CEA Deemed Safer Than Stenting

BY KERRI WACHTER

NEW YORK — Carotid endarterectomy was deemed safer than carotid artery stenting for symptomatic patients based on results from a multicenter study of 1,710 patients, although post-procedure complications suggest that as stent technology evolves, the two approaches will need to be revisited, according to Dr. Frans Moll.

The International Carotid Stenting Study found that there were twice as many strokes (58) for carotid artery stent (CAS) patients in the per-protocol 30-day analysis vs. the 27 experienced by the carotid endarterectomy (CEA) patients. Furthermore, 72 patients in the CAS group had a stroke, MI, or had died at 120 days of follow-up, compared with 43 in the CEA group, for a hazard ratio of 1.73, Dr. Moll said at the Veith symposium on vascular medicine sponsored by the Cleveland Clinic.

However, "the complications occurred not so much during [stenting] but at 1-3 days after the procedure," Dr. Moll said in an interview. "You put in the stent. You give all of the drugs in the correct way. The technology is good. Then the patient goes from the table and you get a call from the neurologist telling you that your patient has got a serious minor stroke at day 2. This [suggests] that maybe some technical features of the stent are not yet as good as we wish they were." It may be that "the development of stent technology has not reached the level that is necessary to replace traditional surgical skills," said Dr. Moll, a professor of vascular surgery at the University Medical Center in Utrecht, the Netherlands.

In this study, patients with symptomatic carotid artery stenosis greater than 50% were randomized to treatment with CAS (853) or CEA (857). To be included, patients had to be deemed as requiring treatment and the stenosis had to be suitable for both stenting and surgery. Ultrasound study of the carotid artery to be treated was performed at or before randomization and at 1 month following treatment—and will continue annually.

Participating surgeons had to have performed more than 50 CEA or 50 CAS procedures—and more than 10 cases/stents a year—at supervised centers included in the study. Several stents were approved for use in this trial. All patients received best medical care including antiplatelet therapy or anticoagulation (when appropriate) and control of medical risk factors. Aspirin plus clopidogrel were provided before stenting.

The researchers were able to analyze the 853 CAS patients and 857 CEA patients by ITT up to 120 days post randomization. The per-protocol analysis included 821 patients in the CEA group and 828 in the CAS group. In terms of secondary outcomes at 120 days (see table), more patients in the CAS group had any stroke (65), compared with the CEA group (34). The hazard ratio for any stroke or death for CAS vs. CEA was 1.91.

In an MRI substudy of 108 CAS patients and 92 CEA patients at five centers, "we see a real difference between CAS and CEA" at up to 6 weeks' follow-up, said Dr. Moll. In terms of new ischemic lesions seen on diffusion-weighted MRI after the procedures, the odds ratio for CAS vs. CEA was 5.24.

"The number of serious strokes was not so much different—disabling strokes were not the biggest difference—but all of these minor strokes and lesions on diffusion-weighted imaging were striking," he said in an interview.

Notably, protection devices were recommended for use during CAS but were not mandatory. A total of 245 patients got CAS without a protection device, and the remainder had protection. There was no significant difference in outcomes regardless of whether a protection device was used, Dr. Moll said. ■

Secondary Safety Results (ITT) of the International Carotid Stenting Study

Outcome	CAS	CEA
Any stroke	65	34
Fatal stroke	9	2
Disabling stroke	17	19
Nondisabling stroke	39	14
Any MI	3	4
Fatal MI	3	0
Nonfatal MI	0	4
Nonstroke, non–MI death	7	5

Note: Based on 120 days' follow-up.

Source: Dr. Moll

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