Systematic Evaluation Of Patients Treated With Neurothrombectomy Devices For Acute Ischemic Stroke: Primary Results Of The STRATIS Registry


BACKGROUND: Although randomized clinical trials have established a role for mechanical thrombectomy in the treatment of selected patients with acute ischemic strokes, its use in real-world settings requires clarification.

METHODS: The authors, coordinated at Tenet South Florida and sponsored by Medtronic (manufacturer of the study thrombectomy devices), examined the severity of disability at 90 days in 984 patients (mean age, 67.8) managed at 55 US centers for acute ischemic strokes due to intracranial large vessel occlusion who were to undergo mechanical thrombectomy within eight hours after symptom onset, without restrictions on imaging protocols or technique. The patients were included in the STRATIS registry of acute ischemic stroke patients. The primary outcome was the severity of disability at 90 days.

RESULTS: The Solitaire thrombectomy device was used in 96.9% of the patients and the Mindframe device in 3.1%. Substantial reperfusion was achieved in 87.9% of the patients. Symptomatic intracranial hemorrhage occurred in 1.4%. By 90 days, a good functional outcome (mRS 0-2) was achieved in 56.5% of the patients and an excellent outcome (mRS 0-1) in 43.2%; the 90-day all-cause mortality rate was 14.4%. On subgroup analyses, clinical outcomes were less favorable with increasing age. Compared with recent randomized controlled trials, the rate of good functional outcome was similar in this study (56.5% vs. 54.0%), and the rate of excellent functional outcome was significantly higher (43.2% vs. 35.8%), despite inclusion of patients with more risk factors.

CONCLUSIONS: This study suggests that in the real-world setting, mechanical thrombectomy with the Solitaire device is as safe and at least as effective as reported in carefully controlled trials.

18 references (muellerkronast@gmail.com – no reprints)

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EDITOR’S COMMENTARY: The authors of this industry-sponsored, multi-center, non-randomized, prospective trial enrolled approximately 1000 patients with large vessel occlusion to demonstrate that patients in a “real-world” setting are as likely to benefit from mechanical thrombectomy as patients who had been previously been highly selectively enrolled through randomized controlled trials performed at large comprehensive stroke centers. The authors found that 56% of the patients achieved a “good” functional outcome (mRS of 0-2) and 43% of patients achieved an “excellent” outcome (mRS of 0-1). They conclude that the Solitaire device is safe and as effective in less carefully selected patients in real-world hospitals. This study is limited by its industry-sponsored bias and high propensity for patient selection bias.