ORIGINAL ARTICLE

POST-AMI: A STUDY OF PLANNED OUTPATIENT ANGIOGRAPHY AFTER SUCCESSFUL THROMBOLYSIS IN STEMI PATIENTS.

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Background: The current recommendations regarding STEMI patients who are treated with thrombolysis in non-PCI centers are to transfer such patients to a facility capable of angiography as soon as possible. However, many emerging PCI-capable centers thrombolyse patients in acute settings because they have not yet achieved primary PCI capability. Could successfully thrombolysed patients undergo nonurgent angiography in such settings without the risk of major complications? In the setting of limited resources, where urgent angiographies could be reserved for rescue or other urgent indications, demonstrating the safety of non-urgent outpatient angiography in successfully thrombolysed patients would be useful. **Methods:** One hundred consecutive patients presenting within 12 hours of symptoms for their first STEMI and meeting our inclusion criteria were given 1.5 MU of Streptokinase and guideline-directed medical treatment. Successfully thrombolysed patients were scheduled to undergo angiography within 72 hours of discharge. The primary outcome was event-free survival up to angiography or major adverse cardiac complications while waiting for outpatient coronary angiography. **Results:** No patients were lost to follow-up. About 80% of patients were males. ST-segment resolution of ≥70% was associated with TIMI III flow at angiography in 90% of patients. TIMI 0 was found in only 8%. All patients survived to have their outpatient angiographies within 72 hours. There were no unscheduled admissions for recurrent angina or reinfarction while waiting for angiography. **Conclusion:** ST-segment resolution of ≥70% is a sensitive marker of good short-term prognosis and a patent infarct-related artery on angiography. Routine outpatient angiography within 72 hours of discharge can be safely undertaken in patients who show resolution of chest pain with 70% or more ST-segment resolution at 90 minutes post-thrombolysis.

Keywords: STEMI; ST-segment Resolution; Thrombolysis; Patent Infarct related artery; TIMI flow

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INTRODUCTION

Primary PCI (Percutaneous Coronary Intervention) is the recommended treatment of choice for patients with ST-Segment Elevation Myocardial Infarction (STEMI).[1] However, timely primary PCI is not possible in many centers across the country, and thrombolysis with streptokinase remains a viable alternative mode of revascularization.[2] Several strategies have been applied for invasive angiography in patients who receive thrombolysis as the primary mode of revascularization. Facilitated PCI is angiography performed immediately after thrombolysis. Such a strategy has shown a higher incidence of adverse events and is not recommended.[3] Rescue PCI is performed in patients who have evidence of failed thrombolysis or hemodynamic instability.[1] The so-called ischemia-driven strategy refers to angiography and PCI if required in patients with evidence of spontaneous or provoked ischemia only.[4] The current standard of care is routine urgent transfer to PCI-capable centers after thrombolysis and angiography within 2 to 24 hours. (Pharmacoinvasive strategy). According to the 2023 ESC acute coronary syndrome guidelines, this is a Class 1A recommendation, while the ACC/AHA guidelines place this as a Class I B R recommendation.[5] The ACC/AHA gives rescue PCI a class I recommendation.[6] The ESC and the ACC/AHA guidelines do not explicitly address situations where centers with evolving PCI capabilities perform thrombolysis in the acute settings. Like many centers across the country,[7] our center is an emerging PCI-capable center which lacks round-the-clock PCI facilities. Such centers reserve invasive revascularization strategies for patients with hemodynamic instability, failed thrombolysis, contraindications for thrombolysis, or those patients presenting late with ongoing chest pain. In emerging invasive centers, where rescue PCI is available onsite due to limited resources, routine non-urgent outpatient angiography in successfully thrombolysed patients

could provide a practical solution. This approach may help prioritize time-sensitive and labor-intensive strategies for higher-risk patients requiring urgent PCI. Studies suggest that in low-to-intermediate risk patients who achieve successful thrombolysis, delayed angiography may be as effective as early intervention in terms of major adverse cardiovascular events. (MACE). Chotechuang *et al* found no significant differences in composite outcomes (death, rehospitalization for acute coronary syndrome, heart failure, or stroke at 30 days) with either early (3–24 hours) or delayed (> 24 hours) angiography.[8] Similarly, a Turkish study found insignificant differences in terms of cardiovascular death or heart failure or non-fatal Myocardial infarction, amongst patients who underwent angiography within 24 to 72 hours and those who underwent angiography after 72 hours after successful thrombolysis with Streptokinase.[9] Our center, an emerging PCI-capable facility, designed the POST-AMI study to investigate the safety and outcomes of routine angiography in successfully thrombolysed patients within 72 hours of discharge. We defined successful thrombolysis using stringent criteria: ≥70% ST segment resolution (as opposed to ≥50% [5]) and significant chest pain relief as a criterion to define successful thrombolysis. Patients were discharged after 48 hours to confirm clinical and hemodynamic stability before discharge.

Our objective was to determine if outpatient angiography could offer a safe and effective strategy for patients who undergo successful thrombolysis in our emerging PCI-capable center.

MATERIAL AND METHODS

100 consecutive patients during the study period, with STEMI presenting within 12 hours, fulfilling our inclusion criteria, and who consented to the study were included in this cross-sectional study. The inclusion criteria included age 20 to 75 years, history of chest pain of less than 12 hours duration, and not relieved with sublingual nitrates, 12-lead ECG showing ST elevation. Patients must have received Streptokinase uninterrupted within one hour. Exclusion criteria included chest pain of more than 12 hours, LBBB on ECG, contraindication to Streptokinase, Previous Coronary Artery Bypass Graft surgery, patients with an indication for an urgent inpatient angiography, such as patients in Shock, unsuccessful thrombolysis, or patients with acute heart failure. Other exclusions included age more than 75 years, Silent/Painless Myocardial Infarction, and death before discharge.

STEMI was defined as ST elevation at the J point in two or more contiguous leads with cut-off points ≥ 0.2 mV in leads V2, or V3 (men) or ≥ 0.15 mV (women) and ≥0.1 mv in another chest leads and AVL, Lead I, and Leads II, III, AVF. (Third Universal definition of Myocardial Infarction. Circulation, 2012;126:2020-35).

Successful thrombolysis was defined as

1. Significant relief of pain
2. More than or equal to 70% resolution in ST segment in the lead showing the highest ST elevation.

Patent infarct-related artery was defined as TIMI III flow in the artery most likely to be the infarct-related artery, as per the ECG localization of STEMI.

The categorical verbal rating scale was used to assess the severity and relief of pain. The magnitude of pain was categorized as none, mild, moderate, or severe.[10]

Significant pain relief was defined as follows:

1. If the pain on admission was severe, significant pain relief was defined as no to mild residual pain.
2. If the pain on admission was moderate, significant pain was defined as no to mild residual pain.
3. If the pain on admission was mild, significant pain was defined as no residual pain.

Streptokinase was administered at a dose of 1.5 MU over 1 hour. All patients received a loading dose of Aspirin 300 mg, Clopidogrel 300mg and high-dose Statins. Baseline pulse rate, blood pressure, and oxygen saturation by pulse oximetry were recorded. The vertical height of ST segment elevation in the lead with the maximum ST segment elevation, before and at 90 minutes after finishing thrombolysis, was measured in mm, 80 ms from the J point. Following our protocol, angiography was performed in patients with successful thrombolysis within 72 hours after discharge, and patency was documented according to the TIMI criteria. Patients were advised to report to the cardiology department in case of recurrent chest pain. Categorical variables were summarized as percentages, and numerical variables were summarized as means. The primary end was to determine whether or not patients remain event-free while waiting for angiographies We assumed the maximum tolerated adverse events (recurrent ischemia or reinfarction while waiting for angiography) to be 5%. We needed 60 patients with no recurrent ischemia or reinfarctions while waiting for angiographies to show that the event rate with outpatient angiography was less than 5%. The data was assessed with SPSS version 23. The study was reviewed by our institutional ethics committee.

RESULTS

Table 1 shows the baseline characteristics of the patient population. The majority of the patients were males. The average age of patients was 58.5 years. A little more than 50% of patients had hypertension. A little over one-third of patients were smokers. One-fifth of the patients were Diabetics. 36 patients had Anterior STEMI and 59 patients had Inferior STEMI.

In 80% of patients Time to thrombolysis since pain was less than 6 hours.

90% of patients had TIMI III flow while only 8% had TIMI 0 flow in their angiography within 72 hours after discharge. TIMI I & II flow was registered in 1 patient each. No patient was lost to follow up and there were no deaths or unscheduled admissions for recurrent chest pain.

There were no differences between the site of STEMI and the TIMI grade achieved. (Table 3) 86% of Anterior STEMI patients and 91% of Inferior STEMI patients had TIMI III flow at angiography after they were successfully thrombolysed (p value for difference in TIMI III flow between Anterior & Inferior STEMI was 0.938).

There were no significant differences between men and women in terms of TIMI III grade achieved after successful thrombolysis (*p* value =0.837).

The sensitivity of clinically successful thrombolysis to predict a patent infarct-related artery according to our study was 90%.

The frequency of TIMI III flow did not differ between diabetics and non-diabetics. 88 % of non-diabetics and 95% of diabetics had TIMI III flow after successful thrombolysis. (*p*=0.753)

Table-1: Baseline Characteristics.

Characteristics	Number
Mean Age	58.5±9.5
Males	80
Females	20
Hypertension	52
Diabetes Mellitus	23
Smoker	37
Anterior MI	36
Inferior MI	59
High Lateral MI	4
Posterolateral wall MI	1
Time to Thrombolysis < 6 Hours	80
Time to Thrombolysis > 6 Hours	20

Table-2: The frequency of TIMI 0 to III in successfully thrombolysed patients.

TIMI Grade	Number	Percentage
III	90	90
II	1	1
I	1	1
0	8	8

Table-3: Site of STEMI and TIMI Grade flow.

Site of STEMI	n	TIMI III	*p* value	%	TIMI II	TIMI I	TIMI 0
Ant STEMI	36	31	0.938	86	1	0	4
Inf STEMI	59	54		91	0	1	4
High Lateral STEMI	4	4		100	0	0	0
Posterolateral STEMI	1	1		100	0	0	0

Table-4: Gender distribution of TIMI flow post-thrombolysis.

Gender	n	TIMI III	%	*p*-value	TIMI 0	%
Males	80	71	89	0.837	7	9
Females	20	19	95		1	5

Table-5: TIMI flow Diabetics vs non-diabetics

Status	TIMI III n (%)	*p*-value	TIMI II n (%)	TIMI I n (%)	TIMI 0 n (%)
Diabetic	22 (95)	0.753	0	0	1 (4)
Nondiabetic	68 (88)		1 (1.2)	1 (1.2)	7 (9)

DISCUSSION

Streptokinase, in preference to rTPA remains the mainstay of acute reperfusion strategy in most centers offering thrombolysis due to cost limitations. Primary PCI is offered only in a few centers in Pakistan.[2] Moreover, a pharmacoinvasive strategy, with angiography within 2 to 24 hours on the same admission, may not be feasible in many PCI-capable centers due to resource constraints. Therefore, a simple, sensitive, and non-invasive method would be useful to triage patients who may need urgent angiography from those who can have coronary angiography non urgently. Triaging such patients between those requiring urgent vs nonurgent angiographies would be very useful for PCI-capable centers who have not yet reached a level where they can offer routine early angiography for all thrombolysed patients. Our study has shown that TIMI III flow was present in the infarct-related arteries of 90 % of patients who had ≥70% resolution in their ST segment in the lead showing the highest ST segment elevation, and no to mild pain at 90 minutes post-thrombolysis. Our study also showed that all such successfully thrombolysed patients survived event-free to have their routine angiographies within 72 hours of discharge. Previous studies have shown that rapid resolution of ST segments post-thrombolysis predicts better preservation of left ventricular function and is associated with reduced morbidity and mortality.[11] Similarly, ST-segment non-resolution predicts a worse prognosis.[12] The ST-segment resolution and the relief of pain criteria as a strategy to predict a patent infarct-related artery have been studied before. Sheikh *et al* in their study of 242 patients showed that patients who had more than or equal to 50% resolution of their ST segment post-thrombolysis had TIMI III flow in their infarct-related arteries. The sensitivity of ST segment resolution to predict TIMI III flow was 94.79%, and the specificity was 42%.[13] Our results are also consistent with the study by Stephan H Hohnloser *et al* who showed that more than 50% resolution of ST segment at 90 minutes post thrombolysis was associated with a patent infarct related artery in 97% of patients while a patent infarct related artery was found in only 58% patients with less than 50% resolution of ST segment at 90 minutes.[14] Prediman K Shah in their small

study of 82 patients showed that rapid resolution of ST segment with relief of pain was associated with a patent infarct related artery in 69 out of 82 patients while no resolution was associated with TIMI II or less flow in 13 out of 82 patients.[15] Gabriel I Barbash *et al* used the sum of ST segment elevations at entry and one hour after Alteplase administration in their STEMI population. More than 50% resolution in the sum of ST segment elevations predicted smaller infarct sizes and better clinical outcomes, with a 30-day mortality of 3.5% vs 7.4 % in patients with less than 50% ST segment resolution.[16] These studies, including our study, are consistent in showing that ST segment resolution can be used as a surrogate marker of TIMI III flow at angiography and good short-term prognosis. A sub-study of GUSTO-III and GISSI-2 showed similar results.[17,18] The current recommendations are to perform early routine angiographies in patients undergoing thrombolysis, regardless of whether thrombolysis was successful or not.[5,6] The 2009 TRANSFER AMI trial[19] compared the results of early transfer of patients after thrombolysis for PCI vs standard treatment. Interestingly standard treatment arm included patients with different risk profiles, such as failed thrombolysis and patients with cardiogenic shock or heart failure, in addition to patients with successful thrombolysis who underwent delayed angiography. The results were presented based on differences between the routine early angiography group vs the standard group (which included both stable and highly unstable patients).Moreover, all patients had to be transferred to a different hospital for high-risk or rescue, or routine PCI. The primary end point (recurrent ischemia, composite of Death, reinfarction,new or worsening congestive cardiac failure, cardiogenic shock at 30 days) occurred with a frequency of 17.2% vs 11.0 % in standard vs routine groups, respectively. The study did not mention how the patients who were successfully thrombolysed and underwent delayed angiography compared with patients who underwent routine early angiography after thrombolysis.In our study, we were able to show that successfully thrombolysed patients could be discharged with a planned angiography within 72 hours with no risk of acute readmissions or deaths, or recurrent ischemia. The 2006 WEST study[20] was different from TRANSFER AMI. It compared 3 groups in terms of differences in major cardiovascular events. Group A included patients who underwent thrombolysis and standard care which included delayed angiography, Group B included patients who were thrombolysed and were immediately transferred for Angiography plus those patients who underwent rescue PCI for failed thrombolysis or for hemodynamic instability (unlike the TRANSFER AMI in which rescue PCI patients were reported as part of the standard treatment group), Group C patients were those who received timely Primary PCI. This time there was no difference between the groups in terms of the primary efficacy end point, which was a composite of death, reinfarction, heart failure, Cardiogenic shock, refractory ischemia, or major ventricular arrhythmias. Savio P. D'Souza *et al* published their meta-analysis of 8 trials comparing routine early invasive strategy vs. ischemia-driven revascularization strategy. This meta-analysis showed that the combined endpoint of 30-day mortality, re-infarction, and ischemia was reached in 7.3% of patients in the routine early PCI group and 13.5% of patients in the ischemia-guided PCI group following lysis, favoring the routine early PCI strategy.[21] TRANSFER AMI trial, which influenced the ESC and AHA/ACC guidelines, involved immediate transfer and angiography without any '' Transfer and observe '' arm. Therefore, it shall remain unknown if, in all transferred patients, a strategy of urgent angiography for all patients would have been better or similar to urgent angiography only for those requiring urgent angiography and routine delayed angiography for those patients with successful thrombolysis. Our study tested a different strategy. We did not need to transfer our subjects to a PCI-Capable center. We did not subject our patients with successful thrombolysis to routine early angiography after thrombolysis, nor did we stop at thrombolysis as the destination treatment and wait for the angiography after proving residual ischemia. Angiography was done as a routine procedure in successfully thrombolysed patients (defined more stringently than other studies, i.e., ≥70% ST segment resolution), not within 24 hours but within 72 hours after discharge. Our study opens up a possibility of routine angiography in successfully thrombolysed patients on an outpatient basis, which would relieve emerging centers in our country struggling to meet the demands of an increasing number of STEMI patients awaiting inpatient angiographies.

Limitations:

Our study had some limitations. Our study did not compare a primary PCI strategy with a routine outpatient angiography after successful thrombolysis. The sample size was small, our study, however, opens up the possibility for a large study in which primary PCI could be compared with a strategy of routine outpatient angiography after successful thrombolysis. Our population was a highly selected patient population who were stable at discharge. Such a population would have a better short-term prognosis anyway. High-risk population, including silent Myocardial Infarction and LBBB type STEMI, was excluded. We also excluded patients who had indications for urgent angiography such as acute heart failure and cardiogenic shock. However, such a highly selected patient population who are stable at discharge could be reasonably scheduled for a routine post-discharge angiography. This is a single-center study. A large multicenter study would categorically prove the benefits or otherwise of

an outpatient angiography in successfully thrombolysed patients.

In conclusion, ≥70% resolution of ST segment in the lead, which show the highest ST segment elevation post-thrombolysis and resolution of chest pain predicts TIMI III flow with 90% sensitivity. Routine scheduled angiography within 72 hours is feasible and may be a safe strategy in successfully thrombolysed stable patients after STEMI for centers that have not yet evolved to offer Primary PCI or routine PCI for all STEMI patients within 24 hours of thrombolysis.

AUTHORS' CONTRIBUTION

ZUK: Data collection, results. RA: Data collection, literature review. MIK: Conceiving the project, write-up. SS: Proof reading, composing. AA, MI: Data collection.

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