

EDITORIAL

The State of Coronary Thrombus Aspiration

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Thrombus aspiration in patients with high thrombus burden can decrease thrombus burden, lower rates of distal embolization, improve thrombolysis in myocardial infarction-3 flow, reduce the incidence of no reflow, improve microvascular perfusion, and consequently improve clinical outcomes. However, >2 dozen randomized trials have compared the outcomes of routine thrombus aspiration with primary percutaneous coronary intervention (PCI) alone in patients with ST-segment-elevation myocardial infarction (STEMI) and have not shown a consistent reduction in cardiovascular outcomes. As such, routine thrombus aspiration during primary PCI is not recommended by guideline committees (class III, 2021 American College of Cardiology/American Heart Association guidelines or 2017 European Society of Cardiology guidelines),^{1,2} and selective or bailout use is given a class IIb recommendation only by the Japanese Cardiological Society (Figure).³ The 2015 American College of Cardiology/American Heart Association focused update on primary PCI in STEMI states that the usefulness of selective and bailout aspiration thrombectomy in patients undergoing primary PCI is not well established.⁴

Aspiration thrombectomy was used in ≈29% of patients overall, resulted in more successful PCI (defined as thrombolysis in myocardial infarction-3 flow at the end of the procedure), but was offset by a significant increase in in-hospital deaths and procedural complications (defined as composite of deaths within 30 days of PCI, periprocedural myocardial infarction, cardiac tamponade, cardiogenic shock during and after PCI, emergency operations, bleeding, and other complications) in the adjusted analysis. However, there was heterogeneity of observed effect based on the type of acute coronary syndrome.

In patients with STEMI, 53% underwent aspiration thrombectomy, and although there were higher rates of successful PCI and no excess in-hospital mortality (adjusted odds ratio [aOR], 1.02 [95% CI, 0.94–1.12]), there were excess procedural complications (aOR, 1.17 [95% CI, 1.11–1.24]) with aspiration thrombectomy. Although meta-analysis of small randomized trials⁶ suggested a benefit of routine aspiration thrombectomy with improved rates of ST-segment resolution at 60 minutes, higher thrombolysis in myocardial infarction blush grade 3 after the procedure, and reduction in major adverse cardiovascular events, subsequent large randomized trials failed to show a mortality benefit. In 2013, the TASTE (Thrombus Aspiration in ST-Elevation Myocardial Infarction in Scandinavia) trial, with 7244 patients, showed that routine thrombus aspiration did not reduce 30-day or 1-year mortality or other cardiovascular events.^{7,8} Subsequently, in 2015, the TOTAL (Trial of Routine Aspiration Thrombectomy With PCI Versus PCI Alone in Patients With STEMI) also failed to show a reduction in cardiovascular events and death in 10732 patients with manual thrombectomy, but showed an increased rate of stroke within 30 days and at 1 year.^{9,10} An

See Article by Inohara et al.

With this background, in this issue of *Journal of the American Heart Association (JAHA)*, Inohara et al, using data from the J-PCI (Japanese PCI) registry, evaluated the use of aspiration thrombectomy in 282606 patients with acute coronary syndrome (53% with STEMI) in >1000 hospitals across Japan between 2016 and 2018.⁵

Key Words: Editorials ■ aspiration ■ coronary ■ hospital mortality ■ mechanical ■ myocardial infarction ■ thrombectomy

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COR	LOE	Recommendation
STEMI		
2021 ACC/AHA Revascularization Guidelines		
3: No Benefit	A	In patients with STEMI, routine aspiration thrombectomy before primary PCI is not useful
2015 ACC/AHA Focused Updated on Primary PCI for STEMI		
IIb	C-LD	The usefulness of selective and bailout aspiration thrombectomy in patients undergoing primary PCI is not well established
2017 ESC STEMI Guidelines		
III	A	Routine use of thrombus aspiration is not recommended
2018 JCS Guidelines on Acute Coronary Syndrome		
III: No Benefit	A	Routine manual aspiration thrombectomy in primary PCI is not recommended
IIb	C	Selective or bailout manual aspiration thrombectomy may be considered for patients undergoing primary PCI
Non ST-Segment Elevation ACS		
2021 ACC/AHA Revascularization Guidelines		
No recommendations		
2022 ESC NSTEMI-ACS Guidelines		
No recommendations		
2018 JCS Guidelines on Acute Coronary Syndrome		
III: No Benefit	A	Routine manual aspiration thrombectomy is not recommended

Figure 1. Guideline recommendation on aspiration thrombectomy in patients with acute coronary syndromes undergoing percutaneous coronary intervention.

ACC indicates American College of Cardiology; ACS, acute coronary syndrome; AHA, American Heart Association; COR, class of recommendations; LD, limited data; LOE, level of evidence; NSTEMI, non-ST-segment-elevation; JCS, Japanese Cardiological Society; PCI, percutaneous coronary intervention; and STEMI, ST-segment-elevation myocardial infarction.

individual patient-level meta-analysis of 3 trials (TAPAS [Thrombus Aspiration during Percutaneous coronary intervention in Acute myocardial infarction Study], TASTE, and TOTAL) (n=19047 patients) showed no difference in clinical outcomes with routine thrombectomy, but subgroup analysis in those with high thrombus burden showed fewer cardiovascular deaths at the cost of an increased stroke rate.¹¹ Other analyses have shown that the association of thrombus aspiration with stroke to be weak and driven mainly by the TOTAL trial.¹² As such, the American College of Cardiology/American Heart Association, European Society of Cardiology, and the Japanese Cardiological Society guideline committees give a class III recommendation for routine thrombus aspiration largely for no benefit rather than harm, and the Japanese Cardiological Society gives a class IIb for its selective use during primary PCI. Despite these class III guideline recommendations (including the country's own guidelines), the use of thrombus aspiration for

STEMI was high (53%) in Japan, suggesting perhaps an oculo-thrombotic reflex. In comparison, in the United States, rates of aspiration thrombectomy fell after the publication of the larger trials and updated guideline recommendations, and in the second quarter of 2016, manual aspiration thrombectomy was used in only 4.7% of all primary PCIs.¹³

In the J-PCI registry among patients with non-ST-segment-elevation myocardial infarction and unstable angina, 23% and 5% underwent thrombus aspiration, respectively. Although there was higher successful PCI, there was also excess in-hospital mortality and increased procedural complications with thrombus aspiration despite covariate adjustment. Although measured and unmeasured confounders are likely drivers of excess mortality and procedural complications, the reason for use of thrombus aspiration in this patient population was not clearly outlined in the study. It is likely that a proportion of these patients could have had thrombotic

circumflex coronary artery occlusion, because they can be electrically silent on electrocardiogram or had thrombotic complications during PCI. The TATORT-NSTEMI (Thrombus Aspiration in Thrombus Containing Culprit Lesions in Non-ST-Elevation Myocardial Infarction) trial randomized 440 patients to adjunctive thrombectomy ($n=221$) compared with conventional PCI ($n=219$) in patients with non-ST-segment-elevation myocardial infarction with thrombus-containing lesions. Adjunctive thrombectomy did not reduce the primary end point of the extent of microvascular obstruction, nor were there significant differences in thrombolysis in myocardial infarction flow grade, myocardial blush grade, myocardial salvage index, or infarct size.¹⁴ Surprisingly, in the long-term follow-up (median 4.9 years) of this trial, adjunctive thrombectomy was associated with significant reduction in the composite end point of death, myocardial infarction, or new heart failure, driven by significant reduction in reinfarction ($P=0.01$).¹⁵ The trial was not powered for clinical outcomes, and this observation could represent a chance finding. As such, the American College of Cardiology/American Heart Association and European Society of Cardiology guidelines have no recommendations for thrombus aspiration in non-ST-segment-elevation acute coronary syndrome, whereas the Japanese guidelines give a class III recommendation for routine aspiration thrombectomy in non-ST-segment-elevation acute coronary syndrome (Figure).

What is the state of coronary thrombus aspiration in 2022? Routine aspiration thrombectomy is not supported by randomized trial data. Selective use can be considered for high thrombus burden with precautions to prevent stroke. Whether continuous mechanical aspiration thrombectomy devices, such as the Indigo Aspiration System using the CAT RX aspiration catheter, lead to better thrombus removal while minimizing embolization/stroke needs to be proven in future randomized trials.

ARTICLE INFORMATION

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Disclosures

Dr Bangalore reports ad hoc consulting and speaking for Abbott Vascular, Biotronik, Boston Scientific, Amgen, Pfizer, Merck, and Inari. Dr Pruthi has no disclosures to report.

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