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Quality Improvement Guidelines for the Performance of Cervical Carotid Angioplasty and Stent Placement

Developed by a Collaborative Panel of the American Society of Interventional and Therapeutic Neuroradiology, the American Society of Neuroradiology, and the Society of Interventional Radiology

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Abbreviations: ACAS = Asymptomatic Carotid Atherosclerosis Study, ACR = American College of Radiology, AHA = American Heart Association, ASITN = American Society of Interventional and Therapeutic Neuroradiology, ASNR = American Society of Neuroradiology, CAS = carotid angioplasty and stent placement, CEA = carotid endarterectomy, CREST = Carotid Revascularization: Endarterectomy vs. Stent Trial, NASCET = North American Symptomatic Carotid Endarterectomy Trial, NIHSS = National Institutes of Health Stroke Scale, SIR = Society of Interventional Radiology

PREAMBLE

THE joint Standards of Practice Committee of the American Society of Interventional and Therapeutic Neuroradiology (ASITN), American Society of Neuroradiology (ASNR), and the Society of Interventional Radiology

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Dr. John F. Cardella is chair of the Society of Interventional Radiology Standards of Practice Committee. Dr. David Sacks is Councilor of the Society of Interventional Radiology Standards Division. Dr. Barr is Vice President of the ASITN and Dr. Connors is President of the ASITN; they authored the first draft of this document and served as topic leaders during the subsequent revisions of this draft.

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

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(SIR) is comprised of experts in a broad spectrum of interventional practice from both the private and academic sectors of medicine. Individual members of the Standards of Practice Committee dedicate the vast majority of professional time to diagnostic and interventional practice and the joint committee includes representatives from radiology, neurosurgery, interventional radiology and interventional neuroradiology, a diverse constituency expert on the subject matter under consideration.

Technical documents specifying the exact consensus and literature review methodologies as well as the institutional affiliations and professional credentials of the authors of this document are available on request from SIR, 10201 Lee Highway, Suite 500, Fairfax, VA 22030.

METHODOLOGY

ASITN, ASNR, and SIR Standards of Practice documents are produced using the following process. Standards

documents of relevance and timeliness are conceptualized by the Standards of Practice Committee members. A recognized expert is identified to serve as the principal author for the standard. Additional authors may be assigned depending on the magnitude of the project.

An in-depth literature search is performed with electronic medical literature data bases. Then a critical review and selection of peer-reviewed articles are performed based on study methodology, results, and conclusions. Data compiled from selected articles meeting evidence thresholds are used to develop content and to set standards.

When the evidence of literature is weak, conflicting, or contradictory, consensus for the parameter is reached by a minimum of 12 Standards of Practice Committee members with a Modified Delphi Consensus Method (1,2). For purposes of these documents, consensus is defined as 80% Delphi participant agreement on a value or parameter.

The draft document is critically reviewed by the Standards of Practice Committee members, either by telephone conference calling or face-to-face meeting. The finalized draft from the Committee is sent to the ASITN, ASNR, and SIR membership for further input/criticism during a 30-day comment period. These comments are discussed by the Standards of Practice Committee, and appropriate revisions made to create the finished standards document. Before its publication, the document was endorsed by the ASITN Executive Committee, ASNR Executive Committee, and the SIR Executive Council.

I. INTRODUCTION

This Quality Improvement Guideline for the Performance of Cervical Carotid Angioplasty and Stent Placement was developed by a writing group consisting of members from interventional neuroradiology, neurosurgery, neuroradiology, and interventional radiology. A thorough review of the literature was performed. Thresholds for quality assurance were difficult to set due to the relative paucity of data and lack of uniform reporting of clinical outcomes and complications. The ASITN, the ASNR, and the SIR recognize that brachiocephalic revascularization is undergoing rapid change in technology even as it is being increasingly adopted in clinical practice for the treatment of cerebrovascular pathologies (3). There is a critical need to encourage the development of procedures that may improve outcomes for patients with brachiocephalic and intracranial atherosclerotic stenoses. Furthermore, due to the implications concerning stroke prevention, the ASITN, ASNR, and SIR wish to encourage the careful and scientific study of the safety and efficacy of brachiocephalic revascularization as well as appropriate utilization of these techniques (3).

The published standard of practice for cervicocerebral angiography describes the minimum acceptable requirements for performance of the much less difficult and lower risk procedure of diagnostic cervicocerebral angiography (4); it is the purpose of this standard to describe the minimum prerequisite for the performance of the

far more difficult and higher risk procedure of carotid artery angioplasty and stent placement (CAS). Far more experience and training and fewer complications during diagnostic cerebral angiography are expected of those who perform neurovascular interventions, similar to what is expected of those who perform coronary interventions. At a minimum, performance of CAS requires extensive prior experience and demonstrated competence with diagnostic cervicocerebral angiography, as well as experience with angioplasty and stent placement. Such requirements for additional training and experience in performing CAS have been recognized by the Accreditation Council for Graduate Medical Education (ACGME) as part of the specialty training requirements for endovascular surgical neuroradiology (5).

Stroke is the third leading cause of death in the United States, and ischemic stroke accounts for more than 80% of the morbidity and mortality associated with stroke. Many ischemic strokes are related to large- and medium-vessel atherosclerotic disease within the cerebrovascular circulation. Therefore, procedures such as angioplasty and/or stent placement to reverse critical cerebrovascular stenoses may have great importance. CAS is being performed with rapidly increasing frequency in the United States. We anticipate that more data regarding outcomes and complications will be collected and published in the near future (the National Institutes of Health-supported Carotid Revascularization: Endarterectomy vs. Stent Trial [CREST] as well as other controlled series have begun) (6). Therefore, we recommend that this standard be reviewed and, if necessary, revised within the next 24 months to remain applicable to contemporary medicine concerning this rapidly progressing technique.

CAS is an innovative procedure. Until the true risks and appropriate indications for this procedure are clearly known, the ASITN, ASNR, and SIR recommend that for patients who have average surgical risk, such as those who would have qualified for enrollment in the North American Symptomatic Carotid Endarterectomy Trial (NASCET) and the Asymptomatic Carotid Atherosclerosis Study

(ACAS), CAS should only be performed as part of a randomized clinical trial or an institutional review board-approved investigational program. The inclusion and exclusion criteria for the NASCET and ACAS studies are summarized in **Table 1**. At this time, CAS has shown promise for the treatment of patients known to be at high risk of carotid endarterectomy (Yadav J, presented at the American Heart Association Scientific Sessions, Chicago, November 2002) (5). CAS should only be performed on appropriate patients by an individual or team with training and expertise in cerebrovascular angiography, pathophysiology, hemodynamics, and neurovascular interventions and/or carotid angioplasty/stent placement (7). This recommendation is further extended to encourage multidisciplinary input and concurring opinion in clinical decision making.

II. OVERVIEW

A. Rationale for Carotid Endarterectomy.—Two large randomized studies, NASCET and ACAS, have established that certain selected patients benefit from surgical treatment of significant atherosclerotic stenosis in the cervical carotid artery (8–10), whereas at least two other randomized studies of endarterectomy for asymptomatic carotid stenosis indicated no benefit from surgery (11,12). NASCET and ACAS showed that lowered stroke morbidity can be achieved in selected symptomatic and asymptomatic patients undergoing carotid endarterectomy (CEA) compared with aspirin therapy if surgical endarterectomy can be performed with an acceptably low complication rate. However, they did not evaluate the risk of endarterectomy versus “best” medical therapy that is now currently available. No trial has evaluated the natural history or risk of stroke from cervical carotid atherosclerotic stenosis treated with warfarin, combination warfarin and aspirin, aspirin and dipyridamole, ticlopidine, clopidogrel, or combinations of antiplatelet agents. More importantly, newer drugs such as statins and angiotensin-converting enzyme inhibitors have been proved to stabilize plaque and thus decrease

Table 1
Inclusion/Exclusion Criteria for Carotid Endarterectomy Trials

NASCET [9]

Inclusion

Symptoms of focal cerebral ischemia ipsilateral to a stenosis of <70% (moderate group) or ≥70% (severe group) within 180 days, as shown on angiography
Symptoms lasting <24 hours or producing nondisabling stroke (Rankin score <3)

Exclusion

Age >80 years (initial phase of moderate and severe stenosis; continuing study of moderate stenosis included these patients)
Lack of angiographic visualization of symptomatic artery
Lack of informed consent
Intracranial stenosis more severe than the cervical stenosis
Other disease limiting life expectancy to <5 years
Cerebral infarction limiting useful function in the affected arterial territory
Nonatherosclerotic carotid disease
Cardiac lesions likely to cause cardioembolism
History of ipsilateral carotid endarterectomy

ACAS [8]

Inclusion

Age 40–79 years
Compatible history and findings on physical and neurologic examination
Acceptable laboratory and electrocardiogram results
Arteriography within the previous 60 days indicating stenosis of at least 60% reduction in diameter (if arteriography performed 61–364 days before randomization, repeat Doppler showing artery still patent) or Doppler examination within 60 days showing a frequency or velocity greater than the instrument-specific cut point with 95% positive predictive value or Doppler examination showing a frequency or velocity greater than the instrument-specific 90% positive predictive value cut point confirmed by ocular pneumoplethysmographic examination within the previous 60 days

Exclusion

Cerebrovascular event in the distribution of the affected carotid artery or the vertebrobasilar system
Symptoms referable to the contralateral cerebral hemisphere within the previous 45 days
Contraindication to aspirin therapy
Any disorder that could seriously complicate surgery
Any condition that could prevent continuing participation or likely to produce death or disability within 5 years
Lack of informed consent

myocardial infarction risk as well as lower stroke risk (13,14).

The NASCET and ACAS studies must also be judged using the qualifications of the inclusion and exclusion criteria designed to select their study populations. These studies did not establish safety and efficacy for CEA versus aspirin therapy for the majority of patients with carotid artery stenosis screened at that time. For example, NASCET randomized only those patients with symptomatic events occurring within 120 days of surgery. Patients were excluded from this study if they had a coexistent tandem lesion that was more severe than the proximal internal carotid artery lesion, if they had particular renal, liver, or lung diseases, if they had coexistent cardiac disease that resulted in a valvular or rhythm disorder, or if they had undergone a previous ipsilateral CEA. Initially, patients were also not included in the study if they were 80 years of age or older. These factors resulted in NASCET actually enrolling fewer than

one-half of the potential patients, and a large portion of current candidates for CEA would be excluded from this trial. NASCET did demonstrate that surgery was beneficial for these carefully selected symptomatic patients with more than 70% carotid stenosis (with specific measurement criteria used) and some with more than 50% (9,15). In addition, ACAS exclusion criteria for asymptomatic patients were similar to those of NASCET, which resulted in actual randomization of fewer than 10% of all screened asymptomatic patients. However, in the United States, a large percentage of CEAs is performed on exactly these patients.

CEA has a durable result, with reported restenosis rates ranging from approximately 5% to 20%, and with late stroke rates reported as less than 5% in 5 years (16,17). However, current data indicate that CEA as it is currently practiced bears little resemblance to the populations studied, methods used, or results obtained in

NASCET and the ACAS studies (18–21). More recent evaluation of typical clinical practice indicates a significantly higher perioperative death rate for Medicare patients undergoing CEA at the same institutions participating in the NASCET and/or ACAS studies than for the original study patients (0.6% for NASCET patients, 0.1% for ACAS patients, but 1.4% for all Medicare patients) (20). The perioperative mortality rate for Medicare patients undergoing CEA at nonstudy sites was 1.7% for high-volume institutions, 1.9% for average-volume institutions, and 2.5% for low-volume institutions (as opposed to 0.6% for NASCET and 0.1% for ACAS) (20). Thus, the mortality rate was far higher at all institutions, including high-volume institutions and original trial sites, when unselected Medicare patients were considered. This may be partially explained by the fact that the patients participating in the NASCET and ACAS trials were younger and healthier than the typical Medicare pa-

tients now undergoing CEA at these same or other institutions. Older patients and those with significant comorbidity have repeatedly been shown to be at increased risk of perioperative stroke and death from CEA (20–36). Although recent surgical articles dispute the concept that there is a population of patients who have a significantly higher risk of complications after CEA (37,38), the recently completed Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy (SAPPHIRE) Trial (Yadav J, presented at the American Heart Association Scientific Sessions, Chicago, November 2002) indicates that these “high surgical risk” patients are indeed at higher risk of complications from CEA.

The role of endarterectomy in asymptomatic carotid stenosis is controversial (39–57). Only one randomized, controlled trial (ACAS) has shown surgery to be beneficial, whereas at least two have not (8,11,12). ACAS, however, did not find benefit for CEA versus medical therapy for major stroke, only minor stroke (8). Asymptomatic cervical carotid artery stenosis has been repeatedly shown to be of relatively low stroke risk until the remaining lumen approaches 1 mm in diameter (usually corresponding to stenosis of approximately 80%–90% by NASCET criteria) (8,45,49). Even then, the risk is less than even a moderate stenosis in a symptomatic patient (8,9,54). For asymptomatic patients with stenoses of less than 80%, the risk of ipsilateral stroke is approximately 1% per year or 5% in 5 years with treatment with only aspirin (49,55). Approximately 45% of strokes in patients with asymptomatic stenoses are not caused by the stenosis but rather arise from intracranial or cardiovascular sources, thus further reducing the actual risk of the lesion itself (57). Additionally, contrary to the clinical findings in ACAS, a recent review of the computed tomographic (CT) scans of ACAS patients revealed that carotid endarterectomy does not reduce the frequency of CT-identifiable ipsilateral cerebral infarction in patients with high-grade asymptomatic carotid artery stenosis (58). Based on the ACAS trial, the American Heart Association (AHA) considered CEA to be beneficial for treatment of asymptomatic, angiographically proven ca-

rotid stenosis of more than 60% if the combined perioperative stroke/mortality rate is less than 3% (59), which might only be achievable in otherwise healthy individuals. In contrast to the AHA guidelines for endarterectomy, the Canadian Stroke Consortium reached consensus that there was insufficient evidence to endorse CEA for any level of asymptomatic stenosis (60). Reasons cited were lack of proof of reduction of the risk of major disabling stroke, the question of reproducibility of surgical results in the general population, and the unproven long-term benefit of surgical reconstruction. Even a slight reduction in the intrinsic risk of asymptomatic carotid stenosis achieved by treatment with contemporary pharmaceuticals in addition to (or other than) aspirin, such as statins or angiotensin-converting enzyme inhibitors, might render CEA nonbeneficial in the majority of asymptomatic patients (13,14). Therefore, at best, CEA for asymptomatic patients is only indicated according to the AHA guidelines, and carotid stent placement for asymptomatic patients is rarely indicated outside of clinical trials (many of which are underway) until benefit is demonstrated.

B. Rationale for CAS.—CAS is undergoing rapid evolution. However, it must be remembered that the condition being treated is usually not emergent, and therefore transfer to a facility with the skills, training, and knowledge to perform this procedure with acceptable quality assurance is almost always possible. There are several preliminary single-center experiences that have been published as well as an international multicenter compilation (61–79). Four randomized, controlled trials for evaluation of this technology have been completed and reported.

- The Carotid and Vertebral Artery Transluminal Angioplasty Study (CAVATAS) was a large, prospective, randomized, multicenter trial comparing CEA with carotid artery angioplasty with selective stent placement in 504 patients with symptomatic stenoses (at least 30% luminal diameter reduction) who were suitable for surgery (80). This study did not use distal protection, and stent placement was performed in only 26% of cases.

There was no significant difference in the risk of stroke or death related to the procedure between CEA and CAS. The technical success rate for CAS was 89% (successful balloon inflation or stent placement; the percentage of residual stenosis was not reported). The rate of any stroke lasting longer than 7 days or death within 30 days of first treatment was approximately 10% in both the CEA and CAS groups. The rate of disabling stroke or death within 30 days of first treatment was 6% in both groups. Preliminary analysis of long-term survival showed no difference in the rate of ipsilateral stroke or any disabling stroke in patients up to 3 years after randomization. The rates of stroke or death within 30 days in CAVATAS in both groups are higher than many previous reports but not significantly different from the European Carotid Surgery Trialists (ECST) rate of 7% (53). The 1-year restenosis rate was 20% for CAS and 5% for CEA. Cranial nerve injury (9%) and myocardial ischemia (1%) occurred at the time of treatment in the CEA group only. Long-term follow-up is not yet available.

- The Wallstent Trial was an industry supported prospective, randomized trial comparing CEA and CAS for symptomatic stenosis of 60% or more (81,82). This was an early study, performed without distal protection and without the currently accepted antiplatelet therapy. In this study, 219 patients with symptomatic carotid stenosis of 60%–90% diameter were randomized to CEA or stent placement. The technical success rate for CAS was 97% (successful deployment with less than 30% residual stenosis). The risk of any perioperative stroke or death was 4.5% for CEA and 12.1% for CAS. At 1 year, the risk of a major stroke was 0.9% for CEA compared with 3.7% for CAS. This trial was stopped prematurely due to poor results from CAS.
- A single-center community hos-

Table 2
Inclusion/Exclusion Criteria for the SAPHIRE Trial of Carotid Stent Placement

Inclusion

Asymptomatic stenosis >80% or symptomatic stenosis >50% by angiography or ultrasonography and at least one of the following conditions that would result in high surgical risk:
 Age >80 years
 Congestive heart failure (class III/IV) and/or left ventricular ejection fraction <30%
 Open heart surgery needed within 6 weeks
 Recent myocardial infarction (>24 hours and <4 weeks)
 Unstable angina (CCS class III/IV)
 Severe chronic obstructive pulmonary disease
 Contralateral carotid occlusion
 Contralateral laryngeal nerve palsy
 Severe tandem lesions
 Lesions distal or proximal to the usual location
 Previous endarterectomy with restenosis
 Previous radiation therapy or radical neck surgery

Exclusion

Acute ischemic neurologic event within past 48 hours
 Total occlusion of the target carotid artery
 Surgical or interventional procedure planned within the next 30 days
 Common carotid ostial lesion

pital study (83) randomized 104 symptomatic patients to either CEA or CAS without distal protection. Perioperative stroke or death rate was 2% for CEA and 0% for CAS. Other complications for the CEA group totaled 16% and included hematoma (requiring treatment), cranial/cervical nerve injury, and hypotension (requiring treatment). Other complications for the CAS group totaled 45% and included transient cerebral ischemia, leg amputation, retroperitoneal hemorrhage, bradycardia (requiring temporary pacing), and hypotension (requiring treatment).

- The SAPHIRE trial randomized 307 patients to CEA or CAS with a distal protection device. Perioperative (30 days) results were presented (Yadav J, presented at the American Heart Association Scientific Sessions, Chicago, November 2002). The inclusion and exclusion criteria are listed in **Table 2**. Perioperative stroke and death rates were 7.3% for CEA and 4.4% for CAS. Total major adverse event rate (death, any stroke, or myocardial infarction) for CEA was 12.6% and for CAS was 5.8%. Rates of myocardial infarction were 7.3% for CEA and 2.6% for CAS. Of note,

the stroke or stroke/death rate for asymptomatic patients was 6.1% for CEA and 5.8% for CAS, both of which are worse than medical therapy alone in ACAS, and higher than the recommended AHA guidelines for treatment, albeit in a different patient population.

CAS may have a role in the management of some patients with significant stenoses of the extracranial cervical carotid artery. In addition, percutaneous endovascular therapy offers a less invasive method of repair with apparent reduction of nonneurologic morbidity. In the NASCET study, for example, reported complication rates were 7.6% for cranial nerve palsies, 5.5% for wound hematoma, 3.4% for wound infection, 0.9% for myocardial infarction, and 3.0% for other cardiac complications (9). These complications are virtually all related to the operative procedure, are not trivial, and are rarely associated with CAS.

No large (more than 100 patients) currently reported carotid stent study has achieved periprocedural (as long as 30 days after the procedure) morbidity and mortality rates as low as the natural history of medically treated uncomplicated asymptomatic carotid stenosis (80,84–88). In reported case series and registries of CAS, for exam-

ple, Roubin et al (84) reported an overall stroke rate of 5.9% and a mortality rate of 0.7%; Diethrich et al (86) reported a stroke rate of 10.9% and a mortality rate of 1.7%; Wholey et al (87,88) reported a stroke rate of 4.4% and a mortality rate of 1.4% in their initial report and 4.2% and 0.9%, respectively, in their follow-up report. These results compare favorably with the risk-to-benefit ratio of CEA for symptomatic cervical carotid stenosis but fall short of the intrinsically low risk of stroke for medically treated asymptomatic disease. However, Jordan et al (89), analyzing the same patients and data as did Roubin et al (84), reported a stroke rate of 12.7% and a mortality rate of 1.1% for CAS. In addition, the durability of stents, stent restenosis rates, and long-term rates of subsequent stroke have not been determined. For these reasons, angioplasty and stent placement for asymptomatic carotid artery stenosis should only be considered in special circumstances.

The National Institutes of Health has funded CREST to answer particular questions pertaining to the safety and efficacy of angioplasty and stent placement at the cervical carotid bifurcation and to clarify the specific indications for this procedure. This trial will compare CEA and CAS in patients with a symptomatic severe stenosis (70% or more by ultrasonography or 50% by NASCET angiographic criteria). It is important to note that because CREST has inclusion/exclusion criteria similar to those of NASCET, CREST is not designed to assess the safety and efficacy of stent placement in patients known to be at higher risk of CEA.

C. Cerebral Protection Devices.—CAS is undergoing rapid evolution. An area of intense investigation is the use of various protection devices and techniques to prevent what is perceived to be the most common and severe complication of the procedure: embolization of debris to the brain. This recognition that distal embolization is the major complication associated with CAS has led to the development of numerous devices designed to prevent distal embolization by proximal flow control, distal flow control, or distal particulate filtration (90). Several ongoing trials of CAS have incorporated protection

devices in the study design (91–97), but no one device or type of device has been proved to be superior. A metaanalysis of carotid stent placement series suggests that these protective devices do actually reduce the incidence of periprocedure neurologic deficit (98), but the extent of this reduction remains to be determined in a randomized, controlled trial. The expectation is that these devices will potentially help to further decrease the risk of CAS to the point that this procedure would be equal or superior to CEA (99,100). Recent data also suggest their use is not without difficulty or potential complication (101,102). A prolonged “learning curve” may exist before realization of actual benefit, about which there is still controversy (101,102).

III. INDICATIONS AND CONTRAINDICATIONS

Definitions: *Severe stenosis* is 70% or greater diameter stenosis by NASCET measurement criteria. *Preocclusive stenosis* is 90% or greater diameter stenosis by NASCET criteria or NASCET definition of “near occlusion” (9).

A. Acceptable Indications for CAS

1. Symptomatic, severe stenosis that is surgically difficult to access (eg, high bifurcation requiring mandibular dislocation) (103)
2. Symptomatic, severe stenosis in a patient with significant medical disease that would make the patient high risk for surgery (20–36,104–109, Table 2).
3. Symptomatic severe stenosis and one of the following conditions:
 - a. Significant tandem lesion that may require endovascular therapy
 - b. Radiation-induced stenosis (110,111)
 - c. Restenosis after CEA (112,113)
 - d. Refusal to undergo CEA after proper informed consent
 - e. Stenosis secondary to arterial dissection
 - f. Stenosis secondary to fibromuscular dysplasia
 - g. Stenosis secondary to Takayasu arteritis (1,114)

4. Severe stenosis associated with contralateral carotid artery occlusion requiring treatment before undergoing cardiac surgery
5. Severe underlying carotid artery stenosis revealed after recanalization of carotid occlusion after thrombolysis for acute stroke (presumed to be the etiology of the treated occlusion) or to enable thrombolysis for acute stroke
6. Pseudoaneurysm (115)
7. Asymptomatic preocclusive lesion in a patient otherwise meeting criteria 1–3

B. Relative Contraindications

1. Asymptomatic stenosis of any degree, except in particular circumstances, as described above (A4, A6, A7)
2. Symptomatic stenosis associated with an intracranial vascular malformation
3. Symptomatic stenosis in a patient with a subacute cerebral infarction
4. Symptomatic stenosis in a patient with a significant contraindication to angiography

C. Absolute Contraindications

1. Carotid stenosis with angiographically visible intraluminal thrombus
2. A stenosis that cannot be safely reached or crossed by an endovascular approach

IV. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Rationale for Cervicocerebral Angiographic Skill

Official standards of training have existed for over a quarter century, are the hallmark of medical licensure, board examinations and residency programs, and are recognized as vital by the ACGME, the Federation of State Medical Boards of the United States, Inc., the American Board of Medical Specialties (ABMS), and the National Board of Medical Examiners® (NBME®) (116–118). Standards of training and for performance of medical and surgical procedures are necessary requirements for the practice of medicine. The Joint Commission on Accredi-

tation of Healthcare Organizations (JCAHO) is working with two other accrediting organizations, the National Committee for Quality Assurance and URAC (formerly known as the Utilization Review Accreditation Commission), on coordinating and aligning patient safety standards. Medical societies and accreditation committees routinely formulate minimum standards for the protection and safety of patients, including those for board accreditation, residency training and the practice of medicine. Examples of such standards are those written by the American College of Cardiology (ACC) for the performance of coronary intervention (which require 300 coronary angiograms prior to coronary intervention) (119–121) as well as training and performance standards specifically for peripheral vascular intervention (122,123). Standards of performance and training specifically for peripheral vascular intervention have also been written by the AHA (124), the Society of Cardiac Angiography and Intervention (125), the Society of Interventional Radiology (126, 127) and the Society for Vascular Surgery (128). All training and performance standards above require substantial diagnostic angiographic experience prior to interventional practice in all vascular beds, typically 100 angiograms (119–128). Training standards specifically for neurovascular intervention, including carotid artery stenting, were written by a multispecialty group and unanimously endorsed by each executive committee of the American Society of Neuroradiology, the American Society of Interventional and Therapeutic Neuroradiology, the American Association of Neurological Surgeons, the Congress of Neurological Surgeons (CNS) and the AANS/CNS Section on Cerebrovascular Surgery (5). These neurointerventional training standards require 100 cerebral angiograms as a pre-requisite for entry into the ACGME-approved residency/fellowship in Endovascular Surgical Neuroradiology.

The American College of Radi-

ology's Standard of Practice for Cervicocerebral Angiography was formulated by a consensus panel of ACR, ASITN, ASNR, and SIR members (4). Cervicocerebral angiography has a proven set of indications, contraindications, risks, and benefits due to the fact that cervicocerebral catheterization is technically challenging and the organ supplied is uniquely vulnerable. The proper and safe performance of a cerebral angiogram is fundamental to the performance of cervical CAS, just as diagnostic coronary angiography skills have been recognized by the ACC as a pre-requisite for coronary vascular intervention (119–121).

Stroke is the most feared of all medical conditions and procedural complications. For this reason, any procedure that has "stroke" as a routine potential risk should be performed only by medical professionals with appropriate training and experience. The rate of stroke as a complication of diagnostic cerebral angiography in patients with asymptomatic carotid stenosis was approximately 1.2% in ACAS; this may be greater than the actual risk of stroke caused by the stenosis itself for many patients with asymptomatic stenosis (8,49). Importantly, it has been demonstrated that the amount of cervicocerebral angiographic experience is inversely related to procedural complication rates, which translate into temporary and permanent strokes (129–133). Indeed, the argument has been raised by both vascular surgeons and neurologists that cervicocerebral angiography, even performed by neurovascular specialists, may be too dangerous to be performed for the indication of asymptomatic carotid artery stenosis (134,135). Operator risk factors for stroke/transient ischemic attack (TIA) complications from cerebral angiography are well known and include increased procedure and fluoroscopy time, increased number of catheters used, and performance of arch aortography (130,131,136). Many of the above-mentioned factors, including procedural time and multiple catheter use, are not

independent and are typically related to inexperience and lack of specific training. In several studies, neurological complications (stroke and TIA) occurred more frequently when angiography was performed by a trainee or fellow rather than by an experienced neuroradiologist (130–132,134). A recent report has demonstrated that the rate of stroke during cerebral angiography when performed by an appropriately trained and experienced specialist is very low (137). However, a separate published report confirms that physicians without formal training in catheter angiography did indeed experience a learning curve associated with an unacceptable complication rate that decreased with angiographic experience (130). A significant learning curve has also been demonstrated for the carotid stent procedure itself as well as the use of cerebral embolic protection devices, thus necessitating appropriate training and experience in both components of the procedure: cervicocerebral angiography as well as the carotid stent procedure (78,86,99–102).

B. Physician Qualifications For Carotid Angioplasty And Stent Placement

1. The surgical team must possess particular fundamental knowledge and skills for the appropriate application and safe performance of CAS; these include
 - a. A thorough knowledge of cerebrovascular anatomy, hemodynamics, physiology, and pathophysiology
 - b. Sufficient knowledge of the clinical and imaging evaluation of patients with cerebrovascular disorders to determine those patients for whom CAS is indicated; this includes thorough knowledge of the clinical manifestations and the natural history of cerebrovascular ischemic disease
 - c. Appreciation of the benefits and risks of CAS and the alternatives to the procedure, such as CEA and/or current medical therapy

- d. Familiarity with pharmaceutical agents potentially useful during endovascular procedures
- e. The ability, skills, and knowledge to evaluate the patient's clinical status and to identify those patients who may be at increased risk, who may require additional pre- or postprocedure care, or who have relative contraindications to the procedure; in particular, the physicians must be capable of performing a clinical neurologic examination and understanding any relevant findings before, during, and after the procedure
- f. The capability to recognize procedure, neurologic, and angiographic complications related to the CAS procedure; recognition of angiographic complications necessitates a thorough knowledge of cerebrovascular anatomy and hemodynamics
- g. The capability to provide appropriate endovascular management of vascular complications related to the performance of CAS, including appropriate treatment of embolic complications
- h. The capability to provide the initial clinical management of complications of CAS; basic life support and treatment of cardiac arrhythmias must be immediately available; in addition, the trained personnel, equipment, and pharmacotherapeutics required to identify and to manage heart block, cardiac arrhythmias, and major blood pressure fluctuations must also be immediately available
- i. Adequate training in radiation physics and safety; the physician team must be familiar with the principles of radiation biology, the hazards of radiation exposure to both patients and medical personnel, and radiation monitoring requirements; such training and knowledge are important to maxi-

mize both patient and physician safety

2. The requirements for meeting the qualifications listed in (IV.B.1) may be met by obtaining the following training and experience. This training may be obtained through the appropriate ACGME-approved residency or fellowship (5,138) or through postgraduate experience that should include a, b, and c below. The postgraduate experiential training must be under the supervision of a qualified physician, defined as a physician who has already met the qualifications of section IV with acceptable indications and outcomes.

- a. Performance (under the supervision of a qualified physician and with at least 50% performed as the primary operator) of at least 200 diagnostic cervicocerebral angiograms with documented acceptable indications and outcomes for physicians with no prior catheter experience (4,139), or at least 100 diagnostic cervicocerebral angiograms with documented acceptable indications and outcomes for physicians with experience sufficient to meet the AHA requirements for peripheral vascular interventions (124).
- b. Arterial stent experience as either:
 1. 25 non-carotid stent complete procedures, plus attendance at and completion of a "hands-on" course in performance of CAS, plus performance and completion of at least four successful and uncomplicated CAS procedures as principal operator under the supervision of an on-site qualified physician; this must be a comprehensive course in which the attendees earn at least 16 hours of AMA category I continuing medical education credit

OR

2. Ten consecutive CAS procedures as principal operator under the supervision of an on-site qualified physician on patients treated for appropriate indications documented by a log of cases performed and with acceptable success and complication rates according to the thresholds contained in this guideline and the ACR guideline for cervicocerebral angiography (4,78,86)
- c. Substantiation in writing by the director of the department, the chief of the medical staff, or the chair of the credentials committee of the institution in which the training procedures were performed and the institution in which privileges will be granted that the surgical team is familiar with all of the following:
 1. Indications and contraindications for CAS
 2. Preprocedural assessment and intraprocedural physiologic, cerebrovascular, and neurologic monitoring of the patient
 3. Appropriate use and operation of fluoroscopic and radiographic equipment and digital subtraction angiography systems
 4. Principles of radiation protection, hazards of radiation exposure to the patient and to the radiologic personnel, and radiation monitoring requirements
 5. Anatomy, physiology, and pathophysiology of the cerebrovascular system
 6. Pharmacology of contrast agents and cardiac antiarrhythmia drugs and recognition and treatment of adverse reactions to these substances

7. Recognition and treatment of cardiac arrhythmias associated with CAS
8. Technical aspects of performing CAS
9. Recognition of any cerebrovascular abnormality or complication related to the CAS procedure
10. Postprocedural patient management, particularly the recognition and initial management of procedure complications

Maintenance of competence requires continuing activity including

1. Regular performance of sufficient numbers of neurovascular procedures to maintain success and complication rates as outlined below
2. Participation in a quality improvement program that monitors these rates
3. Participation in courses that provide continuing education on advances in CAS
4. Continuing education should be in accordance with the ACR Standard for Continuing Education

V. SPECIFICATIONS OF THE PROCEDURE

A. Technical Requirements

There are several technical requirements that are necessary to ensure the safe and successful performance of CAS. These include adequate clinical facilities, angiographic and monitoring equipment, and support personnel. The minimal facility requirements are

1. An angiographic suite with sufficient space to allow positioning of patient-monitoring equipment and anesthesia equipment, while leaving adequate room for the circulating staff to move without contaminating the sterile field
2. A high-resolution image intensifier and imaging chain with the ability to acquire and store images digitally; imaging and recording must be consistent with the as low as reasonably achievable (ALARA) radiation safety guidelines

3. Immediate access to computed tomography or magnetic resonance imaging to allow evaluation of any suspected complication (eg, intracranial embolization)
 4. Adequate physiologic monitoring equipment for use during and after the procedure, including equipment for cardiopulmonary resuscitation and temporary cardiac pacing
- B. Emergency Support**
There should be prompt access to medical, surgical, and interventional personnel and resources needed for management of medical or surgical complications.
- C. Patient Care**
1. Preprocedural care
 - a. The history and indications for the procedure must be recorded in the patient's medical record; relevant medications, allergies, and bleeding disorders should be noted
 - b. The vital signs and physical (general and neurologic) examination must be documented
 - c. Neurologic assessment must include documentation of the National Institutes of Health Stroke Scale (NIHSS) (140)
 2. Procedural care
 - a. Vital signs should be obtained and recorded at regular intervals during the course of the procedure
 - b. Cardiac rhythm should be monitored continuously
 - c. Intravenous access must be available for administration of fluids and drugs
 - d. If the patient is to receive conscious sedation, pulse oximetry must be used; administration of sedation should be in accordance with the ACR Standard for Conscious Sedation; anesthesia personnel, a registered nurse, or other appropriately trained personnel should be present and have primary responsibility for monitoring the patient; all medication doses and times should be recorded
 - e. Neurologic deterioration should be documented and quantified by the NIHSS
 3. Postprocedural care
 - a. A procedure note must be written in the patient's medical record summarizing the procedure, any immediate complications, and the patient's status at the end of the procedure; this information should be communicated to the referring physician as soon as possible; the note may be brief if the formal report will be dictated and available the same day
 - b. All patients should be carefully observed during the postprocedure period; the patient's vital signs and neurologic examination, along with the status of the puncture site and the peripheral pulses should be monitored at regular intervals by a nurse or other qualified personnel
 - c. The physician performing the procedure or a qualified designee (physician or nurse) should evaluate the patient after the initial postprocedure period; these findings should be recorded in a progress note in the patient's medical record; the physician and/or designee should be available for continuing care before and after the patient's discharge from the hospital
 - d. Neurologic assessment must include documentation of the NIHSS

VI. EQUIPMENT QUALITY CONTROL

The facility must have documented policies and procedures for monitoring and evaluating the effective management, safety, and proper performance of imaging and interventional equipment. The quality control program should maximize the quality of the diagnostic information. This may be accomplished as part of a routine preventive maintenance program.

VII. DOCUMENTATION

A. Informed Consent and Procedure Risk.—Informed consent must be obtained in compliance with institutional policy and state law. The physician should be committed to the Principles of Medical Ethics and the opinions on clinical investigation, informed consent, and prescribing of drugs and devices as stated in the Code of Medical Ethics of the Council on Ethical and Judicial Affairs of the American Medical Association (141). Risks cited should include infection, bleeding, allergic reaction to contrast, cardiac arrhythmia, stroke, and death. The potential need for emergency treatment of complications should be discussed. The relative risks and benefits of medical therapy and/or CEA should also be discussed.

B. Documentation.—The results of all CAS procedures should be monitored on a continuous basis. Records should be kept of immediate and long-term results and complications. The number and types of complications should be documented.

A permanent record of each procedure should be maintained (conventional film or digital media); labeling should include facility name, patient name, identification number and/or date of birth, and examination date.

The physician's report should include the procedure undertaken, method of anesthesia, specific balloons and stents used, and immediate complications, if any (including treatment and outcome). Reporting should be in accordance with the ACR Standard on Communication.

At least 30 days of clinical follow-up is necessary to obtain the necessary data for proper quality assurance. A permanent record of the patient's neurologic status before and after treatment must be maintained. The long-term outcome and any delayed complications (including treatment and response) must be recorded. Restenosis after CAS may occur as it may after CEA. Therefore, long-term follow-up of vessel patency with non-invasive imaging is recommended 6, 12, 18, and 24 months after treatment (142).

VIII. THRESHOLDS, SUCCESS AND COMPLICATION RATES

There is insufficient information to define technical success scientifically. For extremity and renal angioplasty, technical success requires less than 30% diameter residual stenosis by angiography and may require improvement in transstenotic pressure gradient (143,144). In the coronary literature, technical success for balloon angioplasty and stent placement had originally been defined as 20% relative improvement with a decrease in stenosis to less than 50%, but it has recently been revised to a decrease in stenosis to less than 20% (119,120). However, unlike extremity, renal, or coronary stenoses, carotid stenoses are very rarely symptomatic due to hemodynamic compromise. Rather, symptoms arise from embolization from a carotid plaque. It is unknown what degree of correction of carotid stenosis is necessary to reduce the risk of embolization, but removal of the embolic source is fundamental. It is possible that in the attempt to more completely eliminate residual stenosis by full balloon dilation, additional emboli may be produced during the procedure that could cause a higher risk of procedure complications. Alternatively, leaving a higher degree of residual stenosis may lead to a higher rate of late restenosis, which at this time is of uncertain clinical significance. Some carotid stent placement trials have defined technical success as residual stenosis of less than 30% (Yadav J, presented at the American Heart Association Scientific Sessions, Chicago, November 2002). Others have used a definition of residual stenosis of less than 50% (Eles G, The ARChER Trial, presented at the SIR Annual Scientific Meeting, Salt Lake City, UT, March 2003). In the absence of definitive scientific evidence, technical success in this document is arbitrarily defined as stent placement resulting in improvement of the stenosis by 20% or more with a final residual stenosis of less than 50% with NASCET measurement criteria. Some practices may prefer to use a lesser degree of residual stenosis as their desired endpoint for technical success.

As with many endovascular and surgical techniques, there is a learning curve associated with CAS. Complications will be more frequent when the

procedure is performed by less experienced practitioners. This phenomenon is also recognized with the performance of CEA as well as coronary intervention. To account for the level of physician experience, an ad hoc committee of the AHA Stroke Council (145) proposed that a "beginning surgeon be assigned 100 trouble-free cases as a theoretical statistical basis." For example, 75 cases would be added proportionately by indication categories to a beginning surgeon's 25 cases to form a statistical basis of 100 total cases. The number of trouble-free cases is decreased by the number of real cases performed until the practitioner has actually performed 100 cases. With this system, a new physician would be considered to have a 5% complication rate, rather than 50%, if he or she had complications with five of the first 10 cases. This concept appears to be a valid method to account for physician inexperience. Because we have recommended relatively high thresholds (see Table 3) for the complications associated with CAS, the number of trouble-free cases assigned to a new physician should be less than the 100 cases used for evaluation of CEA. Otherwise, excessive complications might continue without triggering a review. For the performance of CAS, 30 trouble-free cases will be assigned (in both the asymptomatic and symptomatic patient categories) to new physicians for initial statistical analysis that will be performed as described in the AHA document.

Previous reports of experience with CAS have described complications, particularly neurologic, in an inconsistent and nonstandardized fashion. We recognize the need for more detailed, clinically relevant, and uniform outcome measures. Both the duration and severity of neurologic complications are important. The necessity for significant postoperative interventions, such as emergency thrombolytic therapy, is also thought to be important. However, defining precisely what would constitute a "significant" posttreatment intervention would be difficult, as would reporting and analyzing all such interventions. Use of the NIHSS facilitates rapid and uniform assessment of neurologic complications. In addition, the NIHSS may serve as a reasonable surrogate measure for significant posttreatment interventions.

The rationale for using the NIHSS for this purpose is that small increases in the NIHSS are thought to be much less likely to result in significant interventions, including repeated angiography and thrombolytic therapy. Therefore, adoption of the NIHSS as a standard outcome measure will allow uniform assessment of complications and approximate the incidence of significant postoperative interventions. Differentiation between outcomes and complications in patients with asymptomatic versus symptomatic arterial stenoses is critical. The natural history of the two groups of patients differs dramatically, with much lower risk of stroke in asymptomatic patients. As with CEA, the risks associated with CAS appear to be lower in asymptomatic patients and the risk-to-benefit ratio for CAS appears to be significantly different for asymptomatic versus symptomatic patients.

Definitions.—Neurologic complication: neurologic deterioration evidenced by an increase in the NIHSS score of one or more points

Transient deficit: a neurologic complication having complete resolution within 24 hours

Reversible stroke: a neurologic complication having a duration of more than 24 hours and up to 30 days

Permanent stroke: a neurologic complication having a duration of more than 30 days

Minor deficit: neurologic deterioration evidenced by an increase of the NIHSS score of less than four points without the presence of aphasia or hemianopsia

Major deficit: neurologic deterioration evidenced by an increase of the NIHSS score of four or more points or the presence of aphasia or hemianopsia

Technical success: inflation of angioplasty balloon/placement of stent in the carotid stenosis with improvement of the stenosis by 20% or more with a final residual stenosis of less than 50% using NASCET measurement criteria

While practicing physicians should strive to achieve perfect outcomes (eg, 100% success, 0% complications), in practice, all physicians will fall short of this ideal to a variable extent. Thus, indicator thresholds may be used to assess the efficacy of ongoing quality improvement programs. For the purpose of these guidelines, a threshold is a specific level of an indicator that

Table 3
Thresholds for Indications, Technical Success, and Complications

	Complications Threshold	
	Asymptomatic Patient (%)	Symptomatic Patient (%)
Neurologic complication		
Minor transient deficit	*	*
Major transient deficit	*	*
Minor reversible stroke	3.5	6
Major reversible stroke	2	3
Minor permanent stroke	3	4.5
Major permanent stroke	2	3
Death	0†	0†
Indications		
Meets the indications listed in section III.A		95%
Technical success		90%

Inappropriate comparison of the thresholds in this table to the reported incidences of complications after CEA might lead to an erroneous conclusion that higher rates of neurologic complications are acceptable for CAS compared with lower rates for CEA: (a) A "threshold" is not intended to represent a desirable incidence of complications. A "threshold" implies a complication rate that is significantly above the expected rate of complications, such that an audit should be conducted to examine the cause of the unexpectedly high incidence of complications. (b) These thresholds are significantly higher than the complication rates for CEA published in the randomized ACAS and NASCET trials. Those trials included only low-risk patients. The thresholds in this document pertain only to high-risk patients. Except for patients treated as part of an approved investigational trial, patients considered to have normal risk of CEA do not fall within the acceptable indications for carotid artery angioplasty and stent placement as defined in this document. (c) The thresholds described in this document are comparable with the incidences of complications resulting from CEA performed on similar high-risk patients. (d) The thresholds described in this document do not apply to low-risk patients treated under an approved investigational trial. Lower thresholds, comparable with the well-established experience with CEA in low-risk patients, would apply for CAS performed under these conditions. (e) The definitions for the neurologic complications on which these thresholds are based differ from those used in many reported series. No accepted, standardized methodology for reporting all neurologic complications exists. The neurologic complications defined in this document should be applicable to a broad range of cerebrovascular interventions and surgery. (f) The thresholds described in this document reflect complications occurring within 30 days of CAS, not immediate postoperative results. (g) Thresholds for the reversible stroke categories are based on the expectation that reversible deficits are likely to be slightly more common than permanent strokes. We recognize that there is not yet adequate scientific literature to confirm this.

* At present, there are minimal and insufficient data available to suggest threshold values for transient deficits after CAS. We believe that these data should be collected and reported to further our understanding of CAS and, perhaps, to help to decrease the incidence of permanent neurologic complications. When adequate data about transient neurologic complications become available, this document will be revised to include threshold values for such transient complications.

† All deaths should be reviewed.

sociated with CAS (60–88). A review may be triggered when the threshold values described in **Table 3** are exceeded. The thresholds were derived from critical evaluation of the literature and evaluation of empirical data from the committee members' practices. Consensus on statements in this document was obtained with a modified Delphi technique (1,2).

IX. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION CONCERNS

Policies and procedures related to quality, patient education, infection control, and safety should be developed and implemented in accordance with the ACR Policy on Quality Control and Improvement, Safety, Infection Control, and Patient Education Concerns.

These data should be used in conjunction with the thresholds described in Section VIII to assess angioplasty and stent placement at the cervical carotid bifurcation procedural efficacy and complication rates and, as defined in that section, to trigger institutional review when the thresholds defined in that section are exceeded.

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should prompt a review. When measures such as indications or success rates fall below a (minimum) threshold or when complication rates exceed a (maximum) threshold, a review should be performed to determine

causes and to implement changes, if necessary. Routine periodic review of all cases having less than perfect outcomes is strongly encouraged. Intracranial embolization and subsequent stroke are the major complications as-

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The clinical practice guidelines of the ASITN, the ASNR, and the SIR attempt to define practice principles that generally should assist in producing high-quality medical care. These guidelines are voluntary and are not rules. A physician may deviate from these guidelines, as necessitated by the individual patient and available resources. These practice guidelines should not be deemed inclusive of all proper methods of care or exclusive of other methods of care that are reasonably directed toward the same result. Other sources of information may be used in conjunction with these principles to produce a process leading to high-quality medical care. The ultimate judgment regarding the conduct of any specific procedure or course of management must be made by the physician, who should consider all circumstances relevant to the individual clinical situation. Adherence to the ASITN, ASNR, and SIR Quality Improvement Programs will not ensure a successful outcome in every situation. It is prudent to document the rationale for any deviation from the suggested practice guidelines in the department policies and procedure manual or in the patient's medical record.