Outcomes following sonothrombolysis in severe acute ischemic stroke: subgroup analysis of the CLOTBUST trial.

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Abstract
BACKGROUND: Sonothrombolysis is safe and may increase the likelihood of early recanalization in acute ischemic stroke patients.

AIMS: In preparation of a phase III clinical trial, we contrast the likelihood of achieving a sustained recanalization and functional independence in a post hoc subgroup analysis of patients randomized to transcranial Doppler monitoring plus intravenous tissue plasminogen activator (sonothrombolysis) compared with intravenous tissue plasminogen activator alone in the CLOTBUST trial.

METHODS: We analyzed the data from all randomized acute ischemic stroke patients with pretreatment National Institutes of Health Stroke Scale scores ≥ 10 points and proximal intracranial occlusions in the CLOTBUST trial. We compared sustained complete recanalization rate (Thrombolysis in Brain Ischemia flow grades 4-5) and functional independence (modified Rankin Scale 0-1) at 90 days. Safety was evaluated by the rate of symptomatic intracranial hemorrhage within 72 h of stroke onset.

RESULTS: Of 126 patients, a total of 85 acute ischemic stroke patients met our inclusion criteria: mean age 71 ± 11 years, 56% men, median National Institutes of Health Stroke Scale 17 (interquartile range 14-20). Of these patients, 41 (48%) and 44 (52%) were randomized to intravenous tissue plasminogen activator alone and sonothrombolysis, respectively. More patients achieved sustained complete recanalization in the sonothrombolysis than in the intravenous tissue plasminogen activator alone group (38-6% vs. 17·1%; P = 0·032). Functional independence at 90 days was more frequently achieved in the sonothrombolysis than in the intravenous tissue plasminogen activator alone
group (37.2% vs. 15.8%; P = 0.045). Symptomatic intracranial hemorrhage rate was similar in both groups (4.9% vs. 4.6%; P = 1.00).

**CONCLUSIONS:** Our results point to a signal of efficacy and provide information to guide the subsequent phase III randomized trial of sonothrombolysis in patients with severe ischemic strokes.