

Carotid Stenting, Stroke Prevention, and Training

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Abbreviations: ACGME = Accreditation Council for Graduate Medical Education, CAS = carotid artery stenting

CAROTID endarterectomy is a procedure proved to decrease the long-term risk of stroke but only if performed with excellent results and very few complications on appropriate patients. Carotid stenting is a minimally invasive alternative that must fulfill these same criteria to be beneficial. Carotid stent procedural training has been included in relatively few formal training programs in the past, thus necessitating these postgraduate guidelines; future practitioners would ideally acquire these skills in formal fellowships with appropriate supervision. The critical necessity of procedural excellence, combined with the potentially dangerous nature of this new procedure, was fundamental to the consensus recommendations in the current issue of *JVIR* for training to perform the procedure of carotid artery stenting (CAS) (1). This consensus was written by members of the neurology, neurosurgery, neuroradiology, interventional neuroradiology, vascular neurology, and interventional radiology specialties and endorsed by their respective professional societies. These recommendations include minimum specified formal training in both cognitive neuroscience and technical/procedural skills and can be summarized as follows:

1. A minimum of 6 months of formal cognitive neuroscience training in an Accreditation Council for Graduate Medical Education (ACGME) approved program is required in neuroradiology, neurosurgery, neurology, and/or vascular neurology.
2. All neuroscience societies reaffirm the validity of defined ACGME-approved training programs.
3. Cervicocerebral angiography training and resultant credentialing is required with an accumulated total of 100 diagnostic cervicocerebral angiograms before postgraduate training in carotid stenting.
4. Carotid stent training sufficient to meet previously published standards (Pathway 1: 25 non-carotid stent procedures, plus a 16-hour comprehensive CME CAS "hands-on" course, and least four supervised successful and uncomplicated CAS procedures; or Pathway 2: 10 consecutive supervised CAS procedures) (2).
5. Outcomes of cases during and following training for both diagnostic cervicocerebral angiography and carotid stenting must meet the quality thresholds of previously published standards (2).

These recommendations are not without controversy. Criticisms might include:

- The lack of coauthorship with members from the specialties of cardiology and vascular surgery.
- The possible logistical difficulty of obtaining sufficient experience

in diagnostic cervicocerebral angiography at a time when this procedure may be declining in frequency due to noninvasive imaging.

- The logistical difficulty of obtaining the recommended neuroscience cognitive training.
- The suggestion that measuring outcomes is more "relevant" than requiring specific training.
- The possibility that these recommendations are motivated by the desire to protect the "turf" of carotid stenting for radiologists, who have historically been the only profession with ACGME residency training programs that include diagnostic cervicocerebral angiography and have performed the vast majority of these procedures.
- The suggestion that the recommendations will reduce access to care for patients who can benefit from carotid stenting.
- The effect of these recommendations on those who are already performing this procedure but do not meet the recommendations.

These authoring societies include every clinical specialty with formal cognitive neuroscience training; the recognized complexity of neurologic conditions was used as a basis for recommending an appropriate amount of such training as a prerequisite for performing interventions affecting the brain. It would be ideal to have consensus on training from all of the medical specialties involved in this procedure. However, the described controversies have prevented consensus within the American Heart Association for years. One stent and embolic protection device

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have been narrowly recommended for approval for carotid stenting by a Food and Drug Administration (FDA) advisory panel, another was recently approved for use, and it is expected reimbursement by insurers will soon follow. Due to the intense interest in performing this innovative but dangerous procedure with varying degrees of benefit for individual patients, our societies believed it was essential to have an expert consensus recommendation for training.

Are these training recommendations reasonable? Training standards have been in existence for decades and are the hallmark of medical education, but are usually defined in terms of months rather than procedures. These requirements for defined formal cognitive training as well as procedural training in diagnostic arteriography are, however, directly analogous to the requirements to perform coronary interventions. Official American College of Cardiology requirements include 24 months of cognitive training and 300 diagnostic coronary angiograms (with resultant credentials to perform cardiac catheterization) before postgraduate training in coronary interventions (3–7). Six months of neuroscience training prior to neurovascular interventions is considerably more lenient than the training required *prior* to coronary vascular interventions—24 months—and certainly far less than the minimum total for credentialing in coronary intervention—36 months. Some of our authors strongly felt that 12 months would be more appropriate, but the final consensus was to mandate 6 months as this is felt to be extremely reasonable. For radiologists, confirmation of the necessary cognitive training is documented by passing the radiology board certification examination, including the neuroradiology and interventional radiology sections. Regarding technical skills, it is necessary to be fully trained in diagnostic neurovascular procedures prior to performing interventions, similar to coronary training. Peer-reviewed published scientific evidence demonstrates a substantial learning curve in the performance of diagnostic cervicocerebral angiography with 100–200 cases necessary to become truly proficient (8). Prior recommendations from the American Heart Association for peripheral vascular intervention mandate 100 procedures before peripheral

intervention (9); to require less for the least forgiving end-organ in the body would appear foolish. It is for this reason that a requirement of 100 diagnostic cervicocerebral angiograms has been previously mandated in published literature by the specialties of neurology, neurosurgery, neuroradiology, and interventional neuroradiology prior to training in the specialty of endovascular surgical neuroradiology (10,11) and was again specified in the current document.

In previously published statements, both the field of cardiology (for cardiac interventional procedures) and the neuroscience specialties do not lower the number of training cases for those with prior catheter experience, but the training requirements are designed to be minimally sufficient for those who have no prior experience. Would a physician with prior extensive and sophisticated catheter skills, such as an interventional cardiologist, vascular surgeon, or interventional radiologist with peripheral (nonneurologic) experience possibly require a lesser degree of training to achieve comparable outcomes? Would a physician with extensive experience treating cerebrovascular arterial occlusive disease with surgical techniques similarly need a lesser degree of training? Many of these physicians believe that their current skills in other vascular beds significantly overlap the skills necessary to perform diagnostic and interventional neurovascular procedures. Published series indicate that prior endovascular experience is certainly advantageous to learning this new procedure, but peer-reviewed published series of carotid stenting experience by just such highly trained and competent individual physicians suggest that there is still a very long learning curve even for the very “best of the best” (12,13). There is no evidence or consensus at this time to confirm that neurovascular training can be abbreviated by the majority of physicians who have catheter skills in other vascular territories.

While it is recognized that some practitioners may indeed learn faster than others, every medical society with ACGME-approved training in the neurosciences believes that a specified minimum of training for carotid stenting is entirely reasonable. This is particularly true in view of the fact

that these requirements represent only a fraction of the case requirements specified by the American College of Cardiology, the American Heart Association, the Society for Vascular Surgery, and other vascular societies for peripheral endovascular interventions (3,9,14–16). For a procedure with stroke and death as a routine occurrence, and with peer-reviewed documented evidence of a considerable learning curve, it is the belief of neurovascular experts that short-cuts in training would not be optimal for the patients who are to be treated in the future.

There is no question that outcomes are critical to a quality improvement program. However, post hoc review cannot substitute for suitable training by an appropriately qualified supervisor. Poor performance due to inadequate training will indeed show up as poor outcomes, but by then it is too late to prevent the harm to patients, which in this case would be stroke and death. Diagnostic cervicocerebral angiography carries a permanent stroke risk of 0–5.7% (8,17–22) and is higher among those with the least training and experience (18,23). Carotid stenting carries a stroke risk of 4.4%–12% (24–32) and also has a substantial learning curve (12,13). Adequate training prior to the granting of credentials is the standard and accepted means of protecting patients in all medical disciplines, and should be essential in this arena as well.

It is possible for many physicians to acquire the necessary training and experience in 100 diagnostic cervicocerebral arteriograms. The most recent Medicare data show that, in 2002, at least 92,000 cervicocerebral arteriograms (CPT codes 75680 and 75676 for bilateral or unilateral cervical carotid arteriography) were performed, compared to 109,000 5 years previously (33). This is an ample number of appropriately indicated procedures to train large numbers of physicians. However, these current requirements will be no easier to meet for radiologists in training than for other specialties. Current general radiology graduates will almost uniformly be unqualified and a recent survey of specialty training in interventional radiology fellowships indicates that only 11% of current trainees will have performed this number of diagnostic cervicocerebral

arteriograms during their fellowship training (34). Therefore, it is expected that the overwhelming majority of radiologist, neuroradiologist, and interventional radiologist trainees will not meet this standard and will require additional training. This fact has caused considerable angst among the radiology authors and the members of our represented societies, as well as those from the fields of Neurology and Neurosurgery. This recommendation for high-quality training was based on what we thought was best for patient care. The possible difficulty in meeting this recommendation does not mean that the standard should be lowered if such training is necessary to achieve good clinical outcomes. Protecting the "turf" of carotid stenting for radiology was not our motivation, and the current recommendations for training will actually vastly decrease the numbers of radiologists that could offer this service. The motivation for these recommendations for training was based on peer-reviewed evidence and the belief that these procedures, involving the unforgiving organ—the brain—should be performed only by physicians with adequate preparation, training, and skill.

Will patients be denied care that they need if physicians need to fulfill rigorous training requirements to perform carotid stenting? Industry estimates of numbers of carotid stent procedures range from 20,000 to 100,000 per year within this decade. If an interventionist were to perform only one procedure per day, or 250 per year, this would necessitate only 300 doctors in the United States to provide the care for the entire population of patients now undergoing endarterectomy. Increasing the number of physicians to 500 with 10 cases performed each week would allow these physicians to perform 250,000 procedures. An increase of 100 practitioners every year would easily allow for an additional 50,000 cases per year. Even if there are far fewer diagnostic cerebral arteriograms performed in future years (compared to the 92,000 performed on Medicare patients alone in 2002), there should still be ample numbers to train the number of physicians needed to provide carotid stenting services in this country.

The recommendations will reduce geographic access to care for patients

to be treated with carotid stenting; every small hospital in the nation may not be doing this procedure. Carotid stenting is an elective procedure. Transfer to an appropriate expert/facility is therefore entirely reasonable and has been the standard of care for cardiac disease for decades. As with carotid endarterectomy, a satisfactory benefit/risk ratio from carotid stenting is critically dependent on being able to achieve an extremely low rate of perioperative stroke, myocardial infarction and death in the perioperative period and a high rate of stroke reduction compared to the long-term natural history of the disease (35). The intent of these standards is that carotid stenting will be properly limited to expert physicians with adequate training and experience to perform this procedure for appropriate indications with excellent outcomes in order for this procedure to actually have the desired result of decreasing the number of total strokes.

There are physicians who are already credentialed to perform carotid stenting in their institutions who may not meet our recommendations. No procedure springs fully developed into clinical practice like Athena from the head of Zeus. Innovative and pioneering physicians have created and developed the procedure of carotid stenting and in the process have worked through their own personal learning curve, some with great difficulty and sacrifice. Training and credentialing standards follow this innovative work, similar to the process for new interventional radiology procedures such as TIPS, uterine artery embolization for treatment of fibroids, and vertebroplasty. It would be an inappropriate abuse of the training standards we offer to use them to deny the validity of credentials and competency for carotid stenting already earned by those physicians who have documented acceptable outcomes.

What does the future hold? In the short term, there will be other training standards suggesting other training criteria for carotid stenting issued by other specialty societies who were not authors of the current document (15). Hospital credentialing committees will be faced with conflicting standards and will have to make decisions as to which standards they will follow. The authors of the current document

have done their best to base our standards on scientifically supported evidence and with concern for patient safety paramount. The most valid scientific support will come from studies that need to be performed that evaluate patient outcomes versus training for interventionists experienced in other vascular areas. Simulators will play a role in training, but at this time it is an unknown role, and at present there is no proved scientific validation for accepting working on a computer as a substitute for approved supervised training on a real patient. An "educated guess" was used in our document to say that simulators might replace as much as 20% of the live training cases, but truly the role of simulators is not yet known. Many physician societies are in the process of evaluating their appropriate role in initial training as well as recertification.

More studies are needed demonstrating the clinical value of carotid artery stenting compared to carotid endarterectomy compared to best medical therapy, and are ongoing. The FDA panel was sharply divided as to whether carotid stenting is appropriate for asymptomatic patients at high surgical risk (36). It is unknown if stenting is appropriate for any patients at average surgical risk, where large, lengthy, and well-controlled randomized trials have produced results that have been marginal for the benefit of endarterectomy for asymptomatic patients even when performed by excellent surgeons. It is unknown if the results of carotid stenting in published trials can be generalized to routine clinical practice, but currently published results do not support the generalized application to large numbers of asymptomatic patients. The costs of not knowing these answers could be strokes and deaths for some patients. Within the radiology community there will need to be a shift in performance of diagnostic cervicocerebral arteriography to more experienced practitioners to achieve the recommended high degrees of proficiency. To meet the training numbers for carotid stenting, diagnostic cases may need to be performed by physicians who do or will perform carotid interventions, and cease to be performed by others. Finally, the neurovascular stroke coalition that created these carotid stent training standards has opportunities

to work together as a multispecialty group to advance stroke education and care for the benefit of our patients.

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