

# 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 (PCI) for ST Elevation Myocardial Infarction (STEMI).

**Study Design:** Descriptive case series study

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

**Duration:** From 5<sup>th</sup> January 2019 To 4<sup>th</sup> July 2019

**Material and Methods:** All the patients of age between 18 to 80 years, patients diagnosed with Acute Myocardial Infarction, patients undergoing Primary PCI and either gender were included. Study outcomes such as in-hospital mortality, cardiogenic shock, heart failure, no reflow phenomenon, and ventricular arrhythmia were recorded. Data was collected via study proforma and analysis was done by using SPSS version 26.

**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 PCI, ST Elevation Myocardial Infarction (MI).

## 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 burden of cardiovascular disease as a the leading cause of mortality worldwide, around 78% of all mortality rate and 86.3% of all disability-adjusted life years.<sup>1,2</sup> Acute myocardial infarction is one of the most common causes of death and morbidity around the world.<sup>3</sup> It has been suggested that early mechanical or pharmacological reperfusion should be performed in patients who present with occurrence of ST-segment elevation of MI during twelve hours of the onset of sign and symptoms and those having persistent ST-segment elevation or new or newly assumed left bundle-branch block.<sup>4</sup>

Primary PCI has replaced thrombolysis as the preferred modality of reperfusion for acute STEMI, it has shown benefits in terms of recurrent myocardial infarction, and mortality.<sup>5-7</sup> The thrombolysis in Myocardial Infarction (TIMI) risk score, that is a simple evaluation basis on clinically data during arrival of the cases at hospital and provides valuable predictive information by allowing correct assessment of high-risk cases, can be used to risk stratify STEMI patients.<sup>8,9</sup> High risk patients are those

having TIMI risk score of  $\geq 5$ .<sup>10,11</sup> Despite primary PCI showing greatest benefit in high risk patients,<sup>10,12</sup> it has been seen that the risk of death and adverse events increase as risk factors increase.<sup>13-15</sup> 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. In developing countries like Pakistan, financial restrictions and big time spending in judgement due to patients' and relatives' lack of understanding of the time importance in management of critical illnesses like myocardial infarction have demonstrated to be significant obstacles to following door-to-balloon time suggestions.<sup>16-18</sup> González-Pacheco H et al found out that the incidence of mortality and adverse complications among high risk cases 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%.<sup>11</sup> 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.<sup>16</sup> 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 gives a compelling case for doing research 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 5<sup>th</sup> January 2019 to 4<sup>th</sup> July 2019. All the patients of age between 18 to 80 years, patients diagnosed with Acute MI, cases underwent PCI and both genders were included. Patients with a past history of Acute MI, those who have had any cardiac surgery, and those who refuse to give consent were all excluded. Prior to enrollment, all participants were informed regarding the study's goal and benefits, and the primary investigator obtained verbal informed permission from all the cases. Demographic detail age (years), height (cm), weight (kg), and gender were obtained and history regarding diabetes mellitus, hypertension, obesity, family history and smoking status was taken. All primary PCI interventions were carried out by a senior cardiologist having minimum experience of >5 years. All of the study subjects were monitored during 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. By closely adhering to inclusion and exclusion criteria as well as stratification, confounding variables and bias were avoided. Only authorized people had access to information regarding patients, which was maintained secure. Data were entered and analysis using SPSS version-21.

## **RESULTS**

The incidence of in-hospital death and complications among high-risk cases following primary PCI for ST elevation MI were investigated in a total of 150 cases aged 18 to

80 years who met the study's inclusion criteria. Out of 144 patients, 81.3% were male and 18.7% were female. Patients' average age was  $58.41 \pm 13.51$  years. Mean height, weight and BMI was  $156.70 \pm 6.35$  cm,  $73.20 \pm 11.57$  kg and  $29.71 \pm 3.67$  kg/m<sup>2</sup>. Among 150 patients, 16.7% had diabetes mellitus, 42.7% were hypertensive, 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 age, gender, 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). There was a 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 ( $p=0.010$ ), results shown in 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 demographic characteristics (n=150)

Variables		Cardiogenic Shock		P-Value	Heart Failure		P-Value
		Yes	No		Yes	No	
Gender	Male	18	104	0.030*	26	96	0.083**
	Female	00	28		2	26	
Age group	≤60 years	9	73	0.672**	12	70	0.164**
	>60 years	9	59		16	52	
Diabetes Mellitus	Yes	3	22	1.000**	6	19	0.453**
	No	15	110		22	103	
Hypertension	Yes	9	55	0.502**	20	44	0.001*
	No	9	77		8	78	
Family History	Yes	8	49	0.548**	9	48	0.479**
	No	10	83		19	74	
Smoking	Yes	4	33	0.798**	7	30	0.964**
	No	14	99		21	92	
Obesity	Yes	15	96	0.336**	24	87	0.117**
	No	03	36		4	35	

\*Significant at 0.05 levels

\*\* Not Significant at 0.05 levels

**TABLE – 3.** Frequency of no reflow phenomenon & ventricular arrhythmia according to demographic characteristics (n=150)

Variables		No Reflow		P-Value	Ventricular Arrhythmias		P-Value
		Yes	No		Yes	No	
Gender	Male	31	91	0.140**	24	98	0.010*
	Female	11	17		00	28	
Age group	≤60 years	24	58	0.704**	10	72	0.163**
	>60 years	18	50		14	54	
Diabetes Mellitus	Yes	9	16	0.329**	4	21	1.000*
	No	33	92		20	105	
Hypertension	Yes	18	46	0.977**	11	53	0.732**
	No	24	62		13	73	
Family History	Yes	20	37	0.130**	8	49	0.607**
	No	22	71		16	77	
Smoking	Yes	11	26	0.787**	7	30	0.577**
	No	31	82		17	96	
Obesity	Yes	32	79	0.703**	14	97	0.056**
	No	10	29		10	29	

**TABLE – 4.** Mortality according to demographic characteristics (n=150)

Variables		MORTALITY		TOTAL	P-Value
		Yes	No		
Gender	Male	19	103	122	0.512**

	Female	3	25	28	
<b>Age group</b>	≤60 years	5	77	82	0.001*
	>60 years	17	51	68	
<b>Diabetes Mellitus</b>	Yes	6	19	25	0.148**
	No	16	109	125	
<b>Hypertension</b>	Yes	8	56	64	0.518**
	No	14	72	86	
<b>Family History</b>	Yes	9	48	57	0.761**
	No	13	80	93	
<b>Smoking</b>	Yes	5	32	37	0.819**
	No	17	96	113	
<b>Obesity</b>	Yes	11	100	111	0.005*
	No	11	28	39	

\*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 PCI 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), suggesting that individuals whose survived the initial phase of a STEMI managed by primary PCI have a good long-term prognosis, and that late cardiac mortality in unselected all-comers is equivalent to that of earlier selected cases,<sup>19</sup> 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).<sup>12</sup> The shock trial found that early revascularization improves survival in CS patients who have had primary PCI<sup>116</sup>, but the best revascularization method for shock patients with MVD is unknown. This is especially important because MVD affects up to 87 percent of CS<sup>12</sup> patients and is linked to a higher mortality rate.<sup>21-23</sup> 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 death from any cause and any reinfarction have not

changed 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.<sup>24,25</sup> 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.<sup>26-28</sup> Killip class remains the best predictor of all mortality cause and any reinfarction, regardless of function of left ventricular or the amount of coronary artery disease at baseline. This represents the severity of haemodynamic impairment in these cases, that can be easily detected clinically. Age, left ventricular ejection fraction (EF), hypertension, final TIMI flow, and CK peak value, which have been consistently identified in the previous reports as predictors of the mortality and reinfarction in the cases of STEMI treated by the fibrinolysis along with primary PCI, also were observed to be predictors of the mortality and reinfarction.<sup>29</sup> They showed that an increasing in the TIMI risk score for STEMI is related with a higher incidence of in-hospital death and has a strong predictive value for mortality that is comparable to the CADILLAC risk score in the same group of patients who received primary PCI. The CADILLAC risk score is said to have a better predictive value regarding death at thirty days and a year compared to other risk scores of primary angioplasty since it combines angiographic data like as the occurrence of three-vessel disease and final TIMI flow, and also the ventriculography-determined left ventricle EF.<sup>11</sup> 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.<sup>11</sup> 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.<sup>30</sup> Four key characteristics at the time of presentation were identified by Negasso et al. in a decision-tree structure predictive classification for acute MI underwent PCI to observed the in-hospital complications and cardiogenic shock, heart failure, ageing, and diabetes are all factors to consider after intervention.<sup>31</sup> Although the TIMI risk score was designed to predict the death rate, it also observed as a group of the high-risk cases having TIMI risk 5, with frequent in-hospital mortality and complications rate like cardiogenic shock, heart failure, no-reflow phenomenon and the ventricular arrhythmias ( $p=0.001$ ). There was no difference in the incidence of reinfarction and stroke between the high-risk and low-risk groups.<sup>11</sup> The advanced age, diabetes, previous history of stroke, Killip class  $>2$ , and the ischemic duration have all been linked to the development of the no-reflow phenomena in 25% of patients following primary PCI.<sup>32,33</sup> 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,  $p=0.01$ ).<sup>11</sup> 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,<sup>34</sup> 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.<sup>35</sup> The frequency of using a GpIIb/IIIa antagonist was lower in the high-risk group, as was the lack of embolectomy, which has been shown to be beneficial. The majority of patients suffered cardiogenic shock during their hospital stay<sup>36</sup>, and Lindholm et al. found that initial PCI does not prevent it.<sup>37</sup> 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 cases underwent primary PCI due to ST-elevation MI having higher in Hospital mortality rate. Further, among adverse events, no reflow phenomenon was the most observed event followed by heart failure, ventricular arrhythmia, and cardiogenic shock. After primary PCI 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 identify a subset of STEMI cases undergoing primary PCI, identified a subset of cases who are at higher risk for not only increased in-hospital mortality rate but also longer lengths of stay in the hospital including other adverse events as heart failure, no-reflow, ventricular arrhythmias and the cardiogenic shock.

## Ethical Approval:

As per international standard or university standard written ethical approval has been collected and preserved by the author(s).

## Consent

As per international standard or university standard, Participants' written consent has been collected and preserved by the author(s).

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