

## Does manual thrombus aspiration help optimize stent implantation in ST-segment elevation myocardial infarction?

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treated with TA had less prevalence of multivessel disease (39.7% vs 54.7%,  $P = 0.003$ ) and higher prevalence of initial thrombolysis in myocardial infarction flow  $< 3$  ( $P < 0.001$ ) than NTA group. There was a higher rate of direct stenting (58.7% vs 45.5%,  $P = 0.009$ ), with shorter ( $24.1 \pm 11.8$  mm vs  $26.9 \pm 15.7$  mm,  $P = 0.038$ ) and larger stents ( $3.17 \pm 0.43$  mm vs  $2.93 \pm 0.44$  mm,  $P < 0.001$ ) in the TA group as compared to NTA group. The number of implanted stents ( $1.3 \pm 0.67$  vs  $1.5 \pm 0.84$ ,  $P = 0.009$ ) was also lower in TA group.

**CONCLUSION:** In an "all-comers" STEMI population, the use of TA resulted in more efficient procedure leading to the implantation of less number of stents per lesion of shorter lengths and larger sizes.

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**Key words:** ST-segment elevation myocardial infarction; Primary percutaneous coronary intervention; Manual thrombus aspiration; Stent; Thrombolysis in myocardial infarction flow

### Abstract

**AIM:** To evaluate the impact of thrombus aspiration (TA) on procedural outcomes in a real-world ST-segment elevation myocardial infarction (STEMI) registry.

**METHODS:** From May 2006 to August 2008, 542 consecutive STEMI patients referred for primary or rescue percutaneous coronary intervention were enrolled and the angiographic results and stent implantation characteristics were compared according to the performance of manual TA.

**RESULTS:** A total of 456 patients were analyzable and categorized in TA group (156 patients; 34.2%) and non-TA (NTA) group (300 patients; 65.8%). Patients

**Core tip:** Thrombus embolization is highly detected in ST-segment elevation myocardial infarction (STEMI) leading to unfavorable clinical outcomes. To prevent thrombus embolization, manual thrombus aspiration (TA) receives a high recommendation during primary percutaneous coronary intervention (PCI) by clinical practice guidelines. However, the TASTE trial, recently published, showing no impact of manual TA on short-term mortality, has reopened the debate about the role of this technique in STEMI. This study is one the first showing that manual TA optimizes stent implantation during primary PCI resulted in more efficient procedures, leading to the implantation of fewer, shorter and larger stents.

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## INTRODUCTION

ST-segment elevation myocardial infarction (STEMI) occurs as a result of atherosclerotic plaque rupture or erosion and platelet and coagulation activation leading to thrombus formation and complete coronary occlusion<sup>[1]</sup>. Primary percutaneous coronary intervention (PCI) with stent implantation is the preferred method to restore epicardial flow in STEMI<sup>[2,3]</sup>. Several thrombectomy devices have been developed with the aim to avoid any suboptimal myocardial reperfusion related to thrombus embolization, which might lead to unfavorable clinical outcome<sup>[4]</sup>.

The randomized clinical trial (RCT) TAPAS, in particular, showed that manual thrombus aspiration (TA) improved myocardial reperfusion and reduced mortality in STEMI patients at 1-year follow-up<sup>[5,6]</sup>. These results, confirmed by other studies<sup>[7-10]</sup>, including a meta-analysis<sup>[11]</sup> of 11321 patients from 20 RCT showing lower rates of late mortality, reinfarction and stent thrombosis in patients underwent manual TA compared with conventional primary PCI, led to a recommendation class IIa for manual TA in patients undergoing primary PCI for STEMI<sup>[12]</sup>. Nevertheless, the use of the thrombectomy devices is still controversial and not routine in STEMI patients, especially because some studies have shown no impact on clinical outcome<sup>[13-20]</sup>, such as the TASTE trial<sup>[21]</sup>. This RCT, recently published, did not show any impact of manual TA on mortality or any of several other clinical outcomes at 30 d. Furthermore, the potential effect of TA on optimization of stent implantation has not been elucidated yet.

Therefore, we sought to investigate the factors which can lead to the use of the manual TA in STEMI and its impact on acute angiographic success and stent implantation characteristics in a real-world STEMI population.

## MATERIALS AND METHODS

### Study population

Between May 2006 and August 2008, all consecutive patients with STEMI referred to our hospital for primary or rescue PCI were enrolled. There were no exclusion criteria. Clinical and angiographic characteristics of all patients were prospectively collected. All patients signed a written informed consent prior to PCI procedure and agreed to be clinically followed. At the time of the study an IRB approval was not formally necessary for observational registries that use a CE-mark approved device.

### Procedure

Patients treated with primary PCI were pretreated with aspirin (300 mg), clopidogrel loading dose (300 mg) and unfractionated heparin adjusted to weight. The use of glycoprotein (GP) IIb/IIIa inhibitors was left at the discretion of the operators in case of significant thrombus, slow or non-reflow of thrombotic complications. PCI was performed according to conventional clinical practice. Manual TA; using the 6-French Pronto V3<sup>®</sup> aspiration catheter (Vascular Solutions Inc, Minneapolis, MN) and the 6-French Export<sup>®</sup> aspiration catheter (Medtronic, Minneapolis, MN), was performed according to the operator's choice; and patients were thereafter classified in TA group and non-thrombus aspiration (NTA) group.

Manual TA technique was performed as follows. The aspiration was started 2-cm before the culprit lesion and the aspiration catheter was advanced very slowly, crossing the lesion with continuous aspiration. The catheter was removed under aspiration even into the guiding catheter, with generous backflow after retrieving the thrombectomy device. At least two or three passages were performed. Manual TA was especially considered, in case of high thrombus burden and initial slow thrombolysis in myocardial infarction (TIMI) flow.

### Definitions and end-points

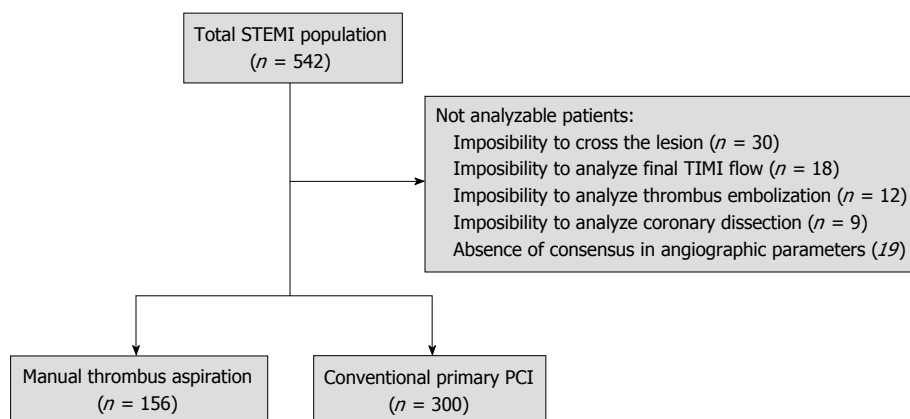
Time to treatment was defined as time from symptom onset to initial intracoronary therapy by TA or balloon inflation of the infarct-related coronary artery<sup>[22]</sup>.

TIMI flow grade was evaluated pre guide-wire and post-PCI<sup>[6]</sup>.

No-reflow was defined as a TIMI flow grade < 2 in absence of coronary dissection, coronary hematoma, occlusive coronary thrombosis or epicardial spasm<sup>[10]</sup>. Thrombus embolization was defined as circumscribed filling defects and/or abrupt cut off of a vessel distal to the target lesion or in other coronary vessel on the angiogram after PCI<sup>[23]</sup>. Coronary dissection was defined by the presence of a curvilinear filling defect parallel to the vessel lumen, contrast medium outside of the vessel lumen persisting after passage of contrast medium, or a spiral-shaped filling defect partially or totally obstructing the coronary artery lumen<sup>[24]</sup>.

ST was defined and categorized, according to Academic Research Consortium<sup>[25]</sup>. Angiographic success was defined as final TIMI flow equals 3 plus absence of any angiographic complication.

The angiographic assessment was performed by consensus of two independent experienced interventional cardiologists. The primary end-point of this study was the rate of angiographic success, as above defined. Secondary end-points included technical and clinical issues related to the procedure as the number of implanted stents, the rates of direct stenting and post-dilatation, the maximal diameter of the implanted stents, the total stented length segment, the final TIMI flow and the resolution of the ST-segment elevation after primary PCI.



**Figure 1 Study flowchart.** STEMI: ST-segment elevation myocardial infarction; PCI: Percutaneous coronary intervention; TIMI: Thrombolysis in myocardial infarction.

### Clinical follow-up

A clinical follow-up up to 3 years was performed by a clinical visit or telephone interview. Clinical outcomes were evaluated by measuring the rate of the major adverse cardiac events (MACE) defined as the combination of cardiac death, myocardial infarction (MI) and need for cardiac artery by-pass grafting (CABG) and its individual components, as well as the rate of all-cause death, and the need for target vessel and non-target vessel PCI revascularization. MI was defined according to the World Health Organization extended definition<sup>[20]</sup>.

### Statistical analysis

Continuous variables were explored for normal distribution with the Kolmogorov-Smirnov test. Normally distributed variables were expressed as mean (1 standard deviation) and non-normally distributed variables were expressed as median (inter-quartile range) and were compared using *t*-student or with Mann-Whitney tests as appropriate. Categorical variables were expressed as count (percentage) and were compared using the  $\chi^2$  test.

In order to exclude confounding factors in primary end-point (angiographic success), multivariable logistic regression models were fitted to assess independent predictors. The following variables were tested for the predictors of the primary end-point: manual TA, age, gender, smoking history, prior MI, primary PCI, Killip class > I, initial TIMI flow = 0, use of GP II b/IIIa inhibitors and the use of drug-eluting stents (DES). The result was reported as HR together with the 95%CI.

All *P* values were 2-tailed, with statistical significance set at a level of < 0.05. Statistical analyses were performed using SPSS Statistics 20.0 (SPSS Inc., Chicago, IL, United States).

## RESULTS

### Baseline clinical and angiographic features

A total of 542 patients were prospectively included during the recruitment period. Of them, 30 patients were not analyzable because impossibility to crossing the culprit lesion by the TA device and 56 patients because

inability to analyze the angiographic data. The remaining 456 patients were finally studied and classified in TA (*n* = 156) and NTA groups (*n* = 300) (Figure 1).

Baseline characteristics are presented in the Table 1. TA group exhibited lower prevalence of dyslipidemia (19.2% *vs* 30.7%, *P* = 0.009) and multivessel disease (39.8% *vs* 54.7%, *P* = 0.003) in comparison with NTA group. Conversely, TA was more often used in primary PCI (73.1% *vs* 68.7%, *P* = 0.013), in presence of initial TIMI flow < 3 (*P* < 0.001), and with concomitant use of GP II b/IIIa inhibitors (65.3% *vs* 50.6%, *P* = 0.012) in comparison with NTA group.

### Procedural results

Main procedural results are presented in the Table 2. Patients included in TA group showed higher prevalence of angiographic success (78.8% *vs* 68%, *P* = 0.015) and better final TIMI flow (TIMI flow 3: 85.9% *vs* 78.3%, *P* = 0.04) in comparison with NTA group. Patients treated with TA received higher rate of direct stenting (58.7% *vs* 45.5%, *P* = 0.009), less number of stents implanted ( $1.3 \pm 0.67$  *vs*  $1.5 \pm 0.84$ , *P* = 0.009), with larger ( $3.17 \pm 0.43$  mm *vs*  $2.93 \pm 0.44$  mm, *P* < 0.001) and shorter sizes ( $24.1 \pm 11.8$  mm *vs*  $26.9 \pm 15.7$  mm, *P* = 0.038). The use of DES was lower in the TA group (DES; 11.3% *vs* 16.3%, *P* = 0.008). In multivariate analysis, TA was associated with angiographic success (HR = 2.3; 95%CI: 1.2-4.3) (Table 3).

### In-hospital and long-term outcomes

In-hospital and long-term data are presented in the Table 4. No difference in major cardiac events was observed between groups during hospitalization. The only difference was a significantly higher CK peak [2563 (1284-4542) UI/L *vs* 1517 (744-3816) UI/L, *P* = 0.02] observed by the use of TA.

At three years clinical follow-up ( $36 \pm 7$  mo), no differences between manual TA and conventional PCI were observed in the rates of MACE (17.0% *vs* 21.6%, *P* = 0.25), all-cause death (17.0% *vs* 19.6%, *P* = 0.5), cardiac death (8.3% *vs* 7.9%, *P* = 0.83), MI (6.8% *vs* 10%, *P* = 0.27), need for CABG revascularization (1.4% *vs* 3.5%, *P* = 0.39),

**Table 1** Baseline clinical and angiographic features *n* (%)

Characteristics	Thrombus aspiration <i>n</i> = 156	Conventional PCI <i>n</i> = 300	<i>P</i> value
Age, mean ± SD	63.2 ± 12.8	64.3 ± 12.8	0.410
Female sex	38 (24.4)	62 (20.7)	0.370
Previous or current smoker	94 (60.3)	205 (68.3)	0.085
Hypertension	82 (52.6)	166 (55.3)	0.570
Dyslipidemia	30 (19.2)	92 (30.7)	0.009
Peripheral vasculopathy	9 (5.8)	19 (6.3)	0.800
Previous MI	10 (6.7)	36 (12.3)	0.065
Previous PCI	8 (5.1)	29 (9.7)	0.092
Previous CABG	2 (1.3)	10 (3.3)	0.190
Indication			0.013
Primary	114 (73.1)	206 (68.7)	
Rescue	42 (26.9)	94 (31.3)	
Classification			0.650
Anterolateral	69 (44.2)	133 (44.3)	
Inferoposterior	83 (53.2)	152 (50.7)	
Non-Q MI	3 (1.9)	12 (4)	
LBBB	1 (0.6)	3 (1)	
Killip			0.058
I	182 (86.3)	228 (76.5)	
II	13 (8.5)	35 (11.7)	
III	1 (0.7)	7 (2.3)	
IV	7 (4.6)	28 (9.4)	
Number of diseased vessels			0.003
1	94 (60.3)	136 (45.3)	
2	43 (27.6)	95 (31.7)	
3	19 (12.2)	69 (23)	
Infarct related artery			0.650
LAD	68 (43.6)	137 (45.7)	
LCx	15 (9.6)	35 (11.7)	
RCA	69 (44.2)	116 (38.7)	
LM	4 (2.6)	8 (2.75)	
Bypass	0	1 (0.3)	
GP II b/IIIa inhibitors			0.012
IABP	7 (4.5)	25 (8.4)	0.120

PCI: Percutaneous coronary intervention; MI: Myocardial infarction; CABG: Coronary artery by-pass graft; LBBB: Left bundle branch block; LAD: Left anterior descending; LCx: Left circumflex; RCA: Right coronary artery; LM: Left-main; IABP: Intra-aortic balloon pump; GP: Glycoprotein.

target vessel PCI revascularization (5.4% *vs* 8.9%, *P* = 0.2), and non-target vessel PCI revascularization (4.8% *vs* 5.7%, *P* = 0.68) and definite ST (1.4% *vs* 4.4%, *P* = 0.15).

## DISCUSSION

The major findings of this study were: (1) manual TA was used more often in primary PCI and in patients with worse TIMI flow; (2) its use was subsequently related to optimization of procedural technique; and (3) TA was independently associated with acute angiographic success.

### Optimization of angiographic outcomes and stent implantation by manual TA in real-world

According to clinical trials and real-world registries, our work confirms that manual TA is more often used in the

**Table 2** Procedural data and angiographic results *n* (%)

Characteristics	Thrombus aspiration <i>n</i> = 156	Conventional PCI <i>n</i> = 300	<i>P</i> value
Time to treatment, median (IQR)	273 (170-477)	300 (180-480)	0.610
Initial TIMI flow			< 0.001
0	111 (71.2)	143 (48.8)	
1	9 (5.8)	16 (5.5)	
2	16 (10.3)	38 (13)	
3	20 (12.8)	96 (32.8)	
Initial TIMI flow < 3	136 (87.2)	204 (67.2)	< 0.001
Final TIMI flow			0.140
0	2 (1.3)	9 (3.1)	
1	1 (0.6)	6 (2.1)	
2	19 (12.3)	50 (17.1)	
3	133 (85.8)	227 (77.7)	
Final TIMI flow < 3	22 (14.1)	65 (21.7)	0.040
Angiographic complication			0.450
Non-reflow	6 (3.8)	16 (5.4)	
Thrombus embolization	7 (4.5)	22 (7.4)	
Coronary dissection	2 (1.3)	7 (2.4)	
Angiographic success	123 (78.8)	200 (68)	0.015
Direct stenting	88 (58.7)	131 (45.5)	0.009
Type of stent			0.008
BMS	133 (88.7)	238 (79.3)	
DES	17 (11.3)	62 (20.7)	
Length of stented segment (mm), mean ± SD	24.1 ± 11.8	26.9 ± 15.7	0.038
Diameter of stented segment (mm), mean ± SD	3.17 ± 0.43	2.93 ± 0.44	< 0.001
Number of stents, mean ± SD	1.3 ± 0.67	1.5 ± 0.84	0.009
LVEF, mean ± SD	49.6 ± 9.8	49 ± 10.4	0.610

PCI: Percutaneous coronary intervention; IQR: Interquartile range; TIMI: Thrombolysis in myocardial infarction; BMS: Bare metal stents; DES: Drug-eluting stents; LVEF: Left ventricle ejection fraction.

presence of high thrombus burden, such as in patients with initial low TIMI flow (0-1) or primary PCI indication. This registry confirms as well that use of TA achieves better angiographic results than conventional PCI, with greater reduction in thrombus burden and higher rate of final TIMI flow 3. Of note is the recent article by Ahn *et al*<sup>[27]</sup> which showed that the addition of II b/IIIa inhibitors (Abciximab) to manual TA improves the index of micro-circulatory resistance and the microvascular obstruction assessed by cardiac magnetic resonance. This leads us to hypothesize that the optimal strategy to optimize myocardial perfusion would be the synergistic use of these two therapeutic options.

Moreover, it appeared that the use of TA allowed immediate good angiographic results before stent implantation, so that fewer, larger and shorter stents could be more often implanted. Previous clinical trials and real-world registries failed to show any differences in the length, diameter and number of implanted stents be-



**Table 3 Multivariate analysis of angiographic success**

	HR (95%CI)	P
Thrombus aspiration	2.3 (1.2-4.3)	0.007
Primary PCI	4.4 (2.1-9)	< 0.001
Active smoking	1.76 (0.9-3.4)	0.093
Age	1.031 (1.001-1.063)	0.044
Initial TIMI flow = 0	0.46 (0.25-0.84)	0.012

PCI: Percutaneous coronary intervention; TIMI: Thrombolysis in Myocardial Infarction.

**Table 4 In-hospital and long-term outcomes n (%)**

	Thrombus aspiration n = 156	Conventional PCI n = 300	P value
In-hospital			
CK peak UI/L, median (IQR)	2563 (1284-4542)	1517 (744-3816)	0.020
ST resolution at 30 min	75 (71.4)	174 (74)	0.610
Intra-procedural death	2 (1.3)	5 (1.7)	1.000
In-hospital cardiac death	15 (9.6)	22 (7.3)	0.400
Non-target vessel PCI revascularization CABG	12 (7.7)	41 (13.8)	0.059
	0 (0)	1 (0.3)	1.000
Follow-up			
MACE	25 (17.0)	61 (21.6)	0.250
All-cause death	26 (17.0)	57 (19.6)	0.500
Cardiac death	13 (8.3)	23 (7.9)	0.830
MI	10 (6.8)	28 (10)	0.270
CABG	2 (1.4)	10 (3.5)	0.390
Target vessel PCI revascularization	8 (5.4)	25 (8.9)	0.200
Non-target vessel PCI revascularization	7 (4.8)	16 (5.7)	0.680
Definitive stent thrombosis	2 (1.4)	12 (4.4)	0.150
Probable stent thrombosis	1 (0.7)	2 (0.7)	1.000
Possible stent thrombosis	2 (1.4)	6 (2.2)	0.720

PCI: Percutaneous coronary intervention; CABG: Coronary artery by-pass graft; MACE: Major adverse cardiac events; MI: Myocardial infarction; IQR: Interquartile range; ST: Stent thrombosis.

tween patients treated with or without TA<sup>[6,7,10,20,28]</sup> except for one brief work<sup>[29]</sup> that demonstrated a higher stent diameter after manual TA, in STEMI patients treated with bare metal stents. Recently, the TASTE trial<sup>[21]</sup> also showed the need for fewer stents per procedure in manual TA group in comparison with conventional PCI. It is well known that intra-stent restenosis and ST are directly related to the characteristics of the stents<sup>[30,31]</sup>. Thus; optimizing on stent implantation using fewer stents and stents of larger diameter and smaller length, during STEMI could have long-term prognostic implications by reducing the intra-stent restenosis and ST.

Besides, in light of these results we might hypothesize that TA may be cost-saving. Therefore, further studies on

cost-effectiveness implications by the use of manual TA in primary PCI are warranted.

### Clinical outcomes of TA in real-world

This registry reflected real-world clinical practice in STEMI population as no exclusion criteria was applied. Additionally, both primary and rescue PCI patients were included.

Unlike other studies with strict inclusion criteria<sup>[6,10]</sup>, this registry demonstrated no impact of TA on both short and long-term outcomes. In the TAPAS trial<sup>[5,6]</sup>, only patients with primary PCI were included; in another real-world registry<sup>[10]</sup>, only patients with primary PCI indication and TIMI flow 0-1 were included. Conversely, our clinical results are consistent with studies with broad inclusion criteria, such as the TASTE trial<sup>[21]</sup>, that evaluated the primary end-point at short-term and with the largest published real-world registry in manual TA<sup>[20]</sup> that had a very extended follow-up. Both studies included patients with initial TIMI flow from 0 to 3 and rescue or primary PCI indication. Thus, differences in inclusion criteria and in follow-up periods between the various trials and inherent selection bias induced in clinical registries may explain the different impact of the TA on long-term outcome.

Furthermore, it is noteworthy that in our study MACE rate was numerically higher in NTA group, although it did not reach statistical significance, probably due to the small number of patients included in our registry.

Of note is that no difference in target-vessel revascularization or stent thrombosis was found between the two groups, despite implantation of larger and shorter stent in TA than NTA group: this finding may be explained by the higher rate of DES implanted in NTA group than TA group.

This interesting controversy will continue until the publication of the results of the TOTAL trial<sup>[32]</sup>. The TOTAL trial is a multicenter, prospective, open, international, randomized trial with blinded assessment of outcomes which will recruit 10700 STEMI patients to compare routine manual TA with the Export aspiration catheter *vs* conventional primary PCI alone. The primary outcome will be the composite of cardiovascular death, recurrent myocardial infarction, cardiogenic shock, or new or worsening New York Heart Association class IV heart failure up to 180 d.

### Study limitations

First, this study is a non-randomized, prospective registry and there were differences in baseline clinical and angiographic characteristics that could lead to a worse baseline risk profile in NTA group. Second, the use of GP II b/IIIa inhibitors was higher in the TA group and this difference could also affect angiographic results in this group. Third, in our study manual TA was only used in one third of cases, whereas current use of manual TA in recent all-comer RCT<sup>[33-35]</sup> is around two thirds of patients. This was related to the relatively lack of evidence of manual thrombectomy at the time of the recruitment of the registry. Fourth, the relative small number of patients

included in our study could preclude any conclusions regarding clinical efficacy of TA.

In this all-comer registry, TA was able to optimize stent implantation technique, leading to the implantation of less number of stents per lesion of shorter lengths and larger sizes, and was associated with angiographic success following PCI for STEMI.

## COMMENTS

### Background

In ST-segment elevation myocardial infarction (STEMI) patients, manual thrombus aspiration (TA) is effective to reduce thrombus burden. Nevertheless, the effect on optimization of stent implantation has not been elucidated yet. Therefore, the objective of this study is to evaluate the impact of manual TA on acute angiographic success and stent implantation characteristics in a real-world STEMI.

### Research frontiers

Manual TA reduces thrombotic burden, receiving a recommendation class IIa during the performance of primary percutaneous coronary intervention. However, the TASTE trial, recently published, showing no impact of manual TA on 30-d mortality, has reopened the debate about the role of this technique in STEMI setting.

### Innovations and breakthroughs

Thrombus embolization is detected up to 15% of STEMI population and is responsible for suboptimal myocardial reperfusion, leading to unfavorable clinical outcomes. Manual TA reduces thrombotic burden and receives a high recommendation during the performance of primary percutaneous coronary intervention. The TASTE trial, demonstrating absence of impact of manual TA on short-term mortality, has reopened the debate about the use of this technique in STEMI patients. In the present study the authors want to investigate, in a real-world STEMI population, the factors which can lead to the use of manual thrombectomy in STEMI and its impact on angiographic and stent implantation characteristics.

### Applications

The study results suggest that manual TA during primary percutaneous coronary intervention is associated with a higher rate of angiographic success and optimization on stent implantation compared with conventional primary percutaneous coronary intervention, in a real-world population. However, it seems to have no impact on long-term clinical outcomes.

### Terminology

STEMI: It is a type of acute coronary syndromes, which occurs when a coronary artery becomes totally blocked by a blood clot, causing the heart muscle supplied by the artery to die; Primary percutaneous coronary intervention: It is a non-surgical procedure used to open the occluded coronary arteries during STEMI; Manual TA device: It is a type of thrombectomy device, which comprises a monorail catheter with a central lumen connected proximally to a syringe for manual aspiration, designed to extract thrombotic material during percutaneous coronary intervention.

### Peer review

In this study, Diego *et al* reported that the thrombus aspiration therapy in patients with AMI were associated with high procedure success and contributed to optimize the implantation of stents. As a non-randomized, prospective registry study, it provide their some new insights about the use of thrombus aspiration in the real world.

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