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EDITORIAL

Manual aspiration thrombectomy in acute ST elevation myocardial infarction: New gold standard?

Brent Rochon, Youssef Chami, Rajesh Sachdeva, Joe K Bissett, Nick Willis, Barry F Uretsky

Brent Rochon, Youssef Chami, Rajesh Sachdeva, Joe K Bissett, Nick Willis, Barry F Uretsky, Department of Medicine, Central Arkansas Veterans Health System, University of Arkansas for Medical Sciences, Little Rock, AR 72205, United States

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Correspondence to: Barry F Uretsky, MD, Department of Medicine, Central Arkansas Veterans Health System, University of Arkansas for Medical Sciences, 4300 West Seventh Street, Little Rock, AR 72205, United States. buretsky@gmail.com
Telephone: +1-501-2575795 Fax: +1-501-2575796
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Abstract

Percutaneous coronary intervention (PCI) is the preferred method to treat ST segment myocardial infarction (STEMI). The use of thrombus aspiration (TA) may be particularly helpful as part of the PCI process, insofar as the presence of thrombus is essentially a universal component of the STEMI process. This article reviews evidence favoring the routine use of TA, and the limitations of these data. Based on current evidence, we consider TA to be an important maneuver during STEMI PCI, even in the absence of visible angiographic thrombus, and recommend it whenever the presence of thrombus is likely.

Key words: Aspiration thrombectomy; Myocardial infarction; Guidelines; Thrombus

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THROMBUS IN ACUTE MYOCARDIAL INFARCTION

A major component of the acute coronary syndrome, and especially ST segment myocardial infarction (STEMI), is thrombus. In treating STEMI with percutaneous coronary intervention (PCI), preventing distal embolization may be important in improving clinical outcomes by preventing "clogging" of the microvasculature and subsequent worsening of myonecrosis[1]. Previous studies have utilized devices to prevent distal embolization, including distal embolic protection devices and mechanical aspiration devices. Neither category of devices has demonstrated clinical efficacy[2,3]. This presentation reviews currently available data, utilizing full-length refereed publications, particularly randomized studies, (excluding abstracts and conference presentations) on manual aspiration thrombectomy, and addresses whether evidence is strong enough to recommend its use in all STEMI cases, even those without angiographically visible thrombus (Figure 1).

THE TAPAS STUDY: THE STRONGEST EVIDENCE IN FAVOR OF ROUTINE USE FOR MANUAL ASPIRATION THROMBECTOMY

The Thrombus Aspiration during Percutaneous Coronary

Table 1 One-year clinical outcomes in selected randomized ST segment myocardial infarction trials from 2000 to 2010

Study	Yr	Intervention	Control	*n*	All-cause death (%)		Cardiac mortality (%)		MI (%)	
					C	S	C	S	C	S
NORDISTEMI[16]	2010	All PCI	Selective	276	3.0	2.2	NA	NA	9.0	3.0
HORIZONS AMI[17]	2009	Bivalurudin	Hep/Gp	3602	4.8	3.5	3.8	2.1	NA	NA
TAPAS[5]	2008	TA + PCI	PCI/no TA	1071	7.6	4.7	6.7	3.6	4.3	2.2
DANAMI-2[18]	2008	PCI	Lytic	1424	1.3	1.4	NA	NA	0.9	1.3
Transfer with Tirofiban for PCI Thrombolysis with STEMI[19]	2007	Transfer/PCI	Lytic	401	NA	NA	12.5	7.0	7.5	3.5
SESAMI[20]	2007	DES	BMS	320	4.3	1.8	NA	NA	1.8	1.8
TYPHOON[21]	2006	DES	BMS	712	2.2	2.3	1.4	2.0	1.4	1.1
PASSION[22]	2006	DES	BMS	619	NA	NA	6.5	4.5	1.9	1.6
ADMIRAL[23]	2004	Abciximab + PCI	PCI	400	12.5	6.0	10.5	5.0	6.0	1.0
STENTIM-2[24]	2000	BMS	BA	211	1.9	3.0	NA	NA	5.5	4.0

BA: Balloon angioplasty; BMS: Bare metal stent; C: Control group; DES: Drug-eluting stent; Gp: Glycoprotein Ⅱb/Ⅲa inhibitors; Hep: Heparin; MI: Myocardial infarction; NA: Not applicable; S: Study (intervention) group; TA: Thrombus aspiration; PCI: Percutaneous coronary intervention.

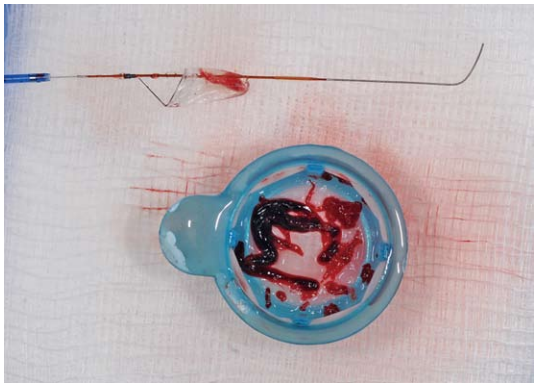

Figure 1 Findings from the use of both a distal embolic protection device and manual aspiration thrombectomy in a patient with ST segment myocardial infarction secondary to saphenous vein graft occlusion with visible angiographic thrombi. Please note the huge amount of thrombus removed and the relatively small amount of debris found in the filter.

Intervention in Acute Myocardial Infarction (TAPAS) Study randomized 1071 STEMI patients to manual aspiration thrombectomy (n = 535) prior to stenting using the Export device (Medtronic, Santa Rosa, CA, USA) or to PCI, usually with stenting, but without thrombus aspiration (TA) (n = 536). The primary endpoint was the myocardial blush grade (MBG) after intervention. Secondary endpoints included the degree of ST-segment elevation resolution, degree of persistent ST-segment elevation after PCI, and presence of pathological Q waves. Patients treated with TA showed a higher MBG ($P < 0.001$), less persistent ST segment elevation ($P < 0.001$), more resolution of the ST segment elevation ($P < 0.001$), and fewer pathological Q waves ($P = 0.001$). Patients with all of these characteristics of improved perfusion after thrombus aspiration showed a trend toward decreased death rates at 30 d ($P = 0.07$), decreased reinfarction ($P = 0.11$), and decreased combined major adverse cardiac events (MACE) ($P = 0.12$). The TAPAS results suggested that TA decreased microvascular obstruction and increased myocardial reperfusion[4]. At 1-year follow-up, there was a decrease in clinical events in the TA group *vs* the non-TA group: all-cause mortality (4.7% *vs* 7.6%, $P = 0.04$), cardiac death (3.6% *vs* 6.7%, $P = 0.02$), and rates of reinfarction (2.2 *vs* 4.3%, $P = 0.05$)[5]. The investigators did not measure either residual LV function and or infarct size.

One year mortality in both the control and treatment arms of the TAPAS trial is relatively high compared with other contemporary STEMI studies such as HORIZONS-AMI (Table 1). It is uncertain whether the high mortality in the control group may have accounted for the significant difference in clinical outcomes, i.e. a chance occurrence *vs* a true effect of TA.

WHAT OTHER EVIDENCE SUGGESTS A CLINICAL BENEFIT OF TA IN ACUTE MYOCARDIAL INFARCTION?

Several randomized trials have evaluated the use of different aspiration thrombectomy devices in STEMI (Table 2). Primary endpoints were typically related to angiographic and electrocardiographic findings.

The Randomized Evaluation of the effect of MEchanical reduction of Distal embolization by thrombus aspiration In primary and rescue Angioplasty (REMEDIA) trial[6] has shown improvement in the primary endpoints of ST-segment resolution (STR) ⩾ 70% and MBG ⩾ 2 (STR: 44.9% *vs* 36.7%, $P = 0.02$; MBG: 68.0% *vs* 58.0%, $P = 0.034$) using the Diver CE device (Invatec, Brescia, Italy). In a 50-patient myocardial contrast echocardiography substudy, TA reduced microvascular obstruction acutely and demonstrated a trend to a decrease in 6-mo adverse left ventricular remodeling[7].

In a similar study design, De Luca and colleagues[8] have shown, in 76 anterior STEMI patients, STR in 81.6% of TA *vs* 55.3% of non-TA patients ($P = 0.02$), and MBG 3 of 36.8% for TA and 13.1% for non-TA patients ($P = 0.03$).

Kaltoft *et al*[9] have randomized 215 STEMI patients to PCI with or without TA using a 4.5 Fr Rescue extraction catheter (Boston Scientific/Scimed, Maple Grove, MN, USA). This study did not show improvement in the primary endpoint of scintigraphic myocardial salvage at

Table 2 Randomized studies utilizing manual aspiration devices in ST segment myocardial infarction and primary percutaneous coronary intervention[1]

Study	Yr	*n*	Device	Primary endpoint(s)	Outcomes[1]
EXPIRA[14]	2009	175	Export (Medtronic, Minneapolis, MN, USA)	MBG > 2, STR	Improvement
VAMPIRE[11]	2008	355	TVAC (Nipro, Osaka, JP)	SR or NR	Trend to improvement
TAPAS[5]	2008	1071	Export (Medtronic, Minneapolis, MN, USA)	MBG	Improvement
De Luca et *al*[8]	2006	76	Diver CE (Invatec, Brescia, IT)	MBG > 2, STR	Improvement
Kaltoft *et al*[9]	2006	215	Rescue (BSC, Maple Grove, MN, USA)	Myocardial salvage	No improvement
DEAR-MI[10]	2006	148	Pronto (Vascular Solutions, Minneapolis, MN, USA)	STR, MBG 3	Improvement
REMEDIA[6]	2005	99	Diver CE (Invatec, Brescia, IT)	MBG > 2, STR	Improvement

[1]Please see text for study data. MBG: Myocardial blush grade; NR: No reflow; SR: Slow reflow; STR: ST segment resolution.

30 d, based on the difference between myocardium at risk and final infarct size[9]. In fact, the final infarct size was significantly larger in the TA group (15% *vs* 8%, P = 0.004). Although the reason for this latter finding is not certain, the device used in this study was relatively bulky (4.5 Fr), and possibly provoked embolization during its passage.

In the Dethrombosis to Enhance Acute Reperfusion in Myocardial Infarction (DEAR-MI) study, 148 patients with STEMI were randomized to primary PCI without or with TA using the Pronto extraction device (Vascular Solutions, Minneapolis, MN, USA)[10]. There was a significant improvement in the primary endpoints of complete STR (68% *vs* 50%, $P < 0.05$) and MBG 3 (88% *vs* 44%, $P < 0.0001$). In addition, there was improvement in no reflow (3% *vs* 15%, $P < 0.05$), angiographic embolization (5% *vs* 19%, $P < 0.05$%) and peak creatine kinase MB ($P < 0.0001$). This study was not powered to evaluate long-term clinical events[10].

The VAcuuM asPIration thrombus REmoval (VAMPIRE) Trial randomized 355 patients to a single lumen aspiration catheter device (TVAC; Nipro, Osaka, Japan) attached to a motorized vacuum system (n = 180) or conventional PCI without TA (n = 175). The primary endpoint was slow or no-reflow defined as thrombolysis in myocardial infarction (TIMI) flow grade < 3 not attributable to occlusive thrombus, dissection or epicardial spasm. There was a trend to improvement with TA (12.4% *vs* 19.4%, P = 0.07). MBG grade 3 was higher in TA patients (46.0% *vs* 20.5%, $P < 0.001$). Although there was no significant difference in 30-d outcomes, there was a 38% decrease incidence in MACE at 8 mo ($P < 0.05$), with less target lesion revascularization (TLR) ($P < 0.05$) and repeat PCI ($P < 0.05$), but no significant difference in mortality. A subgroup analysis of patients presenting < 6 h from symptom onset showed the most benefit with TA. These patients showed a decrease incidence in no reflow (P = 0.01), improved MBG (P = 0.04), improved TIMI flow (P = 0.01), decreased TLR (P = 0.03), and decreased MACE (P = 0.04)[11].

The age of the aspirated thrombus in STEMI and its relationship to outcome was analyzed in 1315 consecutive patients[12]. Fresh thrombus (< 24 h) was characterized mostly by erythrocytes, granulocytes, platelets, and fibrin. Older thrombus was defined as showing necrotic areas from red and white blood cells, as well as smooth muscle growth potentially with neovascularization and connective tissue deposition. No material was aspirated in 326 patients (24.7%). Fresh thrombus was found in 552 patients (42.0%), whereas older thrombus was found in 372 patients (28.2%). Patients with older thrombus had significantly higher risk of all-cause mortality at 4 years (16.0% *vs* 7.4%; hazard ratio 1.82, 95% CI: 1.17-2.85, P = 0.008). These data are consistent with STEMI being the culmination of an iterative thrombus-producing event in many patients.

It is well established that timely reperfusion is crucial for restoration of myocardial blood flow during acute infarction to preserve left ventricular (LV) function. In a retrospective cohort (n = 195) with 109 patients receiving TA with stenting and 86 receiving conventional angioplasty without TA, left ventriculography was performed pre- and post-procedure, and patients were followed up for 6 mo to determine the effect of TA on LV remodeling (defined as an increase in LV end-diastolic volume index by > 20%). Adverse LV remodeling was significantly lower at 6 mo follow-up in the group treated with TA (22%) compared with the conventional group (44%, P = 0.01)[13].

In a recent randomized trial of 175 patients with STEMI with PCI, with or without TA, investigators evaluated LV function by contrast-enhanced magnetic resonance imaging (CE-MRI), 3-5 d after PCI and again at 3 mo[14]. The two groups showed no difference in infarct size, end-systolic and diastolic volumes, or ejection fraction 3-5 d after PCI. However, the TA group had significantly greater MBG (P = 0.0001), and ST-segment resolution (P = 0.0001). CE-MRI showed significantly greater microvascular obstruction in the conventional PCI group as compared with the TA group. At 3 mo, the TA group had a significantly smaller infarct size than the conventional PCI group. At 9 mo, the TA group had a lower incidence of cardiac death (0% *vs* 4.6%, P = 0.02)[14].

A Bayesian meta-analysis in STEMI patients randomized to PCI with or without aspiration thrombectomy (both manual and mechanical methods) identified 21 eligible trials with 4299 patients. Adjunctive thrombectomy was shown to improve early markers of reperfusion, but had no effect on reinfarction, 30-d post-MI mortality, or stroke[15]. This study was limited in evaluating manual aspiration because it included mechanical aspiration device

studies, which have not been shown to be effective in individual studies in improving clinical outcomes.

CONCLUSION

In STEMI, primary PCI is the standard of care[1]. It is extremely effective in rapidly recanalizing an occluded vessel. However, it may also provoke distal embolization of soft thrombus that may be removed easily by manual aspiration. Routine TA, even in the absence of a large thrombus burden, has been shown to be a quick and simple method of improving, in an MI cohort, early markers of reperfusion including MBG, TIMI flow, and ST-segment resolution. There may be design and operational issues that favor certain systems over others, but at present, there is a paucity of data to identify the preferred manual aspiration device. TA may also improve TLR, MACE and LV remodeling[3,5]. Routine TA may also have a mortality benefit as shown in the TAPAS study, particularly if employed early[5,12,14]. The American College of Cardiology/American Heart Association guidelines update has recognized these data by making it a Class Ⅱa indication for STEMI[1]. Additional data are required to confirm the salutary effects of routine TA on long-term outcomes of mortality and MACE in order that it be a Class Ⅰ indication, i.e. the standard of care.

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