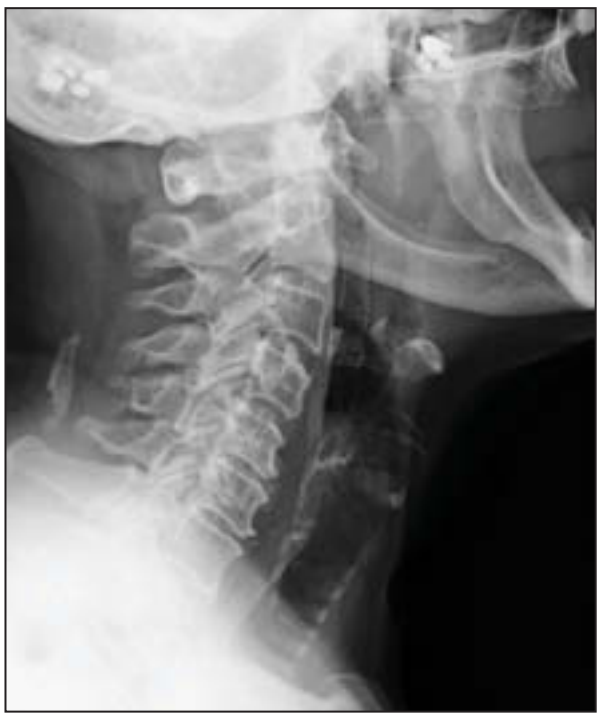
Jury Out on Incidence of Carotid Stent Fractures

BY PATRICE WENDLING

FROM THE ANNUAL MEETING OF THE MIDWESTERN VASCULAR SURGICAL SOCIETY

INDIANAPOLIS – A retrospective analysis has shed some light on the prevalence of carotid artery stent fracture but ultimately underscores how little is known about the durability of carotid stents.

No accepted standard currently exists for carotid artery stent surveillance specific to fracture identification. In addition, the etiology of these fractures is unknown, as is their clinical relevance, Dr. Anthony Nigliazzo said at the meeting.



COURTESY MCLAREN REGIONAL MEDICAL CENTER

"Fish scaling" along the lateral border of this carotid artery stent, along with a high degree of angulation, makes fracture identification difficult.

He presented a retrospective analysis of 91 patients who received 107 carotid artery stents from January 2002 through December 2009 at the Michigan Vascular Center in Flint, a group that has significant carotid artery stenting (CAS) experience, including 14 CAS trials.

Two vascular surgeons and two radiologists independently reviewed anteroposterior and lateral cervical x-rays taken at a median follow-up of 28 months to evaluate for stent fractures. Because the reviewers did not all agree, a peer review consensus conference was held to determine whether fractures had occurred, Dr. Nigliazzo said. Information from duplex ultrasounds obtained at 30 days, 6 months, and 1 year was also used to determine flow velocities and to correlate with a fracture diagnosis.

Ultimately, the experts agreed that 4 of the 107 stents (3.7%) were fractured. Only one of the fractures had any evidence of restenosis, and none had clinical sequelae or were symptomatic at the time of identification.

When the team asked outside expert Dr. Michael Dake, a pioneer in endovascular stent development from Stanford (Calif.) University Medical Center, to review the same films, however, the fracture rate reached 7.7% for the 91 patients and 107 stents.

Overall, Dr. Nigliazzo said that the prevalence of carotid artery stent fracture appears to be low, but added that "the true incidence of stent fracture remains elusive."

Part of the difficulty in making the diagnosis is that some fractures could not be seen on certain x-ray projections, and many stents had deformities. One such deformity – called "fish scaling," in which layers of an open-cell stent protrude – makes it appear that a fracture is present when it is not. Although vessel angulation greater than 45 degrees and calcification have been identified as risk factors for stent fracture, this was not apparent in the analysis, said Dr. Nigliazzo, a senior resident with the department of surgery at Michigan State University in Flint.

He noted that reported prevalence rates of carotid stent fracture vary widely, from 1.9% to 29%. "We believe this magnifies the difficulty in identifying stent fractures and the different modalities that investigators are using," he said.

The researchers, led by Dr. Robert G. Molnar, who is with the Michigan Vascular Center and is chief of vascular surgery at McLaren Regional Medical Center, also in Flint, called for further research to determine the ideal methods for long-term CAS surveillance. For the time being, they recommended obtaining anteroposterior/lateral and oblique images for poststent fracture surveillance. One attendee cautioned that this type of surveillance may be "overkill" until it's known whether clinical sequelae are associated with stent fracture.

Dr. Nigliazzo responded that the argument can go both ways, and highlighted a recent prospective Italian study reporting that stent fracture was significantly associated with restenosis (J. Vasc. Surg. 2010;51:1397-405).

Limitations of the current study include its retrospective design and the analysis of only 33% of the 272 patients who received stents during the study.

The cohort had a mean age of 71.6 years and was mostly male (61%). Overall, 45% had received a carotid stent after carotid endarterectomy whereas 15% did so after radiation. Only 4% were classified as low risk by entry criteria for the CREST and CARESS trials. ■

Higher Stroke, Death Rates Persist With Carotid Stenting

BY MARY ANN MOON

FROM THE ARCHIVES OF NEUROLOGY

Carotid artery stenting carries higher intermediate- and long-term risks than does carotid endarterectomy, not just higher periprocedural risks, according to the largest, most comprehensive meta-analysis of evidence from randomized trials to date.

The safety and efficacy of carotid stenting as an alternative to endarterectomy are controversial. Studies have shown that stenting is more likely to cause periprocedural stroke, but data on longer-term outcomes are limited, said Dr. Sripal Bangalore of New York University, New York, and his associates.

They examined 13 randomized controlled trials that reported outcomes at 30 days or later and included 3,754 patients assigned to stenting and 3,723 to endarterectomy. The mean follow-up in the trials was 2.7 years.

In the short term, stenting was associated with a 31% increase in periprocedural death, MI, or stroke, compared with endarterectomy. Absolute rates of periprocedural death, MI, or stroke were 5.7% with stenting and 4.7% with endarterectomy, they said.

In the long term, the risk for that composite outcome plus later ipsilateral stroke or death was 19% higher after stenting than it was after endarterectomy. In comparison with endarterectomy, stenting carried a 38% higher risk of the composite outcome of periprocedural stroke or death plus later ipsilateral stroke, a 24% higher risk of the composite outcome of death or stroke, and a 48% increased risk of any stroke.

VITALS

Major Finding: The long-term risk of stroke is 48% higher after carotid stenting than after carotid endarterectomy, and the long-term risk of death or stroke is 24% higher.

Data Source: A meta-analysis of 13 recent randomized clinical trials comparing the two approaches.

Disclosures: One investigator reported receiving research grants from AstraZeneca, Bristol-Myers Squibb, Eisai, Ethicon, Heartscape, Sanofi Aventis, and the Medicines Company.

These increases in long-term risks were consistent across several subgroups: symptomatic or asymptomatic, low risk or high risk, American or non-American; and regardless of whether an embolic protection device was used, Dr. Bangalore and his colleagues wrote (Arch. Neurol. 2010 Oct. 11 [doi:10.1001/archneurol.2010.262]).

However, the rate of periprocedural MI was significantly lower with carotid stenting (0.3%) than with endarterectomy (1.2%). And stenting was associated with an 85% reduction in the risk of cranial nerve injury, all of which occurred in the periprocedural period. ■

Paclitaxel-Coated Catheter Trims Lumen Loss in Leg Arteries

BY CHRISTINE KILGORE

FROM TRANSCATHETER CARDIOVASCULAR THERAPEUTICS 2010

WASHINGTON – An investigational paclitaxel-coated balloon catheter resulted in significant reductions in late lumen loss at 6 months compared with standard balloon angioplasty in a randomized study of 101 patients with femoropopliteal disease.

The LEVANT I study randomized patients to angioplasty – with or without stenting – using a regular angioplasty balloon catheter or the Moxy (Lutonix) paclitaxel-coated balloon catheter.

Six-month late lumen loss, the primary end point, was 0.46 mm in the paclitaxel-coated balloon group and 1.09 in the traditional angioplasty group, a statistically significant difference, reported Dr. Dierk Scheinert of the Heart Center Leipzig/Park Hospital, Germany.

Late lumen loss was reduced with the paclitaxel-coated balloon catheter in both the stented and nonstented patients. There also was a trend toward lower target lesion revascularization among patients who received treatment with the Moxy balloon catheter.

The paclitaxel-coated balloon catheter appears to have a "strong biologic effect … on the inhibition of neointimal hyperplasia," Dr. Scheinert said at the meeting, sponsored by the Cardiovascular Research Foundation.

The study suggests that a shorter duration of antiplatelet therapy is feasible in the peripheral vasculature when such treatment is employed, he noted. Patients who were not stented were prescribed 1 month of a dual-antiplatelet regimen. Those who were stented were prescribed 3 months of the regimen.

The Moxy device is designed so that paclitaxel is retained during transit of the balloon catheter and is delivered during the 30- to 60-second inflation time. A larger and longer prospective randomized trial to look at primary patency of the target lesion and various clinical end points – LEVANT II – was pending approval, Dr. Scheinert said.

The trial was sponsored by Lutonix Inc., maker of the Moxy catheter. Dr. Scheinert had no disclosures. ■