



Analysis of the Efficacy and Safety of Recombinant Tissue Plasminogen Activator for Chinese Patients over 80 Years of Age with Acute Ischemic Stroke: A Pilot Study

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Dear Editor,

Recombinant tissue plasminogen activator (rt-PA) remains the only proven therapy for acute ischemic stroke patients who meet the selection criteria for treatment [1–3]. A small number of studies have investigated the efficacy of rt-PA for elderly stroke patients in Japanese and Caucasian populations [4, 5]. According to the American Heart Association/American Stroke Association Guidelines, patients over 80 years of age can be selected for rt-PA thrombolysis [6] and the Third International Stroke Trial found that the benefit of rt-PA did not diminish in patients older than 80 years [7]. However, the Chinese Guidelines for Stroke Management do not recommend rt-PA thrombolysis for these patients, due to the possibility that it increases the risk of intracranial hemorrhage transformation and subsequent nosocomial mortality [8]. In addition, an epidemiological study in Europe showed that >30% of the people included in their study who were >80 years old developed ischemic stroke after rt-PA treatment [5]. In China, there have been no such studies. Therefore, there is an urgent need to confirm the safety and efficacy of rt-PA in

these patients [4, 5]. The present study aimed to reveal whether rt-PA could be safely and efficiently used on Chinese patients >80 years old with acute ischemic stroke. To do this, measures of safety and neurological function of these patients after rt-PA thrombolysis were compared with their younger counterparts (60–80 years) who also received rt-PA thrombolysis and patients >80 years old who did not receive rt-PA thrombolysis.

This study was approved by the Human Research Committee of the Sichuan Branch of the Shanghai First People's Hospital and written, informed consent was given by all participants. One hundred and eighteen patients aged between 60 and 80, and 62 patients >80 years old received rt-PA, and the remaining 74 patients >80 years old did not receive rt-PA but instead were treated with conventional therapies (see “Methods” in the supplementary material).

Measures of safety showed that there was no significant difference in hemorrhage transformation between the three groups (16.9% vs 20.9% vs 21.6%, $P = 0.675$), nor was there a difference in the prevalence of fatal intracranial hemorrhage (3.3% vs 9.6% vs 7.4%, $P = 0.20$). The mortality prevalence after 90 days was 11%, 22.6%, and 16.2% and the prevalence of mortality was higher in the patients >80 years old than in their younger counterparts. However, rt-PA did not increase the risk of fatal intracranial hemorrhage and mortality among patients >80 years old. In fact, these patients had a modified Rankin score (mRS) of 0–2, which indicates a good recovery after a stroke and the patients continued to live independently. In the present study, we measured the efficacy of rt-PA in elderly patients by comparing the percentages with an mRS of 0–2 90 days after onset between the groups who received rt-PA. The percentages of patients with an mRS 0–2 were 56.8% in patients aged between 60 and 80 years and 38.8% in patients >80 years old (odds ratio 2.08, 95% confidence interval 1.11–3.86). The difference between these groups was

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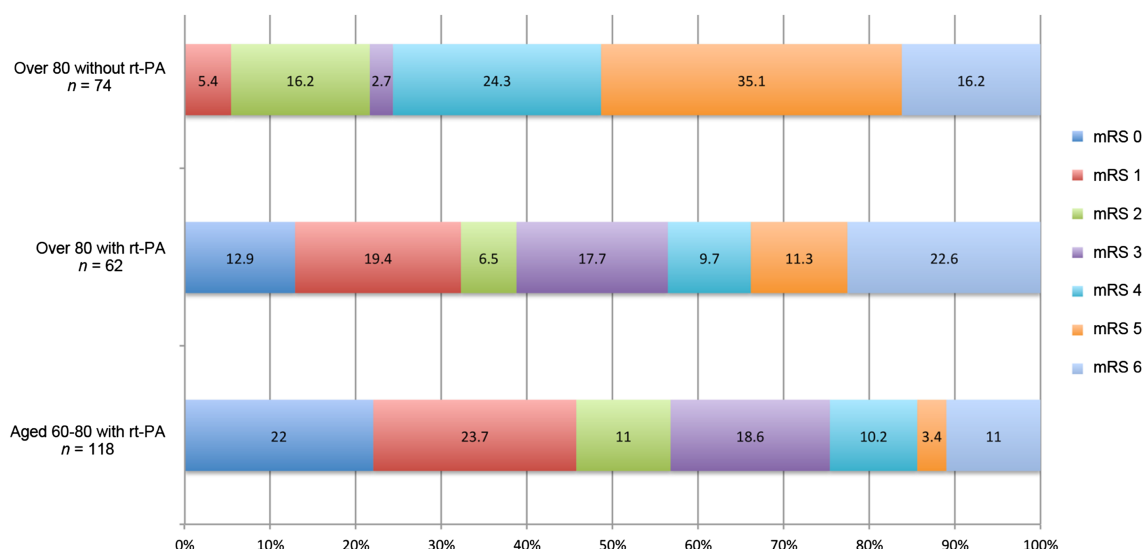


Fig. 1 Comparison of the modified Rankin score (mRS) among the three groups, 90 days after treatment. The percentage of patients with each mRS is color-coded and the percentage is shown in the color-coded bar. An mRS of 0–2 in the patients aged 60–80 was

significant ($P = 0.021$). This showed that the younger patients had a better recovery than the older patients after receiving rt-PA, as evidenced by more than half of the younger patients being able to continue living independently after the stroke (Fig. 1). Among the patients >80 years old who did or did not receive rt-PA, 24 (38.8%) or 16 (21.6%) had an mRS of 0–2, respectively (odds ratio: 1.81, 95% confidence interval 0.80–4.06) (Fig. 1). There was no significant difference between these groups ($P = 0.098$); however, the median mRS was 3 (0–6) and 5 (1–6), respectively, which was a significant difference ($P = 0.008$). This suggests that there is a tendency for patients >80 years to benefit from rt-PA injection. More than half of the patients >80 and receiving rt-PA continued to live independently, whereas over half of the patients >80 years old who did not receive rt-PA relied on support. This is consistent with the results of a large cohort study [9]. In conclusion, the results of the present study suggest that rt-PA is safe for patients over 80 years old and that these patients receive a greater benefit from treatment with rt-PA thrombolysis following an acute stroke, than without.

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significantly more frequent than in both patient groups >80 years old, but an mRS of 0–2 in patients >80 years old who received rt-PA was not significantly more frequent than that of patients >80 years old who did not receive rt-PA treatment.

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