Scientific Research Publishing

Health, 2025, 17(10), 1242-1251
https://www.scirp.org/journal/health
ISSN Online: 1949-5005
ISSN Print: 1949-4998

Observation on the Clinical Efficacy of Intravenous Thrombolysis with Alteplase in Acute Ischemic Stroke across Different Age Groups

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How to cite this paper: Huang, J. and Zhou, Q. (2025) Observation on the Clinical Efficacy of Intravenous Thrombolysis with Alteplase in Acute Ischemic Stroke across Different Age Groups. *Health*, **17**, 1242-1251.
https://doi.org/10.4236/health.2025.1710082

Received: September 19, 2025
Accepted: October 19, 2025
Published: October 22, 2025

Abstract

Objective: Analyzing the differences in clinical efficacy and safety of intravenous thrombolysis with alteplase in patients with acute ischemic stroke across different age groups. **Methods:** A retrospective analysis was conducted on 319 patients with acute ischemic stroke who received intravenous thrombolysis with alteplase within 4.5 hours of onset. These patients were treated in the Cerebrovascular Disease Department of Zhuhai People's Hospital between April 2019 and December 2024. Their ages ranged from 29 to 93 years (mean age 66.34 ± 12.79). The patients were divided into five age groups: Group A (29 - 49 years, n = 24), Group B (50 - 59 years, n = 85), Group C (60 - 69 years, n = 78), Group D (70 - 79 years, n = 78), and Group E (>80 years, n = 54). The study compared major risk factors across age groups, NIHSS scores before thrombolysis and at 24 hours and 7 days after thrombolysis, clinical efficacy, modified Rankin Scale (mRS) scores at discharge, and the incidence of post-thrombolysis bleeding events (including intracranial bleeding, oral bleeding, subcutaneous bleeding, and gastrointestinal bleeding) among the different age groups. **Results:** Statistically significant differences were observed among the five groups in terms of age, BMI, smoking, alcohol consumption, diabetes, hypertension, and the prevalence of atrial fibrillation ($P < 0.05$). Significant differences were also found in NIHSS scores before thrombolysis, at 24 hours, and at 7 days after thrombolysis ($P < 0.05$). However, no significant difference was detected in the overall cure rate among the groups ($P > 0.05$). In contrast, significant differences were observed in the total bleeding rate ($P < 0.05$) and the mortality rate ($P < 0.05$). **Conclusion:** Patients with ischemic stroke across different age groups can benefit from intravenous thrombolysis; however, the

risk of post-thrombolysis bleeding and mortality increases with age.

Keywords

Acute Ischemic Stroke, Alteplase, Intravenous Thrombolysis, Age, Clinical Efficacy

1. Introduction

Acute ischemic stroke (AIS) is a leading cause of disability and mortality. Currently, intravenous thrombolysis is one of the most effective treatments for AIS within the therapeutic time window. It can promptly and effectively improve blood perfusion in the damaged brain area, salvage the ischemic penumbra, restore neurological function, and reduce disability and mortality rates [1]. With the aging of the population, the number of AIS patients has increased significantly; however, the proportion of elderly AIS patients receiving intravenous thrombolysis remains relatively low [2]. The safety and efficacy of thrombolytic therapy in very elderly AIS patients have attracted considerable attention. Studies have shown that advanced age is associated with reduced vascular recanalization rates and increased risk of bleeding, yet systematic analyses of differences across specific age groups are still lacking, especially regarding the efficacy and safety of thrombolysis in patients over 80 years old. This study retrospectively analyzed data from AIS patients who received intravenous alteplase thrombolysis within 4.5 hours of onset at the Department of Cerebrovascular Diseases, Zhuhai People's Hospital over the past five years. The aim was to evaluate the clinical outcomes of intravenous alteplase thrombolysis across different age groups, particularly in patients aged over 80, so as to provide evidence for individualized thrombolytic treatment in AIS.

2. Materials and Methods

2.1. Study Population

A total of 319 patients with AIS who received intravenous thrombolysis with alteplase within 4.5 hours of onset were enrolled from the Department of Cerebrovascular Diseases, Zhuhai People's Hospital between April 2019 and December 2024. Among them, 226 were male and 93 were female, with ages ranging from 29 to 93 years (mean 66.34 ± 12.79). All diagnoses met the criteria outlined in the 2023 Chinese Guidelines for the Diagnosis and Treatment of Acute Ischemic Stroke [3]. Cerebral CT or MRI confirmed AIS and identified culprit lesions consistent with clinical symptoms. The patients were divided into five age groups: Group A (29 - 49 years, n = 24), Group B (50 - 59 years, n = 85), Group C (60 - 69 years, n = 78), Group D (70 - 79 years, n = 78), and Group E (>80 years, n = 54).

Inclusion criteria: 1) Age ≥ 18 years; 2) Diagnosis of cerebral infarction meeting the criteria of the *Chinese Guidelines for the Diagnosis and Treatment of*

Acute Ischemic Stroke 2023, with intravenous thrombolysis using alteplase administered within 4.5 hours of symptom onset; 3) No intracranial hemorrhage detected on emergency cranial CT upon admission; 4) Informed consent obtained from the patient or their family members.

Exclusion criteria: 1) Patients who underwent bridging endovascular therapy following intravenous thrombolysis; 2) Those with a history of severe cerebral infarction resulting in significant residual neurological deficits; 3) Cases with incomplete clinical data; 4) Patients presenting with severe cardiac, pulmonary, hepatic, renal, or other major organ dysfunction.

2.2. Assessments and Outcome Measures

Baseline variables Collected clinical data included gender, age, body weight, BMI, NIHSS score, smoking history, alcohol consumption history, as well as comorbidities (including diabetes, hypertension, atrial fibrillation, hyperlipidemia, and hyperhomocysteinemia) and bleeding events. Laboratory tests comprised assessments of liver and kidney function, complete blood count, blood glucose, lipid profile, homocysteine levels, and coagulation function. Imaging studies included electrocardiogram (ECG), cranial MRI, magnetic resonance angiography (MRA), cardiac ultrasound, and carotid vascular ultrasound.

Methods of Intravenous Thrombolysis

All patients received intravenous thrombolysis with alteplase (produced by Boehringer Ingelheim, Germany; specifications: 50 mg/vial and 20 mg/vial). The standard dosage regimen was administered as follows: a total dose of 0.9 mg/kg body weight (maximum 90 mg) was dissolved in 100 mL of 0.9% normal saline. Ten percent of the total dose was administered as a slow intravenous bolus over 1 minute, followed by intravenous infusion of the remaining 90% over 60 minutes. Cranial non-contrast CT was repeated 24 hours after thrombolysis. Patients without evidence of hemorrhage were subsequently administered antiplatelet agents and medications to improve circulation.

Observation Indicators

1) Efficacy Evaluation

Neurological function was assessed using the NIHSS at three time points: before thrombolysis, 24 hours after thrombolysis, and 7 days after thrombolysis. Lower NIHSS scores indicate better neurological function.

The improvement rate of NIHSS score at 7 days after thrombolysis was calculated as follows:

NIHSS improvement rate (%) = (NIHSS score before thrombolysis − NIHSS score after thrombolysis)/NIHSS score before thrombolysis × 100%

The therapeutic effect was classified based on the improvement rate:

- **Markedly effective**: improvement rate ≥ 70%
- **Effective**: improvement rate between 30% and 69%
- **Ineffective**: improvement rate < 30%

The cure rate was defined as the combination of markedly effective and effective

cases.

Functional outcome was evaluated at discharge using the modified Rankin Scale (mRS). Lower mRS scores indicate better prognosis. Outcomes were categorized as follows:

- **Good outcome**: mRS score 1 - 2
- **Poor outcome**: mRS score 3 - 5
- **Death**: mRS score 6

2) Safety Evaluation Post-thrombolysis bleeding events were recorded, including: Skin bleeding; Gastrointestinal bleeding; Intracranial hemorrhage; Oral bleeding.

2.3. Statistical Analysis

Statistical analysis was performed using SPSS 26.0 software. Measurement data were expressed as mean ± standard deviation (±s). Normality was assessed using the Kolmogorov-mirnov (K-) test. For multiple-group comparisons of normally distributed data, one-way ANOVA was applied. Homogeneity of variances was tested using Levene's test. If variances were homogeneous, the LSD post-hoc test was used for multiple comparisons; if not, Welch's ANOVA followed by Dunnett's T3 test was employed. For data that did not follow a normal distribution, the nonparametric Kruskal–Wallis H test was used. Categorical data were analyzed using the chi-square test. A P-value < 0.05 was considered statistically significant.

3. Results

3.1. Baseline Characteristics

Statistically significant differences were observed among the five groups in terms of age, BMI, smoking history, alcohol consumption, diabetes, hypertension, and the prevalence of atrial fibrillation ($P < 0.05$). Specifically, Group A had the highest BMI values; Group E showed the lowest proportions of smoking and alcohol history; Group A had the lowest rate of hypertension; Group E had the highest prevalence of atrial fibrillation; both Group A and Group E exhibited the highest rates of diabetes, while Group D had the lowest. No significant differences were found among the groups in the proportions of hyperhomocysteinemia or hyperlipidemia ($P > 0.05$). Details are presented in Table 1.

Table 1. General characteristics of the five groups.

Variable	A (n = 24)	B (n = 85)	C (n = 78)	D (n = 78)	E (n = 54)	P value
Sex (Male/Female) n	(20/4)	(63/22)	(61/17)	(49/29)	(33/21)	0.0561
Age, years	42.00 ± 4.39	55.21 ± 2.89	65.03 ± 2.75	74.33 ± 3.01	85.04 ± 3.06	0.000
BMI (kg/m^2)	26.93 ± 3.11	24.79 ± 3.06	23.68 ± 3.24	23.27 ± 3.31	23.4 ± 3.59	0.000
Smoking, n (%)	(12, 50%)	(43, 50.5%)	(38, 48.7%)	(29, 37.1%)	(10, 18.5%)	0.0015
Alcohol, n (%)	(14, 58.3%)	(33, 38.8%)	(29, 37.1%)	(19, 24.3%)	(7, 12.9%)	0.0002

Continued

Diabetes, n (%)	(8, 33.3%)	(22, 25.8%)	(24, 30.7%)	(9, 11.5%)	(18, 33.3%)	0.0197
Hypertension, n (%)	(14, 58.3%)	(53, 62.4%)	(48, 61.5%)	(20, 25.6%)	(43, 79.6%)	0.000
Atrial fibrillation, n (%)	(2, 8.3%)	(8, 9.4%)	(8, 10.2%)	(4, 5.1%)	(12, 22.2%)	0.0345
Hyperlipidemia n (%)	(13, 54.2%)	(44, 51.8%)	(30, 38.5%)	(39, 50%)	(18, 33.3%)	0.1495
Hyperhomocysteinemia n (%)	(5, 20.8%)	(24, 28.2%)	(12, 15.4%)	(23, 29.5%)	(16, 29.6%)	0.2003

3.2. Comparison of NIHSS Scores

Statistically significant differences in NIHSS scores were observed among the five patient groups before thrombolysis, at 24 hours, and at 7 days after thrombolysis ($P < 0.05$). Specifically, Group A demonstrated the lowest NIHSS scores at all three time points, while Group E showed the highest NIHSS scores both before and at 24 hours after thrombolysis. Detailed data are provided in Table 2.

Table 2. NIHSS scores before thrombolysis, at 24 hours, and at 7 days after thrombolysis of five groups.

	A (n = 24)	B (n = 85)	C (n = 78)	D (n = 78)	E (n = 54)	P value
before thrombolysis NIHSS ($\bar{x} \pm s$)	4.25 ± 3.35	5.86 ± 4.67	5.23 ± 3.67	6.28 ± 4.96	7.13 ± 4.44	0.035
24 h NIHSS ($\bar{x} \pm s$)	2.71 ± 3.91	3.73 ± 5.73	2.59 ± 2.76	4.56 ± 5.70	5.11 ± 4.89	0.013
7d NIHSS ($\bar{x} \pm s$)	2.08 ± 3.88	2.65 ± 5.63	1.17 ± 2.57	3.73 ± 5.83	3.42 ± 4.43	0.007

3.3. Comparison of Clinical Efficacy (n, %)

The NIHSS improvement rate at 7 days after thrombolysis was calculated using the formula:

NIHSS improvement rate (%) = (NIHSS score before thrombolysis -NIHSS score after thrombolysis)/NIHSS score before thrombolysis × 100%.

Therapeutic outcomes were categorized as follows:

Markedly effective: improvement rate ≥ 70%;

Effective: improvement rate 30% - 69%;

Ineffective: improvement rate < 30%;

The overall response rate was defined as the combined proportion of markedly effective and effective cases. No statistically significant difference was observed in the overall clinical response rate among the five groups ($P > 0.05$). Detailed results are presented in Table 3.

Table 3. Clinical Efficacy of five groups.

	A (n = 24)	B (n = 85)	C (n = 78)	D (n = 78)	E (n = 54)	P value
Markedly effective	13	50	48	41	25	
Effective	7	18	18	15	18	
Ineffective	4	17	12	22	11	
Total effective	20 (83%)	68 (80%)	66 (84.6%)	56 (71.8%)	43 (79.6%)	0.369

3.4. Comparison of Bleeding Events (n, %)

No statistically significant differences were observed among the five groups in the incidence of bleeding at specific sites, including skin, gastrointestinal tract, intracranial, and oral/gingival bleeding ($P > 0.05$). However, a significant difference was found in the total bleeding rate ($P < 0.05$), with higher bleeding risk correlated with older age groups. Detailed data are presented in Table 4.

Table 4. Bleeding events of five groups.

	A (n = 24)	B (n = 85)	C (n = 78)	D (n = 78)	E (n = 54)	P value
skin	0	3 (3.5%)	2 (2.6%)	4 (5.1%)	6 (11.1%)	0.124
gastrointestinal tract	0	0	0	1 (1.3%)	2 (3.7%)	0.1779
intracranial	0	4 (4.7%)	5 (6.4%)	6 (7.7%)	4 (7.4%)	0.661
oral/gingival	0	0	1 (1.3%)	3 (3.8%)	0	0.177
total bleeding	0	7 (8.2%)	8 (10.3%)	14 (17.9%)	12 (22.2%)	0.02

3.5. Comparison of mRS Scores at Discharge and Mortality (n, %)

Significant differences were observed in modified Rankin Scale (mRS) scores at discharge among the five groups ($P < 0.05$). Group A demonstrated the lowest mRS scores, indicating the most favorable functional outcomes, while Group E exhibited the highest mortality rate. Detailed results are presented in Table 5.

Table 5. mRS Scores of five groups.

	A (n = 24)	B (n = 85)	C (n = 78)	D (n = 78)	E (n = 54)	P value
0 - 1 分	19 (79.2%)	54 (63.5%)	59 (75.6%)	36 (46.2%)	25 (46.3%)	0.0002
2 - 3 分	3 (12.5%)	25 (29.4%)	12 (15.4%)	26 (33.3%)	19 (35.2%)	0.020
4 - 5 分	2 (8.3%)	6 (7.1%)	7 (9%)	15 (19.2%)	7 (13%)	0.135
6 分	0	0	0	1 (1.3%)	3 (5.5%)	0.036

4. Discussion

Currently, stroke is one of the leading causes of death and disability in China, with acute ischemic stroke (AIS) accounting for approximately 80% of cases. As the population ages, the proportion of elderly patients with cerebral infarction is increasing annually. Studies have shown that after the age of 55, the risk of AIS doubles with every 10-year increase in age [4]. According to a 2019 survey, the incidence of AIS was 6.58% in individuals aged 65 - 69, rising to 12.81% in those aged 80 and above [5]. Another study reported that over 30% of AIS patients are older than 80 years [6]. Compared with younger patients, elderly AIS patients tend to experience more severe neurological deficits, higher disability rates, and increased mortality [7]. This study included 319 AIS patients who were admitted to the Department of Cerebrovascular Diseases at Zhuhai People's Hospital between April 2019 and December 2024, all within 4.5 hours of symptom onset. Among them,

226 were male and 93 were female, with ages ranging from 29 to 93 years. All patients were diagnosed according to the 2023 Chinese guidelines for the diagnosis and treatment of AIS and received intravenous thrombolysis with alteplase. The patients were divided into five groups based on age: Group A (29 - 49 years) with 24 cases, Group B (50 - 59 years) with 85 cases, Group C (60 - 69 years) with 78 cases, Group D (70 - 79 years) with 78 cases, and Group E (>80 years) with 54 cases. Consistent with these findings, the present study also demonstrated that Group A had the lowest NIHSS scores at all three time points, while Group E exhibited the highest NIHSS scores before and 24 hours after thrombolysis. Furthermore, NIHSS scores showed a gradual increase with advancing age.

Currently, intravenous thrombolysis remains the primary treatment for patients with ischemic stroke who are ineligible for mechanical thrombectomy but present within the therapeutic time window. This approach can promptly and effectively restore blood perfusion to the damaged brain area. Recombinant tissue plasminogen activator (rt-PA) thrombolysis has been confirmed as an effective treatment for acute cerebral infarction, demonstrating significant efficacy across all age groups, with better outcomes observed in younger patients [8]. Some studies have also indicated that patients of different age groups can benefit from intravenous thrombolysis, with younger patients experiencing greater benefits and more favorable prognoses [9]. The results of this study showed no statistically significant difference in the clinical response rate among the five age groups after thrombolysis, indicating that patients in all age groups derived benefit from intravenous thrombolysis, with effective improvement in neurological deficits. International studies have further supported that intravenous thrombolysis can significantly reduce disability rates in patients with ischemic stroke. Neurological recovery was more pronounced in younger age groups, and greater improvements in daily living abilities were observed, with the most significant effects seen in the youngest patients [10] [11].

Regarding the risks associated with intravenous thrombolysis, the most common complications are bleeding events, which include intracranial, oral, skin, and gastrointestinal bleeding, among others. This study found no statistically significant differences among the five groups in the incidence of intracranial, oral, skin, or gastrointestinal bleeding. However, a significant difference was observed in the total bleeding rate, which increased progressively with age. This indicates that older patients face a higher risk of overall bleeding complications. In terms of functional outcomes, as measured by the modified Rankin Scale (mRS) at discharge, younger age groups exhibited lower (better) mRS scores. With respect to mortality (mRS score of 6), there was one death among the 78 patients in Group D and three deaths among the 54 patients in Group E, while no deaths occurred in the first three younger groups. This study suggests that patients over 80 years of age undergoing intravenous thrombolysis have a higher mortality risk. However, in reality, even without intravenous thrombolytic therapy, the mortality rate among elderly patients is already significantly higher. This indicates that differ-

ences in treatment alone cannot fully account for the increase in mortality with age, and there may be underlying age-related pathophysiological factors at play. This may be attributed to a higher prevalence of underlying comorbidities, polypharmacy, and multi-organ dysfunction in the very elderly. Furthermore, advanced age is often associated with a higher incidence of atrial fibrillation, more severe neurological deficits, increased complications, and slower recovery, all of which can adversely affect prognosis [12] [13]. However, a study by Xia Xin *et al.* in China indicated that intravenous thrombolysis in patients ≥ 85 years old did not significantly increase mortality or the risk of intracranial hemorrhage [14]. Research by Ge *et al.* suggested that while thrombolysis increases the risk of bleeding in patients with acute minor ischemic stroke, it does not raise mortality [15]. The possibility that worse outcomes in older patients may be confounded by higher initial stroke severity, rather than being solely attributable to age as a factor in treatment response. A meta-analysis of multiple RCTs on AIS patients treated within 4.5 hours of onset demonstrated that the efficacy of intravenous alteplase thrombolysis was similar between patients over and under 80 years old [16]. Furthermore, the occurrence of symptomatic intracranial hemorrhage within 7 days after thrombolysis was not significantly correlated with age [17]. Intravenous thrombolysis in very elderly patients can significantly improve neurological deficits without increasing in-hospital mortality [18]. Therefore, intravenous thrombolysis can be considered relatively safe for elderly patients. The increased bleeding risk primarily manifests as minor events, such as oral, gastrointestinal, and skin/mucosal bleeding, and does not significantly elevate the risk of intracranial hemorrhage.

5. Conclusion

In summary, patients with acute ischemic stroke (AIS) across different age groups can benefit from intravenous thrombolysis, with younger patients generally experiencing greater benefits and more favorable prognoses. Although advanced age is associated with higher risks of bleeding and mortality, the overall advantages of thrombolysis still outweigh the risks for elderly patients. This treatment significantly improves clinical outcomes and reduces disability rates, underscoring its important clinical value in this population. During thrombolysis in very elderly patients, close monitoring of vital signs and early detection of complications are essential to enable timely and effective interventions. The generalizability of our findings is limited by the single-center, retrospective nature of the study, which carries an inherent risk of selection bias.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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