

Symptomatic Intracerebral Hemorrhage after Intravenous Thrombolysis in Chinese Patients: Comparison of Prediction Models

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Background: To assess the performance of risk scores in predicting symptomatic intracranial hemorrhage (SICH) after intravenous thrombolysis (IVT). *Methods:* A multicenter prospective study was performed in 811 patients who underwent IVT with standard-dose recombinant tissue plasminogen activator within 4.5 hours of acute ischemic stroke (AIS) onset in 67 stroke centers involved in the Thrombolysis Implementation and Monitor of acute ischemic Stroke in China program from May 2007 to April 2012. SEDAN (blood sugar, early infarct signs, [hyper]dense cerebral artery sign, age) score, Safe Implementation of Thrombolysis in Stroke (SITS)-SICH score, Glucose Race Age Sex Pressure Stroke Severity (GRASPS) score, Multi-center Stroke Survey (MSS) score, and Stroke Prognostication using Age and National Institutes of Health Stroke Scale (SPAN)-100 index were calculated in selected patients, and their predictive performance for SICH was compared according to the National Institute of Neurological Disorders and Stroke (NINDS), Safe Implementation of Thrombolysis in Stroke-Monitoring Study (SITS-MOST), and European Cooperative Acute Stroke Study (ECASS)-II criteria. *Results:* For predicting the risk of SICH (NINDS definition) after IVT, the area under the receiver operating characteristic (ROC) curve of MSS score was the highest (.71, $P < .0001$). For predicting the risk of SICH (SITS-MOST definition) after IVT, the area under the ROC curve of GRASPS score was the highest (.73, $P = .005$). For predicting SICH (ECASS-II definition) after IVT, the area under the ROC curve of MSS score was the highest (.73, $P < .0001$). *Conclusions:* SITS-SICH, GRASPS, and MSS scores predicted the risk of SICH after IVT in patients with AIS, but only the latter 2 were better in the Chinese population. MSS score had the best predictive performance for SICH using NINDS and ECASS-II definitions, whereas GRASPS score was the best for SICH using the SITS-MOST definition. **Key Words:** Ischemic stroke—intravenous thrombolysis—symptomatic intracranial hemorrhage—risk score—recombinant tissue plasminogen activator.

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Introduction

Intravenous thrombolysis (IVT) using recombinant tissue plasminogen activator (rt-PA) is presently the most effective treatment and the gold standard for acute ischemic stroke (AIS).^{1,2} However, this treatment option also significantly increases the risk of hemorrhagic transformation.^{2,3} In particular, symptomatic intracranial hemorrhage (SICH), a severe complication of IVT,⁴ is the main concern for physicians when deciding whether to use this therapy. The definition of SICH currently in common use mainly includes the following 3 criteria: National Institute of Neurological Disorders and Stroke (NINDS) criteria,² European Cooperative Acute Stroke Study (ECASS)-II criteria,⁵ and Safe Implementation of Thrombolysis in Stroke-Monitoring Study (SITS-MOST) criteria.⁶

Previous studies have developed a variety of rating scales for predicting the risk of SICH after IVT, aiming to establish a clinical scoring system for effective prediction of SICH before IVT therapy. Different risk rating models have also been verified in many patients with AIS. At present, clinical applications mainly use the Hemorrhage After Thrombolysis (HAT) score,⁷ SEDAN (blood sugar, early infarct signs, [hyper]dense cerebral artery sign, age),⁸ SITS-SICH,⁹ Multicenter Stroke Survey (MSS),⁴ Glucose Race Age Sex Pressure Stroke Severity (GRASPS),¹⁰ Stroke Prognostication using Age and National Institutes of Health Stroke Scale (SPAN)-100,¹¹ and iScore¹² scores. However, previous studies have been carried out on SICH defined using different criteria, thereby, reducing the consistency and comparability of the results and bringing difficulties for selection of effective prediction tools. To date, few studies have performed horizontal comparison analysis of different scores predicting the risk of hemorrhage after thrombolysis.

The present study compared the performance of 5 predictive scores for SICH in AIS patients undergoing IVT and retrieved from the Thrombolysis Implementation and Monitor of acute ischemic Stroke in China (TIMS-China) database. We hypothesized that different scoring systems have varying predictive values for SICH after IVT in the Chinese population.

Methods

Study Objects

A multicenter prospective study was performed in 811 patients who underwent IVT therapy with standard-dose rt-PA within 4.5 hours of AIS onset in 67 stroke centers involved in the TIMS-China during May 2007-April 2012. The patients were consecutively enrolled in accordance with the following inclusion criteria: (1) hospitalized patients; (2) aged 18-80 years; (3) clinical diagnosis of ischemic stroke that caused assessable neurologic

impairment, and a computed tomography (CT) scan of the brain that showed no evidence of intracranial hemorrhage; (4) undergoing IVT therapy within 4.5 hours of stroke onset; (5) stroke symptoms lasting at least 30 minutes, with no significant improvement before treatment; (6) IVT with rt-PA at a dose of .9 mg/kg (total dose \leq 90 mg); and (7) acquisition of informed consent.

Study Methods

SEDAN, SITS-SICH, GRASPS, MSS, and SPAN-100 scores were calculated in the selected patients undergoing IVT therapy with standard-dose rt-PA within 4.5 hours of AIS onset. The performance of the 5 predictive scoring systems for SICH after IVT as defined by the NINDS, SITS-MOST, and ECASS-II criteria was estimated.

The study protocol was approved by the Ethics Committee of Beijing Tiantan Hospital. The registry was regularly monitored independently by the quality monitoring committee of TIMS-China and an independent research organization. All patients or patients' care providers gave written informed consent before thrombolysis, patients with disturbance of consciousness, aphasia, and other reasons cannot sign the consent, their families (next of kin or legally authorized representative) consented on the behalf of participants. All patients were followed up for 3 months.

Definition of SICH

NINDS criteria²: Post-IV t-PA SICH is defined as neurologic worsening within 36 hours of t-PA administration that is attributed to ICH verified by CT or magnetic resonance imaging.

SITS-MOST criteria⁶: SICH, per the SITS-MOST protocol,¹³ was defined as local or remote parenchymal hemorrhage type 2^{14,15} on the 22-36-hour post-treatment imaging scan, combined with a neurologic deterioration of 4 points or more on the National Institutes of Health Stroke Scale (NIHSS) from baseline, or from the lowest NIHSS value between baseline and 24 hours, or leading to death.

ECASS-II criteria⁵: SICH was defined as blood at any site in the brain on the CT scan (as assessed by the CT reading panel, independently of the assessment by the investigator), documentation by the investigator of clinical deterioration, or adverse events indicating clinical worsening (eg, drowsiness and increase of hemiparesis) or causing a decrease in the NIHSS score of 4 or more points.

Statistical Analysis

All analyses were performed using SAS version 9.1.3 (SAS Institute, Cary, NC). The area under the receiver operating characteristic curve was calculated to determine the predictive performance of each SICH predictive

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