

# Intravenous Thrombolysis with Recombinant Tissue-type Plasminogen Activator for Acute Ischemic Stroke in Patients with Metabolic Syndrome

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**Background:** The metabolic syndrome (MetS) is common in patients with acute ischemic stroke (IS); however, its impact on outcome after intravenous thrombolysis (iv-thrombolysis) remains unclear. Thus, we aimed at evaluating the relationship between MetS and functional long-term outcome, mortality, and the presence of hemorrhagic complications in patients with IS treated with iv-thrombolysis. **Methods:** We retrospectively evaluated the demographic and clinical data of 535 Caucasian patients with acute IS who were consecutively treated with iv-thrombolysis from September 2006 to June 2013 in 2 experienced stroke centers in Poland. A favorable functional long-term outcome was defined as a modified Rankin scale score less than or equal to 2 points on day 90, and hemorrhagic complications were assessed with European Cooperative Acute Stroke Study criteria. **Results:** MetS was recognized in 192 (35.9%) patients (44.8% men; mean age,  $70.8 \pm 11.1$  years), diabetes in 29.7%, dyslipidemia in 79.2%, and arterial hypertension in 75.5%. At 3 months, favorable outcome was found in 55.3% of patients, symptomatic intracerebral hemorrhage (SICH) in 18.3%, and 4.4 % of patients died. There was no difference regarding the presence of favorable outcome between patients with and without MetS (52.6% versus 56.9%,  $P = .34$ ). The presence of SICH and 3-month mortality were more frequent in patients with MetS than without MetS (6.8% versus 2.9%,  $P = .03$  and 23.4% versus 15.5%,  $P = .02$ , respectively); however, a multivariate analysis showed no impact of MetS on mortality or SICH. **Conclusions:** Results of our study provide no data to suggest that the effect of intravenous tissue-type plasminogen activator differs based on the presence or absence of MetS. **Key Words:** Metabolic syndrome—acute ischemic stroke—rt-PA—intravenous thrombolysis.

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## Introduction

Metabolic syndrome (MetS) is a cluster of cardiovascular risk factors that is highly prevalent in the adult population of developed countries and significantly increases the risk of cardiovascular events and all-cause mortality.<sup>1-4</sup> An increased risk of ischemic stroke (IS) associated with MetS mainly derives from its high potential to enhance the early development and further progress of atherosclerosis in brain-supplying arteries and to defect endogenous fibrinolysis.<sup>5-9</sup> Consequently, MetS is more common in IS patients than in the general population and significantly predicts a poor outcome after IS.<sup>10-12</sup>

Numerous proatherothrombotic effects of MetS on endogenous fibrinolysis and the vascular endothelium may also contribute to a higher resistance to thrombolytic interventions in patients with IS. Patients with MetS show impaired response after thrombolytic therapy for acute myocardial infarction and a higher incidence of major adverse cardiac events after percutaneous coronary intervention.<sup>13,14</sup> However, the impact of MetS on the safety and efficacy of cerebral systemic thrombolysis (intravenous [iv] thrombolysis) with tissue-type plasminogen activator (t-PA), which is the only proven medical therapy for IS, is not clear. Studies of iv-thrombolysis in patients with MetS have had inconsistent results, regarding both outcome and complication rates. Moreover, published analyses are based on a relatively limited number of subjects and inconsistent definitions of MetS.<sup>15-17</sup>

Therefore, we aimed at evaluating the relationship between MetS and functional long-term outcome, mortality, and the presence of hemorrhagic complications in a cohort of Caucasian patients with acute IS consecutively treated with iv-thrombolysis.

## Materials and Methods

We retrospectively evaluated the demographic and clinical data of 535 Caucasian patients with acute IS (52.7 % men; aged 41-92; mean age,  $70.8 \pm 11.9$ ) who were consecutively treated with iv-thrombolysis from September 2006 to June 2013 in 2 experienced stroke centers in Poland (the Department of Neurology and the Stroke Unit of the Holy Spirit Specialist Hospital in Sandomierz and the Department of Neurology and Stroke Unit of the Saint Lucas Hospital in Końskie). These study centers are recognized as stroke units according to the Polish national criteria, are equipped with the proper monitoring and diagnostic facilities, and provide a 24-hour stroke service 7 days a week.<sup>18</sup>

### Protocol

Participating stroke units performed diagnostic and treatment procedure protocols with respect to unified reg-

ular protocols of the management of acute IS and secondary prevention, according to international recommendations.<sup>19,20</sup> A stroke physician examined all patients at the time of admission, and the severity of stroke symptoms was assessed using the National Institutes of Health Stroke Scale (NIHSS).<sup>21</sup> Stroke onset was defined as the last occasion on which the patient was known to be without neurologic deficit. Examinations to evaluate the coagulation status in all patients were performed. Computed tomography scans were taken on admission to the hospital to establish the indication for treatment, between 22 and 36 hours and on the seventh day after iv-thrombolysis. Intravenous recombinant t-PA (rt-PA) was applied according to the recommendations for thrombolytic treatment. Since the publication of the European Cooperative Acute Stroke Study (ECASS-III) trial and data from the Safe Implementation of Thrombolysis in Stroke (SITS) registry, patients were treated within the 4.5-hour time window.<sup>22-24</sup> To evaluate the etiology of stroke in patients, transcranial Doppler, carotid duplex ultrasonography, Holter electrocardiography, transthoracic echocardiography, and in case of some patients transesophageal echocardiography were performed.

The 90-day stroke outcomes were measured using the modified Rankin scale (mRS).<sup>25</sup> A favorable outcome was defined as an mRS score less than or equal to 2 points, whereas an unfavorable outcome was defined as an mRS score of 3-6 points. Hemorrhagic transformation and symptomatic intracerebral hemorrhage (SICH) rates were assessed according to the ECASS II criteria,<sup>26</sup> by an experienced radiologist blinded to patients' functional status and risk factor profile.

### Metabolic Syndrome Definition

We used the definition of MetS according to an American Heart Association/National Heart, Lung, and Blood Institute Scientific Statement, defining MetS as the presence of 3 or more of the following: (1) an elevated waist circumference of more than 102 cm for men and more than 88 cm for women; (2) elevated triglycerides greater than 150 mg/dL or on drug treatment for elevated triglycerides; (3) reduced HDL cholesterol of less than 40 mg/dL for men and less than 50 mg/dL for women or on drug treatment for reduced HDL cholesterol; (4) elevated blood pressure of 130 mm Hg or more of systolic blood pressure or 80 mm Hg or more of diastolic blood pressure or on antihypertensive drug treatment in patients with a history of hypertension; (5) elevated fasting blood glucose greater than or equal to 100 mg/dL or on drug treatment for elevated glucose.<sup>27</sup>

The ethics committee approved all data analyses (Ethics Committee of Świętokrzyska Medical Chamber), and all patients treated with iv-thrombolysis were reported to the SITS registry.

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