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To Study Comparative Efficacy and Safety of Thrombolytics (Streptokinasev / Stenecteplase) Based on ECG Changes in Stemi Patients

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Abstract: ***This prospective observational study evaluates and compares the efficacy and safety of two thrombolytic agents, Streptokinase and Tenecteplase, in patients presenting with ST-Elevation Myocardial Infarction (STEMI) at GMC Kathua. A total of 100 patients were included, divided equally between the two treatment groups. The assessment focused on electrocardiographic changes, symptom relief timing, and incidence of adverse effects following thrombolytic therapy. Findings showed a greater proportion of patients in the Tenecteplase group achieving ST-segment resolution above 50% and higher early symptom relief rates. Additionally, Tenecteplase was associated with fewer complications, including zero reported cases of cardiogenic shock, arrhythmia, anaphylaxis, or stroke/bleeding, while the Streptokinase group reported multiple adverse outcomes. Despite comparable baseline characteristics and risk factors across both groups, Tenecteplase demonstrated a more favorable safety and efficacy profile. These results highlight its clinical potential in scenarios where primary PCI is not immediately available.***

Keywords: STEMI, thrombolytic therapy, Streptokinase, Tenecteplase, ECG changes

1. Introduction

Acute myocardial infarction with ST elevation on ECG (STEMI) constitutes a medical Emergency with potentially life-threatening and chronic consequences. The initial(30-day) fatality rate after acute myocardial infarction (AMI) is 30%, with over half of these fatalities transpiring prior to the patient's arrival at the hospital. The thrombotic process diminishes microcirculatory perfusion by decreasing coronary artery flow due to epicardial vascular stenosis and by distal thrombus embolisation. This pathophysiology justifies the use of fibrinolytic and antithrombotic medications.

Thrombolytics facilitate the recanalisation of thrombotic occlusions linked to ST-segment Elevation Myocardial Infarction (STEMI), and the restoration of coronary flow diminishes infarct size while enhancing myocardial function and survival in both the short and long term

Primary percutaneous coronary intervention (PCI) is unequivocally the preferable reperfusion approach for patients with ST-elevation myocardial infarction (STEMI). In certain circumstances, initial PCI may not be executed promptly, creating an urgent want for fibrinolytic therapy as an alternative to avert myocardial injury. Consequently, considering fibrinolytic therapy as a final option.

Thrombolytic treatment may be offered to individuals who present within 12 hours after symptom onset. Thrombolytic therapy is prompt.ly and easily delivered, readily accessible, requires minimal training equipment, and is more effective the sooner it is done following the onset of symptoms. **Streptokinase (STK)**is a thrombolytic agent is utilised to dissolve clots. It is administered intravenously. Adverse consequences including nausea, haemorrhage, hypotension and allergic reactions.

Tenecteplase is a modified form of the native tissue-type Plasminogen Activator(tPA) molecule.

The approximate half-life of 18minutes permits single-bolus delivery.

Tenecteplase was linked to a reduced occurrence of non-cerebral bleeds and adiminished.

2. Aims and Objective

Aim

To study Comparative efficacy and safety of thrombolytics (Streptokinase v/s Tenecteplase) based on ECG changes in STEMI patients.

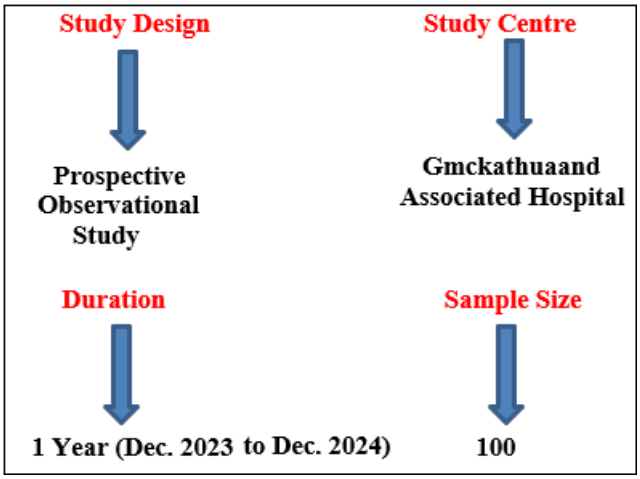
Objectives

Primary-

To study the efficacy of trombolytics (streptokinase and tenecteplase) in STEMI patients.

Secondary-

To assess safety and compare the outcomes of both fibrinolytics based on ECG changes.



3. Material and Methodology

Sampling technique: Simple random sampling method was used to include the sample in the study.

Inclusion and Exclusion criteria The study subjects were chosen as per the inclusion and exclusion criteria:

Inclusion Criteria

1) Patient above 18 yr of age to 80 yr of age
2) Witten informed consent
3) Presence of any two of the following were included:
   a) Chest pain consistent with acute myocardial infarction of <12hour duration
   b) Electrocardiography changes i.e ST elevation > 0.2mv in at least two contiguous chest leads or >0.1mv in at least two contiguous limb leads.
   c) New or presumablynew left bundle branch block on electrocardiography;
   d) Raised levels of cardiac enzymes (CPK-MB) more than double of reference value or positive troponin I/T test.

Exclusion criteria

1) Patients with non-ST elevation myocardial infarction (NSTEMI)
2) Subjects who were not given thrombolytics due to contraindications to the therapy
3) Thrombolytics given in other hospitals
4) Symptoms to needle time of more than 24 hours and patient who had undergone primary angioplasty
5) Hemorrhagic stroke (previous or acute)

Methodology

This prospective interventional study will be conducted in the department of General Medicine on STEMI patients who will receive fibrinolytic therapy (**Streptokinase:** Dose- 1.5 million units in 100ml NS over 60 minutes intravenous v/s **Tenecteplase:** Dose-

Dose- Depends on weight of patient
<60Kg- 6ml or 30 mg
60- 70Kg- 7ml or 35mg
70- 80 Kg- 8ml or 40mg
80- 90 KG- 9ml or 45 mg
> 90kg- 10 ml or 50mg

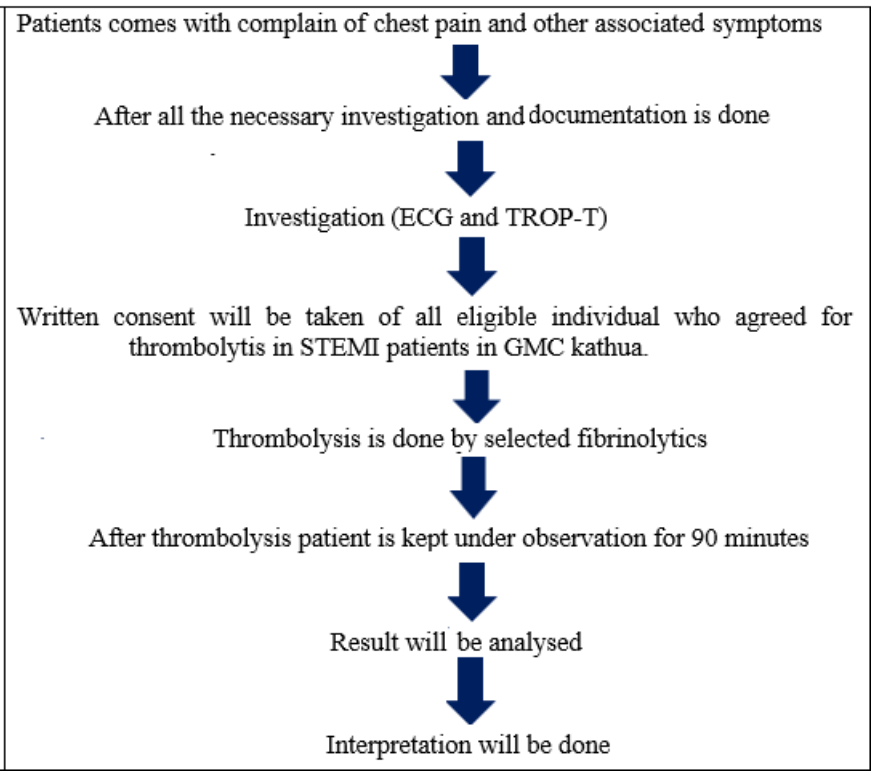
Route–intravenousbolus 15 mg over 10 seconds

Followed by 50 mg i/v in first 30 minutes

Followed by 35 mg over next 60 minutes

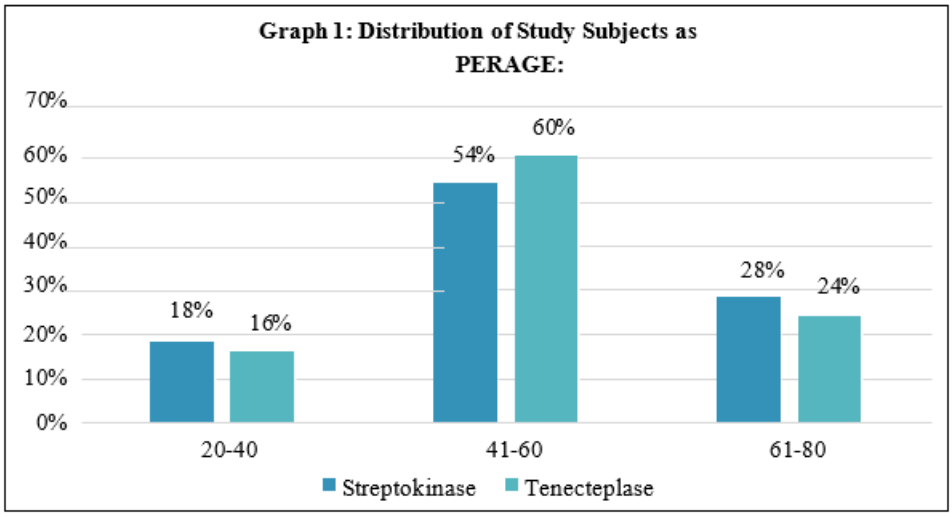
Interpretation: After Receiving the therapy (1) The ECG changes was interpreted after 90 minutes and it was effective by decreasing 30-50% ST segmenton ECG or (2) decrease in chest pain of patients (3) And monitored for any adverse drug reaction bleeding from any part of body, hypotension, etc.

Procedure Planned

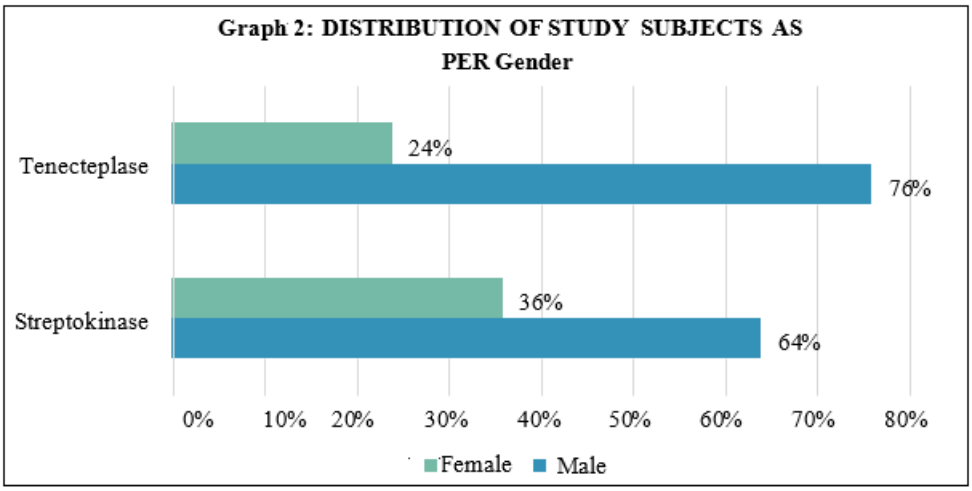


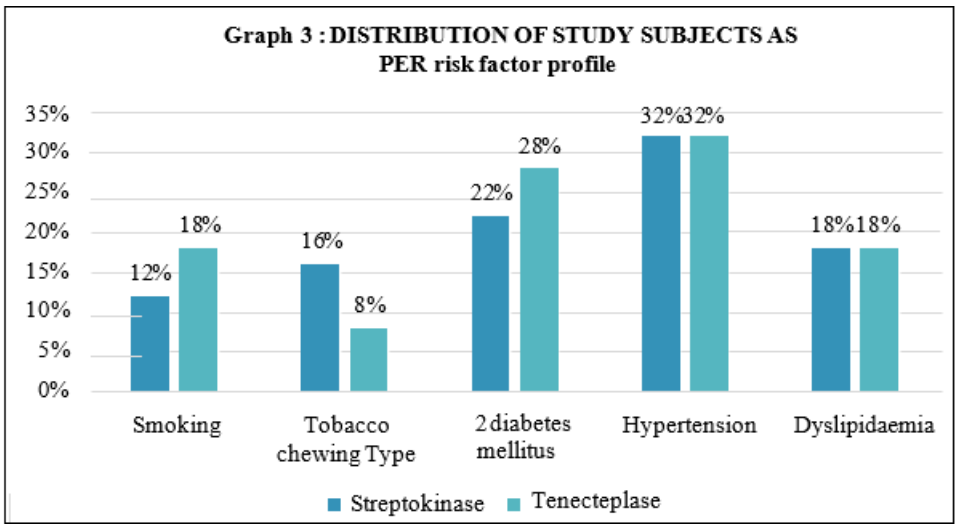
4. Observation and Results

The results of this study on the comparative efficacy and safety of thrombolytics (Streptokinase vs Tenecteplase) based on ECG changes in STEMI patients provide valuable insights into the differential impact of the seagents on myocardial reperfusion. The analysis focuses on key electrocardiographic parameters, including ST-segment resolution, arrhythmic events, and overall clinical outcomes.

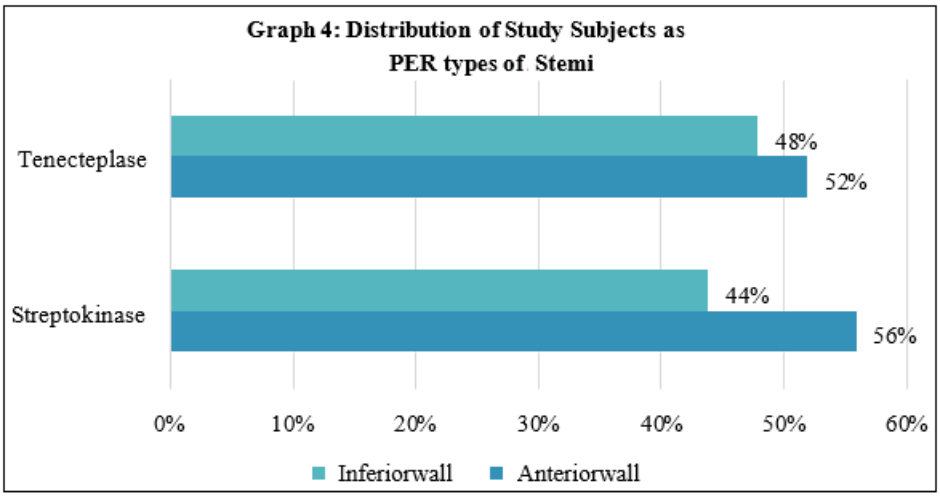


Both treatment groups included a total of 50 subjects each. The mean age of subjects in the Streptokinase group was 59.6 years with a standard deviation of 8.7, while the Tenecteplase group had a mean age of57 years with a standard deviation of 9.2.



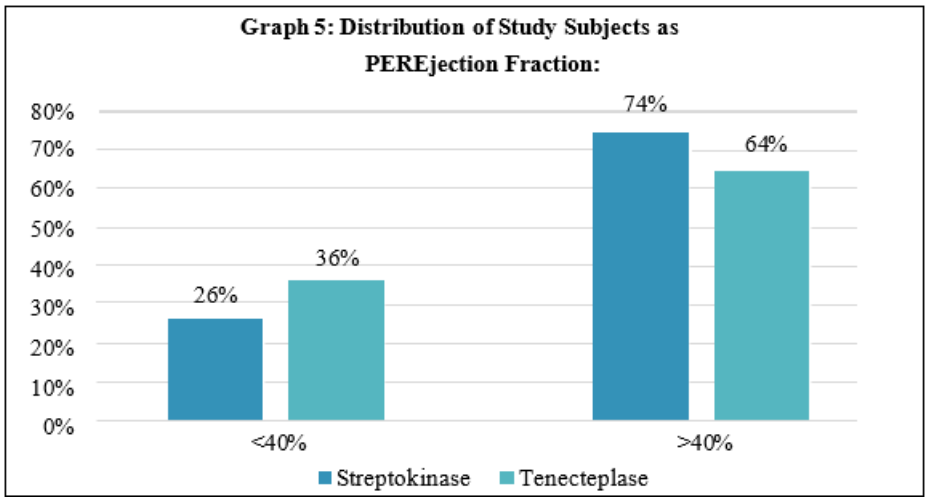


Smoking was reported in 12% (6subjects) of the Streptokinase group and 18% (9 subjects) of the Tenecteplase group. Tobacco chewing was observed in 16% (8 subjects) of the Streptokinase group and 8% (4 subjects) of the Tenecteplase group. Type 2 diabetes mellitus was present in 22% (11 subjects) of the Streptokinase group and 28% (14subjects) of the Tenecteplase group. Hypertension was found in an equal proportion of 32% (16 subjects) in both groups. Dyslipidemia was also equally distributed, affecting18% (9 subjects) in each group.

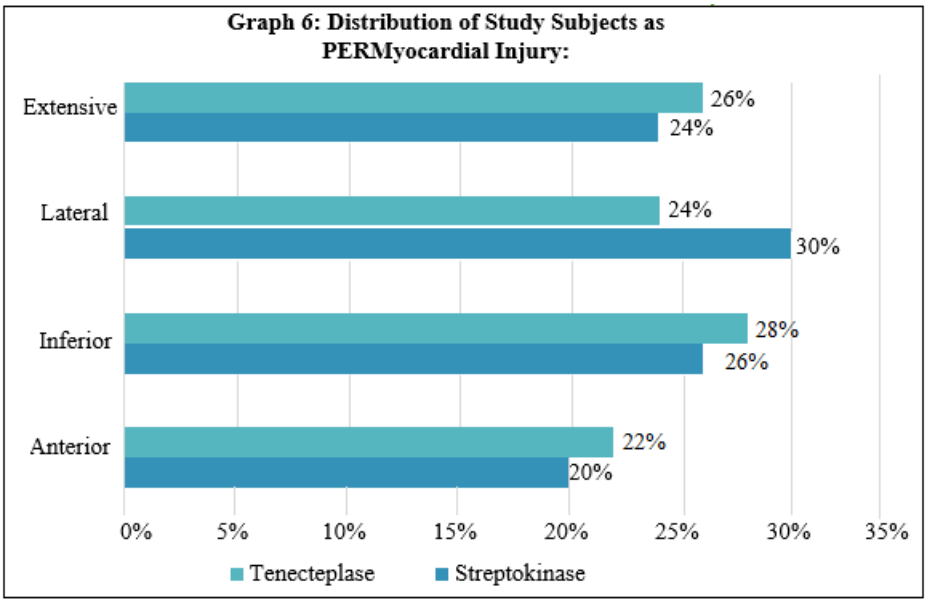


Anterior wall STEMI was observed in 56% (28 subjects) of the Streptokinase group and 52% (26 subjects) of the Tenecteplase group. Inferior wall STEMI was presenting 44% (22 subjects) of the Streptokinase group and 48% (24 subjects) of the Tenecteplase group.

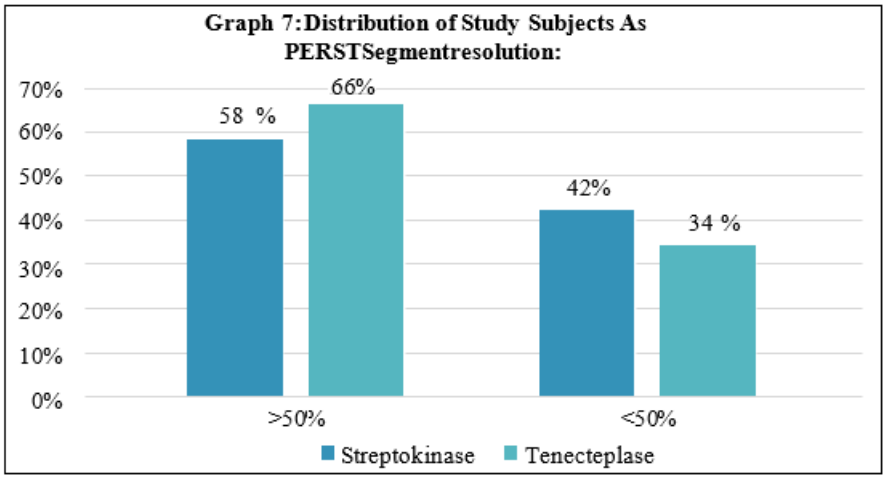
Both treatment groups comprised 50 subjects each.



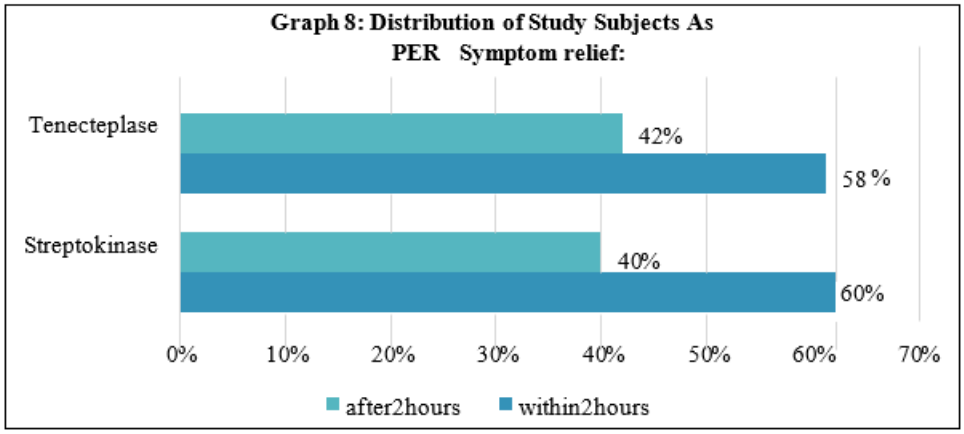
An EF of less than 40% was observed in 26% (13 subjects) of the Streptokinase group and 36% (18 subjects) of the Tenecteplase group. Conversely, an EF greater than 40% was seen in 74% (37 subjects) of the Streptokinase group and 64% (32 subjects) of the Tenecteplase group. Both groups consisted of 50 subjects each.



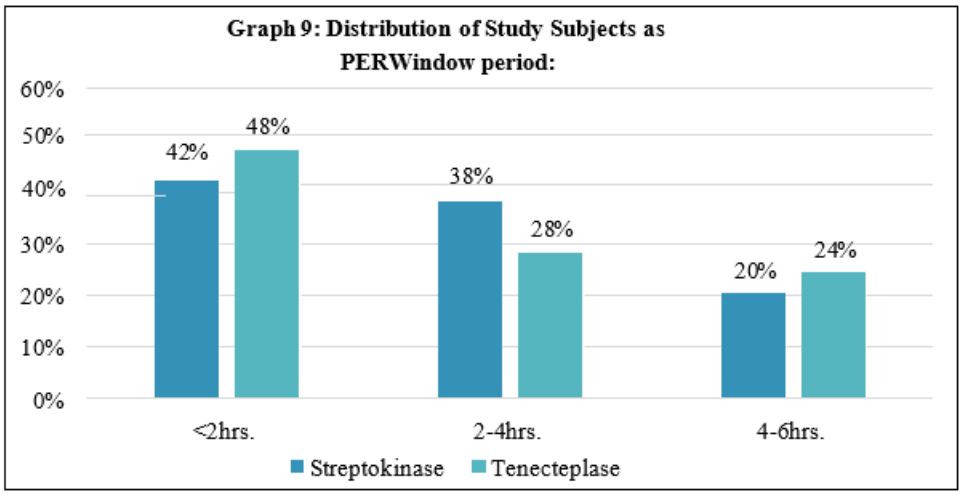
Anterior myocardial injury was observed in 20% (10 subjects) of the Streptokinase group and 22% (11 subjects) of the Tenecteplase group. Inferior myocardial injury occurred in 26% (13 subjects) of the Streptokinase group and 28% (14 subjects) of the Tenecteplase group. Lateral myocardial injury was found in 30% (15 subjects) of the Streptokinase group and 24% (12 subjects) of the Tenecteplase group. Extensive myocardial injury affected 24% (12 subjects) in the Streptokinase group and 26% (13 subjects) in the Tenecteplase group.



The distribution of study subjects based on ST segment resolution was analyzed for the Streptokinase and Tenecteplase groups. ST segment resolution of more than 50% was observed in 58% (29 subjects) of the Streptokinase group and 66% (33 subjects) of the Tenecteplase group. Conversely, ST segment resolution of less than 50% was seen in 42% (21 subjects) of the Streptokinase group and 34% (17 subjects) of the Tenecteplase group. Both treatment groups consisted of 50 subjects each.



The distribution of study subjects based on symptom relief was assessed for the Streptokinase and Tenecteplase groups. Symptom relief within 2 hours was experienced by 60% (30 subjects) of the Streptokinase group and 58% (29 subjects) of the Tenecteplase group. On the other hand, symptom relief after 2 hours was reported by 40% (20 subjects) in the Streptokinase group and 42% (21 subjects) in the Tenecteplase group. Both treatment groups consisted of 50 subjects each.



The distribution of study subjects based on the window period for symptom relief was analyzed for the Streptokinase and Tenecteplase groups. A window period of less than 2 hours was observed in 42% (21 subjects) of the Streptokinase group and 48% (24 subjects) of the Tenecteplase group. For the 2 to 4-hour window period, 38% (19 subjects) of the Streptokinase group and 28% (14 subjects) of the Tenecteplase group experienced symptom relief. In the 4 to 6-hour window period, 20% (10 subjects) of the Streptokinase group and 24% (12 subjects)

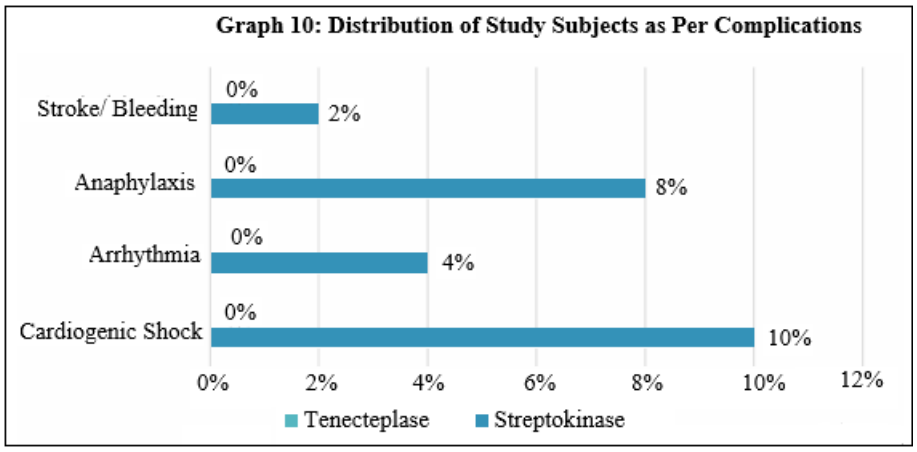


Table 10 presents the distribution of complications among study subjects treated with Streptokinase and Tenecteplase. Among the 50 patients receiving Streptokinase, 10% developed cardiogenic shock, 4% experienced arrhythmias, 8% had anaphylaxis, and 2% suffered from stroke or bleeding complications. In contrast, no complications were observed in the Tenecteplase group. This data suggests that Streptokinase is associated with a higher incidence of adverse effects, particularly cardiogenic shock and anaphylaxis, whereas Tenecteplase appears to be a safer thrombolytic agent with no reported complications in this.

5. Discussion

Study	Ahmad et al 2022	Serpytis et al. (2012)	Hassa n et al. (2021)
Avg Age	54.9	50 to 65	53.5
M> F	54%	3:1	63%
HT N	30%	20%	35%
AW MI			55%
ST resolution	71% (S)	31.9%/ 74.5% (S/T)	95.61%
Complications	More with fast infusion	low	High with S>T

In our study mean age of S/T was 59.6/57 years, majority belongs to 41 to 61 years.

Males constitute higher proportion of participants in both treatment groups with 64%/76% in S/T group respectively.

Prevelance of major CVS risk factors varies between 2 groups HTN 32% and Dyslipidemia 18% were equal in both groups and smoking more frequent in T/S (18/20%).

AWMI was slightly more common in S group then T group (56/52%).

High proportion on ST segment resolution >50% seen with T>S (66% > 58%).

Symptom relief within 2 hours was observed in 60% of Streptokinase- treated patients and 58% of Tenecteplase

treated patients, while delayed symptom relief (>2 hours) was slightly more frequent in the Tenecteplasegroup (42%).

Complications were higher in S as compared to T and mortality at 30days were also higher in S group (2%).

So, overall, our study coincides with Hassan et al (2021) more as compared to other studies.

6. Conclusion

This study provides valuable insights into the comparative efficacy and safety of Streptokinase and Tenecteplase in the management of ST-Elevation Myocardial Infarction (STEMI). The findings indicate that Tenecteplase offers superior clinical outcomes, particularly in terms of higher ST-segment resolution (>50%) and better ejection fraction recovery. Additionally, Tenecteplase demonstrated a significantly lower complication rate, with no reported cases of cardiogenic shock, arrhythmias, anaphylaxis, or stroke/bleeding, unlike Streptokinase. Mortality at 30 days was also lower in the Tenecteplase group, further highlighting its potential as a safer thrombolytic agent. Despite some demographic variations in risk factors and symptom relief timing, Tenecteplase was associated with a more favorable safety profile and improved patient outcomes. Given these findings, Tenecteplase appears to be a more effective and safer option for thrombolysis in STEMI patients compared to Streptokinase. Further large-scale randomized controlled trials are warranted to validate these results and optimize thrombolytic strategies in acute myocardial infarction management.

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