

Neurology Coalition Sets Carotid Stent Standards

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Senior Writer

A coalition of neurovascular medical specialties has outlined a set of training and credentialing standards for performing carotid stenting that goes far beyond those released by interventional cardiologists and vascular surgeons.

The guidelines were developed by the American Academy of Neurology, the American Association of Neurological Surgeons, the American Society of Interventional and Therapeutic Neuroradiology, the American Society of Neuroradiology, the Congress of Neurological Surgeons, and others. They were simultaneously published in several medical journals.

These standards come at a critical time, said Anthony Furlan, M.D., a neurologist who helped develop the guidelines, since the Food and Drug Administration recently approved the Guidant Rx AC-CULINK carotid stent and issued conditional approval to Cordis Corp.'s PRECISE OTW Nitinol Self-Expanding Stent.

And officials at the Centers for Medicare and Medicaid Services are poised to allow coverage for carotid stenting outside of clinical trials in patients who would be high-risk candidates for endarterectomy and who have symptomatic carotid artery stenosis of at least 70%.

"Our role here is to provide guidance to credentialing committees," said Dr. Furlan, who serves on the American Academy of Neurology's Stroke Systems Task Force and heads the section of stroke and neurologic intensive care at the Cleveland Clinic Foundation.

The new standards are also an attempt to combine the broad knowledge of the neurological communities, said John J. Connors III, M.D., director of interventional neuroradiology at Baptist Hospital of Miami. "With the potential for so many different specialties to be performing carotid stenting, these standards are an opportunity to provide quality assurance based on the collective knowledge of experts in the fields of the neurological sciences," Dr. Connors said in an interview.

"Many physicians may be experts in one area, but with carotid stenting they need to have a basic fund of knowledge in addition to being masters of a variety of skills," he said. Importantly, a basic knowledge of

the brain is required, he said. The neurovascular guidelines call for any physician performing carotid stenting to have had a minimum of 6 months of formal training approved by the Accreditation Council for Graduate Medical Education (ACGME) in at least one of the neurosciences.

In addition, before beginning postgraduate training in cervicocerebral interventional procedures, physicians must be appropriately trained in and must competently complete at least 100 diagnostic cervicocerebral angiograms.

Under these standards, many physicians would need to engage in additional training in order to achieve competency in these procedures, Dr. Connors said. But he noted that even these guidelines are a low bar considering that the potential adverse outcomes in carotid stenting are stroke and death.

The Neurovascular Coalition guidelines are aimed at creating a minimal standard for training in these procedures, Dr. Connors said, but they aren't aimed at locking any specialties out of the field.

However, Dr. Connors said he is concerned that guidelines developed jointly by the Society for Cardiovascular Angiography and Interventions, the Society for Vascular Medicine and Biology, and the Society for Vascular Surgery (SCAI/SVMB/SVS) do not require sufficient training.

For example, the SCAI/SVMB/SVS guidelines released call for physicians to perform a minimum of 30 diagnostic carotid angiograms and 25 carotid-stenting procedures in order to attain competence in carotid stenting. "This is exactly one-tenth of the training required for coronary artery stenting," Dr. Connors said.

But Dr. William A. Gray, M.D., director of endovascular care at the Swedish Heart Institute in Seattle and one of the authors of the SCAI/SVMB/SVS guidelines, does not agree that performing 100 angiograms is necessary to show proficiency. In fact, he sees that requirement as a bit excessive.

"We look at this as a potential barrier to entry for otherwise qualified operators," Dr. Gray said in an interview. Instead, the threshold of 30 diagnostic angiograms is consistent with the experience of many cardiologists who have been working in the field for years, and with the experience of operators in the recently completed carotid stent trials.

Postsurgical Survival Not Affected

Revascularization from page 1

larization in a large group of patients."

The study included patients with stable coronary artery disease who were scheduled to have aortic or infrainguinal vascular surgery. Physicians at the 18 participating Veterans Affairs medical centers screened nearly 6,000 patients, of whom about 80% were excluded because they had insufficient cardiac disease, required urgent vascular surgery, had a comorbidity, or were otherwise not eligible.

The remaining 1,190 patients had angiography, and more than half were excluded from the sample because they did

not have obstructive coronary disease, their disease was not amenable to revascularization, they had 50% or greater stenosis in their left main coronary artery, or their ejection fraction was less than 20%. The remaining 510 patients were randomized to revascularization by either coronary bypass surgery or percutaneous coronary intervention, or they skipped revascularization and went directly to vascular surgery.

Of the 258 patients randomized to the revascularization group, 240 (93%) actually had a coronary procedure; 99 had by-

pass surgery, and 141 had percutaneous coronary intervention. The choice between surgery and a percutaneous procedure was left to each patient's physician. About a third of the patients had single-vessel disease, another third had two-vessel disease, and the remainder had triple-vessel disease. All patients were placed on an optimal medical regimen that usually included a β -blocker, aspirin, and a statin.

Among the 252 patients who did not have immediate revascularization, 94% had scheduled vascular surgery, which took place a median of 18 days after randomization. Among the patients assigned to revascularization, 87% actually had scheduled vascular surgery, which occurred a median of 41 days after the per-

cutaneous coronary intervention procedures and a median of 48 days after bypass surgery. The results showed that revascularization led to a "substantial delay" in vascular surgery, Dr. McFalls said.

Thirty days after vascular surgery, the incidence of death was about 3% and of myocardial infarction, about 12%, in both groups. After a median follow-up of 2.7 years, the mortality rate was again virtually the same, about 22%, in both groups.

Many patients who did not have revascularization initially avoided the procedure for up to 5 years of follow-up. During follow-up, only 20% of patients who initially avoided revascularization eventually required coronary artery treatment, Dr. McFalls said.

Comparing the Recommendations

SCAI/SVMB/SVS Writing Group

Neurovascular Coalition

Cognitive Skills

Recommends that physicians understand the basic epidemiology, pathophysiology, natural history, diagnostic methods, and therapeutic alternatives for both extracranial carotid artery disease and stroke, and the relationship between the two.

Requires a minimum of 6 months of formal cognitive neuroscience training in an ACGME-approved training program in radiology, neuroradiology, neurosurgery, neurology, and/or vascular neurology. Mandates training on stroke syndromes and formal training and competency in the National Institutes of Health Stroke Scale.

Technical Skills

In cerebral angiography, requires interventionalists with the proper credentials and experience in noncerebrovascular vessels to perform 30 supervised angiograms, half as the primary operator in a supervised setting. In carotid intervention, requires interventionalists to perform a minimum of 25 patient procedures in a supervised setting, half as a primary operator. Prior to this training, the physician is expected to demonstrate a baseline proficiency in a broad base of catheter-based intervention.

Recommends appropriately supervised cervicocerebral angiography training and credentialing with a total of 100 diagnostic cervicocerebral angiograms before postgraduate training in cervicocerebral interventional procedures, including carotid stenting.

Clinical Skills

Recommends that physicians have specific clinical management skills, including the ability to weigh risks and benefits, counsel patients and families, admit patients, write orders, obtain informed consent, monitor hemodynamic and cardiac rhythm status, and coordinate poststent surveillance and clinical outpatient follow-up.

Recommends that physicians have the ability to recognize and manage procedural complications through studying, performing, and correctly interpreting a large number of diagnostic procedures with proper instruction.

Sources: *Neurology* 2005;64:190-8; *Catheter. Cardiovasc. Interv.* 2005;64:1-11

Dr. Gray said he respects the work that went into the neurovascular document, but believes the guidelines developed by the interventional cardiologists and vascular surgeons are a better reflection of the reality of performing carotid stenting and its program development.

Another concern is the requirement for physicians to complete 100 angiograms could lead to some unnecessary procedures, said Kenneth Rosenfield, M.D., of

Massachusetts General Hospital in Boston and an author of the SCAI guidelines.

With the need for diagnostic angiograms declining, some physicians might be inclined to perform the procedure just to satisfy the requirements for performing carotid artery stenting, he said.

"It should not be about setting barriers," he said. "It should be about allowing patients access to these procedures," Dr. Rosenfield said. ■