



Association of the use of manual thrombus aspiration with intracoronary thrombotic burden in patients with ST segment elevation myocardial infarction in the real world

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1. Introduction

The primary percutaneous coronary intervention (PCI) is routinely used in patients with ST-elevation myocardial infarction (STEMI). Additional use of manual thrombus aspiration (MTA) could reduce local thrombus load and distal embolization resulting in microvascular obstruction. Since this technique was first described in 1980 by DeWood MA et al. [1,2], it has been improved during the last decades. However, several studies have progressively reduced the evidence of its routine use in the interventional treatment of patients with STEMI, becoming a class III recommendation with a level of evidence A [3,4], as it has shown no benefit in clinical outcomes and increases the risk of ischemic strokes [5]. Still, this strategy could be used in cases with a high intracoronary thrombus burden, in which a recent meta-analysis showed a trend to decrease the risk of cardiovascular death, despite an increase in ischemic strokes [6].

The routine use of MTA in patients with STEMI does not provide a benefit compared to conventional primary PCI [3]. However, there are still certain gaps regarding the role of MTA in a high

thrombus burden scenario during daily clinical practice [7], since, due to the random nature of the MTA studies [5,8,9], intracoronary thrombus burden was not an element for determining its use. We do not currently know of studies which have evaluated the decision to use MTA based on the intracoronary thrombus burden. This study assessed if the use of MTA in the real clinical practice in patients with STEMI was directly related to a high intracoronary thrombus burden as defined by the TIMI scales and/or the TIMI scale modified by Sianos G et al. [10,11], and evaluated if the use of this technique was related with major cardiovascular events.

2. Methods

2.1. Study design and population

This is a retrospective cohort study in patients with STEMI undergoing PCI, with and without the use of MTA during one year (2016) in a single center. The study was approved by the institutional ethics committee. Retrospectively, all patients over the age of 18 were included if they underwent coronary arteriography plus PCI due to STEMI, regardless of the time elapsed or pharmacological reperfusion therapy received. The data were gathered from each of the medical charts, and the information was collected on a form containing the definition of each of the variables.

MTA was performed with Export Advance[®] 6Fr catheter (Medtronic Inc, Santa Rosa, CA, USA). The patients were classified

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Table 1
Thrombus burden scales by coronary angiography.

*TIMI thrombus grade – Coronary angiography	
Grade 0	No angiographic evidence of thrombus
Grade 1	Angiographic features suggestive of thrombus (decreased contrast density, haziness of contrast, irregular lesion contour, a smooth convex meniscus at the site of a total occlusion, suggestive, but not firmly diagnostic of thrombus)
Grade 2	Definite thrombus present in multiple angiographic projections (marked irregular lesion contour with a significant filling defect, the greatest dimension of thrombus is <1/2 vessel diameter)
Grade 3	Definite thrombus appears in multiple angiographic views (greatest dimension from >1/2 to <2 vessel diameters)
Grade 4	Definite large size thrombus present (greatest dimension >2 vessel diameters)
Grade 5	Definite complete thrombotic occlusion of a vessel (a convex margin that stains with contrast, persisting for several cardiac cycles)
**Modified TIMI thrombus classification (modification introduced by Sianos G et al.)	
Grade 0 of the TIMI scale	No residual thrombus
Grades 1–3 of the TIMI scale	Small residual thrombus
Grade 4 of the TIMI scale	Large residual thrombus
Grade 5 of the TIMI scale	Persistent occlusion

* **TIMI scale [10]**: Scale used to describe coronary thrombi during angiography according to the classification described by the TIMI group.

** **Scale modified by Sianos G et al. [11]**: The angiographic detection of a TIMI grade 5 thrombus leads to an additional exploration of the occlusive thrombotic content. An intervention guidewire, or a small (1.5 mm) angioplasty balloon, is advanced through the total occlusion, which may result in restored anterograde flow in the treated vessel, and a reclassification of the thrombus grade.

into two groups: Group 1, patients who underwent MTA plus PCI (MTA Group); and Group 2, patients with conventional PCI in whom MTA was not used (Non-MTA Group). The thrombus grade of each patient was classified according to the TIMI and modified TIMI thrombus grading scales [10,11], reviewing and analyzing each angiography on the OsiriX MD® system. TIMI thrombus grade was classified according to the presence and size of thrombus from grade 0 to 5. The modified TIMI thrombus scale was used when the thrombus burden in TIMI scale scored 5, leading to an additional exploration of the occlusive thrombotic content reclassified in not thrombus present, small residual thrombus or persistent occlusion. TIMI and modified TIMI thrombus grading scales are described in Table 1. High thrombus burden was defined as a grade ≥ 4 in both scales. Initial and final coronary flow were also evaluated, along with the type of percutaneous coronary intervention performed. Patients for whom no coronary arteriography film was found, were excluded.

2.2. Main outcomes

The primary objective of this study was to estimate the association between the use of MTA and the thrombus burden grade according to the TIMI and modified TIMI classification in patients with STEMI, regardless of the time elapsed. Secondary outcomes were to describe the patients clinical features and final angiographic characteristics, and estimate the cardiovascular death and ischemic stroke rates during the hospitalization of patients undergoing MTA versus conventional PCI [12].

2.3. Statistical analysis

The clinical and demographic variables were extracted retrospectively from the patients medical charts, while the description of the angiographic variables was obtained through a new review of the coronary angiographies. The qualitative variables were presented as absolute values and percentages, and were compared using Chi square and Fisher's exact tests. The quantitative variables were presented as means with their respective standard deviations. Data analysis was performed using SPSS v24.0.

3. Results

3.1. Sociodemographic and clinical Characteristics.

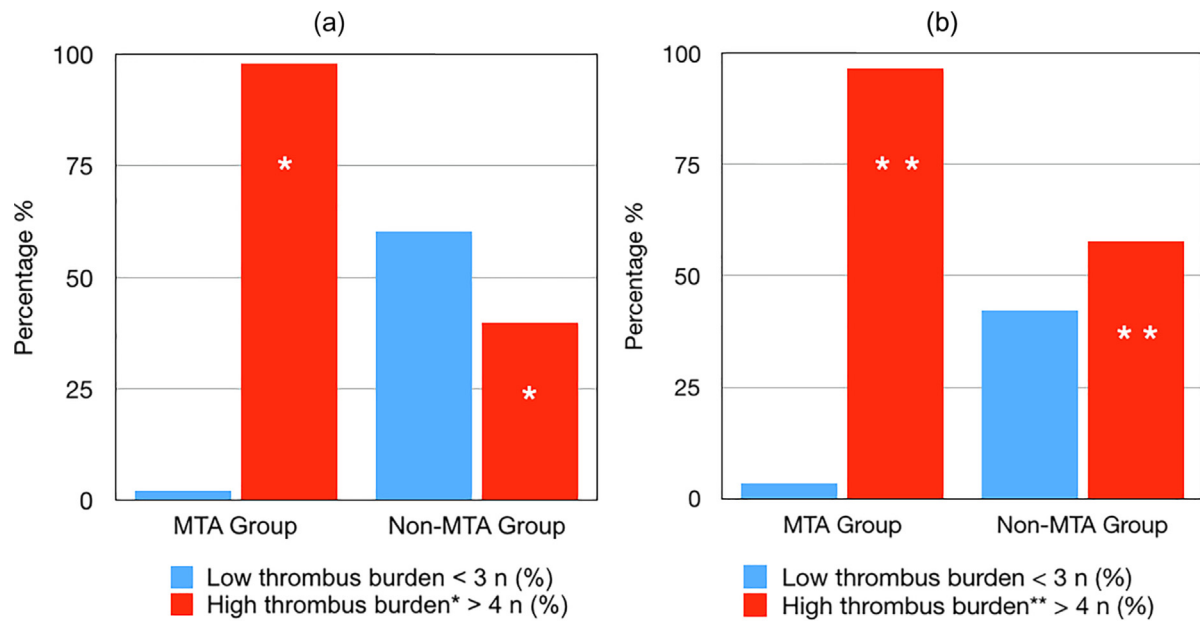
A total of 205 patients with a diagnosis of STEMI plus PCI were found in the interventional cardiology database. Altogether, 33

Table 2
Sociodemographic and Clinical Characteristics.

Variable	MTA Group N = 52	Non-MTA Group N = 121
Male sex; n (%)	41 (71.8)	94 (78.3)
Age (years); mean \pm SD	59.1 \pm 11.6	62 \pm 11.5
Diabetes; n (%)	7 (13.4)	37 (30.5)
Dyslipidemia; n (%)	19 (36.5)	51 (42.1)
Arterial hypertension; n (%)	23 (44.2)	71 (58.6)
Stent thrombosis presentation; n (%)	2 (3.8)	6 (4.5)
Active smoker; n (%)	10 (19.2)	23 (19.4)
Prior coronary intervention; n (%)	6 (11.5)	18 (15.1)
Antiplatelet therapy		
Clopidogrel; n (%)	41 (78.8)	102 (84.3)
Ticagrelor; n (%)	8 (15.3)	10 (8.2)
Prasugrel; n (%)	3 (5.7)	9 (7.5)
Prior pharmacologic reperfusion therapy; n (%)	6 (11.5)	38 (31.4)
Infarct site		
Anterior; n (%)	12 (23)	60 (49.5)
Inferior; n (%)	38 (73)	55 (45.5)
Lateral; n (%)	1 (1.92)	4 (3.3)
No specific location; n (%)	1 (1.92)	2 (1.6)
Killip-Kimball		
Killip-Kimball 1; n (%)	37 (71.1)	98 (81.6)
Killip-Kimball 2; n (%)	2 (3.8)	8 (6.6)
Killip-Kimball 3; n (%)	1 (1.92)	3 (2.5)
Killip-Kimball 4; n (%)	12 (23)	11 (9.1)
Time elapsed from beginning of symptoms at hospital admission	N = 48*	N = 119*
< 1 h; n (%)	3 (6.3)	9 (7.5)
1 h - \leq 12 h; n (%)	36 (75)	46 (38.7)
12 h \leq 24 h; n (%)	9 (18.7)	28 (23.5)
24 h \leq 48 h; n (%)	0	26 (21.9)
48 h \leq 72 h; n (%)	0	3 (2.5)
\geq 72 h; n (%)	0	7 (5.9)

* Information available only in 48/52 patients in MTA group and 119/121 in non-MTA.

patients were excluded: 22 for not having complete angiographic information and 10 for having myocardial infarction without ST elevation, or underwent PCI in a non-culprit vessel. A total of 173 patients were analyzed; 52 were assigned to the MTA group, and 121 to the Non-MTA group. Most of the patients in both groups were males (71.8% MTA Group and 78.3% Non-MTA Group). The mean patient age was 59.1 \pm 11.6 years in the MTA group, versus 62 \pm 11.5 years in the Non-MTA group. All the patients in the MTA group presented to the hospital within 24 h of the beginning of symptoms and prior pharmacologic reperfusion was more



*Statistically significant association of the high thrombus burden by TIMI classification (Grade ≥ 4) in the MTA Group (98.1%) versus the Non-MTA Group (39.7%) ($p < 0.0001$). **Statistically significant association of the high thrombus burden by the modified TIMI classification (Grade > 4) in the MTA Group (96.6%) versus Non-MTA Group (57.8%) ($p = 0.0007$).

Fig. 1. (a) Low and high thrombus burden by TIMI scale in the MTA Group and Non-MTA Group. (b) Low and high thrombus burden by the modified TIMI scale in the MTA Group and Non-MTA Group.

frequent in the Non-MTA group. Other clinical characteristics are described in Table 2.

3.2. Characteristics of the diagnostic coronary angiography

With regard to the angiographic findings during diagnostic arteriography, most lesions in both groups were type B2 and C, according to the American Heart Association (AHA) classification. The most frequently treated target vessel in the MTA group was the right coronary artery (59%), while in the Non-MTA group it was the anterior descending artery (50%). The radial approach was used in 63% and 74% of the MTA and Non-MTA groups, respectively (Supplementary Table 1).

3.3. Association of the thrombus burden classified by the TIMI and modified TIMI scales with the use of MTA

According to the TIMI scale classification of thrombus burden, 98% of the patients in the MTA group had a thrombus burden ≥ 4 , compared with 36% of the patients in the Non-MTA group, showing a significant association of this high thrombus burden with the use of MTA ($p < 0.0001$) (Fig. 1a). Angiographic classification using the modified TIMI scale was only possible in 52 patients, finding that 96% of the patients in the MTA group continued to have a high thrombus burden, compared to 57% of those in the Non-MTA group. In these patients, there was also a significant association between the persistence of a high thrombus burden (high thrombus burden \geq Grade 4) and the use of MTA ($p = 0.0007$) (Fig. 1b) (Table 3).

3.4. Secondary outcomes

There was no significant difference in the final TIMI flow between the two groups ($p = 0.1333$). A grade 3 myocardial blush

Table 3

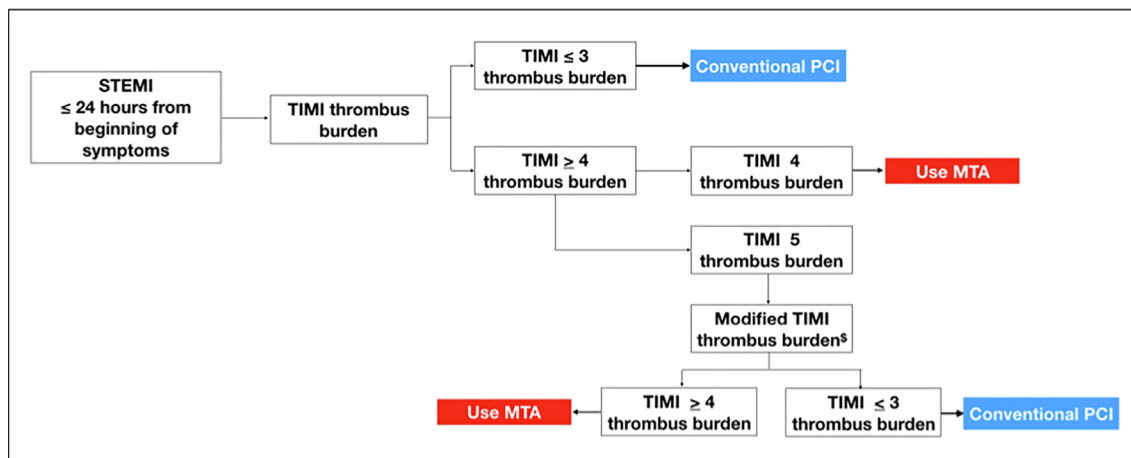
Comparison of the MTA group versus the Non-MTA group, according to the thrombus burden classified by the TIMI and modified TIMI scales.

Variable	MTA Group N = 52	Non-MTA Group N = 121
<i>TIMI Thrombus Burden</i>		
TIMI 0; n (%)	0	14 (11.5)
TIMI 1; n (%)	0	27 (22.3)
TIMI 2; n (%)	0	28 (23.1)
TIMI 3; n (%)	1 (1.9)	4 (3.3)
TIMI 4; n (%)	5 (9.6)	13 (10.7)
TIMI 5; n (%)	46 (88.4)	35 (28.9)
Low thrombus burden $\leq 3n$ (%)	1 (1.9)	73 (60.3)
High thrombus burden $\geq 4n$ (%)*	51 (98.1)	48 (39.7)
<i>Modified TIMI Thrombus Burden</i>		
Grade 0; n (%)	0	2 (10.5)
Grade 1–3; n (%)	1 (3)	6 (31.5)
Grade 4; n (%)	17 (51.5)	1 (5.2)
Persistent grade 5 TIMI; n (%)	15 (45.5)	10 (52.6)
Low thrombus burden \leq Grade 3; n (%)	1 (3.4)	8 (42.1)
High thrombus burden \geq Grade 4; n (%)**	32 (96.6)	11 (57.8)

* Statistically significant association between a high thrombus burden (thrombus Grade ≥ 4) and the use of MTA ($p < 0.0001$).

** Statistically significant association between a high thrombus burden on the modified TIMI scale (thrombus Grade ≥ 4) and the use of MTA ($p < 0.0007$).

was achieved in 68% of the patients in the MTA group versus 80% of the Non-MTA group. In patients with a high thrombus burden there was also no significant difference between the groups in final TIMI flow ($p = 0.564$) and myocardial blush ($p = 0.427$). The no-reflow phenomenon presented in fewer than 20% of cases in both groups, and there were no significant differences overall ($p = 0.789$), nor in patients with a high thrombus burden ($p = 0.525$) (Supplementary Table 2). We also evaluated secondary outcomes in subgroups with different baseline characteristics and high thrombus burden (eg. time elapsed from beginning of



[§] Modified TIMI thrombus grading scale which is applied after guidewire insertion or pre-dilatation with a small, 1.5 mm angioplasty balloon.

Fig. 2. Proposed algorithm for the use of MTA.

symptoms, target vessel, and American Heart Association type of lesion) without significant differences. There were no ischemic strokes or deaths due to cardiovascular causes in the MTA group during hospitalization. Meanwhile, in the Non-MTA group, there were three deaths due to cardiovascular causes and two ischemic strokes. The rate of bleeding, as classified by the BARC scale, was less than 8% in both groups.

4. Discussion

Our study found a statistically significant association between a high thrombus burden and the use of MTA in patients with STEMI undergoing percutaneous coronary intervention. There was a high thrombus burden, defined in this study as a TIMI grade ≥ 4 , in 98% of the patients who underwent MTA, while in the Trial of Routine Aspiration Thrombectomy with PCI versus PCI Alone in Patients with STEMI (TOTAL) and Thrombus Aspiration in ST-Elevation Myocardial Infarction in Scandinavia (TASTE) studies, the percentage of patients with this thrombus burden on whom MTA was performed was 79% and 32%, respectively. With regard to the Non-MTA group, a high thrombus burden was found in only 39.6%, compared with 79% of the patients in the TOTAL study and 29% of the patients in the TASTE study [5,9]. In the Thrombus Aspiration during Percutaneous Coronary Intervention in Acute Myocardial Infarction Study (TAPAS), there was no classification of thrombus burden, simply a description of whether or not there was a visible thrombus, which was present in 48.6% of the patients undergoing MTA, versus 44% in the Non-MTA group [8]. This difference in thrombus burden in the various studies may be due to the mainly random methodology of the routine use of MTA, which could have, in turn, influenced the non-significant final clinical results.

Although the TIMI thrombus grade classification is universally accepted, the precision of grade 5 for determining the actual thrombus burden is debated, since the histological relationship of the amount of atherosclerotic plaque and the thrombus burden is unknown. Therefore, it is not strictly true that there must always be a high thrombus burden when there is a total occlusion [13]. Thus, in our study, we analyzed the modified TIMI thrombus grading scale which is applied after guidewire insertion or pre-dilatation with a small, 1.5 mm angioplasty balloon [10,11,14]. In this reclassification, a high thrombus burden was defined as a TIMI grade ≥ 4 or a persistent grade 5. A total of 52 patients were able

to be evaluated, of whom 33 belonged to the MTA group and 19 to the Non-MTA group. The percentage of patients in the MTA group with a modified thrombus burden ≥ 4 was 96%, compared to 57.8% in the Non-MTA group, indicating that almost 42% of the patients with a TIMI 5 thrombus burden in the PCI group were reclassified as a lower thrombus burden, and the reason for not using the MTA technique could lie in these patients. Recently, high thrombus burden was analyzed in the TOTAL trial, where the routine use of MTA versus PCI in patients with a high thrombus burden (>3 or >4) did not show any improvement in the outcome composed of death due to cardiovascular causes, recurrent myocardial infarction, shock or heart failure at 30 days [15].

In 100% of the patients on whom MTA was used, the symptoms began during the 24 h prior to hospital admission, which matches the studies where the time to consultation is approximately within the first three hours after the beginning of symptoms. It is important to clarify that the arrival times of patients with STEMI in our study reflect the reality of the population of centers with installed capacity for PCI in our country, which is not comparable with randomized studies performed in other countries. In our study, the percentage of patients who received pharmacologic reperfusion therapy prior to PCI was 11% in the MTA group versus 31% in the Non-MTA group, while in the TASTE study the percentage was much lower, only 1.9%. Meanwhile, in the TOTAL study, these patients were not eligible [5,9].

The use of glycoprotein IIb/IIIa (GpIIb/IIIa) inhibitors was greater in the MTA group (65.3%), contrasting with TASTE and TOTAL, in which the use of these medications was 15.4% and 37.5%, respectively. In addition, they were only used in 32% of the patients with a high thrombus burden [5,6,9]. This could be important due to the possible synergy shown by INFUSE-AMI between the use of GpIIb/IIIa inhibitors and thrombus aspiration, decreasing the size of the infarction measured by magnetic resonance [16].

The clinical outcomes of cardiovascular deaths and ischemic strokes were only determined during hospitalization, which makes it difficult to compare them with results from other studies in which follow up was for at least 30 and 180 days, and even up to one year [17,18]. However, the lack of ischemic strokes in the MTA group indicates that this therapy can be safe, as long as it is carried out in the population that requires it. It should also be pointed out that not all ischemic stroke risk should be attributed

to this type of intervention, given that the risk of events between days 90–180 in the TOTAL study continued to be greater in the group which employed MTA; thus, there is currently no precise explanation of this risk beyond chance [19]. In respect to the Non-MTA group, the rate of cardiovascular deaths and ischemic strokes was 2.4% and 1.6%, respectively. This result concurs with the TASTE data which reported a cardiovascular death rate of 3% and a 0.5% ischemic stroke rate, and the TOTAL data which reported a 3.5% and 0.3% rate at 180 days [5,9].

These results can only propose future hypotheses for determining if patients benefit or not from MTA. There is still no established pathway for determining its use in patients with STEMI, in spite of the fact that the 2017 European guidelines clarified that it could be useful in patients with a high thrombus burden (TIMI grade ≥ 3). This was based on a meta-analysis which showed a benefit from thrombus aspiration in significantly reducing cardiovascular mortality, despite a greater probability of ischemic strokes. In this meta-analysis, when the results were evaluated with a thrombus burden ≥ 4 , there was no statistically significant difference in the cardiovascular mortality outcome [3,6]. In spite of this, in our study, a high thrombus burden was classified as ≥ 4 , bearing in mind that in the modified TIMI thrombus classification this grade is defined as a large residual thrombus [10,14].

Algorithms have been described for determining the use of MTA. However, they are prior to the latest studies, and although they take into account both flow and thrombus burden [20], we propose this diagram for determining the use of manual thrombus aspiration based solely on thrombus burden (Fig. 2).

The main limitation of this study is its retrospective nature, in a single center, as well as the sample size. This means that the inference capacity of this study is limited to the subjects included in the analysis, and therefore it is not possible to extrapolate the results to other populations or make clinical decisions based on its results. Another limitation is the difference in time to intervention following STEMI, however, this represents the actual situation in developing regions. Although, we performed additional analysis of secondary outcomes in different subgroups of patients with high thrombus burden we did not find any significant difference; still, probably further prospective analysis could demonstrate benefit with this technique in this type of patients.

5. Conclusion

A high thrombus burden, classified according to the TIMI and modified TIMI scales, is significantly associated with the use of manual thrombus aspiration in our hospital, without this technique being related to an increase in cardiovascular deaths or ischemic strokes.

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The authors report no conflict of interest or funding for the current manuscript. The authors declared also that there are no additional disclosures to report.

Appendix A. Supplementary material

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.ijcha.2019.100436>.

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