Quality Improvement Guidelines for Adult Diagnostic Cervicocerebral Angiography: Update

Cooperative Study between the Society of Interventional Radiology (SIR), American Society of Neuroradiology (ASNR), and Society of NeuroInterventional Surgery (SNIS)

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ABBREVIATIONS

CCA = catheter cerebral angiography, DSA = digital subtraction angiography, 3D = three-dimensional

PREAMBLE

The membership of the Society of Interventional Radiology (SIR) Standards of Practice Committee represents experts in a broad spectrum of interventional procedures from both the private and academic sectors of medicine. Generally, Standards of Practice Committee members dedicate the vast majority of their professional time to performing interventional procedures; as such, they represent a valid broad expert constituency of the subject matter under consideration for standards production.

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 upon request from SIR, 3975 Fair Ridge Drive, Suite 400 North, Fairfax, VA 22033.

METHODOLOGY

SIR produces its Standards of Practice documents 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 dependent upon the magnitude of the project.

An in-depth literature search is performed by using electronic medical literature databases. Then, a critical review of peer-reviewed articles is performed with regard to the study methodology, results, and conclusions. The qualitative weight of these articles is assembled into an evidence table, which is used to write the document such that it contains evidence-based data with respect to content, rates, and thresholds.

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 by using a modified Delphi consensus method (Appendix A). 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 by telephone conference calling or face-to-face meeting. The finalized draft from the Committee is sent to the SIR membership for further input/criticism during a 30-day comment period. These comments are discussed by the Standards of Practice

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Committee, and appropriate revisions are made to create the finished standards document. Prior to its publication, the document is endorsed by the SIR Executive Council.

INTRODUCTION

The present document represents a more extensive revision than the typical update. Upon reviewing the previous Quality Improvement Guidelines for Adult Diagnostic Neuroangiography published in 2003, it became apparent that several very significant changes had occurred and needed to be addressed (1–38). To begin with, the title was updated to reflect the current terminology.

Second, noninvasive imaging (computed tomographic [CT] angiography and, to a lesser extent, magnetic resonance [MR] angiography) have evolved to the point that noninvasive imaging has replaced catheter angiography for many of the traditional indications. At the same time, the continued growth of the field of interventional neuroradiology has brought about several new indications for diagnostic catheter angiography. The list of appropriate indications in the present document reflects these changes.

Third, the angiography suite of today bears little resemblance to that of a decade ago. Modern technology provides the capability to produce a much more sophisticated examination, including such tools as three-dimensional (3D) imaging, sophisticated roadmapping, and the ability to choose optimal projections. As a result, the concept of the "complete diagnostic cervicocerebral angiogram" has become outdated. In evaluating success rates, the standard should not be whether a "complete" examination was performed, but rather whether the examination provided the information for which it was performed while minimizing radiation exposure and contrast agent volume.

Fourth, the discussion of complications has been revised to reflect the complications associated with current practice. The section on neurologic complications has been revised to reflect the current definition of stroke and widely used tools for the assessment of stroke severity and outcome, such as the National Institutes of Health Stroke Scale and the modified Rankin score.

Because of the significant paradigm change in practice of neurointerventional radiology, in many scenarios, less invasive techniques such as CT angiography and MR angiography have replaced digital subtraction angiography (DSA) as the initial tool in diagnosis, treatment planning, and monitoring of patients with cerebrovascular diseases. For example, in patients with stroke, CT angiography could not only identify the presence and burden of the target thrombus, but also evaluate the aortic arch, the extracranial and intracranial anatomy, and collateral flow guiding therapeutic decision making and intervention. In the face of these changes, the importance of catheter cerebral angiography (CCA) is not diminished as new procedures such as carotid stent placement and stroke interventions are being performed in increasing numbers in academic and private centers across the globe. Furthermore, technical innovations in DSA technology are creating new applications for CCA as a primary diagnostic tool and for surveillance purposes. Therefore, despite the shift in indication and utility, the fundamental competencies and expertise required to perform CCA remains an essential and critical aspect of neurointerventional radiology practice.

CCA is a safe and effective technique for evaluating various intracranial and extracranial disorders. CCA can be performed as an initial investigation, when the results of noninvasive imaging are inconclusive, or when additional anatomical or hemodynamic information is needed and to facilitate therapeutic intervention. The information obtained by CCA, combined with clinical and noninvasive imaging findings, can be used for diagnosis, treatment planning, or evaluation of the results of a therapeutic intervention. As an indispensible member of a multidisciplinary team, an angiographer plays a key role in management of an individual patient, from selection of the most appropriate investigation to successful execution, intraprocedural monitoring, postprocedural follow-up, and admission of patients undergoing CCA.

DSA allows for acquisition of images with high spatial and temporal resolution. Typically acquired pixels are 0.1 mm^2 in size and obtained at 4–15 frames per second. Higher spatial and temporal resolutions are achievable, but their acquisition is limited in practice to minimize radiation exposure. Modern systems are, capable of acquiring 3D tomographic images. CT angiography is based on the same principle as cerebral angiography, and acquires data during the passage of an iodine-based contrast agent through the vasculature. Typical CT angiography examinations provide images with high spatial resolution (0.4-mm^3 pixels). As is the case with DSA imaging, higher resolutions can be achieved, but usually at the cost of increased radiation dose. Use of 64- and higher-slice multidetector CT, dual-source CT, cone-beam CT, and advanced postprocessing algorithms such as iterative reconstruction allows for acquisition of angiography with lower radiation and intravenous contrast agent doses. Effective dose of flat-panel CT in comparison to multidetector CT is in comparable range, and effective dose of 3D angiography is identical to 2D DSA (31). MR angiography is obtained based on different properties of vessel wall or blood and allows images to be obtained of the arterial system, the venous system, the capillary bed, or a combination of those. Besides conventional methods such as time-of-flight imaging, phase-contrast imaging, and contrast-enhanced MR angiography, newer techniques such as time-resolved imaging, constrained reconstruction, and parallel imaging are making the acquisition of imaging with high temporal and spatial resolution possible. In acquiring MR angiographic images irrespective of field strength and technique used, usually there is a trade-off between scan time, desired spatial and temporal resolution, and signal-to-noise ratio. Time-of-flight imaging is useful for the assessment of a wide range of cerebrovascular diseases, including ischemic stroke, carotid atherosclerosis, and vessel malformations such as arteriovenous malformations or vascular tumors. Phase-contrast imaging can be performed with cardiac gating to allow for an assessment of the blood velocities at various phases throughout the cardiac cycle. Implementation of innovative tools such as hybrid angiography suites, cone-beam CT angiography, and perfusion imaging, and the growing necessity of multiparametric (anatomic, flow, functional, and metabolic) data in diagnosis and management of patients with cerebrovascular diseases, coupled with heightened awareness of potential harm of medical radiation exposure, have raised the stakes and complexity of decision making for angiographers.

The present quality-improvement document aims to provide an update on terminology; a brief overview of technique and current indications and contraindications for diagnostic catheter angiography; success and complication rates; and threshold rate based on contemporary evidence in the literature.

These guidelines are written to be used in quality-improvement programs to assess adult diagnostic cervicocerebral angiography. The most important processes of care are (i) patient selection, (ii) performing the procedure, and (iii) monitoring the patient. The outcome measures or indicators for these processes are indications, success rates, and complication rates. Outcome measures are assigned threshold levels.

DEFINITION AND PROCEDURAL OVERVIEW

Cervicocerebral catheter angiography is a process by which intracranial and extracranial head and neck vasculature, hemodynamics, and pathologic conditions are evaluated. It consists of placement of a catheter selectively into extracranial cervical vessels under fluoroscopic guidance, followed by serial/sequential image acquisition during intravascular injection of contrast material to delineate anatomy of interest and to identify pathologic conditions. The catheter is usually inserted via a common femoral arterial access site, but other access sites (eg, axillary, brachial, radial) may be used in selected cases. Arch aortography may be performed to evaluate suspected pathologic conditions of the aortic arch or its first-order branches, to delineate the origins and/or tortuosity of the extracranial cervical vessels before selective catheterization, or to reveal the anatomic basis of a technically difficult vessel catheterization. Selective catheterization and examination of the appropriate first-order branches and their respective vascular territories should be performed unless contraindicated. Nonselective injection of contrast medium into the aortic arch has been associated with a greater risk of complications than selective angiography (4). Arch injection may be indicated, however, if selective catheterization is not possible or if the risk/benefit ratio of selective catheterization is unfavorable because of excessive tortuosity, plaque, or other pathologic condition. Selective angiography allows optimal assessment of the extracranial and intracranial vasculature and better defines pathologic conditions such as arterial occlusions or stenoses (atherosclerotic or caused by other vasculopathy), aneurysms, vasospasm, low- or high-flow arteriovenous shunts, and coincident and/or contributory conditions. Evaluation of the intracranial circulation is an essential component of the angiographic study of all pathologic conditions involving the cervicocerebral vessels (39–63).

When performing CCA for any diagnosis, the field of view should include all vessels potentially affected by or contributing to the suspected pathologic condition. The injection of contrast media must be at a rate and volume that safely and adequately opacifies the vascular territory of interest. Image acquisition should include arterial, capillary, and venous phases as indicated. Images are acquired and stored digitally on computerized storage media. Imaging and patient radiation dose recording should be guided by applicable SIR standards (40).

A traditional "complete" cerebral angiogram includes images of the intracranial and extracranial carotid and vertebral arteries bilaterally in at least two planes (or documentation of the absence or occlusion of one or more of the vessels, such as a vertebral artery) (5). The angiographer should not be constrained by this definition of "complete," and is obliged to interrogate all the vessels, obtaining all the necessary projections based on available information such as working diagnosis, results of previous noninvasive imaging, clinical information, treatment history, or planned future interventions. For example, when diagnostic CCA is performed for evaluation of posterior circulation ischemic symptoms, the vertebral artery origins, cervical vertebral arteries, intracranial vertebral arteries, and basilar artery should be examined. Frontal views with caudal and cranial angulation and angled lateral views may need to be obtained to adequately assess the vertebral arteries, vertebrobasilar junction, and basilar artery and its branches (particularly the posterior cerebral arteries). Evaluation of the anterior circulation may be indicated depending on circumstances and findings. Likewise, when diagnostic CCA is performed in the setting of suspected aneurysmal subarachnoid hemorrhage, it is necessary to thoroughly investigate the sites where cerebral aneurysms frequently arise. Tailored views and supplemental rotational and/or 3D angiography are often necessary. Additional projections and adjustment of contrast agent bolus and acquisition rate may be necessary in the setting of other diagnoses such as arteriovenous malformations, in which rapid flow may mandate higher frame rates and adjustment of contrast agent bolus volume and injection rate to produce opacification of all vessels and adequate separation of arterial, capillary, and venous phases. Although the necessary images must be obtained, efforts should be made to minimize the radiation exposure and contrast agent volume received by the patient. Adoption of simple techniques such as replacing arterial access evaluation by DSA with fluoroscopy, using lower pulse rate fluoroscopy and roadmap guidance, choosing variable frame rates for DSA, and using real-time radiation dose monitoring if available could lower radiation dose in cerebral angiography procedures.

Appropriate, effective, accurate, and safe use of image-based diagnosis and treatment planning requires the integration of patient history, physical examination findings, and prior imaging studies with the CCA findings, while being mindful of the potential risk of the procedure such as risk of radiation exposure and stroke. Therefore, the angiographer should have an understanding of the clinical context and specific contribution of CCA in management of an individual patient. The physician performing the CCA must fully appreciate the indications, expectations, benefits, alternatives, and risks of the procedure. He or she must have a thorough understanding of clinical neurologic examination, extracranial and intracranial vascular anatomy (including congenital and developmental variants and common collateral pathways), the angiographic equipment, radiation safety considerations, and physiologic monitoring equipment, and must have access to an adequate resources such as variety of catheters, guide wires, and dedicated team to safely perform the procedure. The physician must understand the principles of prevention and appropriate management of access-related and catheter-related complications such as thromboembolic phenomena with anticoagulation and catheter flushing, the need for adequate hydration, puncture site hemostasis, and management of angiographic complications such as vessel dissection, thrombosis, or flow-limiting vasospasm. In addition, the performing physician must be alert and vigilant to detect and appreciate the clinical significance of unsuspected findings and be able to handle such events.

Although 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. Therefore, indicator thresholds may be used to assess the efficacy of ongoing quality-improvement programs. For the purposes of these guidelines, a threshold is a specific level of an indicator that should prompt a review. "Procedure thresholds" or "overall thresholds" reference a group of indicators for a procedure, eg, major complications. Individual complications may also be associated with complication-specific thresholds. When measures such as indications or success rates are 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. For example, if the incidence of permanent neurologic deficit is one measure of the quality of adult diagnostic cervicocerebral angiography, values in excess of the defined threshold, in this case 1%, should trigger a review of policies and procedures within the department to determine the causes and to implement changes to lower the incidence of the complication. Thresholds may vary from those listed here; for example, patient referral patterns and selection factors may dictate a different threshold value for a particular indicator at a particular institution. Therefore, setting universal thresholds is very difficult, and each department is urged to alter the thresholds as needed to higher or lower values to meet its own quality-improvement program needs.

Complications can be stratified on the basis of outcome. Major complications result in admission to a hospital for therapy (for outpatient procedures), an unplanned increase in the level of care, prolonged hospitalization, permanent adverse sequelae, or death. Minor complications result in no sequelae; they may require nominal therapy or a short hospital stay for observation (generally overnight; **Appendix B**). The complication rates and thresholds in this document refer to major complications.

INDICATIONS

Imaging of cerebrovascular disease has evolved into a multimodal, multiparametric model in which noninvasive imaging techniques such as CT angiography and MR angiography are complemented by CCA depending on the indication and individual patient situation. Also, it should be noted that the utility of CCA may vary based on locally available tools, technique, and expertise in each institution. Indications for CCA may include the following (1,4,6–8,28,41,64–160):

1. Evaluate cervicocerebral circulation when CT angiography or MR angiography is inconclusive or rendered nondiagnostic as a result of patient-related factors such as significant metal artifact or poor cardiac output.
2. Define presence/extent of intracranial and extracranial vascular occlusive disease and thromboembolic phenomena, especially when dynamic information such as the presence and nature of collateral supply is needed.

3. Define etiology of hemorrhage (subarachnoid, intraventricular, parenchymal, craniofacial, cervical).
4. Define presence, location, and anatomy of intracranial aneurysms and cervicocerebral vascular malformations.
5. Evaluate vasospasm related to subarachnoid hemorrhage.
6. Investigate reversible cerebral vasoconstriction syndrome.
7. Define presence/extent of trauma to cervicocerebral vessels (eg, dissection, pseudoaneurysm).
8. Define vascular supply to tumors.
9. Define presence/extent of vasculitis (infectious, inflammatory, drug-induced).
10. Evaluate subjective and/or objective pulsatile tinnitus or cranial bruit.
11. Define presence of venous occlusive disease (eg, dural sinus, cortical, deep).
12. Outline vascular anatomy for planning and determining the effect of therapeutic measures.
13. Perform physiologic testing of brain function (eg, Wada test).
14. Evaluate anatomy and collateral circulation in conjunction with physiologic testing of brain perfusion (balloon test occlusion).
15. Determine presence of intracranial flow for the purpose of documenting angiographic brain death, especially when nuclear medicine blood flow study is inconclusive or not able to be performed
16. Evaluate cervicocerebral circulation before planned neurointervention or after neurointervention.

The threshold for these indications is 95%. When fewer than 95% of procedures are performed for these indications, the department will review the process of patient selection.

CONTRAINDICATIONS

There are no absolute contraindications to adult diagnostic CCA. Relative contraindications include iodinated contrast media allergy, hypotension, severe hypertension, coagulopathy, renal insufficiency, and congestive heart failure. Patients should be screened for these predisposing and perpetuating risk factors and conditions, and every effort should be made to control or correct them periprocedurally (43,161).

SUCCESS RATE

A successful examination is defined as sufficient selective technical evaluation and image interpretation to establish or exclude pathologic conditions of the extracranial and intracranial circulation. Successful CCA routinely is performed in one session. Rarely, more than one session may be necessary because of limitation of vascular access, contrast media dose limit, patient intolerance, inadequate anesthesia, or comorbid illness such as congestive heart failure, which prevents prolonged supine positioning. Evaluation of certain conditions such as subarachnoid hemorrhage may require more than one examination if the initial examination has negative findings. Vasospasm associated with subarachnoid hemorrhage may require more than one examination if recurrent spasm is suspected and noninvasive methods such as transcranial Doppler examination are inconclusive or not technically feasible. The reported success rate for complete diagnostic CCA is 98%; the threshold is 98% (162–164). The rate of success is related to patient age, presence and severity of atherosclerosis, and presence of hypertensive disease (162–165).

COMPLICATIONS

The complications of CCA can be divided into neurologic complications specific to this procedure and complications associated with catheter angiography in general (**Table 1**) (42,58,59,143,149,161,166–207).

Neurologic

The risks of CCA are generally higher in patients with advanced age, severe atherosclerosis, pre-existing symptomatic cerebrovascular disease, or acute subarachnoid hemorrhage. The risks are related to the duration of the procedure, level of experience of the performing physician, number of catheter exchanges, catheter size, extent of catheter manipulation, and amount of contrast media used. Femoral introduction of the diagnostic catheter is easier and safer for cerebral angiography. The arch anatomy can present challenges for an upper-extremity approach (42,55,56,58,59,143,149,161,166–207).

Neurologic complications that occur within 24 hours of angiography are, by definition, attributed to the angiography and are defined by the duration and severity of the neurologic deficit. A deficit lasting less than 24 hours is a transient ischemic attack. A deficit lasting more than 24 hours is defined as a stroke (161). Strokes range in severity from trivial to life-threatening. All strokes should be considered major complications according to the definitions in **Appendix B**. If a postprocedural neurologic deficit is identified, an objective measure of stroke severity should be made by using the National Institutes of Health Stroke Scale (**Table 2**). This allows stratification of stroke severity and can be compared with patient status before angiography. A practitioner trained and certified in its use should administer this test. The modified Rankin disability score (**Table 3**) is easily performed and is a useful tool to assess the ultimate outcome of procedure-related neurologic complications.

Nonneurologic

Nonneurologic complications can be stratified on the basis of outcome. Major complications result in admission to a hospital for therapy (for outpatient procedures), an unplanned increase in the level of care resulting in prolonged hospitalization, permanent adverse sequelae, or death. Minor complications result in no sequelae; they may require nominal therapy or a short hospital stay for observation (generally overnight; **Appendix B**). The complication rates and thresholds in the present document refer to major complications. Any death for which the onset of cause is within 24 hours of the procedure or a puncture-site infection should be reviewed as part of the institution-wide quality-improvement program (43,44,161).

The nonneurologic complications of CCA are the same as those of catheter angiography in general. These encompass access site, systemic (including contrast agent reactions and contrast agent–induced nephropathy), and catheter-induced complications. These are discussed at length in the Society of Interventional Radiology Quality Improvement Guidelines for Diagnostic Arteriography (161). The same thresholds for these complications apply in this setting (**Table 4**) (161).

Published rates for individual types of complications are highly dependent on patient selection and are based on series comprising several hundred patients, which is a volume larger than most individual practitioners are likely to treat. Generally, the complication-specific thresholds should be set higher than the complication-specific reported rates listed here. It is also recognized that a single complication can cause a rate to cross

Table 1. Published Neurologic Complication Rates and Suggested Thresholds

Specific Neurologic Complication	Reported Rate (%)	Suggested Complication-Specific Threshold (%)
Reversible neurologic deficit (TIA)	0–2.3	> 2
Permanent neurologic deficit (stroke)	0–5	> 1

TIA = transient ischemic attack.

Table 2. National Institutes of Health Stroke Scale

Instruction	Scale Definition
1a. Level of consciousness	
The investigator must choose a response, even if a full evaluation is prevented by such obstacles as an endotracheal tube, language barrier, orotracheal trauma/bandages. A 3 is scored only if the patient makes no movement (other than reflexive posturing) in response to noxious stimulation.	0, Alert; keenly responsive; 1, not alert, but arousable by minor stimulation to obey, answer, or respond; 2, not alert, requires repeated stimulation to attend, or is obtunded and requires strong or painful stimulation to make movements (not stereotyped); 3, responds only with reflex motor or autonomic effects, or totally unresponsive, flaccid, areflexic.
1b. Level of consciousness questions	
The patient is asked the month and his or her age. The answer must be correct: there is no partial credit for being close. Aphasic and stuporous patients who do not comprehend the questions will score 2. Patients unable to speak because of endotracheal intubation, orotracheal trauma, severe dysarthria from any cause, language barrier, or any other problem not secondary to aphasia are given a 1. It is important that only the initial answer be graded and that the examiner not “help” the patient with verbal or nonverbal cues.	0, Answers both questions correctly; 1, answers one question correctly; 2, answers neither question correctly.
1c. Level of consciousness commands	
The patient is asked to open and close the eyes and then to grip and release the nonparetic hand. Substitute another one-step command if the hands cannot be used. Credit is given if an unequivocal attempt is made but not completed as a result of weakness. If the patient does not respond to command, the task should be demonstrated to them (pantomime) and score the result (ie, follows none, one, or two commands). Patients with trauma, amputation, or other physical impediments should be given suitable one-step commands. Only the first attempt is scored.	0, Performs both tasks correctly; 1, performs one task correctly; 2, performs neither task correctly.
2. Best gaze	
Only horizontal eye movements will be tested. Voluntary or reflexive (oculocephalic) eye movements will be scored, but caloric testing is not done. If the patient has a conjugate deviation of the eyes that can be overcome by voluntary or reflexive activity, the score will be 1. If a patient has an isolated peripheral nerve paresis (cranial nerve III, IV, or VI) score a 1. Gaze is testable in all aphasic patients. Patients with ocular trauma, bandages, pre-existing blindness, or other disorder of visual acuity or fields should be tested with reflexive movements and a choice made by the investigator. Establishing eye contact and then moving about the patient from side to side will occasionally clarify the presence of a gaze palsy.	0, Normal; 1, partial gaze palsy (score given when the gaze is abnormal in one or both eyes but forced deviation or total gaze paresis are not present); 2, forced deviation or total gaze paresis not overcome by the oculocephalic maneuver.
3. Visual	
Visual fields (upper and lower quadrants) are tested by confrontation by using finger counting or visual threat as appropriate. The patient must be encouraged, but if they look at the side of the moving fingers appropriately, this can be scored as normal. If there is unilateral blindness or enucleation, visual fields in the remaining eye are scored. Score 1 only if a clear-cut asymmetry including quadrantanopia is found. If the patient is blind from any cause, score 3. Double simultaneous stimulation is performed at this point. If there is extinction, the patient receives a 1, and the results are used to answer question 11.	0, No visual loss; 1, partial hemianopia; 2, complete hemianopia; 3, bilateral hemianopia (blind including cortical blindness).

(Continued)

Table 2. National Institutes of Health Stroke Scale (*Continued*)

Instruction	Scale Definition
4. Facial palsy	
Ask or use pantomime to encourage the patient to show his or her teeth or smile and close his or her eyes. Score the symmetry of a grimace in response to noxious stimuli in the poorly responsive or noncomprehending patient. If facial trauma/bandages, orotracheal tube, tape, or other physical barrier obscures the face, they should be removed to the extent possible.	0, Normal symmetrical movement; 1, minor paralysis (flattened nasolabial fold, asymmetry on smiling); 2, partial paralysis (total or near-total paralysis of the lower face); 3, complete paralysis (absence of facial movement in the upper and lower face).
5/6. Motor arm and leg	
The limb is placed in the appropriate position: extend the arms 90° (if sitting) or 45° (if supine) and the leg 30° (always tested supine). Drift is scored if the arm falls before 10 s or the leg before 5 s. The aphasic patient is encouraged by using urgency in the voice and pantomime but not noxious stimulation. Each limb is tested in turn, beginning with the nonparetic arm. Only in the case of amputation or joint fusion at the shoulder or hip may the score be 9, and the examiner must clearly write the explanation for scoring as a 9.	Arm: 0, no drift, the arm holds 90° (or 45°) for full 10 s; 1, drift, the arm holds 90° (45°) but drifts down before full 10 s; does not hit the bed or other support; 2, some effort against gravity, limb cannot get to or maintain (if cued) 90° (or 45°), drifts down to the bed, but has some effort against gravity; 3, no effort against gravity, the arm falls; 4, no movement; 9, amputation, joint fusion (5a, left arm; 5b, right arm). Leg: 0, no drift, leg holds 30° position for full 5 s; 1, drift, the leg falls by the end of the 5-s period but does not hit the bed; 2, some effort against gravity, the leg falls to the bed by 5 s but has some effort against gravity; 3, no effort against gravity, the leg falls to the bed immediately; 4, no movement; 9, amputation, joint fusion (6a, left leg; 6b, right leg).
7. Limb ataxia	
This item is aimed at finding evidence of a unilateral cerebellar lesion. Tests with eyes open. In case of visual defect, ensure testing is done in an intact visual field. The finger-nose-finger and heel-shin tests are performed on both sides, and ataxia is scored only if present out of proportion to weakness. Ataxia is absent in the patient who cannot understand or is hemiplegic. Only in the case of amputation or joint fusion may the item be scored 9, and the examiner must clearly write the explanation for not scoring. In case of blindness, test by touching the nose from the extended arm position.	0, Absent; 1, present in one limb; 2, present in two limbs (if present, is ataxia in right arm: yes [1], no [2], amputation or joint fusion [9; explain]; left arm: yes [1], no [2], amputation or joint fusion [9; explain]; right leg: yes [1], no [2], amputation or joint fusion [9; explain]; left leg: yes [1], no [2], amputation or joint fusion [9; explain]).
8. Sensory	
Sensation or grimace to pinprick when tested, or withdrawal from noxious stimulus in the obtunded or aphasic patient. Only sensory loss attributed to stroke is scored as abnormal, and the examiner should test as many body areas (arms [not hands], legs, trunk, and face) as needed to accurately check for hemisensory loss. A score of 2, “severe or total,” should be only given when a severe or total loss of sensation can be clearly demonstrated. Stuporous and aphasic patients will therefore probably score 1 or 0. The patient with brainstem stroke who has bilateral loss of sensation is scored 2. If the patient does not respond and is quadriplegic, score 2. Patients in a coma (item 1a, 3) are arbitrarily given a 2 on this item.	0, Normal; no sensory loss; 1, mild to moderate sensory loss, patient feels a pinprick is less sharp or is dull on the affected side or there is a loss of superficial pain with a pinprick but the patient is aware that he or she is being touched; 2, severe to total sensory loss, patient is not aware of being touched.

(Continued)

Table 2. National Institutes of Health Stroke Scale (*Continued*)

Instruction	Scale Definition
9. Best language	
A great deal of information about comprehension will be obtained during the preceding sections of the examination. The patient is asked to describe what is happening in the attached picture and name the items on the attached list of sentences. Comprehension is judged from responses here as well as to all of the commands in the preceding general neurologic examination. If visual loss interferes with the tests, ask the patient to identify objects placed in the hand, repeat, and produce speech. The intubated patient should be asked to write. Patient in a coma (question 1a, 3) will arbitrarily score 3 on this item. The examiner must choose a score for the patient with a stupor or limited cooperation but a score of 3 should be used only if the patient is mute and follows no one-step commands.	0, No aphasia, normal; 1, mild to moderate aphasia; some obvious loss of fluency or facility of comprehension, without significant limitation on ideas expressed or form of expression. (Reduction of speech or comprehension, or both, however, makes conversation about the provided material difficult or impossible. For example, in conversation about provided materials, the examiner can identify a picture or naming card from a patient's response.) 2, Severe aphasia; all communication is through fragmentary expression; a great need for inference, questioning, and guessing by listener; range of information that can be exchanged is limited; the listener carries the burden of communication; the examiner cannot identify materials provided from a patient response; 3, mute, global aphasia; no usable speech or auditory comprehension.
10. Dysarthria	
If the patient is thought to be normal, an adequate sample of speech must be obtained by asking the patient to read or repeat words from the attached list. If the patient has severe aphasia, the clarity of articulation of spontaneous speech can be rated. Only if the patient is intubated or has another physical barrier to producing speech may the item be scored 9, and the examiner must clearly write an explanation for not scoring. Do not tell the patient why he or she is being tested.	0, Normal; 1, mild to moderate; the patient slurs at least some words and, at worst, can be understood with some difficulty; 2, severe; the patient's speech is so slurred as to be unintelligible in the absence of or out of proportion to any dysphasia, or is mute/anarthric; 9, intubated or other physical barrier.
11. Extinction and inattention (formerly neglect)	
Sufficient information to identify neglect may be obtained during the prior testing. If the patient has severe visual loss preventing visual double simultaneous stimulation, and the cutaneous stimuli are normal, the score is normal. If the patient has aphasia but does appear to attend to both sides, the score is normal. The presence of visual spatial neglect or anosognosia may also be taken as evidence of neglect. As neglect is scored only if present, the item is never untestable.	0, No abnormality; 1, visual, tactile, auditory, spatial, or personal inattention or extinction to bilateral simultaneous stimulation in one of the sensory modalities; 2, profound hemi-inattention or hemi-inattention to more than one modality; does not recognize his or her own hand or orients to only one side of space.
12. Distal motor function	
The patient's hand is held up at the forearm by the examiner and the patient is asked to extend his or her fingers as much as possible. If the patient cannot or does not extend the fingers, the examiner places the fingers in full extension and observes for any flexion movement for 5 s. The patient's first attempts only are scored. Repetition of the instructions or of the testing is prohibited.	0, Normal (no flexion after 5 s); 1, at least some extension after 5 s, but not fully extended. Any movement of the fingers not to command is not scored; 2, no voluntary extension after 5 s; movement of the fingers at another time are not scored (a, left arm; b, right arm).

Administer stroke scale items in the order listed. Record performance in each category after each subscale exam. Do not go back and change, review, or revise scores. Follow directions provided for each exam technique. Scores should reflect what the patient does, not what the clinician thinks the patient can do. The clinician should record answers while administering the exam and work quickly. Except where indicated, the patient should not be coached (ie, repeated requests to the patient to make a special effort). If any item is left untested, an explanation must be clearly given in the discharge summary. All untested items will be reviewed by the medical monitor and discussed with the examiner.

Table 3. Modified Rankin Disability Scores

Grade	Description
0	No signs or symptoms
1	No significant disability; able to carry out all usual activities of daily living (without assistance). Note: this does not preclude the presence of weakness, sensory loss, language disturbance, etc, but implies that these are mild and do not or have not caused the patient to limit his or her activities (eg, if employed before he or she is still employed at the same job).
2	Slight disability; unable to carry out some previous activities, but able to look after own his or her affairs without much assistance (eg, unable to return to prior job; unable to do some household chores, but able to get along without daily supervision/help).
3	Moderate disability, requiring some help but able to walk without assistance (eg, needs daily supervision; needs assistance with small aspects of dressing and hygiene; unable to read or communicate clearly. Note: an ankle-foot orthotic or cane does not imply needing assistance).
4	Moderately severe disability; unable to walk without assistance and unable to attend bodily needs without assistance (eg, needs 24-h supervision and moderate/maximum assistance on several activities of daily living, but still able to do some activities by himself or herself or with minimal assistance)
5	Severe disability; bedridden, incontinent, and requiring constant nursing care and attention
6	Stroke death
9	Unknown (not obtainable from history or no follow-up)

Note–This scale is not intended for evaluation in the setting of acute stroke; it is used to quantify the outcome of an acute stroke, generally at 1 or 3 mo after the event.

Table 4. Published Nonneurologic Complication Rates and Suggested Thresholds (161)

Specific Nonneurologic Complication	Reported Rate (%)	Major Adverse Event Threshold (%)
Access site complications		
Hematoma (requiring transfusion, surgery, or delayed discharge)	0.5–1.7	> 3
Occlusion	0.14–0.76	> 1
Pseudoaneurysm/arteriovenous fistula	0.04–0.1	> 0.2
Systemic complications		
Contrast-induced nephropathy	0.6–2.3	> 5
Major contrast reaction	0.0–3.13	> 5
Other	0.0–0.46	> 1
Catheter-induced complications (other than stroke and puncture site)		
Arterial dissection/subintimal passage	0.43	> 1
Subintimal injection of contrast medium	0.0–0.44	> 1

above a complication-specific threshold when the complication occurs within a small patient volume (eg, early in a quality-improvement program). In this situation, the overall procedure threshold is more appropriate for use in a quality-improvement program. All values in **Table 4** are supported by the weight of literature evidence and panel consensus.

OVERALL PROCEDURE THRESHOLD

The overall procedure threshold for major complications resulting from adult diagnostic cervicocerebral angiography is 2%. This threshold refers to any complication that requires additional therapy, results in prolonged hospitalization, or causes permanent adverse sequelae as defined in **Appendix B**.

APPENDIX A. CONSENSUS METHODOLOGY

Reported complication-specific rates in some cases reflect the aggregate of major and minor complications. Thresholds are derived from critical evaluation of the literature, evaluation of empirical data from Standards of Practice Committee members' practices, and, when available, the SIR HI-IQ System national database.

Consensus on statements in this document was obtained by using a modified Delphi technique (208,209).

APPENDIX B. SIR STANDARDS OF PRACTICE COMMITTEE CLASSIFICATION OF COMPLICATIONS BY OUTCOME

Minor Complications

A. No therapy, no consequence; or
B. Nominal therapy, no consequence; includes overnight admission for observation only.

Major Complications

C. Require therapy, minor hospitalization (< 48 h);
D. Require major therapy, unplanned increase in level of care, prolonged hospitalization (> 48 h);
E. Have permanent adverse sequelae; or
F. Result in death.

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The clinical practice guidelines of the Society of Interventional Radiology 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 towards 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 SIR Quality Improvement Program will not assure 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.