

Carotid Endarterectomy Beat Stenting at 30 Days

BY MITCHEL L. ZOLER
Philadelphia Bureau

PHILADELPHIA — The periprocedural rate of death or stroke in patients undergoing carotid artery stenting was about 40% higher than for similar patients who had a carotid endarterectomy, on the basis of a metaanalysis that included data from seven trials including nearly 3,000 patients.

This is the first statistically significant difference seen in serious adverse events during the first 30 days after treatment with these two alternatives for clinically significant carotid stenosis. The new analysis included recently reported results from two European studies, which together doubled the number of patients available for analysis, Hans-Henning Eckstein, Ph.D, said at the Vascular Annual Meeting.

He cautioned that the finding was from a preliminary analysis that included as-yet unpublished data. Also, “we have to wait for at least 2 years, and even better

would be to wait for 3, 4, or 5 years to look at stroke prevention” by the two interventions, said Dr. Eckstein, head of vascular surgery at the Technical University of Munich. But, he added, the new metaanalysis of the 30-day rate of death or stroke is useful for helping patients select the treatment.

Until this spring, five randomized controlled trials had compared carotid artery stenting with endarterectomy. These five studies involved a total of 1,269 patients, and a metaanalysis published about a year ago showed that the incidence of any stroke or death during the first 30 days was 33% higher in patients treated with stenting, compared with those who had endarterectomy (Stroke 2005;36:905-11); this difference was not statistically significant.

This is the first statistically significant difference seen in serious adverse events during the first 30 days after treatment with these two alternatives.

One of the new studies, the Stent-Protected Percutaneous Angioplasty of the Carotid vs. Endarterectomy (SPACE) trial, included 1,183 patients, who were treated at any of 37 medical centers in Germany, Austria, or Switzerland. All of the patients were symptomatic (with amaurosis fugax, a transient ischemic attack, or a stroke within the previous 180 days) and also had at least 50% stenosis in their carotid artery based on the criteria of the North American Symptomatic Carotid Endarterectomy Trial (NASCET).

Patients who were randomized to stenting could be treated with any of three different carotid stents: the Acculink, the Precise, or the Wallstent. Treatment with an embolic-protection device was optional, and was used on about

a third of the patients. The outcomes of the patients treated with embolic-protection devices were no different from those in whom no device was used. The study was primarily sponsored by the German Ministry of Science, but it also received support from Guidant Corp., which markets the Acculink stents, and from Boston Scientific Corp., which markets the Wallstent.

The periprocedural rate of death or stroke was 6.84% in the patients treated with carotid stenting and 6.34% in those treated with endarterectomy—a non-significant difference, Dr. Eckstein said.

Results from a similarly designed French study were reported in mid-May at the European Stroke Conference in Brussels. The Endarterectomy vs. Angioplasty in Patients with Symptomatic Severe Carotid Stenosis (EVA-3S) study enrolled 520 patients. The 30-day rate of death or stroke was 9.6% among 261 patients treated with carotid stenting and 3.9% among those

treated with endarterectomy.

When the results of both the SPACE and EVA-3S trials were added to the previously reported metaanalysis results, the overall numbers showed an 8.2% periprocedural death or stroke rate among 1,492 patients treated with stenting, and a 5.9% rate among 1,480 patients treated with endarterectomy, a significant difference.

“I’m sure there will be a place for carotid stenting in the future,” but randomized, controlled trials against endarterectomy must be done to determine its proper role, Dr. Eckstein said.

Also, there may now be enough experience in the metaanalysis database to run stratified analyses and identify which subgroups of patients did best. The experience and technique of the operators will also be an important factor. In the multicenter results that Dr. Eckstein reported, there was a clear difference in outcomes among the centers; one hospital had a perioperative event rate of more than 20%. ■

Stenting Lowers 5-Year Stroke, Restenosis Rates

SCOTTSDALE, ARIZ. — The results of carotid stenting appear to be similar to endarterectomy results for at least 5 years after the procedure, based on a cohort study of 2,172 patients treated at four European centers.

In the cohort of patients enrolled prospectively between 1993 and 2004, the rate of ipsilateral major stroke or death from any cause was 4% at 1 year, 10% by 3 years, and 16% by 5 years, among the 138 patients followed, Dr. Patrick Peeters said at an international congress on endovascular interventions sponsored by the Arizona Heart Foundation.

Several different, self-expanding stents were used in the series, as chosen by individual interventionalists at the time of the procedure, with the most common being a closed-cell, cobalt chromium alloy stent, used in 62% of the patients. And 4% of patients received only balloon dilation.

The restenosis rates were 1% at 1 year, 2% at 3 years, and 3% at 5 years (139 patients); restenosis was considered to be 50% narrowing as imaged with ultrasound, noted Dr. Peeters, head of the department of cardiovascular and thoracic surgery at Imelda

Hospital, Bonheiden, Belgium.

Previous studies reported restenosis rates at 1 year ranging from 3% to 8%. Moreover, although the earliest studies of carotid stenting had major, perioperative complication rates as high as 9%, 99.7% of cases in this series were technically successful. The results with stenting also compare well with endarterectomy, he noted. The European Carotid Surgery Trial reported a rate of major stroke or death of 15% at 3 years, very similar to the 13% rate of this series.

Although stenting did not make a significant difference in the stroke/death rate, compared with ballooning only, it did in the restenosis rate. Restenosis at 5 years was 3% in the stented patients but 15% in the ballooned-only patients.

Predilatation of the artery before stent placement also made a significant difference, Dr. Peeters said. Of the stented patients, 30% were predilated. Their stroke and death rate at 5 years was 10% (33 patients) versus 17% for those not predilated. There was no difference in stroke and death in the series between patients who were symptomatic or asymptomatic.

—Timothy F. Kirn

Carotid Stenting and Endarterectomy Yield Similar Outcomes at 2 Years

BY TIMOTHY F. KIRN
Sacramento Bureau

SCOTTSDALE, ARIZ. — In a major study comparing carotid endarterectomy and carotid stenting, 2-year results show similar death and stroke rates for the two procedures, Dr. Rodney A. White said at an international congress on endovascular interventions sponsored by the Arizona Heart Foundation.

And those event rates appear to be better than one would expect based on some previously reported case series and studies, said Dr. White, the vascular surgery division chief at the Harbor-UCLA Medical Center, Los Angeles.

The 1-year results from the study, known as the CARESS (Carotid Revascularization Using Endarterectomy or Stenting Systems) trial, were recently published (J. Vasc. Surg. 2005;42:213-9).

At 1 year after the procedure, there were 30 deaths or strokes among the 254 patients who underwent carotid endarterectomy, for an event rate of 14%. There were 13 deaths or strokes among the 143 patients who underwent carotid stenting, for an event rate of 10%. When the researchers included in the analysis the acute myocardial infarctions that occurred among the study patients, the event rates increased to 14% and 11%, respectively.

At the 2-year follow-up, the number of events had increased somewhat, but the pattern remained the same. The death and stroke rate was 15% for the en-

arterectomy group and 13% for the stenting group. Adding acute myocardial infarctions did not change the event-rate percentages.

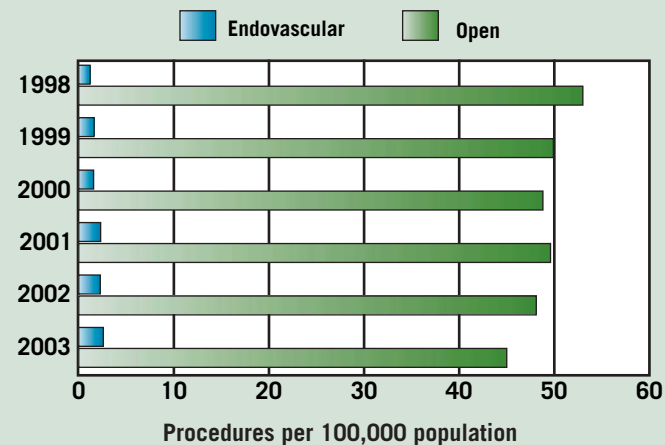
Dr. White did not report on the restenosis or reintervention rates at 2 years. In the previous 1-year follow-up report, restenosis occurred in 4% of the endarterectomy patients and 6% of the stenting patients, a difference that was not statistically significant.

Restenosis was defined as 75% narrowing, or 50% narrowing that required treatment.

A main purpose of the trial was to design a study that reflected current clinical practice, Dr. White noted. Hence, the patients were not randomized, and almost 70% of the patients in both groups had high-grade, carotid stenosis but were asymptomatic. ■

DATA WATCH

Open Carotid Surgery vs. Endovascular Repair



Sources: J. Vasc. Surg. 2006;43:205-16, U.S. Census Bureau