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CHARACTERISTICS OF PATIENTS GOING FOR BAILOUT THROMBECTOMY DURING PRIMARY PERCUTANEOUS CORONARY INTERVENTION

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Contribution

MAA conceived, designed and did statistical analysis & manuscript writing. MA did data collection and manuscript writing. AE did review and final approval of manuscript

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ABSTRACT

Objective: To study the baseline characteristics, angiographic variables and clinical outcomes of patients going for primary PCI(PPCI) who needed bailout thrombectomy and compare them to patients going for (PPCI) alone.

Methodology: This cross sectional study consisted of all patients diagnosed with acute STEMI according to the third universal definition of acute myocardial infarction who underwent primary PCI (PPCI) at the Cardiology Department, Tanta University hospital, and Om Alkora cardiology center were included in the study from 1st March 2015 to 31st March 2017. We enrolled patients going for PPCI. They were admitted to the cathertization laboratory for PPCI. Patients who underwent bailout thrombectomy constituted group 1 while rest of the patients constituted group 2. The primary outcome was a composite of death from cardiovascular causes, recurrent myocardial infarction, cardiogenic shock, or New York Heart Association (NYHA) class IV heart failure while the second outcome was stroke and renal impairment.

Results: Total of 830 patintes were included . Group 1 consisted of 130 patients (16%) and group 2 consisted of 700 patients. Women constituted the majority of patients in group 1; 54.6 vs 37.2% ($p=0.003$). In group 2, they were significantly more diabetic; 53 vs 44%, $p=0.004$ and more co-morbidities. There were more smokers in group 2; 80 vs 6 %, $p<0.0001$, more peripheral vascular disease and liver disease 28 vs 10 %, 23 vs 1.5 %, $p=0.015$ and 0.001 respectively. Patients in group 1 had more renal impairment during hospital stay; 7 vs 4 %, $p=0.034$, and more patients developed stroke; 1.3 vs 0.7%, $p=0.045$.

Conclusion: Patients with STEMI who were admitted to the catheterization laboratory for PPCI, and needed bailout thrombectomy were more women, more diabetics and showed co-morbidities, they suffered more renal impairment and cerebrovascular events during hospitalization.

Key Words: STEMI, Thrombectomy, Primary PCI

INTRODUCTION

Acute coronary artery thrombosis is the main underlying cause for ST-segment elevation myocardial infarction (STEMI) so thrombus aspiration followed by primary PCI may be superior to medical management of such patients.[1] Thrombus aspiration is mostly restricted to patients presented in the early hours after the acute event where the intra-coronary thrombus is still fresh and easy to be aspirated.[2] However thrombus aspiration may be a treatment option in patients with late presentation.[3]

Although It is known that final myocardial blush grade (MBG) and/or thrombolysis in myocardial infarction (TIMI) flow is a predictor of mortality after acute myocardial infarction, routine thrombus aspiration during PCI for STEMI did not reduce longer-term clinical outcomes and might be associated with an increase in stroke incidence.[4-6] As a result, thrombus aspiration can no longer be recommended as a routine strategy in STEMI.[7] However in the subgroup of patients with high thrombus burden [TIMI thrombus grade $\geqslant$ 3], thrombus aspiration was associated with fewer cardiovascular deaths so, in cases of large residual thrombus burden after opening the vessel with a guide wire or a balloon, thrombus aspiration may be considered (bailout thrombectomy).[1,8]

This work aimed to study the characteristics, angiographic data and clinical outcomes of the patients presented with acute STEMI and in need for bailout thrombus aspiration after stent deployment or balloon dilatation and their in-hospital outcome and compare them to patients who underwent primary PCI alone.

METHODOLOGY

This cross sectional study was conducted from March 2015 to March 2017. All patients diagnosed with acute STEMI according to the third universal definition of acute myocardial infarction who underwent primary PCI (PPCI) in the cardiology department of Tanta University hospital, and Om Alkora cardiology center were included in the study.

The patients were classified according to the need for bailout thrombectomy into two groups; group1 comprised of patients who were in need for bailout thrombectomy group 2, comprised patients who went for PPCI without the need for thrombectomy. All patients diagnosed as having acute STEMI who underwent bailout thrombus aspiration followed by primary PCI or had primary PCI without thrombus aspiration were included. Patients with STEMI presented late after 24 hours, patients needed coronary artery bypass graft (CABG) and the use of fibrinolytic therapy were excluded.

All patients were subjected to history taking and clinical examination with stress on the coronary artery disease (CAD) risk factors: diabetes mellitus (DM), hypertension, hypercholesterolemia and smoking.

Electrocardiogram (ECG) was done within 10 minutes of initial presentation to determine any abnormalities and echocardiography was performed to study segmental wall motion abnormalities (SWMA) and measure left ventricular ejection fraction (EF) by biplane Simpson's method in the first day after PPCI, however it was performed earlier if the patients presented with heart failure, cardiogenic shock or when the diagnosis was uncertain. Blood sample was extracted for: complete blood picture, kidney function tests, troponin I, international randomized ratio (INR) and creatine phosphokinase (CKmb).

Patients were admitted to the cardiac catheterization laboratory as early as possible after the diagnosis. Diagnostic coronary angiography and culprit lesion assessment as regards the following: site and severity of the occlusion, TIMI flow grade (assessed before wire passage), myocardial blush grade and thrombus TIMI grade, followed then by PPCI. [10-12] Bailout thrombus aspiration was done after failure to open the vessel with TIMI 0 flow in the presence of large thrombus after balloon pre-dilatation. Bailout thrombus aspiration was also done in the presence of large thrombus [TIMI thrombus grade $\geqslant$ 3] after stent deployment irrespective of the TIMI flow grade. [13]

At first we passed a steerable floppy guide-wire across the target lesion and when we established an ante-grade flow balloon dilatation was performed, and if that was not possible a 6-French Export Aspiration Catheter (Diver, Invatec, Roncadelle, Italy) was advanced into the target coronary segment. Thrombus aspiration was done using a minimum of 2 syringes 40 ml each. Thrombus was aspirated using the thrombectomy catheter. We kept the guiding catheter engaged in the coronary ostium during withdrawal and then the guiding catheter was aspirated after thrombus aspiration to avoid air or thrombus embolization. To guarantee maximal coronary artery vasodilatation for proper stent sizing and deployment intracoronary nitrates were injected

Aspirin (a loading dose of 300 mg), and clopidogrel (a loading dose of 600 mg) and heparin (5000 IU) were given to the patients before PCI. In case of angiographic evidence of slow or no reflow or large thrombus Glycoprotein IIb/IIIa inhibitors were used,also the patients received appropriate medications following PPCI. [12,14,15]

ECG and cardiac markers level were assessed and compared before and after PCI. We reported the in-hospital outcome of the patients. The primary outcome was a composite of death from cardiovascular causes, recurrent myocardial infarction, cardiogenic shock, or New York Heart Association (NYHA) class IV heart failure while the second outcome was stroke and renal impairment. Death was reported if it was clearly attributed to cardiac cause,

recurrent infarction was defined according to the third universal definition of acute myocardial infarction. [9] Patients were classified into early presentation if the presented within 12 hours of symptom onset and late if they presented after 12 hours of symptom onset. A written consent was obtained from all patients and the study was approved by the local ethical committee.

Statistical analysis was done using SPSS 23. Baseline data were expressed as mean ± standard deviation (SD). Categorical variables were expressed as numbers and percentages.

Two tailed Student unpaired T test and chi square tests were used to compare continuous and discrete variables in the 2 groups as appropriate. To study the in-hospital outcome of the patients we used the general linear model for multivariate analysis. P value is considered significant if it is found to be < 0.05.

RESULTS

A total of 830 patients were included in the study and were divided into 2 groups; group1 included only 130 patients (as the rest of the patients did not show large thrombus burden or TIMI thrombus grade>3) who underwent thrombus aspiration after either stent deployment or balloon dilatation and group 2 included 700 patients who underwent PPCI alone without the need for thrombus aspiration.

Women constituted the majority of patients in group 1; 54.6 vs 37.2% in group 2 (p=0.003) They were more diabetics 53 vs 44%, (p=0.004) in group 1 having more comorbidities. Baseline characteristics of the patients in both groups are shown in table 1.

Table 1: Demographic,Clinical, and CAD Risk Factors for the Studied Patients (n=830)

	Group one	Group two	p value
Number of patients	130	700	-
Age in years range (mean±SD)	35 -85 (59.96±11.8)	35 -84 (61.1±11.6)	0.073
Gender (female)	71/130 (54.6%)	260/700 (37.2%)	0.003*
DM	70/130 (53.8%)	310/700 (44.3%)	0.004*
HTN	59 (45.4%)	300 (42.9%)	0.232
Smoking	8/130 (6.1%)	562/700 (80.2%)	<0.0001*
Hypercholesterolemia	75 /130 (57.7%)	410/700 (58.6%)	0.15
PH of CAD	11/130(9%)	62/700(8.5%)	0.119
PH of MI	10/130(8%)	52/700(7.5%)	0.12
PH of PCI	11/130(9%)	56/700(8%)	0.23
PVD	14/130 (10.8%)	167/700 (28.3%)	0.015*
Liver disease	2/130 1.5%	66/700 23%	0.001*
Thyroid disease	7/130 5.3%	5/700 0.7%	0.003*
Anemia	23/130 17%	14/700 2%	0.002*
Renal disease	35/130 26.9%	22/700 3.1%	0.002*
PH of CVA	9/130 (6.9%)	38/700 (5.4 %)	0.045*
Family history of CAD	40/130 30.7%	216/700 30.8%	0.12

DM= diabetes mellitus, HTN=hypertension, CAD= coronary artery disease, MI= myocardial infarction, PCI= percutaneous coronary intervention, PVD= peripheral vascular disease and CVA= cerebrovascular accident.

Patients in group 1 had significantly severer clinical presentation as cardiogenic shock; 9 vs 7%, p=0.037 and heart failure; 17 vs 14%, p=0.047. Clinical presentation and ECG pattern are shown in table 2. Patients in group 1 had significantly higher random blood sugar;263 vs 200 mg/dl (p =0.038), higher serum creatinine; 1.48 vs 1.09 mg/dl (p=0.045) and lower hemoglobin level; 10 vs 13gm/dl (p=0.039), while patients in group 2 had significantly higher liver enzymes. (Table 3)

Table 2: Clinical and ECG at Presentation, Duration of Hospital Stay for Both Groups (n=830)

Clinical Presentation	Group 1	Group 2	p-value
Cardiogenic shock	12/130 (9.2%)	50/700 (7.1%)	0.037*
Killip class>2 Heart failure	22/130 (16.9%)	102/700 (14.57%)	0.047*
Early presentation	43/130 33.1%	224/700 32%	0.06
Late presentation	87/130 66.9%	476/700 68%	0.068
ECG: Anterior MI	67/130 (51.5%)	405/700 (57.9%)	0.049*
Inferior MI	44/130 (33.9%)	200/700 (28.6%)	0.036*
ER ECG presentation	19/130 (14.6%)	99/700 (14.1%)	0.087
Duration of hospital stay in days Range, (mean±SD)	3-8 6 ±1.9	3-6 4±05	0.039*

ECG=electrocardiogram. MI= myocardial infarction *=significant P value

Table 3: Laboratory Findings of the Study Patients (n=830)

LAB.findings	Group 1	Group 2	p value
RBS mg/dl ,Range (mean±SD)	74-520 (263.3±106.13)	80-405 (200.15±95)	0.038*
Serum creatinine mg/dl .Range (mean±SD)	0.6-2.6 (1.48±0.41)	0.7-2.3 (1.09±0.41)	0.045*
Hb gm/dl, Range (mean±SD)	7-15.8 (10.6±1.38)	9.8-16 (13.45±1.31)	0.039*
WBCs /mm3,Range (mean±SD)	3400-10700 (5839.7±1883.66)	3500-10650 (6005.14±2147.36)	1
Platelets/mm3 Range (mean±SD)	105000460000 (249669.2±94192)	106000- 400000 (248100±92513.55)	0.16
ALT in units, range (mean±SD)	25-56 37±9	30-89 55±18	0.01*
AST in units, range (mean±SD)	22-45 20±7	35-90 54±12	<0.002*
INR, Range (mean±SD)	1-1.8 (1.12±0.16)	1-1.4 (1.09±0.11)	0.23
CKmb U/L,Range (mean±SD)	35-245 (93.84±48.5)	30-250 (94.84±49.19)	0.81
Troponin I in units Range (mean±SD)	0.3-10 (24.3±18.2)	1.2-8 (25.1±17.4)	0.09

TIMI=thrombolysis in myocardial infarction, MBG=myocardial blush grade, MIN=minutes, * indicates significant P value.

RBS= random blood sugar,Hb=hemoglobin, WBCs= white blood cells, ALT= alanine transaminase, AST=aspartate transaminase, INR= international normalized ratio and CK mb= the mb fraction of the enzyme creatine kinase. *= significant P value

Coronary angiographic data showed that patients in group 1 had significantly more total occlusion due to grade 4 thrombus than patients in group 2; 69 vs 64 %, p=0.04, longer procedure time; 60.3±12.5 min vs 45.4±10.7 min, p=0.02, more no reflow; 37 vs 20 %, p=0.01 and more usage of glycoprotein IIb/IIIa. Angiographic data of the patients in both groups is shown in table 4. Patients in group 1 had more renal impairment during hospital stay; 7 vs 4 %, p=0.034, and more patients developed stroke; 1.3 vs 0.7%, p=0.045.(Table 5)

Multivariate analysis for in-hospital outcome was done using the general linear model. Factors associated with the in-hospital outcome in group 1 were patients with history of PVD (p=0.01) and late presentation (p = 0.001). In group 2 the only factor that was found to be associated with in-hospital outcome was history of PVD (p=0.025).

Table 4: Angiographic Data of Both Groups. (n=830)

	Group 1	Group 2	p value
Time from hospital door to procedure in MIN.	30-120 60 ±20	30-130 62 ± 22	0.24
Culprit vessel			
LAD	65/130 (50%)	329/700 (47%)	0.14
LCX	43/130 (33%)	224/700 (32%)	0.43
RCA	20/130(15.5%)	119/700 (17%)	0.15
Others	2/130 (1.5%)	28/700 (4%)	0.032*
Multi-vessel disease	52 (40%)	260 (37.1%)	0.045*
Initial TIMI thrombus grade			
GRADE 0	3/130(2%)	17/700(2.5%)	0.12
GRADE 1	5/130(4%)	38/700(5.5%)	0.06
GRADE 2	15/130(12%)	91/700(13%)	0.8
GRADE 3	17/130(13%)	106/700(15%)	0.23
GRADE 4 (TOTAL OCCLUSION)	90/130(69%)	448/700(64%)	0.04*
Before intervention		490/700	
TIMI 0	90/130 (69.2%)	(70%)	0.12
TIMI 1	40/130 (31.1%)	210/700 (30%)	0.27
MBG			
GRADE 0	77 (59.2%)	520(74.3%)	0.004*
Grade 1	53 (40.8)	180 (25.7%)	0.001*
Anticoagulants			
UFH	104/130(80%)	546/700(78%)	0.67
ENOXAPARIN	26/130(20%)	154/700(22%)	0.63
Glycoprotein IIBIIIA use	130/130 (100%)	492/700 (70.6%)	0.005*
BALLOON PREDILATAION	130/130 (100%)	490/700 (70%)	0.006*
STENT USAGE	52/130(40%)	504/700(72%)	0.005*
Thrombus aspiration	130/130 (100%)	0%	
After PCI			
TIMI 0(no reflow)	49 (37.7%)	140(20%)	0.01*
TIMI 3	81 (62.3%)	560(80%)	0.001*
TIME OF PROCEDURE IN MIN	40-90 60	30-70 45	0.02*
Contrast volume ml Range (mean±SD)	130-260 192.1±66.2	120-240 180.7±65.14	0.03*

Table 5: In-Hospital Outcome of Both Groups (n=830)

Events	Group 1	Group 2	p value
CV death	2/130 (1.5%)	8/700 (1.1%)	0.687
Re - infarction	2/130 (1.5%)	11/700 (1.6%)	0.129
Cardiogenic shock	5/130 (3.8%)	21/700 (3%)	0.78
Heart failure	4/130 (3.07%)	21/700(3%)	0.41
New renal impairment	10/130 (7.7%)	33/700 (4.7%)	0.034*
Major bleeding	2/130 (1.2 %)	6/700 (0.9%)	0.09
Stroke post procedure	3/130 (1.3%)	5/700(0.7%)	0.045*

DISCUSSION

This work is a retrospective multicenter study designed to study patients presented with STEMI and in need of bailout thrombectomy and compare them to the patients going for PPCI alone, we examined all patients going for PPCI in a matter of 2 years and divided them into group 1 (16%) who needed bailout thrombectomy and group 2 included patients going for PPCI alone.

Group 1 included more diabetic women and showed more co-morbidities as thyroid disease, renal disease and anemia, They also had previous history of stroke, this may be attributed to the fact that cardiovascular disease in women is still under-diagnosed and they are not properly followed up for risk factors control in Egypt. Smoking was found less commonly in these patients as it is less prevalent in Egyptian women. This wasn't found in the previous researches tackling aspiration thrombectomy because they had a different design as they randomized patients presented with STEMI to either routine upfront thrombectomy or PPCI alone.[16-18]

On hospital admission they had severer presentation with cardiogenic shock and heart failure, inferior MI was a more common presentation as well, they stayed in the hospital for longer duration than patients in group 2 as their presentation was more complicated and they experienced more events during hospitalization as renal dysfunction and cerebrovascular events, these data were not found in previous trials as they had different design and included more patients from multiple centers.[16,17]

The patients who needed bailout thrombectomy showed more frequent total occlusion of the coronary arteries with larger thrombus burden so Glycoprotein IIB/IIIA and balloon pre-dilatation were used in all of them. Stents were less deployed in these patients as they experienced more no-reflow after thrombus aspiration and balloon pre-dilatation.

Patients in group 1 showed more cerebrovascular events during their hospital stay as compared with patients in group 2 (1.3 vs 0.7%) most probably due to embolization of thrombus or air to the brain during the procedure, and this was also found in TAPAS meta-analyses 16 but in the TOTAL trial eighteen 1% of patients in the thrombectomy group showed stroke vs 0.5% in the PCI-alone group at 180 days not during hospital stay as our patients and they could not find explanation for this. The TASTE eighteen trial showed no difference in stroke rates (0.5% vs. 0.5%) at the initial hospitalization probably due to different population of patients.

We noticed worsening of renal function in the bailout thrombectomy group (7.7 vs 4.7%) that was not mentioned in previous trials as more patients in group 1 were diabetics with history of renal dysfunction and their procedure was lengthy using larger amount of contrast materials causing more renal damage.[16-18]

The current work found out that thrombus aspiration post balloon and late presentation were associated with worse in-hospital outcome in group 1 because these patients showed comorbidities, were presented more with cardiogenic shock and heart failure, their vessels showed more total occlusion and underwent lengthy procedure while history of peripheral vascular disease was associated with worse in-hospital outcome in group 2 as the majority of patients in this group were smokers.

Limitations

We did not study the patients after hospital discharge, as most of the patients did not adhere to their follow up visits.

CONCLUSION

Patients with STEMI who were undergoing PPCI, and needed bailout thrombectomy were more women, more dabetics and showed co-morbidities, they suffered more renal impairment and cerebrovascular events during hospitalization.

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