

# Minor Nonintracranial Hemorrhage and Poor Prognosis among Stroke Patients Undergoing Intravenous Thrombolysis

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*Background:* Whether nonintracranial hemorrhage (NICH) associated with intravenous thrombolysis (IVT) is a predictor of intracranial hemorrhage (ICH) and poor prognosis is ambiguous. We sought to analyze the rate of NICH and the relationship between NICH and poor outcome in the ischemic stroke population undergoing IVT. *Methods:* This is a single-center, hospital-based prospective study. All ischemic stroke patients undergoing IVT between December 2015 and November 2016 were included. NICH was defined according to the criteria of the Bleeding Academic Research Consortium (BARC). ICH associated with IVT was defined based on the European Cooperative Acute Stroke Study II definition. On the basis of the modified Rankin Scale (mRS), 90-day outcome was divided into favorable outcome (mRS score 0-1) versus unfavorable outcome (mRS score 2-6) and independency (mRS score 0-2) versus dependency and death (mRS score 3-6). *Results:* A total of 212 patients undergoing IVT were included in the analysis. Forty-five NICH events were reported in 42 patients (19.8%). Older age was independently associated with NICH ( $P = .049$ , odds ratio [OR] = .97, 95% confidence interval [CI] .94-1.0). Neither NICH with BARC class 1 or higher ( $P = .56$ , OR = .61, 95% CI .11-3.24) nor NICH with BARC class 2 or higher ( $P = .87$ , OR = 1.19, 95% CI .14-10.23) was associated with ICH. NICH with BARC class 1 or higher was not associated with unfavorable outcome ( $P = .67$ , OR = 1.17, 95% CI .56-2.45) and dependence and death ( $P = .47$ , OR = .72, 95% CI .30-1.75), neither was NICH with BARC class 2 or higher ( $P = .97$ , OR = 1.02, 95% CI .46-2.27 and  $P = .30$ , OR = .59, 95% CI .22-1.62). *Conclusions:* NICH was common among ischemic stroke populations receiving IVT. NICH with BARC class 2 or lower was not associated with ICH and poor outcome. **Key Words:** NICH—ischemic stroke—tPA—thrombolysis—intracranial hemorrhage—prognosis.

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## Introduction

It has been widely accepted that intravenous thrombolysis (IVT) with tissue plasminogen activator (tPA) is one of the most effective thrombolytic treatment in acute ischemic stroke (AIS).<sup>1-3</sup> Concern about intracranial hemorrhage (ICH) associated with thrombolysis has become the central issue in the safety of tPA treatment; as a result, much research has focused on ICH.<sup>4,5</sup> On account of the fact that nonintracranial hemorrhage (NICH) may be a response to the dysfunction of coagulation due to tPA, NICH may increase the risk of hemorrhage of the brain

and other organs, consequently causing poor outcomes. Although NICH is more common than ICH,<sup>6</sup> little attention has been paid to NICH and its relation to unfavorable outcomes of AIS. Therefore, in clinical practice whether NICH is a predictor for ICH and poor prognosis is still ambiguous. In the present study, we evaluated the relationship between NICH and ICH, and also revealed the relationship between NICH and 90-day outcome. Finally, risk factors for NICH were analyzed.

## Methods

### *Study Population*

The present study was approved by the ethics board committee of our hospital and informed consent was obtained from all the participants. Patients included in the present study were derived from the database of the prospective stroke registry of our stroke center, which is a single-center hospital-based cohort study of consecutive AIS patients who received a .9 mg/kg dose of intravenous tPA within 4.5 hours of stroke onset between December 2015 and November 2016. All patients were prospectively identified, and their data were first recorded using paper case report forms and then entered into the computerized stroke registry database designed by EpiData software package (version 3.1, The EpiData Association, Odense, Denmark). The case report forms included age, sex, clinical features, medical history, antiplatelet drugs and oral anticoagulation treatment, physical examination, laboratory tests, electrocardiography, transcranial Doppler, magnetic resonance imaging, carotid imaging, National Institutes of Health Stroke Scale (NIHSS) score, and modified Rankin Scale (mRS) score.

Our stroke registry follows established guidelines to administer intravenous tPA to AIS patients.<sup>7</sup> Intravenous tPA was used with 10% of the total dosage as a bolus within 1 minute and the rest within more than 1 hour.

### *Definition of NICH and ICH*

NICH was defined by the criteria of Bleeding Academic Research Consortium (BARC), in which class 3c bleeding and class 4 bleeding were excluded in our study because these 2 classes indicate bleeding related to coronary artery bypass grafting and ICH.<sup>8</sup>

ICH associated with IVT was divided into hemorrhagic infarction and parenchymal hemorrhage on the basis of imaging characteristics, referring to the European Cooperative Acute Stroke Study II definition.<sup>2</sup>

### *Evaluation of Outcome*

The NIHSS score was assessed by stroke neurologists certified to perform an NIHSS evaluation at presentation, 24 hours after IVT and discharge, and 90-day outcome was evaluated by a stroke neurologist using mRS per-

formed by telephone. The outcome was divided into favorable outcome (mRS score 0-1) versus unfavorable outcome (mRS score 2-6), and independency (mRS score 0-2) versus dependency and death (mRS score 3-6).

### *Statistical Analysis*

All statistical analyses were performed by the SPSS software package (version 16.0; SPSS Inc., Chicago, IL). Continuous variables were tested for normality and were given as median and range or mean and SD as appropriate. Categorical variables were presented as frequencies and percentages. In group comparisons, continuous variables were analyzed by *t*-test; categorical variables were analyzed by chi-square tests and the Fisher exact test if counts were less than 5. To identify independent predictors for NICH, multivariate binary logistic regression analysis was carried out.

## Results

### *Baseline Characteristics and Treatment*

From December 2015 and November 2016, a total of 212 ischemic stroke patients undergoing IVT with tPA were included in our study, and the outcome evaluation of these patients was completed on February 2017. Patient characteristics are presented in [Table 1](#). The median age was 67 years (interquartile range, 58.0-76.8) and 59% were male. The median NIHSS score at admission was 5 (interquartile range, 3-10). At day 90, the median mRS score was 0, with 152 patients (71.7%) achieving a favorable outcome and 176 (83%) an independent outcome. Seven ICHs (3.3%) occurred; among these ICHs, one was hemorrhagic infarction and six were parenchymal hemorrhage.

### *NICH and Risk Factors*

Among the 212 treated patients, 45 NICH events were reported in 42 patients (19.8%). Among all the bleeding events, 40 occurred during IVT and 5 occurred within 24 hours after IVT. Gingival bleeding was reported in 31 events (68.9%). Dermatorrhagia was revealed in 7 events (15.6%). Hemorrhage of the tracheal mucosa, gastrointestinal tract, and tongue was observed in 2 events (4.4%) separately, and hemorrhage from incision during cystostomy was presented in 1 patient (2.3%) ([Table 2](#)). There were 7 events with BARC class equal to 1, 36 with BARC class equal to 2, and 2 with BARC class equal to 3a. Most events were temporary except for 2 events of gastrointestinal tract bleeding, which was treated with antacid drugs and blood transfusion. IVT was withdrawn because of gingival bleeding during tPA treatment in 2 patients.

[Table 3](#) summarizes the results of univariate and multivariate analyses of predictors for NICH. As shown in the univariate analysis, older age ( $P = .027$ , odds ratio [OR] = 1.03, 95% confidence interval [CI] 1.00-1.06) and

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