



## SHORT TERM OUTCOME IN PATIENTS UNDERGOING PRIMARY PTCA IN A TERTIARY CARE HOSPITAL

### Cardiology

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### ABSTRACT

**Objective:** To determine the outcomes of primary percutaneous coronary intervention in a tertiary care cardiac centre.

**Materials and Methods:** This is a prospective single centre review of all patients receiving primary PCI for STEMI between august 2012-december 2013. Demographic, procedural and outcome data were analysed.

**Results :** There were 478 patients who underwent primary PCI. The mean age was  $52.6 \pm 7.5$  years. Median door-to-balloon time was 46 minutes and 67.78 % and 30.96% had anterior and inferior STEMI, respectively. The majority of patients presented with Killip class I (63.17%); however, 7.11 % were in Killip class IV. Single vessel disease was found in 57.7%. Angiographic PCI success (defined as residual stenosis <50% with TIMI 3 flow) was achieved in 93 %. No patients required transfer for emergency coronary bypass surgery as a result of PCI complication. The mean post-infarct left ventricular ejection fraction was 44.1%. In-hospital and 30-day mortality rates were 4.9% and 2.51% respectively. Stent thrombosis occurred in 1.88%.

**Conclusion:** High procedural success and favourable clinical outcomes matching the international data achieved in our patients undergoing primary percutaneous coronary intervention

### KEYWORDS

#### BACKGROUND

The treatment of acute myocardial infarction (AMI) via mechanical reperfusion strategy was advocated in 1983 by Hartzler et al.

Primary percutaneous coronary intervention (PCI) is now well established as the best re-perfusion strategy for STEMI myocardial infarction (STEMI). A meta-analysis comparing primary PCI and fibrinolytic showed a significant reduction in mortality in patients receiving primary PCI (7% vs 9% at 4 to 6 weeks). Furthermore, there is also significantly less re-ischaemia, re-infarction and stroke.<sup>1</sup>

Survival in Patients presenting with STEMI depends on early, complete, and sustained reperfusion of infarct-related artery.<sup>2,3</sup> Mechanical reperfusion with primary percutaneous intervention (PCI) can restore complete flow in up-to 95% of patients and is associated with a lower rate of reocclusion.<sup>4</sup> There is no question that primary PCI, when available is the treatment of choice.<sup>5</sup>

Although widely adopted as the default strategy for patients presenting with STEMI in developed nations, there are limited data on the applicability, success and outcomes of primary PCI in third-world nations, particularly the Indian subcontinent. A few small studies from India have suggested the potential feasibility of primary PCI, but had limited follow up and did not have the power to determine predictors of mortality. Data regarding revascularization in STEMI from India came from study by Jose and Gupta (2004) and CREATE study.<sup>6,7</sup>

As developing countries brace themselves for a cardiovascular epidemic, the question arises: Is primary PCI a viable therapeutic option in these countries?

The primary aim of our study was to determine the patient characteristics, short term outcomes and predictors of mortality in patients undergoing primary PCI for STEMI. Our secondary aim was to compare our results with the published literature from developed countries.

#### METHODS

Prospective, observational study of all patients presenting with ST segment elevation myocardial infarction (STEMI) within 12 hours of onset of chest pain who underwent primary percutaneous coronary intervention (PCI) as a reperfusion strategy at our hospital from August 2012 till December 2013.

#### Study population:

All the patients of acute coronary syndrome having the following features were included for this analysis

1. Patient presented with chest pain and ECG changes suggestive of STEMI
2. Duration of pain < 12 hours
3. Age group > 18 years and above who underwent primary PCI as reperfusion strategy.

#### Medications and technique:

All patients received Aspirin 325 mg, Clopidogrel 600mg or Prasugrel 60mg or Ticagrelor 180mg and Atorvastatin 80mg in the emergency department as per departmental protocol.

From the emergency department, patients were shifted directly to the catheterization laboratory. Intravenous unfractionated heparin (UFH) was used in the catheterization laboratory to all patients during the procedure with a target ACT of 300 to 350 seconds during primary PCI. Femoral arterial and venous access was achieved immediately. Diagnostic angiogram was performed quickly first taking one or two shots of the arterial system presumed not to be involved taking a 6F diagnostic catheter. Then the presumed culprit artery angiogram was taken using a 7F guide catheter, followed by PCI of the infarct-related artery. TPI was implanted if bradycardia or heart block was present at any time from presentation. We used thrombus aspiration catheter just after passing the guide wire across the lesion if there was any visible thrombus burden. Pre-dilatation with balloon was done if lesion morphology was complex and tight stenosis was seen at the occlusion site after thrombus aspiration. We performed angioplasty of the infarct related artery only during the primary PCI. Drug eluting or bare metal coronary stents were implanted according to affordability of the patients. Post dilatation with non-compliant balloon was routinely done after stent implantation. Intracoronary Sodium Nitroprusside, Diltiazem and Adenosine were used to manage slow flow or no flow that were commonly observed during primary PCI. Two intra-venous boluses of GPII<sub>b</sub>/III<sub>a</sub> receptor blocker Tirofiban were given according to weight followed by maintenance infusion for 24 hours in patients with high TIMI thrombus grade. Sheaths were removed after procedure when ACT comes to less than 200 seconds. Dual anti-platelet therapy was continued as per standard recommendations. All patients were initially monitored for at least 24 hours in the coronary care unit (CCU) and later shifted to the ward. Unstable patients were continuously monitored in the CCU till they were stable enough for shifting. Intra Aortic Balloon Pump (IABP) was used in patients

presenting with cardiogenic shock or in patients who subsequently became hemodynamically unstable.

All information of the patients regarding age, gender, history of diabetes, dyslipidemia, hypertension, smoking, diet habit etc were collected at admission. Left ventricular function was assessed by 2D echocardiography at bed side in all patients. Angiographic and procedural details like culprit vessel, use of coronary stents and GPII<sub>b</sub>/III<sub>a</sub> inhibitors were also collected. Timing variables were computed including time to presentation which was defined as the time from symptom onset until arrival at the hospital. Door-to balloon time was the time from arrival at the hospital until first thrombus aspiration/balloon inflation in the cardiac catheterization laboratory. Procedural success was defined as achievement of vessel patency to a residual <30% stenosis without serious adverse events.

Study end points were in-hospital mortality and procedural success. All the variables were entered into SPSS 14 for data analysis. Descriptive statistics were computed and presented as means and standard deviations for continuous variables like age, left ventricular ejection fraction (LVEF) and median for onset of pain to emergency department arrival in minutes, door-to-balloon time in minutes. Categorical variables were reported in frequencies and percentages for gender, hypertension, diabetes mellitus, dyslipidemia, procedural success and in-hospital mortality.

### Results:

Total 478 patients were included in this analysis from September 2012 to December 2013. Minimum age included was 24years, maximum 83years with mean age 52.6± 7.5yrs. Majority of the patients 362 (82.84%) were male. Risk factor analysis showed 178 (37.23%) were hypertensive, 118 (24.46 %) were diabetics, and 202(42.43%) were current smokers (Fig1) . Two third of the procedure 273 (57.11%) were performed during off time (5 pm to 9am). 324(67.78%) of patients presented with anterior wall myocardial infarction, 148 (30.96%) with inferior wall myocardial infarction, and 6(1.25%) with true posterior or lateral wall myocardial infarction. The median time from the onset of symptoms to presentation was 314 minutes. At our hospital, mean door to needle time was 46±16 minutes. (Table-1)

**Table-1 Baseline characteristics**

Baseline demographic & clinical characteristics	N=478 (%)
Age in years (mean/SD)	52.6± 7.5
Male	362(82.84)
Female	116(17.16)
Past medical history	178(37.23)
Hypertension	118(24.46)
Diabetes mellitus	202(42.43)
Smoking(current /previous)	
Admission characteristics	324(67.78)
Anterior myocardial infarction	148(30.96)
Inferior wall myocardial infarction	6(1.25)
Lateral/Posterior wall myocardial infarction	302(63.17)
Killip class I	103(21.54)
Killip class II	39 (8.15)
Killip class III	34(7.11)
Killip class IV	144(30.12)
Left ventricular ejection fraction <40%	
Timing variables	314
Onset of pain to ED time (minutes) median	46±16
Door to Balloon time (minutes) mean	32±8
Femoral artery access time (seconds) mean	

ED-Emergency department

Single vessel diseases was found in 276(57.7%) of patients, double vessels disease in 130 (27.2%) of patients and 72(15.06%) of patients were having triple vessel disease. Significant left main coronary artery disease was noted in 9(1.88%) of patients. Left anterior descending coronary artery (LAD) was the culprit vessel in 324(68%) cases. Right coronary artery (RCA) in 96 (20%) and Left circumflex coronary artery (LCX) was the culprit vessel in 58(12%) of the cases (Table-2)

**Table-2: Angiographic and procedural characteristics**

VARIABLE	N=478(%)
CULPRIT VESSEL	324(67.78)
LAD	96(20.08)
RCA	58(12.13)
LCX	

MULTIVESSEL DISEASE	276(57.74)
SVD	130(27.19)
DVD	72(15.06)
TVD	9(1.88)
LEFT MAIN	
USE OF STENT	451(94.36)
POBA	27(5.64)
DES	276(57.74)
BMS	175(36.61)

Thrombus aspiration catheters were used in over 406(84.9%) of the procedures. Drug eluting coronary stents were implanted in 276 (57.74%) and bare metal coronary stents in 175(36.61%) of patients. Only balloon angioplasty was performed in 27(5.64%) patients because of unsuitable coronary anatomy for stenting like diffuse disease, non-sizeable vessel or normal looking vessel after thrombus aspiration etc. During procedure, complications like arrhythmias (ventricular tachycardia, supra-ventricular tachycardia, atrial fibrillation, and bradyarrhythmias including complete heart block) occurred in 85( 17.72 %), and cardiogenic shock was noted in 34( 7.11% ) of patients. 6.56% of patients were given IABP support. Cardiac tamponade was seen in 6 patients (1.25%). No coronary artery perforation was reported.

No patient required emergency bypass surgery as a result of catheterization –laboratory complications. Patients were discharged on 3rd day if they were clinically stable. 30 day survival rate were 443 (93%) . Acute or sub-acute stent thrombosis (according to academic research consortium criterion) was noted in 9 patients (1.88%). (Table-3)

**Table 3. Major Adverse Cardiac Events (MACE) in Patients who underwent PCI**

OUTCOME	ALL CAUSE MORTALITY( %)	STENT THROMBOSIS (%)	STROKE(%)
IN HOSPITAL	21(4.39)	-	2(0.41)
30 DAY	12(2.51)	9(1.88)	1 (0.20)

### DISCUSSION

Primary PCI is now considered the treatment of choice for patients with STEMI, provided skilled interventional cardiologist and catheterization laboratory with surgical backup are available and the procedure can be performed timely. A meta-analysis demonstrated that primary PCI was better than thrombolytic therapy in reducing overall short-term mortality, non-fatal myocardial re-infarction, and stroke.

There is no question that primary PCI if available is the treatment of choice. But in our country it is not widely used as reperfusion strategy due to lack of facilities. Only a few centers in our country are performing primary PCI but mostly during the office hours.

The study population comprised mostly male like all over the world, mean age being 55.8± 11.5yrs, youngest patient being of 24 years old. Unlike other studies reporting hypertension as the most common risk factor, our study reported smoking as the most prevalent risk factor.<sup>8</sup>

Primary PCI holds a survival advantage if it can be performed in a timely fashion. The principle that “time is muscle” applies to both fibrinolysis (door to needle)<sup>9</sup> and primary PCI (door to balloon)<sup>10</sup>. Our door to needle time was 47 minutes, which is comparable with the published literature.<sup>11,12</sup>

Despite having comparable door to balloon time, our study showed higher mortality rate when compared to other studies.<sup>13</sup> This could be because of two reasons: firstly, the mean time of presentation of patients from the symptom onset was slightly higher (314minutes) in our study. It is accepted fact that if patient presents beyond golden hour, the mortality is directly related to the delay. This emphasizes the need for increase awareness in general population about STEMI and also importance of good & prompt referral services from non-PCI capable centers. Secondly, in our study maximum mortality was seen in patients with cardiogenic shock. Earlier studies excluded this subset of patient with cardiogenic shock which might be the reason that they reported lower mortality rates.<sup>14</sup> Our study also confirmed the fact that there is still high mortality in this subset of patients despite marked advancement in percutaneous intervention. The complication rates observed in this cohort are like those of other studies, no patients

needed emergency CABG as a part of cath lab complication. Our procedural success was 94.35% and overall survival rate of 92.10%. There was no statistically significant difference in early outcome of patients implanted with either drug eluting or bare metal coronary stents.

#### Conclusion:

Primary angioplasty is the recommended way of revascularization in STEMI if facilities are available. Time is most important factors to save myocardium as well as outcome in patients.

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