Original Article

Outcomes of primary Percutaneous Coronary Intervention (PCI) in a Tertiary Care Cardiac Centre

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Abstract

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

Methods: Medical records of 104 consecutive patients presented in our hospital between January 2006 to December 2007 with acute ST elevation myocardial infarction (STEMI) and treated with primary PCI as a mode of reperfusion were reviewed. The primary end point was in hospital mortality and secondary end points were 30 day mortality, myocardial infarction, recurrent angina and congestive cardiac failure, from discharge to one month follow up.

Results: The procedural success was 97%. Six (5.8%) patients died during hospital stay including one on table death. Out of six patients who died, five (83.3%) had cardiogenic shock. No mortality was observed in the 30 days follow up from discharge while other complications like myocardial infarction, recurrent angina and congestive cardiac failure were 1%, 1% and 5% respectively.

Conclusions: Our findings suggest that favourable outcomes, matching the international data can be achieved in our patients with primary PCI in the management of life threatening illness like STEMI despite all the limitations. Primary PCI as a preferred method of reperfusion strategy needs to be practiced more often in our part of the world (JPMA 59:426; 2009).

Introduction

Cardiovascular diseases, including myocardial infarction (MI) and heart failure, remains the leading cause of death in developed countries. It is of increasing concern in low- and middle-income countries as risk factors such as smoking and obesity are becoming more common around the globe.[1] MI is generally the result of acute rupture or ulceration of an atherosclerotic plaque in a major epicardial coronary artery. Exposure of the intimal layer initiates a cascade of platelet activation and thrombosis resulting in occlusion of the vessel and infarction of the subjacent myocardium.[2] The aim of acute treatment of ST elevation myocardial infarction (STEMI) is restoration of myocardial perfusion by recanalization of the occluded vessel. Early reperfusion is associated with better outcomes .Thrombolytic therapy and primary percutaneous coronary intervention (PCI) are used as reperfusion strategies. Several randomized trials and meta-analyses have shown that primary angioplasty is superior to thrombolysis in the treatment of STEMI in terms of death, reinfarction, and stroke.[3]

Primary PCI is preferred if a skilled interventional cardiologist and catheterization laboratory with surgical backup are available and if the procedure can be performed preferably within 90 minutes after initial medical contact with the patient.[4] Few studies from India including a study by Reddy et al concluded that primary angioplasty is safe and effective with high procedural success (99%) and lower rates of recurrent ischaemic events (5%).[5] Study by Ranjan et al showed good procedural success rate (98%) even with transradial approach which is technically more demanding.[6] There are very few studies found after a robust literature search based on our community that can determine the outcome of primary PCI. This provides a very strong rationale to conduct such a study so as to determine the outcome of primary PCI in our population and to compare it with international data.

Patients and Methods

Medical records of 104 consecutive patients who had presented to the emergency department of Tabba Heart

Institute, Karachi, form January 2006 through December 2007 were retrospectively reviewed. These patients had come with STEMI and chest pain of less than 12 hours duration with electrocardiographic evidence of ST segment elevation of ≥ 1mm in ≥ 2 contiguous leads or new left bundle branch block without previous history of thrombolytic therapy, coronary angioplasty or coronary artery bypass grafting. All these patients underwent primary PCI as a mode of reperfusion, through femoral route.

All patients in emergency department received aspirin 300mg, clopidogril 600 mg, parenteral beta blockers as per indications and initial weight based bolus of unfractionated heparin. Glycoprotein (GP) IIb/IIIa antagonist tirofiban/eptifibatide was administered to majority of patients (71%) either in emergency room (50%) or in cardiac catheterization laboratory (20%). Patients underwent diagnostic angiogram followed by primary PCI of the infarct-related artery. All primary PCI were performed through the femoral route. Coronary stenting, intracoronary nitroprusside and adenosine use were at the judgment of the operators. Stent size selection was primarily based on visual assessment of lesion length and vessel diameter. All patients were prescribed aspirin 75mg daily for indefinite period and clopidogrel 75mg daily for a minimum of one month for bare metal stent and one year for drug eluting stent receiving patients. Post PCI all patients initially remained in coronary care unit and later shifted to coronary step down unit before discharge. Routine follow up was done after one week and four week of discharge.

Performa was designed to collect information including, age, gender, 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), smoking , 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 SBP > 90 mmHg). Angiographic and procedural details (culprit vessel, number of diseased vessels, use of stents, GP IIb/IIIa inhibitors and Thrombolysis in Myocardial Infarction (TIMI) flow) were also collected. Hospital charts were reviewed for further information including need of intubation, electrocardiogram (ECG) ST-segment analysis and laboratory data including haemoglobin, serum creatine and cardiac enzymes etc.

Timing variables were computed including time to presentation which is 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 balloon inflation in cardiac catheterization laboratory. Coronary flow in the infarct related artery was assessed visually by the operator and classified according to the TIMI grading system on a scale of 0 to 3 both before and after the PCI. PCI success was defined as achievement of vessel patency to a residual ≤ 30%. Significant groin haematoma was defined as a haematoma > 10 cm in diameter or requiring transfusion.

The primary end point was in-hospital mortality and secondary end points included 30 day outcomes from discharge including mortality, reinfarction (defined as recurrence of clinical symptoms (or new electrocardiographic changes) and new elevation of creatine kinase MB fraction), recurrent angina (defined as any new episode of angina, with new electrocardiographic changes requiring readmission and initiation of a nitroglycerin infusion) and congestive heart failure (defined as a history of paroxysmal nocturnal dyspnoea, dyspnoea on exertion or pulmonary congestion on chest x-ray).

Statistical Analysis

All the variables were entered into the Statistical Package for Social Sciences software, version 14 (SPSS Inc) for data analysis. Descriptive statistics were computed and presented as means and standard deviations were calculated for continuous variables like age, LVEF and median for onset of pain to ER, door to balloon time, in minutes. Categorical variables reported in percentages for the gender, hypertension, diabetes mellitus, hyperlipidaemia, cardiogenic shock, left ventricular failure, multivessel diseases, procedural success, mortality and thirty day outcome variables like myocardial infarction, recurrent angina and congestive heart failure.

Results

Total of 104 patients were included in this study. Table-1 shows the demographic and clinical characteristics as well as outcomes of the studied cohort. The mean age was just over 55.4 ± 11.7 years. There were 83 (80%) males and 21 (20%) females, with 40 (38.5%) patients having diabetes and 57% hypertension. Cardiogenic shock was encountered in 11 (10.6%) patients and 12 (11.5%) required intubation during their hospital stay. Anterior STEMI was diagnosed in 58 (55.7%) patients. The mean left ventricular ejection fraction (LVEF) was 44%. The median time from onset of symptoms to presentation was 120 minutes and the median door-to-balloon time was 115 minutes. Majority of patients (70%) received GP IIb IIIa inhibitor. Table-2 shows the angiographic and procedural details of the patients undergoing primary PCI. Left anterior descending artery (LAD) was the most commonly identified culprit vessel 58 (55.7%) followed by right coronary artery and left circumflex artery 36 (34.6%) and 10 (9.6%) respectively. Multivessel disease (defined as > 50% stenosis in ≥ 2 epicardial vessels) was present in 72 (69.2%) patients. Stents were deployed in 91% patients and multivessel PCI was

Table-1: Characteristics of patients undergoing primary PCI for STEMI.

Baseline Demographic and Clinical characteristics:	N= 104 (%)
Mean Age (years)	55.44 ± 11.78
Male (Gender)	83 (79.8)
Past Medical history:	
Hypertension	59 (56.7)
Diabetes Mellitus	40 (38.5)
Current smokers	37 (35.6)
Hyperlipidaemia	52 (50)
Family history of Coronary Artery Disease	64 (61.5)
Prior Cerebral Vascular Accident	2 (1.9)
Admission characteristics:	
Cardiogenic shock	11 (10.6)
Left ventricular failure	14 (13.5)
Left ventricular Ejection fraction (mean / SD)	43.70 (7.94)
Required Intubation	12 (11.5)
Anterior myocardial infarction	58 (55.7)
Timing variables:	
Onset of pain to ER time (minutes) median	120
Door to Balloon time (minutes) median	115
Glycoprotein IIb / IIIa inhibitors use:	
Started in Emergency room	22 (21.2)
Started in Cathetrization laboratory	52 (50.0)
Not given	30 (28.8)
In hospital events:	
Death in hospital (all patients)	6 (5.8)
Death in hospital (patient with cardiogenic shock)	5 (45.4)
Death in hospital (patient without cardiogenic shock)	1 (1)
Table death	1 (1.0)
In hospital CABG	1
Stent thrombosis	1
Groin haematoma	7 (6.7)
Contrast Induced Nephropathy	6 (5.8)

Table-2: Angiographic and procedural characteristics of patients undergoing primary PCI for STEMI.

	No of Cases (%)
Culprit vessel:	
Left Anterior Descending	58 (55.7)
Left Circumflex	10 (9.6)
Right Coronary Artery	36 (34.6)
Multivessel CAD	72 (69.2)
Multivessel PCI	9 (8.7)
Procedural success	101(97)
Use of Stent	94 (90.4)
Plain old balloon angioplasty (POBA)	10 (9.6)
Intra-Aortic Balloon Pump	10 (9.6)
Type of contrast used:	
Ionic	14 (13.5)
Non-ionic	90 (86.5)

CAD: Coronary Artery Disease.
PCI: Percutaneous Coronary Intervention.

performed in 9 (8.7%) patients. Procedure was successful in 101 (97%) patients. Ten (9.6%) patients needed intra aortic balloon counterpulsation support and 1 (1%) patient was referred for urgent surgical revascularization. Groin haematoma occurred in 7 (6.7%) patients, subacute stent thrombosis occurred in 1 (1%) patient and 6 (5.8%) patients had contrast induced nephropathy. Six patients died in hospital (5.8%) including one table death. Out of six patients who died, five (83.3%) had cardiogenic shock.

Post discharge 30-day outcomes of the studied cohort showed no death. Major complications during one month follow up were myocardial infarction 1%, unstable angina 1% and congestive cardiac failure was seen in five (4.8%) patients.

Discussion

Cardiologists had recognized the importance of early reperfusion in limiting ischaemic damage to the myocardium. First benefit identified with the use of thrombolytic therapy to achieve reperfusion was primarily due to two landmark large trials: the Second International Study of Infarct Survival Group (ISIS-2)[7] and an Italian group (GISSI).[8] Both studied the effects of intravenous streptokinase given to patients with suspected acute MI.

The undoubted benefits of thrombolysis are offset by its nonspecificity for the coronary circulation resulting in risk of bleeding complications and time-dependent uncertainty about the efficacy of reperfusion. In addition, there is limited evidence of the benefit of thrombolytic therapy in a number of high-risk groups including older patients and in the context of cardiogenic shock.[9] PCI has potential benefits of specific and confirmed recanalization of the culprit vessel as well as knowledge of the detailed coronary anatomy. Clinical trials comparing the efficacy of thrombolysis and primary angioplasty have concluded that superior outcomes can be obtained with an invasive approach. A meta-analysis by Keeley and colleagues, 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 ($p<0.0001$).[10]

A more recent evaluation of patients recruited into the PRAGUE-2 Study found that, at 5 years after the procedure, 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.[11] The possible risks associated with primary PCI includes bleeding, procedure related immediate complications and radiographic contrast-related acute renal failure.[12]

Benefits of primary PCI in older patients has been addressed by several studies. GUSTO IIb trial found a reduced mortality associated with primary invasive approach when offered to patients >65 years of age.[13]

As angioplasty offers reduced rates of complications, patients are discharged earlier and are less likely to be readmitted with a related cardiac event. Hospital costs are therefore considerably reduced in patients receiving PCI, accounting for the reduced cost after one year.[14]

Our study shows an excellent procedural success rate (97%) with an excellent overall in-hospital survival rate (94.2 %). One patient out of 93 patients without cardiogenic shock died (1%) which is comparable to international data which showed in-hospital mortality of 5.2% in second national registry of myocardial infarction (NRMI2)[15] and 3% in ASSENT 4 trial.[16] In our study 11 patients had cardiogenic shock out of them 5 died (45%)which is again comparable to international data which showed higher mortality in patients with cardiogenic shock i.e. 32% in NRMI 2,[15] 46.4% in SHOCK registry[17] and 59.1% in American College of Cardiology-National Cardiovascular Data Registry (ACC-NCDR).[18] Studies from India by Reddy et al[5] showed an in-hospital mortality of 2.2% in non-cardiogenic shock group, similar outcomes were observed in a JCIA certified local study with mortality of 43.9% and 2.1% in patients undergoing primary angioplasty for STEMI with and without cardiogenic shock respectively.[19]

Door to balloon time is an important determinant of quality of care. Recommended time as per American College of Cardiology (ACC)/ American Heart Association (AHA) guidelines is 90 minutes, however achieving this time is possible only in ideal world scenario. In developing countries like Pakistan, financial constrains and delay in decision making due to lack of knowledge on behalf of patients and their relatives regarding importance of time in management of critical illness like myocardial infarction, turned out to be the major obstacle in following door to balloon time recommendations. In our study the median door to balloon time was 115 minutes with 40% of patients having PCI performed at or more than 90 minutes due to above mentioned reasons. However if we look at recent study by Zhang conducted in China, the median door-to-balloon time reported for primary PCI was 132 min and only 22% of patients had PCI performed in $\leq$ 90 minutes.[20]

Our results are encouraging and comparable to results from western centers. We conclude that with increasing awareness and the wider availability of primary angioplasty, this procedure will be performed more frequently and thrombolytic therapy will no more be the first choice therapy for treatment of STEMI in our part of world.

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