Cost-effectiveness analysis of TAVI compared to standard treatment of symptomatic aortic stenosis in patients at high surgical risk

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SUS

Aortic Stenosis

- Pathological constriction of aortic valve → restriction of blood flow to the left ventricle into the aorta
- Caused by calcification of the aortic valve
- Symptomatic patients → worse prognosis, survival 2-3 years and increased risk of sudden death
- Consequences → ventricular arrhythmia, heart failure, angina, endocarditis, sudden cardiac death, etc.

SUS

Treatments

- SAVR – Surgical Aortic Valve Replacement

Symptomatic improvement and increased survival. Contraindicated for high surgical risk patients (30%)

- Pharmacological treatment
- Balloon valvuloplasty
- TAVI – Transcatheter Aortic Valve Implantation

TAVI

- Implantation of transcatheter valve → passage through the diseased aortic valve by a catheter
- Despite being minimally invasive TAVI may be related to serious complications

Procedures in Brazilian Public Health System (SUS)

- Opening of valvular aortic stenosis (without prosthesis)
- Percutaneous aortic valvuloplasty, corresponding to balloon valvuloplasty
- Valve replacement surgery, corresponding to SAVR

Justification

- Prevalence: 2% to 4% of the population over 65 years
- Population aging
- High mortality
- Impact on quality of life
- Lack of Brazilian studies in progress recorded

Question

PICO	
Population	Patients with severe symptomatic aortic stenosis
Intervention	TAVI - Transcatheter Aortic Valve Implantation
Comparation	Standard Treatment
Outcomes	Mortality AVC Rate of rehospitalization Pacemaker Cardiac reintervention (New TAVI, SAVR, balloon valvuloplasty) QALY

Search strategy

- The Cochrane Library, CRD, Medline (Pubmed), Embase, Lilacs and Tripdatabase

(("Heart Valve Prosthesis Implantation"[Mesh]) OR "Cardiac Catheterization"[Mesh]) OR "Catheterization, Peripheral"[Mesh]) OR (transcatheter aortic valve implantation) OR (transcatheter aortic valve replacement) AND "Aortic Valve Stenosis"[Mesh]) AND ((systematic[sb] OR Meta-Analysis[ptyp] OR Randomized Controlled Trial[ptyp]) AND "humans"[MeSH Terms] AND (English[lang] OR Spanish[lang] OR Portuguese[lang]))

- Grey literature

Search strategy

- Eligibility criteria: evaluation of efficacy and safety of TAVI, use of prostheses registered in Brazil, compared to conservative treatment and patients with symptomatic aortic stenosis

PARTNER B

PARTNER B

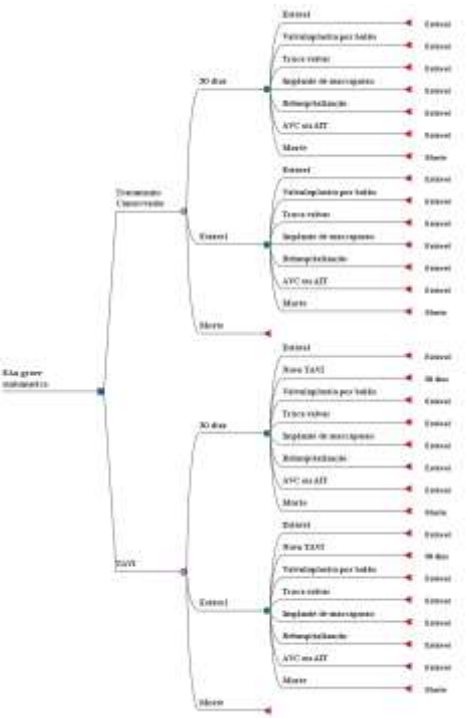
- RCT
- Cohort B: TAVI x Standard Treatment
- n=358
- Primary Outcome→ all-cause mortality
- Secondary outcomes → cardiovascular mortality; rehospitalization; stroke and heart attack.

Modeling

- Markov model
- Time frame → 2 years
- Discount rate → 5% per year
- Monthly cycles

Modeling

- Costs → Search across multiple platforms and health agencies → ?
- Questionnaire → SBHCI (Brazilian society of interventional cardiology and hematology) and 35 institutions of REBRATS (Brazilian Network of Health Technology Assessment)



Results

- Cost TAVI: R$ 91.132,59 ~U$ 29,226.96
- Cost ST: R$ 8.044,47 ~ U$ 2,579.93

  ➡ R$ 83.088,11 ~ U$ 26,647.03 (IC)
- Effectiveness TAVI: 1 QALY
- Effectiveness ST: 0,75 QALY ➡ 0,25 QALY
- ICER = 332.352,44 R$/QALY ~ U$ 106,588.13
- TAVI is not cost effective (willingness to pay threshold of R$ 67.206,00 ~ U$ 21,553.51, equivalent to three times the annual GDP per capita)

Tornado Diagram

Source: TreeAge Pro 2013.

Sensitivity analysis

- Price of TAVI prosthesis: To be cost-effective, the price of the prosthesis should be 5 times less;
- Relative risk of death: Even considering maximum benefit to TAVI (rr = 0.43), the technology is not cost-effective yet;
- Multivariate sensitivity analysis: To be cost-effective, considering the variation of the RR from 0.43 to 0.73), the prosthesis should cost up to U$ 6.400

Scenario analysis

- Scenario analysis → New frame time of 10 years
- Favors TAVI → it is assumed that the benefits of the procedure were kept
- ICER = R$ 85,720.32 ~ U$ 27,430.50 → TAVI is not cost-effective

Discussion

- Benefit of TAVI in reducing mortality x Aging population
- Very high monetary cost to the SUS
- Uncertainty about the magnitude of the benefit and risk of adverse events in the Brazilian reality
- Brazilian Ministry of Health → Do not incorporation

Conclusions

- TAVI in patients with symptomatic severe aortic stenosis with contraindications to SAVR → not cost-effective, despite the gain in survival and QALY → high costs related to the procedure
- Cost of prosthesis → value should be reduced by about 5X to become cost-effective

Thank you!

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