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# ENCHANTED results challenge reduced alteplase dose in Asian stroke patients

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By Eleanor McDermid

A reduced dose of alteplase has failed to prove itself noninferior to the standard dose in a predominantly Asian population of patients with ischaemic stroke.

A low dose of 0.6 mg/kg is approved in Japan because of fears of a higher risk of major symptomatic intracranial haemorrhage (ICH) in Asian patients.

Although patients treated with this dose in the current trial - the ENCHANTED trial - did have fewer major symptomatic ICHs (SITS-MOST criteria) than those treated with the standard 0.9 mg/kg dose, at 1.0% versus 2.1%, they did not achieve better overall outcomes, [show the findings in \*The New England Journal of Medicine\*](#).

Specifically, 53.2% of 1607 patients given the low dose and 51.1% of 1599 given the standard dose met the primary endpoint of death or disability at 90 days, defined as a modified Rankin Scale score of 2-6.

This equated to an odds ratio of 1.09, with a confidence interval of 0.95 to 1.25, and the upper limit of the confidence interval exceeded the prespecified 1.14 for noninferiority. The same was true in adjusted analyses of the intention-to-treat and per protocol populations and in subgroup analyses including Asian patients (63.2% of the population).

Significantly fewer patients in the low-dose group had a fatal ICH, at 1.3% versus 2.5% of the standard-dose group. However, more patients died from other causes, such as their initial ischaemic stroke, with 8.5% versus 10.3% dying overall - a nonsignificant difference.

The slight reduction in mortality among the low-dose patients "was accompanied by more patients surviving with mild to moderately severe grades of residual disability", say Craig Anderson (George Institute for Global Health, Sydney, Australia) and co-researchers, who reported their findings today at [the European Stroke Organisation conference in Barcelona, Spain](#).

In [an accompanying editorial](#), Cathy Sila (University Hospitals-Case Medical Center, Cleveland, Ohio, USA) says: "ENCHANTED provides no compelling evidence for using low-dose alteplase for acute ischemic stroke in Asian or other populations on the basis of safety considerations or clinical outcomes."

But she says that cost may become a consideration, noting that the average cost of alteplase has doubled over the past decade, and warns: "Using less effective therapies to save short-term costs will only increase the costs of long-term care for disabled stroke survivors."

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Source:

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