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STROKE

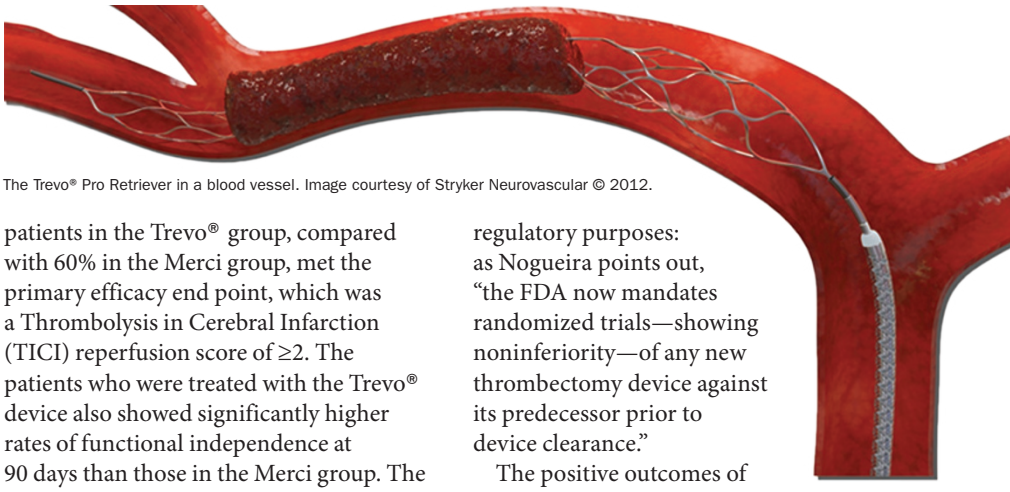
New mechanical clot retrieval devices show superiority in patients with acute ischaemic stroke

Two new mechanical clot retrieval devices are superior to the current standard device for achieving recanalization in cases of stroke caused by large-vessel occlusion, according to new trial results published in *The Lancet*. The Trevo® Retriever (Stryker Neurovascular, Mountain View, CA, USA) and the Solitaire Flow Restoration Device (Covidien/ev3, Dublin, Ireland) were both found to be more effective than the Merci Retriever (Stryker Neurovascular), which was the first clot retrieval device to be approved by the FDA.

Mechanical clot retrieval is a treatment option for patients with large-vessel occlusion strokes who are ineligible for—or have failed to respond adequately to—thrombolysis with recombinant tissue plasminogen activator. The retrieval device is deployed to the occluded vessel via a microcatheter. Unlike the Merci Retriever, which uses a corkscrew-shaped coil, the new devices employ a stent-like cage to trap the clot. Stent retrievers are thought to offer a number of advantages over coil retrievers, including better engagement with the clot, and a reduced propensity to damage the wall of the blood vessel.

"There was a clinical need for better stroke thrombectomy devices, since the previously available devices fail to achieve recanalization in as many as 20–40% of proximal artery occlusion strokes," explains Raul Nogueira from the Emory University School of Medicine, Atlanta, GA, USA, who was involved in both studies and led the TREVO 2 trial. "Moreover, they took a long time to achieve recanalization and required a great deal of technical expertise."

In TREVO 2, an open-label randomized controlled trial, Nogueira and his colleagues randomly assigned 178 patients with large-vessel occlusion stroke to treatment with the Trevo® Retriever ($n = 88$) or the Merci Retriever ($n = 90$). Following use of the devices, 86% of patients in the Trevo® group, compared with 60% in the Merci group, met the primary efficacy end point, which was a Thrombolysis in Cerebral Infarction (TICI) reperfusion score of ≥2. The patients who were treated with the Trevo® device also showed significantly higher rates of functional independence at 90 days than those in the Merci group. The two devices were comparable with regard to safety end points.



The Trevo® Pro Retriever in a blood vessel. Image courtesy of Stryker Neurovascular © 2012.

The Solitaire Flow Restoration Device was tested in a randomized, parallel-group, noninferiority trial known as SWIFT (Solitaire With the Intention For Thrombectomy). A team led by Jeffrey Saver from the University of California, Los Angeles, CA, USA recruited 113 patients with acute ischaemic stroke, 58 of whom were treated with the Solitaire device, and 55 of whom were treated with with the Merci Retriever.

The primary efficacy end point —a score of 2 or 3 on the Thrombolysis in Myocardial Ischaemia (TIMI) scale without symptomatic intracranial haemorrhage after clot retrieval—was met by 61% of patients in the Solitaire group but only 24% of patients in the Merci group. Like the Trevo® Retriever, the Solitaire device produced better neurological outcomes 90 days after treatment than did the Merci Retriever. In addition, the Solitaire device performed better than the Merci Retriever in terms of safety outcomes.

TREVO 2 and SWIFT are the first randomized trials to directly compare two different endovascular recanalization techniques in patients with acute ischaemic stroke. Such head-to-head trial designs are essential for regulatory purposes: as Nogueira points out, "the FDA now mandates randomized trials—showing noninferiority—of any new thrombectomy device against its predecessor prior to device clearance."

The positive outcomes of the two trials are particularly promising in light of the investigators' relative lack of experience with the Trevo® and Solitaire devices compared with the Merci Retriever—a factor that might have been expected to bias the results against the newer devices.

"Given our encouraging results, we plan to use the Trevo® Retriever in a prospective randomized trial of endovascular therapy against medical treatment alone," says Nogueira. "The hope is to establish endovascular therapy as the standard of care for proximal arterial occlusion strokes."

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Original articles Nogueira, R. G. *et al.* Trevo versus Merci retrievers for thrombectomy revascularisation of large vessel occlusions in acute ischaemic stroke (TREVO 2): a randomised trial. *Lancet* doi:10.1016/S0140-6736(12)61299-9 | Saver, J. L. *et al.* Solitaire flow restoration device versus the Merci Retriever in patients with acute ischaemic stroke (SWIFT): a randomised, parallel-group, non-inferiority trial. *Lancet* doi:10.1016/S0140-6736(12)61384-1

Further reading Nogueira, R. G. *et al.* The Trevo device: preclinical data of a novel stroke thrombectomy device in two different animal models of arterial thrombo-occlusive disease. *J. Neurointerv. Surg.* **4**, 295–300 (2011) | Pérez, M. A. *et al.* Intracranial thrombectomy using the Solitaire stent: a historial vignette. *J. Neurointerv. Surg.* doi:10.1136/neurintsurg-2011-010149