



Original Article

Primary percutaneous coronary intervention for acute ST elevation myocardial infarction: Outcomes and determinants of outcomes: A tertiary care center study from North India



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ABSTRACT

Background: Primary percutaneous coronary intervention (PCI) is the current standard of care for acute ST elevation myocardial infarction (STEMI). Most of the data on primary PCI in acute STEMI is from western countries. We studied the outcomes of primary PCI for acute STEMI at a tertiary care center in North India.

Methods: Consecutive patients undergoing primary PCI for STEMI were prospectively studied during the period from February 2103 to May 2015. The outcomes assessed were all cause in hospital mortality, factors associated with mortality, major adverse cardiac and cerebrovascular event rate (composite of all cause in hospital mortality, non-fatal re infarction and stroke) and procedural complications.

Results: 371 patients underwent primary PCI during the study period. The mean age was 54 years and 82.7% were males. The mean total ischemia time and door to balloon times were 6.8 h and 51 min respectively. 96.4% patients underwent successful primary PCI. The total in hospital mortality was 12.9%. Mortality with cardiogenic shock at presentation was 66.7% while non-shock mortality was 2.6%. In hospital MACCE rate was 13.5%. Factors significantly associated with mortality were KILLIP class (OR: 8.4), door to balloon time (OR 1.02), final TIMI flow (OR 0.44) and severe LV dysfunction (OR 22.0). Procedure related adverse events were rare and there was no non-CABG associated major TIMI bleeding.

Conclusion: Primary PCI for acute STEMI is feasible in our setup and associated with high success rate, low mortality in non-shock patients and low complication rates.

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1. Introduction

Coronary artery disease (CAD) is one of the leading causes of mortality worldwide with increasing incidence in developing countries like India.¹ Acute STEMI is the most lethal presentation of CAD with mortality rates in community ranging from 15 to 20%.² Acute STEMI accounted for 60% and 37% of acute coronary syndromes in India as per CREATE³ and Kerala ACS registries⁴ respectively and was associated with highest mortality among the ACS spectrum.

Primary percutaneous coronary intervention (PCI) has been established as the treatment of choice for patients presenting with acute ST elevation myocardial infarction (STEMI). However

widespread availability and affordability of primary PCI is still an important consideration in our country. As per the latest data from Kerala ACS registry,⁴ only 19.6% of STEMI patients underwent coronary angiography and 12.9% underwent primary PCI.

To achieve optimal results with primary PCI it needs to be performed in a timely manner at high volume centers by expert operators. Whether results similar to those reported from West can be achieved in our settings or not, is not known. So, this study was conducted with intent to look into the outcomes of primary PCI performed at a tertiary care center in North India.

2. Methods

2.1. Study design

This was an observational prospective study of consecutive STEMI patients undergoing primary PCI at the All India Institute of

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Medical Sciences, New Delhi. The study period was from February 2013 to May 2015. All patients presenting with acute ST elevation MI and undergoing primary PCI were included in the study. STEMI Patients managed with thrombolytic therapy, or patients undergoing rescue or facilitated PCI were excluded from the study.

All the included patients were followed up till discharge from the hospital or in hospital death and pertinent data were prospectively collected. The study was ethically approved by the Institute Ethics Committee.

2.2. Primary PCI procedure

Selection of patients for primary PCI was as per guideline recommendations.⁵ All patients presenting within 12 h of onset of symptoms were considered for primary PCI. Patients presenting between 12 and 24 h of onset of symptoms were also taken up for primary PCI if they had ongoing ischemic symptoms.

Catheterization team was activated immediately on confirmation of STEMI diagnosis. After loading with dual antiplatelets, patients were immediately shifted to catheterization laboratory.

After gaining vascular access, non-culprit vessel angiogram was done first followed by the culprit vessel angiogram. Once the decision to go ahead with angioplasty was taken, heparin was administered in dosage of 70–100 U/kg to achieve an ACT of 250–300. GPIIb/IIIa inhibitor use was left to operator's discretion. The choice of guidewire, balloon, stent, thrombus aspiration and IABP was on operator's discretion. Manual thrombus aspiration was done with the "Thrombuster" thrombus aspiration catheter (Atrium, Osaka Japan).

Only culprit vessel angioplasty was done except in cases with cardiogenic shock where non-culprit angioplasty was also considered. Post procedure patients were immediately shifted to CCU. Sheaths were removed once ACT was below 180.

Hemodynamically stable patients were kept in CCU for 24–48 h and subsequently shifted to step down unit and were discharged on 4th or 5th day. At discharge statins in dose of 40–80 mg and dual anti platelet (DAPT) agents were prescribed to all patients. ACEI/ARB and beta blockers were used in all patients without contraindications for their use.

2.3. Outcomes

The outcomes studied were all cause in hospital mortality rate, factors associated with mortality, Major adverse cardiac and cerebrovascular events (MACCE) and procedural complication rate.

2.4. Definitions

STEMI: It was defined as symptoms of ischemia associated with ST-segment elevation of ≥ 1 mm in limb leads and/or ≥ 2 mm in chest leads in ≥ 2 contiguous leads, or new left bundle branch block, or true posterior myocardial infarction with ST depression of ≥ 1 mm in ≥ 2 contiguous anterior leads.

Cardiogenic shock: Persistent hypotension with systolic blood pressure less than 90 mmHg for at least 30 min, despite adequate fluid administration and associated with features of tissue hypoperfusion.

Severe LV dysfunction: It was defined as left ventricular ejection fraction $\leq 30\%$ by echocardiography.

Dyslipidemia: Fasting lipid profile values were taken within 24 h of presentation with dyslipidemia defined as presence of one or more of following characteristics:

Total cholesterol ≥ 200 mg/dl, LDL cholesterol ≥ 130 mg/dl, HDL cholesterol ≤ 40 mg/dl in males, ≤ 50 mg/dl in females and/or triglycerides ≥ 150 mg/dl.

Total ischemia time: Time from the onset of symptoms to revascularization.

Door to balloon time: Time from arrival at the Institute to revascularization.

Successful PCI: PCI success was defined as achievement of vessel patency with a residual stenosis of $< 20\%$.

Re-infarction: It was defined as recurrence of ischemic symptoms with new ECG changes suggestive of re-infarction.

Major bleeding: It was defined as per standard TIMI criteria⁶ for non CABG and CABG associated bleeding.

Significant non-infarct related artery (IRA) disease: It was defined as presence of $\geq 70\%$ disease in epicardial vessel other than the culprit vessel. Cut-off of 50% was used for diagnosis of significant left main disease.

MACCE: It was defined as a composite of all cause in hospital mortality, non-fatal reinfarction and stroke.

2.5. Statistical analysis

The data analysis was done with 'STATA 13' (STATA CORP, Texas, USA). Quantitative variables are presented as mean \pm standard deviation. Categorical variables are presented as percentages. The chi square test was used to analyze association of categorical variables with the primary outcome. Logistic regression analysis was used to analyze the association between quantitative variables and the primary outcome. Multivariate logistic regression analysis was used to study the independent association of variables with the primary outcome.

3. Results

3.1. Study population

Overall 383 patients presented with acute STEMI during the study period. Of these, 7 patients died in the emergency before being shifted for primary PCI and 5 did not consent for primary PCI and were thrombolysed. The study included the remaining 371 patients who underwent primary PCI at the institute from February 2013 to May 2015. Baseline characteristics of these patients are presented in Table 1. Of the 371 patients, almost 83% were males. Mean age of the patients was 54 years with 12% patients below 40 years of age.

Among coronary risk factors notable was high prevalence of smoking (57%) and relatively lower prevalence of dyslipidemia (18.6%). Importantly 37 patients (10%) had no conventional coronary risk factors.

The mean total ischemia time and door to balloon times were 6.8 h and 51 min respectively. Anterior wall MI was the commonest presentation and almost half of the patients were in KILLIP class I. A relatively high percentage of patients were in KILLIP IV at presentation.

3.2. Angiographic and procedural variables (Table 2)

Femoral was the preferred route in majority of cases. Significant non-infarct related artery disease was present in 50% of cases with 26% having triple vessel disease (TVD) and 24% double vessel disease (DVD).

PCI was successful in almost 96% of cases with majority of them receiving stents. Glycoprotein IIb/IIIa inhibitors were used in 83% of patients, initiated in the catheterization laboratory.

Emergency CABG was done in 5 patients, indication being left main CAD in one, triple vessel disease in one, failure to cross guidewire in two and severe MR in one patient.

Table 1

Baseline characteristics. Data are number of patients (%) unless otherwise indicated.

Total	371
Age (mean) (SD)	54.2 years (12.7 years)
Males	307 (82.75%)
Females	64 (17.25%)
Under 40 years	46 (12.3%)
Diabetes mellitus	118 (31.8%)
Dyslipidemia	69 (18.6%)
Hypertension	158 (42.6%)
Current smokers	211 (56.9%)
Family history	19 (5.1%)
Obesity	56 (15.1%)
Total ischemia time (h) (mean, SD)	6.8, 4.04
Door to balloon time (min) (mean, SD)	51.1, 29.0
Door to balloon ≤ 90 min	357 (96.2%)
Door to balloon ≤ 60 min	325 (87.6%)
Anterior MI	211 (56.9%)
Inferior MI	148 (39.9%)
Lateral	11 (2.9%)
Posterior	32 (8.6%)
RVTMI	26 (7%)
KILLIP I	186 (50.1%)
KILLIP II	111 (29.9%)
KILLIP III	14 (3.8%)
KILLIP IV	60 (16.2%)
Severe LV dysfunction	150 (40.4%)
Congestive heart failure	97 (26.1%)
Complete heart block (CHB)	39 (10.5%)
Primary VT/VF	20 (5.4%)
Secondary VT/VF	8 (2.1%)

3.3. Mortality

Total all cause in hospital mortality was 12.9% (48 deaths). Mean duration of hospital stay prior to death was 2.2 days. Of these, almost 60% died within 24 h of admission. Mortality rates varied significantly within the cohort. Those in whom cardiogenic

Table 2

Angiographic findings and procedural variables. Data are number of patients (%) unless otherwise indicated.

Infarct related artery – LAD	210 (56.6%)
Infarct related artery – LCX	49 (13.2%)
Infarct related artery – RCA	105 (28.3%)
Infarct related artery – Others	7 (2.5%)
Sig Non-IRA disease	189 (50.1%)
Left main CAD	9 (2.43%)
Double vessel disease	90 (24.2%)
Triple vessel disease	97 (26.07%)
Normal coronaries/slow flow	5 (1.3%)
TIMI 0	322 (86.8%)
TIMI 1	14 (3.8%)
TIMI 2	16 (4.3%)
TIMI 3	19 (5.1%)
Dual antiplatelet loading	371 (100%)
Statin loading	371 (100%)
GpIIb/IIIa	308 (83%)
PCI successful	345/358 (96.4%)
PCI unsuccessful	13/358 (3.6%)
PCI with stenting	313/345 (90.7%)
POBA	24 (6.9%)
Thrombus aspiration	143 (41.4%)
Thrombus aspiration alone	8 (2.3%)
BMS	121 (37.9%)
DES	198 (62.1%)
Number of stents (mean)	1.16
Emergency CABG	5 (1.3%)
IABP	14 (3.7%)
TPI	39 (10.5%)
Final TIMI 0	22 (5.9%)
Final TIMI 1	5 (1.3%)
Final TIMI 2	37 (9.9%)
Final TIMI 3	307 (82.7%)

Table 3

Factors associated with mortality (multivariate analysis).

Variable	Odds ratio (95% CI)	p value
Door to balloon time	1.02 (1.00–1.05)	0.025
Killip class	8.47 (3.47–20.68)	<0.001
Final TIMI	0.411 (0.17–0.96)	0.041
Severe LV dysfunction	22.0 (1.14–421)	0.04
Female sex	0.3 (0.05–1.67)	0.167
Age	0.99 (0.93–1.06)	0.963
Diabetes mellitus	0.98 (0.26–3.67)	0.982
Total ischemia time	1.10 (0.96–1.27)	0.156
Anterior MI	1.01 (0.16–6.36)	0.988
CHB	0.78 (0.1–5.94)	0.811
Significant non-IRA disease	4.98 (0.77–32.02)	0.09
TVD	0.3 (0.06–1.58)	0.159
Thrombus aspiration	0.36 (0.05–2.26)	0.278
CABG	7.5 (0.03–1775.8)	0.47
CHF	0.82(0.2–3.18)	0.783
Primary VT/VF	1.93 (0.21–17.55)	0.558
Secondary VT/VF	18.24 (0.63–525.85)	0.09

Bold values indicate variables significantly associated with mortality.

shock was initial presentation had an in-hospital mortality rate of 66.7% as compared to 2.6% in those not in cardiogenic shock. Emergency CABG was associated with in hospital mortality of 60%.

Cardiogenic shock was the most common cause of death accounting for 77% of deaths followed by CHF in 10% and VT/VF in 8%. One patient died from hospital acquired pneumonia with severe sepsis and one patient died from LV free wall rupture.

Factors significantly associated with mortality (Table 3) on multivariate analysis were the KILLIP class, door to balloon time, the final TIMI flow and presence of severe LV dysfunction. Those in KILLIP class four had eight-fold higher risk of mortality as compared to others. Increase in the door to balloon time by one minute lead to 2% increase in mortality rates. Final TIMI 3 flow was associated with almost 60% lower mortality as compared to those without TIMI 3 flow. The risk of death was 22-fold higher in those with severe LV dysfunction.

3.4. Complications (Table 4)

Complications related to vascular access were infrequent with only 2.7% having local hematomas. All of them were managed conservatively and none required transfusion or re intervention for the same. There were no pseudoaneurysm or AV fistulas.

Two patients had re-infarctions in the same territory during the index hospital stay and were caused by subacute stent thrombosis. Both were managed successfully with balloon angioplasty. There was no non-CABG related TIMI major bleeding, while two patients had CABG related major bleeding namely requiring more than 5 units of packed RBC transfusions during 48 h. The total MACCE rate was 13.5% including 48 mortalities and two re infarctions secondary to stent thrombosis. There were no strokes in our study population.

Table 4

Complications. Data are number of patients (%) unless otherwise indicated.

Local vascular complications	10 (2.7%)
Coronary perforation/tamponade	0
No reflow	9/345 (2.6%)
Re infarction	2 (0.5%)
Subacute stent thrombosis	2 (0.5%)
TIMI major bleeding (non-CABG related)	0
Stroke	0
Contrast reactions	0
Contrast induced nephropathy	4 (1.1%)
MACCE	50 (13.5%)

3.5. Discharge medications

The mean duration of hospital stay prior to discharge was approximately 5 days. Guideline directed medical therapy was provided to all the patients at discharge. Dual antiplatelet therapy and statins were prescribed to all the discharged patients (323,100%). Beta blockers were prescribed to 80% patients at discharge while ACEI/ARBs were prescribed to 85% of discharged patients.

4. Discussion

This is the first large scale registry data on primary PCI for acute STEMI from our Institute and North India. The 24 × 7 free primary PCI program at our Institute was initiated in February 2013, and over a period of 2 years and 3 months, almost 97% of acute STEMI patients (371 out of 383) underwent primary PCI. In this study, we have reported the demographic, clinical and angiographic features and outcomes of these patients.

The mean age of patients in this study (54 years) was almost a decade lesser than the western population.^{7,8} The earlier occurrence of acute MI in South East Asian population is well established fact.^{3,9,10} The possible reasons for earlier occurrence of CAD in South East Asian patients are multiple including genetic predisposition, higher prevalence of abdominal obesity, higher Apolipoprotein(Apo)B/ApoA1 ratio etc.

Among risk factors smoking was the most widely prevalent risk factor, especially among the younger population (less than 40 years), often being the sole risk factor. The percentage of current smokers in this study is higher than that seen in American¹¹ and European registries.¹² This high prevalence of smoking in Indians has been documented earlier also,¹³ with stronger association with coronary artery disease in younger individuals.¹⁴

Dyslipidemia was another risk factor which needs special mention. It was seen in 18.6% of our patients which is significantly lower than that seen in western population.^{15,16} However studies from India^{10,17} have consistently reported a lower prevalence of dyslipidemia as seen in our study. The higher risk of CAD even in absence of dyslipidemia as currently defined, signifies the need of redefining or modifying the cut offs for the Indian population.

Mean total ischemia time (6.9 h) in our study was significantly longer than that reported in studies from South India¹⁰ and western countries.^{1,11} One possible reason for higher mean total ischemia time was inclusion of patients with duration of symptoms between 12 and 24 h with ongoing ischemia or cardiogenic shock. Lack of awareness among patients and long travel times also accounted for longer total ischemia time. The Kerala ACS registry⁴ also reported that a diagnosis of STEMI was associated with higher probability of symptom to door time of more than 6 h and lack of any formal education.

The mean door to balloon time, a measure of operational efficacy of system, was 51 min in our study, well below the recommended limit of 90 min. This is comparable to door to balloon times achieved in studies from west⁸ and other centers in our country.¹⁰ We could achieve good door to balloon times due to coordinated efforts of the emergency medical team, a 24 × 7 ready to operate catheterization laboratory and a dedicated team of experienced interventional cardiologist.

The overall in hospital mortality seen in our trial was significantly higher than the 5–9% mortality reported from large registries from western countries^{18,19} and from Indian studies.^{3,4,10} The higher mortality rate seems to be driven mainly by the high percentage of patients with cardiogenic shock in this study. However, the mortality rates in patients who were not in shock at

initial presentation was only 2.6% which is compatible with mortality seen in large randomized controlled trials.^{20,21}

As mentioned earlier, the percentage of patients with cardiogenic shock at presentation (16%) was significantly higher than 7–10% incidence of shock reported in other studies on acute myocardial infarction.^{22,23} Longer total ischemia time, high percentage of anterior wall MI and inclusion of all patients in cardiogenic shock for primary PCI irrespective of time delay as endorsed by recent guidelines,⁵ seem to be responsible for this high percentage of cardiogenic shock in our study.

The factors associated with mortality on multivariate analysis were door to balloon time, KILLIP class, final TIMI flow and presence of severe LV dysfunction. This data is consistent with findings of other studies looking into predictors of mortality in patients undergoing primary PCI.^{24,25}

Among complications, notable feature of our study was lack of any non-CABG related TIMI major bleeding despite extensive use of potent DAPT, heparin and GPIIb/IIIa inhibitors. Careful monitoring of ACT, avoidance of GP IIb/IIIa in elderly patients and restriction of their use in patients with ACT above 300 were key components in avoiding excessive bleeding. Also reassuring was absence of any stroke in our study. Thrombus aspiration in a recent large trial²⁶ showed increased risk of stroke (0.7%) at 30 days. This was not seen in our study.

4.1. Limitations

The main limitation of this study was its observational nature. The lack of randomization precludes assessment of impact of therapies like GPIIb/IIIa, thrombus aspiration, IABP etc. on mortality. Also, this was a single center study conducted at a high volume tertiary care teaching Institute and results obtained may not be applicable at lesser centers with lower case volumes. Finally, there was no follow up in this study and long term outcomes remain unknown.

5. Conclusion

Prompt primary percutaneous coronary intervention for acute STEMI is feasible in our setup and is associated with high success rate, low mortality rates in non-shock patients and low complication rates. The mortality associated with cardiogenic shock continues to be high. Important predictors significantly associated with mortality are the door to balloon time, Killip class, final TIMI flow and severe LV dysfunction.

Conflicts of interest

The authors have none to declare.

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