

# Carotid Artery Angioplasty and Stent Placement: Quality Improvement Guidelines to Ensure Stroke Risk Reduction

John J. Connors, III MD, David Sacks, MD, Gary J. Becker, MD, and John D. Barr, MD

J Vasc Interv Radiol 2003; 14:S317-S319

**Abbreviations:** AHA = American Heart Association, CAS = carotid artery stent placement, CEA = carotid endarterectomy.

CERVICAL carotid atherosclerotic stenosis has been correctly surmised to be a potentially preventable cause of stroke for a half-century. For most of this time, neither the absolute risk of the condition nor the specific contributing factors were known. Not surprisingly, therefore, medical therapy was poorly understood and offered a limited armamentarium. Prior dogma maintained that medical therapy alone neither significantly affected the progression of atherosclerosis nor caused its regression. Today an extensive body of literature confirms that cervical carotid artery atherosclerosis is common, relatively easy to evaluate, a major health threat, and surgically correctable. The appropriateness of carotid endarterectomy (CEA) has been evaluated by at least seven randomized trials, and further study is warranted and ongoing. While great strides have been made in the last decade in understanding cervical carotid atherosclerotic stenosis, there are still

many important unknowns concerning the clinicopathologic condition, its various manifestations, precipitating biochemical and pathophysiologic events, specific patient risk characteristics, optimal medical therapy, as well as indications for, and best methods of, surgical and interventional therapies.

Perhaps one of the best examples of the evolutionary nature of knowledge in this field is the relatively new concept that the principal culpability for clinical neurologic events is not the "degree-of-stenosis" per se, but rather the pathology of the plaque and the ischemia produced by atherothrombotic emboli. This belief is universally accepted in the cardiovascular community but seems to be under-appreciated in the neuroscience community. The ultimate confirmation of this concept is the 10-fold or greater difference in risk for someone with an 80% "non-embologenic" (ie, "asymptomatic") carotid stenosis as compared to an 80% "embologenic" (symptomatic) stenosis. For the former there is about 1% to 2% per year stroke risk from the lesion itself as compared to the latter, which has about 10% to 20% risk of stroke in the first year (1,2).

Further, recent studies of newer pharmacologic agents including antiplatelet agents (such as clopidogrel) and plaque-stabilizing agents (such as HMGCoA-reductase inhibitors ["statins"] and angiotensin converting enzyme ["ACE"] inhibitors) do indeed demonstrate that the natural history of atherosclerotic plaques can be posi-

tively influenced in a way that changes the risk/benefit ratio of all therapies for not only coronary atherosclerosis but also for carotid atherosclerosis (3,4). However, none of these new medical therapies have been systematically compared to CEA or carotid artery stent placement (CAS) in controlled clinical trials aimed at evaluating the best method to reduce stroke and stroke-related morbidity and mortality.

In March 2000, the American Society of Interventional and Therapeutic Neuroradiology (ASITN), the specialty organization then composed primarily of neuroradiologists and neurosurgeons most involved with cervico-cerebral angiography and cervical and intracranial endovascular intervention, published a review and analysis of the current literature on carotid atherosclerosis and its treatment (5). Since that time, continued progress has been made in further understanding the nature of carotid atherosclerosis, improving surgical techniques, advancing the pharmaceutical armamentarium, and refining a potential endovascular therapy: carotid artery angioplasty and stent placement. Three medical societies that include training in cervico-cerebral angiography as part of their ACGME defined residency programs, the ASITN, the American Society of Neuroradiology (ASNR), and the Society of Interventional Radiology (SIR), recognize the importance of carotid atherosclerosis and its appropriate management. In this issue of the *Journal of Vascular and*

This article also appears in J Vasc Interv Radiol 2003; 14:1095-1097.

From the Miami Cardiac and Vascular Institute, Miami, FL (J.J.C., G.J.B.), Department of Radiology, Reading Hospital and Medical Center, Reading PA (D.S.), and Mid-South Imaging and Therapeutics, Memphis, TN (J.D.B.). Received July 3, 2003; accepted August 6. Address correspondence to J.J.C., MCVI, 8900 Kendall Dr, Miami, FL 33176. E-mail budmancon@aol.com

J.J.C. and J.D.B. have identified a potential conflict of interest.

© SIR, 2003

DOI: 10.1097/01.RVI.0000086538.86489.2

*Interventional Radiology*, these societies have published their joint recommendations for appropriate quality and performance criteria for the innovative procedure of carotid artery balloon angioplasty and stent placement. Further documents on this topic will be forthcoming from other multispecialty writing groups including the American Heart Association (AHA).

Some may argue that quality and performance criteria for CAS are premature. CAS is not currently approved by Medicare for reimbursement outside of a Food and Drug Administration (FDA) approved study protocol. There are at present no FDA-approved carotid stents or cerebral embolic protection devices. Despite these restrictions, CAS is widely performed in both academic and community hospital settings and this necessitated the development of quality and performance guidelines at this time. The attraction of CAS is that it is minimally invasive, relies on techniques already present in the interventional endovascular community, and might produce better outcomes in those patients thought to be at higher risk of complications or poor outcome if treated with surgical endarterectomy. However, similar to endarterectomy, cerebral angiography, and coronary intervention—all of which have performance and training standards—there is a learning curve for performing CAS, and outcomes depend on physician expertise and institutional experience as well as appropriate patient selection. The stroke rates in some CAS studies are sobering (6,7). Results from the most experienced centers may not reflect the general experience. Just as the AHA recognizes that carotid endarterectomy has benefit only if performed with a high degree of technical proficiency on appropriate patients, the same holds true for carotid stent placement.

Since benefit must be weighed against risk, indications for CAS have also been listed as a means of selecting patients for an adequately high benefit-to-risk ratio. All of these criteria are in flux. These Quality Improvement Guidelines were developed over a period of 3 years by a multispecialty group from neuroradiology, neurosurgery, interventional radiology, and interventional neuroradiology. Consensus among the authors was reached

based on the best currently available data. The results of several ongoing trials studying “high surgical risk” symptomatic and asymptomatic patients, some of whom are randomized to surgery, will add further understanding to the role of endovascular therapy in the treatment of carotid artery disease. CEA for asymptomatic carotid stenosis is increasingly controversial, even more so now that further analysis of prior trials has been performed (8–10) and now that medical therapy has improved (3,4). Some might consider controversial the recommendation that, at present, most patients with asymptomatic carotid stenoses not be treated with CAS outside of trials. Although the document lists as an acceptable indication “asymptomatic patients at high surgical risk,” high surgical risk produced by associated medical comorbidities does not necessarily imply a naturally occurring high risk for stroke from the “asymptomatic” lesion itself. The Asymptomatic Carotid Atherosclerosis Study (ACAS) and the AHA determined that CEA in particular, but generalizable to any form of intervention, should only be performed if the risk of the procedure was less than 3% stroke and/or death; with new medical therapies, this number may need to be even lower (10–12). A favorable benefit:risk ratio for CAS in asymptomatic patients remains to be demonstrated but is certainly fertile ground for further research.

Training and experience requirements described in the Quality Improvement Guidelines in this issue may be considered by some to be controversial. Experts in CAS come from many backgrounds, but fundamentally, all worked long and hard to acquire the skills, knowledge and training to become experts in their own field as well as with this innovative procedure. The authors of the CAS Quality Improvement Guidelines believe that patient safety should never be compromised and that “stroke” as a procedural risk warrants the highest level of skill, knowledge, and training. It is clear that extensive prior experience with diagnostic catheterization and with interventions in other vascular beds overlaps with the training required for CAS. The document requires 200 diagnostic cervicocerebral angiograms for physicians without

prior catheter experience, but 100 cervicocerebral angiograms for physicians with sufficient prior experience to meet the AHA training requirements for peripheral vascular interventions (13). Of note, for “peripheral” vascular intervention accreditation, the AHA training requirements specify “peripheral” vascular experience regardless of prior experience in other vascular beds (13). This concept is of utmost importance when considering the unique and vulnerable nature of the brain. The choice of 100 diagnostic cervicocerebral angiography cases was derived from multiple disparate but consistent sources, including the AHA peripheral interventions guidelines (13), the peripheral vascular training documents from the SIR (14,15), the American College of Cardiology (16,17), the Society for Vascular Surgery (18), and the Society for Cardiac Angiography and Interventions (19–21), as well as the multisociety neurointerventional training standards from the ASNR, ASITN, the American Association of Neurological Surgeons, the AANS/CNS Section on Cerebrovascular Surgery, and the Congress of Neurological Surgeons (22). The latter document requires 100 diagnostic cervicocerebral angiograms prior to even entering residency/fellowship training in endovascular surgical neuroradiology and was unanimously approved by each and every executive committee of these five neurological societies. This consensus was based on the belief that there are challenges and dangers unique to the selection of carotid arteries and performance of carotid and cerebral interventions. These facts combine to necessitate mastery of catheter skills, clinical knowledge, and vascular anatomy specific to the carotid and cerebral circulations. It was for these reasons that the authors chose a requirement of 100 diagnostic cerebral angiograms even with prior experience in other vascular beds.

With the diminishing use of diagnostic carotid angiography due to improvements in noninvasive carotid imaging, both radiologists and other specialists may find it difficult to achieve this procedural training. However, these Guidelines represent the consensus of the authors on the necessary core knowledge and skills that must be acquired by a physician to safely perform CAS without supervi-

sion, recognizing that only a minority of the most highly trained and skilled practitioners from any background may fulfill the requirements for performing this procedure.

CAS is almost universally an elective procedure and patients can be referred or transferred to a center with the personnel and experience necessary to perform this procedure with the high level of competence it deserves. As stated in the Quality Improvement document, "any procedure that has 'stroke' as a routine potential risk should be performed only by medical professionals with appropriate training and experience." Until further validated, CAS should be reserved for suitable patients at high intrinsic risk for stroke and with high risk factors for CEA. CAS may ultimately offer a less invasive and safer means than CEA for reducing the risk of stroke in appropriately selected patients. Further research to clarify the roles of CEA, the new "best medical therapy," and CAS is needed and encouraged, and should be supported by all health care professionals, specialty societies, the National Institutes of Health, and relevant foundations. It is the intended purpose of the CAS quality improvement guidelines to provide physicians with the tools to measure the quality of care they provide as they consider offering this procedure.

#### References

1. North American Symptomatic Carotid Endarterectomy Trial Collaborators. Beneficial effect of carotid endarterectomy in symptomatic patient with high-grade carotid stenosis. *N Engl J Med* 1991; 325:445-508.
2. European Carotid Surgery Trialists Collaborative Group. Risk of stroke in the distribution of an asymptomatic carotid artery. *Lancet* 1995; 345:209-212.
3. Golledge J, Greenhalgh RM, Davies AH. The symptomatic carotid plaque. *Stroke* 2000; 31:774-781.
4. Gorelick PB. New horizons for stroke prevention: PROGRESS and HOPE. *Lancet Neurol* 2002; 1:149-156.
5. Connors JJ 3rd, Seidenwurm D, Wojak JC, et al. Treatment of atherosclerotic disease at the cervical carotid bifurcation: Current status and review of the literature. *AJNR* 2000; 21:444-450.
6. Diethrich EB, Ndiaye M, Reid DB, et al. Stenting in the carotid artery: Initial experience in 110 patients. *J Endovasc Surg* 1996; 3:42-62.
7. Jordan WD Jr, Voellinger DC, Fisher WS, et al. A comparison of carotid angioplasty with stenting versus endarterectomy with regional anesthesia. *J Vasc Surg* 1998; 28:397-403.
8. Barnett HJ, Meldrum HE, Eliasziw M for the North American Symptomatic Carotid Endarterectomy Trial (NASCET) collaborators. The appropriate use of carotid endarterectomy. *CMAJ* 2002; 166:1169-1179.
9. Inzitari D, Eliasziw M, Gates P, et al. The causes and risk of stroke in patients with asymptomatic internal-carotid-artery stenosis. North American Symptomatic Carotid Endarterectomy Trial Collaborators. *N Engl J Med* 2000; 342:1693-1700.
10. Gebel JM, Brott TG, Howard VJ, et al. Brain injury as detected by computerized tomography in CT scan in ACAS [abstract]. *Stroke* 2003; 34:238.
11. Executive Committee for the Asymptomatic Carotid Atherosclerosis Study. Endarterectomy for asymptomatic carotid artery stenosis. *JAMA* 1995; 273:1421-1428.
12. Biller J, Feinberg WM, Castaldo JE, et al. Guidelines for carotid endarterectomy: A statement for Healthcare Professionals from a Special Writing Group of the Stroke Council, American Heart Association. *Stroke* 1998; 29:554-562.
13. Levin DC, Becker GJ, Dorros, et al. Training standards for physicians performing peripheral angioplasty and other percutaneous peripheral vascular interventions. A statement for Health Professionals from the Special Group of Councils on Cardiovascular Radiology, Cardio-Thoracic and Vascular Surgery, and Clinical Cardiology, the American Heart Association. *Circulation* 1992; 86:1348-1350.
14. Singh H, Cardella JF, Cole PE, et al. Quality improvement guidelines for diagnostic arteriography. *J Vasc Interv Radiol* 2002; 13:1-6.
15. Standards of Practice. Committee of the Society of Cardiovascular and Interventional Radiology. Angioplasty standard of practice. *J Vasc Interv Radiol* 1992; 3:269-271.
16. Spittell JA, Nanda NC, Creager MA, et al. Recommendations for training in vascular medicine. American College of Cardiology Peripheral Vascular Disease Committee. *J Am Coll Cardiol* 1993; 22:626-628.
17. Spittell JA, Creager MA, Dorros G, et al. Recommendations for peripheral transluminal angioplasty: Training and facilities. *J Am Coll Cardiol* 1993; 21:546-548.
18. White RA, Hodgson KJ, Ahn SS, et al. Endovascular interventions training and credentialing for vascular surgeons. *J Vasc Surg* 1999; 29:177-186.
19. Wexler L, Dorros G, Levin D, King S. Guidelines for performance of peripheral percutaneous transluminal angioplasty. The Society for Cardiac Angiography and Intervention, Interventional Cardiology Committee, Subcommittee on Peripheral Interventions. *Cathet Cardiovasc Diag* 1990; 21:128-129.
20. Babb JD, Collins TJ, Cowley MJ, et al. Revised guidelines for the performance of peripheral vascular intervention. *Catheter Cardiovasc Interv* 1999; 46:21-23.
21. Sacks D, Becker GJ, Matalon TAS. Credentials for peripheral Angioplasty: Comments on Society of Cardiac Angiography and Intervention Revisions. *J Vasc Interv Radiol* 2001; 12:277-280.
22. Higashida RT, Hopkins LN, Berenstein A, et al. Program requirements for Residency Fellowship Education in Neuroendovascular Surgery/Interventional Neuroradiology: A Special Report on Graduate Medical Education. *AJNR* 2000; 21:1153-1159.