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Comparison of Pharmacoinvasive PCI and Delayed Regular PCI in ST-Elevation Myocardial Infarction Patients with Short-Term Hospital Outcomes

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Abstract **Original Research Article**

Background: Primary PCI remains a challenge due to the factors like few PCI performing centres, financial issues, delay in timely transfer to such centres. Thus, thrombolytic therapy continues to be the most common reperfusion modality in our setup. The optimal treatment after thrombolysis is still unclear. ***Objective:*** To comparison between pharmacoinvasive PCI and delayed routine PCI in ST-elevation myocardial infarction patients with short-term hospital outcomes. ***Materials and Method:*** This was a prospective observational comparative study which was conducted in Department of Cardiology, Northeast Medical College, Sylhet, We enrolled total of 120 thrombolysed ST- segment elevation myocardial infarction (STEMI) patients that underwent PCI after considering inclusion and exclusion criteria. Depending on the timing of PCI performed after thrombolysis, two groups were divided as pharmacoinvasive PCI group (refers as PCI performed within 3-24 hrs after thrombolytic therapy) and delayed routine PCI group (refers to PCI performed >24 h to 2 weeks after thrombolytic therapy). In-hospital MACEs (Myocardial re-infarction, target vessel revascularization, heart failure, stroke, and cardiac death) were observed and recorded. All patients were followed up for a period of 30 days. Then findings of 2 groups were compared. ***Result:*** In-hospital outcome comparing two groups: incidence of cardiac re-infarction, target vessel revascularization, heart failure and cardiac death were higher in delayed routine PCI group than pharmacoinvasive PCI group (8.2% vs 4.0%, 4.1% vs 2.0%, 10.2% vs 6.0% and 4.1% vs 2.0) and p value (0.329, 0.492, 0.346 and 0.492) respectively, which did not show statistically significant difference. ***Conclusion:*** Even after 24 h of thrombolytic treatment in STEMI patients, delayed routine PCI can be performed with comparable outcome to that of PCI within 24 h.

Keywords: Percutaneous coronary intervention (PCI), ST Elevation myocardial infarction (STEMI), Major adverse cardiovascular events (MACEs).

INTRODUCTION

Cardiovascular diseases (CVDs) are the most common cause of premature death worldwide, accounting for 17.7 million deaths per year [1]. This figure is expected to grow to 23.6 million by the year 2030 [2]. Very little is known about the exact prevalence of coronary artery disease in Bangladesh. Recent data indicates that coronary artery disease prevalence is 1.85% to 3.4% in rural population and it is 19.6% in urban population [3]. Primary percutaneous coronary intervention (pPCI) is the treatment of choice in ST-elevation myocardial infarction (STEMI), challenges may arise in accessing this intervention for certain geodemographic groups. Pharmacoinvasive strategy (PIs) has demonstrated comparable outcomes when delays in pPCI are anticipated, but real-world data on long-term outcomes are limited [4].

Primary percutaneous coronary intervention (pPCI) is the recommended reperfusion strategy for patients with ST-segment elevation myocardial infarction (STEMI), if delivered within 120min from diagnosis at an experienced centre with a 24/7 pPCI service [5]. In geographical areas with >120min expected time delay to pPCI, a pharmacoinvasive (PI) strategy (ie, fibrinolysis on place followed by immediate transportation to a PCI capable hospital for rescue PCI in case of failed fibrinolysis, and otherwise routine coronary angiography within 2–24hours) is recommended within 12 hours from symptom onset, for patients without contraindications [5].

A pharmacoinvasive strategy refers to use of intravenous thrombolytic therapy in a primary care center followed by immediate transfer to a tertiary hospital, where early, systematic coronary angiography and percutaneous coronary angioplasty should be performed within 3 to 24 hours, even in cases of successful reperfusion, which is Class IIa recommendation according to ACCF/AHA 2013 guidelines [6]. Delayed routine PCI refers to PCI performed 24 hours to 2 weeks after thrombolytic therapy, regardless the presence of ischemia or myocardial viability in stable patients. At present, delayed routine PCI in stable patients is a Class IIb indication for STEMI, according to the ACCF/AHA 2013 guideline [7].

In spite of the above treatment options in thrombolysed STEMI patients, the optimal timing of intervention is still lacking. Further, current data on different strategies of pharmacoinvasive PCI is limited, with majority of studies comparing primary PCI with fibrinolysis. Direct comparison of post thrombolysis PCI within 24 hour and delayed routine PCI before discharge is very limited in our setup. In this study, we sought to compare Pharmacoinvasive therapy and delayed routine PCI after thrombolysis with streptokinase in a patient with acute STEMI, in relation to major adverse cardiovascular events (MACEs) during in-hospital admission and 1 month follow up.

MATERIALS AND METHODS

Prospective observational comparative study was carried out at the Department of Cardiology, Northeast Medical College, Sylhet during study period all patients >18 years of aged diagnosed with the first occurrence of STEMI and received streptokinase for thrombolysis as primary treatment and underwent PCI at Department of Cardiology, Northeast Medical College, Sylhet were initially approached and then selected as case on the basis of inclusion and exclusion criteria. Depending on the timing of PCI performed after thrombolysis, two groups were divided as "Pharmacoinvasive PCI group" (refers as PCI performed within 3-24hrs after thrombolytic therapy) and other was "Delayed routine PCI group" (refers to PCI performed >24 h to 2 weeks after thrombolytic therapy). A total of 120 patients were included in this study. The eligible patients were explained about the study and informed written consent was taken from patient or next of kin. Then baseline characteristics, clinical presentation, detailed medical history, cardiovascular risk factors, relevant physical examination findings and investigation findings data collected from patient's file and recorded in a semi structured data collection sheet. Coronary angiogram (CAG) and PCI to infarct-related artery were performed by respective consultant. Before going for PCI all of the study patients were pre-treated with loading dose of Ticagrelor and Aspirin, and other medications like Heparin, Nitrates, Statins, Beta blockers, ACEIs/ARBs, Calcium channel blockers, as appropriate. During PCI all of the patients received heparin and choice and dose of the glycoprotein IIb/IIIa inhibitors as an anticoagulant was as appropriate, according to judgement of respective consultant. Less than twenty percent (<20%) residual stenosis and TIMI grade 3 flow after procedure were counted as successful PCI. Study patients received post procedure medication according to guideline directed medical therapy (GDMT). After the procedure, sheath removal, patient mobilization and discharge from hospital done by respective consultant according to standard protocol. During hospital stay in-hospital MACEs (Myocardial re-infarction, target vessel revascularization, heart failure, stroke, and cardiac death) were observed and recorded. After editing, data analysis was carried out by using the Statistical Package for Social Science (SPSS) version 23.0 windows software. Continuous data were expressed as mean (SD) and analyzed by Student's t-test. Categorical data were expressed as frequency and percentages and analyzed by Chi-Square test.

RESULTS

There was no significant difference between the pharmacoinvasive PCI and delayed regular PCI groups in terms of age, gender, BMI, SBP, DBP, and heart rate (P=0.94, P=0.54, P=0.17, P=0.16, P=0.83, and P=0.77). Male predominance and overweight were noted in both groups (Table 1). Most of the patients had multiple risk factors in each group. Overall hypertension was the most prevalent risk factor. Hypertensive patients were more prevalent in delayed routine PCI group (83.3%) than pharmacoinvasive PCI group (70.0%) which was not statistically significant (p=0.08). Diabetes mellitus, dyslipidemia, smoking and family history of CAD were not statistically significant (p>0.05) between two groups (Table-2). The majority of the patients in each group presented with anterior MI which was 43.3% of patients in pharmacoinvasive PCI group and 51.7% in delayed routine PCI group. The difference was not statistically significant (Table-3). The difference of mean serum creatinine, HbA1c, potassium, total cholesterol, TG, LDL, HDL and left ventricular ejection fraction were not statistically significant (p>0.05) between two groups (Table-4). In-hospital outcome comparing two groups: incidence of cardiac re-infarction, target vessel revascularization, heart failure and cardiac death were higher in delayed routine PCI group than pharmacoinvasive PCI group (8.2% vs 4.0%, 4.1% vs 2.0%, 10.2% vs 6.0% and 4.1% vs 2.0) and p value (0.329, 0.492, 0.346 and 0.492) respectively, which did not show statistically significant difference (Table-5).

Table 1: Baseline characteristics of the patients subjects (N=120)

Variables	Pharmacoinvasive PCI (n=60)	Delayed routine PCI (n=60)	p-value
Age (years)	52.08±6.74	52.16±7.55	[a]0.94[ns]
Gender			
Male	45 (75.0%)	42 (70.0%)	[b]0.54[ns]
Female	15 (25.0%)	18 (30.0%)	
BMI (kg/m^2)	24.66±1.73	25.10±1.87	[a]0.17[ns]
SBP (mmHg)	138.25±16.09	142.16±14.42	[a]0.16[ns]
DBP (mmHg)	91.33±14.92	91.83±11.82	[a]0.83[ns]
Heart rate (bpm)	75.5±10.95	74.91±11.04	[a]0.77[ns]

Table 2: Distribution of risk factors among the study subjects (N=120)

	Pharmacoinvasive PCI (n=60)	Delayed routine PCI (n=60)	p-value
Hypertension	42 (70.0%)	50 (83.3%)	0.08[ns]
Diabetes mellitus	30 (50.0%)	40 (66.7%)	0.06[ns]
Dyslipidaemia	22 (36.7%)	19 (31.7%)	0.56[ns]
Smoking	20 (33.3%)	14 (23.3%)	0.22[ns]
Family history of CAD	20 (33.3%)	21 (35.0%)	0.84[ns]

Table 3: ECG finding of the study patients (N=120)

ECG finding (STEMI)	Pharmacoinvasive PCI (n=60)	Delayed routine PCI (n=60)	p-value
Anterior MI	26 (43.3%)	31 (51.7%)	[a]0.362[ns]
Inferior MI	13 (21.7%)	12 (20.0%)	[a]0.711[ns]
Lateral MI	18 (30.0%)	16(26.7%)	[a]0.592[ns]
Inferior + Posterior MI	3 (5.0%)	1 (1.67%)	[b]0.508[ns]

Table 4: Baseline investigations of the study patients (N=120)

	Pharmacoinvasive PCI (n=60)	Delayed routine PCI (n=60)	p-value
S. creatinine (mg/dl)	1.21±0.12	1.22±0.13	0.72[ns]
HbA1c (%)	7.37±1.31	7.83±1.23	0.05[ns]
Potassium (mmol/L)	4.58±0.60	4.50±0.60	0.46[ns]
LVEF (%)	46.21±7.72	46.15±7.15	0.96[ns]
Total cholesterol (mg/dl)	193.70±36.92	195.76±35.65	0.88[ns]
TG (mg/dl)	195.76±35.65	194.50±34.17	0.84[ns]
LDL (mg/dl)	106.71±17.54	111.05±19.14	0.19[ns]
HDL (mg/dl)	43.63±4.62	43.90±4.81	0.75[ns]

Table 5: Comparison of short-term hospital outcomes between two groups (N=120)

Major adverse cardiovascularevents (MACEs)	Pharmacoinvasive PCI (n=60)	Delayed routine PCI (n=60)	p-value
Myocardial re-infarction	3 (5.0%)	5 (8.2%)	0.329[ns]
Target vessel revascularization	2 (3.3%)	4 (4.1%)	0.492[ns]
Heart failure	5 (8.3%)	6 (10.2%)	0.346[ns]
Stroke	2 (3.3%)	0 (0.0%)	0.505[ns]
Cardiac death	2 (3.3%)	1 (4.1%)	0.492[ns]

DISCUSSION

There was no significant difference between the pharmacoinvasive PCI and delayed regular PCI groups in terms of age, gender, BMI, SBP, DBP, and heart rate (P=0.94, P=0.54, P=0.17, P=0.16, P=0.83, and P=0.77). Male predominance and overweight were noted in both groups which was comparable previous study done in western countries by Clever *et al.*, [7] reported that 62.3±10.9 years in early PCI group and 64.6±9.9 years in delayed PCI group. Cader *et al.*, [8] reported that the mean age of STEMI patients in Bangladesh was 55.6±11.8 which is comparable to our study. This study reflects the younger age presentation of STEMI among the population in Bangladesh. In study of Zubaid *et al.*, [9] reported the mean age was 52.3 ± 10.2 years for the

PhI group and 53.7 ± 10.2 years for the primary PCI group. Similar to a study done by Clever *et al.,* [7] (2011) reported 78.7% in early PCI group and 80% in delayed PCI group. Cader *et al.,* [8] reported 77% of STEMI patients in Bangladesh were male. The reason for male predominance in this study can be explained by a high prevalence of STEMI among males than females, smoking habit in male, higher proportion of male patients admitted in the context of Bangladesh, and a handful of female patients underwent PCI due to inadequate financial support.

Overall hypertension was the most prevalent risk factor between 2 study groups. Hypertensive patients were more prevalent in delayed routine PCI group (79.6%) than pharmacoinvasive PCI group (68.0%) (p=0.190). Distributions of other risk factors were almost identical between the study groups. In this study, diabetes mellitus, dyslipidaemia, smoking, family history of CAD was found 48.0%, 36.0%, 34.0%, and 32% in pharmacoinvasive PCI group and 61.2%, 32.7%, 24.5%, and 36% in delayed routine PCI group respectively (p=0.190, p=0.186, p=0.726, 0.299 and p=0.620 respectively). Zubaid *et al.,* [9] reported common cardiovascular risk factors including obesity, hypertension, diabetes mellitus, or dyslipidemia. STEMI location was similar between the two groups with anterior infarction being the most common. Compared to the PhI group, patients in the primary PCI group were more likely to have a higher Killip class on admission and a personal history of stroke. Clever *et al.,* [7] reported hypertension, diabetes, dyslipidaemia, smoking were 61.7%, 50.0%, 29.8%, 43.6% in early PCI group and 57.3%, 58.3%, 30.1%, 35.9% in the delayed PCI group respectively. Cader *et al.,* [8] has reported that among STEMI patients in Bangladesh 68.1% have hypertension, 65.0% have diabetes, 52.8% have dyslipidemia and 33.6 % are smoker which is comparable to our findings.

The majority of the patients in each group presented with anterior MI which was 43.3% of patients in pharmacoinvasive PCI group and 51.7% in delayed routine PCI group. The difference was not statistically significant. Karim *et al.,* [12] has reported that among STEMI patients in Bangladesh**,** presentation with Anterior STEMI, Inferior STEMI were 45% and 32% respectively which is comparable to our study. This study reflects that anterior wall STEMI is the most common presentation of STEMI in patients of Bangladesh.

In this study, In-hospital outcome comparing two groups: incidence of cardiac re-infarction, target vessel revascularization, heart failure and cardiac death were higher in delayed routine PCI group than pharmacoinvasive PCI group (8.2% vs 4.0%, 4.1% vs 2.0%, 10.2% vs 6.0% and 4.1% vs 2.0) and p value (0.329, 0.492, 0.346 and 0.492) respectively, which did not show statistically significant difference. Scheller *et al.,* [10] reported that the rate of cardiac death were lower in immediate stenting group than delayed stenting group (4.9% vs 9.9%, p=0.179). Similar observations was also reported by Bohmer *et al.,* [11] study. Zubaid *et al.,* [9] Patients were randomized to receive either primary PCI or PhI therapy with coronary angiography within 6–24 hours. The primary end point (a composite of death, shock, congestive heart failure or re-infarction within 30 days) was similar between the two intervention arms (12.4% in the PhI group and 14.3% in the primary PCI). At one-year follow-up, all-cause mortality and cardiac mortality were similar between treatment groups [13].

CONCLUSION

: The result of this study suggests that PCI done even after 24 hours of thrombolysis has comparable outcomes in terms of MACEs to that of PCI within 24 hours, during hospital stay in our clinical setup, where primary PCI is not readily available, pharmacoinvasive strategy is a valuable option.

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