



ORIGINAL ARTICLE

Direct Stenting versus Aspiration of Thrombus on Final Myocardial Blush Score and Outcome in Patients with Acute ST-Elevation Myocardial Infarction.

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ABSTRACT

Background : In patients with STEMI, PCI cause thrombus dislodgment leading to microvascular function impairment, which is a negative independent predictor of myocardial function recovery. Compared with conventional stenting, pretreatment with aspiration thrombectomy during PPCI has been proposed to prevent embolization in order to improve outcomes. **Aim:** Evaluation of value of thrombus aspiration devices in primary PCI compared to conventional primary PCI. **Methods:** The study included 60 patients with AMI undergoing primary PCI, patients were divided : Group A: 30 patients subjected to primary PCI only .Group B: 30 patients subjected to thrombectomy device before primary PCI. **Results:** The present study showed a statistically significant difference among both studied groups regarding post-thrombectomy TIMI flow grade.

Our study showed a statistically significant difference among both studied groups regarding post-thrombectomy thrombus score 1, 2 and 3%, as 93.3% of group II had score <2 versus 70% of group I, mean of thrombus score among group II was 1.27 ± 0.82 versus 2.15 ± 0.75 in group I. The present study showed no statistically significant difference among both studied groups regarding post-procedural angiographic characteristics, except post-stenting MBG, 90% of group II had MBG of ≥ 2 versus 70% of group I.

Our study showed no statistically significant difference among both studied groups regarding cardiac death on follow up 1-month and 3-months post-procedure. **Conclusions:** In the treatment of STEMI, aspiration thrombectomy device is safe to use preserving microvascular integrity and although it did not affect the Post-stenting TIMI flow grade or EF% it significantly improved the MBG.

Keywords: Thrombus Aspiration; Thrombectomy device, Acute Myocardial infarction



INTRODUCTION

Percutaneous coronary intervention (PCI) is considered the gold standard method of treatment for patients presented with ST elevation myocardial infarction (STEMI) (1). Indeed, early effective myocardial reperfusion must be the principal objective in the management of such patients presenting with STEMI (2). Several studies reported that low final thrombolysis in myocardial

infarction (TIMI) flow and/or myocardial blush grade (MBG) that are perfect markers for myocardial reperfusion, are important independent predictors of mortality in patients presented with myocardial infarction (3).our study aims to evaluate the effect of using of aspiration (TA) & direct stenting before primary PCI on the final myocardial reperfusion & its effect on out come in the treatment of patients presenting with acute STEMI.

METHODS

The study was done in Cardiology department, Zagazig university hospitals, and Alahrar Teaching Hospital and included sixty patients who were presented to ER with STEMI and underwent primary PCI. Inclusion criteria were patients presented within 12 h from the onset of symptoms (typical chest pain lasting more than 30mins), diagnosed with acute ST elevation myocardial infarction and treated with primary PCI. Exclusion criteria were patients with pre-hospital thrombolysis, cardiogenic shock, stent thrombosis and culprit lesion localized on coronary artery bypass graft. All the patients were subjected to the careful history taking, to rule out exclusion criteria and to evaluate of cardiovascular risk factors (hypertension, diabetes mellitus, cigarette smoking, obesity and family history of CAD), general and local examination, including Blood pressure measurement, resting heart rate, respiratory rate measurement, additional heart sounds namely S3 and S4., systolic murmurs of Mitral regurgitation, Ventricular septal rupture and Tricuspid regurgitation.

Investigations including : Electrocardiogram at ER arrival and 90 min after the procedure for all patients with chest discomfort (or angina equivalent) or other symptoms suggestive of ACS. Transthorathic echocardiography was done on admission for assessment the heart including LV ejection fraction. Laboratory Investigations, Cardiac biomarker (CK-MB) was done after angiographic procedure. Peak values were taken for each of them in 1st 24 hours. 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.

Primary PCI procedure:

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 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. Both TIMI flow and myocardial blush were graded on the angiograms made immediately after the primary coronary angioplasty procedure. Grading was done on cine film at 15 frames/s made in a "SIEMENS digital, GE & PHILIPS INTEGRIS" coronary imaging catheterization laboratory. 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. 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. 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; In the first 24h, recurrent symptoms of ischemia with new ST elevation > 0.1 mv in 2 leads lasting at least 30 minutes, 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, at 30 days, follow up data were obtained from hospital records and through direct patient contact, 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, 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.

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. And a major adverse cardiac event (MACE) was defined as death, reinfarction or target-vessel revascularization.

Angiographic data were collected including:

Lesion location, severity of the culprit lesion, AHA/ACC classification of the lesion, presence of thrombus and the presence of multi-vessel involvement.

Angiographic Analysis:

Coronary angiograms were analyzed off-line by two expert interventional cardiologists in a blinded manner. The advancement of manual aspiration thrombectomy device was filmed, and quantitative coronary analysis was performed before and after the procedure. TIMI flow grade and MBG were estimated visually. The occurrence of slow flow (TIMI flow grade decreasing from 3 to 2 during the procedure) or no reflow (TIMI flow grade decreasing from 2 or 3 to 0 or 1 during the procedure) was

assessed. Thrombus burden at lesion site was graded from 0 to 5 according to the TIMI TS. All data were determined at baseline, after thrombectomy, and at the end of the procedure.

Patients follow up:

A clinical follow-up was also performed at 3 months. We evaluated the occurrence of major adverse cardiac events (MACE) [cardiac death, Q and non-Q wave MI, target vessel revascularization] at 3 months. We also assessed the incidence of stent thrombosis indicated as “definite,” “probable,” and “possible” according to the Academic Research Consortium (ARC) definition. The primary composite angiographic end-points was the occurrence of post-thrombectomy thrombus score (TS) ≤ 2 and TIMI ≥ 2, and post-stenting myocardial blush grade (MBG) ≥ 2. Written informed consent was obtained from all participants and the study was approved by the research ethical committee of Faculty of Medicine, Zagazig University. The work has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

Statistical analysis

Data were analyzed using IBM SPSS 23.0 for windows . Quantitative data were expressed as mean ± standard deviation. Qualitative data were expressed as frequency and percentage. Independent-samples t-test of significance was used when comparing between two means. Chi-square (X2) test of significance was used in order to compare proportions between two qualitative parameters. Fisher Exact test is a test of significance that is used in the place of chi square test in 2 by 2 tables, especially in cases of small samples. Probability (P-value): P-value <0.05 was considered significant, P-value <0.001 was considered as highly significant and P-value >0.05 was considered insignificant.

RESULTS

This study included 60 patients with STEMI eligible for primary PCI admitted to Zagazig Universty Hospital & Alahrar Teaching Hospital to compare the usage of thrombus aspiration devices versus conventional primary PCI on outcome . 75% of studied group were males with mean age of 64 years old (tabe 1). 68.3% of studied group had thrombus score of 4% and 18.3% had score 3%, while only 11.7% and 1.7% of them had score 2 and 1 respectively, with mean score of 3.59 Ts (table 2). And 51.7% of studied group had TIMI flow grade of III and 28.3% had grade II, while only 18.3% and 1.7% of them had grade I and 1.7% TIMI Flow 0 respectively (table 3).

There was no statistically significant difference among both studied groups regarding baseline procedural characteristics (table 4). There was no statistically significant difference among both studied groups regarding post-thrombectomy TIMI flow grade, as 73.3% of group II were of grade 3% versus 30% of group I, while 40% of group I had 2% grade versus 16.7% of group II (Figure 1).

There was statistically significant difference among both studied groups regarding post-thrombectomy thrombus score 1, 2 and 3%, as 93.3% of group II had score <2 versus 70% of group I, mean of thrombus score among group II was 1.27 ± 0.82 versus 2.15 ± 0.75(table 5)(Figure2).

There was no statistically significant difference among both studied groups regarding post-procedural angiographic characteristics, except post-stenting MBG, 90% of group II had MBG of ≥2 versus 70% of group I (table 6)(figure3).

There was statistically significant difference among both studied groups regarding cardiac death on follow up 1-month post-procedure (table 7).

There was no statistically significant difference among both studied groups regarding outcomes on 3 months follow up (table 8).

Table (1): Demographic data of the studied population.

Variables	Studied population(n=60)	
	N	%
Gender		
Male	45	75
Female	15	25
	Mean ± SD	
Age	64.3 ± 10.2	

Table (2): Pre-thrombectomy thrombus characteristics among studied group.

Variables	Studied population N =60	
	N	%
Thrombus score (%)		
1	1	1.7
2	7	11.7
3	11	18.3
4	41	68.3
	Mean ± SD	
Thrombus score (Ts)	3.59 ± 0.69	

Table (3): Post-thrombectomy TIMI flow grade among studied group.

TIMI flow grade (%)	Studied group N =60	
	N	%
0	1	1.7
1	11	18.3
2	17	28.3
3	31	51.7

Table (4): Difference in baseline procedural characteristics of both studied groups.

Variables	Studied population				X2	P-value
	Group I=30		Group II=30			
	N	%	N	%		
Location of IRA						
LM	0	0.0	0	0.0	-----	----
LAD	14	46	13	43	0.098	0.574
LCX	5	16.7	5	16.7	0.131	0.718
RCA	4	13.3	5	16.7	0.131	0.718
Multi-vessel disease	5	16.7	4	13.3	0.131	0.718
Bifurcation	2	6.7	3	10	0.218	0.64
Pre-thrombectomy TIMI flow grade (%)						
0	22	73.3	24	80	0.373	0.542
1	8	26.7	6	20		
	Mean ± SD		Mean ± SD		t-test	P
Lesion length (mm)	14.3 ± 3.7		14.7 ± 3.5		0.43	0.669
Vessel reference diameter (mm)	2.9 ± 0.5		2.9 ± 0.5		0.00	1.0
MLD before thrombectomy (mm)	0.5 ± 0.1		0.5 ± 0.01		0.00	1.0

Table (5): Post-thrombectomy thrombus characteristics of both studied groups.

Variables	Studied population				X2	P-value
	Group I=30		Group II=30			
	N	%	N	%		
Thrombus score (%)						
0	1	3.3	5	16.7	Fisher	0.09 (NS)
1	4	13.3	15	50	Fisher	0.002 (S)
2	16	53.3	8	26.7	4.44	0.04 (S)
3	8	26.7	2	6.7	Fisher	0.04 (S)
4	1	3.3	0	0	Fisher	0.321 (NS)
Score ≤2	21	70	28	93.3	5.45	0.02 (S)
	Mean ± SD		Mean ± SD		t-test	P
Thrombus score (Ts)	2.15± 0.75		1.27 ± 0.82		4.34	<0.001 (HS)

Table (6): Post-procedural angiographic characteristics among both studied groups.

Variables	Mean ± SD				t-test	P-value
	Group I=30		Group II=30			
Post-stenting MLD (mm)	2.9 ± 0.6		2.9 ± 0.8		0.105	0.411 NS
Post-stenting stenosis diameter (%)	2.8 ± 0.5		2.9 ± 0.8		0.581	0.564 NS
CK-MB peak (U\l)	171 ± 13		167 ± 12		1.24	0.221 NS
	N	%	N	%	X2	P
90 min ST segment resolution (%)	10	65	11	82	0.07	0.787
Post-stenting TIMI flow grade (%)						
0	1	3.3	0	0	Fisher	0.321
1	1	3.3	0	0	Fisher	0.321
2	6	20	5	16.7	Fisher	0.739
3	22	73.4	25	83.3	0.884	0.347
Post-stenting MBG (%)						
0						
1	1	3.3	0	0	Fisher	0.321 (NS)
2	8	26.7	2	6.7	Fisher	0.04 (S)
3	11	36.7	14	46.7	0.617	0.432 (NS)
	10	33.3	14	46.7	1.11	0.292 (NS)
MBG (%) ≥2	21	70	28	90	5.45	0.02 (S)

Table (7): Clinical outcomes on 1 month follow up among both studied groups.

MACE (%)	Mean ± SD				Test	P-value
	Group I=30		Group II=30			
	N	%	N	%		
Cardiac death (%)	1	3.3	0	0.0	Fisher	0.321 (NS)
Non Q MI	0	0.0	0	0.0	----	----
Q MI	0	0.0	0	0.0	----	----
TVR	0	0.0	0	0.0	----	----

Table (8): Clinical outcomes on 3 months follow up among both studied groups.

MACE (%)	Mean ± SD				P-value
	Group I=29		Group II=30		
	N	%	N	%	
MACE	5	17.2	2	6.7	0.228 (NS)
Cardiac death (%)	1	3.4	0	0.0	0.241
Non Q MI	0	0.0	1	3.3	0.321
Q MI	1	3.4	0	0.0	0.241
PCI TVR	2	6.9	1	3.3	0.554 (NS)
Definite stent thrombosis	1	3.4	0		0.241
Probable stent thrombosis	0	0.0	0		----
Possible stent thrombosis	1	3.4	0		0.241

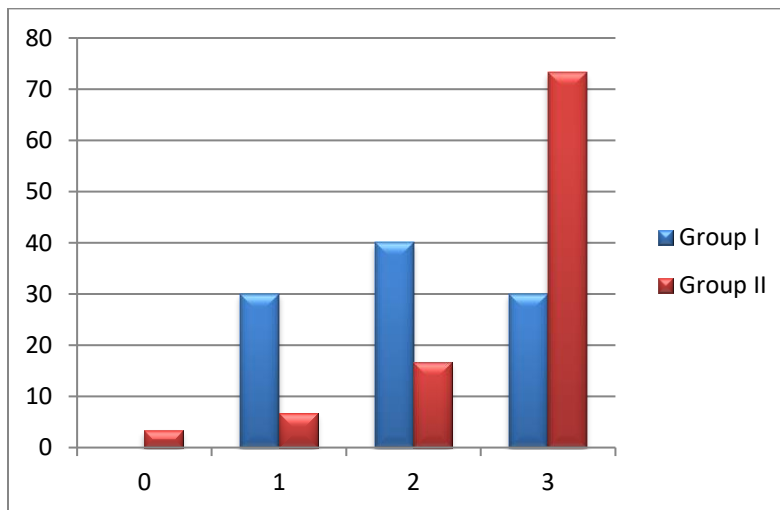


Figure (1): Post-thrombectomy TIMI flow grade among both studied groups.

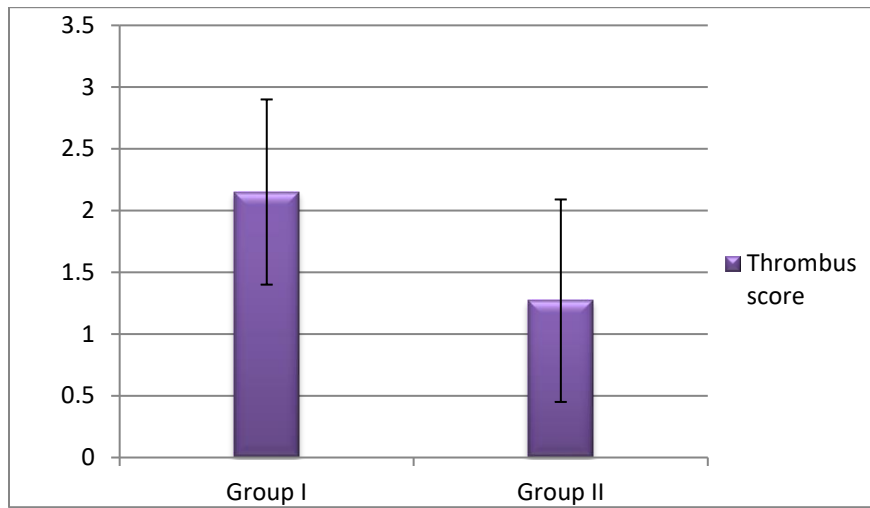


Figure (2): Post- thrombectomy thrombus score among both studied groups

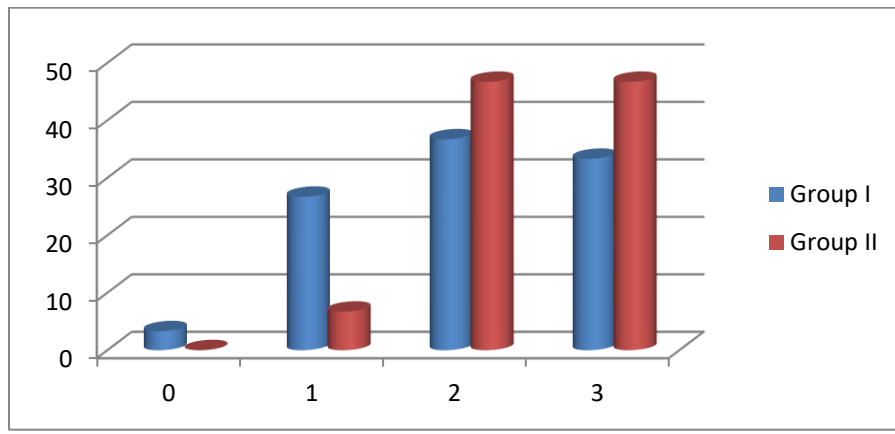


Figure (3): Post-stenting MBG among both studied groups.

DISCUSSION

Several randomized trials demonstrated the efficacy and safety of pre-treatment with manual thrombectomy during primary PCI (4). Sianos et al (5) have shown that both angiographic and clinical outcomes are poorer in patients with a big thrombus burden as it is associated with a greater frequency of major adverse cardiac events and is a strong independent predictor of late mortality. Moreover, Napodano et al (6) found that patients with RCA 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. Improvement in MBG with aspiration was not better in patients with RCA infarcts vs non-RCA infarcts, and was not better in patients with a visible thrombus compared with patients without a visible thrombus (7). 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), and clinical (enhanced survival free from heart failure events) (8).

We aimed in our study to determine the effect of thrombus use of aspiration (TA) & direct stenting use before primary PCI on the final myocardial reperfusion & its effect on out come in the treatment of patients presenting with acute STEMI.

Our study was done on sixty patients who were admitted to Cardiology department, Zagazig university hospitals, and Alahrar Teaching Hospital within 12 hours of acute onset ST elevation myocardial infarction who underwent Primary PCI. They are divided into Two groups , group(I): 30 patients underwent direct stenting and group (II): 30 patients underwent manual aspiration thrombectomy before primary PCI. These groups were followed up for complications, and major cardiac events were recorded in cath lab . It was noted that neither the in-hospital mortality nor MACE showed any

significant statistical difference between the two groups.

In the present study, that the mean age of the study population was 64.3 ± 10.2 without significant difference between two groups, where the mean age in group I was 64.1 ± 10.2 vs. 63.4 ± 12.5 in group II ($P=0.813$). Also, no significant difference between two groups as regard to gender ($p=0.766$), diabetes mellitus ($p=0.766$), hypertension ($p=0.787$) and Smoking ($p=0.796$).

In agreement with our study, Mostafa et al. (9) found that 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 ($p=0.35$), DM ($p=0.43$), hypertension ($p=0.3$) and Smoking ($p=0.07$).

We concluded in our study that there was no statistically significant difference between both groups regarding baseline clinical and angiographic characteristics. This came in agreement with Sardella et al. (10) who found the baseline clinical and angiographic characteristics were similar between the two groups.

In the present study, manual thrombus aspiration group showed a significantly lower TS (1.27 ± 0.82 vs. 2.15 ± 0.75 , $P < 0.0001$) than direct stenting group. Accordingly, the separate analysis of each score showed that group II had higher rates of TS 0 (16.7% vs. 3.3%, $P = 0.09$) with no significant difference and significantly higher rates of TS 1 (50.0 vs. 13.5%, $P = 0.002$), and significantly lower rates of TS 2 (26.7 vs. 53.3%, $P = 0.04$) and significantly lower rates of TS 3 (6.7 vs. 26.7%, $P = 0.04$). The primary endpoint of TS ≤ 2 occurred more frequently in group II (92.3% vs. 69.3%, $P = 0.0052$). This came in agreement with Sardella et al. (10) who found the same results and the primary endpoint of TS ≤ 2 occurred more frequently in group II (93.3% vs. 70%, $P = 0.02$).

In the present study, patients treated with manual thrombus aspiration had a significantly lower incidence of TIMI 1 (6.7 vs. 30.0%, $P = 0.02$), and a higher TIMI 3 flow (73.3 vs. 30.0%, $P < 0.0001$). Other post-thrombectomy procedural and angiographic characteristics were similar between groups. This came in agreement with Sardella et al. [10] who found patients treated with manual thrombus aspiration had a significantly lower incidence of TIMI 1 (5.8 vs. 30.7%, $P = 0.0017$), and a higher TIMI 3 flow (72.6 vs. 30.7%, $P < 0.0001$).

In disagreement with our study, Mostafa et al. (9) found that there was no difference in the myocardial salvage predictors as regard to TIMI flow grade 3 ($p=0.3$) and a Significant improvement was observed when TIMI flow grade was 0 (from 86.7 to 1.7%).

In the present study, after stent implantation, the rate of MBG ≥ 2 was significantly higher in group II (90.0 vs. 70.0%, $P = 0.02$). This came in agreement with Sardella et al. (10) who found the rate of MBG ≥ 2 was significantly higher in group II (88.2 vs. 69.3%, $P = 0.029$).

Also, Kumbhani et al. (11) found that MBG was in greater number of patients who underwent aspiration ($p=0.0001$).

Mostafa et al. (9) found that myocardial blush grade ≥ 2 was higher in the aspiration group ($p=0.002$).

Svilaas et al. (12) found that the myocardial blush grade 0/1 occurred in 17.1% with thrombus aspiration group and 26.3% in the conventional primary PCI group ($p=0.001$).

In the present study, the ejection fraction was similar between both groups. This came in agreement with Kumbhani et al. [11] who found that the ejection fraction was similar between both groups with no significant difference.

Also, Mostafa et al. (9) found that there was no difference in the myocardial salvage predictors as regard to EF% ($p=0.74$).

In the present study there was no statistical differences were observed for the relative ST-segment resolution 90 min after the index procedure (65.0% (group I) vs. 82.0% (group II), $P = 0.787$). This came in agreement with Sardella et al. (10) who found the same results.

In disagreement with our study, Kumbhani et al. (11) and Mostafa et al. [9] found that ST segment resolution was in greater number of patients who underwent aspiration ($p=0.0001$, 0.001 respectively). Svilaas et al. (12) also disagree with our study and found that complete resolution of ST elevation was observed in 56.6% in the aspiration group and 44.2% in the conventional PCI group ($p < 0.001$). This difference may be due to large sample size of their study.

In the present study, no significant differences were observed in terms of MACE at 1 and 3 months after the index intervention. During follow-up, all cardiac deaths occurred during hospitalization because of complications of cardiogenic shock. We observed in group I one case of definite stent thrombosis. This came in agreement with Sardella et al. (10) who found there was no significant differences were

observed in terms of MACE at 1 and 3 months between both groups.

Also, Intracoronary Abciximab and Aspiration Thrombectomy in Patients with Large Anterior MI (INFUSE AMI) trial done by Stone et al. (13) failed to show difference in the 30 days outcome between aspiration thrombectomy and conventional primary PCI.

Mostafa et al. (9) found that distal embolization occurred in 13.3% of patients in group I (direct stenting), while 10% in group II (manual thrombus aspiration) ($p=0.6$), No reflow in 3.3% of patients in both groups, residual thrombus in 10% of patients of group I but no patient in group II ($p=0.24$) and no cases of dissections, perforation or arrhythmia in both groups.

In disagreement with our study that Kumbhani and co investigators [11] 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. These differences can be explained by small sample size and short follow up duration in our study.

In the present study, only one cardiac death occurred in group I while no cardiac death occurred in group II during in hospital or within 30 days after PCI. None of the patients of both groups had target vessel revascularization (TVR) during first month of follow up and only 2 cases in group I and 1 case in group II had TVR on 3 months follow up.

Mostafa et al. (9) found that none of the patients of both groups had target vessel revascularization, re-infarction, death, or the combination of major adverse cardiac events (MACE) from intra procedural, in hospital or within 30 days after PCI.

Limitations

This study represents a single-center experience in a limited number of patients and was not powered and designed to test differences in clinical outcomes. And one of the major limitations of this study is that we did not use Fragmented QRS and QRS distortion (a simple ECG modality), which are the other parameters of angiographic reperfusion. These parameters could have provided additional benefits to our study.

CONCLUSIONS

In the treatment of acute ST elevation myocardial infarction, manual aspiration thrombectomy device is safe to use and represents an adjunct to pharmacotherapy on the prevention of distal embolization of thrombus, preserving microvascular integrity and although it did not affect the Post-

stenting TIMI flow grade or EF% it significantly improved the MBG.

Authors admitted No conflict of interest

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