Original Article

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AN UPDATE ON PROCEDURAL OUTCOMES OF PRIMARY PERCUTANEOUS CORONARY INTERVENTIONS (PCI) IN PATIENTS WITH ST SEGMENT ELEVATION MYOCARDIAL INFARCTION (STEMI) AND ITS IMPACT ON IN-HOSPITAL MORTALITY AT A TERTIARY CARDIAC CARE CENTER

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ABSTRACT

Objective: To determine the primary and secondary outcomes of primary percutaneous coronary interventions (PCI) in ST segment elevation myocardial infarction and to measure the success rate of primary PCI procedure at AFIC/NIHD.

Study Design: A descriptive cross-sectional study.

Materials and Methods: The study was conducted in the Cardiology department of AFIC/NIHD, a tertiary care cardiac institute at Rawalpindi. The data was collected from an ongoing registry. It is an update on procedural outcome of PPCI over the 4 year duration from October 2011 to January 2016. Total 2136 patients who underwent primary PCI were included in this study. Procedural outcome, success and in hospital mortality were notable variables.

Results: The mean age was 59 ± 10.88 years. Patients of age group 58-75 and above 75 year were having high mortality rate of 2.1% and 2.5% respectively (p-value<0.783). There were 1975 (92.3%) males and 164 (7.7%) female. 378 (17.6%) patients were found to be diabetic (p<0.554), 608 (28.4%) hypertensive (p<0.736), and 637 (29.7%) patients were smokers (p<0.868). Family history of ischemic heart disease was positive in 323 (15.1%) patients, which is a significant factor with the p-value=0.028. Anterior, inferior and lateral myocardial infarction was present in 1116 (53.8%), 920 (44.3%) and 19 (0.9%) patients respectively (p<0.800). The Median time from the onset of symptoms to the arrival in the hospital was 210 ± 562.8 min (p< 0.001) and median door to balloon time was 56.25 ± 2.6 min (p<0.566). Left anterior descending (LAD) was the culprit artery in 1115 (56.1%) patients followed by right coronary artery (RCA) 659 (33.2%) & left circumflex artery (LCX) in 174 (8.8%) cases (p<0.001). 44 (2.1%) patients died in the hospital.

Conclusion: High success rate with low mortality rates can be achieved in our set up. However more studies and long term follow up is required to validate our results.

Keywords: Primary percutaneous coronary intervention (P.PCI), ST segment elevation myocardial infarction (STEMI).

INTRODUCTION

The coronary arteries disease (CAD) is the most leading cause of death throughout the world. In which almost half of the cases occurs in Asia[1,2]. Smoking and obesity like risk factors are becoming more frequent with increased concern in developing countries [1].

Myocardial infarction is the result of increased myocardial metabolism demand, decreased delivery of oxygen and nutrients to myocardium through coronary circulation due to rupture or ulceration of unstable atherosclerotic plaque resulting in occlusion of vessels causing infraction of subjacent myocardium[3].

PPCI is a farm of coronary reperfusion therapy which is preferred in patients with chest pain consistent with myocardial infarction of duration less than 12 hours with associated ST-segment elevation in ECG performed by experienced operators under guideline mandated time. Superiority of PPCI on hospital fibrinolysis in PCI capable centers is shown in many randomized trials[4,10]. But this 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 this causes the shortage of data availability from this part of the world. AFIC & NIHD started

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primary PCI program that commenced from 2011 during the working hours in the day time and then extending the availability of PPCI facility to the off hours. The basic purpose of the study is to know the outcome of PPCI in our center[5,7].

Procedural success of primary PCI was defined as achievement of vessel patency with TIMI 3 flow and residual stenosis of less than 20%. Time to presentation of the symptoms was defined as time from the onset of symptoms to arrival in the hospital. Door to balloon time is the time starting from arrival in the hospital to first balloon inflation during the procedure of primary percutaneous coronary intervention. The primary end point was procedural success and in-hospital mortality. Outcome (primary and secondary) - An outcome variable of interest in the trial (also called an end point). Differences between groups in the outcome variable(s) are believed to be the result of the differing interventions. The primary outcome is the outcome of greatest importance. Data on secondary outcomes are used to evaluate additional effects of the intervention[27].

MATERIAL AND METHODS

It was a descriptive cross sectional study carried out at cardiology department of Armed Forces Institute Cardiology & National Institute of Heart Diseases (AFIC/NIHD) from October 2011 to January 2016. 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 of less than 12 hours duration with electrocardiographic evidence of ST segment elevation of > 1mm in 2 or more contiguous leads or new left bundle branch block[25]. Patients who had history of CABG, thrombolytic therapy and coronary angioplasty, suspicious with MI but normal, and those patients, who were taken to cath lab for the purpose of P.PCI and were decided and taken out to be surgical cases or had normal coronary angiograms, were excluded.

Data source and study sample

Cardiac cath lab registry is an initiative of the Armed Forces Institute Cardiology & National Institute of Heart Diseases, which is basically the modification of American College of Cardiology (ACC) Foundation and the Society for Cardiovascular Angiography and Interventions registry. Cath P.PCI registry has been approved from institutional ethical review board in 2011. Data is entered on SPSS version-22 software. Data quality assurance is achieved by proper management of data entry staff and it gets validated on monthly basis. A descriptive study regarding the procedural outcome has been published in 2014[22]. This article is an update on primary and secondary outcomes of cath primary PCI and our purpose is to determine primary percutaneous coronary intervention success rate in our population.

Total of 2136 patients were included in the study through non-probability consecutive sampling. Written consent was taken and signed from the patient himself or from the available patient attendee. In this study we determined the outcome of patients undergoing P.PCI and to measure the success rate of primary PCI procedure at AFIC/NIHD. We examined 2,136 patients undergoing P.PCI for STEMI at AFIC/NIHD Rawalpindi in the Catheterization lab PPCI Registry between Oct 2011 and Dec 2016. Patients were grouped on the basis of success rate and in-hospital mortality and their outcome was determined by calculating p-values. The temporal trend in the rate of radial versus femoral approach was determined. We compared mortality and success rate with age, gender, co-morbidities, clinical characteristics and complications so that we can find the significant factors involved in success of patients having primary percutaneous coronary infarction.

All these patients underwent primary PCI as a mode of reperfusion according to set protocols. All patients received 300 mg aspirin, loading with 600 mg of Clopidogeral and an intravenous I/V bolus of unfractionated heparin at the dose of 70 IU/Kg body weight. Patients were shifted to catheterization laboratory. In our study population the commonest access site was Right radial

approach. Angiography followed by primary PCI was performed according to set protocol of the hospital[26].

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. Other medication, selections of stent, use of thrombectomy device, temporary pacemaker (TPM), intra-aortic balloon pump (IABP) and ventilatory support was left to the discretion of the operator. Coronary flow in the infarct related artery was assessed visually by the operator according to the TIMI grading system on a scale of 0 to 3 before and after the PCI[22 25]. At the completion of procedure the patients were nursed in cardiac care unit (CCU) to coronary step down unit. These patients were observed indoor, generally for 48 to 72 hours before discharge. These patients were prescribed aspirin 150mg daily for the first month followed by 75 mg daily indefinitely and Clopidogeral 75 mg for 3 months in case of bare metal stents and for one year in case of drug eluting stents[22].

Data was extracted from cardiology data base registry retrospectively. Data collection performa was developed comprising demographics, co-morbidities, ECG measures, cardiogenic shock (defined as a systolic blood pressure of < 90 mmHg or requirement of inotropes to maintain a SBP > 90 mmHg), clinical findings, procedural details, timings and outcome variables.

Data entries were done on statistical package for social sciences software (SPSS) and Descriptive statistics like mean, median, S.D and percentages for gender, co-morbid, cardiogenic shock, various procedural variables and mortality were applied for qualitative and quantitative variables by using SPSS version-22. Chi-square test and independent sample T-test were used to calculate the p-values. *p*-value <0.05 is considered to be significant.

Table-1: Demographic and clinical history of primary PCI (n=2136).

Variables Vav	Mortality (n=44)	Successful (n=2092)	*p*-pvalue
Demographics			
Age			
21-38	01 (4%)	25 (96%)	
39-57	08 (1.6%)	472 (98.4%)	0.783
58-75	29 (2.1%)	1353 (97.9%)	
>76	06 (2.5%)	228 (97.5%)	
Gender			
Male	36 (81.9%)	1935 (98.2%)	0.017
Female	08 (18.1%)	156 (95.1%)	
History & Co-Morbidities			
Diabetes	09 (2.4%)	368 (97.6%)	0.554
Hypertension	11 (1.8%)	596 (98.1%)	0.736
Smoking	12 (1.89%)	623 (98.1%)	0.868
Family history	02 (0.62%)	320 (99.3%)	0.028
History of CABG	01 (1.4%)	70 (98.6%)	0.978
PCI in past	01 (1.12%)	88 (98.8%)	0.810
Presenting Symptoms			
Chest pain	44 (2%)	2095 (98%)	0.979
Dysponea	00 (0%)	01 (100%)	

RESULTS

Total of 2136 patients were included in this study. As mentioned in table -1&2 the mean age was 59 ± 10.88 years. Patients of age 58yr and above were having high mortality rate (p-value<0.783). The overall mortality was more in males 36 (81.9%) than in females 08 (18.1%) and

it is statistical significant with the *p*-value of 0.017. Clinical characteristics and co-morbidities including diabetes in 378 (17.6%) patients (*p*<0.554), 608 (28.4%) were hypertensive (*p*<0.736), and 637 (29.7%) patients were smokers (*p* <0.868). Family history of ischemic heart disease was positive in 323 (15.1%) patients, which is a significant factor with the *p* -value=0.028. Left ventricular failure was in 37 (2.1%) no of patients with the *p* -value of 0.09. Cardiogenic shock was associated with high mortality 43 (2%) with the *p* -value of <0.001. Anterior, inferior and lateral myocardial infarction was present in 1116 (53.8%), 920 (44.3%) and 19 (0.9%) patients respectively (*p* >0.800). The Median time from the onset of symptoms to the arrival in the hospital was 210 ± 562.8 min (*p* < 0.001) and median door to balloon time was 56.25 ± 2.6 min (*p* <0.566).

Clinical characteristics and procedural details are shown in table no.2. Radial and femoral approach was used in 1987 (92.8%) and 152 (7.1%) patients respectively (*p* >0.407). Left anterior descending (LAD) was the commonest infarct related artery accounting for culprit artery in 1115 (56.1%) followed by right coronary artery (RCA) & left circumflex artery (LCX) in 659 (33.2%) and 174 (8.8%) cases respectively with the *p* value of <0.001. Out of

Table-2: Clinical findings and cardiac complications of primary PCI (n=2136).

Cardiogenic shock	**06 (13.9%)**	**37 (86.1%)**	**0.001**
Pulmonary edema (LVF)	37 (2.1%)	1711 (97.8%)	0.900
Rhythm: Normal Rhythm disturbance	 07(1%) 05 (3.26%)	 698 (99%) 148 (96.7%)	0.001
BP Systolic Diastolic	 106 ± 26.27 87.3 ± 109.4	 126.2 ± 24.7 79.33 ± 16.8	0.001
Duration of symptoms	709.8 ± 1359.69	343.2 ± 532.2	0.001
Door to balloon time	56.25 ± 2.6	53.28 ± 32.4	0.566
Access site: Radial Femoral	 38 (1.9%) 06 (4%)	 1938 (98.1%) 146 (96%)	0.407
Multi vessel disease	33 (2.67%)	1202 (97.3%)	0.029
Visible thrombus	06 (1.6%)	375 (98.4%)	0.555
Thrombus aspiration	01 (1.3%)	74 (98.7%)	1.000
Culprit artery: LAD RCA LCX	 26 (2.3%) 08 (1.21%) 02 (1.15%)	 1079 (97.6%) 650 (98.8%) 172 (98.8%)	<0.001
POBA	03 (4.7%)	61 (95.3%)	0.134
Type of stent: Drug eluting stent (DES) Bare metal stent (BMS)	 15 (1.6%) 19 (2%)	 917 (98.4%) 929 (98%)	0.002
TPM	13 (16%)	68 (84%)	<0.001
No-Reflow	05 (11.4%)	13 (0.6%)	<0.001
Intra aortic balloon pump (IABP)	05 (14.3%)	30 (85.7%)	0.001
Coronary angiogram findings: SVCAD DVCAD TVCAD	 06 (1.14%) 08 (1.48%) 21 (4.7%)	 519 (98.9%) 532 (98.6%) 428 (95.3%)	0.002

44 mortality cases, 33 (75%) of patients were having multi vessel disease (defined as ≥ 50% stenosis in ≥ two epicardial arteries) and it was found to be a significant factor (*p* <0.015). 381 (17.8%) patients had visible thrombus whereas thrombectomy device was used only in 75 (3.5%) patients. 308 (14.4%) patients received GP IIb IIIa inhibitors. Angioplasty with stenting and POBA only was done in 1954 (91%) and 64 (3%) patients respectively. Drug eluting stents (DES) were used in 932 (43.5%) and bare metal stents were deployed in 950 (44.3%) patients. TPM was inserted in 81 (3.8%) patients and rhythm disturbances were observed in 156 (7.2%). No-reflow was measured and observed in 05 (11.4%) patients and then managed accordingly (*p* <0.001). Intra-aortic balloon pump was used in 35 (1.6%) patients. Overall mortality rate was 44 (2.1%).

DISCUSSION

Using data from a broadly representative contemporary primary PCI registry, we are reporting several remarkable observations. This study was done amongst the patients who presented to the Tertiary Cardiac Care Institute with ST elevation MI and who were provided with PPCI to determine about the procedural outcomes and in-hospital mortality. Around 59 years was the mean age of the study population. Studies from all over the world had shown similar age group having STEMI[15], although some studies conducted in western countries showed older mean age group[17]. Males were predominant in this cohort, their preponderance was around 81.9% (*p* <0.017), while in other studies it was around 70% – 80%. The important factors to such an out of proportion of male preponderance were entitlement of large number of serving, retired, military and civilian males [19]. Hafeez et al reported mean age of patients suffering STEMI were 58± 11 years and 78% of them were males. In our study population 608 (28.4%) were hypertensive, 378 (17.6%) were diabetic and 637 (29.7%) were smokers. Their results are similar to other regional and international studies. Anterior myocardial infarction was the commonest followed by inferior wall MI. In our study cohort mean presenting time to onset of symptoms was 5.84±9.37hrs, while Arshad et al had shown a median presenting time since the onset of symptoms of 3.8 hrs ranging from two to 8.5 hrs [18]. In our cohort door to balloon time was around 1hr because of availability of expert staff, close proximity of the cath lab to the ER provide a shorter door to balloon time. Farman et al., had proven a mean door to balloon time of 98.4 minutes[14]. 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. American heart association / American cardiac center (AHA / ACC) endorsed a class-I recommendation for DTBT of 97 minutes or less[4]. Because of this recommendation given by AHA / ACC Door to balloon time has become the focus of quality improvement initiative.

LAD was found to be the commonest infarct related artery with a percentage of 56.1% (1115) followed RCA 659 (33.2%) and LCX 174 (7.9%) with similar findings by other investigators[14]. 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 [20,12,14,18]. Jaffery et al quoted in-hospital mortality of almost 8.3%, out of which 43.9% mortality cases were of Cardiogenic shock and 2.1% of non shock patients. Whether, Hunain et al from the same centers documented 2.9% mortality. In our study mortality cases were 44 (2.1%), out of which 6(13.9%) were had Cardiogenic shock and it was a significant finding is *p*-value was <0.001.

In our study 2142 stents were deployed out of which 948 (44.3%) were bare metal stents and 932 (43.5%) were drug eluting stent, although in some other studies 42.7% were bare metal stents and 57.3% were drug-eluting stents[21]. Stent thrombosis is a major complication particularly after primary percutaneous coronary intervention in STEMI. No study was found that has looked for sub acute stent thrombosis (SAT) in a heterogeneous group of patients who underwent PCI for ACS and stable CAD.

Majority of our patients had primary PCI for STEMI and we found that 2.4% of our patients developed either definite or probable SAT.[21, 23].

CONCLUSION

Our study represents outcomes of primary PCI at a tertiary care centre. We found that indications and outcome in our patients are comparable to international data. The results of our study suggest that favorable outcome with PCI can be achieved in our setting[21].

CONFLICT OF INTEREST

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

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