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Primary Percutaneous Coronary Intervention in Patients with Acute Myocardial Infarction: An Analysis from Tanta-AMI Multicenter Registry

Salma Mohamed El-Shokafy [a*], Suzan Bayoumy El-Hefnawy [a], Ehab Abdel Wahab Hamdy [a], Hanan Kamel Kassem [a] and Medhat Mohamed Ashmawy [a]

[a] *Cardiovascular Medicine Department, Faculty of Medicine, Tanta University, Tanta, Egypt.*

Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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ABSTRACT

Background: The goal of reperfusion therapy in acute myocardial infarction is to swiftly and persistently reperfuse the at-risk myocardium. Traditional reperfusion treatments include thrombolysis and primary percutaneous coronary intervention (PCI), with the latter being the optimal option if administered immediately by an experienced team. This study characterized the presentation, processes, and predictors of care and outcomes of patients with acute myocardial infarction (MI) undergone primary PCI with a focus on procedural and angiographic characteristics and in hospital mortality.

**Corresponding author;*

Methods: This prospective observational registry was conducted on 945 STEMI patients and treated with PCI, they underwent history taking, full Clinical examinations including resting 12 leads ECG, cardiac examination, venous sampling for laboratory data, cardiac catheterization to perform primary PCI, echocardiography, medical treatment after discharge.
Results: It was found that EF of patients at discharge ranged from 22.0-70.0 with a mean value of 45.97 ± 10.07, while at one month follow up was 25.0-70.0 with mean SD 48.87 ± 8.17, at 3 month was 25.0-70.0 with mean SD 48.72 ± 8.26 and at 6 month was 30.0-70.0 with mean SD 48.18 ± 8.13, so there was a significant different in EF at discharge and follow up periods (P value = 0.001). It was noticed that there are significant differences in MACE during follow up periods. There a statically significant different as regard mortality, heart failure, stent thrombosis, repeated hospitalization and re-infarction between follow up after one and three months, one and six months, three and six months (P value < 0.001).
Conclusions: PCI is the most common reperfusion therapy for STEMI. Older individuals had a greater risk of in-hospital mortality, AKI, and bleeding complications following PCI than younger patients. Transradial intervention may decrease the frequency of periprocedural complications in PCI patients who are elderly.

Keywords: Primary; percutaneous coronary intervention; acute myocardial infarction.

1. INTRODUCTION

Despite a substantial decline in cardiovascular disease-related mortality over the last decade, acute myocardial infarction (AMI) continues to be the leading cause of morbidity and death in industrialized nations [1].

Reperfusion treatment with intravenous fibrinolysis or primary percutaneous intervention is the major objective in the management of acute STEMI. Nevertheless, Primary percutaneous intervention is the preferred procedure if performed quickly by a medically skilled practitioner [2].

Primary percutaneous coronary intervention (PCI) or early invasive treatment improves mortality and morbidity considerably. To further enhance prognosis, secondary prevention through lifestyle adjustment and usage of guideline-directed medical treatment (GDMT) following discharge are crucial [3].

ST-elevation myocardial infarction (STEMI) continues to be the major cause of death among women who develop cardiovascular illness at a later age than men, despite the fact that women have more risk factors. Moreover, the onset age of STEMI is typically young and frequently younger [2,4].

Due to the incidence of coronary artery disease in older individuals. We may anticipate an increase in the number of older individuals presenting with STEMI, which is linked with a high death rate owing to the aging-related increase in comorbidities [5,6].

In younger patients with STEMI, primary percutaneous intervention has been shown to be effective; however, in the elderly, it is linked with improved survival compared to medical treatment alone [7]. The objective of this study was to characterize the predictors, presentation, processes of care, and outcomes of patients with acute MI who underwent primary PCI, with a particular emphasis on procedural and angiographic characteristics and in-hospital mortality.

2. PATIENTS AND METHODS

This prospective observational registry was carried out on 945 patients presented with STEMI and treated with primary percutaneous intervention between November 2019 and November 2021 at primary percutaneous intervention capable centers in Tanta as (Tanta University Educational Hospital and Cardiology Department at Tanta University Hospitals). The data were extracted from Cath. Lab. data base.

2.1 Inclusion Criteria

Inclusion Criteria were patients admitted to the cardiac ICU with acute STEMI and underwent primary PCI according to recent ESC guidelines [1]. Patients were allocated according to catheterization lab availability or the presence of any contraindications to thrombolytic therapy. Where those with contraindications to primary PCI and those who received thrombolytic therapy were excluded.

All patients were subjected to 1- history taking (age, sex, body mass index, smoking,

dyslipidemia, past history of chronic diseases as hypertension, diabetes, chronic kidney disease, stroke, past cardiac history of prior MI, prior PCI or CABG, family history for coronary artery disease and history of taking medications).

Systemic hypertension defined as SPB of 140 mm Hg or more and/or DBP of 90 mm Hg or more measured on 3 separate occasions with or without treatment before admission [8]. Patient defined as having diabetes if he had previous history or current diagnosis of DM. Dyslipidemia is defined as serum total cholesterol level over 200mg /dl or triglycerides more than 150 mg /dl or current treatment with lipid lowering medication. Current smoking, an adult who has smoked 100 cigarettes in his or her lifetime and who currently smokes cigarettes [9]. Renal impairment, recent surgery and trauma. Family history of premature coronary artery diseases.

2.2 Full Clinical Examinations Including

Clinical presentation of the patients as regard symptoms including (chest pain, palpitation, shortness of breath, any associations as abdominal pain, nausea, vomiting and sweating) and signs of life threating arrhythmia or cardiogenic shock. Vital signs as respiratory rate, blood pressure and heart rate.

General examination and local cardiac examination as abnormal pulsation, Heart murmurs & sounds.

2.3 Resting 12 leads ECG

Standard 12-lead ECG was obtained within 10 minutes of first medical contact (FMC) according to ESC guidelines 2017 including: (limb leads I, II, III, aVR, aVL, aVF, and Chest leads from V1to V6) for all patients on admission. Right pericardial leads (V3R, V4R, V5R, V6R) and posterior chest leads (V7 to V9) were done for some patients to detect posterior wall and right ventricular infarction [1].

Typical criteria for ST-segment elevation in acute myocardial infarction [4]: Measured at the J point.

2.4 Venous Sampling for Laboratory Data Including

Biomarkers of myocardial injury (Troponin and CK-MB), Serum creatinine (sCr), Complete blood count, Lipid profile, Liver Enzymes, Random blood sugar, INR, Virology.

2.5 Cardiac Catheterization to Perform Primary PCI with Emphasis on Coronary Angiographic Procedure Details Including

Onset of symptoms, Door to reperfusion time, vascular access, number of diseased vessels, culprit vessel, use of anticoagulation or glycoprotein IIb IIIa inhibitors during procedure, stent utilization, pre- and post-dilatation, thrombus aspiration, TIMI flow before and after procedure, amount of dye used during procedure.

2.5.1 PCI for Infarct Related Artery (IRA): Preparation before primary PCI

A loading dose of dual anti platelet (Aspirin 300mg chewable) plus P2Y12 inhibitor (Ticagrelor 180 mg or Clopidogrel 600mg), plus IV unfractionated heparin (UFH) with a dose as shown in Table 6. Glycoprotein IIb IIIa inhibitors (Eptifipatide or Tirofiban) were used before or during the procedure in selected cases according to operator point of view [9].

The arterial access, in this study, both femoral and radial arterial approaches were used.

Left and right coronary imaging was done with the standard approaches and the infarcted related artery (IRA) was identified. An interventional cardiologist identified the culprit lesion on the basis of the infarct location on the admission ECG and the angiographic findings (target vessel, lesion characteristics).

Multi-vessel disease was defined as presence of ≥ 1 lesion with >50% stenosis in ≥ one major epicardial coronary artery or its major branches remote from the IRA [10].

PCI with or without stenting was immediately performed using the standard femoral or radial approach with a 6-Fr guiding catheter. Thrombus aspiration, balloon pre-dilatation and post-dilatation were performed when indicated. The choice of using stents (drug-eluting stent) was left to the operator's discretion.

Reperfusion success is measured by TIMI blood flow grade: Reperfusion was considered successful (TIMI 3) or abnormal (TIMI 0-1-2) according to the TIMI blood flow grade.

2.6 Echocardiography

All studies were performed using (a GE vivid seven Cardiac ultrasound phased array system

with tissue Doppler imaging using M4S transducer 4 M.HZ.). Two- Dimensional echocardiographic assessment by M-mode and modified Simpson method were done during admission after successful PCI.

2-D Echocardiography was done in partial left lateral decubitus position to assess LV systolic function and assess segmental wall motion abnormalities and global wall motion.

2.7 Medical Treatment after Discharge Including

(Dual anti-platelets, statins, beta-blockers, ACE inhibitors or ARBS**,** and Nitrates if indicated).

Data were recorded at the time of procedure, during the admission and upon discharge.

2.8 The Study Involved the Following Two Phases

Phase I: Baseline measurement of process of care and health care services. A registry form will be filled out on cath lab. data base for each patient Presented with STEMI on admission and over a period of 6 months.

Phase II: Follow up assessment. This will involve assessment at 1 month, 3 months, 6 months after the index procedure.

The observational outcomes were:

1) Clinical condition & symptomatology of the patients, procedural characteristics and complications and bleeding complications during hospital admission.
2) Assessment of LV systolic function by echocardiography and detection of occurrence of any major adverse cardiac events (MACE) as mortality, re-hospitalization, re-infarction, stent thrombosis and heart failure at follow up.

2.9 Statistical Analysis

Version 20.0 of the IBM SPSS software programme was used to enter and analyze computer-entered data (Armonk, NY: IBM Corp). Quantitative and percentage descriptors were offered for qualitative data. The Kolmogorov-Smirnov test was performed to determine the distribution's normality. Interquartile range, range, mean, standard deviation, and median were used to quantify data (IQR). The importance between the various phases was established using the McNemar and Marginal Homogeneity Tests. Comparing two eras using the paired t-test for normally distributed quantitative data. To compare two periods or phases, ANOVA needs repeated measurements of quantitative variables with normal distributions. Dunn's post hoc test for pairwise comparisons. Significance of the obtained results was judged at the 5% level.

3. RESULTS

3.1 Regarding the TIMI Flow Score

3.1.1 Base Line TIMI Flow

493 (52.2%) patients had TIMI flow zero, 217 (23.0%) patients had TIMI flow 1, 161 (17.0%) patients had TIMI flow 2 and 74 (7.8%) patients had TIMI flow 3.

3.1.2 Final TIMI Flow

118 (12.5 %) patients had TIMI flow zero, 44 (4.7 %) patients had TIMI flow 1, 137 (14.5 %) patients had TIMI flow 2 and 646 (68.4 %) patients had TIMI flow 3.

3.2 Laboratory Findings and Length of Hospital Stay

Hb level had a mean value of 12.43 ± 1.93 mg/dl. CrCl ranged from 22-123 ml/min with mean 62.75 ± 17.19 ml/min. Duration of hospital stay: the duration of hospital stay ranged from 1 -15 days with mean 3.03 ± 1.75 days.

3.2.1 Comparison of EF at discharge and during follow up periods

It was found that EF of patients at discharge ranged from 22.0-70.0 with mean SD 45.97 ± 10.07, while at one month follow up was 25.0-70.0 with mean SD 48.87 ± 8.17, at 3 month was 25.0-70.0 with mean SD 48.72 ± 8.26 and at 6 month was 30.0-70.0 with mean SD 48.18 ± 8.13, so there was a significant different in EF at discharge and follow up periods with P value 0.001.

It was noticed that there are significant differences in MACE during follow up periods. There was significant difference as regard mortality, heart failure, stent thrombosis, repeated hospitalization and Re-infarction between follow up after one and three months, one and six months, three and six months (P <0.001).

Table 1. Distribution of the studied cases according to demographic data, prevalence of risk factors and heart rate, blood pressure, killip class, rhythm, location of infarction and onset of symptoms and door to reperfusion (n = 945)

	No	%
Age (years)		
<60	469	49.6
≥60	476	50.4
Mean ± SD.	58.19 ± 12.85	
Sex		
Male	723	76.5
Female	222	23.5
Prevalence of risk factors		
DM	442	46.8
HTN	411	43.5
Dyslipidemia	576	61.0
Smoker	553	58.5
Family history	114	12.1
IHD history	331	35.0
CVS	144	15.2
Previous CABG	99	10.5
Previous PCI	203	21.5
HR	76.74 ± 17.86	
Systolic	127.95 ± 21.11	
Diastolic	73.51 ± 12.58	
Killip		
I	602	63.7
II	179	18.9
≥III	164	17.4
Rhythm		
SR	749	79.3
Other	196	20.7
Location of infarction		
Ext.Ant	399	42.2
Inferior	269	28.5
Posterior	68	7.2
Inferior, Posterior	37	3.9
Lateral	60	6.3
Anteroseptal	60	6.3
Right	17	1.8
Inferior, right	35	3.7
Onset of symptoms	7.73 ± 4.25	
Door to reperfusion	109.79 ± 50.29	

3.2.2 As regard medications at discharge and compliance at follow up

882 (93.3%) of the patients were discharged on DAPT, 841 (89.0%) were discharged on statins, 816 (86.3%) were discharged on ACE inhibitors, and 791 (83.7%) were discharged on Beta Blockers. From the whole study population only 389 (41.2%) were compliant on their medications at 6 month follow up.

4. DISCUSSION

The objective of reperfusion treatment in acute myocardial infarction is to reperfuse the at-risk myocardium rapidly and persistently. Traditionally, reperfusion might be achieved with thrombolysis or primary PCI [11].

Regarding risk factors for developing STEMI: and 43.5 %were hypertensive, 46.8% patients were

diabetics, while 58.5% were active smokers, this was supported by Chow et al. Quitting smoking may be the most (cost-) effective secondary preventive measure [12].

Regarding the clinical presentation on hospital admission, 49.4%of the study population presented by anterior STEMI in which LAD was the culprit lesion, 6.3% patients presented by anteroseptal, 28.5%patients presented by inferior STEMI and 6.3%patients presented by lateral STEMI, 3.9% patients presented with posterior STEMI where culprit was PDA and 3.9% patients presented with combined inferior and posterior STEMI and 3.7% patients were inferior and right STEMI.

In addition, the majority of patients in this study (63.7%) presented as Killip class I, whilst 18.9% and 17.4% presented as Killip classes II and III, respectively. This was reinforced by the STREAM trial, in which the majority of their research sample consisted of patients presenting with anterior STEMI and Killip class I [13].

Table 2. Distribution of the studied cases according angiographic and procedural characteristics and amount of dye in ml (n = 945)

	No.	%
Access		
Radial	467	49.4
Femoral	478	50.6
MVD	442	46.8
IRA		
LAD	471	49.8
RCA	192	20.3
LCX	127	13.4
PDA	107	11.3
Diagonal	48	5.1
Thrombus aspiration	85	9.0
Types of intervention		
Stent utilization	798	84.4
Pre-dilatation	602	63.7
Post-dilatation	407	43.1
GPIIbIIIa	437	46.2
Dye in ml	219.63 ± 62.99	

It was found that 442 of the patients had multi-vessel coronary disease (46.8 %) and 503 patients had single culprit vessel disease. In which case multi-vessel disease was defined as presence of ≥ 1 lesion with > 50 % stenosis in ≥ 1 major epicardial coronary artery or its major branches remote from the IRA [10].

Table 3. Descriptive analysis of baseline and final TIMI flow

	Baseline TIMI flow		Final TIMI flow	
	No.	%	No.	%
TEMI				
0	493	52.2	118	12.5
1	217	23.0	44	4.7
2	161	17.0	137	14.5
3	74	7.8	646	68.4

McN: McNemar test MH: Marginal Homogeneity Test

Regarding angiographic findings 471 of the patients had LAD as culprit vessel (49.8%),192 patients had RCA culprit (20.3%), 127 patients had LCX as culprit (13.4%), 48 patients had diagonal as culprit (5.1%) and 107 patients had PDA as culprit (11.3%).

Regarding baseline TIMI flow in coronary angiography in the current study, 493 patients presented with TIMI 0 (52.2%), 217 patients had TIMI 1 (23.0%), 161 patients had TIMI 2 (17.0%), and 74 patients had TIMI 3 (7.8%).

Table 4. Laboratory findings and length of hospital stay of the studied cases (n= 945)

	Mean ± SD.
Hb	12.43 ± 1.93
CrCl	62.75 ± 17.19
Length of hospital stay	3.03 ± 1.75

After PCI, patency rates were high with final TIMI III achieved in 646 patients (68.4%), 137 patients had TIMI 2 flow (14.5%), 44 patients had TIMI 1 flow (4.7%) and 118 patients (12.5%) with TIMI 0.

The majority of fibrinolysis-treated patients (58.5%) in the STREAM study comparing TIMI flow in primary and pharmaco-invasive PCI had TIMI III at baseline, while the majority of primary PCI patients had TIMI 0. (59.3%). Nevertheless, the ultimate TIMI III flow was equivalent between the groups treated with pharmaco-invasive method and primary PCI, 91% and 92%, respectively [13].

In addition, 18% of FAST-MI patients treated with primary PCI had initial TIMI flow. And 37% of patients who were treated with fibrinolysis. While the final TIMI flow in the main PCI group was 89% and in the fibrinolysis group it was 84 percent, the final TIMI flow in the fibrinolysis group was 89% [14].

Table 5. Distribution of the studied cases according to major adverse cardiac events during admission (n = 945)

	No.	%
Dissection	122	12.9
Cerebrovascular stroke	98	10.4
CIN	193	20.4
Vascular complications	73	7.7
Bleeding complications	177	18.7
Mortality	265	28.0
Reinfarction	101	10.7
Heart failure	231	24.4

Table 6. Comparison between EF % at discharge and different follow up periods

EF	Discharge (n= 945)	Follow up (n= 838)	Follow up 3 months (n= 482)	Follow up 6 months (n= 373)	F
Min. - Max	22.0 - 70.0	25.0 - 70.0	25.0 - 70.0	30.0-70.0	F
Mean ± SD	45.97 ± 10.07	48.87 ± 8.17	48.72±8.26	48.18 ± 8.13	14.956*
Median (IQR)	45.0(39.0- 55.0)	50.0(40.0-55.0)	50.0(40.0-55.0)	50.0(40.0-55.0)	
p1		<0.001*	0.001*	0.001*	

Table 7. Comparison between the different periods according to MACE in follow up

	Follow up one month (n= 945)		Follow up 3 months (n= 945)		Follow up 6 months (n= 945)	
	No.	**%**	**No.**	**%**	**No.**	**%**
Mortality						
No	602	63.7	476	50.3	369	39.0
Yes	37	3.9	62	6.6	63	6.7
Lost Follow up	306	32.3	407	43.0	513	54.2
Sig.bet.Grps	$p_1<0.001^*$, $p_2<0.001^*$, $p_3<0.001^*$					
HF						
No	581	61.4	519	54.9	415	43.9
Yes	58	6.1	19	2.0	17	1.8
Lost Follow up	306	32.3	407	43.0	513	54.2
Sig.bet.Grps	$p_1<0.001^*$, $p_2<0.001^*$, $p_3<0.001^*$					
Stent thrombosis						
No	565	59.7	509	53.8	374	39.5
Yes	74	7.8	29	3.1	58	6.1
Lost Follow up	306	32.3	407	43.0	513	54.2
Sig.bet.Grps	$p_1<0.001^*$, $p_2<0.001^*$, $p_3<0.001^*$					
Repeated hospitalization	**(n= 911)**		**(n= 925)**		**(n= 926)**	
No	583	61.6	499	52.8	353	37.3
Yes	56	6.1	39	4.2	79	8.3
Lost Follow up	306	32.3	407	43.0	513	54.2
Sig.bet.Grps	$p_1<0.001^*$, $p_2<0.001^*$, $p_3<0.001^*$					
Re infarction						
No	625	66.1	501	53.0	373	39.4
Yes	14	1.5	37	3.9	59	6.2
Lost Follow up	306	32.3	407	43.0	513	54.2
Sig.bet.Grps	$p_1<0.001^*$, $p_2<0.001^*$, $p_3<0.001^*$					

*Fr: Friedman test, Sig. bet. periods were done using Post Hoc Test (Dunn's), p: p value for comparing between the different periods, p_1: p value for comparing between Follow up one month and follow up 3 months, p_2: p value for comparing between Follow up one month and follow up 6 months, p_3: p value for comparing between Follow up 3 months and follow up 6 months, *: Statistically significant at p ≤ 0.05*

Regarding major adverse outcome during hospital admission, regarding in-hospital mortality: 265 patients died during admission (28.0 %) and regarding angiographic complication, Dissection occurred in 122 patients (12.9 %), Contrast induced nephropathy occurred in 193 patients (20.4%), Congestive heart failure symptoms occurred in 231 patients (24.4%).

Bleeding complication occurred in 177 patients (18.7 %) suffered from different types of bleeding complication and 98 patients were complicated with cerebrovascular stroke 73 patients with vascular complications.

In the current work, during the follow-up visits, there was a significant different similarity in incidence of MACE during follow up periods after one, three and six months, 37 patients died after one month from the follow up, 62 patients during the three months of follow up and 63 patients during six month follow up. Also, there was statistically significant difference at follow up periods as regard MACE (congestive heart failure, stent thrombosis, rehospitalization and re-infarction).

Table 8. Distribution of the studied cases according to medications at discharge and medication compliance at 6 month follow up (n = 945)

	No.	%
DAPT at discharge	882	93.3
Statin at discharge	841	89.0
ACE at discharge	816	86.3
Beta blocker at discharge	791	83.7
Medication compliance at 6 months follow up	389	41.2

In addition, Larson et al. constructed a prospective registry of 2,624 consecutive STEMI patients and 31 referring non-PCI institutions to demonstrate the safety and feasibility of a pharmaco-invasive reperfusion technique in rural patients who expected PCI delays owing to long-distance transfers. STEMI patients who received fibrinolytic therapy at hospitals more than 60 miles from the PCI center were promptly transported for PCI. Despite a 93-minute longer door-to-balloon time, there were no differences in 30-day mortality, stroke, serious bleeding, or reinfarction/ischemia between patients who had a pharmaco-invasive approach and those who went directly to the PCI facility [15].

In the FAST-MI study, 5-year mortality in STEMI patients from the French registry of Acute ST-elevation or non-ST elevation myocardial infarction (FAST-MI) 2005 was assessed based on the type and method of reperfusion treatment. 447 (30%) of 1492 STEMI patients with initial call 12 hours after start had fibrinolysis (60% pre-hospital; 97% with subsequent angiography, 84% with subsequent PCI), 583 (39%) underwent pPCI, and 462 (31%) did not get reperfusion. There was an increase in reinfarction, stroke, and ventricular fibrillation with the fibrinolytic-based strategy, but there was an increase in cardiogenic shock with initial PCI. None of the problems encountered in the hospital were substantially different between the two reperfusion treatments. In the FAST-MI study, there was no significant difference in the incidence of serious bleeding difficulties between the main PCI and secondary PCI groups [16].

Two-thirds of the patients had fibrinolytic therapy before hospitalization. Those who did not get reperfusion treatment had a much greater death rate. Comparing the two reperfusion techniques, the pharmaco-invasive approach had at least as excellent of outcomes as the main PCI treatment [16].

Regarding difference in echocardiographic data at discharge and during follow up: echocardiographic assessment of EF showed significant improvement between EF at discharge and during follow up periods with no significant difference between each follow up period and the other with median ejection fraction 50% with a statistical significance (P=0.001).

Regarding medications at discharge and compliance during follow up: Łukasz Pietrzykowski, et al. conducted a trial on 225 post-MI patients treated with PCI. The investigation of treatment plan implementation (adherence to medicine given upon hospital discharge) included only paid medications: ACEIs, P2Y12 receptor inhibitors, and statins. Sufficient adherence was defined as ≥ 80%. During the one-year follow-up, adherence to all three drug classes was 64 ± 25%, with 67 ± 32% for ACEIs, 62 ± 34% for P2Y12 receptor inhibitors, and 64 32% for statins. From 65 ± 26 % in the first quarter of follow-up to 51 ± 34% in the final quarter of follow-up, there was a progressive reduction in adherence ($p < 0.001$).

After MI, adherence to pharmacotherapy diminishes similarly for all major drug classes

administered after MI. Numerous socioeconomic and clinical factors identified to influence medicine adherence over time.

Our analysis of changes in adherence during successive quarters of follow-up revealed a progressive decline in the percentage of patients with an adherence level of 80% or above. The third and fourth quarters had the largest fall for all pharmaceutical groups analyzed. For ARB/ACEI, beta-blockers, and statins, Korhonen et al. identified myocardial infarction patients with an adherence rate of 80% or greater. According to Mathews, 31 percent of patients stopped at least one ARB/ACEI, aspirin, statin, beta-blocker, or P2Y12 receptor inhibitor within the first six months of medication.

5. CONCLUSIONS

PCI is the most frequent reperfusion treatment for STEMI. After PCI, older patients had a higher risk of in-hospital mortality, acute kidney injury, and bleeding problems than younger patients. Transradial intervention may reduce the incidence of periprocedural problems in elderly PCI patients. Also extended follow up is not feasible and was limited in our study population specially after 6 month and the adherence rate to medications was relatively low, this may be attributed to cultural and economic issues.

CONSENT AND ETHICAL APPROVAL

The study was done after being approved from the institutional ethical committee, Tanta University. Informed consent taken from all patients included.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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