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My patient has intracranial stenosis, does he need an intracerebral stent? Results of the SAMMPRIS study

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Why is this study important?

Atherosclerotic stenosis of the major intracranial arteries is one of the most common causes of stroke worldwide. It causes 30% to 50% of strokes in Asians and 8% to 10% of strokes in North American Caucasians. Intracranial atherosclerosis preferentially affects Asians, Hispanics, Far East Asians and Blacks.

Patients with a recent transient ischaemic attack (TIA) or stroke and severe stenosis (70 to 99% of the diameter of a major intracranial artery) are at particularly high risk for recurrent stroke in the territory of the stenotic artery (approximately 23% at 1 year).

There are two treatment strategies that have emerged for the management of high-risk patients: aggressive medical therapy (combination anti-platelet therapy and intensive management of risk factors) and percutaneous Tran's luminal angioplasty and stenting (PTAS).

There is uncertainty regarding the safety and efficacy of aggressive medical management alone as compared with aggressive medical management plus PTAS with the use of the Wingspan stent system. For this reason this trial (SAMMPRIS) was the first trial started in November 2008 to compare the two treatment options in high risk patients with intracranial arterial stenosis.

Who were the participants?

SAMMPRIS was an investigator-initiated, randomized, double-blind, multi-center clinical trial funded by the National Institute of Neurological Disorders and Stroke and conducted at 50 sites in the United States. Population of interest included both inpatients and outpatients at the participating sites. Patients were recruited if they had a TIA or non-disabling stroke within 30 days before enrollment, attributed to angiographically verified stenosis of 70 to 99% of the diameter of a major intracranial artery.

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A total of 451 patients underwent randomization, 227 were assigned to the medical-management group and 224 to the PTAS group. There were no significant differences between the two groups with respect to any of the baseline characteristics of the patients.

What was the intervention?

Medical management was identical in the two groups and consisted of aspirin, at a dose of 325 mg per day; clopidogrel, at a dose of 75 mg per day for 90 days after enrollment; management of the primary risk factors (elevated systolic blood pressure and elevated low-density lipoprotein [LDL]cholesterol levels); and management of secondary risk factors (diabetes, elevated non-high-density lipoprotein [non-HDL] cholesterol levels, smoking, excess weight, and insufficient exercise) with the help of a lifestyle modification programme. The target for systolic blood pressure of less than 140 mm Hg (<130 mm Hg in the case of patients with diabetes) and an LDL cholesterol level of less than 70 mg per deciliter (1.81 mmol per liter).The aspirin, clopidogrel, one drug from each major class of antihypertensive agents, rosuvastatin, and the lifestyle programme were provided to the study patients.

PTAS were performed by neurointerventionists who were selected by a committee of experienced neurointerventionists. Patients who were randomly assigned to PTAS were required to undergo the procedure within 3 business days after randomization. Patients who were not taking clopidogrel at a dose of 75 mg each day for at least 5 days before PTAS were given a 600-mg loading dose of clopidogrel between 6 and 24 hours before PTAS.

On April 5, 2011, the trial's independent data and safety monitoring board recommended that enrollment be stopped because of safety concerns regarding the risk of per procedural stroke or death in the PTAS group and because futility analyses indicated that there was virtually no chance that a benefit from PTAS would be shown by the end of the follow-up period if enrollment continued. Although follow-up of patients is ongoing, the clinical importance of these findings mandated the reporting of the current results.

What was the outcome?

The primary end point the 30-day rate of stroke or death was 14.7 % (33 patients) in the PTAS group (nonfatal stroke, 12.5%; fatal stroke, 2.2%) and 5.8% (13 patients) in the medical-management group (nonfatal stroke, 5.3%; non-stroke-related death, 0.4%) ($p<0.002$). Beyond 30 days, stroke in the same territory occurred in 13 patients in each group. Currently, the mean duration of follow up which is ongoing, is 11.9 months.

The probability of the occurrence of a primary end-point event over time differed significantly between the two treatment groups ($p<0.009$), with 1-year rates of the primary end point of 20.0% in the PTAS group and 12.2% in the medical-management group. In secondary end points the rates of any stroke and of any major hemorrhage 14.1% vs. 22.3%) were significantly ($p<0.03$) higher in the PTAS group than in the medical-management group. The difference between the two groups in the rate of death or any stroke (16.3% vs. 23.2%) was not significant ($p<0.06$). In terms of myocardial infarction there was no significant difference between two groups (3.1% vs. 2.2% $p<0.60$).

What were the conclusions?

In patients with intracranial arterial stenosis, aggressive medical management was superior to PTAS with the use of the Wingspan stent system, both because the risk of early stroke after PTAS was high and because the risk of stroke with aggressive medical therapy alone was lower

than expected.

How does this impact our clinical practice?

Intracranial atherosclerosis is an important cause of ischaemic stroke in our population. In our country where there are significant financial constraints and lack of expertise in neuro intervention, this study showed aggressive medical management plays an important role in preventing recurrent stroke from intracranial stenosis. Clinicians are advised to actually strive to achieve medical targets in their patients with intracranial stenosis.

Acknowledgement and Disclosure Statement

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Recommended Reading

1. Chimowitz MI, Lynn MJ, Derdeyn CP, Turan TN, Fiorella D, Lane BF, et al. Stenting versus aggressive medical therapy for intracranial arterial stenosis. *N Engl J Med* 2011; 365: 993-1003.
2. Chimowitz MI, Lynn MJ, Turan TN, Fiorella D, Lane BF, Janis S, et al. Design of the stenting and aggressive medical management for preventing recurrent stroke in intracranial stenosis trial. *J Stroke Cerebrovasc Dis* 2011; 20: 357-68.