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Standards of practice: Carotid angioplasty and stenting

Kenneth Ouriel, MD, Jay Yadav, MD, and **Richard M. Green, MD,** *Cleveland, Ohio; and Rochester, NY*

Carotid endarterectomy has been used to treat carotid bifurcation disease for more than 50 years. Over this period of time, the indications for repair have been refined and the surgical technique has undergone minor modification. This operation has held up to the scrutiny of large multicenter randomized trials, and more carotid endarterectomies are now being performed than at any time in the history of the operation. Although a cervical incision is inescapable, carotid endarterectomy is associated with a remarkably low morbidity and mortality, especially when performed in patients without severe medical comorbidities.

Despite the wide acceptance of carotid endarterectomy, a consensus statement that summarizes the evidence-based recommendations for treatment has never been prepared by the vascular surgical societies. By contrast, several interventional radiology societies have recently published guidelines for carotid artery stenting, a relatively new therapeutic option.[1,2] These documents were prepared by the joint Standards of Practice Committee of three societies: the American Society of Interventional and Therapeutic Radiology, the American Society of Neuroradiology, and the Society of Interventional Radiology. Representatives from radiology, interventional radiology, neurosurgery, and interventional neuroradiology participated in the preparation of this guideline document. Importantly, the radiology document is not limited to a discussion of carotid stenting; rather, the practice of carotid endarterectomy is a major component of the publication—with recommendations on the appropriateness of endarterectomy for patients with and without symptoms.

The radiology documents suggests that evidence to support the use of carotid endarterectomy for symptom-free patients is based on but one randomized trial, the Asymptomatic Carotid Atherosclerosis Study (ACAS).[3] Recently reported data from the Asymptomatic Carotid Surgery Trial, a randomized European trial of carotid endarterectomy versus best medical management in patients with asymptomatic stenoses, also demonstrated a statistically significant benefit for surgery after 5-year follow-up.[4] The authors of the radiology guideline documents suggest that ACAS failed to find benefit for the end point of major stroke, and that even a slight reduction in the risk of medical management of asymptomatic stenosis with the availability of contemporary pharmaceutical agents might render endarterectomy nonbeneficial in the majority of symptom-free patients. A review of the ACAS publication, however, suggests that after a median follow-up of 2.7 years, endarterectomy was associated with a significant reduction in the risk of ipsilateral stroke and any perioperative stroke or death (risk reduction 53%, 95% confidence interval 22%-72%).

Concerning carotid artery stenting, the radiology guidelines document opines that the benefit of embolic protection devices is controversial and without evidence based upon randomized, prospective studies. Such evidence may never be available, but each of the ongoing carotid stent trials mandates the use of such protection devices. Further, in a conference of opinion leaders, consensus was reached on the uniform use of emboli protection devices once they become available.[5] The Global Carotid Artery Stent Registry documented a 5.3% rate of stroke and procedure-related death in 6753 cases done without the use of an emboli protection, contrasted with a 2.2% rate in 4221 cases performed with emboli protection.[6] A systematic review of the literature revealed that 2537 carotid stent procedures had been performed without protection devices; 896 procedures had been performed with protection devices.[7] Both groups were similar with respect to demographics, risk factors, age, and indications. The combined 30-day stroke and death rate was 1.8% in patients treated with cerebral protection devices compared with 5.5% in patients treated without cerebral protection devices ($P < .001$). While this data did not originate from randomized, prospective studies, certain procedures and techniques become the standard of care without the availability of Level One evidence when their benefit is so intuitively clear that randomized trials cannot be justified. The use of heparin for carotid endarterectomy is one such example. Although never tested in a randomized trial, anticoagulation during endarterectomy achieved widespread use because of its intuitive value, and subsequent surveys of practice outcome have supported its benefit.[8] We strongly believe that embolic protection devices for carotid stenting are a similar example and practitioners should be discouraged from performing carotid stenting in routine situations without use of such a device.

At best, the radiology guidelines document for carotid stenting is premature. In currently available trials, such as

From the Cleveland Clinic Foundation and the University of Rochester Rochester, NY.
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Correspondence: Kenneth Ouriel, MD, FACS, FACC, Chairman, Division of Surgery, Desk E32, Cleveland, OH 44195, 9500 Euclid Avenue, Cleveland, OH 44195 (e-mail: ourielk@ccf.org).
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the Stenting with Angioplasty and Protection in Patients at High-Risk for Endarterectomy (SAPPHIRE) trial, there are not sufficient available data to separate recommendations for patients with and without symptoms on the basis of the outcome of carotid stenting .[9] Recommendations on the appropriateness of carotid stenting for stenosis secondary to fibromuscular dysplasia, giant cell arteritis, and arterial dissection are based on a paucity of even anecdotal data. Even more controversial than recommendations on the indications for carotid stenting are the stated requirements for physician qualifications in the radiology guidelines document. The radiology societies recommended a minimum of 200 *supervised* diagnostic cervicocerebral angiograms with documented acceptable indications and outcomes prior to credentialing for independent carotid stenting—a requirement that appears self-serving and not consistent with current practice, where the indications for diagnostic carotid procedures are strikingly few.

In direct contrast to the radiology guidelines documents' requirement for a large number of diagnostic procedures is the rather low minimum requirement for interventional therapeutic procedures for credentialing. Arterial stent experience is suggested, defined by a threshold of 25 non–carotid stent procedures and the completion of a hands-on carotid stenting course with only four successful carotid stenting procedures as principal operator. An alternative to this pathway is also suggested—successful completion of 10 carotid stenting procedures as the primary interventionist, with supervision by an on-site qualified physician. These numbers are significantly lower than the minimal requirements to participate in any of the ongoing clinical trials of carotid stenting—for example, the Carotid Revascularization Endarterectomy versus Stent Trial.[10] We believe that the minimum number of carotid stent procedures to establish credentialing should be dependent on the practitioner's endovascular experience, but in all cases should exceed the thresholds specified in the radiology guideline documents. The skills required to safely perform carotid stenting are natural extensions of those utilized in treating other arterial targets. Those qualified in these other areas, whether coronary or noncoronary, should be able to learn the unique aspects of carotid stenting with cerebral protection devices. Furthermore, the use of adjunctive training methods such as computer-based simulation is likely to alter the numbers of both diagnostic and therapeutic studies necessary to achieve proficiency.

Although specialties may differ over the precise indications for carotid stenting and the determination of which practitioners are best suited to perform the procedure, few would dispute that carotid stenting can be a useful clinical tool and one that should be approved for use by the Food and Drug Administration and reimbursable by the Centers for Medicare and Medicaid Services and other payers in appropriate patients. At a time when the medical community is interested in these goals, we believe that the stakeholders of carotid stenting should join forces to accomplish their goals. Rather than creating position papers by single societies or even groups of societies, it is incumbent upon us to work together to assure accessibility of carotid stenting and to continue to garner industrial and government support for well-designed clinical trials to evaluate new technology.

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