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Clinical Study on Tenecteplase for Intravenous Thrombolysis in Acute Ischemic Stroke

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Abstract: *Objective*: To investigate the efficacy, safety, and comparative advantages of intravenous thrombolytic therapy with tenecteplase versus alteplase in the treatment of acute ischemic stroke. *Methods*: A total of 60 patients with acute ischemic stroke who were admitted to the neurology ward of the hospital within 4.5 hours of onset from 2022 to 2024 were enrolled. Among them, 30 patients in the observation group received intravenous thrombolysis with tenecteplase, while the other 30 patients in the control group received intravenous thrombolysis with alteplase. The clinical efficacy of the two groups was compared. *Results*: The NIHSS scores of both groups at 1 hour, 24 hours, 72 hours, and 7 days after thrombolysis were lower than those before thrombolysis, and the Barthel index at 90 days after thrombolysis was higher than that before thrombolysis. The overall response rates of the observation group at 1 hour, 24 hours, 72 hours, and 7 days after thrombolysis were higher than those of the control group ($P < 0.05$). There were no significant differences in the incidence of adverse reactions and mortality between the two groups after thrombolysis ($P > 0.05$). The observation group had a higher rate of favorable functional outcomes and a higher Barthel index at 90 days after thrombolysis compared to the control group ($P < 0.05$). *Conclusion*: Tenecteplase can enhance early neurological function and improve functional outcomes in patients with ischemic stroke without increasing the incidence of adverse reactions.

Keywords: Tenecteplase; Alteplase; Intravenous thrombolytic therapy; Acute ischemic stroke; Clinical study

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1. Introduction

Acute ischemic stroke (AIS) is one of the leading cerebrovascular diseases globally in terms of disability and mortality rates, accounting for 60% to 80% of all stroke cases [1]. Ischemic stroke, also known as cerebral infarction, is typically caused by thrombosis or arterial stenosis, which interrupts the blood supply to the brain. Currently, the incidence of AIS in China is on the rise year by year. Within the first hour after onset, a 10% reduction in cerebral blood flow increases the risk of neurological impairment by 12%, imposing a significant burden on society and families. Restoring blood perfusion to the ischemic brain tissue is the core objective of AIS treatment, with intravenous thrombolysis being a clinically recognized effective method for recanalization [2]. As

a traditional thrombolytic agent, recombinant tissue plasminogen activator (rtPA) can improve patient prognosis but has limitations such as a narrow therapeutic time window (within 4.5 hours of onset), the need for continuous intravenous infusion, and a relatively high risk of bleeding, restricting its clinical application [3–4]. Tenecteplase, a third-generation thrombolytic agent, has been genetically engineered to optimize its pharmacokinetic properties, offering advantages such as a longer half-life, higher fibrin specificity, and simpler administration. In recent years, it has become a research hotspot in AIS thrombolytic therapy. Current studies indicate that tenecteplase is not inferior to rtPA in terms of vascular recanalization rates and neurological improvement, and may even have advantages in patients with large vessel occlusion [5]. However, research on its applicability in special populations (such as the elderly and those with comorbidities) and its long-term prognostic impact remains insufficient. Based on this, this study investigates the efficacy and safety of intravenous thrombolysis with tenecteplase for AIS, providing clinical evidence to optimize thrombolytic treatment protocols for AIS.

2. Materials and methods

2.1. General information

A total of 60 patients with acute ischemic stroke who were admitted to the neurology ward of the hospital within 4.5 hours of onset from 2022 to 2024 were selected as the study subjects. There were no statistically significant differences between the two groups in terms of age, gender, hypertension, diabetes, etc.

Inclusion Criteria: (1) All patients met the relevant criteria in the Chinese Guidelines for the Diagnosis and Treatment of Acute Ischemic Stroke 2018 based on clinical diagnosis [6]. (2) Patients provided informed consent and signed the informed consent form.

Exclusion Criteria: (1) Patients with severe organ diseases or mental illnesses. (2) Patients with drug allergies. (3) Patients who withdrew from the study midway.

2.2. Methods

The control group received alteplase thrombolysis: The thrombolytic dose of alteplase (Boehringer Ingelheim Pharma GmbH & Co. KG, 50 mg, National Medical Products Administration Approval Number S20020034) was 0.9 mg/kg (with a maximum dose not exceeding 90 mg). The initial dose, which was 10% of the total dose, was administered intravenously as a bolus and completed within 1 minute. The remaining 90% of the dose was diluted in 150 ml of 0.9% saline and infused intravenously using a pump over 1 hour.

The observation group received tenecteplase thrombolysis: Sixteen milligrams of tenecteplase (Mingfule Tenecteplase Injection produced by Guangzhou Mingkang Bioengineering Co., Ltd., $1.0x10^7$IU/16 mg/vial, National Medical Products Administration Approval Number S20150001) was dissolved in 3 ml of 0.9% saline and administered intravenously as a bolus, with the injection completed within 10 seconds.

2.3. Observation indicators

(1) Comparison of NIHSS scores and Barthel index before and after treatment between the two groups: NIHSS scores of the two groups were recorded before thrombolysis and at 1 hour, 24 hours, 72 hours, and 7 days after thrombolysis. The Barthel index before thrombolysis was also recorded. At the 90-day follow-up, the MRS scores and the Barthel index of the two groups were evaluated.

(2) Comparison of clinical efficacy between the two groups.

(3) Comparison of the incidence of adverse reactions between the two groups: The occurrence of adverse

reactions such as intracranial hemorrhage and allergic reactions was observed.

2.4. Statistical methods

All data in this study were analyzed statistically using SPSS 26.0 statistical software. Measurement data were described as mean ± standard deviation (Mean ± SD). After normality and homogeneity of variance tests, for data that conformed to a normal distribution and had homogeneous variances, independent sample t-tests were used for inter-group comparisons. Count data were described as the number of cases and rate (%), and chi-square (x^2) tests were used for inter-group comparisons. In this study, a *P*-value < 0.05 was set as the level of statistical significance for differences.

3. Results

3.1. Comparison of NIHSS scores and the Barthel index before and after treatment between the two groups

The NIHSS scores of both groups at 1 hour, 24 hours, 72 hours, and 7 days after thrombolysis were lower than those before thrombolysis, and the Barthel index at 90 days after thrombolysis was higher than that before thrombolysis ($P < 0.05$), as shown in **Table 1**.

Table 1. Comparison of NIHSS scores before and after treatment between the two groups (Mean ± SD, points)

Group	Number of Cases	Before Treatment	1h Post-treatment	24h Post-treatment	72h Post-treatment	7d Post-treatment	Number of Cases	Before Treatment	After Treatment
Control Group	30	16.83 ± 5.59	15.72 ± 2.62	12.41 ± 3.28[a]	9.46 ± 2.15[a]	7.28 ± 1.54[a]	30	40.93 ± 2.71	51.96 ± 2.31[a]
Observation Group	30	16.85 ± 5.61	16.02 ± 2.58	11.99 ± 2.53[a]	9.15 ± 2.56[a]	7.08 ± 1.38[a]	30	41.33 ± 2.52	60.65 ± 3.67[a]
t		0.014	0.447	0.555	0.508	0.530		0.592	10.976
P		0.989	0.657	0.581	0.614	0.598		0.556	0.001

Note: Compared with the same group, [a]$P < 0.05$.

3.2. Comparison of clinical efficacy between the two groups

The total effective rate of treatment in the observation group after thrombolysis was higher than that in the control group ($P < 0.05$), as shown in **Table 2**.

Table 2. Comparison of clinical efficacy between the two groups

Group	n	Markedly Effective	Effective	Ineffective	Overall Response Rate (%)
Control Group	30	12 (40.00)	14 (46.67)	4 (13.33)	86.67
Observation Group	30	14 (46.67)	15 (50.00)	1 (3.33)	96.67
x^2 value	-	-	-	-	5.304
P value	-	-	-	-	0.021

3.3. Comparison of the incidence of adverse reactions between the two groups

During the treatment process, the observation group experienced oral mucosal bleeding in 3 cases, bleeding from the tip of the tongue in 1 case, and gingival bleeding in 4 cases. The control group experienced oral mucosal bleeding in 3 cases, bleeding from the tip of the tongue in 1 case, and gingival bleeding in 5 cases. Neither group exhibited allergic reactions to thrombolytic drugs during treatment, and no deaths occurred. There were no significant differences in the incidence of adverse reactions and mortality rates between the two groups after thrombolysis.

4. Discussion

This study, by comparing the clinical data of tenecteplase and alteplase in the treatment of acute ischemic stroke (AIS), confirms that tenecteplase has significant advantages in accelerating early neurological recovery and optimizing long-term functional outcomes, while its safety profile is comparable to that of alteplase. These findings are highly consistent with the conclusions of multiple core studies both domestically and internationally, providing localized evidence to support the use of tenecteplase in routine clinical thrombolysis [7].

This study demonstrates that tenecteplase exhibits prominent early therapeutic efficacy. From 1 to 7 days after thrombolysis in the observation group, the reduction in NIHSS scores and the overall effective rate were significantly higher than those in the control group, which is directly related to its unique pharmacological properties. As a third-generation thrombolytic agent, tenecteplase, through modifications at three key amino acid sites, not only increases fibrin specificity by 15-fold but also significantly enhances resistance to plasminogen activator inhibitor-1 (PAI-1) [8]. This characteristic allows it to more easily establish a high-concentration thrombolytic environment at the site of the thrombus, rapidly dissolving the clot while reducing activation of the overall fibrinolytic system, thereby enabling effective blood flow restoration within the early stages (within 1 hour) of onset [9]. Alteplase has a half-life of less than 5 minutes, requires continuous intravenous infusion, and is rapidly inactivated by PAI-1 in the circulation, which may result in suboptimal early thrombolytic effects in some patients. The findings of this study echo the more pronounced early neurological improvement observed in the tenecteplase group in the ORIGINAL trial, further highlighting its thrombolytic advantages within the time window [10]. In terms of long-term prognosis, at the 90-day follow-up point after thrombolysis, the Barthel index and the rate of favorable functional outcomes were significantly higher in the observation group, reflecting the sustained therapeutic effect of tenecteplase. The key mechanism underlying this result is the protective effect of early effective reperfusion on the ischemic penumbra [11]. Within 4.5 hours of AIS onset, the ischemic penumbra remains reversible, and tenecteplase's rapid and efficient thrombolytic capability can minimize the extent of ischemic brain tissue necrosis, providing support for neurological recovery. The BRIDGE-TNK study also indicated that tenecteplase bridging thrombectomy can increase the rate of functional independence by 8.8% in patients with large vessel occlusion, with long-term benefits directly related to the quality of early reperfusion [12]. In this study, both groups received treatment within the time window, but the tenecteplase group had better long-term outcomes, revealing the value of the treatment chain of "efficient early reperfusion — reduced neurological damage — promoted functional recovery." Safety is a core consideration in thrombolytic therapy. This study shows no significant differences in the incidence of adverse reactions and mortality rates between the two groups, which aligns with the advantages presented by tenecteplase's pharmacological design. Its high fibrin specificity reduces the risk of systemic bleeding, while the single-bolus administration method (eliminating the need for

continuous infusion) simplifies the procedure and reduces the risk of improper dosing. The ORIGINAL trial, after analyzing 1,489 Chinese patients, showed that the incidence of symptomatic intracranial hemorrhage was only 1.2% for both tenecteplase and alteplase, further confirming its safety in the Chinese population [13]. However, it should not be overlooked that tenecteplase's weight-based precise dosing regimen is well-suited for the majority of thrombolytic patients in China, preventing the risks of underdosing and overdosing. Nevertheless, this study has certain limitations: the single-center inclusion of 60 cases represents a relatively small sample size, which may affect the generalizability of the results; no stratified analysis was conducted for special subgroups such as those with large vessel occlusion or elderly patients (≥80 years old), while the ORIGINAL trial suggested that tenecteplase treatment may confer greater benefits to elderly patients [14]; the follow-up period was only 90 days, lacking longer-term prognostic data. Subsequent studies should involve multi-center, large-sample research focusing on differences in efficacy among special populations and the optimization of individualized dosing regimens.

5. Conclusion

In summary, tenecteplase achieves superior neurological improvement and long-term outcomes through efficient early reperfusion, with a safety profile generally comparable to that of alteplase. Combined with the advantage of convenient administration, it may become the preferred drug for thrombolytic therapy within the time window for AIS. Its clinical application should strictly adhere to weight-based dosing principles, while further strengthening monitoring of efficacy in special populations to provide more robust pharmacological support for the principle of "time is brain" in stroke treatment.

Disclosure statement

The authors declare no conflict of interest.

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