



Original Article

Left ventricular global longitudinal strain following revascularization in acute ST elevation myocardial infarction – A comparison of primary angioplasty and Streptokinase-based pharmacoinvasive strategy



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ABSTRACT

Objective: Tenecteplase-based pharmacoinvasive percutaneous coronary intervention (PCI) has been shown to yield outcomes comparable to primary PCI in the setting of acute ST elevation myocardial infarction (STEMI). This study was designed to compare the efficacy of pharmacoinvasive PCI following successful thrombolysis with Streptokinase versus primary PCI in patients with STEMI.

Methodology: We conducted a prospective single center observational study in 120 patients with STEMI who underwent primary PCI ($n=60$) and Streptokinase-based pharmacoinvasive PCI ($n=60$). Patients with Killips class 3 or 4 at presentation, and those with evidence of failed fibrinolysis were excluded. The primary outcome was LV systolic function after angioplasty, as assessed by 2D global longitudinal strain (GLS) using speckle tracking echocardiography (STE), as well as 2D LVEF using Simpson's biplane method. **Results:** LV systolic function after PCI was significantly lower in the pharmacoinvasive arm as compared to the primary PCI arm, both by 2D STE (GLS: -9% vs -11% ; $p=0.03$) and 2D Simpson's biplane method (LVEF: 40.7% vs 45.1% ; $p=0.02$). TIMI flow in the culprit vessel prior to angioplasty was better in the pharmacoinvasive arm indicating successful thrombolysis, whereas post angioplasty flow was not different. There was no in-hospital mortality in either group. There was a trend toward increased incidence of acute kidney injury in the pharmacoinvasive arm.

Conclusion: LV systolic function is significantly better after primary angioplasty as compared to pharmacoinvasive PCI following successful thrombolysis with Streptokinase.

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1. Introduction

Primary percutaneous coronary intervention (PCI) is the recommended mode of reperfusion in the setting of acute ST elevation myocardial infarction (STEMI). Logistic feasibility remains a hindrance to the implementation of this strategy in developing countries like India. In the light of available evidence from non-randomized trials from India^{1,2} and randomized trials conducted in various parts of the world, pharmacoinvasive strategy, whereby the patient is administered thrombolysis with a fibrinolytic agent and subsequently taken up for coronary angiogram (within 3–24 h of successful thrombolysis), is being seen as a feasible alternative to primary PCI.

The role of routine PCI within 24 h of fibrinolysis was investigated in several trials, such as the GRACIA-1 trial,³ the

CAPITAL-AMI trial,⁴ the SIAM-III trial⁵ and the CARESS-IN-AMI⁶ trials, which demonstrated the superiority of pharmacoinvasive strategy over conservative management in terms of death, reinfarction or refractory ischemia at 30 days. However, the TRANSFER-AMI⁷ and the NORDISTEMI trials⁸ did not show significant reduction in the primary end point of death, reinfarction, stroke, or new ischemia at 12 months with the pharmacoinvasive approach. A meta-analysis of 7 trials showed a significant reduction in reinfarction (OR=0.55; 95% CI, 0.36–0.82) with the pharmacoinvasive approach compared to stand-alone fibrinolysis, with no significant reduction in mortality or increase in major bleeding.

The more recent STREAM trial⁹ assessing the outcomes of pharmacoinvasive strategy in STEMI patients presenting within 3 h of symptom onset and unable to undergo primary PCI within 1 h, compared with those of primary PCI performed beyond 1 h, demonstrated similar cardiac mortality in both the arms. A multicentric observational study from India,^{1,2} including 200 patients, demonstrated that pharmacoinvasive strategy resulted in outcomes that were comparable with primary PCI at 2 years.

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Overall, these data suggest that a pharmacoinvasive strategy is likely to yield results comparable to those of primary PCI.

The impact of these results at a community level practice has been so profound that pharmacoinvasive strategy is often offered as an equivalent alternative to primary PCI, even in settings where immediate transfer for primary PCI without undue delay is very much feasible. However, before extrapolating these conclusions to real life Indian scenario where Streptokinase is the fibrinolytic agent used in the large majority of cases, it needs to be emphasized that the aforementioned benefits of pharmacoinvasive strategy were demonstrated in studies which used fibrin specific thrombolytic agents like tenecteplase.

This study is probably the first of its kind, comparing pharmacoinvasive strategy following successful thrombolysis with Streptokinase with primary PCI. This study was designed with the objective of establishing the efficacy or the lack thereof of Streptokinase-based pharmacoinvasive strategy as opposed to primary angioplasty in patients with STEMI. The pharmacoinvasive arm included only those patients who had clinical and ECG evidence of successful thrombolysis. Those patients who required emergency rescue angioplasty were not included in the pharmacoinvasive arm, as this would have tilted the balance in favor of primary angioplasty at the outset. The primary outcome studied was the left ventricular systolic function following PCI, as assessed by 2D global longitudinal strain (GLS) and LVEF.

2. Materials and methods

2.1. Study design

The study was conducted as a prospective single center observational study among the patients presenting with acute STEMI in a tertiary care referral center in South India. The study proposal was approved by the institutional review board and the ethics committee. All patients presenting with acute ST elevation myocardial infarction to the institution are considered for primary PCI (Percutaneous Coronary Intervention) with drug eluting stent. If the patient is financially prepared for PCI at the time of presentation and the catheterization lab is available, primary PCI is done. Others undergo thrombolysis with Streptokinase, if not contraindicated. In patients with successful thrombolysis who are willing for PCI subsequently, coronary angiogram is done within 3–24 h as pharmacoinvasive strategy. All the patients undergoing angioplasty (primary or pharmacoinvasive) were considered for inclusion in the study, if they satisfied the inclusion and exclusion criteria.

Thrombolysis was done with 15 lakhs units of intravenous Streptokinase given as an infusion over 30–60 min in all patients.^{10,11} All patients received loading doses of Aspirin and Clopidogrel as per standard guidelines,¹¹ as well as 80 mg of Atorvastatin prior to reperfusion. Post procedure, they were continued on dual antiplatelet therapy and 40 mg of Atorvastatin as per guidelines.¹¹ All patients undergoing PCI, were initiated on weight adjusted intravenous infusion of Tirofiban prior to PCI, and continued for 24 h. All patients received intravenous bolus of unfractionated Heparin (50–70 units/kg) during PCI. Thrombus aspiration was done as a bail-out procedure at the discretion of the primary operator.

2.2. Patients

All patients with acute ST elevation myocardial infarction¹² presenting to the department of Cardiology within 12 h of onset of chest pain and undergoing coronary angioplasty as primary PCI or as a part of pharmacoinvasive strategy between October 2015 and April 2016 were considered for the study. Exclusion criteria

included presentation after 12 h of onset of chest pain; historical or ECG evidence of prior or evolved myocardial infarction; documented LV dysfunction or history suggestive of cardiac failure in the past; use of thrombolytic agents other than Streptokinase; and Killips class III or IV at the time of presentation. Thrombolysis was presumed to be successful if the patient had pain relief, along with 50% or more resolution of the ST segment in the lead with maximal ST elevation, after completion of thrombolysis. Patients undergoing emergency rescue angioplasty, following failed thrombolysis, or recurrence of chest pain or ECG changes suggestive of re-infarction, were also excluded from the study.

2.3. Outcomes

Baseline data including demographic profile, cardiovascular risk factor profile, hemodynamic variables and the lab data were collected. The primary outcome analyzed was LV systolic function after angioplasty. The secondary outcome variables were the angiographic TIMI flow before and after coronary angioplasty, in-hospital all-cause mortality, in-hospital complications including clinical evidence of worsening or new onset congestive cardiac failure, supraventricular or ventricular arrhythmias (excluding supraventricular or ventricular premature contractions and accelerated idioventricular rhythm), myocardial re-infarction,¹³ acute kidney injury (defined as increase in serum creatinine by 0.3 mg/dL or more within 48 h of PCI),¹⁴ TIMI major or minor bleeding,¹⁵ and dynamic TIMI score.¹⁶

Left ventricular systolic function was assessed within 48 h following coronary angioplasty by the principal investigator by means of 2D speckle tracking echocardiogram (STE) as well as 2D LVEF estimated using Simpsons biplane method. Global longitudinal strain (GLS) was estimated by 2D STE using QLAB software (Philips CX 50). Coronary angiograms were reviewed by the principal investigator, and the angiographic data including TIMI flow before and after angioplasty, and the number of vessels affected (visual assessment) were documented.¹⁷ The patients were followed up till discharge from the hospital.

2.4. Statistical methods

Based on the data from a pilot study of thirty patients, it was estimated that a minimum of 58 subjects need to be enrolled in each group for the study to have 80% power to detect a minimum difference of 5% in the LVEF and/or 2% in GLS between both the groups. Finally, a total of one hundred and twenty patients were included in the study – sixty in each group. Type I error (two sided) was set at 5% for all statistical tests.

Acquired data were summarized using mean with standard deviation or median with interquartile range for continuous variables, and percentage for categorical variables. Continuous variables were compared using independent *t*-test (after log transformation for non-normal data). Chi square test was used for categorical variables. Statistical analysis of the acquired data was done using Stata/IC 13.1 software.

3. Results

The study included 120 patients with acute ST elevation myocardial infarction who presented to the department of cardiology, Christian Medical College Vellore, and satisfied the inclusion and exclusion criteria as mentioned. There were 60 patients in each arm – the primary angioplasty arm, and the pharmacoinvasive strategy arm.

The mean age of the study population was 55 (± 12) years (range: 27–85 years), of which 88% were males. The baseline

Table 1
Baseline characteristics.

Baseline characteristics	Primary (n = 60)	Pharmacoinvasive (n = 60)	Overall (n = 120)	p-Value
Age (mean)	57 ± 13	54 ± 11	55 ± 12	0.13
Sex (%)				0.41
-Males	90	85	87.5	
-Females	10	15	12.5	
Diabetes mellitus (%)	55	41.6	48.3	0.34
-Newly detected	21	20	20.7	
Systemic hypertension (%)	51.7	36.7	44.2	0.1
Dyslipidemia (%)	6.7	13.3	10	0.22
Smoking (%)	40	21.7	30.8	0.02
Family h/o premature CAD(%)	3.3	5	4.2	0.65
TIMI score (STEMI)	3.2 ± 1.7	3.2 ± 1.7	3.2 ± 1.7	0.91
Killips class (%)				1
-1	86.7	86.7	86.7	
-2	13.3	13.3	13.3	
Type of MI (%)				0.26
-Anterior wall MI	56.7	66.7	61.7	
-Others	43.3	33.3	38.3	
Extent of CAD (%)				0.385
-Single vessel	61.7	68.3	65	
-Double vessel	21.7	23.3	22.5	
-Triple vessel	16.6	8.4	12.5	

characteristics are shown in Table 1. Overall, both the groups were well balanced in terms of their demographic and risk factor profile, except that the primary PCI arm had more number of current smokers.

The median time for revascularisation from the onset of index chest pain was 5.0 h (interquartile range: 3–8 h) in the primary angioplasty group, and 4.5 h (interquartile range: 2.5–7 h) for thrombolysis in the pharmacoinvasive arm. Coronary angiogram (with an intent to revascularize) was performed within a median of 14 h (interquartile range: 7.5–17 h) after thrombolysis in the pharmacoinvasive arm.

The culprit lesion in the primary PCI arm was left anterior descending artery in 56.7%, right coronary artery in 36.3% and left circumflex artery in 7% of the patients. The culprit lesion in the pharmacoinvasive PCI arm was left anterior descending artery in 66.7%, right coronary artery in 19.5% and left circumflex artery in 13.8% of the patients. 91% in the primary PCI arm and 88% in the pharmacoinvasive arm received either ACE inhibitor or Angiotensin receptor blocker; 96% in the primary PCI arm and 100% in the pharmacoinvasive arm received beta blocker. 42% in the primary PCI arm and 57% in the pharmacoinvasive arm were on Aldosterone antagonist at the time of discharge, reflecting the lower ejection fraction values in the pharmacoinvasive group.

92% in the pharmacoinvasive group had TIMI 2 or 3 flow at the time of angiogram, and none had completely occluded culprit artery, whereas 75% in the primary PCI group had occluded culprit artery at angiogram, with only 5% having TIMI 3 flow. 35% of the patients in the primary PCI arm underwent thrombus aspiration during the PCI; whereas only 5% in the pharmacoinvasive arm received thrombus aspiration. This corroborates the fact that most patients in the pharmacoinvasive arm had successful thrombolysis resulting in minimal residual thrombus burden in the culprit artery. Only the culprit lesion was treated during the procedure. None of the patients included in the study underwent non-culprit vessel revascularization during the same hospital admission. Post angioplasty, 98% in the primary PCI arm, and 100% in the pharmacoinvasive arm had TIMI 2 or 3 flow in the distal vessel. Echocardiogram was performed within a median duration of 22.5 h after the coronary angiogram in the primary angioplasty group and 13 h (i.e. a median of 27 h after thrombolysis) in the pharmacoinvasive group.

3.1. Outcomes

The primary outcome, LV systolic function, as assessed by LV ejection fraction (2D Simpsons biplane method) and global longitudinal strain (2D speckle tracking), was significantly low in the pharmacoinvasive group as compared to the group which underwent primary angioplasty (Fig. 1). TIMI flow in the culprit vessel prior to angioplasty was significantly better in the pharmacoinvasive arm indicating successful thrombolysis, whereas the flow post angioplasty was similar in both the groups (Table 2).

The in-hospital mortality was nil in the study population, which is explicable as patients who presented with shock and frank pulmonary edema were excluded at the outset. The median dynamic TIMI score was 3 in both the groups. Among the in-hospital complications, a statistically significant trend toward increased incidence of acute kidney injury was noticed in those patients who underwent PCI following thrombolysis. However, there were no instances of oliguric renal failure warranting dialysis. Two patients developed self-limiting macroscopic hematuria warranting temporary discontinuation of Tirofiban infusion. There was no instance of TIMI major bleeding. There were two instances of paroxysmal atrial tachycardia, which were managed pharmacologically.

4. Discussion

The study was designed with the objective of establishing the efficacy or the lack thereof of Streptokinase-based pharmacoinvasive strategy as opposed to primary angioplasty in patients with STEMI. Hence those patients in whom primary angioplasty would be the unequivocal choice of revascularization (for example those with cardiac failure and shock) were excluded at the outset. Even in this low risk cohort of patients with STEMI, pharmacoinvasive strategy failed to demonstrate equivalence of efficacy with primary angioplasty in terms of the impact on LV function, which is a surrogate marker for long term outcomes.

The strikingly low incidence of secondary outcomes such as arrhythmias, re-infarction, cardiac failure and in-hospital mortality in the study population is probably attributable to the stringent selection criteria followed in order to exclude higher risk STEMI patients from the study. The significant trend toward increased

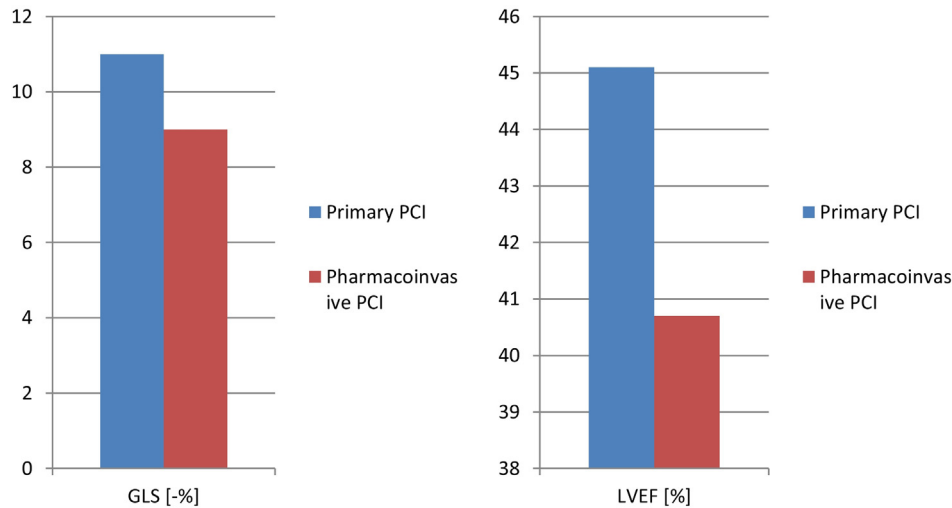


Fig. 1. LV systolic function following primary and pharmacoinvasive PCI.

incidence of acute kidney injury in the pharmacoinvasive arm warrants further research. The increased incidence of acute kidney injury may assume significance in the setting of failed thrombolysis and rescue angioplasty, where the hemodynamics may be less favorable.

As is demonstrated in this study, primary angioplasty fares better than streptokinase-based pharmacoinvasive strategy in terms of post revascularization LV function, even in patients without failure or shock at presentation. This was found to be true despite the fact that the median time to revascularization was more in the primary angioplasty group. Given the fact that more than 90% of the patients in the pharmacoinvasive arm had patent culprit vessel (TIMI 2 or 3 flow) at the time of angiogram, it is possible that the benefits of primary angioplasty extend beyond those attributable to the re-establishment of flow in the culprit vessel.

It may be argued that the primary outcome is a surrogate marker rather than a hard clinical endpoint. However, in a carefully selected cohort of low-intermediate risk STEMI patients in which hard outcome variables such as in-hospital mortality and

DYNAMIC TIMI score were negligibly low, LV systolic function exemplifies a valid surrogate endpoint to detect the differences in outcomes of the treatment strategies adopted.

Left ventricular dysfunction has long been recognized as a major factor determining the mortality outcomes in STEMI.¹⁸ It has been included as a strong predictor of adverse outcomes in the risk stratification scores for patients undergoing PCI both for mortality and major adverse cardiac events. The association between LV function and adverse mortality outcomes is likely to be related to progressive heart failure and arrhythmias.

Though LV systolic function is likely to improve with time following revascularization, both LVEF and GLS determined as early as 24 h post myocardial infarction have been shown to be independent predictors of short and long term outcomes.¹⁹ The amount of myocardial damage following STEMI and myocardial salvage following PCI has been shown to closely correlate with LV systolic dysfunction. Left ventricular GLS as measured by 2D speckle tracking echocardiography immediately after primary PCI has also been shown to be an excellent predictor of adverse LV remodeling and cardiac events in patients with acute myocardial

Table 2
TIMI flow in the culprit vessel prior to angioplasty.

Primary outcome	Primary (n = 60)	Pharmacoinvasive (n = 60)	Overall (n = 120)	p-Value
GLS (%)	-11 (-8.5 to -14)	-9 (-8 to -12)	-10 (-8 to -13)	0.03
LVEF (%)	45.1 (36–49)	40.7 (33.9–44.5)	42.1 (35–47)	0.02
Secondary outcomes				
TIMI flow (% of patients)				
-Pre angioplasty				
0	75	0	37.5	0.00
1	6.7	8.3	7.5	
2	13.3	16.7	15	
3	5	75	40	
-Post angioplasty				
0	0	0	0	0.26
1	1.7	0	0.8	
2	5	11.7	8.4	
3	93.3	88.3	90.8	
In-hospital mortality	0	0	0	
Acute kidney injury	1	6	7	0.05
Heart failure	2	0	2	0.15
Myocardial re-infarction	0	1	1	0.31
Arrhythmia	1	1	2	1.0
Major bleeding	0	0	0	
Minor bleeding	1	1	2	1.0
Stroke	0	0	0	
DYNAMIC TIMI score	3	3	3	1.0

infarction.^{10,20} As compared to LVEF, GLS has the advantage of minimal inter-observer variability.

It is possible that the potential benefits of thrombolysis were offset by a median duration of 4.5 h between symptom onset and administration of thrombolytic therapy. Similarly, the median time to revascularization in the primary angioplasty group was 5 h, which could have equally impacted the primary outcome. However, this is highly representative of the real world time-to-reperfusion in a semi-urban Indian scenario, where pharmacoinvasive strategy is most likely to be promoted ahead of primary angioplasty.

The study is limited by the fact that it was a single center observational study. The sample size, although small, was adequately powered to provide statistically valid results on the hypothesis of interest. Although anterior wall myocardial infarction was numerically more in the pharmacoinvasive group, this could not have influenced the results of the study, as the difference was not statistically significant.

It is noteworthy that despite a statistically significant difference in LV GLS and ejection fraction, pharmacoinvasive strategy fared similar to primary angioplasty in most of the other outcome variables in this low risk STEMI cohort. This corroborates the fact that Streptokinase based pharmacoinvasive strategy, albeit inferior to primary angioplasty, holds its own niche in the realm of STEMI management, and should be offered wherever primary PCI is not deemed feasible.

5. Conclusion

The myocardial salvage, and thereby the post MI LV function indicated by global longitudinal strain following Streptokinase-based pharmacoinvasive strategy in acute ST elevation myocardial infarction, fares inferior to primary angioplasty. The positive impact of primary angioplasty in the recovery of myocardial function possibly extends beyond the benefits achieved by the establishment of epicardial coronary arterial flow. Primary angioplasty should remain the reperfusion strategy of choice in acute STEMI wherever feasible. There was a statistically significant trend toward increased incidence of acute kidney injury in the pharmacoinvasive group, which warrants further research.

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Conflicts of interest

The authors have none to declare.

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