Medical management alone may be best treatment course for stroke prevention

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Patients with narrowed arteries in the brain who received intensive medical treatment had fewer strokes and deaths than patients who received a brain stent in addition to medical treatment, according to the initial results from the first, nationwide stroke prevention trial to compare the two treatment options. The results of the National Institutes of Health (NIH) study called Stenting versus Aggressive Medical Management for Preventing Recurrent Stroke in Intracranial Stenosis (SAMMPRIS) are published in the online first edition of the *New England Journal of Medicine*.

Rush University Medical Center is the only hospital in Chicago and one of two sites in Illinois that participated in the clinical trial funded by the National Institute of Neurological Disorders and Stroke (NINDS), which is part of the NIH.

"Stenting was associated with a higher stroke and death rate at 30 days (14.7 percent) versus aggressive medical management alone," said Dr. Shyam Prabhakaran, neurologist and site lead investigator at Rush. "At this time, stenting cannot be supported in routine practice; however, whether subgroups may benefit from this or other interventions in the future needs further study."

"This study provides an answer to the longstanding question of what to do to prevent a devastating second stroke in a high risk population," said Prabhakaran, co-author of the New England Journal of Medicine article. "All patients should be managed aggressively with medications."

The medical regimen used in the study included daily blood-thinning medications and aggressive control of blood pressure and cholesterol.

New enrollment in the study was halted in April because early data indicated that strokes and deaths occurred more significantly among the stented patients at the 30-day mark compared to a group of study participants who received medical management alone.

In addition to the intensive medical program, half of the patients participating in the study received an intervention of a self-expanding stent that widens the major artery in the brain and facilitates blood flow. Study authors suggest one possible explanation for the higher stroke rate in the group that received stents. Patients who have had recent stroke symptoms sometimes have unstable plaque in their arteries which the stent could have dislodged.

The device used in the study, called the Gateway-Wingspan intracranial angioplasty and stenting system, is the only system currently FDA approved for certain high-risk stroke patients.

Study participants were in the highest risk category with blockage or narrowing of the arteries from 70-99 percent. Stroke patients with moderate cerebral arterial blockage (50-69 percent) were excluded because their risk of stroke is low with the usual medical management and because researchers thought this group would be unlikely to benefit from stenting.

The SAMMPRIS trial enrolled 451 patients at 50 hospital sites in the U.S. Study investigators analyzed whether patients had a second stroke or died within 30 days of enrollment, or had a stroke in the same area of the brain from 30 days to the end of follow-up. Patients in the study were between 30 and 80 years of age and had experienced a recent transient ischemic attack, a type of stroke that resolved within 24 hours,

or another type of non-disabling stroke, which was caused by a large degree of stenosis in the cerebral artery.

The initial hypothesis was that the addition of intracranial stenting to intensive medical therapy would decrease the risk of stroke of death by 35 percent over two years. Instead, researchers found that 14.7 percent of patients in the stenting group experienced a stroke or died compared to the 5.8 percent of patients treated with drug therapy alone.

The study's design for medical management included a daily dosage of 325 milligrams of aspirin, and 75 milligrams a day of clopidogrel, which is a medication used to prevent blood clots, for 90 days after enrollment. Also, patients received aggressive management of key stroke risk factors including high blood pressure and high levels of low density lipoprotein (LDL), the unhealthy form of cholesterol. All patients also participated in a lifestyle modification program which focused on quitting smoking, increasing exercise, and controlling diabetes and cholesterol.

All patients that participated in the trial will continue to be followed for two years to determine longer-term effects of both interventions.

"The SAMMPRIS study is a call to arms to all physicians caring for patients with this high risk condition. It provides evidence that highly effective medications when used in combination and when strict targets for risk factor modification are met can have substantial stroke prevention benefits," said Prabhakaran.

Provided by Rush University Medical Center