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Thrombolytic therapy for acute ischaemic stroke: is the hype justified?

To the Editor—Implementation of thrombolytic therapy for acute ischaemic stroke¹ has to be viewed in an appropriate context.

The main justification for such therapy relies on findings from a relatively small, randomised controlled trial known by the acronym NINDS (National Institute of Neurological Disorders and Stroke rt-PA trial),² about which there are serious reservations.³ Overall treatment benefits (if any) were trivial, whilst there were very high risks of adverse events such as intracranial haemorrhage, and immense logistical and financial implications. This was in marked contrast to the very favourable benefits of thrombolysis for acute myocardial infarction.

Moreover, in two particularly important respects, the NINDS trial can be regarded as flawed.⁴ First, part 2 of the trial (the main impetus for this treatment) relied on a global test statistic as the primary outcome, and not on incontrovertible hard endpoints. The latter arbitrary statistic was itself a composite of four neurological scores (Table). Clinically and statistically significant differences depending on any such composite of inter-related overlapping soft endpoints must be inherently suspected. Second, patients in both the control and active treatment groups received no aspirin in the first 24 hours, so that those treated with recombinant tissue plasminogen activator (t-PA) were compared with controls who received suboptimal standard therapy. To overcome the risk of serious intracranial bleeding from combined t-PA plus aspirin therapy, dummy aspirin should have been administered to the active treatment group and genuine aspirin to the controls.

Under these circumstances, is the hype surrounding this form of treatment for acute ischaemic stroke appropriate and justified?

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References