Study compares outcomes for stent vs. medications for narrowed artery within the brain

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Among patients with symptomatic intracranial arterial stenosis (narrowing of an artery inside the brain), the use of a balloon-expandable stent compared with medical therapy (clopidogrel and aspirin) resulted in an increased of stroke or transient ischemic attack (TIA), according to a study in the March 24/31 issue of *JAMA*.

Intracranial arterial stenosis is a common cause of stroke worldwide. The recurrent stroke risk with severe symptomatic intracranial stenosis may be as high as 23 percent at 1 year, despite medical therapy, according to background information in the article.

Osama O. Zaidat, M.D., M.S., of the Medical College of Wisconsin/Froedtert Hospital, Milwaukee, and colleagues randomly assigned 112 patients with symptomatic intracranial stenosis (narrowing of 70 percent or greater) to receive a balloon-expandable stent plus medical therapy (stent group; n = 59) or medical therapy alone (medical group; n = 53). Medical therapy consisted of clopidogrel (75 mg daily) for the first 3 months after enrollment and aspirin (81-325 mg daily) for the study duration. This international trial (VISSIT) enrolled patients from 27 sites (January 2009-June 2012) with last follow-up in May 2013. Enrollment was halted by the sponsor after negative results from another trial prompted an early analysis of outcomes, which suggested futility after 112 patients of a planned sample size of 250 were enrolled.

The 30-day safety end point of any stroke within 30 days or hard TIA (defined as a transient episode of neurological dysfunction caused by focal brain or retinal ischemia lasting at least 10 minutes but resolving within 24 hours) within 2 to 30 days was 9.4 percent (5/53) in the medical group and 24.1 percent (14/58) in the stent group. Ischemic stroke was observed in 3 patients (5.7 percent) in the medical group and in 10 patients (17.2 percent) in the stent group. Intracranial hemorrhage occurred in 5 patients (8.6 percent) in the stent group and in 0 in the medical group. The 1-year outcome of stroke or hard TIA occurred in more patients in the stent group (36.2 percent) vs the medical group (15.1 percent).

Thirty day all-cause death was 3 of 58 patients (5.2 percent) in the stent group and 0 in the medical group. A measure of disability worsened in more patients in the stent group than in the medical group.

"These findings do not support the use of a balloon-expandable stent for patients with intracranial arterial stenosis," the authors conclude.

Marc I. Chimowitz, M.B.Ch.B., of the Medical University of South Carolina, Charleston, and Colin P. Derdeyn, M.D., of the Washington University School of Medicine, St. Louis, comment in an accompanying editorial.

"For endovascular therapy (e.g., angioplasty alone or new stents) to have any role, multicenter pilot studies will be required to establish the safety and potential efficacy of these devices in carefully defined patient populations. Given the disappointing performance of intracranial stenting in both VISSIT and SAMMPRIS [a trial with similar results], it is difficult to foresee how these necessary steps will happen anytime soon."

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