

A Validation of the Essen Stroke Risk Score in Outpatients with Ischemic Stroke

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Background: Little is known about the predictive accuracy of the Essen Stroke Risk Score (ESRS) for Chinese stroke outpatients. Our goal was to perform an external validation of the ESRS using a large multicenter cohort of outpatients with ischemic stroke (IS). **Methods:** We estimated the 1-year cumulative event rates for both recurrent stroke and combined vascular events for patients in different ESRS categories using data from a prospective cohort of 3316 outpatients with IS admitted to 18 hospitals in China. In addition, we evaluated the predictive accuracy of the ESRS for both recurrent stroke and combined vascular events using C statistic. **Results:** In the nonatrial fibrillation IS outpatients, the cumulative 1-year event rate was 2.47% (95% confidence interval [CI], 1.97%-3.06%) for recurrent stroke and 4.32% (95% CI, 3.65%-5.06%) for combined vascular events. The event rates were significantly higher in patients in higher ESRS categories. The ESRS had a predictive accuracy of .63 (.57-.69) for recurrent stroke and .63 (.58-.68) for combined vascular events. **Conclusion:** Among the Chinese outpatients with IS, the ESRS was able to stratify the risk of both recurrent stroke and combined vascular events equally well. A prediction model suitable for Chinese IS populations is needed. **Key Words:** Ischemic stroke—the Essen Stroke Risk Score—validation—outpatients. © 2016 Published by Elsevier Inc. on behalf of National Stroke Association.

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Introduction

Recurrent stroke and subsequent cardiac events post stroke do the greatest harm to stroke victims. The recurrence rate is approximately 4%-12% in the first year after the onset of stroke.¹⁻³ Therefore, we need tools to determine which ischemic stroke (IS) patients have a higher risk of recurring vascular events in clinical practice. With such tools, we can adopt a more positive and effective stratification approach to clinical care, making treatment decisions to achieve the best risk-benefit ratio.

As a prediction model based on risk factors, the Essen Stroke Risk Score (ESRS) is an internationally recognized predictive tool for IS recurrence.^{4,5} The effectiveness of the ESRS was preliminarily established through the Reduction of Atherothrombosis for Continued Health (REACH) Registry and the European Stroke Prevention Study 2.^{6,7} Although the ESRS was validated for nonatrial fibrillation (AF) IS inpatients and outpatients in those

studies, the performance of the ESRS in a large Chinese stroke population has not been examined.

In 2011, the ESRS was validated for acute IS inpatients in China,⁸ using data from the China National Stroke Registry (CNSR).⁹ The results showed that the ESRS could accurately predict the occurrence of 1-year stroke recurrence and combined vascular events in acute IS patients, with area under the curve (AUC) values of .59 and .60. However, there is no large cohort study to verify the validity of the ESRS for outpatients in the nonacute phase of IS.

Therefore, the goal of the present study was to perform an external validation of the ESRS in a large multicenter cohort of Chinese outpatients with IS so that the hierarchical management of secondary prevention strategies for IS patients in China could be improved and the recurrence of vascular events reduced without increasing the risk of bleeding. As a result, the prognosis for these patients could eventually be improved and medical costs could be reduced.

Materials and Methods

Study Population

Data from a substudy of Registry of Outpatients with Ischemic Stroke in Urban China (ROOTS) were analyzed in this report. The substudy was a multicenter prospective cohort study of consecutive outpatients with IS who were admitted to 18 hospitals in Beijing between July 1, 2010, and November 30, 2012.

Inclusion Criteria

Patients who met the following criteria were included in the present study:

- 1) Age 18 years or older
- 2) Clinical diagnosis of IS, excluding cerebral hemorrhage, subarachnoid hemorrhage, and transient ischemic attack (TIA)
- 3) Occurrence of IS 1-6 months before enrollment

IS is defined as stroke that consists of a sudden onset of focal or systematic clinical signs of neurological deficit that persists beyond 24 hours (World Health Organization definition). The diagnosis of IS was performed by neurologists from grade II or III urban hospitals. Computed tomography evaluation excluded other nonvascular causes of brain dysfunction (such as primary brain tumor, brain metastases, subdural hematoma, seizures, paralysis, or brain trauma).

- 4) Completion of 3-, 6-, and 12-month visits

Exclusion Criteria

Exclusion criteria included the following:

- 1) Asymptomatic cerebral infarction

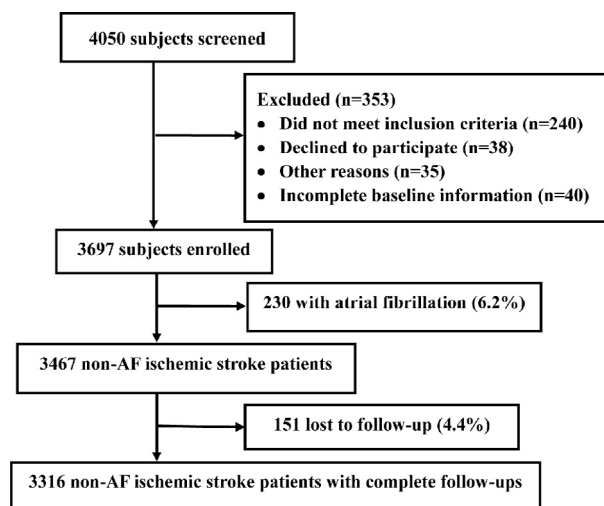


Figure 1. Flowchart of the subject enrollment. Abbreviation: AF, atrial fibrillation.

- 2) Noncerebrovascular disease (e.g., primary brain tumor, brain metastases, subdural hematoma, seizures, paralysis, or brain trauma)
- 3) Atrial fibrillation, which was defined as a previous diagnosis of atrial fibrillation with at least 1 confirmation via electrocardiogram (ECG) or current use of medication, or an ECG indication of atrial fibrillation confirmed and diagnosed in an outpatient clinic.
- 4) Lack of written informed consent
- 5) Subject involvement in other clinical trials

These inclusion and exclusion criteria were evaluated by specialized neurologists and were evaluated for each subject using the subject's medical records. The study was approved by the central Institutional Review Board at Beijing Tiantan Hospital, Capital Medical University, and all clinical investigations were conducted according to the principles expressed in the Declaration of Helsinki. Written informed consent was obtained from the patient or from the patient's legally authorized representative.

Subject Enrollment

A detailed patient recruitment flowchart is illustrated in [Figure 1](#).

Baseline Data Collection and Data Management

The subjects' information was collected prospectively using unified paper-based registry forms. All of the neurologists or physicians who participated in the study went through professional program training. Each participating site collected the outpatients consecutively during the study period. Baseline information included the following:

- 1) Basic information: sex, age, height, weight, employment status before stroke onset, per capita

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