Original Article

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In-Hospital Mortality and Determinants in Patients with Prolonged Total Ischemia Time Undergoing Primary PCI in Nepal.

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Abstract

Background: Prompt recognition and timely performed myocardial reperfusion with primary percutaneous coronary intervention (PCI) in patients with ST-segment elevation myocardial infarction (STEMI) is critical in reducing morbidity and mortality. The aim of our study was to determine the frequency of in-hospital mortality and determinants in patients with prolonged total ischemia time underwent primary PCI at Shahid Gangalal National Heart Centre (SGNHC), Kathmandu.

Methods: A cross-sectional analytical study with logistic regression analysis of 111 patient presented with Acute STEMI within a window period of 12 hours and underwent primary PCI at Shahid Gangalal National Heart Centre, Kathmandu, Nepal was conducted.

Results: The average age of the patients in the study was 57.05±11.76 years. Frequency of in-hospital mortality in patients with total ischemia time >240 minutes undergoing primary PCI was 8.1%. Risk of in-hospital mortality was higher in 61-80 years of age group and in female patients. Risk of in-hospital mortality was significantly associated with Killip class III and IV, TIMI Risk Score 7-8 and above 8 and 3 vessel disease. In Multivariate analysis, risk of in-hospital mortality was only significantly associated with Killip class III and IV after adjusting the other confounders.

Conclusion: The study showed that the frequency of in-hospital mortality in patients with total ischemia time >240 minutes was higher than in patients with total ischemia time ≤ 240 minutes.

Key Words: Coronary artery disease, STEMI, Ischemia time, Primary PCI, In-hospital mortality

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Introduction

Coronary artery disease (CAD) is a leading cause of morbidity and mortality globally.[1] Around 30% of the patients with acute coronary syndrome (ACS) present with ST-elevation myocardial infarction (STEMI) in the developed countries.[2] On the other hand, studies have shown that incidence of STEMI has been increasing in developing countries as well.[3] Myocardial reperfusion with primary percutaneous coronary intervention (PCI), performed in a timely fashion, is the central therapy for ST-segment elevation myocardial infarction (STEMI). Therefore, prompt recognition and early management of acute STEMI is critical in reducing morbidity and mortality.[4] A key factor in the treatment of STEMI is the ischemic time which is a better predictor than just door to balloon time for 30-day mortality and infarct size.[5] The total ischemic time which is measured from symptom onset to the opening of occluded artery with balloon inflation thus has a significant importance for the outcomes of patients with STEMI.

Even in developed countries with well-established health care system including better emergency medical services (EMS) and people's knowledge about acute myocardial infarction there are

still prolonged ischemia time.[6,7] With improvements in door-to-balloon times only, there was no significant overall change in in-hospital and 30 days mortality so additional strategies are needed for better outcome.[8] In Nepal, a significant delay in onset to door occurs due to lack of awareness about acute myocardial infarction, geographic barriers like tough terrain causing inadequate road networks, insufficient health facilities including prompt EMS, financial constraints and so on. Therefore, all efforts should be made to shorten total ischemic time.

Studies have confirmed that infarct size and mortality are strongly correlated with the total ischemic time and total ischemia time 240 minutes was identified as independent predictor of mortality.[9]

Our aim was to study the frequency of in-hospital mortality in patients with prolonged total ischemia time undergoing primary PCI at Shahid Gangalal National Heart Centre (SGNHC), Kathmandu. We believe this study will aid more emphasis on reducing total ischemia time mainly onset to door time in the management of STEMI for better outcome.

Materials and Methods

This study was a single-center cross-sectional analytical study with logistic regression analysis conducted in the Department of cardiology at Shahid Gangalal National Heart Centre Kathmandu for 6 months from 15th June 2021 to 15th December 2021. Informed written consent was taken in either Nepali/English language whichever they feel comfortable assuring full confidentiality. Consent was taken from the patient party if patient was unable to give consent. Formal permission for the study was taken from the institutional review board of Shahid Gangalal National Heart Centre (Ref no.: SGNHC/IRB No : 25-2020). Sample size was calculated based on the study done by Sanam Khowaja et al published in Journal of the American College of Cardiology in the year 2019. 111 Consecutive samples were enrolled for the study.

Sample selection:

Inclusion criteria

1. Patients >40 years of age presenting with Acute STEMI within a window period of 12 hours and willing to undergo Primary PCI was included in the study.

Exclusion criteria

1. Patients presenting with Acute STEMI after 12 hours.
2. Patients who opted reperfusion other than Primary PCI.
3. Patients who refuse to participate in the study.

Data Collection

For each patient, data including clinical information on symptom onset, medical history, prior medication, History of HTN, DM, Dyslipidemia, vitals, Killip classification, and the Thrombolysis in Myocardial Infarction (TIMI) risk score for STEMI were collected. Data including time of arrival, duration of out-of-hospital treatment, transport to the PCI center, and transfer to the catheterization laboratory as well as time of puncture and first balloon inflation were also collected. Total ischemic time which is the summation of onset-to-door and door-to-balloon times was recorded.

Data Analysis

The collected data were entered using data validation tool (MS-Excel worksheet 2010). Statistical analyses were performed with statistical software (IBM SPSS® statistics 25 for Windows) and data were presented in tables. Mean ± SD was calculated for age, onset to door time, door to balloon time, total ischemia time. Qualitative variables like gender, Diabetes mellitus (DM), Hypertension (HTN), Dyslipidemia, Killip class, in-hospital mortality was computed for frequency and percentage. Effect modifiers like age, gender, Comorbidity, TIMI score, Killip class, and target vessel was dealt through uni-variable analysis by chi-square test and to ensure that potential confounders were not excluded prematurely, those variables found to have p value ≤ 0.05 was run in multi-variable model used logistic regression. P value≤ 0.05 was considered as significant. Odds ratio in univariate and adjusted odd ratio for multivariate with 95 percent confidence interval was calculated.

Results

The average age of total 111 patients was 57.05±11.76 years, mean Onset to Door time, Door to Balloon time, Total Ischemia Time and ejection fraction are reported in Table 1. 85(76.58%) were male, 61.3% were smokers, 49.5% had hypertension, 23.4% had Diabetes Mellitus, 3.6% had Dyslipidemia and 1.8% had family history of CAD (Table 2). Regarding Killip classification and TIMI score for STEMI, almost 71% were in Killip class I, 23% in Killip class II and 6.3% were Killip class –III and IV, 75% of the patients had 2 to 4 TIMI risk score, 10% patients had 5-6 TIMI risk, 6% patients had 7-8 TIMI risk and 6% had 9-11 TIMI risk score as shown in table 3. Common culprit artery was LAD and RCA i.e. 77% and 51% respectively, DES was used in 85% patients, Frequency of in-hospital mortality in patients with TIT >240 minutes undergoing primary PCI was 8.1% (Table 4).

In univariate analysis, risk of in-hospital mortality was 13 times high in 61-80 years of age [OR=12.9; 95%CI1.56-107.33]. It was less likely in male than female [OR=0.12; 95%CI: 0.03-0.53]. However, Smoking, hypertension, diabetic mellitus, and dyslipidemia was not statistically associated with in-hospital mortality as shown in table 5. Risk of in-hospital mortality was significantly associated with Killip class III and IV, TIMI Risk Score 7-8 and above 8 and 3 vessels disease as shown in table 6. In Multivariate analysis, risk of in-hospital mortality was only significantly associated with Killip class III and IV [AOR=71.86; 95%CI 2.83-1827.5] after adjusting the other confounders as shown in table 7.

Table 1: Descriptive Statistics of the Patients

Variables	Mean ± SD	Median (IQR)	Mini-mum	Maxi-mum
Age (Years)	57.05±11.76	56(20)	40	80
Onset to Door time (min)	341.58±173.36	300(150)	180	1440
Door to Balloon time(min)	45.00±15.53	40(20)	24	98
Total Ischemia Time(min)	382.88±173.52	330(155)	242	1495
Ejection Fraction (%)	39.32±5.49	40(10)	30	55

Table 2: Risk factors, n=111

Gender, Risk factors	Number	Percent
Male	85	76.58%
Smoking	68	61.3%
Hypertension	55	49.5%
Diabetes Mellitus	26	23.4%
Dyslipidemia	4	3.6%
Family History of CAD	2	1.8%

Table 3: Killip class and TIMI Score, n=111

Killip class and TIMI score		Number	Percent
Killip Class	I	79	71.17%
	II	25	22.52%
	III	6	5.41%
	IV	1	0.90%
TIMI Score	2-4	86	77.48%
	5-6	11	9.91%
	7-8	7	6.31%
	9-11	7	6.31%

Table 4: Angiography Findings, type of stent used and in-hospital mortality

Coronary angiography findings, type of stent used		Number	Percent
Culprit artery	LAD	85	76.6%
	LCX	37	33.3%
	RCA	57	51.4%
	RI	3	2.7%
	LM	3	2.7%
No of coronary arteries with significant stenosis	1	58	52.3%
	2	34	30.6%
	3	19	17.1%
Type of stent used	DES	94	84.68%
	BMS	15	13.51%
	POBA	2	1.80%
In-hospital mortality with TIT ≤ 240 min		2	4.1%
In-hospital mortality TIT >240 min		5	8.1%

Table 5: Univariate Analysis Showing the Factors Associated with In-hospital Mortality

Variables	In-hospital Mortality		Total	Unadjusted Odds ratio [95%CI]	P-Value
	Yes	No			
Age (Years) 40-60 61-80	1(1.6%) 8(17%))	63(98.4%) 39(83%)	64 47	Ref 12.9 [1.56-107.33]	0.004
Gender Male Female	3(3.5%) 6(23.1%)	82(96.5%) 20(76.9%)	85 26	0.12 [0.03-0.53] Ref	0.005
Smoking Yes No	5(7.4%) 4(9.3%)	63(92.6%) 39(90.7%)	68 43	0.77 [0.19-3.06] Ref	0.73
Hypertension Yes No	6(10.9%) 3(5.4%)	49(89.1%) 53(94.6%)	55 56	2.16 [0.51-9.12] Ref	0.32
Diabetes Mellitus Yes No	1(3.8%) 8(9.4%)	25(96.2%) 77(90.6%)	26 85	0.38 [0.05-3.21] Ref	0.68
Dyslipidemia Yes No	1(25%) 8(7.5%)	3(75%) 99(92.5%)	4 107	4.13 [0.38-44.35] Ref	0.29

Table 6: Univariate Analysis Showing the Clinical Factors Associated with In-hospital Mortality

Variables	In-hospital Mortality		Total	Unadjusted Odds ratio [95%CI]	P-Value
	Yes	No			
Killip Class					
Class-I	1(1.3%)	78(98.7%)	79	Ref	
Class –II	2(8%)	23(92%)	25	6.78[0.58-78.21]	0.143
Class-III & IV	6(85.7%)	1(14.3%)	7	468[25.94-8450]	0.0005
TIMI Risk Score					
2-6	2(2.1%)	95(97.9%)	97	Ref	
7-8	3(42.9%)	4(57.1%)	7	35.63[4.59-276.7]	0.001
>8	4(57.1%)	3(42.9%)	7	63.33[8.15-491.91]	0.0005
Total Ischemia Time					
≤ 240 min	2(4.1%)	47(95.9%)	49	Ref	
>240 min	5(8.1%)	57(91.9%)	62	0.49[0.09-2.62]	0.46
Target vessel					
1	2(3.4%)	56(95.6%)	58	Ref	
2	2(5.9%)	32(94.1%)	34	1.75[0.23-13.03]	0.585
3	5(26.3%)	14(73.7%)	19	10.00[1.75-57.05]	0.010

Table 7: Multivariate Analysis Showing The Clinical Factors Associated With In-hospital Mortality

Variables	Adjusted Odds ratio [95%CI]	P-Value
Total Ischemia Time		
≤ 240 min	Ref	0.53
>240 min	2.45[0.15-39.74]	
Age (Years)		
40-60	Ref	
61-80	1.90[0.08-42.06]	0.521
Gender		
Male	0.19[0.03-1.44]	0.68
Female	Ref	
TIMI Risk Score		
2-6	Ref	
7-8	3.92[0.18-104.75]	0.41
>8	21.39[0.58-786]	0.09
Killip Class		
Class-I and II	Ref	
Class-III & IV	71.86[2.83-1827.5]	0.010*
Target vessel		
1and 2	Ref	
3	5.48[0.21-141.31]	0.305

Multivariate logistic regression used
Model Accuracy= 97.3% Cox & Snell R Square=0.305
Hosmer and Lemeshow Test; p= 0.120

Discussion

Primary percutaneous coronary intervention (PCI) is considered as the first-line treatment for patients with acute ST-segment elevation myocardial infarction (STEMI)[10-13], and there is evidence that primary PCI can improve the outcomes of patients with acute STEMI[14-16]. Still, many patients do not benefit from PCI, and the factors of poor prognosis include sex, thrombolytic in myocardial infarction (TIMI) classification, slow flow, infarct size, microvascular obstruction, intra-aortic balloon pump (IABP), use of β-blockers, use of angiotensin-converting enzyme inhibitors (ACEI)/ angiotensin receptor blockers (ARB), symptom-to-door time (SDT), symptom-to-balloon time (SBT), ejection fraction (EF)[17-18]. The total ischemic time (TIT), time between onset of chest and ballooning or device activation, is a stronger prognostic marker than DTB time as increase in microvascular obstruction area is reported to be associated with prolonged ischemia .[11]

Studies have showed that TIT is a good prognostic marker, that mortality rate is linearly related to TIT, and that every hour following the onset of chest pain raises the chance of death by about 5% (OR=1.05).[19,20] The TIT has an optimal prognostic cutoff value of 240 minutes, after which the probability of death increased exponentially. The frequency of in-hospital mortality in our study showed that in patients with prolonged total ischemia time >240 minutes undergoing primary PCI was 8.11%. A study published in Journal of the American College of Cardiology revealed 7.8 % in-hospital mortality if total ischemia time is more than 240 minutes.[9]

An editorial highlighted that the myocardium gets injured with every passing second; therefore, TIT should be targeted in STEMI patients to reduce the mortality rate.[21] Prolonged TIT is a problem not specific

to a certain geography or population, it exists across the world with varying degrees of intensity. For example, a study conducted in Australian population by Chandrasekhar et al. reported prolonged TIT (>240 min) for more than one third (34.2%) of the STEMI patients. They also reported that TIT was strongly correlated and found as an independent predictor of major adverse cardiovascular events (MACE).[22] An Indian study by Doddipalli et al. reported that lack of awareness and time taken by patients in recognizing symptom were the main contributors to prolonged TIT and the mean TIT was reported to be significantly higher among expired patients, (8.0±3.6 h vs. 6.2±2.8 h; p<0.05) as compared to alive patients.[23] Results from a Korean nationwide registry observed that shorter (<3 h) TIT was associated with reduced risk of mortality at one month.[24] So, utilization of mobile coronary care unit (CCU) is an effective strategy to reduce TIT which subsequently reduced 1-year mortality among STEMI patients.[25] Similarly, another study also revealed TIT was a better predictor of mortality than DTB time, TIT was also a good predictor of infarct size and 30-day mortality than DTB time.[26]

Comparable gender differences in mortality have been found in various studies. They have showed that women with STEMI treated with Primary PCI have higher mortality rate than men.[27-29] Our study result was also consistent to those studies, in our study female had 23.1% mortality rate while male had only 3.5% mortality rate.

In our study, risk of in-hospital mortality was significantly associated with Killip class (class III and IV) and high TIMI Risk Score. This is similar to the results of studies conducted by Hayıroğlu Mİ et al.[30] and Çinar T et al[31]. Another study by Gao et al also suggested that AKI, Killip class and TIMI grade are important risk factors for in-hospital mortality in patients with STEMI.[18]

As in our study, other studies addressing the impact of TIT in STEMI management, agreed to the fact that TIT holds prognostic utility. In fact, it proved to be a better predictor of mortality (immediate, short, and long term) than DTB time.[22-24] One of underlying mechanism of increased mortality with prolongation of ischemic time, as reported in animal model study, is that infarct size significantly affects myocardial tissue and keeps on damaging with every passing second of ischemic time. Hence, even with optimal reperfusion (primary PCI), prolonged ischemic time may cause higher mortality and less myocardial salvage.[32-34] Decrease in DTB time is unlikely to render the ultimate desired reduction in mortality after primary PCI, and it should not be considered the sole quality indicator. Therefore, along with strategies to reduce DTB time, the matrix of focus must be shifted to reduce overall TIT to improve the survival from STEMI.[26]

LIMITATIONS

It was a single-center, observational cross-sectional study with short study duration and small sample size. Another limitation of this study is the absence of post-discharge follow-up data and subsequent cardiovascular events. It is a preliminary study which can provides a base for future larger studies in our context. Hence larger study and long-term follow-up would more likely reflect the true pictures.

CONCLUSION

In our study frequency of in-hospital mortality was 8.1% in patients with prolonged total ischemia time i.e. >240 minutes undergoing primary PCI. Therefore, in Nepal where there is a lack of awareness regarding acute myocardial infarction, geographical challenges like difficult terrain with poor road networks, inadequate healthcare facilities, comprehensive patient awareness initiatives, a robust Emergency Management System (EMS) and optimizing in-hospital workflows are essential to decrease total ischemia time and achieve better outcome.

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CONFLICT OF INTEREST

None

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