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Review Article

Thrombus Aspiration in Primary Percutaneous Coronary Intervention; To Use or Not To Use?

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Introduction

The use of thrombus aspiration devices in the context of Primary Percutaneous Coronary Intervention (PPCI) for ST Elevation Myocardial Infarction (STEMI) has been the subject of intense scrutiny and debate over the last decade. A number of clinical trials have been undertaken, using varying randomisation methodologies, aiming to identify and objectively quantify the impact of thrombectomy use in PPCI, and several subsequent meta-analyses have been conducted, albeit with conflicting results. As such, uncertainty remains and no exclusive guidance has so far been internationally agreed upon as regard to the definitive usefulness or otherwise of the practice. Therefore, the use of thrombectomy in PPCI has become adhoc or at best discretionary, with different individual interventional cardiologists having differing rules as to when to perform it, thereby in a way reflecting the conflicting evidence that currently exists.

This article aims to critically review the available evidence, aiming to extrapolate new highlights about the relationship between the thrombus burden and the existing lesion severity on the one hand, and the extent of myocardial damage and complications in general on the other hand in STEMI patients. The authors argue that the severity of the underlying coronary lesion in the infarct related artery (IRA) can be an independent predictor of infarct size, no-reflow and mortality in selected STEMI patients. Furthermore, the extent of thrombus burden within the lesion only becomes of clinical significance if the underlying lesion itself was non-flow limiting prior to the event. Therefore, the authors conclude that thrombus aspiration in PPCI is mostly beneficial if performed early in IRA lesions that were initially non-flow limiting prior to the event, but have suddenly become occluded with a large thrombus burden. In contrast, thrombectomy provides little or no benefit if attempted in IRA lesions that were initially severely flow-limiting prior to the event. The authors believe that a major role – *in limiting the extent of myocardial damage in STEMI patients whose lesions were flow-limiting to begin with* – is played by the ischaemic pre-conditioning effect produced by the tight flow-limiting stenoses together with the retrograde collateralisation that is often present in those situations. Therefore, the impact of thrombectomy during PPCI in such patients is of little significance. The authors conclude that clearer guidance needs to be devised about the usage of thrombectomy in PPCI to further clarify that while thrombus aspiration is not routinely recommended in all STEMI cases, its use should nevertheless be considered in those

whose IRA has a large thrombus burden that has developed within a non-flow limiting coronary lesion.

The evidence

We reviewed 17 randomised controlled trials that evaluated the role of thrombectomy during PPCI in STEMI patients between 2004 and 2015. The total number studied was 22,222 patients. However, not all trials adopted a unified randomisation methodology or design. Rather, while some relied purely on symptoms and ECG criteria, others had varying additional angiographic inclusion & exclusion criteria.

In six trials, where a total of 12,509 patients were studied, the randomisation step, to thrombectomy versus conventional PPCI, was conducted *before* coronary angiography was undertaken, so patients were randomised upon inclusion solely on the basis of standard STEMI symptoms and ECG criteria. In the remaining eleven trials, where a total of 9,713 patients were studied, the randomisation took place *after* coronary angiography was undertaken, thereby taking into account certain angiographic parameters which had not been considered by the other six trials. Furthermore, thirteen meta-analyses that have so far been conducted on all the above studies, and we have taken their findings into consideration on writing this review.

This article elaborates on each of those clinical trials & meta-analyses, discusses the flaw within the evidence and details the reasoning for the authors' argument that new guidance should be devised to encourage the use of thrombectomy in selected PPCI cases.

Studies where randomisation was done *before* coronary angiography:

The REMEDIA[1] study was one of the first clinical trials to examine the feasibly of unselected use of manual thrombus aspiration during PPCI in STEMI back in 2004. Only 100 patients were randomized and the data of 99 patients were analysed. No angiographic exclusion criteria were used. The study multivariate analysis demonstrated that thrombus aspiration was a significant independent predictor of achievement of myocardial blush grade (MBG) $\geq$2 and ST segment Resolution (STR) $\geq$70% ($p = 0.013$). The investigators therefore concluded that manual thrombus aspiration in unselected STEMI patients undergoing primary or rescue PCI was clinically feasible and would result in better angiographic and ECG myocardial reperfusion rates in comparison with standard PCI. The main study limitation is the small number of patients, and the fact that it wasn't designed to measure clinical outcome end points. Therefore, it is rather difficult to generalise its findings to the wider STEMI population, or to speculate a link between those findings and definitive clinical outcomes such as cardiac mortality, hospitalisation or re-infarction.

In another randomized study, Silva-Orrego *et al*[2] tested the usefulness of thrombus aspiration in 140 unselected STEMI patients back in 2005. No angiographic exclusion criteria were used. Although the incidence of in-hospital clinical events was shown to be similar in the two groups, the multivariate analysis revealed that thrombus aspiration was associated with significant improvement in STR and MBG, in addition to reduction in no-reflow and creatine kinase mass band fraction release. Again, the patients' number was too small to generalize, but the study findings seemed to replicate those of the REMEDIA study, thereby adding further credibility to its conclusion.

The VAMPIRE[3] study was a larger, multicentre study that randomized 355 STEMI patients to thrombectomy versus direct PPCI in 2007, and its findings demonstrated a trend towards better myocardial perfusion and lower clinical events in the thrombectomy arm that did not reach statistical significance (12.4% vs. 19.4%, $p = 0.07$). The study also suggested that those presenting after 6 hours of symptoms onset benefit the most from thrombus aspiration (slow flow rate: 8.1% vs. 37.6%, $p = 0.01$). The results seemed to

back those of the two aforementioned earlier studies, albeit with no statistical significance. The correlation between flow improvement in the IRA and clinical improvement remained unclear.

The TAPAS[4] trial was a single centre yet larger study that was published in 2008, wherein 1071 STEMI patients were randomized prior to coronary angiography to thrombectomy versus direct PPCI. Like the preceding trials, MBG & STR were shown to have significantly improved in the thrombus aspiration arm. In addition, the rates of death and adverse events at 30 days were shown to inversely correlate with MBG and STR, thereby demonstrating for the first time that thrombus aspiration does have a positive impact on survival and morbidity irrespective of the baseline angiographic characteristics. Furthermore, data analysis at 1 year[5] revealed that cardiac death remained significantly less in the thrombus aspiration group (3.6% versus 6.7%, p = 0.02) and so was cardiac death & non-fatal re-infarction (5.6% versus 9.9%, p = 0.009).

In 2009, Liistro *et al*[6] published the findings of their relatively small study, wherein 111 STEMI patients were randomized to thrombectomy versus direct PPCI. End points like STR, TIMI flow, myocardial contrast echocardiography score index, course of wall-motion score index and left ventricular ejection fraction have all been shown to have very significantly improved in the thrombectomy arm. The small number of studied patients was a limitation, but the findings nevertheless supported the use of thrombectomy. Therefore, for some subsequent years, the general consensus remained in favour of routine thrombectomy usage in PPCI, until 2015 when the findings of the TOTAL study were published.

TOTAL[7] was by far the largest randomized trial that studied manual thrombus aspiration versus routine PPCI. 10,732 STEMI patients were included. The primary outcome was a composite of death from cardiovascular causes, recurrent myocardial infarction, cardiogenic shock, or New York Heart Association (NYHA) class IV heart failure within 180 days. The key safety outcome was stroke within 30 days. The study results revealed no significant difference between the two arms in the primary outcome (P = 0.86, 0.34 & 0.9.5 respectively), but there was a significant difference in favor of the PPCI-alone group in the incidence of stroke within 30 days (P = 0.02). As such, it was concluded that routine manual thrombectomy, as compared with PPCI alone, did not reduce the risk of cardiovascular death, recurrent myocardial infarction, cardiogenic shock, or NYHA class IV heart failure within 180 days but was associated with an increased rate of stroke within 30 days. This trial served as a landmark study in the reversal of the then popular trend of routine thrombus aspiration during PPCI. The practice has since become discouraged, and at best discretionary, which continues to remain the case until now.

Studies where randomisation was done *after* coronary angiography:

Parallel to the above set of clinical trials, other similar yet more specific studies were being conducted wherein STEMI patients had to satisfy additional angiographic inclusion criteria before being randomized.

Antoniucci *et al*[8] conducted published their study findings in 2004, randomising 100 first acute myocardial infarction (AMI) patients to rheolytic thrombectomy versus IRA stenting. Pre-randomisation coronary angiography served solely to determine the IRA and to confirm the need for PCI. The primary end point was early ST-segment elevation resolution, and the secondary end points were corrected TIMI frame count, infarct size, and 1-month clinical outcome. The primary and most other end points were shown to be significantly better in the thrombectomy arm (P = 0.022, 0.032, 0.032 & 0.010 respectively), apart from the 1-month clinical outcome where no major adverse cardiac events were recorded in

either arm, which can be attributed to the small number of participants.

Thereafter, the XAMINE ST[9] trial was published in 2005, which included 201 AMI patients with TIMI flow grade 0-1 and randomised them to either X-Sizer thrombectomy or direct PPCI. The primary end point was the magnitude of ST segment resolution after PCI. Thrombus scoring (0 – 5) was performed as an additional angiographic inclusion criterion, together with TIMI flow grade 0-1 in a de novo IRA lesion. It is unclear however whether any patients had been excluded upfront due to an IRA thrombus score of zero, which is a study limitation. Nevertheless, there was a significant difference in ST segment resolution and myocardial perfusion in favour of the thrombectomy arm. Yet, there was no significant difference between the two groups in the rate of major adverse cardiovascular & cerebral events (MACCE) both at one and at six months.

Subsequently, a similar size study was published by Kaltoft *et al*[10] in 2006, wherein 215 STEMI patients were randomised to either thrombectomy or standard PPCI. The primary end point was myocardial salvage measured by sestamibi SPECT, calculated as the difference between area at risk and final infarct size determined after 30 days. Secondary end points included final infarct size, ST-segment resolution, and Troponin T release. In the thrombectomy group, the final infarct size was increased ($P = 0.004$). Therefore, the investigators concluded that performing routine thrombectomy during PPCI did not increase myocardial salvage and could worsen the final infarct size. However, while coronary angiography was performed as a pre-requisite for randomization, patients' eligibility for participation in the study was stated to have been determined if PCI was indicated and the treating physician found the IRA suitable for thrombectomy, a rather vague way of randomization. No thrombus burden quantification method was documented to have been used.

Later, the EXPERIA[11] study was conducted and its results were later published in 2009. 175 STEMI patients were randomized to manual thrombectomy versus direct PPCI. A thrombus score ≥ 3 was clearly stated as an inclusion criterion, together with TIMI flow grade ≤ 1, IRA diameter ≥ 2.5 mm in addition to other standard STEMI symptoms and ECG criteria. Both MBG and STR were found to be significantly better in the thrombus aspiration group ($p = 0.001$ & 0.001). There was a lower incidence of cardiac deaths in the thrombectomy group ($p = 0.02$). Despite the relatively smaller study size, proper IRA thrombus burden scoring had been undertaken, and only those with a significant amount of thrombus burden were included in the study, thereby conceptualising the idea of selective, rather than routine, thrombectomy in STEMI patients.

The PIHRATE[12] trial, published subsequently in 2010, randomized 196 STEMI patients to thrombectomy versus routine PPCI, the primary end point being ECG STR. Secondary end points included: direct stenting rate, final TIMI grade 3 flow, corrected TIMI Frame Count (cTFC), final MBG grade 3, peri-procedural angiographic complications, combination of STR $\geq 70\%$ and MBG 3, and in-hospital major adverse cardiac events (MACE). The primary and other end points were shown to be significantly better in the thrombectomy arm, with the exception of death & and re-infarction a 6 months which was similar in both groups. The investigators therefore concluded that, while thrombectomy in PPCI was safe and improved coronary flow and myocardial perfusion, it had no effect on mortality or re-infarction. In addition to the small number of included patients, the study is limited by its assessment criteria for IRA thrombus burden, which lacked clarity and objectivity. Apparently, one third of patients had little or no visible thrombus, yet they were still randomised into either arm, which might have influenced the results in a major way.

In 2011, Ciszewski *et al*[13] published the results of their single centre study that examined the usefulness of thrombus aspiration in PPCI. 137 patients were randomised to undergo thrombectomy or direct PPCI. Angiographic evidence of thrombus was one of the inclusion criteria, and therefore patients who had no visible thrombus were excluded from the study. The primary endpoint was myocardial salvage index (MSI) as assessed by ^{99m}Tc-sestamibi SPECT imaging. MSI was larger in aspiration thrombectomy group than in control patients (25.4% versus 18.5% respectively, $P = 0.02$), and the final infarct size was smaller in the thrombectomy group (23.1% versus 28.9%, $P = 0.002$). The investigators therefore concluded that aspiration thrombectomy improves myocardial salvage with angiographic evidence of thrombus. Although the angiographic inclusion criteria were reasonably clear, particularly in relation to the presence of visible thrombus, the small number of study participants and the fact that it was a single centre study casted some weakness on its credibility, which prevented the applicability of the study findings in a wider context.

The MUSTELA[14] study was published in 2012, which randomised 208 STEMI patients with a high thrombus load to thrombectomy versus direct PPCI. Cardiac magnetic resonance imaging (cMRI) at three months was performed to quantify the infarct size, its transmurality and the microvascular obstruction (MVO). The primary endpoints were STR >70% at 60 min and 3-month infarct size. There was a higher STR rate and final MBG grade 3 in the thrombectomy arm (P = 0.004 & 0.03 respectively). MVO was significantly less in the thrombectomy group (P = 0.02) but there was no difference between the two groups in infarct size or transmurality.

The larger INFUSE-MI[15] study was conducted between 2009 and 2011 in 37 sites, and its findings were later published in 2012. The investigators studied 452 high risk STEMI patients to determine whether bolus intracoronary abciximab, manual aspiration thrombectomy, or both reduce infarct size. Patients were randomized into four arms: bolus intracoronary abciximab, manual thrombectomy, both intracoronary abciximab & manual thrombectomy, and direct PPCI alone. The primary end point was infarct size at 30 days assessed by cardiac magnetic resonance imaging (cMRI). Patients randomized to intracoronary abciximab compared with no abciximab had a significant reduction in 30-day infarct size ($P = 0.03$), while patients randomized to aspiration thrombectomy versus no aspiration had no significant difference in infarct size at 30 days ($P = 0.51$). Therefore it was concluded that intracoronary abciximab was beneficial in reducing the infarct size at 30 days but aspiration thrombectomy was not. The same conclusion was reached after a year follow up was completed[16]. The study however did not specify any angiographic inclusion criteria related to thrombus load or visibility, and therefore it could be presumed that a proportion of the included participants had little or no visible thrombus, which represents a methodology flaw as further discussed below.

The TASTE[17] study, published in 2013, was a much larger multicentre trial that randomized 7,244 STEMI patients (pulled from the Swedish Registry) to manual thrombectomy & PPCI versus PPCI alone. The primary end point was all-cause mortality at 30 days. In addition to STEMI standard ECG and symptoms criteria, coronary angiography was performed prior to inclusion to confirm patients' eligibility for PPCI. However, no IRA thrombus burden quantification was undertaken, nor were patients without evidence of thrombus excluded from the trial. In addition, there was a significant cross over between the two groups after randomization involving 16% of patients. Notwithstanding those limitations, the results still demonstrated

better absolute figures in favor of thrombectomy, but statistical significance could not be reached. Death from any cause occurred in 2.8% of patients in the thrombus-aspiration group (103 of 3621), as compared with 3.0% in the PCI-only group (110 of 3623) (P = 0.63). The rates of hospitalization for recurrent myocardial infarction at 30 days were 0.5% and 0.9% respectively in the two groups (P = 0.09), and the rates of stent thrombosis were 0.2% and 0.5% respectively (P = 0.06). There were no significant differences between the groups with respect to the rate of stroke or neurologic complications at the time of discharge (P = 0.87). The investigators therefore concluded that *routine* thrombus aspiration before PCI as compared with PCI alone did not reduce 30-day mortality among patients with STEMI. The results remained the same after one year of follow up[18].

Also in 2013, Pyxaras *et al*[19] published the results of their medium sized retrospective registry, in which they divided 644 STEMI patients to four groups: conventional PPCI alone; PPCI & abciximab; PPCI & thrombectomy; and PPCI, abciximab & thrombectomy. The primary end point was the composite of MACE, defined as overall mortality, myocardial infarction, target vessel revascularization, and major bleedings at 1 year. MACEs at 1 year in groups 1 to 4 were 29%, 22%, 19% and 13% respectively (log-rank $P = 0.001$). It was therefore concluded that the combination of pharmacologic and mechanical antithrombotic treatment during PPCI was associated with better 1-year clinical outcome. Although the study design was somewhat similar to that of INFUSE-MI, the results have been discordant as far as thrombectomy was concerned. Furthermore, no clear method for thrombus burden assessment was documented to have been observed as part of the inclusion or exclusion criteria.

Finally, a small study was conducted by Onuma *et al*[20], in which 141 STEMI patients were randomised to PPCI versus thrombectomy. No prognostic end points were measured. The primary end point was the minimum flow area post procedure, and the study concluded that it was similar in the two groups.

Meta-analyses Reviews:

Several meta-analyses have been conducted to further scrutinise the evidence, albeit with similarly conflicting conclusions.

Brodie[21] conceded that the findings of randomised trials have indeed been conflicting and concluded that, while the totality of evidence didn't support the routine use of thrombectomy during PPCI in STEMI patients, adjunctive thrombectomy was beneficial and would be appropriate to perform prior to PPCI in patients with large thrombus burden. Later, De Luca *et al*[22 23] reached a similar conclusion to Brodie's after having meta-analysed 21 randomised trials involving 4,514 patients. That is, thrombectomy mustn't be routinely recommended, but should be selectively used in cases of large intracoronary thrombus. The reviews also agreed that mechanical thrombectomy seemed to be associated with an increased incidence of stroke and mortality.

The meta-analyses conducted by Bavry *et al*[24], Francesco *et al*[25] and Kumbhani *et al*[26] have examined 30, 11 & 20 randomised controlled studies encompassing 6,415, 2,686 & 11,321 patients respectively have concluded that thrombectomy in PPCI had a beneficial effect in mortality reduction and reduction of adverse clinical outcomes. Conversely, other meta-analyses conducted by Deng *et al*[27] and Islam *et al*[28] have reached an opposing conclusion following the review of 26 & 17 trials encompassing 11,780 & 20,960 patients respectively. That is, aspiration thrombectomy in PPCI was not associated with any clinical benefit and might increase the risk of stroke.

The other large meta-analyses, conducted by Mongeon *et al*[29], Tamhane *et al*[30] and Sanjit *et al*[31] have reached more neutral conclusions after reviewing a total of 41 trials involving 27,255 participants. That is, thrombectomy was show to improve early markers of reperfusion but there was no overall demonstrable impact on 30-day post-MI mortality, re-infarction, and stroke, with a trend towards survival benefit with manual devices and worsening outcomes with mechanical ones.

Ischaemic Pre-Conditioning:

Towards the end of the 1990s, ischaemic pre-conditioning (IPC) has become conceptualized as a powerful form of endogenous protective mechanism against myocardial infarction. Several animal studies have demonstrated that subjecting the myocardium to a transient ischaemic impact results in a smaller infarct size when the myocardium is subjected to permanent cessation of coronary blood flow shortly afterwards. The same concept has been shown to exist in isolated human cardiomyocytes.

Due to understandable ethical constrains, no randomized controlled studies have been conducted in humans. However, multiple observational human data, obtained from patients undergoing PCI and coronary artery bypass grafting surgery (CABG) where no collateral blood supply was present have indicated that IPC does exist in humans[32]. Resistance to ischaemia seems to be affected by medicines that operate on Potassium Adenosine Tri-Phosphate (K-ATP) channels. In 2009, the CRISP Stent study[33] assessed the ability of remote IPC on the magnitude of cardiac Troponin-I release in 242 patients randomized to standard elective PCI versus remote IPC plus PCI, and demonstrated that remote IPC did significantly reduce chest discomfort during PCI and was associated with a significant reduction in procedure-related Troponin-I release. After 6 years of follow up[34], the MACCE rate continued to remain significantly lower in the remote IPC group.

More recently, in 2016, Zhen-bing *et al*[35] randomized 119 STEMI patients to remote IPC prior to stenting versus direct PPCI, and demonstrated that the ischaemic reperfusion injury was alleviated in the remote IPC group, with resultant significant reduction in infarct size ($P = 0.042$).

Discussion: The flaw within the evidence

One of the main reasons why the multiple randomised studies that examined the feasibility of thrombectomy in PPCI have continued to consistently reach conflicting conclusions is that not all the relevant clinical variables have been exclusively accounted for. The methodologies of most of those trials seemed to have implicitly presumed that the variability in STEMI outcomes was solely dependent on the IRA site (*left main stem, left anterior descending, left circumflex or right coronary*), the IRA acute occlusion location (*proximal, mid or distal*), the door to balloon time, and the size of the affected myocardium. Furthermore, those methodologies also seemed to have implicitly presupposed that STEMI patients, in whom the above mentioned variables are similar, would somehow be expected to pursue closely similar post MI courses and final outcomes.

However, the authors argue that there are other additional factors that do substantially influence both the immediate and the longer term STEMI outcomes, such as the IRA lesion severity *prior* to the index STEMI event, the size of thrombus contained with the IRA, and the presence of IPC or established collateral blood supply to the IRA territory *prior* the event. Those factors are variable and interdependent across a continuum of STEMI spectrum in patients who may otherwise have total similarities of

the more formally recognised variables mentioned in the above paragraph.

On one end of the STEMI spectrum, the acute occlusive thrombus forms within an initially tight flow-limiting coronary stenosis whose myocardial territory is already trained for ischaemia, with an already established IPC and/or collateral blood supply. As such, the occlusive thrombus (*within the tight IRA lesion*) is often small in size and barely visible on coronary angiography, and the affected myocardium is often highly resistant to ischaemia. Therefore, performing thrombus aspiration in such patients is unlikely to result in any tangible benefit in comparison to direct PPCI, because there is virtually no thrombus to aspirate, and because of the protective anti-ischaemic effects of IPC and/collateralisation. The authors also argue that STEMI patients at this end of the spectrum tend to end up with smaller infarcts and fewer MACCE outcomes.

On the other end of the STEMI spectrum, the acute occlusive thrombus forms within an initially non flow-limiting coronary lesion (*perhaps amounting to only 40 or 50%*) whose myocardial territory has neither been preconditioned for ischaemia nor does it have collateral blood supply. The occlusive thrombus is therefore often large in size and clearly visible on coronary angiography. The affected myocardium is often poorly resistant to ischaemia. Therefore, performing thrombus aspiration in such patients is very likely to result in a significant benefit compared to direct PPCI, because aspiration will help remove the bulk of the occlusive material (the thrombus), and because doing so will reduce the risk of no-reflow & distal coronary embolisation. The authors also argue that STEMI patients at this end of the spectrum tend to end up with larger infarcts and more MACCE outcomes.

With the exception of the three small studies: EXPERIA, MUSTELA and the study conducted by Ciszewski *et al*; none of the aforementioned thrombectomy trials has used any objective or meaningful thrombus burden quantification method in its inclusion or exclusion criteria in a way that would ensure that only STEMI patients with visible coronary thrombi get included and randomised. Furthermore, neither the IRA lesion severity *prior* to the STEMI event, nor the presence of IPC and/or collateralisation has been taken into consideration during the design or the undertaking of any of the above described randomised clinical trials. Therefore, patients from within the entire range of the STEMI spectrum ended up being simply randomised to thrombectomy versus no thrombectomy. Thus, it was left to pure chance whether some STEMI patients with large thrombi ended up being randomised to direct PPCI while other STEMI patients with virtually no thrombi ended up being randomised to thrombus aspiration. As such, the end statistical results have either regressed to the mean and showed no net benefit for thrombectomy, or revealed conflicting results of seemingly similarly designed trials, thereby leading to more confusion.

Conclusion

Notwithstanding the large number of clinical trials that investigated the role of adjunctive thrombectomy in PPCI, confusion about the usefulness of the practice remains far from cleared. Repeated major design and methodology flaws have led to conflicting results and have fuelled confusion within the realm of interventional cardiology. The missing piece in this jigsaw is a large clinical trial that only randomises STEMI patients with large visible IRA thrombi. The trial should collect data on the culprit lesion degree of severity and on the presence or absence of IRA territory collaterals. The assumption being that tight IRA lesions indicate the presence of IPC and vice versa. The authors anticipate that, if conducted properly, the trial shall unequivocally confirm that thrombectomy confers

significant benefit in selected STEMI patients with visible thrombi and not-so-tight IRA lesions, thus paving the way for the composition of clear international guidance stating the same. Until such a study is undertaken however, the evidence remains deficient, and it remains premature to decisively conclude in favour of either PPCI strategy. Therefore, no universal guidance is devisable at this stage. Rather, the status quo of discretionary use of thrombus aspiration shall continue to prevail for the time being.

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