

Thrombolysis in Patients Aged over 80 Years Is Equally Effective and Safe

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Background: Despite stroke's high prevalence in the elderly, intravenous thrombolysis is licensed in Europe only for patients younger than 80 years old. We aimed to compare the functional outcomes and complication rates in patients older versus younger than 80 years old treated with intravenous thrombolysis. **Methods:** A retrospective observational study of patients who received intravenous thrombolysis in a stroke unit between January 1, 2009, and June 30, 2012, was conducted. Variables were compared between 2 subgroups (≤ 80 and > 80 years). **Results:** Overall, 512 patients underwent intravenous thrombolysis, of which 13.1% were over 80 years. The mean age was 65.4 years in the younger subgroup and 82.9 years in the older subgroup. Prior independence rates did not differ between the subgroups. Prevalence of atrial fibrillation and cardioembolic stroke was higher in the older subgroup ($P = .004$ and $.026$). Only 3% of the elderly with atrial fibrillation were taking oral anticoagulants. Symptoms-to-needle time was lower in the older subgroup ($P = .048$). Stroke severity was higher in patients over 80 years ($P = .026$). There was significant improvement in the National Institutes of Health Stroke Scale score 7 days after intravenous thrombolysis ($P < .001$) in both subgroups. The proportion of patients with 3 months' favorable outcome and independence, hemorrhagic transformation, and mortality rates were similar in both subgroups. **Conclusions:** Elderly patients' benefits and outcomes from intravenous thrombolysis treatment were identical to the younger subgroup without excess hemorrhagic transformation or mortality. These results favor the use of intravenous thrombolysis in patients over 80 years. **Key Words:** Stroke—elderly—thrombolysis—over 80 years.

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Introduction

Stroke is a major cause of mortality and morbidity constituting the second most frequent cause of death and

the third main cause of disability-adjusted life-years worldwide.¹

Age is the most important nonmodifiable risk factor for stroke. In fact stroke's incidence increases with age in both genders, with an incidence of 38% in adults over 75 years old.²⁻⁴

However, despite stroke's high prevalence in the elderly, intravenous alteplase (intravenous recombinant tissue plasminogen activator [IV-rtPA]), the only approved treatment for pharmacological revascularization in acute ischemic stroke, is licensed only in Europe for use in patients younger than 80 years old.⁵ This seems to be related with frequent under-representation or exclusion of patients over the age of 80 years from clinical trials leading to uncertainty about the risk-benefit profile in these patients.⁶

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Received December 28, 2015; revision received February 23, 2016; accepted March 3, 2016.

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1052-3057/\$ - see front matter

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<http://dx.doi.org/10.1016/j.jstrokecerebrovasdis.2016.03.007>

Data regarding IV-rtPA treatment in this age group are conflicting and result mainly from observational studies. Most studies seem to show worse outcome and increased mortality in patients aged over 80 years old with acute ischemic stroke treated with IV-rtPA when compared with younger counterparts.⁷⁻¹⁷ Nevertheless, patients from this age group still seem to benefit from this treatment and do not seem to have an increased risk of symptomatic intracranial hemorrhage after IV-rtPA, as demonstrated in several observational studies^{7-9,11-14,16,18-25} and also in a randomized controlled trial.²⁶ Thus, there is increasing evidence supporting the finding that old age, by itself, should not be a reason to exclude patients from treatment with IV-rtPA.

Aims

In the present study, we aimed to compare the functional outcomes and complication rates in patients older versus lower than 80 years old who were treated with IV-rtPA in our stroke unit. This study, which may be subjected to the bias inherent to the retrospective analysis, provides the benefit of the analysis on a real population, in a real setting, facing the need for clinical decisions in daily clinical practice.

Methods

We conducted a retrospective analysis of our prospective registry of patients who underwent IV-rtPA in our stroke unit between January 1, 2009, and June 30, 2012.

The patients were dichotomized in 2 subgroups: patients aged 80 years or younger and patients over 80 years old. Variables were compared between these subgroups.

Data were obtained from patient files and corporate database and were collected in Microsoft Office Excel 2010 (Microsoft Corporation, Redmond, WA).

Informed consent for IV-rtPA was obtained from patients aged over 80 years old or their relatives.

The information collected included demographic data (sex and age), stroke risk factors, time course data (date/hour at the beginning of symptoms, arrival at the hospital, arrival at the computed tomography scan room, and beginning of IV-rtPA), vascular territory involved, subtype of ischemic stroke according to the Trial of Org 10172 in Acute Stroke Treatment (TOAST) classification, intracranial hemorrhage, and mortality. Severity was assessed by the National Institutes of Health Stroke Scale (NIHSS) (baseline, 2 and 24 hours, and 7 days after IV-rtPA). Functional outcomes at 90 days were measured according to modified Rankin Scale (mRS) and were assessed in a structured follow-up medical appointment 90 days after the stroke.

The primary outcomes that were defined for the present study were mortality rate; hemorrhagic transformation rate per Safe Implementation of Thrombolysis in Stroke-Monitoring Study (SITS-MOST), per European Cooperative

Acute Stroke Study 2 (ECASS-2), and per National Institute of Neurological Disorders and Stroke (NINDS); and favorable outcome after 90 days, defined as an mRS score of 0-1 in patients aged 80 years old or younger and in patients over 80 years old. Secondary outcomes were stroke severity (NIHSS score) 2 and 24 hours and 7 days after IV-rtPA and rate of independent outcome (mRS score 0-2) and of severe disability/death (mRS score 5-6) 90 days after stroke in both age groups.

Statistical analysis was performed in SPSS Statistics 17.0 (SPSS Inc., Chicago, IL). Continuous variables are presented as means and standard deviations, and ordinal variables are presented as medians and interquartile ranges. Variables were compared between 2 two age subgroups using paired-samples *t*-test, independent-samples *t*-test, chi-square test, and Mann-Whitney *U*-test as indicated. A *P* value less than .05 was considered representative of statistical significance.

Results

Study Population

A total of 512 patients underwent IV-rtPA in our unit between January 1, 2009, and June 30, 2012. All patients were included in the present study. Among these patients, 67 (13.1%) were aged over 80 years.

Baseline Characteristics

The baseline characteristics of the patients in the present study are illustrated in [Table 1](#).

The patients' age ranged between 22 and 92 years old. The mean age was 65.4 ± 12.3 years in the younger group and 82.9 ± 2.4 years in the older group ($P < .001$). Majority of the patients (56.8%) were male in the general population. In older patients, even though most patients were males, the percentage of female patients (46.3%) was slightly higher than that in younger patients (42.7%, $P = .582$).

The functional independence before stroke, defined by an mRS score of 1 or lower, did not differ significantly between age groups (95.1% in younger patients, 92.5% in older patients; $P = .390$).

The risk factors for stroke differed between older and younger patients. Hypertension was the most prevalent risk factor in both groups and was more prevalent in older patients, but the difference was not statistically significant ($P = .066$). Hyperlipidemia was the second more common risk factor in both groups. Atrial fibrillation was significantly more prevalent in patients over 80 years than in younger patients ($P = .004$). Smoking was significantly more likely (27.2%) in younger patients ($P = .007$).

Patients over 80 years were previously medicated with acetylsalicylic acid significantly more often (37.3%) than younger patients (20.7%) ($P = .002$). In both age groups, most patients with atrial fibrillation were not medicated

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