increased minimal microvascular resistance and an impairment of CFR. This finding may have pertinent implications for the interpretation of physiology indices in clinical practice.

euroPCR Coronary interventions

Euro15A-OP184

The randomised physiologic assessment of thrombus aspiration in ST-segment elevated myocardial infarction patients treated with primary PCI (PATA STEMI) study: final results

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Aims: Routine thrombus aspiration is superior to conventional primary percutaneous coronary intervention (PCI) in terms of improved myocardial perfusion in patients with acute myocardial infarction with ST-segment elevation (STEMI), but its clinical usefulness is still questionable. Myocardial perfusion after thrombus aspiration has not been evaluated by a quantitative index of microcirculatory resistance (IMR) in a randomised fashion.

Methods and results: We performed a randomised, controlled clinical trial to evaluate the impact of manual thrombus aspiration (the Eliminate aspiration catheter, Terumo Medical Supply, Japan) on microcirculatory resistance after primary PCI in 128 patients with the first STEMI randomly assigned either to the thrombus aspiration or the conventional primary PCI group before coronary angiography. The primary endpoint was defined as a mean value of IMRcorr in thrombus aspiration compared to conventional PCI group. Myocardial perfusion grade, resolution of ST-segment elevation, enzymatic infarct size, left ventricle remodelling and rate of adverse cardiac events were secondary endpoints. Manual thrombus aspiration, as compared with conventional PCI, resulted in significantly lower IMRcorr (27.5±16.8 U vs. 39.9±32.7 U, p=0,039). Treatment with thrombus aspiration, as compared with conventional PCI, resulted in similar rates of myocardial perfusion grade 0 or 1 (21.5% vs. 28.6%; RR 0.75; 95% CI: 0.41 to 1.38; p=0.36) and complete resolution of ST-segment elevation (61.5% vs. 49.2%; RR 1.25; 95% CI: 0.91 to 1.71, p=0.16), with lower infarct size (AUC CK 26,157.6±40,090.0 U vs. 32,013.6±52,676.1 U, p=0.026) and similar median value of WMSI (1.23 vs. 1.23), LV spherical volume index (0.43 vs. 0.41) and a similar rate of LV remodelling (27.9 vs. 18.5%, p=0.21). The rate of adverse events (death, myocardial infarction, stroke or hospitalisation for heart failure) was similar at 4.6% vs. 11.1%, p=0.20. In a multiple regression model with the log-transformed IMR as dependent variable, after adjusting for clinical, angiographic and procedural variables, thrombus aspiration was not an independent predictor of lower IMR (28.4 U; 95% CI: 24.7 to 32.8 U, vs. 32.4 U; 95% CI: 28.1 to 37.4 U; estimate 0.877, 95% CI: 0.715 to 1.077, p=0.21). Histopathological examination confirmed successful thrombus aspiration in 89.6% of patients.

Conclusions: Manual thrombus aspiration reduces microcirculatory resistance indicating better myocardial perfusion compared to conventional PCI in patients with STEMI. However, routine manual thrombus aspiration is not an independent predictor of reduced microcirculatory resistance. Reduction in microcirculatory resistance of 12.3% achieved by routine manual aspiration is not sufficient to allow echocardiographic or clinical improvement in STEMI patients at midterm follow-up.

euroPCR Coronary interventions

Euro15A-OP185

The effect of stent implantation on coronary microcirculatory status during primary percutaneous coronary intervention in patients with ST-elevation myocardial infarction

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Aims: Primary percutaneous coronary intervention (PPCI) usually with coronary stent implantation is the optimal treatment for patients presenting with ST-elevation myocardial infarction (STEMI). Despite this invasive approach, post-procedural myocardial perfusion is still abnormal in a significant minority of patients. An elevated index of microcirculatory resistance (IMR) reflects microvascular function and when measured immediately after PPCI, it can predict an adverse clinical outcome. We measured coronary microvascular function in patients presenting with STEMI and compared sequential changes before and after stent implantation.

Methods and results: In 85 patients admitted with STEMI fractional flow reserve (FFR), coronary flow reserve (CFR) and IMR were measured using a pressure wire (Certus; St. Jude Medical, St. Paul, MN, USA) immediately before and after stent implantation. Deploying a stent during PPCI significantly improved all of the measured parameters of coronary physiology including IMR from 67.7 (56.2-95.8) to 36.7 (22.7-59.5, p<0.001). However, IMR remained elevated (>40) in 28 (32.9%) patients after stenting. A high initial IMR did not fall to <40 in 15/85 patients and these patients were more likely to be late presenters (pain to wire time >6 hours). The extent of jeopardised myocardium (beta: –0.26, p: 0.009) and pre-stenting IMR (beta: –0.34, p: 0.001) predicted advantageous change in IMR (ΔIMR=post-stenting IMR – pre-stenting IMR) while thrombotic burden (beta: 0.24, p: 0.01) and deployed stent volume (beta: 0.26, p: 0.01) were mainly associated to a potentially deleterious increase in IMR.

Conclusions: Stent deployment during PPCI results in improved perfusion in most patients. However, this beneficial response to stent implantation is not universal and up to one third of patients have an elevated IMR at completion of treatment. Defining microvascular function before stent implantation with angiographic assessment may identify a group of STEMI patients who could benefit from additional therapies.

Influence of the amount of myocardium subtended to a coronary stenosis on the index of microcirculatory resistance: implications for the invasive assessment of microcirculatory function in ischaemic heart disease

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Aims: The index of microcirculatory resistance (IMR) is increasingly used to quantify microcirculatory function. However, in normal coronary arteries, resistance increases with the branching of the coronary tree, which suggest that IMR could be influenced by the amount of myocardial mass (MM) downstream. We aimed to evaluate the influence of the amount of MM subtended to an intermediate stenosis on the IMR.

Methods and results: IMR, fractional flow reserve and coronary flow reserve (CFR) were measured in 123 coronary arteries (102 patients) with intermediate stenosis. Jeopardised MM was estimated with the myocardial jeopardy index (MJI). MM was inversely associated with IMR (R^2=0.16, p<0.001). Differently, CFR was MM-independent (R^2=0.0). Vessels with IMR ≥30 U subtended lower amounts of MM than vessels with IMR<30 (MJI: 13.0% [Q1-3, 12.5-18.2%] vs. 20.4% [Q1-3, 15.10-25.5%], p<0.001), and at multivariate analyses, MM, aortic pressure, minimum lumen diameter and age were independent IMR predictors (R^2=0.24, p<0.001). Vessels with IMR ≥30 U and preserved CFR supplied the smallest MM amounts, suggesting an anatomically reduced but functionally preserved vascular bed.

Conclusions: The amount of myocardium subtending to a coronary stenosis has modest influence on IMR, and does not have an effect on CFR. Therefore, CFR could help refine microcirculatory function assessment with IMR.

Influence of microvascular resistance on anatomical and function severity of coronary artery stenosis

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Aims: Coronary angiography has been a standard diagnostic tool for assessing the anatomical severity of coronary artery disease. However, there are mismatches between anatomical and functional severity. The purpose of this study was to evaluate the influence of microvascular resistance on anatomical and functional severity of coronary artery stenosis.

Methods and results: We enrolled 85 patients (58 males, 63±10 years), who had 104 coronary lesions. Quantitative coronary angiography, fractional flow reserve (FFR) and hyperaemic microvascular resistance index (hMVRI) were measured at all of the lesions using a 0.014-inch intracoronary dual pressure Doppler sensor-tipped guidewire. FFR was calculated as distal pressure (Pd) divided by proximal pressure (Pa) and hMVRI was calculated as distal pressure (Pd) divided by hyperaemic APV. Lesions with diameter stenosis (DS) ≥50% and FFR >0.80 were defined as the mismatch group and lesions with DS <50% and FFR ≤ 0.80 were defined as the reverse mismatch group. There were 46 lesions (44%) mismatched and 58 lesions matching. Thirty-one (31) lesions (30%) were included in the mismatch group and 15 lesions (14%) were included in the reverse mismatch group. The mean FFR, diameter stenosis (%) and hMVRI were 0.79±0.11, 56.5±9.9 and 2.23±1.24. hMVRI was 2.03±1.03 in the match group (n=58), 2.96±1.53 in the mismatch group (n=31) and 1.50±0.31 in the reverse mismatch group (n=15). hMVRI was significantly higher in the mismatch group (p<0.01, by ANOVA). The reverse mismatch group had a tendency of lower hMVRI values. Thirteen lesions (87%) out of 15 reverse mismatch lesions were in left anterior descending artery.

Conclusions: There was considerable mismatching between anatomical and functional stenosis severity. Functional physiologic assessments with a microvascular function test should be required for percutaneous coronary intervention in myocardial ischaemia-related lesions.

Coronary interventions

Euro15A-OP188

Invasive assessment of myocardial capillary density using wave intensity analysis

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Aims: Assessment of the coronary microcirculation is hampered by the availability of adequate techniques. In particular, selective exploration of the capillary domain would be insightful given its size and its involvement in cardiac diseases, including acute coronary syndromes. Wave intensity analysis is a measure of energy exchange within a fluid medium constructed from simultaneously acquired pressure and flow that attempts to address this using separated interrogation of the capillary domain. Using this technique the myocardial-originating backward decompression wave has been shown to be most important for driving coronary flow. Direct *in vivo* evidence to validate wave-intensity analysis is lacking. In order to assess its histological basis we performed invasive intracoronary wave intensity in a population of cardiac transplant patients, prone to develop microvascular allograph vasculopathy, who underwent simultaneous angiography and cardiac biopsy.

Methods and results: Fifteen (15) cardiac transplant patients with normal systolic function who were scheduled for routine follow-up cardiac catheterisation and whose coronary arteries were angiographically free of stenoses were included in this study. Aortic pressure was obtained from the catheter tip and flow velocity measurements were performed in the mid segment of the left anterior descending coronary artery with a 0.014 inch intracoronary Doppler guidewire. Hyperaemia was induced using 60 µg intracoronary adenosine boluses and coronary flow reserve calculated. Offline wave intensity analysis was performed using a bespoke Matlab programme. Ventricular biopsies were obtained using a 7 Fr biopsy forceps. The tissue was fixed with paraldehyde and immersed in 10% buffered formalin. Haematoxylin staining was used to identify and analyse intramyocardial small arteries. Capillaries were identified with specific antibodies against endothelium (CD34; Dako, Glosturp, Denmark). Quantitative morphometric analysis of the histological sections was performed with a Leica Q500 MC micromorphometry workstation and the density of capillaries (capillaries per 1 mm^2) was assessed. Mean age was 49 (11 male) with the majority of transplantations having been undertaken for dilated cardiomyopathy (60%). Four (27%) patients were breathless on exertion and the remainder asymptomatic. Mean coronary flow reserve was 2.3±0.16 and was not correlated with capillary density (r^2=0.18, p=0.1). Conversely, a significant correlation was demonstrated between capillary density and both cumulative (r^2=0.44, p<0.01) and peak (r^2=0.33, p=0.03) backward decompression wave.

Conclusions: The results of this study, strengthened by micro-morphometric evidence obtained in endomyocardial biopsies, supports coronary wave intensity analysis as a promising technique to identify pathological modifications in capillary density that were not detected by coronary flow reserve. Further research on prognostic implications should follow not only in cardiac transplant patients, but also in the more common clinical scenarios that impact on the capillary domain of coronary microcirculation (acute coronary syndromes, ventricular hypertrophy and cardiomyopathies).

Coronary interventions

Euro15A-OP189

The prognosis of patients with STEMI and multivessel disease with PCI of the culprit artery without significant residual ischaemia on non-invasive stress testing

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Aims: In about 50-70% of patients with ST-segment elevation myocardial infarction (STEMI), there is significant atherosclerotic disease in other coronary arteries in addition to the culprit vessel. A central question is what is the prognosis of STEMI patients with multivessel disease who have undergone culprit-vessel primary percutaneous coronary intervention (PCI) where subsequent non-invasive testing did not detect significant ischaemia? We sought to compare the prognosis of these patients with patients with single-vessel disease.

Methods and results: The study included 720 patients with single-vessel disease and 185 patients with multivessel disease who underwent culprit only primary-PCI and subsequent non-invasive stress testing demonstrated no significant ischaemia. Mean follow-up was 83.6 (± standard deviation of 32 months). Patients with multivessel disease were older (57±12 vs. 62±10 years, p<0.001), more likely to have hypertension and previous MI (53.8% vs. 40.3%, p=0.001 and 13.1% vs. 6.5%, p=0.015, respectively) and less likely to be smokers than patients with single-vessel disease (51.1% vs. 62.4%, p=0.007). A greater proportion of patients with single-vessel disease presented with anterior MI compared with patients with multivessel disease (53% vs. 40%, p=0.005). Neither Killip class nor left ventricular systolic function was significantly different between the groups. MACE rates calculated by time to first event up to 1 and 3-years were similar between the 2 groups (8.6% vs. 10.9%, Log-Rank p=0.39 and 20.0% vs. 17.1%, Log-Rank p=0.45, respectively). There were no mortality events in the multivessel disease group during the first year after the index procedure (excluding the first 30 days) compared with 2.5% mortality rate in the single-vessel disease group (p=0.03). At 3-years mortality rate of patients with multivessel disease was similar to that of patients with single-vessel disease (5.4% vs. 5.0%, Log-Rank p=0.89). One and 3-year rates of re-infarction (3.3% vs. 2.8%, Log-Rank p=0.4 and 5.3% vs 4.8%, Log-Rank p=0.38, respectively) and revascularisation (8.1% vs. 7.6%, Log-Rank p=0.83 and 11.7% vs. 13.5%, Log-Rank p=0.53, respectively) did not differ between patients with single-vessel disease and those with multivessel disease. On Cox proportional hazards regression multivessel disease did not emerge as an independent predictor for MACE and its components at 1 and 3-years.

Conclusions: Patients with STEMI and multivessel disease treated with PCI of the culprit artery who do not demonstrate significant residual myocardial ischaemia on non-invasive stress testing have similar short- and long-term prognosis to STEMI patients with single vessel disease. These data support a strategy employing non-invasive stress testing to assess for ischaemia in patients with STEMI and multivessel disease following the culprit artery PCI. Such strategy can guide the management and prevent unnecessary interventions in this STEMI patient population.

Clinical benefits of complete revascularisation in ST-elevation myocardial infarction and multivessel disease: a meta-analysis of randomised controlled trials

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Aims: Current guidelines recommend culprit only revascularisation in haemodynamically stable patients with ST-segment elevation myocardial infarction (STEMI) and multivessel (MV) disease. Contrary to this there is a growing body of evidence available from recent randomised controlled trials (RCTs) demonstrating improved outcomes with complete MV-percutaneous coronary intervention (PCI).

Methods and results: An updated meta-analysis of RCTs comparing complete MV-PCI with non-complete MV-PCI in STEMI and MV disease was performed. Multiple databases along with congress proceedings from major cardiovascular societies meetings were screened for relevant studies. The primary endpoint was the composite of major adverse cardiac events (MACE). Secondary endpoints were cardiovascular mortality, recurrent MI and repeat revascularisation. Outcomes were analysed at longest available follow-up with differences accounted for with adjusted models by persons-years. A total of seven RCTs (N=1,303) were included. The median follow-up was 12 months. A significant 41% reduction of the odds of MACE was demonstrated with complete MV-PCI as compared to no-complete MV-PCI: OR (95% CI): 0.59 (0.36-0.97); p=0.04. This benefit was driven by a significant 52% reduction of the odds of recurrent MI: OR (95% CI): 0.48 (0.27-0.85); p=0.01 and 49% significant reduction of the odds of repeat revascularisation: OR (95% CI): 0.51 (0.31-0.84); p=0.008. Complete MV-PCI was associated with a non-significant trend towards reduced cardiovascular mortality (OR [95% CI]: 0.54 [0.26-1.10]; p=0.09).

Conclusions: In STEMI and MV disease, complete MV-PCI as compared to non-complete strategy yields higher benefits on clinical events driven by a significant reduction of myocardial infarction and repeat revascularisation rates.

The impact of the presence of CTO in a non-infarct-related coronary artery in ACS patients: validation in a subset of patients with preserved left ventricular function after successful primary PCI

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Aims: Chronic total occlusion (CTO) in a non-infarcted-related artery was reported to worsen immediate clinical outcome in acute myocardial infarction (AMI) patients. However, the prognosis of such patients with preserved left ventricular function after successful primary percutaneous coronary intervention (PCI) has not been clarified yet. We aimed to evaluate whether the presence of CTO contributes to worse prognosis even in patients with preserved left ventricular function after primary PCI.

Methods and results: We retrospectively analysed 353 consecutive patients with acute myocardial infarction, whose left ventricular ejection fraction (LVEF) was not less than 40% in the echocardiography performed 1 day after primary PCI. We divided patients into two groups according to the presence (n=25) or absence (n=328) of CTO in the non-infarct-related coronary artery, and compared the clinical outcome of patients between the two groups. The LVEF estimated by echocardiography after primary PCI was similar between patients with and without CTO (55.1±8.6% vs. 58.0±9.4%; p=0.07). The peak creatine kinase value was also similar between the two groups (1,539 vs. 1,921 U/L; p=0.33); however, CTO patients were significantly more likely to undergo intra-aortic balloon pumping (56.0% vs. 12.5%; p<0.001) during primary PCI, and 30-day mortality was significantly higher in CTO patients (12.0% vs 0.9%; p<0.001). By multivariate analysis, cardiogenic shock at arrival was significantly correlated with 30-day mortality.

Conclusions: In AMI patients with CTO, even if their LVEF was preserved after successful primary PCI, the short-term prognosis is poor as compared to that of AMI patients without CTO. The cause of such poor prognosis was strongly associated with initial cardiogenic shock at the time of arrival at the hospital.

EuroPCR Coronary interventions

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Prognostic impact of a chronic total occlusion in a non-infarct related artery in STEMI

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Aims: There is growing interest on the importance of coronary CTOs and their treatment. We aimed to evaluate the impact of multivessel disease (MVD), with and without a CTO in a non-infarct-related artery on in-hospital and one-year outcomes in patients presenting with STEMI.

Methods and results: We retrospectively studied 426 consecutive patients admitted with STEMI in our institution, between 2008 and 2012. We defined 3 groups: single vessel disease (SVD), MVD without a CTO and MVD with a CTO (MVD-CTO). In-hospital outcomes (shock, death, major bleeding, stroke, re-infarction, acute renal failure and left ventricular systolic dysfunction [LVSD]), 1-year survival and major adverse cardiovascular events (MACE) free survival rates (death, nonfatal myocardial infarction, myocardial revascularisation for symptoms or silent ischaemia, stroke) were studied. Among the 426 patients included, 175 (41%) had SVD, 197 (46%) had MVD without a CTO and 54 (13%) had MVD-CTO. Patients with MVD-CTO were older (MVD-CTO 67±12 vs. MVD without CTO 64±14 vs. SVD 60±12 years, p<0.001), more often diabetic (MVD-CTO 37% vs. MVD without CTO 28% vs. SVD 19%, p=0.021) and hypertensive (MVD-CTO 72% vs. MVD without CTO 70% vs. SVD 45%, p<0.001) and had, more frequently, chronic renal disease (MVD-CTO 45% vs. MVD without CTO 29% vs. SVD 14%, p<0.001). Compared with SVD and MVD without a CTO, patients with MVD-CTO had a higher incidence of cardiogenic shock (MVD-CTO 23% vs. MVD without CTO 8% vs. SVD 6%, p=0.001), severe LVSD at discharge (MVD-CTO 35% vs. MVD without CTO 13% vs. SVD 8%, p<0.001) and in-hospital mortality (MVD-CTO 20% vs. MVD without CTO 10% vs. SVD 5%, p=0.003). The presence of CTO (and not MVD without a CTO) was an independent predictor of cardiogenic shock (OR 3.7, 95% CI: 1.2-11.6, p=0.023) and severe LVSD (OR 5.1, 95% CI: 2.1-12.4, p<0.001), but not of in-hospital mortality. There were no significant differences in major bleeding, stroke, re-infarction and acute renal failure between groups. Patients with MVD with and without a CTO, had lower one-year survival rates (MVD-CTO 78% vs. MVD without CTO 85% vs. SVD 91%, p=0.03) and lower one-year MACE free survival rates (MVD-CTO 74% vs. MVD without CTO 79% vs. SVD 87%, p=0.021). After adjustment for baseline differences, Killip class ≥2 and left ventricular ejection fraction ≤45% were independent predictors of 1-year outcomes, but MVD and CTO were not.

Conclusions: In patients with STEMI, the presence of a coronary CTO is associated with worse outcome and represents an independent predictor of cardiogenic shock and severe LVSD.

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Clinical impact of the revascularisation of chronic total occlusions in non-infarct-related arteries in patients with ST-elevation acute myocardial infarction undergoing primary percutaneous coronary intervention (from the CREDO-Kyoto registry Cohort-2)

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Aims: The aim of this study was to investigate the clinical impact of successful percutaneous coronary intervention (PCI) for chronic total occlusions (CTO) in non-infarct-related arteries (non-IRA) in patients with ST-segment elevation acute myocardial infarction (STEMI) undergoing primary PCI.

Methods and results: The CREDO-Kyoto AMI registry is a large-scale cohort study of acute myocardial infarction (AMI) patients undergoing coronary revascularisation in 2005-2007 at 26 hospitals in Japan. Among 5,429 patients enrolled in the registry, 4,436 STEMI patients were treated by PCI. After excluding 55 patients with a prior history of CABG and 3,934 patients without concurrent CTO in non-IRA, the current study population consisted of 447 patients with concurrent CTO in non-IRA undergoing primary PCI for STEMI. They were categorised into 2 groups: patients who underwent successful CTO-PCI (CTO-PCI group) and patients who underwent non-attempted or failed CTO-PCI (non-CTO-PCI group). Clinical outcomes were compared between the 2 groups. Of 447 patients, 85 patients (19%) underwent successful CTO intervention whereas 52 patients (11.6%) underwent failed CTO intervention and 310 patients (69.4%) attempted no intervention. As for clinical characteristics, previous MI, previous PCI, end-stage chronic kidney disease, anaemia and chronic obstructive pulmonary disease were more prevalent in the non-CTO-PCI group than in the CTO-PCI group. The number of proximal CTO is significantly larger in the CTO-PCI group but the number of CTO and the location of target CTO lesion is not significantly different between the groups. The cumulative five-year incidence of all-cause death was significantly lower in the CTO-PCI group than that in the non-CTO-PCI group (26.9% versus 38.7%, p=0.02). Nevertheless, after adjusting for confounders, the risk for all-cause death in the CTO-PCI group was not significantly lower than that in the non-CTO-PCI group (hazard ratio [HR]:0.69, 95% CI: 0.43-1.08, p=0.11). The cumulative five-year incidence of cardiac death, non-cardiac death, MI, stroke and any coronary revascularisation were not significantly different between the 2 groups.

Conclusions: Successful PCI for CTO in non-IRA was not associated with better five-year mortality in STEMI.

Impact of incomplete revascularisation as assessed by the SYNTAX revascularisation index on very long-term mortality in STEMI patients undergoing primary PCI

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Aims: We sought to evaluate the capacity of SYNTAX revascularisation index (SRI) to predict very long-term mortality in patients with STEMI undergoing primary PCI.

Methods and results: The baseline SYNTAX score (bSS) and residual SYNTAX score (rSS) were assessed in 571 patients who were treated with primary PCI in 2009 in a high-volume catheterisation laboratory. Patients with non-culprit lesions were referred to staged revascularisation. Baseline SYNTAX score was calculated by scoring the culprit lesion after the coronary wire passage and prior to stent implantation. The following formula was used to calculate SRI: (1 – [rSS/bSS]) x 100. Mortality rates were analysed according to the predefined three categories: SRI 100% (complete revascularisation), SRI 50-99% and SRI <50%. Patients deferred to urgent surgical revascularisation (n=10) were excluded from the analysis. The overall mortality rate after median follow-up of 4.5 years (IQR 4.3-4.75) was 18.4%. Median SYNTAX score at baseline (bSS=9, IQR 5-16) was reduced after primary PCI to a median rSS of 2 (IQR 0-8). Complete revascularisation (SRI 100%) was achieved in 47.1% (n=269) of patients, while SRI 50-99% was present in 19.8% (n=114) and SRI <50% in 33.1% (n=188). The median SRI was 83.3% (IQR 36.4-100). Mortality rates according to the estimated completeness of revascularisation were as follows: 11.2% in patients with SRI 100%, 24.6% for SRI 50-99% and 25.0% in patients with the reduction in SYNTAX score of less than 50% (SRI <50%). Log-rank test showed significant difference between the cumulative mortality curves for the three categories (p<0.001), with significantly lower mortality rate in patients with complete revascularisation. Area under curve for SRI as continuous variable was 0.626 (95% CI: 0.567-0.685, p<0.001) with an estimated cutoff value of 85%. The agreement between observed and expected events was good according to the Hosmer-Lemeshow test (Chi2=6.61, p=0.16). Patients with SRI <85% had significantly higher mortality rates during median follow-up as compared to SRI ≥85% (24.7% vs. 11.7%, p<0.001). Multivariable analysis, taking into account known baseline risk factors showed that SRI independently predicted mortality after primary PCI, with an increase in 10% of SRI amounting to a predicted 23% reduction in mortality (HR 0.977, 95% CI: 0.956-0.999, p=0.04).

Conclusions: The completeness of revascularisation as assessed by the SYNTAX revascularisation index correlates with very long-term mortality after primary PCI. Subsequent analysis showed that complete revascularisation offers survival benefit over virtually any degree of incomplete revascularisation. Ongoing large randomised studies will show the true impact of complete revascularisation in STEMI patients undergoing primary PCI, with particular attention to the question of timing of non-culprit intervention.

Incomplete revascularisation: the residual SYNTAX score, target SYNTAX score and baseline SYNTAX score in ST-Elevation Myocardial infarction patients.

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Aims: This study sought to describe the synergy between PCI With TAXUS and cardiac surgery (SYNTAX) scores in 245 patients undergoing percutaneous intervention (PCI) following ST-elevation myocardial infarction, in a large, high-volume tertiary Australian centre, to objectively investigate the degree of incomplete revascularisation in our real-world cohort.

Methods and results: The SYNTAX score is a validated objective technique for quantifying the complexity of coronary artery disease primarily used in stable coronary disease. We directly determined the target SYNTAX score (tSS) (the SYNTAX score of the culprit lesion); baseline SYNTAX score (bSS) (the SYNTAX score of the entire coronary tree prior to PCI); and residual SYNTAX scores (rSS) (the SYNTAX score of the entire coronary tree post-index PCI) for all patients. SYNTAX scores were determined by 2 of 4 reporting interventional cardiologists for each patient. Of the 245 patients included for analysis 213 (87%) were male, 50 (21%) had diabetes, 111 (46%) had hypertension, 147 (61%) were smokers, 62 (26%) had a family history of ischaemic heart disease, 110 (45%) had dyslipidaemia and 23 (9%) previous acute myocardial infarct, no significant differences were seen in rSS, bSS or tSS across SYNTAX tertiles for these factors. Increasing age was associated with significantly higher bSS and rSS (p=0.035 and p=0.004, respectively) but not for tSS. Results were as follows: median age (for bSS tertiles bSS≤9 vs. bSS >9-16 vs. bSS >16, respectively), 56.8±14.3 vs. 53.6±13.0 vs. 59.2±13.3; p=0.035. Median age (for rSS tertiles rSS=0, vs. rSS 1-8, vs. rSS >8, respectively) 54.4±16.7 vs. 55.2±12.6 vs. 60.0±14.4; p=0.004. Conversely stent length was significantly higher with higher tSS (18.0±13.0 vs. 24.0±22.0 vs. 26.0±16.0 respectively from for tSS tertiles tSS ≤9 vs. tSS >9-16 vs. tSS >16; p=0.003) but not significantly different across bSS and rSS tertiles. Patients with a left anterior descending artery infarct in segments 6 or 7 were more likely to have a high bSS and tSS (p=0.023)(p<0.001) and more likely to have a low rSS (p=0.045). Incomplete revascularisation was common, only 58 patients (24%) had a rSS of 0, 96 patients (39%) had a rSS=1-8, and 91 patients (37%) had a rSS>8. The mean overall rSS was 7.23±6.53. Multivessel disease (MVD) with stenosis of ≥70% in 2 or more major epicardial vessels was present in 89 patients (37%); only 2 (2.2%) patients with MVD with stenosis of ≥70% had complete (rSS=0) revascularisation. MVD was associated with a higher mean bSS than single vessel disease (21.0±7.7 vs. 13.8±6.8; p<0.001) and higher mean rSS (11.7±6.3 vs. 4.7±5.2; p=<0.001) but not tSS (11.6±7.3 vs.10.5±6.5; p=0.46). Staged procedures were performed in 20 patients (8.2%), 12 patients (4.9%) had a planned staged procedure as an inpatient within 5 days.

Conclusions: In our cohort, older age and multivessel disease with 70% stenosis were associated with high residual SYNTAX scores, but a significant difference was not evident in diabetic patients. A higher baseline SYNTAX did not significantly increase implanted stent length. Debate regarding the appropriate levels of incomplete revascularisation and the optimal timing for non-culprit PCI in STEMI remain. In our institution, high residual SYNTAX scores are common after treatment of ST-elevation myocardial infarction.

EuroPCR Coronary interventions

Euro15A-OP196

Validation of the hybrid algorithm for coronary CTO-PCI: the RECHARGE registry

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Aims: The hybrid algorithm has the potential to improve the current success rates of coronary CTO-PCI. With the prospective, multicentre registry of CrossBoss and hybrid procedures in France, The Netherlands, Belgium and the United Kingdom (RECHARGE), we attempt to validate the efficacy of the hybrid algorithm by collecting data on 1,000 hybrid procedures.

Methods and results: From January to December 2014, patients treated with PCI for a coronary CTO using the hybrid algorithm were enrolled prospectively in 18 centres. The primary endpoint was procedural success. To date, 392 CTOs have been included, which were classified according to the Japanese CTO difficulty score. Procedural success was reached in 87% of all cases. Easy, intermediate, difficult and very difficult CTOs could be treated successfully in 100%, 96%, 88% and 77% respectively. The algorithm combines four techniques: antegrade wire escalation, antegrade dissection and re-entry, retrograde wire escalation and reverse controlled antegrade and retrograde subintimal tracking. Each technique was used 319 (81%), 86 (22%), 52 (13%) and 87 (22%) times during the 392 procedures respectively (multiple strategies possible per procedure) and was successful in 68% (218/319), 62% (53/86), 29% (15/52) and 64% (56/87) respectively. When used as a primary strategy, each technique was successful in 69% (211/305), 59% (19/32), 27% (6/22) and 64% (21/33) respectively, resulting in a total success of 66% (257/392) with the first strategy. Upon failure, applying a second, third and/or fourth bailout strategy resulted in an additional success of 71% (85/119), with antegrade and retrograde dissection and re-entry techniques most preferred and successful (40% [34/85] and 41% [35/85], respectively).

Conclusions: Although these data are preliminary, the hybrid algorithmic approach leads to high success rates in CTO-PCI, especially by combining different strategies.

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Euro15A-OP197

The first clinical experience with a novel "locking" microcatheter in chronic coronary total occlusion

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Aims: We describe the first clinical experience of a novel microcatheter developed to address persisting CTO-PCI technical difficulties and improve overall recanalisation success.

Methods and results: The Nhancer microcatheter (NHM; Interventional Medical Device Solutions, Roden, The Netherlands) is an over-the-wire microcatheter with a uniquely designed torquer on a compressible shaft that allows any 0.014" guidewire and the device to be locked together. Locking improves efficiency of force transmission and allows dynamic alterations in column strength and guidewire characteristics to overcome resistant or tortuous anatomy. The NHM was assessed prospectively in 92 unselected CTO cases across 6 European sites between June and November 2014. Mean J-CTO score was 2.79 (±1.36) and 56.6% (n=52) had a J-CTO score of 3 or greater. Technical success was defined by TIMI 3 flow and less than 30% residual stenosis. Procedural technical success was 85.9% (n=79) for the study group (n=92) and 97.5% for patients with a J-CTO score of 0-2 (n=40). Stents were implanted in 78 of the 79 successful procedures. Antegrade wire escalation (AWE) was the initial strategy in 82.6% of cases and final successful strategy in 73.4% of cases, consistent with a high rate of AWE success. Locking facilitated guidewire penetration of the proximal cap in 23 cases, distal cap in 11 cases and advancement through the CTO body in 10 cases. Locking also assisted delivery of the NHM past the occlusion and onwards to the distal vessel in 20 cases. In total, locking permitted guidewire or microcatheter advancement in 68.9% (n=42) of the 61 cases in which it was used. Multivariable regression analysis of CTO characteristics suggested the NHM was effective in overcoming resistance anatomy, consistent with our locking results. Neither calcification (OR 0.56; 95% CI: 0.05-6.27, p=0.56) nor a blunt proximal cap (OR 0.49; 95% CI: 0.08-2.89, p=0.48) affected technical success in our population. The only independent predictor of reduced success with the NHM was within-CTO tortuosity (OR 0.10; 95% CI: 0.01-0.93, p=0.04). Procedural complication rate was 1.1% with one incidence of tamponade following wire exit not consequent on locking. No myocardial infarction, emergency surgical revascularisation or deaths were observed.

Conclusions: Guidewire locking with the NHancer is helpful in overcoming resistant anatomy. Using the NHM in CTO-PCI is associated with a high degree of procedural success and very low complication rate. In patients with a J-CTO score 0-2 technical success was equivalent to non-CTO-PCI.

Relevant complications with the retrograde approach: subanalysis of data from a 5-year Japanese multicentre CTO registry

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Aims: The Retrograde Summit registry was initiated by the Retrograde Summit in 2009 to understand current results of percutaneous coronary interventions (PC) for chronic total occlusions (CTO) in Japan and observe trends based on the enhancement of operators' skills. According to the results from this registry, procedure success of PCI for chronic total occlusion has improved; however, occurrence of complications related to the retrograde approach are still reported.

Methods and results: A total of 2,194 cases receiving retrograde CTO-PCI were enrolled prospectively in the Retrograde Summit registry between January 2009 and December 2013 from 57 centres in Japan. Two hundred and forty-one (241,11.0%) complications related to the retrograde approach were reported. Collateral channel injury occurred in 210 (9.57%) cases. In these cases, 61 (2.8%) of reported channel injuries required treatment and the incident rate of cardiac tamponade was 0.4% (9/2,194). Donor artery complications such as stenting required due to dissection, spasm, ischaemia due to pre-existing lesions and thrombosis were reported in 11(0.5%) cases.

Conclusions: Despite the occurrence of collateral channel injury, the incidence of severe complications such as cardiac tamponade was very low. The results show the safety of the retrograde approach for CTO-PCI.

Chronic coronary total occlusion and low left ventricular ejection fraction: treatment and follow-up

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Aims: We aimed to analyse major adverse events and functional class of angina and left ventricular failure in patients with a chronic total coronary occlusions (CTO) and with low left ventricular ejection fraction (LVEF).

Methods and results: Between June 2010 and December 2012 we conducted a registry of 256 consecutive patients with at least one CTO and <40% LVEF. Patients were divided into 2 groups: in group I CTO, we include those patients who were treated percutaneously (PCI); and in group II all the other patients. Characteristics of the global population: medium age 65.5±11.7 years, 14% women, 71% hypertension, 60% dyslipidaemia, 43% diabetes, 64% previous or current smoker, previous myocardial infarction 47%, previous CABG 11.7%, ACEF score 2.39±0.77. Only 12.5% were asymptomatic for angina and 40% were in class I NYHA. Angiographic characteristics: 74% had 1 CTO, 70% had multivessel disease. Medium LVEF was 30±7%. Fifty-seven (57) patients were included in group I. All the parameters between both groups were similar except that in group I patients were younger (62±10.4 vs. 66.5±11.8; p=0.021), there were more women (22.8% vs. 11.6%; p=0.033), less hypertension (49% vs. 77.4%; p<0.001), worse LVEF (28.7±7.7% vs. 31.1±7%; p=0.028) and more multivessel disease (84% vs. 58%, p=0.036). Complete revascularisation were obtained more often in patients sent to PCI (60% vs. 21% p<0.001). PCI-CTO success was 72%, similar in both groups. During the follow-up (710±378 days) there were no differences between groups on the incidence of AMI (8% group II vs. 5% group I, p=0.58), cardiovascular death (20.1% group II vs. 12.3% group I, p=0.18), all causes of death (21.6% group II vs. 14% group I; p=0.21). Patients in group II were referred to CABG more often (20.6% vs. 1.8% p=0.001) and had a worse clinical status (asymptomatic for heart failure in group II 33% vs. 58% in group I, p=0.001; and angina 82% vs. 94%, p=0.037).

Conclusions: Even though adverse events did not reach statistical significance the observed incidence of each parameter is higher in the group of patients not sent to PCI. PCI provides a less symptomatic status and a higher incidence of complete revascularisation.

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Euro15A-OP200

Impact and outcome of re-attempted CTO-PCI against procedural lesions

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Aims: It has been reported that re-attempted (previously attempted but failed) treatment of CTO lesions was an independent parameter in itself of measuring successful interventional revascularisations. However, it is unclear whether re-attempted interventional CTO lesions may affect clinical and procedural results compared to the initial interventional CTO lesions.

Methods and results: We evaluated consecutive 310 lesions underwent CTO-PCI regarding whether initial or re-attempted procedures (251 vs. 59 lesions), which were evaluated as to clinical and procedural characteristics. In the J-CTO score, the re-attempted lesions had a much higher value of the J-CTO score than the initial attempted lesion (3.3+/-1.0 vs. 1.4+/-1.1, p<0.001). In detailed assessment of other parameters of the J-CTO score, angiographic-evident-calcification-within-CTO-segment had the most impact in re-attempted lesions (52.5% [31/59] vs. 24.7% [62/251], p=0.00019). Occlusion length-â'§20 mm (57.6% [34/59] vs. 34.7% [87/251], p=0.0018) and bending >45 degrees within the CTO route (45.8% [27/59] vs. 23.9% [60/251], p=0.0027) were respectively of impact in the re-attempted lesions than the initial procedural lesions. Whereas, a-blunt-shape-of-entry was seen as relatively the same between the re-attempted and initial procedural lesions (57.36% [34/59] vs. 48.6% [122/251], p=0.26). Re-attempted CTO-PCI procedures had significantly lower success rates compared to initial procedures (69.5% [41/59] vs. 89.6% [225/251], p=0.0022), despite of higher utilisation of the retrograde approach (55.9% [33/59] vs. 13.9% [35/251], p<0.001), longer fluoroscopic time (min.) (81.1±49.1 vs. 52.2±38.2, p<0.05), and more radiation dose (Gycm^2) (471.5±291.6 vs. 356.7±248.8, p<0.05)

Conclusions: Re-attempted CTO lesions were more complicated and had lower successful interventional revascularisation rate, requiring complex and longer procedural times.

euro PCR Coronary interventions

Euro15A-OP201

Long-term follow-up of coronary bypass patients with pre-operative and new post-operative native coronary artery chronic total occlusions

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Aims: Chronic total occlusions (CTOs) of native coronary arteries are a frequent finding among patients who are being referred for surgical revascularisation with coronary artery bypass grafting (CABG). The long-term clinical significance of native coronary artery CTO identified at baseline and at 1-year, post-CABG is unknown.

Methods and results: All patients who underwent 1-year follow-up angiography as part of the multicentre radial artery patency study (RAPS) were assessed for late clinical events. At a median follow-up of 7.3±2.9 years, the study group of 388 patients had the following outcomes: 39 (10%) deaths, 6 (1.5%) with non-fatal myocardial infarction and 19 (4.9%) underwent PCI. CTO of ≥1 native coronary artery in the baseline pre-operative coronary angiogram was demonstrated in 240 (61.9%) patients. The composite of all-cause death, non-fatal myocardial infarction and PCI occurred significantly more often in patients with at least one pre-operative CTO than in patients without a pre-operative CTO (20% versus 11%, p=0.048). A new native coronary artery CTO at 1-year post-surgery occurred in 169 (43.6%) patients. The composite of all-cause death, non-fatal myocardial infarction and PCI, occurred significantly more often in patients with a new CTO at 1-year post-CABG compared to those who did not (21.3% versus 12.8%, p=0.028).

Conclusions: In patients undergoing CABG, both pre-operative CTOs and new CTOs that develop 1-year following surgery are associated with adverse long-term clinical outcomes.

Long-term, 7-year clinical outcomes of successful vs. failed revascularisation using drug-eluting stents for the treatment of coronary chronic total occlusion

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Aims: The long-term benefits of successful revascularisation for CTO remain controversial. To investigate the long-term, 7-year clinical outcomes of patients who received successful vs. failed revascularisation using a drug-eluting stent (DES) for the treatment of chronic total occlusion (CTO).
Methods and results: In this prospective cohort study, 377 consecutive CTO patients were divided according to successful (n=253) or failed (n=124) DES revascularisation. We compared a composite index that consisted of death, myocardial infarction (MI), stroke, and target vessel revascularisation (TVR) at 7 years using propensity score matching and inverse probability of treatment weighted (IPTW) analyses. Compared with the failed-revascularisation group, patients in the successful-revascularisation group were significantly younger, more likely to have an occluded left anterior descending artery, lower incidences of renal failure, history of MI, previous heart failure, and prior coronary intervention. After a median follow-up period of 2,561 days (interquartile range=1,533-2,996 days), the successful-revascularisation group demonstrated a slightly lower incidence of the composite endpoint than the failed-revascularisation group (26.5 vs. 34.3%; log-rank p=0.27) After IPTW adjustment, the risk of clinical outcomes (hazard ratio [HR]=1.00; 95% confidence interval [CI]: 0.58-1.74; p=0.99) was not statistically different between the groups. Propensity score matching analysis (91 matched pairs) revealed similar outcomes (HR=1.09; 95% CI: 0.62-1.90; p=0.77).
Conclusions: Successful CTO revascularisation does not demonstrate beneficial long-term clinical outcomes over 7 years.

The benefits conferred by radial access for cardiac catheterisation are offset by a paradoxical increase in the rate of vascular access site complications with femoral access: the radial paradox

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Aims: We sought to assess whether the benefits conferred by radial access (RA) at a patient level are offset by an increased rate of vascular access site complications (VASCs) associated with femoral access (FA) at a population level.
Methods and results: We studied two cohorts of consecutive patients (n=17,059) referred for diagnostic or therapeutic procedures. We compared a contemporary cohort of femorally accessed (FA) patients (n=5,474) and radially accessed (RA) patients (n=4,663), with a historical cohort (n=6,922) where only FA was used. All patients were systematically followed-up for VASCs at 1 month, as part of a quality control program for catheterisation-related complications. VASCs included major haematoma (FA: >10 cm; RA: >5 cm), pseudoaneurysm, arteriovenous fistula, retroperitoneal haematoma and major bleeding. We calculated the odds ratios (OR) and 95% confidence intervals (CI) of VASCs adjusted for demographic variables, clinical presentation and comorbidities (Elixhauser comorbidity index), using multivariate logistic regression. Subsequently, we calculated the adjusted attributable risk of VASCs in FA patients due to the emphasis on RA. In the contemporary cohort, n=256 and n=66 VASCs occurred in FA and RA patients, respectively. In the historical cohort, n=200 VASCs were observed. As expected, in the contemporary cohort, RA experienced less VASCs than FA (1.42% vs. 4.68%, p<0.0001). This observation was confirmed by adjusted analysis (OR: 0.33, 95% CI: 0.23 to 0.48; p<0.0001). However, we observed a higher rate of VASCs in FA patients of the contemporary cohort, as compared with the historical cohort (4.68% vs. 2.89%, p<0.0001). This finding was confirmed by adjusted analysis (OR: 2.16, 95% CI: 1.67 to 2.81; p<0.0001) and was consistently observed in a sensitivity analysis: FA patients of the contemporary cohort were more likely to suffer a VASC, when considering both diagnostic (OR: 2.30, 95% CI: 1.36 to 3.91; p=0.002) and therapeutic (OR: 2.24, 95% CI: 1.64 to 3.06; p<0.0001) procedures separately. At a population level, the increase in VASCs in FA patients of the contemporary cohort offset the benefit conferred by RA: there was no difference in the unadjusted rates of VASCs between the overall contemporary (FA+RA) and historical (FA only) cohorts (3.18% vs. 2.89%, p=0.29). Importantly, adjusted analysis showed that belonging to the overall contemporary cohort was an independent predictor of VASCs (OR: 1.48, 95% CI: 1.17 to 1.89; p=0.001). Finally, we calculated that the adjusted attributable risk of a VASC in FA patients in the contemporary cohort was 53%.
Conclusions: In a contemporary cohort, we found that 53% of VASCs occurring in FA patients are attributable to the emphasis on RA. This finding remained present when diagnostic and therapeutic catheterisations were considered separately. At a population level, the benefit of RA is offset by a paradoxical increase in VASCs among FA patients. The existence of this "radial paradox" should be acknowledged and taken into consideration, especially among trainees and default radial operators.

Coronary interventions

Euro15A-OP204

Identifying the best strategy for *post hoc* percutaneous coronary intervention in patients with poor radial access: the "Little Women" trial

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Aims: To assess optimal strategy ensuring effective and potentially complex *post hoc* transradial coronary intervention in patients with poor radial access.

Methods and results: The "Little Women" trial compared the feasibility of percutaneous coronary intervention using a 6 Fr guiding catheter in women shorter than 160 cm after transradial coronary angiography had been performed with either 5 Fr or 6 Fr diagnostic catheters (always inserted through a 6 Fr introducer sheath). Consecutive eligible patients were randomised to one of the two strategies, and those eventually undergoing *post hoc* revascularisation were enrolled in the trial (n=120, mean age 68±11 years). Among them, coronary angiography has been performed using 5 Fr or 6 Fr diagnostic catheters in 57 (47.5%) and 63 (52.5%) cases, respectively. No significant difference in height was observed between the two groups (154±6 cm vs. 155±5 cm, p=0.86). Radial spasm and switching to another access to perform intervention occurred more frequently among women who underwent coronary angiography with 6 Fr rather than 5 Fr diagnostic catheter (43% vs. 25%, p=0.03 and 2% vs. 11%, p=0.04, respectively). Time-to-guidewire lesion crossing was also significantly higher when percutaneous coronary intervention has been preceded by 6 Fr rather than 5 Fr coronary angiography (23±11 min vs. 16±7 min, p=0.013).

Conclusions: The "Little Women" trial shows that in patients with poor radial access, the most straightforward and effective strategy allowing for even complex *post hoc* transradial percutaneous revascularisation procedures involves the following "6-5-6"sequence: a 6 Fr introducer sheath placement, 5 Fr coronary angiography and 6 Fr coronary intervention.

Coronary interventions

Euro15A-OP205

Radial artery ultrasound preceding transradial coronary angiography

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Aims: Transradial approaches (TRA) became the preferred vascular access during conventional coronary angiography (CCA). In fact, a smaller mean radial artery diameter (RAD) may lead to higher rates of vascular access complications (VAC); however, there are no data regarding the effect of radial cross sectional area (CSA) and perimeter. We therefore evaluated the impact of pre-procedure radial artery diameter, CSA and perimeter on vascular complications.

Methods and results: We conducted a single-centre prospective analysis of 207 patients underwent CCA. A radial artery ultrasound performed pre- and post- CCA to measure RAD, CSA, and perimeter. The average RAD, CSA and perimeter were (2.7±0.55 mm), (6.3±1.9 mm^2), (9.2±1.7 mm), respectively. The same measurements were significantly larger in men than in women (2.8±0.5 vs. 2.3±0.4 mm [p<0.0001], 6.7±1.8 vs. 4.9±1.4 mm [p<0.0001], and 9.6±1.5 vs. 9±1.7 mm [p=0.001], respectively). Fourteen patients (6.8%) had VACs. The RAD, CSA and perimeter were significantly smaller in procedures with VACs than in procedure with no complications (2.1±0.5 vs. 2.7±0.5 [p=0.014], 4.6±1.4 vs. 9.4±1.6 [p=0.014], and 7.2±1.8 vs. 9.4±1.6 [p=0.022], respectively). Univariate logistic regression showed that radial ultrasonic parameter scans independently predict VACs as follows: RAD (odds ratio (OR)=1.4, 95% CI: 1.08-1.68, p=0.07) for RAD, (OR=2.26, 95% CI: 1.11-4.58, p=0.24) For CSA and (OR=2.86, 95% CI: 1.3-6, p=0.006) for perimeter.

Conclusions: Ultrasonic study of the radial artery before CCA can provide important information regarding the vascular access. We found that a smaller radial diameter, CSA and perimeter are associated with higher rates of VACs.

Subcutaneous nitroglycerin to facilitate transradial access in coronary procedures

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Aims: Although the usefulness of intra-arterial nitroglycerin to prevent radial artery spasm once the access is obtained has been demonstrated, its routine use by subcutaneous administration before radial puncture has not been evaluated. We assess whether the administration of peri-arterial subcutaneous nitroglycerin along with a local anaesthetic agent facilitates the access and the perception of the radial pulse ("pulse score"), decreases number of puncture attempts, improves access and/or procedural time, decrease patient discomfort or number of transfemoral crossovers.

Methods and results: A prospective, double-blind trial performed in four centres in Argentina including 736 patients scheduled for coronary intervention who were randomised in two groups according to the subcutaneous local anaesthesia: group A (379 patients) received 2% lidocaine+nitroglycerin (200 mcg) and group B (357 patients) received 2% lidocaine+placebo. Demographic, clinical and haemodynamic status, total number of puncture attempts, total access and procedural time, pre- and post-procedural "pulse score" (PS) and a local "discomfort scale" (DS) were recorded. In a sub-group of patients, radial artery Doppler ultrasound was performed to evaluate pre- and post-procedural characteristics. Technique and materials used were left according to the discretion of each centre/operator. Seven hundred and thirty-six (736) patients were randomised, 379 patients in group "A" (nitroglycerine) and 357 patients in group "B" (placebo); 65.6% of the patients were male and the mean age was 64.8±10.1 years. NSTEMI and STEMI were the reason of the procedure in 41.2% and 8.6%, respectively. Coronary angiography alone was performed in 73.1% of the cases and combined with angioplasty in 23.5%. There were no statistical significant differences in the number of puncture attempts (1.70"A" vs.1.76 "B" p=0.42), access time (61.1 sec "A" vs. 63.0 sec "B" p=0.66) and conversion to femoral access in the group receiving subcutaneous nitroglycerine (27/379"A" vs. 30/357 "B" p=0.52). The final PS was significantly better in group A (2.47 vs. 2.22 p<0.001), as well as the total PS<3 (158/379 "A" vs. 204/357 "B", p<0.001 OR=0.54). The final DS was significantly better in group A (2.34 vs. 2.76, p<0.001), with a significantly higher incidence of DS 0/1 (130/379 vs. 90/357 p=0.088 OR=1.55) and lower incidence of DS>3 (group "A" 127/379 V vs. group "B"180/357 p<0.001 OR=0.48). Ultrasound was performed in 70 patients (35 patients group A, 35 patients group B), resulting in a significant increase in the radial artery diameter post-procedural in group A, (post-longitudinal 31.1 mm vs. 24.3 mm p<0.002 and post-transversal 28.3 mm vs. 24.1 mm, p<0.002). No significant differences in local complications were evident, although a lower incidence of local haematoma was recorded (23/379 "A" vs. 35/357 "B" p=0.059), probably related to the smaller number of punctures needed to gain the access. More episodes of headache (12/379 vs. 2/357 p<0.009 OR=5.8) were recorded in group A.

Conclusions: The use of subcutaneous nitroglycerin along with a local anaesthetic agent significantly improves "pulse score" post-intervention and radial artery diameters measured by ultrasound and allows better access tolerance, as measured by a local discomfort scale.

Rotterdam radial access research: echo-based radial artery evaluation for diagnostic and therapeutic coronary procedures (the R-RADAR study)

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Aims: This study sought to determine patterns of radial artery healing after cannulation for coronary angiography or intervention and the consequent impact on loss of radial pulsation and subjective discomfort or functio laesa.

Methods and results: The radial artery was scanned with a very-high resolution 40 MHz Ultrasound at 3 segments (entry site, and 4 mm distally and proximally) at baseline before cannulation, and 3 hours and 30 days after the procedure. Subjective discomfort, functional compromise and radial artery pulsations were evaluated at 3 hours and at 30 days after the procedure. A total of 90 patients underwent right transradial coronary artery angiography or intervention. Radial artery lumen consistently decreased in the proximal and distal segments from baseline to 3 hours and 30 days post-procedure. The lumen size at the entry site shrunk after 3 hours, but practically restored at 30 days. Total wall thickness of the radial artery tripled at 3 hours after puncture (p<0.0001) and grew a further 28% at 30 days (p<0.0001). Morphologic traumatic changes of the radial artery wall occurred in all patients: 1) radial dissection in 90% of patients at 3 hours and in 83% at 30 days; 2.) intramural haematoma in 74% at 3 hours and in 65% at 30 days; 3) pseudo-aneurysm in 15% at 3 hours and in 56% at follow-up. Dissection and intramural haematoma were associated with concomitant smaller vessel lumen size at the entry site at 30-day follow-up. Radial artery pulsation disappeared in 6% of patients at three hours after procedure and in 9% at 30 days. A history of peripheral arterial disease, radial artery wall calcifications and baseline radial artery diameter at the entry site were associated with pulse loss at 30 days, with a significant 23% increased risk of radial artery pulse loss for every 0.1 mm lumen decrease (OR 1.23; p=0.049). Overall, morphologic changes were not associated with loss of radial pulsation at 30 days, subjective discomfort or functional compromise.

Conclusions: Arterial wall healing after transradial catheterisation is a dynamic process characterised by increased wall thickness and reduction in radial lumen size at 30 days. Morphologic changes were ubiquitous but did not affect post-procedural radial pulsation or subjective discomfort.

Coronary interventions

Euro15A-OP208

Transradial percutaneous coronary interventions using a sheathless Eaucath guiding catheter compared to standard guiding catheter: a randomised study

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Aims: Guiding catheter (GC) characteristics play an important role in the success of transradial (TR) percutaneous coronary intervention (PCI). We compared TR PCI with sheathless Eaucath GC to standard GC in women and patients with complex lesions requiring large bore GC.

Methods and results: Between 2011 and 2013, we randomised 233 men with ostial and bifurcation lesions and all women undergoing transradial PCI between standard Medtronic Launcher GC (6 Fr in women and 7 Fr in men) and the sheathless Eaucath GC (6.5 Fr in women and 7.5 Fr in men). The procedures were performed at a single tertiary academic centre. Our primary endpoints corresponding to procedural success (successful PCI without GC-induced coronary complications) and procedural safety (absence of haematoma >5 cm, radial occlusion by duplex scanning, PCI and vascular complications) showed no significant differences between both groups. Mean PCI duration, fluoroscopy and cannulation times, contrast media volume and conversion to transfemoral approach (<1%) were not different between both groups. Crossover rate to the other GC types was inferior in the sheathless group (2.7% versus 8.4%, p=ns). However, when including both cross over and additional technique ("mother in child" technique), there was a significant difference in favour of the sheathless arm (2.7% versus 29.4%, p<0.001). Subjective assessment by patients revealed less arm pain while navigating the sheathless GC through the arm (1.9±1.9 versus 4.8±3.6, p<0.001). Arm crossability was graded by the operators as easier with sheathless GC (8.7±1.5 vs 5.1±3.5, p<0.001).

Conclusions: The use of the sheathless Eaucath GC in transradial PCI was as safe and effective compared to standard GC. Crossover to the sheathless Eaucath GC after standard GC failure allowed successful transradial PCI to be performed in most patients of the studied population (i.e., women, men requiring large bore GC). The transradial approach represents at least, if not more, a valid alternative to the transfemoral approach even when large bore GC are required.

Coronary interventions

Euro15A-OP209

The left versus the right radial approach in the setting of primary percutaneous coronary intervention for ST-elevation myocardial infarction

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Aims: Growing evidence suggests left radial approach (LRA) is related to decreased coronary procedure duration and less cerebrovascular complications as compared to right radial approach (RRA) in elective percutaneous coronary intervention (PCI). However, the feasibility of LRA in primary PCI for ST-elevation myocardial infarction (STEMI) has not yet been fully evaluated. Therefore, our aim was to evaluate the efficacy of LRA compared with RRA for primary PCI.

Methods and results: A total of 200 consecutive patients with STEMI who received primary PCI were randomised to LRA (n=100) or RRA (n=100). The study endpoint was needle-to-balloon time defined as the time from local anaesthesia infiltration to the first balloon inflation. Radiation dose by measuring cumulative air kerma (CAK) and CAK dose area product (CAK DAP), fluoroscopy time and contrast volume were also investigated. There were no significant differences in baseline characteristics between the two groups. The coronary procedural success rate in LRA was higher than that in RRA (98% vs. 94%). Compared with RRA, LRA had significantly shorter needle-to-balloon time (16.0±4.8 vs. 18.0±6.5 minutes, p=0.02). Additionally, fluoroscopy time (7.4±3.4 vs. 8.8±3.5 minutes, p=0.01) and CAK DAP (51.9±30.4 vs. 65.3±49.1 Gycm^2, p=0.04) were significantly lower with LRA than with RRA.

Conclusions: Primary PCI can be performed via LRA with earlier blood flow restoration in infarct-related artery and lower radiation exposure compared with RRA, and therefore the left radial approach may become a feasible and attractive alternative to performing primary PCI for STEMI patients.

EuroPCR Coronary interventions Euro15A-OP337

Feasibility of transcatheter closure of large atrial septal defect-secundum with absent superior or inferior rims

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Aims: To evaluate the feasibility of transcatheter closure of large ASD-secundum with absent superior or inferior rims.

Methods and results: From July 2011 to December 2014 five female patients underwent this trial in the Ibn- Albitar Center for Cardiac Surgery. Their ages ranged from 14 to 31 years. To provide a stable rim for device anchorage, we used either a covered or uncovered CP-stent in the superior or inferior vena cava, respectively. Part of the stent acted as either the superior or the inferior rim of the defect. We used either a 45 or 39 mm length stent, cutting part of it to be deployed in the SVC or IVC with a part protruding into the right atrium. Even without modifying the stent, we noticed that balloon inflation of the stent would create a fold at the site of SVC or IVC rim which could be the future rim. The stents used in this trial were covered and uncovered CP-stents, 45 and 39 mm length inflated by BIB or Z- Med balloon sizes 18, 20, 22 and 25 mm; 4 cm. The devices which have been used were 34 and 36 mm Amplatzer septal occluders and 30 and 40 mm Occlutech septal occluders. All patients had no residual shunt immediately after closure, were given 100 mg aspirin and 75 mg clopidogrel for 6 months. They have now been followed for 15 to 33 months with sinus rhythm and without any evidence of thrombosis in the SVC or IVC.

Conclusions: All these patients with large secundum atrial septal occluder with absent superior or inferior rims underwent successful transcatheter closure of their defect using implantation using either covered or uncovered CP stent in the SVC or IVC, respectively, with ASO and without any complication over a follow-up of 15-33 months. Still, longer-term follow-up data are still needed to assess long-term safety and efficacy of this technique.

EuroPCR Interventions for hypertension & heart failure Euro15A-MA063

Balloon pulmonary angioplasty for inoperable patients with chronic thromboembolic pulmonary hypertension: preliminary experience in Spain in a series of eight patients

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Aims: The aim of the present study was to evaluate the safety, therapeutic efficacy and complications of balloon pulmonary artery angioplasty (BPA), in inoperable patients with chronic thromboembolic pulmonary hypertension (CTEPH).

Methods and results: Since 1996, a total of 188 patients were diagnosed with CTEPH in our unit. Of these, 100 patients judged as operable underwent PEA, while 88 patients judged as non-operable were treated medically. From May 2013, our institute started performing BPA for distal-type CTEPH non-operable patients with severe clinical signs and/or severe haemodynamics under optimal medical therapy. A total of 26 BPA sessions were performed in 8 patients (average 3.2 sessions per patient). Mean age was 60±13 SD years (41-82), 6 females, 2 males, all World Health Organisation-Functional Class (WHO-FC) III or IV. The assessment of operability was conducted by cardiologists and cardiac surgeons. The number of lobes treated per session was 1.2 and the number of segmental branches dilated per session was 2.4. The required contrast medium was 290±62 ml per session. One patient died because of reperfusion pulmonary oedema after BPA. In the remaining 7 patients, BPA did produce a significant clinical improvement during follow-up (mean 6.8±6.3 months;1-20). The WHO-FC improved from 3.7 to 2.3 ($p<0.01$). Haemodynamic parameters also improved: mean pulmonary arterial pressure 51.4±15.6 vs. 41.1±14.7 mmHg ($p=0.2$), pulmonary vascular resistance 9.9±4 vs. 6.2±2 W.U. ($p<0.05$) and cardiac index 2.5±0.7 vs. 2.8±0.6 L/min/m^2 ($p=0.2$), baseline vs. follow-up, respectively. Reduced right ventricular strain was indicated by lower plasma levels of plasma B-type natriuretic peptide at the end of the procedures: 1.415±857 vs. 790±725 pg/dL ($p=0.1$). Four of the 7 patients on epoprostenol therapy before BPA were able to completely discontinue this drug after the procedures. Three of 26 procedures (11%) had reperfusion pulmonary oedema as the chief complication. Two cases were asymptomatic. The third patient was symptomatic with haemoptysis and desaturation and required mechanical ventilation and extracorporeal membrane oxygenation. She finally died 8 days after the procedure as a result of a brain haemorrhage (periprocedural mortality 12.5%). We had no pulmonary artery perforation as technique complication in our series.

Conclusions: In our experience, BPA could be considered as a therapeutic approach for patients with selected distal-type CTEPH non-operable patients. It improves haemodynamics, functional capacity and biomarkers and allows tapering off intravenous epoprostenol in a percentage of patients. However, it is associated with major, possibly fatal, complications, like reperfusion pulmonary oedema. So, it is necessary an expertise approach to determine which patients will benefit more from this interventional procedure.

EuroPCR Interventions for hypertension & heart failure Euro15A-OP210

Infarct-related cardiogenic shock: comparison of percutaneous left ventricular assist devices versus intra-aortic balloon counterpulsation

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Aims: The leading cause of death in patients with acute myocardial infarction is cardiogenic shock (CS). Mortality rates are up to 80% although advanced and early reperfusion strategies. Only small studies compared percutaneous ventricular assist devices (pVAD) with intra-aortic balloon counterpulsation (IABP), showing better haemodynamic support with pVADs. With the ImpellaCP there is a new pVAD available, which provides sufficient haemodynamic support up to 4l/min in patients suffering from CS. Real-world data from patients with CS and the use of the ImpellaCP are not available. In the present study, we sought to evaluate the current use of the pVAD (ImpellaCP) in patients with confirmed CS complicating an ACS undergoing PCI compared to the use of IABP.

Methods and results: The Dresdener Shock registry (DSR) of the University Heart Centre, Dresden is an ongoing monocentric, prospective registry, which includes patients with cardiogenic shock or implantation of pVADs. A total of 58 patients are included at this time, whereas 42 patients were identified with infarct-related cardiogenic shock, with 28 patients supported by a pVAD and 14 patients by an IABP. All patients received revascularisation by percutaneous coronary intervention with implantation of a coronary stent. The use of a percutaneous assist device was on the operator´s decision. By means of the registry the intra-hospital and 30-day mortality, the length of invasive ventilation, time to haemodynamic stabilisation and rates of MODS have been investigated. Furthermore, the use of catecholamines, course of laboratory parameters as well as complications has been recorded. One hour after admission the mean arterial pressure was significant higher in the pVAD group compared to the IABP group (74±7.6 mmHg vs. 57.13±10.8 mmHg, p=0.012) with simultaneous reduction of administered catecholamines within 24 h (norepinephrine: 0.38±0.18 µg/kg/min to 0.17±0.13 µg/kg/min, p=0,.034; and 0.41±0.17 µg/kg/min to 0.44±0.38 µg/kg/min, ns; dobutamine: 12.2±8.77 to 7.9±3.63 µg/kg/min, ns. and 10.25±3.28 to 11.75±6.27 µg/kg/min, n.s.). The elevated serum-lactate-levels at admission in both groups could be lowered much more effectively in the pVAD group compared to the IABP group (pVAD: 7.5±5.28 mmol/l to 1.92±1.05 mmol/l and IABP: 7.56±3.07 mmol/l to 5.29±3.02 mmol/l, p=0.04). Intra-hospital mortality rates did not differ significantly between both groups at that time (pVAD 45% vs. IABP 75%, ns). There were no significant differences in severe bleedings.

Conclusions: The implantation of a pVAD in infarct-related cardiogenic shock leads to improvement of haemodynamic parameters with concomitant reduction of the use of catecholamines and of serum-lactate levels compared to IABP. Furthermore, the implantation of pVAD is safe without increased bleeding complications. If intra-hospital and long-term mortality could be improved, this has to be addressed in larger cohorts.

EuroPCR Interventions for hypertension & heart failure Euro15A-OP211

The extra-corporeal membrane oxygenation epidemic: is there an answer?

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Aims: Extra-corporeal membrane oxygenation (ECMO) has experienced an exponential rise in utilisation over recent years. In order to understand this increase, we undertook a systematic review of the literature with the intent to determine if there had been a significant improvement in outcomes that might explain this surge in the use of this technique.

Methods and results: A PubMed review of all studies enrolling ECMO patients from 1992 through 2011 was undertaken. Only studies enrolling 40 or greater patients were included to minimise the bias of small observational reports. An assumption was made that the increase in utilisation of ECMO has been based on improved outcomes. As such, the studies were reviewed specifically for complication rates including neurologic, renal, vascular and major bleeding. In addition, mortality, both 30-day and in-hospital was collected. Heart recovery, defined as successful weaning from ECMO, was also reviewed. These results were examined by era of enrolment in order to determine if there was evidence of any improvement over time. In addition, the results were compared to another recent study for validation. Nineteen studies were identified with a total of 2,448 patients. Renal injury was the most common complication seen, occurring in 30-87% of patients. A similar number of patients required haemodialysis. Vascular complications including limb ischaemia were seen in 5-21% with amputation required in up to 7%. Major bleeding was seen in 21-50% of patients with 100% of reported patients being transfused. Haemolysis was reported in 14-33% of patients. Gastrointestinal bleeding was noted in up to 25% of patients. Neurologic complications were seen in one third of patients with stroke in up to 15% and other cerebrovascular events in up to 22%. A left ventricular assist device or heart transplantation was required in up to 52% of patients. Weaning of ECMO and heart recovery was achieved in only 7-29%. Thirty-day mortality occurred in 62-79% and in-hospital mortality in 47-79%. When the results were reviewed by era of enrolment, the only complication that was seen to decrease was that of renal injury. However, this decrease was not consistent. The incidence of all other complications appeared to be consistent or showing a trend toward an increase. When we compared our results to a recently published meta-analysis of 20 studies from 1992 to 2010 our findings were similar in all regards.

Conclusions: The results of our review demonstrate that complications remain prevalent and mortality rates are high with the use of ECMO. In addition, there appears to be no improvement in the incidence of complications, mortality rates or the ability to achieve heart recovery. These results do not explain the exponential rise in the utilisation of ECMO.

The use of micro-axial flow assist devices for acute circulatory support in heart failure and cardiogenic shock: results from a single high-volume heart centre

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Aims: The Impella is a micro-axial rotary pump that is placed across the aortic valve expelling aspirated blood from the left ventricle (LV) into the ascending aorta. The less invasive device could be used in acute haemodynamic instable situations, e.g., in acute coronary syndrome (ACS) complicated by cardiogenic shock. Smaller mono-centre studies and only some bigger multicentre registry studies evaluated the efficacy and safety. However, more clinically relevant data of the Impella device are necessary, especially in regard of the outcome of a severely ill patient population.

Methods and results: We performed a retrospective record review of 88 consecutive patients who underwent implantation of an Impella device in our heart centre between May 2006 and 2014. Evaluations were made for data concerning baseline patient characteristics including indications for Impella implantation, hospital outcomes including procedural characteristics, safety endpoints and complications. Moreover, the short- and long-term outcome was evaluated. The mean age of the patients was 62.2±12.3 years and 72% of the patients were male. The mean LV ejection fraction was 26±14% and in the most of the patients (86%) a coronary heart disease was present. Moreover, 36% of the patients were already on IABP (intra-aortic balloon pump) support and overall 48% of the patients had been resuscitated for cardiac arrest. In almost all patients, a cardiogenic shock was the indication for the Impella support (93%). In 74%, an ACS was complicated by the cardiogenic shock and causative, in 3 of 4 cases a STEMI was present. In predominate cases (86%), an Impella 2.5 was implanted. The overall average duration of support with the Impella device was 4.6±4.3 days. The most common complication was a thrombocytopenia and a moderate bleeding. Only in 15% of the cases, the explantation of the Impella device due to a related complication had to be performed. The Kaplan-Meier survival analysis indicated the severity of illness in this patient population with an in-hospital mortality of 34%, a 30-day mortality of 55% and the 1-year mortality reached 72%. As expected, the 30-days and 1-year-suvival rate had a strong tendency to be lower after cardiopulmonary resuscitation in all and ACS patients. Interestingly, a body mass index >25 kg/m^2 tended to result in a higher 30-days and 1-year mortality, and a smaller body size could be identified as a significant predictor of higher mortality in our patient cohort ($p<0.05$). The timing of initiation of Impella support (as early as possible, e.g., initial coronary angiography vs. delayed implantation, e.g., bailout strategy after IABP implantation) was also included as a target candidate in the multivariate analysis model and could be identified as a very strong independent predictor of mortality at 1-year ($p<0.01$). The Kaplan-Meier curves for age and timing of Impella support identified that especially in patients >70 years the long-term mortality was higher if the Impella support had not been initiated as early as possible.

Conclusions: The present study is to our knowledge the largest series of patients undergoing Impella device implantation in one centre. It could indicate clinically relevant data concerning the Impella device that could be important to optimise patient selection and timing of implantation in order to reduce the high levels of short- and long-term mortality in this high-risk patient group.

Outcome after implantation of a microaxial-flow pump in patients with cardiogenic shock

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Aims: The Impella Circulatory Support System has been developed to unload the left ventricle in patients with severely reduced systolic function and to maintain basic circulation in such patients. We therefore enrolled all patients undergoing implantation of an Impella-pump into a registry to further analyse patient characteristics and predictors of outcome.

Methods and results: Since July 2011, all patients who received an Impella microaxial pump were enrolled in our registry. Data on baseline characteristics and in-hospital treatment including cardiovascular risk factors, details on coronary angiography, haemodynamic parameters and laboratory parameters were documented in detail. Furthermore, data on the outcome of those patients including follow-up until 12 months after implantation were recorded. In total,153 patients underwent implantation of an Impella pump at our centre. Complete data including follow-up until 12 months are available in the first 47 patients. Cardiogenic shock was the indication for implantation in 81% of the cases, in the other patients the purpose for the implantation were high-risk percutaneous coronary interventions. In those patients mean age was 62 years (19-83 years); 74% of the patients were male. Coronary heart disease was excluded by coronary angiography in 21%. Median device time was 3 days (interquartile range [IQR] 1-5 days). In-hospital survival was 50%, decreasing to 43% after 6 months and 38% after 12 months. Higher body mass index (28.3 vs. 25.9; $p<0.01$), right heart failure (42% vs. 11%, $p<0.05$) and persistently elevated central venous pressure after 6 hours (15 mmHg vs. 11 mmHg, $p<0.05$) were more common in non-survivors. There was a trend towards younger age in survivors (59 vs. 70 years, $p=0.053$).

Conclusions: Implantation of an Impella pump is performed more frequently in cardiogenic shock patients. Our preliminary data emphasise the impact of early haemodynamic parameters.

EuroPCR Interventions for hypertension & heart failure Euro15A-OP214

Impella on top of ECMO treatment in cardiogenic shock results in effective left ventricular unloading

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Aims: Extracorporeal membrane oxygenation (ECMO) support is often utilised to stabilise patients presenting with severe cardiogenic shock (CS). Despite improved oxygenation and peripheral circulation, LV unloading may be completely impeded due to increased afterload by ECMO. This is associated with severe complications including LV stasis with thrombus formation within the heart as well as severe pulmonary oedema. Therefore, we describe here, for the first time, a large series with patients treated with a combination of ECMO and Impella CP, a percutaneous LV assist device for the treatment of CS.

Methods and results: Impella CP (Abiomed) was implanted via the femoral arteries on top of veno-arterial ECMO (CARDIOHELP, Maquet) in 16 patients (mean age 55.5±3.7, n=13 male) presenting with CS refractory to conventional management directly after admission. Anterior STEMI was the underlying diagnosis in 7 patients, while the others had a primary diagnosis of DCM and low output failure. Lactate as sign of shock could be significantly reduced from baseline to 6 h (7.9±3.7 to 3.4±0.5, mmol/L, $p<0.05$). Bleeding was a common complication and red cell concentrates (RCCs) were infused in 93% of the patients (23.8±4 RCCs). Interestingly, ECMO insertion was the main problem in most patients in regard to bleeding complications, while in only 2 patients the arterial access site of the Impella using a 14 Fr sheath was compromised by a bleeding event. In only 1 of 16 patients, LV unloading was compromised, which was associated with LV thrombus formation. Cumulative support time of Impella and ECMO was 124 days with 10.7±2.6 days per surviving patient. Three patients could not be weaned from Impella and ECMO and were converted to conventional LVAD. Survival was relatively high, with 44% due to combined ECMO and Impella treatment.

Conclusions: The combination of ECMO together with Impella was associated with low severe complications due to improved LV unloading. The survival of the presented 16 patients was high for severe cardiogenic shock, making this treatment an attractive possible option. Comparison to ECMO-only patients are currently being performed retrospectively to gain insights into treatment efficacy of this new combination and will be finished for presentation. Future randomised and controlled trials have to evaluate the usage of this combination prospectively.

EuroPCR Interventions for hypertension & heart failure Euro15A-OP215

Acute reduction of aortic stiffness in patients with resistant arterial hypertension as a marker of efficacy of renal denervation therapy

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Aims: The aim of this study was to evaluate the acute variations of pulse wave velocity (PWV) after percutaneous transcatheter renal denervation (RDT) as an index of arterial stiffness variation in selected patients affected by real resistant arterial hypertension (RAH). The interruption of the nerve fibres that run along principal axes of both renal arteries with RDT could modulate the systemic sympathetic tone reducing arterial stiffness and its indirect index, the PWV. Secondary endpoints are the acute reduction of systolic (SBP), diastolic (DBP) and mean (MBP) blood pressure values and heart rate (HR).

Methods and results: We enrolled 10 consecutive patients affected by RAH (8 men, 2 women, mean age 50 years). The entire cohort underwent bilateral RDT procedure with the EnligHTN System (St. Jude Medical, St. Paul, MN, USA) and invasive measurement of PWV before and after procedure using a dedicated catheter FS-Stiffcath (Flag Vascular, Monza, Italy). PWV, evaluated before and after RDT, decreased from 14.32 to 10.91 m/sec, with a reduction of 3.41 m/sec (p-value 0.001, CI 95%); mean SBP decreased from 153 mmHg to 123 mmHg (p-value 0.01, CI 95%). Mean DBP decreased from 77 mmHg to 64 mmHg (p-value 0.010; CI 95%). MBP decreased from 102 mmHg to 84 mmHg (p-value 0.001; CI 95%). HR decreased from 73 to 72 bpm (p-value 0.74, CI 95%). Also percentage differences, analysed with paired samples T-test, demonstrated the same results; in particular, we can underline that PWV decreased by about 23%; SBP and DBP had been reduced by 19.4 and 15% respectively, instead MBP decreased of about 17%. The Pearson's correlation analysis did not demonstrate significant correlations between the change in PWV and changes in HR ($r=0.335$, $p=0.345$), SBP ($r=0.176$, $p=0.626$), DBP ($r=0.178$, $p=0.623$) and MBP ($r=0.192$, $p=0.596$).

Conclusions: The bilateral RDT procedure produced an acute statistically significant decrease in PWV. There was also an acute significant reduction of SBP, DBP and MBP, which, however, did not show a significant relationship with the PWV changes. This suggests that improvement of arterial stiffness by RDT might be, at least in part, blood pressure independent, probably in relation to the reduction of the stiffening effect of the sympathetic activity on the arterial wall. The acute decrease in PWV could be indicative of an immediate reduction of sympathetic tone and it could be considered as a marker of the real efficacy of RDT procedure.

Retinal microperfusion after renal denervation in the treatment resistant hypertension

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Aims: High pulsatile pressure and flow in the arteries causes microvascular damage, and hence increased cardio-, and cerebrovascular complications. With advanced stages of hypertensive disease, an exaggerated pulsatile retinal capillary flow has been shown, but data about interventional effect is missing.

Methods and results: Fifty-one patients with true treatment resistant hypertension (office blood pressure ≥140/90 mmHg and daytime ambulatory blood pressure ≥135/85 mmHg, despite treatment with at least 3 antihypertensive drugs including a diuretic) underwent renal denervation using the Symplicity Flex™ catheter and were followed for 12 months. Retinal capillary flow was assessed non-invasively using Scanning laser Doppler flowmetry before, 6 and 12 months after renal denervation. Retinal capillary flow was measured in systole and diastole and pulsed retinal capillary flow (difference of retinal capillary flow in systole minus diastole) was calculated. In addition, flicker-light induced vasodilation (representing vasodilatory capacity) was assessed. Systolic and diastolic office blood pressure as well as 24-h ambulatory blood pressure decreased significantly 6 and 12 months after renal denervation compared to baseline values (all $p<0.001$). There was a significant reduction of pulsed retinal capillary flow 6 months (231±81 versus 208±68 AU, $p=0.046$) and 12 months (194±72 AU, $p=0.001$) after renal denervation, whereas the mean retinal capillary flow was unchanged. Moreover, there was a significant increase of flicker-light induced vasodilation after renal denervation ($p=0.043$).

Conclusions: In hypertensive patients with treatment resistant hypertension, we observed a decrease of pulsed retinal capillary flow 6 and 12 months after renal denervation and an increase of vasodilatory capacity, in parallel to decreases of blood pressure and heart rate. The reduction of pulsed retinal capillary flow after renal denervation implies a decrease of shear stress on the vascular wall by the pulsed blood flow. This and the increment of vasodilatory capacity suggests an improvement of retinal (and potentially cerebral) microcirculation.

The intra-procedural reduction of the veno-arterial norepinephrine gradient correlates with blood pressure response after renal denervation

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Aims: No widely available read-out is currently available to evaluate the extent of nerve ablation by renal denervation (RDN). We prospectively evaluated the association of intra-procedural reduction of renal veno-arterial norepinephrine gradient with blood pressure (BP) response after RDN.

Methods and results: In 46 consecutive RDN patients, pre- and post-procedural norepinephrine concentrations were measured in each renal artery and vein. The veno-arterial difference was defined as norepinephrine gradient. BP responders were defined as patients with reduction of office systolic BP ≥10 mmHg at follow-up. We observed a reduction of the office systolic BP from 176±19 mmHg to 165±24 mmHg ($p=0.02$) at three months and 163±22 mmHg ($p=0.02$) at six months. There was a decrease of the norepinephrine gradient during RDN (pre: 301±1,061 pg/mlvs, post: 80±361 pg/ml, $p=0.02$). BP responders showed a greater reduction of the norepinephrine gradient compared to non-responders (–290±450 pg/mlvs, –4±106 pg/ml, $p=0.01$). Patients with reduction of norepinephrine gradient in both kidneys showed the most pronounced decrease of the systolic BP (–24±14 mmHg) compared to patients with reduction of norepinephrine gradient in only one kidney (–7±15 mmHg) or patients without norepinephrine reduction (–3±19 mmHg, $p=0.03$ vs. bilateral reduction).

Conclusions: Measuring renal norepinephrine gradient during RDN may be a method to gauge the extent of renal nerve ablation.

EuroPCR Interventions for hypertension & heart failure

Euro15A-OP218

Noninvasive renal denervation study using externally delivered focused ultrasound in severe resistant hypertension

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Aims: The Kona Medical Surround Sound™ System is a noninvasive device for renal denervation that delivers externally focused ultrasound to the renal nerves using Doppler-based image guidance to track and correct for renal artery motion during the procedure. Our aim was to evaluate the safety and efficacy of an entirely noninvasive approach to renal denervation using externally delivered focused ultrasound with real time Doppler-based image guidance.

Methods and results: Twenty-seven patients with severe, treatment resistant hypertension, defined as persistent systolic blood pressure (SBP) >160 mmHg despite 3 or more antihypertensive medications, were treated noninvasively with the Kona Medical Surround Sound System™. Focused ultrasound energy was delivered to the renal arteries bilaterally and surrounding tissue using Doppler-based imaging and continuous tracking with automatic correction for kidney motion throughout treatment. Patients received conscious sedation during the treatment period. At this time, all patients have completed >24 weeks of follow-up. At 3 weeks post-denervation, the mean changes from baseline in BP were –16.8/–8.6 mmHg, –23.2/–10.8 mmHg at 6 weeks, –29.7/–13.1 mmHg at 12 weeks and –21.6/–8.7 mmHg 24 weeks post-treatment. No serious device-related events have been reported to date. Forty-one percent of subjects (11/27) reported mild back pain immediately following the denervation treatment. The majority of cases (8/11) completely resolved within three-days post-treatment without any significant intervention and no case was associated with any motor, sensory deficits.

Conclusions: This is the first study in humans using a noninvasive renal denervation system in severe and resistant hypertension. Results showed large reductions from baseline in office BP through 24 weeks post-denervation. The procedure was well-tolerated, with no serious adverse events. This technology should enable patients to benefit from renal denervation therapy without the invasive risks associated with catheter-based techniques. Sham-operator controlled studies with the Kona systems to evaluate the safety and efficacy of this novel noninvasive treatment are in the planning stages.

EuroPCR Interventions for hypertension & heart failure

Euro15A-OP220

Durable 24-hour blood pressure reduction in a hypertensive swine model using a multi-electrode catheter system for sympathetic renal nerve ablation

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Aims: We evaluated for long-term BP response a diet-induced drug-resistant hypertension (HTN) swine model, treated with a RF ablation system (EnligHTN™ Multi-Electrode Renal Denervation System, SJM).

Methods and results: A cohort of 12 Ossabaw swine were implanted with telemetry monitors providing continuous monitoring of BP and ECG before and after Tx. Animals were enrolled on a high-calorie regimen throughout the entire in life phase of the study. The group mean (M) and standard deviation (SD) weight (wt) was 87.2 (9.2) kg at telemetry implant. After 5 months group wt. increased 60% to 139.7 (21.1) kg. HTN was achieved in all swine defining the Pre-RARFA-Tx baseline with a mean 24-hr. SBP/DBP of 169.53/128.26 (14.30/12.37) mmHg. Subjects were randomly assigned to treatment groups. Average BP and wt. were evaluated to reduce potential group bias. The RF group (n=9) received bilateral renal ablation in three RARFA-Tx groups (4, 8 and 12 lesions) with three animals in each group. An additional three animals were enrolled in the surgical/chemical denervation (SCDN) group receiving bilateral mechanical stripping of the surrounding renal artery connective tissues and 10% phenol application. This group served as positive control. There were three post-operative mortalities (one each in the 8 and 12 lesion and SCDN groups) involving advanced HTN/cardiac hypertrophy complications during procedure recovery. Mean active hour (7:00-12:00) all RARFA group (n=9) SBP (mmHg) and SDs at pre-therapy (pre-Tx) baseline: 179 (16), Tx+15: 168 (22), Tx+30: 167 (22), Tx+60: 171 (17) &, Tx+90 days: 171 (15). Mean active hour all RARFA group SBP change (Δ) (mmHg) & SDs from baseline at Tx+15: –10 (8), Tx+30: –12 (12), Tx+60: -8 (7) &, Tx+90 days: –7 (4). Mean active hour all RARFA group SBP % Δ from baseline & SDs at Tx+15: -6 (5), Tx+30: –7 (7), Tx+60: –5 (4) &, Tx+90 days: –4 (2). Mean active hour all RARFA group DBP & SDs at pre-Tx baseline: 136 (13), Tx+15: 125 (16), Tx+30: 126 (18), Tx+60: 127 (13) &, Tx+90 days: 127 (11). Mean active hour all RARFA group DBP Δ (mmHg) from baseline & SDs at Tx+15: 125 (16), –11 (7), –8 (5), Tx+30: 126 (18), –10 (8), –8 (6), Tx+60: 127 (13), –9 (5), –7 (3) &, Tx+90 days: 127 (11), –9 (4), –7 (3). Mean active hour RARFA group DBP % Δ from baseline & SDs at Tx+15: –8 (5), Tx+30: –8 (6), Tx+60: –7 (3) &, Tx+90 days: –7 (3). At termination, kidneys were analysed for norepinephrine NE (ng/g) showing group M NE (SD) values of 67 (40), 58 (20), 49 (1) &, 57 (21) for the 4, 8 &, 12 RARFA lesion and SCDN groups, respectively. Histopathology was performed on RARFA treatment sites to evaluate injury and examine the cellular response of the vessels. There was no focus of arterial mural disruption and no loss of tunica media integrity. There was no evidence of aneurysm, mural thinning or perforation in any treated or non-treated site.

Conclusions: Catheter-based renal denervation using a multi-electrode system resulted in a significant and durable reduction in active hour SBP & DBP in this hypertensive animal model.

Comparison of safety and efficacy between percutaneous alcohol-mediated perivascular renal denervation and single-electrode radiofrequency ablation in the porcine model at 3 months: a randomised study

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Aims: We compared the safety, efficacy and procedure time of renal denervation with percutaneous alcohol-mediated chemical neurolysis using the Peregrine System™ Infusion Catheter to the currently approved single-electrode Symplicity™ radiofrequency catheter in a porcine model.

Methods and results: This was a prospective, randomised and blinded study. Pigs were assigned to bilateral renal denervation using the single-electrode radiofrequency catheter (4 ablations per renal artery) or percutaneous alcohol-mediated chemical neurolysis. Twelve pigs underwent radiofrequency ablation (RF) (N=4) or alcohol-mediated neurolysis by infusion of 0.3 mL (N=4) or 0.6 mL (N=4) alcohol into the perivascular space of each renal artery. The predefined primary efficacy endpoints were maximal ablation depth (distance from the renal artery lumen) and renal tissue norepinephrine concentration (high-pressure liquid chromatography coupled with electrochemical detection). There were no complications in any of the procedures. The median procedure times were 29 minutes for the RF group and 9 minutes for the alcohol groups ($p<0.01$). At 90 days, maximal depths of renal nerve injury were 3.9±1.2 mm, 6.6±1.2 mm and 8.2±2.2 mm with RF and chemical neurolysis with 0.3 mL and 0.6 mL alcohol, respectively ($p<0.05$ for both doses of alcohol compared with RF). Compared to historical controls (no treatment), reductions in median renal tissue norepinephrine concentrations were 66%, 76% and 83% after RF and chemical neurolysis with 0.3 mL and 0.6 mL, respectively ($p=0.095$ for chemical neurolysis compared with RF). No renal artery stenoses were observed at 45- and 90-day angiographic follow-up. Based on a semi-quantitative histology score for nerve injury of 0 to 4 (none to marked), the mean score for RF was 1.5, and for the alcohol groups 1.6 (0.3 mL) and 2.4 (0.6 mL). Staining for tyrosine hydroxylase was scored 0 to 3 (none to strong); mean scores were 1.5 for FR, and 1.4 and 0.7 for neurolysis with 0.3 mL and 0.6 mL alcohol, respectively (low tyrosine hydroxylase staining scores indicate non-functional efferent nerves). Total ablation area (morphometric analysis) was significantly greater in both the 0.30 mL and 0.6 mL groups ($p=0.0001$) than RF; at 30.8±13.7 mm^2, 41.6±7.5 mm^2 and 11.0±7.5 mm^2, respectively.

Conclusions: Our findings demonstrate that: 1) the efficacy of percutaneous renal denervation is device-dependent; 2) based on the parameters evaluated in this animal model, alcohol-induced chemical neurolysis via the Peregrine System is as safe as and more effective than single-electrode RF using the Symplicity catheter; 3) the procedure time for alcohol-mediated neurolysis was significantly shorter (approximately one third) compared to single-electrode RF; 4) superior efficacy and shorter procedural times with the Peregrine System were achieved without any prior operating experience, suggesting ease-of-use and procedural efficacy is independent of operator experience.

Renal denervation; the initial UK experience: a report from the UK renal denervation affiliation

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Aims: Renal denervation (RDN) may lower blood pressure (BP) in people with resistant hypertension. Here we report the combined UK experience of RDN.

Methods and results: The UK renal denervation affiliation is an independent investigator-led initiative of 16 centres, each of which had done >5 cases. A standardised dataset was collected retrospectively, anonymised and submitted to the coordinating centre for analysis. Results from 246 cases from 16 centres are reported. The average number of cases per centre was 15. Five different ablation technologies were used: unipolar catheters in 198 and multipolar in 48. Mean age was 56.7 years, 53% were female, 87% Caucasian, and diabetes 27%. Previous stroke/TIA was reported in 24%, 15% myocardial infarction, and 26% had proteinuria. Patients were selected by an average of 1.6 specialists with an interest in hypertension and 86% attended specialist hypertension clinics. On average, 4.7 drugs were used before RDN; 95% were on ≥3 drugs; 90% were taking RAS blockers, 90% diuretics, and 56% aldosterone antagonists. Pre-RDN mean office BP was 186/102 mmHg. Ambulatory blood pressure monitoring (ABP) data were available for 179 patients (73%). Average pre-procedural daytime ABP was 170/98; night-time ABP was 154/86. Average follow-up was 10.7 months. Mean office BP post-RDN was 164/93, a fall of 22/9 mmHg ($P<0.001$). In 24%, office systolic BP fell ≥ 40 mmHg. Average post-RDN daytime ABP was 158/92 and night-time ABP 145/81; fall in daytime ABP was 12/6 mmHg ($p<0.001$); 18% had a drop in day systolic ABP ≥ 20 mmHg; 9% had a fall of ≥30 mmHg. On average, 0.8 drugs were withdrawn per patient and 0.3 drugs added between RDN and follow-up. A decrease in GFR of ≥25% was seen at 10 months in 5% of patients. Otherwise, no significant complications were observed.

Conclusions: In 246 patients undergoing RDN in 16 UK centres, a significant improvement in BP control was observed with a 22/9 mmHg reduction in office BP and 12/6 mmHg in daytime ABP. Drug withdrawals/additions do not appear to explain this fall. This suggests that carefully selected patients with resistant hypertension, with few remaining medical options, do have a significant BP reduction following RDN.

EuroPCR Interventions for hypertension & heart failure Euro15A-OP223

The safety and long-term effect of renal artery denervation on blood pressure and renal function in real-world patients with uncontrolled hypertension from the Global SYMPLICITY registry

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Aims: We evaluated the long-term follow-up of a large cohort of hypertensive patients with a high proportion of comorbidities including renal dysfunction.

Methods and results: The Global SYMPLICITY Registry is a prospective, open-label, multicentre registry. Patients are enrolled from 245 centres in 37 countries and are treated per the Symplicity™ renal denervation system protocol.. Office and 24-hour ambulatory blood pressure change, laboratory values and protocol-defined safety events are collected. Patient selection is at the discretion of the treating physician according to local guidelines. In the first 1,000 enrolled patients, the mean age was 61±12 years, 61% were male and mean body mass index was 30±6 kg/m^2. Comorbidities included diabetes mellitus (39%), renal dysfunction (estimated glomerular filtration rate [eGFR] <60 ml/min/1.73 m^2, 23%), and history of cardiac disease (51%). Baseline office blood pressure was 165/89±24/16 mm Hg and baseline 24-hour blood pressure was 154/86±18/14 mmHg. At 1-year post-denervation, the composite safety endpoint was 3.9% (34/862), comprising 0.8% cardiovascular death, 1.6% hospitalisation for hypertensive crisis, 0.2% new renal artery stenosis >70%, 0.4% renal artery re-intervention, and 0.4% new-onset end-stage renal disease. The 1-year office systolic blood pressure reduction (n=740) was -13.0±26.3 mmHg (p<0.001) and 24-hr systolic blood pressure change (n=390) was -8.3±17.8 mmHg (p<0.001). Among the 231 patients with baseline renal dysfunction, the office systolic blood pressure was reduced -10.6±26.8 mmHg at 1 year (p<0.001). Ambulatory 24-hr systolic blood pressure was reduced by -9.7±20.1 mmHg (n=99, p<0.001). Mean eGFR of the total population decreased from 76.4±25.1 at baseline to 71.9±24.6 ml/min/1.73 m^2 at 1-year. The subgroup of patients with chronic kidney disease at baseline had a mean eGFR of 48.7±16.5 ml/min/1.73 m^2 which declined slightly at 1-year to 45.7±17.4 ml/min/1.73 m^2 for 149 patients in this group.

Conclusions: Renal denervation in a large real-world population resulted in significant blood pressure reductions 1-year post-procedure. Renal function, even among patients with baseline renal dysfunction, declined to a much lesser extent than would be expected based on published observations of renal function change in patients with uncontrolled hypertension. There were no long-term safety concerns following the denervation procedure. Two-year follow-up data for approximately 600 patients will be available for presentation in May.

EuroPCR Interventions for hypertension & heart failure Euro15A-OP224

Safety analysis of renal function following renal denervation: analysis from SYMPLICITY HTN-3 and the Global SYMPLICITY registry

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Aims: Hypertension and, in particular, resistant and uncontrolled hypertension, is a risk factor for decline in renal function with the potential for subsequent development of severe chronic kidney disease. Published data shows a correlation between the level of untreated hypertension and the decline of estimated glomerular filtration rate (eGFR) over time (approximately -12 ml/min/year for a systolic blood pressure of 178 mm Hg).The Global SYMPLICITY registry (GSR) and the SYMPLICITY HTN-3 randomised, blinded, sham-controlled trial, provide two large contemporary patient cohorts with uncontrolled hypertension at high-risk for a progressive decline in renal function. This analysis examines the effect of renal denervation on renal function in patients from these studies.

Methods and results: A total of 531 patients, 305 from SYMPLICITY HTN-3 and 226 from the GSR, who had undergone renal artery denervation and had estimated glomerular filtration rate (eGFR) data at baseline, 6 and 12 months were included in the analysis. Only patients with a baseline office systolic blood pressure ≥160 mm Hg were included from the GSR. Patient mean age was 59.8±10.5 years and 61% of patients were male. Approximately 30% of patients had a history of renal disease (eGFR <60 ml/min/1.73 m^2) at baseline and 45% had diabetes. Overall, mean number of antihypertensive medications was 4.7±1.2 at baseline. Baseline office blood pressure was 179/95±16/16 mm Hg. Baseline eGFR was 73.8±19.1 ml/min/1.73 m^2. At 6 and 12 months, the mean eGFR was 71.0±20.0 and 70.6±21.5 ml/min/1.73 m^2, respectively. Change in eGFR was analysed by tertiles of baseline office systolic blood pressure. Overall at 6 months, the decline in eGFR was -4.3±13.7 for the tertile of greatest baseline blood pressure (≥182.3 mm Hg), -2.1±13.9 for the 169 to 182.3 mm Hg tertile and -2.1±11.5 for the ≤169 mmHg tertile. At baseline, the GSR patients were older and had more pre-existing renal dysfunction than the HTN-3 patients. There was no significant difference in eGFR change between GSR and HTN-3 patients at 6 months for any tertile. However, at 12 months in the third tertile (baseline systolic blood pressure ≤169 mm Hg), the eGFR decline was significantly greater in the GSR patients than in HTN-3 patients (-6.0 vs. 01.2, p<0.001). Similar results were observed when African American patients were excluded from the analysis.

Conclusions: A small decline in eGFR occurred at 6 and 12 months after renal denervation, but this decline is less than would be expected based on published analysis of the natural progression of uncontrolled hypertension. The eGFR decline is greatest in the patients with the highest baseline systolic blood pressure, which is consistent with observations in hypertensive patients who have not received renal denervation.

Safety and performance of the next generation EnligHTN renal denervation system in patients with drug-resistant hypertension: 18-month results from a first-in-human multicentre study

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Aims: Catheter-based renal artery denervation therapy is under evaluation as a therapeutic option in patients with resistant hypertension. We further investigated the safety and performance of the next generation EnligHTN™ Renal Denervation System (St. Jude Medical) in patients with drug-resistant hypertension. This is the first report of data through 18 months of follow-up on patients treated with the EnligHTN next generation system.

Methods and results: The EnligHTN Renal Artery Ablation catheter has 4 electrodes attached on a basket mounted at the tip of the catheter. The next generation EnligHTN RF Ablation Generator utilises a novel algorithm for the delivery of 1 minute of radiofrequency energy, optimised for simultaneous delivery of therapy through all 4 electrodes, with an interactive, intuitive user interface. Renal denervation was performed on 39 patients across 6 centres meeting the following inclusion criteria: 18-80 years of age, an office systolic BP ≥ 160 mmHg, an average daytime systolic ambulatory BP >135 mmHg, on three or more antihypertensive agents (including a diuretic), and renal artery diameter ≥4 mm and length ≥20 mm. Renal artery CT angiography was repeated at 6 months in all patients. To date 18/38 patients have completed 18-months of follow-up post-procedure. Through 12 months of follow-up, there were no serious device related adverse events during the procedure, including no renal artery damage (i.e., no renal artery dissections, aneurysms, flow-limiting renal artery vasospasms, or renal artery stenosis) as adjudicated by an independent Clinical Events Committee. There was one reported serious procedure-related vascular access site complication (pseudoaneurysm of the femoral artery) which resolved after manual compression and thrombin injection. There were no clinically significant changes in renal function through 12-months as observed in eGFR, serum creatinine, cystatin C or urine albumin-to-creatinine ratio. Eighteen-month office BP reductions from baseline are thus far –24.2/–9.5 mmHg, which are statistically significant. Renal artery denervation procedures were performed successfully in all patients, with an average of 4.33 ablation sets and 15.85 ablations performed per patient. The median procedure time from initiation to completion of RF energy delivery was 13 min and mean ablation time was 4.33 min per patient.

Conclusions: Accumulated 18-month results from all sites will be presented at the meeting. After 12-months follow-up post-procedure in this first-in-human study, we conclude that data demonstrates that the next generation EnligHTN Renal Denervation system continues to be safe, rapid, and effective in the treatment of patients with drug-resistant, uncontrolled hypertension.

Safety and performance of the EnligHTN renal denervation system in patients with drug-resistant hypertension: pooled analyses from the EnligHTN I, II and III trials

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Aims: Catheter-based renal artery denervation therapy is under evaluation as a therapeutic option in patients with resistant hypertension. Despite promising data from initial studies, the lack of a clear treatment effect from the SYMPLICITY HTN 3 trial raised concerns around the efficacy of renal denervation. Subsequent sub-analysis has suggested significant treatment effects if patients receive more and circumferential lesions, suggesting that multi-electrode renal denervation systems may reduce the risk of an inadequate renal denervation procedure. In order to gain insights from a large patient dataset, we investigated the safety and performance of the EnligHTN™ Renal Denervation System (St. Jude Medical) in patients with drug-resistant hypertension using poled data from all trials performed to date. This is the first report of pooled data from the EnligHTN I, II and III trials.

Methods and results: The EnligHTN renal artery ablation catheter has 4 electrodes attached on a basket mounted at the tip of the catheter. We analysed data from the EnligHTN I, III and III trials which met the following criteria: 18-80 years of age, an office systolic BP ≥160 mmHg, on three or more antihypertensive agents (including a diuretic), and renal artery diameter ≥ 4 mm and length ≥ 20 mm. All trials used the same renal artery ablation catheter, but in the EnligHTN I and early phase of the EnligHTN II trials, sequential delivery of radiofrequency energy was performed, whereas with the later phase of the EnligHTN II trial and the EnligHTN III trial the next generation simultaneous delivery of radiofrequency was performed. To date 187 patients met this criteria from these 3 studies, with 6-month follow-up data available (EI n=46, EII n=104, EIII n=37). Mean age for the dataset was 61 years with mean office systolic BP at baseline of 179 mmHg and at 6 months of 158 mmHg. Therefore a 6-month reduction in office systolic BP of 21 mmHg was noted ($p<0.05$). Mean 24 hr systolic ABP at baseline was 155 mmHg and at 6 months was 147 mmHg. This 8 mmHg drop was statistically significant ($p<0.05$). With regards to BP reduction within this dataset, baseline systolic office and 24 hour ambulatory BP value, and the use of ACEI/ARB and aldosterone antagonists at baseline were predictors of the level of BP reduction. Enrolment within the first in human trials (EI&III) had larger observed reductions in BP. Complete safety analysis including renal function and adverse events will be included in the presentation.

Conclusions: Pooled data from the complete EnligHTN clinical trial dataset meeting traditional study definitions of resistant hypertension confirm the efficacy and safety of the EnligHTN multi-electrode system for renal artery denervation. Future randomised controlled trials in the patient population with next generation multi-electrode renal denervation systems are warranted.

EuroPCR Interventions for hypertension & heart failure

Euro15A-OP357

Left ventricular resizing and reshaping with the Revivent myocardial anchor system: effect on mitral valve tenting

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Aims: Following myocardial infarction (MI), left ventricular (LV) dysfunction and geometric distortion together with LV dilation could be involved in the genesis of functional mitral regurgitation (FMR). The Revivent myocardial anchor system is used in post-MI ischaemic cardiomyopathy to plicate the myocardial scar and resize and reshape the LV to a more physiological state. Thus, we hypothesised that the use of the Revivent System may have beneficial effects on the mitral valve morphology and function.

Methods and results: We retrospectively analysed the effects of a volume reduction and geometry modification post-MI scar plication using myocardial anchors to assess changes in mitral valve tenting parameters in 20 patients undergoing the intervention with the Revivent myocardial anchor system. By the trial design, only patients with mild to moderate MR were included from a broader multicentre study.

Clinical and haemodynamic parameters at baseline and six months post implant are categorised as following: [Baseline / 6 months/ p (Paired t-test)] NYHA Class: 2.5 (0.5), 1.7 (0.8), 0.003; 6MW (m): 322 (98), 407 (93), 0.001; QoL Score: 46.2 (21.3), 15.9 (14.3), 0.002; LV EDV (ml): 181.9 (46.7), 146.7 (44.2), 0.0006; LV ESV (ml): 128.2 (42.2), 94.9 (37.1), 0.0007; EF (%): 29.7 (7.4), 36.5 (7.9), 0.001; Short axis–ED (cm): 6.2 (0.7), 5.8 (0.8), 0.005; Short axis–ES (cm): 5.1 (0.8), 4.6 (0.7), 0.03; Long axis–ED (cm): 9.9 (0.7), 8.4 (0.9), 0.001; Long axis–ES (cm): 9.4 (0.7), 7.9 (0.9), 0.001. Mitral valve tenting and geometrical parameters, mean (SD) are categorised as following: [Baseline / 6 Months / p (Paired t-test)] Tenting Area (cm): 4.3 (2.1), 3.4 (1.8), 0.005; Annular circumference (mm): 78.7 (13.5), 73.8 (10.8), 0.01; Coaptation depth (mm): 8.9 (2.2), 7.8 (1.9), 0.04.

Conclusions: Clinical and haemodynamic parameters significantly improved 6-months post-MI scar plication with the Revivent myocardial anchor system. These favourable changes were also associated with improved mitral valve tenting and a decrease in annular circumference and coaptation depth. Consequently, changes induced by the Revivent system to the LV size and geometry may positively impact mitral valve function and functional mitral regurgitation in ischaemic dilated cardiomyopathy.

EuroPCR Interventions for structural heart disease

Euro15A-MA021

Non-contrast enhanced magnetic resonance angiography is not inferior to contrast enhanced multislice computed tomography for correct aortic sizing before transcatheter aortic valve implantation

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Aims: We sought to establish a useful method for aortic root sizing without the use of contrast media in renal impaired patients. To do this we compared comprehensive non-contrast three dimensional steady-state free-precession (SSFP) magnetic resonance (MRI) imaging and a contrast-enhanced magnetic resonance angiography (CE-MR). Conventional contrast-enhanced multislice computed tomography (MSCT) serving as the reference standard.

Methods and results: Forty-two patients who underwent transcatheter aortic valve replacement had previously undergone MSCT and MRI examination, respectively. MRI examination included a 3D SSFP sequence covering the entire ascending aorta and CE-MR. Minimal and maximal aortic root diameters of all three imaging modalities were analysed by two blinded readers in consensus. Decisions for SAPIEN XT valve size of all three imaging modalities were compared. Mean aortic root diameter as measured by MSCT was 24.5±2.1 mm. CE-MR yielded a mean diameter of 25.8±3.0 mm with a correlation coefficient to MSCT r=0.64 ($p<0.0001$). Mean aortic root diameter on 3D SSFP images was 24.5±2.0 with good correlation to MSCT (r=0.93, $p<0.0001$). Decision for valve size showed good correlation between MSCT and CE-MR (=0.61) and better correlation between MSCT and 3D SSFP (=0.93).

Conclusions: In conclusion, both MRI techniques, CE-MR and 3D SSFP show good correlation to MSCT in the assessment of the aortic root and valve sizing. The 3D SSFP sequence yielded better correlation to MSCT and might offer an alternative without necessity of nephrotoxic exogenous contrast agent for the evaluation before transcatheter aortic valve replacement.

Impact of systole and diastole on prosthesis sizing in transcatheter aortic valve implantation

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Aims: Multislice computed tomography (MSCT) compared to echocardiography provides greater accuracy in valve sizing before transcatheter aortic valve implantation (TAVI), which translates into better clinical outcomes and increased safety. However, the aortic annulus is a dynamic structure and its changes during the cardiac cycle have been poorly quantified.

Methods and results: We reviewed 100 MSCT scans and measured aortic annular diameter, perimeter and area both in diastole (70-80% of cardiac cycle) and systole (40-50% of cardiac cycle). We analysed differences in measurements and tried to determine how much this variance would impact on the choice of prosthesis size. Out of 100 CT scans where annular dimensions were analysed in diastole, in 18 cases the quality of systolic images was considered insufficient to perform accurate measurement of the annulus. The annular diameter resulted to be significantly larger in systole compared to diastole (24.4±1.9 vs. 23.7±1.9 mm, p<0.001), as were perimeter (77.1±5.8 vs. 75.1±5.76 mm, p<0.001) and area (460.2±71.7 vs. 433.8±68.5 mm^2, p<0.001). Also, the ratio of minimum to maximum diameter increased in systole, indicating that the shape of the annulus tends to become more circular. According to manufacturer's recommendations and based on annulus area, in 70% of cases assessing measures in diastole or systole would not affect the choice of an Edwards SAPIEN 3 prosthesis. In 4% of cases, the annular size was in a "grey zone" either in diastole or systole, while measurement in the other phase of cardiac cycle corresponded to a single prosthesis size. In 21 patients (26%), measurements in systole or in diastole would lead to choose a different prosthesis size. If the self-expanding CoreValve prosthesis was used, in 83% of cases the phase of cardiac cycle would not affect the sizing; in 2.2% it would partially (one of the two measurements is in a grey zone), while in 8% of patients a different prosthesis size would be chosen. In most cases (60%), a CoreValve 29 mm would fit the annulus. For the Direct Flow Medical valve, based on perimeter-derived diameters as per instructions for use, there would be no change in 62% of cases, a possible change in 11% and a definite change in 27% of cases.

Conclusions: Measurement of aortic annulus diameter in systole leads to a small, but significant oversizing compared to diastolic images; in a non-negligible proportion of patients, this could alter the choice of prosthesis size. It remains to be determined if this could translate into any difference in clinical outcomes.

Transcatheter aortic valve implantation in patients with reduced ejection fraction and low transaortic gradient

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Aims: This multicentre study aimed to clarify the prognostic role of reduced left ventricular ejection fraction (LVEF) and low mean transaortic gradient (MTG) after transcatheter aortic valve implantation (TAVI).

Methods and results: From 2007 to 2012, 764 consecutive patients with severe symptomatic aortic valve stenosis underwent TAVI. Fifty-three (6.9%) had a LVEF≤30% (group 1), 87 (11.4%) between 31-40% (group 2), 129 (16.9%) between 41-50% (group 3) and 495 (64.8%) ≥51% (group 4). Each group was then divided according to a mean transvalvular gradient (MTG) above or under 40 mmHg. Three-year mortality did not differ for patients with low or high MTG in group 1 (54% vs. 52.7%, p=0.48), group 3 (52.3% vs. 42.1%, p=0.8) and group 4 (26.1% vs. 28.6%, p=0.48). In patients with a moderate impairment of LV function (group 2), a low MTG had a significant negative impact on mid-term mortality (75.7% vs. 35.8%, p=0.007). These results were confirmed by multivariate analysis, as only in patients with LVEF between 31-40%, a low MTG was significantly related to an increased risk of midterm mortality (HR 2.37, confidence interval [CI]: 1.25-4.48; p=0.008).

Conclusions: Patients with moderate left ventricular dysfunction and low mean aortic pressure gradient are at high risk of all-cause death after TAVI: an accurate balance of risk of intervention and of clinical benefits remains mandatory.

EuroPCR Interventions for structural heart disease Euro15A-MA024

Outcome of TAVI in patients with paradoxical low-gradient aortic stenosis results from the Jena-Bonn-Bad Nauheim Cohort

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Aims: Patients with severe aortic stenosis (AS) may present with a mean transvalvular aortic gradient (MPG) <40 mmHg due to a reduced stroke volume despite preserved ejection fraction ("paradoxical" low-flow, low-gradient, PLF-LGAS). Here we analysed the procedural and clinical outcome of patients undergoing transcatheter aortic valve implantation (TAVI) for PLF-LGAS (stroke volume index [SVI] ≤35 ml/m², MPG <40 mmHg) versus high-gradient AS (HGAS; MPG ≥40 mmHg) based on data of a clinical registry from three independent institutions.

Methods and results: A total of 1,260 patients undergoing TAVI were included in this study. PLF-LGAS and HGAS were present in n=484 (41.8%; MPG: 27.1±8.3 mmHg; SVI=26.9±5.4 ml/m²) and n=776 (58.7%; MPG: 54.8±20.8 mmHg; SVI=37.5±11.3 ml/m²) patients, respectively. EuroSCORE I (27.81±15.7 vs. 24.09±13.5; p<0.001) and patient age (81.1±5.9 vs. 82.5±6.1 p=0.017) were significantly different between groups. TAVI was performed transfemorally in the majority of patients (overall 71.4%) with a high procedural success rate (>98%). Patients with PLF-LGAS had a significantly higher in-hospital mortality (10.9% vs. 6.7%, p=0.011) and 1-year mortality (32.0% vs. 24.1%; p=0.008) compared to patients with HGAS. The rate of VARC-defined secondary endpoints was without significant differences between the groups: new pacemaker: 13.2% vs. 17.3%; p=0.07.; stroke – Rankin Scale≥2: 3.4% in each group). However, patients with PLF-LGAS required a longer duration of hospital treatment compared to those with HGAS (18.3±13.4 vs. 16.1±10.7 days; p=0.05). In both subgroups, NYHA-class improved significantly after TAVI (PLF-LGAS NYHA≥III: 91.8% at baseline vs. 19.9% at 30 days; p<0.001; HGAS: NYHA≥III: 90.9% at baseline vs. 13.6% at 30 days; p<0.001), confirming the clinical benefit in each AS-subtype.

Conclusions: Patients with low-gradient AS and preserved LV function have a higher in-hospital and 1-year mortality after TAVI compared to patients with high-gradient AS, a finding contrasting earlier registry data. However, long-term survivors benefit from TAVI with functional improvement irrespective of the subtype of AS.

EuroPCR Interventions for structural heart disease Euro15A-MA025

Impact of left ventricular geometric pattern on outcome after transcatheter aortic valve implantation

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Aims: Little is known of the prognostic significance of left ventricle hypertrophy (LVH) pattern on transcatheter aortic valve implantation (TAVI). We investigated the prognostic impact of LVH pattern on outcomes after TAVI using the recently proposed new LVH classification based on LV dilatation (high LV end-diastolic volume [EDV] index) and concentricity (mass/end-diastolic volume [M/EDV]2/3).

Methods and results: We examined 511 consecutive patients with severe AS (aortic valve area <1.0 cm²) who underwent transfemoral-TAVI using 2-dimensional and Doppler echocardiography. Patients with LVH (LV mass/body surface area ≥ 116 and ≥ 96 g/m² in men and woman, respectively) were divided into four groups—eccentric non-dilated (normal M/EDV and EDV), eccentric dilated (increased EDV, normal M/EDV), concentric non-dilated (increased M/EDV, normal EDV), and concentric dilated (increased M/EDV and EDV)—and compared with patients with normal LVM. The LVs were categorised as eccentric non-dilated in 49.1%, eccentric dilated in 14.9%, concentric non-dilated in 12.5%, concentric dilated in 8.6%, and normal LVM in 14.9% at baseline. Patients with concentric dilated group had the highest 1-year all-cause mortality of all groups (60.9%, log-rank: <0.001). Both concentric and eccentric dilated groups showed highest 1-year cardiovascular mortality and composite endpoint (log-rank: 0.034, 0.020 respectively). In multivariable analysis, the concentric dilated pattern was the strongest predictor of mortality (adjusted HR: 17.35, 95%CI: 2.23-135.17; p=0.006).

Conclusions: Severe aortic stenosis LVH patients undergoing TAVI can be reclassified into four groups based on echocardiographic geometric patterns. Concentric dilated group had the highest 1-year mortality and was demonstrated to be the strongest predictor of mortality. These findings have implications for the evaluation and subsequent management of severe AS patients undergoing TAVI.

Preclinical evaluation of a novel self-positioning steerable transseptal access system

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Aims: Transseptal catheterisation is a critical step for left atrial interventions (atrial fibrillation ablation, left atrial appendage closure, mitral valve interventions). The availability of suitable tools and techniques is essential to safely perform the transseptal puncture, effectively deliver radiofrequency lesions, deploy left atrial devices, and anticipate difficult procedural situations in which complications may arise. We report preclinical results of a novel integrated system combining an extendable radiopaque loop wire to aid in localising the fossa ovalis (FO); an innovative flexible needle to enable precise selection of the puncture site; and steerable sheath for left atrial navigation.

Methods and results: Preclinical evaluation was conducted in 11 healthy swine in compliance with institutional guidelines and federal animal protection law. Control experiments were conducted in two animals using standard-of-care devices. Procedures were performed using the novel transseptal device with percutaneous approach through venous femoral access using solely fluoroscopic guidance. Venous puncture was followed by introduction of the steerable sheath in to the right atrium. A radiopaque loop was advanced to engage the FO superior rim. The wire loop served as a stabiliser and as a radiopaque landmark to guide the needle towards the desired puncture site (superior, inferior FO). Intracardiac echocardiography was used to assess the transseptal puncture location. Standard ablation catheters were used to evaluate orientation and manoeuvrability in engaging pulmonary veins. Handling, stability and fluoroscopic visibility of the system was rated according to a grading scale from 1 (not acceptable) to 4 (excellent). Upon procedure completion animals were euthanised and macromorphological examination of the explanted heart performed. Transseptal puncture was successfully performed in all animals, with average procedural time of 12±6 min and fluoroscopy time of 1.8±6 min. The radiopaque loop and the steerable features guaranteed a stable positioning and targeting of the FO puncture site. Left atrial navigation grading score was 3.8 on average, and the operators were able to reach the target areas within the left atrium in all animals. No device-related and procedure related adverse events occurred. The needle, loop and dilator were retrieved without applying significant tension or friction and without tissue tears. In all animals the location of the puncture by intracardiac echocardiography was consistent with the planned target area. Pathology showed no injury of the inferior vena cava, cardiac chambers and valves, coronary lesions or pericardial effusion. No significant difference was observed in transseptal puncture mean diameter (Study Device system: 2.81±1.4 mm; conventional needle puncture: 3.45±1.5 mm). Analyses of blood samples showed no evidence of systemic inflammatory response during the procedure in both groups.

Conclusions: The novel system allows simplified and safe fluoro-guided transseptal puncture. In all animals precise location of the FO puncture was obtained with low procedural and fluoroscopy times, without the need for echo-guidance.

Pre-stenting for prevention of Melody valve stent fractures: a systematic review and meta-analysis

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Aims: The Melody valve is a transcatheter pulmonary valve designed as a non-surgical alternative for treatment of right ventricular outflow tract (RVOT) dysfunction. It consists of a bovine jugular vein conduit mounted on a balloon-expandable stent. Stent fracture is a known complication of Melody valve implants; it can be associated with restenosis, aneurysmal formation, vessel perforation and embolisation. The role of RVOT pre-stenting with BMS or covered stents in the prevention of stent fractures is not well defined. We aimed to perform a systematic review and meta-analysis comparing the incidence of stent fractures in Melody valve transcatheter pulmonary implants with and without pre-stenting.

Methods and results: PubMed, EMBASE and Cochrane Central were searched for studies that reported the incidence of stent fractures in Melody valve transcatheter implants stratified by the presence or absence of RVOT/conduit pre-stenting. The following medical subject heading terms were included "Melody valve" OR "transcatheter pulmonary valve" OR "percutaneous pulmonary valve". Due to anticipated heterogeneity, odds-ratio was computed using a random-effects model. Results were confirmed with the Mantel-Haenszel fixed-effect model to avoid overweighting small studies. Heterogeneity was examined with the Cochran Q test and I^2 statistics. Publication bias was evaluated by using funnel-plot graphs. Subgroup analyses were also performed for (1) stent fractures requiring reintervention and (2) type II or type III stent fractures, which are associated with a loss of stent integrity. The search strategy yielded 255 studies. After analysis of inclusion criteria, six studies and 465 patients were included, of whom 228 (49%) received pre-stenting of the RVOT before Melody valve deployment. Follow-up ranged from 12 to 30 months. Stent fractures were significantly reduced among the pre-stenting group (10.9%) when compared to the no pre-stenting (21.1%) group (OR: 0.37; 95% CI: 0.22-0.64; p<0.001). In the subgroup analyses, stent fractures remained significantly reduced in patients who received pre-stenting when considering only (1) stent fractures requiring reintervention (0.8% in pre-stenting vs. 8.1% in no pre-stenting; OR: 0.15; 95% CI: 0.02-0.92; p=0.04); and (2) only type II or III stent fractures (2.1% in pre-stenting vs. 13.2% in no pre-stenting; OR: 0.16, 95% CI: 0.05-0.49; p=0.001). Results remained statistically significant in fixed-effect analysis. Funnel plots showed no evidence of publication bias. I^2 of 0% indicates no heterogeneity.

Conclusions: The results of our study suggest that pre-stenting is associated with a decreased incidence of stent fractures in Melody valve pulmonary implants. Our findings also suggest pre-stenting has the potential to decrease Melody valve stent fractures associated with loss of stent integrity, as well as those that require reintervention. Randomised trials are warranted to confirm the effectiveness of pre-stenting in the prevention of Melody valve stent fractures.

EuroPCR Interventions for structural heart disease

Euro15A-MA033

Transapical approach for transcatheter mitral perivalvular leak closure: midterm outcomes of a single centre experience

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Aims: Significant prosthetic paravalvular leaks could have serious clinical consequences and impairs survival. Reoperation is associated with a high mortality rate, and percutaneous closure is a new treatment modality for high-risk patients. The aim of this study is to assess safety and midterm clinical outcomes of transcatheter mitral PVL closure using the transapical approach.

Methods and results: From September 2011 to November 2014, 21 consecutive patients with severe mitral regurgitation due to paravalvular leak underwent transapical transcatheter closure at our Institution. Mean age was 70±12 years, 58% were male and logistic EuroSCORE was 27±17%, STS score 9±4%. Most patients were in NYHA class III or IV (86%) and 95% were at their second or more reoperation. One patient had combined mitral and aortic paravalvular leaks and another had mitral paravalvular leak concomitant with mitral bioprosthesis structural failure. Before intervention, all but two patients were in NYHA class III-IV and had haemolytic anaemia requiring blood transfusions. All the transapical closures were performed under general anaesthesia in a hybrid operating room. In all cases, Amplatzer Vascular Plug II and III devices were used (median 2, range 1-6). Procedural success was 91% (two conversions to surgery because of dislocation of the device and one ventricular rupture). All the patients had less than moderate residual valve regurgitation after the procedure and in-hospital survival was 95%. The one-year survival rate was 83% (12 patients). After a mean follow-up of 21.5±13.5 months, clinical efficacy (i.e., survival free of stroke, rehospitalisation, New York Heart Association 3/4, haemolytic anaemia and device-related dysfunction) was 62%.

Conclusions: In this single-centre experience, the midterm outcomes confirmed that transapical transcatheter closure of mitral paravalvular leak is a safe and effective solution in selected high-risk patients. It has a reduced risk of hospital mortality and maintained an acceptable clinical efficacy after the first year.

EuroPCR Interventions for structural heart disease

Euro15A-MA034

Acute haemodynamic effects of the MitraClip® System: focus on v-wave and acute reduction of mitral regurgitation (MR); analysing 266 consecutive patients from the AK St. Georg, Hamburg, Germany

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Aims: Haemodynamic changes after MitraClip® procedure are rarely described. Most of the existing experience results from the Everest Trials including patients with organic MR (DMR). In Europe and especially Germany 2/3 of the patients treated with the MitraClip® System suffer from functional MR (FMR). Aim of this work was to improve the understanding of the acute haemodynamic effects in all these patients.

Methods and results: From September 2009 to November 2014, 496 patients in 518 procedures were treated with the MitraClip® System at the AK St. Georg in Hamburg. Haemodynamics have been evaluated via Swan Ganz catheterisation and thermodilution method directly before and after Clip deployment. Left atrial (LA)-pressure has been evaluated via transseptal measurements by either SL1 Sheath, standard Pigtail catheter or the Clip Device System (CDS) itself directly before and after Clip deployment. Systolic pulmonary artery pressure (PAPs) increased slightly from 39.6 mmHg (±12.1) to 42.1 mmHg (±11.9) ($p<0.05$). Cardiac output (CO) increased from 3.9 l/min (±1.2) to 4.9 l/min (±1.5) directly after the procedure ($p<0.001$). The average amount of Clips used was 1.4 (±0.3). LA pressure (mean) was reduced significantly ($p<0.001$) from 15.37 mmHg (±6.3) to 12.7 mmHg (±6.0). V-wave fell from 26.5 mmHg (±11.9) to 19.5 mmHg(±9.51). Focussing v-wave reduction by reduction in MR, we could not find a statistical significant difference in patients achieving a MR reduction of either three grades or none (p=n.s.). In addition, we could not find a statistical significant difference concerning the pathology of the MR. FMR and DMR showed no difference in v-wave reduction related to MR reduction (p=n.s.). V-wave reduction in patients with DMR was generally higher than in FMR patients ($p<0.05$). Grade of MR assessed by echo was reduced stable and significantly from 3.1(±0.3) before to 1.1 (±0.6) directly after and 1.8 (±0.7) after 6 months, $p<0.001$. This result remained stable after 1 year although the number of patients lost to follow-up was high.

Conclusions: The MitraClip® is a safe and effective treatment of MR in patients considered high risk for surgical treatment. We have shown that this non-open chest treatment of MR improves the CO up to 25% while reducing LA pressure and v-wave significantly. The decrease of the v-wave is not dependent on MR reduction either in the whole sampling of patients, or focussed on the origin of MR (FMR or DMR), although acute decrease of v-wave is higher in DMR than in FMR patients.

Transcatheter closure of aortic perivalvular leak using IVUS guidance: rationale and case series

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Aims: Clinical significant periprosthetic paravalvular leak (PVL) is an uncommon but serious complication after surgical aortic valve replacement. Percutaneous closure has been utilised as an alternative to surgical repair in high-risk surgical patients. Unsuccessful percutaneous closure of leaks may be related to morphologic characteristics of the defects. Standard fluoroscopy and 2D transthoracic echocardiography (TTE) offer minimal assistance in delineating PVL anatomy. Use of 3D TEE can help but due the complexity of PVLs and limitation of the echocardiography, especially in the aortic position, the evaluation of the PVL can be difficult. Use of IVUS imaging can allow a correct sizing of perivalvular defect and guide the selection of the appropriate device.

Methods and results: Between February 2010 and December 2014, 17 patients (mean age 68.3±9.2 years, 66% male) who were believed to be poor operative candidates (Heart Team evaluation) underwent PVL closure with Amplatzer Vascular Plug III device. Five patients underwent IVUS imaging on top of standard imaging evaluation (2D TEE and 3D TEE). Ten patients (58%) had mitral paravalvular leak, seven (42%) had aortic one. The median time since valve replacement (biologic prosthesis 88% and mechanical prosthesis 12%) was 36±9 months. Technical procedural success was achieved in 94% of cases, respectively 100% in aortic paravalvular leak and 90% in mitral. In six patients (50%) more than one device was necessary. IVUS imaging was performed in the 85% of the aortic cases. IVUS enabled the determination of the leak's size and shape allowing a correct sizing of waist diameter of the device. At follow-up (ranging between 3-20 months), clinical success was achieved in 83% (10 of 12 patients). One patient underwent a second procedure with a third device implantation 49 days after first closure; two patients, with persistent residual leak and haemolysis parameters worsening, underwent surgical repair. At 12 months, 83.3% of patients were alive.

Conclusions: In our experience, percutaneous closure of PVL is feasible and safe. It may be considered in selected patients in whom re-surgical intervention is deemed high risk or is contraindicated. The success rate in device deployment is also probably related to anatomic characteristics of the dehiscence. This series highlights the importance and benefit of IVUS guidance in correct sizing of aortic perivalvular defect and right selection of an appropriate device.

The impact of new generation balloon-expandable prostheses on procedural results and clinical outcomes of transcatheter aortic valve implantation in Switzerland

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Aims: We compared clinical outcomes between SAPIEN 3 (S3) and SAPIEN (XT) in transcatheter aortic valve implantation (TAVI).

Methods and results: In a nationwide, prospective, multicentre cohort study (Swiss TAVI Registry, NCT01368250) outcomes of transfemoral TAVI patients treated with the S3 (year 2014) versus the XT (years 2011-2014) were investigated. Events were reported according to the Valve Academic Research Consortium guidelines and adjudicated by a clinical event committee. Pre-specified endpoints were more than mild paravalvular regurgitation, vascular complications, major bleeding, disabling stroke, new permanent pacemaker implantation and mortality after 30-day of follow-up. An overall of 153 consecutive S3 patients were compared to 445 consecutive XT patients. No significant differences were found for baseline characteristics including age (82.2±6.1 years vs. 82.2±6.8 years, p=0.935), STS PROM (7.2±6.5% vs. 8.5±7.9%, p=0.073), mean aortic valve gradient (47.2±22.0 mmHg vs. 43.7±17.3 mmHg, p=0.063) and aortic valve area (0.71±0.23 cm^2 vs. 0.71±0.22 cm^2, p=0.88) between S3 and XT patients, respectively. Post-procedural mean trans-prosthetic gradient (6.5±3.0 mmHg vs. 7.8±6.3, p=0.167) did not differ between S3 and XT patients, respectively. The rate of more than mild paravalvular regurgitation (1.3% vs. 5.3%, p=0.04) as well as of vascular (5.3% versus 16.9%, p=0.002) and major bleeding complications (4.0% vs. 8.4%, p=0.036) were all significantly lower in S3 patients than in patients receiving the XT prosthesis. There were no significant differences for disabling stroke (S3 1.3% vs. XT 3.2%, p=0.251) and all-cause mortality (S3 3.3% vs. XT 4.5%, p=0.776) between both groups. A numerical difference with more new permanent pacemaker implantations was observed in patients receiving the S3 compared with XT patients (17.3% versus 11.2%, p=0.098).

Conclusions: The SAPIEN 3 balloon-expandable transcatheter heart valve is associated with a significant reduction of more than mild paravalvular regurgitation, vascular complications and major bleeding when compared with the SAPIEN XT. Furthermore, S3 is associated with a very low risk of stroke and favourable clinical outcomes in contemporary clinical practice.

euroPCR Interventions for structural heart disease

Euro15A-MA047

Transcatheter aortic valve implantation: does age really matter? Results for a nonagenarian population

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Aims: As the nonagenarian patient population continues to grow, more patients aged 90 and over are being referred for transcatheter aortic valve implantation (TAVI). The aim of this study was to evaluate if the procedure is safe and effective in this patient group and compare the outcomes in patients aged <90 years.

Methods and results: We performed a retrospective database analysis of 468 consecutive TAVI from March 2008 to September 2014. Data were obtained for the two groups i.e., ≥90 (group A) and <90 (group B). Multimodal assessments were performed in all cases and reviewed at a multidisciplinary meeting. Data were retrospectively analysed from our prospectively maintained database. Mortality data were obtained from the Office of National Statistics, UK. Univariate comparison between groups was made using t-test or Mann-Whitney U and a chi-square or Fisher exact for categorical outcome (SPSS v20.0). Sixty-nine patients (14.7%) were identified as being age ≥90 at the time of the procedure. Logistic EuroSCORE in group A and group B was 23.5±12.1% vs. 20.5±12.1% respectively. STS score was 8.8% ±4.2% vs. 5.4±3.2%. Excluding age as a risk factor, patients in group A had a lower risk profile compared to group B (diabetes mellitus (22% vs. 38%, p=0.058), hypertension (59% vs. 67%, p=0.229), previous CABG (9% vs. 32%, p<0.01), previous valve surgery (4% vs. 10%, p=0.043), chronic lung disease (17% vs. 24%, p=0.177) and peripheral vascular disease (9% vs. 15%, p=0.103). However, the nonagenarians group had a lower baseline eGFR (34.8±13.4 vs. 46.6±28.1 p=0.001). Access for TAVI was similar in the two groups (TF: group A 51%, group B 50%). Periprocedural complications were similar in the two groups. Major vascular complications were seen in 4% in group A and 3% in group B (p=0.610). Stroke occurred in 4% in group A and 3% in group B (p-value=0.610). New pacemaker was implanted in 7.2% in group A and 1.5% in group B. Early and medium-term mortality were similar in the two groups. 30 day: 10% in group A vs. 6% in group B (p=0.217); 1-year: 26% in group A vs. 20% in group B (p=0.264).

Conclusions: In our cohort of TAVI patients, we have demonstrated that TAVI can be performed safely and with acceptable periprocedural risks in the nonagenarian population. Provided patients can be selected carefully in a multi-disciplinary environment, acceptable early and medium-term outcomes can be achieved.

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Euro15A-MA048

Determinants of left ventricular mass regression in patients with severe symptomatic aortic stenosis undergoing transcatheter aortic valve implantation

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Aims: The dynamics in left ventricular mass (LVM) regression following relief of chronic left ventricular (LV) pressure overload is prone to variation. We sought to identify determinants of LVM regression following transcatheter aortic valve implantation (TAVI).

Methods and results: The study included 134 patients undergoing TAVI. We retrospectively analysed the LVM indexed to body surface area (LVMi) calculated by transthoracic echocardiography at baseline and at 6-12 months post-TAVI. At 6-12 months after TAVI there was a significant reduction in mean LVMi (from 118.2±26.67 g/m^2 to 103.4±27.07 g/m^2, p<0.001) driven by a decrease in LV wall thickness. The relative wall thickness (RWT) decreased (0.54±0.10 cm vs. 0.51±0.09 cm, p=0.006), whereas the prevalence of concentric remodelling (RWT≥0.42) remained unchanged (85.1% vs. 80.6%, p=0.3). However, 47 patients (35.1%) did not demonstrate significant LVMi regression. They had a lower baseline LVMi than patients who demonstrated significant regression (109.8±25.8 g/m^2 vs.122±26.1 g/m^2, p=0.008) but had otherwise similar characteristics. A greater magnitude of LVMi reduction was associated with a greater baseline LVMi (r=0.39, p<0.001), where patients with LVMi in the highest quartile had the most substantial LVMi reduction (p<0.001). Multivariable analysis identified pre-TAVI LVMi as the sole independent predictor of LVMi regression at 6-12 months post-TAVI (β=0.45, 95% CI: 0.255-0.534, p<0.001).

Conclusions: LVM regression 6-12 months post-TAVI was variable with about one-third of the patients not demonstrating significant regression. Only baseline LVM predicted LVM regression; patients with higher baseline LVM demonstrated greater regression.

Comparison of clinical outcomes of patients undergoing transcatheter aortic valve implantation in Japanese and French cohorts: insight from the OCEAN-TAVI registry

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Aims: Little is known about real-world clinical outcomes after transfemoral transcatheter aortic valve implantation (TF-TAVI) in the East-Asian population with small body size compared with the European population.

Methods and results: Patients included in the optimised transcatheter valvular intervention (OCEAN-TAVI, Japan) and the Institut Cardiovasculaire Paris Sud (Massy, France) registries were evaluated. For the analysis, we included 112 patients from the OCEAN-TAVI registry and 53 patients from the MASSY registry who underwent TF-TAVI using the Edwards SAPIEN XT™ (Edwards Lifesciences, Irvine, CA, USA). Combined safety endpoint at 30 days, which was defined based on VARC2 criteria, was compared between the two registries. Body surface area was significantly smaller in the OCEAN-TAVI cohort (1.41±0.15 vs. 1.74±0.20 m^2, p<0.001), although other baseline characteristics and operative risks of both cohorts were almost similar. The greater amount of patients in OCEAN-TAVI cohort was implanted with 23 mm valve compared with Massy cohort (73.2% vs. 30.2%, p<0.001), reflecting the smaller annulus diameter calculated by the computed tomography (21.8±1.6 vs. 23.5±2.1 mm, p<0.001). Device success was similar (98.2 vs. 94.3%, p=0.329), as well as combined safety endpoint (11.6 vs. 17.0%, p=0.339).

Conclusions: Despite an unfavourable aortic anatomy in the Japanese cohort, their clinical outcomes after TF-TAVI were excellent and as safe as that of an experienced European institute.

Transfemoral transcatheter aortic valve implantation (TAVI) in patients with small peripheral vessels

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Aims: The transfemoral (TF) vascular access route for TAVI has become the default strategy due to a number of advantages including shorter procedure and recovery times. In spite of significant improvements in TAVI delivery design, a minimal lumen diameter (MLD) of 6 mm is still recommended and thus a significant minority of patients are denied TF-TAVI and exposed to more invasive access routes and associated potential complications. Furthermore, in some patients, alternate access sites are not thought to be a viable alternative. We describe our experiences of performing TF-TAVI in patients with small peripheral vessels.

Methods and results: All patients that underwent TF-TAVI with current generation TAVI devices (CoreValve (Medtronic, Minneapolis, MN, USA), SAPIEN XT (Edwards Lifesciences, Irvine, CA, USA), Lotus valve (Boston Scientific, Natick, MA, USA) and Direct Flow Medical (Direct Flow Medical, Santa Rosa, CA, USA) at the San Raffaele Scientific Institute, Milan, Italy between January 2011 - October 2014 were included. Small peripheral vessels were defined as an MLD of <6 mm bilaterally in the femoral or common iliac arteries as assessed by computed tomography (CT) with contrast of the peripheral vasculature and/or inability to advance the TAVI large-bore sheath. Twenty-three patients presented with small peripheral vessels and proceeded to TF-TAVI. All patients underwent a TF procedure on the side of the larger vessel diameter. To facilitate passage of the delivery system, pre-dilatation with an 8 mm non-compliant balloon or the use of the balloon-expandable SoloPath® sheath (Terumo, Somerset, NJ, USA) was undertaken. Following removal of the sheath, the peripheral access site was closed percutaneously with either one Prostar XL (Abbott Vascular, Santa Clara, CA, USA) or two ProGlide (Abbott Vascular) vascular closure devices. The MLD on the intervention side was 5.2±0.8 mm and, as expected, was larger than the contralateral non-interventional side (4.6 ±0.7 mm). Seventeen (73.9%) patients underwent peripheral vessel predilatation with peripheral angioplasty balloons and six (26.1%) patients underwent peripheral dilation with a Solopath® sheath. TAVI devices were successfully delivered and deployed in all patients via the TF route, with no requirement to change access route. Periprocedural vascular complications occurred in six (26%) patients but none had a vessel perforation. Two patients suffered limited dissections of the common iliac artery, which were managed conservatively without further complication. Three patients suffered dissections that were associated with evidence of thrombus formation and poor peripheral flow and were successfully managed with implantation of a single stent. One patient suffered a thrombotic occlusion of the femoral artery which was successfully treated with Forgarty catheter embolectomy. At 30-day follow-up, all patients were free of symptoms and signs or symptoms of peripheral vascular disease, with well-functioning TAVI prostheses as evaluated by echocardiography.

Conclusions: Our single-centre experience demonstrates that when alternate vascular access routes are of limited feasibility, TF-TAVI in patients presenting with small peripheral vessels (as identified by CT) can be considered provided peripheral vessel preparation and rescue techniques are available.

EuroPCR Interventions for structural heart disease Euro15A-MA051

Added clinical value of intracardiac echocardiographic support during fluoroscopy-guided transfemoral aortic valve implantation under local anaesthesia and conscious sedation

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Aims: Improvements in procedural safety have set the stage for simplified transcatheter aortic valve implantation (TAVI) with fluoroscopic guidance only, discarding routine intraprocedural transoesophageal echocardiography. However, fluoroscopy alone may not provide sufficient diagnostic information in case of unexpected events. Aim of this study is to investigate the potential clinical advantage of adjunctive intracardiac echocardiography (ICE) during transfemoral TAVI under local anaesthesia and conscious sedation (LACS).

Methods and results: All TAVI cases in which ICE was used as an adjunctive imaging tool were identified through interrogation of our institutional database. Procedural reports, angiographic and ICE images were analysed to retrospectively assess the benefit of ICE during TAVI. Outcomes were documented according to the Valve Academic Research Consortium 2 criteria. Between October 2011 and May 2014, 180 patients (mean age 80.3±7.8 years, 43.9% male, Logistic EuroSCORE-I 15.7±8.6%) were treated with ICE assisted transfemoral TAVI under LACS (59.4% Edwards SAPIEN XT and 40.6% Medtronic CoreValve). Adjunctive ICE provided significant added benefit during 41 (22.8%) TAVI procedures, mainly in decision making regarding post-implantation aortic regurgitation (AR) (n=28) and early detection or exclusion of pericardial effusion (n=8). Discharge echocardiography showed moderate AR in 11 (6.3%) patients and no cases of severe AR. The device success and composite safety endpoints were reached in 155 (86.1%) and 27 patients (15.0%), respectively. Thirty-day mortality was 3.9%.

Conclusions: Supportive ICE imaging seems a valuable tool during TAVI under LACS, providing benefit in approximately one in four procedures by facilitating procedural flow and rapid decision making in different TAVI-associated scenarios.

EuroPCR Interventions for structural heart disease Euro15A-MA053

A comparison of the risk of cerebral embolisation after transfemoral implantation of the Edwards SAPIEN aortic valve with or without prior balloon valvuloplasty

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Aims: To assess the risk of cerebral embolisation after transfemoral direct implantation of the Edwards SAPIEN Aortic Valve compared to Edwards SAPIEN with prior balloon valvuloplasty (BAV).

Methods and results: Cerebral diffusion weighted magnetic resonance imaging (DW-MRI) was performed in 77 consecutive patients (mean age 83.7±5.2 years, 48% male) without contraindications two to three days after TAVI, in 47 patients after direct Edwards SAPIEN implantation and in 30 consecutive patients who underwent BAV before Edwards SAPIEN implantation. Demographic data were not significantly different between the groups. The incidence, number and volume of new ischaemic lesions in DW-MRI were evaluated blinded to the patient's actual treatment. None of the patients experienced a stroke.

Conclusions: The implantation of the Edwards SAPIEN aortic valve without BAV is associated with a higher risk of cerebral embolisation compared to the implantation with prior BAV.

Amount of non-coronary cusp annulus calcium predicts new permanent pacemaker implantation after balloon-expandable transcatheter aortic valve replacement

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Aims: The aim of this study is to evaluate the association between quantity and localisation of aortic valve calcification (AVC) and new permanent pacemaker (PPM) implantation after transcatheter aortic valve replacement (TAVR).

Methods and results: Between January 2013 and September 2014, 184 consecutive patients with severe aortic stenosis underwent balloon-expandable TAVR (SAPIEN [n=57] or SAPIEN XT [n=127]) and had contrast cardiac CT. A recently validated score for AVC using contrast CT based on volume of pixels with ≥850 Hounsfield Unit threshold (HU-850) was calculated for each patient. The use of contrast scans facilitated the reliable anatomical localisation of calcium volume. AVC was divided by leaflet sector and regions of the aortic valve complex (leaflet, annulus, left ventricular outflow tact [LVOT]). Asymmetry was assessed using the maximum absolute difference in volume scores between any two leaflet sectors for each region (Δ leaflet calcium, Δ annulus calcium, Δ LVOT calcium). The LVOT region was defined as the cross-sectional region 5 mm inferior to the annular plane. The annular region was defined as the cross-sectional region 2 mm inferior to the annular plane to 3 mm superior to the annular plane. The leaflet region was defined as the cross-sectional region 3 mm superior to the annular plane to the cranial portion of the leaflet. The incidence of in-hospital PPM implantation after TAVR was recorded. Receiver operator characteristic curves (ROC) were plotted for the prediction of the respective endpoints. Mean age was 81.7±8.5 years, mean logistic EuroSCORE was 22.0±15.9%, and mean total AVC (HU-850) was 218.5±232.2 mm^3. AVC was highest in the non-coronary cusp, followed by the right coronary cusp and the left coronary cusp (mean 102.8, 67.6 and 57.9 mm^3, respectively). The incidence of PPM implantation was 7.61% (n=14). In ROC curve analysis, the strongest predictor of new PPM implantation was non-coronary cusp annulus AVC scores (p=0.006, area under the curve [AUC]=0.721). Other predictors that were found to be associated with new PPM implantation were LVOT calcium scores, asymmetry LVOT calcium AVC scores, and total annulus calcium AVC scores (p=0.040, AUC=0.666; p=0.040, AUC=0.665; p=0.047, AUC=0.660, respectively).

Conclusions: In our contemporary practice, non-coronary cusp annulus calcium was the strongest predictor for new PPM requirement post-balloon-expandable TAVR.

Transfemoral implantation of a fully repositionable and retrievable TAVI device for pure, non-calcified aortic regurgitation

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Aims: Pure aortic regurgitation (AR) without leaflet calcification is considered a contraindication for most percutaneous aortic valve prostheses because calcification is required for a stable valve position. The Direct Flow Medical (DFM) aortic valve may be suitable for pure AR, because it is fixed by two expandable rings placed below and above the native valve which may not require calcification for stable positioning. The aim of this study was to evaluate the safety and feasibility of the DFM valve for the treatment of patients with severe AR without calcification.

Methods and results: Seven high-surgical-risk patients (74.9 years, range 46 to 87, one male) with severe AR and no or trivial valvular calcification were enrolled in three centres in Germany, Italy and Switzerland. All patients were in New York Heart Association (NYHA) class III. Ejection fraction ranged from 20% to 70%. The mean logistic EuroSCORE / Society of Thoracic Surgeons (STS) score were 18.6 and 11.6, respectively. The intervention in the 46-year-old patient was a bridge to heart transplantation. Annulus diameter was measured by multislice computed tomography (MSCT) and we aimed to oversize the prosthesis by at least 3 mm to ensure stable fixation. One patient received a 25 mm device, two patients a 27 mm device and four patients a 29 mm DFM valve. In all seven patients, a DFM valve was successfully implanted. During the procedure, there were two pull-throughs in one patient and three in another patient with the valve successfully retrieved in all cases. Residual AR was zero in five patients, trivial paravalvular regurgitation in one patient and mild paravalvular in one patient. Valve embolisation into the left ventricular outflow tract occurred in one patient 3-days post-procedure. *Post hoc* analysis demonstrated oversizing of the prosthesis of only 2 mm. This patient subsequently underwent surgical aortic valve surgery under stable conditions and made an uneventful recovery. No other adverse events occurred at 30-day follow-up. No patient required implantation of permanent pacemaker.

Conclusions: In high-risk patients with severe non-calcified pure AF, transfemoral implantation of the DFM aortic valve is feasible. Significant valve oversizing, however, is crucial to achieve a stable position of the prosthesis. Further studies are needed to learn more about appropriate patient selection.

euroPCR Interventions for structural heart disease

Euro15A-MA056

Left atrial appendage occlusion for stroke prevention in patients with atrial fibrillation and chronic renal failure: a substudy of the multicentre registry with the Amplatzer cardiac plug

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Aims: The aim of the study was to investigate the safety and efficacy of left atrial appendage occlusion using the Amplatzer cardiac plug in patients with renal failure, defined as an estimated glomerular filtration rate <60 ml/min/1.73 m^2.

Methods and results: Among the cohort of the Amplatzer cardiac plug multicentre registry, 1,014 patients (75±8 years) with serum creatinine and glomerular filtration rate values available, were identified and included in the study. At baseline, patients with chronic kidney disease (N=374, group 2; CHA_2DS_2-VASc: 4.9±1.5, HASBLED: 3.4±1.3) were at higher risk than patients with normal renal function (N=640, group 1; CHA_2DS_2-VASc: 4.2±1.6, HASBLED: 2.9±1.1; p<0.001 for comparison of both scores). Procedural (97 vs. 98%) and occlusion (95 vs. 94%) success were similarly high in group 1 and 2 (p=NS). Periprocedural major adverse events were observed in 5.0% in group 1 vs. 6.6% in group 2 (p=NS) including 0.8% of death in both groups. In patients successfully implanted with a complete follow-up (1,345 patients-years, 19 patients lost to follow-up), the actual annual stroke+transient ischaemic attack rate was 2.5% in group 2 (60% reduction as compared with the estimated risk) and 1.9% in group 1 (63% reduction); p=0.55 between groups. The observed bleeding rate was 2.5% in group 2 (61% reduction) and 1.7% in group 1 (64% reduction); p=0.41 between groups. Thrombus on the device was observed in 4.1% and 4.6% in group 1 and 2, respectively. Medication at last follow-up was limited to aspirin in 77% of CKD patients, while only 3.7% of them were under anticoagulant therapy. Kaplan-Meier analysis showed a similar overall survival (95.8±1% vs. 93.5±9% and 91.6±1% vs. 90.7±2% at one and two years, respectively; p=0.32) and event-free survival (93.9±1% vs. 91.2±2% and 87.6±2% vs. 85.4±2% at one and two years, respectively; p=0.11) among patients of group 1 and 2.

Conclusions: Despite a different risk profile at baseline, left atrial appendage occlusion using the Amplatzer cardiac plug device has a similar procedural efficacy and safety in patients with chronic kidney disease than in patients with normal renal function, for stroke prevention in patients with atrial fibrillation. Left atrial appendage occlusion using the Amplatzer cardiac plug in patients with chronic kidney disease offers a dramatic reduction of stroke+transient ischaemic attack rate (2.5 vs 6.3%, 60% reduction) and of bleeding rate (2.5 vs 6.5%, 61% reduction) as compared with the expected annual risk. Safety and efficacy of left atrial appendage occlusion using the Amplatzer cardiac plug for the prevention of atrial fibrillation-related thromboembolism in patients with chronic kidney disease is persistent at 2-years follow-up, while 94.3% of them are left untreated with anticoagulant therapy.

euroPCR Interventions for structural heart disease

Euro15A-MA057

Safety and efficacy of left atrial appendage occlusion in elderly patients

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Aims: The objective of the present study is to explore the safety and efficacy of left atrial appendage occlusion in elderly patients.

Methods and results: Data from the Amplatzer Cardiac Plug (ACP) multicentre registry were analysed. For the purpose of the study, the cohort was categorised in two groups (<75 years vs. ≥ 75 years). A total of 1,050 subjects were included in the registry. Of them, 219 (20.7%) were excluded for combined procedures during left atrial appendage occlusion. As a result, 828 subjects were included in the analysis and 452 (54.6%) had ≥75 years. Compared with the younger group, patients ≥75 years had a lower body mass index (26.3% in ≥75 years vs. 28.2%; p<0.001), a higher proportion of women (55.1% vs. 22.2%; p<0.001) and higher CHA_2DS_2VASc (5.1 vs. 3.9; p<0.001) and HASBLED (3.4 vs. 3.0; p<0.001) scores. Interventional characteristics showed no differences in procedural success (97.3% in both groups) and periprocedural complications including death (1.3% vs. 0.3%), stroke (1.1% vs. 0.7%), device embolisation (0.9% vs. 0.5%), major bleeding (1.3% vs. 0.8%) and pericardial effusion (2.9% vs. 2.1%) but a higher rate of cardiac tamponade in the older group (2.2% vs. 0.5%, p=0.04). At 1-year, there were no significant differences between groups in stroke (HR 1.69; 95% CI: 0.31 to 9.24) and major bleeding (HR 1.27; 95% CI: 0.21 to 7.63) rates. Interestingly, all-cause mortality was higher in the elderly group (HR 3.9; 95% CI: 1.64 to 9.58) but this difference was due to a higher non-cardiovascular mortality (HR 7.2; 95% CI: 1.7 to 31.3) as depicted by a similar cardiovascular mortality among groups (HR 2.3; 95% CI: 0.74 to 7.3). After adjusting for possible confounders, all-cause mortality (HR 3.72; 95% CI: 1.41 to 9.83) and non-cardiovascular mortality (HR 10.9; 95% CI: 1.44 to 83.29) persisted higher in patients ≥75 years.

Conclusions: Left atrial appendage occlusion seems to be associated with similar procedural outcomes in patients <75 years and ≥75 years old. The rates of stroke and major bleeding were similar among groups at 1-year. In addition, although all-cause mortality at 1-year was higher in elderly patients, cardiovascular death did not differ between groups.

Procedural outcomes of transcatheter left atrial appendage occlusion alone versus within combined interventions: a single centre experience using Amplatzer systems

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Aims: We examines whether left atrial appendage occlusion (LAAO) in combination with other structural, coronary, or electrophysiological procedures is equally feasible and safe or may be associated with overall adverse procedural outcome.

Methods and results: From 2009 to 2014, 407 consecutive pts underwent LAAO and were included in the prospective Bern LAAO Registry. Exclusively dedicated Amplatzer devices (Amplatzer Cardiac Plug [ACP] and Amulet) were used. Procedures were performed under local anaesthesia and fluoroscopic guidance without use of procedural echocardiography. Device sizing was performed by LAA angiography. Procedural outcomes in non-combined (NC) versus (vs.) combined cases (C, which were defined as concomitant PCI, ASD, or PFO closure, or TAVI, MitraClip, or pulmonary vein isolation [PVI]) were compared. The latter were performed before LAAO except ASD and PFO closure. Mild sedation was used for TAVI and PVI and general anaesthesia with transoesophageal echocardiography for MitraClip interventions. All data of the 407 consecutive pts (mean age 74±10 years; 70% male, 30% female, mean CHA_2DS_2-VASc Score 4.0±1.7 and mean HAS-BLED score 2.8±1.2) were analysed. NC (LAAO only) interventions were performed in 170 pts (42%) and C in 237 pts (58%). Double interventions were performed in 188 pts (46%), triple in 40 pts (9.8%) and quadruple in 9 pts (2.2%). Concomitant procedures included PCI in 26%, PFO closure in 22%, ASD closure in 4.4%, TAVI in 5.4%, MitraClip in 2.2% and PVI in 6%. Between the two groups, there were no differences in age, gender mix, renal function, or anticipated stroke risk (CHA_2DS_2-VASc score 4.0±1.6 vs. 4.0±1.7, p=1.0, NC vs. C), whereas the NC group showed a higher bleeding risk (HAS-BLED score 3.0±1.1 vs. 2.6± 1.2, p=0.0007, NC vs. C). LAAO was successful in 397 of 407 patients (98%) in total and in 164 NC vs. 233 C (96% vs. 98%, p=0.33). NC cases required less contrast medium (187±87 vs. 267±108 ml, p=0.0001, NC vs. C,) and fluoroscopy minutes (15.5±16.6 vs. 22.5±13.8, p=0.0001, NC vs. C). The predefined combined safety endpoint of in-hospital death (1 NC pt vs. 1 C pt, p=1.0), any stroke (2 NC pts vs. 4 C pts, p=1.0), major stroke (0 NC pt vs. 1 C pt, p=1.0), need for surgery (4 NC pts vs. 3 C pts, p=0.45), cardiac tamponade (7 NC pts vs. 8 C pts, p=0.79), Valve Academic Research Consortium (VARC) kidney injury grade 3 (1 NC pt vs. 2 C pts, p=1.0), or VARC major vascular complications (0 NC pt vs. 3 C pts, p=0.26) showed no difference between the groups (15/170, 8.8% vs. 21/237, 8.8%, p=1.0).

Conclusions: LAAO with Amplatzer devices, as a part of combined interventions, is feasible and safe. It shows similar procedural outcomes as isolated LAAO procedures. The tendency for higher rates of major vascular complications and strokes in patients undergoing combined interventions appears justified by the avoided additional complementary procedures.

A comparison of angiographic and transoesophageal echocardiographic measurements of left atrial appendage dimensions during catheter-based left atrial appendage occlusion: implications for sizing and procedural success

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Aims: We assessed how strongly left atrial appendage (LAA) measurements derived from angiography correlate with transoesophageal echocardiographic (TEE) measurements, and whether these two imaging modalities consistently predict device size, peri-device leak and procedural failure due to unsuitable appendage anatomy.

Methods and results: 2D-TEE measurements of the isthmus and neck of the LAA were performed in orthogonal planes at 0, 45, 90, and 135 degrees. During LAA angiography, the LAA neck was measured in the right anterior oblique (RAO) caudal projection and the depth in the RAO cranial plane. The diameter of a 5 Fr pigtail catheter was used as standard reference for the angiographic measurements. Fifty-two patients underwent LAAO. LAA closure was performed with a WATCHMAN device in 38 patients (70%), a Coherex device in 11 patients (20%), and an Amplatzer plug in the remaining three patients. Eight procedures had to be abandoned, two because of complications and six because of unsuitable LAA anatomy. Peri-device leaks greater than 1.5 mm were detected on TEE in eight patients. On angiography, the mean LAA isthmus length was 21 mm (range, 8-38 mm) and the mean depth was 34.9 mm (range, 16-72 mm). Conversely, on 2D-TEE mean LAA isthmus length was 19.7 mm (range, 10-33 mm) and mean depth was 28.1 mm (range, 15-47 mm). The average discrepancy between mean LAA neck measurements derived from LAA angiography and 2D-TEE was 1.6 mm, whereas the average discrepancy between mean depth measurements was 7 mm, with TEE consistently undersizing the LAA dimensions compared to angiography. By contrast, in procedures abandoned due to unsuitable appendage anatomy, TEE estimates either significantly under- or over-estimated LAA dimensions compared to angiography. The Pearson correlation coefficient between the maximal TEE and angiographic measurements of the LAA isthmus and LAA depth was =0.51 and =0.42, respectively, suggesting only modest concordance between the two imaging modalities. The diameter of the implanted device was on average 6.7 mm and 5.2 mm larger than the LAA neck length measured by 2D-TEE and LAA angiography, respectively. In contrast, in those procedures where a non-negligible peri-device leak was detected, the discrepancy between imaging estimates and size of device deployed was slightly larger (7.4 mm and 6.1 mm, respectively). The Pearson correlation coefficient between TEE and angiographic estimates of LAA neck size and the implanted device size was =0.73 and =0.3, respectively, suggesting that TEE predicts device size better than angiography.

Conclusions: TEE systematically underestimates LAA dimensions compared to angiography. In procedures abandoned due to unsuitable appendage anatomy, TEE either significantly under- or over-estimated angiographic measurements. Implanted device diameter is on average 7 mm and 5 mm greater than the LAA neck length derived from TEE and angiography, respectively, although in procedures complicated by peri-device leak, this discrepancy was slightly larger. Finally, our experience suggests that TEE predicts implanted device size better than angiography.

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Efficacy and safety of left atrial appendage occlusion with the watchman device without post-procedure oral anticoagulation

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Aims: Left atrial appendage occlusion (LAAO) has emerged in recent years as a safe and effective alternative to warfarin for stroke prevention in patients with non-valvular atrial fibrillation who are intolerant of oral anticoagulation (OAC). The WATCHMAN (Boston Scientific, Natick, MA) occlusion device is the only device that has been evaluated in randomised clinical trials and in prospective registries. Following WATCHMAN device deployment, OAC is recommended for 45 days post-procedure, in addition to antiplatelet therapy, to allow for device endothelialisation. Patients who are candidates for the WATCHMAN device, however, often have absolute contra-indications to oral anticoagulation because of life-threatening haemorrhagic events or bleeding diatheses. The safety of WATCHMAN device deployment without warfarin transition has not been evaluated extensively. We present the results of an observational study evaluating the safety and efficacy of LAAO without oral anticoagulation post-procedure.

Methods and results: The study was a prospective, multicentre, non-randomised study of LAAO with the WATCHMAN device in patients with atrial fibrillation who are intolerant of OAC. Approval for the procedure was obtained at a conjoint cardiology/cardiothoracic surgery meeting. The efficacy endpoints included ischaemic stroke, haemorrhagic stroke, systemic embolism, and cardiovascular/unexplained death. The safety endpoint included periprocedural complications and longer-term device-related complications. Follow-up consisted of transoesophageal echocardiography at 45 days, and clinical visits at three monthly regular intervals thereafter. Forty-nine patients underwent LAAO with the WATCHMAN device during the period February 2010 to December 2014. The device was successfully deployed in 40 patients (success rate: 82%). Reasons for procedural failure included unsuitable left atrial appendage anatomy in five patients, and serious procedural complications in four patients. The mean age was 72 years, and 69% of the patients were male. The median CHA_2DS_2VASc score was 4. Out of 40 successful occlusions, 28 patients (70%) at high risk of bleeding were treated with dual or single antiplatelet therapy (DAPT) post-procedure and 12 patients (30%) with OAC. We prospectively followed patients for an average of 31 months (range: 0-60 months). Compared with the OAC group, patients in the DAPT group had a marginally higher mean CHA_2DS_2VASc score (3.9 versus 3.5, P=0.71), had a lower rate of previous thromboembolism (41% versus 46%; P=0.78), and a shorter mean follow-up (26 months versus 39 months, P=0.04). During follow-up, no ischaemic strokes occurred. By contrast, the expected annual ischaemic stroke rate in our cohort was 4%, and the observed rates in the WATCHMAN and warfarin arms of the PROTECT-AF trial were 1.4% and 2.2%, respectively, despite the former patient cohorts having lower mean CHA_2DS_2VASc score. One patient in the DAPT group suffered a fatal intracranial haemorrhage 6-weeks post-procedure. One patient died as a result of LAA perforation and cardiac tamponade; 3/49 (6.1%) additional patients developed a pericardial effusion requiring drainage. No device embolisation, device thrombosis or other serious complications occurred.

Conclusions: Our experience suggests that in patients with atrial fibrillation at high risk of embolic stroke and serious contra-indications to OAC, WATCHMAN device deployment without warfarin transition may be safe and effective.

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Euro15A-OP234

TAVI device retrieval or reposition increases the risk of post-procedural acute kidney injury

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Aims: There is the potential that patients that require a non-retrievable TAVI device to be repositioned or retrieved are exposed to a longer procedure duration and more iodinated contrast media (ICM). This could lead to an increase in the incidence of acute kidney injury (AKI), which is strongly linked to post-procedural mortality. This study aimed to investigate whether patients that require a TAVI device to be repositioned or retrieved had an associated increased incidence of AKI.

Methods and results: The TAVI database in a single TAVI centre was interrogated to investigate those patients that required retrieval or reposition of the non-retrievable TAVI device. Those that required the device to be repositioned or retrieved were labelled group A. Those that did not were labelled group B. Pre- and post-procedural serum creatinine levels were analysed and AKI was determined by the Valve Academic Research Consortium (VARC 2) criteria. Key baseline characteristics were measured, including the existence of chronic kidney disease (CKD) and the Society of Thoracic Surgeons (STS score). Other relevant procedure related variables were analysed, including procedure time, fluoroscopy time and ICM volume used. Mortality was also compared at 30 days and one year. Of 209 patients having TAVI procedures for severe aortic stenosis, seven required the device to be repositioned or retrieved (group A). The remaining 202 patients were in group B. Of the seven patients in group A, 6 (86%) developed AKI, in comparison to 77 patients (38%) in group B (p=0.02). five patients (71%) had pre-existing CKD in group A vs. 80 patients (40%) in group B but this did not reach significance (p=0.123). STS scores were not significantly different with a median score of 4.31 (2.61-6.03 [95%CI]) in group A vs. 5.3 (4.64-5.97) in group B (p=0.31). Median procedure time was longer for group A: 1 hour 32 minutes vs. 1 hour 14 minutes in group B (p<0.001). Median ICM use was higher in group A: 300 cc (421-179 [95%CI]) vs. 220 cc (205-235) (p<0.001). Fluoroscopy time was also higher: 43.6 (25.1-62.1) minutes vs. 17.1 (15.8-18.6) minutes. No significant difference in mortality was noted at 30 days (0 [0%] group A vs. 11 [5%] group B p=1.00) or one year post-procedure (0 [0%] group A vs. 21 [10%] group B p=1.00).

Conclusions: Patients that require a non-retrievable TAVI device to be retrieved or repositioned are at a higher risk of developing AKI. Possible mechanisms appear to be procedural related and may linked to the increased ICM volume used or the act of repositioning itself. Retrieval or repositioning of the TAVI device had no significant impact on mortality at 30-days or one year.

Establishing radiation dose levels during TAVI procedures for the patient and the multidisciplinary Heart Team

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Aims: The radiation used during interventional procedures that require fluoroscopy is potentially harmful to patients and staff and legislation requires that radiation doses should be periodically monitored. Transcatheter aortic valve implantation (TAVI) is an established procedure in the treatment of severe aortic stenosis and, like percutaneous coronary intervention (PCI), it relies on high-quality fluoroscopic imaging. This study aimed to establish average patient and staff radiation dose levels during TAVI procedures and compare them to PCI procedures.

Methods and results: Staff and patient doses were monitored for TAVI and single vessel PCI procedures for three months in a single TAVI centre. Radiation dose parameters collected were: fluoroscopy time (FT), predicted skin entrance dose (ENT), dose area product (DAP) and number of digital acquisitions (DA). Patient weight and access route were recorded. In line with the literature, DAP was used as the primary dose measure for patients. "Dose to the patient" was measured using a calibrated DAP meter within the x-ray tube housing. Key staff were monitored using a commercially available personal dosimeter (Instadose™), worn on the outside of the lead apron. This was downloaded after each procedure and the dose was recorded. Key staff for TAVI were: first operator, second operator, anaesthetist and transoesophageal echo (TOE) operator. For PCI procedures, only the first and second operators were monitored. Twenty-eight TAVI procedures were performed in the period, 23 transfemoral, and five transaortic access. In the same period, 170 single vessel PCI procedures were performed, 99 via the radial artery and 71 via the femoral artery. Median patient weight was 75 (69-81 [95%CI]) kg in the TAVI group, less than the median of 86 (82.97-89.03) kg in the PCI group (p=0.005). Median FT between the TAVI group and PCI group was not significantly different: 15.3 (Interquartile range =9.75-18.75) minutes, vs. 12.8 (8.8-19.6) minutes respectively (p=0.746). Median ENT in the TAVI group was lower: 632 (439-1058) mGy vs. 1747 (947-2,548) mGy in the PCI group (p<0.001). However, median DAP in the TAVI group was higher: 105 (53.72-135.24) $Gycm^2$, vs. 85.15 (56.25-16.76) $Gycm^2$ in the PCI group (p=0.003). A median of 11 (9-19.5) DA were taken in the TAVI group vs. a median of 23 (17-28) DA in the PCI group (p<0.001). Median staff doses in the TAVI group were: first operator: 0.05 (0.03-0.07 [95%CI]) mSv, second operator: 0.02 (0.01-0.03) mSv, anaesthetist: 0.02 (0.01-0.03) mSv, TOE operator: 0.08 (0.06-0.09) mSv. The median first operator dose in the PCI group was significantly lower: 0.03 (0.02-0.04) mSv (p=0.013) and the second operator dose was also lower 0.01 (0.01-0.02) mSv, however, this did not reach significance: p=0.164.

Conclusions: This study established median radiation doses for patients and the Heart Team for TAVI procedures. It demonstrated that the patient dose is higher for TAVI than during PCI procedures and that the primary operator received a higher dose. Also, it demonstrated that the TOE operator is exposed to 1.6 times the radiation dose of the first operator, a result which may trigger additional protection measures for those staff.

Primary percutaneous thrombectomy with coronary Right Judkins 8 Fr guide catheter for the treatment of high-risk acute pulmonary embolism

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Aims: To assess the patency of the pulmonary arteries by thrombus aspiration with right coronary guide catheter by improving the function of the right ventricle.

Methods and results: A total of 76 patients, 40 female and 66 male between 28 and 64 years were included. In 42 patients the obstruction was bilateral, in all patients, the degree of obstruction was greater than 80% of the main branches. After puncturing, the femoral vein was accessed by a metal sheath of 8 Fr, 80 cm in length, o the trunk of the pulmonary artery and this was passed through a guide catheter handle 4 Judkin right coronary to the site of thrombosis and 20 ml syringe practice with sustained suction catheter to remove it, slowly withdrawing the introducer. Subsequently purging the catheter to aspirate thrombi. This manoeuvre was repeated several times and finally a catheter angiography was performed to confirm the patency of the pulmonary branches. In all cases permeability of the pulmonary branches at 80% saturation was restored and blood pressure in the following hours. Of the 56 patients, seven died during the procedure and another patient had haemoptysis. The procedure had a mortality rate of 5.3% and a morbidity of 2.63%.

Conclusions: In all cases permeability of the pulmonary branches at 80% saturation was restored and blood pressure in the following hours.

EuroPCR Interventions for structural heart disease Euro15A-OP271

Percutaneous vs. surgical treatment strategy in patients with severe aortic stenosis and concomitant coronary artery disease: a 30-day outcome single-centre analysis

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Aims: Concomitant significant coronary artery disease (CAD) is frequent in patients with severe aortic stenosis. An area of uncertainty exists around the management of these patients. So far, the impact of a percutaneous treatment strategy (TAVI and PCI) on prognosis is unclear when compared to surgical valve replacement and CABG. In this retrospective single-centre study we analysed the outcome of patients undergoing either PCI and TAVI or surgical aortic valve replacement and CABG.
Methods and results: Between November 2010 and February 2014, 121 consecutive patients from our cathlab with severe aortic stenosis and significant CAD were included in the study. Seventy-nine patients underwent simultaneous CABG and surgical aortic valve replacement (SURGICAL), whereas 42 patients underwent staged PCI and TAVI (PERCUTANEOUS), as advised by the Heart Team. Risk score assessment revealed a logistic EuroSCORE of 19.5% for the PERCUTANEOUS group vs. 10.7% for the SURGICAL group (p<0.0001), similar differences were observed for EuroSCORE 2 (9.9% vs. 5.1%; p<0.0001) and STS score (8.3% vs. 4.4%; p<0.0001). The PERCUTANEOUS group was characterised by a higher NYHA-classification (2.83 vs. 2.15; p<0.0001), and atrial fibrillation was more common among patients scheduled for TAVI and PCI (53.6% vs. 24.1%; p<0.0021). Clinical outcome at 30 days showed no significant differences in terms of overall mortality (4.88% PERCUTANOUS vs. 5.06% SURGICAL; n.s.) and cardiovascular mortality (2.44% vs. 5.06%; n.s.). Furthermore, there was no significant difference in the occurrence of acute kidney injury (9.76% PERCUTANEOUS vs. 15.19% SURGICAL; p=0.5732) and major stroke (0% vs. 0%). There was a tendency for the 30-day combined VARC safety endpoint to be lower in the PERCUTANEOUS compared to the SURGICAL group; however, this failed to reach statistical significance (9.76% vs. 21.52%; p=0.1382). Device success rate at 30 days was comparable in both groups with excellent valve performance in the PERCUTANEOUS group (Pmax 15.5 mmHg vs. 28.75 mmHg; p<0.0001), and without moderate or severe aortic regurgitation or need for valvular re-intervention in either group. Conduction disturbances requiring permanent pacemaker implantation were more frequent in the PERCUTANEOUS group (24.4% vs. 7.6%; p=0.0206). On the other hand, the percutaneous TAVI/PCI strategy resulted in a significantly shorter mean stay in hospital (15.9 days PERCUTANEOUS vs. 19.2 days SURGICAL; p=0.0257) and intensive care unit (2.8 days vs. 5.7 days; p=0.0003).
Conclusions: This single-centre study indicates that a combined percutaneous TAVI/PCI approach in patients suffering from severe aortic stenosis and CAD is safe and comparable to CABG and surgical valve replacement with respect to 30-day outcome despite a predicted higher risk in the PERCUTANEOUS group. Prospective randomised trials are warranted to confirm these preliminary data.

EuroPCR Interventions for structural heart disease Euro15A-OP272

Baseline anaemia is a predictor of impaired outcome after transcatheter aortic valve implantation

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Aims: Anaemia is common in elderly patients and is linked to adverse results after cardiac and non-cardiac surgery. However, data on the prevalence and outcomes associated with anaemia in patients undergoing transcatheter aortic valve implantation (TAVI) are scarce. We sought to evaluate this relationship in order to identify patients at particular risk for adverse outcomes after TAVI.
Methods and results: TAVI was performed in 977 consecutive patients with severe aortic stenosis at high surgical risk for surgery from 2008-2013 at a single institution. According to the World Health Organization, anaemia was defined as baseline haemoglobin <12 g/dl in women and <13 g/dl in men. Data were retrospectively analysed following the updated Valve Academic Research Consortium definitions with emphasis on anaemia at baseline and its impact on outcome. Anaemia was prevalent in 59.5% of patients at baseline. Comorbidities associated with anaemia included history of gastrointestinal bleeding (OR 5.19, p<0.01), impaired renal function (OR 3.01, p<0.01), pulmonary hypertension (OR 1.94, p<0.01) and diabetes (OR 1.78, p<0.01). Estimated operative risk was higher in patients with anaemia (log EuroSCORE 21.9±14.0 vs. 19.7±12.6%, p=0.01). Despite similar rates of bleeding events or access site complications, blood transfusions after TAVI were more frequent in anaemic patients (OR 5.11, p<0.01), as was a higher rate of post-procedural acute kidney injury (stages 2/3: OR 2.17, p<0.01). Functional improvement 30-days after TAVI was less pronounced in patients with anaemia (NYHA classes III/IV: 23.1 vs. 18.1%, p=0.01). With similar early survival, an increased midterm mortality was observed in patients with baseline anaemia (54.7 vs. 40.1% at 3 years, log rank p<0.01) and anaemia qualified as an independent predictor of 3-year mortality (OR 1.36, p=0.01).
Conclusions: Anaemia is a common condition in patients undergoing TAVI. It is associated with various baseline comorbidities, decreased functional improvement after TAVI, and impaired midterm survival. As an objective and easily accessible risk factor, baseline anaemia should be incorporated in the individual patient's risk assessment and optimisation of this condition needs to be evaluated to improve outcomes after TAVI.

Impact on prognosis of haematological parameters after transcatheter aortic valve implantation: a retrospective analysis

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Aims: Inflammation has been linked to adverse prognosis after transcatheter aortic valve implantation (TAVI) and we sought to evaluate haematological parameters before and after TAVI procedure.

Methods and results: All consecutive TAVI patients (except patients with a defined diagnosis of sepsis) from May 2008 to October 2013 were included. The impact on 30-day death of white blood cell count, platelets count and red cell distribution width, evaluated before the procedure, at day one and day five, was appraised. Sensitivity analyses were performed for gender, age, presence or absence of coronary artery disease in the population and bleedings with necessity for transfusion. One hundred and eighty-two (182) patients with severe symptomatic aortic stenosis underwent TAVI. Twenty-two patients (12%) died at 30 days, and they had lower platelets count at day one post-procedure (129*109/L vs. 176*109/L, p=0.05) and higher day five post-TAVI white blood cell count (9.9*109/L vs. 8.1*109/L, p=0.02). At multivariate analysis only day five post-procedure white blood cell count demonstrated to be an independent predictor of 30-day mortality (odd ratio 1.3; CI: 1.0-1.6; p=0.02).

Conclusions: Increase in white blood cell count shortly after TAVI represents a predictor of 30-day mortality after the procedure, independently from clinical manifestation of sepsis and/or severe inflammation response.

Pulmonary hypertension in patients undergoing transcatheter aortic valve replacement: incidence, clinical impact and evolution, insights from the Italian registry

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Aims: A certain degree of pulmonary hypertension (PHy) is very common in patients undergoing transcatheter aortic valve replacement (TAVR) and a severe PHy is known to negatively affect the outcome. However, a clear understanding of the incidence, the clinical impact and evolution of the different grades of PHy in the setting of TAVR is lacking.

Methods and results: In the CoreValve Italian Registry, 990 consecutive patients included were included from eight high-volume centres and divided as follows: group 1, sPAP <40 mm Hg (none/mild PHy: 376 patients, 38%); group 2, sPAP 40 to 55 mmHg (mild to-moderate PH: 485 patients, 49%); and group 3, sPAP ≥55 mmHg (severe PH: 129 patients, 13%). Patients were followed up for 1-year. As compared to patients in group 1, patients in group 2 and 3 had a higher one-year overall mortality: (HR 1.5 [1.2-3.1], p=0.01, and HR 2.3 (1.9-2.9], p=0.001, respectively). At one year, the systolic pulmonary pressure (SPP) decreased of at least 10 mmHg in 25% and 35% of the patients in group 2 and 3, respectively. After adjustment, persistent severe PHy after 1-month was an independent predictor of mortality. At 1-year, an improvement in the NYHA class as well as the rate of hospitalisation for heart failure were consistent across all the groups

Conclusions: Moderate to severe PHy is associated with higher 1-year all-cause mortality after TAVR. The persistence at one month post-TAVR of severe PHy independently predicts mortality.

EuroPCR Interventions for structural heart disease Euro15A-OP275

Effects of pre-procedural tricuspid regurgitation on outcomes after transcatheter aortic valve implantation

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Aims: Limited data are available about the clinical prevalence and prognostic impact of clinically relevant TR (≥3+) in patients undergoing transcatheter aortic valve implantation (TAVI). We aimed to identify the clinical impact TR≥3+in patients treated by TAVI at 1-year follow-up.
Methods and results: Between 2012 and 2014, 346 patients underwent TAVI at our institution after informed consent. For the aim of this study, only patients with complete 1-year echocardiographic follow-up were included (167 patients). Patients were divided according to the severity of preoperative TR (≤2+vs. ≥3+). All clinical outcomes were defined according to the Valve Academic Research Consortium 2 definitions. At baseline, TR≥3+was present in 16 patients (9.6%). Patients with and without significant TR were comparable with regards to pre-interventional characteristics such as age, baseline EF, associated coronary artery disease, renal failure, NYHA class, severity of associated mitral regurgitation and pulmonary artery systolic pressure; while prevalence of previous permanent PM implantation (p=0.02), associated right ventricular dysfunction (p=0.0005) and diabetes (p=0.03) were higher in patients with TR≥3+. Thirty-day mortality was 19% in patients with TR≥3+and 8% in patients with TR≤2+(p=0.1). No differences were observed in terms of acute kidney injury, myocardial infarction, cerebrovascular events or vascular complications. TR improved in four patients at 30 days (25%). Actuarial survival at one year was 62±12% and 81±3% in patients with TR≥3+ and ≤2+, respectively (p=0.05). Cox regression analysis did not confirm baseline TR≥3+ as an independent risk factor of mortality at follow-up (p=0.08; HR 2.3). At 1-year, only three patients of the non-TR group developed significant TR (2%). No differences were observed in terms of NYHA class, EF, MR severity, while the prevalence of severe pulmonary hypertension was higher in patients with TR≥3+ (p=0.01).
Conclusions: In patients undergoing TAVI, significant pre-procedural TR was present in about 10% of patients and associated with more comorbidities and worst RV function. Although TR≥3 was associated with a 20% increased mortality at follow-up, significant TR was not an independent predictor of 1-year mortality. The response of TR to TAVI was largely variable. However, the results of this study point out that associated TR is a marker of more advanced stage of the disease.

EuroPCR Interventions for structural heart disease Euro15A-OP276

Transcatheter aortic valve replacement (TAVI) in patients with clinically significant mitral regurgitation: impact on severity of MR, pulmonary artery pressure and tricuspid regurgitation

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Aims: The effect of transcatheter aortic valve replacement (TAVI) on severity of mitral regurgitation (MR) and right ventricular afterload is still a matter of debate. The aim of this study was to analyse the short- and midterm impact of TAVI on MR as well as consecutive changes of pulmonary artery (PA) pressure and tricuspid regurgitation (TR).
Methods and results: Five hundred and sixteen (516) patients undergoing TAVI were enrolled into a prospective institutional registry. The present analysis focuses on patients with MR≥ grade II. Patients with any other mitral valve pathology (e.g., mitral stenosis, prosthetic mitral valve) were excluded. MR was graded on a 0-3 scale (0=none, 1=mild, 2=moderate, 3=severe). Severity of MR, TR and PA-pressure were defined as primary endpoints and assessed at baseline and consecutively at one, three and six months after TAVI by colour-flow echocardiography. Secondary endpoints included in-hospital mortality as well as TAVR-complications according to VARC-criteria. One hundred and six (106; 20.5%) patients with MR≥II (age 80.9±6.6 years, female 66 (62.3%), EuroSCORE 32.91±18.18) were included in this analysis. In this subgroup, the mean transaortic gradient was decreased during TAVI from 40.7±16.8 mmHg to 10.2±4.7 mmHg (p<0.001). The reduction in left ventricular (LV) afterload was associated with a significant decrease of MR from 2.21±0.34 at baseline to 1.79±0.65 at hospital discharge (n=86; p<0.001) and remained significantly below baseline after one (n=52: 1,61±0,58), three (n=37: 1,7±0,59) and six (n=35: 1,61±0,58) months. This was associated with a significant reduction of PA-pressure from 47.6±13.8 mmHg to 37.9±11.8 mmHg (p<0.05) and a decrease of TR-severity from 1.88±0.79 to 1.59±0.8 (p<0.05) after one month. Post-operative NYHA-class (3.0±0.57 vs. 2.5±0.55; p<0.001) as well as 6-minute walking distance (94.18±94.1 m vs. 162.4±114.4 m at one month vs. 249.0±132.94 m at 3 months; p<0.001) improved, demonstrating a functional benefit in patients with MR≥II at 30 days after TAVI. In-hospital-mortality was 3.7% (n=4). At one, three, six and 12 months after TAVI, mortality was 6.6% (n=7), 15.09% (n=16), 17% (n=18) and 22.6% (n=24%), respectively.
Conclusions: Transcatheter aortic valve replacement results in LV-afterload reduction with a significant and sustained improvement of ≥ grade II MR, pulmonary artery pressure and tricuspid regurgitation. These haemodynamic changes are associated with a significant functional benefit with improvement of NYHA-class and increased six minute walking distance.

Impact of pre-operative left ventricular hypertrophy on clinical outcomes of patients with residual aortic regurgitation after TAVI

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Aims: Residual aortic regurgitation (AR) ≥2 after transcatheter aortic valve implantation (TAVI) for the treatment of aortic stenosis has been associated with impaired outcomes. Left ventricular hypertrophy (LVH) with reduced diastolic compliance have been advocated as a possible cause of this phenomenon, although clear data in this regard are still lacking. We evaluated the impact of pre-operative left ventricular hypertrophy by means of Left Ventricle Mass Index (LVMI) on clinical outcomes of patients with residual aortic regurgitation ≥2 after TAVI at our Institution.

Methods and results: Between July 2008 and September 2014, 715 patients were treated with TAVI at our Institution. All patients underwent a standardised prospective in-hospital data collection pathway and were enrolled in our dedicated outpatient follow-up clinic. We selected all patients with a pre-operative diagnosis of severe symptomatic aortic stenosis, available pre-operative echocardiographic LVMI data from our dedicated TAVI echo-lab, acute post-procedural residual AR≥2 as assessed by transthoracic echocardiography. One hundred and twelve (112) patients were found to meet the study criteria. Pre-operative patient characteristics included: mean age 79.4±7.3 years, 52% female, median Logistic EuroSCORE 15.5% (IQR 8-31), median Society of Thoracic Surgeons score 5.5% (IQR 4-10), associated AR≥2 in 51.8% of patients, mean end diastolic volume (EDV) 102±43 ml, mean ejection fraction (EF) 56±13%, mean LVMI 154±42 g/m^2. Transfemoral access was used in 89% of cases. Acute residual AR was grade 2 in 102 (91.1%), grade 3 in 8 (7.1%) and grade 4 in 2 (1.8%) patients. All patients completed follow-up. Freedom from overall and cardiac death was 52.9% and 87.8% respectively at four years. A univariable Cox regression analysis higher baseline LVMI (p=0.003, HR 1.02, CI 1.0-1.02) and lower EF (p=0.007, HR 0.91, CI 0.90-0.98) but not EDV (p=0.66) or pre-operative AR≥2 (p=0.28) were associated with increased follow-up cardiac mortality. LVMI values ≥195 g/m^2, as observed at ROC analysis (area under curve 0.8, specificity 88%, sensitivity 73%) were markedly associated with increased cardiac mortality (p=0.002, HR 9.7, CI 2.4-40.5) at multivariable analysis after adjusting for EF. Higher LVMI was also associated with increased rate of rehospitalisation due to heart failure (p<0.001, HR 1.02, CI 1.01-1.02) and more frequent NYHA class III-IV at follow-up (p=0.037, HR 1.01, CI 1.0-1.02). At last follow-up NYHA class III-IV was found in 18.9% of patients and residual AR grade 3-4 in 23% of patients (p<0.001 increase vs. baseline). Follow-up AR 3-4 was associated with more frequent cardiac death (although not statistically significant, p=0.17), heart failure rehospitalisation (p=0.05) and NYHA III-IV (p=0.02). When focussing upon only patients with grade 2 post-procedural residual AR, LVMI was still associated with increased cardiac mortality (p=0.009 in multivariable Cox regression model with EF) and heart failure rehospitalisation (p<0.001), and showed a trend towards more frequent NYHA class III-IV (p=0.07).

Conclusions: Pre-operative higher LVMI predicts higher rates of cardiac death, rehospitalisation due to heart failure and poor NYHA class in patients with residual AR≥2 after TAVI.

First report from the RESPOND study: post-market evaluation of a fully repositionable and retrievable aortic valve in 250 patients treated in routine clinical practice

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Aims: The objective of the RESPOND post-market study is to evaluate clinical and device performance outcomes with the fully repositionable and retrievable Lotus Aortic Valve System when used in routine clinical practice for the treatment of severe calcific aortic stenosis. This analysis will present the primary endpoint results from a pre-specified interim analysis of the first 250 patients enrolled in the study.

Methods and results: The RESPOND study is a prospective, open-label, single-arm, multicentre, observational study that will enrol 1,000 patients at up to 60 sites in Europe, Asia-Pacific and Latin America. All TAVI patients selected to receive a Lotus Valve at each site will be evaluated for enrolment. Clinical follow-up will occur at 30 days and annually to five years. The primary endpoint of the study is the rate of all-cause mortality at 30 days and 1-year post-procedure; mortality at 30 days will be compared to a pre-specified performance goal of 14% (expected rate of 10% plus a testing margin of 4%). Secondary endpoints include the rates of in-hospital mortality, the safety composite of all-cause mortality and disabling stroke at 30 days and 1-year, VARC-2 clinical efficacy and safety composites and individual VARC-2 endpoints at 30 days and 1-year, quality of life assessments as evaluated by the EQ-5D questionnaire, and device performance, including the grade of paravalvular aortic regurgitation pre-discharge. An independent core laboratory will adjudicate all transthoracic echocardiograms. In a key secondary hypothesis, the pre-discharge rate of moderate and severe paravalvular aortic regurgitation, as adjudicated by the core laboratory, will also be compared to a pre-specified performance goal of 16.5% (based on the FRANCE 2 registry).

Conclusions: The RESPOND post-market study will complete the pre-specified 250 patient interim analysis milestone in February 2015. Primary endpoint results for the first 250 patients treated commercially with the Lotus Valve in this study will be available at the time of the meeting.

EuroPCR Interventions for structural heart disease Euro15A-OP279

Primary endpoint results of the REPRISE NGDS First Human Use Study: percutaneous aortic valve implantation with the next generation of a fully repositionable and retrievable aortic valve

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Aims: The Lotus Valve Next Generation Delivery System (Lotus NGDS) incorporates the same innovative performance and safety features from the currently available Lotus Valve, but uses a new delivery system to provide enhanced deliverability. Key changes to the Lotus NGDS include: 1) removal of the pre-formed J-curve to increase catheter flexibility; 2) reduced proximal shaft profile to improve deliverability; and 3) reduced overall multi-lumen catheter diameter to further enhance deliverability. The goal of the first human use REPRISE NGDS study is to evaluate the safety and performance of the Lotus NGDS.

Methods and results: This prospective, single-arm study has enrolled 10 surgical-high-risk patients with symptomatic aortic valve stenosis (defined as an initial aortic valve area ≤1.0 cm^2 or aortic valve area index of ≤0.6 cm^2/m^2 and either a mean pressure gradient ≥40 mm Hg or a jet velocity ≥4 m/s, as measured by echocardiography), and New York Heart Association Functional Class ≥II at 2 Australian sites. The primary endpoint of the study was technical success (defined as successful vascular access, delivery, positioning, and deployment of one Lotus NGDS with uncomplicated delivery system retrieval). Secondary endpoints included device performance endpoints (successful repositioning/retrieval if attempted), paravalvular regurgitation at discharge/7 days, mean aortic valve pressure gradient and effective orifice area, and VARC safety and efficacy endpoints (including mortality, stroke, myocardial infarction, bleeding, and vascular complications). Patient follow-up was at baseline, peri- and post-procedure, discharge/7 days, and 30 days, and will continue through six months and one year. Independent core laboratories assessed echocardiography, angiography, and histopathology, and an independent clinical events committee has adjudicated clinical events.

Conclusions: The REPRISE NGDS is a first human use study designed to evaluate outcomes with LOTUS NGDS. Primary endpoint results will be available for presentation for the first time at EuroPCR 2015.

EuroPCR Interventions for structural heart disease Euro15A-OP280

The DISCOVER registry: early outcomes of a fully repositionable and retrievable transcatheter aortic valve in a real-world population

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Aims: The Direct Flow Medical transcatheter aortic valve system has a non-metallic design with a pressurised support structure, which allows precise positioning, retrieval and full haemodynamic assessment of valve performance prior to permanent implantation. The DISCOVER registry is a European prospective multicentre study to evaluate the real-world performance of the DFM valve for the treatment of severe symptomatic aortic stenosis in high- and extreme-risk patients.

Methods and results: A total of 250 patients with a logistic EuroSCORE ≥20 or other high surgical risk comorbidities not reflected by the logistic EuroSCORE were enrolled at 21 centres in Europe. Patients were 82.6±5.4 years, and logistic EuroSCORE and STS were 18.3 ±13.5% and 7.9±7.9%, respectively. Other comorbidities included coronary artery disease in 66%, prior CABG 18%, and chronic kidney disease 33%. Two percent of patients received a 23 mm valve, 48% a 25 mm valve, 37% a 27 mm valve and 13% a 29 mm valve. At the time of abstract submission, 30-day clinical status was available for all of the 250 patients. The rate of acute kidney injury was 2.0%. A new permanent pacemaker was implanted in 12% of patients. At 30-days, moderate or severe aortic regurgitation was reported in only 2.4% of patients, with none or trace regurgitation in 84% of patients. NYHA functional class 1 or 2 was achieved in 87% of patients. Overall 30-day survival was 98.0% and freedom from death and stroke was 95.6%. Additional follow-up status will be available at the time of presentation.

Conclusions: The Direct Flow Medical transcatheter aortic valve system demonstrates excellent real-world outcomes in high- and extreme-surgical-risk patients with severe aortic stenosis.

The Italian DFM registry: real world results of a next generation fully repositionable TAVI device

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Aims: The Direct Flow Medical transcatheter aortic valve system has a non-metallic design with a pressurised support structure, which allows precise positioning, retrieval and full haemodynamic assessment of valve performance prior to permanent implantation. The Direct Flow Italian registry is a nationwide registry enrolling patients treated with the Direct Flow Device in the aortic position since early 2012 to evaluate outcomes of the device in a real world setting.

Methods and results: A group of 141 consecutive patients treated after February 2012 in five Italian centres has been enrolled in the registry. Mean age was 82.8±6.1 years, mean EuroSCORE was 20.4±15.3%. Patient comorbidities were: COPD in 27.8%; moderate or severe kidney disease in 31%; peripheral vessel disease in 33.3%; previous MI in 19.1%, previous CABG in 17.0%; 67.9% of patients were in class NYHA 3 or 4. At a median follow up of 11.2 (IQR 3.0-19.0) months, 9.2% of patient died and the stroke rate was 2.1%. PM rate within 30 days of the procedure was 12.7%. Vascular complications occurred in 2.1%; conversion to cardiac surgery in 1.4% and the Direct Flow device was retrieved to switch to a different valve in 2.1% of patients. A procedural learning curve was apparent and mean fluoroscopy times significantly decreased with greater operator experience from 45.4±22.8 to 29.6±8.6 minutes when comparing the first and fourth quartiles (p=0.02). Moderate or severe PV leak at the last available echo at a median follow-up of more than 11 months was present in only 2.1% of cases.

Conclusions: The Direct Flow Medical transcatheter aortic valve system demonstrates excellent real-world outcomes in high-risk patients with severe aortic stenosis, with an overall low death stroke and pacemaker rate and a good valve performance.

The DISCOVER trial: 2-year outcomes of a fully repositionable and retrievable transcatheter aortic valve

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Aims: The Direct Flow Medical transcatheter aortic valve system is a non-metallic design with a pressurised support structure, which allows precise positioning, retrieval and full haemodynamic assessment of valve performance prior to permanent implantation. The DISCOVER trial is a prospective, multicentre evaluation of the safety and efficacy of the Direct Flow Medical Percutaneous Aortic Valve System for the treatment of severe symptomatic aortic stenosis in high and extreme risk patients.

Methods and results: One hundred patients with a logistic EuroSCORE ≥ 20 or other high surgical risk comorbidities were enrolled at 10 centres in Europe. Clinical and haemodynamic outcomes were assessed. All echocardiographic and angiographic data were evaluated by an independent core laboratory (MedStar) and adverse events adjudicated by an independent clinical event committee using VARC definitions. Patients were 83.1±6 years, logistic EuroSCORE 22.5±11.3% and STS scores 9.7±8.7%. Other comorbidities included coronary artery disease in 59%, prior CABG 23%, chronic kidney disease 24%, and severe COPD in 14%. A 25 mm valve was implanted in 59% and a 27 mm in 41% of cases. At one year, overall survival was 90% and freedom from death and stroke was 84%. Aortic regurgitation was none to mild in all patients, with paravalvular regurgitation graded as none or trace in 84% of patients. Mean pressure gradient and effective orifice area remained stable (12.2±6.6 mmHg and 1.57±0.42 cm^2 at 12 months compared to 12.6±5.8 mmHg and 1.50±0.48 cm^2 at 30 days), with 95% of patients in NYHA functional class 1 or 2 at one year. Two-year outcomes and echocardiographic data are being evaluated and will be presented.

Conclusions: The Direct Flow Medical transcatheter aortic valve system demonstrates excellent 1-year clinical and haemodynamic outcomes in high- and extreme-surgical-risk patients with severe aortic stenosis. Two-year outcomes will be available at the time of the meeting for the first time.

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Euro15A-OP283

One-year outcomes of the multicentre clinical trial on the third generation balloon-expandable transcatheter heart valve in high risk elderly patients with aortic stenosis

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Aims: The SAPIEN 3 transcatheter heart valve was introduced into clinical practice by means of an investigational trial for commercial approval in the European Union.

Methods and results: A total of 150 patients were prospectively enrolled at 16 sites in Europe and Canada from January 2013 until November 2013. Valve delivery was accomplished by transfemoral access in 64.0%, transapical access in 32.7% and transaortic access in 3.3% of patients. Clinical and functional outcomes including adverse events and core laboratory evaluations of transthoracic echocardiograms will be reported at EuroPCR. Baseline mean patient age was 83.6+5.0 years and 54% were female. Predicted mortality risk was 7.4±4.5% by logistic EuroSCORE. New York Heart Association Class III/IV was reported in 86.7%. Reported comorbidities included coronary artery disease (64.0%), renal insufficiency (40.0%), anaemia (30.7%), chronic obstructive pulmonary disease (26.7%) and peripheral vascular disease (24.7%). Atrial fibrillation was seen in 44.7% of patients. The 1-year overall composite incidence rate of death, all stroke and total aortic insufficiency >moderate was 27.8%. The Kaplan-Meier event rate of all-cause mortality for all patients at one year was 14.2±2.9%; for transfemoral patients it was 8.5±2.9%. The Kaplan-Meier event rate for all strokes was 4.3±1.7% and 2.2±1.5% in the transfemoral cohort. The incidence of total aortic regurgitation > moderate was 1.3%. New pacemaker implantation at one year for conduction abnormalities was 14.2±2.9%. Myocardial infarction was reported in four patients at one year (Kaplan-Meier rate=2.9±1.4%). At one year, the Kaplan-Meier rate of transfusions was 26.4±3.6% and 2.8±1.4% for access site infections. The majority of patients (93.3%) were in New York Heart Class I/II at one year and the European quality of life Visual Analog Scale showed continued improvement at 61.7±19.5. Rehospitalisation for symptoms of aortic stenosis and/or complications of the valve procedure at one year was 5.1±1.9%; it was 3.3±1.9% for the transfemoral only group. Corelab-evaluated echocardiographic results of aortic paravalvular regurgitation at one year were none in 56.0%, trace in 30.7%, mild in 6.7% and moderate in 1.3%. No severe paravalvular regurgitation was reported at one year. An effective orifice area of 1.5±0.4 cm and mean gradient of 10.9±4.9 mmHg at one year are comparable to haemodynamic parameters reported for other SAPIEN valves.

Conclusions: SAPIEN 3 transcatheter heart valve safety and clinical effectiveness continue to be excellent at 1-year follow-up with low all-cause mortality in this selected cohort of high-risk patients. There were low rates of TAVI-related events, beneficial functional improvements and consistent haemodynamic parameters. Paravalvular regurgitation of ≥ moderate severity was documented in only 1.3% of patients, which is a significant improvement, compared to earlier generation SAPIEN valves.

euroPCR Interventions for structural heart disease

Euro15A-OP284

Six-month performance of a self-expanding valve in a study of best implantation practices: the ADVANCE II study

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Aims: Accumulating clinical experience has led to the development of best-practice recommendations aimed at improving the results of the transcatheter aortic valve implantation (TAVI) procedure with the CoreValve system. Besides pre-TAVI patient screening and valve size selection using multislice computed tomography, these recommendations include control of implant depth to 6 mm or less relative to the aortic annulus and adherence to international guidelines to determine the need for post-TAVI permanent pacemaker implantation. The purpose of this study was to implement best practices for CoreValve implantation and to apply rigorous data collection and core laboratory analysis standards to assess clinical outcomes.

Methods and results: The ADVANCE II study was a prospective observational study that enrolled patients with severe aortic stenosis at nine experienced TAVI centres in Europe. The primary endpoint was the incidence of permanent pacemaker implantation (PPI) for class I or II indications in patients with the device implanted ≤6 mm below the aortic annulus. Echocardiograms and electrocardiograms (ECGs) were collected at baseline and multiple post-procedure time points out to 6-months. All data, including angiographic assessment of valve implant depth, were analysed by an independent core laboratory. Safety-related adverse events were adjudicated to the Valvular Academic Research Consortium 2 definitions by an independent clinical events committee. From October 2011 to April 2013, 200 patients were enrolled, and 194 were implanted. The mean age was 80.2±6.7 years, 47.5% were male, and the mean Society of Thoracic Surgeons (STS) risk score was 7.2±6.8%. At six months, all-cause mortality was 9.2%, cardiovascular mortality was 5.3%, and the rate of stroke was 2.6%. The overall rate of PPI was 26.0%. According to the primary endpoint definition when international pacing guidelines were followed and the CoreValve was implanted at ≤6 mm, the PPI rate was 14.5%. A paired analysis demonstrated that the development of new-onset left bundle branch block (LBBB) and first degree atrioventricular (AV) block was frequent within 48 hours of TAVI (44.0% and 40.0% of patients with normal conduction at baseline, respectively), however 36.4% of new-onset LBBB and 77.8% of first degree AV block had resolved by six months. The rate of moderate and severe paravalvular leak (PVL) was 9.8% at seven days post-TAVI, 8.5% at one month, and 4.3% at six months, a decrease which was statistically significant over time (p=0.022). Of the 17 patients with moderate or severe PVL at day seven, one had died, six showed persistent PVL, seven showed PVL resolution, and three had no data available at six months. A decrease in the overall trend over time was seen for both left ventricular mass and left ventricular mass index between baseline and six months (281.7 g vs. 272.8 g, p<0.01; 158.2 g/m^2 vs. 151.9 g/m^2, p<0.01), as well as in interventricular septal wall thickness and left ventricular posterior wall thickness (14.1 mm vs. 13.5 mm, p<0.01; 11.6 mm vs. 11.1 mm, p=0.07).

Conclusions: In the ADVANCE II study, adherence to best clinical practices during CoreValve implantation translated into lowered adverse event rates and significant improvement in cardiac function as soon as six months post-TAVI.

Three-year midterm post approval study outcomes with a second generation balloon-expandable transcatheter heart valve

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Aims: TAVI is an alternative treatment for high-risk and inoperable patients with severe symptomatic aortic stenosis. The second-generation balloon-expandable transcatheter valves and delivery devices were developed to address TAVI-related adverse events and their sequelae. The post-approval SAPIEN XT™ Aortic Bioprosthesis Multi-Region Outcome Registry (SOURCE XT) was designed to evaluate the long-term (5-year) safety and effectiveness of the SAPIEN XT™ Transcatheter Heart Valve in contemporary clinical settings.

Methods and results: The SOURCE XT™ Registry is a multicentre, prospective, observational post approval study that enrolled 2,688 patients at 99 sites in 17 countries. The transfemoral NovaFlex+ or the transapical/transaortic Ascendra+ delivery systems were employed during implantation. Three-year patient follow-up was completed in 90.4% (n=1,426) of eligible patients (n=1,577). The mean patient age was 81.4±6.6 years, and 57.7% were female. The mean Society of Thoracic Surgeons Predicted Risk of Operative Mortality was 7.9±6.6% and 76.9% were classified in New York Heart Association III/IV. Common baseline comorbidities included congestive heart failure (60.9%), angina (44.3%), diabetes (29.4%) and renal insufficiency/failure (29.0%).The majority of surviving patients were free of heart failure symptoms and remained in New York Heart Association I/II (90.0%) at 3-year follow up. At three years, the Kaplan-Meier cumulative event rate of death was 35.5%, cardiac death was 17.6%, stroke was 9.1%, myocardial infarction was 3.3% and new permanent pacemaker implantation was 13.7%. The incidence of late endocarditis was low at 1.7%. Haemodynamic functions were well preserved at three years with sustained effective orifice area (1.7±0.93 cm^2) and low mean gradient (11.3±10.6 mmHg), and there was a low incidence of moderate (6.6%) and severe (0.5%) paravalvular regurgitation in the 666 patients with evaluable echocardiograms.

Conclusions: Three-year results of the SOURCE XT post approval study show that TAVI with the second generation SAPIEN XT™ transcatheter heart valve is safe and effective in routine clinical practice with a low risk of TAVI prosthesis-related adverse events, sustained quality of life and preserved haemodynamic valvular performance.

The impact of device evolution on the incidence of procedural complications: a report on the Edwards third generation valve system in 2,154 patients

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Aims: Whilst the clinical benefits of transcatheter aortic valve implantation (TAVI) are undisputed, procedural complications such as paravalvular leakage (PVL) and annulus rupture are still a cause of concern. Both are directly related to valve sizing and implantation depth. We aimed to assess procedural complications with the third generation balloon-expandable prosthetic heart valve Edwards SAPIEN 3 which has been specifically designed to address these complications.

Methods and results: Periprocedural parameters and outcomes with no further clinical follow-up were recorded between January and November 2014 by clinical specialists. Valve sizing was assessed based on a sizing algorithm considering the type of valve chosen relative to the annular geometry based on using 3D images reconstructed from CT scanning before TAVI. Implantation depth as well as the presence of paravalvular leakage was assessed by the implanting physician after the procedure. Descriptive statistics was applied for the available variables by patient. A total of 2,154 patients undergoing SAPIEN 3 implantation were included with a mean age of 81.7 years (range 44-97). The degree of PVL was 20.3% trace (n=421), 7.1% mild (n=147), moderate 0.5% (n=10), severe 0.1% (n=2) with the majority of patients (72.1%; n=1,498) having no PVL. On the other hand, five patients (0.2%) experienced ruptures of the annulus. Based on these data we looked into the size of the valve in relation to the annulus as well into implantation depth as possible determinants of PVL. We found a trend towards a minor impact of the implantation depth (% above / below the annular plane) on the rate of moderate / severe PVL with 2.0% for 50/50, 1.2% for 60/40, 0.7% for 70/30 and 0.3% for 80/20 (p=0.0144). Furthermore, we found a trend (p=0.0159) for less PVL with increasing valve sizes relative to the annular geometry (no PVL: undersized 61.9%, normal sized 70.4%, over sized 80.4%). There was no such association between sizing and PVL, however, for the rate of moderate/severe PVL (undersized 1.1%, normal sized 0.5%, over sized 3.9%). We were not able to formally assess the incidence of annular rupture in relation to valve sizing and implantation depth, since the event rate was low (0.2%). The documented cases of annular ruptures (n=5), however, were recorded in patients in any sizing category and across all levels of implantation depth.

Conclusions: Continuous improvement in valve design, in conjunction with specific education on its appropriate use, is able to further reduce paravalvular leakage after TAVI that is a major obstacle for its use in lower risk patients.

euroPCR Interventions for structural heart disease Euro15A-OP287

Three-year midterm haemodynamic and durability outcomes of the European pivotal trial for second-generation balloon-expandable transcatheter heart valves

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Aims: Second-generation balloon-expandable SAPIEN XT transcatheter heart valves and delivery systems were designed to address valve-related and vascular complications and their consequences. Echocardiographic measurements obtained over the first three years of clinical trial follow-up were analysed to evaluate valvular function and haemodynamic outcomes.

Methods and results: The PREVAIL EU (transfemoral) and PREVAIL TA (transapical) trials collected safety and efficacy data in 20 TAVI study centres in five European countries. Combined enrolment included 434 patients and SAPIEN XT was implanted in 409 patients. Pre-procedure baseline transthoracic or transoesophageal echocardiograms were available for all patients implanted with the study valve. Post-index procedure transoesophageal echocardiograms were completed at hospital discharge, 30 days, 6 months and annually for the first 3 of 5 years. Three-year echocardiograms were available in 72.1% of 244 eligible patients. Mean patient age of the implanted population was 82.2±5.6 years and 47.9% were female. Mean Society of Thoracic Surgeons-Predicted Risk of Mortality was 8.2±5.5%. New York Heart Association class III/IV was reported in 80.9%. The most prevalent baseline cardiovascular comorbidities included mitral valve disease (63.6%), coronary artery disease (62.1%), hyperlipidaemia (62.1%) and congestive heart failure (53.3%). Renal insufficiency was noted in 28.9% and chronic obstructive pulmonary disease in 24.7%. The majority of patients received a size 26 mm transcatheter heart valve (42.1%) followed by size 23 mm (29.1%) and size 29 mm (28.9%). The mean native annular diameter was 23.2±2.3 mm (range 18.0-28.0 mm), with mean device oversizing of 12.4±5.0%. Post-dilatation was performed in 13.0%. At 3 years, mean effective orifice areas were 1.71± 0.31 cm, mean indexed effective orifice area 0.93± 0.16 cm/m, mean gradients 10.38±4.13 mmHg and mean left ventricular ejection fraction was 55.32±11.10%. In patients with measurements available at discharge and 3 years, paired comparisons showed no significant difference in effective orifice area (n=42; median 0.1 cm; min, max -0.5,0.6, p=0.933), indexed effective orifice area (n=37; median 0.0 cm/m; min, max -0.5,0.4; p=0.435), mean gradient (n=61;median 0.8 mmHg; min, max -11.1,11.5, p=0.284), paravalvular regurgitation (n=35; median 0.0; min, max -2.0,2,0; p=0.222) and total aortic regurgitation (n=53; median 0.0; min, max -2.0, 2.0; p=0.563) indicating consistent and sustainable valve function during the observation period. At discharge and 3 years, respectively, paravalvular leak was evaluated as none/trace in 54.6% and 56.7%, mild in 36.1% and 33.3%, moderate in 8.8% and 8.3%, and severe in 0.4% and 1.7%. No valve thrombosis or structural valve deterioration has been reported to date. Final valve size-related results will be available at the time of the EuroPCR meeting.

Conclusions: Echocardiographic outcomes in high-risk aortic stenosis patients treated with the SAPIEN XT THV have provided evidence at three years to show that prosthetic haemodynamic valve function is very stable with low mean gradients and non-obstructive EOAs without signs of structural valve deterioration. PVL severity has not worsened over time with low rates of moderate and severe regurgitation.

euroPCR Interventions for structural heart disease Euro15A-OP288

Three-year clinical and echocardiographic follow-up of aortic stenosis patients implanted with a self-expanding bioprosthesis

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Aims: The worldwide adoption of transcatheter aortic valve implantation (TAVI) shows an exponential increase during the past years. Still, longer-term data on larger cohorts are sparse. The aim of the ADVANCE study was to evaluate outcomes following implantation of a self-expanding transcatheter aortic valve system in a fully monitored, multi-centre 'real-world' patient population in highly experienced centres. Herein, we present 3-year clinical and echocardiographic follow-up data.

Methods and results: The ADVANCE study enrolled 1,015 "real-world" patients with severe aortic stenosis who underwent femoral, subclavian or direct aortic implantation of the CoreValve device at 44 centres in Western Europe, Asia and South America. Baseline characteristics include mean age 81.1±6.4 years, 51% female, and log EuroSCORE 19.4±12.3%. The primary endpoint was a composite of major adverse cardiac and cerebrovascular events (MACCE), and additional clinical endpoints included Valvular Academic Research Consortium-1 (VARC-1) complications. The patients were followed by annual visits and echocardiographic investigations. Endpoint-related events were adjudicated according to VARC-1 definitions by an independent Clinical Events Committee. All-cause mortality at 3 years was 33.7%, cardiovascular mortality was 22.3%, and the stroke rate was 6.5%. All-cause mortality was associated with the risk profile of the patients with 26.0%, 31.1%, and 41.4% in patients with a EuroSCORE ≤10%, >10-20%, and >20%, respectively (p<0.01). While there was a significant improvement in New York Heart Association (NYHA) symptom status early after implantation of the valve, the rate of patients in NYHA class III or IV increased from 13.4% to 19.5% beyond two years after the procedure (p<0.01). Implantation of the CoreValve led to a significant improvement in haemodynamics and an increase in the effective aortic valve orifice area which was sustained over time (mean aortic gradient 9.0 mmHg, mean effective orifice area 1.7 cm at 3 years). Moderate or severe aortic regurgitation significantly impaired survival (p<0.001), while the grade of aortic regurgitation remained unchanged over time.

Conclusions: In a "real-world" TAVI population with respective multiple comorbidities there is a continuous decrease in survival over three years after interventional treatment of severe aortic stenosis. There is evidence that the rate of patients in NYHA class III or IV may increase beyond two years, which is potentially associated with age and comorbidities. Notably, the ADVANCE study shows a durable haemodynamic benefit after implantation of the CoreValve along with a remarkably low stroke rate over three years.

Five-year outcome after transcatheter aortic valve implantation with CoreValve prosthesis

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Aims: The objective of this analysis was to assess 5-year outcome of transcatheter aortic valve implantation (TAVI) using the current technology of self-expanding CoreValve prosthesis.

Methods and results: Starting from June 2007, all consecutive patients with severe aortic stenosis undergoing TAVI with the third-generation 18 Fr CoreValve device (Medtronic Inc., Minneapolis, MN, USA) in 8 Italian centres were prospectively included in the ClinicalService® Project. For the purposes of this study we included only consecutive patients with 5-year follow-up available (n=353). All outcomes were reported according to VARC 1 criteria. All-cause mortality rates at 1, 2, 3, 4 and 5 years were 21%, 29%, 38%, 48% and 55.0%, respectively. Cardiovascular mortality rates at 1, 2, 3, 4 and 5 years were 10%, 14%, 19%, 23%, and 28.0%, respectively. The overall neurological event rate at 5 years was 7.5%, of which more than two thirds occurred early after the procedure. During follow-up, there were 241 re-hospitalisations for cardiovascular reasons in 164 (46%) patients. Among all re-hospitalisations, acute heart failure was the most frequently reported (42.7%), followed by requirement of PPM implantation (17.4%). On echocardiography, mean transaortic gradients decreased from 55.6±16.8 mmHg (pre-TAVI) to 12.8±10.9 mmHg (5-year post-TAVI) ($p<0.001$). Late prosthesis failure occurred in five cases (1.4%); among these, re-do TAVI was successfully carried out in two patients (0.6%) presenting with symptomatic prosthesis re-stenosis. The remaining three cases of prosthesis failure did not undergo further invasive interventions. Ten patients (2.8%) showed late mild stenosis with a mean transaortic gradient ranging from 20 to 40 mmHg. No other cases of structural or nonstructural valvular deterioration were observed. Valve thrombosis or late valve embolisation were not reported.

Conclusions: TAVI with the current generation of the CoreValve device was associated with sustained clinical outcomes up to 5-year follow-up, with a low rate (1.4%) of significant prosthetic valve degeneration. The procedure appears to be an adequate and lasting resolution of aortic stenosis in selected high-risk patients.

Quantitative multislice computed tomography assessment of the mitral valvular complex for transcatheter mitral valve interventions

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Aims: Geometrical measurements of the mitral valvular complex may have implications for the design of transcatheter mitral valve replacement (TMVR) devices and for patient selection. This study sought to quantify the dynamic geometry of the mitral valvular complex in patients with significant functional mitral regurgitation (FMR) using multislice computed tomography (MSCT).

Methods and results: MSCT images were acquired in 32 patients with symptomatic, moderate or severe FMR. Two independent observers analysed image sets using a dedicated software package and a standard measurement methodology. A meta-analysis of 24 studies reporting equivalent measurements in patients without mitral regurgitation (MR) was performed. In patients with FMR, the mean mitral annulus intercommissural and aorto-mural diameters were respectively 41.5±5.2 mm and 38.7±5.9 mm in systole, and were 41.5±4.4 mm and 40.0±4.7 in diastole. In patients without MR, the diameters were respectively 33.6±5.1 mm and 28.8±8.0 mm in systole, and 36.2±4.5 mm and were 31.6±7.9 mm in diastole. The obstacle-free zone below the mitral annulus averaged more than 20.0 mm and varied by less than 1 mm between systole and diastole, which is not statistically significant. The aorto-mitral angle was 129.7±10.5° in systole 131.0±9.4° in diastole.

Conclusions: The mitral annulus is larger in dimension, more circular and less dynamic in patients with FMR. In FMR, the obstacle-free zone below the mitral annulus is relatively constant during the cardiac cycle. Measurements of the mitral valvular apparatus vary considerably between patients, which suggests that tri-dimensional imaging will play an important role in the sizing and patient selection for TMVR.

euroPCR Interventions for structural heart disease

Euro15A-OP291

Percutaneous remodelling of the tricuspid valve with a novel cinching device: acute and chronic experience in an *in vivo* animal model

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Aims: To evaluate the safety, technical feasibility and performance of a new transcatheter tricuspid repair system.

Methods and results: Thirty-one adult swines underwent implantation of a transcatheter tricuspid remodelling system (TriCinch, 4Tech Cardio Ltd, Galway, Ireland). Among them, 17 underwent acute implantation by a percutaneous approach to evaluate the technical feasibility and performance of the device, while the remaining 14 chronic animals were submitted to a hybrid approach to evaluate histology at 90 days after implantation. A 10 Fr sheath was placed in the left femoral vein for intracardiac echocardiography. The steerable transcatheter device was introduced through a 24 Fr femoral sheath in the right femoral vein and delivered to the tricuspid annulus, on the beating heart. A fixation element was implanted into the tricuspid annulus, between the antero-posterior commissure and the mid-anterior annulus, using echo and fluoroscopic guidance. Following implantation, a second delivery system was used to couple the fixation element with a self-expanding nitinol stent. The device was tensioned to reshape the tricuspid valve and increase the coaptation length, on the beating heart, under echo-guidance. Finally, the stent was deployed in the inferior vena cava (IVC) to maintain the tension applied. The transcatheter device was successfully implanted in all the animals (n=31). Cinching of the tricuspid annulus resulted in an increase of coaptation length by 70% (4.55±0.71 mm to 7.78±1.36 mm), an increase in trans-tricuspid peak velocity by 79% (0.38±0.08 m/s to 0.68±0.09 m/s), and a reduction in septo-lateral dimension by 30% (35.5±5.7 mm 24.8±5.1 mm). All the animals survived the implant and no adverse effects occurred such as iatrogenic pericardial effusion. At necropsy, the fixation element was firmly attached to the annulus within a fibrotic tissue, with no coronary lesions observed. The stent was deployed in the IVC, without delayed displacement or change in the stent shape. Follow-up of the chronic animals demonstrated safety and durability of the implant. Further histological evaluation of the 14 chronic animals showed evidence of healing, annular tissue ingrowth and marked integration into the IVC of the implanted device. No thrombus deposition was noted and IVC patency was maintained.

Conclusions: Percutaneous remodelling of the tricuspid annulus with a cinching device is feasible and is associated with increased leaflet coaptation. This approach may be an alternative to open surgical tricuspid repair in high-risk patients.

euroPCR Interventions for structural heart disease

Euro15A-OP292

Mitral loop cerclage (MLC) as a variant form of "mitral cerclage annuloplasty" by adding an CSTV device for preventing its potential complications: a preclinical study with advanced developed devices

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Aims: Although mitral cerclage annuloplasty has shown excellent efficacy in reducing mitral regurgitation, the potential risk of surrounding tissue erosion and /or its consequent conduction block by thin suture are still a barrier to widespread use in humans. Here, in this preclinical study, we aimed to prove the concept of a novel approach (mitral loop cerclage, MLC) that is specially designed to prevent these shortcomings.

Methods and results: MLC consists of a novel device called the "coronary sinus and tricuspid valve protective device" or CSTV, composed of a tension locker and nylon coated braided stainless rope (0.6 mm in thickness) with a coronary artery protective device in a single unit (cerclage rope). The outer surface of CSTV is coated with ePTFE. Tension locking was made at the tip of CSTV stem with a specially designed tension stopper. Other procedure related dedicated devices were also developed and used for the MLC procedure. The MLC procedure was almost the same as that of mitral cerclage annuloplasty. However, delivering the CSTV device through the cerclage rope was an added step to that of typical mitral cerclage annuloplasty. Nine healthy farm swine underwent MLC in short-term (2 weeks, n=4) and midterm (6 weeks, n=5) survival experiments. The most advanced prototype for human trials was used in the midterm group. x-ray fluoroscopy was used for imaging guidance for the procedure. Echocardiogram and cardiac CT were checked before the procedure and during follow-up. The results were as follows: procedural success rate was 100%. MLC resulted in a significant reduction of the septal lateral dimension of mitral annulus (24.58±2.16. vs. 21.26±1.43 mm, p=0.04) and LV volume (75.9±3.9 vs. 70.6±5.0 ml, p=0.04, in diastole) and, in the midterm group (n=5). No other serious complication was noted except trivial TR in all cases (n=9). Conduction abnormality was not noted (n=9). LV ejection fraction did not deteriorate during the 6-week follow-up (63.7±3.7 in baseline vs. 68.6 ±1.4% in MLC, p=0.08, n=5). Necropsy findings showed no evidence of tissue erosion and excellent biocompatibility of the implanted devices.

Conclusions: MLC, as a novel approach for catheter based MV repair, appears to be feasible and effective without raising any significant safety issues. This promising preclinical result could warrant human trials.

A transseptal catheter-based hybrid approach for left ventricular partitioning and treatment of mitral regurgitation

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Aims: Left ventricular partitioning with the Parachute® device is an attractive treatment option to decrease ventricular volumes, myocardial work and wall stress in high-risk surgical patients with left ventricular apical aneurysms. So far only the retrograde trans-arterial approach has been approved (CE mark) for implantation. Unfortunately, severe functional mitral regurgitation (MR) restricts the use of the Parachute® device in patients with apical aneurysm formation. Thus, we were intrigued to combine MitraClip therapy and Parachute® implantation as a new transvenous transseptal hybrid-concept.

Methods and results: As a first step, Parachute® implantation was performed via a transseptally placed MitraClip guide in n=6 consecutive patients (age 73.8±5.2; 66% male, log EuroSCORE I: 27.9±10.0%). Immediately after Parachute® implantation, MR was treated as a second step in the procedure by MitraClip implantation (both interventions in a single setting). In addition, invasive right and left heart haemodynamic measurements were taken in all patients before, during and at the end of the procedure. Procedural success was 100% and there was no fatality within 30 days. Parachute® implantation induced numeric increases in cardiac output (+36.4; p=0.15) and stroke volume (+30.1%; p=0.09) despite some evidence of MR aggravation (e.g., increased left atrial pressure). Subsequent MitraClip implantation successfully reduced MR (a total of 12 clips were implanted) at least to mild in 5 patients and to moderate in 1 patient. Invasive haemodynamics demonstrated a further increase in stroke volume (+44.3% p=0.03) and cardiac output (+44.5%; p=0.03) with a significant reduction in left atrial pressures.

Conclusions: The study documents for the first time the feasibility and safety of transseptal and transmitral Parachute® implantation. Nevertheless, preprocedural severe MR seems to counteract the beneficial effects on forward stroke volume with a significant risk of MR-aggravation after Parachute® implantation. Hence, only the combined implantation of MitraClip and Parachute® seems to be the appropriate hybrid-strategy in patients with significant mitral regurgitation and left ventricular apical aneurysm.

Mitral valve direct annuloplasty system: interim results from multicentre safety and feasibility trial

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Aims: The Cardioband system (Valtech Cardio, Or Yehuda, Israel) enables percutaneous implantation of an adjustable "surgical-like" mitral annuloplasty ring using a transseptal approach. The aim of the reported study was to evaluate the feasibility, safety and performance of a transcatheter adjustable mitral annuloplasty system in patients with functional mitral regurgitation for up to 6 months in a multicentre study.

Methods and results: Between February 2013 and November 2014, 30 high-risk patients with significant functional mitral regurgitation were enrolled at 5 sites in Europe. After a Heart Team evaluation, all patients were screened by echocardiography and cardiac CT to assess feasibility. Echocardiographic data were analysed by an independent corelab. Mean age was 72±7 years; twenty-five patients were males (83%). Mean Log EuroSCORE 20±13% and median STS score 7% (1.0%-33.8%). At baseline, 97% of patients were in New York Heart Association class III-IV with a mean ejection fraction of 35±10% (15%-57%). Device implantation was feasible in all patients (100%). Acute procedural success (device successfully implanted with acute reduction of mitral regurgitation <2+) was achieved in 93% of the patients (28/30). After cinching of the device, an average of 20% reduction of the septo-lateral diameter was observed (from 36±4 mm to 29±5 mm; p<0.01). Thirty-day mortality was 6.7% (adjudicated unrelated to the device). At six months follow up (N=17), 81% of patients were in New York Heart Association class I-II with significant improvement in quality of life (Minnesota living with heart failure questionnaire from 38 to 18; p<0.05) and 82% of patients had MR≤2+.

Conclusions: Results up to 6-months suggest that transseptal direct annuloplasty with an adjustable "surgical-like" ring is feasible, with a comparable safety profile similar to other transcatheter mitral procedures. Effective reduction in mitral regurgitation severity is observed in most patients related to a significant septo-lateral dimension reduction. Mitral regurgitation reduction is stable and consistent at six months, with clinical benefit.

EuroPCR Interventions for structural heart disease Euro15A-OP295

The EVEREST II REALISM continued access study: one year outcomes by mitral regurgitation aetiology in high surgical risk patients

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Aims: To report the one year high risk EVEREST II REALISM study results.

Methods and results: REALISM high-surgical risk patients had 3+ or 4+ MR and were deemed high riskfor surgery as predicted by a STS risk calculator operative mortality of ≥12% or surgeon assessment based on pre-specified high-surgical risk factors. Outcome measures included NYHA functional class, quality of life measures, hospitalisations for heart failure, and echocardiographic measurements by an independent corelab. A total of 628 patients (FMR n=439; DMR n=189) were treated with the MitraClip device in the high-risk arm of the REALISM study. Patients were elderly (mean age: FMR 74±10; DMR 83±9 years) with a mean predicted surgical mortality by STS calculator of 10.4±6.9% and 12.6±7.0% for FMR and DMR patients, respectively. FMR patients had a higher incidence of baseline comorbidities compared to DMR patients, including coronary artery disease (FMR 84%; DMR 64%), cardiomyopathy (FMR 70%; DMR 20%), diabetes (FMR 41%; DMR 25%), and prior CABG (FMR 62%; DMR 35%). At baseline, left ventricular ejection fraction (FMR 42±12%; DMR 60±10%) and left ventricular internal diameter in systole (FMR 4.7±1.0 cm; DMR 3.5±0.8 cm) were significantly different between the two aetiologies. Despite these differences, FMR and DMR patients were equally symptomatic with 86% and 84% of patients in NYHA functional class III or IV at baseline, respectively. At one year, freedom from mortality was 76% in FMR and 80% in DMR and a majority of patients (FMR 83%; DMR 82%) experienced MR reduction to ≤2+ accompanied by reductions in LV volumes and dimensions in both aetiology subgroups. At one year, 81% of FMR and 90% of DMR patients were in NYHA class I or II. Significant improvements for the physical (PCS) and mental (MCS) components of the SF-36 were observed for both FMR and DMR patients between baseline and one year. The annual rate of hospitalisations for heart failure one year pre- and post- the MitraClip procedure decreased by 30% in FMR patients (from 0.67 to 0.47) and by 77% in DMR patients (from 0.56 to 0.13). The overall rates of major adverse events at one year were comparable between the two aetiologies (FMR 34%; DMR 28%).

Conclusions: One-year results in the high-risk arm of the REALISM study demonstrate that despite significant differences in baseline characteristics and comorbidities, patients with either FMR or DMR aetiology achieve significant reduction in MR and symptomatic and functional improvement following percutaneous treatment with the MitraClip device.

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Early and 1-year outcomes after MitraClip implantation with respect to preprocedural left ventricular ejection fraction: data from the ACCESS-EU phase I, prospective, multicentre, nonrandomised post-approval study of MitraClip therapy in Europe

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Aims: To report early and midterm outcomes of the ACCESS-EU Phase I study (ACCESS-Europe A Two-Phase Observational Study of the MitraClip System in Europe).

Methods and results: A total of 567 patients with significant mitral valve regurgitation (MR) underwent MitraClip therapy at 14 European sites. Of those 393 (69.3%) patients had a FMR (ischaemic: 42%; non-ischaemic 58%) and were further subdivided according to their pre-procedural LVEF (A: 10-20%, B: >20-30%, C: >30-40% and D: >40%). Procedural safety and efficacy, as well as treatment outcomes including grade of MR, functional capacity according to New York Heart Association (NYHA), 6-minute walk test (6MWT), and the Minnesota Living with Heart Failure questionnaire (MLHFQ) were analysed at baseline, 30 days and 12 months, respectively. Mean logistic EuroSCORE at baseline was 24.8±18.9; 84.2% patients were in NYHA functional class III or IV. Patients of group A had the highest prevalence of congestive heart failure (A: 94.2%, B: 78.3%, C: 67.9%, D: 55.7%). There was no incidence of death, stroke or respiratory failure intra-procedurally and in the immediate post-operative period. A total of 11 (2.8%) patients died within 30 days (no differences among subgroups; A: 3.8%; B: 2.5%; C: 4.7%; D: 1.5%). The Kaplan-Meier survival at 1 year was 81.8% (A: 71.0%; B: 79.2%; C: 87.2%; D: 85.7%). Average intensive care unit and hospital length of stay was 2.8±7.6 days and 7.9±9.1 days, respectively. Single leaflet device attachment was reported in 11 patients (2.8%), requiring surgery in two patients and re-intervention in five patients. There was a significant improvement in the severity of MR at 30 days and at 12 months ($p<0.0001$) with 78.5% of patients free from MR >2+ at 12 months (A: 77.3%; B: 78.8%; C: 78.4%; D: 78.2%). At 12 months, all subgroups experienced a similar improvement according to NYHA, 6 MWT and MLHFQ.

Conclusions: The very low rates of hospital mortality and adverse events in patients with FMR – even in patients with very severe reduced LVEF – provide additional evidence of a substantial benefit after MitraClip implantation.

Gender in the ACCESS-EU registry: a prospective, multicentre, non-randomised post-market approval study of percutaneous mitral valve repair therapy in Europe

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Aims: Gender has been an important factor in outcomes after mitral valve surgery, with decreased repair and higher short-term mortality. The effect of gender on outcomes after percutaneous mitral valve end-to-end clip therapy has not been well studied. The aim of this study is to report effect of gender on outcomes of a European prospective, multicentre, non-randomised post-approval study of percutaneous mitral valve repair therapy.

Methods and results: A total of 205 female and 362 male patients with significant mitral regurgitation underwent the MitraClip procedure at 14 European sites from October 2008 to April 2011. Women had a similar mean logistic EuroSCORE at baseline, with a higher rate of degenerative valve disease (32% vs. 18%). The percutaneous clip implant rate was over 99% for both genders. Women were more likely to have one clip implanted (72% vs. 54%) but had a similar length of admission in the intensive care unit (2.6±4.1 days, median 1) and overall length of stay (8.0±6.9 days, median 6) compared to men. They were also less likely to be discharged home: 71.9% of women went home compared to 83.9% of men and 25% of women went to skilled nursing facilities or rehabilitation compared to 15% of men. Thirty-day and 12-month safety results were similar between genders, as was 12-month efficacy (echocardiographic and clinical). Multivariate analysis showed no effect of gender on 12-month survival.

Conclusions: In a real-world, post-approval experience in Europe, female patients who undergo percutaneous mitral valve repair therapy experience safety and efficacy results similar to those of males. However, the discharge rates to skilled nursing facilities rather than home may indicate a need for better optimisation of the female patient's physical and social comorbidities prior to intervention and during the hospitalisation period.

Predictors of long-term outcomes after edge-to-edge percutaneous mitral valve repair

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Aims: To investigate the long-term outcomes and prognostic predictors of mortality from a multicentre registry of patients with severe mitral regurgitation (MR) undergoing MitraClip implantation.

Methods and results: Consecutive patients undergoing MitraClip therapy between October 2008 and November 2013 in 4 Italian centres were analysed. The primary endpoint of interest was all-cause-death. The secondary endpoint was the composite of mortality or rehospitalisation for heart failure (HF). A total of 304 patients were included, of which 79% had functional MR and 17% were in New York Heart Association (NYHA) functional class IV. Acute procedural success was obtained in 92% of cases, with no intraprocedural death. The cumulative incidences of all-cause death were 3.4%, 10.8% and 18.6% at 30 days, 1 year and 2 years, respectively. The corresponding incidences of the secondary endpoint were 4.4%, 22.0% and 39.7%, respectively. In the Cox multivariate model, NYHA functional class IV at baseline and ischaemic aetiology were found to significantly and independently predict both the primary and secondary endpoints. A baseline left ventricular end-systolic volume >110 ml was found to be an independent predictor of mortality or rehospitalisation for HF. Acute procedural success was independently associated with lower risk of mortality and the combination of mortality or rehospitalisation for heart failure at long-term follow-up.

Conclusions: In a real life population of patients undergoing MitraClip therapy, those presenting at baseline with ischaemic functional aetiology, severely dilated ventricles or advanced heart failure and those undergoing unsuccessful procedures carried the worst prognosis at long-term follow-up.

EuroPCR Interventions for structural heart disease Euro15A-OP299

Percutaneous mitral repair in the setting of severe mitral annular calcification: midterm results from a single centre experience

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Aims: Severe mitral annular calcification (MAC) represents a notorious challenge for mitral surgery, since it is associated with suboptimal long-term recurrent mitral regurgitation (MR), is technically demanding and is a risky procedure for both repair and replacement. On the other hand, severe MAC has been frequently considered a contraindication for percutaneous mitral repair in the past years. We reviewed our single centre experience with percutaneous mitral repair with the MitraClip system in the setting of MAC.

Methods and results: Between July 2008 and December 2014, 244 patients were treated with MitraClip at our Institution after Heart Team discussion. All patients underwent a standardised prospective in-hospital data collection pathway, and were enrolled in our dedicated outpatient follow-up clinic. Ten (4.1%) patients showed pre-operative severe MAC, all patients with moderate or less MAC having been excluded. Pre-operative patient characteristics included: mean age 77±9 years, New York Heart Association (NYHA) class III-IV in 9 (90%) of patients, mean Logistic EuroSCORE 27±12%, median Society of Thoracic Surgeons score 4.5% (IQR 2.1-7.3). Mean left ventricle end-diastolic diameter (EDD) was 58±11 mm, mean ejection fraction (EF) 52±17%, mean systolic pulmonary artery pressure (sPAP) 64±18 mmHg. MR mechanism was degenerative in 7 (70%), functional in 2 (20%) and mixed in 1 (10%) patient. One clip was implanted in 4 (40%), 2 clips in 5 (50%) and 3 clips in 1 (10%) patient, with a mean procedural time of 82±19 minutes. Acute residual MR was ≤1+ in 7 (70%), 2+ in 1 (10%) and 3+ in 2 (20%) patients. Residual MR 3+ was due to a significant posterior leaflet cleft in 1 case and to clip commissural entanglement in the setting of calcium extending to the posterior leaflet in the other case. There was no In-hospital mortality; the only observed major post-operative complication was 1 retroperitoneal bleeding that entailed endovascular embolisation, multiple transfusions and acute renal failure. Mean post-operative length of stay was 6.5±3.4 days, with home discharge in 9 (90%) patients. Median follow-up time was 38 months (IQR 1.5-43.5, up to 53). At last follow-up one single death due to pneumonia was observed 3.8 years after the procedure. All 10 (100%) patients were in NYHA class I-II ($p<0.01$ vs baseline). Echocardiography showed: mean EDD 54±11 mm ($p=0.07$ vs baseline), mean EF 54±11, mean sPAP 38±13 mmHg ($p<0.01$ vs baseline), mean valve area 2.9 cm^2, residual MR ≤2+ in 8 (80%) patients. One patient with residual MR 3+ underwent elective mitral replacement 1 month after the procedure; another underwent a successful re-MitraClip 4 years after the initial procedure.

Conclusions: Percutaneous mitral repair with MitraClip in the setting of severe MAC was feasible, safe and acceptably effective in our experience. Midterm results up to 4 years showed remarkable improvement in symptoms without MR recurrence. Although larger numbers and longer follow-up are needed, percutaneous mitral repair with the MitraClip system may be considered in selected symptomatic patients with severe MAC who are high risk for open surgery or inoperable.

EuroPCR Interventions for structural heart disease Euro15A-OP300

Left ventricular outflow tract phenotype and the need for permanent pacemaker implantation after transcatheter aortic valve implantation

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Aims: To study left ventricular outflow tract (LVOT) characteristics and the need for permanent pacemaker implantation (PPI) after transcatheter aortic valve implantation (TAVI).

Methods and results: In a total cohort of 290 patients, we used a multislice CT scan at baseline to study the amount of calcium and the perimeter of the LVOT before TAVI, evaluating the subsequent depth of implantation within the LVOT and device size relative to LVOT dimension after TAVI. The mean age was 79±8 years. TAVI was executed using a Medtronic CoreValve in 200 patients, Balloon-expandable valves in 57 patients with the SAPIEN XT in 38 patients, the SAPIEN 3 in 19 patients and the Lotus device in 28 patients. Overall, 65 patients (22%) needed a new permanent pacemaker after TAVI. The need for PPI was 22% with CoreValve, 32% with Lotus, 10% with the SAPIEN XT and 32% with the SAPIEN 3. The need for PPI was significantly correlated with the depth of valve implantation within the LVOT ($p=0.002$), with a trend for device oversizing relative to the LVOT ($p=0.056$). Using ROC curve analysis, we found different cut-off values of relative LVOT oversizing for the different valve types. Overall, the percent oversizing cut-off associated with the need for PPI was 15%. This varied from 3% with the Lotus device, 5% with the SAPIEN 3, 14% with SAPIEN XT and 16% with CoreValve. Additional analysis in a broader patient population will be ready for presentation at EuroPCR 2015.

Conclusions: Our preliminary data confirm the importance of LVOT characteristics before and after TAVI in the need for permanent pacemaker implantation. Especially depth of valve implantation and device oversizing relative to the LVOT seem relevant and needs further study. Of note, device oversizing with second-generation devices (Lotus and SAPIEN 3) are particularly prone to a need for pacemaker implantation when oversized.

Impact of prosthesis implantation depth on atrioventricular and intraventricular conduction and pacemaker implantation rates after latest generation balloon-expandable TAVI

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Aims: To investigate the impact of SAPIEN 3 valve (S3-THV) position (depth in LVOT) on electrocardiographic changes suggestive of atrioventricular and/or intraventricular conduction abnormalities and 30-day PPMI rate.

Methods and results: Between March and December 2014, 47 consecutive patients without pacemaker treated with S3-THV (20 males, mean age 81.7±5.0 years, mean logistic EuroSCORE 26.9±19.8%) were included in the study. All patients underwent pre- and post-TAVI clinical evaluation, 12-lead ECG and echocardiography. The valve placement was assessed by the off-line evaluation of procedural fluoroscopic images. We measured the final depth of the valve in the LVOT at the septal and the non-septal side. Changes of PQ segments and QRS complexes observed after 24-48 hours from the procedure (ΔPQ and ΔQRS respectively) were used as markers of atrioventricular and intraventricular conduction disturbances. In our population, six patients (12.8%) needed PPMI after TAVI. The rate of PPMI was significantly higher in those patients with low implantation of the valve (aorto-ventricular ratio ≤60:40) (42.9% vs. 7.5%; p=0.010). Logistic regression analysis showed that for each mm of increase in the depth of the valve at the septal side the risk of PPMI increased by 1.52 times (95% CI: 1.07-2.17; p=0.022). Conversely, the depth of the valve at the non-septal side was not significantly associated with PPMI risk (OR=1.27, 95% CI: 0.89-1.82; p=0.189). Furthermore, a low implant of the valve (aorto-ventricular ratio ≤60:40) is the most powerful predictor of PPMI (OR=9.25, 95% CI: 1.38-62.09). In addition, linear regression analysis showed that ΔPQ was significantly associated with depth of the valve at the septal side (beta=0.333, p=0.022) while ΔQRS was not (beta=0.167, p=0.263). In patients with low implantation of the valve (aorto-ventricular ratio ≤60:40) ΔPQ and ΔQRS were higher vs. patients with higher implant, although only approaching statistical significance (35.7±64.8 vs. 10.2± 2.1 msec, p=0.053, and 28.6±24.1 vs. 14.2±20.7 msec, p=0.105, respectively).

Conclusions: The correlation between the valve depth in LVOT with the PQ and higher rate of PPMI suggests the need of a S3-THV implantation technique different from XT-THV. An aorto-ventricular prosthesis ratio >60:40 was associated with lower rates of PPMI, similar to literature-reported rates for older balloon-expandable valves.

Design specific patterns of electrical conduction dynamics after transcatheter aortic valve implantation

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Aims: To study electrical conduction changes after transcatheter aortic valve implantation (TAVI) and identify specific patterns related to three different transcatheter heart valves.

Methods and results: Twelve-lead ECGs were analysed before TAVI and daily afterwards up to discharge and at 30 days. A total of 90 patients underwent TAVI with balloon-expandable (43%), self-expanding (23%) or mechanically expanded transcatheter heart valves (34%). Median age was 80 (IQR 74-84), 48% were female, 2% had a permanent pacemaker at baseline. Twenty-five % of patients needed a permanent pacemaker within 30 days after valve implantation. Overall, the PR interval did not change immediately after TAVI (174±33 at baseline vs. 180±37, p=0.146) yet prolonged significantly up to day 3 (179±33 ms to 207±53 ms, p=0.01) and normalised again towards 30 days (197±49 ms vs. 181±28 ms, p=0.042). QRS duration significantly prolonged immediately after the valve implantation (from 113±25 ms at baseline to 136±29 ms after TAVI, p<0.001). At 30-days, the QRS segment narrowed again but remained significantly longer as compared to baseline. With the balloon-expandable Edwards SAPIEN 3 and the self-expanding CoreValve, the QRS segment prolonged immediately after valve implantation with a trend to narrowing again between 4 and 30 days. After Lotus implantation with mechanical expansion, the QRS segment widened immediately and started narrowing after the fourth day, a trend that persisted and became significant at 30 days. These preliminary data will be extended with additional analyses in a broader patient cohort.

Conclusions: Our preliminary data confirm dynamic changes in electrical conduction within 30 days after TAVI and suggest different patterns with different transcatheter valve designs. Comprehensive understanding of these valve specific patterns may help guide decisions related to the need and timing for permanent pacemaker implantation post-TAVI.

EuroPCR Interventions for structural heart disease Euro15A-OP303

Comparison of stroke rates between the balloon-expandable Edwards SAPIEN valve and the self-expandable CoreValve after transcatheter aortic valve replacement

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Aims: Transcatheter aortic valve implantation (TAVI) has been used increasingly to treat inoperable or high-surgical-risk patients with severe symptomatic aortic stenosis. Although mortality rates are declining, stroke continues to be an issue. The aim of our study was to compare thirty-day rates between the balloon-expandable Edward SAPIEN Valve (ESV) and the self-expandable Medtronic CoreValve system (MCV).

Methods and results: Five hundred and seventy-three (573) patients with severe aortic stenosis and high-surgical risk-underwent TAVI consecutively under local anaesthesia between April 2010 and October 2014. Major and minor stroke was defined according to the VARC II criteria; 30-day stroke rate and 30-day mortality rates were evaluated. Three hundred and sixty-one (361) pts (age 80.6±0.34 years) with severe aortic stenosis (p-mean 43.1±0.77 mmHg, AVA 0.68±0.01 cm^2) and high-surgical-risk (log EuroSCORE 22.0±0.67%) underwent TAVI successfully with the MCV and 212 pts (age 81.7±0.41 years, log EuroSCORE 18.6±0.82%, p-mean 44.2±1.12 mmHg, AVA 0.68±0.02 cm^2) underwent TAVI with the ESV. In the total cohort occurred 12 strokes (2.1%) during the first 30 days. There was no significant difference between the 30-day stroke rate between the two valve types (MCV vs. ESV=1.7% vs. 2.8%; p=0.264), but there were more major strokes in the ESV group compared to the MCV group (MCV vs ESV: 0.8% vs. 2.4%; p=0.273). There was a trend to more pre-dilation in the 30-day stroke group, but this did not reach statistical significance: 83.3% in the stroke group vs. 69.1% in the group without stroke, p=0.235. Mortality at 30 days was significantly higher in patients with stroke compared to those without stroke (25% versus 3.9%; p=0.013). Mortality at 30 days in the MCV group (5.5%) compared to the ESV group (2.4%) was higher, but this did not reach statistical significance (p=0.052).

Conclusions: TAVI was associated with a 30-day stroke rate of 2.1%. There was no significant difference in 30-day stroke rates between the two valve types, although there was a trend of more major strokes in the ESV group. Mortality was significantly higher at 30 days in patients with stroke.

EuroPCR Interventions for structural heart disease Euro15A-OP304

Incidence and predictors of debris embolising to the brain during transcatheter aortic valve implantation

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Aims: To identify variables associated with tissue fragment embolisation during transcatheter aortic valve implantation (TAVI).

Methods and results: A total of 81 patients underwent TAVI with a dual filter-based embolic protection device deployed in the brachiocephalic trunk and left common carotid artery. Both balloon-expandable and self-expanding transcatheter heart valves (THV) were used. Filters were retrieved after TAVI and sent for histopathological analysis. Overall, debris was captured in 86% of patients. Captured material varied in size from 0.1 to 9.0 mm. Thrombotic material was found in 74% of patients and tissue-derived debris in 63%. Tissue fragments were found more often with balloon-expandable THV (79% vs. 56%, p=0.05). The embolised tissue originated from the native aortic valve leaflets, aortic wall or left ventricular myocardium. By multivariable logistic regression analysis balloon-expandable THV (OR: 7.315 [1.398-38.289], p=0.018) and cover index (OR: 1.141 [1.014-1.283], p=0.028) were independent predictors for tissue embolisation.

Conclusions: Debris is captured with filter-based embolic protection in the vast majority of patients undergoing TAVI. Tissue derived material is found in 63% of cases and is more frequent with the use of balloon-expandable systems and more oversizing.

Incidence, impact and predictive factors of delirium after TAVI

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Aims: To investigate the incidence, impact and predictive factors of postoperative delirium (POD) among patients treated with transcatheter aortic valve implantation (TAVI).
Methods and results: A retrospective observational cohort study of 268 consecutive (mean age 80±7 years) TAVI patients was conducted. Delirium was diagnosed according to the Diagnostic and Statistical Manual of Mental Disorder, 4rd Edition (DSM-IV) criteria. Outcomes were defined according to the VARC-2 criteria. The primary outcome of this study was the presence of in-hospital POD after TAVI. Multivariable logistic regression was used to identify independent baseline predictors of delirium. Cumulative survival was analysed using Kaplan-Meier analysis. The incidence of POD after TAVI was 13.4% (n=36). Of these cases, 18 (50%) were associated with ≥ 1 post-procedure complication(s), including major vascular complications/bleeding (n=4), stroke (n=3), acute kidney injury stages II-III (n=3), atrial fibrillation (n=4) and infectious disease (n=4). POD was most frequently diagnosed on the second day after TAVI (IQR: 1-5) and was associated with prolonged in-hospital stay regardless of complications (in uncomplicated TAVI: 6 [5-10] vs. 5 [4-5] days, p<0.001; and in complicated TAVI: 9 [8-15] vs. 6 [5-9] days, p=0.002). Kaplan-Meier analysis showed higher mortality for patients who developed POD (36% vs. 16%; p<0.001) after a median follow-up of 16 [6-27] months. POD remained a significant independent predictor of mortality when adjusted for age, sex and occurrence of complications (Hazard Ratio: 2.34 [1.17-4.67], p=0.015). Predictors of POD were age (Odds Radio [OR] 1.09 [1.00-1.18]), carotid stenosis (OR 2.85 [0.96-8.47]), atrial fibrillation (OR 2.63 [1.14-6.08]), current smoking (OR 4.12 [1.25-13.6]) and alternative (transapical/transaortic) access (OR 7.53 [3.19-17.73]).
Conclusions: There is a 13% incidence of delirium after TAVI which occurs primarily early on in the postoperative course. Patients who develop POD show prolonged in-hospital stay and impaired survival. Surgical (transapical/transaortic) access is strongly associated with the occurrence of POD.

Safety and efficacy of self-expanding covered stents for percutaneous treatment of vascular access complications after TAVI

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Aims: To evaluate the short- and medium-term safety and efficacy of the Viabahn self-expanding covered stent (Gore, USA) when used to treat vascular injury induced by transfemoral TAVI.
Methods and results: Over a 40-month period, 354 patients underwent a true percutaneous transfemoral TAVI using the CoreValve (Medtronic, USA) and Prostar-XL closure system (Abbott Vascular, USA). A vascular access complication (VAC) leading to acute intervention occurred in 72 patients (20.3%): of these, 18 were managed by balloon angioplasty, 48 were treated by Viabahn stenting (technical success rate: 98%), and six needed surgical intervention. This management resulted in a major VAC rate of 3.1% (n=11) in our patient population. When compared to patients without VAC, length of hospitalisation and 30-day mortality were comparable in patients treated with a Viabahn covered stent. Two patients presented with new-onset claudication; one of them had the stent implanted covering the deep femoral artery. At medium-term follow-up, duplex ultrasound showed full patency of all Viabahn stents with no signs of stent-fracture or in-stent stenosis or occlusion.
Conclusions: The use of self-expanding covered stents is safe and effective in cases of transfemoral TAVI-induced vascular injury with good short- and medium-term outcomes. If confirmed by long-term follow-up studies, this strategy for treating VAC may be used routinely in high-risk patients.

EuroPCR Interventions for structural heart disease Euro15A-OP307

Predictors of paravalvular regurgitation following implantation of a fully repositionable and retrievable transcatheter aortic valve in 250 patients: results from the REPRISE II trial extended cohort

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Aims: This analysis evaluated the incidence and predictors of paravalvular regurgitation at 30 days following implantation of the Lotus Valve in the extended REPRISE II cohort of 250 patients.

Methods and results: The prospective, single arm, multicentre REPRISE II and REPRISE II Extension studies enrolled 250 symptomatic, high-surgical-risk patients with calcific aortic stenosis and an annulus of 19-27 mm. Two valve sizes of 23 mm or 27 mm were available in these studies. Paravalvular regurgitation was assessed by echocardiography at discharge and 30 days according to VARC-2 criteria, and aortic valve dimensions and calcification by CT in end-systole; both were analysed and reported by an independent corelab. At 30 days, 80.2% (142/177) of patients had no paravalvular regurgitation, 5.6% (10/177) had trace/trivial regurgitation, 13.6% (24/177) had mild regurgitation, 0.6% (1/177) had moderate regurgitation, and no patients had severe paravalvular regurgitation. Baseline and procedural predictors of mild or moderate paravalvular regurgitation at 30 days (or at discharge if 30-day data were not available) were determined by using a multivariate regression model (n=229). Significant independent predictors of mild/moderate paravalvular regurgitation included the ratio of device area to annulus area (odds ratio 0.87; 95% CI: 0.83, 0.92; p<0.001), calcium volume in the left ventricular outflow tract (odds ratio: 2.85 per 100 mm^3 increase; 95% CI: 1.44, 5.63; p=0.003), and annulus area (odds ratio per 10 mm^2 increase: 0.89; 95% CI: 0.82, 0.96; p=0.002). Calcium volume in the leaflet and annulus was a borderline-significant predictor (odds ratio: 1.07 per 100 mm^3 increase; 95% CI: 1.00, 1.16; p=0.06). When the nominal valve area was smaller than the annulus, i.e., device:annulus area ratio <1, the rate of mild or moderate paravalvular regurgitation was 53.1% (17/32). The rates of mild/moderate paravalvular regurgitation with 0-5%, 5-10%, and >10% annular oversizing by area were 17.5% (11/63), 2.9% (2/70), and 3.2% (2/63), respectively.

Conclusions: Paravalvular aortic regurgitation rates were low overall with the Lotus Valve and consisted almost exclusively of mild paravalvular regurgitation in the 250 patient REPRISE II Extension cohort.

EuroPCR Interventions for structural heart disease Euro15A-OP308

Interventional paravalvular leakage closure after surgical and interventional heart valve replacement: midterm results

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Aims: Percutaneous transcatheter techniques emerge in the treatment of inoperable patients with valvular heart disease. Paravalvular leakage closure (PLC) has slowly evolved since his first description in 1992 and has become an alternative treatment option to open heart surgery due to the development of new closure devices and 3D transoesophageal echocardiographic guidance. The objective of this study is to describe functional and clinical outcome after transcatheter PLC of prosthetic valves in aortic and mitral position.

Methods and results: This is a prospective study of 25 patients, which underwent PLC (56% male, age 68.4±11.4 years; EF 54,1±16,2, EuroSCORE 21.2±9.8) between May 2010 and May 2013. Seventeen patients had a paravalvular leakage of the mitral valve, 8 in aortic position; 12 (48%) had a history of infective endocarditis and 15 of 25 patients (60%) had a mechanical valve. Successful implantation of closure devices was achieved in 18 patients (72%) whereas 7 patients could not receive a leakage closure due to difficult anatomical conditions. Fifteen of 18 treated patients (83%) improved by more ≥ two New York Heart Association functional class. The same 15 patients showed a functional improvement in paravalvular insufficiency of ≥ two grade. The survival rates for implanted patients at 6 and 12 months after PLC were 89% and 86%. Fourteen (78%) implanted patients completed 6-month FU and 9 implanted (50%) patients completed 12-month FU, which confirmed successful leakage closure in 83% (6-months) and 89% (12-months) of patients with only 1 patient experiencing a relevant progression of valve insufficiency. Three of seven patients in which leakage closure was not possible died during the first six months. No periprocedural death occurred.

Conclusions: Closure of paravalvular leakages in patients at high operative risk is safe and feasible and seems to have favourable midterm effects. High-risk patients with a relevant paravalvular leakage have a poor outcome if treated conservatively.

Transcatheter aortic valve implantation with and without balloon aortic valvuloplasty: impact on paravalvular leak

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Aims: Transcatheter aortic valve implantation (TAVI) is now considered as a viable alternative for patients suffering from symptomatic severe aortic stenosis who are considered inoperable or at high-risk for surgical aortic valve replacement. Paravalvular leak has been identified as a negative prognostic factor after TAVI. Balloon aortic valvuloplasty is commonly conducted prior to prosthesis expansion during TAVI. The potential effects of balloon aortic valvuloplasty in post-TAVI paravalvular leak are not known. In the present study, we sought to identify potential differences in post-TAVI paravalvular leaks between patients who underwent or did not undergo balloon aortic valvuloplasty prior to the TAVI.

Methods and results: We retrospectively studied 190 consecutive patients who underwent TAVI with (147 patients; 78 males; 81±5 years) or without (43 patients; 22 males; 79±8 years) prior BAV under angiographic-only procedural guidance. All patients received a self-expandable porcine bioprosthesis for treatment of native aortic valve stenosis. Paravalvular leak was evaluated a) immediately after bioprosthesis implantation under aortography and b) at patient discharge (~5-7 days post-TAVI) under transthoracic echocardiography. Baseline clinical characteristics were comparable between the balloon aortic valvuloplasty and no-balloon aortic valvuloplasty groups. Mild or moderate paravalvular leak immediately after TAVI (angiographic assessment) was more frequently observed in patients who underwent BAV vs. those who did not undergo balloon aortic valvuloplasty prior to TAVI (33% vs. 16%, respectively; p=0.031). Still, the occurrence of PVL at discharge (assessed by TTE) was comparable between the two groups (mild or moderate post-TAVI paravalvular leak: 13% vs. 10%, balloon aortic valvuloplasty vs. no-balloon aortic valvuloplasty group, respectively; p=0.656).

Conclusions: In the present study, balloon aortic valvuloplasty as a pre-treatment for TAVI has been shown to be related to a higher post-TAVI frequency of mild or moderate paravalvular leak as assessed by angiography. However, this difference was not observed at discharge echocardiographic patient evaluation. While greater PVL rates were observed only immediately after TAVI, and not at discharge, the potential benefits from pre-TAVI BAV may be questioned. Further studies are needed to evaluate these findings.

Device area/annulus area ratio as a predictor of 30-day paravalvular regurgitation after balloon-expandable transcatheter aortic valve implantation

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Aims: Paravalvular regurgitation (PVR) following transcatheter aortic valve implantation (TAVI) is associated with poor survival. In addition, recent multicentre analysis showed that post-procedural PVR is an independent risk factor for 1-year mortality. The purpose of this study was to assess the correlation between device area /annulus area ratio and post-procedural PVR incidence following TAVI.

Methods and results: Device size selection (23 mm, 26 mm or 29 mm) was done using systolic multislice computed tomography (MSCT) annulus cross-sectional area measurements in 225 patients who had severe symptomatic aortic stenosis and were treated with balloon-expandable TAVI (SAPIEN/SAPIEN-XT; Edwards Lifesciences, Irvine, CA, USA). Thirty-day post-procedural PVR was evaluated using transthoracic echocardiogram (TTE). All patients were divided into 4 categories based on device area /annulus area ratio (DAR): <5% oversizing (group 1, n=43), 5-15% oversizing (group 2, n=77), 15-25% oversizing (group 3, n=63) and >25% oversizing.(group 4, n=42). The minimal DAR was 16.9% undersizing and the maximal DAR was 62.6% oversizing. The overall rate of >mild thirty-day post-procedural PVR was 31.6%. There was a significant association between the degrees of DAR and the post-procedural PVR at 30 days (p<0.001, area under the receiver-operating characteristic curve [AUC], 0.706). The group of <5% oversizing had the highest risk of PVR. Valve dislodgement or annulus rupture was not observed in any patients and there were no differences in the occurrence of stroke, myocardial infarction and death between these groups. The incidence of new pacemaker implantation was higher in the group of >25% oversizing (p=0.025, group1=0.6%, group 2=0.9%, group 3=0.8%, group 4=21%).

Conclusions: Device area/annulus area ratio was predictive for post-procedural 30 days PVR after balloon-expandable TAVI. Moreover, selection of 5- 25% area oversizing is best to reduce the risk of post-procedural PVR and new pacemaker implantation.

EuroPCR Interventions for structural heart disease Euro15A-OP311

Are next generation transcatheter heart valves able to overcome paravalvular leakage in TAVI patients? Angiographic, echocardiographic and haemodynamic evaluation of an all-comers study cohort

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Aims: More than mild paravalvular aortic regurgitation (AR) after transcatheter aortic valve implantation (TAVI) is associated with increased mortality and morbidity. Next generation transcatheter heart valves (THVs) have been introduced to eliminate paravalvular leakage by specific design modifications such as paravalvular sealing mechanisms and/or repositionability. The aim of our study was to evaluate and compare established THVs with so-called next-generation THVs.

Methods and results: We compared the post-procedural result in 375 consecutive patients undergoing TAVI at our heart centre using imaging modalities (angiography, echocardiography) and haemodynamics (aortic regurgitation index). Severity of paravalvular AR and outcome were assessed in accordance with the VARC-2 criteria. The dimensionless AR Index was calculated as ratio of the transvalvular gradient between diastolic blood pressure (DBP) in the aorta and left-ventricular end-diastolic pressure (LVEDP) to the systolic blood pressure (SBP) according to the formula: [(DBP-LVEDP)/SBP] x 100. Three hundred and seventy-five (375) patients (mean age 81.3±6.4 years, 51.7% male, mean left-ventricular ejection fraction 52.9±13.7%, median EuroSCORE II 5.4 [3.4-9.0]) underwent TAVI with use of the Medtronic CoreValve (N=241), Edwards SAPIEN XT (N=50), Symetis Acurate (N=8), Direct Flow Medical (N=27), Medtronic Evolut R (N=8), Boston Lotus (N=25), and Edwards SAPIEN 3 (N=16). Thirty-day and 1-year all-cause mortality were 4.8% (18/375), and 17.3% (65/375), respectively. Echocardiographic evaluation revealed that 124/375 (33.1%) of the patients had no relevant aortic regurgitation, 224/375 (59.7%) trace or mild AR, whereas 27/375 (7.2%) of the patients suffered from moderate paravalvular AR after the procedure. More than mild paravalvular AR occurred significantly less frequently ($p<0.001$) in patients undergoing TAVI with next generation THVs: Medtronic CoreValve (7.5%), Edwards SAPIEN XT (10.0%), Symetis Acurate (25%), Direct Flow Medical (3.7%), Medtronic Evolut R (0.0%), Boston Lotus (4.0%), and Edwards SAPIEN 3 (0.0%). The post-procedural AR index was significantly higher ($p<0.001$) with use of the Boston Lotus (37.6±9.1) and the Direct Flow Medical (31.2±7.7) valve compared with the Medtronic CoreValve (28.6±7.2), Edwards SAPIEN XT (28.0±7.0), Symetis Acurate (24.4±5.5), Medtronic Evolut R (23.8±7.0), and Edwards SAPIEN 3 (27.8±6.2).

Conclusions: TAVI with the use of next-generation transcatheter heart valves leads to a reduction of paravalvular AR and might provide more beneficial haemodynamics than established THVs.

EuroPCR Interventions for structural heart disease Euro15A-OP312

Surgical and transcatheter aortic valve replacement in Germany from 2007 to 2012: in-hospital outcomes of 96,149 patients

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Aims: Since 2007, the number of transcatheter aortic valve replacement (TAVR) procedures increased dramatically with no comprehensive evidence on how this has affected surgical aortic valve replacement (sAVR) numbers and the relative outcomes and patient profiles of each. The aim of our analysis was to confirm how patients are treated for aortic valve disease today and if the real world evidence is aligned with clinical guidelines.

Methods and results: We obtained data from the federal bureau of statistics for all (100%) isolated AVR and TAVR procedures in Germany from 2007 to 2012. For each patient record, we retrieved data on patient characteristics (age, gender, previous interventions, etc.), diagnoses (aortic stenosis, aortic insufficiency, etc.), procedure and outcomes (mortality, complications, etc.). When calculating the logistic EuroSCORE for each patient, we were able to populate all fields except for critical preoperative state and left ventricular function and thus calculated a best-case scenario. There were a total of 96,149 procedures between 2007 and 2012 with 70,717 sAVR and 25,432 TAVR (16,410 transfemoral access and 8,889 transapical). sAVR patients in comparison with TAVR were on average younger (68.8 vs. 80.8 years), predominantly male (58% vs. 42%) and at lower risk (log EuroSCORE of 6.22% vs. 22.53%). TAVR patients were more likely than sAVR patients to have had previous surgery (19.4% vs. 8.3%), coronary artery disease (46% vs. 16%) peripheral vascular disease (12% vs. 4.3%) and overall had a higher incidence of all cardiovascular disease markers. In-hospital mortality for each group over the entire period was 3.5% and 7.1% for sAVR and TAVR respectively. When examined annually, mortality in both groups declined between 2007 and 2012: AVR from 4.3% to 3.3% and TAVR from 11.1% to 5.8% (although mean EuroSCORE values remained largely unchanged in both groups). In terms of procedural volumes over time there was very little change in the numbers of AVR in the <75 and 75-79 year groups (≈10,000 per year) and a reduction in AVR annually from around 2,000 to 1,250 in patients aged ≥80 years. For TAVR there has been a steady increase in all age groups but predominantly in those aged ≥80 years.

Conclusions: We present here the complete data on all TAVR and isolated sAVR procedures performed in Germany from 2007 to 2012. TAVR implantation rates have grown steadily since 2007 with only a small reduction in the number of isolated sAVR procedures. Substantial differences in patients risk profiles remain stable over time and TAVR is largely performed in patients aged ≥80 years with elevated risk score in comparison to sAVR. The use of TAVR seems to follow the recent position paper of the German Cardiology Society and current ESC/EACTS guidelines.

Haemodynamic performance of transcatheter and surgical prosthetic valve for aortic valve stenosis with small aortic roots

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Aims: Surgical aortic valve replacement (SAVR) in a small aortic root is still challenging with regard to the surgical technique and prosthesis size selection, which often causes patient-prosthesis mismatch (PPM). On the other hand, because a prosthetic valve of the transcatheter valve is implanted inside a native valve either by a balloon or is self-expanding in nature, a larger effective orifice area (EOA) may be obtained. The aims of this study are to elucidate that haemodynamic performance of transcatheter valves (TV) and surgical valves (SV) in the same anatomical characteristics of aortic roots evaluated by ECG-gated MSCT (Study 1) and to examine the predictors for PPM (defined as the effective orifice area index ≤0.85 cm^2/m^2) in the both groups (Study 2).
Methods and results: Two hundred and fourteen (214) patients, who underwent TAVI (n=154; age 83.4±5.9 years) and SAVR (n=60; age 75.1±5.9 years) for aortic valve stenosis, were enrolled. Preoperative ECG-gated multislice CT (MSCT) and echocardiography immediately before a discharge were performed in all patients. In study 1: a propensity score matching (TV: n=42, SV: n=42) revealed that except for age (TV:SV=83.8±5.0:75.1±5.3; p<0.0001), there was no significant difference in preoperative characteristics including sex, body surface area, EOAi, and aortic root characteristics (the diameters of annulus, Valsalva sinus, and ST junction on ECG-gated CT findings). Postoperative haemodynamic performance of TV revealed significantly less Vmax (2.1±0.3 vs 2.6±0.5 m/s, p<0.0001), less mean pressure gradient (9.5±3.1 vs 14.9±5.2 mmHg, p<0.0001), and larger EOAi (1.13±0.23 vs 0.99±0.22 cm^2/m^2, p=.007) comparing with that of SV, respectively. Consequently, PPM was more frequently in SV compared to TV (31.0 vs 9.5%; p=.014). In study 2: a multivariate analysis in SAVR identified small ST junction with only predictive factor of PPM (odds ratio [OR], 1.52; 95% CI: 1.02-2.26; p=.041) and ROC curve analysis showed the cut-off value of 22.5 mm in the ST Junction diameter for PPM (AUC, 0.76). Moreover, although the prosthetic valve performances of TV have no difference between ST Junction ≥ and <22.5 mm, those of SV for the small STJ <22.5 mm were inferior to the large STJ ≥22.5 mm. On the other hand, regarding TV, there was no predictor for PPM in preoperative characteristics.
Conclusions: The haemodynamic performance of transcatheter valve is superior to that of surgical valve in a patient with small aortic root, in particular, small ST junction.

Thirty-day clinical outcome and echocardiographic data after transfemoral aortic valve implantation in an all-comer-TAVI population: comparison of the new balloon-expandable SAPIEN 3 versus the SAPIEN XT

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Aims: To compare 30-day clinical outcome and especially the incidence and magnitude of post-TAVI paravalvular aortic regurgitation (PVL) after CT-guided implantation of the transfemoral 14/16F Edwards SAPIEN 3 (ESV-3) to its precursor model 16/20F-ESV-XT using the Heart Navigator algorithm for all patients.
Methods and results: Between August 2012 and October 2014, 209 consecutive pts (age 81.6±0.41 years, 130 female) with high-surgical-risk (EuroSCORE 18.5±0.86%) underwent successfully transfemoral TAVI in local anaesthesia using either the ESV-XT (23,26,29 mm) or the ESV-3 (23, 26,29 mm). CT-imaging including the Heart Navigator algorithm was used for prosthesis size selection and valve implantation plane selection. Clinical events and post-TAVI PVL was evaluated after 30 days according to the VARC-II criteria. There were 102 pts (mean age 81.97±0.5 years) with severe aortic stenosis (p-mean 47.6±1.52 mmHg, mean AVA 0.76 ±0.11 cm^2) and high-surgical-risk (mean log EuroSCORE I 16.9±0.86%) underwent TAVI successfully with the ESV-XT; and 107 pts (mean age 81.4±0. 6 years, mean log EuroSCORE I 20.2±1.39%) underwent TAVI with the ESV-3 under local anaesthesia. Concerning the procedural outcome: device success was 101/102 (99.2%) in ESV-XT and 100% in ESV-3, respectively. Compared to TAVI with the ESV-XT, the ESV-3 procedures had shorter mean fluoroscopy time (10.0±0.5 min in vs. 11.8±0.5 min, p=0003), and less contrast media was needed (188.9±5.6 ml vs. 170.4±4.7 ml, p=0.04). The procedure time (skin-to-skin) was not significantly different (108.3±4.6 min vs. 101.3±3.6 min, p=0.496). In-lab strokes and death did not occur in both groups. Thirty-day clinical outcome: 30-day all-cause mortality was similar for both valves implanted (ESV-XT vs. ESV-3: 2.9% vs. 1.9%; p=0.494), as was major/minor stroke rates (ESV-XT vs. ESV-3: 3.9% vs. 1.9%; p=0.333). There was no significant difference between the two valve types concerning major vascular complications (ESV-XT vs ESV-3: 6.9% vs. 9.3%; p=0.322) and the rate of new pacemaker implantation (ESV-XT vs. ESV-3: 16.7% vs 12.1%, n.s.). Thirty-day echocardiographic data: the rate of no/trace AR (optimal result) was significantly higher in the ESV-3 compared to the ESV-XT (ESV-3 vs ESV-XT: 89.7% vs. 37.3%; p<0.001). Mild AR is found in in 62.7% after ESV-XT and in only 10.3% after ESV-3-implantation (p<0.001). There was no severe AR in both groups, in the ESV-XT there were 2.9% of patients with moderate AR compared to 0 in ESV3.
Conclusions: In an all-comer TAVI-population, after implantation of ESV-XT and ESV-3 using CT-guidance including the Heart Navigator algorithm, AR >1 after 30-days is extremely rare. Mild AR is significantly more frequent after ESV-XT-implantation while clinical outcome is excellent for both valve types. The persistence of the result over time and the impact of mild AR on clinical long-term outcome needs to be determined in further studies.

EuroPCR Interventions for structural heart disease Euro15A-OP315

Comparison of safety and efficacy between two balloon-expandable transcatheter heart valves (SAPIEN XT versus SAPIEN 3): a single centre analysis

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Aims: For patients with severe aortic stenosis who are at extreme or high risk for surgical aortic valve replacement transcatheter aortic valve implantation (TAVI) has become a well-established treatment option. In this study, we analyse safety and efficacy in a direct comparison of TAVI using either the Edwards SAPIEN XT or Edwards SAPIEN 3 balloon-expandable THV.

Methods and results: This retrospective analysis comprises 314 consecutive patients treated with either Edwards SAPIEN XT (XT; N=157) or Edwards SAPIEN 3 (S3; N=157) THV between September 2012 and October 2014 at our centre. Both groups were compared according to clinical and echocardiographic baseline characteristics as well as echocardiographic, procedural and clinical outcomes. All clinical endpoints were defined according to VARC2 criteria. Access site for TAVI was mainly transfemoral (XT: 75.2% vs. S3: 77.7%), followed by a transapical (XT: 24.8% vs. S3: 21.7%) and a direct aortic approach (XT: 0% vs. S3: 0.6%). Calculated risk (XT vs. S3: logistic EuroSCORE I 16.8±12.0% vs. 17.7±11.8%, p=0.45; STS PROM 6.9±6.6% vs. 7.2±5.4%, p=0.14) as well as mean age (XT vs. S3: 81.1±6.7 years vs. 81.7±6.3 years) did not differ between groups. Mean transvalvular gradient before intervention was lower in the XT-group (XT vs. S3: 31.0±15.8 mmHg vs. 36.5±19.7 mmHg; p=0.01). Successful deployment of the THV was achieved in all patients. Criteria for device success were comparably met (XT vs. S3: 94.9% vs. 97.5%; p=0.38). Mean transvalvular gradient after TAVI at discharge by transthoracic echocardiography was 8.5±3.6 mmHg and 11.2±3.9 mmHg in the XT- and the S3-group, respectively (p=0.0001). Rate of moderate or severe aortic regurgitation (AR) after TAVI was not different between groups (XT vs. S3: 6.4% vs. 3.8%, p=0.41). However, more patients in the S3-group had no AR or AR ≤ trace compared to the XT-group (XT vs. S3: 39.3% vs. 52.3% [p=0.03] and 61.9% vs. 73.5% [p=0.05], respectively). Intraprocedural mortality was similar in both groups (0.6%), whereas in-hospital mortality was higher in the XT-group (10.2% vs. 3.8%, p<0.05). Rate of major stroke post-implantation was not significantly different between the XT- and the S3-group (5.1% vs. 1.9%, p=0.22). Also, prevalence of post-procedural pacemaker implantation due to grade 3 atrioventricular block did not differ between groups (XT vs. S3: 7.0% vs. 8.9%, p=0.68). Major access site complications were insignificantly more frequent in the XT- than S3-group (11.5% vs. 5.7%, p=0.11). Combined safety endpoint occurred more often in the XT-group (24.2% vs 13.4%, p=0.02).

Conclusions: In this study, the balloon-expandable SAPIEN 3 valve was found to be superior to the SAPIEN XT valve by means of in-hospital mortality and combined safety. Even though device success rates were high for both THVs, the rate of post-implantation AR was lower with SAPIEN 3. Further multicentre analysis will have to confirm this single centre experience.

EuroPCR Interventions for structural heart disease Euro15A-OP316

Multicentre assessment of TAVR in failed aortic bioprostheses: implantation depth and elevated post-procedural gradients in SAPIEN vs. CoreValve valve-in-valve implantation

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Aims: Aortic valve-in-valve (VinV) is limited by device underexpansion and elevated post-procedural gradients. Supra-annular position of the transcatheter heart valve (THV) device in relation to the failed surgical valve is suggested to be advantageous. No comprehensive analysis of implant depth in valve-in-valve and post-procedural haemodynamics has been reported.

Methods and results: Analyses of cases included in the global VinV registry were performed. Only cases with implantation of either SAPIEN XT or CoreValve were included in the analysis. Cases performed inside surgical valves without fluoroscopic markers (e.g., stentless, homografts), or those with suboptimal images, were excluded. Implant depth was defined in CoreValve cases in absolute length and in SAPIEN cases in percentage of the THV device below the surgical valve ring. Evaluation of implantation depth was performed by an analyst blinded to clinical outcomes. Elevated post-procedural gradients were defined as mean ≥20 mmHg. A total of 108 aortic VinV cases were analysed (68% CoreValve, 32% SAPIEN). Median implanted depth of the CoreValve device was 7.4 mm (interquartile range, IQR, 5.2-10 mm) and of the SAPIEN device median of 20.3% of device length below the ring (IQR 7.9-25.5%). Post-implantation echocardiographic results in the total group included: aortic valve area 1.49±0.47 cm^2, mean gradient 16±6.9 mmHg. Elevated post-procedural gradients were recorded in 26.9% of patients (16.2% of CoreValve cases, 42.5% of SAPIEN cases). In CoreValve cases, implant depth was strongly associated with elevated gradients (≥6 mm, 23.2%, <6 mm, 0%, p=0.04), but not with the surgical valve size (label≤21 mm 17.2%, >21 mm 15.6%, p=0.34). In SAPIEN cases, association between elevated gradients and surgical valve size existed (label≤21 mm 66.7%, >21 mm 28%, p=0.02), but not with implant depth (≥20% below the bioprosthesis ring, 45%, <20% below the bioprosthesis ring, 40%, p=0.87).

Conclusions: Elevated post-procedural gradients are common after aortic VinV. Significant contributors for elevated gradients were deep implantation of a CoreValve device and SAPIEN implantation inside a small surgical valve.

Core laboratory adjudicated comparison of a first-generation self-expanding and a second-generation mechanically expanding transcatheter aortic valve prosthesis

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Aims: New generation transcatheter aortic valve systems are emerging in clinical trials and routine practice with design features aimed at improving safety and efficacy. To date, these devices have not been compared systematically to current first-generation devices. We aim to determine whether transcatheter aortic valve implantation (TAVI) with the second-generation, mechanically expanded Lotus valve (Boston Scientific) offers potential benefits over treatment with the first-generation, self-expanding CoreValve (Medtronic).
Methods and results: One hundred patients (83.4±4.8 years, 44% male, STS PROM 5.5±2.4) were enrolled. Fifty consecutive patients receiving a Lotus TAVR and 50 matched patients receiving a CoreValve. An independent core laboratory reviewed all echocardiographic data and an independent clinical events committee adjudicated all events. Twenty-six patients (52%) in the Lotus cohort were treated with the smaller Lotus device (23 mm) while 22 patients (44%) in the CoreValve group received the smaller CoreValve prosthesis (26 mm), p<0.001. There was greater perimeter oversizing (3.6±5.7% versus 14.0±6.2%, p<0.001) and area oversizing (13.0±12.3 versus 36.6±15.4%, p<0.001) in the CoreValve cohort. All patients left the catheterisation laboratory with a functioning TAVR prosthesis. The primary outcome measure of Valve Academic Research Consortium 2 (VARC2) defined device success was achieved in 84% of the Lotus cohort and 64% of the CoreValve cohort (p=0.02). The components of this outcome measure were 100% absence of procedural mortality versus 96% (p=0.15), 100% correct positioning of a single prosthesis versus 86% (p=0.06), a 96% mean gradient across the prosthesis less than 20 mmHg versus 100% (p=0.16), absence of prosthesis patient mismatch 92% versus 86% (p=0.68) and no more than mild aortic regurgitation 96% versus 83.3% (p=0.04) in the Lotus and CoreValve cohorts, respectively. All-cause death was 0% in the Lotus cohort and 4% in the CoreValve cohort at 7-days with one additional death in the Lotus cohort and one additional death in the CoreValve cohort at 30-days. Cardiovascular mortality (0% vs. 4%, p=0.32), rates of major stroke (4% vs. 2%, p=0.56) and permanent pacemaker insertion (28% versus 18%, p=0.23) were not different at 30-days, in the Lotus and CoreValve cohorts, respectively. The mean transprosthetic gradients were 12.6±6.5 and 8.2±2.6 mmHg, (p<0.001) for the Lotus and CoreValve cohorts, respectively. The mean effective orifice areas (EOA) were similar in both cohorts (1.7±0.4 versus 1.8±0.4 cm^2, p=0.17). Moderate PAR occurred in 0% and 6.4% of patients in the Lotus and CoreValve cohorts, respectively, with no cases of severe PAR at 30-days (p=0.01). There was a significant improvement in New York Heart Association score in both cohorts with 79.2% of subjects in the Lotus group and 82.9% in the CoreValve group improving by one class or more.
Conclusions: In this matched comparison of high-surgical-risk patients undergoing transcatheter aortic valve implantation, the use of the Lotus device was associated with higher rates of VARC2 defined device success when compared with the CoreValve. This was driven by higher rates of correct anatomical positioning and lower incidences of moderate paraprosthetic regurgitation. The clinical significance of these differences needs to be tested in a large randomised control trial.

Transfemoral aortic valve implantation with the repositionable Lotus valve compared with the balloon-expandable Edwards SAPIEN 3 valve

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Aims: The rate of paravalvular aortic insufficiency (AI) with transcatheter aortic valve implantation (TAVI) using first generation devices was higher compared with surgical replacement. Residual AI after TAVI has been linked to an increased mortality rate. We compared two second-generation TAVI devices – the repositionable Lotus valve with the balloon-expandable Edwards SAPIEN 3 valve – regarding procedural and 30-day outcome.
Methods and results: In 78 patients with severe aortic stenosis undergoing transfemoral TAVI we evaluated post-procedural paravalvular AI, device success and early safety according to VARC criteria. Valve size was based on a 256-multisclice computed tomography. Patients were followed for 30 days. The Lotus valve (N=26) and the Edwards SAPIEN 3 valve (N=52) were implanted under fluoroscopic guidance. Baseline characteristics were similar between groups. Perimeter derived annulus diameter did not differ with 25.7±1.6 mm for Lotus and 25.2±2.1 mm for Edwards SAPIEN 3 patients. After TAVI, aortography and transthoracic echocardiography revealed no moderate or severe AI. The rate of mild AI was 12% for Lotus and 15% for Edwards SAPIEN 3 (p=0.62). There were no deaths, stroke, annulus rupture or coronary obstruction. Device success was 96% and 98% (p=0.61), early safety according to VARC 11.5% in both groups (p=1.0) and need for pacemaker implantation 27% and 4% (p<0.003), respectively.
Conclusions: TAVI with second-generation devices was associated with no moderate or severe AI and a low rate of mild AI. Device success was high for Lotus and Edwards SAPIEN 3, while the need for a permanent pacemaker was significantly higher with the Lotus valve.

EuroPCR Interventions for structural heart disease Euro15A-OP319

Gastrointestinal bleeding in patients with atrial fibrillation and anticoagulant therapy: the role of percutaneous atrial appendage closure

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Aims: Gastrointestinal bleeding (GIB) is highly prevalent in patients with atrial fibrillation (AF) subject to oral anticoagulant therapy (OAC). Percutaneous left atrial appendage closure (PAC) has become a therapeutic alternative for patients with atrial fibrillation and contraindication for OAC. We aimed to analyse the treatment and evolution of patients with GIB and OAC.

Methods and results: We report the results of a single-centre registry of all consecutive patients with GB and AF on OAC. The management of these patients involves the performance of a comprehensive GI tract examination to elucidate the underlying disease and provide an appropriate aetiological therapy. OACs are usually reintroduced following stabilisation. We made a clinical or phone follow-up. Between February 2012 and December 2013, 41 patients were admitted in our centre for GIB+AF+ACO. Medium age 79.8±6.1 years, 51% men, 82% hypertension, 32% diabetes mellitus, CHA_2DS_2-VASc 4.00±1.05, INR 3.14±1.31. Patients were divided in 3 groups: group I: 30 had a cause of bleeding (a specific treatment was given and ACO reintroduced). group II: seven had no evident cause of GIB and ACO was not reintroduced because of frailty, patient decision or contraindication. group III: four patients with no evident cause of GIB and PAC were done and OAC withdraw. We made a follow-up of 452+196 days. During the follow-up 50% of patients from group I were admitted because of bleeding or left heart insufficiency, all-causes of mortality account for 17%. In group II, readmission was 57% and mortality reached 27%. In group III there was no mortality, 1 re-admission due to pin device thrombosis resolved by reintroduction of heparin for 1 week.

Conclusions: Obscure or intractable GI bleeding in patients with AF on OACs is a major cause of morbidity and mortality. Percutaneous LAA closure and OAC discontinuation may well be an optimal therapeutic option to protect patients against both GIB and arterial embolism.

EuroPCR Interventions for structural heart disease Euro15A-OP320

Indications for left atrial appendage occlusion and the impact on procedural safety and long-term outcome: a report from the Amplatzer Cardiac Plug multicentre registry

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Aims: To investigate the impact of indication for therapy on procedural safety and long-term patient outcome.

Methods and results: Data from the Amplatzer Cardiac Plug (ACP) multicentre registry on 1,047 consecutive patients were analysed. Procedural safety variables included death, stroke, transient ischaemic attack (TIA), myocardial infraction, device embolisation, cardiac tamponade, and major bleeding (grouped as major adverse events, MAEs), and minor bleeding. Clinical outcome variables included death, stroke, TIA, major and minor bleeding. The mean age was 75±8 years, and permanent AF was present in 594 patients (57%). The mean CHA_2DS_2-VASc score was 4.5±1.6.The mean HAS-BLED score was 3.1±1.2. The main indication for LAAO was previous major bleeding (493 patients; 47.1%) classified to: intracranial (198 patients; 18.9%), gastrointestinal (151 patients; 14.4%), and non-specified (144 patients; 13.8%). Other indications were high risk for bleeding (365 patients; 34.9%), CAD and stenting (228 patients; 21.8%), drug interaction (191 patients; 18.2%), stroke on warfarin (163 patients; 15.6%), previous minor bleeding (160 patients; 15.3%), renal/hepatic disease (142 patients; 13.5%), labile INR (99 patients; 9.5%) and risk of falls (79 patients; 7.5%). The composite of previous bleeding (major or minor) and high-bleeding risk was 73%. Procedural success was 97.3%. There were 51 (4.9%) MAEs. Follow-up was complete in 1,001/1,019 (98.2%) of successfully implanted patients (average 13 months – total 1,349 patient-years). One-year all-cause mortality was 4.2%. There were 9 (0.9%) strokes, 9 (0.9%) transient ischaemic attacks, 15 (1.5%) major bleedings and 17 (1.7%) minor bleedings during follow-up. Patients with an indication of major gastrointestinal bleeding had more periprocedural major bleedings (4.6 vs. 0.8%, p=0.002), more cardiac tamponades (4.6 vs. 0.7%, p=0.001), more MAEs (11.3 vs. 3.8%, p<0.001), and more bleedings during follow-up (6.2% vs. 3.4%, p=0.013). All other indications were not associated with significant differences.

Conclusions: Previous major gastrointestinal bleeding as an indication for LAAO was associated with more periprocedural adverse events and with increased frequency of bleeding during follow-up.

Procedural outcome of patients with estimated low, intermediate, or high stroke risk undergoing transcatheter left atrial appendage occlusion using Amplatzer systems

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Aims: To clarify whether left atrial appendage occlusion (LAAO) in pts with estimated low, intermediate, or high stroke risk (SR) may be associated with adverse procedural outcome along with increasing SR.

Methods and results: From 2009 to 2014, 407 consecutive pts underwent LAAO at our institution and were included in the prospective Bern LAAO Registry. Exclusively dedicated Amplatzer devices (Amplatzer Cardiac Plug [ACP] and Amulet) were used. Procedures were almost invariably performed under local anaesthesia and fluoroscopic guidance without use of procedural echocardiography. Device sizing was performed by LAA angiography. Concomitant additional procedures were performed in 237 pts (58%). Procedural outcomes were compared with regard to annual SR using the CHA_2DS_2-VASc score. Risk stratification was performed as: low SR with CHA_2DS_2-VASc Score of 0-1 points as group 1 (0.8-2.0%), intermediate SR with 2-3 points as group 2 (3.7-5.9%), and high SR with 4-9 points as group 3 (8.5%-23.6%). All data of the 407 pts (mean age 74±10 years; 70% male, 30% female, mean CHA_2DS_2-VASc Score 4.0±1.7, mean HAS-BLED score 2.8±1.2) were included and baseline characteristics, procedural data, and adverse events were compared among the three groups using one-way analysis of variance and chi square tests. group 1 comprised 30 pts (7%); group 2, 125 pts (31%) and group 3, 252 pts (62%). As expected, baseline characteristics were different between the three groups of low, intermediate, and high SR: mean age 59±7.5, 69±10, and 77±7.6 years, respectively, p<0.0001; gender: 10%, 18%, and 36% female pts, respectively, p<0.0001; mean CHA_2DS_2-VASc Score: 0.7±0.5, 2.6±0.5, and 5.0±1.1 points, respectively, p<0.0001; and mean HAS-BLED score: 1.2±1.0, 2.6±0.5, and 3.3±1.0 points, respectively, p<0.0001. The prevalence of coronary artery disease and left ventricular systolic dysfunction were also different among the three groups and renal function showed a trend towards a progressive impairment along increased risk for stroke or bleeding: 82±17, 99±75, and 112±72, creatinine in µmol/l, respectively, p=0.07. Procedural success was equivalent among all groups: 96.7%, 96.8%, and 98.0%, respectively, p=0.73. No difference was found either in contrast medium use or fluoroscopy time: 229±87, 234±101, and 235±112 ml, p=0.96, and 18.5±11.7, 20.3±15.6, and 20.0±15.8, respectively, p=0.90. The predefined combined safety endpoint of in-hospital death, stroke, tamponade, or need for surgery showed no difference between the three groups and was met in 3 (10%), 7 (5.6%), and 19 patients (7.5%), respectively, p=0.64.

Conclusions: Despite distinct differences in anticipated stroke and bleeding risk, age, gender, or load of cardiac morbidities, transcatheter left atrial appendage occlusion with Amplatzer devices shows similar procedural outcomes among the three groups with estimated low, intermediate, or high stroke risk.

Percutaneous left atrial appendage (LAA) closure: effect of the positioning of the closure device on outcome

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Aims: The Amplatzer Cardiac Plug (ACP) consists of an anchoring lobe and a disc. The disc is meant to cover the ostium of the left atrial appendage (LAA). Frequently, the disc prolapses partially or completely into the neck of the LAA. It is unknown whether such a disc position compromises the outcome and should be corrected.

Methods and results: The outcome of 169 consecutive patients with successful LAA closure was analysed according to the position of the disc of the ACP: complete coverage of the LAA ostium by the ACP disc (group A) versus partial coverage with part or all of the disc in the LAA neck (group B). Transoesophageal echocardiography was performed after 4-6 months. A composite of pericardial effusion or tamponade, device embolisation, procedure-related stroke, major bleeding, and device thrombus defined the safety endpoint. A composite of death, neurological events (ischaemic and haemorrhagic stroke, transient ischaemic attacks), and systemic embolism defined the efficacy endpoint. Mean age of the patients was 73±10 years and mean CHA_2DS_2-Vasc score and HASBLED score were 4.2±1.7 and 2.9±1.1, respectively. Complete disc coverage of the ostium was present in 76 patients (45%, group A) and partial sealing in 93 (55%, group B). Mean follow-up of the study population was 13.4 (95% confidence interval, [CI] 12.0-15.0) months. Overall, the composite safety and efficacy endpoints occurred in 35 (21%) and 6 patients (4%), respectively. There was no difference in the occurrence of the safety or efficacy endpoints between group A and B (16 (21.1%) versus 19 (20.0%), p=0.97 and 3 (6.6%) versus 3 patients (3.2%), p=0.79, respectively).

Conclusions: No difference in safety and efficacy was found between complete and incomplete ACP disc coverage of the LAA ostium. The risk of repositioning attempts in case of incomplete coverage does not seem to be warranted.

euroPCR Interventions for structural heart disease Euro15A-OP323

Left atrial appendage occlusion for stroke prevention in atrial fibrillation: midterm results of the Belgian Amplatzer Cardiac Plug registry

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Aims: Left atrial appendage occlusion was developed as an alternative therapeutic option for stroke prevention in patients with atrial fibrillation who were not candidates for anticoagulant therapy. The aim of the present study was to evaluate the efficacy and the safety of the Amplatzer Cardiac Plug in Belgium, at midterm follow-up.

Methods and results: Between June 2009 and November 2014, 153 consecutive patients from 7 Belgian centres (93 males, 74±7 yrs, CHA_2DS_2-VASc 4.8±1.8, HASBLED 3.3±1.3), were included in the study. Procedural success was 97.4%, the mean size of the Amplatzer Cardiac Plug was 25±3 mm, the mean number of attempts was 2.3±1. There were nine periprocedural major adverse events (5.8%) including one death (0.6%), 5 tamponade (3.2%), 2 device embolisations (1.3%) and one major bleeding (0.6%). Among patients successfully implanted with a complete follow-up (198 patient-years, mean follow-up 473 days), the actual annual stroke+transient ischaemic attack rate was 2.5%, lower than the expected stroke risk (6.1%, 59% reduction). The observed bleeding rate was 0.6%, while the calculated risk was 5.2% (88% reduction). Kaplan-Meier analysis showed an overall survival at 91±2 and 82±4%, and an event-free survival at 89±3 and 82±4% at 1 and 2-yrs follow-up, respectively.

Conclusions: Our data suggest that left atrial appendage occlusion using the Amplatzer Cardiac Plug is effective and safe in Belgium to prevent atrial fibrillation-related thromboembolism, at midterm follow-up.

euroPCR Interventions for structural heart disease Euro15A-OP324

Safety and efficacy of left atrial appendage closure with the cardiac plug in high-risk patients with non-valvular atrial fibrillation and contraindications to oral anticoagulation

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Aims: Oral anticoagulation is recommended in the majority of patients with atrial fibrillation. Interventional left atrial appendage closure (LAAC) using devices such as the Amplatzer Cardiac Plug (ACP, St. Jude Medical, St. Paul, MN, USA) was introduced to avoid long-term oral anticoagulation. Data on ACP in patients with absolute contraindications for oral anticoagulation, however, are inconsistent and limited due to small sample sizes. The aim of the current analysis was therefore to assess the safety and efficacy of LAAC with the ACP device in a cohort of real-world patients ineligible for oral anticoagulation.

Methods and results: From March 2009 until June 2014, data from 88 consecutive patients undergoing fluoroscopic- and echocardiographic-guided LAAC with the ACP device at a tertiary care centre were collected. At baseline, clinical, laboratory, and procedural data were assessed. Fifty-three patients (60.2%) underwent routine transoesophageal echocardiography (TEE) after 9.3±6.3 months. Clinical follow-up was available in 81 patients (92.0%) at 12.3±10.4 months following the index procedure. The primary safety endpoint was a composite of procedural complications including major bleeding according to BARC criteria, pericardial effusion/tamponade, device embolisation, and periprocedural cerebral ischaemia. The primary efficacy endpoint was the combined events of stroke (ischaemic and haemorrhagic), major bleeding, systemic embolism, and cardiovascular death during the follow-up period. Mean age was 76±6 years and the CHA_2DS_2-VASc score was 5.4±1.5 at a HAS-BLED score of 3.3±1.0. Almost half of the patients (n=38, 43.2%) experienced severe bleeding prior to LAAC. The procedure was successful in all patients. Following LAAC, most patients received a short-term dual antiplatelet therapy (n=73, 83.0%) and no patient was discharged on oral anticoagulation. The primary safety endpoint occurred in six patients (6.8%; pericardial effusion/tamponade n=4 [4.5%]; periprocedural cerebral ischaemia n=2 [2.3%]). At TEE follow-up, two patients (3.8%) had a clinically silent device thrombosis. The primary efficacy endpoint occurred in 10 patients (12.3%; stroke n=2 [2.5%]; cardiovascular death n=8 [9.9%]). No major bleeding events were observed. The ischaemic stroke rate was less than expected based on the CHA_2DS_2-VASc score (~ 6.7% per year).

Conclusions: In this, so far the largest cohort of high-risk patients with non-valvular atrial fibrillation and absolute contraindications for oral anticoagulation, LAAC with the ACP device appears to be safe at a low rate of systemic thromboembolic events at long-term follow-up. Nevertheless, these patients remain at high risk for cardiovascular death.

Embolisation of left atrial appendage closure devices: a systematic review of cases reported with the WATCHMAN device and the Amplatzer Cardiac Plug

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Aims: Device embolisation is a known complication of LAA closure procedures. The goal of this study is to provide a systematic review of reported cases of LAA closure device embolisation by focusing on the two most commonly implanted devices: the WATCHMAN (WM) (Boston Scientific, Plymouth, MA, USA), and the Amplatzer Cardiac Plug (ACP; St. Jude Medical, Minneapolis, MN, USA).

Methods and results: A comprehensive search of PubMed database from inception through October 1, 2014, was conducted using pre-defined criteria. Studies were included if they described at least one case of embolisation of the WM and/or the ACP. A total of 20 studies reporting 31 cases of device embolisation was identified including 13 cases with WM and 18 cases with ACP. The timing of embolisation was described in 29 cases and was categorised as "acute" (i.e., during hospital stay) in 20 cases (65%, 13 out of 20 cases were intraprocedural) and "late" (i.e., following hospital discharge) in nine cases (30%). The anatomical location of embolised devices was reported in 21 cases: into the aorta in 9 cases (30%; WM 7/9, ACP 2/9), into the left ventricle (LV) in 9 cases (30%; WM 3/9, ACP 6/9) and into the left atrial cavity in 3 cases (10%; ACP 3/3). The device was retrieved by percutaneous methods in 17 patients (55%, WM 8/17, ACP 9/17), while 10 patients underwent surgical retrieval (32%, WM 4/10, ACP 6/10). As compared to embolisation into the Ao or the LA cavity, device embolisation into the LV was associated with a higher rate of surgical retrieval (8/9 vs 2/12; 88% vs. 17%, p=0.0019). Major adverse events related to device embolisation occurred in 3 patients: 1 case of internal bleeding during percutaneous retrieval, 1 case of Ao cusps damage requiring Ao valve replacement and 1 case of death due to cardiogenic shock.

Conclusions: Device embolisation is a rare but serious complication of percutaneous LAA closure and occurs mainly in the periprocedural period. Although embolisation into the Ao or the LA can be successfully managed by percutaneous techniques in most cases, device embolisation into the LV is associated with a high rate of surgical retrieval, increasing thereby procedure-related morbidity.

TAVI in the UK: adoption and economic evidence

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Aims: The United Kingdom (UK) has the second largest population and economy in Western Europe. Yet there is published evidence that the uptake of TAVI has languished behind most of Europe with estimates putting the numbers of implants per capita behind all major European countries except for Portugal and Ireland. The aim of our analysis was to review all available published data on TAVI volumes and economic evidence in the UK to validate these perceptions.

Methods and results: Numbers of TAVI procedures were derived from public data including the BCIS (British Cardiovascular Intervention Society) and NHS (National Health Service) England HES (hospital episode statistics) database. Data on reimbursement and payments to service providers (hospitals) were obtained from providers and commissioners. A systematic literature review of economic evidence on TAVI was performed and found five published articles and two National clinical guidance. TAVI procedures have grown annually by approximately 200 per year according to figures presented by the BCIS to around 1,500 in 2013 (24 per million). However, official data from NHS England for the same period reported only around 870 TAVI (or 16.4 per million for England only). This indicates approximately 20% of TAVI procedures in England are not funded directly through the public health service. In addition to the low total number we found enormous variability of service across England and Scotland with localised rates ranging from 0 to 9.36 TAVI per million. At the current time TAVI is still not reimbursed nationally and fees varied widely according to discussions between hospitals and healthcare commissioners. In 2014 these fees ranged from approximately £19,000 to almost £30,000 with the device reimbursed separately in some cases and as part of the total fee in others. In terms of economic analysis of TAVI in the UK we found a total of 15 published peer-reviewed articles on comparative cost-effectiveness of which five were UK specific, each concluding TAVI is cost-effective.

Conclusions: The use of TAVI has grown annually in the UK although slower than other countries and there is an unresolved difference between the numbers of implants reported by centres and those financed directly by the UK health service. TAVI outcomes are at least on a par with other European countries and procedures are limited to extreme risk/inoperable patients. We present here data that TAVI is much less frequently performed compared with most European countries and volumes and reimbursement conditions vary widely within the UK. This is despite comparable clinical outcomes with published data, no apparent differences in the epidemiology of aortic stenosis in the UK and an abundance of economic data concluding that TAVI is cost-effective.

EuroPCR Interventions for structural heart disease Euro15A-OP327

Healthcare resources in patients diagnosed with aortic stenosis: an Italian analysis

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Aims: To evaluate the consumption of healthcare resources (e.g., hospital admissions, specialist visits, drug treatments, diagnostic tests, etc.) by patients diagnosed with aortic stenosis (AS) according to method and timing of intervention (if any).

Methods and results: An observational retrospective analysis has been performed by integrating administrative databases of healthcare resource consumption (e.g., pharmaceuticals database, hospitalisations database, laboratory tests, diagnostic tests and specialist visits database) from 3 Italian Local Health Units (LHU) located in 3 different regions. All patients aged ≥70 years with at least one hospitalisation with AS diagnosis between January 1, 2010 and December 31, 2012 were included. All patients were classified based on the presence or absence of any aortic valve replacement procedure, either surgical (sAVR) or transcatheter (TAVI). Patient demographics, comorbidities and the Charlson comorbidity index were reported. The consumption of healthcare resources was evaluated in the 12 months before and after any interventional procedure or in the 12 months before and after the index hospitalisation where no aortic valve intervention was reported. A total of 3,698 patients were included in the analysis: 595 (16.1%) underwent sAVR, 137 (3.7%) received TAVI and 2,966 (80.2%) had no record of any valve intervention. Those with no recorded intervention were marginally older than the other groups and predominantly female (mean age 81.2±6.2 years, 37.7% male). TAVI patients were notably older than sAVR patients (80.2±5.0 vs. 76.7±4.3 years) and had more existing comorbidities. Rates of death in the 12 months following index hospitalisation and procedure were 18.6%, 11.7% and 5.1% for no intervention, TAVI and sAVR respectively. The proportion of patients with at least one hospitalisation in the same 12-month period was 28.4%, 43.0% and 19.9% for no intervention, TAVI and sAVR respectively. The costs (mean±standard deviation) of healthcare resources for the 12 months after intervention were €3,825±€6,562 in the sAVR group and €4,952±€5,324 in the TAVI group. In those patients with no intervention, the costs were highly variable, from €2,627 ±€4,848 in patients without any rehospitalisation for cardiovascular causes (71.6%) to €10,934±€10,647 in patients with at least one rehospitalisation for cardiovascular causes (28.4%). These results are unadjusted for relative differences in survival or patient severity.

Conclusions: The consumption of healthcare resources in patients who underwent sAVR or TAVI was not significantly different in the 12 months following the procedure. On the contrary, in the group of patients who did not undergo a replacement procedure, the consumption of healthcare resources was higher overall and has shown considerable variability depending on the characteristics of the patient and on the frequency of rehospitalisation for cardiovascular causes.

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Clinical and economic outcomes of TAVI vs. balloon aortic valvuloplasty as a bridge therapy: a single-centre experience

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Aims: Although TAVI has proven as a safe and effective therapy for the treatment of aortic stenosis in high-risk patients, reasonable clinical indications to balloon aortic valvuloplasty still exist. In fact, this technique is sometimes indicated as a "bridge" to TAVI that may eventually be performed after clinical recovery in critical patients. We present here the clinical and economic outcomes of patients at prohibitive risk for surgery that have been treated at our centre with TAVI and/or balloon valvuloplasty with this "bridging" intent.

Methods and results: Data of 126 consecutive patients with severe aortic stenosis treated at our centre between 2010 and 2014 were collected and analysed retrospectively. One-hundred and seven patients (84.9%) underwent TAVI as a first choice, while 19 patients (15.1%) received balloon aortic valvuloplasty. Subsequently, 7 of these patients (36.8%) had sufficient clinical recovery and underwent TAVI. Prospective follow-up was collected for a mean of 12.8 months in TAVI patients and for 5.6 months in valvuloplasty patients. On average, TAVI patients were aged 81 years, 73% were in NYHA class III/IV, and had a mean logistic EuroSCORE of 27.9%. Balloon valvuloplasty treated patients were mean-aged 78 years, but had a substantially higher proportion of NYHA class III/IV (95%) and were at higher operative risk (logistic EuroSCORE 37.3%). In-hospital mortality was 2.8% for TAVI and 10.5% for BAV. Median length of hospital stay was similar for both interventions: 9 days on general ward for both, while 2 days and 1 day for TAVI and balloon valvuloplasty patients, respectively, were spent in intensive care unit. During follow-up, there were an average of 0.44 rehospitalisations per TAVI patient with mean length of stay of 14.3 days, while balloon aortic valvuloplasty had 0.63 rehospitalisations per patient with an average length of stay of 22.3 days. For each patient, costs were estimated for the initial procedure and all subsequent hospitalisations. As expected, the index procedure costs were much less for valvuloplasty compared with TAVI (€9,222 vs. €29,400). However, observed follow-up costs at 12 months were just €1,861 for TAVI against €9,474 for aortic valvuloplasty. Based on the projected survival curves at 1, 2 and 3 years, the incremental cost-effectiveness ratio, defined as the difference in cost divided by the difference in life expectancy, was calculated. At 1-year, the incremental cost-effectiveness ratio for TAVI vs. BAV was €61.500 per year of life gained, decreasing to €19.500 by the second year. From the third year, TAVI was anticipated to be more effective and less costly ("dominant" strategy) than aortic valvuloplasty for these extreme-risk patients.

Conclusions: Treatment of severe aortic stenosis with TAVI bears excellent clinical outcomes, at least comparable with those published in literature, even when actually restricted to patients denied surgery due to extreme risk. However, balloon aortic valvuloplasty may be chosen as destination or "bridge" therapy in a limited group of patients at even higher risk that may eventually recover and became TAVI candidates. Despite absolute risk differences, TAVI seems overall a more effective clinical option, and becomes cost-effective compared to balloon aortic valvuloplasty for patients that survive longer than 12 months; therefore, accurate clinical selection of critical patients is mandatory.

Early discharge after transfemoral transcatheter aortic valve implantation

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Aims: The aim of this study was to assess the feasibility and the safety of early discharge (within 72 hours) after transfemoral transcatheter aortic valve implantation (TAVI) and to identify baseline features and/or periprocedural variables, which may affect post-TAVI Length-of-Stay (LoS) duration.

Methods and results: Patients discharged within 72 hours of TAVI (early discharge group) were compared with consecutive patients discharged after 3 days (late discharge group). Propensity-matched cohorts of patients with a 2:1 ratio were created to better control confounding bias. Among 465 patients, 107 (23.0%) were discharged within 3 days of the procedure. Multivariable regression analysis of unmatched patients demonstrated that baseline NYHA IV (OR: 0.22, 95%CI: 0.05-0.96; p=0.045) and any bleeding (OR: 0.31, 95%CI: 0.74-0.92; p=0.031) were less likely to be associated with early discharge after TAVI. Conversely, the year of procedure (OR: 1.66, 95%CI:1.25-2.20; p<0.001) and the presence of a permanent pacemaker (PPM) before TAVI (OR: 2.80, 95%CI: 1.36-5.75; p=0.005) were associated with a higher probability of early discharge. In both unmatched and matched populations, patients in the early discharge group reported lower incidence of in-hospital bleeding, major vascular complications and PPM implantation, whereas after discharge, at 30-day, no significant differences were reported between groups in terms of death, bleeding, PPM implantation, rehospitalisation.

Conclusions: Early discharge (within 72 hours) after transfemoral TAVI is feasible and does not seem to jeopardise the early safety of the procedure, when performed in a subset of patients selected by clinical judgment. Patients undergoing TAVI in unstable haemodynamic compensation and patients experiencing bleeding after the procedure demonstrated to be poorly suitable to this approach, whereas increasing experience in post-TAVI management was associated with a reduction of LoS.

The outcomes of TAVI; revisiting gender equality? Insight from a collaborative, patient-level meta-analysis of 11,310 patients

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Aims: There has been conflicting clinical evidence with respect to the influence of female sex on outcome after transcatheter aortic valve implantation (TAVI). We aimed to assess the impact of gender on clinical outcome in TAVI.

Methods and results: We conducted searches of the published literature using MEDLINE, EMBASE, and the Cochrane library databases through June 2014. A database containing individual patient-level time-to-event data was generated from the registries of each of the studies selected. The primary outcome of interest was all-cause mortality. The safety endpoint was the combined 30-day safety endpoints of major vascular complications, bleeds and stroke as defined by the Valve Academic Research Consortium (VARC) where available. A total of 5 studies and their ongoing registry data with 11,310 patients were included. Women comprised 48.6% of the cohort and had less comorbidities than men. The majority of the overall cohort had a TAVI performed via the transfemoral approach followed by transapical and transsubclavian approaches. Women had a higher rate major vascular complications (6.3% vs. 3.4%, p<0.001), major bleeding (10.5% vs. 8.5%, p=0.003) and stroke (4.4% vs. 3.6%, p=0.029) but a lower rate of significant aortic incompetence (≥ Grade 2; 19.4% vs. 24.5%, p<0.001). There was no difference in procedural or 30-day mortality between women and men (2.6% vs. 2.2%, p=0.24 and 6.5% vs. 6.5%, p=0.93) but female sex was independently associated with improved survival at median follow-up of 387 days (interquartile range [IQR] 192 to 730 days) from the index procedure (adjusted hazard ratio (HR) 0.79 (95% CI: 0.73 to 0.86, p=0.001). Female sex was consistently associated with improved survival regardless of valve type and route of access when sub-analyses were performed in these sub-groups.

Conclusions: Although women experience more bleeding, vascular and stroke complications, female gender is an independent predictor of long-term survival after TAVI. This should be taken into account during patient selection for treatment of severe aortic stenosis.

EuroPCR Interventions for structural heart disease Euro15A-OP331

Self-expanding transcatheter aortic valve: a pathology study

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Aims: We aimed to determine the cause of death and pathological findings at autopsy following CoreValve (CV) TAVI.

Methods and results: Cases from the CV US Pivotal Trial of extreme- and high-risk patients were examined at autopsy. We stratified the groups by time (<30; 30 to 90; and >90 days). Whole hearts and valve explants were radiographed, grossly analysed and scanned by micro-CT. Pathologically, we divided the valve in three zones (inflow, midflow and outflow), and the leaflets by surface (aortic and ventricular). The valve components and the leaflets were independently reviewed and scored for thrombus, inflammation, neointima, degeneration, and calcification. A total 23 cases were analysed. Male were found in 48% (11) of the cases and the mean age was 82.9±9.9 years. Mean implant duration was 90.7±176.6 days. Causes of death <30 days were deteriorating heart failure (HF) in 6/11 (55%), myocardial infarction (MI) in 2/11 (18%), valve thrombosis 2/11 (18%) and procedural in 1/11 (9%). At 30 to 90 days, HF was noted in 5/7 (71%) and MI in 2/7 (29%) patients. At >90 days, HF was confirmed in 4/5 (80%) while a single valve showed endocarditis (20%). Paravalvular gap (PG) was noted at 30 days and absent >90 days. No valve frame fractures were observed on x-rays or Micro CT. Thrombi were greatest at 90 days and declined thereafter while neointimal coverage increased over time peaking at 90 days (score by duration 0 vs. 2 vs. 2.7, p<0.01). Inflammation increased up to 90 days and thereafter a plateau was observed. Neointimal thickening of leaflets increased over time and peaked at 90 days (score by duration 0.006 vs. 0.34 vs. 0.42, p<0.0001). Structural leaflet changes were minimal for all devices. Three valves however, exhibited thrombosis with embolic complication in two. Leaflets inflammation was minimal and peaked at 90 days.

Conclusions: The primary cause of death in patients with CoreValve TAVI was heart failure. Neointimal coverage over frame and leaflets peaked at 90 days. Inflammation and leaflet degeneration were minimal. The decline in clinically observed paravalvular leaks over time was confirmed at autopsy.

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Long-term histopathological changes and durability of Edwards SAPIEN transcatheter aortic valves following implantation in humans

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Aims: Bioprosthetic surgical heart valves have many advantages but pathologic studies have reported limited durability due to calcific and non-calcific deterioration over time. The long-term pathological changes observed in Edwards SAPIEN transcatheter aortic valve (ESTAV) following implantation in humans have not been well characterised.

Methods and results: From our ESTAV pathology registry, 29 cases (mean age 82.6±7.9 years, 52% men) with ESTAV were included, which had been removed either at autopsy or surgery. Valve leaflets were embedded in paraffin, sectioned and stained with haematoxylin and eosin (HE), Movat's pentachrome (MO) and Von Kossa for calcium (VK). Neointima formation, thrombus, inflammation, structural changes (degeneration) and calcification of valve leaflets were evaluated histologically and semi-quantitatively graded for both aortic and ventricular surfaces of the leaflet (Score 0-4). Patients with infective endocarditis were excluded. Pathological finding were assessed by duration (≤30 days; 31 days-1 years; 1-3 years; >3 years) of implant. No patients with valves implanted between 1 and 3 years were available. The mean duration following implantation of ESTAV was 210±500 days. The majority of valves had implant durations ≤30 days and 5 valves implanted beyond 3 years were available for study (≤30 days=20 [69%]; 31 days-1 years=4 [14%]; 1-3 years=0 [0%]; >3 years=5[17%]). Of 29 patients, there were single ESTAV (n=21), ESTAV-in-ESTAV (n=5), and ESTAV-in-surgical aortic valve (n=3). Neointimal growth and structural degeneration of the valve leaflets increased over time but overall changes were mild even beyond 3 years; neointima was primarily observed at the base of the leaflet and structural changes consisted primarily of fluid insudation (overall neointima formation; ≤30 days: 0.02±0.08, 31 days-1 years: 0.13±0.10, >3 years: 0.77±0.09, p<0.0001; degeneration; ≤30 days: 0.02±0.04, 31 days-1 years: 0.11±0.13, >3 years: 0.48±0.49, p=0.0004). Inflammation and thrombus scores for valve leaflets did not differ significantly over time and were generally mild (thrombus; ≤30 days: 0.87±0.54, 31 days-1 years: 0.97±0.61, >3 years: 0.71±0.32, P=0.75, inflammation; ≤30 days: 0.79±0.68, 31 days-1 years: 1.21±0.71, >3 years: 0.98±0.29, p=0.47). Calcification was observed in two valves beyond 3 years: one valve (4 years) showed formation of early microcalcifications in a single leaflet near a commissure; a second valve demonstrated aortic stenosis due to calcification 5 years following implantation.

Conclusions: All explanted valves demonstrated intact leaflets with mild inflammation, thrombus and neointima up to 5 years. Non-calcific degradation was minimal and stenosis due to calcification was seen in only one valve at 5 years, a complication also seen in surgical aortic bioprosthetic valves of similar duration. The pattern of calcification in ESTAV recapitulated that reported for surgical valves with early microcalcifications found predominately at a commissure (region of high stress). Overall, valve leaflet durability for ESTAV appears to be comparable to surgical bioprosthetic valves.

One year clinical comparison of Amplatzer and Occlutech occluders for percutaneous closure of patent foramen ovale

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Aims: To compare the acute and long-term results of patent foramen ovale closure with two occluder devices based on different technologies.

Methods and results: Overall, 363 consecutive patients (48±13 years, 219 women) undergoing percutaneous closure of patent foramen ovale with either the Amplatzer PFO Occluder (n=165) or the Occlutech Figulla Flex (n=198) were enrolled in a multicentre, prospective, registry. All patients were followed-up with contrast transthoracic echocardiogram and clinical evaluation at 24 hours, 6 months and 12 months after the procedure. At baseline, a right-to-left shunt > grade 1 was detected in 82% of patients and atrial septal aneurysm was present in 100 of them. A high procedural and technical success was observed in both groups and no differences were recorded in patent foramen ovale closure efficacy. Despite a trend toward a higher incidence of acute residual shunt immediately after device deployment among patients treated with the Occlutech device, a residual right-to left shunt > grade 1 was observed in 4% of all patients, independently of the device implanted to close the patent foramen ovale. The only difference reported with Occlutech was a significantly lower rate of atrial fibrillation and supraventricular arrhythmias compared to Amplatzer (16.9% vs. 9.0%, p=0.02).

Conclusions: According to this multicentre study, percutaneous closure of patent foramen ovale with the Occlutech Figulla Flex device appears as safe and effective as with the well-established Amplatzer PFO Occluder.

Management of relevant residual shunt following percutaneous closure of patent foramen ovale

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Aims: Residual shunt following percutaneous patent foramen ovale closure has been described in up to 49% of the patients (depending on the device used) and is associated with a higher risk of recurrent cerebrovascular events. Increasing device size and the presence of an atrial septal aneurysm have been identified as predictors. The aim of this study was to investigate the safety, feasibility, and midterm outcome of transcatheter residual shunt closure.

Methods and results: Between April 1994 and April 2014, 2,436 patients underwent percutaneous patent foramen ovale closure at our institution. After 6 months of follow-up, a minimal, moderate or large residual shunt was detected by transoesophageal echocardiography in 7%, 3% and 2%, respectively. In 87 patients (3.6%) a second device was implanted. At baseline, all patients had a right-to-left shunt grade 3 according to transoesophageal echocardiography. The indication for initial patent foramen ovale closure was ischaemic stroke in 46 patients (53%), transient ischaemic attack in 28 (32%), peripheral embolism in 3 (3%), diving accident in 3 (3%), migraine headache in 1 (1%), and others in 6 (7%). Initial and repeat procedures were performed under fluoroscopic guidance only. At first procedure, 7 different devices were used. The Amplatzer PFO Occluder accounted for 82%. The proportion of patients requiring transcatheter residual shunt closure was very variable according to the type of device used, ranging from 3.2% for the Amplatzer PFO Occluder to 11.5% for the Cardia-PFO-STAR. Compared to the whole population, a significantly higher rate of atrial septal aneurysm (59% versus 31%; p<0.001) and a larger size (≥30 mm) of the first implanted device (52% versus 15%; p<0.001) were observed in the patients with relevant residual shunt. Two patients (2%) experienced a recurrent transient ischaemic attack before the second intervention. Residual shunt closure failed in two patients (2%) due to inability to cross the defect. The CardioSEAL Occluder was used in 1 patient (1%), the Lifetech Cera Occluder in 2 (2%), the Sideris Occluder in 2 (2%), the Amplatzer ASD Occluder in 3 (4%), the Amplatzer Vascular Plug in 3 (4%), and the Amplatzer PFO Occluder in the remaining 74 patients (87%). The mean procedural duration was 28±20 minutes including a mean fluoroscopy time of 9±11 minutes. A mean of 83±60 ml of contrast medium were used. There were no procedural or late complications. After 6 months of follow-up, complete closure was achieved in 81% of the patients. Minimal residual shunt persisted in 14%. In four patients with moderate to severe residual shunt (0.2% of the whole cohort), a third procedure was performed resulting in complete closure in all.

Conclusions: Transcatheter residual shunt closure can be safely performed under fluoroscopic guidance only achieving complete closure in most of the patients. A very small number of patients require a third intervention.

EuroPCR Interventions for structural heart disease

Euro15A-OP335

Recurrent cerebral ischaemia after patent foramen ovale percutaneous closure in older patients: a two-centre registry study

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Aims: Registry data and recent randomised trials about patent foramen ovale closure are focused on patients younger than 55 years. The aim of this study is to describe the cerebral ischaemia recurrence rate after percutaneous patent foramen ovale closure in patients older than 55 years and their outcomes, compared with younger patients.

Methods and results: Four hundred and fifty-eight (458) patients underwent PFO closure for cryptogenic cerebral ischaemia and were stratified into an "older" (≥55 years, 151 patients) and a "younger" (<55 years, 307 patients) group. Older patients had a mean age of 63±6 years and more atrial septum aneurysm (p=0.05), hypertension, diabetes and dyslipidaemia (p=0.001). Procedural success was achieved in 100% of cases. Mean follow-up was 4.5±2.8 years (range 19-5,217 days). Older patients had a higher rate of ischaemic recurrence (0.3% vs. 4.0%, p=0.002), after a mean time of 3.1±2.6 years. The Kaplan-Meier curve confirmed an event-free survival significantly higher in the younger group (p=0.008). None of the patients with ischaemic recurrence had significant residual shunt. Age and hypertension were correlated to ischaemic recurrence, but age was the only independent predictor at multivariate analysis. The rates of death, device-related complications, need for a second closure and atrial fibrillation onset were not different in the two subgroups.

Conclusions: Recurrent cerebral ischaemia after patent foramen ovale closure is more frequent in patients above 55 years and most likely related to age itself than to paradoxical embolism. The closure in older patients is as safe as in younger patients, bearing a low rate of procedural and long-term device-related events.

EuroPCR Interventions for structural heart disease

Euro15A-OP336

First human use and intermediate follow-up of a septal occluder with a bioresorbable framework

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Aims: The objective of this study is to investigate the effectiveness and the safety of a new intracardiac septal closure device with biodegradable framework (Carag Bioresorbable Septal Occluder CBSO) in the treatment of secundum atrial septum defects (ASD) or patent foramen ovale (PFO).

Methods and results: Device closure of appropriately indicated ASD & PFO is standard of care in most countries. Current devices use a metal framework and occlusive patch material. Metal frameworks are recognised as the major cause of serious complications (e.g., erosion, perforation, arrhythmia), reported as late as 10 years following implantation. An occluder with bioresorbable framework has long been desired. Until now, successful development and human use of an effective bioresorbable framework has not been achieved. We report on the initial 7 patients implanted with the Carag Bioresorbable Septal Occluder (CBSO) under an approved protocol at the Cardiovascular Center, Frankfurt. The CBSO comprises of a poly lactic-co-glycolic acid (PLGA) monofilament framework with polyester patches attached. Available in 3 sizes (S-M-L), it treats defects ≤25 mm stretched diameter (SD). It is delivered using a 0.018'' guidewire, a 12 Fr transseptal sheath and fluoro/TEE guidance. The first in human trial is a single centre clinical investigation in up to 15 adults with clinically significant ASD/PFO, SD ≤25 mm, and (for PFO) tunnel length ≤4 mm. Follow-up at 1, 6, 12 and 24 months includes clinical examination, cardiac ultrasound, ECG & blood studies. Closure effectiveness is determined by TEE at 6 months. Recruitment of patients is ongoing. Seven patients (5 male / 2 female), age 49.5±9.6 years have been treated. PFO (n=6) ranged from 4.5 to 9.9 mm in diameter. A small CBSO (device diameter 26 mm) was used in all PFO cases. ASD (n=1) was 22 mm with balloon sizing. A large CBSO (device diameter 33 mm) was used. All devices were successfully implanted without complication. Average time for loading and placement of the device was 27.1±13.0 minutes. Valsalva bubble study shows complete closure in 4 of 5 PFO patients at 1 month and 3 of 4 at 6 months. The one residual shunt is classified as small to moderate. Colour Doppler studies showed complete closure of the ASD after 1 month. There have been no complications and no arrhythmias during follow-up.

Conclusions: A septal occluder with bioresorbable framework (CBSO) can be readily implanted in humans with excellent acute and early follow-up results. Additional patients and longer follow-up is needed to assess long-term outcomes. A device with bioresorbable framework has been achieved.

Predictors of procedural failure in patients undergoing percutaneous closure of large atrial septal defects

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Aims: Owing to their more complex anatomy, large atrial septal defects (ASD) can present unique challenges for percutaneous closure. Previous reports observed a much higher procedural failure rate in this specific subgroup when compared to small and moderate defects. We sought to determine clinical and anatomical predictors of procedural failure in patients undergoing percutaneous closure of large ASDs (>24 mm) using the Amplatzer™ Occluder device (St.Jude Medical Inc., St. Paul, MN, USA).

Methods and results: Adult patients referred between January 2006 and August 2012 for percutaneous closure of a secundum ASD with a stretched diameter higher than 24 mm were included in this study. Clinical, imaging and procedural data were retrospectively collected from index admission to last follow-up. Patients underwent ASD closure according to standard indications under transoesophageal and fluoroscopic guidance. Procedural success was defined as deployment of prosthesis with no significant shunt and no major complication. A total of 90 patients, mean age 47±16 years, 60% female, met inclusion criteria. Patients presented with right heart failure symptoms in 81.1% of cases, 93.3% had right ventricular enlargement and 7.8% had a prior embolic event. Median non-stretched and stretched ASD diameters were 24.0 mm (IQR: 20-28) and 29.0 mm (IQR: 25.5-34) respectively. Procedural success rate was 81.1%. One patient (2.2%) required emergent surgery because of a ruptured septum after sizing-balloon inflation resulting in cardiac tamponade. During a median follow-up of 19.5 months, we observed 4 (4.4%) episodes of systemic thrombo-embolism, 5 (5.5%) episodes of new onset supraventricular tachyarrhythmias, no cardiac erosion, no device embolisation and no cardiovascular death. In univariate logistic regression, predictors of procedural failure were non-stretched diameter (OR=1.25 per mm; p=0.0002), stretched diameter (OR=1.6 per mm; p<0.0001), absence of any type of margin (OR=4.8, p<0.0001) and absence of postero-inferior margin (OR=39.3; p<0.0001). Multivariate regression analysis identified non-stretched diameter (OR=1.17 per mm; p=0.05), absence of any type of margin (OR=5.25; p=0.0004) and absence of postero-inferior margin (OR>100, p=0.05) as independent predictors of procedural failure.

Conclusions: In our cohort, percutaneous closure of large ASDs was feasible in most with favourable periprocedural and long-term safety profile. However, procedural success rate was lower when compared to previous reports including small and moderate defects. A sizeable unstretched diameter, absence of any type of margin and more specifically absence of postero-inferior margin were independently associated with procedural failure. These characteristics can be assessed prior to the procedure and could improve patient selection for percutaneous ASD closure.

Comparison between the two strategies to close atrial septal defects with less invasion

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Aims: Both percutaneous atrial septal defect (ASD) occlusion and minimally invasive cardiac surgery (MICS) closure have proved to be safe and effective, but there have been few reports of comparing the two techniques. The goal of this study was to evaluate percutaneous interventional and MICS surgical closure of secundum ASD in adults.

Methods and results: All patients who underwent either percutaneous ASD occlusion or MICS surgery at our hospital between December 2000 and December 2013 were included. Percutaneous ASD occlusion was carried out from March 2011 onward. In the device group, either transoesophageal echocardiography or intracardiac echocardiography was used for intraprocedural guidance. The Amplatzer septal occluder is the only approved device in our country and thus it was the device used. In the MICS surgery group, the multiple small incisions or ports in the chest wall were the only route to reach the heart and closure of the ASDs were performed either by direct closure or patch closure. A total of 134 patients underwent percutaneous ASD occlusion and 220 patients underwent MICS surgery. We reviewed the records of secundum ASD patients older than 10 years old at the time of the closure. The procedure attempt success rate was 98% for the device group and 100% for the MICS group. In one case, the ASD was too large for the available device and in the other case the atrial rim was insufficient. In the MICS group, there was no conversion to a full sternotomy. The mean length of hospital stay was 3.6 days for the device group and 7.3 days for the MICS group. Patients in the device group had significantly shorter hospital stay. (p<0.001). There was no surgical or device related death in either group. Major complications occurred in one patient (0.7%) in the device group and eight (3.6%) in the MICS group (p=0.161). The major complication in the percutaneous closure group was one pulmonary oedema. The major complications in the MICS group were; cardiac arrhythmias requiring major treatment in two patients, cerebral infarction in 3 patients, procedural myocardial infarction in one patient, and repeat surgery for wound complication in one patient. Minor complications occurred in 16 patients (11.9%) in the percutaneous group and 46 (20.9%) in the port access MICS group (p=0.032). Multivariate analysis to test the role of risk factors in occurrence of total complications was performed using multiple logistic regression. The following independent variables were used in the univariate analysis: age at surgery, type of repair (MICS/percutaneous closure), sex (female/male), weight, medical history: congestive heart failure, hypertension, diabetes, coronary heart disease, pulmonary artery systolic pressure, Qp/Qs and ASD size. At logistic regression multivariable analysis, the selection of MICS surgery/percutaneous closure (HR: 3.001, 95% CI: 1.546-5.826; p=0.001) and older age (HR: 1.026, 95% CI: 1.008-1.044; p=0.028) were independently associated with increase in the outcome complications.

Conclusions: The percutaneous device closure and MICS surgery can both be performed with acceptable clinical results, but the percutaneous closure is less invasive and could be performed with less complications as well as shorter hospital stays.

EuroPCR Interventions for structural heart disease Euro15A-OP340

Outcomes of patients undergoing balloon aortic valvuloplasty in the TAVI era: a multicentre registry

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Aims: The introduction of transcatheter aortic valve implantation (TAVI) has generated a renewed interest in the treatment of high-risk patients with severe aortic stenosis and serious contraindication for aortic valve replacement. This study describes the indications and long-term outcomes of balloon aortic valvuloplasty in recent years.

Methods and results: All patients undergoing BAV in our centres from 2005 to 2013 were enrolled. All-cause death at follow-up were the primary endpoint, while need of re-intervention, myocardial infarction and stroke the secondary ones, along with periprocedural complications according to VARC criteria (death, bleeding, vascular complications, acute kidney injury). Among 586 consecutive patients, balloon aortic valvuloplasty as bridge to TAVI was performed in 277, (47.3%), as bridge to surgical aortic valve replacement in 71 (12.1%) and as destination therapy in 238 (40.6%). Median age wad 82.1±7.4 years, 54.1% of them being female, with a median ejection fraction of 48.3±15.8%. In-hospital mortality was 8.5%, 5.2% after excluding patients presenting with cardiogenic shock, consisting of acute kidney injury (10.7%) as the most frequent complication. Cardiogenic shock and a renal clearance below 60 ml/min/m^2 were independent predictors of all-cause death in a multivariate analysis. After a median follow-up of 240 days, 31.4% of patients died, 5.6% were rehospitalised for heart failure and 33.8% performed a new intervention (10.1% repeated balloon aortic valvuloplasty, 71.2%TAVI, 18.7% surgical aortic valve replacement). Echocardiography showed that the medium and peak transaortic gradients decreased after valvuloplasty from 46 mmHg (IC 44.3-48.2) to 39 mmHg (IC 37.8-44), and from 78 mmHg (IC 74.8-81.5) to 59 mmHg (53-64) respectively. After 6 months, medium gradient was 36 mmHg (IC 28.7-38.1) and peak gradient 54 mmHg (IC 46.4-62.9), showing durability of the valvuloplasty. Aortic valve area increased after valvuloplasty from 0.67 cm^2 (IC 0.64-0.69) to 1.50 cm^2 (IC 1-1.9) and 0.95 cm^2 (IC 0.8-1) after 6 months.

Conclusions: Balloon aortic valvuloplasty is nowadays safe and effective, with a durable effect in the reduction of transaortic valve gradient. Clinically, after 10 months follow up, no reintervention is needed in most of these patients.

EuroPCR Interventions for structural heart disease Euro15A-OP341

Balloon aortic valvuloplasty for patients with cardiogenic shock: insights from the TAVI era

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Aims: Patients with severe aortic stenosis presenting with cardiogenic shock are exposed to a high risk of death after the onset of symptoms but are often denied surgical intervention due to unacceptable intra/perioperative risks. Balloon aortic valvuloplasty may represent a feasible option although little contemporary evidence is available.

Methods and results: Among all the 811 patients undergoing balloon aortic valvuloplasty for severe aortic stenosis in our centres, 18 (2.2%) presented with cardiogenic shock. Symptom relief was immediately observed in all patients undergoing successful aortic valvuloplasty. After the procedure, peak gradient significantly decreased from 64±20 to 43±14 mmHg (p=0.01), mean ejection fraction raised from 26±13% to 39±20% (p=0.03). Creatinine clearance increased from 40±28 to 50±18 ml/min. Total in-hospital mortality was 39% (7 of 18 patients). After a mean follow-up of 227±157 days, 2 more patients died. Two patients underwent TAVI and one aortic valve replacement, respectively 36, 66 and 70 days after valvuloplasty. The Kaplan-Meier curve showed a cumulative survival of 47.6±12.4% at 17 months.

Conclusions: Balloon aortic valvuloplasty is a feasible option in patients with aortic stenosis and cardiogenic shock and may be undertaken with an acceptable risk even in the most critical clinical situations. The procedure relieves the symptoms and permits the left ventricular function to improve and the haemodynamic profile to stabilise, allowing the assessment of the risk of further aortic valve intervention and the bridge towards TAVI or aortic valve replacement.

Balloon aortic valvuloplasty as a bridge-to-decision in high-risk patients with severe aortic stenosis

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Aims: To analyse the role of percutaneous balloon aortic valvuloplasty in the decision-making of patients with severe aortic stenosis and high-risk features or potential contraindications to transcatheter aortic valve implantation (TAVI) and surgical aortic valve replacement.

Methods and results: Among 645 balloon aortic valvuloplasty procedures performed at our institution between July 2007 and December 2012, 202 patients underwent the procedure as a "bridge-to-decision", motivated by the presence of a potentially reversible contraindication to a definitive treatment such as aortic valve replacement or TAVI. The indication was based on the Heart Team recommendation in all cases, and a second clinical, cognitive and echo evaluation was planned at 1 month. Patients were divided in five subgroups according to the main clinical condition which prevented the final decision-making at first evaluation (some patients belong to more than one group): 1) low ejection fraction (defined as left ventricular ejection fraction, LVEF≤30%) (n=44); 2) moderate/severe to severe (≥3+) mitral regurgitation, MR (n=33); 3) haemodynamic instability (NYHA class IV and/or pulmonary oedema and/or cardiogenic shock) (n=103); 4) frailty, defined by the Frailty Index of Rockwood score 3 or 2 if associated with defined comorbidities) (n=13); 5) major comorbidities (pulmonary hypertension >60 mmHg, indication to major non cardiac surgery, etc.) (n=47). Procedural outcome was: vascular complications 10 (5%), stroke 2 (1%), acute severe aortic regurgitation 2 (1%), in-hospital deaths 9 (4.5%). After re-evaluation: LVEF improved in 68% and mitral regurgitation in 51.5% of cases. Haemodynamic instability was solved in 72%, frailty "reduced" in 69.2%, and patients with comorbidities reclassified to a better profile in 47.8% of the cases, respectively. After multidisciplinary re-evaluation, 140 patients (69%) became suitable for a definitive treatment (24% AVR, 45% TAVI).

Conclusions: Balloon aortic valvuloplasty plays a pivotal role as a "bridge-to-decision" in high-risk patients with severe aortic stenosis who cannot be immediately candidate to a definitive treatment.

Repeated balloon aortic valvuloplasty in elderly patients with aortic stenosis who are not candidate to surgical or transcatheter aortic valve replacement

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Aims: A sizable group of patients with symptomatic aortic stenosis (AS) are not suitable for both surgical aortic valve replacement (AVR) and transcatheter aortic valve implantation (TAVI). The aim of this study was to assess the potential role of repeated balloon aortic valvuloplasty (BAV) in these patients.

Methods and results: Within the prospective BAV registry of the University Hospital of Bologna, Italy, we retrospectively selected 105 patients who underwent ≥2 BAV procedures between 2005 and 2012, for a total of 224 BAV (3 BAVs in 9.5%, 4 BAVs in 2.8%, 5 BAVs in 0.9%). Indication for the first BAV was made by the local Heart Team. The repeated procedures were always driven by symptoms recurrence in the presence of persisting contraindication to definitive treatment. All procedures were performed with the Cristal Balloon™ (Balt, Montmorency, France) using the standard retrograde technique. We assessed the in-hospital outcome for all procedures and the incidence of adverse events at 1, 2 and 3 years after the first BAV according to the Valve Academic Research Consortium (VARC) 2 definitions. Mean age was 84±6 years, logistic EuroSCORE 23.6±13.4 years. No intraprocedural death occurred. In-hospital events for the 224 BAV procedures were: MI 4%, stroke 0.9%, vascular complications 8% (1.8% major, 6.2% minor), bleedings 5.9% (life-threatening 0.9%, major bleedings 1.8%). Acute aortic regurgitation occurred in 6 cases (2.7%) and it was always managed and resolved during the procedure. Median follow-up was 785 days (IQR 518-1286). Average time between the first and the second BAV was 409 days, and 301 days between the second and the third one. Interestingly, the second BAVs were associated with less vascular complications ($p<0.0001$) and bleedings ($p<0.0001$), without significant difference for other events. Bleedings (OR: 6.88; CI 95%: 1.58-29.88) and vascular complications (OR: 4.8; CI 95%: 1.19-19.31) occurred after the first procedure were independent predictors for adverse events during the repeated procedures. All-cause mortality at 1, 2 and 3-year were 15.2%, 41.3% and 57.2%, respectively. Hospital re-admission for heart failure, including BAV repetition, was 40.7% at one year, 61.7% at 2 years, and 77.6% at 3 years follow up.

Conclusions: Standalone BAV is associated with poor long-term clinical outcome. However, when no other therapeutic options are feasible, a strategy of repeated palliative BAV appears to be safe and might be associated with improved clinical outcomes.

Interventions for structural heart disease Euro15A-OP344

Predictors of early restenosis after intracardiac echocardiography guided antegrade balloon aortic valvuloplasty in high-risk or inoperable patients

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Aims: Antegrade BAV may be more effective than retrograde balloon aortic valvuloplasty (BAV). However, occasional early restenosis (ER) is found within three month after BAV. To evaluate the factor of ER after intracardiac echocardiogram (ICE) guided antegrade BAV.
Methods and results: Fifty patients with severe aortic stenosis (AS) underwent antegrade BAV procedures with ICE. ICE was used in transseptal puncture and for the measurement of aortic annulus, intraprocedural monitoring of aortic or mitral regurgitation and pericardial effusion. ER was defined as mean aortic valve pressure gradient (PG) >40 mmHg. There were no cases of intraprocedural deaths, arrhythmia, ischaemic complications or heart failure. After discharge, no patient deaths were reported in the following 30 days. However, during this nearly one-year follow-up period, 6 patients died and 2 patient underwent aortic valve replacement. Reasons for deaths were 2 cardiac, 2 pneumonia, 1 cancer, 1 stroke. Two cardiac deaths were caused by congestive heart failure due to severe aortic stenosis. Of these, the mean aortic valve PG was >40 mmHg in 13 (26%). Procedural, clinical and haemodynamic data were collected. The mean age of the patient population was 85.4±7.6 years, the mean STS score and EuroSCORE were 7.8±1.1 and 14.6±4.1, respectively. The mean aortic valve PG decreased from 63.4±19.8 mmHg to 28.5±10.1 mmHg ($p<0.0001$). Baseline characteristics were similar between the two groups. There is no significant difference of mean aortic valve PG immediate after BAV (ER; 30±8.8 mmHg, non-ER; 20±6.1 mmHg, p=ns). Univariate analysis showed patients with ER group had significantly higher rate of left ventricular hypertrophy (especially posterior wall), pulmonary hypertension and high mean aortic valve PG at admission ($p<0.05$). Multivariate analysis revealed high mean aortic valve PG at admission as independent predictors of ER.
Conclusions: ICE guided antegrade BAV may be effective for severe AS. However, left ventricular hypertrophy (especially posterior wall), pulmonary hypertension and high mean PG at admission were predictor of ER. Early intervention should be considered for these patients.

Interventions for structural heart disease Euro15A-OP345

How to predict mortality in patients undergoing transcatheter aortic valve replacement: development of a score system based on data of the German Aortic Valve Registry (GARY)

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AIMS Based on data from the German Aortic Valve Registry (GARY) a novel scoring system to predict peri-interventional and one-year mortality in patients undergoing transcatheter aortic valve replacement was developed.
Methods and results: This ongoing, non-randomised national multicentre registry includes of 3,875 patients undergoing TAVI. In-hospital mortality was chosen as a binary outcome measure. First, potential risk factors were tested in an univariate manner by Fisher's exact test for significant influence on mortality and multiple logistic regression with backward and forward selection. Calibration was ascertained by the Hosmer-Lemeshow method. In order to define the quality of discrimination, the area under the receiver operating characteristic (ROC) curve was calculated. In 3,772 of the 3,875 (97.3%) patients, survival status was known and in 3,221 (85.4%) a complete data set was available. One-year mortality was 22.7% (n=730) for all patients. Based on multiple logistic regression, 22 risk factors impacting mortality were identified, including age, body mass index and left ventricular function categorised in two (left ventricular function) or three subgroups (age). The area under the ROC curve with a value of 0.712 affirmed the quality of discrimination of the established scoring model.
Conclusions: Based on GARY data the above model allows the prediction of 1-year mortality after TAVI in low-, moderate- and high-risk groups, thus supporting continuous improvement of patient selection for interventional aortic valve procedures.

Risk stratification in patients undergoing TAVI: logistic European system for cardiac operative risk evaluation score, the European system for cardiac operative risk evaluation II score, the Society of Thoracic Surgeons score and the German aortic valve registry score

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Aims: The aim of our study was to compare the prognostic performance of 4 risk scores (logistic European system for cardiac operative risk evaluation [EuroSCORE], European system for cardiac operative risk evaluation II [EuroSCORE II], Society of Thoracic Surgeons [STS] score and German aortic valve registry score [GARY]) to predict short and long-term outcomes in patients undergoing TAVI.

Methods and results: Five hundred and twenty (520) consecutive patients underwent TAVI at our institution. Co-primary endpoints of our study were all-cause mortality at 30 days and at 2 years. Follow-up data were collected during routine outpatient visits (after 3, 12, and 24 months), from hospital discharge letters, or via telephone interviews with the referring cardiologists or primary care physicians. The logistic EuroSCORE, EuroSCORE II, STS score and GARY scores were all calculated according to the published algorithms. These 520 consecutive high-risk patients reflected by a mean logistic EuroSCORE (24.8±16.6), EuroSCORE II (6.3 [3.8-10.8]), STS score (6.5 [4.1-10.5]), and GARY score (4.7 [2.9-9.5]) underwent TAVI. All-cause mortality at 30 days and at 2 years was 5.4% (28/520) and 24.4% (127/520), respectively. Patients who died during the first 2 years of follow-up had significantly higher risk scores than patients who survived (P<0.001 for all risk scores). The GARY score was highly correlated with logistic EuroSCORE (r=0.64) and the STS score (r=0.73), but only moderately with the EuroSCORE II (r=0.48). In receiver operating characteristics curve analysis, the logistic EuroSCORE (area under the curve 0.72, 95% CI: 0.57-0.86) had the highest area under the curve for the prediction of 30-day mortality compared to the other risk scores: EuroSCORE II (0.67, 95% CI: 0.53-0.81), STS score (0.67, 95% CI: 0.53-0.81), and the GARY score (0.70, 95% CI: 0.58-0.82), but was only poorly calibrated, as it largely overestimated the 30-day mortality rate. For the prediction of 2-year mortality, the logistic EuroSCORE (area under the curve 0.74, 95% CI: 0.69-0.81) again had the highest area under the curve compared to the other risk scores: EuroSCORE II (0.69, 95% CI: 0.63-0.76), STS score (0.73, 95% CI: 0.67-0.79), and the GARY score (0.73, 95% CI: 0.67-0.79) showed good calibration for this non-prespecified endpoint.

Conclusions: Aortic valve-specific risk scores such as the German aortic valve registry (GARY) score are promising and show good results in daily clinical practice. However, they still need better calibration and validation in an independent dataset.

Impact of pulmonary hypertension haemodynamic presentation on clinical outcomes in patients with severe symptomatic aortic valve stenosis undergoing transcatheter aortic valve implantation: insights from the new proposed pulmonary hypertension classification

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Aims: Pulmonary hypertension (PH) frequently co-exists with severe aortic stenosis (AS) and PH severity has been shown to predict outcomes after transcatheter aortic valve implantation (TAVI). The impact of PH haemodynamic presentation on clinical outcomes after TAVI is unknown.

Methods and results: Of 606 consecutive patients undergoing TAVI, 433 (71.4%) patients with severe AS and a pre-procedural right heart catheterisation were assessed. Patients were dichotomised according to whether PH was present (mean pulmonary artery [PA] pressure ≥25 mmHg) (n=325) or not (n=108). PH patients were further dichotomised by left-ventricular end-diastolic pressure (LVEDP) into post-capillary (LVEDP >15 mmHG; n=269) and pre-capillary groups (LVEDP ≤15 mmHg; n=56). Finally, post-capillary PH patients were divided into isolated (n=220) and combined (n=49) subgroups according to whether the diastolic pressure difference was normal (<7 mmHg) or elevated (≥7 mmHg). Primary-endpoint was mortality at 1-year. PH was present in 325/433 (75%) patients and was predominantly post-capillary (n=269/325; 82%). Compared with baseline, PA systolic pressures immediately improved after TAVI in post-capillary combined (57.8±14.1 vs 50.4±17.3 mmHg, p=0.015), but not pre-capillary (49.0±12.6 vs 51.6±14.3, p=0.36) patients. As compared with no PH, a higher 1-year mortality rate was observed in both pre-capillary (hazard ratio [HR] 2.30, 95% confidence interval [CI] 1.02-5.22, p=0.046) and combined (HR 3.15, 95% CI 1.43-6.93, p=0.004) but not isolated PH patients (p=0.11). Following adjustment, combined PH remained an independent predictor of 1-year mortality after TAVI (HR 3.28, p=0.005).

Conclusions: Invasive stratification of PH according to haemodynamic presentation predicts acute response to treatment and long-term mortality after TAVI.

EuroPCR Interventions for structural heart disease Euro15A-OP348

Soluble ST2 for risk stratification and the prediction of mortality in patients undergoing transcatheter aortic valve implantation

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Aims: Transcatheter aortic valve implantation (TAVI) may lead to substantial reductions in mortality and morbidity in carefully selected patients. However, up to 50% of the patients die during the first year after the procedure. Soluble ST2 (sST2) is a novel biomarker of mechanical stress measurable in serum that has been shown to be physiologically linked to cardiac hypertrophy, fibrosis, and ventricular dysfunction and, therefore, could be considered as a parameter for further risk stratification in patients suffering from symptomatic aortic valve stenosis. The aim of our study was to assess the prognostic performance of sST2 for short- and long-term mortality and whether this biomarker is suitable for risk stratification in TAVI patients.

Methods and results: Four hundred and sixty-two (462) patients underwent TAVI after Heart Team discussion at our heart centre. In all patients, serum creatinine, troponin I, and NT-proBNP levels were measured before the procedure. Serum samples were stored at -80°C and thawed once for the measurement of sST2. Intra-hospital mortality after TAVI was the primary endpoint of our study. Other outcomes were recorded according to the recently updated VARC-2 criteria. Follow-up data were collected during routine outpatient visits (after 3, 6, and 12 months), from hospital discharge letters, or via telephone interviews with the referring cardiologists or primary care physicians. No patient was lost to follow-up. In 462 TAVI patients, we found a median baseline sST2 level of 20.0 (14.0-29.0) ng/ml. Elevated sST2 levels were significantly associated with both intra-hospital mortality (survivors: 19.8 (13.8-28.2) ng/mL vs. non-survivors: 24.5 (16.3-38.9) ng/mL; p=0.027) and all-cause mortality at 1 year (survivors: 19.0 (13.6-27.2) ng/mL vs. non-survivors: 22.4 (15.4-36.4) ng/mL; p=0.005). In receiver operating characteristic (ROC) curve analysis, sST2 (area under curve (AUC): 0.63 [95% CI: 0.51-0.71]) had the highest AUC for the prediction of all-cause mortality at 30 days compared with other cardiac biomarkers (troponin: AUC 0.53 (95% CI: 0.41-0.66); NT-proBNP: AUC 0.60 (95% CI: 0.49-0.72); creatinine: AUC 0.59 (95% CI: 0.47-0.70). We then stratified our patient cohort according to the median level of NT-proBNP (2,960 pg/mL) and the sST2 cut off value of 35 ng/mL (as suggested in the literature) in four groups. Patients with an elevation of both biomarkers had a significantly worse prognosis compared with other risk groups in Kaplan-Meier analysis (1-year mortality: 37.3% vs. 15.4%, 24.7%, and 19.0%; p=0.001).

Conclusions: Baseline sST2 is strongly associated with adverse short-term outcome after TAVI and might be useful for the prediction of intra-hospital outcome. Soluble ST2 provides additional prognostic information beyond established biomarkers such as NT-proBNP for the prediction of 1-year outcome after TAVI.

EuroPCR Interventions for structural heart disease Euro15A-OP349

B-type natriuretic peptides and long-term outcomes following transcatheter aortic valve implantation

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Aims: Natriuretic peptides increase in patients with aortic stenosis and predict short-term outcomes following transcatheter aortic valve implantation (TAVI). The long-term predictive impact of B-type natriuretic peptide (BNP) and the relative prognostic utility of single vs. serial peri-interventional measurements of BNP and amino-terminal-pro-BNP (NT-pro-BNP) are unknown. This study sought to determine the impact of BNP levels on long-term outcomes following TAVI, and to compare utility of BNP vs. NT-pro-BNP measured pre- and post-intervention.

Methods and results: A total of 340 patients with severe, symptomatic aortic stenosis and baseline, pre-TAVI assessment of BNP were analysed. In 219 patients, BNP and NT-pro-BNP were measured serially pre- and post-intervention. Patients were followed for 2 years and Valve Academic Research Consortium-2 defined outcomes were recorded. Patients with high baseline BNP (higher tertile, >591 pg/ml) had increased risk of all-cause mortality (adjusted hazard ratio [HR]: 3.16, 95% confidence intervals [CI]: 1.84-5.42; p<0.001), cardiovascular death (adjusted HR: 3.37, 95% CI: 1.78-6.39; p<0.001) and the composite of death, myocardial infarction or stroke at 2 years (adjusted HR: 2.61, 95% CI: 1.50-4.55; p<0.001). Outcomes were most unfavourable in patients with persistently elevated BNP levels pre- and post-intervention. Comparing single measurements of the two biomarkers, NT-pro-BNP levels assessed post-TAVI showed the highest prognostic discrimination for 2-year mortality (area-under-the-curve: 0.75; p<0.01). Baseline-to-discharge reduction of BNP, but not of NT-pro-BNP, were related to greater New York Heart Association functional improvement over 2 years.

Conclusions: High pre-intervention BNP independently predicts 2-year outcomes following TAVI, particularly when elevated levels persist following the intervention. BNP and NT-pro-BNP and their serial periprocedural changes provide complementary prognostic information for symptomatic improvement and survival.

Stent-graft implantation in ileofemoral arteries for treatment of access-site bleeding following transcatheter aortic valve implantation

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Aims: Transcatheter aortic valve implantation (TAVI) is commonly performed in patients with severe aortic stenosis who are at high-surgical-risk. TAVI is usually performed via transfemoral vascular access; however, these patients have a high burden of atherosclerotic disease. Access-site bleeding is a common complication of TAVI and is associated with increased morbidity and mortality. Percutaneous ileofemoral stent-graft implantation enables percutaneous intra-procedural control of bleeding without need for surgical repair; however, the safety and efficacy of this approach are unknown.
Methods and results: From our prospective institutional TAVI registry, we identified patients who had undergone intra-procedural ileofemoral stent-graft implantation due to access-site bleeding. Follow-up was performed from a computerised database and TAVI clinic visits. Of 192 TAVI procedures performed at our institute, 181 (94%) cases were performed via transfemoral access. Closure of the femoral artery puncture site was performed with the Prostar device (Abbott Laboratories). Angiography was routinely performed following sheath removal for identification of bleeding. Persistent ileofemoral bleeding was identified in 29 (16%) patients and was treated with implantation of 34 stent-grafts. Mean patient age was 81±7 years and 18 patients (62%) were female. In 32 patients, bleeding was due to failure of the Prostar device and in 2 patients it was due to iliac artery trauma. Stenting was confined to the common femoral artery in 23 patients and included the external iliac artery in six patients. Bleeding was successfully controlled in all cases. A single periprocedural complication occurred in a morbidly obese woman with severe retroperitoneal haemorrhage in whom the stent-graft was implanted across the origin of the superficial femoral artery, who developed mild ischaemia in the right leg with perfusion of the distal limb via collaterals. During follow-up of 536±44 days (range: 18-1517) no additional vascular complications occurred and no vascular interventions were required.
Conclusions: Ileofemoral stent-graft implantation provided effective percutaneous control of severe access site bleeding following transfemoral TAVI with minimal periprocedural complications. Mid-term safety of ileofemoral stent-graft implantation was excellent.

Percutaneous treatment of femoral-iliac artery dissection/rupture after TAVI using a covered stent as a bailout procedure: a single centre experience and 1-year follow-up

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Aims: Vascular access and bleeding complications (dissection, perforation and haematoma) are reported to occur in up to 15% of patients undergoing transcatheter aortic valve implantation (TAVI) and are associated with significantly higher 30-day rates of complications. Femoral artery or iliac rupture may require emergency surgical intervention; however, contralateral self- or balloon-expandable bare or covered stent implantation may suffice in most cases to obtain haemostasis. We report a consecutive series of 35 patients treated percutaneously with the crossover technique at our centre.
Methods and results: In patients undergoing TAVI a digital subtraction angiography of the iliac-femoral artery used for access was routinely performed at the end of the procedure, before sheath removal. In 35 cases (mean age 82+2.1; mean L-EuroSCORE 31%; male 40%) arterial perforation or dissection of the iliac-femoral access was evident by angiography. After partial neutralisation of heparin with protamine, in crossover through the contralateral femoral artery, a covered stent was advanced and expanded at the level of the rupture. Successful closure of the vascular artery was obtained without other complications. After 1 year from the procedure, follow-up visits and ultrasounds at the vascular access site were performed. In all cases, the stents were patent without significant intimal hyperplasia.
Conclusions: Percutaneous management of vascular complication after TAVI using a covered stent as a bailout procedure is safe, with high rates of technical success and favourable long-term clinical outcomes. Peripheral covered stents remain patent at 1-year follow-up in all cases.

EuroPCR Interventions for structural heart disease Euro15A-OP352

Comparison of suture-based vascular closure devices in transfemoral transcatheter aortic valve implantation

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Aims: No studies comparing two vascular closure devices (VCD), Prostar and ProGlide (Abbott Vascular Devices, Redwood City, CA, USA), have been published so far. The aim of this study was to compare outcomes with the use of two haemostasis strategies after transfemoral transcatheter aortic valve implantation (TAVI) using them: 1 Prostar vs. 2 ProGlide.

Methods and results: This is a retrospective study enrolling consecutive patients undergoing fully percutaneous transfemoral TAVI in our centre (Ferrarotto Hospital, Catania, Italy) from January 2012 to October 2014. All patients were dichotomised according to the VCD used for common femoral artery haemostasis (Prostar vs. ProGlide). All outcomes were defined according to VARC-2 criteria. Study population encompassed a total of 278 patients. Of these, 153 (55.1%) underwent TAVI using the Prostar and 125 (44.9%) using the ProGlide. Vascular complications occurred in 48 patients (17.3%), being more frequent in the ProGlide group (11.8% vs. 24.0%, p=0.007). Patients who had TAVI using the ProGlide were also more likely to have a higher rate of percutaneous closure device failure (4.6% vs. 12.8%, p=0.013). Percutaneous peripheral intervention was performed in 13.7% and 28.0% of Prostar and ProGlide cases, respectively (p=0.003). No differences were reported in terms of unplanned vascular surgery, in-hospital mortality, bleeding and stroke (all p=NS).

Conclusions: Patients undergoing transfemoral TAVI had significantly lower rates of vascular complications and percutaneous closure device failures when the Prostar was used as with ProGlide. The use of Prostar was not associated with reduced mortality, bleeding and stroke rates during hospitalisation.

EuroPCR Interventions for structural heart disease Euro15A-OP353

Transapical access closure of transcatheter aortic valve implantation: a patient-specific mathematical model of suture closure tension

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Aims: Transcatheter aortic valve implantation (TAVI) is widely adopted for treatment of severe aortic stenosis in high-risk and inoperable patients. In nearly 90%, the preferred approach is transfemoral. The transapical approach is primarily reserved for patients receiving SAPIEN XT or 3 (Edwards Lifesciences, Inc., Irvine, CA, USA) with unsuitable vascular access from severe peripheral artery disease, calcification or tortuosity. While select centres are strong advocates of the transapical approach, the risks of apical tearing and rupture are of concern in frail elderly patients. The goal of our study was to develop a mathematical model that would determine apical closure tension to provide pre-surgical evaluation of apical rupture risk.

Methods and results: A TAVR patient was recruited and underwent preoperative cine-cardiac magnetic resonance imaging (MRI) to acquire 3D left ventricular geometry at end-systole and end-diastole. Boundaries of the epicardium and endocardium were manually contoured using MeVisLab, an imaging processing tool. The 3D endo- and epicardial surfaces were reconstructed and 3D surfaces at end-systole were imported into TrueGrid to create a patient-specific left ventricle finite element (FE) mesh. A 10 mm transapical access opening was created in the FE model, and the hole was closed using a virtual suture technique in the FE analysis. Two horizontal mattress virtual sutures were applied. The LV model underwent diastolic filling and systolic contraction for FE analysis of suture tension. The virtual suture technique successfully closed the apical access site. The peak axial force on the virtual sutures at end-diastole and end-systole was 0.042 N and 0.112 N, respectively.

Conclusions: We developed the first mathematical model to evaluate the suture forces of transapical access site closure. Further development of this approach in relation to myocardial mechanics will be critical to allow pre-surgical evaluation of apical rupture risk.

Acute and 30-day results of the STASIS trial: a multicentre study on a novel apical closure device for transapical transcatheter aortic valve implantation

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Aims: Transapical access for transcatheter aortic valve implantation (TA-TAVI) has become a routine procedure for patients at high surgical risk and is a valid alternative to transfemoral TAVI. Transapical access has seen little standardisation of technique due to the absence of automated preclosure and carries a risk for bleeding complications. Here we describe the use of a novel device designed to facilitate safe and reliable, automated transmyocardial access and closure during structural heart interventions such as TA-TAVI.

Methods and results: A total of 30 patients in four German centres underwent transapical TAVI through mini-thoracotomies using the Permaseal closure device (STASIS trial). All patients received Edwards SAPIEN 3 or SAPIEN XT valves. The closure device consists of 8 polypropylene anchors connected by a braided polyester pre-tied suture allowing for sheath sizes up to 30 Fr. Anchors are mechanically deployed into the myocardial tissue near the anatomical apex using an over the wire system. After removal of the TAVI sheath, haemostasis is achieved by suture tying and approximation of the anchors without need for fast pacing. All patients were prospectively followed for 30 days. The Permaseal apical closure device was successfully deployed in all patients. In 27 of 28 patients (96%) haemostasis was achieved with no or only one additional pledgeted suture after sheath removal and anchor approximation by closing of the pre-tied suture. In one patient additional sutures had to be applied to resolve ongoing bleeding from the apical access site. Two patients (one roll-in patient and one protocol deviation) were excluded from the efficacy analysis. Four patients (15.4%) required transfusion either periprocedurally or prior to discharge. No patients suffered strokes, myocardial infarctions or died during 30 d follow-up. Mean operation time was 86±22.5 min and mean length of stay in the hospital 9.5±3.2 days.

Conclusions: The Permaseal device allows for minimally invasive reproducible access and closure of the left ventricular apex for TA-TAVI. The device complies with the beating heart and shows no interference with wall motion while leaving only little foreign material behind. It may help to reduce OR time, abate blood loss, and simplify transapical access for TAVI.

Transactor access for TAVI; a safe pathway: short and midterm results

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Aims: Transcarotid (Tc) vascular access for transcatheter aortic valve implantation (TAVI) has been proposed as an access route for patients not suitable for transfemoral TAVI. Little data exist, however, on the feasibility and safety of this technique. We sought to describe procedural and clinical outcomes of patients undergoing Tc TAVI included in the French Transcarotid TAVI registry.

Methods and results: The prospective multicentre French Transcarotid TAVI registry was initiated in 2009. This voluntary registry includes data from consecutive patients undergoing Tc TAVI in three high-volume TAVI centres in France. Patients underwent extensive preprocedural screening, including cerebral magnetic resonance angiography to delineate the components of the circle of Willis and determine the adequacy of collateral blood flow. All data were collected prospectively and clinical outcomes were defined and adjudicated according to the updated Valve Academic Research Consortium criteria. Stroke was an endpoint of particular interest and was adjudicated centrally. Among 96 patients undergoing Tc TAVI, the mean age was 79.4±9.2 years and the mean STS PROM score was 7.1±4.1. Successful carotid artery vascular access (left=88.5%) was achieved in all patients. The Medtronic CoreValve (92.7%) and Edwards SAPIEN (7.3%) systems were used. Procedural complications included: THV embolisation (3.1%); VIV (3.1%); cardiac tamponade (4.2%). Major bleeding and major vascular complications occurred in 4.2% (none involved the carotid artery). Post-implantation aortic regurgitation ≥grade 2 was observed in 21.5%. Procedural and 1-year mortality rates were 3.1% and 16.7%, respectively. All patients suspected of having a neurological event post TAVI had neuroimaging and/or neurology assessment. VARC-defined in-hospital stroke (n=0) or TIA (n=3) occurred in 3.1%. At 30-days, three further TIAs were observed, yielding a 30-day stroke/TIA rate of 6.3%. In-hospital atrial fibrillation was noted in four of these cases. At 1-year, the rate of stroke (n=1) or TIA (n=6) was 7.3%.

Conclusions: Tc TAVI is feasible and is associated with encouraging short and medium-term clinical outcomes. Prospective studies are required to ascertain if this technique yields equivalent safety and efficacy to other non-femoral access routes.

Interventions for structural heart disease

Euro15A-OP356

Transcatheter valve-in-valve implantation using six different devices in four anatomic positions: technical considerations and clinical outcomes

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Aims: Transcatheter valve-in-valve implantation (ViV) is emerging as a novel option for treatment of deteriorated bioprostheses. We report our cumulative experience using six different types of transcatheter heart valves (THV) in all four anatomic positions with an emphasis on technical considerations.

Methods and results: Seventy (70) consecutive patients (73.8±13.2 years, 51.4% male (36/70), log EuroSCORE I 25.9±18.4%, STS Score 8.5±7.4%) receiving ViV procedures from 2008 through 2014 at our centre were included for analysis. Data were prospectively gathered and retrospectively analysed. ViV implantation was performed in aortic (n=51), mitral (n=15), tricuspid (n=2) and pulmonary (n=2) positions. THV used were Edwards SAPIEN/SAPIEN XT/SAPIEN 3 (n=36), Medtronic CoreValve/CoreValve Evolut R (n=24), St. Jude Portico (n=3), Boston Scientific Lotus (n=3), JenaValve (n=2) and Medtronic Engager (n=2). Mean interval from index procedure to ViV was 9.8±5.5 years. Access was transapical in 54.3% (n=38), transfemoral in 41.4% (n=29), transaortic in 2.9% (n=2) and transjugular in 1.4% (n=1). ViV was successful in 96.7% (58/60), in two cases of aortic ViV distal embolisation of THV required implantation of a sequential valve. Overall all-cause 30-day mortality was 7.1% (5/70) and it was 3.9% (2/51) in the aortic position. No periprocedural strokes were observed. Paravalvular leakage was ≤ grade I in all cases. After aortic ViV, resultant gradients were max/mean 34.4±22.5 / 17.6±18.3.6 mmHg and effective orifice area (EOA) was 1.7±0.5 cm^2. Corresponding values after mitral ViV were gradient max/mean 10.9±6.7 / 2.8±0.9 mmHg and EOA 2.1±0.5 cm^2.

Conclusions: ViV can be performed in all anatomic positions with acceptable haemodynamic and clinical outcome in this high-risk patient population. Different types of THV are needed to provide optimal care. Meticulous planning, considering cardiac anatomy as well as technical specifications of deteriorated surgical valves is mandatory. In the light of increasing use of surgical bioprostheses, growing importance of ViV can be anticipated for the future.

Interventions for structural heart disease

Euro15A-OP358

Percutaneous ventricular restoration (PVR) therapy using the Parachute® device in subjects with ischaemic dilated heart failure: one year meta-analysis

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Aims: Left ventricle (LV) remodelling after anterior wall myocardial infarction (AWMI) leads to increased LV volumes, myocardial stress, and ultimately heart failure (HF). Treatment options are limited for these high-risk HF patients. Our primary objective was to assess one year safety and efficacy of the CardioKinetix Parachute Implant System in the partitioning of the left ventricle in subjects with heart failure due to ischaemic heart disease across trials completed to date (PARACHUTE Cohort A, PARACHUTE US Feasibility, and PARACHUTE III).

Methods and results: One hundred thirty-four subjects with NYHA class II-IV HF secondary to AWMI, with akinetic or dyskinetic wall motion abnormality, and LV ejection fraction <40%, were enrolled in Europe and the United States. The major endpoints evaluated at one year will be stroke, all-cause death, and the combination of all-cause death and repeat hospitalisation for worsening HF. Haemodynamic assessments will be evaluated with echo, and functional capacity assessed by NYHA and 6MWT. Of the 134 subjects enrolled, 128 were successfully treated (96%). The rates of stroke, all-cause death, and the combination of all-cause death and repeat hospitalisation for worsening HF were 2.4%, 8.8%, and 23.6%, respectively. Improvement of systolic cardiac function ($p<0.05$) was noted in LV volume indices, EF%, stroke work, and contractility index, along with a trend in fractional shortening, at 1-year follow-up relative to baseline values. This was accompanied by a significant reduction ($p=0.05$) in left atrial volume suggesting improved diastolic function. The 1-year mean NYHA class of subjects (1.9±0.7) was significantly reduced ($p<0.0001$) from baseline NYHA Class (2.5±0.5) reflecting functional improvement. Performance on 6-minute walk test with also improved from 369 meters at baseline to 391 at one year ($p<0.01$).

Conclusions: The meta-analysis of the Parachute data confirms the safety and efficacy of the Parachute device in treating HF.

EuroPCR Interventions for structural heart disease Euro15A-OP359

PARACHUTE China primary endpoint results: a multicentre, prospective, single-arm clinical evaluation of the safety and efficacy of the Parachute percutaneous left ventricle partitioning system

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Aims: Left ventricle (LV) remodelling after anterior wall myocardial infarction (AWMI) leads to increased LV volumes, myocardial stress, and ultimately heart failure (HF). Treatment options are limited for these high-risk HF patients. The primary objective is to assess three-month safety and efficacy of the CardioKinetix Parachute implant system in the partitioning of the left ventricle in subjects with heart failure due to ischaemic heart disease.

Methods and results: Thirty-one subjects with NYHA class II-IV HF secondary to AWMI, with akinetic or dyskinetic wall motion abnormality, and LV ejection fraction 15%-40%, were enrolled in China. The primary outcome measure is comparison of reduction in left ventricle end systolic volume index (LVESVi) after three months with baseline LVESVi. Evaluation will be performed via transthoracic echocardiography (TTE) by an independent central ultrasound laboratory (Yale University Clinical Research). Secondary endpoints include evaluation of safety based on central reports of procedural and device related MACE, NYHA, 6MWT, and EQ5D. Of the 31 subjects enrolled, 30 were successfully treated (97%). The primary endpoint data will be available and analysed in time for EuroPCR 2015 since enrolment was completed on December 11, 2014.

Conclusions: The patient profile and treatment success are similar to historical PARACHUTE clinical trials. The outcomes will be analysed once patient follow-up is complete.

EuroPCR Interventions for structural heart disease Euro15A-MA071

Comparison of radiation dose between a flat-plate angiography systems and new-generation hybrid technology for interventional cases in the cardiac catheterisation laboratory

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Aims: A new generation of hybrid cardiac catheterisation laboratories offers potential reduction in radiation dose. We compared case time, fluoroscopy time and dose-area product (DAP) between a Philips Allura-FD20 suite and a new Siemens Artis-Zeego hybrid system for TAVI and PCI procedures.

Methods and results: Data was collected for 47 single-vessel PCI and 35 TAVI (21 CoreValve TAVI, 14 Edwards SAPIEN TAVI) using the FD20, versus 30 PCI and 22 TAVI (14 CoreValve, 8 SAPIEN) with the Zeego over an overlapping ±12-month period. All procedures were performed by the same four experienced interventional cardiologists. Mean patient age (±1SD) was 77±11.7 years, mean weight (±1SD) was 75.6±16.8 kg; 62% were male. Median case time (minutes, interquartile range), fluoroscopy time (minutes, interquartile range) and DAP (Gy/cm^2, interquartile range) for PCI were: 70.0 (60.0-80.0), 9.2 (6.3-12.1) and 74.0 (51.2-125.0) with the FD20 versus 65.0 (40.0-80.0), 7.3 (5.3-11.1) and 52.4 (28.3-91.3) with the Zeego; for CoreValve: 92.5 (78.3-134.3), 23.2 (19.2-26.9) 102.2 (63.2-139.7) with the FD20 versus 95.0 (93.0-97.0) 23.8 (20.1-26.2) and 111.3 (61.2-151.3) with the Zeego; for SAPIEN: 83.5 (60.0-101.5) 23.8 (18.3-32.1) and 100.5 (66.3-134.1) with the FD20 versus 92.0 (85.0-108.0), 28.5 (23.2-29.1) and 134.0 (112.6-243.6) with the Zeego; for combined TAVI: 89.5 (75.0-107.3), 23.8 (19.1-29.1), and 102.2 (65.9-136.3) with FD20 versus 94.0 (86.8-105.3), 24.3 (21.9-28.5), and 113.0 (73.9-156.2) with the Zeego. There were no significant differences between SAPIEN and CoreValve TAVI procedures. Case time and fluoroscopy times were greater for combined TAVI than PCI with both systems ($p<0.003$ for all). There was no difference in DAP between PCI and combined TAVI with the FD20 (74.0 versus 102.2, p=NS), but DAP for PCI was less than combined TAVI with the Zeego (52.4 versus 113.0, $p<0.006$).

Conclusions: Specific dose-reducing features of the hybrid system (such as stored fluoroscopy) may be more suitable for reducing DAP for PCI but not TAVI, as structural heart interventions use additional cine-acquisition (e.g., "spin technology") not necessary for PCI.

EuroPCR Interventions for structural heart disease

Euro15A-MA072

Key nurse-sensitive outcomes in post-transcatheter aortic valve implantation (TAVI) procedure recovery

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Aims: To map the trajectory of recovery for octogenarian patients following TAVI and to identify key nurse sensitive outcomes in post-procedure recovery.

Methods and results: A descriptive exploratory design involving a retrospective chart audit of patient medical records was used. A random sample of 28 patients was generated from a total of 50 patients who underwent TAVI at a major metropolitan Australian hospital during 2008-2010. The phases of recovery identified were: pre- and peri-procedure, hyper-acute (first 24 hours), acute (24-72 hours) and intermediate (from 72 hours to remaining hospital stay). Data were descriptively analysed using SPSS for measures of central tendency and dispersion. Ethics approval was granted by the relevant ethics committees. The mean age was 83 years (SD±6.87), 60.7% (n=17) male. All implants were successful. There was 1 in-patient death at the intermediate phase. Four key nursing-sensitive outcomes were identified: cardiac arrhythmia, vascular access site, post-procedure pain and functional recovery management. Arrhythmias were recorded throughout the recovery phases. The 3 predominant arrhythmias were left bundle branch block 60.7% (n=17), 1st degree heart block 53.6% (n=15) and complete heart block 35.7% (n=10). Permanent pacemaker insertion occurred for 32.1% (n=9). Minor vascular access site complications were haematomas 32.1% (n=9) and bleeding 35.7% (n=10), occurring predominantly in the hyper-acute phase. Post-procedural pain was experienced by 92.9% (n=26) of patients in the hyper-acute phase, with 64.3% (n=18) having pain into the intermediate phase. The most common sites for pain were: neck (from intravenous catheters) 35.7% (n=10), back 21.4% (n=6) and pre-existing pain 17.9% (n=5). Functional recovery management recorded a NYHA functional classification improvement from 96.4% at class III or greater at baseline to 92.8% at class II or less at discharge. Mobility returned for 64.3% (n=18) of patients sitting out of bed in the hyper-acute phase and 53.6% (n=15) of patients mobilising in the acute phase. The mean length of stay was 7.71 days (SD±3.36).

Conclusions: This study has identified four key nurse-sensitive outcomes in the recovery phase post-TAVI, identifying the specific care needs and specialised (cardiac critical care and geriatric) nursing skills required to optimise recovery for octogenarians undergoing TAVI. It has provided foundational data to inform and improve nursing practice during the recovery phase for the TAVI patient and identified key areas for future nursing research.

EuroPCR Nurses & Technicians

Euro15A-MA074

An audit of resuscitation medication administered intra procedurally in the cardiac catheterisation laboratory

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Aims: The cardiac catheterisation laboratory is a challenging environment with multiple professionals undertaking complex cardiac procedures, many of which may be performed under emergency conditions. The administration of resuscitation type medication is common. The aim of this audit is to quantify the usage of intraprocedural intravenous resuscitation medications.

Methods and results: Data was collected over a 12 month period from the reporting system (Medcon). The database was interrogated for the intraprocedural use of the following intravenous medications; adrenaline, atropine, amiodarone and metaraminol (Aramine). Inclusion criteria were all patients undergoing an interventional or diagnostic cardiac procedure during this time frame. Exclusion criteria were patients undergoing electrophysiology procedures. During the period of January 2013 to December 2013, there were 2,121 interventional or diagnostic cardiac procedures. Intraprocedural intravenous resuscitation medication was administered on 132 occasions in 105 cases (4.9% of total cases). Types of intraprocedural intravenous resuscitation medication included: adrenaline n=15 (11%), atropine n=28 (21%), amiodarone n=8 (6%), Aramine n=81 (61%). The types of cases these drugs were administered in were emergency coronary intervention in hours n=34 (32%), emergency coronary intervention "out of hours" n=26 (25%), planned coronary intervention n=26 (25%), diagnostic coronary procedures n=19 (18%).

Conclusions: This audit has demonstrated that intraprocedural intravenous resuscitation medications are used often in the cardiac catheterisation laboratory, especially during emergency cases in the "out of hour's scenario". This highlights the need to provide appropriately skilled staff with advanced cardiac life support credentialing to provide a safe level of care. Furthermore, quantifying the use of intraprocedural intravenous resuscitation medications locally provides the opportunity to benchmark practice with clinical registries.

Left atrial appendage closure

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Aims: LAA closure is an interventional technique applied to prevent stroke in atrial fibrillation. The left atrial appendage (LAA) is a small, ear-shaped sac in the muscle wall of the left atrium (top left chamber of the heart). It is unclear what function, if any, the LAA performs. When a patient has atrial fibrillation, the electrical impulses that control the heartbeat do not travel in an orderly fashion through the heart. Instead, many impulses begin at the same time and spread through the atria. The fast and chaotic impulses do not give the atria time to contract and/or effectively squeeze blood into the ventricles. Because the LAA is a little pouch, blood collects there and can form clots in the LAA and atria. When blood clots are pumped out of the heart, they can cause a stroke. Catheter-based ALL occlusion is a safe and effective method to prevent stroke. The aim of this article is to show the technical aspects of this structural intervention and the role of the cathlab staff.
Methods and results: A catheter-based ALL occlusion is a minimally-invasive procedure in which a special Amplatzer device is deployed into the LAA via delivery catheter system. The device is made of braided nitinol wires with shape memory characteristics which means that the device will return to its memorized shape even if it is stretched to deploy via catheter. Nursing interventions pre-, during- and post-procedure include close vigilance, care and teaching the client about the procedure and related self-care. Potential risks of this procedure include, but are not limited to, the following: air embolus, contrast-induced allergic reactions, vascular access complications, foreign body embolisation, perforation, pericardial effusion, vascular and valvular complications, MI and stroke.
Conclusions: In summary, catheter-based ALL occlusion is a relatively safe procedure to reduce the risk of emboli and secondary stroke because of atrial fibrillation, if it has an experienced and professional back up in cathlab. Inter-professional training of cathlab staff including nurses and technicians is an integral part of this success.

Significant radiation dose saving with removal of anti-scatter grid from the flat panel detector with minimal image degradation

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Aims: In searching for ways to lower procedural radiation dose, we entailed to measure the effects on removing the anti-scatter grid from the flat panel detector on our Toshiba Infinex system. We also analysed any image quality loss of such a technique.
Methods and results: All flat panel detectors have an anti-scatter grid that is comprised of a plastic or carbon fibre layer that has parallel lead or aluminium thin vertical strips along its entire surface. This honeycomb of dense metal increases the contrast and resolution of the x-ray image by absorbing divergent scattered x rays from the patient and allowing the majority of the primary beam x-rays through. A simple analogue is the use of polarised sunglasses to reduce glare. However, this process attenuates the amount of x-rays to the detector initiating a larger x-ray tube output to compensate for this lower detector input dose, similar to the fashion in which polarised sunglasses darken the view. During this experiment, we performed fluoroscopy at low Ma settings and 7.5 fps, on a 25 cm an anatomical chest phantom in the Ap projection with and without the anti-scatter grid. X-ray beam dose was measured with the inbuilt ion chamber in the systems collimator. To measure any loss of image contrast and resolution a Westmead phantom test was used to measure image contrast and line pair resolution of the resultant images. Our findings were a radiation dose of 3.1 mGy/min with the grid in place and 1.6 mGy/min on the removal off the anti-scatter grid, a dose saving of 48.4%. The image quality test showed that with the grid in place, line pairs of 1.8/mm were evident as was a range of ten on the contrast range. On removal of the grid, resolution dropped to 1.6/mm and a range of 9 was seen on the contrast range test. To the naked eye image quality on the 25 cm anatomical phantom was negligible.
Conclusions: From these results, it is seen that for small to medium patients, removal off the anti-scatter grid will significantly reduce radiation dose to both the patient and the operator with acceptable loss of image quality.

Nurses & Technicians

Euro15A-OP227

Experience of spouses after cardiac surgery

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Aims: The objective of the study is to explore how the spouses of patients undergoing cardiac surgery experience how their everyday conduct of life and well-being is affected through the course of the disease. Furthermore, it will explore what spouses find significant during hospitalisation and how healthcare professionals can attend to this.

Methods and results: A qualitative approach was used to explore this issue. Seven spouses were individually interviewed in a semi-structured format. The interviews took place two weeks after their partners were discharged from hospital. The overall theoretical approach is based on the analytical term "everyday conduct of life'" by Klaus Holzkamp and the theory of sense of coherence by Aaron Antonovsky is also included. Three main themes of interest appeared: 1) "The organisation"; the spouses had to face certain terms within the hospital setting which affected their everyday life. This was the fact as there was a risk of postponement of the operation and that the spouses generally did not have the opportunity to talk to the surgeon after the operation; 2) "Contact with the nurses", the spouses experienced a lack of involvement and information during the hospitalisation, which left them insecure, anxious and uncertain; 3) "Everyday life changes" showed how the spouses experienced emotional, psychological and social changes in their everyday life when they were back home with their partner.

Conclusions: Spouses are affected in their everyday conduct of life and well-being due to the high burden of responsibility, anxiety and insecurity. The usual daily routines are not yet adapted, as a new daily pattern of life is a fact, which the spouses have to become familiar with. The spouses find it significant that the healthcare professionals involve and inform them about their partner's course of disease. The healthcare professionals could accommodate this need by making sure that post-operative talks are conducted and by general involvement during the daily work routines.

Nurses & Technicians

Euro15A-OP228

The nurse's role in the informed consent process

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Aims: The practice of informed consent presents complex legal and ethical challenges. Complete, clear and individualised information should be provided, and enough time should be allowed for multidisciplinary (e.g., the Heart Team) and patient-centred discussion. Challenging scenarios include *ad hoc* PCI, emergencies and mental capacity of an ageing population.

Methods and results: The informed consent process allows patients to meaningfully participate in the decision-making process and make important decisions about their healthcare choices. To be able to do this their physician is responsible for informing them of (a) the nature of the procedure, (b) its risks and benefits, and (c) its alternatives with their risks and benefits. This makes the informed consent process the legal, ethical, and moral responsibility of the physician. Nevertheless, as patient advocates, nurses also have a professional interest in fully understanding the legal guidelines and ethical considerations of the informed consent process. Physicians and nurses facilitating this process should keep in mind that the seemingly complex process is simply the practical application of respect for persons not just a waiver of liability. The priority in any decision making process should be effective communication, and physicians and nurses should ensure that medico-legal requirements do not obscure this key element of the decision-making process. Comprehension of the information provided is a precondition for obtaining a valid informed consent and the physician is responsible for ensuring patient's understanding of the risks and benefits of a proposed procedure. Nurses could contribute toward maximizing comprehension by using a repeat-back process after informed consent discussions. This method has been suggested to improve patient's understanding when they are asked to recount what they have been told in the informed consent discussion. Nurses may be more familiar with and skilled in the repeat-back method and identify gaps or inaccuracies in the information relayed back to them. It has been shown that patients are excessively optimistic about the potential benefits of intervention. A systematic review of observational studies of patient understanding of coronary revascularisation demonstrated that 78% of patients erroneously believed that PCI would extend life expectancy and 71% erroneously believed that PCI would prevent future myocardial infarction even though such claims were not made by their physician. Also, for the majority of the age group we are seeing in our cathlabs, the medical profession is considered authoritative, and the consent process one of acceptance, whereby the patient simply agrees with what the physician recommends and entirely dependent on him or her, rather than on their own comprehension, reflection and decision. It is not unusual for nurses to be asked for more information after the physician has left the room.

Conclusions: With this understanding, educated nurses possess a unique opportunity to collaborate with the physicians and achieve patient autonomy, especially in the presence of challenging scenarios, such as patients who decline surgery and prefer a percutaneous option (PCI, TAVI), ageing patients with limited mental capacity, and patients with surrogate decision makers. Therefore, the topic of informed consent is worthy of studying further and conduct research into to determine the extent and importance of the nurse's role in this process.

Delay-times with improvement potential in primary percutaneous coronary intervention

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Aims: In patients with ST-elevation myocardial infarction (STEMI), primary-PCI is the preferred treatment according to current guidelines, provided that target times are achieved. Data from the SWEDEHEART- Registry, (Swedish Web-system for Enhancement and Development of Evidence- based care in Heart-disease) annual report 2010 shows that a majority of regions in Sweden meet target times in less than 50% of patients. In this study, we have analysed time-delays in patients undergoing primary PCI at a general hospital in the south of Sweden offering primary-PCI as a treatment for STEMI during working hours.
Methods and results: Between 2010 and 2011, STEMI-patients undergoing primary PCI at the General Hospital and registered in SWEDEHEART were included retrospectively in the study. Patients were grouped according to first medical contact: emergency medical services/ 112 (EMS), community health centre or emergency department (ED). Time-variables were obtained from EMS-forms, ED- triage sheets and patient-journal database. Variables were measured as patient delay-time from symptoms onset to diagnostic electrocardiogram (ECG), and system delay-time as ECG to balloon- and door-to-balloon- time. Participating patients were asked in a follow-up to judge whether they related their initial symptoms to represent myocardial infarction or not. They were also asked to grade their chest- pain using a 0-10 self-assessing visual analogue scale (VAS). Out of 117 STEMI- patients, 63 (54%) contacted EMS and were diagnosed in a pre- hospital setting by tele-transferred ECG. This group achieved the shortest median-time from symptoms-onset to reperfusion, 121 minutes (90-180). In 31 (26%) patients diagnosed at community health centre, time- delay was 195 minutes (125-260). Twenty- three (20%) patients diagnosed at the ED had the longest delay: time of 235 minutes (119-332). Patients diagnosed through EMS achieved the shortest door-to-balloon-time, 34 minutes. If diagnosed in community health centre, the door-to-balloon-time was 38 minutes. Patients diagnosed at the ED had the longest door-to-balloon-time, 75 minutes (49-91). Patients that related their symptoms to myocardial infarction contacted to a greater extent (70%) EMS compared to those that did not (35%). Patients contacting community health centres experienced a lower grade of chest-pain, VAS 4 (2-5.5), than those contacting EMS and ED, VAS 7 (5-10).
Conclusions: STEMI patients calling emergency medical services had the shortest time to reperfusion whereas patients diagnosed at the emergency department had the longest. Improvement in logistics of STEMI patients at the emergency department and community health centres is warranted. Repeated community education campaigns may be important to reduce patient delay-time.

Early nursing transfer after primary-PCI: the Salento model

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Aims: The early transfer into the intensive coronary care Spoke unit of STEMI patients after coronary revascularisation of "culprit" artery with primary-PCI in a Hub-centre allows for the elimination of the deeply rooted concept of therapy centralisation. This also allows us to highlight the role of intensive coronary care Spoke unit, with a strong acquisition of emergency management skills, above all for nursing team.
Methods and results: This work aims to give an overview about the early transfer (within 2 hours) into the region's (Salento) intensive coronary unit Spoke centres of STEMI patients who underwent primary PCI revascularisation. The data analysed refer to 399 patients involved in the local coronary emergency network, called SalentIMA, from January 2012 to December 2014. The incidence of the early local transfer vs. the hospital remaining has been analysed in relation to adverse events (malignant arrhythmia, slow-flow, no-reflow, intra-stent thrombosis, intra-aortic balloon pump, multivessel coronary artery disease, endo-tracheal intubation), the arterial access and the network itinerary covered by patients. From the analysis, we see that 72.3% of the 399 patients are male, with a medium age of 63.4±11.6 years. In 49.4% of the cases (197 patients), an early nursing transport has been used. Throughout the cases analysed, 33 adverse events occurred, in 78.8% of them a hospital transfer to the intensive coronary unit Hub has been chosen as per internal protocol. Of the 52.5% of patients who had femoral artery access 22.5% were transferred to the Spoke centre, whereas for those with a radial access (74.6%) the percentage rises to 56.3%. In cases of a shift from the radial to the femoral artery (2.9%), only 30% of patients received local early transfer. As far as the itinerary is concerned, it appears that 47.6% of patients who arrived to the cathlab from the centre Hub, directly through services for health urgency and emergencies (118 telephone number), had an early transfer after primary PCI. The percentage rises up to 65.5% in case of routing from the first aid Spoke to cathlab, and up to 77% in case of routing from services of health urgency and emergencies (118) to first aid Spoke to cathlab.
Conclusions: The early treatment network of SalentIMA, for STEMI patients in the territory of Lecce, gives nurses more autonomy and responsibility for local early transfer of stable revascularised patients through nurse-only equipped ambulances. Our results underline a significant use of the early transfer to the intensive coronary care unit Spoke from the Hub centre for patients who are haemodynamically and electrically stable (TIMI III coronary flow, ST resolution >50%, no angina, lack of sign of heart failure). This organisation leads to two important effects: first, it provokes a useful reduction of intensive coronary unit Hub crowding, which allows the Hub to concentrate on the real and complicated needs of unstable patients; second, territory assistance acquires an a co-starring role in coronary emergency and acute cardiology cases management, on the scene of an efficient network of STEMI treatment.

euroPCR Nurses & Technicians Euro15A-OP231

Understanding system delays when door-to-balloon time is >90 minutes: a seven-year prospective cohort study

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Aims: Timely treatment for ST-segment elevation myocardial infarction (STEMI) is critical to patient outcomes. Primary percutaneous coronary intervention (PPCI) is considered the gold standard management for STEMI, however this procedure is "time critical" with recommendations suggesting a door-to-balloon time (DTBT) of 90 minutes. The last decade has witnessed the implementation of many systems of care to reduce DTBT. We sought to examine specific timeframes within the prospectively measured DTBT continuum, to pinpoint where delay in STEMI management occurs and highlight areas for improvement.

Methods and results: A seven-year review was undertaken on consecutive STEMI patients who presented to the emergency department at a Melbourne metropolitan hospital and were subsequently treated with PPCI. Individual DTBT was prospectively collected and broken down to into six specific timeframes: 1) door-to-ECG; 2) ECG-to-code-call; 3) code-call to-team-call; 4) team-call-to-cathlab-arrival; 5) cathlab-arrival-to-needle-to-skin; 6) needle-to-skin-to-first-device. Comparisons were made for baseline demographics, clinical characteristics and mortality out to 12 months. Chi-square analysis and Student's t tests were undertaken to identify differences between groups. Data were expressed as percentage, mean+SD or median (IQR_{1-4}). A total of 695 consecutive STEMI patients were examined. The mean age of the cohort was 63±13 years, 21% were female, 57% presented out of operating hours, 37% presented via ambulance using a pre-hospital notification (PHN) system, and 27% of patients recorded a Thrombolysis In Myocardial Infarction (TIMI) risk score >5. The overall DTBT median (IQR_{1-4}) was 72 ($_{48-99}$) minutes, with 32% of patients recording a prolonged DTBT ≥91 minutes. When comparing DTBT <90 to ≥91 minutes, delay was identified in four of the six timeframes examined, Door to ECG: 0 vs. 9 min (p<0.0001); team-call-to-cathlab-arrival: 24 vs. 35 min (p<0.0001); cathlab-arrival-to-needle-to-skin: 10 vs. 13 min (p<0.0001); needle-to-skin-to-first-device: 17 vs. 23 min (p<0.0001). Subgroup analysis identified difference between groups for gender: 29% females vs. 29% males (p=0.02); time of presentation: 19% presentation in operating hours vs. 41% out of operating hours (p<0.0001); TIMI risk score: 28%TIMI <5 vs. 46% TIMI>5 (p<0.0001) and type of presentation: 54% self-referral vs. 43% "via ambulance with no PHN" vs. 7% "via ambulance with PHN" (p<0.0001) all experiencing prolonged DTBT. Mortality was higher for patients with prolonged DTBT, 12.6% vs. 4.3% (p<0.00001). Numerical difference was found in mortality for females who experienced delay; 10% vs. 6% (p=0.06) and statistically significant difference in mortality found for those who had a TIMI risk score >5; 28% vs. 2% (p<0.00001).

Conclusions: Despite improvements in timely treatment for STEMI over the past decade, there remain a proportion of patients who fail to achieve the target time for DTBT. This study highlighted the areas where delay occurs within the DTBT continuum, and identified subgroups of the STEMI population more likely to experience delay in treatment. Further multivariate analysis is required to reveal the predictive value of this data to provide a framework to target specific delay in the DTBT continuum for these STEMI subgroups.

euroPCR Nurses & Technicians Euro15A-OP232

Gender disparities in cardiovascular care

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Aims: By 2030, it has been predicted that more than 23 million people will die annually from cardiovascular disease (CVD). Additionally, this pervasive disease continues to maintain its dubious distinction as the primary cause of death for women and "accounts for more female deaths than all cancers and lung disease combined". Despite their substantial burden of cardiovascular disease, women continue to be under-represented in clinical trials which equates to a paucity in gender-specific analyses. Importantly, discrimination persists in the management and treatment of CVD as women are often under-diagnosed (hence, under treated) - as the presentation, progression and outcomes of the disease is still not well understood. There is a growing body of data in both the US and Europe demonstrating important gender differences and disparities. The scope is to address the disparities in care, the scarcity of prospective data and the implication of gender disparity in cardiovascular care.

Methods and results: Review of published data and overview of evidence based medicine evaluating outcomes and disparities of women undergoing evaluation for cardiovascular care: women were less likely to undergo exercise ECG testing, less likely to be referred for coronary angiography, had less coronary revascularisation, higher occurrence of death and MI as well as a higher rate of heart failure.

Conclusions: Although there has been progress in raising awareness about cardiovascular disease in women, there remains a global misconception regarding the severity of the impact on females. The paradox still persists demonstrating a higher mortality despite less severe obstructive disease. We must strive to heighten the focus on clinical risk factor control, awareness of atypical symptoms, and discriminatory management of this disease. Gender-specific basic and clinical cardiovascular research is needed to address these issues, with rigorous application required for the emerging body of evidenced based medicine.

Euro15A-OP233

Patient experience of radial puncture by the use of a thin-walled hydrophilic arterial introducer sheath

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Aims: The aim of this study was to investigate the patient experience of radial puncture using a new thin-walled hydrophilic sheath with a smaller outer diameter compared to a standard sheath.
Methods and results: One hundred and seven (107) patients were included in this prospective, open-label trial. A hydrophilic sheath (Glidesheath Slender®; Terumo Medical Cooperation, Tokyo, Japan) was used in 63 consecutive patients (58.9%) during a period of three weeks. Then a standard sheath (Radifocus® Introducer II Transradial Kit; Terumo Medical Cooperation, Japan) was used in 44 consecutive patients (41.1%) for three weeks. The patients were asked to estimate the level of discomfort or pain using the visual analogue scale (VAS). There was a significant difference in pain measured by VAS between the groups: hydrophilic sheath: 2.0, (0.0-3.0]), standard sheath: 2.5, (1.0-5.0) (median, interquartile range 25-75%, p=0.04). The median difference in score of VAS was (95% CI): 1, (2.0-3.0). Furthermore, in the hydrophilic sheath group, there was a significant difference in pain between the male and female, 1 (0.0-3.0) versus 3 (0.75-6.25) (median, [interquartile range 25-75%], p=0.02). In addition, there was a significant difference in pain between the male and female in the control group, 2 (1.0-3.5) versus 5 (2.0-7.0), p=0.05.
Conclusions: In this non-randomised, clinical trial, there was a significantly less pain and discomfort when using the hydrophilic sheath compared to a standard sheath. This might be associated with lower incidence of radial spasm and perhaps a higher success rate of the procedures, which need to be evaluated in a randomised trial with adequate power to detect differences in procedural success rate.

Euro15A-OP236

Ultrasound visualisation of the radial artery access after coronary angiography or PCI with a 40 MHz external probe: the footprint of a transradial puncture

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Aims: This study aims to visualise morphologic changes in the wall of the accessed radial artery 3 hours and 30 days after transradial catheterisation by means of very-high resolution ultrasound. Such changes may explain complications like spasm of the radial artery, late total occlusion and decrease in pulsation.
Methods and results: Of 100 patients, who gave written informed consent and who underwent transradial coronary angiography and/or PCI, the radial artery was visualised using a 40 MHz linear external ultrasound probe. The target radial artery was visualised prior to the procedure, 3 hours post-procedure (when the compression bandage was removed) and 30 days post-procedure by two experienced operators. The artery was visualised with a long view projection and a cross-section run moving the probe from distal to proximal. All images were recorded in DICOM format. In 17 patients, the same acquisitions were made with a conventional low frequency ultrasound system (6.2 MHz). Besides an indication on the wrist where the ultrasound operators felt the strongest pulse, the physician was blinded for the ultrasound images and performed the radial access procedure according to local standards. The very-high resolution 40 MHz ultrasound allowed for detailed assessment of the radial vessel wall including intima and media layers. The structural changes that were observed 3 hours and 30 days post-procedure were among others dissections (scored when an endoluminal flap was visible), haematoma (blood visible between vessel layers), pseudo-aneurysm (haematoma outside the arterial wall, communicating with the artery), thrombus, spasm (radial artery constriction) and spontaneous echo contrast (distinct white noise artefacts due to slow- or turbulent blood flow). Three patients showed an occluded radial artery and one patient showed a fistula or shunt of the radial artery and vein after the puncture. Due to retrograde filling from the ulnar artery, not all closures resulted in loss of pulsation. The structural changes were observed from the images derived with the 40 MHz linear probe and were not visible on the images from the conventional low frequency ultrasound system. There were no complications related to the 40 MHz ultrasound acquisition.
Conclusions: Ultrasound acquisition of the radial artery pre- and post-procedure with a 40 MHz linear external probe is safe and feasible. Structural changes were observed 3 hours post-procedure and at 30-days follow-up. The 40 MHz linear probe was superior in visualising these changes compared to a conventional low frequency ultrasound probe.

EuroPCR Nurses & Technicians

Euro15A-OP237

The nursing management of the radial artery access: the relationship between radial artery occlusion and elastic bandage compression after coronarography and angioplasty

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Aims: The primary outcome of the study was to assess the incidence of the acute and late radial artery occlusion in patients submitted to coronarography or angioplasty and elastic bandage compression. The secondary outcomes were the detection of pseudoaneurysm, fistula and bleeding.

Methods and results: A prospective study including 139 patients undergoing transradial coronary catheterisation was conducted from May to July 2014 in a cathlab and in a cardiology ward. We designed a new and specific protocol, finalised to haemostasis and to prevent complications. The sheath was immediately removed at the end of the procedure. Patients were controlled using radial pulse palpation, the pulse oximetry (modified Barbeau test), and radial artery echo-Doppler evaluation. The protocol required two elastic compressive bandages: the first external and more gripped, was removed after one hour; the second, internal and less gripped, was removed after four hours. The patients were evaluated at four different stages: at sheath removal, after four hours (second elastic compressive bandage removal), at discharge and at thirty-days post-catheterisation with echo-Doppler evaluation. We obtained the one-month follow-up of 107 on 139 patients (77%). Radial artery occlusion occurred in a single case in these 107 patients at follow-up at thirty-days (0.93%); pseudoaneurysm occurred in a single case at discharge (0.72%); bleeding prevalence was 4/139 (2.88%) at one-hour and 2/139 (1.44%) at four-hours; no fistulas were found. The study was designed and conducted by the nursing team to underline the importance of the nurses role.

Conclusions: The incidence of the radial artery occlusion after elastic bandage compression at discharge and at follow-up is extremely low; if this is confirmed by a larger study, a simple and economic method could be used to obtain similar or even better results than dedicated devices.

EuroPCR Nurses & Technicians

Euro15A-OP238

SAMOVAR: is it safe to mobilise patients very early after cardiac catheterisation

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Aims: The standard post-procedure regimen for patients undergoing coronary angiography (CAG) or percutaneous coronary intervention (PCI) includes immobilisation and bedrest in the attempt to limit femoral access site complications. Previous studies have indicated that immediate ambulation after CAG or PCI when a closure device is used to obtain haemostasis in the groin, is not associated with an increased rate of access site complication compared to a standard bedrest regimen. These studies included a relatively small number of participants and patient comfort was not evaluated. The purpose of this study is to investigate the occurrence of a combined endpoint including bleeding, haematomas or pseudoaneurysms of clinical importance in a large number of patients undergoing CAG or PCI via the femoral artery route randomised to either immediate mobilisation after the procedure, or mobilisation after two hours (standard regimen). In addition, the level of comfort connected with mobilisation will be evaluated.

Methods and results: Patients having undergone CAG or PCI procedures using femoral access, in whom haemostasis is obtained immediately after the procedure using the AngioSeal closure device without visible haematomas are eligible for inclusion in the study. After informed written consent is obtained, the patients are randomised using a computerised randomisation program to either immediate or the standard mobilisation regimen. The activated clotting time is reversed using intravenous protamine sulphate in patients undergoing PCI. On arrival in the stationary department, careful examination of the patient is performed after 30 minutes, 2 hours and before discharge in order to observe the presence of haematomas, bleeding, and pseudoaneurysms. In addition, possible vasovagal reactions are recorded, and patient comfort rated by a numeric rating scale is used in four defined areas 2 hours after procedure. A calculation of statistical power estimated the required sample size to 2,000 patients.

Conclusions: A more detailed introduction to the setting and design will be presented. The study is currently including patients. At present 1,300 patients are included.

Endovascular interventions in Takayasu arteritis involving aorta and aortic arch vessels

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Aims: Takayasu arteritis of the supra aortic vessels is a widespread pan-arteritis prevalent in India, Southeast Asia, Africa and South America. The exact aetiology although unknown is thought to be of an autoimmune aetiology and associated with abnormalities of humoral and cellular immunity. These lesions are densely fibrotic, multifocal and have a strong tendency to reoccur at the same or at different sites. Surgical reconstruction is difficult because of extensive fibrosis and adhesions of peri-arterial tissues. Endovascular interventions are now emerging a treatment of choice.

Methods and results: One hundred and forty-three (143) consecutive patients with Takayasu Arteritis involving aorta and carotid and subclavian arteries were treated by endovascular interventions: balloon angioplasty/stents/stent grafts. Access was gained by the femoral artery or brachial artery approach. Lesions were initially dilated with optimal sized balloons and then stented if required. The patients were put on dual antiplatelet therapy (aspirin 75 mg and clopidogrel 75 mg/day) and immunosuppressive therapy in form of prednisolone (1 mg/kg/day). The disease activity was monitored by the erythrocyte sedimentation rate and levels of C reactive proteins. Angiography was done at the end of one year and 3 years.The results are as follows: carotid artery (CA)=25, including 19 common carotid, 6 internal carotid, subclavian artery (SA)=74; aorta (Ao)=47, including 29 thoracic aorta, 18 abdominal aorta; stenosis-CA=21, SA=71, Ao=31; aneurysm-CA=01, SA=03, Ao=16; stents CA=11, SA=24, Ao=18; technical success-CA=22/25 (88 %), SA=88 %; Ao=47/47 (100 %). Follow-up at 3 yrs-CA=restenosis in 9 pts (treated by PTBA/stent), SA=12.5% (treated by PTBA/stent), Ao=restenosis in 7 % (aneurysm in 2, new lesions in 4, disease reactivity in 5).

Conclusions: Endovascular interventions have emerged as the treatment of choice for both stenotic and aneurysmal lesions. It is easy, safe and efficacious. Multiple lesions and multiple vessels can be treated at the same time. Stents have improved the results although drug-eluting and cutting balloons have also been successfully used.

Angioplasty and renal artery stenting in patients after kidney transplantation from a live relative-donor

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Aims: To analyse the indications and outcomes of PTRA in patients after kidney transplantation with renal artery stenosis.

Methods and results: Eight patients after renal transplantation from a live relative-donor were enrolled with critical renal artery stenosis, in all cases in vessels anastomotic zone. Patients underwent 12 PTRA/stenting. The age of patients ranged from 20 to 60 years (38.1± 14.1 on average). Four patients were male. Period from the transplantation to emergence of renal artery stenosis was 3-8 months (4.9±1.6 on average). In all, patients during the surveillance and duplex scanning examination were identified with the following signs: marked acceleration of blood flow in the place of anastomosis (3.3±0.82 m/s), resistance index RI was (0.64±0.05). Recorded growth of indicators of blood waste. The results of angiography showed critical stenosis in the place of artery anastomosis of the recipient (usually in internal or external iliac artery) and artery of the graft in all cases. Seven of 8 patients underwent balloon angioplasty of stenotic segment and in one case, stenting was the initial procedure with good immediate results. There was a marked decrease of indicators of urea and creatinine on the next day after the intervention (creatinine 335.9±138.3 mmol/l before and 171.4±82.8 mmol/l the day after angioplasty; p=0.02). Indicators of urea were fixed 22.2±12.0 mmol/l before and 11.8±4.8 mmol/l after, respectively (p=0,.03). After 14 days, the indicators were 142.4±52.8 mmol/l for creatinine and 9.8±4.8 mmol/l for urea. We fixed marked normalisation of speed indicators in anastomotic zone (1.15±0.11 m/s) on 3-14 post-operative days. In the period from 1 to 4 months after balloon angioplasty, three patients from the observed group underwent stenting because of restenosis. In one case, we used 2 drug eluting stents (DES) for renal artery bifurcation. In cases with restenosis a marked regrowth of waste and change of speed indicators of blood flow were observed.

Conclusions: Renal artery stenosis after kidney transplantation usually occurs in the period between 3-6 months after operation and is characterised by obvious clinical manifestations and dynamics of biochemical indicators. The simple and safe method, which allows saving the graft, is angioplasty and stenting of stenotic segment. Restenosis after angioplasty was observed in one-third of patients in the period of 1-4 months and requires stenting. The rationale to use of DES questionable and need further investigation.

Peripheral interventions

Euro15A-MA064

Results of re-dilatation of new cobalt-chromium stents in the treatment of coarctation of the aorta: a single centre experience

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Aims: We present results of stent re-dilatation in the patients with coarctation of the aorta (CoA) and re-coarctation (ReCoA).

Methods and results: Between December 2010 and November 2014, 19 patients underwent stent re-dilatation: 18 with coarctation of the aorta and 1 with re-coarctation. The procedures were performed using high-pressure balloons. All patients were implanted Andrastents XL/XXL (Andramed GmbH, Reutlingen, Germany). The average age of the patients was 26.69 years (9-53). The mean gradient before stent implantation was 55.95 mmHg (20-94), after stent implantation 20.47 mmHg (0-63). Time from stent implantation to stent re-dilatation was 12.16 months (4-24). Mean gradient before stent re-dilatation was 26.84 mmHg (10-59), after stent re-dilatation 10.68 mmHg (0-38).

Conclusions: The procedure of stent implantation and re-dilatation was successful in all patients. In 3 patients with coarctation of the aorta with a stiff lesion, residual pressure gradient after procedure remained >20 mmHg. There were no significant complications (stent fracture, aneurysm formation, etc.) observed in any patients during follow-up. Staged treatment of coarctation of the aorta (CoA) and re-coarctation (ReCoA) with stent implantation of Andrastents XL/XXL and then stent re-dilatation is usually an effective method of treatment.

Peripheral interventions

Euro15A-MA065

Impact of end-stage renal disease for wound healing in patients with critical limb ischaemia

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Aims: End-stage renal disease (ESRD) can accelerate the deterioration of PAD and provoke critical limb ischaemia (CLI). Our aim this study was to assess the impact of ESRD for wound healing in CLI with tissue loss.

Methods and results: This retrospective single centre study enrolled 213 patients (male 70%, mean age 72±12 years) (271 limbs, 299 wounds) who underwent undergoing endovascular therapy for CLI with tissue loss. They were divided into two groups according to the presence of ESRD. Mean follow-up term was 21±19 months. Primary endpoint was wound healing rate. Secondary endpoints were wound healing time and the recurrence of wound in patients who once achieved wound healing. This study included 152 patients with ESRD (135 limbs, 152 wounds) and 112 patients without ESRD (133 limbs, 146 wounds). There was no significant difference in the two groups concerning wound and angiographic characteristics, except for lower patency of pedal arch in patients with ESRD (49% vs. 70%, p=0.001). The wound healing rate was significant lower in patients with ESRD (78.0% vs. 93.3%, p=0.002). Though wound healing time was similar between the two groups (170±139 days in ESRD vs. 140±158 days in non-ESRD, p=0.19), the recurrence of a wound was more frequently observed in ESRD patients than in non-ESRD patients (30% vs. 11%, p=0.001). In the Cox proportional hazard model, independent predictors of the recurrence of wound was ESRD (OR: 3.63, p=0.002) and isolated infrapopliteal lesions (OR: 3.38, p=0.004).

Conclusions: ESRD was related with lower wound healing rates in patients with CLI. In patients who achieved wound healing, ESRD was not related with the wound healing time, but with the recurrence of the wound. ESRD and isolated infrapopliteal lesions were independent predictors of the recurrence of a wound.

Initial results of a multicentre registry evaluating the safety of carotid artery stenting in symptomatic and asymptomatic carotid artery stenosis patients by cardiologists in Japan (CASSIS registry)

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Aims: The aim of the present study is to elucidate safety and efficacy of carotid artery stenting (CAS) in symptomatic and asymptomatic carotid artery stenosis patients performed by Japanese cardiologists.

Methods and results: CASSIS registry is a prospective multicentre registry study of carotid artery stenting performed by Japanese cardiologists. Symptomatic patients with internal or common carotid artery stenosis more than 50% revealed by ultrasound or angiogram and asymptomatic patients with more than 80% were included to the registry. Each patient was considered suitable condition for CAS by primary physician. The primary endpoint was major adverse events (MAE) including myocardial infarction (MI), stroke and death within 24 hours, at 30 days and at 1 year. In all patients the NIH stroke scale (NIHSS) was used by a neurologist before and after the procedure. If possible, diffusion-weighted magnetic resonance imaging (DW-MRI) of the brain was taken and interpreted by a radiologist before and after CAS. Between 2012 March to 2014 August, a total of 168 cases were enrolled from 32 centres. Average age was 74±7. Twenty-five percent were over 80. Eighty-nine percent was male gender. Contralateral carotid artery occlusion or significant stenosis was seen in 15%. Twenty percent of patients were symptomatic. All patient was successfully treated with CAS. In all patients, protection devices were used (distal protection: 80%, proximal protection: 20%). Stop/slow flow phenomenon was seen in 6% and debris was found at the filter in 34%. Intravascular ultrasound was used in 64% and plaque protrusion was seen in 6%. High intensity spots were detected by DW-MRI after CAS in 28% (22% in ipsi-lateral, 6% in contra-lateral). MAE at 30 days was 1.3%: 0% MI, 1.3% stroke, 0.6% death. Death or any stroke rate at 30 days was 0.8% in asymptomatic and 3.0% in symptomatic patients.

Conclusions: The rate of MAE at 30 days was very low and initial results of the CASSIS trial were acceptable. Though all patients were treated with CAS under protection, DW-MRI indicated that distal embolism occurred in some cases without clinical symptoms. However, we believe protection would be indispensable and effective to reduce complications during CAS.

Short-term and long-term outcomes of carotid artery stenting with the use of proximal cerebral protection

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Aims: Today carotid artery stenting (CAS) is recognised as equal to open surgery in the management of atherosclerotic lesions of the internal carotid artery (ICA). However, the choice of the type of embolic protection for CAS is still controversial. In multicentre registries, carotid artery stenting with the use of proximal cerebral protection demonstrates lower rates of stroke then those which use distal cerebral protection. We evaluated short-term and long-term outcomes of carotid stenting with proximal cerebral protection in real-world settings.

Methods and results: A prospective analysis was performed of the treatment of 427 consecutive patients with atherosclerotic lesions of the cervical segment of the internal carotid artery who underwent 483 carotid artery stenting procedures with the use of proximal cerebral protection at a single centre during the period from January 2010 to December 2013. The mean age was 67.3±9.1 years, 71.7% were males. 69.8% of ICA lesions were symptomatic. The internal carotid artery lesion was covered with the closed cell stent/closed cell part of a stent in 92.1% of cases. All patients had neurological assessment before and after the procedure. The study's primary endpoints included any stroke, myocardial infarction, all-cause death and the composite of any stroke, myocardial infarction or all-cause death at 30 days and the composite of any ipsilateral stroke or all-cause death at 12 months after intervention. During the 30 days after intervention there were 2 (0.4%) fatal strokes, 3 (0.6%) minor strokes and no acute myocardial infarctions. The rate of the composite endpoint at 30 days after intervention was 1.0%. There was no significant difference between procedures for symptomatic and asymptomatic lesions in the incidence of the composite endpoint at 30 days after intervention (1.2% vs. 0.7%, respectively; p=1.0). At 12 months of follow-up, 5 (1.0%) patients had a stroke, 5 (1.0%) patients died. The incidence of the composite endpoints at 12 months was 2.1%.

Conclusions: Carotid stenting with the use of proximal cerebral protection demonstrates low rates of stroke, myocardial infarction, death within 30 days after intervention and low rates of ipsilateral stroke and death at 12-month follow-up.

Peripheral interventions

Euro15A-MA068

Cerebral protection during transcatheter heart valve implantation by using an endovascular dual filtration system

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Aims: Endovascular cerebral protection devices aim for the reduction of periprocedural stroke rates during transcatheter aortic valve implantation (TAVI). The aim of this study was to evaluate the device success rate as well as rate of stroke or TIA after TAVI performed with the dual filtration system Claret Montage™ which has been replaced by the Claret Sentinel™ (introduced in 03/2014).

Methods and results: The analysis comprises 90 patients, who underwent TAVI between September 2011 and October 2014 in two heart centres. Inclusion criterion was a suspected increased risk for stroke. Patients had atrial fibrillation in 48.8%, mobile structures or very severe calcification at the aortic valve in 42.8%, history of stroke in 19.8%, or a present LAA-thrombus in 7.8% of cases. In 18.9%, TAVI was performed as a valve-in-valve procedure. A second-generation, repositionable device was used in 8.4% of patients. After administration of heparin (ACT >250 sec), the cerebral embolic protection devices (Claret Montage™ n=51, Claret Sentinel™ n=39) were inserted immediately before initiation of any valvular manipulation via the right radial (n=87) or brachial artery (n=3). Data of clinical stroke/TIA was retrospectively analysed and will be prospectively collected during a follow-up of 12 months. Patients were 58.9% male with a mean age of 79.9±7.6 years. All patients were considered to be at high-risk for surgical aortic valve replacement, reflected by a mean logistic EuroSCORE I of 22.4±16.3% and a mean STS PROM of 6.1±5.6%. Successful deployment of the protection devices was achieved in all but 3 patients (96.8%). No device associated major vascular complications were observed. No acute stroke/TIA occurred within 48 hours post-procedure. Thirty-day stroke/TIA rate after TAVI was 1.1% (TIA n=1, stroke n=0), all-cause 30-day mortality rate was 8.9% (n=8). One patient with a mitral mechanical prosthetic valve and a thrombus in the left atrial appendix died from a non-cerebral vascular embolic event leading to acute mesenteric ischaemia 10 days after TAVI.

Conclusions: Use of the Claret montage™ and Claret sentinel™ devices is safe and results in a low 30-day stroke/TIA rate. However, the results need to be validated in a larger, randomised clinical trial.

Peripheral interventions

Euro15A-MA069

Transcatheter revascularisation of the brain in the treatment of atherosclerotic lesions complicated by mental disorders

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Aims: This research investigates the effectiveness of the method of brain transcatheter revascularisation in the treatment of ischaemic lesions accompanied by mental disorders.

Methods and results: One thousand, two hundred and thirty-eight (1,238) patients aged 29-81 years (average age 75) suffering from various types of atherosclerotic lesions of cerebral vessels were examined undergoing computed tomography of the brain (CT), magnetic resonance imaging (MRI), scintigraphy of the brain (SG), rheoencephalography (REG), cerebral multi-gated angiography (MUGA), laboratory examination and assessment of the severity of dementia, cognitive disorders and everyday life disorders. Of these, 735 (59.37%) patients – 529 (71.97%) male, 206 (28.03%) female – also had mental disorders. Seven hundred and two (702) patients were selected for transcatheter treatment. According to the severity of dementia, the patients were divided into the following groups: Group 1 (severity of dementia corresponds to CDR-1), 394 (56.13%) patients; Group 2 (severity of dementia corresponds to CDR-2), 199 (28.35%) patients; Group 3 (severity of dementia corresponds to CDR-3), 109 (15.53%) patients. For main intracranial arteries revascularisation, high-energy laser systems were used, for distal intracranial branches revascularisation, low-energy ones. Good immediate angiographic outcome manifested in vascular lumen and patency restoration and collateral revascularisation was obtained in 698 (98.01%) cases. After the interventional laser treatment, practically complete restoration of motor functions and intellectual ability and decline of cognitive disorders to MMSE 27-30, IB 90-100 were considered a distant good clinical outcome; partial restoration of motor functions and intellectual ability, IB 75-85 were considered a satisfactory clinical outcome; partial restoration of motor functions and intellectual ability, IB 60-70 were considered a relatively satisfactory clinical outcome. In 12 months, various groups of the treated patients demonstrated the following clinical outcome: initial Group 1 – good clinical outcome was obtained in 319 (80.96%) cases, satisfactory clinical outcome in 58 (14.72%) cases, relatively satisfactory clinical outcome in 17 (4.31%) cases; initial Group 2 – good clinical outcome was obtained in 88 (44.22%) cases, satisfactory clinical outcome in 67 (33.68%) cases, relatively satisfactory clinical outcome in 44 (22.11%) cases; initial Group 3 – good clinical outcome was obtained in 12 (11.00%) cases, satisfactory clinical outcome in 34 (31.19%) cases, relatively satisfactory clinical outcome in 63 (57.81%) cases. It should be noted that the restoration of motor functions went on slower than the restoration of intellectual ability and to a greater degree depended on the size of the post-ischaemic cyst and the timing of transcatheter treatment after the stroke.

Conclusions: Mental disorders mostly develop against the background of distal lesions of intracranial arterial branches. The method of transluminal laser revascularisation of cerebral vessels is an effective transcatheter method of small traumas for the treatment of atherosclerotic lesions of the brain. It allows restoring the patency and lumen of vessels of various diameters simultaneously causing collateral revascularisation of the ischaemic area and near located tissue. The effect persists for a long time and promotes regression of mental disorders greatly improving the quality of life of these patients.

EuroPCR Peripheral interventions Euro15A-MA070

Safety and efficacy of carotid stenting in the treatment of carotid artery stenosis: immediate results and long-term follow-up in our experience

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Aims: Carotid artery stenting may be an alternative to surgical endarterectomy for the treatment of atherosclerotic carotid artery stenosis. The aim of our study was to analyse retrospectively the procedures of carotid artery stenting performed in our centre between January 2004 and December 2013.
Methods and results: This analysis includes 653 procedures performed in 602 patients (69% males; mean age: 72 years old). Symptomatic patients with carotid artery stenosis greater than 50% were the 45%; we treated asymptomatic patients affected by stenosis greater than 70%. Of these, 72% of patients were considered at high surgical risk: 37% with severe contralateral stenosis; 24% with severe or unstable angina, poor left ventricular function, left main disease or trivascular coronary artery disease, severe cardiac valve disease; 6% of patients presented restenosis after surgical treatment. Five percent of patients were treated with urgent coronary artery by-pass grafting (CABG) immediately after carotid artery stenting; 19% of patients underwent staged CABG one month after carotid artery stenting. Distal cerebral protection devices were used in 85% of the procedures. Soft plaques were present in 18% of patients. Nine % of patients were submitted to carotid artery stenting for bilateral carotid artery stenosis. We obtained a successful immediate angiographic result in 99% of patients. Major complications occurred in 1.8% of patients and included death (1 fatal stroke), major stroke (3), intracerebral haemorrhagic stroke (1), minor stroke (5), acute in-stent thrombosis (1 patient treated with thrombo-endarterectomy and stent removal). Puncture site haematoma occurred in 4 patients treated with vascular surgical repair, one patient died for haemorrhagic shock. We had a complete follow up in 95% of patients. In-stent restenosis occurred in 6 patients (<1%) and was successfully treated with new stenting. Fifty patients died (22 for cardiovascular causes), but none died for causes directly related to carotid artery stenting.
Conclusions: In our experience, carotid artery stenting is a safety procedure with low complications even in high-risk patients; the long-term efficacy of carotid artery stenting is very good with low rates of restenosis.

EuroPCR Peripheral interventions Euro15A-OP240

Safety and efficacy of carbon dioxide digital subtraction angiography in endovascular therapy for renal artery stenosis

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Aims: The aim of our study was to evaluate the safety and efficacy of carbon dioxide digital subtraction angiography (CO2-DSA) in endovascular therapy (EVT) for renal artery stenosis (RAS).
Methods and results: EVT for RAS was performed in 72 patients (92 lesions) at our institute from January 2011 to July 2013. Of these lesions, we analysed only *de novo* 79 lesions and evaluated safety and efficacy of CO2-DSA compared to EVT with iodinated contrast medium only. Endpoints were 30-day complication rates and the patency rate at 6 months. The mean age was 71.5-years-old, 81% were male. Of 79 lesions, 24 lesions were performed with CO2-DSA only or by using CO2-DSA as a supplement of iodinated contrast medium. CO2-DSA group had worse renal function compared to iodinated contrast medium only group (non CO2-DSA group) (27.3±3.0 vs. 51.6±2.1 ml/min/1.73 m^2, p<.0001). There were no significant differences in usage rate of stent, stent size and usage rate of intravascular ultrasound and distal protection device. Although one EVT for renal artery obstruction caused when endovascular aneurysm repair failed to recanalise, the others were able to obtain angiographic success. CO2-DSA group was performed with significantly lower amounts of contrast medium (28.3±8.6 vs. 109.8±5.7 ml, p<.0001). Thirty-day complications occurred in 7 cases; 2 exacerbation of heart failure, 4 deteriorations in renal function and 1 splenic embolism. No significant differences in 30-days complications existed between the two groups (8.33% vs. 9.09%, p=.91). There was also no significant difference in the patency rate at 6 months (88.9% vs. 89.1%, p=0.92).
Conclusions: Our data suggests EVT for RAS with CO2-DSA has similar midterm outcomes with lower amounts of contrast medium and without the increase in complications compared to EVT with iodinated contrast medium only.

euroPCR Peripheral interventions

Euro15A-OP242

The learning curve in transradial carotid artery stenting: results from RADCAR, the radial access for carotid artery stenting study

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Aims: To determine whether radial artery access is associated with a reduction in fluoroscopy time, x-ray dose, procedure time, contrast consumption and other procedural variables over a 3-year period during the RADCAR multicentre study comparing the femoral and radial approach for carotid artery stenting.

Methods and results: The clinical, angiographic and procedural data of 260 consecutive patients with a high-risk for carotid endarterectomy, who were treated between 2010 and 2012 by carotid stenting with cerebral protection, were evaluated. Patients were randomised to transradial (n=130) or transfemoral (n=130) groups and several parameters were evaluated. The primary combined endpoint: major adverse cardiac and cerebral events, rate of access site complications. Secondary endpoints: angiographic outcome of the procedure, fluoroscopy time and x-ray dose, procedural time, crossover rate to another puncture site and hospitalisation in days. Procedural data were collected and the interventions were analysed by the first, second and third year to investigate the procedural results over time. Procedural success was achieved in all 260 patients (100%); in the TR group the success by year was 86.2%, 81.8% and 95.6% (p=ns). Procedure time (1,620 [1,230-2,100] vs. 1,500 [1,080-2,100], p=ns) and fluoroscopy time (540 [411-735)] vs. 501[378-702], p=ns) was not significantly different, but the radiation dose was significantly higher in the TR group (195 [129-274] vs. 148 [102-237] Gycm^2, p<0.05). In the third study year, the fluoroscopy time (476 [361-630)] vs. 558 [383-904], p<0.05) and procedure time (1,500 [1,155-1,800] vs. 1,800 [1,350-2,055], p<0.05) was significantly lower in the TR group, but the radiation dose was significantly higher (195 [134-273] vs. 121 [71-211], p<0.05). Puncture time, cannulation time and procedure time in the TR group was 30-20-15 sec (p<0.05), 60-65-62 sec (p=ns) and 1,920-1,800-1,500 sec (p<0.05). The x-ray dose and fluoroscopy time in the TR group was 199 (121-344) – 177 (130-282) – 195 (134-273) Gcm^{2}y (p=ns) and 714 (510-863) – 600 (452-729) – 476 (361-630) seconds (p<0.05). Contrast volume in the TR group was 135 (100-150) -140 (100-150) - 140 (91-165) and 100 (75-125) ml. Hospitalisation days were significantly lower in the TR group (1.17±0.40 vs. 1.25±0.45, p<0.05). Major access site complication was encountered in one patient (0.9%) in the TR and in one patient (0.8%) in the TF group (p=ns). The incidence of major adverse cardiac and cerebral events was 0.9% in the TR and 0.8% in the TF group (p=ns).

Conclusions: The transradial approach for carotid artery stenting is safe and efficacious; however, the crossover rate is higher with transradial access. There are no differences in total patient population in procedure duration and fluoroscopy time between the two approaches, but the radiation dose is significantly higher in the radial group and the hospitalisation is shorter with the transradial access. The incorporation of the radial access approach for carotid artery stenting led to a decrease in fluoroscopy time, procedure time and contrast consumption over the last 3 years.

euroPCR Peripheral interventions

Euro15A-OP243

The PALADIN study: an update

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Aims: Here we update the molecular findings from the biomedical, mechanistic PALADIN study on the pathophysiological approach to the interventional therapy of limb atherosclerotic disease. Lower extremities artery disease is a major public health issue. Despite its high prevalence and dramatic evolution, little is still known about plaque characteristics and their relation to disease progression. Understanding the pathophysiology of progression of the long lesions could help to identify better treatment options, both at systemic and local level. We conducted a prospective observational trial aimed at investigating: 1) the morphological and cellular features of the vascular lesions and 2) the status of the Notch signalling, an atherosclerosis-related pathway, in plaques material obtained from 20 symptomatic patients with long femoropopliteal obstructive lesions undergoing a first revascularisation procedure.

Methods and results: Morphological analyses included duplex ultrasound, quantitative peripheral vessel and optical coherence tomography. Masson's trichrome and Oil-Red O staining were used to determine collagen and fat content and tissue morphology. Macrophages and vascular smooth muscle cells (VSMCS) content was assessed by immunostaining for CD68 and α-smooth muscle actin (SM22). Protein levels of receptors Notch 1 and 3 and of their ligands Jagged 1 and Delta-like 4 (Dll4) were also determined by immunohistochemistry. Quantitative RT-PCR was used to determine the expression levels of the Notch target genes Hes1, Hey1, Hey2, HeyL, of the inflammation markers cyclooxygenase 2 (COX2) and VCAM1 (vascular cell adhesion molecule 1) and of the gene coding for the anti-apoptotic protein B-cell lymphoma 2 (Bcl2). Quantitative RT-PCR was also used to determine levels of miRNAs related to Notch regulation and/or atherosclerosis: miR^{2}1-5p, miR155, miR125a, miR424, miR126 and miR146. Spearman's correlation coefficients for hierarchical clustering analyses were calculated on gene expression data. We had previously reported high heterogeneity among plaques in terms of fibrous tissue, fat, thrombus and macrophages and ubiquitous expression of Notch 3. We now show ubiquitous expression of Notch 1 and Dll4 and positivity for Jagged 1 and for the cleaved active form of Notch 1 staining in 55.5% and 38.9% of plaque material, respectively. Furthermore, we found that Dll4-activated Notch signalling was associated to high levels of inflammation markers (VCAM1; COX2, miR155) in contrast with Jagged1-activated Notch signalling which was associated to the expression of SM22, a marker of quiescent, contractile VSMCs phenotype.

Conclusions: Plaque material from long femoropopliteal obstructive lesions differs among patients in the expression levels of Notch ligands, Notch target genes and inflammation markers. Differential effects of ligands Delta-like 4 and Jagged 1 on Notch signalling activation may play a role in the evolution of the femoropopliteal obstructive lesions.

Primary lesion treatment with an orbital atherectomy system enhances paclitaxel deposition in calcified peripheral arteries

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Aims: There are multiple factors that limit clinical benefits of drug-coated balloons (DCB) in treating peripheral atherosclerosis, calcium being one of them. It has been hypothesised that efficacy of DCB can be improved through treatment of the calcified plaque with orbital atherectomy. The objective of this study was to determine the effects of orbital atherectomy system (OAS) treatment on the paclitaxel distribution in cadaveric samples of human peripheral arteries with substantial calcified plaque burdens.

Methods and results: Five fresh human lower limbs were obtained from a certified research institution and maintained on ice for further evaluation. Computed tomography was performed on all limbs to identify distribution and severity of calcification in the peripheral vasculature. Intravascular sheaths were inserted proximally and distally to simulate the arterial flow. Under fluoroscopic guidance, a guide catheter was advanced through the sheath into designated peripheral arteries and angiographic images obtained with contrast media to identify locations for atherectomy. The superficial femoral, popliteal and tibial arteries were divided through angiographic measurements into approximately equal segments, and the proximal or distal segment of each artery treated using the DIAMONDBACK 360® OAS (Cardiovascular Systems, Inc., St. Paul, MN, USA). IVUS images of the target vessels were obtained pre- and post-atherectomy. The arteries were harvested for further evaluation. Explanted arteries were cut in pairs of 3 cm in length along atherectomy-treated vs. non-treated demarcation lines, further trimmed to reduce edge effects, lumenally infused with a buffered solution (PBS/4% BSA) of radiolabeled (^{14}C, 10 µm) or fluorescent (Oregon Green 488, 10 µm) paclitaxel and incubated in drug-free buffered solution for 1 h at 37°C in a shaking water bath. At the end of 1 h, incubated segments were rinsed and processed for scintillation counting or fluorescent microscopy. Quantification of ^{14}C-labeled paclitaxel was conducted for drug deposition in atherectomy-treated vs. non-treated arteries. There was a clear trend of increasing drug deposition in the calcified artery tissues after atherectomy treatment, ranging from 20% more in superficial femoral and popliteal arteries to more than 400% increase in tibial arteries. The average increase of drug deposit in OAS treated arteries was above 50% (N=10). Fluorescent microscopy revealed drug distribution patterns that supported the tissue retention trends exhibited by radiolabeled paclitaxel. Whereas fluorescent paclitaxel in non-atherectomised arteries was characterised predominantly by condensed superficial penetration (20-40 µm) of the luminal surface of the arterial tissue, OAS modification of atheromatous artery walls resulted in more homogenous and deeper diffusion (100-300 µm) of fluorescent paclitaxel.

Conclusions: These data illustrate for the first time that the DIAMONDBACK 360® peripheral orbital atherectomy system can safely modify calcified plaque barriers to intravascular drug delivery, significantly improving drug diffusion and retention in the diseased tissues throughout the superficial femoral, popliteal and below the knee artery beds.

Pudendal artery angioplasty for the treatment of complex erectile dysfunction in males

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Aims: Erectile dysfunction (ED) is an important and growing health problem. It is estimated that more than 200 million men (between the ages of 40-70 years) suffer from ED. The real prevalence could be much higher as it is under reported and under treated. Pudendal artery stenosis is the most common aetiology in patients who fail PDE–5 inhibitors therapy (complex ED). These properly selected patients can be successfully treated by pudendal artery angioplasty. We present our experience of 36 consecutive patients (which is probably the largest in the world).

Methods and results: Three hundred and thirty-eight (338) patients of erectile dysfunction because of varied aetiologies were screened for pudendal artery stenosis as the possible aetiology. Of these, 36 patients were found to be having pudendal artery stenosis as the aetiology and these patients underwent pudendal artery angioplasty. Endocrinal, urological and psychological causes were excluded and then these patients were subjected to a penile Doppler study (after intra cavernosal injection of papaverine). In patients where the peak systolic penile velocity was less than 25 cm/sec, pudendal artery stenosis was strongly suspected. These patients then underwent selective angiography for identification of pudendal artery stenosis. If the stenosis was found, they were subjected to super-selective pudendal artery cannulation and angioplasty or stenting using a drug-eluting balloon (DEB) or zotarolimus-eluting stents (DES). Patients were followed up at 3, 9, 12 months and then after every year by Duplex scans. The procedure was successful in all patients. There were no death, perineal or penile gangrene. In follow-up, the mean penile velocity increased from base line of 16 cm/sec to 44, 50, 58 cm/sec at 3, 6, 12 months respectively. Improvement >4 points in international index of erectile functions (IIEF -6) score at 3, 6 and 12 months was 68%, 75% and 78%, respectively.

Conclusions: Angioplasty of focal stenosis of internal pudendal artery by DEB or DES appears to be a very promising therapy for male erectile dysfunction. It is safe, feasible and leads to sustained improvement of male erectile dysfunction.

euroPCR Peripheral interventions

Euro15A-OP246

Drug coated balloon angioplasty versus conventional angioplasty for the treatment of the superficial femoral artery and first popliteal segment in patients with peripheral artery disease: updated interim results of the FREERIDE study

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Aims: The use of a paclitaxel-coated DCB during percutaneous transluminal angioplasty (PTA) treatment of the femoropopliteal lesions in PAD patients might result in a significant reduced restenosis rate. Thus, the FREERIDE study investigates the inhibition of restenosis by the FREEWAY DCB versus plain balloon (POBA) in the treatment of occluded or stenotic lesions in the superficial femoral artery (SFA) and popliteal arteries (PI segment).

Methods and results: Two hundred and eighty (280) patients will be randomised either to FREEWAY DCB or to POBA in 23 centres worldwide. The primary endpoint is clinically driven target lesion revascularisation rate (TLR) at 6 months. The secondary endpoints include late lumen loss and patency rate at 6 months, TLR at 12 and 24 months follow-up (FU), improvement in Rutherford classification and Ankle-Brachial index (ABI) and MAE. At present, over 100 patients have been enrolled; over 80 of them completed the 6-month FU. At the 6-month FU, positive trends were observed for the TLR rate (7.1% vs. 16.7% after POBA) and MAE (7.1% vs. 23.4% after POBA). Furthermore, there are positive trends in the patency rate and in the improvement of Rutherford classification after FREEWAY PTA vs. POBA.

Conclusions: The continuously updated interim results indicate that FREEWAY DCB might provide an advantage for angioplasty in SFA and PI-segment lesions. DCB might overcome the existing limitations in the treatment of peripheral disease.

euroPCR Peripheral interventions

Euro15A-OP247

How to ameliorate the disappointing: 1-year results of bioabsorbable stents in superficial femoral artery lesions (the Belgian Remedy registry)

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Aims: In the treatment of superficial femoral artery (SFA) lesions, nitinol stents are commonly used with good results. But the incidence of in-stent stenosis or occlusion is increasing, and their treatment remains a difficult and yet unresolved issue. We wanted to investigate if the placement of a "temporary" bioabsorbable stent can be a solution.

Methods and results: The Belgian multicentre prospective follow-up study used the bioabsorbable semi-self-expandable REMEDY™ stent (Kyoto Medical Planning Co Ltd, Kyoto, Japan) for the treatment of short (≤8 cm) SFA lesions. This stent is made of a biodegradable polymer and has a zigzag helical coil stent design. At present, it is available in 2 lengths, 36 and 78 mm, on a 7 Fr device. We have treated 100 patients with TASC II A and B lesions in the SFA region. Mean lesion length was 35 mm (2-80 mm). Technical success rate was 98%. There were no intervention-related deaths. Follow-up ultrasound at 6 months revealed primary patency rate 70.2%, assisted patency rate 88.5% and target lesion revascularisation rate 17.9%. At 12-month follow-up, primary patency rate was approximately 65%. For optimisation of these disappointing results, we now are doing a small trial with 30 patients where we combine the use of a drug-coated balloon (Legflow; Cardionovum, Bonn, Germany), the new designed bioabsorbable Remedy stent and one-year double antiplatelet therapy (aspirin and clopidogrel; EG, Brussels, Belgium).

Conclusions: Bioabsorbable stent technology might improve the mid- and long-term durability of the SFA endovascular treatment. The early results were encouraging, but the 12-month results were rather disappointing. The combination of drug-coated balloon, Remedy stent and one-year double antiplatelet therapy is under ongoing investigation to see if this could improve the results. A better understanding and even adjustments of the kinetic and mechanical characteristics of the stent structure are necessary and are under investigation.

Clinical outcome of drug-eluting stent implantation for small superficial femoral artery lesions as compared to bare metal stents

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Aims: It has been reported that small vessel diameter is one of the predictors of restenosis after bare metal stent (BMS) implantation for superficial femoral artery lesions. However, little data exists on patients who have undergone drug-eluting stent (DES) implantation for "small" superficial femoral artery lesions. We compared clinical outcomes of DES with BMS.
Methods and results: This was a single centre, non-randomised retrospective study. From April 2007 to April 2013, 157 patients (165 lesions) who underwent DES (Zilver® PTX® stent; Cook Medical, Bloomington, IN, USA) or bare-metal stent (S.M.A.R.T.® stent; Cordis, Johnson & Johnson, Warren, NJ, USA) implantation for *de novo* "small" superficial femoral artery lesions were included. All patients were followed for 12 months after stenting. A "small vessel" is defined as a vessel with a reference vessel diameter <5 mm measured by quantitative vascular analysis (QVA). The patients were classified into two groups: patients with Zilver PTX stents (Z group, 38 patients, 43 lesions) and patients with S.M.A.R.T. stents (S group, 119 patients, 122 lesions). We compared clinical outcomes at 12 months after stent implantation. For patients and lesion characteristics, there were no significant differences between the two groups in age, gender, and the percentage of diabetes mellitus, haemodialysis, critical limb ischaemia, poor run-off, lesion length >150 mm, and Trans-Atlantic Inter-Society Consensus (TASC) II classification C/D. The mean reference vessel diameters were similar (4.38±0.52 vs. 4.27±0.49, p=0.24). The primary patency at 12 months was similar between the Z group and the S group (76.7% vs. 83.6%, Log rank p=0.79).
Conclusions: Clinical outcome of DES implantation for "small" superficial femoral arteries was similar to that of bare metal stent (BMS).

Randomised clinical trial favours the use of drug-coated balloons over plain balloons for the post-dilatation of nitinol stents in the superficial femoral artery and first popliteal segment to lower restenosis rate

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Aims: Stents are needed in up to 50% of all peripheral interventions where PTA with plain or drug-coated balloons alone will not reopen the vessel sufficiently. Nevertheless, the restenosis rate of stents is still a major limitation of peripheral arterial interventions. Drug-coated balloons potentially overcome the problem of in-stent restenosis when used for post-dilatation after primary nitinol stenting in the SFA and PI segment.
Methods and results: The Freeway Stent Study is a prospective, randomised, international trial started in 15 centres in Germany and Austria. Two hundred (200) patients will be enrolled and randomised equally to primary nitinol stenting followed by either DCB (Freeway™) or plain balloon post-dilatation. The primary endpoint is clinically driven target lesion revascularisation (TLR) at 6 months, secondary endpoints include further clinical and safety evaluations such as a shift in Rutherford classification and ABI, LLL, patency rate and MAE. Over 170 patients have been enrolled to date, of which over 130 have finished the 6-month, and 100 the 12-month, follow-up. The results highly favour the use of Freeway™ DCB over the plain balloon based on clinically-driven TLR (only 2.9% vs. 11.9% at 6 months and 9.1% vs. 18.0% at 12 months). This is supported by a statistically significant better clinical outcome for PAD patients treated with DCB as a post-dilatation device regarding primary patency rate, ABI and Rutherford classification at six months.
Conclusions: The use of DCB as post-dilatation device is investigated in a new approach to decrease the restenosis rate after nitinol stenting in the SFA and PI segment. The latest interim results of the Freeway Stent Study show that DCB might significantly lower the in-stent restenosis rate in the treatment of PAD patients.

Peripheral interventions

Euro15A-OP250

The distal femoropopliteal vessel diameter measured by IVUS as a predictor of stent restenosis

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Aims: To evaluate the predictor of self-expanding nitinol stent patency for the treatment of femoropopliteal disease.

Methods and results: Between August 2011 and September 2013, the registry enrolled 44 patients (39 men; 73±8 years) 58 lesions with symptomatic 75% stenosis or occlusion of the superficial femoral or popliteal arteries treated by endovascular intervention. Smoking history was 79.5%, hypertension 81.8%, dyslipidaemia 52.3%, diabetes 52.3%, chronic kidney disease 56.8%, haemodialysis 9.1%. Rutherford class 1-3: 77.6%, Rutherford class 4: 3.4%, Rutherford class 5: 13.8%, Rutherford class 6: 5.2%. ABI 0.60±0.14. Mean length of the 58 lesions was 202±88 mm. Vessel diameter was measured using intravascular ultrasonography (IVUS). Mean proximal and distal vessel diameter 6.5±1.0 mm, 5.7±1.0 mm. Chronic total occlusions were seen in 38 (65.5%) vessels. TASC A and B were 12 lesions, C was 21 lesions, and D was 25 lesions. Primary study endpoints were the need for target lesion revascularisation (TLR). At 6- and 12-months post-intervention, peak systolic velocity ratio (PSVR) of duplex scan was estimated. Primary patency was defined as PSVRï'2.5. In the study period, self-expanding nitinol stents were successfully deployed in the 58 lesions. All lesions were examined at 12-months post-procedure. The overall TLR rate was 24.1% at 1-year. Primary patency was recorded in 72.4% and 69.0% patients evaluated at 6-months and 1-year post-procedure. The Rutherford grade improved or remained stable in the majority of patients (98.2%) after 1 year. Stent fractures in 6.9% of stents examined at 1-year. Distal vessel diameter <6 mm was predictor of primary patency from multivariate analysis.

Conclusions: The vessel diameter measurement by IVUS is useful in predicting self-expanding nitinol stent patency in femoropopliteal lesion.

Peripheral interventions

Euro15A-OP251

A prospective, multicentre study on the safety and efficacy of a novel, mesh-covered carotid stent in patients with symptomatic and asymptomatic carotid artery stenosis: the CGuardCARENET (carotid embolic protection using MicroNet™) trial

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Aims: To evaluate the safety and efficacy of a novel thin strut nitinol stent combined with a PET-mesh covering (CGuard™ system) in the treatment of carotid artery lesions in consecutive patients suitable for CAS.

Methods and results: Thirty (30) consecutive eligible patients (71.6 years, 63% male) were enrolled in 4 centres in Germany and Poland. The primary endpoint was 30-day MACE (death, stroke or myocardial infarction). Secondary endpoints included device success, procedural complications and the incidence, number and volume of new lesions assessed by DW-MRI at 48 hours post-procedure, and at 30 days. Among the risk factors, 23% were diabetics and 27% had a prior MI. Ten patients (33.3%) had a symptomatic carotid artery stenosis. Distal filter protection devices were used in 29 patients, proximal balloon protection in one. Predilatation was done in 70.9% of the cases and post-dilatation in 77.4%. The CGuard™ System was delivered and deployed in all cases, device success was 100%, the 30-day MACE was 0.0%. The flow in the external carotid artery after stenting was unimpeded in each case. The incidence of patients with new ischaemic lesions at 48 hours was 46.1%, the average lesion volume 0.06 cm^3, which is a 50% reduction in the incidence and 10-fold reduction in lesion volume compared to studies also using filter protection for CAS (PROFI, JACC, April 2012, ICSS Lancet, March 2010).

Conclusions: The use of the MicroNet™ covered stent in patients undergoing CAS is feasible and safe and suggests that it offers clinical benefits for patients undergoing CAS.

The WIRION Trial: a pivotal multicentre trial in high-risk surgical patients undergoing carotid artery stenting using the WIRION embolic protection device

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Aims: High success rates of embolic protection in carotid artery stenting procedures have been shown to reduce the rate of major adverse cardiac and cerebrovascular events. We present the European experience in patients undergoing carotid artery stenting in high-risk patients using a novel guidewire-independent distal filter.

Methods and results: The WIRION embolic protection device is a rapid exchange pre-crimped distal filter system used with any 0.014" guidewire according to physician preference. It is a stent-like system in form and operation. The WIRION system is deployed after a 0.014" guidewire of choice is positioned across the lesion in a standard fashion. Then the WIRION stand-alone filter unit can be delivered, positioned and locked anywhere along the guidewire, resulting in smooth crossing of the lesion and optimal protection position along the artery. One hundred and twenty (n=120) high-surgical-risk patients with no exclusion criteria based on risks for carotid stenting, mean age of 73.9 years were enrolled in the WISE study. Fourteen patients were symptomatic and 106 were asymptomatic. The lesions treated had an average stenosis of 84%. The 30-day composite primary endpoint of major cardiac and cerebrovascular event (MACCE) was 3.3%, with 0% death. Of these patients, one patient had contralateral stroke and a second patient had type 2 NSTEMI secondary to new untreated anaemia. Both were decided by the clinical event committee as non-procedure-related events. Only two patients (1.7%) experienced procedure-related events. The MACCE rate in the WISE study group was compared with an historical control group of high-surgical-risk patients showing significantly better performance. The device success rate was 99.2% (119/120). Angiographic success was achieved in 97.5% (117 patients).

Conclusions: The WIRION embolic protection device in carotid artery stenting is safe and highly effective when compared to the historical data in a population that include high-risk carotid artery stenting patients. It is simple to use and is highly rated by its multiple users. The ability to cross the lesion over a guidewire of choice and deploy the filter in the exact desired location creates a unique, natural and appealing advantage for all indications.

Novel PARADIGM in carotid revascularisation

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Aims: PARADIGM (Prospective evaluation of All-comer peRcutaneous cArotiD revascularisation In symptomatic and increased-risk asymptomatic carotid artery stenosis using CGuard™ Mesh-covered embolic prevention stent system) seeks to evaluate feasibility and outcome of routine anti-embolic stent use in unselected, consecutive patients referred for carotid revascularisation.

Methods and results: This investigator-initiated, prospective, all-comer study in a tertiary cardiovascular academic centre aims to evaluate, in the 1st phase, 50 consecutive CGuard™ embolic prevention stent procedures in unselected (i.e., all referred) patients. Angiographic and neurologic assessment are operator-independent. Asymptomatic subjects have at least one documented target lesion characteristics of increased symptomatic transformation risk. Primary endpoints are periprocedural (≤48 h) and 30 day major adverse cardiac or neurological events (MACNE – death, stroke or myocardial infarction). Secondary endpoints are device success, procedure success, and Doppler velocities and MACNE at 1 and 5 years. By abstract submission point, 41/50 procedures were performed in 40 patients (55-83 years, 55% symptomatic, 33% women) with no stent system use other than CGuard™ in the whole referral series, and 36 patients completed 30-day follow-up. Acute neurologic symptoms as indication were present in 3 patients (7.5%) and recent symptoms in 9 (22.5%). Target vessel was left/right internal carotid artery in 46/54%. Angiographic stenosis severity was 78.3% (58-98%) (mean, range). As embolisation risk is not limited to stent placement/post-dilatation, all procedures were performed under temporary neuroprotection (filters – 70.7%; proximal protection – 29.3%, MoMa/Gore Flow-Reversal). Challenging access anatomy (type 3/bovine arch) was present in 4 (9.8%). Lesion thrombus was present in 3 (7.3%), string-sign in 7 (17.1%), extreme-calcium in 5 (12.2%). Predilatation was performed in 90.2%. In two instances (4.9%), 2 stents were used. All stents (100%) were post-dilated. The stent system success and procedure success rate were 100%. Mean residual stenosis was 14.8% (3-26%) in absence of stent malapposition or external carotid artery flow impairment. Periprocedural complications occurred at 0%. By operator-independent neurologist and cardiologist evaluation, no MACNE occurred periprocedurally or at 30 days. Target vessel peak Doppler velocities were reduced from 3.7(1.8-6.2) /1.2 (0.5-2.7) to 0.68(0.29-1.12)/0.18(0.09-0.29) m/s ($p<0.001$).

Conclusions: Emerging evidence indicates that the CGuard™ mesh-covered embolic prevention stent system use is feasible in an all-comer carotid revascularisation population and is associated with a favourable angiographic and clinical outcome of endovascular reconstruction of the carotid bifurcation. Routine use of the mesh-covered carotid stent system, a significant technological and clinical advancement, may form a new paradigm in carotid revascularisation.

Peripheral interventions

Euro15A-OP254

Carotid artery plaque modification during carotid stenting assessed by near-infrared spectroscopy and intravascular ultrasound

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Aims: Atherosclerotic carotid artery disease is a common determinant of thromboembolic stroke. However, limited insights *in vivo* into the pathophysiology of carotid stenosis are available. Prediction of lesion-related atheroembolic potential and selection of patients who would benefit most from carotid endarterectomy or carotid stenting (CAS) is challenging. Traditionally, thin cap fibroatheroma with large necrotic core is considered a vulnerable plaque. Necrotic core contains great proportion of semi-liquid pool of extracellular lipids. We conducted a prospective single-centre study of near-infrared spectroscopy (NIRS) combined with intravascular ultrasound (IVUS) during CAS. Lipid core plaque (LCP) presence and distribution in carotid arteries and modification of LCP after CAS has not been described *in vivo* with NIRS up to now. The primary objective was to evaluate safety and feasibility of NIRS-IVUS imaging of carotid arteries and to describe size and distribution of LCPs before and after CAS. The following parameters were used to quantify size and localisation of LCPs: lipid core burden index (LCBI), maximal lipid core burden index in any 4 mm segment of the artery (LCBImax) and lipid core burden index in 4 mm segment at minimal luminal area (LCBImla).

Methods and results: A total of 32 patients at high risk for surgical endarterectomy (62% male, mean age 64.3±6.7 years) – and therefore scheduled for CAS – were enrolled. Three NIRS-IVUS pullbacks were performed: before stent implantation, after stent implantation and after balloon post-dilatation. High quality NIRS data were obtained in all cases (100%) before and after CAS. There were no periprocedural complications related to NIRS-IVUS imaging, and no periprocedural stroke or death. Mean LCBI decreased from 107.4±95.4 before CAS to 44.2±59.2 after stent implantation ($p<0.001$) and 29.4±38.8 after post-dilatation ($p=0.075$). Mean LCBImax decreased from 352.7±208.5 before CAS to 175.7±166.8 after stent implantation ($p<0.001$) and 156.2±153.8 after post-dilatation ($p=0.215$). Mean LCBImla decreased from 206.1±224.5 before CAS to 52.1±123.1 after stent implantation ($p<0.001$) and 26.1±65.6 after post-dilatation ($p=0.098$). Lipid rich plaques were significantly more frequent elsewhere than at the minimal luminal area (MLA) (LCBImax before CAS 352.7±208.5 vs. LCBImla before CAS 206.1±224.5; $p<0.001$). LCBI ($r=-0.24$; $p=0.177$) and LCBImla ($r=-0.05$; $p=0.782$) did not correlate with MLA.

Conclusions: Our results suggest that the performing of NIRS-IVUS during CAS is safe and feasible and provides additional information about atherosclerotic plaques in carotid arteries. We observed significant reduction of NIRS-derived lipid core size parameters during CAS. Further research is needed to determine the significance of lipid core reduction in relation to cerebral embolism and outcomes.

Peripheral interventions

Euro15A-OP255

Long-term neurocognitive effect of carotid artery stenting in patients with severe carotid occlusive disease

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Aims: Carotid artery stenting (CAS) improves 3-month neurocognitive function (NCF) post-procedurally in patients with severe occlusive carotid disease and ipsilateral cerebral hypoperfusion, but the long-term effects are not clear.

Methods and results: We prospectively enrolled 88 patients with carotid artery diseases (27 with occlusion, 61 with severe stenosis) in whom CAS were attempted. Computed tomography perfusion (CTP) and NCF assessments including Mini-Mental State Examination (MMSE), Alzheimer Disease Assessment Scale-Cognitive Subtest (ADAS-Cog), verbal fluency, Colour Trail Making A and B were applied prior to intervention, at 3 months and at more than 1 year after intervention. Successful recanalisation was achieved in 19 of the 27 occlusion patients (70%), and all 61 severe stenosis patients. Two cases were excluded due to procedural cerebral complications. The patients were divided into 3 groups: group 1 (n=8) were patients with baseline ipsilateral abnormal cerebral perfusion in whom CS failed; group 2 (n=49) were patients with baseline ipsilateral abnormal cerebral perfusion in whom CS were successful; and group 3 (n=29) were patients without baseline ipsilateral abnormal cerebral perfusion in whom CS were successful. Baseline MMSE and Colour Trail Making A results in group 2 were worse than those in group 3. Only in group 2, were there significant short- and long-term improvement in ADAS-Cog (pre- vs. 3-month vs. 1-year: 7.9±6.7 vs. 5.9±4.5 vs. 5.2±4.4, $p=0.0003$), MMSE (pre- vs. 3-month vs. 1-year: 26.2±2.9 vs. 27.2±2.8 vs. 28.0±2.0, $p<0.0001$), Colour Trail Making A (pre- vs. 3-month vs. 1-year: 114.2±60.9 vs. 97.6±53.3 vs. 106.1±70.0, $p=0.0011$) and Colour Trail Making B (pre- vs. 3-month vs. 1-year: 188.1±83.9 vs. 180.9±80.2 vs. 173.4±88.1, $p=0.0292$) after CAS. Significant differences in changes from 3 months to baseline and at 1 year to baseline were observed in the ADAS-Cog, MMSE and Colour Trailing Making A groups.

Conclusions: Neurocognitive improvement after CAS is persistent up to 1 year only in those patients with severe occlusive carotid disease and ipsilateral cerebral hypoperfusion.

Paclitaxel-coated balloon for the treatment of infrapopliteal arteries: 12-month results from the BIOLUX P-II randomised trial

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Aims: Plain old balloon angioplasty of infrapopliteal arteries is associated with high restenosis rates. Recently, drug-releasing balloons have emerged as a viable treatment alternative. BIOLUX P-II assesses the safety and performance of the novel Passeo-18 Lux paclitaxel-releasing balloon versus the uncoated Passeo-18 balloon for the treatment of stenosis, restenosis or occlusion of infrapopliteal arteries.

Methods and results: BIOLUX P-II is a prospective, international, multicentre, randomised, controlled, first-in-man (FIM) clinical trial with follow-up investigations at 30 days, 6 and 12 months. Subjects with single or sequential, *de novo* or restenotic lesions in the infrapopliteal arteries (≥30 mm) were included in the study. Lesions should not have extended beyond the ankle joint, and a maximum of two different vessels were treated. The safety and performance primary endpoints were major adverse events (MAE) at 30 days and target lesion primary patency at 6 months (assessed by an independent angiographic core laboratory via quantitative vascular angiography), respectively. Seventy-two subjects, 79.2% men, mean age 71.3±9.7 years were randomised 1:1 at six European sites. At baseline, subjects presented with hypertension (86.1%), hyperlipidaemia (68.1%), diabetes (66.7%) and critical limb ischaemia (77.8%). At 30-days, MAE was 0.0% for the DCB vs. 8.3% for POBA, p=0.239. At 6-months, target lesion primary patency showed a trend in favour of the DCB of 84.3% vs. 75.9% for POBA (p=0.330) and major amputations were 3.3% for DCB vs. 5.7% for POBA (p=0.655). Clinical improvement at 6 months, reflected by improvement in Rutherford class was 59% in favour of DCB vs. 47% for POBA, with 0% of DCB subjects worsening vs. 6% POBA (p=0.326). Clinical improvement of Rutherford 5 subjects was significant for the DCB group (p=0.002) compared to POBA (p=0.058). At 12-months, safety of the Passeo-18 Lux DCB is confirmed with no increase in major amputations at 3.3% DCB vs. 5.6% POBA (p=0.631).

Conclusions: In a small FIM patient population including claudicants and CLI patients, DCB treatment has proven to be safe. At 12-months, no increase in major amputations confirmed the 6-month results. The study was not powered to evaluate clinical endpoints. Further evaluations will be needed from trials adequately powered for clinical outcomes to determine the role of DCB in infrapopliteal disease.

The PES-BTK-70 study: final results of the assessment of the first self-expanding nitinol paclitaxel eluting stent in below-the-knee lesions

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Aims: Previous studies have shown that treatment with drug-eluting stents is safe and effective in patients with critical limb ischaemia due to occlusive infrapopliteal disease. The results with currently available DES come from balloon-expandable stents. However, self-expanding nitinol stents traditionally yield better results in arterial anatomies that are prone to flexing, elongation, compression and bending. This study investigates primary stenting using the first self-expanding nitinol paclitaxel-coated DES (STENTYS, Paris, France) in below-the-knee lesions.

Methods and results: This study is a multicentre, single-arm study, which prospectively evaluates the 6- and 12-month safety and effectiveness of the STENTYS DES in 70 patients with critical limb ischaemia. The 70 patients were enrolled in 5 centres in 2012 and 2013. Inclusion criteria were evidence at screening of >50% *de novo* lesions, reference vessel diameter between 3.0 mm and 4.5 mm, lesion length shorter than 50 mm. Patients with previous bypass or major distal amputation in target limb, untreated flow limiting inflow lesions, in-stent restenosis, or severe calcification were excluded. Predilatation of the target lesion was mandatory. Primary patency rate, defined as absence of restenosis (>50% stenosis) or occlusion within the originally treated lesion based on angiography, was evaluated by a core laboratory at 12 months follow-up (primary endpoint). Mean age was 74.6 years, 33 patients (47.1%) were in Rutherford class 5, and 28 patients (40.0%) presented diabetes mellitus. Mean lesion length was 19.7 mm. Technical and procedural success was 97.1%. At 12 months follow-up, primary patency rate was 72.6%, freedom from target lesion revascularisation was 79.1%, survival rate was 89.4%, and limb salvage rate was 98.5%.

Conclusions: The final results of the study will be presented at EuroPCR 2015, including the primary endpoint as well as the technical and procedure success rates, rates of limb salvage rate and target lesion revascularisation, survival rate, improvement in ankle-brachial index and Rutherford class. These final results confirm that the self-expanding paclitaxel-coated STENTYS stent is a valid alternative in below-the-knee lesions.

Peripheral interventions

Euro15A-OP258

First experience with an everolimus-eluting, bioresorbable scaffold below-the-knee: 6-month clinical and imaging outcomes

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Aims: Restenosis rates after standard balloon-angioplasty for occlusive tibial arterial disease are reduced with the use of drug-eluting stents; however, the ongoing presence of a permanent metal scaffold may have deleterious effects on the local vessel. The aim of this study was to investigate a new bioresorbable vascular scaffold for the treatment of focal tibial and distal popliteal lesions.

Methods and results: Tibial and distal popliteal angioplasty and scaffold placement was performed with an everolimus-eluting, bioresorbable scaffold. Clinical and ultrasound follow-up was performed at 1, 3, 6 and 12 months to detect binary restenosis, evaluate safety, midterm restenosis rate and clinical improvement. Fifteen limbs in 14 patients were treated for critical limb ischaemia (CLI) (47%) or severe claudication (53%). Twenty-one scaffolds were used to treat a total of 18 lesions with a mean length of 22.2±14.0 mm. Immediate technical success was 100%, although a single limb suffered two scaffold thromboses on the first day, which required salvage with repeat endovascular intervention. During a follow-up period of 6.1±3.9 months, all patients were available for follow-up and none had died. Of the 15 limbs in the analysis, clinical improvement was present in 12 (80%). There was no evidence of binary restenosis or occlusion on follow up sonographic examination. Complete wound healing occurred in 50% of those treated for tissue loss, with no major amputation recorded in those patients with CLI, resulting in a limb-salvage rate of 100%.

Conclusions: Midterm follow-up for this small pilot sample demonstrates acceptable safety and patency results, together with freedom from all major adverse limb events using the ABSORB bioresorbable vascular scaffold below-the-knee.

Peripheral interventions

Euro15A-OP259

Peripheral pressure-wire measurement of the below-the knee arteries in critical limb ischaemia: validation with angiography and laser Doppler measurements

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Aims: The aim of the study was to assess the correlation between non-invasive versus invasive measured parameters by pressure-wire during rest and after maximal hyperaemia (peripheral fractional flow reserve [pFFR]) before and after below-the-knee angioplasty.

Methods and results: We enrolled 20 patients in a prospective study with below-the-knee stenosis in critical limb ischaemia. Inclusion criteria were critical chronic ischaemia of the lower limb (Rutherford 4-6) and angiographically proven significant lesion of the distal lower limb (DS>69%). Exclusion criteria were chronic total occlusion to the wound that made pFFR measurement impossible or unacceptably risky, diabetic foot syndrome and non-viable distal lower limb. Routine quantitative angiography measurements were performed before and after angioplasty. We have measured the resting peripheral blood pressure (invasively assessed systolic gradient and fractional flow reserve [rest FFR]) and hyperaemic peripheral blood pressure (invasively assessed calculated pFFR value [hyperaemia induced by 40 mg intra-arterial papaverin]) before and after intervention. Laser Doppler was assessed with a commercially available laser Doppler system (PeriFlux system 500). Doppler perfusion units and transcutaneous O2 saturation were measured at rest and during stress. The intervention was done by routine angiographic guidance. The intervention was performed with good angiographic result in all patients. Diameter stenosis improved from 83.64±11.06% to 17.21±10.92% ($p<0.05$). Resting systolic gradient was 53.65±29.64 Hgmm before and 25.45±20.17 Hgmm after the intervention ($p<0.05$). Rest FFR improved from 0.74±0.15 to 0.85±0.12 ($p<0.05$). pFFR improved from 0.58±0.15 to 0.75±0.14 ($p<0.05$). Resting and stress Doppler perfusion units before the intervention were 29.08±20.01 at rest and 138.7±71.75 after stress and 29.31±20.04 (p=ns.) at rest and 166.1±83.93 ($p<0.05$.) after provocation. The percentage change in perfusion units improved from 561.2±474.5 to 650.5±485.5 ($p<0.05$). Resting and stress transcutaneous pO2 before intervention was 25.77±19.36 and 91.01±107.4 and after intervention it was 23.50±9.76 (p=ns.) and 102.2±118.40 ($p<0.05$). The percentage change in TcpO2 was 204.1±194.7 before and 238.7±241.9 after intervention ($p<0.05$). Significant correlation was found between diameter stenosis and pressure gradient, pFFR ($p<0.05$) and between Tc PU % increase and Dp, rest FFR. TcO2 pressures showed non- significant correlation with invasive parameters. Toe pressure also correlated significantly with distal invasive pressures. The limb survival at one-month follow up was 100%.

Conclusions: Diameter stenosis, toe pressure and laser Doppler perfusion unit change during stress shows significant correlation with invasively assessed resting gradient and pFFR. All invasive parameters improved after successful intervention. Further and larger patient series are necessary to clarify the real benefit of the direct pressure measurement during BTK interventions.

EuroPCR Peripheral interventions Euro15A-OP260

Advanced management of below-the-knee revascularisation

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Aims: Treatment of critical limb ischaemia continues to be the biggest challenge in peripheral arterial disease. Use of BMS and DES is not appealing to treat these patients because of the risk related to a permanent implants and poor long-term clinical outcomes. Drug-eluting balloons with paclitaxel coatings have recently shown promising clinical results in the superficial femoral and popliteal arteries. However, critical limb ischaemia patients were excluded from these trials, leaving a significant unmet clinical need in search for alternative solutions. Yet, critical limb ischaemia represents 20% of the peripheral arterial disease today and is expected to exceed 40% by 2018 due to the growing numbers of diabetics and increase in the aging population. CardioProlific Inc. (Hayward, CA, USA) is developing a novel approach to treat critical limb ischaemia patients using a conventional POBA in conjunction with ultrasound-enhanced delivery of paclitaxel to the vessel wall. Ultrasound energy is used to change compliance of the media plaque/calcium and to increase vessel permeability.

Methods and results: A total of 24 critical limb ischaemia patients with severely diseased and long and calcific arteries were randomly assigned to the study. All arteries above-the-knee were treated with a conventional balloon angioplasty and ultrasound radial energy using the Genesis™ System. Paclitaxel in mixture with contrast agent (Iopromide 370) at 1.0 μg/mm³ concentration was delivered to the treatment area after ultrasound energy exposure. The paclitaxel/contrast mixture was shielded with a distal flow protection balloon and aspirated after 60 seconds. Arteries below-the-knee were only treated with a conventional balloon angioplasty. The mean age of 24 patients was 74.5±7.7 years. Eighteen patients were smokers or previous smokers; eighteen patients had CTOs, and 4 patients had in-stent occlusions. The mean lesion length was 162±43 mm and lesion diameter was 5.5±.5 mm. The primary endpoint of the study was safety. The secondary endpoints were angiographic restenosis rate and treated lesion revascularisation rates at 6 months, amputations, clinical restenosis rate and treated lesion revascularisation rates at 12 months. There were no adverse events attributable to the procedure; all 24 patients tolerated the procedure well. At 6 months; no complications; no deaths; no amputations; restenosis rate was 4.3% (1/23), treated lesion revascularisation was 0% (0/24). At 12 months; no amputations; treated lesion revascularisation rate was 4.5% (1/22); two patients died, 8.3% (2/24) for non-related issues.

Conclusions: Our pilot study showed very promising clinical results for critical limb ischaemia patients at 6- and 12-month follow-up. This encouraging outcome demonstrates that ultrasound energy may change compliance of the intimal plaque/calcium, increases vessel permeability, enhances arterial delivery of paclitaxel after balloon angioplasty, and presents an attractive therapeutic potential. A larger multicentre clinical study is required to validate this new approach.

EuroPCR Peripheral interventions Euro15A-OP261

Covered endovascular reconstruction of aortic bifurcation: a haemodynamically proven technique for treating extensive aortoiliac occlusive disease

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Aims: We developed and tested the covered endovascular reconstruction of aortic bifurcation or CERAB technique for extensive and/or recurrent aortoiliac occlusive disease using V12 balloon-expandable covered stents (Atrium; Maquet Getinge Europe BV, Rastatt, Germany) to rebuild the aortic bifurcation.

Methods and results: Endovascular bi-femoral recanalisation of the aortoiliac axes was performed, and a 12 mm V12 LD was placed and expanded in the distal aorta (9 Fr). The already expanded V12 stent was picked with a large balloon (adapted to the aortic diameter). The balloon was so positioned that the distal marker was approximately 15 mm proximal to the distal stent margin. After positioning and expansion, the distal stent part became funnel-shaped. Two iliac covered stent grafts were then placed in this segment in a "kissing stent" configuration and inflated. Both stents were tightly linked and moulded together with the aortic stent, simulating a new bifurcation. The present study was a two-centre physician-initiated, prospective, non-randomised follow-up. We treated >100 patients with acute, chronic, or recurrent aortoiliac occlusive diseases. Technical success was almost 95%. During follow-up (3-60 months), 8 patients died of non-interventional causes. Six patients re-occluded mainly due to progressive distal peripheral diseases. They received treatment of the outflow problems. The other patients showed no complications.

Conclusions: CERAB is safe and feasible and can be performed completely percutaneously. However, a larger population and a longer follow-up is required; distal peripheral outflow should be sufficient. It can be combined as a '"hybrid" procedure. CERAB can be used for the treatment of recurrent or in-stent disease. A haemodynamic *in vitro* investigation showed a superior outcome compared with other techniques.

Peripheral interventions

Euro15A-OP262

Chimney CERAB: an alternative new technique for extensive or juxtarenal aortoiliac occlusive disease

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Aims: Based on the promising results of "Covered Endovascular Reconstruction of the Aortic Bifurcation" technique or CERAB, we wanted to see if this configuration can be used to treat juxtarenal and extensive aortoiliac occlusive disease in combination with chimney stents to preserve visceral and renal arteries

Methods and results: Patients were treated with the chimney-CERAB technique. Endovascular bi-femoral and brachial access; recanalisation of both the aortoiliac axes and predilatation. For preservation of mesenteric and/or renal vessels placement was as follows: first, a V12 balloon-expandable covered stent (Atrium; Maquet Getinge Europe BV, Rastatt, Germany) in the visceral artery (from brachial) and the placement of a 12 mm V12 large-diameter in the distal aorta (9 Fr femoral). Simultaneous inflation was performed and, if needed, post-dilatation of the proximal part of the already expanded V12 stent with a large balloon and extension of the aortic stent distally. Two iliac covered stents were then placed in this distal segment, in a "kissing-stent" configuration and inflated. Both stents were now making a very tight combination, simulating a new bifurcation. Multicentre, non-randomised, follow-up study. At present, we have treated 11 patients (January 2013 to July 2014) with aortoiliac occlusive disease and the technical success rate is 100%. Follow-up at 3 to 18 months. No 30-days mortality or SAE were observed. All reconstructions are still patent.

Conclusions: Chimney-CERAB is a safe and feasible technique and can be performed completely percutaneously. This technique can be an alternative option for the combined treatment of aortoiliac occlusive disease and "at risk" visceral arteries

Peripheral interventions

Euro15A-OP263

Clinical outcomes of the BIOFLEX-I study: utilisation of self-expanding stents in the iliac arteries

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Aims: Percutaneous transluminal angioplasty has historically been the standard in minimally invasive treatment of peripheral artery disease (PAD). In iliac arteries, self-expanding, nitinol stent technology has evolved as an effective treatment of atherosclerotic lesions. BIOFLEX-I evaluates the safety and efficacy of the Astron stent in the iliac arteries.

Methods and results: The BIOFLEX-I study was a prospective, multicentre, non-randomised, single-arm, investigational device exemption (IDE) study performed in the United States, Canada and Europe. Thirty (30) study centres enrolled 161 evaluable study subjects for treatment of *de novo* or restenotic lesions (≤140 mm length) or occlusions (≤100 mm length) in common or external iliac arteries with reference vessel diameters from 6 to 9 mm. The primary endpoint was the composite rate of procedure or stent related major adverse events (MAEs) at 12-months post-index procedure. MAEs were defined as 30-day mortality, clinically-indicated target lesion revascularisation (TLR) and index limb amputation at 12 months. Results were compared to a pre-specified performance goal based on prior prospective, multicentre studies utilising nitinol-based, self-expanding stents for the treatment of iliac lesions similar to those in this study. Core laboratories were utilised for independent confirmation of angiography and duplex ultrasound findings. All site reported MAEs were adjudicated by an independent Clinical Events Committee. For the BIOFLEX-I study of patients with iliac disease treated with the Astron stent, the primary endpoint was met. The 12-month composite endpoint of MAE was 2.1% (3/146) ($p<0.001$) 95% CI: (0.4%, 5.9%). The 30-day mortality rate was 0.7% (1/146) 95% CI: (0.0%, 3.8%). Target lesion revascularisation (TLR) rates at 12 months were 1.4% (2/146) 95% CI: (0.2%, 4.5%), and 12-month index limb amputation was 0.0% (0/146) 95% CI: (0.0%, 2.5%). The secondary endpoint of primary patency was 89.8% (115/128) 95% CI: (83.3%, 94.5%) at 12 months.

Conclusions: The 12-month outcomes of the BIOFLEX-I study for the Astron stent in iliac indications demonstrate a low MAE rate, high primary patency, and a low rate of TLR. This supports the safety and efficacy of the self-expanding, nitinol stent for treatment of atherosclerotic lesions in the iliac arteries.

euro PCR Peripheral interventions Euro15A-OP264

Clinical and angiographic outcome after a jailed internal iliac artery (IIA)

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Aims: In the primary stenting from the common iliac artery (CIA) to the external iliac artery (EIA), jailing the internal iliac artery (IIA) has a risk of compromised IIA.

Methods and results: A retrospective study was performed of patients who underwent endovascular intervention for iliac artery presented from February 2007 to April 2014. Subjects were 58 patients/63 lesions with iliac arteries who underwent attempted recanalisation with the self-expandable or balloon-expandable stent. We divided these subjects into two following groups; IIA ostium stenosis, 21 patients (23 lesions) and IIA no stenosis, 37 patients (40 lesions). Technical success obtained was 100%. Regarding acute or 12-month occlusion rates of IIA, no difference was seen between (ostium stenosis vs. no stenosis: acute phase 5% vs. 0%, p=NS; 12-month: 5% vs. 0%, p=NS). Occlusion rates for the internal iliac (IIA) were extremely low and complaints of pelvic organ ischaemia were not seen when treated with crossover stenting, for either IIA in the acute phase as well as at 12-months whether the IIA ostium had stenosis or not.

Conclusions: Primary stenting from the common iliac artery (CIA) to the external iliac artery (EIA) with jailing of the internal iliac artery (IIA) is safe.

euro PCR Peripheral interventions Euro15A-OP266

Early results of the use of a next-generation drug-coated balloon for the treatment of femoropopliteal atherosclerotic lesions

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Aims: We wanted to investigate a next-generation drug-coated balloon on safety, efficacy and patency for the treatment of stenotic and/or occlusive femoropopliteal arterial lesions.

Methods and results: We used the Legflow paclitaxel-(PTX)-releasing peripheral balloon (Cardionovum, Bonn, Germany) with a unique "SAFEPAX" balloon surface drug coating. Compared to first- and second-generation drug-coated balloon coatings, which use coating mixtures out of a highly water-soluble drug excipient matrix with relatively large PTX crystals, this newer type balloon catheter is covered with a coating based on nanotechnology and the use of the smallest PTX particles (non-visible 0.1 µm). Because of the stable and unique balloon surface coating characteristics, it does not require the use of an extra DCB protection and insertion tool. Furthermore, it cannot be wiped or fall off the balloon surface during catheter manipulation. A single-centre, prospective, consecutive, physician initiated, real-life ongoing registry. From June 2013 to November 2014 we included 51 patients treated with the Legflow for *de novo*, recurrent and in-stent stenosis or occlusion in the femoral and popliteal artery. Patients had mainly Rutherford Becker stage 3 & 4. Mean lesion length was 102.6 mm. Technical success: 100%. In more than 50% of the cases, no predilation balloon was used. Bail-out stenting: 20%. There was no evidence for distal embolisation. Follow-up was done with ultrasound. Six-month primary patency was 92% and the preliminary results for 1-year (at the moment ±50% of the patients) seems promising at 76%.

Conclusions: Drug-coated balloon technology seems to improve the mid- and long-term durability of the SFA endovascular treatment. Early results using the new generation Legflow DCB are very encouraging; it is a safe and reliable balloon, but long-term results need to be obtained with larger patient groups.

Peripheral interventions

Euro15A-OP267

Midterm clinical outcome of femoropopliteal stenting with paclitaxel-eluting stents for diabetic patients in comparison with bare metal stents

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Aims: To investigate the advantage of endovascular therapy (EVT) with drug-eluting stents (DES) for femoropopliteal (FP) lesions in diabetic patients.
Methods and results: This is a single centre, retrospective study. Between July 2008 and April 2013, 74 lesions in 58 diabetic patients were treated with bare metal stents (BMS group). Fifty-two lesions in 42 diabetic patients were treated with Zilver PTX paclitaxel-eluting nitinol stents (DES group). We evaluated the clinical outcomes as primary patency, freedom from re-occlusion, major adverse limb events (MALE) and all-cause death after EVT. Stent patency was assessed by either duplex ultrasound or angiography. Mean follow-up period were 616±346 days in BMS group and 372±141 days in DES group. Primary patency at 1-year were 82% and 87% (p=0.96). Freedom from re-occlusion at 1-year were 92% and 91% (p=0.29). Freedom from MALE were 94% and 91% (p=0.45). Survival rates were 86% and 95% (p=0.18). Multivariate logistic regression analysis revealed TASC II class C/D increased the risk of restenosis/reocclusion with an odds ratio (95% confidence interval) of 3.34 (1.30 to 9.03) (p=0.01).
Conclusions: FP stenting for diabetic patients with DES offers no significant advantage over BMS in midterm clinical outcomes.

Peripheral interventions

Euro15A-OP268

A novel approach to cross chronic total occlusions: safety, efficacy and feasibility of optical coherence tomography

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Aims: The crossing of a chronic total occlusion (CTO) is the key step for an endovascular treatment. The Ocelot catheter is a novel device that combines a drilling distal tip with optical coherence tomography (OCT) technology. It provides intraluminal imaging to help the crossing of CTOs in the femoropopliteal segment. The aim of the study was to determine the safety and feasibility of the device.
Methods and results: Between 10/2011 and 01/2013, all patients where the conventional endovascular crossing of CTOs failed, were prospectively enrolled. Technical success was defined as the ability of OCT to cross CTOs and was the primary endpoint. Risk factors for technical failure and long-term results were analysed. Overall, 84 patients (49 male) were enrolled. The mean age was 70 years (range 47-90). According the Rutherford classification, 58 (69.0%) had claudication and 26 (31.0%) CLI. Nine CTOs (10.7%) reached the popliteal artery and 34 (40.5%) were TASC D classified with 22 (26.2%) showing severe calcification. The mean length was 195.4 mm (range 30-600). The technical success rate was 88.1% (74/84); however, in 13 of 74 (17.5%) an additional re-entry-device was needed to complete the crossing. Balloon angioplasty alone was used in 16/74 patients (21.6%), provisional stenting in 58/74 (78.4%) and atherectomy in 3/74 (4.1%). Complications occurred in 4/84 patients (4.7%), with 4 perforations and one associated distal embolisation. In 3 of these, the procedure failed. In one, a stent graft and loco-regional thrombolysis were required. Calcification of the vessel was the only statistically significant risk factor for failure (p=0.018). Through 26 months of follow-up (mean 18, range 5-26), 11 re-interventions occurred. The primary and secondary patency at 26 months were 75.4% and 91.9%, respectively.
Conclusions: OCT-guided crossing is a useful endovascular tool when conventional techniques failed. Severe calcification remains a limitation and in some patients an additional device was required.

The AURORAA registry: 3-year results using interwoven nitinol stents for extensive distal femoropopliteal occlusive disease

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Aims: In the endovascular treatment of extensive disease in the distal superficial femoral and popliteal level, you can encounter flow-limiting problems, where stent placement is needed after balloon angioplasty. Most of the standard, bare-nitinol stents will have difficulties in these areas. With the introduction of the Supera vascular mimetic implant (Abbott Vascular, Santa Clara, CA, USA) we may have an answer to treating these problematic lesions.

Methods and results: Due to the design of the Superas, including 6 interwoven nitinol wires, it has excellent characteristics. It is very flexible as well as being kink, fracture and crush resistant together with great radial force. These features enable it to mimic the forces and movement of the native vessel. We have treated more than 117 patients with extensive distal femoropopliteal disease (TASC II C & D) that had not responded to balloon angioplasty and who needed stent placement, and all treated with placement of Superas. Results of the single-centre prospective AURORAA registry with follow-up by ultrasound. Seven patients died of non-interventional causes. Nine patients had an occlusion due to progressive distal peripheral arterial disease. Six-month primary patency was more than 90%. Twelve-month primary patency was 80.3% and at 24 months, it was more than 70%, 36-months around 70%. No stent fractures or flow-limiting kinking were observed. Average lesion length: 14 cm; average stent length: 18 cm. Technical success rate: 96%.

Conclusions: The Supera vascular mimetic implant due to its special characteristics that truly mimic the native vessels movements and working forces is a possible solution when the use of a "classic" nitinol stent is not indicated.

Why do women have poorer clinical outcomes after stent implantation for femoropopliteal lesions than men?

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Aims: It has already been reported that women have poorer clinical outcomes after stent implantation for femoropopliteal lesions than men. However, the reason for this has not been reported. One of the reasons might be that women, on average, have smaller vessel sizes than men do. Our aim was to investigate this in our study.

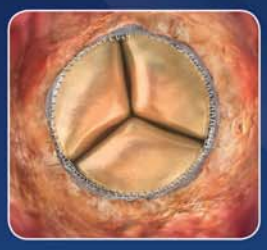
Methods and results: This was a single-centre, non-randomised retrospective study. From April 2007 to April 2013, 83 patients (94 lesions) who underwent bare metal stent (S.M.A.R.T. stent; Cordis, Johnson & Johnson, Warren, NJ, USA) implantation for *de novo* "small" femoropopliteal artery lesions were included. A "small vessel" was defined as a vessel with a vessel diameter <5 mm measured by quantitative vascular analysis (QVA). All patients were followed for 12 months after stenting. The patients were classified into two groups: female patients (F group, 33 patients, 39 lesions) and male patients (M group, 50 patients, 55 lesions). We compared clinical outcomes at 12 months after stent implantation. For patient and lesion characteristics, there were no significant difference between the two groups in terms of age and the percentage of diabetes mellitus, haemodialysis, critical limb ischaemia, poor run-off, lesion length >150 mm, and Trans-Atlantic Inter-Society Consensus (TASC) II classification C/D. The mean reference vessel diameters were significantly smaller in the F group than the M group (4.39±0.30 mm vs. 4.57±0.33 mm, $p<0.05$). The primary patency at 12 months was similar between the F group and the M group (82.1% vs. 85.5%, Log rank $p=0.61$). Multivariable analysis revealed that lesion length >150 mm and reference vessel diameter were independent predictors of restenosis within 12 months (odds ratio [OR]=5.01 [1.41-24.7], $p<0.05$, and OR=0.12 [0.01-0.78], $p<0.05$). In this study, gender was not the predictor of restenosis.

Conclusions: This study suggests that smaller vessel diameter is an important factor of restenosis after stent implantation and the reason why woman have poorer clinical outcomes is that women tend to have smaller vessel diameters.

Lotus™

Valve System

The Power of Control



Lotus™ conforms to the anatomy and promotes annular sealing

- Confidence knowing your procedural result before valve release
- Help reduce complications with precise placement and complete repositionability
- Minimize paravalvular leak with the innovative Adaptive Seal™[1]

1 Meredith, IT. REPRISE II one year results, presented at TCT 2014

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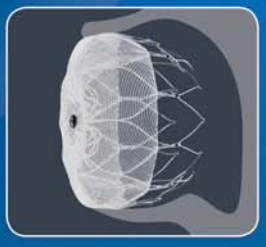
WATCHMAN™

Left Atrial Appendage Closure Device

First and Only FDA Approved LAA Closure Device*

WATCHMAN™ offers a minimally invasive solution for Stroke Risk Reduction in AF Patients



* In countries where CE mark is the regulation in force, the WATCHMAN™ LAA Closure Technology is intended to prevent thrombus embolization from the left atrial appendage and reduce the risk of life-threatening bleeding events in patients with non-valvular atrial fibrillation who are eligible for anticoagulation therapy or who have a contraindication to anticoagulation therapy. In the USA the WATCHMAN™ LAA Closure Technology is indicated to reduce the risk of thromboembolism from the left atrial appendage in patients with non-valvular atrial fibrillation who:
- Are at increased risk for stroke and systemic embolism based on CHADS2 or CHA2DS2-VASc scores and are recommended for anticoagulation therapy;
- Are deemed by their physicians to be suitable for warfarin and have an appropriate rationale to seek a non-pharmacologic alternative to warfarin, taking into account the safety and effectiveness of the device compared to warfarin;

The WATCHMAN™ Access System is intended to provide vascular and transseptal access for all WATCHMAN™ Left Atrial Appendage Closure Devices with Delivery Systems.

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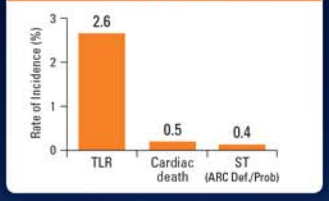
SYNERGY™

Everolimus-Eluting Platinum Chromium Coronary Stent System

EVOLVE II (n = 831) Clinical Trial[1] 1-Year Results



EVOLVE II Clinical Trial[1] Baseline Characteristics

% < 2.25 mm	23.9 %
% B2/C Lesions	76.8 %
Lesion Length (mm)	14.09 mm
% Unstable Angina	33.9 %
% DM	31.1 %
% NSTEMI	25.9 %

ZERO Definite ST after 24 hours[1] for the SYNERGY Stent and exceptionally low 0.4% ARC Definite / Probable ST at 1-year

ZERO ST after 3 years in EVOLVE Clinical Trial[2]

HEAL
WITH CONFIDENCE

1. Evolve II Clinical Trial presented by Dean Kereiakes, MD at AHA 2014. Data on File. Graph shown includes TLR, ST, and CD for the intent-to-treat (ITT) population.
2. Evolve Clinical Trial, Presented by Ian T. Meredith AM, MBBS, PhD, PCR 2014. n = 291 patients

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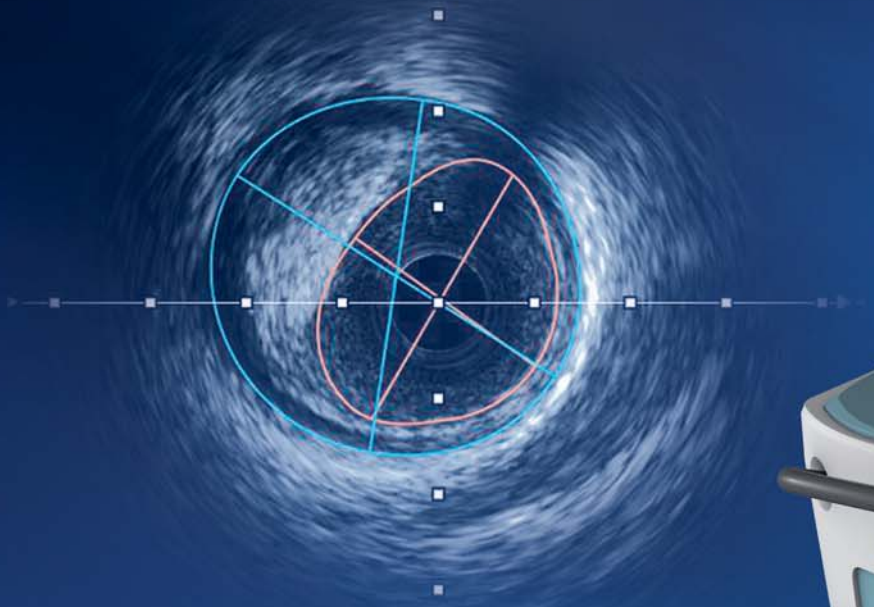
POLARIS

NEW PCI Guidance System



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1 CLICK

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