Clinical Profile and Outcomes of Patients Undergoing Primary Percutaneous Coronary Intervention in Employee Scheme Insurance Beneficiaries in India

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ABSTRACT

BACKGROUND

We wanted to assess the clinical profile and in-hospital outcomes of Primary Percutaneous Coronary Intervention (PPCI) for ST-segment Elevation Myocardial Infarction (STEMI) in India in ESI (Employee Scheme Insurance) beneficiaries.

METHODS

From January 2017 to July 2018, 122 consecutive acute STEMI patients undergoing PPCI under ESI scheme were included in the study. Patients' clinical profile, detailed procedural characteristics, time variables along with in-hospital major adverse cardiovascular events (MACE) were also assessed.

RESULTS

122 patients underwent primary PCI during the study period. In the study, mean age was 55.23 (27 - 85) years; 94 (77.04 %) were males; 53 (43.44 %) were hypertensives; 38 (31.14 %) were smokers; and 44 (36.06 %) were diabetics. Ten (8.19 %) patients were in cardiogenic shock (CS). Anterior myocardial infarction was present in 70 (57.37 %) patients. The median chest-pain-onset to hospital-arrival-time was 270 (70 - 720), door-to-balloon time was 55 (20 - 180) and total ischemic time was 325 (105 - 780) minutes. In-hospital adverse events occurred in 14 (11.4 %) patients [death 8 (6.55 %), major bleeding 2 (1.63 %), urgent CABG 3 (2.45 %) and stroke 1 (0.81 %)]. Seven patients with cardiogenic shock died.

CONCLUSIONS

The mean age of our cohort was 55.23 years. In our study, majority of patients were males (77.05 %), hypertension was associated with 43.44 %, and diabetes was associated with 36.06 % of patients. Procedural success was achieved in 95.89 %. The overall in-hospital mortality was 6.55 % and 70 % in the cardiogenic shock subset.

KEYWORDS

Primary PCI, STEMI, ESI, PCI

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BACKGROUND

Acute STEMI is caused by the rupture or erosion of coronary artery atherosclerotic plaque, thereby initiating intra luminal thrombosis which leads to occlusion (partial or complete) of the affected coronary artery.[1,2] Reperfusion established through primary percutaneous coronary intervention has become the treatment of choice for patients with STEMI. The prognosis has improved over the period of time as evidenced by fall in-hospital mortality rate from 11.2 % during 1990 to 9.4 % in 1999.[3]

Coronary Artery Disease (CAD) has become the most common non-infectious disease in India. Acute ST-segment elevation myocardial infarction is the most catastrophic manifestation of CAD. Acute STEMI carries high morbidity and mortality where timely reperfusion therapy has proved beyond doubt to reduce major adverse events.[4]

Primary PPCI has been proven as the most effective therapy for STEMI. It achieves rapid and more resilient reperfusion with low complication rate when compared to conventional thrombolysis.[5] Our observational study tries to evaluate the clinical profile, practical feasibility and in-hospital outcome of PPCI in India in ESI beneficiaries.

METHODS

The study was conducted at Sri Jayadeva Institute of Cardiovascular Sciences and Research, ESI Branch, Bangalore, as a prospective hospital based cross sectional study from January 2017 to July 2018 after obtaining necessary permissions from college authority and Ethical Committee. ESI beneficiary, acute STEMI patients those who underwent percutaneous coronary intervention within the 12 hours period since the onset of anginal chest pain were included in the study after obtaining informed consent. Patients who develop Cardiogenic Shock (CS) were also included in the study. Patients who required rescue PCI were not included in the study.

Sample size was determined after evaluating number of patients admitted with ACS (Acute Coronary Syndrome) undergoing primary PCI in the last 2 years in our hospital. A total of 122 subjects were included in the study randomly after proper informed consent was obtained.

Once patient was received in the ICU (Intensive Care Unit), ECG (Electro-Cardio-Gram) was done to confirm the diagnosis of STEMI. Each patient was asked for history to rule out possible contraindications for taking dual antiplatelet therapy. A quick clinical examination and bedside echocardiography were done. After obtaining informed consent and excluding any possible mechanical complications each patient was given loading dose of aspirin, clopidogrel or ticagrelor and atorvastatin and transferred to the catheterization laboratory immediately.

Procedure was performed through radial or femoral route according to operator convenience. Intra-aortic balloon pump was also used whenever needed. Non culprit artery was initially imaged with a diagnostic catheter to look for flow limiting critical lesions. Additional heparin was given then to maintain the Activated Clotting Time (ACT) between 250 and 300 sec. Infarction Related Artery (IRA) was imaged with an appropriate size guide catheter. After assessing the culprit vessel, the lesion was crossed with the help of soft non-hydrophilic 0.014" guiding wire. Again, after crossing lesion, the vessel was assessed for TIMI (Thrombolysis In Myocardial Infarction) flow and thrombus burden. The lesions were stented directly if flow was TIMI III with low thrombus burden. Thrombus aspiration was performed using export aspiration catheter whenever there was large thrombus burden. Planned balloon dilatation of lesion was done whenever the lesion was too tight, or it was not possible to assess the anatomy of the distal vessel. Epicardial coronary artery spasm was ruled out by giving Intracoronary (IC) nitroglycerin injection whenever the haemodynamics permitted. Depending on the operator's choice Drug-Eluting Stents (DES) or Bare Metal Stents (BMS) were used. In patients with multivessel disease, PPCI was done only to the culprit artery unless patient was having critical stenosis of vessel with less than TIMI III flow in a non-ischemia related artery or patient was having cardiogenic shock. Time variables like door-to-balloon time, time from pain onset to hospital arrival and total ischemic time were also recorded.

After the procedure patients were shifted to CCU (Cardiac Care Unit) and removal of arterial sheath was done when ACT was less than 150 sec. Clinically stable patients were shifted to the general wards after 24 h and they were discharged on the next day. During discharge, all the patients were advised to continue dual antiplatelets, high dose statin, and beta blockers and ACEI (Angiotensin Converting Enzyme Inhibitors) if no contraindications. During hospital stay any adverse events like major bleeding, stroke, reinfarction, urgent CABG (Coronary Artery Bypass Grafting) or death were recorded.

Definitions[6]

STEMI - Typical Angina / anginal equivalent persisting for > 20 minutes and ECG showing ST-segment elevation of ≥ 1 mm in ≥ 2 contiguous leads / new onset left bundle branch block / true posterior MI with ST depression of ≥ 1 mm in ≥ 2 contiguous anterior leads.

Cardiogenic Shock (CS) - Persistent hypotension with blood pressure systolic less than 90 mm Hg for more than 30 minutes, not responding to fluid administration and associated with clinical features of tissue hypoperfusion.

Diabetes Mellitus (DM) - Patients on treatment for DM or fasting blood glucose > 126 mg / dL.

Systemic Hypertension (HTN) - Patients on treatment for HTN or blood pressure systolic > 140 mm Hg and or diastolic > 90 mm Hg.

Dyslipidaemia - Patients on treatment for dyslipidaemia or blood fasting total cholesterol > 200 mg / dL.

Multivessel Disease - Coronary angiogram showing more than 50 % stenosis involving ≥ 2 epicardial coronary arteries.

Door-to-Balloon Time - Time from patient's entry to hospital to achieving flow in culprit artery.

Total Ischemic Time - Total time from onset of chest pain to achieving flow in culprit artery.

Coronary Flow - Blood flow in the culprit artery was assessed by the operator visually. According to the TIMI grading system classified on a scale of 0 - 3 both before and after the PCI procedure.

Procedural Success - Primary PCI was considered successful when culprit vessel TIMI II - III flow was achieved with a residual stenosis of < 30 %.

Major Bleeding - Any of the following bleeding events were considered as major bleeding: intraocular bleeding, intracranial bleeding, puncture site haemorrhage requiring surgery or a radiological or interventional procedure, retroperitoneal bleeding, the puncture site hematoma measuring ≥ 5 cm in diameter, ≥ 4 g / dL fall in haemoglobin level without an overt source of bleeding, ≥ 3 g / dL fall in haemoglobin level with an overt source of bleeding, bleeding leading to re-operation, or bleeding leading to use of any blood product.

Statistical Analysis

SPSS Ver. 16 was used for the analysis of the data. Continuous variables like age were presented as means. Time variables for example chest-pain-onset to hospital-arrival-time, hospital-arrival to reperfusion time and total ischemic time are represented as median with range. Categorical variables like sex, risk factors, multi-vessel disease, cardiogenic shock, mortality and procedural success were all reported as percentages. Between January 2017 and July 2018, 122 primary PCIs were done at our centre were included in the study.

RESULTS

Table 1 depicts the demographic details along with clinical characteristics of our study population. In our study males were 77.05 % significantly more than females ($p < 0.05$), significant majority had anterior wall MI (Myocardial Infarction) (57.37 %, $p < 0.05$), 43.44 % ($p < 0.05$) of patients had hypertension and 36.06 % of the patients were diabetics.

Table 2 depicts the angiographic and procedural characteristics. Most common culprit vessel was left anterior descending coronary artery accounting for 68 (55.73 %) significantly higher ($p < 0.05$) among the patients, which is followed next by the Right Coronary Artery (RCA) in 39 (31.96) patients. In our study multi-vessel coronary artery disease was noted in 38 (31.14) patients. Drug eluting stents were placed in 108 (88.5) patients and multivessel intervention was done in 2 (1.63) patients. Primary PCI was successful in case of 117 (95.89) patients.

Characteristic	Number (%)	P Value
Age (mean) (years)	55.23 years	NS
Male Gender	94 (77.05 %)	< 0.05
Past Medical History		
Systemic Hypertension	53 (43.44)	< 0.05
Diabetes	44 (36.06)	0.07
Dyslipidemia	19 (15.57)	0.06
Current Smoker	38 (31.14)	0.08
Clinical Characteristics		
Anterior Myocardial Infarction	70 (57.37)	< 0.05
Cardiogenic Shock	10 (8.19)	-
Intra-Aortic Balloon Pump	6 (4.91)	-
Temporary Pacemaker	20 (16.39)	-

Table 1. Baseline Demographic and Clinical Characteristics

Characteristic	Number (%)	P Value
Culprit-Vessel		
Left Anterior Descending artery (LAD)	68 (55.73)	< 0.05
Left Circumflex Artery (LCX)	10 (8.19)	NS
Right Coronary Artery (RCA)	39 (31.96)	NS
LMCA	3 (2.45)	
Multi-Vessel CAD	38 (31.14)	
Pre-PCI TIMI flow		
TIMI 0	83 (68.03)	< 0.05
TIMI I	13 (10.65)	-
TIMI II	20 (16.39)	-
TIMI III	6 (4.91)	
PTCA + Stenting	108 (88.5)	< 0.01
Only PCI without Stenting	8 (6.55)	-
Multivessel PCI	2 (1.63)	-
Total Number of Stents Used	127	-
Thrombosuction	34 (27.86)	
Glycoprotein IIb - IIIa Inhibitor Use	116 (95.08)	-
Post Primary PCI TIMI Flow Grade		
TIMI-0	0	
TIMI-I	5 (4.10)	
TIMI-II	7 (5.73)	
TIMI-III	110 (90.16)	< 0.01
Procedural Success	117 (95.89)	

Table 2. Procedural Characteristics

Table 3 shows the time intervals during PCI. The median of onset of symptoms to hospital arrival time was 270 (range 70 - 720) minutes. The median time for door-to-balloon was 55 (range 20 - 180) minutes. The median total ischemic time was 325 (range 105 - 780) minutes.

Table 4 summarizes in-hospital outcomes. In our study 14 (11.4) patients had Major Adverse Cardiovascular Events (MACE). The overall mortality in the hospital was 6.5 %. The mortality rate was 70 % in cardiogenic shock patients. Three (2.45 %) patients had emergency coronary artery bypass surgery. Major TIMI bleeding requiring transfusion occurred in 2 (1.63 %) patients.

Time-Variables	Numbers (%)
Onset of Symptoms to arrival at hospital time {median (range)}	270 (70 - 720)
≤ 120 mins	12 (9.83)
121 – 240 mins	20 (16.39)
241 - 360 mins	44 (36.06)
> 360 mins	46 (37.70)
The Door to balloon time {median (range)}	55 (20-180)
≤ 60 mins	67 (54.91)
60 - 90 mins	35 (28.68)
91 - 120 mins	14 (11.47)
> 120 mins	6 (4.91)
Total Ischemic Time [median (range)]	325 (105 - 780)
< 120 mins	4 (3.27)
121 – 240 mins	20 (16.39)
241 – 360 mins	38 (31.14)
> 360 mins	60 (49.18)

Table 3. Timing Variables

Adverse Event	In-Hospital (%)
Death	8 (6.5)
Death (Cardiogenic Shock)	7 (70.0)
Death (No Cardiogenic Shock)	1 (0.81)
Re-Infarction	0 (0.0)
Mechanical Complications	0 (0.0)
CABG	3 (2.45)
Major Bleeding	2 (1.63)
Stroke	1 (0.81)
Total Event Rate	14 (11.4)

Table 4. In-hospital Major Adverse Cardiovascular Events (MACE)

Comparison between timing variables and MACE revealed trend towards reduced adverse events with lesser hospital arrival time, lesser door to balloon time and having better TIMI flow.

Time Variables	Number (%) (n = 122)	Mace (%) (n = 14)
Symptom onset to hospital arrival time [median (range)]		
• ≤ 120	12 (9.83)	0
• 121 - 240	20 (16.39)	1 (7.14)
• 241 - 360	44 (36.06)	5 (35.71)
• > 360	46 (37.70)	8 (57.14)
Door to balloon time [median (range)]		
• ≤ 60	67 (54.91)	2 (14.28)
• 60 - 90	35 (28.68)	7 (50)
• 91 – 120	14 (11.47)	5 (35.71)
PrePCI TIMI flow grades		
• TIMI-0	83 (68.03)	8 (64.28)
• TIMI-I	13 (10.65)	4 (28.57)
• TIMI-II	20 (16.39)	2 (14.28 %)
• TIMI-III	6 (4.91)	0

Table 5. Comparison between Timing Variables and MACE

DISCUSSION

Major findings of our study -

1. hypertension was associated with 43.44 %
2. major group of patients were males (77.05 %),
3. diabetes was associated with 36.06 % of patients
4. the overall in-hospital mortality was 6.55 % and 70 % in the cardiogenic shock subset. Cardiogenic shock was seen in 8.19 % of patients which is slightly more than seen in other Indian studies.

Fewer studies in India which included a study of Reddy et al. have concluded that PPCI is effective and safe. PPCI is associated with higher procedural success of 99 % and low rate of recurrence of ischaemic events of 5 %.[7] In Ranjan et al. study[8] even in technically demanding trans radial approach the procedural success rate was 98 %.

The basis of acute STEMI therapy is prompt restoration of coronary flow in the culprit artery thereby rapidly establishing myocardial perfusion. Though both primary PCI and thrombolytic therapy are effective to achieve these goals, primary PCI in many respects outperforms thrombolytic therapy. Primarily thrombolytic therapy restores the culprit artery patency in 40 – 60 % of patients but primary PCI does it in > 90 % of patients. Second, thrombolytic therapy becomes less effective if total ischemic time is > 6 hours when thrombus matures. Third, thrombolytic therapy has contraindications in up to 25 % of acute STEMI patients.[9] Lastly, primary PCI has improved outcomes like mortality, MI, stroke and major bleeding which makes it the preferred choice of therapy in acute STEMI settings.[5] Even then in India, the percentage of patients getting this therapy still remains low. In CREATE registry, which included patients presenting with Acute Coronary Syndrome (ACS) in various parts of India, primary PCI was done in 8 % of the patients presenting with STEMI.[10] Though PCI capable centres have increased in numbers, proportion of patients getting primary PCI is less than expected.[11]

	Our Study	Vijayakumar Subban et al[6]	Create Registry[10]	D. Rajasekhar et al[12]	PAMI Trial[13]
Age (mean in years)	55.23	52	56 · 30	54.5 ± 11.5	63.5 (median)
Male %	77.05	86.3	81 · 5	84.5 %	75.4
Hypertension	43.44	40.9	31 · 4	38.0 %	39.8
Diabetes	36.06	50	26 · 9	35.8 %	17.5
Smoking	31.14	25.1	34 · 1	48.7 %	63.7
Prior IHD	7.37	5.1	11 · 5		12.9
Dyslipidemia	15.57	15.3	-		-
AWMI	57.37	59.2	-		-
Cardiogenic Shock	8.19	4.6	-	5.7 %	0.9
IABP use	4.91	6	-		-
TPI use	16.39	7.7	-	13.0 %	-
Culprit vessel-					
LAD	55.73	56.2		58.0 %	
RCA	31.96	30.1		29.9 %	
PTCA + STENT	88.5 %	76.3 %		96.5 %	
Thrombosuction	27.86	33.9		29.0 %	
GP IIB IIIA inhibitor use	95.08	57.8			
Procedural success	95.89	95.1			
Death	6.55	4.2		3.6 %	
Death in cardiogenic shock	70	61.3			

Table 6. Comparison of Our Study Results with Other Studies

In our study, the mean age of patients was 55.23 years. This is considerably lesser than STEMI patients in the west but similar to acute STEMI subgroup of CREATE registry. In our study 77.05 % were male patients which is slightly less compared to CREATE registry subgroup. Hypertension, diabetes and smoking are the common associated risk factors like in CREATE registry. Prior history of MI was less common in our study cohort.

In study by D. Rajasekhar et al[12] patients mean age was 54.5 ± 11.5 years. In their study cardiogenic shock was encountered in 5.7 % of patients at the time of presentation. The average time for door to balloon was 62.5 ± 15.0 mins. Thrombus aspiration was done in 29.0 % of patients during PPCI. Mortality rate during hospital stay was 3.6 %.

Though door to balloon time achieved in majority of our patients, due to delayed presentation; majority of the patients had longer total ischemic time.

CONCLUSIONS

The mean age of our cohort was 55.23 years. In our study majority of patients were males (77.05 %, $p < 0.05$), hypertension was associated with 43.44 % ($p < 0.05$) and

diabetes was associated with 36.06 % of patients. Procedural success was achieved in 95.89 %. The overall in-hospital mortality was 6.55 % and 70 % in the cardiogenic shock subset. Comparison between timing variables and MACE revealed a trend towards reduced adverse events with lesser hospital arrival time, lesser door to balloon time and having better TIMI flow.

Primary PCI is a reperfusion strategy that can be performed safely and effectively in this subgroup of STEMI patients in a tertiary cardiac care center with reasonably low door to balloon time and lower rates of major adverse cardiovascular events.

Limitations

This is a single center prospective cross-sectional study. Sample size was small. Patients were not followed up for a long period of time.

Data sharing statement provided by the authors is available with the full text of this article at jebmh.com.
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