Original Research Article

COMPARATIVE STUDY OF IN HOSPITAL OUTCOMES OF PRIMARY PERCUTANEOUS CORONARY INTERVENTION VERSUS PHARMACO-INVASIVE THERAPY IN STEMI PATIENTS UNDER 45 YEARS OF AGE

G. Sivachandran[1], P. Jaisankar[2], A.B Rajasekar[3]

[1]Postgraduate, Department of Cardiology, Thanjavur Medical College, Thanjavur, Tamilnadu, India
[2]Professor, Department of Cardiology, Thanjavur Medical College, Thanjavur, Tamilnadu, India.
[3]Assistant Professor, Department of Cardiology, Thanjavur Medical College, Thanjavur, Tamilnadu, India.

Abstract

Background: ST-Elevation Myocardial Infarction (STEMI) is a type of acute coronary syndrome that requires immediate and efficient reperfusion therapy to restore myocardial perfusion and reduce cardiac damage. Primary percutaneous coronary intervention (PPCI) and pharmaco-invasive treatment are two well-established ways to achieving this goal. This study aims to conduct a comprehensive comparative analysis of PPCI and pharmaco-invasive therapy in STEMI patients aged less than 45 years. **Materials & Methods:** In tamilnadu, there is a specialized government programme called as TN-Heart attack management program which functions as hub and spoke model. This was a prospective observational study conducted at Hub Thanjavur Medical College, a tertiary referral hospital in South India. As we are HUB hospital, we compared the clinical outcomes of 60 patients who reached our hospital directly within 12 hours of onset of symptoms undergoing Primary Percutaneous Coronary Intervention (PPCI) versus 60 patients who were referred from spoke hospital after thrombolysis undergoing pharmaco-invasive therapy in STEMI patients aged less than 45 years and evaluate the procedural complications associated with PPCI and pharmaco-invasive therapy in younger STEMI patients. **Results:** All-cause mortality was slightly higher in the PPCI group (6.7%) compared to the PI group (3.3%), but this difference was not statistically significant (p=0.402). Cardiovascular mortality was similar in both groups at 3.3%. However, post-infarction heart failure was significantly more common in the PPCI group (21.6%) than the PI group (8.3%) (p=0.048). The PPCI group also had a higher incidence of arrhythmias (11.6% vs. 1.6%, p=0.028).55 out of 60 participants (91.67%) had stent placement in PPCI group whereas only 33 (55%) has only undergone stent placement in PI group. **Conclusion:** In our study, no significant differences were found between the two groups regarding mortality and bleeding episodes, the PPCI group showed significantly higher rates of post-infarction heart failure and arrhythmia in hospital stay. Comparatively more requirement of stent placement in PPCI group in less than 45 years of age.

INTRODUCTION

ST-Elevation Myocardial Infarction (STEMI) is a type of acute coronary syndrome that requires immediate and efficient reperfusion therapy to restore myocardial perfusion and reduce cardiac damage. Primary percutaneous coronary intervention (PPCI) and pharmaco-invasive treatment are two well-established ways to achieving this goal. Timely reperfusion is critical in patients with ST-elevation myocardial infarction (STEMI). The decision between primary percutaneous coronary intervention (PPCI) and intravenous fibrinolytic medicines is determined by the time to effective treatment administration, availability, and overall ischemia time.[1,2] Primary percutaneous coronary intervention (PPCI) is preferable to alternative therapies when performed within 90 minutes of first medical contact for field transfers and 120 minutes of FMC for patients presenting to a non-PCI-capable facility. However, some of this superiority is lost when door-to-balloon time exceeds 120 minutes, a circumstance

549

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that might arise when adverse factors such as lack of qualified staff, weather, traffic, and terrain are present. When primary PCI cannot be performed within the time frame recommended by guidelines, the pharmacoinvasive (PI) strategy—a reperfusion approach that involves administering a fibrinolytic agent and then performing early angiography and PCI—has been promoted as an alternative to the delayed primary PCI strategy.[3] The treatment strategy for STEMI in younger patients, specifically those under 45 years of age, poses unique challenges and considerations. Younger STEMI patients often have different risk profiles compared to their older counterparts, with a higher prevalence of smoking, substance abuse, and familial hyperlipidemia, but fewer comorbidities such as diabetes and hypertension. These factors influence not only the pathophysiology and presentation of STEMI but also the outcomes and complications associated with different treatment modalities. Despite the critical importance of optimizing treatment strategies for younger STEMI patients, there is a paucity of data specifically comparing the efficacy and safety of PPCI versus pharmaco-invasive therapy in this demographic population. Most existing studies and clinical guidelines are based on broader age groups, potentially overlooking the distinct characteristics and needs of younger patients. This study aims to fill this gap by conducting a comprehensive comparative analysis of PPCI and pharmaco-invasive therapy in STEMI patients aged less than 45 years.

Objectives:
1. To compare the clinical outcomes of Primary Percutaneous Coronary Intervention (PPCI) versus pharmaco-invasive therapy in STEMI patients aged less than 45 years
2. To evaluate the procedural complications associated with PPCI and pharmaco-invasive therapy in younger STEMI patients.

MATERIALS AND METHODS

Study design: Prospective Observational Study
Study area: The study was conducted in the Department of Department of Cardiology, Thanjavur medical college, Tamilnadu, india.
Study subjects: The patients of age less than 45 years, who were admitted in the cardiology department with STEMI, between April 2023 to March 2024
Inclusion Criteria
• Patients presenting within 12 hours of onset of symptoms for Primary PCI
• Patients referred from spoke hospital after thrombolysis for pharmacoinvasive approach.
Exclusion Criteria
• Patients presenting above 12 hours of onset of symptoms
• Known case of CAD on or not on treatment
• Previous PCI, CABG, stroke
• Previous STEMI and thrombolysis

Operational Definition: STEMI was defined as the new ST elevation at the J-point in at least two contiguous leads:
• **In leads V2–V3**
  ➢ ≥2.5 mm in men <40 years,
  ➢ ≥2 mm in men 40 - 45 years,
  ➢ 1.5 mm in women regardless of age
• **In other leads:** ≥1 mm (in the absence of left ventricular [LV] hypertrophy or left bundle branch block [LBBB]).

Sample size: 120 patients in two groups of 60 patients each. Selected through convenient sampling.
Methodology: This was a prospective observational study conducted at Thanjavur Medical College, a tertiary referral hospital in South India.In tamilnadu, there is a specialized government programme called as TN-Heart attack management program(4). It primarily functions on a Hub and Spoke model. An H1 hub is a 24/7 primary PCI-capable hospital, whereas an H2 hub has main PCI capabilities but is not available at all times. S1 spokes are typically located more than 30 minutes' drive from a hub hospital and are thrombolysis capable. An S2 spoke is typically positioned within 30 minutes of a hub and transports a patient directly to the hub for primary PCI upon ECG confirmation of STEMI Study area .(5) Thanjavur Medical college is a Hub H1centre and receive patients from spoke hospitals. As we are HUB hospital, we compared the clinical outcomes of 60 patients who were reached hospital directly within 12 hours of onset of symptoms undergoing Primary Percutaneous Coronary Intervention (PPCI) versus 60 patients who were referred from spoke hospital after thrombolysis undergoing pharmaco-invasive therapy in STEMI patients aged less than 45 years and evaluate the procedural complications associated with PPCI and pharmaco-invasive therapy in younger STEMI patients.

When a patient presents to the cardiology department with clinical features of acute coronary syndrome, a clinical assessment, including vital signs such as pulse rate, blood pressure, respiratory rate, temperature, and oxygen saturation was done. A detailed general and cardiovascular assessment was also performed with ECG and bedside screening Echocardiography was done to confirm their diagnosis. According to protocol, those who meet the criteria for Primary PCI was transferred to the Cath lab (Group-I). Those patients who were thrombolysed at a spoke hospital or elsewhere and referred for Pharmacoinvasive procedure to our hospital. (Group 2). Following effective procedure, the patients were kept under observation. All the parameters were recorded.

Data analysis: Data was entered in MS excel sheet and analyzed using SPSS software. Continuous variables were represented as mean and standard deviation. Categorical variables were represented in frequencies and percentages. Chi square test was used to determine the significance of the association between two categorical variables. Student 't' test was used to determine the significance between the

association between a continuous variable and a categorical variable with two categories. p value less than 0.05 was considered significant.

Ethical Considerations: Institutional ethical committee approval was obtained before conducting the study. Informed written consent was obtained from the patients included in the study. Patients were given the right to decide whether to continue participating in the study or withdraw according to their willingness. They were assured that withdrawing from the study would not compromise their treatment in any way.
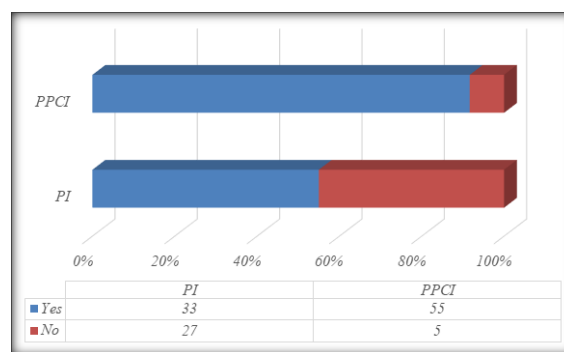
RESULTS

Figure 1: Distribution according to stent placement between PI and PPCI

Table 1: Baseline characteristics between PI and PPCI among the participants

Variable	PI		PPCI		P value
	N=60	%	N=60	%	
Mean Age (in years)	41.15	3.21	40.98	3.51	0.782
Males	52	86.7	51	85	0.793
Smoker	22	36.7	24	40	0.707
Alcoholic	38	63.3	36	60	0.707
Diabetes	15	25	13	21.7	0.666
Hypertension	23	38.3	24	40	0.851
Dyslipidemia	31	51.7	28	46.7	0.583
Chronic Kidney Disease	6	10	6	10	1

Table 2: Clinical symptoms and signs between PI and PPCI among the participants

Variable		PI		PPCI		P value
		N=60	%	N=60	%	
Symptoms	Typical angina	58	96.7	57	95	0.647
	Atypical Chest pain	2	3.3	3	5	0.647
	Dyspnea	11	18.3	13	21.7	0.648
	Syncope	2	3.3	3	5	0.647
	Cardiac Arrest	1	1.7	1	1.7	1
ECG Findings	Atrial Fibrillation	2	3.3	1	1.7	0.558
	High grade AV block	1	1.7	3	5	0.309
Infarct Localization	Anterior	32	53.3	28	46.7	
	Inferior	18	30	19	31.7	0.71
	Lateral	10	16.7	13	21.7	

Table 3: Mortality and hospital outcomes between PI and PPCI

Variable	PI		PPCI		P value
	N=60	%	N=60	%	
All-cause mortality	2	3.3	4	6.7	0.402
Cardiovascular mortality	2	3.3	3	3.3	0.647
Post infarction heart failure	5	8.3	13	21.6	0.048
Cardiogenic shock	5	8.3	4	6.7	0.728
Post infarction angina	3	3.3	4	6.7	0.696
Cerebrovascular event	0	0	2	3.3	0.153
Arrythmia	1	1.6	7	11.6	0.028
Major bleeding	0	0	3	5	0.079

DISCUSSION

This prospective observational study was conducted for a one-year period at Thanjavur Medical College, a tertiary referral hospital in South India in patients with Acute STEMI of age less than 45 years.120 patients were enrolled for the study, and they were divided into 2 groups of 60 patients each. One group was administered PPCI and other was Pharmaco Invasive therapy and the outcomes were compared.

The mean age of participants in both the group, PI and PPCI were 41.15 years and 40.98 years respectively. The baseline characters were similar with no significant difference between the groups. The incidence of outcome measures like Mortality, Cardiogenic shock, Angina, Cerebro vascular events and major bleeding episodes were similar between both the groups. However, post-infarction heart failure was significantly more common in the PPCI group (21.6%) than the PI group (8.3%).

The STREAM trial (the Strategic Reperfusion Early after Myocardial Infarction) have demonstrated that Pharmaco-Invasive approach (PI) and primary PCI (PPCI) had similar rates of primary composite outcomes in the management of acute STEMI (6). However, the incidence of Congestive heart failure was higher among Primary PCI group than with PCI management in hospital stay. This observation was similar to the findings of our study where the post infarction cardiac failure was common in PPCI group.[6]

Similarly, the STEPP-AMI study (Study comparing TEnecteplase facilitated PCI versus Primary PCI in Indian patients with Acute Myocardial Infarction) showed that PIT was not inferior to PPCI in treating acute STEMI, with both approaches yielding similar results.[7] The study observed that the primary endpoint, comprising death, cardiogenic shock, reinfarction, repeat revascularization of the culprit artery, and congestive heart failure, showed no difference between the two groups at 30 days, 3 months, 6 months, and 1 year of follow up.

The study by Zubaid et al in the middle east also showed a similar result that there was no significant difference between primary PCI and Pharmaco-Invasive therapy (PhI) regarding the composite outcome of death, heart failure, re-infarction, and stroke during the in-hospital period or during the one-year follow-up. In addition to that, the two treatment groups in the study showed no significant differences in bleeding events, although the primary PCI group had a higher rate of blood transfusions compared to the PhI group.[3]

Regarding Stent placement, 91.67% of participants had stent placement in PPCI group whereas 55% undergone stent placement in PI group. This result is similar to the observations in STEPP-AMI study which showed a 100% requirement of Stents in PPCI group.[7] Similarly the study done by Rashid et al in Canada also had similar observation in which 90.3% of the patients with primary PCI required stent placement.[8]

In our study, it was observed that, the PPCI group had a higher incidence of arrhythmias when compared to Pharmaco Invasive group .The study by Shah et al among the Myocardial Infarctions observed an increased risk of development of arrhythmias followed by Primary PCI intervention.[9] Mehta et al in their study also observed the similar result that incidence of Ventricular tachycardia and/or ventricular fibrillation (VT/VF) occurred in 4.3% of patients who undergone primary PCI.[10] But the studies comparing the outcomes of primary PCI and Pharmacoinvasive therapy have reported that no significant difference was observed between both the groups regarding arrhythmias.[11]

The major limitation of our study is that the follow up of the patients for the assessment of the long term outcomes was not done. This hampers the comparison of effectiveness of the procedures on long term and also can underestimates the complications related to procedures , some of which could have occurred beyond the observation period of this study. The study included only patients who attended the Hub hospital after the early Lysis at Spoke hospital for pharamco invasive group. This might have missed few patients who have not survived after the procedure before reaching the hub hospital. This can attribute to the difference in immediate complications between the groups.

CONCLUSION

In our study comparing primary PCI and Pharmaco-invasive PCI among STEMI patients, no significant differences were found between the two groups regarding mortality and bleeding episodes, the PPCI group showed significantly higher rates of post-infarction heart failure and arrhythmia during present hospital stay. Comparatively more requirement of stent placement in PPCI in less than 45 years of age. The choice between PI and PPCI should consider these potential risks and benefits, as well as individual patient factors. Further research with larger sample sizes may be needed to confirm these findings and explore the underlying mechanisms for the observed differences in complications.

REFERENCES

1. Araiza-Garaygordobil D, Gopar-Nieto R, Cabello-López A, Martinez-Amezcua P, Eid-Lidt G, Baeza-Herrera LA, et al. Pharmacoinvasive Strategy vs Primary Percutaneous Coronary Intervention in Patients With ST-Elevation Myocardial Infarction: Results From a Study in Mexico City. CJC open. 2021 Apr;3(4):409–18.
2. Bainey KR, Armstrong PW, Zheng Y, Brass N, Tyrrell BD, Leung R, et al. Pharmacoinvasive Strategy Versus Primary Percutaneous Coronary Intervention in ST-Elevation Myocardial Infarction in Clinical Practice. Circ Cardiovasc Interv [Internet]. 2019;12(10):e008059. Available from: https://www.ahajournals.org/doi/abs/10.1161/CIRCINTERVENTIONS.119.008059
3. Zubaid M, Khraishah H, Alahmad B, Rashed W. Efficacy and Safety of Pharmacoinvasive Strategy Compared to Primary Percutaneous Coronary Intervention in the Management of ST-Segment Elevation Myocardial Infarction : A Prospective Country-Wide Registry. Ann Glob Heal. 2020;86(1):1–10.
4. Heart Attack Management Program | National Health Mission Tamil Nadu, Department of Health & Family Welfare Govt. of Tamil Nadu, India [Internet]. Tn.gov.in. 2022 [cited 2024 Nov 18]. Available from: https://www.nhm.tn.gov.in/en/node/6270 .
5. Alexander T, Mullasari AS, Nallamothu BK. Management strategies for acute STEMI in low- and middleincome countries: experience of the Tamil Nadu ST-segment elevation myocardial infarction programme. AsiaIntervention. 2021;7(1):27–34.
6. Armstrong PW, Gershlick AH, Goldstein P, Wilcox R, Danays T, Lambert Y, et al. Fibrinolysis or primary PCI in ST-segment elevation myocardial infarction. N Engl J Med. 2013 Apr;368(15):1379–87.
7. Ami SS, Victor SM, Subban V, Alexander T, Bahuleyan CG, Srinivas A, et al. A prospective , observational , multicentre study comparing tenecteplase facilitated PCI versus primary PCI in Indian patients with. Open Hear. 2014;1(e000133):1–8.
8. Rashid MK, Guron N, Bernick J, Wells GA, Blondeau M, Chong A-Y, et al. Safety and Efficacy of a Pharmacoinvasive Strategy in ST-Segment Elevation Myocardial Infarction: A Patient Population Study Comparing a Pharmacoinvasive Strategy With a Primary Percutaneous Coronary Intervention

552

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Strategy Within a Regional System. JACC Cardiovasc Interv [Internet]. 2016;9(19):2014–20. Available from: https://www.sciencedirect.com/science/article/pii/S1936879816310603

9. Shah JA, Hussain J, Hassan M, Shah G, Naz F, Kumar R, et al. Incidence of Cardiac Arrhythmias in Acute Myocardial Infarction Patients Undergoing Primary Percutaneous Coronary Intervention and Associated Outcomes During the First 24 Hours.Cureus 13(1): e12.

10. Mehta RH, Harjai KJ, Grines L, Stone GW, Boura J, Cox D, et al. Sustained ventricular tachycardia or fibrillation in the cardiac catheterization laboratory among patients receiving primary percutaneous coronary intervention: {Incidence}, predictors, and outcomes. J Am Coll Cardiol. 2004 May;43(10):1765–72.

11. TAIMUR SDM, KHAN SR. In Hospital Outcome of Pharmaco-invasive Therapy versus Primary PCI In ST-segment elevation Myocardial Infarction in Dhaka, Bangladesh. Univ Hear J. 2023;19(1).

553

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