Flow Reversal May Improve Embolic Protection

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SCOTTSDALE, ARIZ. — The flow reversal technique may be a better way to prevent emboli from reaching the brain during a carotid stenting procedure, but not all the evidence is in, Dr. Juan Carlos Parodi said at an international congress on endovascular interventions sponsored by the Arizona Heart Foundation.

In 200 high-risk patients treated so far at his institution, using the Parodi Anti-Emboli system to create flow reversal, 30-day stroke and mortality has been 1.5%, with no ipsilateral ischemic strokes, said Dr. Parodi, professor of surgery and radiology at Washington University, St. Louis.

Those results are good, but not definitive, because clinical outcome is only one way to measure that a technology is truly intercepting emboli created by the procedure, he said. The other ways are diffusion-weighted MRI and transcranial Doppler, both of which have shown that when a distal filter is used during the procedure, it appears that some small emboli do escape and reach the brain, where they do block vessels.

The SAPPHIRE (Stenting and Angioplasty with Protection in Patients at High-Risk for Endarterectomy) trial is the only randomized, controlled trial of a distal filter, Dr. Parodi said. It reported a 30% reduction in 30-day stroke, death, and myocardial infarction with the filter.

But, diffusion-weighted MR studies suggest that even with a filter somewhere between 9% and 43% will still develop new clinical or subclinical lesions, and transcranial Doppler studies suggest that every procedure releases emboli showers, not all of which is caught by a filter. By comparison, new lesions are seen with the MR technique in 6%-12% of patients who have undergone endarterectomy.

How important these small lesions are remains an open question. Most disappear over time. However, studies have reported that necrotic tissue is sometimes seen around the sites of the lesions, and silent infarctions are associated with a doubling of the risk of dementia, Dr. Parodi said.

Dr. Parodi's flow reversal device, the Parodi Anti-Emboli system, uses a balloon inflated in the common carotid proximal to the lesion being treated, obstructing the flow and creating a negative pressure gradient. A second balloon is inflated in the external carotid artery for internal carotid procedures to prevent backflow, and suction is applied, Dr. Parodi said. The device was recently sold to W. L. Gore and Associates Inc. ■

Emboli Filters May Not Work, MRI Shows

SCOTTSDALE, ARIZ. — Cerebral protection devices used during carotid stenting procedures do not catch small emboli, and may not prevent stroke and brain damage, according to preliminary results from a study that used diffusion-weighted MRI.

"Cerebral protection devices may not reduce the incidence of new ischemic defects on diffusion-weighted MR," Dr. Michel S. Makaroun said at an international congress on endovascular interventions sponsored by the Arizona Heart Foundation. "Further investigation is definitely warranted."

He presented the results of the first 36 patients treated in a planned larger trial comparing distal-filter protection with no protection; the trial is using MRI of the patients' brains before and after a carotid stenting procedure to visualize lesions that might not be readily clinically apparent.

There was no difference, said Dr. Makaroun, director of the endovascular surgery program at the University of Pittsburgh Medical Center. Of 18 patients who were treated with cerebral protection, 13 had at least one white lesion seen on diffusion-weighted imaging after the procedure that had not been there before. In comparison, 8 of 18 patients treated without protection had any white lesion afterward.

The difference was not statistically significant, given the small number of patients, noted Dr. Makaroun.

The average number of new lesions was the same for both groups, six, and the average size of the lesions was the same as well. Two perioperative strokes occurred, one in each treatment group.

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