

Clinical competence statement on carotid stenting: Training and credentialing for carotid stenting—multispecialty consensus recommendations

A Report of the SCAI/SVMB/SVS Writing Committee to Develop a Clinical Competence Statement on Carotid Interventions

INTRODUCTION

Percutaneous carotid intervention with distal embolic protection is a rapidly emerging field that is being incorporated into interventional cardiovascular, vascular surgery, vascular medicine, and interventional radiology practices. The recently published SAPHIRE trial has established carotid stenting in high-surgical risk patients as an effective alternative to carotid endarterectomy.¹

Contemporary techniques for carotid stenting and embolic protection were developed by multiple specialists, including interventional cardiologists, vascular surgeons, interventional radiologists, and vascular medicine specialists, transferring technology, interventional skills, and adjunctive medical therapies perfected in their coronary and peripheral vascular experience.¹⁻⁵

Cardiologists, as board-certified cardiovascular specialists, have recognized the systemic nature of atherosclerotic disease and appropriately taken an increasingly active role in the management of noncardiac vascular diseases, including stroke prevention. Comprehensive and coordinated management of cardiovascular disease (both cardiac and noncardiac) has become the standard of care in contemporary clinical and interventional practice. Vascular surgeons have traditionally performed the

majority of carotid endarterectomy procedures and helped validate carotid revascularization as an effective therapy for stroke prevention. Vascular surgeons have recently gained experience in percutaneous catheter based therapies and increasingly utilize the endovascular approach to treat a wide variety of peripheral vascular disorders. As carotid stenting has emerged as an alternative for patients at increased risk for surgery, it is appropriate that vascular surgery will have a significant role in this important therapy for carotid bifurcation disease. Similarly, physicians trained in vascular medicine frequently manage extracranial cerebrovascular disease, which is an essential element in the care of their patients with generalized vascular disease. Vascular medicine physicians, trained as interventionalists, will offer stenting as an alternative for treatment of carotid disease.

The purpose of this document is to provide recommendations regarding physician training and credentialing to facilitate the safe and orderly dissemination of this new therapy into clinical practice. Prior to undertaking focused training in cerebral angiography and carotid stenting, physicians should first comply with the recommendations outlined in the recently published Clinical Competence Statement on Vascular Medicine and Catheter-Based Peripheral Vascular Interventions.⁶ Our document should be viewed as an extension of that earlier competence statement on peripheral vascular interventions and should be considered to represent the minimum requirements for training and preparation to perform cerebral angiography and carotid stenting.

RATIONALE FOR A TRAINING AND CREDENTIALING STATEMENT IN CAROTID STENTING

The emergence of carotid stent placement as an accepted alternative to high-surgical-risk carotid endarterectomy has been facilitated by device innovation, refinements of technique, and careful patient selection. Carotid revascularization involves interventional skills, equipment, and clinical management skills that differ significantly from

Competition of interest: none.

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those employed in other vascular distributions. Moreover, it involves treatment of a uniquely sensitive organ system, wherein minor errors or complications can have catastrophic effects. Given the high-risk nature of carotid revascularization and the availability of alternative treatment modalities, decisions regarding optimal therapy require a comprehensive knowledge base of the disease and its ramifications in order to properly assess the risk-benefit ratio of each therapeutic option.

Published results demonstrate improved patient outcomes with increasing operator experience, thereby confirming a learning curve for this procedure.¹⁻⁵ This, in addition to the unique aspects of the disease process and end organ, underscores the need for careful and thorough training and preparation. Medical specialists from several different disciplines, each of which emphasizes a particular set of skills, expertise, and approach, are involved in the management of carotid disease and will be performing carotid stent procedures. This statement is intended to delineate the core elements that are required to achieve competence in carotid stenting, regardless of specialty, in order to maintain high-quality outcomes.

PHYSICIAN TRAINING AND CREDENTIALING IN CAROTID STENTING

General Principles of Training for Carotid Intervention

Physicians who wish to perform carotid stenting with embolic protection must meet or exceed the minimum qualifications deemed necessary to offer safe and effective therapy. These qualifications include proficiency in the cognitive, technical, and clinical skills necessary to care for patients with carotid artery disease (Tables I–III). The requisite fundamental knowledge base includes a comprehensive understanding of the risk factors, epidemiology, pathology, pathophysiology, natural history, clinical presentation, and therapeutic alternatives for patients with extracranial carotid artery disease. Appropriate decision-making regarding indications, limitations, and complications of the procedure necessitates a high level of skill in patient assessment and sound clinical judgment. Knowledge about angiographic laboratory equipment, including physiologic recorders, pressure transducers, X-ray imaging equipment, and digital image archiving, as well as familiarity with the full range of interventional catheters, guidewires, and other devices, is critical. Understanding and anticipation of peri- and postprocedural issues, and appropriate management of these with adjunctive therapies, are also essential to optimize both short- and long-term outcomes.

Physicians representing multiple subspecialties with diverse backgrounds and varying levels of expertise will seek training for carotid intervention. There are many precedents for this in surgery and medicine. Examples include carotid endarterectomy, which is performed by vascular, general, and neurosurgeons; peripheral interventions, performed by vascular surgeons, vascular and general radiolo-

Table I. Cognitive Requirements for Performance of Carotid Stenting*

Cognitive elements including the fund of knowledge regarding cerebrovascular disease, its natural history, pathophysiology, diagnostic methods, and treatment alternatives.

- I) Pathophysiology of carotid artery disease and stroke
 - a) Causes of Stroke
 - i. Embolization (cardiac, carotid, aortic, other)
 - ii. Vasculitis
 - iii. Arteriovenous malformation
 - iv. Intracranial bleeding (subdural, epidural)
 - v. Space-occupying lesion
 - b) Causes of carotid artery narrowing
 - i. Atherosclerosis
 - ii. Fibromuscular dysplasia
 - iii. Spontaneous dissection
 - iv. Other
 - c) Atherogenesis (pathogenesis and risk factors)
- II) Clinical manifestations of stroke
 - a) Knowledge of stroke syndromes (classic and atypical)
 - b) Distinction between anterior and posterior circulation events
- III) Natural history of carotid artery disease
- IV) Associated pathology (e.g. coronary and peripheral artery disease)
- V) Diagnosis of stroke and carotid artery disease
 - a) History and physical examination
 - i. Neurologic
 - ii. Non-neurologic (cardiac, other)
 - b) Non-invasive imaging and appropriate use thereof
 - i. Duplex ultrasound
 - ii. MRA
 - iii. CTA
- VI) Angiographic anatomy (arch, extracranial, intracranial, basic collateral circulation, common anatomic variants, and non-atherosclerotic pathologic processes)
- VII) Knowledge of alternative treatment options for carotid stenosis and their results (immediate success, risks, and long-term outcome)
 - a) Pharmacotherapy (e.g. anti-platelet agents, anticoagulation, lipid-lowering agents)
 - b) Carotid endarterectomy
 - i. Results from major trials (NASCET, ACAS, ECST, ACST)
 - ii. Results in patients with increased surgical risk
 - c) Stent revascularization
 - i. Results with and without distal embolic protection
- VIII) Case selection
 - a) Indications and contraindications for revascularization to prevent stroke
 - b) High risk criteria for carotid endarterectomy
 - c) High risk criteria for percutaneous intervention
- IX) Role of post-procedure follow up and surveillance

*In addition to baseline cognitive skills encompassed in the Competency document.⁶

gists, cardiologists, and vascular medicine physicians; and spine surgery, performed by orthopedic surgeons, neurosurgeons, and general surgeons.

Training and credentialing requirements must recognize this diversity, acknowledge the relevant background experience of individuals from each specialty, and be tailored to the particular needs of the individual seeking training. This approach will lead to comparable and acceptable outcomes for patients treated by physicians from different backgrounds.

Table II. Technical Requirements for Performance of Carotid Stenting*

Minimum numbers of procedures to achieve competence

I) Diagnostic cervico-cerebral angiograms - 30 (\geq half as primary operator)[†]

II) Carotid stent procedures - 25 (\geq half as primary operation)[†]

Technical elements for competence in both diagnostic angiography and interventional techniques

I) High level of expertise with antiplatelet therapy and procedural anticoagulation

II) Angiographic skills

- Vascular access skills
- Selection of guidewires and angiographic catheters
- Appropriate manipulation of guidewires and catheters
- Use of "closed system" manifold
- Knowledge of normal angiographic anatomy and common variants
- Knowledge of Circle of Willis and typical/atypical collateral pathways
- Proper assessment of aortic arch configuration, as it affects carotid intervention
- Familiarity with use of angulated views and appropriate movement of the x-ray gantry

III) Interventional skills

- Guide catheter/sheath placement
- Deployment and retrieval of embolic protection devices
- Pre- and post-dilation
- Stent positioning and deployment

IV) Recognition and management of intra-procedural complications

- Cerebrovascular events
 - Stroke or cerebrovascular ischemia
 - Embolization
 - Hemorrhage
 - Thrombosis
 - Dissection
 - Seizure and loss of consciousness
- Cardiovascular events
 - Arrhythmias
 - Hypotension
 - Hypertension
 - Myocardial ischemia/infarction
- Vascular access events
 - Bleeding
 - Ischemia
 - Thrombosis

IV) Management of vascular access

- Proper sheath removal and attainment of hemostasis
- Closure device utilization

*In addition to technical skills encompassed in the Competency document ⁶.

[†]Angiograms and stenting procedures may be performed in the same sitting (e.g. in the same patients), provided that one performs 15 angiograms as primary operator before performing the first stent as primary operator.

Training of Interventionalists in Clinical Trials to Date

Carotid stenting with embolic protection is a new procedure with a new set of challenges. Unique features related to percutaneous carotid revascularization include appropriate patient selection (e.g., deciding on stent versus alternative therapy); the difficulty of gaining catheter access in tortuous cervical vessels; the complexity of both the extra- and the intracranial (e.g., circle of Willis) circulations as a source of collateral blood flow with interdependent

Table III. Clinical Requirements for Performance of Carotid Stenting*

Clinical elements, including the ability to manage inpatients and outpatient care

I) Determine the patient's risk/benefit for the procedure

II) Outpatient responsibilities

- Adjust medications pre-procedure
- Counsel patient and family

III) Inpatient responsibilities

- Admit patients (privileges required) and write orders
- Obtain informed consent for procedures
- Provide pre and post-procedure hospital care
 - Neurological evaluation pre and post procedure
 - Post-procedure pharmacotherapy
 - Monitoring of hemodynamic and cardiac rhythm status

IV) Coordinate post-stent surveillance and clinical outpatient follow-up

*In addition to clinical skills encompassed in the Competency document ⁶.

vascular distributions; the vulnerability of the brain to emboli; the technical aspects related to selection and use of catheters, guidewires, self-expanding stents, and emboli protection devices; and clinical management of patients undergoing carotid stenting, including the unique hemodynamic consequences. Most importantly, small errors in the performance of this procedure may have catastrophic consequences. Current clinical trials of carotid stent placement have employed rigorous quality assurance methodology, including requiring a threshold of experience before entry, a track record of successful procedures, and independent monitoring of operator outcomes. The training, oversight, and quality assurance programs in clinical practice must be equally rigorous, if the excellent results of these clinical trials are to be duplicated.

Establishing Training Pathways

Carotid stenting, as a relatively new clinical procedure, has not been widely incorporated into the curriculum of existing training programs. Over the next several years, it will need to be taught both to new trainees and to physicians already in practice, who have previously completed their specialty or subspecialty training. Physician training will therefore initially require two training pathways. The first pathway will occur within an accredited postgraduate residency or fellowship training program (i.e., interventional cardiology, interventional radiology, or vascular surgery) in conjunction with peripheral angioplasty training that will be inclusive of the carotid territory. The second pathway, the practice pathway, will apply to physicians who have completed their training and will likely be trained to perform carotid stenting in a clinical practice environment. The setting for these two pathways will differ. However, the fund of knowledge, as well as the cognitive, clinical, and procedural skills necessary to achieve competency, will be identical.

Physicians from various clinical backgrounds (surgery, cardiology, radiology, vascular medicine, neurology, etc.), whether in formal fellowship programs or training in the practice pathway, will begin at different points along the

interventional learning curve. For example, a surgeon may have little experience with 0.014@ guidewire balloon and stent systems, or with embolic protection devices, but may have a thorough understanding of the diagnosis, management, and pathophysiology of extracranial carotid artery disease. Similarly, an interventional cardiologist may possess advanced interventional skills, but have superficial knowledge of the natural history, neurovascular anatomy, or alternative therapies for stroke prevention. Training programs must take into consideration the variability of the starting point of the trainee and be flexible and adaptable to the trainee's baseline level of experience. Diversity of physician backgrounds in this field is advantageous and should be encouraged. However, upon completion of training, operators from each of the specialties involved should have acquired mastery of the necessary cognitive, clinical, and technical skills to achieve comparable levels of proficiency with carotid intervention.

The excellent results of carotid stenting in clinical trials indicate that cardiologists, surgeons, radiologists, and other interventionalists possessing peripheral vascular interventional skills, but with relatively limited prior experience in cerebral angiography or carotid intervention, can perform both cerebral angiography and carotid stenting safely. Furthermore, there are no data from carotid stenting trials to support a requirement for a large number of diagnostic cervicocerebral angiograms in order to perform carotid stenting safely and effectively. Indeed, establishment of any such threshold may encourage unnecessary angiographic procedures in an era when the diagnosis and treatment decisions for carotid disease are increasingly and accurately being made on the basis of noninvasive modalities.

Preparation for Carotid Stent Training

Physicians training in carotid stenting are expected to demonstrate a baseline high level of proficiency in catheter-based intervention in other vascular beds. Credentials and skills in diagnostic procedures alone, cerebrovascular or otherwise, are not sufficient preparation. Physicians engaged in accredited interventional or endovascular training programs may be trained in carotid intervention concurrently with other vascular beds, at the discretion of the supervising faculty member. These individuals should achieve at least the minimum procedure volumes in both carotid angiography and carotid intervention and demonstrate procedure proficiency as a part of their accredited training program. In programs where the exposure falls short of the volume required to achieve competence, the experience accrued in the training program may be counted toward completion of carotid training after fellowship.

Physicians in the practice pathway should be fully credentialed to perform peripheral interventions at their local institution and should be actively performing endovascular procedures prior to undertaking focused carotid training in order to ensure adequate catheter-based skills with, and knowledge of, equipment and devices that are utilized during carotid angioplasty and stenting.

Elements of Competency for Carotid Intervention

Competency can be subdivided into cognitive, technical, and clinical components. To prepare the physician properly for safe performance of this procedure as an independent operator, training programs for carotid stenting must enable the practitioner to obtain a certain predetermined level of expertise or proficiency in each of these three areas.

Cognitive skills requirements (Table I). Physicians performing carotid intervention must first possess a comprehensive knowledge base regarding cerebrovascular disease and its ramifications. They must understand the basic epidemiology, pathophysiology, natural history, diagnostic methods, and therapeutic alternatives for both extracranial carotid artery disease and stroke, as well as the relationship between these two entities. A working knowledge of the cerebrovascular anatomy and manifestations of stroke syndromes is also essential.

Stroke is the most important manifestation of extracranial carotid artery disease. The physician must possess a comprehensive understanding of the epidemiology and pathophysiology of stroke, including nonatherosclerotic etiologies (i.e., embolization from cardiac chamber/valve or ascending aorta, cerebral vasculitis, intracranial arteriovenous malformations, subdural or epidural bleeding, tumor, and arterial or venous thrombosis). The risk factors for stroke must be recognized and factored into decision-making regarding revascularization of extracranial carotid artery stenosis. The physician caring for patients with carotid disease should understand the various clinical manifestations of stroke and have basic command of the neurologic history and physical examination (evaluation of cranial nerves, as well as cognitive, sensory, and motor functions). Ordering and interpreting pertinent diagnostic laboratory tests are important components in the evaluation of stroke. The physician should be familiar with the various imaging methods available to confirm the diagnosis of acute stroke. These include computerized tomography and magnetic resonance arteriography (including diffusion-weighted magnetic resonance imaging), each of which has distinct uses and advantages.

Prior to procedural training, the carotid interventionist should be knowledgeable about extracranial carotid artery disease, including its epidemiology, pathophysiology, risk factors, natural history, and likelihood to cause stroke. The physician must appreciate differences in presentation, natural history, and therapeutic options for fibromuscular dysplasia and spontaneous dissection of the carotid arteries, both important nonatherosclerotic causes of extracranial carotid artery disease. Understanding the accuracy, advantages, and limitations of carotid duplex ultrasonography, magnetic resonance arteriography, and computed tomographic arteriography is a necessity for developing a diagnostic algorithm for extracranial carotid artery stenosis. The indications for performance of cerebral arteriography should be clearly understood.

Alternative therapies to carotid artery stenting must be appreciated by the interventionist and presented to patients during consultation. Physicians must be cognizant of the role of aggressive medical intervention, including tobacco cessation and appropriate antiplatelet, antihypertensive, and lipid-lowering therapy, in the context of any revascularization strategy. Data regarding success and risk of carotid endarterectomy and carotid artery stenting must be understood and conveyed to patients when deciding on the optimal revascularization strategy. Subsequently, the interventionist should be familiar with the role for postprocedure surveillance of the revascularized vessel and the interpretation of carotid duplex ultrasonography with a stent in place.

Additional cognitive skills required are delineated in the aforementioned competency statement,⁶ such as knowledge of hypercoagulable syndromes and other predisposing factors for thromboembolism, utilization and pharmacodynamics of contrast agents, principles of radiation safety, and familiarity with conscious sedation. Acquisition of most of the cognitive elements delineated above should occur prior to undertaking interventional procedural training. However, cognitive growth is an ongoing process that will continue throughout interventional training and beyond. Physicians in formal training pathway will learn the cognitive aspects while participating in a program approved by the Accreditation Council for Graduate Medical Education (ACGME). Programs that aim to prepare trainees for carotid intervention will be required to develop and administer a rigorous and comprehensive curriculum incorporating all of the cognitive elements described.

Physicians in the practice pathway may already possess an extensive knowledge base regarding carotid artery disease. For instance, those trained in vascular surgery are familiar with the pathology, natural history, and clinical evaluation and management of carotid disease. This knowledge from the prestenting era provides a foundation for further training in percutaneous management. The remaining cognitive knowledge base should be acquired through participation in category 1 educational activities. Examples include didactic courses and conferences, live case presentations, case-based learning modules, and graded Internet courseware. These may be supplemented by textbook study and independent case review. To ensure consistency and completeness across individual physicians and disciplines, courseware utilizing these modalities should be administered as part of a comprehensive defined curriculum. It must also be underscored that, prior to achieving procedural competence in carotid stenting, the interventionist must first acquire certain cognitive and clinical knowledge pertaining to this procedure.

Physicians are expected to document proper acquisition of cognitive skills, including the maintenance of a record of courses attended and category 1 credits accumulated specifically in pursuit of carotid training. Ultimately, the trainee should demonstrate a comprehensive understanding of carotid and cerebrovascular disease and proper case selection for intervention to the experienced carotid

interventionist who supervises subsequent procedural training.

Technical skills requirements (Table II). The technical demands of carotid stenting require that the practitioner already possess a high baseline level of expertise in catheter-based manipulations, including credentials to perform other peripheral endovascular interventions. For the practicing physician who intends to learn this procedure, he or she must have prior experience in a broad range of catheter-based interventions. The baseline skill set must include the following: first, knowledge of appropriate use of X-ray imaging equipment, how to obtain digital and subtracted images, and how to utilize angulated views to optimally examine the vascular tree; second, understanding and proper utilization of contrast agents; third, proper setup and use of closed manifold systems; fourth, facility with use of adjunct equipment and techniques, such as intravascular snares, embolization coils, and intravascular ultrasound. Starting from this baseline, there is a stepwise process of skills acquisition, first establishing competence in diagnostic cerebral angiography and then progressing to the interventional aspects, including the complexities of sheath advancement, placement and retrieval of embolic protection devices, balloon inflation, and stent positioning and deployment. These skills should be objectively assessed by an experienced supervising physician prior to allowing independent operator performance.

Cerebral angiography. Competence in the performance and basic interpretation of diagnostic two- and four-vessel cervicocerebral angiography must be achieved in order to be a carotid stent operator. Complete four-vessel studies are often not indicated for carotid stent procedures; however, knowledge of how to safely perform four-vessel studies, including selective vertebral angiography, is important for those cases in which it is appropriate.

Performance of cerebral angiography requires that the operator understand basic neurovascular anatomy and pathways of collateral circulation to the brain. The physician must be able to recognize intracranial pathology that might have bearing on the outcome of a carotid stent procedure or ongoing patient care (such as, but not limited to, aneurysm, arteriovenous malformation, intracranial stenosis, and acute embolic occlusion). Certain of these important cognitive elements are best (and most safely) acquired by intensive study of basic neurovascular anatomy and pathologic states prior to actual performance of the procedure in patients. This approach reduces the inherent procedural risk, even in a supervised clinical setting. Furthermore, since the training materials can be derived from many sources (e.g., category 1 educational activities, textbooks, Internet courseware, case reviews, and clinical training symposia) and selected to teach specific points, exposure to a much broader range of anatomical variations and pathological conditions is possible and encouraged.

There clearly exists a learning curve for catheter selection and placement, as well as image interpretation during cerebral angiography. However, for those who already possess interventional skills, there is a paucity of data re-

garding the required number of diagnostic cerebral angiograms one needs to perform in the training (e.g., supervised) environment in order to become proficient. Data are available from cerebral angiography performed in conjunction with carotid stenting associated with contemporary trials (e.g., SAPPHIRE, BEACH, SECURITY, ARCHER). In these studies, the majority of procedures were performed by cardiologists, surgeons, and other vascular interventionalists with limited prior exposure to cerebral angiography. The excellent results demonstrated in these trials confirm that experienced catheter-based interventionalists from multiple specialties possess skills that are transferable, and which prepare them well for performing cerebral angiography and intervention. The consensus of experts from the specialties who have performed the significant majority of carotid revascularizations to date is as follows:

To achieve and ensure competency in the safe performance of cervicocerebral angiography, interventionalists with proper credentials and demonstrated expertise in noncerebrovascular vessels can achieve the required level of technical skill by performing 30 supervised angiograms, half as primary operator, in a supervised setting. This recommendation acknowledges the transferable nature of basic and advanced catheter skills acquired in other vascular beds. Prior to performance of these 30 angiograms, the trainee should have acquired extensive knowledge of neurovascular anatomy and pathology through study of appropriate textbooks and case review of angiograms.

This recommendation is consistent with that of the recently published multidisciplinary competency statement, which is supported by the American College of Cardiology, the American College of Physicians, the Society for Vascular Surgery, the Society for Cardiovascular Angiography and Interventions, and the Society for Vascular Medicine and Biology.⁶ Diagnostic angiograms can be accrued during the diagnostic phase of carotid stent procedures, provided that the trainee is designated as primary operator only for the diagnostic portion of the procedure. The trainee should complete the required 15 cervicocerebral angiograms as primary operator and demonstrate competence in performance and interpretation of these studies prior to assuming the role as primary operator for carotid intervention.

Carotid intervention. The interventional skills required for carotid stenting are significantly more complex and difficult to master than those for standalone diagnostic cerebral angiography. These skills include the following: proper selection and placement of large sheaths or guide catheters in (often tortuous and calcified) carotid arteries; safe manipulation of fine 0.014" guidewires; facility with rapid-exchange single-operator systems; proper selection, delivery, and accurate deployment of large self-expanding stents; correct choice and use of pre- and post-dilation balloons, including issues of balloon profile, size, inflation pressure, and inflation time; and proper selection and use of

embolic protection devices. Important aspects of this technical component are the judgment and foresight to ascertain whether navigation of the target vessels will be feasible and what equipment and techniques are best suited to achieve a successful outcome, with the least risk. In addition, the knowledge of how to avoid complications, to anticipate their occurrence, and to treat them when they occur is paramount. The operator must be capable of recognizing and understanding the angiographic findings seen during carotid stenting, including spasm, pseudo-spasm, residual ulceration, and benign intimal disruption. Similarly, the operator must know how to avoid—and manage, should they occur—arterial dissection, stent thrombosis, distal embolization, vessel perforation, and stent malpositioning.

The pathway to achieving technical competence must be designed to address the degree of difficulty and potential risks inherent in this procedure. Prior to undertaking focused training in carotid stenting, the operator is expected to demonstrate a baseline high level of proficiency in a broad base of catheter-based interventions. Credentials and skills in only diagnostic procedures, cerebrovascular or otherwise, are not sufficient preparation, for the reasons noted previously. Likewise, experience in a focused area, such as coronary intervention, aortic stent grafting, or cerebral aneurysm coiling, does not constitute adequate preparation. The operator training in the practice pathway must be fully credentialed for peripheral interventions at his or her institution and actively performing a variety of endovascular procedures.

Once qualified, based on the criteria described, the operator in training progresses to learn the intricacies of guide catheter placement, embolic protection positioning and removal, and stent localization and deployment. Formal recommendations regarding the number of procedures required to become an independent operator are as follows:

Interventionalists training in carotid stenting must perform a minimum of 25 patient procedures in a supervised setting, half as primary operator. "Supervision" implies that the mentor is scrubbed alongside the trainee; "primary operator" implies that, throughout the entire procedure, the trainee is personally directing the guidewires, placing the sheath, positioning and retrieving the distal protection device and balloons, and deploying the stent. Prior to functioning as a primary stent operator, the trainee must have performed at least 15 diagnostic cervicocerebral angiograms as primary operator.

These provisions are consistent with recommendations in the recently published vascular medicine and peripheral vascular intervention competency document.⁶ For the purpose of definition and accounting for procedural experience, an individual may participate in a procedure as a primary mentored operator or as a secondary operator. To qualify as primary mentored operator in a given case, the trainee must, in a supervised setting, evaluate the patient, make decisions, perform the critical catheter manipulations, and provide postprocedural care. Each procedure

may have only one trainee as the primary mentored operator. Careful records must be kept documenting the trainee's role in the intervention, as well as procedural details, outcome, and complications. Operative reports and procedure notes will generally refer to the supervising physician, the individual ultimately responsible, as the "surgeon" or "interventionalist" who performed the procedure. It is understood that a primary mentored operator, as defined above, may be referred to as the "first assistant" within the context of the operative or procedure note. However, simply designating an individual as the "first assistant" within the operative or procedure note does not necessarily indicate that the trainee was primary operator; the individual must have fulfilled the criteria delineated above to qualify as primary operator.

Clinical skills requirements (Table III). The clinical component required for competency assumes that the physician is a clinician who is able to assess and manage the patient before, during, and after the intervention, as well as in follow-up. Specific clinical management skills include the ability to weigh risks and benefits, to inform patients and families of their therapeutic options, and properly care for patients during and after the procedure. The physician must be capable of writing orders, managing inpatients and treating complications that might be encountered. Given the frequent cardiac arrhythmias and hemodynamic instability manifested during and after carotid stent placement, the physician caring for these patients should be certified in advanced cardiac life support, should monitor hemodynamics and cardiac rhythm throughout the procedure, and should be familiar with use of adrenergic, anticholinergic, and vasopressor agents. Finally, it is desirable that the physician placing the carotid stent be involved in the longitudinal follow-up of the patients in order to provide continuity of care, risk factor modification, and surveillance for restenosis or other vascular problems.

Trainees in ACGME-approved programs, in order to establish competency, shall require the same minimum experience as those in the practice pathway. If a recent graduate from a training program has attained partial fulfillment of the minimum requirements, additional postgraduate experience will be necessary. However, the procedure volume and experience obtained during formal training may be applied toward completion of the necessary overall requirements.

Assessment of the trainee's acquired clinical skills should occur in the context of technical training, with confirmation of adequate expertise by the physician proctoring the majority of the procedures.

Industry-Sponsored Device Certification

In addition to the training standards delineated above, successful completion of an industry-sponsored certification course may also be required to ensure familiarization with specific equipment as approved by the Food and Drug Administration. Industry-sponsored programs should assist the individual physician in completion of the requirements suggested above to achieve competency, not supplanting

them. For example, diagnostic and interventional cases performed by an individual during an industry-sponsored program can be counted toward the total number of procedures required to achieve competency. However, completion of an industry-sponsored certification course does not in and of itself confer adequate qualifications for performance of carotid angiography or stent placement as a primary operator. The industry-sponsored training should, at a minimum, include didactic cognitive training, metric-based simulator training to proficiency, and proctoring.

Use of Simulation in Carotid Training

In an effort to assist physicians with differing backgrounds and skills to reach a common benchmark of proficiency, metric-based simulation should be incorporated into training. This will provide skills acquisition in an objective manner, based on real-world situational experience, while removing specialty-based biases from the training process. Prior studies have demonstrated that using this training modality for surgical procedures has been beneficial.⁷

Tracking of Individual Physician Results

During and after training, carotid interventional procedures should be performed with documentation of outcomes, including immediate results, complications, and follow-up. In view of the steep learning curve, careful examination of the results of both individual operators and institutions is crucial, particularly in the immediate post-training period. It is recommended that hospitals administer a quality assurance program that requires independent assessment of carotid stent outcomes by a neurologist or other qualified and National Institutes of Health (NIH) Stroke Scale-certified individual and that provides a systematic review of results from individual operators at standard intervals, i.e., after the initial 20, 50, and 100 cases. Reevaluation on a regular long-term basis, with multidisciplinary peer review, is also important in order to ensure good case selection, technique, and outcomes. We support the creation of a mandatory national multispecialty registry database for reporting of outcomes and assessment of ongoing institutional and individual operator competence.

FACILITIES, EQUIPMENT, AND ALLIED PERSONNEL

Carotid intervention should be performed in facilities that have the necessary imaging equipment, device inventory, staffing, and infrastructure to support a dedicated carotid stent program. Specific minimum requirements are as follows:

First, high-quality X-ray imaging equipment is a critical component of any carotid interventional suite. High-resolution digital imaging systems with the capability of subtraction, magnification, road mapping, and orthogonal angulation are necessary. Image storage, retrieval, and archiving capability are required. Carotid intervention has been performed effectively with image intensifiers of a variety of field sizes, ranging from 9" to 16", and with both

fixed and advanced mobile units. The quality of the image is more important than size of the field.

Second, advanced physiologic monitoring must be available in the interventional suite. This includes real-time and archived physiologic, hemodynamic, and cardiac rhythm monitoring equipment, as well as support staff who are capable of interpreting the findings and responding appropriately. The ability to measure activated clotting time on-site is highly desirable.

Third, a large and diverse inventory of disposable supplies is critical to a successful carotid stent program. This includes, but is not limited to, items such as guidewires (0.035", 0.018", and 0.014"); balloon dilation catheters (coronary and noncoronary balloons in diameters ranging from 2 to 14 mm; balloon lengths from 10 to 40 mm with sufficient useable catheter length); self-expanding (4-10 mm diameter, 20-60 mm length) and balloon-expandable (2-12 mm diameter) stents with sufficient useable catheter length; coronary guide catheters (6-9 Fr) and long arterial sheaths ranging from 6 to 8 Fr in size and at least 85 cm in length; temporary pacemakers; and emboli protection devices. Covered stents, coils, snares, and vascular access closure devices should also be available.

Fourth, emergency management equipment and systems must be readily available in the interventional suite. Specifically, these include resuscitation equipment, a defibrillator, vasoactive and antiarrhythmic drugs, endotracheal intubation capability, and anesthesia support. The procedure staff should be familiar with rapid response to hemodynamic and rhythm instability. Skilled allied health professionals in the laboratory (nurses and technicians) must be trained and experienced in evaluating patients before and after catheter-based interventional procedures. Training in the recognition and management of acute neurological syndromes is required.

Each institution should have a clearly delineated program for granting carotid stent privileges and for monitoring the quality of the individual interventionalists and the program as a whole. The oversight committee for this program should be empowered to identify the minimum case volume for an operator to maintain privileges, as well as the (risk-adjusted) threshold for complications that the institution will allow before suspending privileges or instituting measures for remediation.

OUTCOMES MEASUREMENT AND QUALITY ASSURANCE

Monitoring of outcomes with independent postprocedural neurological assessment using standardized instruments and definitions is critically important to ensure high-quality intervention and patient safety. Institutions offering carotid stent placement must have a quality assurance program specifically designed to assess the results of carotid interventions in their locale. The integrity and accuracy of outcome reporting is reliant on the incorporation of mandatory independent and objective neurologic assessment by a qualified and NIH Stroke Scale-certified individual for all patients undergoing carotid stenting.

Procedure results for each physician performing carotid interventions, as well as the overall institutional experience with carotid interventions, should be monitored and periodically reviewed by a standing multidisciplinary quality assurance committee. Cumulative and current results from individual physicians should be compared to national benchmarks, with careful attention to statistical power and appropriate risk adjustment for case mix. If an individual operator's performance does not meet established standards for procedure volume or outcomes (e.g., appropriate case selection, success, and complication rates), then a probationary period of close surveillance or retraining is indicated. Continued failure to meet established performance standards should warrant termination of privileges for carotid intervention. For physicians deemed by the institutional credentialing committee to have a volume of carotid procedures that is insufficient to remain an independent operator, an ongoing mentoring relationship with a highly experienced operator is suggested as a means of ensuring high-quality outcomes at the institution. Such a relationship enables patients to benefit from the skills and knowledge of the more experienced operator while facilitating training of the low-volume individual.

Quality assurance requires ongoing oversight of case selection as well as outcome. Case selection should be consistent with the most current approved indications or guidelines for carotid stenting. Carotid stent placement should only be offered in institutions that can offer independent neurological assessment and have a standing quality assurance committee that can directly oversee the individual and institutional results of the carotid stent program, ensure that optimal outcomes are being achieved and reported, and confirm that patient safety is being protected.

Institutional participation in a nationally recognized outcomes database, with mandatory submission of individual operator and institutional outcomes data, is desirable. Each institution offering a carotid stent program should be willing to provide adequate resources to collect, review, and submit data to a national carotid registry. The institution should furthermore be willing to allow independent audits to ensure accurate data entry and submission.

MAINTENANCE OF COMPETENCY

Maintenance of proficiency in carotid stenting techniques requires a major commitment to continuing education and improving technical expertise. Since carotid stent placement is a subset of a broader interventional practice, it is important the individual operators meet existing guidelines for maintaining proficiency in their overall practice of peripheral and/or coronary interventions. This includes satisfying both volume and/or performance benchmarks for maintenance of competency in their non-carotid interventional work.

Continuing education in carotid stent techniques is essential and should be documented. Demonstration courses and other interventional seminars are effective methods to stay abreast of evolving indications and changing technology for carotid stenting and distal protection

devices. Participation in formal continuing medical education courses for carotid stenting is recommended. In addition, attendance and participation in regularly scheduled multidisciplinary case review conference is required. This can be done within the context of a preexisting interventional conference structure; however, a dedicated conference for carotid intervention is recommended.

SUMMARY

Carotid artery revascularization using stent placement with embolic protection requires capable operators, well prepared facilities, and appropriate patient selection. The recommendations in this document are intended to assist in the safe and appropriate dissemination of this new technique. Careful systematic evaluation of patient and procedure outcomes, locally and nationally, will ensure adherence to national benchmark standards and competency levels.

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APPENDIX

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