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Comparison of Efficacy and Outcome of Primary Percutaneous Coronary Intervention to Pharmacoinvasive Strategy in Management of ST-Segment Elevation Myocardial Infarction

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Abstract **Introduction:** Primary percutaneous coronary intervention (PPCI) is the best reperfusion option in ST-segment elevation myocardial infarction (STEMI) when performed timely but PPCI is not universally available. Hence, Pharmacoinvasive (PhI) reperfusion strategy is recommended for STEMI patients. However, there are very few studies in Bangladesh for the comparison of efficacy and outcome of PPCI and PhI Strategy. The aim of this study is to compare the efficacy and outcome of PPCI and PhI strategies in patients of Bangladesh. **Methodology and Materials:** This was a prospective observational comparative study. A total of 783 acute STEMI patients were included in Enam Medical College Hospital, Savar, Dhaka, Bangladesh during December-2015 to April-2019. Among them, 103 patients underwent Primary PCI and 184 patients underwent PhI strategy. Data were collected prospectively using a standardized case report form. Chai-squared tests were done to compare the ratio of the frequency of the groups and t-tests were done to compare the mean of the groups with 95% CI where $p<0.05$ considered as significant. **Results:** Among the studied patients, access site complications in PPCI were hematoma, occlusion and pseudo-aneurysm being observed 03(2.91%), 05(4.85) and (0%), whereas, in PhI strategy were 09(4.89%), 08(4.34%), and 02(1.08%) respectively ($P>0.05$). In hospital, primary composite cardiovascular outcome of death, reinfarction, stroke and CHF were noted insignificant in both the strategies ($p>0.05$). On follow-up at 01 month, 06 month and 12 month, the composite cardiovascular outcome of death, reinfarction, stroke and CHF) were 03(3.84%), 04(5.12%), and 05(6.41%), in PPCI and 04(2.81%), 09(6.33%), and 07(4.92%) respectively in PhI strategy ($P>0.05$). **Conclusion:** Similar clinical, in hospital, and followed up outcomes were found when comparing the efficacy and safety Primary PCI to PhI Strategy in patients with STEMI who were eligible for reperfusion. So, both Primary PCI and Pharmacoinvasive strategies are safe and effective in management of patients with STEMI.

Keywords: *ST-Segment elevation myocardial infarction, primary percutaneous coronary intervention, pharmacoinvasive strategy*

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1. Introduction

ST-segment elevation myocardial infarction (STEMI) is responsible for 25–40% of acute coronary syndrome (ACS) cases [1,2,3,4]. Primary percutaneous coronary intervention (PPCI) is considered to be the best reperfusion option in ST-segment elevation myocardial infarction (STEMI) when it can be performed in a timely fashion and by an expert team [5,6]. However, PPCI is not universally available, and delays in performing. Even in some large cities, patients have a high chance of presenting to hospitals not providing around the clock PPCI service. Several studies and practice guidelines have demonstrated the superiority of primary percutaneous coronary intervention (PPCI) over other therapies when performed within 90 minutes of first medical contact (FMC) for field transfer and 120 minutes of FMC for patients presenting to non-PCI-capable facility [3,5]. However, some of this superiority is lost when door-to balloon time exceeds 120 minutes, a situation that can occur when challenging conditions like shortage of skilled manpower, weather, traffic and geography exist [7,8,9]. Pharmacoinvasive (PhI)

strategy, a reperfusion strategy that entails administration of fibrinolytic agent followed by early angiography and PCI, has been advocated as an alternative strategy to delayed primary PCI in settings where primary PCI cannot be undertaken in a guideline recommended time frame [10]. Pharmaco-invasive (PhI) strategy, an early reperfusion strategy encompassing initial prompt fibrinolysis with subsequent early catheterization, has been proposed as a therapeutic option for STEMI patients when timely PPCI is not feasible [11]. However, current evidence on the efficacy and safety of a PhI strategy in patients with STEMI remains limited, and its role is a matter of debate [12]. The recent STREAM trial (Strategic Reperfusion Early After Myocardial Infarction) showed that a PhI Strategy could be a reasonable alternative to PPCI in STEMI patients presenting ≤3 hours of symptom onset and with an expected time delay from first-medical-contact (FMC) to PPCI >1 hour [13]. However, there are very few studies and limited data about the efficacy and safety of Pharmacoinvasive (PhI) Strategy in the treatment of STEMI patients of Bangladesh compared to Primary PCI Strategy. So, we purposively designed this study to compare the safety and efficacy of Primary Percutaneous Coronary Intervention to Pharmacoinvasive Strategy in management of ST-Segment Elevation Myocardial Infarction.

2. Methodology and Materials

2.1. Study Design and Population

This was a prospective observational comparative single center study during the period of December-2015 to April-2019. For this study written approval was taken from the Director of Enam Medical College Hospital, Savar, Dhaka Bangladesh and a total of 783 acute STEMI patients who received reperfusion treatment after STEMI in the hospital registry were included in this study. Among them, 103 patients underwent in primary PCI and 680 patients received thrombolysis with streptokinase to all patients either from outside of the hospital, at off time admission or who gave delayed in decision for Primary PCI, of them 184 patients were included in PhI Strategy and the rest 496 patients were excluded from the study purposively. STEMI was defined as ST segment elevation ≥1 mm in two contiguous leads on a 12-lead electrocardiogram. Data were collected prospectively using a standardized case report form (CRF).

2.2. Objectives

To compare the efficacy and outcome of Primary Percutaneous Coronary Intervention to Pharmacoinvasive Strategy in management of ST-Segment Elevation Myocardial Infarction.

2.3. Data Collection and Analysis

2.3.1. Data Collection Procedures

Data variables were in accordance with American College of Cardiology (ACC) and key data elements and definitions for measuring the clinical management and outcomes of patients with ACS [14]. Incident cases were enrolled on a daily basis for the duration of the study. Critical times in CRFs were measured using ambulance reports, emergency department forms, ECG papers, and catheterization laboratory reports.

Follow-up was done at 01 month, 06 month and 12 months from the date of enrolment. Follow-up was carried out by clinic visit or telephone interview. The composite cardiovascular outcome was measured based on death, congestive heart failure, reinfarction and stroke prospectively ascertained during hospital stay and up to 12 months' follow-up.

2.3.2. Data Analysis

The collected data were analyzed by using SPSS (version 20.0). Continuous variables were presented with frequency, means, standard deviation and percentage. Chai-squared tests were done to compare the ratio of the frequency of the groups and t tests were done to compare the mean of the groups with 95% CI where $p<0.05$ considered as significant.

3. Results

Among 783 STEMI patients, 103 underwent Primary PCI of them 07 patients developed in hospital mortality, 78 patients were followed up at 12 months, and 18patients were lost to follow up. On PhI group, 680 patients of thrombolysis, 184 patients underwent PhI strategy, of them, 13 patients developed in hospital mortality, 142 patients were followed up at 01 year, 29 patients were lost to follow up (Figure 1). Among the studied patient's demographic characteristics are of no significant difference (Table 1). (Table 2) shows the study of CVS risks factors were also having no significant difference except in history of previous stroke were 06(5.83%) in PPCI and 00(0%) in PhI group. On admission clinical profile of the patients (Table 3), the mean serum creatinine (mg/dl) in PPCI was 1.0±0.5 and 0.9±0.2 in PhI, the mean hemoglobin (gm/dl) level in PPCI was 14.3± 2.3 and in PhI was 14.5 ±2.5. In PPCI, Killip Class II at time of arrival, Anterior MI, Inferior MI, Time from symptoms onset to hospital arrival <3 hours, were being 53 (51.45%), 47 (45.63%), 56 (54.36%) and 58 (56.31%), whereas, in PhI group, were 108 (58.69%), 73 (39.67%), 111 (60.32%) and 120(65.21%) respectively. In (Table 4) shows the mean time from symptoms onset to first hospital arrival of the patients of PPCI Strategy was 200 ± 50 minutes and in PhI group was 180 ± 60 minutes. Door-to-balloon time in PPCI was observed 80 ± 15 minutes, whereas Door-to-needle time in PhI group was observed 30 ± 10 minutes and time from administration of fibrinolytic therapy to catheterization of PhI group was observed 18 ± 6 hours. Time from symptom onset to catheterization lab of PPCI group was observed 3 ± 1.5 hours and in PhI group was observed 20 ± 12.5 hours. (Table 5) shows the details of the procedures performed. Stent(s) were placed 100(97.08%) in PCI group whereas in PhI stent were placed 181(98.36%) (p=0.4689). Femoral access was 52(50.48%) in PPCI and 93(50.54%) (p=0.9922) in PhI. Radial access was 51 (49.51%) in PPCI, whereas in PhI

was 91(49.45%) (p=0.9922). Access site complications in PPCI were hematoma, occlusion of access artery and pseudo aneurysm being observed 03 (2.91%), 05 (4.85) and (0%), whereas, in PhI were 09(4.89%), 08 (4.34%), and 02(1.08%) respectively (P>0.05). Study of Culprit artery: LMCA, LAD, Circumflex, RCA were 03(2.91%), 46 (44.66%), 19 (18.44%) and 37(35.92%) in PPCI whereas, in PhI 05 (2.71%), 80 (43.47%), 40 (21.73%) and 71 (38.58%) respectively (p>0.05). (Table 6) shows in PPCI strategy in hospital primary composite cardiovascular outcome of death, reinfarction, stroke and CHF were 07 (6.79%), 01(0.97%), 02 (1.94%) and 11(10.67%), whereas in PhI strategy were 13(7.06%), 03(1.63%), 04(2.17%) and 17(9.23%) respectively (P>0.05). On follow-up at 01 month, 06 month and 12 month, the composite cardiovascular outcome (death, reinfarction, stroke and CHF) were being observed 03(3.84%), 04(5.12%), and 05(6.41%) in PPCI, whereas in PhI strategy, 04(2.81%), 09(6.33%), and 07(4.92%) respectively (P>0.05).

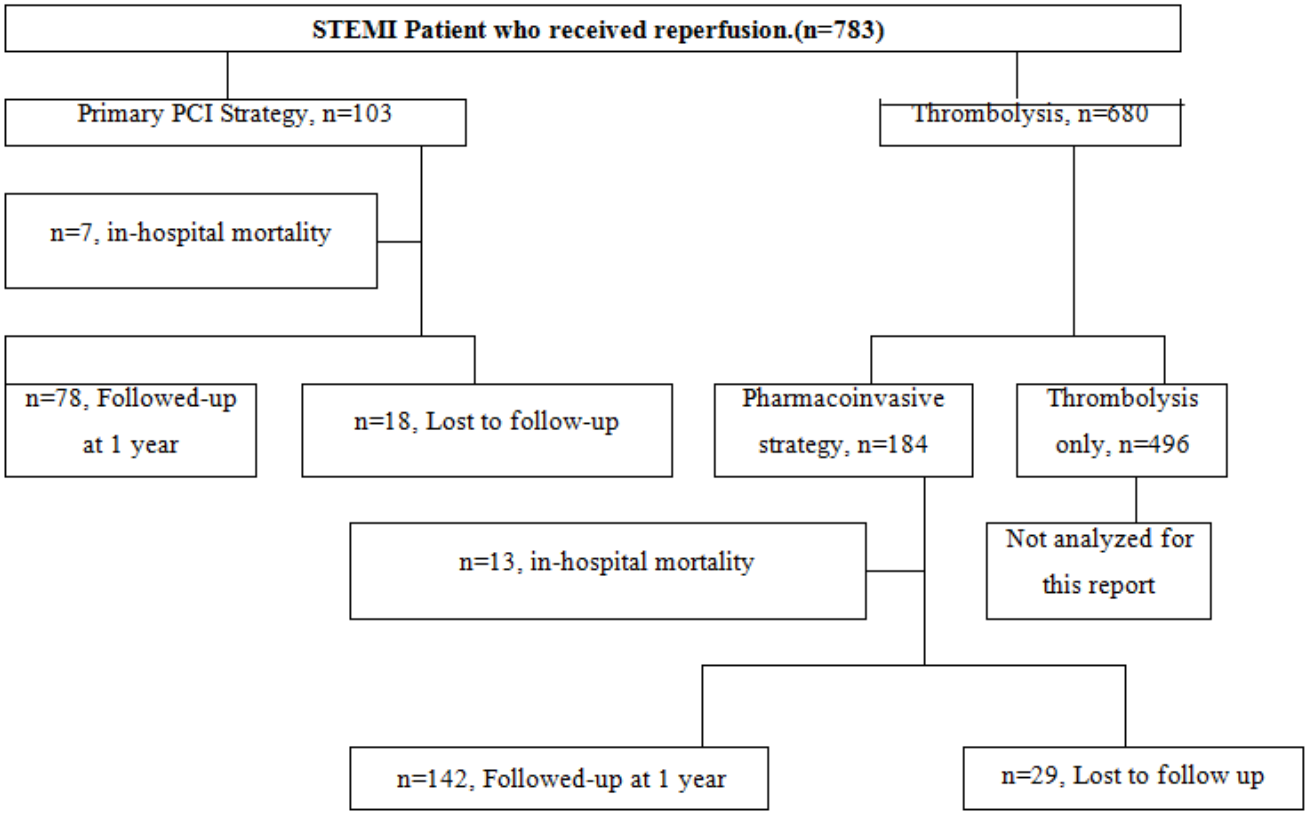

Figure 1. STEMI Patient who received reperfusion (n=783)

Table 1. Demographic characteristics of the patients, n=287

Characteristics	Primary PCI (n=103)	PhI (n=184)	P-Value
Age (mean)	52 ± 15	49 ± 18	0.1524
Male	61(59.22%)	111(60.32%)	0.8555
Female	42(40.77%)	73(39.67%)	0.8555
BMI(kg/m2), mean	25 ± 5	24 ± 6	0.1524

Table 2. Cardiovascular risks factors of the patients n=287.

Variable	PPCI (n=103)	%	PhI (n=184)	%	P-Value
Hypertension	83	80.58	152	82.61	0.6690
Diabetes Mellitus	76	73.79	108	58.70	0.0107
Dyslipidaemia	62	60.19	130	70.65	0.0714
Current or Recent Smoker	69	66.99	119	64.67	0.6922
Family H/O CAD	34	33.00	69	37.50	0.4466
Previous MI	23	22.33	32	17.39	0.3086
Previous PCI	06	5.83	09	4.89	0.7319
Previous CABG	01	0.97	03	1.63	0.6478
Previous Stroke	06	5.83	00	00	0.0010

Table 3. Clinical Profile of the studied patients (n=287)

Variable	PPCI (n=103)	%	PhI (n=184)	%	P-Value
HR (min), mean (SD)	82.99±18.9		79.4 ±18.1		0.1144
SBP (mmHg), mean (SD)	137.1±29.1		135.1 ±28.5		0.5671
S. Creatinine, mean (SD)	1.0 ±0.5		0.9 ± 0.2		0.0173
Hb (g/dl), mean (SD)	14.3±2.3		14.5 ±2.5		1.0000
Killip Class II at Time of Arrival	53	51.45	108	58.69	0.2366
Anterior MI	47	45.63	73	39.67	0.3270
Inferior MI	56	54.36	111	60.32	0.3270
Symptom onset to hospital arrival <3hr	58	56.31	120	65.21	0.1369

Table 4. Key Time Intervals in primary PCI and PhI groups (n=287)

Variable	Unit	PPCI (n = 103)	PhI (n = 184)	P-Value
Time from symptom onset to first hospital arrival	Minute	200 ± 50	200±60	1.0000
Time from hospital arrival to first ECG	Minute	5 ± 02	12 ±3	< 0.0001
Door-to-balloon time among all primary PCI group	Minute	80 ± 15	NA	
Door-to-needle time	Minute	NA	30±10	
Time from administration of fibrinolytic to catheterization of PhI group	Hours	NA	18±6	
Time from symptom onset to catheterization lab	Hours	3 ± 1.5	20±12.5	< 0.0001

Table 5. Details of Procedures of the studied patients performed (n=287)

Variable	PPCI (n=103)	%	PhI (n=184)	%	P-Value
PCI Performed	103	100	184	100	
Stent(s)	100	97.08	181	98.36	0.4689
Access Site:					
Femoral	52	50.48	93	50.54	0.9922
Radial	51	49.51	91	49.45	0.9922
Access Site Complications:					
Hematoma	03	2.91	09	4.89	0.4222
Occlusion	05	4.85	08	4.34	0.8422
Pseudo aneurysm	00	00	02	1.08	0.2907
Culprit artery :					
LMCA	03	2.91	05	2.71	0.9214
LAD	46	44.66	80	43.47	0.8458
Circumflex	19	18.44	40	21.73	0.5089
RCA	37	35.92	71	38.58	0.6560

Table 6. In-hospital and at Follow-up outcome of the studied patients (n=287)

Variable	PPCI (n=103)	%	PhI (n=184)	%	P-Value
In-hospital composite Outcome of death, reinfarction, stroke and CHF:	21(103)	20.38	37(184)	20.10	0.9549
Death	07(103)	6.79	13(184)	7.06	0.9314
Reinfarction	01(103)	0.97	03(184)	1.63	0.6478
Stroke	02(103)	1.94	04(184)	2.17	0.8962
CHF	11(103)	10.67	17(184)	9.23	0.6937
Composite outcome: death, reinfarction, stroke and CHF at follow up					
1 month	3(78)	3.84	4(142)	2.81	0.6339
6 month	4(78)	5.12	9(142)	6.33	0.6769
12 month	5(78)	6.41	7(142)	4.92	0.5946

4. Discussion

In this study a total of 783 STEMI patients were included who received reperfusion of them 103 were included in PPCI group and 184 were included in PhI group and the rest 496 patients were excluded from this study purposively [15]. Among the STEMI patients 172(60%) were male and 115(40%) were female and the mean BMI of the patients was 25±5. The mean age of the patients was 50±15. Study of cardiovascular risks factors in PPCI group, Hypertension were 83 (80.58%), Diabetes Mellitus 76 (73.79%), Dyslipidaemia 62 (60.19%), Current or recent smoker 69 (66.99%), Family H/O CAD 34 (33%), Previous MI 23 (22.33%), Previous PCI 06 (5.83%), Previous CABG 01 (0.97%), Previous Stroke 06 (5.83%). On the other hand, in PhI group, Hypertension were 152 (82.61%), Diabetes Mellitus 108 (58.70%), Dyslipidaemia 130 (70.65%), Current or recent smoker 119 (64.67%), Family H/O CAD 69 (37.50%), Previous MI 32 (17.39%), Previous PCI 09 (4.89%), Previous CABG 03 (1.63%), these finding also found in Rashid et al [16]. In this study femoral access were 52 (50.48%) in PPCI group and 93 (50.54%) in PhI group (p=0.9922). Radial access was used in 51 (49.51%) of patients who underwent PPCI compared to 91(49.45%) of patients undergoing in the PhI group (p=0.9922) the same procedures were performed in the study of Ayman M and Helal et al. [17]. Access site complications in this study were Hematoma 03(2.91%) in PPCI group and 09(4.89%) were in PhI group (p= 0.4222), Occlusion of access artery were 05 (4.85%) in PPCI group and 08(4.34%) were in PhI group (P=0.8422), Pseudo aneurysm of access artery were 02(1.08%) in PhI group (p=0.2907). In this study during hospital stay, the primary composite cardiovascular outcome of death, CHF, reinfarction and stroke occurred in 21 patients (20.38%) in PPCI group and 37 patients (20.10%) in PhI group (P=0.9549), supported by Brouwer et al. [18] but differed by Bendary et al. [19] to some extent. In our study 12 months follow up after discharge, the composite cardiovascular outcome were found at 01 month the composite outcome (death, CHF, reinfarction and stroke) were 03(3.84%) in PPCI group and 04 (2.81%) were in PhI group (p=0.6339), at 06 month, the composite outcome (death, CHF, reinfarction and stroke) were 04(5.12%) in PPCI group and 09 (6.33%) were in PhI group (p=0.6769) and at 12 month, the composite outcome (death, CHF, reinfarction and stroke) were 05(6.41%) in PPCI group and 07 (4.92%) were in PhI group (p=0.5946). However, in hospital and at follow up composite cardiovascular outcome of this study was statistically insignificant in both the groups (p>0.05), agreed by Zubaid et al., Rashid et al. and Larson DM et al. [15,16,20] with the findings of this study. So, in this study we observed the similar clinical, in hospital and followed up outcomes when compared to PPCI with PhI group in patients with STEMI who were eligible for reperfusion.

5. Limitations of the Study

This was a prospective observational registry based study with all the inherent biases that registries might have. The patients who lost to follow up might be nonresidential to local region.

6. Conclusion and Recommendations

Similar clinical, in hospital, and followed up outcomes were detected when comparing the efficacy and safety of Pharmacoinvasive Strategy to Primary PCI in patients with STEMI who were eligible for reperfusion. So, these real-world data support the use of both the Pharmacoinvasive and Primary PCI strategies for the safe and effective reperfusion of STEMI patients.

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