ACR-ASNR-SIR-SNIS PRACTICE PARAMETER FOR THE PERFORMANCE OF DIAGNOSTIC CERVICOCEREBRAL CATHETER ANGIOGRAPHY IN ADULTS

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PREAMBLE

This document is an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. Practice Parameters and Technical Standards are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care 1. For these reasons and those set forth below, the American College of Radiology and our collaborating medical specialty societies caution against the use of these documents 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 practitioner considering all the circumstances presented. Thus, an approach that differs from the guidance in this document, 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 this document when, in the reasonable judgment of the practitioner, such course of action is indicated by variables such as the condition of the patient, limitations of available resources, or advances in knowledge or technology after publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document may consider documenting in the patient record information sufficient to explain the approach taken.

The practice of medicine involves the science, and 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 the guidance in this document 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 purpose of this document is to assist practitioners in achieving this objective.

1 lowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing, 831 N.W.2d 826 (Iowa 2013) Iowa Supreme Court refuses to find that the "ACR Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures (Revised 2008)" sets a national standard for who may perform fluoroscopic procedures in light of the standard's stated purpose that ACR standards are educational tools and not intended to establish a legal standard of care. See also, Stanley v. McCarver, 63 P.3d 1076 (Ariz. App. 2003) where in a concurring opinion the Court stated that "published standards or guidelines of specialty medical organizations are useful in determining the duty owed or the standard of care applicable in a given situation" even though ACR standards themselves do not establish the standard of care.

I. INTRODUCTION

This practice parameter 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 [1]. It is the diagnostic standard for judging the accuracy of other intracranial or extracranial vascular imaging modalities [2].

However, as detailed below, it should be performed only for a valid medical reason and with the minimum radiation dose necessary to achieve an optimal study. Although 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 practice parameter 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 practice parameter will aid in the safe and effective performance of diagnostic cervicocerebral catheter angiography.

Diagnostic cervicocerebral catheter angiography is a process by which the intracranial and/or extracranial head and neck circulation are evaluated [1]. It consists of placement of a catheter selectively into extracranial cervical or intracranial vessels using imaging guidance, followed by injection of contrast material to delineate anatomy of interest and to identify pathologic conditions. The catheter is usually inserted via a common femoral or radial arterial access site, but other access sites may be used in selected cases [1,3]. "Aortic arch injections may be performed to delineate the origins and/or tortuosity of the extracranial cervical vessels prior to selective catheterization" [1] particularly if prior cross-sectional imaging is unavailable. A selective study should be performed unless extreme tortuosity or severe stenotic-occlusive disease prohibits safe selective catheterization. Selective catheter placement allows optimal assessment of the extracranial and intracranial vasculature and better defines pathologic conditions such as arterial occlusion or stenosis (atherosclerotic or caused by other vasculopathies), aneurysms, vasospasm, vascular malformation, arteriovenous malformation, dural arteriovenous fistula, venous anomaly, pial arteriovenous fistula, and coincident and/or contributory conditions [1]. Evaluation of the intracranial circulation is an essential component of the angiographic study of extracranial cerebrovascular disease [1].

The angiographer should select a volume of contrast/injection rate that will safely and adequately opacify the vascular territory of interest. The angiographer also determines the optimal positioning, magnification, and image recording rates, which are necessary to provide sufficient information regarding the disease and vascular territory being studied [1]. Although every examination should be tailored to the anatomy and clinical situation, a 3-D angiogram may be helpful to determine best projections for visualization of pathology and treatment of the targeted area. Findings are acquired and permanently recorded on an archival digital storage medium that allows retrieval and review [1]. Every step of imaging and image recording (more specifically, fluoroscopy as well as digital subtraction image acquisition) must be consistent with the "as low as reasonably achievable" (ALARA) radiation safety philosophy [1].

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

All invasive procedures have a risk of complications that require monitoring within the framework of institutional quality assurance programs.

The establishment and monitoring of internally adjusted quality metrics (indicators) and thresholds for each institution is highly recommended.

For additional information on Definitions, see Appendix A.

II. 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 procedures. 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.

A. Indications for diagnostic cervicocerebral catheter angiography include, but are not limited to [4,5]:

- 1. Evaluation of "cervicocerebral circulation when CT angiography or MR angiography is inconclusive" or further evaluation of an abnormality seen on noninvasive imaging is required "as a result of patient-related factors such as significant metal artifact or poor cardiac output" [5]
- 2. Definition of "presence/extent of intracranial and extracranial vascular stenotic-occlusive disease and thromboembolic phenomena, especially when dynamic information, such as the presence and

- nature of collateral supply, is needed" [5]
- 3. Definition of "etiology of hemorrhage (subarachnoid, intraventricular, parenchymal, craniofacial, cervical)" [5]
- 4. Definition of "presence, location, and anatomy of intracranial aneurysms and cervicocerebral vascular malformations" [5], including lesions with arteriovenous shunting
- 5. Evaluation of "vasospasm related to subarachnoid hemorrhage" [5]
- 6. Definition of "presence/extent of trauma to cervicocerebral vessels (eg, dissection, pseudoaneurysm)" [5]
- 7. Definition of "vascular supply to tumors" [5]
- 8. Definition of presence/extent of vasculopathies (eg, vasculitis (infectious, inflammatory, druginduced), reversible cerebral vasoconstriction syndrome, and Moyamoya disease)
- 9. Evaluation of "subjective and/or objective pulsatile tinnitus or cranial bruit" [5]
- 10. Definition of "presence of venous occlusive disease" [5]
- 11. Outlining of "vascular anatomy for planning and determining the effect of therapeutic measures" [5]
- 12. Prior to the performance of pharmacophysiologic testing of brain function (eg, Wada test)
- 13. Evaluation of "anatomy and collateral circulation in conjunction with physiologic testing of brain perfusion (balloon test occlusion)" [5]
- 14. Determination of the degree of intracranial flow as part of brain death assessment, "especially when nuclear medicine intracranial blood flow study is inconclusive or not able to be performed" [5]
- 15. Evaluation of cervicocerebral circulation in order to plan or assess the result of a neurointerventional procedure
- 16. Provision of assistance to surgeons who are performing intraoperative angiography for the planning or assessment of effectiveness of the operation

The threshold for these indications is 95%. When <95% of the procedures are for these indications, the institution should review the process of patient selection [5].

There are no absolute contraindications to diagnostic cervicocerebral catheter angiography. Relative contraindications include hypotension, severe hypertension, coagulopathy, clinically significant sensitivity to iodinated contrast material, renal insufficiency, and congestive heart failure [1,5]. 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 [1,5,6].

For the pregnant or potentially pregnant patient, see the <u>ACR-SPR Practice Parameter for Imaging Pregnant or Potentially Pregnant Patients with Ionizing Radiation</u> [7].

III. 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 physician 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. The physician must have a thorough understanding of extracranial and intracranial vascular anatomy, including common congenital and developmental variants and common collateral pathway, angiographic equipment, radiation safety considerations, and 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 and techniques of preventing thromboembolism (eg, anticoagulation, catheter flushing, or flush systems) 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, diagnostic radiology or interventional radiology/diagnostic radiology (IR/DR) 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. The physician must have had appropriately supervised training in the interpretation of invasive and noninvasive cervicocerebral neurovascular imaging studies. The physician must demonstrate and document competency in the performance of cervicocerebral angiography. Substantial experience is necessary to safely and competently perform cervicocerebral angiography. It is recommended that the physician have performed at least 25 catheter cervicocerebral angiograms. In emergency circumstances, it is appropriate for physicians who do not have this experience but have adequate skills in selective arterial catheterizations, to perform this procedure. In addition to performing adequate numbers of procedures, documentation of competency in all aspects of the procedure and pre- and postprocedure care by the use of objective outcome-based tools related to angiographic experience is necessary. Attestation of competency by a qualified angiographer who has observed the physician during the performance of cervicocerebral angiographic procedures is required (also see paragraph 4 below).

or

2. Completion of a radiology residency program approved by the Accreditation Council for Graduate Medical Education (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 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 demonstrate and document competency in the performance of cervicocerebral angiography. Substantial experience is necessary to safely and competently perform cervicocerebral angiography. It is recommended that the physician have performed at least 25 catheter cervicocerebral angiograms. In emergency circumstances, it is appropriate for physicians who do not have this experience but have adequate skills in selective arterial catheterizations, to perform this procedure. In addition to performing adequate numbers of procedures, documentation of competency in all aspects of the procedure and pre- and postprocedure care by the use of objective outcome-based tools related to angiographic experience is necessary. Attestation of competency by a qualified angiographer who has observed the physician during the performance of cervicocerebral angiographic procedures is required (also see paragraph 4 below).

or

3. Completion of an ACGME-approved nonradiology residency or fellowship training program that includes-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, the physician must have had appropriately supervised training in the interpretation of invasive or noninvasive cervicocerebral neurovascular imaging studies. The physician must have interpreted invasive or noninvasive cervicocerebral neurovascular imaging studies. The physician must have performed diagnostic catheter angiograms. The physician must demonstrate and document competency in the performance of cervicocerebral angiography. Substantial experience is necessary to safely and competently perform cervicocerebral angiography. It is recommended that the physician have performed at least 25 catheter cervicocerebral angiograms. In emergency circumstances, it is appropriate for physicians who do not have this experience but have adequate skills in selective arterial catheterizations, to perform this procedure. In addition to performing adequate numbers of procedures, documentation of competency in all aspects of the procedure and pre- and postprocedure care by the use of objective outcome-based tools related to angiographic experience is necessary. Attestation of competency by a qualified angiographer who has observed the physician during the performance of cervicocerebral angiographic procedures is required (also see paragraph 4 below). and

- 4. Physicians meeting the qualifications in 1, 2, and 3 above must have written substantiation that they are familiar with all of the following:
 - a. Indications and relative contraindications for the procedure
 - b. Periprocedural and intraprocedural assessment, monitoring, and management of the patient and the access site, including hemostasis
 - 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, the hazards of radiation, and radiation monitoring requirements as they apply to patients and personnel
 - 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 image recording
 - i. Anatomy, physiology, and pathophysiology of intracranial and extracranial vasculature
 - j. Interpretation of intracranial and extracranial head, neck, and aortic arch vascular studies

The written substantiation should come from the chief of interventional radiology, the chief of interventional neuroradiology, or the chair of the department of the institution in which the physician will be providing these services. [1] 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 of the chair who solicits the additional input.

For those who are looking for additional training guidance for endovascular stroke treatment, please see the SIR Training Guidelines for Endovascular Stroke Treatment [8].

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 parameter. Continued competence should depend on participation in a quality improvement program that monitors these rates. Consideration should be given to the physician's lifetime practice experience.

Continuing Medical Education

The physician's continuing education should be in accordance with the <u>ACR Practice</u> <u>Parameter for Continuing Medical Education (CME)</u> [9].

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, the American Board of Science in Nuclear Medicine (ABSNM), or the American Board of Medical Physics (ABMP).

A Qualified Medical Physicist should meet the <u>ACR Practice Parameter for Continuing Medical Education</u> (CME). [9]

The appropriate subfield of medical physics for this parameter is diagnostic medical physics (previous medical physics certification categories including radiological physics, diagnostic radiological physics, and

diagnostic imaging physics are also acceptable). (ACR Resolution 17, adopted in 1996 – revised in 2008, 2012, 2022, Resolution 41f)

C. Non-Physician Radiology Provider (NPRP)

NPRPs are all Non-Physician Providers (eg, RRA, RPA, RA, PA, NP, ...) who assist with or participate in portions of the practice of a radiologist-led team (Radiologists = diagnostic, interventional, neurointerventional radiologists, radiation oncologists, and nuclear medicine physicians). The term "NPRP" does not include radiology, CT, US, NM MRI technologists, or radiation therapists who have specific training for radiology related tasks (eg, acquisition of images, operation of imaging and therapeutic equipment) that are not typically performed by radiologists.

The term 'radiologist-led team' is defined as a team supervised by a radiologist (ie., diagnostic, interventional, neurointerventional radiologist, radiation oncologist, and nuclear medicine physician) and consists of additional healthcare providers including RRAs, PAs, NPs, and other personnel critical to the provision of the highest quality of healthcare to patients. (ACR Resolution 8, adopted 2020).

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[2] the 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.

[1] At 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].

[2] The 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)

*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.

IV. 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.

The written or electronic request for a cervicocerebral catheter angiography procedure should provide sufficient information to demonstrate the medical necessity of the examination and allow for its proper performance and interpretation.

Documentation that satisfies medical necessity includes 1) signs and symptoms and/or 2) relevant history (including known diagnoses). Additional information regarding the specific reason for the examination or a provisional diagnosis would be helpful and may at times be needed to allow for the proper performance and interpretation of the examination.

The request for the examination must be originated by a physician or other appropriately licensed health care provider. The accompanying clinical information should be provided by a physician or other appropriately licensed health care provider familiar with the patient's clinical problem or question and consistent with the stated scope of practice requirements. (ACR Resolution 35 adopted in 2006 – revised in 2016, Resolution 12-b)

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, 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
- d. Diagnostic imaging dates and findings
 Preprocedure documentation should conform to the requirements of the <u>ACR-SIR-SPR</u>
 Practice Parameter for the Reporting and Archiving of Interventional Radiology Procedures
 [10].

Informed consent must be in compliance with all state or federal laws, as appropriate, and the <u>ACR–SIR–SPR Practice Parameter on Informed Consent for Image-Guided Procedures</u> [11]. Adequate hydration should be ensured when possible.

For emergency procedures, a note should be written (or entered into the electronic medical record [EMR]) summarizing the indication for the study, the pertinent history and physical findings, and imaging 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 nonoperating room settings, including bedside procedures. The organization should have processes and systems in place for reconciling differences in staff responses during the official time-out process immediately prior to the procedure.
- b. All patients must have cardiac monitoring continuously during the procedure. See the <u>ACR-SIR Practice Parameter for Minimal and/or Moderate Sedation/Analgesia</u> [12].
- 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, see the <u>ACR-SIR Practice Parameter for Minimal and/or Moderate Sedation/Analgesia</u> [12].
- 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.

 A protocol should be in place to manage the complication of stroke. See the ACR-ASNR-SIR-SNIS Practice Parameter for the Performance of Endovascular Embolectomy and Revascularization in Acute Stroke [13].

3. Postprocedure care

- A procedure note should be completed for all patients in accordance with the <u>ACR-SIR-SPR Practice Parameter for the Reporting and Archiving of Interventional Radiology Procedures</u>
 [10]. In all cases, pertinent findings should be communicated to the referring physician in a timely manner. The performing physician should discuss the results and any complications or concerns with the patient and/or patient's family if the patient is unable to communicate or understand.
- 2. All patients should be monitored and be required bed rest 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.
- 3. During the initial postprocedure period, an experienced licensed provider should periodically monitor the puncture site and the status of the distal vascular distribution.
- 4. The patient should be monitored for neurological deficits, cardiac symptoms, pain, urinary output, and other indicators of systemic complications that may necessitate prolonged observation or intervention.
- 5. Initial ambulation of the patient must be carefully supervised. Vascular perfusion, puncture site stability, and independent patient function and mobility must be ensured.
- 6. 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 and a return to neurological baseline 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 nonphysician provider.

B. 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 flat panel detector (preferred) or image intensifier and image monitor with digital radiographic capabilities. Digital subtraction angiographic (DSA) systems with high spatial resolution are recommended as they allow for reduced volumes of contrast material and reduced examination times. Imaging data are acquired and permanently recorded on an archival digital storage medium that allows retrieval and review. 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 philosophy. Use of last-image-hold, fluoroscopy loops, and pulsed fluoroscopy are recommended for dose reduction. Small focal spots for high-resolution imaging and adjustable frame rates are desirable. The available field of view (FOV) should be able to fit the whole head in frontal and lateral projections. A biplane system is desirable to reduce contrast injections. Modern low-dose DSA settings should be applied when possible, but high-dose settings should be available for situations that require increased diagnostic sensitivity. 3-D/rotational angiography may be a useful tool for dose reduction during diagnostic and interventional neuroradiology procedures [14].
- 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 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 gases. 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.

C. Physiologic Monitoring and Resuscitation Equipment

- 1. Appropriate equipment should be present in the angiography suite to allow for monitoring of 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 Parameter for Minimal and/or Moderate Sedation/Analgesia [12]).
- 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, and ventricular arrhythmias, as well as drugs for narcotic or benzodiazepine reversal and protamine if heparin is administered. Resuscitation equipment should be monitored and checked routinely in compliance with institutional policies.

D. Support Personnel

- 1. Radiologic technologists properly trained in the use of the arteriographic equipment employed in the institution 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 location and 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 their 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 <u>ACR-SIR Practice Parameter for Minimal and/or Moderate Sedation/Analgesia</u> [12]. Individuals should be trained in the location of and the use of the facility's resuscitation equipment and in institutional protocols for code team alerts. Licensed providers must be privileged by the institution to administer moderate

E. Acute Care Support

Although complications of diagnostic cervicocerebral catheter angiography only rarely require urgent surgery, angiographic procedures should be performed in an environment in which operative repair can be instituted promptly. Ideally, this would be an acute care hospital with adequate neurointerventional, 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 and established in cooperation with the receiving acute care hospital.

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 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 (eg, bleeding at the puncture site, new 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 (eg, Section V.F.3 above) and should be 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 postprocedural 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 may occur around the time of the procedure and might predispose the patient to or result in a significant complication should prompt prolonged observation or hospitalization.

- 1. Patients with poorly controlled hypertension in which there appears to be increased risk of hematoma formation
- 2. Patients with significant risk of contrast media—associated nephrotoxicity
- 3. Patients with coagulopathies or electrolyte abnormalities that require correction
- 4. Insulin-dependent patients with diabetes who have labile serum glucose levels in the periprocedural period
- 5. Patients with complications occurring during or after arteriography, including bleeding, anuria, persistent nausea, and vomiting
- 6. Patients who exhibit hemodynamic instability or significant arrhythmia during or after the procedure

Furthermore, prolonged observation or postprocedural hospitalization should be considered when travel time to the hospital or to another acute care facility is >30 minutes from where the patient is to spend the first postprocedure night, or for patients who live alone.

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.

V. DOCUMENTATION

Reporting should be in accordance with the <u>ACR–SIR–SPR Practice Parameter for the Reporting and Archiving of Interventional Radiology Procedures</u> [10].

Estimated radiation dose should be recorded in the medical record in accordance with the SIR Guideline [15]. Radiation dose data for the procedure should be archived according to the <u>ACR-SIR-SPR Practice Parameter for the Reporting and Archiving of Interventional Radiology Procedures</u> [10] and the <u>ACR-AAPM Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures</u> [16].

For further information, see Section IV.A.1 (Preprocedure care) and Section IV.A.3.a. (Postprocedure care).

VI. RADIATION SAFETY IN IMAGING

Radiologists, medical physicists, non-physician radiology providers, radiologic technologists, and all supervising physicians have a responsibility for safety in the workplace by keeping radiation exposure to staff, and to society as a whole, "as low as reasonably achievable" (ALARA) and to assure that radiation doses to individual patients are appropriate, taking into account the possible risk from radiation exposure and the diagnostic image quality necessary to achieve the clinical objective. All personnel who work with ionizing radiation must understand the key principles of occupational and public radiation protection (justification, optimization of protection, application of dose constraints and limits) and the principles of proper management of radiation dose to patients (justification, optimization including the use of dose reference levels). https://www-pub.iaea.org/MTCD/Publications/PDF/PUB1775 web.pdf

appropriate imaging procedures to prevent unnecessary radiation exposure.

Facilities should have and adhere to policies and procedures that require ionizing radiation examination protocols (radiography, fluoroscopy, interventional radiology, CT) to vary according to diagnostic requirements and patient body habitus to optimize the relationship between appropriate radiation dose and adequate image quality. Automated dose reduction technologies available on imaging equipment should be used, except when inappropriate for a specific exam. If such technology is not available, appropriate manual techniques should be used.

Additional information regarding patient radiation safety in imaging is available from the following websites – Image Gently® for children (www.imagegently.org) and Image Wisely® for adults (www.imagewisely.org). These advocacy and awareness campaigns provide free educational materials for all stakeholders involved in imaging (patients, technologists, referring providers, medical physicists, and radiologists).

Radiation exposures or other dose indices should be periodically measured by a Qualified Medical Physicist in accordance with the applicable ACR Technical Standards. Monitoring or regular review of dose indices from patient imaging should be performed by comparing the facility's dose information with national benchmarks, such as the ACR Dose Index Registry and relevant publications relying on its data, applicable ACR Practice Parameters, NCRP Report No. 172, Reference Levels and Achievable Doses in Medical and Dental Imaging: Recommendations for the United States or the Conference of Radiation Control Program Director's National Evaluation of X-ray Trends; 2006, 2009, amended 2013, revised 2023 (Res. 2d). Because of the relatively high radiation doses often required for interventional neuroradiology procedures, particular attention should be paid to protection of operators and staff [17-22]. This includes use of appropriate personal protective equipment and the movable shielding supplied with the fluoroscopic unit [23]. 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 [24]. This equipment should be fitted to the individual to provide maximum radiation protection and reduce ergonomic hazards [25,26].

VII. 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 ACR Position Statement on Quality Control & Improvement, Safety, Infection Control, and Patient Education on the ACR website (https://www.acr.org/Advocacy-and-Economics/ACR-Position-Statements/Quality-Control-and-Improvement). The data developed through these policies and procedures should be used in conjunction with the thresholds described 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.

VIII. QUALITY IMPROVEMENT

When quality measures, such as appropriateness of indication-or angiographic 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 quality measure/indicator at a particular institution. Thus, setting universal thresholds is not feasible and each department is urged to adjust the thresholds as needed to meet its own quality improvement program needs.

A. Success Rates and Thresholds [5,27,28]

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 [1,5] . Successful selective diagnostic cervicocerebral catheter angiography for the evaluation of atherosclerotic disease is usually performed in 1 session [5] . However, >1 session may be necessary due to limitation of vascular access, contrast medium dose limitation, patient intolerance, inadequate anesthesia, or comorbid illness (eg, congestive heart failure that obviates prolonged supine positioning) [5] . "Evaluation of certain conditions, such as intracranial hemorrhage may require multiple studies to define or exclude pathology" [1].

Reported Suggested

Success Rates Threshold

Diagnostic cervicocerebral catheter angiography 98% 98%

"The rate of success is related to the patient's age, severity of atherosclerosis, and presence of hypertensive disease" [1].

B. Complication Rates and Thresholds [1,5,27,29-47]

The risks of diagnostic cervicocerebral catheter angiography are generally higher in patients with advanced age, severe atherosclerosis, preexisting symptomatic cerebrovascular disease, acute subarachnoid hemorrhage, and tortuous vessels, sickle cell disease, and certain vascular dysplasias (eg, Ehlers-Danlos syndrome), and possibly in patients with a history of migraine headache. The risks are also 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 [5].

Transfemoral or transradial introduction of the diagnostic catheter is generally considered safer than axillary or brachial catheterization or direct carotid/vertebral puncture [5]. The risk of contrast medium—induced nephropathy is greater in patients with preexisting 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) [1,5,48,49]

"Strokes range in severity from trivial to life threatening" [5]. To evaluate the outcomes of patients following diagnostic cervicocerebral catheter angiography, an objective measure of stroke severity should be obtained [1,5]. The National Institutes of Health Stroke Scale Score and Modified Rankin Disability Score (Appendix B) are easily performed and allow stratification of stroke severity that can be compared with the status of the patient prior to angiography [1,5].

Neurologic Complication Reported Rates Suggested Threshold

TIA [5] 0%-2% 2%

Stroke [5] 0%-5% 1%

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 [50]. 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 [5]. "Minor complications result in no sequelae, although they may require nominal therapy or a short hospital stay for observation (generally overnight)" [5]. For further information, see the <u>Proposal of a New Adverse Event Classification by the Society of Interventional Radiology Standards of Practice Committee</u> [51]. 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 (eg, early in a quality improvement program). In this situation, the overall procedure threshold is more appropriate for use in a quality improvement program. [1]

Overall Procedure Threshold

Reported Rate

All major complications resulting from diagnostic 2% cervicocerebral catheter angiography [5]

C. Quality Improvement in Radiologic Reporting

- 1. Cervicocerebral angiography done to evaluate for cervical carotid artery stenosisWhen 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) [52]. Care should be taken to avoid recognized pitfalls for NASCET-type measurements. For example, NASCET criteria should not be applied in the presence of a significant poststenotic arterial diameter decrease (ie, near occlusion). Furthermore, 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.
- 2. Documentation of fluoroscopy time or dose [53]

3. Recommendation to stay abreast of documentation requirements for institutional accreditation and certification, recommendations of published societal quality improvement guidelines [5] as well as governmental quality measure documentation requirements for the practice of interventional radiology, for example as recommended by CMS [54]

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Appendix A

For the purpose of this practice parameter, the following definitions apply:

Diagnostic cervicocerebral catheter angiography – a complete patient encounter involving percutaneous passage of a catheter into the carotid and/or the vertebral arteries, followed by injection of contrast material with digital

imaging and diagnostic evaluation of the images obtained Revised 3021 (Resolution 4) tifiable, 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. For further information, see the <u>Proposal of a New Adverse Event Classification by the Society of Interventional Radiology Standards of Practice Committee</u> [5].

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 >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 <1 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)

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 (eg, 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 (eg, 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 (eg, 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 (eg, 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
- 9 = Unknown (not obtainable from history or no follow-up)