Follow-Up Shows Durability of Carotid Stenting

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WASHINGTON — Patients who received carotid stents had an incidence of stroke similar to those who underwent carotid endarterectomy, according to initial follow-up data from two large studies and an ongoing registry, reported Dr. Jay Yadav at a symposium sponsored by the Cardiovascular Research Foundation.

He presented results from the Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy (SAPPHIRE) trial, the U.S. Carotid Feasibility Study (USFS), and the SAPPHIRE registry. Enrollment in SAPPHIRE was terminated not long after it began, as an interim analysis showed that stenting had a marked benefit over surgery. The 3-year follow-up data were not as striking as were earlier findings but still indicated that stenting had durable benefits: Stented patients were less likely to require repeat procedures

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DR. YADAV

compared with those treated by endarterectomy, and stenting reduced the future stroke risk to a baseline rate of 1%, Dr. Yadav, head of vascular intervention at the Cleveland Clinic Foundation's department of cardiovascular medicine, said at a press briefing.

He said the results of the two studies and the SAPPHIRE registry should be heartening to the federal Medicare program. "You're not going to need a repeat procedure, so it's cost effective," he commented."

SAPPHIRE data showed that the 1% incremental annual risk of stroke in the stent arms was similar to that seen with endarterectomy, according to Dr. Yadav, who was an investigator in the study.

In SAPPHIRE, 334 patients—all at high risk for stroke—were randomized to endarterectomy or a stent (Cordis Corp.'s Precise Nitinol self-expanding stent, deployed with the Angioguard XP Emboli Capture Guidewire System). Each patient was seen by a panel consisting of a surgeon, an interventionalist, and a neurologist; if they could not agree on randomization, patients were put in the SAPPHIRE registry. In that group, 406 were deemed an unacceptable risk for endarterectomy, and were given a stent, and 7 were considered an unacceptable risk for stenting and assigned to surgery. The registry then, consists of ultra-high-risk patients, said Dr. Yadav.

For the randomized patients, the absolute change in the stroke rate between 30 days and 3 years was close to 4% for both groups. At 3 years, the incidence of stroke was still comparable at about 7% for each treatment group. At that time point, stroke follow-up data were available for 112 (67%) of the 167 endarterectomy patients and 139 (83%) of 167 stent patients.

There was a more significant difference in the incidence of target lesion revascularization. At 3 years, the rate was 7% for endarterectomy (with follow-up for 67%, or 112 patients), compared with 3% for the stent (with data on 139, or 83% of the group).

"We're seeing now in many, many, studies, once your carotid is fixed by metal stent or surgery, your risk of stroke will drop to 1% per year," said Dr. Yadav, adding that overall there was "clearly a lower repeat procedure rate for stenting." For non-randomized patients in the SAPPHIRE registry, the absolute change in stroke between 30 days and 3 years for stented patients was 5%, and for the USFS, it was 3%.

The USFS was conducted before SAPPHIRE; it was a prospective, nonrandomized study to evaluate the Precise stent, with or without the Angioguard guidewire. In the study, 261 patients who had been deemed too high risk for endarterectomy were divided into symptomatic (greater than 60% stenosis by ultrasound or angiography) or asymptomatic (greater than 80% stenosis). The target lesion revascularization rate at 3 years was 2.5% for the 406 SAPPHIRE registry patients, and 2.7% for the high-risk USFS patients.

Dr. Roxana Mehran, medical director of the data coordinating and analysis center at the Cardiovascular Research Foundation in New York, cautioned that there are not similar 3-year data on endarterectomy, so not much is known about the recurrence rates with the procedure. ■