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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.

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 CREATE[3] and Kerala ACS registries[4] 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 $\geq$1 mm in limb leads and/or $\geq$2 mm in chest leads in $\geq$2 contiguous leads, or new left bundle branch block, or true posterior myocardial infarction with ST depression of $\geq$1 mm in $\geq$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 $\geq$200 mg/dl, LDL cholesterol $\geq$130 mg/dl, HDL cholesterol $\leq$40 mg/dl in males, $\leq$50 mg/dl in females and/or triglycerides $\geq$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 criteria[6] 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 1**3' (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.

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