Core Curriculum

SCAI/SVM Expert Consensus Statement on Carotid Stenting: Training and Credentialing for Carotid Stenting


Carotid artery stenting (CAS) has become an integral part of the therapeutic armamentarium offered by cardiovascular medicine programs for the prevention of stroke. The purpose of this expert consensus statement is to provide physician training and credentialing guidance to facilitate the safe and effective incorporation of CAS into clinical practice within these programs. Since publication of the 2005 Clinical Competence Statement on Carotid Stenting, there has been substantial device innovation, publication of numerous clinical trials and observational studies, accumulation of extensive real-world clinical experience and widespread participation in robust national quality improvement initiatives [5]. Collectively, these advances have led to substantial evolution in the selection of appropriate patients, as well as in the cognitive, technical and clinical skills required to perform safe and effective CAS. Herein, we summarize published guidelines, describe training pathways, outline elements of competency, offer strategies for tracking outcomes, specify facility, equipment and personnel requirements, and propose criteria for maintenance of CAS competency.

Key words: carotid stenosis; carotid stent; expert consensus document; stroke

INTRODUCTION

The comprehensive management of atherosclerotic vascular disease has become standard practice in contemporary cardiovascular medicine and interventional cardiology fellowship training programs. While vascular surgeons have augmented their surgical skills with catheter-based endovascular therapies, interventional cardiologists have applied their catheter skills to non-coronary arterial beds, including the extracranial carotid arteries. This development has resulted in a convergence of specialties in certain vascular territories in which requisite skill sets are not uniquely defined.

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by specialty training. Moreover, interventional cardiologists have partnered with vascular medicine specialists, neurologists, surgeons, and radiologists in the execution of clinical trials that have defined the role of carotid artery stenting (CAS), and carotid endarterectomy (CEA), in the treatment of carotid artery stenosis. Accordingly, CAS has now become an integral part of the therapeutic armamentarium offered by clinical programs across this array of specialties.

Although there is clinical equipoise between CAS and CEA [1,2] the role of contemporary medical therapy alone and in combination with carotid revascularization for the prevention of stroke is under active investigation, particularly with asymptomatic patients. However, the Centers for Medicare and Medicaid Services (CMS) has not revised the current National Coverage Determination (NCD) to state that CAS is reasonable and medically necessary for the entire population of patients for whom it has been approved by the Food & Drug Administration (FDA) as safe and effective. Therefore, the NCD will continue to limit CAS access for many who would potentially benefit. This limitation will not only force patients and physicians into higher-risk surgical situations, but will also have a negative impact on CAS operator volume and ultimately on clinical outcomes.

The purpose of this expert consensus statement is to provide guidance on physician training and credentialing to facilitate the safe and effective incorporation of CAS into clinical practice. Prior to undertaking focused training in the performance of cerebral angiography and CAS, physicians must first meet all recommendations outlined in the ACC/ACP/SCAI/SVMB/VSVM Clinical Competence Statement on Vascular Medicine and Catheter-based Peripheral Vascular Interventions [3]. The present statement is meant to serve as an extension to that competency document with respect to the performance of cerebral angiography and CAS.

RATIONALE FOR UPDATING A TRAINING AND CREDENTIALING STATEMENT ON CAS

CAS with embolic protection was an emerging technology when the 2005 Clinical Competence Statement on Carotid Stenting was published [4]. Since that time, there has been substantial device innovation, the publication of numerous clinical trials, and observational studies, the accumulation of extensive real-world clinical experience and widespread participation in robust national quality improvement initiatives [5]. Collectively, these advances have led to substantial progress in appropriate patient selection, as well as in the cognitive, technical and clinical skills required to perform safe and effective CAS. Notable examples include the characterization of the relationship between operator volume and outcome [6–8], development of CAS risk prediction models [9,10], and risk scores [11], the introduction of novel embolic protection devices (EPDs) [12], the use of transradial [13–15], and transcervical [16] arterial access, a demonstration of CAS benefit among high- and standard-surgical risk patients [2] and the establishment of programmatic accreditation standards. While numerous professional societies support the goals of establishing CAS training guidelines, the content of each document should be left to the discretion of the endorsing societies. Accordingly, this expert consensus statement aims to update the requirements for achieving competence in CAS for interventional cardiologists.

CAS GUIDELINES

Over the last decade, multiple professional societies alone or in collaboration have published guidelines and expert consensus statements on the evaluation and management of patients with carotid artery stenosis and more specifically on carotid artery revascularization. The first multispecialty consensus document was published in 2007 as a Clinical Expert Consensus Document on CAS from the American College of Cardiology (ACC), the Society for Cardiovascular Angiography and Interventions (SCAI), the Society for Vascular Medicine (SVM), the Society for Interventional Radiology (SIR), and the American Society of Interventional and Therapeutic Neuroradiology (ASITN) [17]. Professional CAS guidelines were published by the Society for Vascular Surgery (SVS) in 2008 and 2011 [18,19]; by the European Society for Vascular Surgery (ESVS) in 2009 [20] by an intercollegiate committee of the Royal Australasian College of Physicians (RACP), the Royal Australasian College of Surgeons (RACS), and the Royal Australasian and New Zealand College of Radiologists (RANZCR) in 2010 and 2011 [21,22] by the United Kingdom National Institute for Health and Clinical Excellence (NICE) in 2006 and 2011 [23,24] by the European Society of Cardiology (ESC) in 2011 [25] and by a collaborative group representing the ACC, American Heart Association (AHA), American Stroke Association (ASA), American Association of Neuroscience Nurses (AANN), American Association of Neurological Surgeons (AANS), American College of Radiology (ACR), American Society of Neuroradiology (ASNR), Congress of Neurological Surgeons (CND), Society of Atherosclerosis Imaging and Prevention (SAIP), SCAI, SIR, Society of NeuroInterventional Surgery (SNIS), SVM, and SVS in 2011 [26].

These documents, based on expert consensus, share the broad goal of providing comprehensive and timely Catheterization and Cardiovascular Interventions DOI 10.1002/ccd. Published on behalf of The Society for Cardiovascular Angiography and Interventions (SCAI).
evidence-based guidance for patient evaluation and treatment, but differ with regard to the methodology employed, the assessment of the weight of available evidence and the scope and strength of their recommendations (Tables I and II). Most CAS documents rely on one of four methodologies to grade the quality of evidence and provide recommendations, including the ACC/AHA classification (Supporting Information Table I) [27]; the Grades of Recommendation, Assessment, Development, and Evaluation system (GRADE) (Supporting Information Table II) [28]; the Australian National Health and Medical Research Council (NHMRC) system (Supporting Information Table III) [29]; and the Agency for Healthcare Research and Quality (AHRQ) system (Supporting Information Table IV) [20]. The tables presented herein are designed to provide an overview of the various guidelines. It should come as no surprise that consensus opinions across 14 different societies, in part representing the professional interests of each individual specialty, may differ from the consensus opinion among members of any individual professional society. It is also noteworthy that these documents vary in whether recommendations are provided for symptomatic and asymptomatic patients, as well as whether they are offered for standard surgical-risk versus high surgical-risk patients. Some offer specific recommendations for certain patient subsets.

In addition to practice guidelines, several professional societies have developed guidelines for CAS training and credentialing [4,20,30,31]. The first set of training guidelines was published in 2003 as a collaborative document among several radiological societies, including ASITN, ASNR, and SIR [30]; this document was revised in 2005 in a joint statement from six radiological societies, including AAN, AANS, ASITN, ASNR, CNS, and SIR [31]. Several cardiovascular medicine, vascular medicine, and vascular surgery societies, including SCAI, SVM, and SVS also developed a multidisciplinary consensus document on CAS training and credentialing, which was published in 2005 [4]. Finally, the 2009 ESVS guidelines on carotid disease included a section on carotid training [20]. These training documents share a common goal of improving CAS outcomes by recommending specific criteria for cognitive, technical and clinical training. The specific content of these recommendations varies based on the professional society that issued the document. It is generally accepted that recommendations for training and

### TABLE I. CAS Guidelines Documents

<table>
<thead>
<tr>
<th>Society</th>
<th>Years</th>
<th>Methodology</th>
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<tbody>
<tr>
<td>SVS [18,19]</td>
<td>2008, 2011</td>
<td>GRADE</td>
</tr>
<tr>
<td>ESVS [20]</td>
<td>2009</td>
<td>AHRQ</td>
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<tr>
<td>RACP RACS RANZCR [21,22]</td>
<td>2010, 2011</td>
<td>NHMRC</td>
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<tr>
<td>ESC [25]</td>
<td>2011</td>
<td>ACCF/AHA</td>
</tr>
<tr>
<td>ASA ACCF AHA AAN</td>
<td>2011</td>
<td>ACCF/AHA</td>
</tr>
<tr>
<td>AANS ACR ASNR CNS</td>
<td>2011</td>
<td>ACCF/AHA</td>
</tr>
<tr>
<td>SAIP SCAI SIR SVM SVS [26]</td>
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### TABLE II. Summary of Recommendations for Performance of CAS Based on 2011 Societal Guidelines

<table>
<thead>
<tr>
<th>Class</th>
<th>Level</th>
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<th>Class</th>
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<tbody>
<tr>
<td>Symptomatic</td>
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<td></td>
</tr>
<tr>
<td>Standard risk</td>
<td>I</td>
<td>B</td>
<td>HS</td>
<td>NA</td>
<td>IIb</td>
<td>B</td>
<td>HS</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>High risk</td>
<td>IIa or b*</td>
<td>B</td>
<td>2</td>
<td>B or C*</td>
<td>IIa</td>
<td>B</td>
<td>C</td>
<td>NA</td>
<td>NA</td>
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<tr>
<td>Asymptomatic</td>
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<tr>
<td>Standard risk</td>
<td>IIb</td>
<td>B</td>
<td>2</td>
<td>B</td>
<td>IIb</td>
<td>B</td>
<td>NR</td>
<td>NA</td>
<td>CT</td>
</tr>
<tr>
<td>High risk</td>
<td>NA</td>
<td>NA</td>
<td>CT</td>
<td>NA</td>
<td>IIb</td>
<td>B</td>
<td>NR</td>
<td>NA</td>
<td>CT</td>
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</tbody>
</table>

CAS = carotid artery stenting, ACCF/AHA = American College of Cardiology Foundation/American Heart Association, SVS = Society for Vascular Surgery, ESC = European Society of Cardiology, NICE = National Institute for Health and Clinical Excellence, HS = highly selected patients (see reference), NA = not available, NR = not recommended, CT = acceptable in the framework of a clinical trial. Note that the class of recommendation depends on the definition utilized by the particular society.

*IIA or B for high-risk patients based on anatomical features; IIb or C for high-risk patients based on clinical features.

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Credentialing should apply to practitioners represented by their own professional societies, thus criteria developed by the radiological societies would reasonably apply to radiologists, rather than to cardiovascular medicine specialists or vascular surgeons. Likewise, training criteria for interventional cardiologists should not necessarily apply to neuroradiologists. Nevertheless, it is also recognized that credentialing processes in most instances are institution-wide rather than specialty-specific, which presents some challenges given the potential for variations across specialty-oriented guidance documents. It is the opinion of this Writing Committee that minimum volume standards put forth in this document should apply to all CAS operators, regardless of specialty.

<table>
<thead>
<tr>
<th>TABLE III. Operator Requirements for Participation in Randomized Trials</th>
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<tbody>
<tr>
<td>Study name</td>
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<tr>
<td>------------</td>
</tr>
<tr>
<td>CREST [1]</td>
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<tr>
<td></td>
</tr>
<tr>
<td>SAPPHIRE [2,48]</td>
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<tr>
<td></td>
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<tr>
<td>EVA-3S [33]</td>
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<td></td>
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<tr>
<td>SPACE [34]</td>
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<td></td>
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<tr>
<td>ICSS [35]</td>
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MACCE Major Adverse Cardiac and Cerebrovascular Events, CAS carotid artery stenting, CEA carotid endarterectomy, ICSS (International Carotid Stenting Study), EVA-3S = endarterectomy versus angioplasty in patients with symptomatic severe carotid stenosis; SPACE = stent-supported percutaneous angioplasty of the carotid artery versus endarterectomy; SAPPHIRE = stenting and angioplasty with protection in patients at high risk for endarterectomy; CREST = carotid revascularization endarterectomy versus stenting trial.

aThose with more experience (>30 cases) performed 5–10 procedures in the lead-in phase, and those with less experience (<30 cases) performed 10–20 procedures in the lead-in phase. Operators were selected by the Interventional Management Committee to participate in the randomized portion of the trial based upon experience, training and lead-in results.

In addition, there are two organizations that offer independent accreditation of institutions and physicians for CAS. The Accreditation for Cardiovascular Excellence (ACE, which is sponsored by the ACC and SCAI; http://www.cvexcel.org) and the Intersocietal Accreditation Commission (IAC; http://www.intersocietal.org/carotid) offer paid services leading to accreditation in CAS, which include comprehensive evaluations of staff and physician personnel, facilities, operating procedures, quality assurance processes, outcomes and follow-up. All collected data are benchmarked against national standards and best practices. ACE routinely performs site visits, whereas IAC uses site visits on a selective basis. Detailed information on the application process, levels of accreditation and fees are available on their respective websites.

<table>
<thead>
<tr>
<th>TABLE IV. Requirements for Operator Participation in CREST-2</th>
</tr>
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<tbody>
<tr>
<td>Past year</td>
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<tr>
<td>≥25</td>
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<tr>
<td>15–24</td>
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<td>&lt;15</td>
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<td>&lt;15</td>
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<td>&lt;10</td>
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</tbody>
</table>

Challenges for CAS Training

Despite FDA approval of CAS for patients with symptomatic and asymptomatic extracranial carotid artery disease, the number of CAS procedures has declined...
significantly in recent years [32]. This decline is due to a perception that patients with asymptomatic carotid disease should be managed medically [33–35] and to constraints of the CMS NCD, as well as to uncertainties about CAS reimbursement. The decline in CAS volume and the complexity of decision-making creates challenges in training and in maintaining competent CAS operators.

Training of Interventionalists in Clinical Trials to Date

By contemporary standards, operator experience for participation in some early CAS trials was inadequate [33–35]. Operator requirements for U.S. randomized controlled trials were much higher than for European trials, resulting in superior CAS outcomes (Table III). CREST lead-in data demonstrated superior outcomes for operators from catheter-based specialties such as interventional radiology and interventional cardiology compared with vascular surgery [36], but following conclusion of the training phase and accumulation of greater CAS experience, the quality gap between specialties narrowed [37]. Recent analyses have demonstrated a marked improvement in CAS outcomes over the past decade, due to increasing access to and experience with CAS [1,38]. Recognizing the importance of CAS experience, the NIH-sponsored CREST-2 trial has set the bar for operator experience higher than any prior trial. Patients with asymptomatic carotid stenosis will be randomized to optimal medical therapy alone versus optimal medical therapy plus optimal CAS or CEA. CAS operators must document a minimum of 100 CAS cases as primary operator, including 25 within the prior year (Table IV). In an era of declining CAS volumes, it remains to be seen whether there are enough sites with adequate experience to meet enrollment targets, or whether greater experience will need to be garnered.

The excellent results observed in some CAS trials indicate that physicians who possess the requisite peripheral vascular interventional skills can safely perform cerebral angiography and CAS [1]. There are no data from CAS trials to support a requirement for a large number of diagnostic cervicocerebral angiograms prior to performing CAS, especially since most diagnostic imaging studies rely on computed tomography angiography and magnetic resonance angiography. In contrast, there is an increasing body of evidence suggesting an extended learning curve for CAS, where more experienced operators have superior results than less experienced operators [6].

Training Pathways

CAS training has been incorporated into the curricula of many interventional cardiology training programs, but declining CAS volumes have begun to limit trainee exposure. Physician training typically follows one of two pathways. The first pathway is a traditional Accreditation Council for Graduate Medical Education (ACGME)-certified residency or fellowship program (e.g., interventional cardiology, interventional radiology or neuroradiology, interventional neurosurgery, or vascular surgery) that offers a specific curriculum in CAS, in conjunction with peripheral interventional training. The second pathway applies to practicing physicians who have completed their formal training and are acquiring CAS training once in clinical practice. Given the declining CAS volume in general, many physicians may require both pathways. Although the settings for these two pathways differ, the skills necessary to achieve competency are identical. Upon completion of their training, physicians must master all cognitive, technical and clinical skills for CAS regardless of specialty. Fellowship program directors and/or additional mentor(s) must attest to the level of training and provide written confirmation of the competency of the individual applicant.

Preparation for CAS Training

Prior to CAS training, cardiovascular physicians must already have an extensive foundation of medical knowledge, technical skill, and clinical competency in vascular anatomy, biology, and the pathophysiology of atherosclerotic and nonatherosclerotic arterial diseases (e.g., fibromuscular dysplasia, spontaneous dissection), risk factors for atherosclerosis and their modification, acute, and chronic arterial diseases (including vasculitis, atheroembolism, and connective tissue diseases), thrombosis and thrombophilia; vascular access site selection and technique, management of vascular complications (including hemorrhage, perforation, dissection, occlusion); fundamentals of radiation exposure; conscious sedation; indications and contraindications for invasive and noninvasive vascular imaging; and complications of exposure to radiographic contrast (including anaphylactoid, other allergic reactions, and prevention and management of contrast nephropathy). In addition, physicians must have a high level of baseline technical proficiency in catheter-based skills for invasive diagnostic angiography (including the use of digital subtraction angiography, guidewire and catheter selection and manipulation, image acquisition, processing, and interpretation), and extensive prior experience in endovascular intervention in the coronary and/or peripheral arterial circulation (including the management of acute vascular injuries with stents, covered stents, coils). However, these skills alone are not sufficient to obtain CAS privileges, and must be supplemented by

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TABLE V. Essential Requirements for Training and Credentialing in CAS

Cognitive requirements:
- Normal cerebrovascular anatomy, physiology, and hemodynamics.
- Pathophysiology of atherosclerotic and nonatherosclerotic cerebrovascular disease.
- Natural history of cerebrovascular disease.
- Clinical manifestations of stroke and cerebral ischemia.
- Results of randomized controlled trials of medical and lifestyle therapies that have been proven to reduce the risk of ischemic stroke.
- Results of major trials comparing carotid revascularization plus medical therapy with medical therapy alone.
- Results of major trials comparing endovascular and open surgical carotid revascularization modalities.
- Pharmacology of adjunctive antiplatelet and anticoagulant agents and radiographic contrast media.
- Radiation safety.

Clinical requirements:
- Perform thorough neurological history and physical examination.
- Order and interpret noninvasive and invasive cerebrovascular imaging.
- Appropriate case selection based on assessment of procedural risks and benefits and employment of risk scores where appropriate.
- Provide informed consent.
- Education of catheterization lab operator trainees and non-physician staff.
- Routine preprocedural, intraprocedural, and postprocedural patient care.
- Recognition and management of clinical and angiographic (neurological, cardiovascular, vascular) complications.
- Education of nursing and technical staff on the aftercare of patients who are post carotid stenting.
- Coordination of long-term follow-up.

Technical requirements:
- Documented proficiency in vascular (ideally, transradial, and transfemoral) access and noncarotid vascular angiography and intervention.
- Experience in the performance and interpretation of diagnostic cervicocerebral angiography.
- Catheter selection and usage for more difficult vascular anatomy (e.g., type III arch, bovine left common carotid artery origin).
- Supervised experience as primary operator in carotid stent procedures.
- Expertise in the use of both proximal and distal embolic protection devices.
- Familiarity with the use of both guide catheters and sheaths for performance of carotid stenting.
- Performance of intracranial rescue or timely access to nearby operators/institutions who possess that skill set in the event that it is needed.

Additional cognitive, technical and clinical expertise in diseases of the cerebrovascular circulation.

Elements of Competency

Competency for CAS can be acquired when physicians have mastered the requisite cognitive, technical and clinical skills. Physicians performing carotid intervention must expand their foundation of medical knowledge, technical skill and clinical competence to include diseases of the cerebrovascular circulation (Table V). Since the management of carotid artery disease continues to evolve rapidly, physicians are expected to maintain a commitment to lifelong learning, and to maintain their clinical and technical skills at the highest possible level.

Cognitive elements include knowledge of cerebrovascular disease, which broadly includes anatomy, pathophysiology, natural history, diagnosis, and treatment. Physicians performing CAS should be well-versed in the anatomy of the arterial circulation to the brain (including normal and abnormal anatomy and anomalies of the aortic arch, extracranial carotid and vertebral arteries, intracranial circulation, the Circle of Willis, and collateral circulation), the vascular distribution and territories of the brain supplied by the intracranial circulation and the distribution and components of the anterior and posterior cerebral circulation. They must have a thorough understanding of the pathophysiology of atherosclerotic and nonatherosclerotic diseases of the cerebrovascular circulation, and of the pathophysiology of stroke and transient ischemic attacks (TIA), including cardiac, extracardiac, extracranial, and intracranial causes. The physicians must understand the natural history of asymptomatic and symptomatic carotid artery diseases, the clinical and anatomic characteristics that place patients at high risk of stroke and at high risk of adverse events during revascularization, and the relative risks and benefits of medical therapy, CAS and CEA in the individual patient. Expertise in the pharmacologic management of risk factor modification, risk reduction, and stroke prevention (before and after carotid revascularization) is essential. Physicians must be completely familiar with (or know when to consult neurological specialists on) ischemic syndromes involving the anterior and posterior cerebral circulation, including symptoms, clinical manifestations, neurological examination, differential diagnosis and treatment. Competency in the interpretation of carotid duplex ultrasound, computed tomography angiography and magnetic resonance angiography is essential for every physician who performs CAS. This familiarity must extend beyond the mere assessment of lesion severity and should incorporate the appreciation of plaque morphology and its impact on the risk of recurrent events or the risk of periprocedural stroke. It is important that the physician distinguish between atherosclerotic stenosis and lesions caused by other etiologies, such as fibromuscular dysplasia, carotid artery dissection or vasculitis. It is critical to recognize other cervical and intracranial arterial pathologies that may influence the treatment strategy, such as intracranial stenosis, arterial aneurysm or arterio-venous malformations. It is expected that physicians will have a thorough understanding of published data from randomized clinical trials and large registries that have enrolled
patients undergoing carotid revascularization to be able to advise patients appropriately. In addition, the nuances of imaging the postprocedure patient, which can be different from imaging de novo disease, should be understood.

In general, the technical requirements for CAS include the basic foundation of technical expertise in diagnostic angiography and endovascular intervention upon which technical expertise in diagnostic cerebral angiography and CAS are superimposed. All CAS operators should be able to perform and interpret 2- and 4-vessel cerebral angiography (selective bilateral carotid and vertebral artery angiography), and must become competent at nonselective and selective angiography, manual injection, and power-injector angiography, the selection of optimal injection parameters for different regions of the intra- and extracranial circulation and aortic arch, the selection of appropriate guidewires and catheters for angiography and the use of appropriate image projections to display all aspects of cerebrovascular anatomy. Although four-vessel cerebral angiography is not required for all patients, all CAS operators should be proficient in this technique and must be able to determine when four-vessel angiography is or is not appropriate. Previously published guidelines suggest that experienced interventionalists with proper credentials can achieve safe performance of carotid angiography and expertise in noncerebrovascular territories after completing 30 supervised angiograms (15 performed as the primary operator).

However, the technical requirements for CAS are more extensive than for diagnostic cerebral angiography, and includes the placement and use of all devices necessary for CAS; anticipation, prevention, recognition, and treatment of any and all complications, and a commitment to maintain expert skills. With regard to the necessary devices, operators must have experience with catheter exchanges over 0.035”–0.038” guidewires in the common carotid artery; placement of 6–9 Fr. × 80–100 cm sheaths or guiding catheters in the common carotid arteries (often with challenging arch and carotid anatomy); knowledge and experience with the use of a variety of proximal and distal EPDs (including the advantages and disadvantages of each, and selection of the proper device for a specific patient); facility with 0.014-in. guidewires; proper selection, delivery, and deployment of self-expanding stents (including appreciation of the advantages and disadvantages of open versus closed cell designs, as well as nitinol versus stainless steel material); and the proper selection and use of rapid-exchange monorail balloon systems for pre- and postdilation (including the number of inflations, inflation pressure, and sizing the diameter and length of the balloon).

The clinical skills for CAS require integration of the medical history, physical examination, and imaging studies as they pertain to each specific patient, with the goal of decision-making for medical therapy with or without carotid revascularization. Ultimately, the physician must demonstrate the ability to determine whether revascularization is required at all, before selecting which type of revascularization is optimal for an individual patient.

A key component in determining what type of revascularization procedure is appropriate requires comfort with the clinical assessment of the patient and recognition of anatomical and medical comorbidities that increase the risk of CEA. CAS operators must be able to identify clinical and anatomic characteristics that place patients at risk for complications of CAS and must be able to manage these complications as they arise. This assessment requires an understanding of the aortic arch, and cervical carotid and intracranial carotid artery anatomy, including but not limited to the constraints imposed on catheter manipulations and device positioning and deployment by anatomical variants, vessel tortuosity, calcification, and atherosclerotic disease. CAS-associated complications can be classified as acute neurological (acute stroke or TIA, hyperperfusion syndrome, intracranial hemorrhage), carotid artery (dissection, thrombosis, perforation, vasospasm, pseudolesions, stent migration, or malposition); noncarotid vascular (injury to the femoral, brachial, or radial arteries, including dissection, thrombosis, perforation, hemorrhage); and cardiovascular (vasovagal or vasodepressor reactions, manifested by hypotension and/or bradycardia). The physician should establish a collaborative relationship with personnel experienced with acute stroke triage, including stroke teams, neurology, and neuroradiology and be able to recognize when acute stroke intervention is required.

Finally, an important clinical skill involves providing the patient with a balanced and easily understandable discussion of the risks, benefits and alternatives of medical therapy, CEA and CAS. Many patients fear stroke more than death or myocardial infarction, thus it is important to stress that no therapy offers complete protection from stroke. Patients should understand that the overall risk of major complications is equivalent for CEA and CAS, and that validated risk scores can provide a more accurate estimate of global risk [11]. Finally, patient discussions may involve more than one encounter, to allow patients sufficient time to digest all the information and consider their decisions. Anatomic models and educational materials, such as patient pages in subspecialty journals [39], can be helpful and should be incorporated into the consultative process. Requests for second opinions should be welcomed.
Patient preference should be incorporated into the decision to revascularize as well as the decision as to which revascularization modality to employ, especially when there appears to be clinical equipoise between these strategies.

The primary CAS operator is defined as the individual who is advancing the guidewires; positioning, deploying, and retrieving the EPD, balloons, and stent; and directing patient care after the procedure. The exact number of primary operator CAS procedures required for an interventionalist to achieve acceptable success and minimal complication rates is not yet known. Prior training guidelines have recommended that physicians perform a minimum of 25 supervised CAS procedures, including 12–13 procedures as the primary operator [4]. Although volume is not always an accurate reflection of competency, more recent real world data suggest that optimal proficiency may require a greater number of procedures as the primary operator (see ‘Maintenance of Competency’) [6]. Trainees should be supervised by mentors who are scrubbed in alongside them during the procedure.

The clinical elements for CAS training include the ability to manage outpatient and inpatient care, which may overlap with some aspects of the cognitive skills. Physicians must understand the distinction between symptomatic and asymptomatic carotid disease; be able to determine whether the neurological symptoms are concordant with the anatomic findings; and be able to stratify the risk of stroke based on symptomatic status, stenosis severity, and other pertinent characteristics. The physician must be able to characterize patients as being at high- or standard-surgical risk for CEA, based on commonly accepted clinical and anatomic features.

In the outpatient setting, the physician must prescribe appropriate medications to modify atherosclerotic risk factors and reduce stroke risk; prescribe appropriate antiplatelet therapy in the context of other medical problems and other medications (such as oral anticoagulants for atrial fibrillation); order and interpret the results of noninvasive imaging; recommend invasive angiography when appropriate; and counsel patients and their families about the relative risks of medical therapy, CAS and CEA. In the inpatient setting, the physician must direct the care of the patient before, during and after intervention. Such care requires obtaining a formal independent neurological assessment (an assessment performed by someone other than the primary operator) before and after the procedure, ensuring appropriate medical therapy, including dual antiplatelet therapy, obtaining appropriate monitoring for neurological, hemodynamic, and cardiovascular complications, management of all complications that arise during or after the intervention; and arrangement of follow-up care.

**Industry-Sponsored Device Certification**

Beyond the training standards delineated above, successful completion of an industry-sponsored certification course might be prudent, to ensure familiarity with specific FDA-approved CAS equipment. Industry-sponsored programs should assist the individual physician operator in completing the requirements to achieve competency, and diagnostic and CAS procedures performed during an industry-sponsored program can count toward the total number of CAS procedures required for competency. Ideally, industry-sponsored training should include didactic training, simulator training, and case proctoring. However, completion of an industry-sponsored certification course alone does not confer adequate qualification for carotid angiography or CAS.

**Use of Simulations in CAS**

CAS is a procedure that requires special technical skills and clinical judgment, and there is a steep learning curve that impacts procedural outcomes. Even though there is a clear relationship between operator volume and CAS outcome, volume alone is a crude measure of proficiency. CAS simulators are useful for training and evaluation of performance in carotid angiography [40], have been shown to improve the performance of both novice [41] and experienced [42] interventionalists on procedure time, fluoroscopy time, device handling, and angiographic results [43,44]. Although simulator training should not be used as a substitute for live case performance, it is strongly recommended as an adjunct to CAS training.

**Tracking CAS Outcomes**

All CAS programs, based on physician and institutional outcomes, should maintain a clearly delineated process for initial credentialing and re-credentialing of operators for CAS privileges. Maintenance of CAS privileges should rely on CAS volume, outcomes, and other quality parameters (such as conference attendance and continuing medical education [CME] credits). Outcomes should include procedural success, in-hospital complications (death, stroke, myocardial infarction, vascular injury, blood transfusion, contrast nephropathy), and death and stroke at 30 days. Radiation exposure and EPD dwell times [45] should be monitored and recorded for each patient. It is strongly recommended that institutions participate in at least one national registry, such as the NCDR Peripheral Vascular Interventions (NCDR-
FACILITY, EQUIPMENT, AND ALLIED PERSONNEL

CAS should be performed in a hospital with appropriate resources to ensure safe and effective CAS, including various facility and personnel resources. These minimum requirements must be supplemented with detailed inventory, training, education, and policies to ensure safe conduct of the CAS program.

Facility and Equipment Requirements

1. Advanced X-ray imaging equipment with digital subtraction, road mapping, magnification online image quantitative angiography, and archiving. Image intensifier field size ≥12 in.
2. Advanced hemodynamic and electrocardiographic monitoring with appropriate staff to interpret and respond to results.
3. Point of care activated clotting time (ACT) monitoring.
4. Disposable inventory of appropriate sizes, including catheters, sheaths, wires, balloons, stents, EPDs, vascular closure devices, intracranial clot-retrieval devices, temporary pacemakers, and covered stents.
5. Emergency management equipment in the interventional suite, including a defibrillator, vasoactive, and antiarrhythmic drugs, endotracheal intubation equipment and personnel familiar with their use.
6. Documentation of routine maintenance and testing of laboratory equipment and a radiation safety program. Policies and procedures for monitoring the safety and performance of imaging and interventional equipment.
7. Independent accreditation with ACE or IAC is strongly encouraged.
8. A multidisciplinary Carotid Quality Assurance Committee comprised of CAS experts charged with all CAS-related activities, which should make recommendations to the hospital’s Credentialing Committee for granting and removal of CAS privileges.

Personnel Requirements

1. A Medical Director (licensed, board-certified physician) and a Technical Director (licensed technologist, or registered nurse with a minimum of 5 years of experience working in an invasive angiographic imaging laboratory) at each location in which CAS is performed within the institution (i.e., catheterization laboratory, radiology suite, and operating room).
2. Experienced nurses and technicians involved in the preoperative, intraoperative, and postoperative care of CAS patients.
3. Trained individuals who can confirm the indications for CAS and provide independent neurological evaluations before and after CAS.
4. Access to a dedicated Stroke Team for acute stroke intervention if needed.
5. Adequate resources to collect, review, and submit data to a national carotid registry.

OUTCOMES MEASUREMENT AND QUALITY ASSURANCE

Institutions must have a quality assurance program specifically designed to assess CAS outcomes. The accuracy of outcome reporting is dependent on the performance of independent neurologic assessments by a qualified NIH Stroke Scale-certified individual. This assessment is mandated for all patients before and after CAS. Outcomes should be monitored periodically by a formal Carotid Quality Assurance Committee. Benchmarks for 30-day periprocedural outcomes (such as those recommended by NCDR-PVI Registry) should be established and followed. The Carotid Quality Assurance Committee should also oversee appropriate case selection. Appropriate use criteria should be consistent with the most current guidelines for CAS [26].

The Carotid Quality Assurance Committee relies on several criteria to ensure quality, including CAS volume, appropriate use, and outcomes. Failure to meet established performance standards for appropriate use of CAS or for adverse outcomes should warrant reconsideration of CAS privileges. On the other hand, physicians with insufficient CAS volume should be considered for a mentoring relationship with a highly experienced operator as a means of ensuring high quality outcomes. 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.

Institutional participation is strongly recommended in a nationally recognized outcomes database such as NCDR-PVI Registry or SVS-VQI Registry. Mandatory submission of individual operator and institutional outcomes data >98% inhospital and >80% 30-day data are recommended to ensure a high quality program.
MAINTENANCE OF COMPETENCY

Maintenance of proficiency in CAS requires a commitment to continuing education and to improving technical expertise. It is important for CAS operators to meet existing guidelines for maintaining proficiency in their overall practice of peripheral and/or coronary interventions, including volume and performance benchmarks.

Site and operator experience are critical to maintaining good CAS outcomes. Registry data suggest that sites that have performed over 150 CAS procedures have fewer complications than those that have performed ≤50 [46]. A consistent operator volume–outcome relationship has also been demonstrated in multiple studies, including one postmarket, single-device study that suggested ~72 CAS procedures were necessary to achieve a 30-day stroke and death rate <3% [6] in the asymptomatic nonoctogenarian patient. Other studies have demonstrated that 30-day mortality is higher among very low (<6 per year) than high (≥24 per year) volume operators (adjusted odds ratio = 1.9; 95% CI (1.4–2.7), P < 0.001) [8], operator experience >100 CAS procedures is associated with fewer strokes at 30 days (odds ratio = 0.81; 95% CI (0.67–0.95), and operator volume <50 procedures is a significant predictor of 30-day stroke (P < 0.001) [47]. Pooled data from three randomized trials of patients with symptomatic carotid artery stenosis suggest that annual operator CAS volume may be even more important than lifetime CAS volume [7] and findings from a large postmarketing registry suggest that an increased time interval between consecutive CAS procedures is associated with a greater risk of death, MI, or stroke at 30 days [45].

It is difficult to define the experience necessary to maintain good outcomes, as this will vary based on lifetime experience, background specialty, catheter skills and familiarity with similar platforms (e.g., 0.014” wires and rapid exchange systems), etc. No such volume requirement for competency exists for CEA, although voluminous research over the past two decades confirms a volume–outcome relationship for these procedures as well. While there are ample data that a volume–outcome relationship exists for transradial/transfemoral CAS, there are no available data relating CAS volumes to achievement or maintenance of competency. This Writing Committee believes that in the current era of low CAS volumes, 25 lifetime transradial/transfemoral CAS procedures is a reasonable threshold for achieving, and 10–15 annual transradial/transfemoral CAS procedures for maintaining competency, so long as outcome benchmarks (30-day stroke and death rate of 3% for asymptomatic and 6% for symptomatic patients) are met or exceeded. Lower volume operators should consider ‘double-scrubbing’ and/or be proctored to help satisfy maintenance requirements, or refer to higher volume operators/centers. Lower volume operators might also benefit from simulation training to improve outcomes [40,43].

In addition to CAS volume, attendance at live demonstration courses and other CAS courses may be useful for maintaining clinical, cognitive and technical skills. Participation in institutional CME courses, multidisciplinary case reviews, and grand rounds presentations are encouraged to promote interdisciplinary collaboration.

SUMMARY

Carotid artery stenting with embolic protection requires capable operators, well-prepared facilities, and appropriately selected, well-informed patients. The recommendations herein are intended to assist in the safe, effective, and appropriate application of this established revascularization modality. Continued careful evaluation of relevant process and outcome metrics, both locally and nationally, will ensure maintenance of operator and facility competency and adherence to national quality benchmarks.

REFERENCES


Catheterization and Cardiovascular Interventions DOI 10.1002/ccd.
Published on behalf of The Society for Cardiovascular Angiography and Interventions (SCAI).


Online Supplemental Material

Supplemental Table 1. Definition of ACCF/AHA classification

<table>
<thead>
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<th>Class IIa</th>
<th>Class IIb</th>
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<td>Treatment should be performed</td>
<td>Treatment is reasonable</td>
<td>Treatment may be considered</td>
<td>Avoid treatment</td>
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**Level A**
- Several RCTs and large MA
  - Consistent benefit
  - Some conflicting evidence, but beneficial
  - Greater conflicting evidence, but may be beneficial
  - Consistent harm

**Level B**
- Single RCT or OS
  - Suggest benefit
  - Some conflicting evidence, but seems beneficial
  - Greater conflicting evidence, but may be beneficial
  - Suggest harm

**Level C**
- Case reports, expert opinion
  - Probable benefit
  - Possible benefit, Diverging opinion
  - Greater conflicting evidence, diverging opinion
  - Probable harm

Abbreviations: ACCF/AHA = American College of Cardiology Foundation/American Heart Association, RCTs = randomized clinical trials, MA = meta-analysis, OS = observational studies
Supplemental Table 2. Definition of GRADE classification(28)

Recommendations

1= Strong recommendation
2= Intermediate recommendation
3= Weak recommendation

Strength of Evidence

A= Strong evidence, based on RCTs
B= Consistent evidence, based on observational studies
C= Less consistent evidence, based on observational studies
D= Inconsistent evidence, expert opinion

Abbreviations: GRADE= Grades of Recommendation, Assessment, Development, and Evaluation system, RCT= randomized clinical trials
**Supplemental Table 3. Definition of NHMRC classification** (29)

Recommendation A

- Strong body of evidence suggests benefit
- Evidence from multiple RCTs

Recommendation B

- Good body of evidence suggests benefit
- Single RCT or large MA

Recommendation C

- Body of evidence reasonably suggest benefit
- Some inconsistency in published data

Recommendation D

- Weak body of evidence, inconsistent benefit
- Case reports, extrapolated evidence

Abbreviations: NHMRC= National Health and Medical Research Council (Australia), RCT= randomized clinical trial, MA= meta-analysis
**Supplemental Table 4. Definition of AHRQ classification** (20)

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<td>C</td>
<td>Based on expert consensus or opinion or case studies</td>
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Abbreviations: AHRQ = Agency for Healthcare Research and Quality, RCT = randomized clinical trial
## APPENDIX A. AUTHOR RELATIONSHIPS WITH INDUSTRY AND OTHER ENTITIES (RELEVANT)

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<tr>
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<th>Ownership/Partnership/Principal</th>
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<td>Herbert D. Aronow, MD, MPD</td>
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<td>Tyrone J. Collins, MD</td>
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<td>Michael R. Jaff, DO</td>
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<td>VIVA Physicians, a 501 c 3 not-for-profit education and research</td>
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<tr>
<th>Organization</th>
<th>Robert D. Safian, MD</th>
<th>Piotr S. Sobieszczyk, MD</th>
<th>Siddharth A. Wayangankar, MD, MPH</th>
<th>Christopher J. White, MD</th>
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