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AN OUTCOME OF 200 CASES OF PRIMARY PCI - A SINGLE OPERATORS EXPERIENCE OF A TERTIARY CARE CENTRE

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ABSTRACT

Objective: To evaluate the demographics and in hospital outcomes of the patients presenting with acute STEMI in a tertiary care cardiac centre.

Study Design: Single-centre, prospective observational study.

Place and Duration of Study: The study was carried out in Armed Forces Institute of Cardiology – National Institute of Heart Diseases (AFIC-NIHD) over a period of 14 months from January 2015 to march 2016.

Material and Methods: We collected data of two hundred patients who underwent Primary PCI by a single operator (the index author). Acute myocardial infarction registry by R & D Department was used as a data collection tool. Patients with acute ST segment elevation myocardial infarction (STEMI) reporting to the emergency department of AFIC/NIHD were included in the study. The patients were examined before discharge from the hospital for any complication. Study endpoints included procedure success rate, vascular complications at access site, and major adverse cardiac and cerebrovascular events during hospitalization.

Results: Mean age of the patients was 51 ± 16.8 years and males were more in number 128(64 %) as compared to females 72(36%).92 (46%) patients were found to be diabetic, 81(40.5%) hypertensive, and 91 (45.5%) patients were smokers. Radial and femoral approach was used in 183(91.5%) and 17 (8.5 %) patients respectively. Anterior, inferior and lateral myocardial infarction was seen in 128 (64%), 67 (33.5%) and 5 (2.5%) patients respectively .Left anterior descending (LAD) was the commonest culprit artery in 128 (64%) followed by right coronary artery (RCA) & left circumflex artery (LCX) in 57 (28.5%) and 15 (7.5%) cases respectively . The procedural success rate was 96.3%. Overall mortality was seen in 3(1.5%) cases.Reinfarct and Stroke was seen in4 (2.0%) and 1 (0.5%) patients respectively. Major and minor bleeding was seen in 1(0.5%) and17 (8.5%) patients. The median time from- onset of symptoms to presentation was 170 minutes±93min and the Median door to balloon time was 51.75 ± 5.6 min.

Conclusion: Our study has shown that PPCI is feasible with good outcomes (High success rate with low mortality rates) in our set up. Even though the recommended door-to-balloon time can be achieved in most of the patients the total ischemic time remained long. Increased public awareness is needed to improve outcomes in acute MI.

Keywords: Myocardial infarction, Primary percutaneous (PPCI), ST segment elevation myocardial infarction (STEMI).

INTRODUCTION

The coronary artery disease (CAD) is the leading cause of death throughout the world, in which almost half of the cases occur in Asia[1,2].Acute Myocardial infarction is the result of rupture or ulceration of unstable atherosclerotic plaque resulting in occlusion of vessels leading to decreased delivery of oxygen and nutrients to myocardium and thus causing infraction of myocardium[3]. Diabetes, Smoking and obesity like risk factors are becoming more frequent with increased concern in developing countries.

Acute ST-segment elevation myocardial infarction (STEMI) is the most dramatic manifestation of CAD with high morbidity and mortality and timely reperfusion therapy has undoubtedly proved to reduce these adverse events[4]. Primary percutaneous coronary intervention (PPCI) is the most effective therapy for STEMI and achieves rapid and more consistent reperfusion with low complication rate when compared to thrombolysis[5]. Percutaneous coronary intervention (PCI) is an

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established therapy for patients with symptomatic coronary artery disease including acute coronary syndromes. In patients presenting with ST-elevation myocardial infarction (STEMI), there is considerable body of evidence suggesting that reperfusion with primary PCI provides better short- and long-term outcomes as compared to fibrinolytic therapy. Although widely practiced as the default strategy to treat patients presenting with STEMI in developed nations, it is still not commonly adapted in this part of the world and only few of the patients get this privilege after reporting to PPCI capable centers. Thus there is shortage of data availability from this part of the world. AFIC & NIHD started 24 × 7 PPCI program in 2011 during the working hours in the day time and then extending the availability of PPCI facility to the off hours with an in house cardiologist and catheterization laboratory team so that PCI could be started without delay. Management also introduced a financial policy in which the patient would only pay a token amount as an initial payment (approximately 10% of the procedure cost) before the PPCI is undertaken and the remaining money can be paid at discharge. The basic purpose of the study is to know the the patient demographics, short term outcomes in patients undergoing primary PCI for STEMI in our center.

MATERIAL AND METHODS

We collected data of two hundred patients who underwent Primary PCI by a single operator (the index author). Acute myocardial infarction registry by R & D Department was used as a data collection tool. Patients with acute ST segment elevation myocardial infarction (STEMI) reporting to the emergency department of AFIC/NIHD were included in the study. Acute STEMI was diagnosed on the basis of history of chest pain lasting > 30 minutes associated with an ST-elevation of ≥ 1 mm in ≥ 2 contiguous leads or new left bundle branch block plus time from symptom-onset to presentation ≤ 24 hours. Patients with cardiogenic shock (CS) were also included in the study. Patients who had history of CABG, receiving fibrinolytic therapy, undergoing PCI for non-ST-elevation myocardial infarction (NSTEMI) and those presenting beyond 24 hours following the onset of symptoms were excluded from this analysis. Once a patient was received in the Emergency reception and the diagnosis of STEMI was confirmed, the in-house catheterization laboratory team was notified. All patients underwent brief history taking to rule out any contraindication to dual antiplatelet treatment and a focused clinical examination to assess the need for mechanical ventilation or circulatory support. After obtaining informed consent, all patients were loaded with 300 mg of aspirin, 600 mg of clopidogrel and 40–80 mg of atorvastatin and transferred to the catheterization laboratory as early as possible. Procedure was performed either through radial or femoral route although the vast majority of interventions were performed via the radial route. I/V 70–100 U/kg heparin was administered to maintain the activated clotting time (ACT) between 200 and 250 s. Glycoprotein IIb/IIIa inhibitors were given in the form of two I/V boluses during the procedure and as an intravenous infusion post procedurally to all patients in the absence of contraindications. Infarct related artery (IRA) was engaged with an appropriate sized guiding catheter and the culprit lesion was crossed with non-hydrophilic soft 0.014″ guide wire. After lesion crossing, the TIMI flow and thrombus burden were assessed. If TIMI flow was grade III and thrombus burden was low, the lesion was stented directly. Conversely, when there was large thrombus burden, aspiration thrombectomy was performed and balloon dilatation was done if the lesion was too tight to allow the passage of the stent or when it was difficult to assess the size of the distal vessel. Intracoronary (IC) nitroglycerine was administered when the hemodynamics permitted to exclude any epicardial coronary spasm. IC anti no-reflow medications were given according to the need. Non-infarct related artery was imaged at the end with a diagnostic catheter to rule out any critical lesions with compromised blood flow. As per the hospital protocol, bare metal stents (BMS) and drug-eluting stents (DES) were used. In case of multi-vessel disease, PCI was limited to Infarct Related Artery (IRA) unless patient

had significant stenosis with less than TIMI III flow in a non-IRA or patient was in cardiogenic shock. Time from pain onset to hospital arrival, door-to-balloon time (Time from hospital admission to establishment of IRA flow) and total ischemic time (Time from pain onset to establishment of IRA flow) were recorded. Coronary flow of the infarct related artery was assessed visually by the operator and classified according to the TIMI grading system on a scale of 0–3 both before and after the PCI. Procedural success was defined as achievement of vessel patency to a residual stenosis <30% with TIMI 3 flow.

Table-1: Base line demographics and clinical characteristics.

	n=200
Age (yrs)	**51±18**
Gender	
Male	128 (64%)
Female	72 (36%)
Hypertension	81 (40.5%)
Diabetes mellitus	92 (46%)
Dyslipidemia	121 (60.5%)
Renal dysfunction (s.creat> 1.1 mg/dl)	46 (23%)
Smoking history	91 (45.5%)
Previous pci	34 (17%)

Table-2: Angiographic and Procedural characteristics (n=200).

Procedural Success	192 (96.3%)
Types of guiding catheters used	
EBU/ XB	138(69%)
Judkins	54 (27%)
Amplatz	6 (3%)
Multipurpose	2 (1%)
Access Site	
Radial artery	193 (91.5%)
Femoral artery	17 (8.5%)
STEMI Types	
Anterior MI	128 (64%)
Inferior MI	67 (33.5%)
Lateral MI	5 (2.5%)
Location of target lesio	
Left anterior descending artery	128 (64%)
Left circumflex artery	15 (7.5%)
Right coronary artery	57 (28.5%)
Type of stents used	
Drug eluting (DES)	119 (59.5%)
Bare metal (BMS)	81 (46.5%)

Patients were transferred back to CCU post-procedure and arterial sheath was removed when ACT was less than 150s. Hemodynamically stable patients were transferred to the wards after 24 h and discharged on the third day. At the time of discharge, all the patients were continued on dual antiplatelets, statin, beta-blocker and ACE inhibitor if not contraindicated. In hospital adverse events MACE (death, reinfarction, urgent CABG, bleeding and stroke) were noted.

Vascular complications such as forearm hematoma, radial artery occlusion, forearm ischemia and compartment syndrome were noted. Access site bleeding was defined as major if occurrence of any of the following: intracranial bleeding, retroperitoneal bleeding, access site hemorrhage requiring vascular repair, hematoma ≥5 cm in diameter at the puncture site, reduction in hemoglobin concentration of ≥4 g/dL without an overt source of bleeding or administration of blood transfusions and minor if bleeding at vascular access site only resulted in hematoma formation which did not require specific therapy.

Data Analysis

Data collected was analyzed using SPSS-21 version. Quantitative variables were described with their mean ± S.D while qualitative variables were described with their frequency and valid percentages.

RESULTS

A total of 200 patients were included in this study of which males were more in number 128(64 %) as compared to females 72(36%). Clinical characteristics and demographics shown in Table-1 depict the mean age being 51 ± 16.8 years. Clinical characteristics and co-morbidities included diabetes in 92 (46%) patients, 81 (40.5%) patients were hypertensive, 91 (45.5%) patients were smokers.Dyslipidemia and renal dysfunction was seen in 121 (60.5%) and 46(23%) patients respectively. Anterior, inferior and lateral myocardial infarction was seen in 128 (64%), 67 (33.5%) and 5 (2.5%) patients respectively. The median time from-onset of symptoms to presentation was 170 minutes±93min and the Median door to balloon time was 51.75 ± 5.6 min. Angiographic and procedural details are shown in Table-2. Radial and femoral approach was used in 183(91.5%) and 17 (8.5 %) patients respectively. Left anterior descending (LAD) was the commonest infarct related artery accounting for culprit artery in 128 (64%) followed by right coronary artery (RCA) & left circumflex artery (LCX) in 57 (28.5%) and 15 (7.5%) cases respectively with the *p* value of <0.001. Thrombectomy device was used only in 9 (4.5%) patients. 197 (98.5%) patients received GP IIb/ IIIa inhibitors. PCI with stenting and POBA only was done in 193 (96.5%) and 7 (3.5%) patients respectively. Drug eluting stents (DES) were used in 119 (59.5%) and bare metal stents (BMS) were deployed in 81(40.5%) patients. TPM was inserted in 7 (3.5%) patients .No-reflow was measured and observed in 21 (10.5%) patients and then managed accordingly. The procedural success in our study was 96.3%.Table-3 shows overall mortality was seen in 3(1.5%) cases of which all (100%) had multivessel disease and 2 (67%) had cardiogenic shock. Reinfarct and stroke was seen in4 (2.0%) and 1 (0.5%) patients respectively. Major and minor bleeding was seen in 1(0.5%) and 17 (8.5%) patients.

Table-3. Procedural complications during hospitalization.

	n=200
None	174 (87%)
Major bleed (requiring blood transfusion/ surgical repair)	1 (0.5%)
Minor bruising or Haematoma	17 (8.5%)
Compartment syndrome	0 (0%)
Fore arm ischemia	0 (0%)
MAC	
Death	3 (1.5%
Reinfarct	4 (2%)
Stroke/TIA	1 (0.5%)

DISCUSSION

The incidence of MI increases with age, however, the actual incidence is dependent on predisposing risk factors for atherosclerosis as well[6]. The mean age in our study subjects was

51 ± 16.8 years. This result was in accordance with the results of different studies conducted all around the world[7,8,9]. Males were predominant in this cohort, their preponderance was around 64% , while in other studies it was around 70% – 80%.. Hafeez et al reported mean age of patients suffering STEMI were 58± 11 years and 78% of them were males. Cardiovascular risk factors play a pivotal role in the occurrence of myocardial infarction[10]. Our study results exhibited that smoking ,diabetes and hypertension were major risk factors for MI which is concordant with the previous published data from the developing countries[11]. In our study population 92 (46%) patients were found to be diabetic, 81(40.5%) hypertensive and 91 (45.5%) patients were smokers. These results are similar to other regional and international studies. The common sites of ST-segment elevated myocardial infarction in our study were anterior wall MI 128 (64%) and inferior wall MI 67 (33.5%).This is in agreement with the documented data from both the developed and third world countries[11]. Prompt restoration of blood flow in the occluded coronary artery and rapid establishment of myocardial perfusion forms the basis of STEMI therapy. The amount of salvageable myocardium is time dependant and gave birth to the concept of "time is muscle". Even though both thrombolysis and PPCI have been proven to achieve these goals effectively, PPCI has outperformed thrombolysis in many respects. First, thrombolysis restores the IRA patency in fewer (40–60%) patients in contrast to PPCI (more than 90%). Secondly, thrombolysis is less effective when total ischemic time exceeds 6 h when thrombus maturation occurs. Thirdly, up to 25% of patients have contraindication to thrombolysis[12]. Finally, improved hard outcomes in terms of death, myocardial infarction, stroke and bleeding with PPCI makes this the preferred therapy in the setting of STEMI[13]. Time to treatment or total ischemic time is the most important determinant of not only myocardial salvage but also mortality[14]. It starts from the onset of symptoms of myocardial infarction to the initiation of reperfusion. It encompasses two time periods: (1) the time from onset of chest pain to patient arrival at the hospital and (2) the time from patient arrival to the initiation of reperfusion therapy, commonly known as door-to-balloon time[15]. Door-to-balloon time is the standard metric used to assess hospitals capability to manage STEMI with mechanical reperfusion. Both ACC and ESC propose a door-to-balloon time of 90 min or PCI related delay of 60 min as standard as beyond which the benefit of PPCI over fibrinolysis is lost[16,17]. In our cohort door to balloon time was around 1hr because of availability of expert staff and close proximity of the cath lab to the ER. Though we had an in-house catheterization team with an aim to achieve the optimal door-to-balloon time in all patients, for the most part time was lost in patient making the decision about the revascularization strategy[18]. Menees et al., observed door to balloon time using data from 96,738 admitted patients with STEMI who underwent PPCI from Jul 2005 to Jun 2009 at 515 different hospitals and observed median DTBT vary from 83 in 1st year to 67 minutes in the last year of study. Farman et al., had proven a mean door to balloon time of 98.4 minute[19]. American heart association/American cardiac center (AHA/ACC) endorsed a class-I recommendation for DTBT of 97 minutes or less.(20)The procedural success in our study was 96.3%.Hunain et al demonstrated procedural success rate of 97.1%. Similar success rate was quoted by Jaffery et al (97.1%), Farman et al (98.2%), Shaikh et al (97%) and Arshad et al (98.1%) from private and public sectors hospital in Karachi [18-22]. Jaffery et al [18] quoted in-hospital mortality of almost 8.3%, Whether, Hussain et al[23] from the same center documented 2.9% mortality. In our study mortality was 1.5% which is similar to outcomes in studies of primary angioplasty from both developing countries and the west[18,24]. PCI with stenting and POBA only was done in 193 (96.5%) and 7 (3.5%) patients respectively. Drug eluting stents (DES) were used in 119 (59.5%) and bare metal stents were deployed in 81 (40.5%) patients. TPM was inserted in 7 (3.5%) patients .No-reflow was measured and observed in 21 (10.5%) patients and then managed accordingly.The main determinant of total ischemic time is time from

pain onset to hospital arrival. The various reasons noted for the delay were lack of awareness, paucity of transport facilities, financial difficulties, and inaccurate diagnosis.

CONCLUSION

Our study has shown that PPCI is feasible in our setting with high success rate and good outcomes that are comparable to international data. There is a dire need to make primary PCI more widespread in developing nations, with special emphasis on increased public awareness to reduce the total ischemic time to improve outcomes in acute MI.

CONFLICT OF INTEREST

This study has no conflict of interest to declare by any author.

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