Physician Groups Find Consensus on CAS

Various specialists still disagree on training requirements for performing carotid stenting.

BY AMY ROTHMAN SCHONFELD
Contributing Writer

A clinical expert consensus document has been issued by the American College of Cardiology Foundation to inform and guide clinical practice regarding the use of carotid stenting.

"This is the first multidisciplinary document of its type on carotid artery stenting," Dr. Eric R. Bates, chair of the writing committee, said in an interview. Dr. Bates explained that while there is not enough rigorous evidence available to allow the formulation of evidence-based guidelines, the suggestions made in the consensus document represent a state-of-the-art summary derived from the experience of well-credentialed investigators and the results of registries and clinical trials.

The document is cosponsored by the Society for Cardiovascular Angiography and Interventions, the Society for Vascular Medicine and Biology, the Society for Interventional Radiology, and the American Society of Interventional and Therapeutic Neuroradiology (J. Am. Coll. Cardiol. 2007;49:126-70).

Representatives of six professional societies, including cardiologists, interventional radiologists, neurointerventionalists, and a neurologist, composed the 15-member writing committee. One surgeon was included, but the document was not endorsed by a surgical organization.

Of the almost 1 million stroke-related events occurring in the United States each year, about 5%-12% are caused by carotid occlusive disease that is amenable to revascularization. The consensus document endorses current American Heart Association guidelines that recommend carotid endarterectomy (CEA) in symptomatic patients with stenosis 50%-99%, if the risk of perioperative stroke or death is less than 6%. For asymptomatic patients, CEA is recommended for stenosis 60%-99%, if the risk of perioperative stroke or death is less than 3%, although stenosis greater than 80% is the commonly accepted clinical standard. American Academy of Neurology guidelines indicate that patients eligible for carotid artery stenting (CAS) should be 40-75 years old and have a life expectancy of at least 5 years.

"Although CAS is a new treatment and is still undergoing development and testing, right now it is a reasonable alternative to CEA, especially in patients who are at high risk for CEA," said Dr. Bates, professor of internal medicine and director of cardiac catheterization at the University of Michigan, Ann Arbor.

When stenting the carotid artery, embolic protection devices (EPDs) should be used to reduce the risk of procedure-related stroke, despite the current lack of randomized studies comparing CAS with and without EPDs, the committee recommends. Physicians who perform CAS must also be skilled in placing EPDs.

Current Centers for Medicare and Medicaid Services reimbursement criteria for carotid stenting is limited to individuals at high risk for CEA with symptomatic stenosis greater than 70%, performed by qualified physicians at qualified institutions using Food and Drug Administration–approved stents. Stenting is reimbursed for high-risk patients (symptomatic stenosis greater than 50% or asymptomatic stenosis greater than 80%) in a Category B Investigational Device Exemption trial or postapproval study.

CAS, although new, 'is a reasonable alternative to CEA, especially in patients who are at high risk for CEA.'

DR. BATES

Due to insufficient evidence, CAS is not recommended for high-risk patients with asymptomatic stenosis of less than 80% or in any patient without high-risk features, and the consensus document suggests that further investigation is needed to evaluate the relative merits of CAS compared with optimal medical therapy. "The benefits of revascularization are negated if the risk of revascularization is high, and the fact that CEA is associated with more risk does not mandate that patients undergo CAS." The role of CAS in low-risk patients also awaits further clarification.

The document also examined the issues of training and credentialing operators who perform CAS. Operators come from various subspecialties—mostly cardiologists, surgeons, and radiologists—with different backgrounds, experience, and expertise. Regardless of specialty, all "operators should previously have achieved a high level of proficiency in catheter-based intervention, complete dedicated training in CAS, and be credentialed at their hospital." Operators and institutions are required to track and report outcomes to a national database.

"We tried to go for a fair and balanced document that represents all viewpoints," said Dr. Gary R. Duckwiler, an interventional neuroradiologist at the University of California, Los Angeles, and a member of the writing committee. "There were areas of significant disagreement about the preparatory training and knowledge necessary to perform CAS, and those are identified in the document. For the most part, we all agree that carotid stenting, at least based on the data we have now, can be an excellent procedure in the appropriate patients." ■

Octogenarians Four Times More Likely to Die After Primary PCI

BY BRUCE JANCIN
Denver Bureau

CHICAGO — The benefits of a strategy of primary percutaneous coronary intervention for ST-elevation MI in octogenarians are called into question by the latest data from the American College of Cardiology's National Cardiovascular Data Registry, Dr. Jeptha P. Curtis reported at the annual scientific sessions of the American Heart Association.

Patients aged 80 and older who underwent primary PCI had nearly a fourfold greater in-hospital mortality than did those younger than 80. They also had substantially higher rates of serious nonfatal complications, according to Dr. Curtis of Yale University, New Haven, Conn. (See box.)

A likely major contributor to the high mortality was the fact that octogenarians were at 37% greater relative risk of not receiving complete revascularization of the infarct-related artery, either because their coronary anatomy wasn't amenable to PCI or the procedure didn't achieve full Thrombolysis in Myocardial Infarction (TIMI)–3 grade flow, he added.

He reported on all patients with ST-elevation MI in the ACC national registry who underwent emergency catheterization during 2005, excluding those who underwent hospital transfer, received fibrinolytic therapy, or had a history of coronary artery bypass surgery. Of the19,229 eligible patients, 10% were aged 80 or older.

Octogenarians were more likely than younger patients to present with triple-vessel or left main disease, cardiogenic shock, or heart failure. They were less likely to undergo primary PCI (margin of 84%-87%).

Among patients with primary PCI, octogenarians were less likely to achieve postprocedural TIMI-3 flow, at 93% compared with 97% in younger patients.

Further studies of primary PCI in the elderly are needed, Dr. Curtis added. ■

Complication Rates With Primary PCI

Outcome	Age <80 years (n = 17,325)	Age ≥80 years (n = 1,904)
In-hospital mortality	4.7%	16.6%
Transfusion	9.1%	17.5%
Heart failure	3.5%	6.8%
Renal failure	1.4%	3.8%
Cardiogenic shock	2.9%	5.8%
Access site occlusion	0.05%	0.26%
Pseudoaneurysm	0.36%	0.84%

Source: Dr. Curtis

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Restenosis May Be Ongoing Process After Secondary CAS

BY KERRI WACHTER
Senior Writer

NEW YORK — While procedural complication rates for carotid artery stenting for restenosis after previous ipsilateral carotid endarterectomy are very low, the rate of in-stent restenosis is high and appears to be an ongoing process, according to data presented at the Veith symposium on vascular medicine sponsored by the Cleveland Clinic.

Technical success of carotid artery stenting for restenosis was 100% in one study involving 57 procedures in 55 patients. However, survival without in-stent restenosis fell from 93% at 1 year to 76% at 4 years, said Dr. Gerrit de Borst, of the University Medical Center, Utrecht, the Netherlands.

"Our data demonstrate that restenosis is an ongoing process," said Dr. de Borst.

The researchers followed 55 patients (63% men, mean age 70 years) who underwent 57 carotid artery stent procedures for restenosis after prior ipsilateral carotid endarterectomy between 1998 and 2004. Thirty-four Wallstents, 17 Cordis stents, and 6 other stents were used. Patients underwent serial duplex scanning and clinical evaluation at 3 and 12 months, and yearly thereafter.

The mean interval between the two procedures was 83 months. Only nine patients had symptomatic high-grade restenosis. The procedure was performed using local anesthesia and femoral access.

No deaths or strokes occurred during the procedure. However, two patients had transient ischemic attacks during the procedure. Both patients recovered prior to discharge. One patient had a groin hematoma that was treated conservatively.

Mean follow-up was 36 months. In that time, there were three deaths (because of cardiac reasons). One patient had a transient ischemic attack at 30 months, and one had a minor stroke at 60 months.

Eleven patients had restenosis defined as at least 50% during the follow-up period. Of these, three were detected at 3 months, three at 12 months, two at 24 months, one at 36 months, one at 48 months, and one at 60 months. This indicates that "restenosis is not a process that only occurs early after stent placement," said Dr. de Borst.

Six patients had to have an additional procedure for restenosis. Three had carotid endarterectomy with stent removal. The other three had percutaneous transluminal angioplasty. Reintervention-free survival was 96% at 1 year, 94% at 2 years, 90% at 3 years, and 84% at 4 years.

Dr. de Borst disclosed that he has no conflicts of interest. ■