IN HOSPITAL MORTALITY AND ADVERSE EVENTS IN HIGH-RISK PATIENTS UNDERGOING PRIMARY PERCUTANEOUS CORONARY INTERVENTION FOR ST ELEVATION MYOCARDIAL INFARCTION

Abstract:

Objective: To determine frequency of in hospital mortality and adverse events in high-risk patients undergoing primary percutaneous coronary intervention for ST Elevation Myocardial Infarction.

Study Design: Descriptive case series study

Setting: The Department of Adult Cardiology, National Institute of Cardiovascular Diseases, Karachi.

Duration: From 5th January 2019 To 4th July 2019

Material and Methods: Total 150patientswere included. Study outcomes such as in-hospital mortality, cardiogenic shock, heart failure, no reflow phenomenon, and ventricular arrhythmia were recorded. Descriptive statistics were calculated. Stratification was done and poststratification chi square test was applied. P-value ≤0.05 was considered as significant.

Results: There were 81.9% male and 18.1% female. 16.7% were found with diabetes mellitus, 42.7% with hypertension, 38% with family history, 24.7% with smoking and 74% with obesity. Mortality was 14.7%, cardiogenic shock was 12.0%, heart failure was 18.7%, no reflow phenomenon was 28% and ventricular arrhythmia was 16%. Significant association of mortality was found with age and obesity. Cardiogenic shock with gender. Heart failure with hypertension. Ventricular arrhythmia with gender

Conclusion: Mortality rate was high among STEMI patients who underwent primary PCI. No reflow phenomenon was the most observed event among these patients.

Keywords: Frequency, In Hospital Mortality, Adverse Events, High Risk Patients, Primary Percutaneous Coronary Intervention, ST Elevation Myocardial Infarction.

INTRODUCTION

Cardiovascular disease is a major global health issue that has reached pandemic levels. Low and middle-income nations, such as India and Pakistan in South Asia, play a large role in the worldwide burden of cardiovascular disease, accounting for 78 percent of all deaths and 86.3 percent of all disability-adjusted life years related to this cause.[1,2] Acute myocardial infarction is one of the most common causes of death and morbidity around the world.[3] It has been suggested that early mechanical or pharmacological reperfusion should be performed in patients who present with signs and symptoms of ST elevation myocardial infarction (STEMI) within 12 hours of symptom onset and who have persistent ST-segment elevation or new or presumed new left bundle-branch block.[4]

Primary PCI has replaced thrombolysis as the preferred modality of reperfusion for acute STEMI, it has shown benefits in terms of death, reinfarction and stroke. [5-7] STEMI patients can be risk stratified using the Thrombolysis in Myocardial Infarction (TIMI) risk score which is a simple assessment based on clinical data at the time of patient arrival at the hospital[8] and provides important prognostic information and enables accurate identification of high-risk patients.[8,9] High risk patients are those having TIMI risk score of ≥5.[10,11]Despite primary PCI showing greatest benefit in

high risk patients, [10,12] it has been seen that the risk of death and adverse events increase as risk factors increase. [13-15] The importance of early reperfusion in reducing ischemia damage to the myocardium had long been acknowledged by cardiologists. The time from door to balloon is a crucial factor of care quality. Financial constraints and delays in decision-making due to a lack of knowledge on the part of patients and their relatives about the importance of time in the management of critical illnesses such as myocardial infarction have proven to be major obstacles in following door-to-balloon time recommendations in developing countries such as Pakistan.[16-18] González-Pacheco H et al found out that the incidence of mortality and adverse events in high risk patients with TIMI > 5 undergoing primary PCI were mortality 14.8%; heart failure 15.3%; development of cardiogenic shock 10.9%; ventricular arrhythmias 14.8%; and no-reflow phenomenon 22.4%.[11] After a robust literature search it has been found that there is paucity of local data on the incidence of mortality and adverse events in high risk patient undergoing primary PCI in our community, and with one study finding out that there are hindrances in our society that limit patients in achieving optimum quality of care.[16] We expect the results in our society to be different from that of other part of world, moreover the findings of this study will further help us in allocation of resources so as to further organize our system. This provides a very strong rationale to conduct such a study in our population.

MATERIAL AND METHODS

This descriptive case series study was conducted in the Department of Adult Cardiology, National Institute of Cardiovascular Diseases, Karachi. Study duration was **Six** months from 5th January 2019 to 4thJanuary 2019. Non-probability consecutive sampling was used for the study. All the patients of age between18 to 80 years, patients diagnosed with Acute Myocardial Infarction, patients undergoing Primary Percutaneous Coronary Intervention (PCI) and either gender were included. All the patient with prior history of Acute Myocardial Infarction, patients with prior history of any cardiac related surgery and patients refuse give consent were excluded. Prior to inclusion the purpose, and benefits of the study was explained to all participants and verbal informed consent was taken by the principal investigator from all patients. Demographic detail age (years), height (cm), weight (kg), and gender were obtained and history of the patients was taken regarding hypertension, diabetes mellitus, family history, obesity, and smoking status as per the operational definitions. All the primary PCI procedures were performed by consultant cardiologist of experience more than 5 years. All the patients were kept under observation during their hospital stay (at most for one week) and study outcomes such as in-hospital mortality, cardiogenic shock, heart failure, no reflow phenomenon, and ventricular arrhythmia were recorded by the principal investigator. Confounding variables and biasness were controlled by strictly following inclusion and exclusion criteria and stratification. Patient information was kept secured and available to authorized person only. Data were entered and analysis using SPSS version-21.

RESULTS

Total 150 patients of either gender with age 18 years to 80 years meeting inclusion criteria of study were evaluated to determine frequency of in hospital mortality and adverse events in high risk patients undergoing primary percutaneous coronary intervention for ST elevation myocardial infarction (STEMI). Out of 144 patients, 81.3% were male and 18.7% were female. The overall mean age of patients was 58.41±13.51 years. Mean height, weight and BMI was 156.70±6.35 cm, 73.20±11.57 kg and 29.71±3.67 kg/m^2. Among 150 patients, 16.7% were found with diabetes mellitus, 42.7% with hypertension, 38% with family history,24.7%with smoking and 74% with obesity. In this study cardiogenic shock was 12%, heart failure was 18.7%, no reflow phenomenon was 28%, ventricular arrhythmia was 16% and mortality was 14.7% as presented from Table-1

Stratification with respect to gender, age group, diabetes mellitus, hypertension, family history, smoking and obesity was done to observe effect of these modifiers on outcomes (mortality, cardiogenic shock, heart failure, no reflow phenomenon and ventricular arrhythmia). The results showed significant association of mortality with age (p=0.001) and obesity, cardiogenic shock with gender (p=0.030), heart failure with hypertension (p=0.001), and ventricular arrhythmia with gender (p=0.010). The detailed results of associations are presented from Table-2 to Table-4.

TABLE: 1. Descriptive statistics of the demographic characteristics and outcome **(**n=150)

Variables			**Frequency (%)**
Age			58.41±13.51 years
Height			156.70±6.35
Weight			73.20±11.57
BMI			29.71±3.67
Gender		Male	122(81.3%)
		Female	28(18.7%)
Diabetes mellitus		Yes	25(16.7%)
		No	125(83.3%)
Hypertension		Yes	64(42.7%)
		No	86(57.3%)
Family history		Yes	57(38.0%)
		No	93(62.0%)
Smoking		Yes	37(24.7%)
		No	113(75.3%)
Obesity		Yes	111(74%)
		No	39(26%)
Outcome	**Cardiogenic shock**	Yes	18(12.0%)
		No	132(88.0%)
	Heart failure	Yes	28(18.7%)
		No	122(81.3%)
	No reflow phenomenon	Yes	42(28.0%)
		No	108(72.0%)
	Ventricular arrhythmia	Yes	24(16.0%)

		No	126(84.0%)
	Mortality	Yes	22(14.7%)
		No	128(85.3%)

TABLE – 2. CARDIOGENIC SHOCK AND HEART FAILURE ACCORDING TO GENDER, AGE, DM, HTN, FAMILY HISTORY, SMOKING AND OBESITY (n=150)

Variables		**CARDIOGENIC SHOCK**		**P-Value**	**HEART FAILURE**		**P-Value**
		Yes	**No**		**Yes**	**Yes**	
Gender	**Male**	18(14.8)	104(85.2)	0.030*	26(21.3)	96(78.7)	0.083**
	Female	0(0)	28(100)		2(7.1)	26(92.9)	
	Total	**18**	**132**		**28**	**122**	
Age group	**≤60 years**	9(11)	73(89)	0.672**	12(14.6)	70(85.4)	0.164**
	>60 years	9(13.2)	59(86.8)		16(23.5)	52(76.5)	
	Total	**18**	**132**		**28**	**22**	
Diabetes Mellitus	**Yes**	3(12)	22(88)	1.000**	6(24)	19(76)	0.453**
	No	15(12)	110(88)		22(17.6)	103(82.4)	
	Total	**18**	**132**		**28**	**122**	
Hypertension	**Yes**	9(14.1)	55(85.9)	0.502**	20(31.3)	44(68.8)	0.001*
	No	9(10.5)	77(89.5)		8(9.3)	78(90.7)	
	Total	**18**	**132**		**28**	**122**	
Family History	**Yes**	8(14)	49(86)	0.548**	9(15.8)	48(84.2)	0.479**
	No	10(10.8)	83(89.2)		19(20.4)	74(79.6)	
	Total	**18**	**132**		**28**	**122**	
Smoking	**Yes**	4(10.8)	33(89.2)	0.798**	7(18.9)	30(81.1)	0.964**
	No	14(12.4)	99(87.6)		21(18.6)	92(81.4)	
	Total	**18**	**132**		**28**	**122**	
Obesity	**Yes**	15(13.5)	96(86.5)	0.336**	24(21.6)	87(78.4)	0.117**
	No	3(7.7)	36(92.3)		4(10.3)	35(89.7)	
	Total	**18**	**132**		**28**	**122**	

Chi Square Test was applied.
P-value ≤0.05 considered as Significant.
*Significant at 0.05 levels
** Not Significant at 0.05 levels

TABLE – 3. FREQUENCY OF NO REFLOW PHENOMENON & VENTRICULAR ARRHYTHMIA ACCORDING TO GENDER, AGE, DM, HTN, FAMILY HISTORY, SMOKING AND OBESITY (n=150)

Variables		**NO REFLOW**		**P-Value**	**HEART FAILURE**		**P-Value**
		Yes	**No**		**Yes**	**Yes**	
Gender	**Male**	31(25.4)	91(74.6)	0.140**	24(19.7)	98(80.3)	0.083**
	Female	11(39.3)	17(60.7)		0(0)	28(100)	
	Total	**42**	**108**		**24**	**126**	
Age group	**≤60 years**	24(29.3)	58(70.7)	0.704**	10(12.2)	72(87.8)	0.164**

	>60 years	18(26.5)	50(73.5)		14(20.6)	54(79.4)	
	Total	**42**	**108**		**24**	**126**	
Diabetes Mellitus	**Yes**	9(36)	16(64)	0.329**	4(16)	21(84)	0.453**
	No	33(26.4)	92(73.6)		20(16)	105(84)	
	Total	**42**	**108**		**24**	**126**	
Hypertension	**Yes**	18(28.1)	46(71.9)	0.977**	11(17.2)	53(82.8)	0.001*
	No	24(27.9)	62(72.1)		13(15.1)	73(84.9)	
	Total	**42**	**108**		**24**	**126**	
Family History	**Yes**	20(35.1)	37(64.9)	0.130**	8(14)	49(86)	0.479**
	No	22(23.7)	71(76.3)		16(17.2)	77(82.8)	
	Total	**42**	**108**		**24**	**126**	
Smoking	**Yes**	11(29.7)	26(70.3)	0.787**	7(18.9)	30(81.1)	0.964**
	No	31(27.4)	82(72.6)		17(15)	96(85)	
	Total	**42**	**108**		**24**	**126**	
Obesity	**Yes**	32(28.8)	79(71.2)	0.703**	14(12.6)	97(87.4)	0.117**
	No	10(25.6)	29(74.4)		10(25.6)	29(74.4)	
	Total	**42**	**108**		**24**	**126**	

TABLE – 4. MORTALITYACCORDING TO GENDER, AGE, DM, HTN, FAMILY HISTORY, SMOKING AND OBESITY (n=150)

		MORTALITY		**TOTAL**	**P-Value**
		Yes	**No**		
Gender	**Male**	19(15.6)	103(84.4)	**122**	0.512**
	Female	3(10.7)	25(89.3)	**28**	
	Total	**22**	**128**	**150**	
Age group	**≤60 years**	5(6.1)	77(93.9)	**82**	0.001*
	>60 years	17(25)	51(75)	**68**	
	Total	**22**	**128**	**150**	
Diabetes Mellitus	**Yes**	6(24)	19(76)	**25**	0.148**
	No	16(12.8)	109(87.2)	**125**	
	Total	**22**	**128**	**150**	
Hypertension	**Yes**	8(12.5)	56(87.5)	**64**	0.518**
	No	14(16.3)	72(83.7)	**86**	
	Total	**22**	**128**	**150**	
Family History	**Yes**	9(15.8)	48(84.2)	**57**	0.761**
	No	13(14)	80(86)	**93**	
	Total	**22**	**128**	**150**	
Smoking	**Yes**	5(13.5)	32(86.5)	**37**	0.819**
	No	17(15)	96(85)	**113**	
	Total	**22**	**128**	**150**	
Obesity	**Yes**	11(9.9)	100(90.1)	**111**	0.005*
	No	11(28.2)	28(71.8)	**39**	
	Total	**22**	**128**	**150**	

Chi Square Test was applied.
P-value ≤0.05 considered as Significant.
*Significant at 0.05 levels
** Not Significant at 0.05 levels

DISCUSSION

The goal of this study was to find out how often in-hospital mortality and adverse events were in high-risk patients undergoing primary percutaneous coronary intervention for ST-Elevation Myocardial Infarction (STEMI). Multivessel disease is a well-known factor linked to a greater risk of CS in STEMI patients who have primary PCI. The prevalence of CS in individuals with STEMI has been linked to the extent and severity of coronary artery disease. In our all-comers cohort, cardiac mortality was relatively high (>7%) within the first month, as one might predict. Cardiogenic shock, cerebral anoxia after cardiac arrest, and malignant arrhythmias were the leading causes of death in the aftermath of the index event. However, cardiac mortality dropped significantly after the first month (to 1.5 percent per year), indicating that patients who survive the acute phase of a STEMI treated with primary PCI have an excellent late cardiac prognosis and that late cardiac mortality in unselected all-comers is comparable to that of previously selected participants.[19] and 20 Deaths in the catheterization laboratory or within 24 hours of hospital admission occurred in 7.9% and 29.3% of patients, respectively, in research. Re-infarction (1.9%) or repeat emergency PCI were seen in a limited percentage of patients (3.8 percent). In roughly one-third of patients, recurrent in-hospital cardiac arrest occurred following primary PCI (32.7 percent).[12] The shock trial found that early revascularization improves survival in CS patients who have had primary PCI116, but the best revascularization method for shock patients with MVD is unknown. This is especially important because MVD affects up to 87 percent of CS12 patients and is linked to a higher mortality rate.[21-23] There is certainly a case to be made for more comprehensive revascularization in MVD patients with CS who are resistant to IRA intervention. Despite advancements in reperfusion and adjunctive therapy, independent predictors of all-cause death and any reinfarction have not altered appreciably, according to a study. The GUSTO-I and TIMI trials found that Killip class at presentation was a predictor of death in the fibrinolysis era.[24,25] Similar results were seen throughout the BMS era (CADILLAC) and more recently in the HORIZONS-AMI trial, which compared early-generation paclitaxel-eluting stents against BMS.[26-28] Regardless of left ventricular function or the extent of coronary artery disease at baseline, Killip class remains the strongest predictor of all-cause death and any reinfarction. This reflects the degree of haemodynamic compromise in these patients, which can be recognized easily on clinical grounds. Age, hypertension, left ventricular ejection fraction, final TIMI flow, and CK peak value, which have traditionally been considered major risk factors of ischaemic adverse events after STEMI and have been consistently identified in previous reports as predictors of death and reinfarction among STEMI patients treated with fibrinolysis as well as

primary PCI, were also found to be predictors of death and reinfarction.[29] They used the TIMI risk score for STEMI in a group of patients without cardiogenic shock who underwent primary PCI, and found that an increase in the TIMI risk score is associated with an increased frequency of in-hospital death and has a high predictive value for mortality that is comparable to the CADILLAC risk score in the same group of patients. The CADILLAC risk score, which differs from other primary angioplasty risk scores in that it includes angiographic parameters such as the presence of three-vessel disease and final TIMI flow, as well as the left ventricle ejection fraction determined by ventriculography, is said to have a better predictive value for mortality at 30 days and one year.[11] The success made in lowering in-hospital mortality in STEMI patients emphasises the significance of anticipating other post-procedural problems that could have a significant impact on patient outcomes.[11] Overall mortality and other adverse events such as nonfatal reinfarction, stroke, and haemorrhage were less common in the primary PCI group than in the thrombolysis group, according to Keeley et al's meta-analysis. The highest benefit of primary PCI, according to Kent et al., is found in high-risk patients.[30] Four key characteristics at the time of presentation were identified by Negasso et al. in a decision-tree structure predictive classification for acute myocardial infarction undergoing PCI to predict in-hospital complications after intervention. cardiogenic shock, heart failure, ageing, and diabetes are all factors to consider.[31] Although the TIMI risk score was created to predict mortality, it also identifies a group of high-risk patients (TIMI risk 5) who have an increased frequency of in-hospital adverse events such as heart failure (p=0.0001), development of cardiogenic shock (p=0.0001), ventricular arrhythmias (p=0.001), and no-reflow phenomenon (p=0.01). There was no difference in the incidence of reinfarction and stroke between the high-risk and low-risk groups.[11] The presence of diabetes, advanced age, Killip class >2, previous stroke, and the duration of ischemia have all been linked to the development of the no-reflow phenomena in 25% of patients following primary PCI.[32,33] They report an overall prevalence of 16.4 percent in a study, with a substantially greater prevalence in the high-risk group (22.4 percent vs. 13.6 percent, p=0.01) than in the low-risk group (22.4 percent vs. 13.6 percent, p=0.01).[11] Despite the fact that the high-risk group had all of the risk indicators listed above, it was discovered that a considerable proportion of patients had poor reperfusion despite achieving TIMI 3 flow. This has been linked to the no-reflow phenomena and distal embolization,[134] prompting the use of GpIIb/IIIa antagonists as an additional therapy. There was a significant association between the risk profile and the benefit of adjunct GpIIb/IIIa antagonists in lowering death at 30 days in a meta-analysis by De Luca et al. of STEMI patients undergoing primary PCI.[35] The frequency of using a GpIIb/IIIa antagonist was lower in the high-risk group (66.1 percent vs. 75.8%, p=0.01), as was the lack of embolectomy, which has been shown to be beneficial. The majority of patients suffered cardiogenic shock during their hospital stay[36], and Lindholm et al. found that initial PCI does not prevent it.[37] Patient selection bias is a limitation of the current investigation because it is a nonrandomized, observational registry. Nonrandomized outcomes can potentially be influenced by unidentified confounding variables. The small sample size of our study

was the most significant drawback. A single-center experience and a nonrandomized study design are further drawbacks of the current investigation. Because it was conducted in an urban setting, the results may not be applicable to broader populations.

CONCLUSION

The study results showed that among patients with ST-elevation myocardial infarction who underwent primary percutaneous coronary intervention, the mortality rate was high. Further, among adverse events, no reflow phenomenon was the most observed event followed by heart failure, ventricular arrhythmia, and cardiogenic shock. After primary percutaneous coronary intervention in patients with STEMI, mortality was more observed in male gender, age more than 60 years, and diabetic patients. The TIMI risk score, which is used to STEMI patients undergoing primary PCI, identifies a subset of patients who are at high risk for not just higher in-hospital mortality, but also for other adverse events such no-reflow, heart failure, cardiogenic shock, and ventricular arrhythmias.

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