The Case:
A healthy 60-year-old man presents with acute left-sided weakness 4 hours after symptom onset. National Institutes of Health Stroke Scale score is 8. Head computed tomography shows no hemorrhage or early signs of ischemia. Routine laboratory tests are within normal.

The Questions:
1. Should he be treated with intravenous thrombolysis?
2. Are other tests needed before initiation of treatment?

The Controversy:
Is The 4.5-Hour Time Window for Intravenous Thrombolysis With Recombinant Tissue-Type Plasminogen Activator (rTPA) Firmly Established?

4.5-Hour Time Window for Intravenous Thrombolysis With Recombinant Tissue-Type Plasminogen Activator Is Established Firmly

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prior stroke, among other criteria, from intravenous thrombolysis. It is daily practice, however, that these criteria are not followed to the letter, especially after several analyses from the Virtual International Stroke Trials Archive (VISTA) group and thrombolysis trialists (references 15–18, 20–21, and 28, summarily discussed in Frank et al3), as well as IST-3.4 In fact, even IST-3, a randomized off-label thrombolysis trial, was nearly positive for the primary end point and positive for a change across the whole range of the Oxford Handicap Scale (which in practical terms is nearly identical to the modified Rankin Scale). Furthermore, most countries on this planet have a label similar or equal to the European label including the whole of Europe, Australasia, Russia, some countries in Africa and South America. In fact, the US label is the exception to the rule, not vice versa. As a consequence, in countries such as Germany, currently 10% of all patients with ischemic stroke receive thrombolytic therapy, with much lower door-to-needle times than recently reported in a Get With the Guidelines study, where only 18% of the golden hour patients received rt-PA within 60 minutes from door to needle.5

Final Comments

1. These authors understand the difficulty of adapting a label change in the United States and Canada, necessitating 2 different labels for the 2 time windows as opposed to Europe, where just the time window was extended.

2. These authors cannot follow the actual class I level B rating of thrombolysis within 3 to 4.5 hours1 when compared with the same rating given for, for example, decompressive surgery in space occupying cerebellar infarction or thrombectomy. Strikingly, there seemed to be little hesitation to treat many patients with thrombectomy during the past few years with no evidence-based proof of efficacy over standard intravenous thrombolysis.

3. For us, as stroke physicians in a country were the described patient falls into the label of rt-PA, which is based on clear evidence from many analyses and more importantly a positive randomized controlled large clinical trial, there is only 1 rational conclusion to the question: the patient must be treated, quod erat demonstrandum.

Disclosures

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References


Key Words: controlled clinical trials, randomized ■ stroke ■ thrombolytic therapy
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