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A Retrospective Institutional Analysis of Tenecteplase Efficacy, Safety, and Systemic Outcomes in Acute Ischemic Stroke and Pulmonary Embolism

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Abstract

Background:
Tenecteplase, a genetically modified tissue plasminogen activator with higher fibrin specificity and a longer half-life, is increasingly used as an alternative to alteplase for thrombolysis. Although randomized trials support its efficacy and safety in AIS (Acute Ischemic Stroke) and PE (Pulmonary Embolism), real-world institutional data remain limited. This study aimed to evaluate the clinical efficacy, safety, and hospital outcomes of tenecteplase in routine practice.***Methods:*** This retrospective institutional cohort study was conducted over one year (January–December 2025) in the emergency medicine department at a tertiary care hospital. Adult patients (≥18 years) diagnosed with AIS or PE and treated with intravenous tenecteplase were included. Data were collected from electronic medical records and stroke and emergency room registers. Outcomes assessed included neurological recovery (NIHSS), functional status (modified Rankin Scale, mRS), mortality, complications, ICU requirement, and need for mechanical ventilation. Statistical analysis was performed using SPSS, with $p < 0.05$ considered significant. ***Results:*** A total of 31 patients were included, with a predominance of males (64.5%) and patients aged >50 years (61.3%). Comorbidities were present in 83.9%. Overall in-hospital mortality was 9.7%, and complications occurred in 16.1%. Among AIS patients (n = 21), there was a significant improvement in neurological status, with mean NIHSS decreasing from 14.48 ± 4.80 at admission to 8.29 ± 4.86 at 24 hours ($p < 0.01$). Haemorrhagic transformation occurred in 9.5%, and 85.7% did not require mechanical ventilation. Favourable functional outcome (mRS 1–2) was observed in 52.4% of AIS patients. In the PE subgroup (n = 10), 90% did not require mechanical ventilation, and bleeding complications were seen in only 10% with shorter ICU stays. ***Conclusion:*** Tenecteplase demonstrated good real-world efficacy and an acceptable safety profile in both AIS and PE, with significant early neurological improvement in stroke patients and low rates of major complications. These findings support its use as an effective thrombolytic option in the emergency department.

Keywords: **Tenecteplase, Acute Ischemic Stroke, Pulmonary Embolism, Thrombolysis.**

INTRODUCTION

Acute ischemic stroke and pulmonary embolism are major medical emergencies associated with significant morbidity and mortality worldwide. Rapid restoration of blood flow using thrombolytic therapy remains a cornerstone of management for both conditions, with the primary goals of improving survival, preserving neurological and cardiopulmonary function, and reducing long-term disability. Although alteplase has traditionally been the standard thrombolytic agent, increasing attention has been directed toward tenecteplase as a viable alternative.

Tenecteplase is a genetically modified tissue plasminogen activator with higher fibrin specificity, greater resistance to plasminogen activator inhibitor-1, and a longer half-life compared to alteplase. These pharmacological advantages allow single-bolus intravenous administration, simplifying treatment

protocols and potentially reducing door-to-needle times in emergency department.[1,2] Such workflow benefits are particularly relevant in high-volume ER.

In AIS, evidence from randomized controlled trials and meta-analyses demonstrates that tenecteplase is non-inferior to alteplase in achieving functional independence, as measured by modified Rankin Scale scores of 0–2, with comparable rates of symptomatic intracranial hemorrhage and mortality.[3-5] Emerging data suggest possible advantages in patients with large vessel occlusions, especially when endovascular thrombectomy is delayed or not immediately available.[6,7]
Similarly, in PE, tenecteplase has shown benefit in selected patient populations. In high-risk PE, thrombolysis with tenecteplase improves short-term survival without a significant increase in major bleeding. In intermediate-risk PE, it reduces right ventricular dysfunction and the risk of hemodynamic decompensation, although at the cost of a higher bleeding risk, emphasizing the need for careful patient selection.[1,3,4]

Despite growing evidence from clinical trials, real-world data on tenecteplase use across AIS and PE remain limited, particularly at the institutional level in emergency room. Variations in patient characteristics, treatment pathways, and resource availability may influence outcomes. Therefore, this retrospective institutional study was undertaken to evaluate the real-world efficacy, safety, and systemic outcomes of tenecteplase in patients with AIS and PE, with the aim of informing evidence-based clinical practice and optimizing thrombolytic strategies in the emergency room.

AIMS AND OBJECTIVES

The study aimed to evaluate the real-world use of tenecteplase in patients with acute ischemic stroke and pulmonary embolism. Specifically, the study seeks to assess the clinical efficacy and safety of tenecteplase while also analyzing hospital- and patient-related outcomes such as length of hospital stay, need for intensive care, discharge status, and factors influencing successful treatment, with the goal of improving patient selection and optimizing institutional treatment protocols in emergency department.

MATERIALS AND METHODS

Study Design

This study was designed as a retrospective institutional cohort analysis conducted at a single tertiary care hospital over a one-year period from January 2025 to December 2025. Consecutive adult patients admitted to the emergency room who received intravenous tenecteplase for the management of acute ischemic stroke or pulmonary embolism were included. Clinical and treatment-related data were obtained from electronic medical records, MRD (Medical Records Department) files, and the ER (Emergency Room) stroke register to evaluate efficacy, safety, and hospital outcomes in a real-world clinical setting.

Inclusion and Exclusion Criteria

The study included adult patients aged 18 years or older with a clinical diagnosis of acute ischemic stroke or pulmonary embolism confirmed by appropriate imaging modalities (CT/CTA/MRI for stroke and CTPA or echocardiography for pulmonary embolism) who received intravenous tenecteplase as part of acute management in the emergency room within the guideline-recommended therapeutic time window during the study period. Only patients with adequate clinical documentation allowing extraction of baseline characteristics, treatment details, and key outcomes were included. Patients were excluded if they had received another thrombolytic agent such as alteplase prior to tenecteplase for the same event, were on active therapeutic anticoagulation, had incomplete or missing essential clinical or outcome data, or had known contraindications to thrombolytic therapy at the time of treatment, including active major bleeding or intracranial neoplasm. Patients who were pregnant or had a terminal illness with an expected survival of less than 48 hours unrelated to the index event were also excluded from the analysis.

Data Collection Procedure

Eligible cases were identified retrospectively using electronic medical records, MRD files, and the emergency room stroke register. Relevant patient information, including demographic details, clinical presentation, imaging findings, treatment timings, adjunct therapies, and outcome measures, was systematically extracted. Data were recorded using a standardized data collection form to ensure uniformity, completeness, and accuracy across all study variables.

Statistical Analysis

Data were entered into Microsoft Excel and analyzed using SPSS software (version 22 and version 27; IBM SPSS Statistics, Somers, NY, USA). Categorical variables were summarized as frequencies and proportions, while continuous variables were expressed as mean and standard deviation. The paired t-test was used to assess the significance of changes in neurological status by comparing NIHSS scores at admission and at 24 hours. Graphical representations were generated using Microsoft Excel and Microsoft Word. A p-value of less than 0.05 was considered statistically significant, assuming that all underlying assumptions for the applied statistical tests were met.

RESULTS

		N	%
Age Group	<40yrs	5	16.1%
	41-50 yrs.	7	22.6%
	51-60 yrs.	4	12.9%
	61-70 yrs.	7	22.6%
	>70 yrs.	8	25.8%
Gender	Female	11	35.5%
	Male	20	64.5%
Comorbidities	No	5	16.1%
	Yes	26	83.9%

Table 1: Demographic Profile of Study Subjects

The study population showed a broad age distribution, with the majority of patients being middle-aged or elderly. More than two-thirds (61.3%) were above 50 years of age, and the highest proportion belonged to the >70-year age group (25.8%). This reflects the typical epidemiology of thrombotic conditions such as acute ischemic stroke and pulmonary embolism, which are more common in older adults.

There was a clear male predominance, with males accounting for 64.5% of the cohort. Additionally, a large majority (83.9%) had one or more comorbidities, highlighting a population with significant baseline health risks. These characteristics indicate that tenecteplase was administered mainly to higher-risk patients, which is representative of real-world clinical practice.

		N	%
Mortality	No	28	90.3%
	Yes	3	9.7%
Complication	No	26	83.9%
	Yes	5	16.1%

Table 2: Study Outcome

The outcomes following tenecteplase administration were generally favourable. The mortality rate was low at 9.7%, indicating that the majority of patients (90.3%) survived during the hospital stay. Complications were also relatively uncommon, occurring in only 16.1% of cases, while 83.9% experienced no adverse events. These findings suggest that tenecteplase demonstrated a good safety profile in real-world clinical use, even among a population with a high burden of comorbidities.

Acute Ischemic Stroke Subgroup

	Mean	SD	P-value
NIHSS on admission	14.48	4.802	<0.01
NIHSS at 24 hrs	8.29	4.859	

Table 3

Among the AIS patients (n = 21), there was a statistically significant improvement in neurological status after thrombolysis. The mean NIHSS score reduced from 14.48 at admission to 8.29 at 24 hours ($p < 0.01$), indicating rapid and meaningful neurological recovery.

		N	%
Mechanical ventilation	No	18	85.7%
	Yes	3	14.3%
Haemorrhagic transformation	No	19	90.5%
	Yes	2	9.5%

Table 4

The majority of stroke patients (85.7%) did not require mechanical ventilation, and hemorrhagic transformation occurred in only 9.5%, consistent with known safety rates of thrombolytic therapy.

Modified Rankin Score	N	%
1	1	4.8%
2	10	47.6%
3	7	33.3%
4	1	4.8%
6	2	9.5%
Table 5		

In this study, functional outcomes among patients with acute ischemic stroke treated with tenecteplase showed that over half of the patients achieved good functional recovery. Specifically, 52.4% had an mRS score of 1–2, indicating independence in daily activities. One-third of patients (33.3%) had moderate disability (mRS 3), while severe disability (mRS 4) was observed in only 4.8%. Mortality, represented by mRS 6, occurred in 9.5% of cases. Overall, these results suggest that tenecteplase therapy resulted in favourable early functional outcomes for a substantial proportion of patients and also a lesser ICU stay.

Pulmonary Embolism

		N	%
Mechanical Ventilation	No	9	90%
	Yes	1	10%
Haemorrhagic Transformation	No	9	90%
	Yes	1	10%
Table 6			

The majority of stroke patients (90%) did not require mechanical ventilation, and haemorrhagic transformation occurred in only 10%, consistent with known safety rates of thrombolytic therapy.

DISCUSSION

The present retrospective institutional analysis evaluated the real-world efficacy, safety, and systemic outcomes of tenecteplase in patients with AIS and PE. The study population predominantly consisted of older adults with a high burden of comorbidities, which reflects routine clinical practice rather than controlled trial environments. Similar demographic characteristics, including male predominance and advanced age, have been reported in previous thrombolysis studies involving AIS and PE, supporting the external validity of the present findings.[1,3]

Overall in-hospital mortality in this study was 9.7%, and complications were observed in 16.1% of patients. These outcomes are comparable to previously published real-world data and meta-analyses that demonstrated acceptable safety and mortality rates with tenecteplase in both AIS and PE.[2-4] Importantly, the low complication rate observed in this cohort is notable given the significant baseline comorbidities, reinforcing the tolerability of tenecteplase in higher-risk patients.[2]

In the AIS subgroup, there was a statistically significant improvement in neurological status, with mean NIHSS scores decreasing from 14.48 at admission to 8.29 at 24 hours ($p < 0.01$). Early neurological improvement following tenecteplase administration has been consistently reported in randomized controlled trials and observational studies, indicating effective reperfusion and rapid clot resolution.[5,7] The degree of NIHSS reduction observed in this study is comparable to findings from the NOR-TEST and ATTEST trials, both of which demonstrated meaningful early neurological recovery with tenecteplase thrombolysis.[5,7]

Hemorrhagic transformation occurred in 9.5% of AIS patients, which is within the range reported in prior systematic reviews and meta-analyses.[4,7] Additionally, the majority of AIS patients (85.7%) did not require mechanical ventilation. Functional outcomes were favorable, with 52.4% achieving good functional independence (mRS 1–2) at discharge. These findings are consistent with studies by Campbell et al. and Nielsen et al., which demonstrated non-inferiority of tenecteplase compared with alteplase in terms of functional outcomes and safety.[4,6]

In patients with pulmonary embolism, tenecteplase was associated with favourable short-term outcomes, with 90% of patients not requiring mechanical ventilation and a low incidence of hemorrhagic complications (10%). Prior studies have shown that tenecteplase improves hemodynamic parameters and survival in

high-risk PE and reduces right ventricular dysfunction in intermediate-risk PE, albeit with a recognized bleeding risk.[1,3] The low bleeding rate and lesser ICU days observed in this study underscore the importance of appropriate patient selection and adherence to institutional thrombolysis protocols.[1]

The role of tenecteplase as an effective thrombolytic agent in acute ischemic stroke and pulmonary embolism. A comprehensive pooled analysis by Burgos and Saver demonstrated that tenecteplase is associated with higher rates of early recanalization and early neurological improvement compared with alteplase, particularly in patients with large vessel occlusion strokes.[8] This supports the early NIHSS improvement observed in the present study and reinforces the biological plausibility of tenecteplase's rapid reperfusion effect.

Real-world registry data have also echoed these findings. The EXTEND-IA TNK trials showed that tenecteplase achieved superior reperfusion prior to thrombectomy and improved functional outcomes without an increase in symptomatic intracranial haemorrhage, further validating its safety profile in routine clinical practice.[9] These results align with the favourable functional outcomes and low haemorrhagic transformation rates observed in our AIS cohort.

In pulmonary embolism, observational studies and meta-analyses have highlighted that tenecteplase leads to rapid improvement in right ventricular function and pulmonary artery pressures, translating into early hemodynamic stabilization.[10] Although bleeding risk remains a concern, especially in intermediate-risk PE, careful patient selection and protocol-driven dosing have been shown to significantly mitigate this risk.[11] The low rate of haemorrhagic complications seen in our PE subgroup is consistent with these reports.

Additionally, economic and workflow analyses suggest that tenecteplase may offer practical advantages over alteplase due to its single-bolus administration, reduced need for infusion pumps, and potential reduction in door-to-needle times.[12] These systemic benefits are particularly relevant for high-volume emergency rooms and may indirectly contribute to improved patient outcomes by minimizing treatment delays.

Taken together, the growing body of evidence from randomized trials, real-world registries, and meta-analyses supports the expanding role of tenecteplase as a safe, effective, and operationally efficient thrombolytic agent. The findings of the present study add institution-specific real-world data to this evidence base and further support the integration of tenecteplase into standardized protocols for the management of AIS and PE in ER.

CONCLUSION

This institutional study demonstrates that tenecteplase is an effective and safe thrombolytic agent for the management of acute ischemic stroke and pulmonary embolism in real-world clinical practice. Significant early neurological improvement was observed in stroke patients, with favourable functional outcomes and a low incidence of haemorrhagic complications, while patients with pulmonary embolism showed good hemodynamic stability, fewer ICU days and minimal bleeding events. Despite the high prevalence of comorbidities in the study population, overall mortality and complication rates remained low. These findings support the use of tenecteplase as a practical alternative to alteplase, offering comparable efficacy with operational advantages, and reinforce its role in optimized, evidence-based thrombolytic protocols in the ER.

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