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To Whom Thrombus Aspiration May Concern?

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Abstract

BACKGROUND: Thrombus aspiration for ST-segment elevation myocardial infarction (STEMI) may improve myocardial perfusion. However, these favourable results called into a question by data indicating not only a lack of efficacy but a risk of potentially deleterious complications.

AIM: To assess the effect of thrombus aspiration during the primary percutaneous coronary intervention (PPCI) on procedural angiographic results, stent characteristics, and major adverse cardiac and cerebrovascular events (MACCE).

METHODS: All consecutive STEMI patients candidate for PPCI and admitted to Critical Care Department, Cairo University hospitals, managed either by thrombectomy before primary PCI (if thrombus score ≥ 3) or conventional PPCI, Six hundred seven subjects were enrolled in the study divided into Group with thrombectomy before PPCI (107 subjects, 18%), and group with Conventional PCI (500 subjects, 82%). ST-segment resolution, peak CK-MB, TIMI score, thrombus score, and MBG were assessed; stent number, diameter, length and stented segment were reported and follow up MACCE was reported (in hospital and 1-year post-intervention).

RESULTS: Mean values for peak CKMB were less in thrombectomy group (228 ± 174 I/U vs 269 ± 186 I/U, p = 0.04), ST segment resolution ≥ 70% occurred in {63 subjects (58.9%) vs 233 (46.6%), p = 0.001} in thrombectomy vs conventional group respectively. TIMI score pre procedure was zero in (102 subjects (95%) vs 402 (80.4%), p = 0.001), while TIMI III post procedure was reported in (100 subjects (93.4%) vs 437 (87%), p = 0.06), MBG mean values were (2.4 ± 0.6 vs 2.0 ± 1, p = 0.001), thrombus score was higher in thrombectomy group (4.6 ± 0.4 vs 0.8 ± 1.7, p = 0.001) in thrombectomy vs conventional group respectively .Direct stenting was { 34 patients (31%) vs 102 patients (20%), p = 0.05} , mean stent diameter (2.7 ± 1.3 mm vs 3.5 ± 1.3 mm, p = 0.3), mean stent length was (19.9 mm ± 10 versus 22.7 mm ± 8 in p 0.01). mean stent number was (1.0 ± 0.5 vs 1.2 ± 0.6, p = 0.001), mean stented segment was (22.5 ± 13.5 vs 28.5 ± 15.2 mm, p = 0.001) in thrombectomy vs conventional group respectively. MACCE in hospital were reported in {9 subjects (8.4%) vs 70 (14%), p = 0.07)}. Follow up MACCE after 1 year reported in {6 subjects (5.6 %) vs 80 (16 %), p 0.= 4} in thrombectomy vs conventional group respectively.

CONCLUSION: Thrombus aspiration before primary PCI (in a selected group with thrombus score ≥ 3) improves myocardial perfusion, suggested by better ST-segment resolution, TIMI flow, less peak CKMB and MBG, associated with a higher rate of direct stenting, shorter stent length, stented segments and less number of stents. Although thrombus aspiration was done in more risky patients (higher thrombus score) MACCE (in hospital and 1 year follow up) showed no statistical difference.

Introduction

Although PCI has become established as the dominant reperfusion strategy for the treatment of STEMI, its benefit is sometimes limited. Possible explanations for this limited benefit have included delays in reperfusion and reperfusion injury. Thus, reperfusion injury has become a topic of great interest, and it has been recognised that thrombus burden and embolic debris, thrombus and atherosclerotic plaque might be important contributors [1].

Improved flow is associated with improved indicators of reperfusion, including ST-segment resolution. Infarction size was found to be smaller in patients who underwent thrombectomy before stenting compared with controls who underwent stenting without prior thrombectomy. Finally, thrombectomy is associated with improved clinical outcomes and survival [2], [3].

A recent study showed no benefit of thrombectomy, perhaps unsurprisingly, when PCI was performed late after symptom onset [4]. In addition to the possibility that thrombus removal is not beneficial, several other possible explanations for the absence of benefit observed in these trials should be considered. Managed coronaries may have contained only a small thrombus burden, as observed in the TOTAL

(ThrOmbecTomy *versus* PCI ALone) optical coherence tomography substudy [5]. It is also possible that infarction was nearly complete when PCI was performed, limiting the possible benefit of any intervention, including thrombectomy.

In this study, we aimed to perform a comprehensive analysis to evaluate the outcomes associated with aspiration thrombectomy in terms of myocardial perfusion, stent characteristics, and major adverse cardiac and cerebrovascular events (MACCE).

Patients and Methods

This was a prospective case-control investigational single-centre study involved 607 patients and included all patients admitted to the Critical Care Department of Cairo University Hospitals "presenting with ST-segment elevation myocardial infarction (STEMI) and subjected to primary percutaneous coronary intervention (PCI)."

The total study group included 607 subjects. The subjects were classified into two groups according to the use of thrombus aspiration devices:

A) Group I: Included 107 subjects who underwent PCI with thrombus aspiration.

B) Group II: Included 500 subjects who underwent PCI without thrombus aspiration.

Inclusion criteria

We included all adult patients who presented with acute STEMI and fulfilled the following criteria:

- Prolonged ischemic chest pain (lasting > 30 minutes).

- ECG**:** ST segment elevation (> 1 mm) in 2 or more contiguous leads or ECG findings suggestive of posterior infarction [6].

- Presentation ≤ 24 hours from symptom onset.

Exclusion criteria

- Patients with acute in-stent thrombosis following elective PCI resulting in STEMI.

- Any contraindication for primary angioplasty or antiplatelet therapy.

- Patients with missing or incomplete data records.

- Previous CABG.

Methods

A) *Following admission, all patients underwent the following:*

- Full medical history and demographic characteristics collection.

- Detailed clinical examination on admission (with the determination of Killip class) [7].

- Collection of written informed consent entailing all ethical and moral considerations, as requested by the medical council of the Cairo University Hospitals.

B) Demographic data on admission and medical history:

- Age and gender, risk factors for coronary artery disease (CAD); the presence of DM [8], dyslipidemia [9], or hypertension [10]; smoking history; and positive family history for CAD [11], prior PCI.

C) Twelve-lead electrocardiogram (ECG):

- ECG was performed before the intervention, 1 h post-intervention, and then daily during the hospital stay and whenever indicated.

ST-segment resolution (STR)

- ST-segment resolution was classified as complete (if the resolution was more than 70%), partial (if the resolution was between 30% and 70%), or absent (if the resolution was less than 30%) [12], [13].

D) Laboratory investigations:

- Cardiac enzymes (CK-MB) were examined on admission, 6 hours and 24 hours after intervention, and when needed.

E) Diagnostic coronary angiography and PCI:

- The procedures were performed using the *Integris H 3000 (Philips, NL)* catheterisation laboratory.

- Identification of infarct-related artery (IRA) and the site of occlusion (Ostial, proximal, mid-segment or distal).

- Pain-to-door time, total ischemic time, and procedural time.

- Determination of TIMI flow grading before and after the procedure

- Determination of TIMI thrombus grade:

- To more objectively and quantitatively characterise thrombus on a coronary angiogram, TIMI study group developed and popularised the following thrombus grading system [14]:

- TIMI Thrombus Grade 0: No cine angiographic characteristics of thrombus present.

- TIMI Thrombus Grade 1: Hazy, possible thrombus present. Angiography demonstrates characteristics such as reduced contrast density, haziness, irregular lesion contour, or a smooth convex "meniscus" at the site of total occlusion suggestive but not diagnostic of thrombus.

- TIMI Thrombus Grade 2: Thrombus present – small size: Definite thrombus with greatest dimensions less than or equal to 1/2 vessel diameter.

- TIMI Thrombus Grade 3: Thrombus present – moderate size: Definite thrombus but with a greatest linear dimension greater than 1/2 but less than 2 vessel diameters.

- TIMI Thrombus Grade 4:

Thrombus present – large size: As in Grade 3 but with the largest dimension greater than or equal to 2 vessel diameters.

- TIMI Thrombus Grade 5: Recent total occlusion can involve some collateralization but usually does not involve extensive collateralization, tends to have a “beak” shape and a hazy edge or appearance of distinct thrombus.

F) *Major adverse cardiac events (MACCE), defined as the composite of the following factors:* - Target vessel revascularisation, acute coronary syndromes, death, and Stroke *(*clinical and/or radiological evidence of CVS); - Follow up MACCE was assessed in hospital and after 1 year.

Statistical analysis

Data were collected and coded before analysis using the professional Statistical Package for Social Sciences (SPSS 18). All data are expressed as the mean and standard deviation (SD). - Frequency tables were used for all categorical data. - Student’s *t*-test (unpaired) was used for all continuous data after checking normality. - The Mann-Whitney test was used when the standard deviation value was violated. - The chi-square test was used for all categorical data to test for the presence of an association. For small samples, Fisher’s exact test was used. - A P value < 0.05 was considered significant.

Results

This was a prospective case-control investigational single-centre study; conducted on subjects admitted with (STEMI) and were subjected to primary percutaneous coronary interventions.

The total study group included 607 subjects. The subjects were classified into two groups according to the use of thrombus aspiration devices:

Group I: Included 107 subjects who underwent PPCI with thrombus aspiration.

Group II: Included 500 subjects who underwent PCI without thrombus aspiration.

Demographics and comorbidities

The mean age was 57.3 ± 11 years in total subjects, (56 ± 10 vs 57 ± 11 years, $p = 0.3$) in group I vs group II respectively. The majority were males 488 (80.3%) of the total study group (85% vs; 79%, P = 0.3) in group I vs group II respectively**.**

Table 1: Demographics and comorbidities

	Total		Group I		Group II		*P* Value
	No.	%	No.	%	No.	%	
Male gender	488	80.3	92	85	397	79	0.3
Family history of IHD	197	32	39	36	158	31	0.1
Smoking	395	65	79	73	316	63	0.2
Hypertension	296	48	44	41	252	50	0.5
Diabetes Mellitus	222	36	41	38	181	36	0.3
Dyslipidemia	213	35	46	43	167	33	0.3

IHD: ischemic heart disease.

Myocardial perfusion and angiographic parameters

A) TIMI score:

- TIMI score pre-procedure was zero in (95% vs 80%, p 0.001) in group I vs group II respectively Table 2.

- TIMI III post procedure occurred in (93% vs 87% P: 0.07) while TIMI zero post procedure occurred in (0.9% vs 2.2%, P = 0.07) in group I vs group II respectively**.**

Table 2: Clinical characteristics for the study group

	All subjects Mean ± SD	Group I Mean ± SD	Group II Mean ± SD	*p*-value
Age	57.3 ± 11	56 ± 10	57 ± 11	0.3
Heart rate (HR) (BPM)	86 ± 16	83 ± 16	87 ± 16	0.3
MAP /mmHg	71 ± 12	73 ± 11	71 ± 12	0.1
PDT /h	5.1 ± 2.6	5.1 ± 2.8	5.1 ± 2.4	0.5
Killip class	1.3 ± 0.7	1.2 ± 0.7	1.3 ± 0.7	0.2
Cardiac enzymes (CKMB)				
CKMB 1 U/L	183 ± 148	185 ± 159	183 ± 128	0.9
CKMB 2 U/L (Peak)	262 ± 185	228 ± 174	269 ± 186	0.04
CKMB 3 U/L	195 ± 162	135 ± 114	208 ± 163	0.001
Clinical characteristics of the studied population				
Total ischemic time /h	6.4 ± 3.3	6.5 ± 2.5	6.4 ± 2.8	0.5
Procedure time /minute	42 + 21	44.1 + 16	41.3 + 22	0.1
Glycoprotein IIb/IIIa inhibitor (patient, %)	347 (57%)	78 (72%)	269 (53%)	0.001
ST resolution ≥ 70%	296 (48.8%)	63 (58%)	233 (46%)	0.01
No reflow	71 (11%)	7 (6.5%)	64 (12.8%)	0.04
Primary PCI procedure data				
Stent diameter/mm	3.3 ± 1.4	2.7 ± 1.3	3.5 ± 1.3	0.3
Stent length/mm	22.1 ± 9.1	19.9 ± 10.7	22.7 ± 8.7	0.01
Stented segment/ mm	25.5 ± 14.4	22.5 ± 13.5	28.5 ± 15.2	0.001
Stent pressure/ATM	13.4 ± 4.7	12.1± 6.2	13.6 ± 4.3	0.01
No of stents	1.1 ± 0.6	1.0 ± 0.5	1.2 ± 0.6	0.001

BPM: beat per minute; MAP: mean arterial pressure; PDT: pain to door time.

B) Thrombus score

Thrombus score 5 was present (76% vs 37%, $p = 0.001$) while thrombus score 0 was (0% vs 78%, p 0.001) in group I vs group II respectively Table 3.

Table 3: Angiographic findings

	Group I	Group II	*P* value
TIMI pre-procedure			
0 subjects / (%)	102 (95%)	402 (80.4%)	0.001
I subjects / (%)	5 (4.6%)	31(6.2%)	
II subjects / (%)	0 (0%)	45 (9%)	
III subjects / (%)	0 (0%)	22 (4.4%)	
TIMI post procedure			
0 subjects / (%)	1 (0.9%)	11 (2.2%)	0.07
I subjects / (%)	2 (1.8%)	13 (2.6%)	
II subjects / (%)	4 (3.7%)	39 (7.8%)	
III subjects / (%)	100 (93.4%)	437 (87.4%)	
Thrombus score			
0	0 (0%)	391 (78.2%)	0.001
1	0 (0%)	10 (2%)	
2	4 (3.7%)	4 (0.8%)	
3	6 (5.6%)	18 (3.6%)	
4	15 (14%)	40 (8%)	
5	82 (76.6%)	37 (7.4%)	
MBG			
0 subjects / (%)	6 (5.6%)	51 (10.2%)	0.001
I subjects / (%)	7 (6.5%)	85 (17%)	
II subjects / (%)	37 (34%)	195 (39%)	
III subjects / (%)	57 (53.2%)	169 (33.8%)	

B) Stent characteristics

Stent diameter: mean values were (2.7 ± 1.3 vs 3.5 ± 1.3 mm, *p* 0.3) while *Stent length*: mean was (19.9 ± 10 vs 22.7 ± 8 mm, *p* 0.01). *Stented segment mean* was (22.5 ± 13.5 vs 28.5 ± 15.2 mm, *p* 0.001). *Stent number* mean was (1 ± 0.5 vs 1.2 ± 0.6, *p* 0.001) in group I vs group II respectively.

Major adverse cardiac and cerebrovascular events (MACCE)

I) in hospital MACCE

In the hospital, MACCE was reported in 79 subjects (13%) of total study group {9 (8.4%) vs 70 subjects (14%), *p* 0.07} in group I vs group II respectively Table 4.

Table 4: In Hospital MACCE

	Group I Thrombectomy 9 (8.4%)	Group II Conventional 70 (14%)	P value
Mortality subjects/(%)	9 (8.4%)	59 (11.8%)	
(TVR) subjects / (%)	(0%)	5 (4.3%)	
(MI) subjects / (%)	(0%)	5(4.3%)	
(CVS) subjects / (%)	(0%)	1(0.2%)	0.07

MACCE: major adverse cardiac and cerebrovascular events; TVR: target vessel revascularization; MI: myocardial infarction; CVS: cerebrovascular stroke.

II) Follow up MACCE after 1year

Follow up MACCE after 1 year reported in {(5.6%) vs (16%), *p* 0.4} in thrombectomy vs conventional group respectively Table 5.

Table 5: MACCE after 1year

	Group I Thrombectomy 6 (5.6%)	Group II Conventional 80 (16%)	P value
Mortality subjects/ (%)	3(2.8%)	55 (11%)	
(TVR) subjects / (%)	3 (2.8 %)	21(4.2%)	
(MI) subjects / (%)	0(0%)	4(0.8%)	
(CVS) subjects / (%)	0(0%)	0(0%)	0.4

MACCE: major adverse cardiac and cerebrovascular events; TVR: target vessel revascularization; MI: myocardial infarction; CVS: cerebrovascular stroke.

Kaplan–Meier Estimates for 1-year MACCE

As Shown in the cumulative hazard rates for MACCE (death from cardiovascular causes, recurrent myocardial infarction, TVR, and HF requiring hospitalization), Hazard ratio was non significantly lower in thrombectomy group (72.5; 95% CI, 45.2 to 99.8; *p* = 0.8) vs (85.7; 95% CI, 36.9 to135; *p* = 0.8) in thrombectomy vs conventional group respectively. The rate of the net-benefit for outcome was similar in both groups Figure 1.

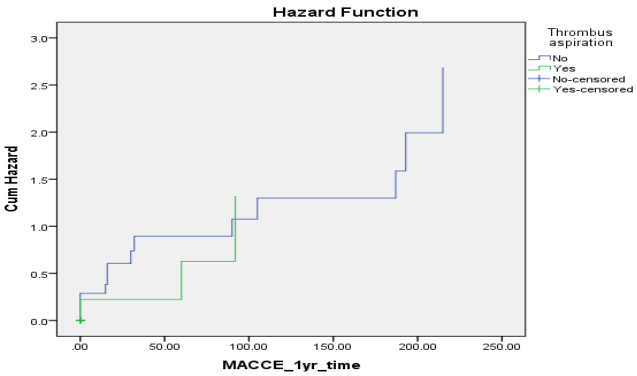

Figure 1: Kaplan–Meier curve for 1-year MACCE

Further Subgroups

We did further sub-grouping according to thrombus burden (high thrombus burden ≥ 3 and low thrombus score ≤ 2), ischemia time (0-6 hrs. and 7-12 hrs.), initial TIMI flow (TIMI ≤ 1 and Normal flow), then multi-regression analysis was done using forest plot assessment for patient outcome.

B) High thrombus burden group showed a tendency in favour of thrombectomy. However, did not reach statistical; significance *p* = 0.2.

C) Subjects with earlier ischemic time (0-6 h) showed favour for thrombectomy. However, it did not reach statistical significance *p* = 0.09.

D) In the group with initial TIMI ≤ 1 also showed preferential for thrombectomy without statistical significance *p* = 0.08 Figure 2.

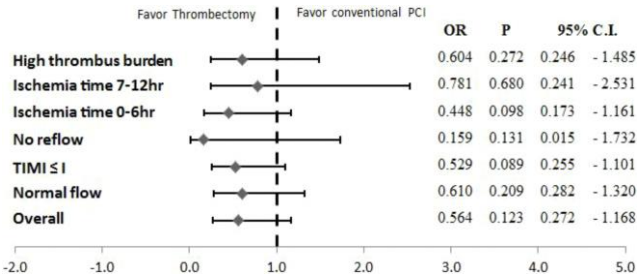

Figure 2: Forest plot in outcome in pre-specified groups

Discussion

The increase in thrombus burden is associated with higher mortality [16], [17] and manual aspiration thrombectomy has the potential to reduce the thrombus burden [18]. After the initial TAPAS [3] trial showed an improvement in myocardial blush and

a reduction in mortality, and a meta-analysis of small trials [19] also showed a reduction in mortality, routine manual thrombectomy became a class IIa treatment recommendation in the American and European Guidelines for STEMI 2013 [20]. Subsequently, however, more recent larger trials, such as TOTAL [21] (N = 10,732) and TASTE [18] (N = 7244), and a meta-analysis [22] showed an increase in the risk of stroke with routine manual thrombectomy without any benefit in terms of MACCE. Consequently, in the updated AHA/ACC 2015 guidelines [23] manual thrombus aspiration was downgraded to a class IIb recommendation for the treatment of STEMI; in the 2017 STEMI guidelines, it was further downgraded to a class III recommendation [24].

Myocardial perfusion

In our study, the thrombectomy group showed better ST segment resolution of ≥ 70% (58% vs 46%, respectively, *p* 0.001) in the thrombectomy group vs the conventional group.

In our study, the peak CK-MB was lower in the thrombectomy group (228 ± 174 U/L vs 269 ± 186 U/L, *p* = 0.04). This is in line with Orrego et al., (2006) [25] who reported peak CK-MB values of (790 ± 132U/L vs 910 ± 128 U/L, *p* = 0.0001) in the thrombectomy group vs the conventional group.

Angiographic procedure

The classic approach of pre-dilation before stent deployment and high-pressure post dilation is associated with increased procedure duration, more radiation exposure, contrast use, and increased costs compared with direct stenting [26], [27].

In our study, direct stenting was more frequent in the thrombectomy group than the conventional group (38% vs 20%, *p* = 0.001). Rodriguez et al., (2014) [28] reported direct stenting rates of (58% vs 45% for the thrombectomy group vs the conventional group, *p* = 0.009).

Yamaguchi et al., (2013) [29] reported in an OCT study (n = 188), that thrombus aspiration before primary angioplasty in patients with STEMI was associated with significantly less tissue protrusion compared with standard PCI; it was also associated with favourably influenced lesion morphologies in the stented segment. From this, we can state that thrombus aspiration can decrease clot volume, which causes a higher thrombus grade.

Stent characteristics

In-stent restenosis [30] and stent thrombosis [31] is directly related to the characteristics of the stents [32]. Thus, the stent type [33] and the use of fewer stents and stents with a larger diameter [34] and a smaller length [33], [34] during STEMI could have long-term prognostic implications by reducing stent restenosis and stent thrombosis.

Certain stent characteristics have been associated with stent restenosis [35], including stent length [36] and stent diameter [37]. In the present study, the mean stent diameter was (2.7 ± 1.3 vs 3.5 ± 1.3 mm, *p* = 0.3), while the stent length was significantly shorter in the thrombectomy group (19.9 ± 10 vs 22.7 ± 8 mm, *p* = 0.01). Also, the mean length of the stented segments was significantly lower in the thrombectomy group than in the conventional group (22.5 ± 13 vs 28.5 ± 15 mm, respectively, *p* = 0.001). Along the same line, Rodriguez et al., (2014) [28] reported a mean length of stented segments of (24.1 ± 11.8 vs 26.9 ± 15.7 mm, *p* = 0.03). In the current study, the thrombectomy group required fewer stents (1 ± 0.5 vs 1.2 ± 0.6, *p* = 0.001).

Multiple factors likely contribute to no-reflow. These include distal embolisation of a plaque and/or thrombus, microvascular damage, myocardial necrosis and stunning [38]. Other studies have noted a higher rate of adverse outcomes in patients with no reflow, regardless of the method of detection. These adverse outcomes include increases in in-hospital heart failure and mortality, left ventricular remodelling at six months, and mortality at one year [39], [40]. In the current study, the incidence of no-reflow was significantly lower in the thrombectomy group than in the conventional group {7 subjects (6.5%) vs 64 (12.8%), *p* = 0.04}. These findings are in line with those of the study by Orrego et al., (2006) [25], who reported that the incidence of no-reflow was significantly lower in the thrombectomy group than in the conventional group (3% vs 15%, respectively, *p* = 0.02).

MACCE

In our study, the rate of in-hospital MACCE was higher in the conventional group, although the difference did not reach statistical significance {9 (8.4%) vs 70 patients (14%), *p* = 0.07}. In comparison, follow-up MACCE after 1 year was reported in {6 subjects (5.6%) vs 80 (16 %), *p* = 0.4} in the thrombectomy group vs the conventional groups. This is in line with the updated meta-analysis by Ghatak et al., (2015) [41], which included 21,281 patients in 20 trials and reported no difference in mortality, recurrent MI, target vessel revascularization, early or late stent thrombosis, or net clinical benefit between thrombectomy and conventional PPCI patients during short-term or long-term follow-up. Conversely, a previous meta-analysis by Kumbhani et al., (2013) [42] that included 18 trials reported that manual thrombus aspiration was associated with a reduction in major adverse cardiac events, including mortality at 6 to 12 months, but had a trend towards a higher risk of stroke. In our study, CVS developed in one patient in the conventional group, who also developed

paroxysmal AF; consequently, we cannot provide a comment regarding CVS. Of note, the TOTAL trial [21] reported that the thrombectomy group showed significant development of CVS compared with the conventional group (0.7% vs 0.3%, p = 0.02). Recent data suggest that thrombus aspiration may be associated with stroke [43], [44]. This was not demonstrated in other single-country studies [45], [46] raising the question of whether technique may play a role. Possible explanations for the association between stroke and thrombus aspiration include catheter-induced embolization of the thrombus into the systemic vasculature; aggressive guide catheter manipulation to pass the aspiration catheter, which dislodges aortic atheroma; and longer procedure times arising from the aspiration procedure [47].

Study Limitations

- This is a single-centre, some information of interest, such as data on the duration of diabetes mellitus ischemic heart disease, were missing.

- The treating physician was aware of the group to which the patients had been assigned.

- Myocardial blush grade assessment requires waiting approximately 5 seconds post-dye injection for proper evaluation, which was not possible for all patients.

- MACCE were assessed after 12 months post discharge. The data were collected by outpatient follow-up, record reviews, and direct contact or phone calls with the patients or their relatives.

In patients with STEMI subjected to PPCI with thrombus score ≥ 3:

- Thrombus aspiration before primary PCI improves myocardial perfusion, as indicated by the findings of better ST-segment resolution and TIMI flow and reduced peak CKMB and MBG.

- Thrombus aspiration before primary PCI was associated with a higher rate of direct stenting, shorter stent length, fewer stented segments and fewer stents.

- Despite the greater risk associated with the pre-procedure thrombus score in the thrombectomy group, there was no difference in MACCE.

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