



# In Hospital Mortality and Adverse Events in High-risk Patients Undergoing Primary Percutaneous Coronary Intervention for ST Elevation Myocardial Infarction

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## Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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## 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 acute myocardial infarction (MI), age between 18 to 80 years, and undergoing Primary PCI of 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.

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**Results:** There were 81.9% males and 18.1% females. 16.7% cases diabetic, 42.7% were hypertensive, 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 and ventricular arrhythmia were significant according to gender and heart failure findings were significantly linked to hypertension ( $p < 0.05$ ).

**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 MI.*

## 1. 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 the leading cause of mortality worldwide, approximately 78.3% of all deaths and 86.3 percent among all disability-adjusted years of the life [1,2]. Acute MI is the most common causes of mortality and morbidity around the world [3]. It has been suggested that mechanical or the pharmacological reperfusion should be conducted as soon as possible in patients who present with occurrence of STEMI during twelve hours of the onset of sign and symptoms and those having persistent STEMI or new or newly assumed left bundle-branch block [4].

Primary PCI has replaced thrombolysis as the preferred modality of reperfusion for acute STEMI, it has shown benefits such as recurrent MI and mortality [5-7]. 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 [8,9]. High risk patients are those having TIMI risk score of  $\geq 5$  [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]. early reperfusion's importance 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 [16-18]. 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% [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 gives a compelling case for doing research in our population.

## 2. MATERIALS AND METHODS

This descriptive case series study was conducted in the Department of Adult Cardiology, National Institute of Cardiovascular Diseases, Karachi, during six months from January 2019 to July 2019. Patients of Acute MI, age between 18 to 80 years and underwent PCI of either gender were included. Patients with a past history of Acute MI, history of any cardiac surgery, and those who refuse to give consent were all excluded. All the participants were informed regarding the study's goal and benefits. Demographic detail and clinical examination were done. 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 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.

### 3. RESULTS

Patients' average age was 58.41±13.51 years and out of all, 81.3% cases were males and 18.7% were females. Mean height, weight and BMI were 156.70±6.35 cm, 73.20±11.57 kg and 29.71±3.67 kg/m<sup>2</sup> respectively. 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 gender, patient's age, hypertension, diabetes mellitus, smoking, family history 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 and obesity (p<0.05), 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	<b>Cardiogenic shock</b>	
	Yes	18(12.0%)
	No	132(88.0%)
	<b>Heart failure</b>	
	Yes	28(18.7%)
	No	122(81.3%)
	<b>No reflow phenomenon</b>	
	Yes	42(28.0%)
	No	108(72.0%)
	<b>Ventricular arrhythmia</b>	
	Yes	24(16.0%)
	No	126(84.0%)
	<b>Mortality</b>	
	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*

Variables	Cardiogenic Shock		P-Value	Heart Failure		P-Value
	Yes	No		Yes	No	
Family History	No	9	77	8	78	0.548**
	Yes	8	49	9	48	
Smoking	No	10	83	19	74	0.798**
	Yes	4	33	7	30	
Obesity	No	14	99	21	92	0.336**
	Yes	15	96	24	87	
	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 according to demographic characteristics (n=150)**

Variables		Mortality		Total	P-Value
		Yes	No		
Gender	Male	19	103	122	0.512**
	Female	3	25		
Age group	≤60 years	5	77	82	0.001*
	>60 years	17	51		
Diabetes Mellitus	Yes	6	19	25	0.148**
	No	16	109		
Hypertension	Yes	8	56	64	0.518**
	No	14	72		
Family History	Yes	9	48	57	0.761**
	No	13	80		
Smoking	Yes	5	32	37	0.819**
	No	17	96		
Obesity	Yes	11	100	111	0.005*
	No	11	28		

\*Significant at 0.05 levels, \*\* Not Significant at 0.05 levels

#### 4. 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 (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. Malignant arrhythmias, cerebral anoxia after cardiac arrest and the cardiogenic shock, were the significant causes of mortality 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 [19], and 20 deaths in laboratory of catheterization or during 24 hours of admission in hospital occurred among 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 cardiac arrest during hospitalization occurred following primary PCI (32.7 percent) [12]. Early revascularization improved the rate of survival in CS patients, according to the shock study, who have had primary PCI 116, but the best revascularization method for the cases of shock having MVD is unknown. This is especially important because MVD affects up to 87 percent of CS 12 patients and is linked to a higher mortality rate [21-23]. There is certainly a case to be made for more comprehensive revascularization among cases of MVD having 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 [24,25]. Similar results were seen in other studies, which compared early-generation paclitaxel-eluting stents against BMS [26-28]. Killip class continues to be the strongest predictor of all causes of death and any subsequent reinfarction, regardless of function of left ventricular or the amount of CAD at baseline. This represents the severity of hemodynamic impairment in these cases, that can be easily detected clinically. Age, hypertension, (LVEF), final TIMI flow, and CK peak value, which have frequently been identified as the 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 in previous studies [29]. They demonstrated that an increasing in the TIMI risk score for STEMI is related with the raised mortality during hospital stay and in the same patient group whose got primary PCI, it provides a good predictive value for death that seems to be comparable towards the CADILLAC risk score. 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 angioplasties 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 [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]. Total mortality rate and other adverse events like as stroke, nonfatal reinfarction 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 MI underwent PCI to observed the in-hospital complications and cardiogenic shock, heart failure, ageing, and diabetes are all factors to consider after intervention [31]. 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 [11]. 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 [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 [34], 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, 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.

## 5. 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.

## CONSENT

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

## ETHICAL APPROVAL

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

## COMPETING INTERESTS

Authors have declared that no competing interests exist.

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