Single Centre Experience and Outcome of Primary Percutaneous Coronary Intervention for Patients with ST-Segment-Elevation Myocardial Infarction

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Abstract: *Background*: Primary percutaneous coronary intervention is an emergent coronary angiography and mechanical reperfusion of the infarct-related artery performed in patients with ST-segment elevation myocardial infarction. The present study aimed to determine the outcomes of primary percutaneous coronary intervention in a tertiary care cardiac centre.

Aims: The present study carried out with the aim to determine the outcomes of primary percutaneous coronary intervention in a tertiary care cardiac centre.

Methods: We evaluated 548 patients presented treated for ST-segment elevation myocardial infarction with primary percutaneous coronary intervention at Sri Venkateswara Institute of Medical Sciences, Tirupati, India from January 2011 to December 2012.

Results: Total 548 patients were included in this study. Mean age of patients was 54.5 ± 11.5 years. Cardiogenic shock, complete heart block and ventricular tachycardia / ventricular fibrillation was encountered in 31 (5.7%), 40 (7.3%) and 49 (8.9%) patients respectively at hospital admission. The average door to balloon time was 62.5 ± 15.0 minutes. Thrombus aspiration was performed in 159 (29.0%) patients during the index procedure. During hospital stay, in-hospital mortality was 20 (3.6%) out of which 15 (2.7%) patients died from cardiac cause. Target vessel revascularization, major bleeding and minor bleeding observed in 5 (0.9%), 5 (0.9%) and 11 (2.0%) cases respectively. Result of this six-month outcome of the studied showed 5 (0.9%) deaths and 5 (0.9%) incidence of target vessel revascularization.

Conclusions: Our data suggest that primary percutaneous coronary intervention for ST-segment elevation myocardial infarction can be safely performed in a regional institution with acceptable door to balloon time and low major adverse cardiac event rates.

Keywords: Percutaneous coronary intervention, ST-segment elevation myocardial infarction, door to balloon, coronary artery disease.

INTRODUCTION

Acute ST-segment elevation myocardial infarction (STEMI) is caused by the rupture or erosion of an atherosclerotic plaque of a coronary artery, initiating intra luminal thrombosis which results into partial or complete occlusion of the affected coronary artery [1, 2]. Reperfusion therapy with primary percutaneous coronary intervention (PCI) has become the treatment of choice for patients with STEMI. However, reperfusion therapy is indicated for the patients with acute STEMI if they arrive within the ideal time. The prognosis has improved over the period of time evidenced by in-hospital mortality rates fell from 11.2% (in 1990) to 9.4% (in 1999) [3]. The decline in mortality is due to use of thrombolytic agents and advent of primary PCI.

Primary PCI is defined as intervention of the infarct related vessel within 12 hour after the onset of symptoms, without prior thrombolytic therapy [4]. It has been performed since 1979 but the randomized clinical trials performed in 1993 showed superior efficacy and safety of primary PCI over thrombolysis [5-8]. Since then, primary PCI has been implemented in daily clinical practice and has become available for a broad range of patients.

Primary PCI is considered to be superior to thrombolytic treatment for STEMI especially in a hospital with angioplasty facilities [9-11]. Door to balloon time (D2B) is an important key factor in the success of primary PCI [12, 13]. So, to determine clinical safety and survival outcomes in patients experienced STEMI and treated with PCI, we evaluated 548 in-hospital patients admitted to our cardiac centre.

METHODS

Study Design and Patient Population

This was a retrospective observational study carried out at Sri Venkateswara Institute of Medical Sciences (SVIMS), Tirupati, India from January 2011 to

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December 2012. The protocol of the study was approved by the institutional ethics committee of the hospital. We had evaluated in-hospital patients diagnosed with STEMI and treated by primary PCI within 12 hours from symptom onset (Figure **1**). The written informed consent was obtained from all the patients enrolled in the study.

Patients were included if the electrocardiogram (ECG) at admission showed ST-segment elevation of at least 0.1 mV in minimum 2 contiguous leads as well as true posterior myocardial infarction or new (or presumably new) left bundle branch block. All these patients underwent primary PCI as a mode of reperfusion through femoral route.

Interventional Procedure and Adjunctive Medications

All patients were routinely treated with aspirin (325 mg upon arrival, and then 100 mg daily), clopidogrel (loading dose of 300 or 600 mg, and then 75 mg daily) and with an intravenous bolus of unfractionated heparin (100 U/kg body weight, or 60 U/kg body weight if abciximab was given). Intravenous administration of abciximab was recommended, but its use was left to the discretion of the operator. Heparin therapy was stopped after the procedure of PCI in all cases except the cases of intra-aortic balloon counterpulsation (IABC) use where heparin was continued until its removal. Abciximab infusion, if used, was continued for 12 hours after the procedure. Beta-adrenergic blockers (β-blockers), angiotensin-converting-enzyme inhibitors (ACE-I) and statins were used as in-hospital standard therapy, if not contraindicated.

ECG was recorded in all patients to assess the left ventricular ejection fraction by Simpson's rule [14] and to exclude mechanical complications (i.e. cardiac tamponade, interventricular septum or left ventricular free wall rupture, acute mitral regurgitation due to papillary muscle rupture).

Data Collection and Follow-Up

Clinical and procedural characteristics were collected through careful review of clinical records. We collected the following variables from the medical record of patient: demographic detail, history of diabetes (defined as a fasting glucose > 126 mg/dl or on treatment), hyperlipidaemia (fasting cholesterol > 200 mg/dl or on treatment), hypertension (systolic blood pressure > 140/90 mmHg or on treatment), left ventricular function (visually estimated, using either echocardiography or left ventriculography), presence of cardiogenic shock (defined as a systolic blood pressure of < 90 mmHg or requirement of inotropes to maintain a systolic blood pressure > 90 mmHg). Angiographic and procedural details (culprit vessel, number of diseased vessels, and use of stents) were also collected. Follow-up information was obtained from the patient's general physician or by direct telephone interview with the patient.

Clinical End-Points and Definitions

The primary end point was in-hospital mortality and secondary end points included 6-month outcomes after hospital discharge which include death from any cause, recurrent myocardial infarction (defined as reoccurrence of clinical symptoms or new ECG changes or re- elevation of creatine kinase MB

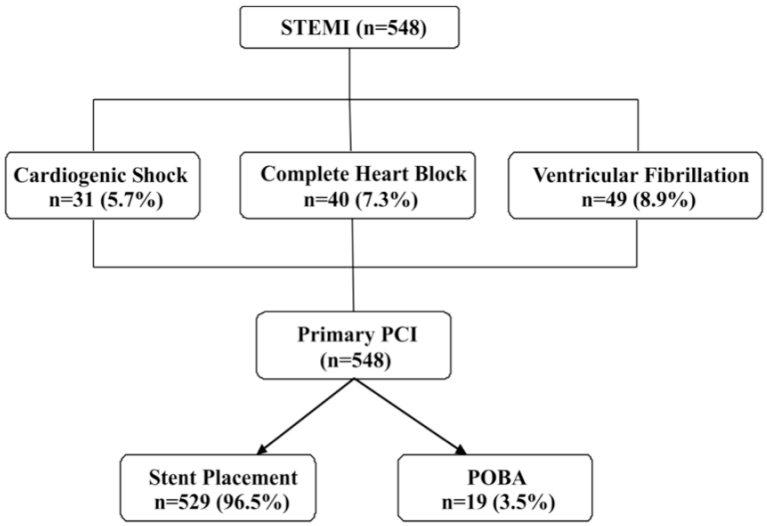

Figure 1: Patients flow diagram.

fraction), target lesion revascularization (TLR) (defined as all reported re-interventions inside the implanted stent during the index procedure or within 5 mm proximal or distal to the stent) target vessel revascularization (TVR) (other repeated PCI in the same vessel), stent thrombosis (defined as definite and probable according to the Academic Research Consortium) [15]; and major/minor bleeding (defined according to the Thrombolysis In Myocardial Infarction (TIMI) classification) [16].

Statistical Analysis

Continuous variables are presented as mean ± standard deviation and categorical variables as counts and percentages. The event free survival curve was calculated according to the Kaplan-Meier method. All data were analysed with the use of Statistical Package for Social Sciences (SPSS; Chicago, IL, USA) program version 15.

RESULTS

Baseline Demographics and Lesion Characteristics

Total 548 patients were included in this study. The clinical characteristics of primary PCI patients are summarized in Table **1**.

Table 1: Baseline Characteristics of the Study Population

Variables	n=548 patients
Age (years)	54.5 ± 11.5
Male, n (%)	463 (84.5%)
Body mass index (kg/m^2)	24.1 ± 4.1
Cardiac risk factors	
Hypertension, n (%)	208 (38.0%)
Diabetes mellitus, n (%)	196 (35.8%)
Current smokers, n (%)	267 (48.7%)
Renal insufficiency, n (%)	4 (0.7%)
Random blood sugar (mg/dl)	179.4 ± 79.0
Prior cerebral vascular accident, n (%)	22 (4.0%)

The average age of patients was 54.5 ± 11.5 years. There were 463 (84.5%) males and 85 (15.5%) females. Total 389 (71%) of the male patients were aged ≤60 years (Figure **2**).

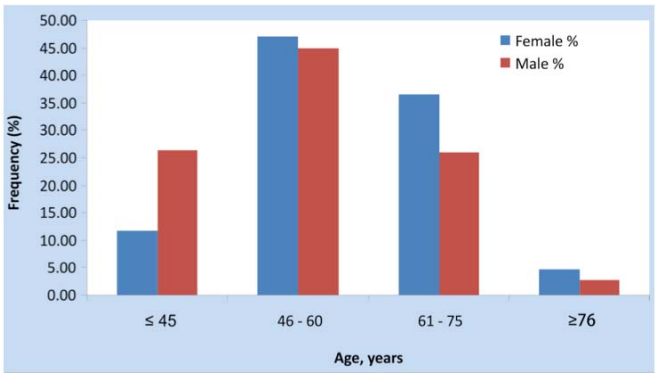

Figure 2: Distribution of patients by different age group, %.

Smoking habits were observed in 267 (48.7%) patients whereas hyprtension and diabetes were present in 208 (38.0%) and 196 (35.8%) patients respectively. Cardiogenic shock, complete heart block and ventricular tachycardia / ventricular fibrillation was encountered in 31 (5.7%), 40 (7.3%) and 49 (8.9%) cases respectively at hospital admission (Table **2**).

Table 2: Patient Characteristics on Hospital Admission

Variables	n=548 patients
Door-to-balloon time (minutes)	62.5 ± 15.0
First monitored rhythm	
Cardiogenic shock, n (%)	31 (5.7%)
Complete Heart Block, n (%)	40 (7.3%)
Ventricular tachycardia / Ventricular Fibrillation, n (%)	49 (8.9%)
Atrial fibrillation, n (%)	10 (1.8%)
Re-Infract, n (%)	15 (2.7%)
Bleeding, n (%)	33 (6.0%)
Renal failure, n (%)	39 (7.1%)
Cerebrovascular accident, n (%)	4 (0.7%)
Pericarditis, n (%)	9 (1.6%)
Left ventricular failure / Pulmonary edema, n (%)	40 (7.3%)
Left ventricular Ejection fraction (%)	44.0 ± 7.9
Hemodynamic Parameters	
Systolic Blood Pressure (mmHg)	122.4 ± 24.5
Diastolic Blood Pressure (mmHg)	78.4 ± 15.2
Killip Class	
Class - 1	320 (58.4%)
Class - 2	177 (32.3%)
Class - 3	37 (6.8%)
Class - 4	14 (2.5%)
Laboratory findings	
Estimated Glomerular Filtration Rate (GFR) (mL/min)	84.2 ± 30.3
GFR > 60	438 (79.9%)
GFR < 60	110 (20.1%)

The mean left ventricular ejection fraction (LVEF) was 44.0 ± 7.9% and 51 (9.3%) patients experienced Killip's class III/IV acute myocardial infarction. The average D2B was 62.5 ± 15.0 minutes. In 110 (20.1%) cases, estimated glomerular filtration rate (eGFR) was less than 60ml/min.

Angiographic and Treatment Data

The commonest vessel intervened was the left anterior descending (LAD) 318 (58.0%). The angiographic and procedural details of the patients undergoing primary PCI is shown in Table **3**. Thrombus aspiration was performed in 159 (29.0%) patients. Stents were deployed in 529 (96.5%) patients with average stent length of 19.2 ± 5.2 mm.

Table 3: Angiographic and Procedural Characteristics

Variables	n=548 Vessels
Number of diseased vessels	
Single vessel disease	366 (66.8%)
Double vessel disease	147 (26.8%)
Triple vessel disease	35 (6.4%)
Culprit vessel	
Left anterior descending	318 (58.0%)
Left circumflex	66 (12.0%)
Right coronary artery	164 (29.9%)
Percutaneous coronary intervention	n=548 patients
Thrombus Aspiration	159 (29.0%)
Stent Placement	529 (96.5%)
Average stent length (mm)	19.2 ± 5.2
Average stent diameter (mm)	2.9 ± 0.6
Plain old balloon angioplasty	19 (3.5%)
Direct Stenting	43 (7.8%)
Temporary pacing implant	71 (13.0%)
TIMI Flow after procedure	
TIMI I/II	21 (3.8%)
TIMI III	527 (96.2%)
ST–segment resolution (%)	57.2 ± 23.4
Procedure Time (minutes)	25.9 ± 9.5
Fluoroscopic Time (minutes)	8.5 ± 4.9

Clinical Outcomes

In-hospital and 6-months clinical outcomes are mentioned in Table **4**. Death in the catheterization laboratory or within 24 hours of hospital admission occurred in 20 (3.6%) patients and 75% of those cases died from cardiac cause. After patient discharge from the hospital, 6-months outcomes of the studied showed no major complication except, 5 (0.9%) deaths and 5 (0.9%) cases of TVR.

Table 4: In-Hospital and 6-Months Clinical Outcomes

Variables	n=548 patients
In-hospital events	
Death	20 (3.6%)
Cardiac Death	15(2.7%)
Non-Cardiac Death	5 (0.9%)
Target vessel revascularization	5 (0.9%)
Major bleeding	5 (0.9%)
Minor bleeding	11 (2.0%)
Non IRA (infract-related artery) revascularization	114 (20.8%)
6-months follow-up events	
Cardiac Death	5 (0.9%)
Target vessel revascularization	5 (0.9%)
Non infract-related artery revascularization	6 (1.1%)

The Kaplan-Meier survival curve (95.4%) at 6-months from admission is shown in the Figure **3**.

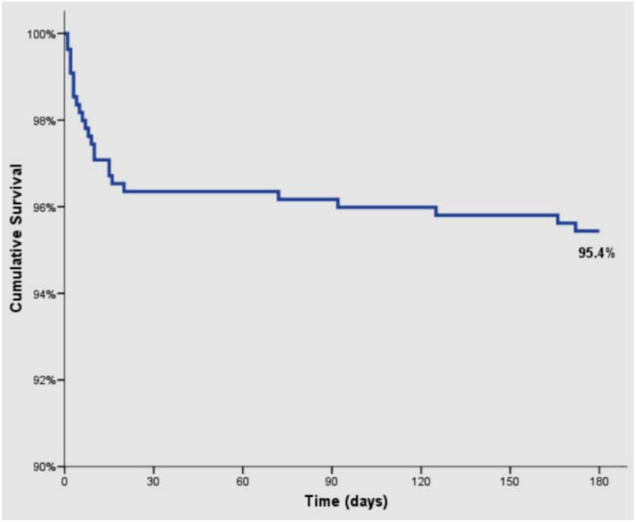

Figure 3: Kaplan-Meier survival curve at 6-months from admission.

DISCUSSION

Our primary PCI registry holds data on consecutive patients with acute STEMI, from single high volume tertiary care centre with enormous operator experience in performing primary PCI.

Compared with intravenous thrombolytic therapy, primary angioplasty for ST-elevation myocardial infarction improves patients' prognosis [17]. Because of the superior efficacy and safety of primary PCI over thrombolysis, primary PCI has become routine clinical practice in our centre. Both European and American guidelines state that primary PCI is the preferred therapeutic option in patients with STEMI admitted within 90 min after diagnosis [18, 19]. Several randomized clinical trials have showed the association between stent use in combination with primary PCI and outcome though results may be less clear [14, 20, 21, 23].

Few studies from India including a study by Reddy *et al.* concluded that primary PCI is safe and effective with high procedural success (99%) and lower rates of recurrent ischaemic events (5%) [24]. Study by Ranjan *et al.* [25] showed good procedural success rate (98%) even with transradial approach which is technically more demanding. Primary PCI continues to evolve and it has changed most radically with adjunctive therapy-glycoprotein IIb/IIIa inhibitors, thienopyridines as well as reliance on stent implantation [20-22, 26, 27]. Furthermore, extensive use of aspirin, statins, β-blockers and the common use of ACE-I may further reduce morbidity and mortality [28-30].

Clinical trials, comparing the efficacy of thrombolysis and primary PCI, have concluded that superior outcomes can be obtained with an invasive approach. A meta-analysis by Keeley and colleagues [17], demonstrated that primary PCI was better than thrombolytic therapy at reducing overall short-term death ($p=0.0002$), non-fatal reinfarction ($p<0.0001$), stroke ($p=0.0004$), and the combined endpoint of death, non-fatal reinfarction, and stroke ($p<0.0001$). A more recent evaluation of patients recruited into the PRAGUE-2 Study found that the incidence of reinfarction, revascularization and death from all causes was considerably reduced in those patients randomized to the PCI arm compared to thrombolytic arm with p value of 0.009, <0.001 and 0.06 respectively after 5 years of the procedure [31]. The possible risks associated with primary PCI include bleeding, procedure related immediate complications and radiographic contrast related acute renal failure [32].

This study proves that guidelines based approach to primary PCI for STEMI is feasible in rural population. The patients enrolled in the study are presenting population from rural areas around Tirupati, Andhra Pradesh. The study group has demonstrated younger age of patients with high prevalence of smoking, diabetes and hypertension.

Dedicated team work made possible to achieve short D2B time, high procedural success rate, reduced mortality along with improved survival. Results are sustained at 6 month follow up. This study shows that primary PCI for STEMI can be delivered successfully in rural setting of India with satisfactory D2B time, low mortality and minimal adverse effect. Mortality during hospital admission and after 6-month follow-up was 3.6% and 0.9% respectively. This compares favourably with data from randomised controlled trials. The meta-analysis of 23 trials showed short-term mortality rate 7% [17].

The mean D2B time is than 63 minutes in our centre and within the range (90 min) recommended by both the American and European guidelines [18, 19]. A further decrease in door to balloon time is desirable, however it might be not essay to achieve it due to the time consuming procedures required prior to ballooning (diagnosis, moving the patient to the coronary care unit, initiation of pre-PCI medication taking the patient to the cath lab then beginning of PCI procedure and finally balloon dilatation).

Thrombus aspiration during primary PCI showed better reperfusion and clinical outcomes in patients with primary PCI for STEMI when compared with conventional PCI [33]. However, Thrombus aspiration during STEMI did not reduce 30 day mortality [34]. In our study patients who underwent manual thrombus aspiration had higher post procedure TIMI flow and ST segment resolution. Presence of base line renal failure was associated with increased short term and long term mortality.

CONCLUSIONS

Primary PCI is a reperfusion strategy that can be performed safely and effectively in unselected high-risk STEMI patients in a regional institution with acceptable door to balloon time and low major adverse cardiac event rates. We can also conclude that with increasing awareness and the wider availability of primary PCI, this procedure will be performed more frequently as first line treatment for STEMI and eliminating thrombolytic therapy as first choice therapy.

STUDY LIMITATIONS

There are some important limitations of our study. First of all, this is not a comparative study with other

hospitals. Secondly, our work represents a retrospective study, and is therefore subject to the limitations of such analyses. Third, the data are derived from a single centre, which limits the extension of the applicability of the results. In addition, we analyzed only the 6-month mortality. Therefore, it is not possible to extend the results beyond the acute phase and to other major cardiovascular events. Finally, the confounders of aneurismal dilation, recurrent MI by biomarkers, other predisposing factors are not excluded, that may have negative impact on study

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