Acute myocardial infarction treatment : from prehospital care to secondary prevention
Atary, J.Z.

Aspiration thrombectomy during primary percutaneous coronary intervention as adjunctive therapy to early (in-ambulance) abciximab administration in patients with acute ST elevation myocardial infarction: An analysis from Leiden MISSION! acute myocardial infarction treatment optimization program.

Tarek A. N. Ahmed[1,2], MD; Jael Z. Atary[1], MD; Ron Wolterbeek[3], MD; Hosam Hasan Ali, MD,PhD[2]; Samir S. Abdel-Kader[2], MD,PhD; Martin J. Schalij[1],MD,PhD; and J. Wouter Jukema[1]*, MD,PhD

[1] Department of Cardiology, Leiden University Medical Center, Leiden, The Netherlands
[2] Department of Cardiology, Assiut University, Assiut, Egypt
[3] Department of Medical Statistics, Leiden University Medical Center, Leiden, The Netherlands

ABSTRACT

Background

The benefits of early abciximab administration and thrombus aspiration in STEMI patients undergoing PPCI have been previously elaborated. However, whether there is adjunctive effect of thrombus aspiration among STEMI patients, with angiographic evidence of thrombus, receiving early abciximab prior to hospital arrival remains unclear. Methods

In the context of a fixed protocol for PPCI, 158 consecutive patients with STEMI were enrolled, in whom abciximab was started early before arrival at the hospital (in-ambulance); 79 patients who had PPCI with thrombus aspiration (thrombectomy-facilitated PCI group), were compared to 79 who had PPCI without thrombus aspiration (Conventional PCI group) in a prospective non-randomized study. The primary end point was complete ST-segment resolution within 90min. Secondary endpoints included enzymatic infarct size as well as LVEF assessed by Gated-SPECT. MACE were evaluated up to 12 months.

Results

Both groups were comparable for baseline clinical and angiographic characteristics. The rate of ST-segment resolution was significantly higher in the thrombectomy-facilitated group (p=0.002), and multivariable logistic regression analysis identified only thrombectomy as an independent predictor of ST-segment resolution (odds ratio= 6.7, 95% CI = 2.4-18.4, p< 0.001). No difference was observed between both groups in enzymatic infarct size assessed by peak CK (p=0.8), and peak Tn-T levels (p=0.5). Also the LVEF at 3-months was similar (p=0.9). At 12 month clinical follow-up, thrombus aspiration was however associated with reduced all-cause mortality (log-rank p= 0.03). Conclusion

Among STEMI patients treated with PPCI and in-ambulance abciximab, it appears that a selective strategy of thrombus aspiration still has additive benefit.

INTRODUCTION

It has been widely observed that primary percutaneous coronary intervention (PPCI) offers greater reperfusion benefits in the setting of acute myocardial infarction (MI) compared to intravenous thrombolytic therapy.[1] However, despite a good epicardial flow after PPCI, a considerable percentage of patients have impaired myocardial perfusion mainly due to embolization of the microcirculation.[2] Poor myocardial reperfusion is associated with adverse outcome including reduced left ventricular function and mortality.[3-5]

Recent studies demonstrated that GP IIb,IIIa platelet receptor antagonists have positive effects on reperfusion in the setting of primary percutaneous coronary interventions, with improved clinical outcome.[6] Many studies showed that these benefits are more apparent when GP IIb IIIa platelet receptor antagonists are introduced as early as achievable in the setting of acute myocardial infarction.[7-12]

Additionally, numerous adjunctive coronary devices have been developed in an attempt to decrease or prevent distal embolization during revascularization and thereby trying to improve clinical outcome as well.

Recent randomized trials demonstrated that patients treated with a thrombectomy catheter showed better angiographic and electrocardiographic signs of myocardial reperfusion, as well as improved 1 year clinical outcome.[13-16] These data have been confirmed by recent meta-analyses demonstrating that adjunctive manual thrombectomy in the setting of primary PCI is associated with improved epicardial and myocardial perfusion, less distal embolization [17], as well as improved clinical outcome.[18]

However, it is still unknown whether there is a possible benefit of using thrombus aspiration devices in the setting of PPCI among STEMI patients receiving early GP IIb IIIa platelet receptor antagonists. Therefore, in this study the results of adjunctive manual thrombus aspiration using aspiration thrombectomy catheter were compared to no thrombus aspiration in a consecutive group of STEMI patients treated with PPCI and early "in-ambulance" abciximab administration according to the adapted Mission protocol.[19,20]

METHODS

Study design

This is a single center non-randomized prospective study. All patients were treated according to the institutional STEMI protocol (MISSION!) implemented at Leiden University Medical Centre (LUMC) since February 2004, which includes a standardized prehospital, in-hospital and outpatient clinical framework for decision making and treatment.[19,20] The tertiary center provides a round-the-clock service of PPCI with highly experienced PCI physicians and dedicated nurses.

Inclusion and exclusion criteria

The inclusion criterion was a diagnosis of acute MI defined by chest pain suggestive of myocardial ischemia for at least 30 minutes, with a time from onset of symptoms of <9 hours before hospital admission, and an ECG with ST-segment elevation of >0.1 mV in ≥2 leads. Exclusion criteria were recent surgery, recent stroke, hemorrhagic diatheses, and known contraindications for therapy with abciximab, aspirin, clopidogrel or heparin.

Study groups

A total of 158 consecutive patients; who fulfilled the inclusion and exclusion criteria for this study, and who received early in-ambulance abciximab, were enrolled: 79 consecutive patients, in whom a thrombectomy catheter was used at the start of the procedure (the thrombectomy facilitated PCI group); were compared to 79 consecutive patients within the same period, in whom thrombectomy catheter was not used (the conventional PCI group). The study complies with the Declaration of Helsinki. The MISSION! protocol has been approved by the local ethics committee.

Medication

All patients received abciximab (Centocor B.V., Leiden, The Netherlands) as a bolus injection of 0.25 mg/ kg bodyweight, followed by 0.125 mcg/kg/min with a maximum of 10 mcg/min as a continuous infusion for 12 hr. Abciximab administration started early in the ambulance according to the adapted MISSION! Protocol.[19,20] Furthermore all patients received an equivalent of 300 mg of acetylsalicylic acid, 600 mg clopidogrel as a loading dose in the ambulance and heparin given as a bolus of 5000 IU at the start of the PCI procedure. After the procedure, all patients received aspirin (75 mg/day) indefinitely and clopidogrel (75 mg/day) for one year. Other medications, including b-blockers, ACE-inhibitors, nitrates, and statins, were prescribed according to MISSION! protocol.

Invasive Procedure and Angiographic Evaluation

All PPCI was performed through a 6F femoral sheath. Patients underwent PPCI and stenting of the IRA according to standard techniques. The choice of stent (bare-metal stent or drug-eluting stent) was left to the operator's discretion. Direct stenting, which is stent placement without balloon pre-dilatation, was performed only in cases presenting clear views of the arterial lesion with adequate flow. We also considered stent placement which was only preceded by thrombectomy as direct stenting. Otherwise, the patient was subjected to balloon angioplasty and stenting was done subsequently. The choice of the balloon size was left to the operator's decision. Stent implantation was successfully completed in all patients, apart from only one patient in the thrombectomy facilitated PCI group where the procedure was complicated by a spiral dissection occurring after thrombectomy and had to undergo emergency coronary artery bypass graft (CABG), and this patient survived and completed the

follow-up period. The choice of performing thrombectomy was left to the operator's discretion. Thrombectomy was often, but not exclusively, performed when high thrombus burden was observed at the initial angiographic image of the target vessel. There was no change in the frequency of use of thrombectomy over the time period of the study. Thrombus was assessed according to the criteria summarized by Mabin et al.[21] These criteria include the presence of an intraluminal central filling defect or lucency surrounded by contrast material that is seen in multiple projections; the absence of calcium within the defect; and persistence of contrast material within the lumen. Thrombus score was graded as previously described by the TIMI Study Group.[22,23] We further categorized the thrombus score into 2 overall grades; a high thrombus grade (grades 4 and 5), and a low thrombus grade (grades 1-3). We decided to use this cut-off value in line with 2 recent studies[24,25] suggesting prognostic implications of this cutoff. Coronary flow was graded according to thrombolysis in myocardial infarction (TIMI) criteria.[26] TIMI flow grade was evaluated at baseline and after the PCI procedure. Procedural success was defined as residual stenosis <20% and TIMI flow grade 3. The coronary angiograms were reviewed off-line by two independent interventional cardiologists who were blinded to the clinical data.

Thrombectomy catheter

The Export Aspiration Catheter (Medtronic Corporation, USA) is a 6F thrombus aspiration catheter.[13] Thrombosuction was started proximal to the occluded site, gently pushing the catheter through the occlusion and then pulling it in a proximal direction, keeping negative pressure once the occlusion was crossed or if there was no longer backflow in the syringe. This could be repeated several times. Withdrawal of the catheter from the artery and from the guiding catheter was performed with permanent negative pressure. After each pass the catheter was flushed and the syringe emptied over a filter, to show the retrieved debris.

End-points and clinical follow-up

According to the MISSION! Protocol all patients were seen at the dedicated out-patient clinic after 1, 3, 6, and 12 months. The primary endpoint was ST-segment resolution within 90 min. after PPCI; secondary endpoints were enzymatic infarct size and LVEF as assessed by Gated-SPECT. Also major adverse cardiac events (MACE) occurring within one year of follow-up were recorded. These include all-cause death, cardiac death, reinfarction, target vessel and target lesion revascularization; death was regarded as cardiac unless an unequivocal non-cardiac cause of death was established. Reinfarction was defined as recurrent symptoms with new ST-segment elevation and elevation of cardiac markers to at least twice the upper limit of normal. Target vessel (TVR) and target lesion (TLR) revascularization were defined as any revascularization procedure of the target vessel or target lesion (from 5 mm distally to the stent up to 5 mm proximally to the stent), respectively. All major adverse cardiac events were assessed and classified by an interventional cardiologist unaware of the treatment allocation.

Electrocardiographic data

The 12-lead ECG was recorded at presentation and within 90 min after PPCI. The magnitude of ST-segment elevation is measured 60 milliseconds from J point. ST-segment score is calculated as the sum of ST-segment elevation > 0.1 mV for leads V1 through V6 and I, II, and aVL in anterior infarction and I, II, aVF, V5, and V6 in non-anterior infarction (27). All ECGs were collected and analyzed by an investigator blinded to the assigned treatment. Total ST-segment elevation at inclusion was compared with that taken within 90 min after PPCI. A complete ST-segment resolution was calculated, defined as resolution of the initial ST-segment elevation of ≥70%.[28]

Enzymatic Infarct Size

Creatine kinase (CK) activity and cardiac troponin-T (Tn-T) concentration in plasma were determined at admission and every 6 hr in the first 48 hr after PPCI. Subsequently these levels were determined every day up to discharge, unless clinical events suggested repeat measurements. Peak levels of CK and Tn-T in plasma were calculated as a measure of infarct size in each patient by an investigator blinded to the assigned treatment.
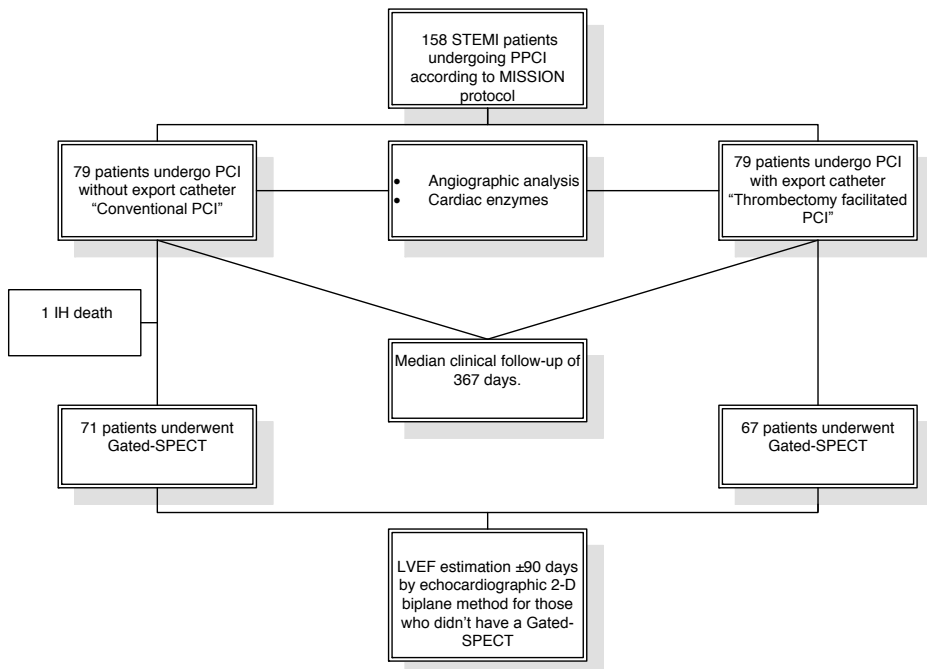
Figure 1. Flow diagram of the study patients.
LVEF: left ventricular ejection fraction; PPCI: primary percutaneous coronary intervention; SPECT: single photon emission computed tomography; STEMI: ST elevation myocardial infarction; IH: in hospital.

Myocardial Perfusion Imaging

According to the MISSION! Protocol all included patients were enrolled for a myocardial perfusion study at 90 days post-PPCI. An ECG gated SPECT acquisition at rest using intravenous Technetium 99 m Tetrofosmin (MYOVIEW, Amersham, Buckinghamshire, UK) was used to measure the left ventricular ejection fraction (LVEF) 90 days after PPCI. LVEF was calculated using an automated and validated method (QGS software, version 2.0; Cedars-Sinai Medical Center, Los Angeles, CA, USA). Detailed methods are described elsewhere.[29] Patients in whom the gated SPECT could not be performed due to technical difficulties, LVEF estimated by echocardiographic biplane method was used instead. LVEF assessment was done by an investigator blinded to the assigned treatment.

Statistical analysis

Categorical variables were compared using the X^2 test or Fisher's exact test. Continuous normally distributed data were tested by student t-test or in the case of a non-Gaussian distribution by a nonparametric test for independent samples (Mann Whitney U test). One year clinical outcomes were analyzed using Kaplan Meier methodology and were compared with log-rank test pooled over strata. Multivariable linear regression and logistic regression analyses were used to create models for both PCI groups (as the variable of interest) corrected for thrombus grade, infarct related artery, proximal location of the culprit lesion and symptoms to balloon time (as potential confounders), to identify whether thrombectomy is an independent predictor for the end points of ST-segment resolution, infarct size assessed by cardiac enzymes or LVEF. All tests were two-sided, and a p-value of < 0.05 was considered significant. All analyses were performed with PASW version 17.0 statistical software (SPSS Inc. - An IBM Company, Chicago, IL, USA).

RESULTS

Study population

One-hundred and fifty-eight patients were included in the study according to the eligibility criteria (Figure 1 Flow diagram). The baseline clinical characteristics were comparable between the two groups (Table 1).

Angiographic and peri-procedural findings

Angiographic and procedural data are summarized in Table 2. There was a significantly higher rate of high grade thrombus in the thrombectomy facilitated group (p<0.001), also there was a significantly higher rate of balloon predilatation in the conventional PCI group (p= 0.002).

Table 1. Baseline characteristics.

	Conventional PCI N=79	Thrombus aspiration N=79	p
Age in years	59±10	56±12	0.1[a]
Male, n (%)	59(75)	62(78)	0.6[b]
History, n (%)			
Hypertension	28(35)	24(30)	0.5[b]
Hypercholesterolemia	17(21)	24(30)	0.2[b]
Smoking	53(67)	49(62)	0.7[b]
Family history	31(39)	36(45)	0.4[b]
Diabetes mellitus	7(9)	6(8)	0.7[b]
Previous MI	8(10)	8(10)	1.0[b]
Previous PCI	5(6)	7(9)	0.5[b]
Previous CABG	1(1)	4(5)	0.2[b]
Symptoms to balloon (min)	135(90-195)	140(93-225)	0.7[c]
Previous aspirin	16(20)	10(13)	0.2[b]
Previous clopidogrel	0(0)	1(1)	1.0[b]
Previous statins	12(15)	13(16)	0.8[b]

Data are presented as mean ± standard deviation, number (%) of patients or median (Interquartile range).

MI, myocardial infarction; PCI, percutaneous coronary intervention; CABG, coronary artery bypass grafting. Hypercholesterolemia= Total cholesterol ≥190 mg/dl or previous pharmacological treatment. Hypertension = Blood pressure ≥140/90 mm Hg or previous pharmacological treatment.

[a] Compared using unpaired t test.
[b] Compared using Chi-square or Fisher exact test.
[c] Compared using Mann-Whitney U test.

Electrocardiographic evaluation:

The rate of post-PCI complete ST-segment resolution of ≥ 70% was observed more frequently in the thrombectomy facilitated PCI group (87% vs. 65%, p=0.002) (Table 3).

Multivariable logistic regression analysis using the aforementioned potentially relevant factors identified only aspiration thrombectomy as an independent predictor of complete ST-segment resolution within 90 min. Post-PPCI (odds ratio= 6.7, 95% CI = 2.4-18.4, p< 0.001).

Enzymatic infarct size assessment

Peak levels of CK and Troponin-T were comparable in both PCI groups (p = 0.8 and 0.5, respectively) (Table 3.). Multivariable linear regression analysis for Peak levels of CK and Tn-T including the aforementioned factors did not identify PCI groups as an independent predictor of higher peak CK (B = 186.3, 95% CI= -515.1 – 887.6, p=0.6) and Troponin T (B = 2.04, 95% CI= -0.51 – 4.58, p=0.1).

Table 2. Angiographic and procedural results.

	Conventional PCI N=79	Thrombus Aspiration N=79	P
Infarct related artery, n (%)			0.2[b]
Left main a.	1(1)	2(2)	
Left anterior descending a.	31(39)	28(35)	
Circumflex a.	15(19)	7(9)	
Right coronary a.	32(40)	42(53)	
Diseased vessels, n (%)			0.2[b]
1-vessel	44(56)	48(61)	
2-vessel	26(33)	28(35)	
3-vessel	9(11)	3(4)	
Proximal culprit lesion, n (%)	35(44)	40(50)	0.4[b]
Abciximab	78(98.7)	79(100)	0.9[b]
Initial TIMI flow grade, n (%)			0.8[b]
0	41(52)	39(49)	
1	14(18)	15(19)	
2	13(16)	17(21)	
3	11(14)	8(10)	
Final TIMI flow grade, n (%)			0.3[b]
1	0(0)	2(2)	
2	11(14)	13(16)	
3	68(86)	64(81)	
Drug eluting stents, n (%)	45(57)	52(70)	0.1[b]
Stent number	1.5±0.7	1.5±1.0	0.8[a]
Multiple stents, n (%)	31(39)	24(32)	0.4[b]
Predilatation, n (%)	66(83)	49(62)	0.002[b]
Thrombus detected, n (%)	75(95)	78 (98.5)	0.8[b]
Thrombus grade, n (%)			<0.001[b]
High thrombus grade (Grades 4, 5)	29(39)	65(83)	
Low thrombus grade (Grades 1, 2, 3)	46(61)	13(17)	

Data are presented as mean ± standard deviation, number (%) of patients.
TIMI, Thrombolysis In Myocardial Infarction.
[a] Compared using unpaired t test. [b] Compared using Chi-square or Fisher exact test.

Three-month LV function evaluation

One-hundred and thirty-eight patients underwent LV function assessment by myocardial perfusion scintigraphy (MYOVIEW) (Figure 1). Patients who did not undergo scintigraphy had their LV function assessed using biplane 2-D echocardiographic evaluation at 3 months, and one patient had unavailable data regarding the LV function assessment post-PCI due to in-hospital death. LVEF was not significantly different between both groups (p=0.9) (Table 4).

Multivariable linear regression analysis including the aforementioned factors did not identify PCI groups as an independent predictor of improved LVEF (B = -1.8, 95% CI= -6.5 – 2.9, p=0.5).

Table 3. Postprocedural electrocardiographic and laboratory results.

	Conventional PCI N=79	Thrombus aspiration N=79	p
90-min. complete ST-segment resolution, (%)	45/69(65)	66/76(87)	0.002[b]
Peak CK (U/l)	2095±1873	2286±2168	0.8[a]
Peak Tn-T(µg/l)	6.2±8.5	5.8±6.1	0.5[a]

Data are presented as mean ± standard deviation, number (%) of patients
CK, creatine kinase; Tn-T, Troponin T.
[a] Compared using Mann-Whitney U test.
[b] Compared using Chi-square or Fisher exact test.

Table 4. Three months scintigraphic and 1-year clinical outcomes.

	Conventional PCI N=79	Thrombus aspiration N=79	p
LVEF by Gated-SPECT	53.35±13.8	53.46±11.8	0.9[a]
Clinical follow up period	368(362-397)	367(188-391)	0.1[c]
Clinical end-points, n (%):			
Cardiac death	3(4)	0(0)	0.08[b]
All-cause death	5(6)	0(0)	0.02[b]
Reinfarction	2(0)	0(0)	0.1[b]
TVR	3(4)	5(6)	0.7[b]
TLR	4(5)	2(2)	0.6[b]
MACEs	10(13)	7(9)	0.4[b]

Data are presented as mean ± standard deviation, number (%) of patients or median (Interquartile range).
LVEF, left ventricular ejection fraction; SPECT; Single Photon Emission Computed Tomography; TVR, target vessel revascularization; TLR, target lesion revascularization; MACE, Major adverse cardiac events.
[a] Compared using unpaired t test.
[b] Compared using Chi-square or Fisher exact test.
[c] Compared using Mann-Whitney U test.

Clinical outcomes

All patients were followed for a median of 367 days, 5 patients died in the conventional PCI group (including one in-hospital death) vs. 0 patients in the thrombectomy facilitated PCI group (p= 0.02), three (4%) of those deaths were cardiac (p=0.08). The 2 non-cardiac deaths were due to hepatic failure and terminal renal failure. Three (4%) patients underwent a target vessel revascularization in the conventional PCI group vs. 5(6%) patients in the

thrombectomy facilitated group (p= 0.7). Target lesion revascularization occurred in 4(5%) patients in the conventional PCI group vs. 2(2%) patients in the thrombectomy facilitated group (p= 0.6). Recurrent myocardial infarction occurred in 2 patients in the conventional PCI group vs. 0 patients in the thrombectomy facilitated group (p= 0.1). Overall MACE occurred in 10(13%) patients in the conventional PCI group vs. 7(9%) in the thrombectomy facilitated group (p= 0.4) (Table 4).The Kaplan-Meier curves showed that allocation to thrombectomy was associated with a significant reduction in 1-year all-cause mortality (log-rank p= 0.03); (Figure 2), and a trend towards a reduction of the combined endpoint of cardiac death or reinfarction (log-rank p= 0.056); (Figure 3)
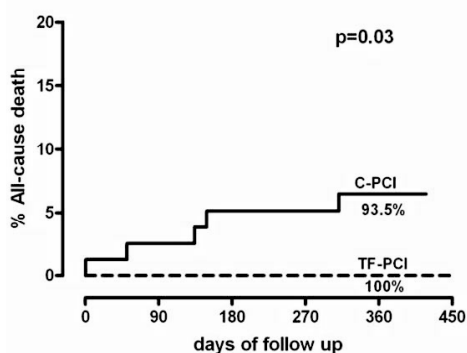
Figure 2. Kaplan-Meier 12 month cumulative event free survival from the endpoint of all-cause death.
TF-PCI: Thrombectomy facilitated PCI group; C-PCI: conventional PCI group.
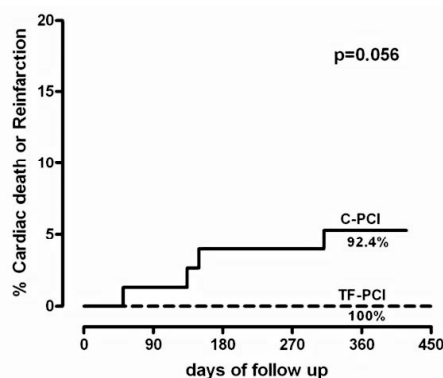
Figure 3. Kaplan-Meier 12 month cumulative event free survival from the combined endpoint of cardiac death or reinfarction. TF-PCI: Thrombectomy facilitated PCI group, C-PCI: conventional PCI group.

DISCUSSION

The main findings of this study are: 1) A strategy of thrombus aspiration before stenting during primary PCI among patients treated with early abciximab was associated with a higher rate of complete ST-segment resolution ($\geq$ 70%) within 90 min post-PCI. 2) Thrombus aspiration was associated with a lower incidence of all-cause mortality, and a trend towards a lower incidence of combined end-point of cardiac death or reinfarction through a 1-year median clinical follow up. TVR, TLR and overall MACE were similar in both groups.

Unlike the TAPAS trial [16], where abciximab was administered during the procedure of PPCI, our study provides a unique experience of the adjunctive influence of thrombus aspiration to early abciximab administration before PPCI. In the ATTEMPT study [18], Burzotta and colleagues have interestingly shown that the benefit of thrombectomy was

more evident in patients who received IIb,IIIa-inhibitors thus suggesting a possible additive benefit of thrombectomy in patients treated with IIb,IIIa-inhibitors. It might be speculated that pharmacological and mechanical thrombus remodeling are synergic to obtain the best myocardial reperfusion and, consequently, the best clinical outcome. Indeed, in the ATTEMPT study, patients treated by both thrombectomy and IIb,IIIa-inhibitors had the lowest mortality rate, those who had none of these treatments had the highest mortality rate, while patients receiving only one of these therapies exhibiting intermediate outcome. On the other hand, in the VAMPIRE trial[40], where GP IIb,IIIa receptor antagonists were not used at all, patients presenting late after STEMI (>6 hours after symptoms) appeared to benefit the most from thrombectomy, suggesting that the use of GP IIb,IIIa receptor antagonists would have influenced the results. In our study, patients received abciximab prior to PCI, where abciximab was started before the arrival to the hospital. The benefits of this has been investigated in previous RCTs[7,8,10-12], and in the study conducted by Hassan et al [9] in the context of the MISSION protocol, where it has been found that very early administration of abciximab (in-ambulance) significantly improves early reperfusion in STEMI patients treated with PPCI, this was also reflected clinically with smaller infarct size, improved LV function and a lower risk of heart failure on follow up. This may explain why some of our study outcomes including enzymatic infarct size, LVEF, and some of the clinical end-points did not differ between the 2 groups, as it is likely that the early abciximab administration supersedes the influence of thrombectomy catheter.

Procedural characteristics

In the current study there was a significantly higher rate of direct stenting among the thrombectomy facilitated group, a finding which is consistent with other randomized controlled trials.[13,14,16,30-34] This can be explained by the fact that thrombus aspiration establishes a better antegrade coronary flow which allows selection and placement of a stent of appropriate length and diameter without the need for further balloon predilatation.

ST-segment resolution

The effect of manual thrombus aspiration on the surrogate markers of myocardial reperfusion has been widely discussed in many studies. ST-segment resolution post-PCI is one of the most widely used and assessed markers. In our study there was a significantly higher rate of complete ST-segment resolution within 90 min in the thrombectomy facilitated PCI group. This outcome is in accordance with some previous randomized controlled trials (RCTs)[14,16,31,34-37], and two recent large meta-analyses[38,39] On the other hand, some other RCTs revealed no significant difference in the rate of ST-segment resolution among both randomized groups.[13,30,33,40,41]

Enzymatic infarct size:

In our study there was no significant difference between both study groups regarding the enzymatic infarct size as estimated by peak levels of CK and Tn-T. Several trials assessing thrombus aspiration devices measured infarct size using biochemical markers with variable results. The largest study published to date, using the Export catheter system, the TAPAS trial, also showed no difference in peak CK and CKMB levels between groups with and without thrombus aspiration.[16]. The same was also noted in the EXPIRIA trial.[14] On the contrary, it has been noted by Kaltoft and colleagues in their randomized trial that peak Tn-T was significantly higher in the thrombus aspiration group [41], a result that has also been reported in the randomized trial by Anderson and colleagues.[42]

Left ventricular ejection fraction (LVEF)

There is a variety of conflicting data about the effect of thrombus aspiration on the infarct size which is the best surrogate end point for the assessment of new therapeutic tools in the setting of acute myocardial infarction[43,44], and which is reflected by improved LV systolic function. In our study there was no benefit in terms of LVEF after thrombus aspiration, which is consistent with some previous trials.[14,30,31,33,40-42,45] Other trials showed different results from our study.[36,46]

Clinical follow-up

In our study clinical data of the patients were available for a relatively long follow-up period (around 1 year), revealing that allocation to export aspiration thrombectomy was associated with lower incidence of all-cause mortality, in accordance with the findings of the 2 large RCTs using the export catheter; TAPAS[16] and EXPIRIA[14], the meta-analysis conducted by Bavry and colleagues[38], and the large patient-data pooled analysis; ATTEMPT study.[18] In our study also there was a trend towards lower incidence of the combined end-points of cardiac death or re-infarction, in agreement with TAPAS trial[16] and ATTEMPT study.[18] On the other hand, the incidence of cardiac death in our study was not different between both groups, unlike the findings in the TAPAS[16] and EXPIRIA[14] trials; however the large meta-analysis presented by Bavry et al[38], as well as the ATTEMPT study [18] only showed benefits in terms of all-cause mortality and not in cardiac mortality, moreover in the TAPAS trial[16] analysis of cardiac death after 30 days showed no significant difference between export aspiration group and conventional PCI group. Our study, in consistence with the TAPAS trial[16], showed no difference between both groups regarding TVR/TLR, suggesting that thrombus aspiration has no influence on neointima hyperplasia.

Limitations

Our study is a single-center, non-randomized, prospective study. However, we tried to overcome this limitation by taking two groups of consecutive patients within the same time

period, who were comparable regarding the baseline clinical and procedural characteristics. All patients were submitted to the fixed MISSION protocol throughout the study period. This is a rigorously standardized protocol concerning pre-, peri-, and post-PPCI treatment up to 1 year[19,20], so it is unlikely that procedural changes over time would have influenced the outcome.

In our study, there was a higher tendency to use the thrombus aspiration catheter in patients with higher thrombus grades. In Kishi et al[47], the size of the thrombus was not a predictor of no-reflow phenomenon or distal embolization. Moreover, in our study there was comparable base-line TIMI flow rate between both groups (TIMI flow 0 was 52% in the conventional PCI group vs. 49% in the export facilitated PCI group).

Better techniques are required to analyze the thrombus burden, especially with the fact that most of the patients are presented with totally occluded infarct related artery on the initial angiography which limits the analysis of the thrombus burden; most of those patients subtend large thrombus burden but still some do not.

CONCLUSION

Among STEMI patients treated with PPCI and receiving early (in-ambulance) abciximab, it appears that the adjunctive use of manual thrombectomy significantly improves post-procedural ST-segment resolution, and may be associated with a lower clinical event rate. Therefore, although no benefit was observed regarding the enzymatic infarct size or LV function as assessed by Gated-SPECT, it appears that a selective strategy of thrombus aspiration still has an additive benefit, even with early abciximab administration. This needs further confirmation in appropriately powered randomized trials.

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