

Value of Thrombus Aspiration Devices in Primary PCI on Intermediate and Short Term Out Come

Abstract

Aim: Is to evaluate the value of thrombus aspiration devices in primary PCI compared to conventional primary PCI on intermediate and short term follow up.

Patients and methods: The study included 60 patients with acute myocardial infarction undergoing primary PCI, all patients submitted to history taking, general and local examination, ECG before procedure and 90 min after, Echocardiography to 24th and 1 month after procedure then before diagnostic angiography was performed, patients were divided randomly into: group A: 30 patients subjected to primary PCI only and group B: 30 patients subjected to thrombectomy device before primary PCI.

Results: There was no difference between two groups as regard to age, gender, risk factors or time from symptom onset to CCU admission. There was significant improvement in the TIMI flow grade after PPCI but there was no significant difference between two groups. Thrombus aspiration was successful in achieving significant better reperfusion by myocardial blush grade (MBG) as 96% in group B had MBG ≥ 2 while only 80% in group A achieved MBG ≥ 2 ($p=0.02$). Although there was no difference in the myocardial salvage predictors as regard to TIMI flow grade 3 ($p=0.3$) or EF% ($p=0.74$) but MBG ≥ 2 and ST resolution (STR) was higher in group A ($p=0.002$ and 0.001 respectively).

Conclusion: Thrombectomy device is safe to use before PPCI and although it did not affect the TIMI flow grade or EF% it significantly, it improved the MBG and STR especially when TIMI flow grade was 0.

Keywords: Thrombus; Aspiration; Thrombectomy device

Research Article

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Shaimaa A Mostafa^{1*}, Victor Fadallah², Mohamed Mahrous¹, Khaled Elrabat¹ and Mohamed Hamoda¹

¹Department of Cardiology, Benha University Hospital, Egypt
²National Heart Institute, Egypt

***Corresponding author:** Shaimaa A Mostafa, Department of Cardiology, Benha University Hospital, Egypt, Tel: 01229122843; Email: shiamaamustafa2011@gmail.com

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Abbreviations: PPCI: Primary Percutaneous Coronary Intervention; STEMI: ST-Segment Elevation Myocardial Infarction; TVR: Target Vessel Revascularization; MACE: Major Adverse Cardiac Event; MI: Myocardial Infarction; SD: Standard Deviation; FET: Fisher's Exact Test; HS: Highly Significant; MBG: Myocardial Blush Grade

Introduction

Reperfusion of myocardial tissue is the main goal of primary percutaneous coronary intervention (PPCI) with stent implantation in the treatment of acute ST-segment elevation myocardial infarction (STEMI) [1].

Although PPCI has contributed to a dramatic reduction in cardiovascular mortality over three decades, normal myocardial perfusion is not restored in approximately one-third of these patients. Several mechanisms may contribute to myocardial reperfusion failure, in particular distal embolization of the thrombus and plaque fragments [2]. In fact, this is a possible complication during PPCI, resulting in micro vascular obstruction and no-reflow phenomenon. The presence of a visible thrombus at the time of PPCI in patients with STEMI is associated with poor procedural and clinical outcomes [2].

Aspiration thrombectomy during PPCI has been proposed to prevent embolization in order to improve these outcomes. Even though numerous international studies have been reported, there are conflicting results on the clinical impact of aspiration

thrombectomy during PPCI. In particular, data on long-term clinical outcomes are still inconsistent [3]. In this review, we have carefully analyzed literature data on thrombectomy during PPCI, taking into account the most recent studies and meta-analyses.

Aim

Is to evaluate the value of thrombus aspiration devices in primary PCI compared to conventional primary PCI on intermediate and short term follow up.

Patients and Methods

Single center controlled prospective study included 60 patients with STEMI admitted to the National heart Institute during the period from January 2014 to April 2015 to evaluate the value of thrombus aspiration devices in PCI compared to conventional primary PCI on intermediate and short term follow up.

Inclusion criteria

- Patients with symptoms suggesting acute myocardial ischemia lasting more than 30 minutes, the onset of symptoms less than 24 hours previously, and ST-segment elevation of more than 0.1 mV in two or more Leads on the ECG.
- Patients with recent onset LBBB.
- Patients eligible for primary PCI.

Exclusion criteria

- a. The performance of a rescue PCI after thrombolysis.
- b. Patients with history of CABG.
- c. The lack of informed consent.
- d. Renal failure.
- e. Liver failure.

Methods

- i. Full history taking.
 - ii. Full clinical examination.
 - iii. Laboratory investigation.
 - iv. ECG.
 - v. Echocardiography.
 - vi. Coronary angiogram with primary PCI with or without thrombus aspiration.
- A. History taking with emphasis on gender, age, risk factors, analysis of current chest pain, history of any medications.
- B. Full general and local examination for assessment of pulse and blood pressure, to detect the signs of cardiogenic shock, peripheral vascular disease or pulmonary edema. Local cardiac auscultatory findings to document the baseline findings including S3 or murmurs for risk stratification and for further follow up and to exclude mechanical complications.

Laboratory Investigations

- a. Creatine kinase MB fraction
- b. Complete blood count.
- c. Kidney function tests.
- d. Coagulation profile (PT, PTT, INR)
- e. Random Blood Glucose.

ECG

12 leads resting surface ECG using FUKUDA device with standard calibration 10 mv and speed 25 msec.

Echocardiography

Using Vivid 3 GE device probe 3 MH (was done within the first 24 hrs of admission and after 30 days to assess cardiac chamber dimensions, systolic function using the Simpson's method to measure the left ventricular ejection fraction, diastolic function, wall motion abnormalities, mitral regurgitation, presence of intracardiac thrombi and pericardial effusion.

Randomization & treatment

Before diagnostic angiography was performed, patients were divided randomly into two groups; group A: 30 patients were subjected to primary PCI only and group B: 30 patients were subjected to thrombectomy device (EXPORT, DIVER -Cor ASAP Suction catheter) before proceeding to the primary PCI.

Pharmacologic treatment before PCI included the administration of aspirin (a loading dose of 300 mg), heparin (5000 IU), and clopidogrel (a loading dose of 600 mg) and after PCI including aspirin 81 mg daily, clopidogrel (150 mg for one week then 75 mg once daily), beta-blockers, lipid lowering agents, and angiotensin converting enzyme inhibitors or angiotensin II.

For all patients the first procedural step was passing of a floppy, steerable guide wire through the target lesion. In patients of the conventional PCI group this step was followed in some cases by balloon dilatation to establish ante grade flow and sometimes was followed by direct stenting. In patients of the Thrombectomy group, this step was followed by advancing of the 6-french Aspiration Catheter (crossing profile, 0.068 in.) into the target coronary segment during continuous aspiration, balloon dilatation was done in some cases before stenting.

- I. Both TIMI flow and myocardial blush were graded on the angiograms made immediately after the primary coronary angioplasty procedure.
- II. Grading was done on cine film at 15 frames/s made in a "SIEMENS digital, GE & PHILIPS INTEGRIS" coronary imaging catheterization laboratory.
- III. In each patient, the best projection was chosen to assess the myocardial region of the infarct related coronary artery, preferably without super positioning of non-infarcted myocardium.
- IV. Angiographic runs had to be long enough to allow some filling of the venous coronary system and backflow of the contrast agent into the aorta had to be present to be certain of adequate contrast filling of the epicardial coronary artery.
- V. Angiographically identifiable thrombus was defined as the presence of a filling defect within the coronary lumen, surrounded by contrast material, seen in multiple projections and in the absence of calcium within the filling defect.

After PCI: assessment of the following

- a) In the first 24h: recurrent symptoms of ischemia with new ST elevation > 0.1 mv in 2 leads lasting at least 30 minutes.
- b) After 24h: Recurrence of ischemic symptoms and re-elevation of ST segment and or New Q waves in 2 leads or further increase in ck-MB or troponin above the upper limit of normal or increase over the previous value.
- c) At 30 days, follow up data were obtained from hospital records and through direct patient contact.
- d) Major bleeding was defined as symptomatic bleeding in a critical area or organ, bleeding causing a decrease in hemoglobin level of 2.0 m mol or more per liter or bleeding that led to blood transfusion.
- e) Re-infarction was defined as recurrent symptoms with new ST-segment elevation and elevation of the levels of cardiac markers to at least twice the upper limit of the normal range for 30 days.
- f) Target vessel revascularization (TVR) was defined as ischemia driven revascularization of the infarct-related artery

performed by means of PCI or surgery (e.g. coronary-artery bypass grafting) during the follow-up period.

g) A major adverse cardiac event (MACE) was defined as death, re-infarction or target-vessel revascularization.

Assessment of outcome: Comparison between the two groups was done regarding the following:

The primary endpoint:

- a) The post procedural frequency of a Thrombolysis in Myocardial Infarction (TIMI) flow grade 3.
- b) Left ventricular function after 30 days as detected by echocardiography.
- c) The absence of persistent ST-segment deviation, target-vessel revascularization, re-infarction, death and the combination of major adverse cardiac events by 30 days after randomization.
- d) Re-Infarction by 30 days after randomization.
- e) Heart failure: radiographic evidence of pulmonary congestion or by clinical examination demonstrating S3 gallop or basal rales.
- f) Target vessel revascularization (TVR) due to recurrence of chest pain or hospital admission due to ACS.
- g) Major bleeding: defined according to the TIMI risk scale as intracranial, retroperitoneal, or intraocular clinically overt bleeding or any bleeding requiring blood transfusion or with hemoglobin decrease > 5g/dl or (hematocrit decrease≥15%).
- h) Minor bleeding: defined as any other clinically overt bleeding not meeting the criteria for major bleeding.

i) Secondary end point: all-cause mortality.

Statistical Analysis

The collected data were summarized in terms of mean±Standard Deviation (SD) and range for quantitative data and frequency and percentage for qualitative data. Comparisons between the study groups were carried out using the t-test or the Mann-Whitney test (z), to compare quantitative data between two groups as appropriate. The test of proportion (Z-test) was used to compare two proportions and the Chi-squared test or Fisher's Exact Test (FET) to compare proportions of two or more groups as appropriate. The corresponding test statistics were calculated and the corresponding p-values were obtained. A P-value <0.05 was considered statistically significant. P-value <0.001 was considered statistically highly significant (HS), while a P-value >0.05 was considered statistically non-significant. The statistical analysis was conducted using STATA version 11.

Results

The study included 60 patients with STEMI legible for primary PCI admitted to National Heart Institute from May 2014 till January 2015 to compare the usage of thrombus aspiration devices vs conventional primary PCI on outcome. Patients were divided into 2 groups; group A: 30 patients were subjected to primary PCI only and group B: 30 patients were subjected to thrombectomy device before proceeding to the primary PCI. The mean age of the study population was 54.9±10.9 without significant difference between two groups, where the mean age in group A was 57.6±9.7 vs. 52.1±11.5 in group B (P=0.05). Also no significant difference between two groups as regard to gender (p=0.35), diabetes mellitus (p=0.43), hypertension (p=0.3) and Smoking (p=0.07) (Table 1).

Table 1: Demographic data of the study population.

Variable		Group A (n=30)	Group B (n=30)	Total (No.=60)	Test	P- Value
		%	%	%		
Age	Mean±SD; (range)	57.6±9.7; (42-80)	52.1±11.5; (31-70)	54.9±10.9; (31-60)	t= 2.00	0.05
Gender	Female	16.7	26.7	21.7	X2 0.88	0.35
	Male	83.3	73.3	78.3		
DM	No	56.7	66.7	61.7	X2 0.63	0.43
	Yes	43.3	33.3	38.3		
HTN	No	43.3	56.7	50	X2 1.07	0.3
	Yes	56.7	43.3	50		
Smoking	No	53.3	30	41.7	X2 3.36	0.07
	Yes	46.7	70	58.3		

Time from symptom onset to admission to CCU

There was no significant difference between 2 groups as regard to time from symptom onset to admission to CCU. Within the first 3 h; 23.3% of the patients were admitted (p=0.54), 22% were admitted within 3-6 h (p=0.59) and 24% were admitted after 6 h (p=0.29).

PCI data

XB guiding catheter was used in all patients who had LAD as the target artery. While JR catheter was used in those who had RCA as the target artery, floppy wire was used in 33.3% of cases, while coated wire was used in 66.7%. Predilatation was done in all cases of conventional group. Manual aspiration devices were used in all study group for aspiration devices. Implantation of

BMS was performed in 90% of patients (42% in group A and 48% in group B), 10% of patients had DES (4% in group A vs 6% in group B), 70% of patients had 1 stent (36% in group A vs 33% in group B) while 30% patients had 2 stents (16.6% in group A vs 13.3% in Group B).

The mean stent diameter was 3.2 ± 0.8 mm while the mean stent length was 15 ± 3.3 mm in both groups. The mean implantation pressure was 13.5 ± 1 ATM. Post dilatation was done in 12% of

patients due to residual stenosis relatively more in group A (7%) than in Group B (5%) with no statistical significance.

Improvement in TIMI flow grade after PPCI

There was significant improvement in the TIMI flow grade after PPCI but there was no significant difference between two groups; TIMI flow grade 0 improved from 86.7 to 1.7%, TIMI grade I from 6.7% to 1.7%, TIMI grade II from 3.3% to 6.7% and TIMI grade III from 0% to 86.7%. Figure 1-3 of patient of group B.

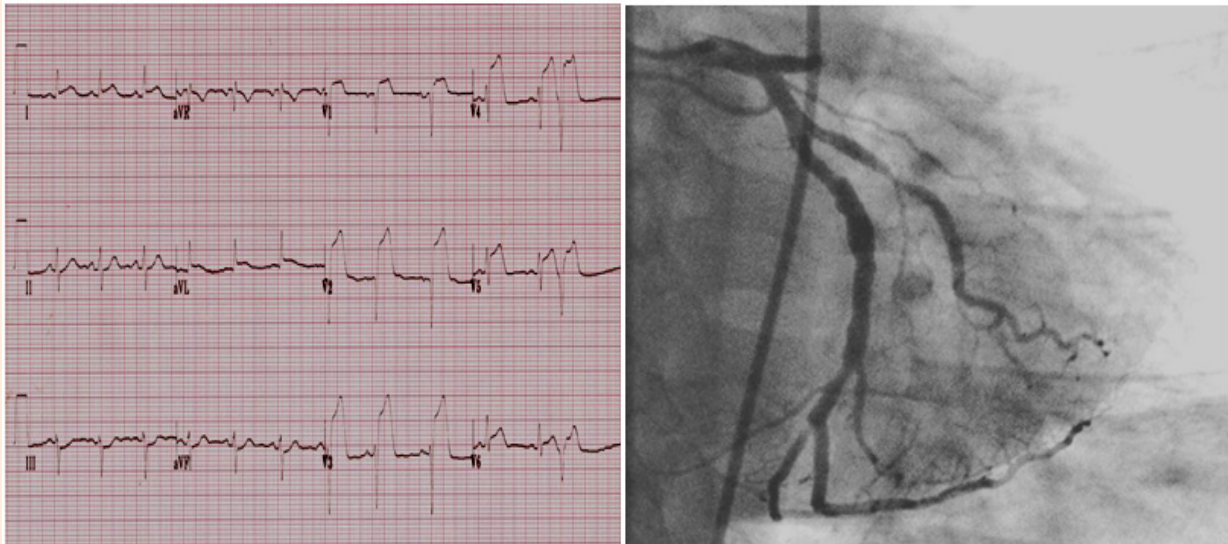


Figure 1: Shows ECG and coronary angiography at time of presentation.

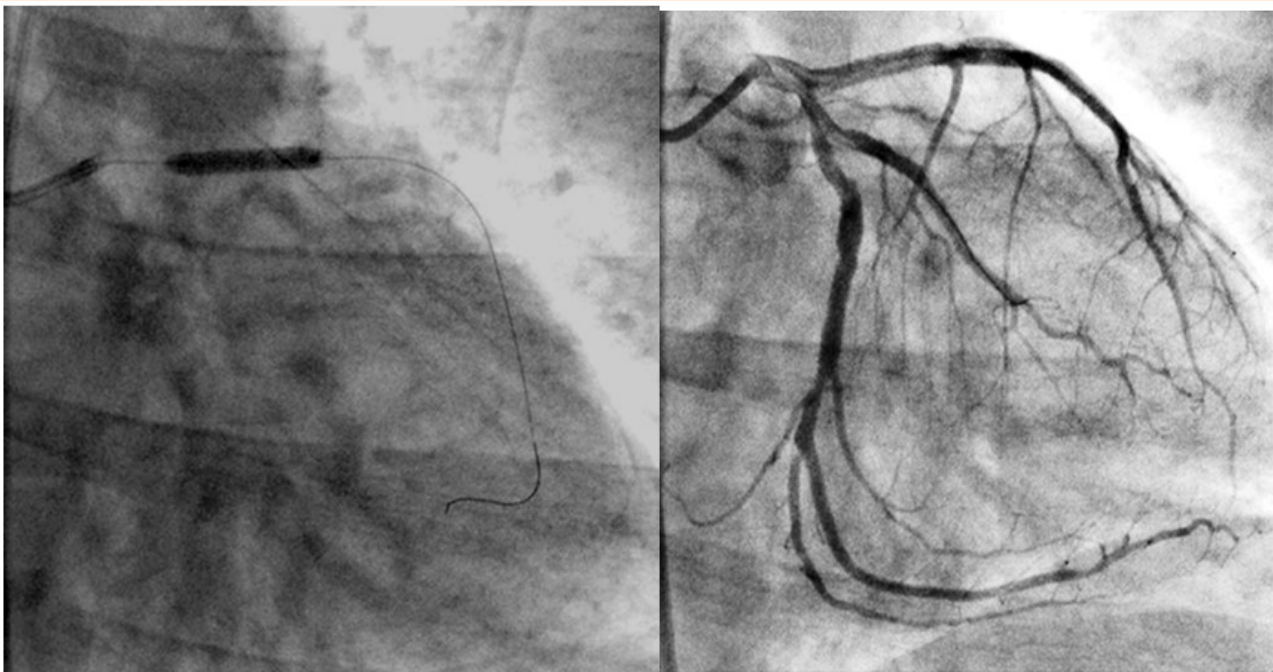


Figure 2: Shows stent implantation after thrombus aspiration and TIMI flow grade III.

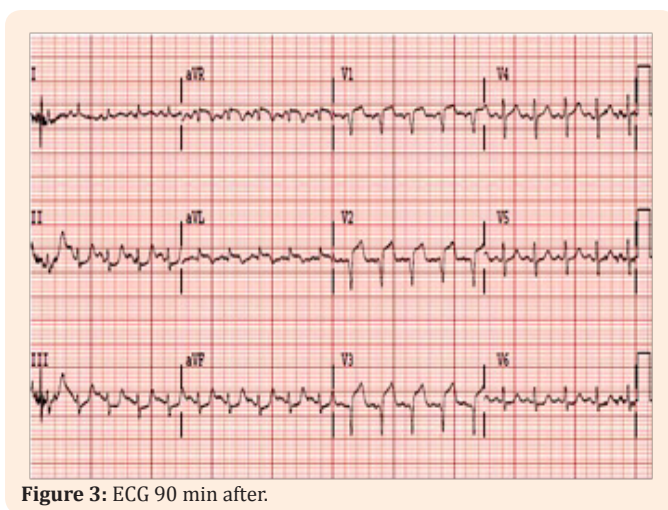


Figure 3: ECG 90 min after.

Myocardial Blush Grades after PPCI

Thrombus aspiration was significantly successful in achieving better reperfusion represented by MBG as 29 cases (96%) in group B had MBG \geq 2 while only 24 patients representing (80%) in group A achieved MBG \geq 2 with p=0.02.

Procedural related complications

Distal embolization occurred in 13.3% of patients in group A, while 10% in group B (p=0.6), No reflow in 3.3% of patients in both groups, residual thrombus in 10% of patients of group A but no patient in group B (p=0.24) and no cases of dissections, perforation or arrhythmia in both groups.

In hospital outcome in study population

No mortality was reported in either group, no reported cases of re infarction, stroke, recurrent ischemia, need for urgent intervention, arrhythmia or major bleeding during the hospital stay but minor bleeding occurred in 10% in group A vs 6.7% of patients in group B, with no statistical difference (p=0.1).

Thirty days outcome in the study population

No mortality was reported in either group, no reported cases for TVR, Stroke, arrhythmia but there were reported cases of re infarction 3.3% in group A vs 1.6% in group B (p=1.00), Heart failure 5% in group A vs 3.3% in group B (p=1.00), recurrent ischemia 13.8% in group A vs 3.4% in group B (p=0.35), Although there was no major bleeding during the hospital stay but minor bleeding occurred in 5 %in group A vs 3.3% of patients in group B (p=0.67) (Table 2).

Table 2: Thirty days outcome in the study population.

Variable	Group A (n=30)	Group B (n=30)	Total No.=60	P-value
	%	%	%	
Minor bleeding	5	3.3	8.3	0.67
Re-infarction	3.3	1.6	5	1
Heart failure	5	3.3	8.3	1
Angina requiring Hospital readmission	13.8	3.4	8.6	0.35

Myocardial salvage predictors at 30 days

Although there was no difference in the myocardial salvage

predictors as regard to TIMI flow grade 3 (p=0.3) or EF% (p=0.74) but myocardial blush grade \geq 2 and STR was higher in group A (p=0.002 and 0.001 respectively) (Table 3).

Table 3: Myocardial salvage predictors at 30 days.

Variable	Group A (n=30)	Group B (n=30)	P-value
	%	%	
TIMI flow grade 3	86.7	86.7	0.3
Myocardial blush grade \geq 2	96	80	0.002
STR	55.6	34.2	0.001
EF%	53.6	54.6	0.74

Discussion

Several randomized trials have demonstrated the efficacy and safety of pre-treatment with manual thrombectomy during primary percutaneous coronary intervention [4]. There are some unanswered questions about thrombus aspiration including whether there is truly a mortality benefit, which subgroups may or may not benefit from aspiration and whether patients with a large thrombus burden are better treated with mechanical

thrombectomy and should an interventional cardiologist use thrombectomy as a default strategy before primary PCI?. The literature and clinical practice clearly show that the impact of thrombectomy on all outcomes is linked to multiple factors during STEMI, in particular time from symptom onset to PCI, infarct-related coronary artery and intracoronary thrombus burden [5].

Sianos et al. [6] have shown that both angiographic and clinical outcomes are poorer in patients with a large thrombus burden as

it is associated with a greater frequency of major adverse cardiac events and is a strong independent predictor of late mortality [6].

Moreover, Napodano et al. [7] found that patients with right coronary artery infarcts, long lesions and a high thrombus score had the highest frequency of distal embolization. We might expect these subgroups to benefit most from thrombectomy [7]. Improvement in MBG with aspiration was not better in patients with right coronary artery (RCA) infarcts vs non-RCA infarcts, and was not better in patients with a visible thrombus compared with patients without a visible thrombus. There was a trend for greater benefit in patients with a reperfusion time of less than 3h, but there were no differential benefits in patients stratified by pre-PCI TIMI flow [8]. Overall, there are few current studies to support selective use of aspiration thrombectomy in any subgroup of STEMI patients treated with PPCI [9].

Myocardial salvage is measured and studied in trials through different parameters: angiographic (thrombolysis in myocardial infarction (TIMI) and myocardial blush grade (MBG), electrocardiographic (ST-segment resolution STR), functional (reduction of infarct size) and clinical (enhanced survival free from heart failure events) [10].

EXPIRA trial [11] was done to evaluate the impact on myocardial perfusion and infarct size as assessed by contrast-enhanced magnetic resonance imaging of a manual thrombectomy device, Export Medtronic (EM), as adjunctive therapy in primary percutaneous coronary intervention in a subset of patients with anterior ST-segment elevation myocardial infarction. The results showed that; Myocardial blush grade 2 occurred more frequently in the aspiration group (88%) vs. (60%) in the conventional PCI group and the difference was highly statistically significant ($p=0.001$) [11].

Also encouraging data for the use of manual aspiration data has been published in the recent issue of JACC 2013 [12] Dharam K and co investigators carried out meta-analysis of 18 randomized trials with 3,836 patients who were randomized to aspiration device and conventional primary PCI with mean follow-up period 6 months. The meta-analysis conclusively showed that: Aspiration devices showed significant reduction in MACE in aspiration group as compared to conventional primary PCI with risk ratio (RR) 0.76; $p = 0.006$. There was 30 days all-cause mortality benefit with aspiration group (RR 0.71; $p = 0.049$). There was a trend in reduction of MI, TVR with manual aspiration devices. However the infarct size and ejection fraction were similar at 1 month, ST segment resolution and MBG 3 were seen in greater number of patients who underwent aspiration ($p=0.0001$). Thrombus aspiration catheter not only provided 30 days benefit but also reduced all-cause mortality at 6 months [12].

In the ATTEMPT trial [13] a meta-analysis of 11 prospective randomized trials suggested that the use of thrombectomy devices is associated with a significant reduction of angiographically evident distal embolization and no-reflow (as assessed by post-procedural myocardial blush grade (MBG) and ST-segment resolution). But data from multicentric trial Thrombus Aspiration in ST-Elevation myocardial infarction in Scandinavia (TASTE) which included 7,244 patients randomized to conventional

primary PCI and manual thrombus aspiration failed to show benefit of routine aspiration before primary PCI as compared to conventional primary PCI. The 30 days mortality was similar in both the arms (2.8% in thrombus aspiration and 3.8% in conventional primary PCI). However the data was for 30 days outcome only [9].

Also Intracoronary Abciximab and Aspiration Thrombectomy in Patients with Large Anterior Myocardial Infarction (INFUSE-AMI) trial failed to show difference in the 30 days outcome between aspiration thrombectomy and conventional primary PCI. There was no difference in the ST segment resolution, TIMI count, 30 days infarct size and MACE. (TAPAS) trial was a single center, prospective, randomized, open trial which involved the blinded evaluation of patients [14]. It enrolled 1,071 patients who were randomized either to thrombus aspiration group with 6F Export catheter or to the conventional primary PCI group. Randomization was done before performing coronary angiography. After passing a guide wire, thrombus aspiration was done followed by the usual PCI procedure. The primary end point of the study was MBG 0/1 which was defined as absent/ minimal reperfusion. Secondary end points were the post procedural frequency of TIMI flow grade 3, complete resolution of ST elevation, target vessel revascularization (TVR), re infarction, death and the combination of MACE after 30 days [15].

Myocardial blush grade 0/1 occurred in 17.1% with thrombus aspiration group and 26.3% in the conventional primary PCI group ($p=0.001$). Complete resolution of ST elevation was observed in 56.6% in the aspiration group and 44.2% in the conventional PCI group ($p<0.001$). At 30 days patients who had MBG 3 had 1% mortality as compared to 5.2% in patients who had MBG 0/1. The rates of adverse events were significantly higher in patients with MBG 0/1 as compared to the patients with MBG 3 [15].

In the present study, although there was no difference in the myocardial salvage predictors as regard to TIMI flow grade 3 ($p=0.3$) or EF% ($p=0.74$) but myocardial blush grade ≥ 2 and STR were higher in the aspiration group ($p=0.002$ and 0.001 respectively). Significant improvement was observed when TIMI flow grade was 0 (from 86.7 to 1.7%). None of the patients of both groups had target vessel revascularization (TVR), re infarction, death, or the combination of major adverse cardiac events (MACE) from intra procedural, in hospital or within 30 days after PCI.

We go back to the question should an interventional cardiologist use thrombectomy as a default strategy before primary PCI? It is not easy to decide. ACC/AHA guidelines give a recommendation of class IIa to the manual aspiration before PPCI [16]. Also Gennaro & Rocco [17] recommended the use of manual thrombectomy as first approach during PPCI to prevent distal embolization in case of culprit vessel diameter >2.5 mm with a TIMI flow 0-1 and a visible thrombus (score >3).

Limitation

Small sample size and short term follow up.

Conclusion

In the treatment of acute myocardial infarction, thrombectomy

device is safe to use and although it did not affect the TIMI flow grade or EF% it significantly improved the MBG and STR especially when TIMI flow grade was 0.

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