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TITLE PAGE

PREDICTORS OF LONG TERM MORTALITY IN PATIENTS WITH ST- ELEVATION MYOCARDIAL INFARCTION AFTER PRIMARY PCI

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Abstract

Background: Ischemic time is vital in ST-segment elevation myocardial infarction (STEMI) patients but it's still uncertain that reducing ischemic time (IT)could improve patient survival. Yet many studies have reported only on door to balloon time, whereas ischemic time is rarely documented.

Aim: The aim of the study was to evaluate the predictors of outcomes in patients presenting with STEMI and underwent primary percutaneous coronary intervention (PCI) with ischemic time (IT) ≤ 3 hrs and >3 hrs.

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Methods: This is a single center, prospective, observational study were239 STEMI patients who underwent primary percutaneous coronary intervention were included. The demographic, clinical, procedural characteristics, in-hospital and three year outcomes were compared between IT ≤ 3 hrs and >3 hrs.

Results: Data of 239 patients was analyzed for the study. Among these patients 45.6% of patients had IT ≤ 3 hrs and 54.4% had IT >3 hrs. Patients with longer IT were slightly older than patients with shorter IT (55.8 ± 11.4 vs 52.4 ± 10.9, p-0.02) left ventricular ejection fraction (LVEF) improved at three months in patients with lesser IT (79.8% vs 39.2%, p- <0.001). Binomial regression analysis of various variables, predicting three-year mortality were LVEF (OR=0.9, CI- 0.89-0.99; p=0.03), need for cardio-pulmonary resuscitation (OR=0.09, CI- 0.01-0.61; p=0.01) and Intra-aortic balloon pump (OR=0.14, CI- 0.03-0.43; p=0.001), total ischemic time (OR=0.9, CI- 0.85-0.98; P-0.05), post LVEF improvement at three months (OR=4.2, CI-1.4-12.2; P=0.007).

Conclusion: In our study the independent predictors of mortality at three years were index LVEF, need of cardio-pulmonary resuscitation, Intra-aortic balloon pump at time of admission, TIT and LVEF improvement at three month follow up. Patients with shorter TIT had significant LVEF improvement at 3 months. Shorter TIT coupled with shorter DTB duration, could be used to predict long-term prognosis in STEMI patients.

INTRODUCTION:

In cardiovascular diseases, acute myocardial infarction is the leading cause of mortality in developing countries especially in India. National Heath mission initiated a ST-Elevation Myocardial Infarction (STEMI) Programme in Tamilnadu in 2012 and endorsed that 10% mortality i.e. around 1100 myocardial infarction deaths per day every year in India and Tamil Nadu reports 20,000-25,000 STEMI deaths every year i.e. 55 STEMI deaths per day[1]. American college of cardiology (ACC)/ American Heart association (AHA)/ European society of cardiology (ESC) guidelines recommend Primary percutaneous coronary intervention (PPCI) as gold standard treatment over thrombolysis in patients with STEMI presenting to hospital within 12hours of onset of chest pain[2,3]. Though PPCI is considered to be a standard of care, timely intervention is associated with better long term outcomes as early reperfusion reduces the extent of myocardial of myocardial damage[4]

The major predictors of outcomes in STEMI patients are time delays which includes the time from symptom onset to first medical contact (FMC), the time from FMC to arrival at a PCI-capable hospital, door to balloon time (DTB), total ischemic time (TIT) on reducing these time delays, optimize patient outcomes. The recommended guidelines for DTB is ≤ 90 minutes[2,5] but the optimal cut off for TIT is still unclear. studies have shown that irrespective of reduction in DTB time has no major advantage in patients with increased TIT[6]. Recent study also showed that TIT has positive correlation in long term mortality in patients with STEMI[7]. Therefore, we aimed to analyse the predictors of long term mortality in patients with STEMI undergoing PPCI.

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Materials and Methods:

This is a prospective, observational, single center study done in tertiary care center located in a major city in south India. The study conforms to ethical principles in the declaration of Helsinki and study has been approved by institutional ethics committee. Informed consent was obtained from all the study participants and patients who were not willing to participate were excluded from the study. From June 2014 to June 2016 all STEMI patients presenting to the emergency department within 12 hours of onset ofchest pain, requiring PPCI were enrolled in the study. Patients who had thrombolysis, stent thrombosis or with past history of bypass surgery and those who failed to achieve Thrombolysis in myocardial infarction (TIMI) grade 3 flow after PPCI were excluded from the study. The aim of the study was to assess the predictors of long term mortality in patients with STEMI presenting to emergency room within 12 hours of symptom onset and undergoing PPCI. All patients were pre-loaded with 325mg of aspirin and 600 mg of clopidogrel (or 180mg of ticagrelor). The objectives of the study to assess the clinical, procedural, in-hospital and three-year clinical outcome in patients presenting with STEMI and they are stratified into two groups based on TIT ≤ 3hrs and >3hrs. A total of 246 patients were included in the study. Patients' demographic, clinical, laboratory and procedural details were recorded. Electrocardiogram and echocardiogram were performed for all the patients at admission and at 3 months follow-up as a part of routine investigation. Left ventricular ejection fraction (LVEF) was assessed using Simpson's method. As per the protocol, patients with cardiogenic shock or pulmonary edema requiring mechanical ventilation or IABP and high grade atrioventricular (AV) block requiring temporary pacing were included in the study once they were stabilized. Coronary angiogram and PPCI were done with PHILIPSFD10 machine at cardiac catheterization laboratory at study site. Epicardial coronary arteries having more than 70% luminal stenosis and left main artery having more than 50% stenosis was considered significant. PPCI is done using standard techniques. The decision to perform thrombosuction, predilatation, stent and use of adjunctive medication such as GlycoproteinIIb/IIIa inhibitor were left to the operator's discretion. Successful PPCI is when TIMI flow grade 3 is achieved or residual stenosis <30%. All patients who underwent PPCI with stenting were treated with dual antiplatelets, statins as per recent guidelines. Other necessary cardiac medications were administered as needed per protocol. All patients were followed up after three months and LVEF were assessed. The patients were followed-up on an outpatient department basis or telephonically at three years.

Definition:

STEMI : Increase in cardiac biomarker values preferably cardiac troponin with at least one value above the 99th percentile URL and with at least any one of the following criteria with (i) symptoms of ischemia, (ii) new significant ST segment–T wave (ST–T) changes or new LBBB, (iii) onset of pathological Q waves in the electrocardiogram, or (iv) new findings of non-viable myocardium or new regional wall motion abnormality in imaging, (v) presence of an intracoronary thrombus either by angiography or autopsy[8] .

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Arrhythmia: Any ventricular or supraventricular arrhythmia causing hemodynamic instability or high degree AV block.

Hypotension: Systolic blood pressure <80 mm Hg requiring inotropic support.

Cardiogenic shock: Sustained hypotension with systolic blood pressure <90 mmHg for at least 30 minutes or when need of any supportive measures to maintain a systolic blood pressure of more than 90 mm Hg. End-organ hypoperfusion is when the extremities are cold or when the urine output is less than 30 mL/h, and a heart rate is greater than or equal to 60 beats per minute[9]

Total ischemic time: The time from onset of symptoms to introduction of first intracoronary device in hours.

Door-to- balloon time: The time from arrival of patient at the emergency room to introduction of first intracoronary device time in hours.

Bleeding based on TIMI bleeding criteria: Major: Any intracranial bleeding excluding microhemorrhage < 10mm that is evident only on gradient echo magnetic resonance imaging and clinically overt signs of hemorrhage with hemoglobin drop of 5g/dl or fatal bleeding results in death within 7 days. **Minor**: Resulting in hemoglobin drop of 3 to <5g/dl or 10% decrease in hematocrit. Any overt sign of hemorrhage but do not meet major bleeding criteria but requiring intervention or prolong hospitalization **Minimal**: any overt bleeding that does not meet the above criteria or any clinically overt sign of hemorrhage with hemoglobin drop <3g/dl or <9% decrease in hematocrit[10].

Stroke: Loss of neurological function caused by an ischemic or hemorrhagic event with residual symptoms at least 24h after onset or leading to death[9]

Stent thrombosis: The presence of a thrombus that originates in the stent or in the segment 5 mm proximal or distal to the stent and presence of at least 1 of the following criteria within a 48-hour time window: acute onset of ischemic symptom at rest or new ischemic ECG changes suggesting acute ischemia or significant rise or fall in cardiac biomarkers or non occlusive thrombus or occlusive thrombus or

TIMI 0 or 1 intrastent or proximal to a stent up to the most adjacent proximal side branch or main branch (if originates from the side branch)[11]

LVEF improvement: LVEF was considered to be improved if there is ≥10% increase from baseline and ≤10% increase or no change in EF was considered no improvement. If LVEF reduced by ≥10%, that was considered as deterioration.

Death: Patient died during hospitalization/ documentation of death during follow-up[9]

Statistical analysis:

Continuous and normally distributed baseline characteristics are presented as mean ± standard deviation. Skewed data are presented as median with interquartile range. Categorical data of baseline characteristics, primary and secondary outcomes are presented as frequency and percentages. Categorical variables were compared using $\chi 2$ or Fisher's exact tests. Comparison between two means were tested using two tailed, unpaired t-tests for normal distribution and Mann-Whitney U test for non-normal distribution. The variables predicting three year mortality have been studied using binary logistic regression model. The likelihood of prediction of

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survival is presented as odds ratio (OR) with 95% confidence intervals (CI). All calculated 'p' values are two tailed and are set at statistical significance of 0.05 and all confidence intervals are set at 95% level. Statistical analysis was performed using the SPSS statistical package, version 25.0 (IBM Corp., Armonk, NY, USA)

RESULTS:

A total of 239 STEMI patients who underwent primary PCI were enrolled. Table 1 shows the baseline clinical and laboratory characteristics of the study population stratified by the TIT. The overall mean age of the patients was 54.2±11.3 years, among them majority of the patients were male (90%). In this cohort 44.8% patients had history of diabetes mellitus and 38.9% had systemic hypertension and 34.7% were smokers. 3.3% required cardio pulmonary resuscitation at admission, 12.5% patients presented in Killip's class III or IV and 7.5% required intra-aortic balloon pump (IABP) support. 41% had pre-procedural hypotension requiring inotrope infusion and 11.7% required a temporary pacemaker insertion. Patients were stratified based on TIT ≤ 3 hrs and > 3hrs. 45.6% patients were observed in TIT ≤ 3 hrs group and 54.4% had TIT > 3hrs. The demographic variables like diabetes mellitus, systemic hypertension, peripheral vascular disease and smoking were comparable between both the groups. Patients with prolonged TIT were slightly older than patients with shorter TIT and it is statistically significant (55.8±11.4 vs 52.4±10.9, p=0.02). Median TIT between both the groups were (420 vs 165, p= <0.001). Patients with prolonged TIT had increased DTB time (60 Vs 50, p=0.003). Angiographic and procedural characteristics are presented in table 2 and it was comparable between both the groups. Table 3 summarizes the in-hospital and three year clinical outcomes. Patients with shorter TIT had better LVEF improvement at three months than with prolonged TIT (79.8% vs 39.2%, p = <0.001). Binomial regression analysis of various variable predicting the three-year mortality are presented in Table 4. The significant predictors of mortality at three years were need of CPR (1/0.09=11.1 times likelihood of mortality, p=0.014), IABP at time of admission (1/0.14=7.1 times likelihood of mortality, p=0.006), LVEF (OR=0.9, CI- 0.89-0.99; p=0.03), TIT, (OR=0.9, CI- 0.85-0.98; P-0.05), post LVEF improvement at three months (OR=4.2, CI-1.4-12.2; P=0.007).

Discussion:

The results of this study shows that TIT, need of CPR, IABP and LVEF at the time of admission and Post LVEF improvement at 3 months were independent predictor for three-year mortality in patients with STEMI undergoing PPCI. The successful therapeutic strategy in STEMI is early restoration of coronary flow to limit the extension of myocardial damage, hence PPCI remains the gold standard treatment of choice but still the symptom onset to FMC is been generally neglected. The association between TIT and outcomes is still controversial so it is necessary to understand the factors which influence the short and long term outcomes in STEMI patients. As in our study Lluva et al showed for each year increase in age, TIT increases by 1.3 minutes (p-0.05) and also patients with shorter ischemic time had shorter DTB[12]. Shiomi et al suggested that the risk of mortality and heart failure is reduced only when the TIT and DBT is shorter than <3hours and <90 minutes respectively[13] because myocardial damage is irreversible after 20

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minutes of occlusion, which in turn contributes to myocardial necrosis after 6 hrs[14] causing LV dysfunction and contributing to significant morbidity and eventual mortality. HORIZONS-AMI trial showed that the extent of myocardial injury increases with longer ischemic time[4]. Hasche et al concluded that mean infarct size on day 7 were less in TIT group < 3 hours, compared with TIT – 3-6 hours and 6- 9 hours[15]. In a study conducted by Luca et al. a total of 1791 STEMI patients who underwent PPCI were enrolled, their clinical, angiographic and follow up data were analyzed which showed TIT >4 hours was an independent predictor of 1- year mortality[16]. Solhpour A et al. stratified 786 STEMI patients into three groups based on TIT and into four groups based on DTB time and concluded that TIT group had increased 30-day mortality and infarct size but was not correlated with DTB[17].

Ray.S.et al studied that LVEF reduces by 0.63% with an increase in TIT by one hour and suggested that TIT a significant predictor of LV function[18]. In the analysis of STEMI patients from six contemporary Acute Coronary Syndrome Israeli Survey 2000-2010 high mortality rate was observed among patients with prolonged TIT (>180 minutes) as compared with shorter TIT (≤180 minutes) 8.7% vs 5.9%, p-value=0.003 at one-year follow-up[19]. In our study patients with prolonged TIT had less LVEF improvement at three months follow up. Ramarathinam.V et al showed TIT as predictors of LVEF improvement at three months[20]. Dodaipalli et al conducted a study on 346 STEMI patients who underwent primary PCI which showed prolonged TIT among expired patients compared with alive patients (8.0 ± 3.6 hours vs 6.2 ± 2.8 hours,-p-0.05) at thirty days and concluded that increase in TIT is due to delay in recognizing the symptoms by the patients[21] and unavailability of attendants, transportation facility, finance, and nearby facility[22]

TIT can be used as a quality indicator for long term prognosis. Hence in STEMI patient's long term mortality could be reduced by shortening the TIT. This can be achieved by organizing various awareness programme among the people about early recognition of symptoms and importance of early accessibility to health care,

educating people about the establishment of a hub and spoke distribution model, use of prehospital ECG, direct activation of cardiac catheterization laboratory by the emergency physician even without cardiology consultation, accepting the patient within 20-30 minutes by the STEMI team by quick clearance of elective cases during regular hours, and allocating a dedicated STEMI team on rotation at night times[21].

Limitation:

The present study has few limitations. Single center observational study and non-randomized designs are key limitations of the study. The commencement of chest pain was recorded in the emergency room based on the patient's or attendant's memory, which could be exaggerated or understated. Finally our sample size involves only small number of patients. Variables like pre and post TIMI have not been studied and could have given more details.

Conclusion:

In our study Index LVEF, requirement for cardiopulmonary resuscitation, intra-aortic balloon pump at time of admission, TIT, and LVEF improvement at three months were all independent predictors of mortality at three-years. Patients with shorter TIT had significant LVEF

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improvement at three months'. TIT coupled with DTB duration, could be used as quality indicator to predict long-term prognosis in STEMI patients. Hence, people should be taught how to discern symptoms early in order to minimize TIT and enhance survival rates.

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Table 1: Baseline clinical characteristics of patients with ischemic time ≤3hrs and > 3hrs

Characteristic	Overall patients n=239	Ischemic time ≤3hrs n=109	Ischemic time >3hrs n=130	'p' value
Age	54.2±11.3	52.4±10.9	55.8±11.4	0.02
Male	215 (90%)	101 (92.7%)	114 (87.7%)	0.3
Female	24 (10%)	8 (7.3%)	16 (12.3%)	
BMI	26.7±4.1	26.8±4.2	26.4±4.1	0.4
Diabetes Mellitus	107 (44.8%)	45 (41.3%)	62 (47.7%)	0.3
Hypertension	93 (38.9%)	39 (35.8%)	54 (41.5%)	0.4
PVD	4 (1.6%)	3 (2.8%)	1 (0.8%)	0.3
Smoking	83 (34.7%)	40 (36.7%)	43 (33.1%)	0.6
Ischemic time, median (min)	260 (175-440)	165 (60,240)	420 (250,720)	<0.001
Door-to-balloon time, median (min)	60 (40-65)	50 (35,66)	60 (45,70)	0.003
CPR	8 (3.3%)	6 (5.5%)	2 (1.5%)	0.1
Hypotension at admission	98 (41%)	46 (42.2%)	52 (40%)	0.8
IABP	18 (7.5%)	7 (6.4%)	11 (8.5%)	0.6
Significant arrythmia	64 (26.7%)	33 (30.3%)	31 (23.8%)	0.3
TPI	28 (11.7%)	14 (12.8%)	14 (10.8%)	0.6
Killip's class III-IV	30 (12.5%)	12 (11%)	18 (13.8%)	0.6
LV DYSFUNCTION				
Severe	28 (11.7%)	13 (11.9%)	15(11.5%)	0.6
Moderate	102 (42.7%)	43 (39.4)	59 (49.4%)	
Mild	65 (27.2%)	29 (26.6%)	36 (27.7%)	
Good	44 (18.4%)	24 (22%)	20 (15.4%)	
RBS (mg/dl)	191.2 ±82.3	184.9±74.7	196.6±88.1	0.3
Total cholesterol(mg/dl)	175.3±45.8	181.4±44.7	170.3±46.4	0.06
LDL(mg/dl)	121.7±39.4	127.1±36.4	117.2±41.4	0.05
HDL(mg/dl)	37.2±9.5	37.7±9.2	36.8±9.8	0.5
Triglycerides(mg/dl)	147.4±83.3	149.7±106	145.5±77.9	0.7

BMI- body mass index, PVD- Peripheral vascular disease, CPR- Cardio pulmonary resuscitation, IABP- intra aortic balloon pump, TPI- Temporary pacemaker, LV- Left ventricular

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Table 2: Baselineangiographic and procedural characteristicsof patients with ischemic time ≤3hrs and >3hrs

Characteristic	Overall patients n=239	Ischemic time ≤3hrs n=109	Ischemic time >3hrs n=130	'p' value
SVD	111 (46.4%)	60 (55%)	51 (39.2%)	0.07
DVD	75 (31.4%)	31 (28.4%)	44 (33.8%)	
TVD	53 (22.2%)	18 (16.5%)	35 (26.9%)	
LAD	131 (54.8%)	60 (55%)	71 (54.6%)	0.8
LCX	30 (12.6%)	12 (11%)	18 (13.8%)	
RCA	73 (30.5%)	36 (33%)	37 (28.5%)	
LAD + LCX	3 (1.3%)	1 (0.9%)	2 (1.5%)	
LAD + RCA	1 (0.4%)	0	1 (0.8%)	
RCA + LCX	1 (0.4%)	0	1 (0.8%)	
POBA	4 (1.7%)	1 (0.9%)	3 (2.3%)	0.6
Thrombus aspiration	17 (7.1%)	4 (3.7%)	13 (10%)	0.07
GPIIb/IIIa	143 (59.8%)	65 (59.6%)	78 (60%)	0.7
BMS	2 (0.8%)	1 (0.9%)	1 (0.8%)	0.3
BVS	2 (0.8%)	2 (1.9%)	-	
DES	230 (96.2%)	105 (97.2%)	126 (99.2%)	

Single vessel disease (SVD), Double vessel disease (DVD), Triple vessel disease (TVD), Left anterior descending artery (LAD), Left circumflex artery (LCX), Right coronary artery (RCA), Plain old balloon angioplasty (POBA), Bare metal stent (BMS), Bioresorbable vascular stent (BVS),Drug eluting stent (DES).

Table 3: In hospital clinical outcomes stratified by ischemic time ≤3hrs and >3hrs

Characteristic	Overall patients n=239	Ischemic time ≤3hrs n=109	Ischemic time >3hrs n=130	'p' value
In-hospital Mortality	11 (4.6%)	4 (3.7%)	7 (5.4%)	0.7
Mortality at 3 years	35 (14.6%)	13 (37.1%)	22 (62.9%)	0.3
Stroke	0	0	0	-
Significant Bleeding	3 (1.3%)	1 (0.9%)	2 (1.5%)	1
Urgent CABG	0	0	0	-
Stent thrombosis	2 (0.8%)	0	2 (1.5%)	0.5
Post PCI EF improvement	138 (57.7%)	87 (79.8%)	51 (39.2%)	<0.001

CABG- Coronary artery bypass graft, PCI- percutaneous coronary intervention, EF- Ejection fraction

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Table 4: Binary logistic Regression analysis for predictors of three-year mortality

Characteristic	'p' value	Odds ratio (OR)	95% CI
Age	0.5	1.01	0.97-1.06
Sex	0.4	1.81	0.48-6.85
CPR at time of admission	0.02	0.09	0.01-0.69
IABP	0.006	0.14	0.03-0.57
LVEF	0.02	0.93	0.88-.98
Hypotension	0.2	0.49	0.19-1.30
Total ischemic time (min)	0.05	0.91	0.85-0.98
Door to balloon time (min)	0.5	0.93	0.88-1.02
Post PCI LVEF improvement	0.007	4.2	1.47-12.16

CPR- Cardio pulmonary resuscitation, IABP- intra aortic balloon pump, LVEF- Left ventricular ejection fraction, PCI – percutaneous coronary intervention, CI- Confidence intervals