New device performs better than old for removing blood clots

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An experimental blood clot-removing device outperformed the FDA-approved MERCI; retriever device, according to late-breaking science presented at the American Stroke Association's 2012 International Stroke Conference.

The SOLITAIRE; Flow Restoration Device is a self-expanding stent-based design that mechanically removes blood clots from blocked vessels after a stroke. After insertion into the clot using a thin tube, or catheter, the device traps the clot then both device and clot are removed, restoring blood flow. The MERCI retriever uses a tiny corkscrew, guided by a balloon-tipped wire, to snare and remove the blood clot.

In the Solitaire With the Intention for Thrombectomy (SWIFT) trial, the first U.S. clinical trial to compare the two devices, 113 stroke patients at 18 hospitals were randomly assigned to undergo clot removal with either device within eight hours of stroke onset between Feb. 2010-Feb. 2011.

The trial was ended at the suggestion of a safety monitoring committee nearly a year earlier than planned due to significantly better outcomes with the new device. The experimental device opened blocked vessels without causing symptomatic intracranial hemorrhage in 61 percent of patients. The currently approved device had the same result in 24 percent of cases - a statistically significant difference, said Jeffrey L. Saver, M.D., lead author of the study, professor of neurology and director of the Stroke Center in the Geffen School of Medicine at the University of California in Los Angeles.

The use of the new device also led to better survival three months after stroke. There was a 17.2 percent mortality rate with the new device versus 38.2 percent with the older one.

Stroke caused by a blood clot blocking a blood vessel supplying the brain is the most common type of stroke, accounting for about 87 percent of all strokes. The FDA-approved treatment for stroke with the most robust body of evidence is use of a clot-busting drug, but the drug must be given within 4.5 hours of symptom onset, and more quickly in older patients. When clot-busting drugs cannot be used or are ineffective, the clot can sometimes be mechanically removed, during or even after the 4.5 hours. The study didn't compare mechanical clot removal to drug treatment.

Although not yet approved in the United States, the new device is approved in Europe.

Other specific findings - all of which were statistically significant - were:

Two percent of SOLITAIRE-treated patients had symptoms of bleeding in the brain compared to 11 percent of MERCI patients.

At the 90-day follow-up, overall adverse event rates, including bleeding in the brain, were similar for the two devices.

Fifty-eight percent of SOLITAIRE-treated patients had good mental/motor functioning at 90 days compared to 33 percent of MERCI patients.

The SOLITAIRE device also opened more vessels when used as the first treatment approach, necessitating fewer subsequent attempts with other devices or drugs.

Patients' average age was 67 years and 68 percent were male. Forty percent had not improved with standard clot-busting medication prior to the study, while the remainder had not received it.

The time from the start of symptoms to start of the clot retriever treatment was on average 4.9 hours for SOLITAIRE and 5.3 hours for MERCI. The study results account for this time difference.

"This heralds a new era in acute stroke care," said Saver. "We're going from our first generation of recanalization procedures, which were only moderately good in reopening target arteries, to now having a highly effective recanalization device. This really is a game-changing result."

Provided by American Heart Association