

Egyptian Experience in Primary Percutaneous Coronary intervention Dual Center Study

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Abstract

Background: Prompt restoration of blood flow in the occluded coronary artery and rapid establishment of myocardial perfusion form the basis of STEMI therapy. Even though both thrombolysis and PPCI have been proven to achieve these goals effectively, PPCI has outperformed thrombolysis in many respects. First, thrombolysis restores the infarct related artery (IRA) patency in fewer (40–60%) patients in contrast to PPCI (more than 90%). Secondly, thrombolysis is less effective when total ischemic time exceeds 6 h when thrombus maturation occurs. Thirdly, up to 25% of patients have contraindication to thrombolysis. We aimed to evaluate our status as regard primary PCI of ST segment elevation MI frequency, complication and outcomes during hospital stay in two Egyptian centers.

Methods: This is a prospective study included 272 patients with STEMI who were eligible for primary PCI. The study was conducted at department of cardiology-Benha University hospital and National Heart Institute in the period from April 2015 to October 2015. We aimed to evaluate our status as regard primary PCI of ST segment elevation MI frequency, complication and outcomes during hospital stay in two Egyptian centers. Patients subjected to the following:- History taking and general and local examination, E.C.G, ECHO:- include EF, wall motion abnormality, Laboratory:-including cardiac biomarkers, s.creatinine, Door to balloon time and Coronary angiography:- all data of PCI procedures will be recorded such as approach, guiding catheter, guide wire, Ballon, stent, TIMI flow, procedural complication, lesion and inhospital morbidity and mortality. All data will be intabulated and statistically analyzed.

Results: The principle findings of current study are: (1) overwhelming majority of patients were males (86.76%), (2) smoking was the most common risk factor (66.54%), (3) the median door-to-balloon time was within international recommendations (64.33 min), (4) femoral was the only approach, (4) most of revascularization was to culprit lesion (5) use of GPIIb/GPIIIa was in 29.41%, aspiration devices was in 41.18% (6) the overall mortality was 1.10% and 61.3% in the Cardiogenic shock subset.

Conclusion: Primary PCI is a safe, feasible and effective treatment option for patients with STEMI. Current study has shown that PPCI is feasible with good outcomes.

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Introduction

The treatment of STEMI includes prompt revascularization and medical therapy. Revascularization can be performed by either primary percutaneous coronary intervention (PCI), fibrinolytic therapy (thrombolytic therapy) or surgically. Primary PCI is preferred if available within a reasonable time-frame (door-to-balloon less than 90 minutes). (Hannan et al, 2010)

Primary PCI defined as an emergent percutaneous catheter intervention in the setting of STEMI, without previous fibrinolytic treatment is the preferred reperfusion strategy in patients with STEMI, provided it can be performed expeditiously (i.e. within guideline-mandated times), by an experienced team, and regardless of whether the patient presents to a PCI-capable hospital. (Freixa et al, 2012)

Primary PCI is the most reliable method of re-opening of the culprit artery in the majority of patients. Coronary artery patency can be confirmed, secured and maintained. There is a lower risk of major, particularly intracerebral, bleeding than with fibrinolytic therapy. For PPCI to provide reliable, timely reperfusion a fully equipped catheter laboratory staffed by an experienced team must be available 24-h a day. (Montalescot et al, 2011)

The best outcomes occur when primary PCI is performed with a door-to-balloon time of < 90 minutes and when symptoms onset was < 12 hours. Primary PCI is only indicated when symptoms duration is 12-24 hours (delayed presentation) if severe congestive heart failure, hemodynamic/electrical instability or continued angina is present. Primary PCI is not recommended when symptom onset is more than 12 hours and the patient is asymptomatic. (Kornowski et al, 2011)

In certain situations, primary PCI is strongly preferred over thrombolytic therapy. This includes primary PCI within 36 hours for patients that develop cardiogenic shock and those with Killip Class III heart failure. There are no situations in which fibrinolytic therapy is preferred over primary PCI unless the patient refuses invasive procedures. Fibrinolytic therapy works best when symptom onset is < 3 hours since fresh thrombus lysis more readily than more organized, subacute thrombus. If symptoms have been present for > 3hours then primary PCI is preferred. (De Luca, et al 2012)

Approximately 50% of STEMI patients have significant multivessel disease. Only the infarct-related artery should be treated during the initial intervention. There is no current evidence to support emergency intervention in non-infarct-related lesions. The only exceptions, when multivessel PCI during acute STEMI is justified, are in patients with cardiogenic shock in the presence of multiple, truly critical ($\geq 90\%$ diameter) stenosis or highly unstable lesions (angiographic signs of possible thrombus or lesion disruption), and if there is persistent ischaemia after PCI of the supposed culprit lesion. However, in patients with multivessel disease and cardiogenic shock, non-culprit lesions without critical stenosis should not routinely be stented. (Cassese et al, 2012)

In primary PCI, drug-eluting stents (DES) reduce the risk of repeated target vessel revascularization, compared with bare-metal stents (BMS). There have been concerns about increased risks of very late stent thrombosis and re infarction with DES, compared with BMS. However, use of DES has not been associated with an increased risk of death, myocardial infarction or stent thrombosis on long-term follow up. (Stone et al, 2012)

The treatment of STEMI does not begin and end with primary PCI or fibrinolytic therapy. The use of numerous pharmacotherapies that have been shown to decrease morbidity and mortality are discussed and emphasized, including beta-receptor blockers, ACEI inhibitors and ARBs, aldosterone antagonists, and statins. The initiation or continuation of high-intensity statins is recommended in all patients with STEMI. Post hospitalization care is similarly emphasized, including smoking cessation and cardiac rehabilitation. (Stone et al, 2011)

A number of clinical, angiographic, and technical variables predict risk of procedural failure in patients undergoing PCI. Major complications include death, MI, or stroke; minor complications include transient ischemic attacks, vascular complications, contrast-induced nephropathy, and a number of angiographic complications. (Romagnoli et al, 2012).

Patients and methods

Study Design

This is a prospective study included 272 patients with STEMI who were eligible for primary PCI. The study was conducted at department of cardiology-Benha University hospital and National Heart Institute in the period from April 2015 to October 2015. We aimed to evaluate our status as regard primary PCI of ST segment elevation MI frequency, complication and outcomes during hospital stay in two Egyptian centers.

Key inclusion criteria were STEMI patients with this diagnostic criteria:

Key inclusion criteria were patients with STEMI presented within 12 hours from onset of chest pain with the following diagnostic criteria:

1. Typical persistent ischemic chest pain.
2. Positive cardiac biomarkers (CPK & CKMB).
3. Electrocardiographic evidence of acute myocardial infarction in the form of new ST elevation in two contiguous leads with the cut off points: ≥ 0.2 mV in men or ≥ 0.15 mV in women in leads V2-V3 and / or ≥ 0.1 mV in other leads (Thygesen et al 2007), often with reciprocal ST-segment depression in contralateral leads (Alpert et al, 2000).

Key exclusion criteria were patients who had one or more of the following criteria:

- 1-Patients who received fibrinolytic therapy will be excluded.
- 2-Patients with non ST segment elevation myocardial infarction.
- 3-Any contraindication to coronary angiography.

Study protocol

Baseline evaluation

All patients had review of medical history, full clinical examination, ECG on admission, cardiac markers (CK-MB) and transthoracic echocardiography.

A. Review of medical history

This included demographic data (age, sex), risk factors for CAD such as (smoking, hypertension, diabetes mellitus, dyslipidemia), prior coronary intervention (CABG –PCI), history of CHF, comorbidities and cardiac medications.

B. clinical examination

With particular emphasis on the pulse and blood pressure of the patients, as well as auscultation of the back to elicit the presence of any clinically detectable pulmonary venous congestion, auscultation of the heart for the presence of third heart sounds or audible murmurs and patient classified according to Killip class:-

Class I	No congestive heart failure.
Class II	Mild congestive heart failure, rales, S3, congestion on chest radiograph.
Class III	Pulmonary edema.
Class IV	Cardiogenic shock.

Killip classification (Killip and Kimball 1967).

C. Electrocardiography

Twelve leads surfaces ECG were done for each patient on admission to the emergency room for diagnosis of acute myocardial infarction. After initiating the reperfusion therapy by 90 minutes and every 6 hours during first 24 hours, and once daily until discharge. It was used for assessing the degree of ST segment elevation early after reperfusion, and then calculating the degree of ST segment resolution. The ECGs was recorded at a paper speed of 25 mm/s and an amplification of 10 mm /mv.

Localization of site of STEMI

1. Anterior or antero-lateral MI diagnosed by ST segment elevation in the precordial leads (V1 to V6) and leads I and AVL.
2. Antero-septal or apical MI diagnosed by ST segment elevation in the precordial leads (V1 to V3) while lateral MI diagnosed by ST segment elevation in the leads V3 to V6.
3. Inferior MI diagnosed by ST segment elevation in leads II, III and AVF while ST segment elevation in right sided precordial leads indicates right ventricular infarction (V3R- V4R).
4. ST elevation in leads placed over the back of the heart such as leads V7 to V9 indicate Posterior wall infarction.
5. New LBBB in the setting of symptoms consistent with acute MI may indicate a large, anterior wall acute MI (Thygesen et al 2007).

D. Cardiac biomarkers (CK-MB): on admission and every 8 hours in first 24 hours.

E. Echocardiography

All patients were evaluated by echocardiography for the assessment of regional wall abnormalities and overall left ventricular systolic function by estimating LV Ejection fraction (EF) (Flachskampf et al., 2011).

Treatment strategy

Primary PCI

- 1-Aspirin 300mg loading, clopidogrel 600mg loading.
- 2-Unfractionated heparin (UFH) 10,000 bolus dose was injected after sheath insertion.
- 3-Femoral approach was the standard in all patients by using 6-7 Fr sheath.
- 4-Diagnostic coronary angiography was done to detect the culprit vessel.
- 5-Culprit vessel was engaged with an appropriate sized guiding catheter.

6-The culprit lesion was crossed with non-hydrophilic soft guide wire unless in failed to cross the lesion we used hydrophilic wire.

7-After lesion crossing, the TIMI flow and thrombus burden were assessed.

8- If TIMI flow was grade III and thrombus burden was low (TIMI grade 1 or 2), the lesion was stented directly.

9-Aspiration devices and glycoproteins inhibitors were used in lesions with heavy thrombus burden and or impaired TIMI flow after PCI.

10-Ballon dilatation was done if the lesion was too tight to allow the passage of the stent.

11-As per the hospital protocol, bare metal stents (BMS) were used in most of the patients and drug-eluting stents (DES) were used when the patient or lesion characteristics were at high risk for restenosis. In case of multi-vessel disease, PCI is limited to culprit unless patient had significant stenosis with less than TIMI III flow in a non-culprit or patient was in cardiogenic shock

11-The sheath was removed 6 hours later from the end of PCI and compression was done manually.

12-Hemodynamically stable patients were transferred to the wards after 24 h and discharged on the third day. At the time of discharge, all the patients were continued on dual antiplatelets, statin, betablocker and ACE inhibitor if not contraindicated.

In hospital adverse events (death, re-infarction, heart failure, bleeding, arrhythmia and stroke) were noted and they were followed up

Myocardial re-infarction: re-elevation of creatinine kinase-MB concentrations to above the upper limit of normal and increased by 50% over the previous value (Mehta et al., 2003) or elevation of ST segment more than 2mm from previous ECG (The HERO-2 Trial Investigators 2001).

Heart failure: presence of new symptoms of dyspnea and/or edema, with one or more of ventricular gallop rhythm, pulmonary crepitations and elevated venous pressure (Richards et al., 2002).

Bleeding: According to (TIMI) study group, “Hemorrhage was defined as “**major**” if there was a reduction of hemoglobin of 5 g/dl or more (or >15% in hematocrit) or any intracranial bleeding. Hemorrhage was classified as “**minor**” if there was an observed blood loss and a drop in hemoglobin of less than 5 g/dl (or in hematocrit from 10% to 15%) from study entry to the time of the lowest hemoglobin (hematocrit) and this was within 10 days.

Stroke: defined as the occurrence of a neurologic deficit with residual symptoms remaining for 24 hours after onset (Mehta et al., 2003).

Mechanical complications: as, free wall rupture, VSR, MR or myocardial expansion.

Major arrhythmia: as, ventricular tachycardia, ventricular fibrillation and asystole.

Death.

Statistical analysis

All data of the patient and PCI procedures will be recorded, intabulated and statistically analysed using Statistical Program for Social Science (SPSS) version 18.0. Quantitative data were expressed as mean± standard deviation (SD). Qualitative data were expressed as frequency and percentage.

Results

Table (1): Demographic data distribution of the study group

Demographic data	No.	%
Age (years)		
≤40 years	41	15.1
<75 y	262	96.32
≥75 y	10	3.68
Range [Mean ±SD]	30-88 [52.71±11.01]	
Sex		
Male	236	86.76
Female	36	13.24

Table (1) shows that out of 272 patients the mean age was 52.71 years, patients <75 years were 262(96.32%) cases out of 272patients, patients ≥75 years 10(3.68%) cases out of 272 patients and young patients ≤40 years was 41(15.1%) out of 272. 236(90%) were males out of 272 patients and 36 (13.24%) were females out of 272 patients.

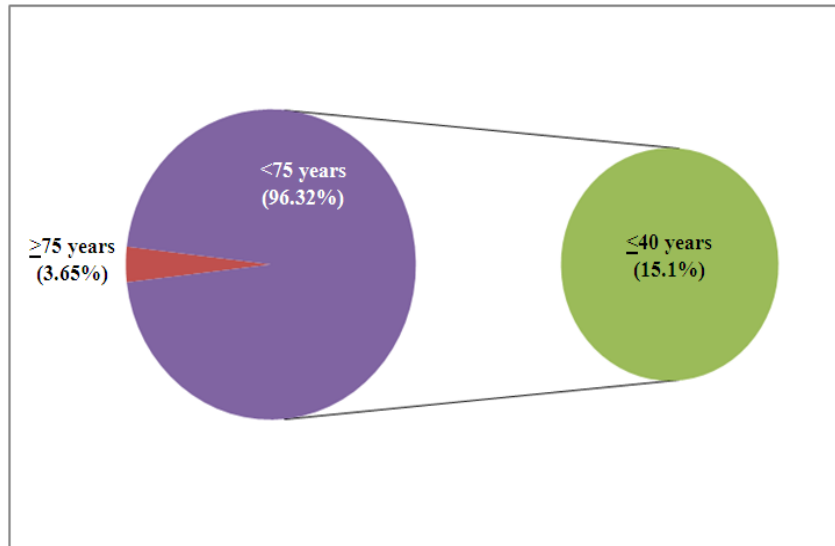


Fig. (1): Pie chart of age distribution.

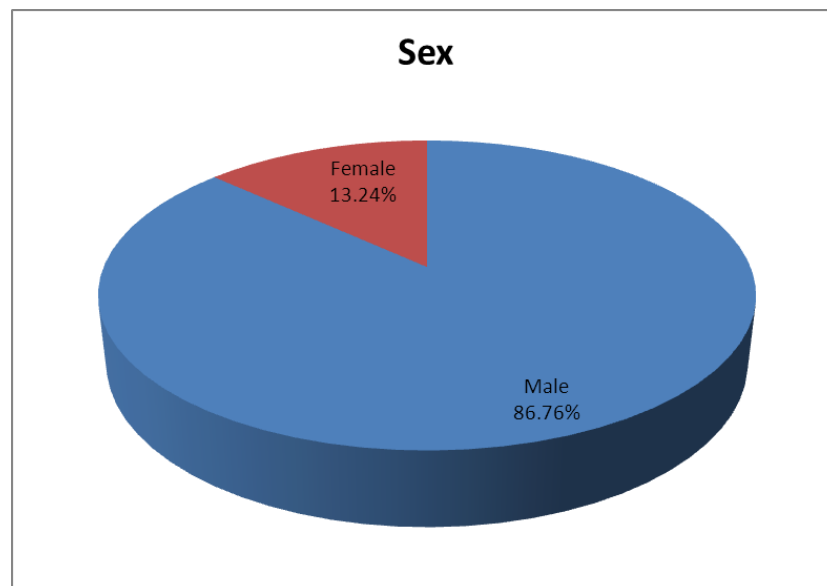


Fig. (2): Pie chart of sex distribution.

Table (2): Risk factors distribution of the study group

Risk factors	No.	%
Smoking		
Yes	181	66.54
No	91	33.46
DM		
Yes	108	39.71
No	164	60.29
Dyslipidemia		
Yes	128	47.06
No	144	52.94
HTN		
Yes	135	49.63
No	137	50.36
Prior PCI		
Yes	15	5.51
No	257	94.49
Prior CABG		
No	272	100.00
Prior CVA		
Yes	13	4.78
No	259	95.22
FH		
Yes	139	51.10
No	133	48.90

Table (2) shows that out of 272 patients 181(66.54%) were smokers, 108(39.71%) had diabetes, 135(49.63%) had hypertension, 128(47.06%) had dyslipidemia 139(51.10%) had positive family history, 15 (5.51%) did prior PCI, 13(4.78%) had history of CVA and there was not history of prior CABG, this percentages out of 272 patients.

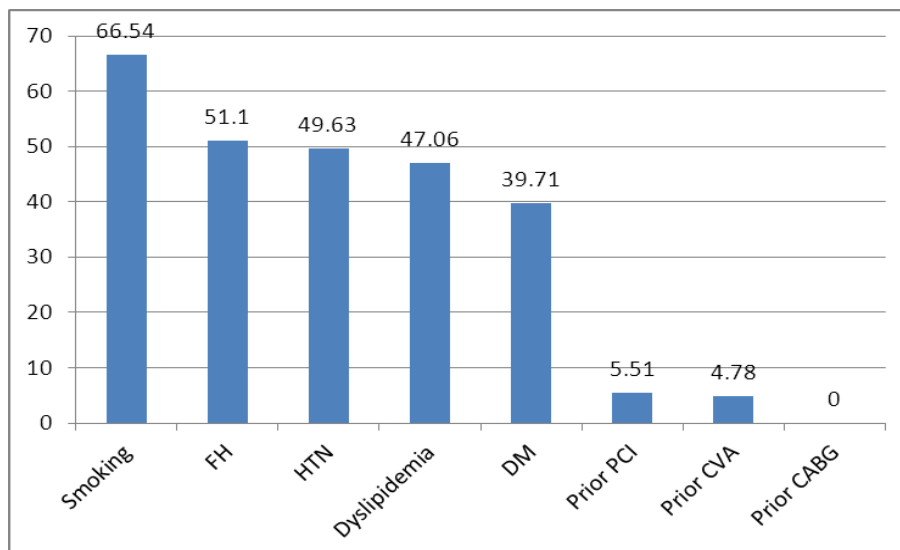


Fig. (3): Risk factors distribution of the study group.

Table (3) Clinical examination, Electrocardiographic

Clinical data	No.	%
KILLIP class		
I	241	88.60
II	24	8.82
IV	7	2.57
ECG		
ANT	204	75.00
LAT	15	5.51
INF	72	26.47
RT	5	1.84
POST	3	1.10

Table (3) shows that out of 272 patients anterior wall MI most common type 204(75%) patients, Lateral wall infarction occurred in 15(5.51%) patients, inferior wall infarction reported in 72(26.47%) patients, right wall infarction occurred in 5(1.84) and 3(1.10%) patients had posterior wall infarction out of 272 patients of the study.

241(88.60%) patients were KILLIP class I, 24(8.82%) patients were KILLIP class II, 7 (2.57%) patients were KILLIP class IV out of 272 patients of the study.

Table (4) Echocardiographic and Laboratory data

	MIN.	MAX.	MEAN	±SD
EF%	0.46	65.5	52.91	36.65
Laboratory				
<i>CK-MB</i>	6.00	5104.00	675.67	812.08
<i>Creatinine</i>	0.50	9.80	1.13	0.93

Table (4) shows out of 272 patients Mean EF was 52%, with range 46-56%. Mean CK-MB was 675.67 and mean Creatinine 1.13.

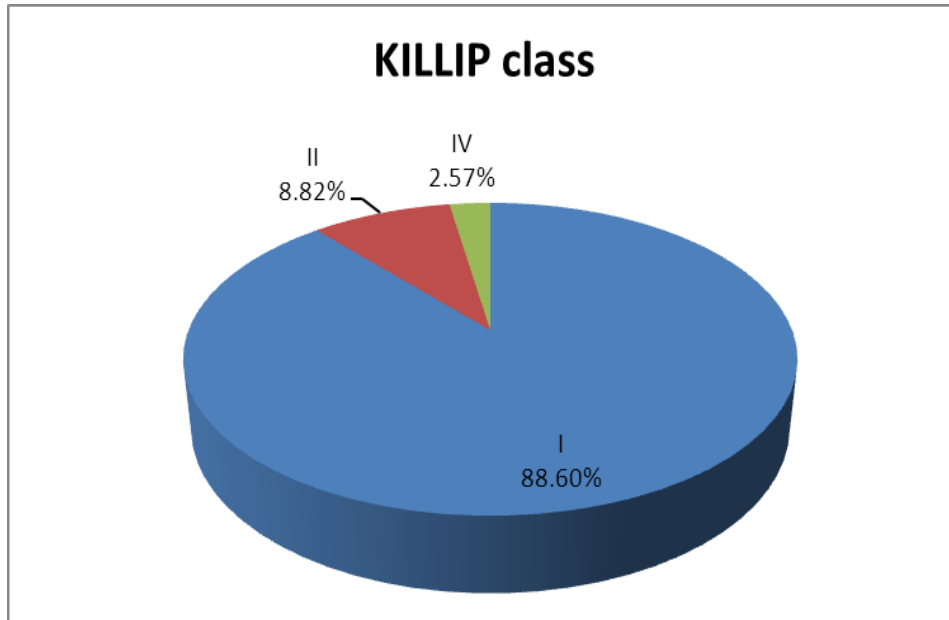


Fig. (4): Pie chart Killip Class distribution of the study group.

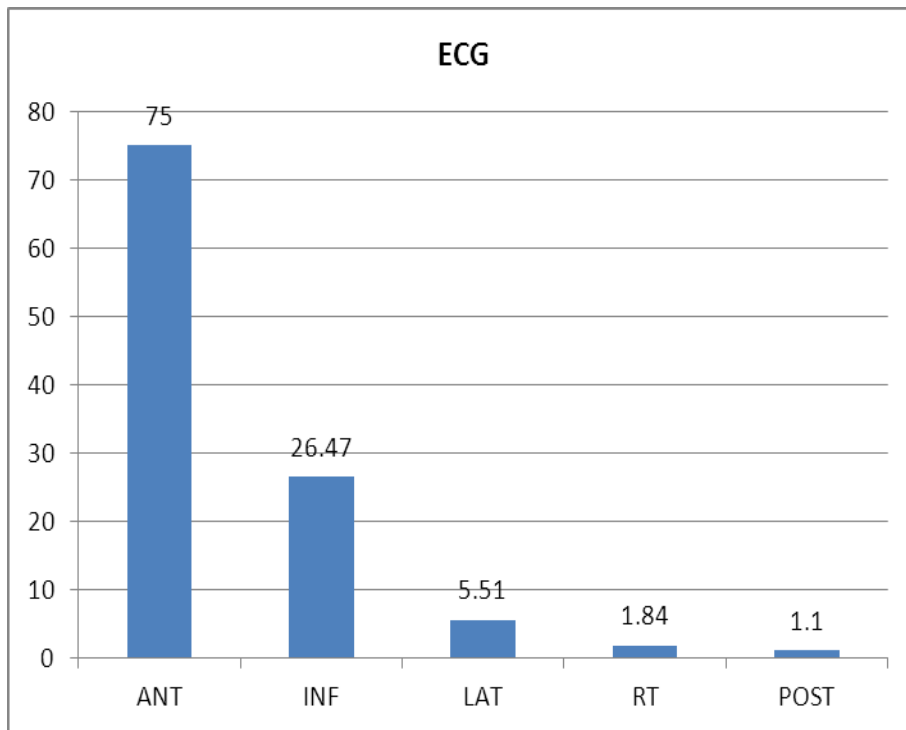


Fig. (5): Bar chart ECG distribution of the study group.

Table (5): Door to balloon time (DTB)

DTB	
Range	50-90
Mean \pm SD	64.33 \pm 11.38
\leq 60 min.	162 (59.56%)
>60-90 min.	110 (40.44%)

Table (5) shows that out of 272 patients mean DTB time was 64 minutes, range 50-90 minutes, 162(59.56%) patients out of 272 patients DTB within 60 minutes and 110(40.44%) patients out of 272 patients DTB from 60-90 minutes.

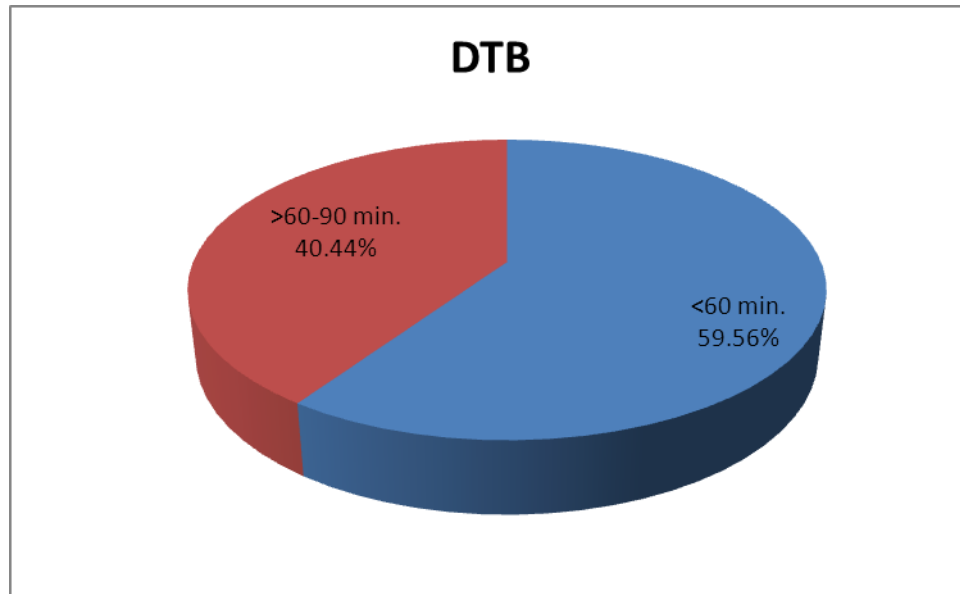
**Fig. (6): Pie chart of DTB time.**

Table (6) coronary angiography, infarct related artery and number of diseased vessel

Catheterization procedure	No.	%
Approach		
Femoral	272	100.00
Infarct related artery		
DIAG	1	0.37
LAD	185	68.01
LCX	29	10.66
RCA	55	20.22
Normal	2	0.74
Number of diseased vessel		
0	2	0.74
1	176	64.70
2	57	20.96
3	34	12.50
4	3	1.10

Table (6) shows that out of 272 patients trans-femoral approach was done in all patients. Diagnostic coronary angiography was done pre PCI. The target artery was LAD in 185(68.01%) of all cases while RCA in 55(20.22%) of cases, LCX in 29(10.66%) cases, Diagonal 1(0.37%) case and there was 2(0.74%) cases were normal out of 272 patients. 176(64.70%) of patients had a single vessel disease, 2 vessels disease were detected in 57(20.96%) of patients, while 3 vessels disease were detected in 34(12.50%) of patients, 4 vessel occurred in 3(1.10%) of patients and there was 2(0.74%) patients were normal out of 272 patients of the study.

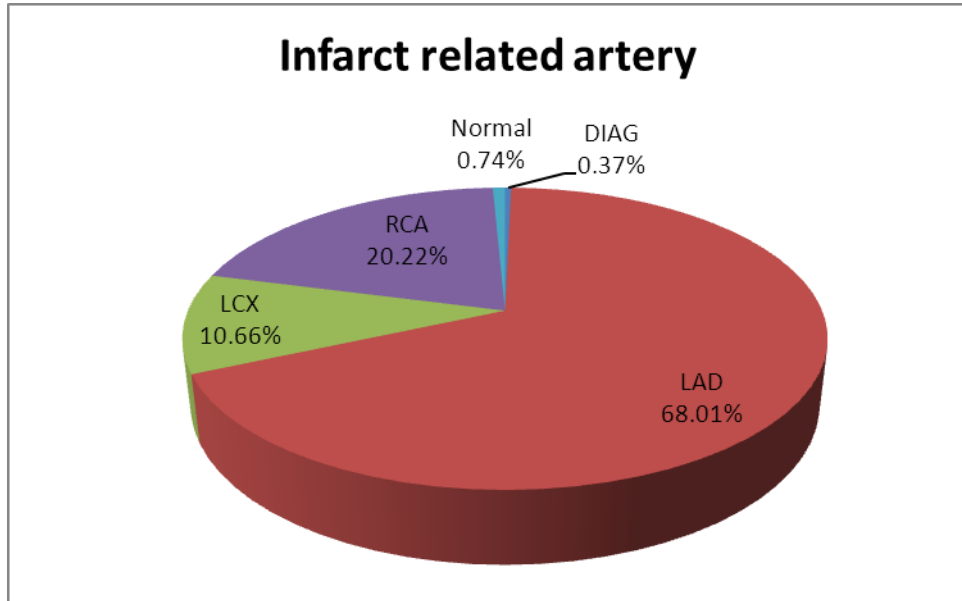


Fig. (7): Pie chart infarct related artery distribution of the study group.

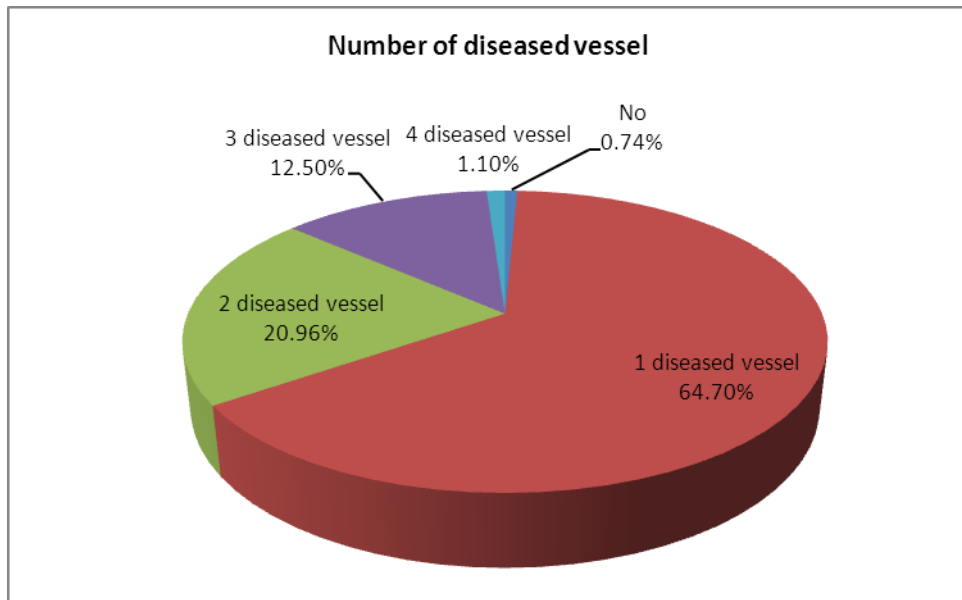


Fig. (8): Pie chart number of diseased vessel distribution of the study group.

Table (7) Guiding catheterization and Guiding wire

Catheterization procedure	No.	%
Guiding catheterization		
EPU	53	18.99
JL	113	40.50
JR	57	20.43
XP	47	16.84
No	9	3.22
Guiding wire		
ASAHI	92	33.82
BMW	67	24.63
FLOPPY	46	16.91
GALIO	28	10.29
PT2	30	11.03
NO	9	3.31

Table (7) shows that out of 272 patients JL guiding catheter was used in 113(40.50%) patients, EPU guiding catheter was used in 53(18.99%), XP guiding catheter was used in 47(16.84%), JR guiding catheter was used in 57(20.43%) and there was 9(3.22%) cases did not use guiding catheter out of 272 patients of the study. ASAHI wire used in 92(33.82%), while BMW wire used in 67(24.63%), FLOPPY wire used in 46(16.91%), GALIO wire used in 28(10.29%), PT2 wire used in 30(11.03%) and there was 9(3.31%) cases did not use wire out of 272 patients of our study.

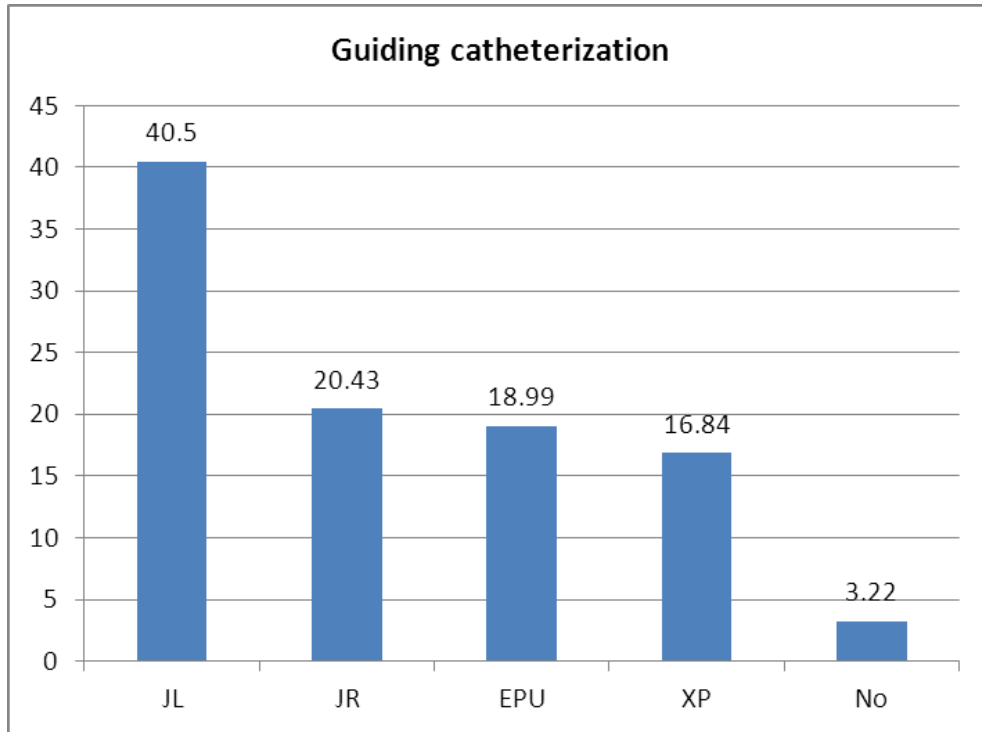


Fig. (9): Bar chart guiding catheterization distribution of the study group.

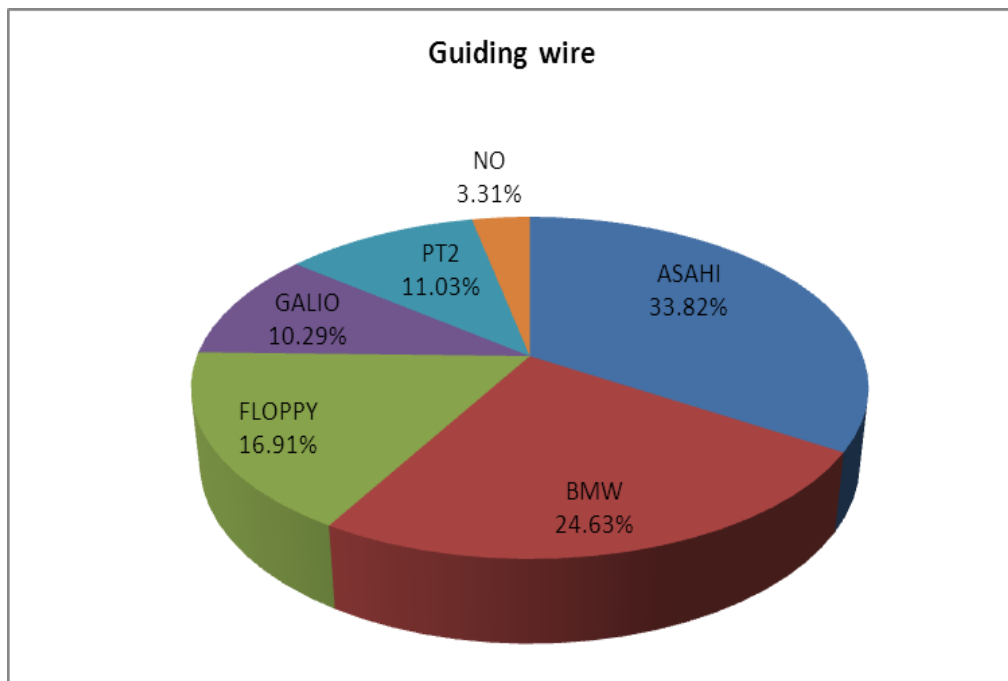
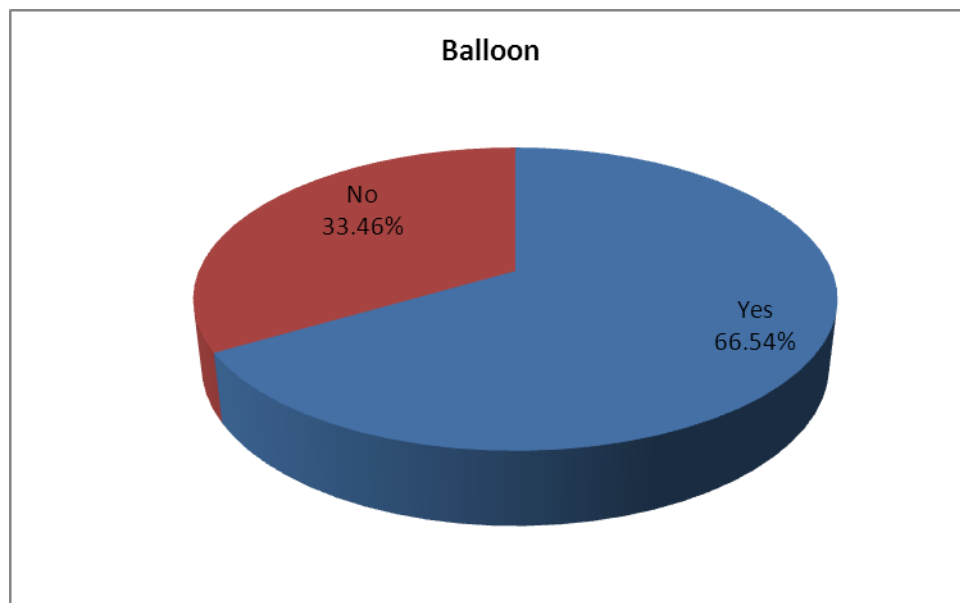


Fig. (10): Pie chart guiding wire distribution of the study group.

Table (8): Balloon and stents

Catheterization procedure	No.	%
Balloon		
Yes	181	66.54
No	91	33.46
Type of stent		
BMS	205	75.37
DES	4	1.47
No	63	23.16
Number of stent		
1	154	56.62
2	54	19.85
3	1	0.37
No	63	23.16

Table (8) shows that out of 272 patients balloon dilation done in 181(66.54%) out of 272 patients either balloon dilation without stenting (PTCA) in 38(13.97%) or balloon dilation with stenting 143(52.57%) patients. Implantation of Bare-metal stent was performed in 205(75.37%) of all patients, implantation of DES stent was used in 4(1.47%) and 63(23.16%) patients did not use stent. 154(56.62%) patients had 1 stent while 54(19.85%) patients had 2 stents and 1(0.37%) patient had 3 stents out of 272 patients of the study.

**Fig. (10): Pie chart using of balloon distribution of the study group.**

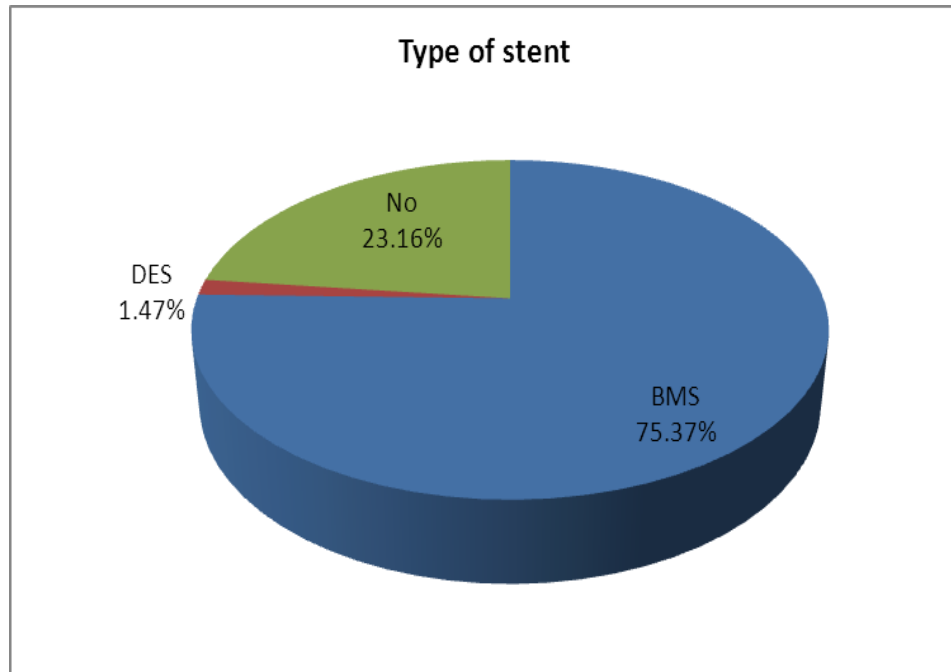


Fig. (11): Pie chart type of stent distribution of the study group.

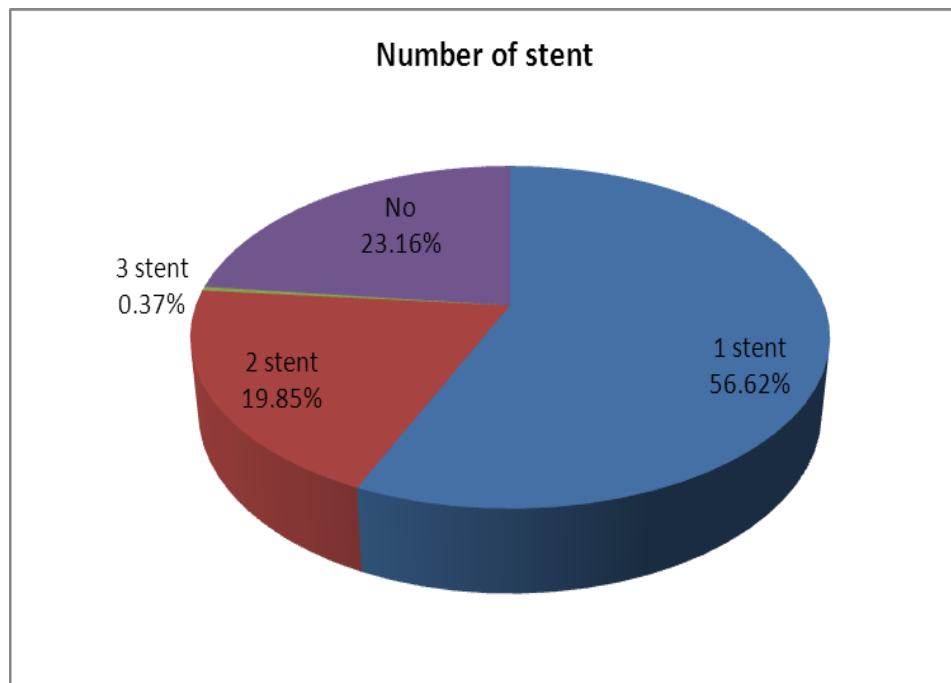


Fig. (12): Pie chart number of stent distribution of the study group.

Table (9) Aspiration device and GP IIb/IIIa inhibitors

Catheterization procedure	No.	%
Aspiration device		
Yes	112	41.18
No	160	58.82
GP IIb/IIIa inhibitors		
Yes	80	29.41
No	192	70.59

Table (9) shows that out of 272 patients intracoronary glycoprotein inhibitors were used in 80(29.41%) cases of 272 patients this was followed by intravenous infusion for an average time 12 hours. Manual aspiration devices were used in 112(41.18%) of patients of 272 cases, large thrombus burden or impaired TIMI flow were the main indications.

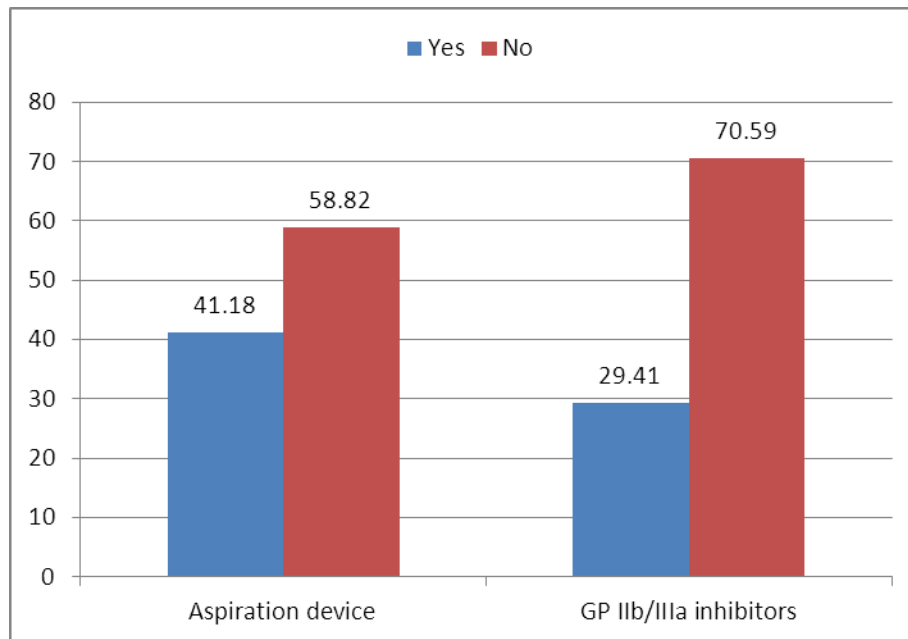
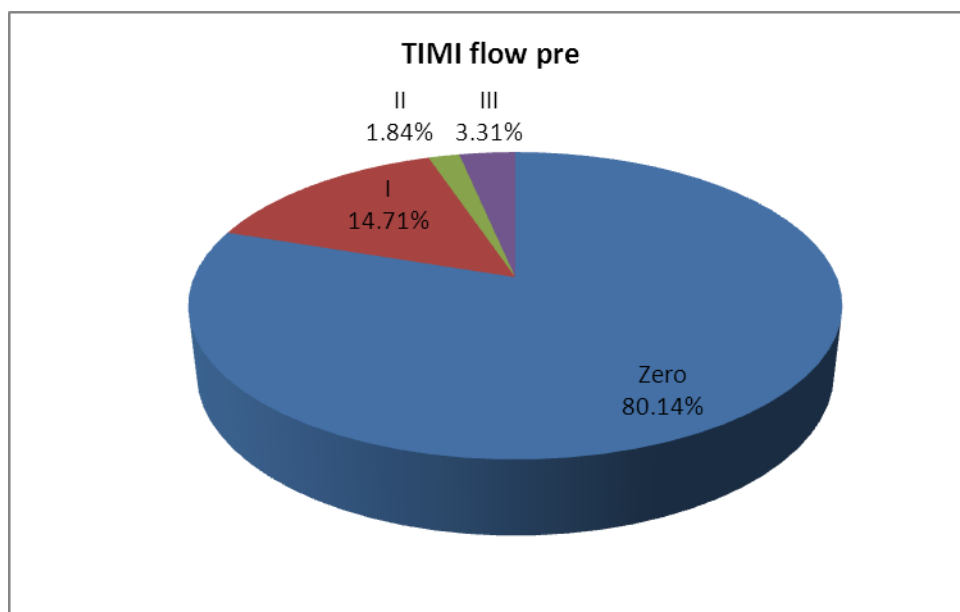


Fig. (13) Bar chart aspiration device and GP IIb/IIIa inhibitors.

Table (10) TIMI flow pre, TIMI flow post

Catheterization procedure	No.	%
TIMI flow pre		
0	218	80.15
I	40	14.71
II	5	1.84
III	9	3.31
TIMI flow post		
0	14	5.15
II	14	5.15
III	244	89.71

Table (10) shows that out of 272 patients pre PCI TIMI flow 0 was detected in 218(80.15%) patients, TIMI I in 40(14.71%) patients while TIMI II flow in 5(1.84%) patients and TIMI III flow in 9(3.31%) patients out of 272 cases of the study. TIMI flow at the end of primary PCI was III in 244(89.71%) patients and II in 14(5.15%) patients and TIMI 0 (failed PCI) was in 14(5.15%) out of 272 cases of the study.

**Fig. (14): Pie chart TIMI flow pre distribution of the study group.**

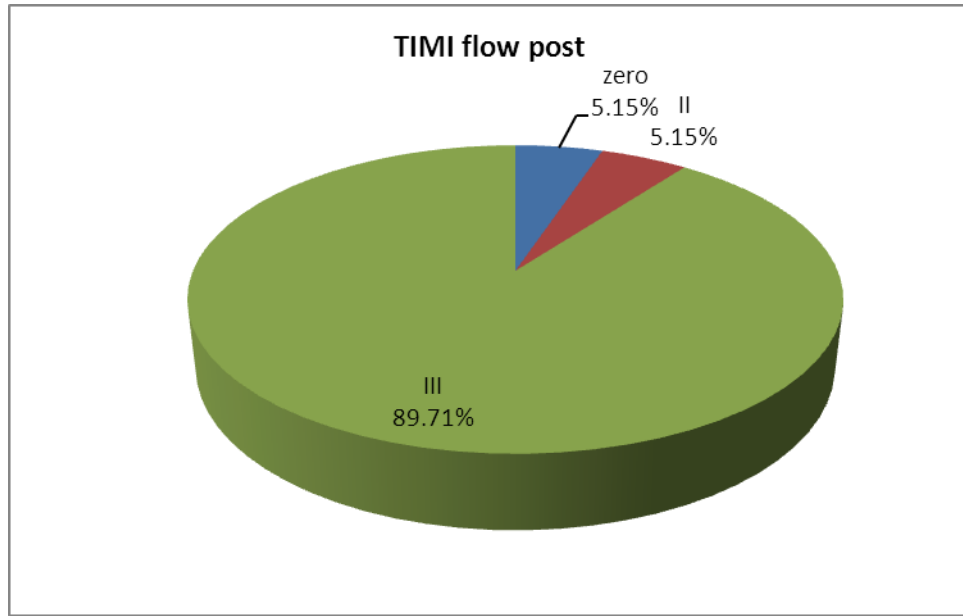


Fig. (15): Pie chart TIMI flow post distribution of the study group.

Table (11): Culprit, Total revascularization

Catheterization procedure	No.	%
Culprit, Total revascularization		
Culprit	237	87.13
- PTCA(Balloon)	38	13.97
- PTCA(Balloon)+ Stent	143	52.57
-Stent without PTCA (Balloon)	56	20.59
Total	12	4.41
Failed	14	5.15
Conservative	9	3.31

Table (11) shows that out of 272 patients culprit vessel revascularization done in 237(87.13%) patients out of 272 patients either culprit (PTCA) in 38(13.97%) patients or culprit (stent and PTCA) in 143(52.57%) patients or culprit (stent without PTCA) in 56(20.59%), total revascularization done in 12(4.41%) patients out of 272 cases, there was 14(5.15%) failed PCI and 9(3.31%) patients was conservative.

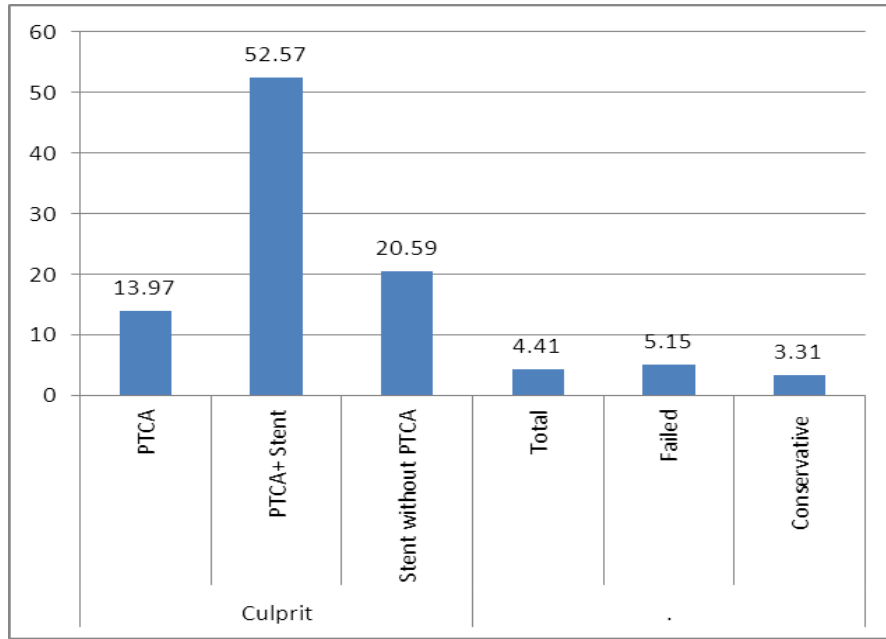


Fig. (16) Culprit, Total revascularization.

Table (12): In hospital outcome distribution of the study group

In hospital outcome	No.	%
Minor bleeding		
Yes	15	5.51
No	257	94.49
Arrhythmia		
Yes	10	3.68
No	262	96.32
Re-infarction		
No	272	100.00
Need for urgent PCI		
No	272	100.00
HF		
Yes	31	11.40
No	241	88.60
Mortality		
YES	3	1.10
No	269	98.89

Table (12) shows that out of 272 patients minor bleeding occurred in 15(5.51%) patients, 10(3.68%) of patients had arrhythmia, 31(11.40%) of patients developed heart failure out of 272 cases of the study, no reported cases of re-infarction or need for urgent PCI during the hospital stay. Mortality cases due to cardiogenic shock were reported in 3(1.10%) patients out of 272 cases of the study.

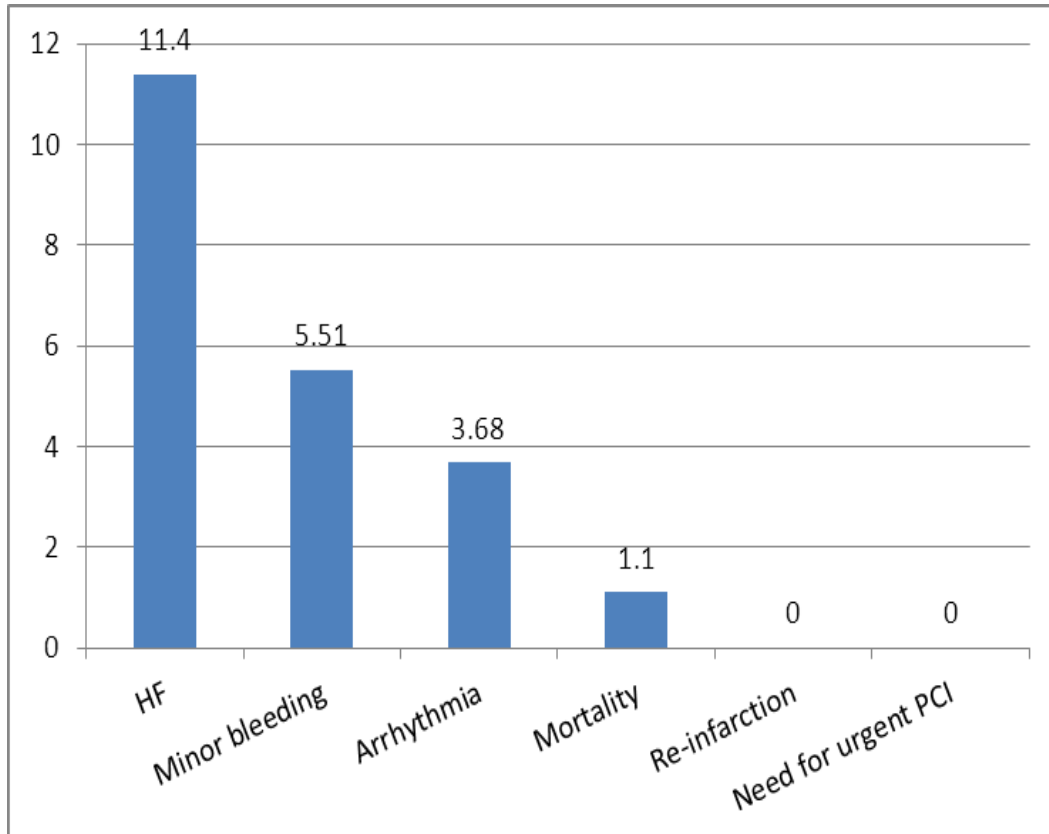


Fig. (17): Bar chart hospital outcome distribution of the study group.

Discussion

Prompt restoration of blood flow in the occluded coronary artery and rapid establishment of myocardial perfusion form the basis of STEMI therapy. Even though both thrombolysis and PPCI have been proven to achieve these goals effectively, PPCI has outperformed thrombolysis in many respects. First, thrombolysis restores the infarct related artery (IRA) patency in fewer (40–60%) patients in contrast to PPCI (more than

90%). Secondly, thrombolysis is less effective when total ischemic time exceeds 6 h when thrombus maturation occurs. Thirdly, up to 25% of patients have contraindication to thrombolysis. (Adam et al, 2010)

Finally, improved hard outcomes in terms of death, myocardial infarction, stroke and bleeding with PPCI makes this the preferred therapy in the setting of STEMI. (Keeley et al, 2003) However, the proportion of patients receiving this treatment remains low, In the prospective CREATE registry, which enrolled patients with acute coronary syndrome in 80 centers in various parts of the India, PPCI was performed in only 8% of the patients presenting with acute STEMI (Xavier et al, 2008).

The principle findings of current study are: (1) overwhelming majority of patients were males (86.76%), (2) smoking was the most common risk factor (66.54%), (3) the median door-to-balloon time was within international recommendations (64.33 min), (4) femoral was the only approach, (4) most of revascularization was to culprit lesion (5) use of GPIIb/GPIIIa was in 29.41%, aspiration devices was in 41.18% (6) the overall mortality was 1.10% and 61.3% in the Cardiogenic shock subset.

The mean age of current study was 52.71 years as shown table (1), considerably younger than patients presenting with STEMI from the west and similar to STEMI subset of CREATE registry. 236 (86.76%) patients out of 272 patients were males, slightly more than the CREATE subset. In current study, smoking was more prevalent while DM and previous history of myocardial infarction was less prevalent in our patients as shown table (2). (Xavier et al, 2008)

Door-to-balloon time, the second part of time to treatment is the standard metric used to assess hospitals capability to manage STEMI with mechanical reperfusion. Both ACC and ESC propose a door-to-balloon time of 90 min or PCI related delay of 60 min as standard as beyond which the benefit of PPCI over fibrinolysis is lost. (Rathore et al, 2009)

DTB time could achieve in nearly 75.3% of the patients. 46% of the patients had door-to-balloon time of less than 60 min. Though there was had catheterization team with an aim to achieve the optimal door-to-balloon time in all patients, for the most part time was lost in patient making the decision about the revascularization strategy. (Victor S.M et al, 2012)

In current study as shows in Table (5) out of 272 patients mean DTB time was 64 minutes, range 50-90 minutes, 162(59.56%) patients out of 272 patients DTB within 60 minutes and 110(40.44%) patients out of 272 patients DTB from 60-90 minutes.

The procedural success in current study was 95.85%. The overall complications (death, re-infarction, urgent PCI, arrhythmia, minor bleeding and HF) occurred in 56 (20.59%) patients. The overall survival was 94.8%. 31(11.40%) patients out of 272 patients due to cardiogenic shock, minor bleeding occurred in 15(5.51%) patients out of 272 patients, 10(3.68%) patients out of 272 patients had arrhythmia as shown in table (12). Almost all the patients were on dual anti-platelets and a high number of patients were on statin, beta-blocker and ACE-inhibitor or ARB. (Mc Namara et al, 2006)

In current study as shown table (3), anterior MI was the most common type of infarction 75% of all patients. Di Mario et al, 2004 reported 55% incidence of anterior infarction, Moreover, in the study derived by Qarawani et al., 2007, anterior infarction was the target one in 51% of patients. However, Varani et al., 2008 in their study, only 45% of patients had anterior infarction. High percentage of anterior MI may be due to missed cases of inferior MI or high flow of anterior MI cases.

Any regional medical system must seek to enable rapid recognition and timely reperfusion of patients with STEMI. System delays to reperfusion are correlated with higher rates of mortality and morbidity (Terkelsen et al, 2011).

In current study as shown table (5), the PCI related delay (i.e. the door to balloon time) was 64.33 ± 11.38 min. The incidence of heart failure and worse outcome was directly related to door to balloon time, no evidence of heart failure between patients who had door to balloon within 60 minutes, but when door to balloon was between 60 and 90 minutes the incidence was 3% and when door to balloon was > 90 minutes the incidence was 7%. Currently, it is estimated that almost 90% of patients presenting to a hospital with PCI capability and without a clinical reason for delay have a door to balloon time \leq 90 minutes (Nestler et al, 2009). De Luca et al, 2004 showed that there was a definite relationship between time delay to treatment and 1year mortality. Each 30 minutes of delay was associated with a relative risk increase by 7.5% at 1year follow-up. Nallamuthu et al, 2004 showed that the mortality benefit associated with primary PCI was lost if the PCI-related delay exceeded 60 min. Combined analysis of the NRM-2 -3 and -4 showed that this accepted PCI-related delay was much longer, i.e. 114 min and varied considerably depending on various factors like symptoms duration, age and infarction location (Pinto et al, 2006).

In the present study as shown table (6), the target artery for PPCI was LAD in 68.01% of all cases while RCA in 20.22% of cases and LCX in 10.66% of patients. In the study derived by Ayaz et al, 2009, LAD was the most common identified culprit vessel in 65 % of patients followed by RCA in 25% and LCX in 10 % of patients. Moreover, Giuseppe et al, 2013 reported that LAD was the target artery in 66% of patients, RCA in 21% and LCX in 13%.

In present study as shown table (9), intracoronary glycoprotein inhibitors were used in 29.41% of cases this was followed by intravenous infusion for an average time 12 hours. Manual aspiration devices were used in 41.18% of patients, large thrombus burden or impaired TIMI flow were the main indications. Yahya and Yadallah, 2013 used GP IIb/IIIa inhibitor in 45% of patients and aspiration devices in 40% of patients. Thrombus aspiration is considered reasonable during PCI in patients with STEMI who have a high clot burden and short ischemic times (Kushner et al, 2009). Glycoprotein IIb/IIIa inhibitor had been found to improve myocardial perfusion when started during PPCI and infused for 12 hours thereafter (Petronio et al, 2005). Guidelines for 2013 indicate that aspiration devices and GPIIb/IIIa inhibitor are considered as class IIa.

In current study as shown in table (8) Balloon dilation done in 66.54% out of 272 patients either balloon dilation without stenting (PTCA) in 13.97% or balloon dilation with stenting 52.57% patients. Implantation of Bare-metal stent was performed in 75.37% of all patients, implantation of DES stent was used in 1.47% and 23.16% patients did not

use stent. 56.62% patients had 1 stent while 19.85% patients had 2 stents and 0.37% patient had 3 stents out of 272 patients of the study.

In current study as shown table (10) TIMI flow grade pre PCI in our study was TIMI flow 0 in 80.15% of patients, TIMI I in 14.71% while TIMI II flow in 1.84% of patients and TIMI III flow in 3.31% of patients. TIMI flow at the end of primary PCI was III in 89.71% of patients and II in 5.15% of patients and TIMI 0 in 5.15% of patients. The STREAM study reported TIMI flow before PCI was TIMI flow 0 in 59% of patients, TIMI I in 30% while TIMI II flow in 11% of patients. TIMI flow after PPCI was III in 92% of patients and II in 8% of patients. In the study derived by Mehta et al, 2003, TIMI grade III flow was achieved in 93 to 96% of patients who underwent primary PCI. In GUSTO Iib, 1997 TIMI flow III was obtained in 88% of patients.

Procedure related complications as shown table (12) in current study were 5.15% of all patients (occurred due to failed PCI). Antoniucci et al, 2001 reported that 17% showed an angiographic no-reflow phenomenon. No reflow occurred in 13% in Umed et al 2006. Yip et al 2002 demonstrated that in patients with AMI who had a high thrombus burden with delayed reperfusion, the rate of no-reflow was higher.

In the present study, the incidence of minor bleeding was 15(5.51%) patients out of 272 patients. This was concordant to the results of Zwolle Group study, the incidence of major bleeding within 48 hours after primary PCI was low 1.6% and the incidence of minor bleeding was 5.6%.

Regarding in-hospital outcomes, heart failure was evident in 11.40% of all patients. The results of this study were concordant with the results from the study by Yahya and Yadallah, 2013 and those of the previous investigators (De Luca et al, 2005) (Zhu et al, 2001). In current study arrhythmia occurred in 10(3.68%) patients out of 272 patients. In current study in-hospital mortality was 3(1.10%) patients out of 272 patients, with 42.8% of cardiogenic shock patients (7patients), which was near to the mortality in SHOCK study.

Conclusion

Primary PCI is a safe, feasible and effective treatment option for patients with STEMI. Current study has shown that PPCI is feasible with good outcomes. Even though the recommended door-to-balloon time can be achieved in most of the patients.

Recommendation

The time factor in patient with STEMI is important so health education is important for the patient to decrease the time from symptom onset and health education for the doctors for early diagnosis of STEMI, more over it is essential to improve the logistics to decrease the time to the cath. lab. All these factors will improve the result of Primary PCI.

Larger sample size & longer follow up period are recommended in the future studies.

Study Limitation

- 1) Relative Small sample size.
- 2) Short follow up period (during hospital stay).

REFERENCES

- 1- Adam Z., and de Belder M.A 2010. Primary percutaneous coronary intervention for ST-elevation myocardial infarction. In: Redwood S., Cruzen N., Thomas M., editors. Oxford Text Book of Interventional Cardiology.1st ed. Oxford University Press; Oxford, UK: pp. 254–277.
- 2-Alpert JS, Thygesen K, Antman E, et al 2000. Myocardial infarction redefined—a consensus document of The Joint European Society of Cardiology/American College of Cardiology Committee for the redefinition of myocardial infarction. *J Am CollCardiol*; 36:959-965.
- 3-Antoniucci D, Valenti R, Migliorini A, et al 2001.Direct infarct artery stenting without pre dilation and no-reflow in patients with acute myocardial infarction. *J Am Heart*; 142:684-690.
- 4-Ayaz H, Muhammad S, Bashir H, et al 2009. Outcomes of prima Percutaneous Coronary Intervention (PCI) in a Tertiary Care Cardiac Centre. *JPMA* 2009; 12:77-85.
- 5-Cassese S, Byrne RA, Ott I, et al 2012: Paclitaxel-coated versus uncoated balloon angioplasty reduces target lesion revascularization in patients with femoropopliteal arterial disease: A meta-analysis of randomized trials. *CircCardiovascInterv* 5:582.
- 6-De Luca G, Dirksen MT, Spaulding C, et al 2012: Drug-eluting vs bare-metal stents in primary angioplasty: a pooled patient-level meta-analysis of randomized trials. *Arch Intern Med* 172(8):611–621, discussion 621–622.
- 7-De Luca G, Suryapranata H, Ottervanger JP, et al 2004.Timedelay to treatment and mortality in primary angioplasty for acute myocardial infarction: every minute of delay counts. *Circulation* 109(10):1223–1225.
- 8-De Luca G, Suryapranata H, Stone GW, et al 2005. Abciximab as adjunctive therapy to reperfusion in acute ST-segment elevation myocardial infarction: a meta-analysis of randomized trials. *JAMA*; 293:1759-65.

- 9-Di Mario C, Sansa M, Airoidi F et al 2004. Single versus multivessel treatment during primary angioplasty: results of the multicenter randomized HZPECOAT -for culprit or multivessel stenting for Acute Myocardial Infarction (HELP AMI) Study. *Int J Cardiovasc Intervent*; 6:128-133.
- 10-Flachskampf FA, Schmid M, Rost C, et al 2011. Cardiac imaging after myocardial infarction. *Eur Heart J*; 32:272–283
- 11-Freixa X, Bellera N, Ortiz-Perez JT, et al 2012. Ischaemic postconditioning revisited: lack of effects on infarct size following primary percutaneous coronary intervention. *Eur Heart J* ;33:103–112.
- 12-Giuseppe B, Imad S, Stefano D, et al 2013. Does the Target Vessel Impact on Results of Percutaneous Coronary Intervention. *J INVASIVE CARDIOL* ; 25:660-665.
- 13-Hannan EL, Samadashvili Z, Walford G, et al 2010. Culprit vessel percutaneous coronary intervention versus multivessel and staged percutaneous coronary intervention for ST-segment elevation myocardial infarction patients with multivessel disease. *JACC Cardiovasc Interv*;3:22–31.
- 14-Hannan EL, Zhong Y, Jacobs AK, et al 2010: Effect of onset-to-door time and door-to-balloon time on mortality in patients undergoing percutaneous coronary interventions for ST-segment elevation myocardial infarction. *Am J Cardiol* 106(2):143–147.
- 15-Keeley EC, Boura JA, Grines CL, et al 2003. Primary angioplasty versus intravenous thrombolytic therapy for acute myocardial infarction: a quantitative review of 23 randomized trials. *Lancet*; 361: 13–20.
- 16-Killip T and Kimball JT 1967. Treatment of myocardial infarction in a coronary care unit. A two year experience with 250 patients. *Am J Cardiol*; 20:457-465.
- 17-Kornowski R, Mehran R, Dangas G, et al 2011. Prognostic impact of staged vs. “one-time” multivessel percutaneous intervention in acute myocardial infarction: analysis from the HORIZONS-AMI (Harmonizing Outcomes with Revascularization and stents in Acute Myocardial Infarction) trial. *J Am Coll Cardiol*;58:704–711.
- 18-Kushner FG, Hand M, King SB, et al 2009. Focused Updates ACC/AHA Guidelines for the Management of Patients With ST-Elevation Myocardial Infarction (updating the 2004 Guideline and 2007 Focused Update) and ACC/AHA/SCAI Guidelines on Percutaneous Coronary Intervention (updating the 2005 Guideline and 2007 Focused Update). *J Am Coll Cardiol*; 54:2205-2241.

- 19-McNamara R.L., Wang Y and Herrin J 2006. Effect of door-to-balloon time on mortality in patients with ST-segment elevation myocardial infarction. *J Am Coll Cardiol.*;47:2180–2186.
- 20-Mehta RH, Harjai KJ, Cox D, et al 2003. Clinical and angiographic correlates and outcomes of suboptimal coronary flow in patients with acute myocardial infarction undergoing primary percutaneous coronary intervention. *J Am Coll Cardiol* 42:1739-1744.
- 21-Montalescot G, Zeymer U, Silvain J, et al 2011. Intravenous enoxaparin or unfractionated heparin primary percutaneous coronary intervention for ST-elevation myocardial infarction: the international randomised open-label ATOLL trial. *Lancet*; 378:693–703.
- 22-Nallamothu BK, Antman EM, Bates ER, et al 2004. Primary percutaneous coronary intervention versus fibrinolytic therapy in acute myocardial infarction: does the choice of fibrinolytic agent impact on the importance of time-to-treatment? *Am J Cardiol*; 94:772:774.
- 23-Nestler DM, Noheria A, Haro LH, et al 2009. Sustaining improvement in door-to-balloon time over 4 years: the Mayo Clinic ST-elevation myocardial infarction protocol. *Circ Cardiovasc Qual Outcomes*; 2:508–513.
- 24-Petronio A, De Carlo M, Ciabatti N, et al 2005. Left ventricular remodeling after primary coronary angioplasty in patients treated with abciximab or intracoronary adenosine. *Am Heart J* ; 150:1015-1022.
- 25-Pinto DS, Kirtane AJ, Nallamothu BK, et al 2006. Hospital delays in reperfusion for ST-elevation myocardial infarction: implications when selecting a reperfusion strategy. *Circulation* 2006; 114: 2019–2025.
- 26-Qarawani D, Nahir M, Abboud M, et al 2007. Culprit only versus complete coronary revascularization during primary PCI. *Int J Cardiol*; 123:288-292.
- 27-Rathore S.S., Curtis J.P. and Chen J 2009. Association of door-to-balloon time and mortality in patients admitted to hospital with ST elevation myocardial infarction: national cohort study. *BMJ*.338:b1807.
- 28-Richards AM, Nichollas MG, Troughton RW, et al. (2002): Antecedent hypertension and heart failure after myocardial infarction. *JACC*; 39:1182-1188.
- 29-Romagnoli E, Biondi-Zoccai G, Sciahbasi A, et al 2012: Radial versus femoral randomized investigation in ST-segment elevation acute coronary syndrome: the RIFLE-STEACS (Radial Versus Femoral Randomized Investigation in

- ST-Elevation Acute Coronary Syndrome) study. *J Am CollCardiol* 60(24):2481–2489.
- 30-Stone GW, Maehara A, Witzenbichler B, et al 2012. Intracoronary abciximab and aspiration thrombectomy in patients with large anterior myocardial infarction: the INFUSE-AMI randomized trial. *JAMA* 307:1817–1826.
- 31-Stone GW, Witzenbichler B, Guagliumi G, et al 2011. Heparin plus a glycoprotein IIb/IIIa inhibitor vs. bivalirudin monotherapy and paclitaxel-eluting stents vs. bare-metal stents in acute myocardial infarction (HORIZONS-AMI): final 3-year results from a multicentre, randomized controlled trial. *Lancet*, 377: 2193-2204
- 32-Terkelsen CJ, Jensen LO, Tilsted H-H, et al 2011. Health care system delay and heart failure in patients with ST-segment elevation myocardial infarction treated with primary percutaneous coronary intervention: follow-up of population-based medical registry data. *Ann Intern Med.*; 155:361–7. 98. Sub study. *Am Heart J*; 147:133-143.
- 33-Thygesen K, Alpert JS, White HD, et al 2007. Joint ESC/ACCF/AHA/WHF Task Force for the Redefinition of Myocardial Infarction. Universal definition of myocardial infarction. *Eur Heart J* 28:2525–2538.
- 34-Umeda H, Katoh T, Izawa H, et al 2006. The distal protection during primary percutaneous coronary intervention alleviates the adverse effects of large thrombus burden on myocardial reperfusion. *Circulation J* 2006; 70: 232–238
- 35-Varani E, Balducelli M, Aquilina M, et al 2008. Single or multivessel percutaneous coronary intervention in ST-elevation myocardial infarction patients. *Catheter Cardiovasc Interv* 2008; 72:927–933.
- 36-Victor S.M., Gnanaraj A., S V., Pattabiram S., et al 2012. Door-to-balloon: where do we lose time? Single centre experience in India. *Indian Heart J.* 64:582–587.
- 37-Xavier D., Pais P and Devereaux P.J 2008. CREATE Registry Investigators Treatment and outcomes of acute coronary syndromes in India (CREATE): a prospective analysis of registry data. *Lancet* 371:1435–1442.
- 38-Yahya Dadjoo and Yadallah Mahmoodi 2013. The Prognosis of Primary Percutaneous Coronary Intervention after One Year Clinical Follow Up. *Int Cardiovasc Res J* ; 7: 21–24.

39-Yip HK, Chen MC, Chang HW, et al 2002. Angiographic morphologic features of infarct-related arteries and timely reperfusion in acute myocardial infarction: predictors of slow-flow and no-flow. *Chest*; 122: 1322– 1332.

40-Zhu MM, Feit A, Chadow H, et al 2001. Primary stent implantation compared with primary balloon angioplasty for acute myocardial infarction: a meta-analysis of randomized clinical trials. *Am J Cardiol* 2001; 88(3):297-301.