

Stenting Less Safe Than Surgery for Carotid Artery Stenoses; Procedure Associated With Vascular Dementia

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November 25, 2009 (New York, New York) — Mounting evidence suggests that carotid artery stenting is much less safe than carotid endarterectomy in patients with symptomatic and asymptomatic carotid artery stenosis. Stroke and death rates were much higher in patients who received carotid artery stents compared with those treated by endarterectomy in the large randomized International Carotid Stenting Study (ICSS).

An analysis of the ICSS findings was presented here at the 36th Annual VEITH Symposium. In addition, a previously unreported smaller study supporting these findings in a subgroup of asymptomatic patients was also presented to conference attendees.

A substudy of ICSS included 5 centers with 108 patients randomly assigned to carotid artery stent and 92 patients randomly assigned to endarterectomy. Magnetic resonance imaging (MRI) scans were performed preprocedure, immediately postprocedure, and again 30 days later.

Frans L. Moll, MD, professor and head of the Department of Vascular Surgery at the University Medical Center in Utrecht in The Netherlands, reported that early postoperative MRI brain scans showed evidence of new ischemia in 50 patients in the carotid artery stent group (46.3%) versus 13 patients in the endarterectomy group (14.1%; odds ratio [OR], 5.24; $P < .001$).

On the 30-day scans, which were performed with diffusion-weighted imaging, there were 28 abnormalities in the stent group (32.2%) vs 6 abnormalities in the endarterectomy group (7.9%; OR, 5.54; $P < .001$).

"These spots in the brain may lead to vascular dementia. Similar evidence of new ischemia in the brain following carotid artery stenting in symptomatic patients is being picked up by investigators in other parts of the world," Dr. Moll stated.

"ICSS confirms that for the moment, outcomes with surgery are more reliable in symptomatic patients in terms of safety. Surgery removes plaque, but stents 'push the plaque behind the wallpaper,' and the plaque continues to exert damage. Perhaps this could change if better, safer stents are developed," said Dr. Moll.

The main downside of stenting, according to Dr. Moll, is impaired cognition and the development of vascular dementia.

Agreeing with the conclusions of Dr. Moll's study, Laura Capoccia, MD, from Sapienza University of Rome, Italy, said, "We may be causing vascular dementia in patients treated with carotid artery stenting."

Smaller Study in Symptomatic Patients

Dr. Capoccia presented a small study of 23 asymptomatic patients who underwent carotid stenting. These patients had carotid stenosis greater than 70% in the absence of symptoms. Dr. Capoccia and coinvestigators found a 21% incidence of new cerebral ischemia on diffusion-weighted imaging after stenting.

"These patients had no evidence of ischemia before the procedure on MRI," she said.

Further, in patients with new lesions, performance on the Mini-Mental Status Exam had deteriorated at 6 months and remained at the same lower level at 12 months.

In addition, 2 biomarkers of brain damage, S100-beta protein and neuron-specific enolase, were elevated only in the patients with new lesions.

"Up to 50% of symptomatic patients treated with stents may have new silent ischemic lesions detected by MRI. We need to include microembolization rate and potential vascular dementia with cognitive impairment as clinical trial endpoints, along with stroke rate. At present, no stent can prevent microembolization. This is why stenting is losing the battle to endarterectomy," Dr. Capoccia stated.

ICSS Safety Data

ICSS, the data from which were presented previously at the European Society of Cardiology, was a large multinational study that enrolled 1713 patients older than age 40 years and had symptomatic carotid stenosis (>50% narrowing).

"Mean age was 70 years, and we had no upper age limit," Dr. Moll said.

Patients were randomly assigned to either carotid artery stenting or carotid endarterectomy. Several different stents were used by investigators, and protection devices (filters, baskets) were used at the discretion of the treating physician.

For the primary composite endpoint of stroke, death, or periprocedural myocardial infarction at 120 days, the hazard ratio of 1.73 favored endarterectomy; 72 patients in the stenting group experienced one of these events vs 43 in the endarterectomy group (P = .004). The difference favoring surgery was even more striking for stroke: 65 (8%) for stenting vs 34 (4%) for endarterectomy.

"There were twice as many strokes with stenting. This is a strong finding. Once we knew these results, many clinics stopped doing stenting in symptomatic patients," Dr. Moll said.

A subgroup analysis of the carotid artery stent arm in ICSS, not previously presented, has financial implications. The investigators found no difference in outcomes in the stenting group, whether or not protective devices, such as filters or baskets, were used.

"The protective device industry accounts for about \$100 million of expenditures for stenting. The subgroup analysis of this well-designed randomized controlled clinical trial suggests that use of filters and protective devices is questionable," Dr. Moll said.

Dr. Moll and Dr. Capoccia have disclosed no relevant financial relationships.

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