

Outcomes of Primary Percutaneous Coronary Intervention (PCI) in NICVD, Dhaka, Bangladesh- Our Initial Experiences

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Abstract

The aim of the study is to determine the outcomes of primary percutaneous coronary intervention (PCI) in patients with acute myocardial infarction in NICVD the only government cardiac hospital of Bangladesh where resources are very limited. Total 73 (male 70, female 3) patients were enrolled in this study who were brought in to our hospital with STEMI between August 2010 to October 2013. Average age was 55.6 ± 11.78. Primary PCI was performed after transferring patient from Emergency Department to cardiac catheterization laboratory. Cardiovascular risk factors among the studied population were Diabetes mellitus, Hypertension, Smoking, Dyslipidemia and Positive family history for IHD. Primary PCI either with Bare Metal Stent (BMS) or Drug Eluting Stent (DES) were performed in total 42 LAD lesions, 28 RCA lesions and 3 LCX lesions. BMS used were 87.7%, DES used were 12.3%. The procedural success was 95.8%. Four patients (5.4%) died during hospital stay. Out of four patients who died, one had cardiogenic shock. No mortality was observed in the 30 days follow up from discharge, while other complications like unstable angina and congestive heart failure were 5.7% and 4.3% respectively. Our findings suggest favorable outcomes, matching the international data which was achieved in our patients with primary PCI in the management of STEMI despite all the limitations. Primary PCI as a preferred method of reperfusion strategy needs to be practiced more often in our part of world.

Keywords- Primary PCI, STEMI

Introduction:

Cardiovascular diseases including myocardial infarction (MI) and heart failure, remains the leading causes of death worldwide. Acute MI results mostly from acute thrombotic occlusion of an epicardial coronary artery, typically after disruption or erosion of an atherosclerotic plaque and exposure of thrombogenic material (Plaque lipid content, collagen and sub endothelial extracellular matrix) to circulating blood. The aim of acute treatment of ST elevation MI (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 terms of death, reinfarction and stroke¹. Primary PCI is performed if a skilled interventional cardiologist and catheterization laboratory with surgical back up are available and if the procedure can be performed preferably

with in 90 minutes after initial medical contact with the patient². Few studies from India including a study by Reddy et al concluded that primary angioplasty is safe and effective with procedural success rate (99%) and lower rates of recurrent ischemic events (5%)³. In Bangladesh there is a single study in Apollo hospital, Dhaka done by A.Q.M Reza et al showed that primary PCI increases higher survival outcome in 28(93.3%) out of 30 patients with acute STEMI⁴. The aim of our study is to evaluate safety and survival outcome & benefit of primary PCI in our only tertiary care cardiac centre at government level where resources are limited. This will provide 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.

Methods:

Patients were randomized from the cases who presented to our emergency department (ED) with the onset of chest pain outside the hospital of any age for at least 30 minutes,

but less than 12 hrs in duration. Total study period was between August 2010 to October 2013. Total number of patient was 73.

Electrocardiographic criteria were associated with ST segment elevation of ≥ 2 mm in chest leads & ≥ 1 mm in limb leads in ≥ 2 contiguous leads. Prior to primary PCI informed written consent were taken from the patient or guardians. All these patient underwent primary PCI as mode of reperfusion through femoral route. All patient in emergency department received Aspirin 300mg, clopidogrel 600 mg as per indication. Patient underwent diagnostic angiogram followed by primary PCI of the infarct related artery.

After thrombus suction where required from the occluded site by a thrombuster sucker, balloon dilatation was done in selected cases. All culprit lesions were stented mostly with bare metal stent (BMS) and few of them by drug Eluting stent (DES). Further smoothing was done by post dilatation whenever required. IVUS was not available in our hospital. Before PCI standard heparin 10,000 units IV bolus was given. Glycoprotein (GP) IIb/IIIa antagonist, Eptifibatide was used both as intra coronary bolus and I.V maintenance in all cases. Intracoronary nitrates & adenosine use were at the judgement of the operator. Stent size selection was primarily based on visual assessment of lesion length and vessel diameter. All patients were prescribed aspirin 75mg daily for indefinite time. Clopidogrel 75mg daily for a minimum of one month in case of BMS and for one year in case of DES. 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 & four week of discharge.

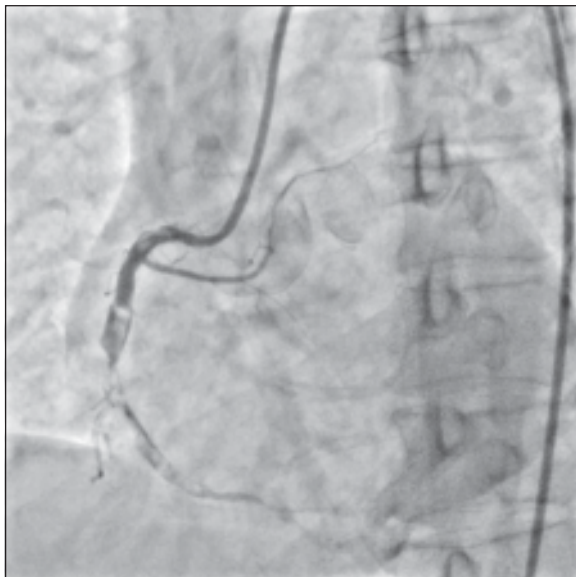


Fig.-1: Thrombus burden and critical stenosis in mid RCA in a patient before Primary PCI



Fig.-2: After thrombus suction and stenting of RCA in same patient.

Performa was designed to collect information including age, gender, history of diabetes (defined as a fasting glucose ≥ 126 mg/dl or on treatment), hypertension BP $\geq 140/90$ mm Hg or on treatment), dyslipidaemia (fasting total cholesterol ≥ 200 mg/dl or on treatment), smoking, left ventricular function (visually estimated using echocardiography), presence of cardiogenic shock (defined as systolic blood pressure < 90 mm or requirement of inotropes to maintain a SBP > 90 mm of Hg) angiographic and procedural details (culprit vessel, number of diseased vessels, use of stents, GP IIb/IIIa inhibitors, Thrombolysis in myocardial infarction (TIMI) flow were also collected. Hospital charts were reviewed for further information including need for intubation, electrocardiogram (ECG) ST-segment analysis and laboratory data including haemoglobin, serum creatinine, 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.

Successful PCI was defined as visually assessed $< 20\%$ residual stenosis with TIMI III distal flow. Significant groin hematoma was defined as a hematoma > 10 cm in diameter or requiring blood transfusion.

The primary end point was in-hospital mortality and secondary end points included 30 days outcomes from discharge including mortality, reinfarction, re-current angina, congestive heart failure.

Statistical Analysis

All the variables were entered in to the statistical package for social science software, version 14(SPSS inc) for data analysis. Descriptive statistics were computed and presented as means, standard deviations were calculated for continuous variables like age, LVEF and median for onset of pain to emergency room, door to balloon time-in minutes. Categorical variables reported in percentages for the gender, hypertension, diabetes mellitus, dyslipidemia, cardiogenic shock, LVF multivessel diseases, procedural success, mortality and thirty day outcome variables like myocardial infarction, recurrent angina, congestive heart failure.

Results:

A total of 73 patients were included in this study.

Table-1
Characteristics of patients undergoing primary PCI for STEMI

Base line demographic and clinical characterizes:	N=73(%)
Mean age (years)	55.6 ± 11.78
Male (gender)	70 (95%)
Female (gender)	3 (5%)
Past medical history:	
Hypertension	35 (47.9%)
Diabetes mellitus	28 (38.3%)
Current smoker	45 (61.6%)
Dislipidaemia	25 (34.2%)
Positive family history for IHD	20 (27%)
Previous MI	0- (0%)
Previous PCI	1 (1.3%)
Previous CABG	0-(0%)
Previous congestive heart failure	0-(0%)
Admission characteristics:	
Cardiogenic shock	2(2.7%)
Left ventricular failure	7(9.5%)
Ventricular arrhythmia	3(4.1%)
LV ejection fraction (Mean/SD)	43.7 ± 7.9%
Anterior MI	42 (57.5%)
Inferior MI	31 (42.4%)
Timing variables:	
Onset of pain to first medical contract time (minutes) mean	120 minutes
Door to balloon time (minutes) mean	110 minutes

Table 1 shows the demographic and clinical characteristics of the patients. The mean age was 55.6±11.2 years. There were 95% male and 5% female patient. The distribution of cardiovascular risk factors were diabetes mellitus 38.3%, hypertension 47%, smoking 61.6%, dyslipidemia 34%, positive family history of IHD 27.3%. One patient was a case of recent NSTEMI with PCI to LAD who developed subacute stent thrombosis during his hospital stay. 2 patients presented with cardiogenic shock. 3 patients had ventricular tachycardia, 7 patients had acute LVF during the admission, mean LV ejection fraction was 43.7%±7.4%. Out of 73 patients 42 patients presented with anterior MI 31 patients presented with inferior MI. The median time from onset of symptom to presentation was 120 minutes and the median door to balloon time was 110 minutes.

Table-II

Angiographic and procedural characteristics of patients undergoing primary PCI for STEMI

Culprit vessel	No of case (%)
Left anterior descending artery	42 (57.5%)
Left circumflex artery	3(6.8%)
Right coronary artery	28(38.3%)
Multivessel CAD	11(15%)
Multivessel PCI	2(2.7%)
Procedural success	69(94.5%)
Use stent	73 (100%)
Plain old balloon angioplasty (POBA)	0 (0%)
Intra-Aortic Balloon Pump	2 (2.7%)
TIMI blood flow on angiography	
Before PCI	
0	51(69.8%)
1	20(27.3%)
2	2(2.7%)
3	0(0%)
After PCI	
0	0(0%)
1	0(0%)
2	2(2.7%)
3	71(97.2%)

Table-2 shows the angiographic & procedural characteristics of patients.

Left anterior descending (LAD) artery is the most common culprit vessel, 42(57.5%) followed by right coronary artery 28(38.3%) and left circumplex artery 3(4.1%). Multivessel disease (defined as >70% stenosis in ≥2 epicardial vessel) was present in 2 cases (15%). Stent were deployed in all cases. Multivessel PCI was performed in one case. The

average dimension of stent and their deployment pressure were as follows $19.5 \pm 7.3 \times 3.2 \pm 0.5 @ 16.1 \pm 4.1$ ATM in LAD, $17 \pm 5.0 \times 3.0 \pm 0.2 @ 15 \pm 1.4$ ATM in LCX and $20.7 \pm 0.6 \times 3.5 \pm 0.3 @ 14.5 \pm 2.3$ ATM in RCA.

Table-III

Average size of stents used with inflation pressure.

Vessel	No(%)	Length (mm)	Diameter (mm)	Inflation pressure (ATM)
LAD	42 (58.5%)	19.5 ± 7.3	3.2 ± 0.5	16.1 ± 4.1
LCX	3(4%)	17 ± 5.0	3.0 ± 0.2	15 ± 1.4
RCA	28(38.3%)	20.7 ± 0.6	3.5 ± 0.3	14.5 ± 2.3

Procedure was successful in 70 (95.8%) patients. Two patients needed intra aortic balloon counterpulsation support. Groin hematoma occurred in two patients (2.7%). No patient needed urgent CABG. No patient developed sub acute stent thrombosis or contrast induced nephropathy.

Table-IV

In-hospital events

Death in hospital (all patients)	4(5.4%)
Death in hospital (patient without cardiogenic shock)	3(4.2%)
Death in hospital (patient with cardiogenic shock)	1(50%)
Groin haematoma	2(2.7%)
Table death	0(0%)
In hospital CABG	0(0%)
Stent thrombosis	0(0%)

Four patients died in hospital (5.4%). Out of four patient who died, one had cardiogenic shock during admission post discharge 30 days out comes of the studied cohort mowed no death. Major complications during one month follow up were unstable angina in 4 patient (5.7%). Congestive cardiac failure was seen in 3 patient (4.3%).

Discussion:

Cardiologists had recognized the importance of early reperfusion in limiting ischemic damage to the myocardium. First benefit identified with the use of thrombolytic therapy to achieve reperfusion was primarily due to two land mark large trials: the Second International Study of infarct survival group (ISIS-2)⁵ and an Italian group (GISSI)⁶. 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 complication 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 shock⁷. 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 ($p<0.0001$)⁸.

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 respectively⁹. The possible risks associated with primary PCI includes bleeding, procedure related immediate complications and radiographic contrast-related acute renal failure¹⁰.

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 year¹¹.

Our study shows an excellent procedural success rate (95.8%) with an excellent over all in hospital survival rate (94.5%). Out of 73 patients 71 patients presented without features of cardiogenic shock and 2 patients presented with features of cardiogenic shock. 3 patients out of 71 who presented without features of cardiogenic shock died (4.2%), which is comparable to international data which showed in hospital mortality of 5.2% in second national registry of myocardial infarction (NRM-12)¹² and 3% in ASSENT 4 trial¹³. In our study two patient had cardiogenic shock. Out of them one died (50%) which is again comparable to international data which showed higher mortality in patient with cardiogenic shock i.e 46.4% in shock registry¹⁴ and 59.1% in American college of cardiology- National Cardio Vascular data registry (ACC-NCDR)¹⁵. Study from India by Reddy at al³ and from Pakistan by Ayaz Hussain et al¹⁶ showed an in hospital mortality of 2.2% and 1% respectively

in non-cardiogenic shock group. In our country previous single study conducted by AQM Reza⁴ had shown in-hospital survival rate 93.8% which is also comparable to our present study where survival rate is 94.5%. In our study we used mainly bare metal stent (BMS). Drug Eluting stent (DES) was used in 9 cases. Although the use of DES and its rate on acute stent thrombosis is still debatable, majority are using BMS. Our patient treated with DES has no documented acute stent thrombosis.

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 Bangladesh, financial constraints 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 110 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 ≤ 90 minutes¹⁷.

Our study has some limitations that deserve attention. This is our observational study performed in selected patient group. There was only three female patient in our study. So out come of primary PCI in female group could not be assessed properly. Lack of availability of IVUS was also a drawback for us to see intravascular thrombus burden and exact stent implantation.

In summary we found that primary PCI is safe and it increased the in-hospital and 30 days survival out come in patient with acute myocardial infarction. We conclude that with increasing awareness and the wider availability of primary PCI, this procedure will be performed more frequently and thrombolytic therapy will no more be the first choice therapy for treatment of STEMI in our set up.

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