

Utilizing Thrombectomy During PCI for STEMI

Current evidence, unresolved questions, and future trials.

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Despite the efficacy of primary percutaneous coronary intervention (PPCI) in achieving epicardial reperfusion in ST-segment elevation myocardial infarction (STEMI), it is often limited by distal atherothrombotic embolization, leading to impaired microvascular perfusion and no-reflow with unfavorable clinical outcomes. Several therapeutic strategies can be performed to tackle coronary thrombus during PPCI, including pharmacological and device-based approaches (eg, thrombectomy). In this article, we provide an overview of the role of thrombectomy in PPCI for treating STEMI.

BACKGROUND

PPCI remains the most effective treatment strategy for patients presenting with STEMI. However, despite the established merits of this reperfusion strategy, it fails to restore optimal myocardial reperfusion in a relatively large proportion of patients (ie, no-reflow).¹ It has become apparent that patency of epicardial infarct-related coronary arteries (IRA) after reperfusion is not a guarantee for adequate microvascular perfusion. Therefore, optimizing tissue-level reperfusion is an important therapeutic goal in the setting of PPCI.

High thrombus burden is known to be associated with an increased incidence of distal embolization, a significant pathogenetic component of no-reflow, and may limit reperfusion at tissue level as measured by myocardial blush grade (MBG) and ST-segment resolution (STR). Moreover, high thrombus burden is associated with a higher frequency of major adverse cardiac events (MACE) and is a strong independent predictor of long-term mortality.²

Accordingly, several therapeutic strategies have been studied that aim to reduce thrombus burden and consist of pharmacological (eg, glycoprotein IIb/IIIa inhibitors) and mechanical (eg, embolic protection devices, manual or mechanical thrombectomy devices) approaches.

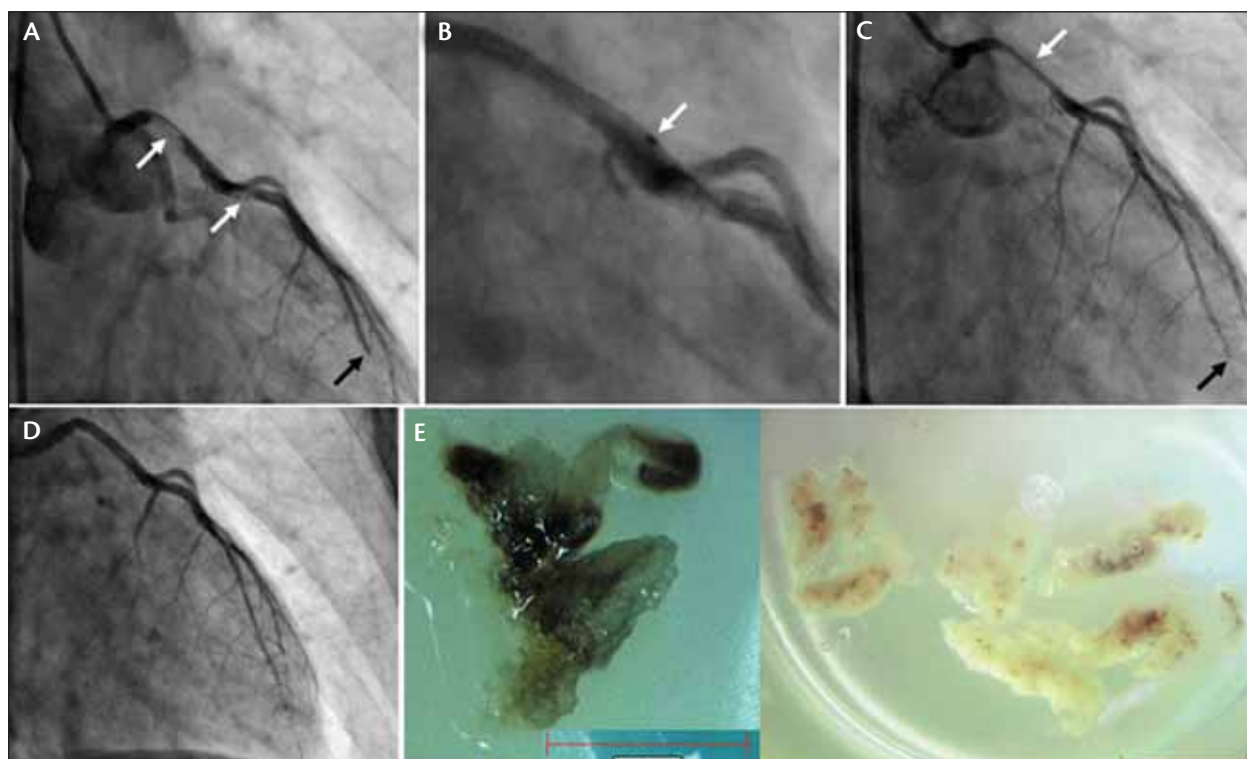
DISTAL ATHEROTHROMBOTIC EMBOLIZATION AND THROMBECTOMY

Plaque rupture produces intraluminal debris that is often thrombogenic (Figure 1). The distal embolization of this material adversely affects coronary capillary flow, especially particulate matter > 200 μ m in diameter.³ Measures that prevent this complication are therefore likely to improve microcirculatory flow.⁴ In this regard, thrombectomy has emerged as a useful tool to further enhance the benefit of reperfusion during PPCI. To date, a variety of commercially available devices have been developed with several differences in design, enabling them to either aspirate or fragment the coronary thrombus (Table 1). The randomized clinical trials investigating manual and mechanical thrombectomy devices in STEMI are listed in Table 2 and are later discussed. Furthermore, Table 3 lists the available thrombus aspiration devices that are currently on the market (as of publication of this article).

MANUAL ASPIRATION THROMBECTOMY

The effects of thrombus aspiration (TA) in STEMI have been evaluated in several clinical trials using a variety of devices. REMEDIA (Randomized Evaluation of the Effect of Mechanical Reduction of Distal Embolization by Thrombus Aspiration in Primary and Rescue Angioplasty) was the first trial to assess the role of thrombectomy with a simple manual aspiration catheter.⁶ This strategy proved to be successful because myocardial perfusion indices, including myocardial contrast echocardiography in a sub-study, were significantly improved compared with conventional PPCI.²⁶ Although the study was not powered for subgroup analysis, TA appeared to be more beneficial in patients presenting with an occluded IRA and those with a high thrombus load.

The benefits of manual TA on myocardial reperfusion markers were confirmed in several clinical trials with different devices.^{7,8} However, these findings were not reproduced in all subsequent studies.^{9,10} Kaltoft et al random-



(Courtesy of Dr. H.M.M. van Busekom)

Figure 1. Manual thrombectomy of atherothrombotic material. Coronary angiography (CAG) showing a thrombotically occluded proximal left anterior descending (LAD) coronary artery with a second filling defect downstream possibly due to dislodgement of thrombus (white arrows) (A). There is an abrupt “cutoff” of the filling in the apical LAD suggestive of distal embolization (black arrow). By thrombectomy with multiple passages across the lesion, a large thrombus load is removed using the Export aspiration catheter (Medtronic, Inc., Minneapolis, MN) with the radiopaque marker at the distal tip (white arrow) (B). CAG showing resolution of the intraluminal defect in the proximal LAD (white arrow) (C). Note that there is restoration of flow in the mid-LAD. However, an abrupt cutoff in the apical LAD remains (black arrow). This was treated with an intracoronary bolus of eptifibatide followed by a continuous infusion for 16 hours. CAG showing a satisfactory luminal gain at the proximal LAD after deployment of a 3-X 18-mm Xience V everolimus-eluting stent (Abbott Vascular, Santa Clara, CA) with persistent apical defect (D). Macroscopy of aspirated thrombi (E). Both white (predominantly platelet rich) and red thrombi (abundance of erythrocytes) are present, showing the mixed nature of these thrombi. The image on the left contains an erythrocyte-rich thrombus with yellowish material, most likely atheromatous debris.

ized 215 patients to PCI with or without TA with the Rescue catheter.⁹ The authors failed to demonstrate any benefit of this technique. In fact, final infarct size (IS), as measured by myocardial nuclear scanning, was increased in the TA group. Although obvious reasons for these findings are lacking, it was speculated that a possible harmful effect of the device might play a role (eg, damage to endothelium, new thrombi, and distal embolization). Unlike the previous trial, a number of clinical trials by other investigators went on to show the beneficial effects of manual thrombectomy.¹¹⁻¹⁴

Importantly, however, none of the aforementioned trials were designed to detect any advantages on hard clinical outcomes. In this regard, convincing evidence in support of manual TA was provided in a more robust trial by Svilaas and colleagues.¹⁵

TAPAS

TAPAS (Thrombus Aspiration During Percutaneous Coronary Intervention in Acute Myocardial Infarction Study) was a landmark trial that facilitated the use of manual thrombectomy as an important myocardial adjunct in the setting of PPCI for STEMI.¹⁵ This trial randomized 1,071 STEMI patients to manual aspiration thrombectomy ($n = 535$) prior to stenting using the Export aspiration catheter or to conventional PCI ($n = 536$). TA resulted in a higher MBG (46% vs 32%; $P < .001$), higher proportion of STR ($P < .001$), more resolution of ST-segment elevation ($P < .001$), and fewer pathological Q-waves ($P = .001$). Moreover, these favorable effects on myocardial reperfusion resulted in fewer clinical events at 30 days (decreased rates of mortality [$P = .07$], reinfarction [$P = .11$], and MACE [$P = .12$]).

TABLE 1. THROMBECTOMY DEVICES IN RANDOMIZED TRIALS

Device	Mechanism of Action	Manufacturer
Aspiration Thrombectomy		
Diver C.E.	Rapid-exchange, 6-F-compatible, thrombus-aspirating catheter with central aspiration lumen and soft, flexible, 0.026-inch, nontraumatic tip with multiple holes (one large anterior and three smaller lateral holes) communicating with the central lumen; 30-mL Luer-lock syringe connected to proximal hub of central lumen for thrombus aspiration	Medtronic, Inc.
Export	6-F catheter with an oblique tip and a 0.041-inch aspiration lumen with a 0.068-inch crossing profile; aspiration is provided by hand with a lockable 20-mL syringe, which allows a suction rate of 1 mL/s	Medtronic, Inc.
Pronto	Dual-lumen monorail design with 6-F-compatible catheter; the smaller lumen accommodates a 0.014-inch guidewire, and the larger extraction lumen allows thrombus removal, which is aspirated with a 30-mL locking-vacuum syringe; the catheter has a round distal tip designed to maximize thrombus aspiration and protect the vessel wall while advancing and during aspiration	Vascular Solutions, Inc.
Rescue ^a	4.5-F catheter advanced over a guidewire through a 7-F guiding catheter; the proximal end of the catheter has an extension tube connected to a vacuum pump (0.8 bar) with a collection bottle; continuous suction is applied while the catheter is advanced and pulled back through the thrombus	Boston Scientific Corporation
TVAC ^b	Single-lumen, rapid-exchange aspiration shaft compatible with a 7-F guiding catheter and has a dedicated vacuum pump; the catheter has a beak-shaped distal tip and a shaft with spring support	Nipro
Mechanical Thrombectomy		
AngioJet	Rheolytic thrombectomy system comprising a drive unit console, disposable pump set, and 4-F catheter; high-velocity saline jets contained within the distal catheter tip, creating a strong negative pressure (Bernoulli effect) that entrains the thrombus to the catheter inflow windows where it is captured, fragmented, and evacuated through the outflow lumen	Medrad Interventional
X-Sizer ^a	Two-lumen, over-the-wire system with a helical shape cutter at its distal tip; the cutter rotates at 2,100 rpm driven by a hand-held battery motor unit; one catheter lumen is connected to a 250-mL vacuum bottle, and aspirated debris is collected in an in-line filter	Covidien
^a This product is not currently available for sale.		
^b This product is available for sale outside of the United States.		

Another interesting observation was that although thrombus was initially visible in only 50% of patients undergoing TA, the rate of retrieval of histopathologically confirmed atherothrombotic material was 73%. These findings support the routine use of TA in STEMI patients undergoing PPCI, especially because the benefit of TA was confirmed in all patient groups including those without angiographically visible thrombus. More importantly, this trial showed a significant mortality reduction with TA at 1 year.²⁷

After TAPAS

A number of clinical studies after TAPAS have provided further confirmatory evidence of the protective effects of manual thrombectomy and have reported improvements in myocardial reperfusion markers.¹⁷⁻¹⁹ Of these, the EXPIRA (Thrombectomy With Export Catheter in Infarct-Related Artery During Primary Percutaneous Coronary Intervention) trial was unique in that it was the first trial to evaluate the effects of thrombectomy on microvascular obstruction (MVO) and IS using cardiac magnetic resonance imaging.¹⁸ In this trial, patients with STEMI were ran-

domly allocated to PPCI with (n = 88) or without (n = 87) TA. The authors demonstrated that manual thrombectomy significantly improved MBG and STR and reduced MVO and final IS. Moreover, TA was associated with reduced cardiac mortality and MACE at 2-year follow-up.²⁸

In summary, the majority of the clinical trials investigating manual thrombectomy are consistent and positive. Certainly, the safety and simplicity of this technique contributed substantially to the observed benefits, as shown by complication rates and symptom-to-balloon times. Ultimately, the TAPAS data provided crucial and solid evidence in favor of routine use of manual aspiration thrombectomy and brought this technique into the mainstream as an adjunct to PPCI for STEMI.

MECHANICAL THROMBECTOMY

The first trials investigating mechanical thrombectomy devices in patients with STEMI were promising. These trials showed that this technique could be successfully applied in the setting of PPCI with favorable effects on myocardial reperfusion.²⁰⁻²³ However, results from a subsequent larger

TABLE 2. RANDOMIZED CLINICAL TRIALS INVESTIGATING THROMBECTOMY IN STEMI^a

Study	Study Acronym	Year	n =	Device	Primary Endpoint and Outcome	Clinical Endpoint and Outcome
Aspiration Thrombectomy						
Dudek et al ⁵	–	2004	72	Rescue	(-) TIMI 3, cTFC, tMPG, (↑) STR	NA
Burzotta et al ⁶	REMEDIA	2005	99	Diver C.E.	(↑) MBG $\geq$ 2, STR	(-) 30-day MACE
De Luca et al ⁷	–	2006	76	Diver C.E.	(↑) MBG 3, STR	(-) 6-month MACE
Silva-Orrego et al ⁸	DEAR-MI	2006	148	Pronto	(↑) MBG 3, STR	(-) in-hospital MACE
Kaltoft et al ⁹	–	2006	215	Rescue	(-) Myocardial salvage	(-) 30-day MACE
Andersen et al ¹⁰	–	2007	122	Rescue	(-) Left ventricular function	NA
Dudek et al ¹¹	PIHRATE	2007	196	Diver CE	(-) STR	(-) 6-month mortality
Chao et al ¹²	–	2008	74	Export	(↑) Post-TIMI flow, MBG	NA
Ikari et al ¹³	VAMPIRE	2008	355	TVAC	(↑, trend) SR/NR (TIMI < 3)	(↑) 8-month MACE ($P < .05$)
Chevalier et al ¹⁴	EXPORT	2008	249	Export	(↑) MBG 3, STR	(-) 30-day MACCE
Svilaas et al ¹⁵	TAPAS	2008	1071	Export	(↑) MBG 0/1	(↑) 1-year mortality ($P = .04$), (↑) 1-year cardiac death ($P = .02$)
Lipiecki et al ¹⁶	–	2009	44	Export	(-) IS	NA
Liistro et al ¹⁷	–	2009	111	Export	(↑) STR	(-) 6-month MACE
Sardella et al ¹⁸	EXPIRA	2009	175	Export	(↑) MBG $\geq$ 2, STR	(↑) 2-year cardiac death ($P = .0001$), (↑) 2-year MACE ($P = .04$)
Ciszewski et al ¹⁹	–	2011	137	Rescue/ Diver C.E.	(↑) Myocardial salvage	(-) In-hospital mortality
Mechanical Thrombectomy						
Beran et al ²⁰	–	2002	46	X-Sizer	(↑) STR	(-) 30-day MACE
Napodano et al ²¹	–	2003	92	X-Sizer	(↑) MBG 3	(-) 30-day MACE
Antoniucci et al ²²	–	2004	100	AngioJet	(↑) STR	(-) 30-day MACE
Lefevre et al ²³	X-AMINE ST	2005	201	X-Sizer	(↑) STR	(-) 6-month mortality, (-) 6-month MACCE
Ali et al ²⁴	AIMI	2006	480	AngioJet	(↓) IS	(↓) 30-day MACE ($P = .01$)
Migliorini et al ²⁵	JETSTENT	2010	501	AngioJet	(↑) STR, (-) IS	(↑) 1-year MACE ($P = .04$)

^a– indicates that an acronym is not available; (↑), improved endpoint; (-), neutral effect on endpoint; (↓), worsened endpoint. Abbreviations: AIMI, AngioJet Rheolytic Thrombectomy in Patients Undergoing Primary Angioplasty for Acute Myocardial Infarction; cTFC, corrected TIMI frame count; DEAR-MI, Dethrombosis to Enhance Acute Reperfusion in Myocardial Infarction; EXPIRA, Thrombectomy With Export Catheter in Infarct-Related Artery During Primary Percutaneous Coronary Intervention; EXPORT, Prospective, Multicentre, Randomized Study of the Export Aspiration Catheter; IS, infarct size; JETSTENT, Comparison of AngioJet Rheolytic Thrombectomy Before Direct Infarct Artery Stenting With Direct Stenting Alone in Patients With Acute Myocardial Infarction; MACCE, major adverse cardiac and cerebral events; NA, not available; NR, no-reflow; PIHRATE, Polish-Italian-Hungarian Randomized Thrombectomy Trial; REMEDIA, Randomized Evaluation of the Effect of Mechanical Reduction of Distal Embolization by Thrombus Aspiration in Primary and Rescue Angioplasty; SR, slow-reflow; STR, ST-segment resolution; TAPAS, Thrombus Aspiration During Percutaneous Coronary Intervention in Acute Myocardial Infarction Study; TIMI, thrombolysis in myocardial infarction flow grade; tMPG, TIMI myocardial perfusion grade; VAMPIRE, Vacuum Aspiration Thrombus Removal; X-AMINE ST, X X-sizer in AMI for Negligible Embolization and Optimal ST Resolution.

trial investigating mechanical thrombectomy in the setting of PPCI were not so encouraging.²⁴ The effects of rheolytic thrombectomy (RT) with the AngioJet (Medrad Interventional, Indianola, PA) were investigated in 480 patients (RT with PCI, $n = 240$; PCI alone, $n = 240$). The investigators failed to demonstrate any advantage of RT in terms of postprocedural thrombolysis in myocardial infarction (TIMI) 3 flow, blush scores, or STR.

Moreover, final IS as measured by myocardial nuclear scanning and the 30-day MACE rate were actually higher in the RT group. The reasons for the negative results are unclear but could be related to a number of factors, such as longer procedure times in the RT group, higher frequency of baseline TIMI 3 flow in the control group, and a low frequency of angiographically visible thrombus in studied patients, suggesting a role for RT in patients with high thrombus load.

Subsequently, interesting observations were made in the recent JETSTENT (Comparison of AngioJet Rheolytic Thrombectomy Before Direct Infarct Artery Stenting With Direct Stenting Alone in Patients With Acute Myocardial Infarction) trial.²⁵ In this multicenter trial, 501 STEMI patients with large angiographic thrombus burden (grade 3–5) in large vessels (≥ 2.5 mm) were randomly allocated to RT before direct IRA stenting or to direct stenting alone. Although STR occurred more frequently in the RT group, no differences were revealed in TIMI flow grade 3, corrected TIMI frame count, TIMI grade 3 blush, and IS as assessed by nuclear scanning between treatment arms.

Interestingly, despite failure to improve the majority of the surrogate markers of myocardial reperfusion, RT resulted in reduced 6-month MACE rates and improved 1-year event-free survival rates. In this regard, appropriate technique during RT (eg, catheter activation proximal to thrombus, second or third pass with catheter in case of evidence of residual thrombus, or TIMI flow grade < 2) may have contributed to the positive effects on clinical outcomes. However, the authors were unable to detect differences in myocardial reperfusion, even though the trial was designed for this purpose. Moreover, the trial had limited power to investigate clinical outcomes. Accordingly, such observations should be regarded with caution.

Overall, clinical trials investigating mechanical thrombectomy in the setting of PPCI have not been overwhelmingly positive. Although the exact reasons for the discrepant findings are not clear, several factors may be expected to play a role. Because most of these devices are relatively bulky, it is plausible that introduction can paradoxically predispose to distal embolization. However, this remains to be determined. Second, the trials investigating mechanical thrombectomy have reported longer procedure times in the

thrombectomy groups compared to the control groups. This might have hampered the benefit of thrombus removal in these patients.

For a current listing of the available mechanical thrombectomy/thrombolysis devices, please see Table 4.

AGGREGATE DATA

The majority of the randomized trials investigating manual and mechanical thrombectomy have been small-to-moderate sized with short follow-up times. Accordingly, these trials were only powered to study the surrogate markers of reperfusion, not hard clinical endpoints. In this light, several meta-analyses have been performed to further evaluate the role of thrombectomy as adjunctive therapy in the setting of PPCI for STEMI.

Simple manual thrombectomy has emerged as the only technique with clinical benefits in the setting of STEMI, as shown in several meta-analyses,^{29–31} whereas mechanical thrombectomy was found to be harmful.²⁹ In the ATTEMPT (Long-Term Clinical Efficacy of Thrombectomy Devices in Acute ST-Elevation Myocardial Infarction) meta-analysis, patient-level data were pooled, including 2,686 patients from 11 trials.³¹ At a median of 1-year follow-up, all-cause mortality, death and myocardial infarction, and MACE were significantly reduced with thrombectomy.

As expected from results of individual trials, the survival benefit observed in this meta-analysis was confined to patients who were treated with manual thrombectomy, which emphasizes the importance of using simple rather than more complex devices for thrombus removal. Interestingly, there was no differential effect of thrombectomy in subgroups according to diabetic status, ischemic time, IRA, or presenting TIMI flow. However, the investigators failed to obtain data from six eligible trials comprising approximately 1,000 patients, which may have biased their results.³¹

Subsequently, updated meta-analyses have been performed that incorporate more trials and use Bayesian statistics.^{32,33} Mongeon et al included 21 trials totaling 4,299 patients and showed that thrombectomy (both manual and mechanical) was able to improve surrogate markers of reperfusion but not reinfarction, 30-day mortality, or stroke.³³ The results were similar in the analysis of manual thrombectomy devices; however, no separate results of mechanical thrombectomy devices were reported.

Likewise, another recent meta-analysis comprising 3,904 patients was unable to detect a difference in 30-day mortality in the overall analysis.³² However, there seemed to be a trend toward a survival benefit with the use of manual aspiration thrombectomy (odds ratio, 0.57; $P = .05$), whereas mechanical devices demonstrated a trend toward increased mortality rates (odds ratio, 2.07; $P = .07$).³²

TABLE 3. CURRENTLY AVAILABLE THROMBUS ASPIRATION DEVICES

Company Name	Product Name	Type	Maximum Tip Diameter (mm)	Minimum Guide Catheter Size (F)	Catheter Length (cm)	Side Hole Segment Length (cm)
Atrium Medical Corporation	Xpress-Way RX	Extraction catheter	1.35, 1.52	6, 7	140	N/A
Control Medical Technology	Aspire Aspirator	Handheld aspirator	N/A	N/A	N/A	N/A
Medrad Interventional	Fetch2 Aspiration Catheter	Variable-pitch coiled proximal shaft, hydrophilic coated, convex tip	1.4	6	135	N/A
Medtronic, Inc.	Export Catheter	Guide catheter braid technology	1.73, 1.98	6, 7	145	N/A
	Export XT Catheter	Full-wall variable hub to tip braiding; hydrophilic coating; short, soft tip	1.73	6	140	
	Export AP Catheter					
		Diver C.E. Aspiration Catheter	Low-profile, rapid-exchange, hydrophilic coating with and without side holes	1.58		145
Merit Medical Systems, Inc.	ASAP Aspiration Catheter	Dual-lumen rapid-exchange catheter	N/A	6	140	N/A
Spectranetics Corporation	QuickCat Extraction Catheter	Indicated for removal of fresh, soft emboli and thrombi from vessels in the arterial system.	1.4	6	145	N/A
Vascular Solutions, Inc.	Pronto V3 Extraction Catheter	Arterial embolectomy; full-length embedded longitudinal wire; hydrophilic coating; patented Silva tip; full-length wire braiding; maximized extraction lumen and force	1.65	6	140	N/A
	Pronto V4 Extraction Catheter		1.65–2.2	6 (> 0.066), 7, 8	138	
	Pronto LP Extraction Catheter	Low-profile arterial embolectomy; hydrophilic coating; patented Silva tip; full-length wire braiding; delivery stylet	1.34	6	140	
	Pronto .035 Extraction Catheter	Large-vessel thrombus aspiration catheter; full-length braiding; patented Silva tip	3.25	10 (sheath)	115	
	Pronto-Short Extraction Catheter	AVG/fistula/arterial embolectomy; patented Silva tip	1.98	6 (sheath)	40	
Abbreviations: AVG, arteriovenous graft.						

CURRENT GUIDELINES

To date, the TAPAS trial represents the largest body of evidence demonstrating the benefits and utility of TA for patients with STEMI irrespective of clinical and angiographic characteristics at baseline.¹⁵ Together with several aforementioned meta-analyses, the study provided the necessary evidence for endorsement of this technique as a class IIa recommendation with level of evidence B in the American College of Cardiology/American Heart Association guidelines³⁴ and with level of evidence A in the European Society of Cardiology guidelines.³⁵

UNRESOLVED QUESTIONS AND FUTURE TRIALS

At present, there is insufficient information to judge how and to what extent several factors, including types of devices and pharmacological therapies (eg, glycoprotein IIb/IIIa inhibitors), influence thrombectomy efficacy. Also, the role of invasive imaging during PPCI to provide reli-

able predictors of effective thrombectomy is unclear. Accordingly, there remain unresolved issues in the setting of STEMI PCI.

Manual Versus Mechanical Thrombectomy

Although benefits of manual thrombectomy on surrogate markers of reperfusion and late clinical outcomes were observed, manual aspiration devices are limited in their ability to remove large thrombus load. As a consequence, this feature can potentially result in incomplete thrombus removal and distal embolization. In this regard, mechanical devices are probably more effective in extracting large thrombi. Nevertheless, they tend to be bulkier and more complex to operate.

Whether the use of mechanical devices is preferred over manual devices in patients with large thrombus load remains elusive. Also, although intuitive, the use of embolic protection devices could play a role in limiting distal embolization

TABLE 4. CURRENTLY AVAILABLE MECHANICAL THROMBECTOMY/THROMBOLYSIS DEVICES

Company Name	Product Name	Sheath Size (F)	Guidewire (inch)	Working Length (cm)	Mode of Operation	US FDA Indicated Use
Ekos Corporation	EkoSonic SV Endovascular System	3	0.014	150	USAT simultaneously delivers ultrasound and thrombolytics to target clot; high-frequency, low-power ultrasonic energy loosens and thins the clot's fibrin structure, allowing thrombolytic agents to access more receptor sites; at the same time, ultrasonic pressure forces the drug deep into the clot and keeps it there so it does not escape downstream	Intended for the controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature; regional infusion of contrast materials into selected vessels in the neurovasculature; to deliver physician-specified fluids to the coronary vasculature
Medrad Interventional	AngioJet XMI OTW	4	0.014	135	High-velocity water jets enclosed in catheter utilize Bernoulli principle for capture, microfragmentation, and removal	Removing thrombus in the treatment of patients with symptomatic coronary artery or saphenous vein graft lesions in vessels ≥ 2 mm in diameter before balloon angioplasty or stent placement
	AngioJet Spiroflex Rapid Exchange					
	AngioJet SpiroflexVG Rapid Exchange	5				Removing thrombus in the treatment of patients with symptomatic coronary artery or saphenous vein graft lesions in vessels ≥ 3 mm in diameter before balloon angioplasty or stent placement
Abbreviations: OTW, over the wire; USAT, ultrasound-accelerated thrombolysis.						

in patients with large thrombus load. However, the combined experience from randomized trials suggests that the use of antiembolic devices does not decrease mortality or other clinical outcomes during STEMI PCI.²⁹ Technical difficulties with most of these devices and anatomical features may limit their use; these devices are inherently bulky, and their mere passage through the highly thrombotic lesions can cause embolization. Therefore, these drawbacks will inhibit their use unless clear clinical benefit is shown.

Subgroups

The patients who are most likely to benefit from an intervention administered as an adjunct to myocardial reperfusion are high-risk patients who present with complete occlusion of the proximal left anterior descending artery, in whom, the area at risk is substantial. In comparison, low-risk patients who present with incomplete occlusion in a relatively small coronary artery might not accrue any benefit from adjunctive therapy. However, this suggestion is not supported by observations from the TAPAS trial, in which the beneficial effects of manual aspiration thrombectomy were not greater in patients who presented with non-right coronary artery infarcts, proximal lesions, or TIMI flow 0 or 1.¹⁵ Interestingly, in the ATTEMPT meta-analysis, the benefit of thrombectomy was more evident in patients receiving glycoprotein IIb/IIIa inhibitors,³¹ suggesting a synergistic effect of platelet inhibition and thrombectomy. However, this finding must be confirmed in a randomized fashion. Currently, it is unknown which subgroups benefit most from thrombectomy.

Role of Invasive Imaging During PPCI

By characterizing coronary plaque and revealing true intraluminal atherothrombotic burden, invasive imaging techniques, such as intravascular ultrasound (IVUS) and near-infrared spectroscopy could potentially play an important role in risk stratification in the catheterization lab. The relation between lesion morphology and distal embolization was investigated by Fukuda et al in 140 consecutive AMI patients, in which preprocedural evidence of an intracoronary mobile mass at IVUS was shown to be a strong predictor of subsequent angiographically evident distal embolization.³⁶

Tanaka et al demonstrated that a lipid pool-like image at IVUS and lesion elastic membrane cross-sectional area were independent predictive factors of no-reflow after reperfusion for AMI.³⁷ Also, the use of near-infrared spectroscopy to determine the lipid content of the culprit lesion may help to identify plaques with an increased risk of embolization after stenting.³⁸ Such novel developments and improvements in intracoronary tissue/plaque characterization may

play a crucial role in the future in identifying cases at high risk of no-reflow after stenting and therefore, help device strategies to prevent this phenomenon.

Future Trials

Clinical trials in which the effect of thrombectomy in PCI for STEMI is currently being investigated are ongoing and hopefully will provide answers for the unresolved questions in this setting. The SMART-PCI (Comparison of Manual Aspiration With Rheolytic Thrombectomy in Patients Undergoing Primary PCI) trial will provide important data regarding the role of mechanical versus manual devices in the setting of STEMI PCI.³⁹ Furthermore, whether the routine use of manual aspiration thrombectomy with the Export catheter can improve clinical outcomes in this group of patients is currently being investigated in the TOTAL (A Trial of Routine Aspiration Thrombectomy With PCI Versus PCI Alone in Patients With STEMI Undergoing Primary PCI) trial, with an estimated enrollment of 4,000 patients, allowing verification of the TAPAS results.⁴⁰

On the other hand, the INFUSE-AMI (A 2x2 Factorial, Randomized, Multicenter, Single-Blind Evaluation of Intracoronary Abciximab Infusion and Aspiration Thrombectomy in Patients Undergoing Percutaneous Coronary Intervention for Anterior ST-Segment Elevation Myocardial Infarction) trial will provide answers on the potential synergistic effect of platelet inhibition and thrombectomy.⁴¹ In this trial, 452 patients with anterior STEMI and presenting TIMI flow 0 to 2 treated with bivalirudin as a foundation anticoagulant will be enrolled in a 2 X 2 factorial, randomized, multicenter fashion. Important data will be provided regarding the efficacy of intracoronary infusion of an abciximab bolus before stent implantation compared to no infusion, with or without TA, on magnetic resonance imaging-derived MVO at 5 days and IS at 30 days. Ultimately, the clinical utility and impact of thrombectomy on clinical outcomes will be determined, at least in part, by these elegant randomized trials.

CONCLUSION

Thrombectomy represents an effective strategy to further enhance the benefit of myocardial reperfusion in patients with STEMI, improving the efficacy of PPCI. However, there appears to be a differing impact on hard clinical endpoints, with improvement seen with manual aspiration thrombectomy and worsening outcomes with mechanical devices. Further clinical evaluation is required to clarify the unresolved issues in this setting and to determine whether thrombectomy as a myocardial adjunct can improve hard clinical outcomes consistently, possibly upgrading the modality to the standard of care. To this end, adequately powered, large, multicenter studies are needed. ■

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