Neurology Coalition Sets Carotid Stent Standards

BY MARY ELLEN SCHNEIDER  Senior Writer

A coalition of neuromedical 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 Neurologic 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, because the Food and Drug Administration recently approved the Guidant Rx ACULINK carotid stent for use 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 on 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 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 Interventionalists for Carotovascular 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.

“What 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.

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.

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lizarization in a large group of patients.” The study included patients with stable coronary artery disease who were scheduled to have aortic or infragenual 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 comorbid condition, 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 or bypass surgery. Of these patients, 48% were randomized to revascularization, and 25% were randomized to bypass surgery. Of the 258 patients randomized to revascularization, 420 (93%) actually had a coronary procedure; 99 had bypass surgery, and 141 had percutaneous coronary intervention. The choice between surgery and a percutaneous procedure was left to each patient’s physician. Among the 232 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 percutaneous 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 attempted to avoid the procedure of 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.