

Evaluation of Pharmaco-invasive PCI in Terms of in Hospital Clinical Outcome of Acute Anterior ST Segment Elevation Myocardial Infarction Patients Compared to Primary PCI

Dhar R¹, Momenuzzaman NAM², Ahmed MU³, Hossain S⁴, Kumar DU⁵, Shuvon AAA⁶

Conflict of Interest: None

Received: 20.02.2023

Accepted: 26.02.2023

www.banglajol.info/index.php/JSSMC

Key Words:

Pharmaco-invasive PCI,
Primary PCI, Acute LVF,
Ventricular fibrillation

ABSTRACT:

Background: The strategic reperfusion early after Myocardial Infarction trial and the French Registry of Acute Anterior ST segment elevation MI suggested that pharmaco-invasive strategy compares favorably with primary percutaneous coronary intervention (PPCI).

Objectives: To evaluate in hospital clinical outcome of patients with acute anterior ST segment elevation myocardial infarction undergoing Primary PCI and pharmaco-invasive PCI.

Methods: This cross sectional study was conducted in United Hospital, Dhaka. A total of 120 patients were studied. These patients were categorized into two groups. Those with acute anterior ST segment elevation MI who underwent primary PCI was denoted as group A (n= 55) and those with acute anterior ST segment elevation thrombolysed by streptokinase followed by PCI confined to pharmaco-invasive PCI was denoted as group B (n=65).

Results: Acute LVF was more in pharmaco-invasive group than in primary PCI group and was statistically significant ($p= 0.032$). 02 patients (3.6%) died in primary PCI group: one of which was due to ventricular fibrillation followed by asystole 3 hours after procedure and the other died due to cardiac arrest 10 hours after the procedure. No major bleeding incidence was found in both groups.

Conclusion: Acute anterior ST segment elevation myocardial infarction patients receiving pharmaco-invasive treatment compared with the Primary PCI had higher incidence of acute LVF and no significant discrepancy was observed regarding bleeding events, death, stent thrombosis, arrhythmia, heart block and cardiac arrest.

[J Shaheed Suhrawardy Med Coll 2023; 15(1): 34-38]

DOI: <https://doi.org/10.3329/jssmc.v15i1.76889>

1. Dr. Rajib Dhar, Assistant Professor, Department of Cardiology, Enam Medical College and Hospital, Savar, Dhaka.
2. Dr. N A M Momenuzzaman, Professor and Chief Consultant, Department of Cardiology, United Hospital Limited, Dhaka.
3. Dr. Moeen U Ahmed, Professor and Head, Department of Cardiology, Enam Medical College and Hospital, Savar, Dhaka.
4. Dr. Solaiman Hossain, Professor, Department of Cardiology, Enam Medical College and Hospital, Savar, Dhaka.
5. Dr. Das Uttam Kumar, Assistant Professor, Department of Cardiology, Holy Family Red Crescent Medical College and Hospital, Dhaka.
6. Dr. Ashfak Al Arif Shuvon, RMO, New Life Medical Services, Nawabganj, Dhaka.

Correspondence: Dr. Rajib Dhar, Assistant Professor, Department of Cardiology, Enam Medical College and Hospital, Savar, Dhaka.

Email: www.drrajibmd2013@gmail.com, Mobile Number: 01825151774

Introduction

Coronary artery disease (CAD) is the most common cause of mortality & morbidity in all over the world¹. Deaths from cardiovascular disease (CVD) jumped globally from 12.1 million in 1990 to 20.5 million in 2021, according to a new report from the World Heart Federation (WHF). CVD was the leading cause of death worldwide in 2021, with four in five CVD deaths occurring in low- and middle-income countries (LMICs). The highest CVD death rates occur in the Central Europe, Eastern Europe, and Central Asia region.² In the United Kingdom (UK), more than 1.4 million suffer from angina³ and 275,000 people have a heart attack annually while in United States of America (USA), 770,000 people suffer from new heart attacks each year⁴. Various studies have pointed out that South Asians have a higher prevalence of CAD as compared with other ethnicities with a higher rate at younger ages⁵.

Acute STEMI is a clinical syndrome defined by characteristic symptoms of myocardial ischemia in association with persistent electrocardiographic (ECG) ST elevation and subsequent release of biomarkers of myocardial necrosis. Diagnostic ST elevation in the absence of left ventricular hypertrophy (LVH) or left bundle branch block (LBBB) is defined for the universal definition of Myocardial Infarction as new ST elevation at the J point in at least 2 contiguous lead >2mm (0.2mV) in men or >1.5mm (0.15mV) in women in lead V2- V3 and or >1mm (0.1mV) in other contiguous chest leads or the limb leads.⁶ New or presumably new LBBB has been considered a STEMI equivalent. The main goal of STEMI management is prompt, complete and sustained restoration of ante-grade flow in the infarct related artery is essential to salvage the myocardium at risk improve ventricular function and reduce morbidity and mortality⁷. Currently, there are three main reperfusion strategies: fibrinolytic therapy, primary PCI and pharmaco-invasive PCI. Primary PCI is the preferred treatment modality in patients with ST-Segment Elevation Myocardial Infarction (STEMI) referred to high volume, well-equipped hospitals with PCI capability due to established superior rates of infarct-related artery patency and thrombolysis in Myocardial Infarction TIMI 3 flow compared with thrombolytic therapy. These positive effects on surrogate endpoints are proven to translate into decreased mortality reverse ventricular remodeling and reduced cardiac dysfunction if primary PCI is performed within 12 hours

after the onset of STEMI. The 12 hours window period has maximum benefit of revascularization strategy because after this time period benefit of revascularization in STEMI is pretty low⁸. On this background, the most recent US and European PCI guidelines set the first medical contact-to-balloon time goal to 120 minutes for inter hospital transfer of STEMI patients, with emphasis on the need to strive for total ischemia times <90 minutes. However, in a sizable proportion of patients, the effectiveness of STEMI reperfusion is still limited by delays in PCI. In particular, there are environments where delays to primary PCI remain too long for logistic reasons and alternative reperfusion strategies are needed⁶.

Pharmaco-invasive therapy means first administering early fibrinolysis and then systematically performing an angiography within 3 to 24 hours after the start of fibrinolytic therapy, regardless of whether fibrinolysis results in successful reperfusion or not. In the event of fibrinolytic failure, a rescue PCI should be immediately performed where one need not wait for the initial 3-hour window. Primary PCI is the preferred reperfusion strategy. However, when this therapy is not available, pharmaco-invasive PCI within 3 to 24 hours appears to be a reasonable. Timely perfusion is the most effective treatment for the STEMI. The risk of 1-year mortality is increased by 7.5% for each 30 min delay in treatment. A delay in undergoing primary PCI greatly reduces the benefit from the invasive procedures⁷.

Unavailability of PCI capable hospital and transport delays have restricted primary PCI to only a small proportion of eligible patients. Initial timely fibrinolysis to open the IRA followed by early PCI- that is a pharmaco-invasive strategy to improve the patency rates is an attractive approach particularly in developing countries like Bangladesh where catheterization facilities are limited.

A substantial amount of patients got admitted in coronary care unit of United Hospital with acute coronary syndrome and were diagnosed as a case of acute anterior STEMI depending on ECG. The aim of this study is to compare in-hospital clinical outcome between primary PCI and pharmaco-invasive PCI in acute anterior STEMI patients as we don't have comparative clinical outcome data between these two groups right now.

Objectives

The objective of this study was to evaluate in hospital clinical outcome of patients with acute anterior ST segment elevation myocardial infarction undergoing Primary PCI and Pharmaco-invasive PCI.

Methods

This cross-sectional study was conducted in United Hospital, Dhaka. All the acute anterior ST segment elevation Myocardial Infarction male or female patients admitted in, CCU of United Hospital Ltd were considered as study population. A total of 120 patients were selected by purposive sampling technique. These patients were categorized into two groups. Those with acute anterior ST segment elevation MI who underwent primary PCI was denoted as group A (n= 55) and those with acute anterior ST segment elevation thrombolysed by streptokinase followed by PCI confined to pharmaco-invasive PCI was denoted as group B (n=65).

Inclusion criteria

- Adult patients (aged 18-75yrs) with acute anterior ST segment elevation myocardial infarction diagnosed by standard surface 12 lead ECG admitted in coronary care unit United Hospital Ltd. Dhaka for primary PCI.
- Adult Patients with acute anterior ST segment elevation myocardial infarction were thrombolysed followed by PCI within 24 hours.
- Patients who were thrombolysed from outside and transferred from non PCI capable hospital to United Hospital for PCI within 3-24 hours.

Exclusion criteria

- Old myocardial infarction patients or post PCI or post CABG patients.
- Causes of ST segment elevation in ECG other than MI i.e. pericarditis, Prinzmetal angina, Brugada syndrome.
- ECG evidence of LBBB, WPW syndrome, ventricular arrhythmia, second degree and third degree conduction defect, ventricular electronic pacing of heart.
- Severe co-morbid conditions such as ESRD, cirrhosis of liver, malignancy.
- Unwilling to participate.

Study Procedure

Patients with suspected acute coronary syndrome admitted in United Hospital through emergency department were assessed first by 12 lead standard surface ECG.

Detailed history and physical examination were done and required data were recorded in preformed data collection sheet. The diagnosis of acute anterior STEMI was done by identifying the findings of the triad i.e. clinical presentation, characteristic ST segment elevation from V_1 - $V_6 \pm I$, aVL or V_1 - V_3 , and/or elevation of cardiac biomarker. A total of 120 patients with the diagnosis of acute anterior STEMI were evaluated by the study physician who fulfilled the inclusion and exclusion criteria and were properly loaded with double antiplatelet drugs and were selected for coronary angiography and PCI followed by data collection, and data analysis. These patients were categorized into two groups. Those with acute anterior ST segment elevation MI who underwent primary PCI was denoted as group A (n=55) and those with acute anterior ST segment elevation thrombolysed by streptokinase followed by PCI confined to pharmaco-invasive PCI was denoted as group B (n=65). Informed consent was taken from all the study subjects or from the legal guardians before enrolling them in the study. All the patients selected as study subjects, were evaluated for demographic profile (age, sex) and risk factors of coronary artery disease like diabetes, hypertension, dyslipidemia, smoking, obesity, and family history of premature CAD. Baseline investigations e.g. ECG, high sensitive troponin I, serum creatinine, lipid profile, random blood sugar and echocardiography were done for each patient.

Grouping

Group A: Patients with acute anterior STEMI who underwent Primary PCI (n=55)

Group B Patients with acute anterior STEMI who underwent Pharmaco-invasive PCI (n=65)

Ethical implications

Prior to commencement of this study, the research protocol was approved by the "Research Review Committee" & the "Ethical Committee" of UICVS, Dhaka. All the patients included in this study were informed about the nature, risk and benefit of the study. Then informed consent was taken from all study subjects or from legal guardians.

Statistical analysis

Data were expressed as Mean \pm SD for continuous variables and as numbers (percent) for categorical variables. Continuous variables were compared by the

unpaired student t-test. Proportions were compared by Chi-square statistics and Fisher's exact test was used where appropriate. The 95% confidence intervals (CI) were calculated for each technique. P value less than 0.05 was considered significant. All statistical calculations were performed using SPSS-23.

Results

Table 1 showed age and gender of study subjects. The difference between the mean age and gender of two groups were not statistically significant.

Table 1: Baseline characteristics between two groups (N=120)

Variables	Group-A (n=55)		Group-B (n=65)		p value
Age (years)					
Mean ± SD	48.4 ± 8.5		49.7 ± 9.3		0.429
Median	49		51		
Range	34 -71		32-70		
Gender					
	Frequency	Percentage	Frequency	Percentage	0.659
Male	54	98.2	63	96.9	
Female	1	1.8	2	3.1	
Male Female ratio	54:1		63:2		

P value derived from unpaired Student t test for age, chi-square test for gender.

Table 2 showed pre-exposure and post-exposure EF in both groups were nearly similar, tachyarrhythmia and cardiogenic shock was slightly more in group B compared to group A, cardiac arrest and death was nil in group B. Acute LVF was more in group B and was statistically significant. Stent thrombosis and major bleeding was absent in both group.

Table 2: Comparison of in hospital clinical outcome in pharmaco-invasive PCI and primary PCI

Variable	Group A Mean ±SD		Group B Mean± SD		P value
ECG findings					
Pre-exposure EF	48.5 ± 9.3		47.2±8.5		0.425
Post-exposure EF	51.5 ± 10.8		50.4 ±9.5		0.554
Outcome within 7 days					
	Frequency	%	Frequency	%	
Tachyarrhythmia	18	32.7	22	33.8	0.897
Cardiac arrest	2	3.6	0	0	0.207
Acute LVF	3	5.5	12	18.5	0.032
Cardiogenic shock	3	5.5	5	7.7	0.624
Death	2	3.6	0	0	0.207
Procedural complication					
Stent thrombosis	0		0		
Major bleeding	0		0		

Discussion

The present study findings were discussed and compared with the previously published relevant studies. The pre-procedural and post-procedural echocardiographic variable of our study between two groups showed non-significant and which was consistent with a study carried out in Korea⁹. The comparison of in hospital outcome parameters of arrhythmias and heart block were non-significant in both groups (p=0.897).² patients (3.6%) died in primary PCI group: one was due to ventricular fibrillation followed by asystole 3 hours after procedure and another died due to cardiac arrest 10 hours after the procedure. This results were similar with studies carried out in Korea⁹ and India¹⁰. In our study, acute LVF was more in pharmaco-invasive group than in primary PCI group (21.5% vs 7.3%) and the result was significant (p=0.029). This result was inconsistent with a study carried out in India.¹¹ Cardiogenic shock was almost similar in both groups and p value was also non-significant (p= 0.624). The result was inconsistent with a study carried out in Korea⁹ No major bleeding incidence was found in both groups and the results were similar with other studies.^{9,10}. This may be due to the fact that both groups had radial access for catheterization and we excluded patients aged >75 years. In present study, there were no stent thrombosis in both groups.

Conclusion

In this study, acute anterior ST segment elevation myocardial infarction patients receiving pharmaco-invasive strategy had higher incidence of acute LVF than primary PCI group. There was no major bleeding incidence in both groups.

Limitation of study

This is a cross sectional study which has few limitations due to small sample size, single center study, expensive procedure and the precise time interval. Owing to the small sample size of the study, our findings may not provide a precise estimate of outcomes (especially safety end points) and definitive conclusions await larger randomized trials.

References

1. Ahmed, M., Majumder, A.A.S., Rahman, A., et al. 2005. Relationship between baseline white blood cell count and angiographic severity of coronary artery disease in patients with acute coronary syndrome. *Bangladesh Heart Journal*. 2005 Vol. 20, No. 1, pp. 6-10. [Ahmed M, Majumder AA, Rahman A, Baqui MA. Relationship between baseline white blood cell count and angiographic severity of coronary artery disease in patients with acute coronary syndrome. *Bangladesh Heart Journal*. 2005; 20 (1):6-10.
2. World Heart Federation report, Geneva, 20 May 2023.
3. Peterson S, Peto V, Scarborough P, Rayner M. *Coronary Heart Disease Statistics-2005 edition* British Heart Foundation Health Promotion Research Group Department of Public Health, University of Oxford, 2006.
4. Rosamond W, Flegal K, Furie K, Go A, Greenlund K, Haase N, et al. *Heart Disease and Stroke statistics -2008 Update: A report from the American Heart Association Statistics Committee and Stroke Statistics Subcommittee*.
5. Manninen, V., Tenkanen, L., Koskinen, P., Huttunen, J.K., Manttari, M., Heinonen, O.P., 1992. Joint effects of serum triglyceride and LDL cholesterol and HDL cholesterol concentrations on coronary heart disease risk in the Helsinki Heart Study: implications for treatment. *Circulation*. 1992; 85: 37-45.
6. O Gara, P.T., Kushner, F.G., Ascheim, D.D., Casey, D.E., Chung, M. K., de Lemos, J. A., et al ACCF/AHA Guideline for the Management of ST- Elevation Myocardial Infarction. 2013. Practice guideline. A Report of the American College of Cardiology. Foundation/American Heart Association Task Force on Practice Guidelines. Available from *Journal of the American College of Cardiology*. 2013; 61(4): 78-140.
7. Dalal JJ, Alexander T, Banerjee PS, Dayasagar V, Iyengar SS, Kerkar PG, Mulasari A, Sathe SP, Wander GS; *Cardiocare STEMI experts*. 2013 consensus statement for early reperfusion and pharmaco-invasive approach in patients presenting with chest pain diagnosed as STEMI (ST elevation myocardial infarction) in an Indian setting. *J Assoc Physicians India*. 2014; 62(6):470-80.
8. Mishra S, Ramakrishnan S, Babu AS, Roy A, Bahl VK, Singru KV, Chugh S, Sengupta S, Kaul U, Boopathy SN, Nirmal Y, Jadhav UM, Jose J, Gupta V, Chopra HK, Singh A, Sastry BK, Thiyagarajan S. Management algorithms for acute ST elevation myocardial infarction in less industrialized world. *Indian Heart J*. 2017; 69(1).
9. Kim JH, Chae SC, Oh DJ, Kim HS, Kim YJ, AHN Y, Cho MC, Kim CJ, Yoon , Park HY, Jeong MH; *Korea Acute MI National Institutes of Health Registry*. *PubMed Circ J* .2016; 80 (6): 1427-36.
10. Victor SM, Subban V, Alexander T G BC, Srinivas A, S S, Mulasari AS. A prospective, observational, multicentre study comparing tenecteplase facilitated PCI versus primary PCI in Indian patients with STEMI (STEPP-AMI). *Indian Heart Journal*. 2016; 68 (2): 170-173.
11. Cantor JW, Fitchett D, Borgundvaag B, Ducas J, Heffernan M, Cohen Ea, Morrison Lj, Langer A, Djavik V, Mehta SR, Laam C, Schwartz B, Casanova A, Goodman SG. *TRANSFER –AMI Trial Investigator*, Routine early angioplasty after fibrinolysis for acute myocardial infarction. *N Engl J M*. 2009; 360(26): 2705-18.