The American College of Radiology, with more than 30,000 members, is the principal organization of radiologists, radiation oncologists, and clinical medical physicists in the United States. The College is a nonprofit professional society whose primary purposes are to advance the science of radiology, improve radiologic services to the patient, study the socioeconomic aspects of the practice of radiology, and encourage continuing education for radiologists, radiation oncologists, medical physicists, and persons practicing in allied professional fields.

The American College of Radiology will periodically define new practice guidelines and technical standards for radiologic practice to help advance the science of radiology and to improve the quality of service to patients throughout the United States. Existing practice guidelines and technical standards will be reviewed for revision or renewal, as appropriate, on their fifth anniversary or sooner, if indicated.

Each practice guideline and technical standard, representing a policy statement by the College, has undergone a thorough consensus process in which it has been subjected to extensive review, requiring the approval of the Commission on Quality and Safety as well as the ACR Board of Chancellors, the ACR Council Steering Committee, and the ACR Council. The practice guidelines and technical standards recognize that the safe and effective use of diagnostic and therapeutic radiology requires specific training, skills, and techniques, as described in each document. Reproduction or modification of the published practice guideline and technical standard by those entities not providing these services is not authorized.

Revised 2011 (Resolution 41)*

ACR–ASNR–SIR–SNIS PRACTICE GUIDELINE FOR THE PERFORMANCE OF DIAGNOSTIC CERVICOCEREBRAL CATHETER ANGIOGRAPHY IN ADULTS

PREAMBLE

These guidelines are an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. They are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care. For these reasons and those set forth below, the American College of Radiology cautions against the use of these guidelines in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the physician or medical physicist in light of all the circumstances presented. Thus, an approach that differs from the guidelines, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in the guidelines when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of the guidelines. However, a practitioner who employs an approach substantially different from these guidelines is advised to document in the patient record information sufficient to explain the approach taken.

The practice of medicine involves not only the science, but also the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment. Therefore, it should be recognized that adherence to these guidelines will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The sole purpose of these guidelines is to assist practitioners in achieving this objective.

I. INTRODUCTION

This guideline was developed and written with the collaboration of the American College of Radiology (ACR), the American Society of Neuroradiology (ASNR), the Society of NeuroInterventional Surgery (SNIS), and the Society of Interventional Radiology (SIR).

Diagnostic cervicocerebral catheter angiography is a proven, safe, and effective procedure for evaluating many intracranial and extracranial disorders, especially vascular abnormalities of the head, neck, and brain. It should be performed only for a valid medical reason (see section III below) and with the minimum radiation dose necessary to achieve an optimal study. It has been considered the diagnostic standard for judging the accuracy of other intracranial or extracranial vascular imaging modalities.

While diagnostic cervicocerebral catheter angiography is an invasive test with defined risks, it is a valuable and informative procedure performed routinely in the evaluation of certain vascular and neurological disorders. The diagnostic information obtained, combined with other clinical and noninvasive imaging findings, can be used to plan or evaluate results of treatment.
This guideline is intended to help practicing physicians ensure that patients undergo diagnostic cervicocerebral catheter angiography for appropriate reasons, that the methods used and the periprocedural care provided are adequate to minimize complications, and that the quality of the studies obtained is sufficient to answer the clinical questions that prompted them. Adherence to this guideline will aid in the safe and effective performance of diagnostic cervicocerebral catheter angiography.

Participation by the angiographer in procedure selection, preprocedural preparation, intraprocedural monitoring, postprocedural follow-up, and management of the patient is important in high-quality diagnostic cervicocerebral catheter angiography and will increase the success rate of the procedure.

This guideline can be used in institution-wide quality improvement programs to assess the practice of diagnostic cervicocerebral catheter angiography. The most important elements of care are 1) patient selection, preparation, and education; 2) expertise in performing and interpreting the procedure; and 3) monitoring of the patient. The outcome measures or indicators for these processes are indications, success rates, and complication rates. Outcome measures are assigned threshold levels.

II. DEFINITIONS AND OVERVIEW

DEFINITIONS

For the purpose of this guideline, the following definitions apply:

Diagnostic cervicocerebral catheter angiography – a complete patient encounter involving percutaneous passage of a catheter into the carotid or the vertebral arteries followed by injection of contrast material and imaging and diagnostic evaluation of the intracranial and extracranial circulation using film or digital imaging systems.

Indicator - a specific, quantifiable, and objective measure of quality.

Major complication – a stroke or other event that results in admission to the hospital for therapy (for outpatient procedures), requires an unplanned increase in the level of care resulting in prolonged hospitalization, or results in permanent adverse sequelae or death (see Appendix A).

Minor complication – a transient ischemic event or other occurrence that results in no sequelae; however, such an event may require minimal therapy or a short hospital stay for observation (generally overnight).

Successful examination – a technically successful procedure and set of images resulting in identification or exclusion of the suspected pathology or other pathology capable of being identified with arteriography.

Stroke – a focal neurological deficit lasting longer than 24 hours, typically documented by imaging findings clinically relevant to the deficit.

Threshold – a specific level of an indicator that should prompt the performance of a review.

Transient ischemic attack (TIA) – a brief episode of neurological dysfunction caused by focal brain or retinal ischemia, with clinical symptoms typically lasting less than one hour, usually without imaging evidence of infarction (some TIAs are associated with diffusion restriction detected on MRI indicating ischemia or infarction with complete resolution of symptoms within 24 hours.)

OVERVIEW

Diagnostic cervicocerebral catheter angiography is a process by which the intracranial and extracranial head and neck circulation is evaluated. It consists of placement of a catheter selectively into extracranial cervical vessels using imaging guidance, followed by contrast injection to delineate anatomy. The catheter is usually inserted via a common femoral arterial access site, but other access sites may be used in selected cases. Aortic arch injections may be performed to delineate the origins and/or tortuosity of the extracranial cervical vessels prior to selective catheterization. A selective study should be performed unless extreme tortuosity or severe occlusive disease prohibits safe selective catheterization. Selective catheter placement optimally evaluates the extracranial and intracranial circulation and better defines occlusive morphology, tandem occlusive lesions, collateral circulation, and coincident and/or contributory abnormalities. Additionally, it carries a lower risk of complications than nonselective aortic arch injection [1]. Evaluation of the intracranial circulation is an essential component of the angiographic study of extracranial cerebrovascular disease.

Injection of contrast medium must be at a rate and volume that safely and adequately opacifies the vascular territory of interest. Optimal positioning, magnification, and filming rates are necessary to provide sufficient information regarding the disease and vascular territory being studied. Several projections may be necessary to best demonstrate the targeted area, but a minimum of two orthogonal projections is essential. Findings are acquired and stored either on conventional film or digitally on computerized storage media. Imaging and image recording must be consistent with the as-low-as-reasonably-achievable (ALARA) radiation safety guidelines.
While practicing physicians should strive to achieve perfect outcomes (i.e., 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. Procedure thresholds or overall thresholds refer to a group of indicators for a procedure, e.g., major complications for selective diagnostic cervicocerebral catheter angiography. Individual complications may also be associated with complication-specific thresholds.

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. 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. Thus, setting universal thresholds is very difficult, and each institution is urged to alter the thresholds as needed to higher or lower values to meet its own quality improvement program needs.

III. INDICATIONS AND CONTRAINDICATIONS

The list of indications presented here helps to focus on the primary indications for diagnostic cervicocerebral catheter angiography and therefore helps to avoid unnecessary testing. However, the physicians caring for the patient and the physician performing the procedure are in the best position to determine the appropriateness of the diagnostic evaluation. In all cases, the indications for the procedure should be documented in the patient’s medical record.

Indications for diagnostic cervicocerebral catheter angiography include, but are not limited to:

A. Definition of the presence and extent of atherosclerotic occlusive disease and thromboembolic phenomena and as an aid in planning intervention.

B. Definition of the etiology of cervicocerebral hemorrhage.

C. Definition of the presence, location, and anatomy of extracranial and intracranial aneurysms and vascular malformations.

D. Evaluation of vasospasm related to subarachnoid hemorrhage or drug-induced vasculopathy.

E. Definition of the presence, nature, and extent of injury to cervicocerebral vessels.

F. Definition of the vascular supply to tumors.

G. Definition of the presence and extent of vasculitis.

H. Diagnosis and definition of the nature and extent of congenital or acquired vascular abnormalities.

I. Definition of the presence of venous occlusive disease.

J. Definition of the relevant vascular anatomy for planning or evaluating a therapeutic intervention.

K. Physiologic testing of brain function (e.g., Wada test).

The threshold for these indications is 99%. When fewer than 99% of the procedures are for these indications, the institution should review the process of patient selection. There are no absolute contraindications to diagnostic cervicocerebral catheter angiography. Relative contraindications include hypotension, severe hypertension, and coagulopathy, clinically significant sensitivity to iodinated contrast material, renal insufficiency, and congestive heart failure. Patient management should address these relative contraindications prior to the procedure. When possible, every effort should be made to correct or control these clinical situations before the procedure.

For the pregnant or potentially pregnant patient, see the ACR Practice Guideline for Imaging Pregnant or Potentially Pregnant Adolescents and Women with Ionizing Radiation.

IV. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Physician

Image-based diagnosis and treatment planning require integration of the angiographic findings with the patient’s history, physical findings, and prior imaging studies. Therefore, the neuroangiographer must be clinically informed and understand the specific questions to be answered by diagnostic cervicocerebral catheter angiography prior to the procedure to plan and perform it safely and effectively.

The physician performing the diagnostic cervicocerebral catheter angiogram must be appropriately trained in the technical and cognitive aspects of catheter angiography, and must fully appreciate the benefits, alternatives, and risks of the procedure. He/she must have a thorough understanding of extracranial and intracranial vascular anatomy including congenital and developmental variants and common collateral pathways, angiographic equipment, radiation safety considerations, physiologic
monitoring equipment and must have access to an adequate supply of catheters, guidewires, and personnel to perform the procedure safely. The physician must understand the principles of preventing thromboembolism with anticoagulation and catheter flushing, the need for adequate hydration, and techniques for puncture site hemostasis. Furthermore, the performing physician must be able to detect and understand the clinical significance of changing or new neurologic findings and be familiar with methods of managing neuroangiographic complications.

Diagnostic cervicocerebral catheter angiographic examinations must be performed by or under the supervision of and interpreted by a physician who has the following qualifications:

1. Certification in Radiology or Diagnostic Radiology by the American Board of Radiology (ABR), the American Osteopathic Board of Radiology, the Royal College of Physicians and Surgeons of Canada, or the Collège des Médecins du Québec, provided the Board examined in this procedure. The physician must have had appropriately supervised training in the interpretation of invasive or noninvasive cervicocerebral neurovascular imaging studies, must have personally interpreted at least 100 invasive or noninvasive cervicocerebral neurovascular imaging studies, and must have performed at least 100 diagnostic catheter angiograms. The physician must demonstrate competency in the performance of cervicocerebral angiograms. While the current Accreditation Council for Graduate Medical Education (ACGME) approved neuroradiology training program requires the performance of at least 50 cervicocerebral angiograms, simple numerical criteria are not an optimal measure of competency. Documentation of competency by the use of objective, outcome-based tools related to angiographic experience is preferable.

or

Completion of a radiology residency program approved by the ACGME, the Royal College of Physicians and Surgeons of Canada (RCPSC), the Collège des Médecins du Québec, or the American Osteopathic Association (AOA) to include a minimum of 6 months of documented formal training in one of the neuroscience specialties that incorporates training in the cervicocerebral vasculature and associated neurological pathophysiology. This training must include appropriately supervised training in the interpretation of invasive or noninvasive cervicocerebral neurovascular imaging studies. The physician must have interpreted at least 100 invasive or noninvasive cervicocerebral neurovascular imaging studies. The physician must also have performed at least 100 diagnostic catheter angiograms. The physician must demonstrate competency in the performance of cervicocerebral angiograms. While the current ACGME approved neuroradiology training program requires the performance of at least 50 cervicocerebral angiograms, simple numerical criteria are not an optimal measure of competency. Documentation of competency by the use of objective, outcome-based tools related to angiographic experience is preferable.

2. Completion an ACGME approved nonradiology residency or fellowship training program that includes a minimum of 6 months of ACGME approved formal education in one of the neuroscience specialties that incorporates training in the cervicocerebral vasculature and associated neurological pathophysiology. During this ACGME approved training he or she must have had appropriately supervised training in the interpretation of invasive or noninvasive cervicocerebral neurovascular imaging studies. The physician must have interpreted at least 100 invasive or noninvasive cervicocerebral neurovascular imaging studies. The physician must have performed at least 100 diagnostic catheter angiograms. The physician must demonstrate competency in the performance of cervicocerebral angiograms. While the current ACGME approved neuroradiology training program requires the performance of at least 50 cervicocerebral angiograms, simple numerical criteria are not an optimal measure of competency. Documentation of competency by the use of objective, outcome-based tools related to angiographic experience is preferable.

and

4. Physicians meeting any of the qualifications in 1, 2, and 3 above must have written substantiation that they are familiar with all of the following:
   a. Indications and contraindications for the procedure.
   b. Periprocedural and intraprocedural assessment, monitoring, and management of the patient and the access site.
   c. Where applicable, pharmacology of moderate sedation medications and recognition and treatment of adverse reactions and complications.
   d. Appropriate use and operation of fluoroscopic and radiographic equipment, mechanical injectors, digital subtraction, and other electronic imaging systems.
   e. Principles of radiation protection, hazards of radiation exposure both to patients and to radiologic personnel, and monitoring requirements.
f. Pharmacology of contrast agents and recognition and treatment of potential adverse reactions.
g. Percutaneous needle and catheter introduction techniques.
h. Technical aspects of performing the procedure, including the use of alternative catheter and guidewire systems, selective angiographic methods, appropriate injection rates and volumes of contrast media, and filming sequences.
i. Anatomy, physiology, and pathophysiology of intracranial and extracranial vasculature.
j. Interpretation of intracranial and extracranial vascular studies.
k. Hemostasis.

The written substantiation should come from the chief of interventional radiology, the chief of neuroradiology, the chief of interventional neuroradiology, or the chair of the department of the institution in which the physician will be providing these services. Substantiation could also come from a prior institution in which the physician provided the services, but only at the discretion of the current interventional, neurointerventional, or neuroradiology chief, or the chair who solicits the additional input.

Maintenance of Competence

Physicians must perform a sufficient number of cervicocerebral catheter angiography procedures to maintain their skills, with acceptable success and complication rates according to this guideline. Continued competence should depend on participation in a quality improvement program that monitors these rates.

Continuing Medical Education

The physician’s continuing education should be in accordance with the ACR Practice Guideline for Continuing Medical Education (CME).

B. Qualified Medical Physicist

A Qualified Medical Physicist is an individual who is competent to practice independently in one or more of the subfields in medical physics. The American College of Radiology considers certification, continuing education, and experience in the appropriate subfield(s) to demonstrate that an individual is competent to practice in one or more of the subfields in medical physics, and to be a Qualified Medical Physicist. The ACR strongly recommends that the individual be certified in the appropriate subfield(s) by the American Board of Radiology (ABR), the Canadian College of Physics in Medicine, or by the American Board of Medical Physics (ABMP).

The appropriate subfield of medical physics for this guideline is Diagnostic Medical Physics. (Previous medical physics certification categories including Radiological Physics, Diagnostic Radiological Physics and Diagnostic Imaging Physics are also acceptable.)

A Qualified Medical Physicist should meet the ACR Practice Guideline for Continuing Medical Education (CME). (ACR Resolution 17, 1996 – revised in 2012, Resolution 42)

C. Registered Radiologist Assistant

A registered radiologist assistant is an advanced level radiographer who is certified and registered as a radiologist assistant by the American Registry of Radiologic Technologists (ARRT) after having successfully completed an advanced academic program encompassing an ACR/ASRT (American Society of Radiologic Technologists) radiologist assistant curriculum and a radiologist-directed clinical preceptorship. Under radiologist supervision, the radiologist assistant may perform patient assessment, patient management, and selected examinations as delineated in the Joint Policy Statement of the ACR and the ASRT titled “Radiologist Assistant: Roles and Responsibilities” and as allowed by state law. The radiologist assistant transmits to the supervising radiologists those observations that have a bearing on diagnosis. Performance of diagnostic interpretations remains outside the scope of practice of the radiologist assistant. (ACR Resolution 34, adopted in 2006)

D. Radiologic Technologist

1. The technologist, together with the physician and nursing personnel, should be responsible for patient comfort and safety. The technologist should be able to prepare and position the

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1At institutions in which there is joint (dual) credentialing across departments doing like procedures, this substantiation of experience should be done by the chairs of both departments to ensure equity of experience among practitioners when their training backgrounds differ [43].

2The American College of Radiology approves of the practice of certified and/or licensed radiologic technologists performing fluoroscopy in a facility or department as a positioning or localizing procedure only, and then only if monitored by a supervising physician who is personally and immediately available*. There must be a written policy or process for the positioning or localizing procedure that is approved by the medical director of the facility or department/service and that includes written authority or policies and processes for designating radiologic technologists who may perform such procedures. (ACR Resolution 26, 1987 – revised in 2007, Resolution 12m)
patient for the arteriographic procedure and, together with the nurse, monitor the patient during the procedure. The technologist should obtain the imaging data in a manner prescribed by the supervising physician. The technologist should also perform regular quality control testing of the equipment under supervision of the physicist.

2. Technologists should be certified by the American Registry of Radiologic Technologists (ARRT) or have an unrestricted state license and documented training and experience in catheter cerebral arteriography.

E. Nursing Services

Nursing services are an integral part of the team for preprocedure and postprocedure patient management and education and are recommended for monitoring the patient during the procedure.

V. SPECIFICATIONS OF THE EXAMINATION

There are several technical requirements that are necessary to ensure safe and successful diagnostic cervicocerebral catheter angiograms. These include adequate arteriographic equipment and institutional facilities, physiologic monitoring equipment, and support personnel.

A. Angiographic Equipment and Facilities

The following are considered the minimum equipment requirements for performing diagnostic cervicocerebral catheter angiography. In planning facilities for diagnostic cervicocerebral catheter angiography, equipment and facilities more advanced than those outlined below may be desired to reduce time of study. In general, at a minimum, the facility should include:

1. A high-resolution image intensifier and image monitor with standard angiographic or digital filming capabilities. Digital subtraction angiographic systems with high spatial resolution are recommended, as they allow for reduced volumes of contrast material and reduced examination times. These digital acquisition systems are sufficient to offer an alternative to conventional film systems and are more flexible and therefore preferable for safe and accurate diagnostic cervicocerebral catheter angiography. Imaging data are acquired and stored either on conventional film or digitally on electronic storage media. It is highly desirable to be able to record and archive images used for guidance and decision making during the procedure, including last-image-hold images and fluoroscopy loops. Imaging, image recording, and archiving must be consistent with the ALARA radiation safety guidelines. Use of last image hold, fluoroscopy loops, and pulsed fluoroscopy are recommended for dose reduction. Rotational angiography may be a useful tool for dose reduction during interventional neuroradiology procedures [2].

2. Adequate angiographic supplies such as catheters, guidewires, needles, flush systems, biohazard disposal systems, hemostatic devices, and introducer sheaths.

3. An angiographic injector capable of varying injection volumes and rates with appropriate safety mechanisms (pressure and monitoring) to prevent overinjection.

4. An angiography suite large enough to allow easy patient transfer from the bed to table and to allow room for the procedure table, monitoring equipment, and other hardware such as intravenous pumps, respirators, anesthesia team and equipment, oxygen tanks, suction, and gasses. Ideally, there should be adequate space for the operating team to work unencumbered on either side of the patient and for the circulation of other technical staff in the room without contaminating the sterile conditions.

5. An area within the institution appropriate for patient preparation prior to the procedure and for observation of patients after the procedure. This might be within the radiology department, in a short-stay unit, or in a routine nursing unit as outlined in section V.E below. Appropriate emergency equipment and medications must be immediately available to treat adverse reactions associated with administered medications and/or procedural complications. The equipment should be monitored and medications inventoried for drug expiration dates on a regular basis. The equipment, medications, and other emergency support must also be appropriate for the range of ages and sizes in the patient population.

*For the purposes of this guideline, “personally and immediately available” is defined in manner of the “personal supervision” provision of CMS—a physician must be in attendance in the room during the performance of the procedure. Program Memorandum Carriers, DHHS, HCFA, Transmittal B-01-28, April 19, 2001.
B. Physiologic Monitoring and Resuscitation Equipment

1. Appropriate equipment should be present in the angiography suite to allow for monitoring the patient’s heart rate, cardiac rhythm, and blood pressure. For facilities using sedation, a pulse oximeter must be available. (See the ACR–SIR Practice Guideline for Sedation/Analgesia.)

2. Emergency resuscitation equipment and drugs should be immediately available and include the following: a defibrillator, oxygen supply and appropriate tubing and delivery systems, suction equipment, tubes for endotracheal intubation, laryngoscope, ventilation bag-valve-mask apparatus, and central venous line sets. Drugs for treating cardiopulmonary arrest, contrast reaction, vasovagal reactions, narcotic or benzodiazepine reversal, and ventricular arrhythmias should also be readily available. Resuscitation equipment should be monitored and checked routinely in compliance with institutional policies.

C. Support Personnel

1. Radiologic technologists properly trained in the use of the arteriographic equipment should assist in performing, imaging, and archiving the procedure. They should demonstrate appropriate knowledge of patient positioning, angiographic imaging and archiving, radiation protection, angiographic contrast injectors, angiographic supplies, and physiologic monitoring equipment. Certification as a vascular and interventional radiologic technologist is one measure of appropriate training. The technologists should be trained in cardiopulmonary resuscitation and in the function of the resuscitation equipment.

2. If the patient does not receive moderate sedation, one of the staff assisting the procedure should be assigned to periodically assess the patient’s status. If the patient is to undergo moderate sedation, a licensed provider must monitor the patient as his/her primary responsibility. This person must maintain a record of the patient’s vital signs, time and dose of medications given, and other pertinent information, as described in the ACR–SIR Practice Guideline for Sedation/Analgesia. Licensed providers must be privileged by the institution to administer sedation.

D. Acute Care Support

Although complications of diagnostic cervicocerebral catheter angiography only rarely require urgent surgery, angiographic procedures should be performed in an environment where operative repair can be instituted promptly. Ideally, this would be an acute-care hospital with adequate surgical, anesthesia, and ancillary support. When these procedures are performed in a freestanding center, detailed protocols for the rapid transport or admission of patients to an acute-care hospital should be formalized in writing.

E. Patient Care

1. Preprocedure care

For elective diagnostic cervicocerebral catheter angiography, the following should be documented:

a. Clinically significant history, including indications for the procedure.

b. Clinically significant physical examination and diagnostic imaging findings, including neurological and vascular examinations appropriate to the procedure performed, and a general examination of relevant organ systems.

c. Laboratory evaluation as appropriate, including but not limited to measurement of hemoglobin, hematocrit, creatinine, electrolytes, and coagulation parameters.

Preprocedure documentation should conform to the requirements of the ACR–SIR Practice Guideline for the Reporting and Archiving of Interventional Radiology Procedures.

Informed consent must be in compliance with all state laws and the ACR–SIR Practice Guideline on Informed Consent for Image-Guided Procedures.

Adequate hydration should be ensured when possible.

For emergency procedures, a note should be written summarizing the indication for the study, the pertinent history and physical findings, if available, and the proposed procedure.

2. Procedural care

a. Adherence to the Joint Commission’s Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™ is required for procedures in non-
operating room settings including bedside procedures.

The organization should have processes and systems in place for reconciling differences in staff responses during the “time out.”

b. All patients must have cardiac monitoring continuously during the procedure, with intermittent blood pressure monitoring. A record of vital signs must be maintained. See the ACR–SIR Practice Guideline for Sedation/Analgesia.

c. All patients must have intravenous access in place for the administration of fluids and medications as needed.

d. If the patient is to receive sedation, pulse oximetry must be used. A registered nurse or other appropriately trained personnel must be present, and his/her primary responsibility must be to monitor the patient. A record must be kept of medication doses and times of administration.

e. All patients must have periodic assessments of their neurological status throughout the course of the procedure.

f. The operator must be vigilant in efforts to prevent stroke. Safeguards are needed at the highest level because of the extreme susceptibility of the brain to procedural injury.

g. A physician must be available during the immediate postprocedure period to ensure that there is adequate hemostasis at the puncture site and that the patient’s cardiovascular status and neurologic status are stable prior to transfer to the postprocedure care area.

3. Postprocedure care

a. A procedure note should be completed for all patients in accordance with the ACR–SIR Practice Guideline for the Reporting and Archiving of Interventional Radiology Procedures. In all cases, pertinent findings should be communicated to the referring physician in a timely manner.

b. All patients should be at bed rest and observed in the initial postprocedure period. The length of this period of bed rest will depend on the site and size of the arteriotomy and the patient’s medical condition.

c. During the initial postprocedure period an experienced licensed provider should periodically monitor the puncture site and the status of the distal vascular distribution.

d. The patient should be monitored for urinary output, cardiac symptoms, pain, and other indicators of systemic complications that may necessitate prolonged observation.

e. Initial ambulation of the patient must be carefully supervised. Vascular perfusion, puncture site stability, and independent patient function and mobility must be assured.

f. Since all diagnostic cervicocerebral catheter angiography studies require catheter manipulation in the thoracic aorta and the brachiocephalic vessels, neurologic status should be assessed frequently and at regular intervals.

g. The operating physician or a qualified designee should evaluate the patient after the procedure, and these findings should be summarized in a progress note. If sedation was administered prior to and during the procedure, complete recovery from sedation must be documented. The physician or a designee should be available for continuing care during hospitalization and after discharge. The designee may be another physician or a nurse.

F. Selection Criteria for Short-Term Observation

The duration of postprocedure observation should be individualized. Diagnostic cervicocerebral catheter angiography can be performed on some patients with a short period of postprocedure observation (less than 8 hours) prior to discharge to home; others require more prolonged observation. Short-term observation should only be considered when all the following conditions can be met:

1. The patient is capable of independent ambulation or has adequate assistance after discharge to provide care as needed.

2. Mental status and neurologic status are intact both before and after the procedure, with the patient capable of following instructions and detecting changes in symptoms. Alternatively, patients with impaired mental or neurologic status should have adequate assistance after discharge to provide care as needed.

3. The patient is provided with instructions on how to recognize potential complications (e.g., bleeding at the puncture site, neurological deficit, decreased urinary output, pain and discoloration distal to the puncture site) and how to obtain medical assistance in the event of such complication.
4. A responsible adult is provided with information regarding recognition of potential complications (e.g., section V.F.3 above) and available to transport the patient and be in attendance during the initial night after discharge.

5. The patient has recovered from the effects of sedation.

G. Relative Contraindications to Short-Term Observation

Several factors must be considered when determining the length of postprocedure observation. Some of the relative contraindications to short-term observation are listed below. This list is not meant to be comprehensive, and any clinical circumstance that might predispose the patient to significant complication should prompt prolonged observation.

1. Patients with poorly controlled hypertension, in which there appears to be increased risk of hematoma formation, may benefit from extended observation.

2. Patients with significant risk of contrast-media-associated nephrotoxicity that might be prevented by hospitalization and intravenous hydration.

3. Patients with coagulopathies or electrolyte abnormalities that require correction must be hospitalized until stable.

4. Insulin-dependent diabetics who have labile serum glucose levels in the periprocedural period should be hospitalized until stable.

5. Complications occurring during or after arteriography, including bleeding, anuria, persistent nausea, and vomiting, must be observed until symptoms resolve.

6. Patients who exhibit hemodynamic instability or significant arrhythmia during or after the procedure must be hospitalized until stable.

7. Travel time to the hospital or to another acute care facility should be 30 minutes or less from where the patient is to spend the first postprocedure night.


The decision for short-term or longer-term postprocedure observation must be individualized, and a patient’s care may vary from the above criteria for sound clinical reasons. The diagnostic neuroangiographer and referring physician must make the decision in each case after reviewing all pertinent data.

VI. DOCUMENTATION

Reporting should be in accordance with the ACR–SIR Practice Guideline for the Reporting and Archiving of Interventional Radiology Procedures.

Estimated radiation dose should be recorded in the medical record in accordance with the SIR Guideline [3]. Radiation dose data for the procedure should be archived according to the ACR–SIR Practice Guideline for the Reporting and Archiving of Interventional Radiology Procedures.

VII. RADIATION SAFETY IN IMAGING

Radiologists, medical physicists, radiologic technologists, and all supervising physicians have a responsibility to minimize radiation dose to individual patients, to staff, and to society as a whole, while maintaining the necessary diagnostic image quality. This concept is known as “as low as reasonably achievable (ALARA).”

Facilities, in consultation with the medical physicist, should have in place and should adhere to policies and procedures, in accordance with ALARA, to vary examination protocols to take into account patient body habitus, such as height and/or weight, body mass index or lateral width. The dose reduction devices that are available on imaging equipment should be active; if not; manual techniques should be used to moderate the exposure while maintaining the necessary diagnostic image quality. Periodically, radiation exposures should be measured and patient radiation doses estimated by a medical physicist in accordance with the appropriate ACR Technical Standard. (ACR Resolution 17, adopted in 2006 – revised in 2009, Resolution 11)

Because of the relatively high radiation doses often required for interventional neuroradiology procedures, particular attention should be paid to protection of operators and staff [4-9]. This includes use of appropriate personal protective equipment and the moveable shielding supplied with the fluoroscopic unit [10]. Personnel who work in an interventional suite on a regular basis should be provided with all necessary personal protective equipment. This includes radiation protection aprons, thyroid shields, and eyewear [11]. This equipment should be fitted to the individual to provide maximum radiation protection and reduce ergonomic hazards [12,13].
VIII. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION

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 appearing under the heading Position Statement on QC & Improvement, Safety, Infection Control, and Patient Education on the ACR web site (http://www.acr.org/guidelines).

The data developed through these policies and procedures should be used in conjunction with the thresholds described in Section IX below to assess diagnostic cervicocerebral catheter angiographic procedural efficacy and complication rates and, as defined in those sections, to trigger institutional review when the thresholds defined in those sections are exceeded.

IX. QUALITY IMPROVEMENT

While practicing physicians should strive to achieve perfect outcomes (i.e., 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 purposes of these guidelines, a threshold is a specific level of an indicator that should prompt a review. Procedure thresholds or overall thresholds refer to a group of indicators for a procedure (e.g., major complications). Individual complications may also be associated with complication-specific thresholds. When measures such as indicators 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. For example, if the incidence of permanent neurological deficit is one measure of the quality of cervicocerebral catheter angiography, then values in excess of the suggested threshold (in this case >1%) should trigger a review of policies and/or practices 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. Thus, 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.

A. Success Rates and Thresholds [14,15]

To perform a complete arteriogram, there must be appropriate preprocedure evaluation and planning, with a clear understanding by the operating physician of the questions that need to be answered by the study. Once the procedure has been planned, a technically adequate diagnostic study is necessary, with proper catheter placement by the physician and appropriate physician supervision of contrast injection rate, filming technique, and patient positioning. To be considered successful, an arteriogram should provide a complete and adequate evaluation of the clinical problem, be appropriately and permanently recorded, and be judged diagnostic by others with skill in interpreting arteriograms. The arteriogram should be followed by an electronic or printed report summarizing the findings of the study, its major technical aspects, and any immediate complications. The report should be available for review by the referring physician in a timely manner.

A successful cervicocerebral examination is defined as one that provides sufficient selective cervicocerebral catheter angiographic technical evaluation and image interpretation to establish or exclude pathology of the extracranial and intracranial circulation. Successful selective diagnostic cervicocerebral catheter angiography for the evaluation of atherosclerotic disease is usually performed in one session. However, more than one session may be necessary due to limitation of vascular access, contrast medium dose limitation, patient intolerance, inadequate anesthesia, or comorbid illness (e.g., congestive heart failure that obviates prolonged supine positioning). Evaluation of certain conditions such as intracranial hemorrhage may require multiple studies to define or exclude pathology.

<table>
<thead>
<tr>
<th>Reported Success Rates</th>
<th>Suggested Threshold</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnostic cervicocerebral catheter angiography</td>
<td>98%</td>
</tr>
</tbody>
</table>

The rate of success is related to the patient's age, severity of atherosclerosis, and presence of hypertensive disease.

B. Complication Rates and Thresholds [1,6,16-69]

The risks of diagnostic cervicocerebral catheter angiography are generally higher in patients with advanced age, severe atherosclerosis, pre-existing symptomatic cerebrovascular disease, acute subarachnoid hemorrhage, tortuous vessels, sickle cell disease, and certain vascular dysplasias (e.g., Ehlers-Danlos syndrome), and possibly in patients with a history of migraine headache. The risks are related to the length of the procedure, the number of catheter exchanges, the catheter size, the extent of catheter manipulation, and the amount of contrast medium used. Transfemoral introduction of the diagnostic catheter is generally considered safer than axillary or brachial catheterization or direct carotid/vertebral puncture. Nonionic low-osmolality contrast media are safer than ionic high-
osmolarity agents in patients with a previous history of contrast medium hypersensitivity or nephropathy. The risk of contrast-medium-induced nephropathy is greater in patients with pre-existing acute or chronic azotemia, particularly in association with diabetes.

Neurologic complications occurring within 24 hours of the angiogram are, by definition, attributed to the angiographic procedure and are defined by the duration and severity of the neurological deficit as stroke or transient ischemic attack (TIA) [70,71].

Strokes range in severity from trivial to life threatening. To evaluate the outcomes of patients following diagnostic cervicocerebral catheter angiography, an objective measure of stroke severity should be obtained. The Modified Rankin Disability Score (Appendix B) is easily performed and allows stratification of stroke severity that can be compared with the status of the patient prior to angiography.

<table>
<thead>
<tr>
<th>Neurologic Complication</th>
<th>Reported Rates</th>
<th>Suggested Threshold</th>
</tr>
</thead>
<tbody>
<tr>
<td>TIA</td>
<td>0%-2.3%</td>
<td>2.5%</td>
</tr>
<tr>
<td>Stroke</td>
<td>0%-5%</td>
<td>1%</td>
</tr>
</tbody>
</table>

Other 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, although they may require nominal therapy or a short hospital stay for observation (generally overnight) (see Appendix A).

The complication rates and thresholds below refer to major complications. Any death occurring within 24 hours of the procedure or any puncture-site infection should be reviewed as part of the institution-wide quality improvement program.

<table>
<thead>
<tr>
<th>Major Complication</th>
<th>Reported Rates</th>
<th>Suggested Threshold</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contrast media associated nephrotoxicity</td>
<td>0%-0.15%</td>
<td>0.2%</td>
</tr>
<tr>
<td>Arterial occlusion requiring surgical thrombectomy or thrombolysis</td>
<td>0%-0.4%</td>
<td>0.2%</td>
</tr>
<tr>
<td>Arteriovenous fistula/pseudoaneurysm</td>
<td>0.01%-0.22%</td>
<td>0.2%</td>
</tr>
<tr>
<td>Hematoma requiring transfusion or surgery</td>
<td>0.26%-1.5%</td>
<td>0.5%</td>
</tr>
</tbody>
</table>

Published rates for individual types of complications are highly dependent on patient selection and are based on series comprising several hundred patients, a volume larger than most individual practitioners are likely to treat. It is also recognized that a single complication can cause a rate to cross above a complication-specific threshold when the complication occurs within a small patient volume (e.g., early in a quality improvement program). In this situation, the overall procedure threshold is more appropriate for use in a quality improvement program.

### Overall Procedure Threshold

<table>
<thead>
<tr>
<th>Reported Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>All major complications resulting from diagnostic cervicocerebral catheter angiography</td>
</tr>
</tbody>
</table>

This number refers to any complication that requires additional therapy or prolonged hospitalization, or that causes permanent adverse sequelae as defined in Appendix A.

### C. Quality Improvement Issues Related to Cervicocerebral Angiography Done to Evaluate for Cervical Carotid Artery Stenosis

With the continued evolution of high-resolution noninvasive cross sectional imaging techniques (computed tomography angiography [CTA] and magnetic resonance imaging angiography [MRA]), conventional catheter angiography is less frequently performed solely for this indication. CT angiography and MRA are the preferred procedures for these indications at many institutions. In some cases where noninvasive studies produce conflicting results, catheter angiography may be indicated.

However, when catheter angiography is performed for the determination of carotid artery stenosis, the final report should reflect the methodology and reference the criteria for percentage of stenosis outlined in the North American Symptomatic Carotid Endarterectomy Trial (NASCET). Care should be taken to avoid recognized pitfalls for NASCET type measurements. Care should also be taken not to calculate percentage ratios in the presence of a poststenotic arterial diameter decrease (near occlusion). The percentage of stenosis must be calculated using the diameter of the distal cervical internal carotid artery (ICA), where the walls are parallel, for the denominator. Furthermore, apart from their lack of risk of neurological complications, CTA and MRA with optimal acquisition parameters and postprocessing techniques can provide reproducible and accurate cross sectional measurements of stenosis that correlate well with properly performed NASCET estimates of the percentage of stenosis obtained with catheter angiography [72]. Some MRA techniques...
may not be amenable to quantitative measurements, in which case qualitative assessment of stenosis should be provided.

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REFERENCES


Appendix A

Society of Interventional Radiology Standards of Practice Committee Classification of Complications by Outcome

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

Major Complications
C. Require therapy, minor hospitalization (<48 hours).
D. Require major therapy, unplanned increase in level of care, prolonged hospitalization (>48 hours).
E. Permanent adverse sequelae.
F. Death.

Appendix B

Modified Rankin Disability Scores

0 = Grade 0: No signs or symptoms.
1 = Grade 1: No significant disability; able to carry out all the 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 patient to limit his/her activities, (e.g., if employed before, is still employed at the same job).
2 = Grade 2: Slight disability; unable to carry out some previous activities but able to look after own affairs without much assistance (e.g., unable to return to prior job; unable to do some household chores, but able to get along without daily supervision or help).
3 = Grade 3: Moderate disability requiring some help but able to walk without assistance (e.g., needs daily supervision; needs assistance with small aspects of dressing, hygiene; unable to read or communicate clearly). NOTE: use of ankle-foot orthotic or cane does not imply that the patient needs assistance.
4 = Grade 4: Moderately severe disability; unable to walk without assistance and unable to attend bodily needs without assistance (e.g., needs 24-hour supervision and moderate to maximum assistance on several activities of daily living but still able to do some activities by self or with minimal assistance).
5 = Grade 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).

*Guidelines and standards are published annually with an effective date of October 1 in the year in which amended, revised or approved by the ACR Council. For guidelines and standards published before 1999, the effective date was January 1 following the year in which the guideline or standard was amended, revised, or approved by the ACR Council.

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