Stenting as effective as endarterectomy for preventing strokes in asymptomatic patients

February 17 2016

The most modern clinical trial to compare the use of carotid-artery stenting with carotid endarterectomy for the prevention of strokes in asymptomatic patients with serious narrowing of the carotid artery finds no significant differences in outcomes between the two procedures over a period of up to five years. The results are receiving Online First publication in the *New England Journal of Medicine* to coincide with their presentation at the International Stroke Conference in Los Angeles.

"Our study showed that carotid-artery stenting is just as safe and just as effective in treating asymptomatic patients as carotid endarterectomy, which has been the standard treatment approach for patients who are not at high risk for open surgery," says Kenneth Rosenfield, MD, MHCDS, head of Vascular Medicine and Intervention in the Massachusetts General Hospital (MGH) Division of Cardiology, lead and corresponding author of the NEJM report. "While a previous, major trial also found equivalent results for the two procedures, it was not able to determine whether that result applied to patients with asymptomatic carotid stenosis."

The authors from eight U.S. medical research centers note that stroke is the fifth leading cause of death - causing more than 170,000 deaths a year - and the number one cause of disability in the U.S. Among the almost 800,000 strokes that occur each year, 20 percent of those involving inadequate blood flow to the brain are caused by narrowing of the carotid artery, the brain's primary blood supply. In carotid endarterectomy, plaque deposits that cause significant narrowing of the

artery are surgically removed, and several major trials have shown that the procedure significantly reduces the incidence of stroke or death in patients with more than 60 percent blockage of the artery.

Carotid-artery stenting involves placement of an expandable mesh scaffold into the area of the blockage via a catheter threaded up through other major arteries. Using a balloon, the stent is expanded against the artery walls to improve blood flow. The plaque is displaced and pressed against the wall by the stent to keep the artery open, which creates a channel and prevents recurrence of the narrowing after the catheter is withdrawn. The procedure also involves the use of umbrella-shaped filtering devices to capture any pieces of plaque that break off during stent placement and remove them before they are able to travel to the brain.

A 2010 study (the Carotid Revascularization Endarterectomy versus Stenting Trial or CREST) found that both procedures had similar outcomes, although in the period immediately after the procedures there was a slightly higher risk of minor stroke with carotid-artery stenting and of heart attack with carotid endarterectomy. But CREST examined patients both with and without prior symptoms of stroke and did not enroll enough asymptomatic participants to determine whether the results applied independently to those patients. The current study, called Asymptomatic Carotid Trial (ACT) I, was designed to investigate that specific question.

Conducted from 2005 to 2013 at 97 U.S. centers, ACT I enrolled 1,453 participants aged 79 or less, all of whom had no stroke-related symptoms despite having narrowing of from 70 to 99 percent of one carotid artery. Their diagnoses were confirmed by either ultrasound or angiogram, often after their physician had detected a characteristic sound called a bruit while listening to the carotid area with a stethoscope. Participants were randomly assigned to either carotid endarterectomy or carotid-

artery stenting and received a complete neurological assessment before and after the procedure; 1, 6 and 12 months later; and then annually for up to five years.

A total of 1,089 patients received carotid stents, while 364 had carotid endarterectomy. In terms of the incidence of stroke, death or heart attack in the 30 days after the procedure, overall rates were very low - around 3.5 percent for each - and with no significant difference between the two groups. The long-term results also were very similar, with 97.3 percent of those in the stenting group and 97.8 percent in the endarterectomy group remaining free of stroke involving the treated side.

The authors note that treatment of carotid stenosis with medications only - platelet-blocking agents, statins and drugs to reduce blood pressure - has become more accepted in recent years. However, whether medical treatment alone outweighs the benefit of eliminating the blockage in asymptomatic patients has yet to be investigated. "We really do not know if patients with severe asymptomatic carotid-artery stenosis can be safely treated with medications only," says study co-author Michael R. Jaff, DO, medical director of the MGH Fireman Vascular Center. "That is the outstanding remaining critical question."

A follow-up to the CREST trial - called CREST 2 - has been designed to investigate the role of stenting or endarterectomy versus intensive medical treatment alone in asymptomatic patients with severe carotid stenosis. Also important to investigate, adds Jaff - who is a professor of Medicine at Harvard Medical School and the Fireman Chair in Vascular Medicine at MGH - will be methods of determining which procedure is best for a specific individual patient.

More information: *New England Journal of Medicine*, dx.doi.org/10.1056/NEJMoa1515706