

# Study finds expensive procedure no more effective than medical therapy to prevent strokes

March 14 2012

---

A catheter procedure that closes a hole in patients' hearts was no more effective than medical therapy in preventing recurrent strokes, according to a new study published in the March 15 issue of the *New England Journal of Medicine*.

In the CLOSURE I trial, clinical researchers compared a [catheter](#) procedure plus [medical](#) therapy with medications alone to prevent new strokes or [transient ischemic attacks](#) (TIAs) in patients between 18 and 60 years old with an unexplained ("cryptogenic") stroke or TIA and a [patent](#) foremen ovale (PFO) – a hole between the heart's two upper chambers.

In the ground-breaking, international multi-site study led by University Hospitals (UH) Case Medical Center and Case Western Reserve University School of Medicine, researchers sought to demonstrate the superiority of the STARFlex® Septal Closure System over medical therapies (aspirin or warfarin) alone. Instead, results showed no statistically significant differences between the two therapies.

"These important findings will serve as a guidepost in the prevention of stroke in patients with PFO," said Anthony J. Furlan, MD, lead investigator of the study and Chairman of the Department of Neurology at UH Case Medical Center and Case Western Reserve University School of Medicine.

In an accompanying editorial, S. Claiborne Johnston, MD, PhD, from the University of California, San Francisco, wrote, "...CLOSURE I provides the best evidence available regarding the role of closure in stroke prevention and should not be ignored. The results of the trial do not support closure of a patent foramen ovale to prevent stroke in patients who have had a stroke or a TIA of unclear etiology."

The editorial also notes that it took nine years for the results of this trial to be reported and during that time, approximately 80,000 patients have had a PFO closed with the use of a device at an average cost of \$10,000 per procedure. "Even if only half these patients were treated by this method for the purpose of preventing stroke, it would suggest that during that period of time \$400 million was spent on a procedure that had no apparent benefit, to say nothing of the potential clinical risks involved," wrote Dr. Johnston.

Strokes of unknown origin – cryptogenic strokes – have several causes, including PFO, a hole that is vital to fetal survival between the heart's two upper chambers if it doesn't close completely after birth. If a blood clot arises in a vein and passes through the hole and reaches the brain (called "paradoxical embolism"), a stroke results. In roughly 20 percent of adults, remnants of the hole persist.

CLOSURE I is the first completed prospective, randomized, two-arm superiority trial of percutaneous PFO device closure versus medical therapy alone in cryptogenic stroke patients using the STARFlex Septal Closure System. The device, attached to a catheter and threaded into the upper heart, applies a "clamshell" patch on both sides of the hole.

The trial's primary endpoint was the difference in the stroke and TIA rates between the two patient groups at two years, death from all causes in the first 30 days, and death from neurological causes at 30 days or more.

Dr. Furlan and colleagues enrolled 909 patients at 87 United States and Canadian sites during 64 months ending October 2008. Researchers randomized patients to either medical therapy (325 mg of aspirin or the appropriate warfarin dose, or a combination of both) or PFO closure and medical therapy (75 mg of clopidogrel for six months and 325 mg of aspirin for two years).

"Based on the trial results, even though a patient had a PFO and a recurrent stroke, the hole may be totally coincidental to the second stroke," Dr. Furlan said. "The undeniable message here is that too many of these holes are being closed with an off-label procedure, but partly that is because we've never had a randomized trial to guide us. Furthermore, our criteria for diagnosing paradoxical embolism and the potential efficacy of PFO closure in patient subgroups require further study. Until then we would advise initial secondary stroke prevention with [medical therapy](#) in most patients with unexplained [stroke](#) or TIA and a PFO. "

Provided by University Hospitals Case Medical Center

Citation: Study finds expensive procedure no more effective than medical therapy to prevent strokes (2012, March 14) retrieved 25 April 2024 from <https://medicalxpress.com/news/2012-03-expensive-procedure-effective-medical-therapy.html>

<p>This document is subject to copyright. Apart from any fair dealing for the purpose of private study or research, no part may be reproduced without the written permission. The content is provided for information purposes only.</p>
--