Evidence check

8 May 2020

Rapid evidence checks are based on a simplified review method and may not be entirely exhaustive, but aim to provide a balanced assessment of what is already known about a specific problem or issue. This brief has not been peer-reviewed and should not be a substitute for individual clinical judgement, nor is it an endorsed position of NSW Health.

Fibrinolysis and PCI for STEMI

Rapid review question

1. What is the evidence for fibrinolysis versus primary percutaneous coronary intervention in the treatment of ST-Elevation Myocardial Infarction (STEMI)?
2. Is there evidence for safety and efficacy of tenecteplase use as fibrinolytic to treat STEMI?
3. What are the current models of care for treatment of STEMI in COVID-19 and non-COVID-19 patient population during the current pandemic?

In brief

- It is well established that most patients with acute STEMI benefit from reperfusion therapy.(1-3)
- Primary PCI has been shown to achieve better outcomes than fibrinolysis(4). Better outcomes are achieved when PCI is performed within 90 minutes of first medical contact.(5, 6)1
- When timely PCI cannot be performed, fibrinolysis is indicated in STEMI patients whose onset of ischaemic symptoms were within the previous 12 hours.(7, 8)
- Primary PCI may be preferred for some patients even when the procedure cannot be performed in a timely manner. This includes patients at high risk of bleeding and those in cardiogenic shock.
- Fibrinolytic agents include streptokinase, alteplase, reteplase, and tenecteplase. Tenecteplase has a lower rate of non-cerebral bleeding events and is given as a single bolus and is often the preferred agent.(9)

COVID-19

- Patients with cardiovascular risk factors and established cardiovascular disease are at heightened risk from COVID-19 infection.(10)
- According to the Cardiac Society of Australia and New Zealand (CSANZ) and the European Society of Cardiology (ESC), the COVID-19 pandemic should not compromise timely reperfusion of STEMI patients. In line with current guidelines, reperfusion therapy remains indicated in patients with symptoms of ischaemia of <12 hours duration and persistent ST-segment elevation in at least two contiguous ECG leads.(7, 11)

[1] AHA/ACC recommendation is within 120 mins of first medical contact (Nielsen, 2011; Wang et al, 2011)

- Early in the COVID-19 pandemic, recommendations from China included the use of fibrinolytic therapy as first line treatment for STEMI because of advantages in speed, logistics and reductions in staff exposure to potential infection.(12)
- However, COVID-19 is associated with STEMI 'mimics' (ST elevation without obstructive coronary artery disease due to microvascular thrombosis or myocarditis) and the use of lysis may confer risk without benefit in some cases, exacerbated by COVID-19-associated coagulation abnormalities.(13, 14)
- Primary PCI remains the standard of care for STEMI patients regardless of COVID-19 status, especially at PCI capable hospitals, when it can be provided in a timely way.(7, 15-17)
- PCI pathways may however be delayed during the pandemic due to disruptions in the delivery of care and the implementation of protective measures.(7, 13, 14, 18)
- A fibrinolytic strategy is considered reasonable for hospitals without PCI-capability or immediate availability for eligible patients.(14, 18)
- Current guidance in Australia is for clinical care of, or procedures on patients who are not suspected of having COVID-19, for usual infection prevention and control precautions to be observed, according to clinical circumstances. Additional COVID-19 specific precautions are not required.(19)
- An unexpected increase in demand for tenecteplase has resulted in an alert from the Australian Therapeutics Goods Administration (TGA) regarding shortages, with a potentially critical impact on patients, particularly those with ischaemic stroke.(20)

Limitations

New evidence on this topic is emerging rapidly. The evidence is generally based on case studies and expert opinion and may differ due to disparate stage and extent of the pandemic in different countries.

Methods (Appendix 1)

Identified systematic review and meta-analyses from 2016 answering the questions under consideration; PubMed, TRIP database and college websites were searched for studies from 2016 onwards on 23 April 2020.

Results

Table 1: Fibrinolytics vs Primary PCI

Title	Study type	Findings	Source link
Peer reviewed literature			
Prehospital fibrinolysis versus primary percutaneous coronary intervention in ST-elevation myocardial infarction: a systematic review and meta-analysis of randomized controlled trials. (Roule, 2016) (21)	SR/MA	• Prehospital fibrinolysis (FL) is associated with similar early and late mortality rates compared with pPCI in patients with STEMI managed early after symptom onset in the prehospital setting. • Prehospital FL is also associated with a decreased risk of cardiogenic shock. However, it was consistently associated with an increased risk of stroke and haemorrhagic stroke. • Meta-analysis suggests that prehospital FL appears to be a valuable alternative to pPCI.	https://link.springer.com/content/pdf/10.1186/s13054-016-1530-z.pdf
Bleeding events associated with fibrinolytic therapy and primary percutaneous coronary intervention in patients with STEMI: A systematic review and meta-analysis of randomized controlled trials. (Bundhun, 2016) (22)	SR/MA	• Twelve studies (10 RCTs) 5,561 patients (2,784 patients from the fibrinolysis group and 2,777 patients from the primary PCI group) were included in this meta-analysis. • Even if the rate of non-intracranial bleeding was not statistically significant between these two reperfusion therapies, fibrinolytic therapy was associated with a significantly higher rate of intracranial bleeding than pPCI. • In addition, pPCI was associated with a significantly lower rate of death, reinfarction and stroke. Therefore, pPCI should be recommended in patients with STEMI, especially in PCI-capable hospitals.	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4907680/pdf/medi-95-e3877.pdf
Comparative efficacy and safety of reperfusion therapy with fibrinolytic agents in patients with ST-segment elevation myocardial infarction: a systematic review and network	SR/MA	• A total of 40 eligible studies involving 128,071 patients treated with 12 different fibrinolytic regimens were assessed. • Reperfusion therapy with fibrin-specific fibrinolytics (accelerated infusion of alteplase, tenecteplase, and reteplase) in combination with parenteral anticoagulants, offer the highest level of efficacy in terms of short-term mortality reduction for patients with STEMI, who cannot access a hospital capable of percutaneous coronary intervention in a timely fashion. • Tenecteplase ranks the lowest in terms of bleeding risk and has a similar mortality benefit across all other fibrinolytics.	https://www.clinicalkey.com.au/service/content/pdf/watermarked/1-s2.0-S0140673617314411.pdf?locale=en_AU&searchIndex=

Title	Study type	Findings	Source link
meta-analysis. (Jinatongthai, 2017) (23)			
Comparing mortality between fibrinolysis and primary percutaneous coronary intervention in patients with acute myocardial infarction a systematic review and meta-analysis of 27 randomized-controlled trials including 11 429 patients (Yanamala, 2017) (24)	SR/MA	• This analysis of 11,429 patients showed a significantly higher mortality rate associated with fibrinolysis compared with pPCI. Hence, compared with fibrinolysis, pPCI is expected to be the preferred method of revascularisation in patients with AMI, especially in PCI-capable centres. • However, when fibrin-specific agents such as tenecteplase were compared with pPCI, even if mortality was higher in the fibrinolytic group, the result did not reach statistical significance.	https://journals.lww.com/coronary-artery/Abstract/2017/06000/Comparing_mortality_between_fibrinolysis_and.8.aspx
Comparative effectiveness of primary PCI versus fibrinolytic therapy for ST elevation myocardial infarction: a review of the literature (Joy, 2016) (25)	Review	• pPCI is the preferred treatment strategy for STEMI. However, FL with subsequent percutaneous coronary intervention remains a viable option for those in rural areas.	https://www.futuremedicine.com/doi/full/10.2217/cer-2015-0011
Modern Management of ST-Segment Elevation Myocardial Infarction (Frampton, 2020) (26)	Review	• The current guidelines recommend that patients with STEMI presenting within 12 hours of symptoms to a PCI-capable facility should undergo primary PCI with a first medical contact-to-device time goal of no more than 90 minutes or should be emergently transferred for primary PCI if there will be no more than 120 minutes between first medical contact and device. • If hospitals cannot achieve that goal, then thrombolysis should be used as the primary reperfusion approach, with administration recommended within 30 minutes of first medical contact. • After thrombolytic therapy, patients should be transferred to a PCI-capable hospital in case rescue PCI is needed or to facilitate early angiography.	https://www.clinicalkey.com.au/service/content/pdf/watermarked/1-s2.0-S0146280618301300.pdf?locale=en_AU&searchIndex=

Title	Study type	Findings	Source link
		• Patients who are not eligible for thrombolytic therapy should be transferred for urgent primary PCI.	
Review of In-Hospital Outcomes of Thrombolysis and Primary PCI in Outer Metropolitan Management of STEMI (May, 2016) (27)	Case series	• 113 patients with STEMI • 65 patients received thrombolysis (45% pre-hospital, 55% in-hospital), 32 received pPCI and 16 received neither (spontaneous ECG resolution or palliative). Reperfusion was achieved in 57% of thrombolysis cases, with the remainder for rescue PCI (rPCI). • Good clinical and safety in-hospital outcomes following the introduction of a prehospital thrombolysis program in outer metropolitan centres using a composite of primary and rescue PC.	http://dx.doi.org/10.1016/j.hlc.2016.06.142
Pre-hospital Thrombolysis in ST-segment Elevation Myocardial Infarction: A Regional Australian Experience (Khan, 2016) (28)	Prospective, non-randomised, consecutive, case series	• 150 patients were administered prehospital thrombolysis (PHT) and 334 patients underwent primary PCI. In the PHT group, 37 patients (27%) needed rescue PCI. The 12-month all-cause mortality rate was 7.0% (PHT, 6.7%; PCI, 7.2%). The incidence of major bleeding 1.3%. • Prehospital thrombolysis is safe and effective in the real-world setting, especially in a region where transport distances to the cardiac catheterisation laboratory are great. • Prehospital thrombolysis can be implemented in regions where timely primary percutaneous coronary intervention for STEMI patients is not available.	https://pubmed.ncbi.nlm.nih.gov/27465767/
Pre-hospital Thrombolysis for ST-segment Elevation Myocardial Infarction in Regional Australia: Long Term Follow Up (Khan, 2019) (29)	a/a	• Above study with median follow up of 6.2 years suggested all-cause mortality was 16% and 19% in the PHT and primary PCI groups respectively.	https://onlinelibrary.wiley.com.acs.hcn.com.au/doi/abs/10.1111/imj.14412

Table 2: Guidelines on PCI vs Fibrinolysis

Title	Recommendations	Source link
2019 Canadian Cardiovascular Society/Canadian Association of Interventional Cardiology Guidelines on the Acute Management of ST-Elevation Myocardial Infarction: Focused Update on Regionalization and Reperfusion.(30)	• The guideline provides a strong recommendation (low-quality evidence) for a goal of first medical contact to thrombolytic needle time of less than or equal to 30 minutes. • However, they strongly recommend (high-quality evidence) against pharmacologic facilitation when access to cardiac catheterisation is available within 120 minutes. • Fibrinolysis remains a suitable alternative for appropriately selected patients who cannot undergo timely PPCI.	https://pubmed.ncbi.nlm.nih.gov/30760415/
National Heart Foundation of Australia and Cardiac Society of Australia and New Zealand: Australian clinical guidelines for the management of acute coronary syndromes. 2016(8)	• Primary PCI is preferred for reperfusion therapy in patients with STEMI if it can be performed within 90 minutes of first medical contact. Otherwise, fibrinolytic therapy is preferred for those without contraindications. • Among patients treated with fibrinolytic therapy who are not in a PCI-capable hospital, early or immediate transfer to a PCI-capable hospital for angiography, and PCI if indicated, within 24 hours is recommended.	https://www.heartlungcirc.org/article/S1443-9506(16)31061-7/pdf
Scottish Intercollegiate Guidelines Network Acute coronary syndrome: A national clinical guideline.	• Guideline recommends When primary percutaneous coronary intervention cannot be provided within 120 minutes of ECG diagnosis, patients with an ST-segment-elevation acute coronary syndrome should receive immediate (prehospital or admission) thrombolytic therapy	https://www.sign.ac.uk/assets/sign148.pdf
Part 9: Acute Coronary Syndromes 2015 American Heart Association Guidelines Update for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care.(31)	• Where prehospital fibrinolysis is available as part of the STEMI system of care and direct transport to a PCI centre is available, prehospital triage and transport directly to a PCI centre may be preferred because of the small relative decrease in the incidence of intracranial haemorrhage without evidence of mortality benefit to either therapy (Class IIb, LOE B-R). • In STEMI patients presenting within two hours of symptom onset, immediate fibrinolysis rather than pPCI may be considered when the expected delay to pPCI is more than 60 minutes.	https://www.ahajournals.org/doi/full/10.1161/cir.0000000000000263

Title	Recommendations	Source link
	• Where prehospital fibrinolysis is available as part of a STEMI system of care, and in-hospital fibrinolysis is the alternative treatment strategy, it is reasonable to administer prehospital fibrinolysis when transport times are more than 30 minutes.	
Thrombolytics for Acute Myocardial Infarction in a Prehospital Setting: A Review of Comparative Safety, and Guidelines.(32)	• No evidence was found regarding the comparative safety of thrombolytic administration performed in a prehospital setting compared with no or significantly delayed thrombolytic administration for the treatment of acute myocardial infarction.	https://www.ncbi.nlm.nih.gov/books/NBK546325/pdf/Bookshelf_NBK546325.pdf

Table 3: Safety and efficacy of Tenecteplase

Title	Study type	Findings	Source link
Safety and efficacy of tenecteplase versus alteplase in acute coronary syndrome: a systematic review and meta-analysis of randomized trials (2016, Guillermin) (33)	SR/MA	• Three studies including 17,325 patients with ACS were included in a quantitative meta-analysis. • The available evidence suggests that tenecteplase is associated with a reduced risk of major bleeding compared to alteplase in ACS without evidence of reduced efficacy.	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5108379/pdf/AMS-12-27239.pdf
Pharmacological Reperfusion Therapy With Tenecteplase in 7,668 Indian Patients With ST Elevation Myocardial Infarction - A Real World Indian Experience (Iyengar, 2017) (34)	Multi-centric, observational	• 7,668 patients from 1,307 investigator sites across India from January 2011 to February 2016. • The findings of this study further reinforce the safety and efficacy of indigenous TNK-tPA in Indian patients presenting with STEMI, including high-risk sub-groups. The study also highlights the importance of early reperfusion therapy.	https://www.japi.org/september_2017/08_oa_pharmacological_reperfusion_therapy_with_tenecteplase_in_7.pdf

Preintensive care: Thrombolytic (streptokinase or tenecteplase) in ST elevated acute myocardial infarction at peripheral hospital (Bawaskar, 2019) (35)	prospective study in rural hospital	• 209 patients had acute STEMI. Of these, 162 received streptokinase (STK) and 47 received tenecteplase. • Thrombolysis of STEMI within 'golden hours' improved the reperfusion. However, one year fatality is significant with streptokinase compared with tenecteplase.	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6396635/?report=classic

Table 4: COVID specific advice for STEMI

Title	Recommendations	Source link
Catheterization Laboratory Considerations During the Coronavirus (COVID-19) Pandemic: From ACC's Interventional Council and SCAI. (Welt, 2020) (36)	• Fibrinolysis can be considered an option for the relatively stable STEMI patient with active COVID-19. • In patients with active COVID-19 and primary PCI is to be performed, appropriate personal protective equipment (PPE) should be worn, including gown, gloves, goggles (or shields) and a N95 mask. • The use of a powered air purifying respirator (PAPR) system may also be reasonable, if transmission risk is high (vomiting CPR and/or intubation). • Importantly, catheterisation labs with normal or positive ventilation will require a terminal clean following the procedure.	https://www.sciencedirect.com/science/article/pii/S0735109720345666?via%3Dihub
Consensus guidelines for interventional cardiology services delivery during covid-19 pandemic in Australia and new Zealand.	• Patients with 'low exposure risk' of COVID-19 can be brought to the catheter lab with appropriate PPE and cleaning procedures applied as per usual practice. • In units where staffing levels are compromised and primary PCI cannot be offered (including lack of PPE) then fibrinolysis may be appropriate if patients are lysis-eligible (commonly TNKtPA single bolus weight-adjusted dosing). • If fibrinolysis is used for STEMI, patients aged ≥75 years should receive ½ weight-adjusted TNK-tPA dose with clopidogrel given (n.b.: omit the loading dose and use 75mg daily).	https://www.csanz.edu.au/wp-content/uploads/2020/03/CSANZ_CONSENSUS_GUIDELINES_FOR_INVASIVE_CARDIOLOGY_SERVICES_DELIVERY_DURING_COVID_PANDEMIC_29-March_2020.pdf
ESC Guidance for the Diagnosis and Management of CV	• Primary PCI remains the reperfusion therapy of choice if feasible within the time frame and performed in facilities approved for the treatment of COVID-19 patients in a safe manner for healthcare providers and other patients.	https://www.escardio.org/Education/COVID-19-

Disease during the COVID-19 Pandemic, European Society of Cardiology. 21 April, 2020 (7)(Fig 1)	• Primary PCI pathways may be delayed during the pandemic (up to 60 minutes – according to multiples experiences) due to delays in the delivery of care and the implementation of protective measures (See Figure 1). • If the target time cannot be met and fibrinolysis is not contraindicated, fibrinolysis should then become first line therapy. • Any STEMI patient should be considered potentially infected and all STEMI patients should undergo testing for SARS-CoV-2 as soon as possible.	and-Cardiology/ESC-COVID-19-Guidance
Cardiovascular Complications of the Coronavirus (COVID-19) Infection (Manolis, 7 April 2020) (37)	• Thrombolysis can be considered an option for the relatively stable STEMI patient with active COVID-19. • Appropriate personal protective equipment (PPE) should be worn including gown, gloves, goggles (or shields) and a N95 mask, during primary PCI in patients with active COVID-19 infection. • The use of powered air purifying respirator (PAPR) systems may also be reasonable, especially for patients who may be vomiting (e.g. inferior STEMI), or those who may require CPR and/or intubation. • Importantly, the vast number of catheterisation labs have either normal or positive ventilation systems and are not designed for infection isolation. Therefore, catheterisation labs will require a terminal clean following the procedure leading to delays for subsequent procedures.	http://rhythmos.gr/index.php/Rhythmos/issue/view/58
How to balance acute myocardial infarction and COVID-19: the protocols from Sichuan Provincial People's Hospital (Zeng,11 March 2020) (38)	• In case of COVID-19 positive patients presenting within the reperfusion time window and no contraindication to thrombolysis, thrombolytic therapy is performed in an isolation ward. • After successful thrombolysis, treatment is continued in the isolation ward. • After the patient has recovered from COVID-19 pneumonia and test of nucleic acid is twice negative, elective PCI should be considered. • Patients presenting within the reperfusion time window with contraindications for thrombolysis or failure of thrombolysis need to be comprehensively evaluated for the risks of PCI and infection control.	https://link.springer.com.acs.hcn.com.au/article/10.1007%2Fs00134-020-05993-9
Considerations for cardiac catheterization laboratory procedures during the COVID-19 pandemic perspectives from the Society for Cardiovascular	• Currently, all STEMI patients should be brought to the CCL for primary percutaneous coronary intervention (PCI). • Although several reports are advising fibrinolytic therapy in these patients if the prevalence of COVID-19 is high or system resources are in danger of becoming overwhelmed. • Alternative therapeutic options such as systemic fibrinolytic therapy may be considered for low risk STEMI (e.g., inferior STEMI without right ventricular	https://onlinelibrary.wiley.com/doi/full/10.1002/ccd.28887

Angiography and Interventions Emerging Leader Mentorship (SCAI ELM) Members and Graduates (25 March 2020) (16)	involvement or lateral myocardial infarction without hemodynamic compromise) depending on local availability of expertise and the prevalence and effects of the COVID-19 disease burden at the institution. A potential downside is that these patients then often require prolonged ICU level of care and may end up utilising vital finite resources.	
CSC Expert Consensus on Principles of Clinical Management of Patients with Severe Emergent Cardiovascular Diseases during the COVID-19 Epidemic (27 Mar 2020) (39)	• Criteria-based prioritisation for invasive procedure: ○ Carefully weigh the relative advantages and disadvantages of treating cardiovascular disease while preventing the risk of SARS-CoV-2 transmission. ○ Where appropriate, preferential use of conservative medical therapeutic approaches to minimise disease spread and goal directed medical therapy, according to recent guidelines recommended for high risk patients. ○ At all times, medical practices and interventional procedures should be conducted according to directives of the infection control department of local hospitals and local health commissions (cardiac catheterisation lab or operating room), including appropriate patient surveillance, full personal protective equipment to prevent staff exposure, and a single, negative pressure procedure room in cardiac catheterisation laboratory followed by strict peri-procedural disinfection.	https://www.ahajournals.org/doi/pdf/10.1161/CIRCULATIONAHA.120.047011
Precautions and Procedures for Coronary and Structural Cardiac Interventions during the COVID-19 Pandemic: Guidance from Canadian Association of Interventional Cardiology (24 March 2020) (17)	• Patients will be treated with thrombolysis, as per regional protocols when there is complete inability to provide pPCI. Otherwise for moderate to high probability of COVID-19 positive patients, pharmacoinvasive or pPCI with aerosol level PPE and N95 mask, at discretion of the treating team is considered.	https://www.sciencedirect.com/science/article/pii/S0828282X20303007
Recommendations for safe and effective practice of	• Patients with low risk for COVID-19 should be managed with PCI if hospital resources and capabilities allowed.	https://journals.najah.edu/media/journals/full_texts/Corona_2019_revised.pdf

interventional cardiology during COVID-19 pandemic: Expert opinion from Jordan and Palestine (5 April 2020) (40)	• Thrombolysis is considered a good option for stable low risk STEMI patient with confirmed or suspected patients with COVID-19. Elective PCI will be considered after recovery from COVID-19 infection. • PCI only to culprit vessel is considered (unless a non-culprit lesion is deemed unstable or multiple culprit lesions are present) in certain conditions after applying maximum protection to prevent staff exposure including effective personal protective equipment (PPE). • When thrombolysis is contraindicated or beyond reperfusion window and the PCI can't be performed due to high risk on staff, patients will be treated conservatively in the CCU.	

Appendix one

PubMed search string:

1. (((((("myocardial infarction"[Title/Abstract] OR "STEMI"[Title/Abstract])) AND ((("tenecteplase"[Title/Abstract] OR "therapeutic thrombolysis"[Title/Abstract]) OR "fibrinolysis"[Title/Abstract]))) AND ((("percutaneous coronary intervention"[Title/Abstract] OR "PCI"[Title/Abstract]))
2. (Tenecteplase[Title/Abstract] AND ((myocardial infarction[Title/Abstract]) OR (STEMI[Title/Abstract])
3. ((((((("myocardial infarction"[Title/Abstract] OR "STEMI"[Title/Abstract])) AND ((("tenecteplase"[Title/Abstract] OR "therapeutic thrombolysis"[Title/Abstract]) OR "fibrinolysis"[Title/Abstract]))) AND ((("percutaneous coronary intervention"[Title/Abstract] OR "pci"[Title/Abstract]))) AND (((((2019-nCoV[title/abstract] or nCoV[title/abstract] or covid-19[title/abstract] or covid19[title/abstract] or "covid 19"[title/abstract] OR "coronavirus"[MeSH Terms] OR "coronavirus"[title/abstract])))))
4. (((((("myocardial infarction"[Title/Abstract] OR "STEMI"[Title/Abstract])) AND ((("tenecteplase"[Title/Abstract] OR "therapeutic thrombolysis"[Title/Abstract]) OR "fibrinolysis"[Title/Abstract]))) AND (((((2019-nCoV[title/abstract] or nCoV[title/abstract] or covid-19[title/abstract] or covid19[title/abstract] or "covid 19"[title/abstract] OR "coronavirus"[MeSH Terms] OR "coronavirus"[title/abstract])))))

TRIP database and Google: 'COVID-19 and Tenecteplase': ‘Fibrinolysis vs PCI’ ‘STEMI management during COVID-19’

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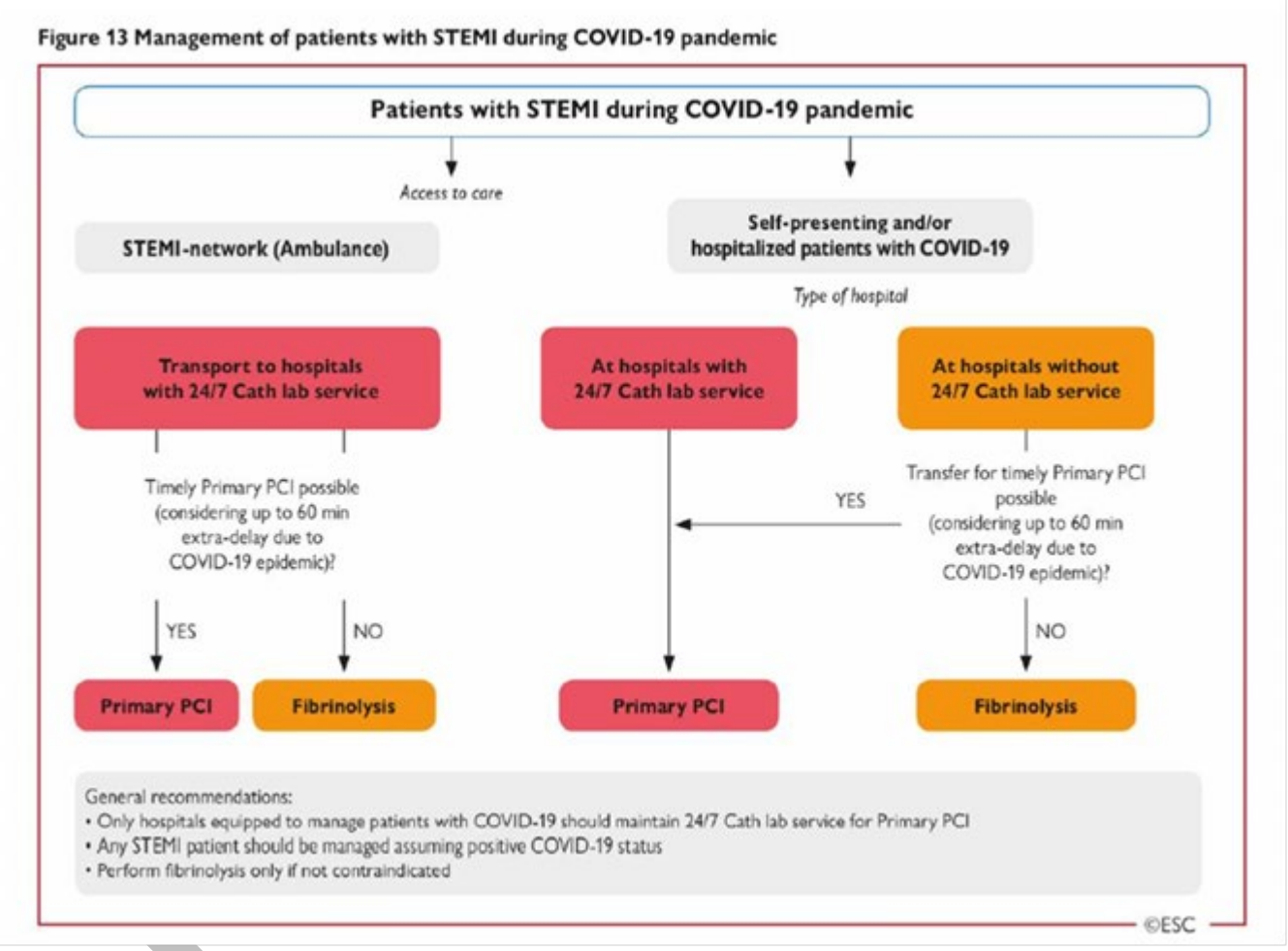

Figure 1: Management algorithm for patient with STEMI during COVID-19 pandemic from European Society of cardiology. (ESC) (7)

Evidence checks are archived a year after the date of publication

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