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Original Research Article

Comparison of clinical outcomes among thrombolyzed and non-thrombolyzed STEMI patients: a single-centre observational study

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ABSTRACT

Background: There is a paucity of data that compare clinical outcomes, especially morbidity and mortality among thrombolyzed and non-thrombolyzed ST-segment elevation myocardial infarction (STEMI) patients in Indian population.
Methods: An observational, single-centre study involving 70 patients who were diagnosed with STEMI from February 2014 to June 2015. Patients were thrombolysed after meticulous evaluation of indications for thrombolytic therapy, and later whenever needed they were subjected to revascularization therapy of either percutenous coronary intervention (PCI) or coronary artery bypass graft (CABG). Then, STEMI patients were categorized into thrombolyzed and non-thrombolyzed groups. Mortality and morbidity parameters such as effort tolerance expressed in terms of New York Heart Association (NYHA) functional class and typical anginal chest pain at 1, 6, and 12-month were primary outcomes.
Results: Mean age of the cohort was 53.2 years: 48 men and 22 women. Of the total, 58 (82.9%) patients underwent thrombolysis. Mean window period of thrombolysis therapy was 8.1±2.0 hours. Revascularization was required in 80% of cases. At 12-month, STEMI patients who were thrombolyzed had significantly better effort tolerance in terms of NYHA class than those who were non-thrombolyzed (25% versus 13.8%; $p<0.005$). At 1 and 6-month, STEMI patients who were thrombolyzed had significantly better effort tolerance in terms of typical anginal pain than those who were non-thrombolyzed (1-month, 82.8% versus 58.3%; $p<0.005$; 6-month, 4.3% versus 0.0%; $p<0.005$).
Conclusions: This study enlightened the effectiveness of thrombolytic therapy together with revascularization (CABG or PCI) in reducing the morbidity rate than revascularization alone.

Keywords: Anginal chest pain, NYHA class, Revascularization, ST-segment elevation myocardial infarction, Thrombolytic therapy

INTRODUCTION

Myocardial infarction (MI) is one of the major causes of mortality and morbidity worldwide. Mortality due to MI has been surging day by day in Indian population. A recent ST-segment elevation myocardial infarction (STEMI)/non-STEMI (NSTEMI) programme conducted by National Health Mission (NHM) indicates approximately 3,50,000 to 4,00,000 annual deaths due to MI in India.[1] According to most of the guidelines, primary percutaneous coronary intervention (PCI) (within 90 min after the first medical contact) is currently the prevailing treatment modality in patients with STEMI.[2,3] In Indian context, timely PCI reperfusion therapy is accessible to <10% of STEMI patients on account of several limitations in medical infrastructure and socioeconomic reasons.[4] In 2021, expert consensus on "the use of thrombolytic agents for STEMI care in India" has been published.[5] This consensus reports highlighted thrombolysis as the most implemented reperfusion strategy in India to be performed within 30 min of hospital arrival, especially when primary PCI is not available to STEMI patients in a timely fashion.

However, thrombolytic therapy is contraindicated in certain circumstances such as in-hospital delay, fibrinolytic checklist, and various conditions such as major surgery or significant trauma in the past 3 months, any known history of haemorrhagic stroke, or stroke of unknown origin, or known history of ischaemic stroke, or transient ischaemic attack in the preceding 6 months etc.[6-8] Studies investigating the influence of thrombolytic therapy on clinical outcomes are still lacking in the main literature. In consideration of the foregoing, we sought to compare clinical outcomes, especially morbidity and mortality in STEMI patients who were thrombolyzed with those who were non-thrombolyzed.

METHODS

An observational, single-centre study was conducted at Deccan College of Medical Sciences, Hyderabad, India during the period of February 2014 to June 2015. A total of 70 consecutive patients who were diagnosed with STEMI were included. Patients with congenital heart disease, valvular heart disease, or idiopathic cardiomyopathy were the main exclusion criteria.

The patient baseline demographic data including age, gender, and occupation as well as clinical data including, risk factors, body mass index (BMI), abdominal girth, chief compliments, cardiac enzyme level (troponin-I), thrombolytic use, vitals, window period, percent ejection fraction, and Killip's class were noted. Patients were treated as per the American Heart Association/American College of Cardiology (AHA/ACC) guidelines for the management of STEMI.[2] STEMI patients were thrombolysed after carefully assessing the indications for thrombolytic therapy, and later on they were subjected to coronary angiography after stabilizing hemodynamics and blood parameters. Whenever needed, STEMI patients were subjected to revascularization therapy of either PCI or coronary artery bypass graft (CABG). Continuous cardiac monitoring was performed during the intensive coronary care unit (ICCU) stay. Vitals were monitored carefully and continuously. Then, STEMI patients were stratified into thrombolyzed (who received thrombolytic therapy followed by revascularization with either PCI or CABG) and non-thrombolyzed groups (who received revascularization with either PCI or CABG). Main clinical outcomes considered were morbidity parameters like effort tolerance expressed in terms of New York Heart Association (NYHA) functional class (Table 1) and typical anginal chest pain, and death at 1, 6, and 12-month. OPQRST patient assessment tool was used to assess anginal chest pain.[9,10]

Ethical approval has been taken from institutional ethics committee (IEC). All patients provided written informed consent and the study conforms to the principles outlined in the Declaration of Helsinki.

Continuous measurements are described as mean±standard deviation and categorical measurements are explained by percentages. Significance is assessed at 5% level of significance. Chi-square test was used to find out the significance of study parameters on a categorical scale between two groups. All statistical analysis was performed using statistical package for the social sciences version 20 (SPSS Inc., Chicago, IL).

Table 1: The New York Heart Association (NYHA) functional classification.[9]

Class	NYHA grading
Class I	No limitations. Ordinary physical activity does not cause undue fatigue, dyspnoea or palpitations (asymptomatic LV dysfunction)
Class II	Slight limitation of physical activity. Ordinary physical activity results in fatigue, palpitation, dyspnoea or angina pectoris (mild CHF)
Class III	Marked limitation of physical activity. Less than ordinary physical activity leads to symptoms (moderate CHF)
Class IV	Unable to carry on any physical activity without discomfort. Symptoms of CHF present at rest (severe CHF)

†Abbreviations: LV: left ventricular; CHF: congestive heart failure

RESULTS

Seventy STEMI patients were analysed in the present study. Mean age of the study cohort was 53.2±12.4 years, men (68.6%) were predominately affected with STEMI. The majority of the patient had chief complaints of chest pain (55.7%) followed by shortness of breath (44.3%). Smoking (54.3%) followed by hypertension (51.4%) was the most prevalent risk factor for STEMI development. Forty-two (60%) patients presented with Killip class I, 19 (27.1%) patients with Killip class II, 8 (11.4%) patients with Killip class III, 1 (1.4%) patient with Killip class IV. Elevated troponin level was found in almost all cases (98.6%). The need for revascularization was reported in 56 (80%) patients. The need of thrombolytic therapy was noted in 58 (82.9%) patients with mean window period of 8.1±2.0 hours. Single vessel disease was most prevalent (35.7%). Remaining baseline demographics are outlined in Table 2.

At 12-month, STEMI patients who were thrombolyzed within the window period and preserved left ventricular (LV) function had significantly better effort tolerance in terms of NYHA class as compared to those who were non-thrombolyzed (25% versus 13.8%; $p<0.005$). At 1 and 6-month, STEMI patients who were thrombolyzed within the window period and preserved LV function had significantly better effort tolerance in terms of typical anginal pain than those who were non-thrombolyzed (1-month, 82.8% versus 58.3%; $p<0.005$; 6-month, 4.3% versus 0.0%; $p<0.005$) (Table 3).

Table 2: Baseline demography and clinical data.

Variables	Total patients (N=70) %
Age (years)	53.2±12.4 (27-85)
Gender	
Men	48 (68.6)
Women	22 (31.4)
Occupation	
Government servant	1 (1.4)
Business	6 (8.6)
Private sector	45 (64.3)
Housewife	18 (25.7)
Chief complaints	
Chest pain	39 (55.7)
Shortness of breath	31 (44.3)
Risk factors	
Diabetes mellitus	31 (44.3)
Hypertension	36 (51.4)
Family history of CAD	1 (1.4)
Previous history of CAD	4 (5.7)
Cerebrovascular accident	2 (2.9)
Smoking	38 (54.3)
Tobacco consumption	8 (11.4)
Zarda consumption	15 (21.4)
Alcohol consumption	0 (0.0)
BMI (kg/m^2)	28.2±3.2 (24-40)
Abdominal girth (inches)	34.2±3.0 (24-44)
Vitals	
Respiratory rate	19.6±3.1 (16-30)
Heart rate	97.4±2.6 (90-100)
SBP (mmHg)	111±10.5 (90-140)
DBP (mmHg)	72.6±7.7 (50-100)
SpO_2	97.5±2.6 (90-100)
Killip's class	
I	42 (60)
II	19 (27.1)
III	8 (11.4)
IV	1 (1.4)
Elevated troponin level	69 (98.6)
% EF	49.0±10.4 (28-70)
RWMA	66 (94.3)
Window period for thrombolysis (n = 44), hours	8.1±2.0 (4-13)
Need for thrombolytic therapy (n=58)	
Reteplase	6 (10.3)
Streptokinase	51 (87.9)
Urokinase	1 (1.7)
Need for revascularization	56 (80)
Coronary angiography	
SVD	25 (35.7)
DVD	20 (28.6)
TVD	14 (20.0)

†Data are presented as mean±SD and range or n (%). CAD: coronary artery disease; BMI: body mass index; SBP: systolic blood pressure; DBP: diastolic blood pressure; SpO_2: oxygen saturation; RWMA: regional wall motion abnormality; EF%: ejection fraction; SVD: single-vessel disease; DVD: double-vessel disease; TVD: triple-vessel disease

Table 3: Comparison of clinical outcomes among thrombolyzed and non-thrombolyzed.

Clinical outcomes	Total patients (N=70) %	Thrombolyzed (n=58) %	Non-thrombolyzed (n=12) %	Statistics
Left ventricular function				
Good	29 (41.4)	26 (44.8)	3 (25)	χ^2=5.537, p>0.005
Mild	20 (28.6)	14 (24.1)	6 (50)	
Moderate	15 (21.4)	14 (24.1)	1 (8.3)	
Severe	6 (8.6)	4 (6.9)	2 (16.7)	
Revascularization	35 (50.0)	28 (48.3)	7 (58.3)	χ^2=1.004, p>0.005
Effort tolerance (NYHA class)				
At 1-month	35 (50.0)	28 (48.3)	7 (58.3)	χ^2=5.727, p>0.005
At 6-month	22 (31.4)	18 (31.4)	4 (33.3)	χ^2=5.657, p>0.005
At 12-month	11 (15.7)	3 (25)	8 (13.8)	χ^2=6.620, p<0.005*
Effort tolerance (anginal chest pain)				
At 1-month	55 (78.6)	48 (82.8)	7 (58.3)	χ^2=6.876, p<0.005*
At 6-month	3 (4.3)	3 (4.3)	0 (0.0)	χ^2=7.387, p<0.005*
At 12-month	2 (2.9)	2 (3.4)	0 (0.0)	χ^2=2.942, p>0.005
Death	7 (10)	4 (6.9)	3 (25.0)	χ^2=3.621, p>0.005

STEMI patients; †data are presented n (%); NYHA: New York Heart Association; *indicate statistically significant values

DISCUSSION

The main objective of this research was to compare clinical outcomes among thrombolyzed and non-thrombolyzed Indian STEMI patients. The primary findings of the current study were: at 12-month, STEMI patients who were thrombolyzed had better effort tolerance in terms of NYHA class as compared to those who were non-thrombolyzed; and at 1-and 6-month, STEMI patients who were thrombolyzed had better effort tolerance in terms of typical anginal pain than those who were non-thrombolyzed.

A report on the management of patients with acute MI has been released by the AHA/ACC stated functional, clinical, and mortality benefits of thrombolytic therapy when given during the initial 12 hours after symptom onset. However, in the absence of contraindications, it is reasonable to administer thrombolytic therapy to patients with symptoms of STEMI beginning within the prior 12–24 hours who have continuing ischemic symptoms and ST-elevation >0.1 mV in at least two contiguous precordial leads or at least two adjacent limb leads.[11] In our study, the average window time for thrombolytic therapy was 8.1±2.0 hours, which is narrow as compared to the time reported in previous guidelines. This could be one of the reasons for achieving improved clinical outcomes and recovery in our thrombolyzed STEMI patients.

Cost-effective analysis revealed that thrombolytic therapy is thrifty than other accepted medical alternatives.[12] Streptokinase is the most widely used thrombolytic agent in many healthcare facilities worldwide, including India, as it is 7–8 times cheaper than alteplase with reasonable efficacy and safety. Consistent with this finding, streptokinase was predominately used thrombolytic therapy in our study population.[13]

One study reported by Kim et al demonstrated the need for PCI and CABG in 3 (1.83%) and 1 (0.63%) patient, respectively in rural Bangladeshi STEMI patients.[14] In our study, revascularization was done in 56 patients, of which 53 patients underwent PCI and 3 patients underwent CABG. Collectively, it is prudent to say that revascularization using PCI with stenting was a more acceptable treatment modality as compared to CABG in STEMI patients. In our study, thrombolyzed STEMI patients had better effort tolerance in terms of NYHA class at long-term follow-up of 12-month, whereas effort tolerance in terms of anginal chest pain was better at short-term follow-up of 1 and 6-month. Moreover, the mortality rate was also reduced in thrombolyzed STEMI patients than non-thrombolyzed STEMI patients, the result was not statistically significant. In our study, following revascularization, morbidity and mortality rate has been reduced and all patients had achieved a better quality of life. Given that the overwhelming number of studies demonstrated the superiority of PCI over thrombolytic therapy in STEMI patients, our study supports the notion that thrombolytic therapy together with revascularization (CABG or PCI) was more effective in reducing the morbidity rate than revascularization alone.[15-17] In literature, there is no study that directly highlights such merely interesting finding.

The study design constitutes a major limitation of the study. The study was observational and non-randomised. Only those patients who were presented with STEMI and underwent coronary angiography, revascularization, and followed-up for one year were considered in the study. Hence, results might not be generalized to the entire Indian population. Also, the number of patients in the non-thrombolyzed group were less compared to the thrombolyzed group, which might have an impact on the final conclusion. Moreover, patients were not followed-up for longer duration. Further multicentre and randomized

studies with a large sample size and long-term follow-up might be more informative to draw a definite conclusion.

CONCLUSION

From this study, it has been concluded that irrespective of the window period for thrombolytic therapy, STEMI patients who received thrombolytic therapy followed by revascularization had achieved reduced morbidity burden compared to those who were not received thrombolytic therapy. This concept has important implications for STEMI care in settings where timely access to primary PCI, the preferred therapy for STEMI, is not readily available.

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