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Amended 1995 (Res. 14)  
Revised 1997 (Res. 5)  
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## **PRACTICE GUIDELINE FOR THE PERFORMANCE OF DIAGNOSTIC ARTERIOGRAPHY IN ADULTS**

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### **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 on 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 by the Society of Interventional Radiology (SIR) in collaboration with the American College of Radiology (ACR) Interventional and Cardiovascular Radiology Committee [1].

Diagnostic arteriography is an established, safe, and accurate method of evaluating vascular disease. Arteriography is considered the diagnostic standard by which the accuracy of other vascular imaging modalities should be judged. However, diagnostic arteriography is an invasive procedure with a small risk of complications.

Due to the varying skill levels and training of physicians performing arteriographic procedures, the potential exists for variation in success rates, complication rates, and diagnostic study quality. The indications for arteriography have developed over time, and there may be considerable variation in practice.

This guideline was developed to provide a guide to practicing angiographers to ensure that patients undergo arteriography for appropriate reasons, that the methods used and the peri-procedural care provided are adequate to minimize complications, and that the quality of the studies obtained is adequate to answer the clinical questions that prompted them. It is intended to provide guidance both in the indications for and the performance of arteriography in vessels other than the coronary or cervicocerebral circulation. Similar documents have been published for the coronary arteries [2] and the cervicocerebral circulation (see the Practice Guideline for the Performance of Diagnostic Cervicocerebral Angiography in Adults). Patients will benefit when appropriate selection criteria, pre- and post-procedure care, and monitoring are used. In all cases, the type of care provided should be directed by the operating physician, and treatment decisions should be made after individual consideration of each case. Variation from this guideline may be necessary and appropriate depending on the specific clinical circumstances.

## II. DEFINITIONS

For the purposes of this guideline, the following definitions are used:

**Diagnostic arteriogram** - a procedure involving percutaneous passage of a needle and/or catheter into an artery followed by injection of contrast material and imaging of the vascular distribution in question using serial film or digital imaging systems.

**Moderate or "conscious" sedation** - defined by the ACR Practice Guideline for Adult Sedation/Analgesia and the ACR Practice Guideline for Pediatric Sedation/Analgesia.

**Indicator** - a specific, quantifiable, and objective measure of quality. For example, when measuring the safety of a procedure as one aspect of quality, specific complications would be the indicators.

**Threshold** - the specific level of an indicator that would cause a review to be performed. For example, if the incidence of contrast media associated nephrotoxicity is used as an indicator of the quality of arteriography, exceeding a defined threshold, in this case 0.2%, should trigger a review of the individual or department to determine causes and to implement changes to lower the incidence.

**Success** - the completion of the arteriogram, including gaining access to the artery, obtaining a set of complete images together with other pertinent data (e.g., hemodynamics) sufficient to support further medical decision making, and the timely and accurate interpretation of the findings. A successful arteriogram does not necessarily imply that the procedure is complication free; one may have a successful arteriogram with or without complications. For example, in the instance of atherosclerotic vascular disease, a complete set of images in the lower extremity is defined as imaging that includes the vessels into the foot.

## III. ALTERNATIVE DIAGNOSTIC STUDIES, INDICATIONS AND CONTRAINDICATIONS

The lists below represent a summary of most of the appropriate indications for diagnostic arteriography. The threshold for the department and for each individual is 95% (i.e., 95% of procedures should be performed for one of the indications listed below). In addition, for the diagnostic arteriogram to be considered as appropriate, its performance should have the potential for enhancing further medical decision making in the clinical care of the patient.

A. As there are continual advances in medical diagnostic, therapeutic, and imaging technology, many of the indications listed below may also be investigated by alternative diagnostic technologies, including, but not limited to:

1. Ultrasound.
2. Magnetic resonance imaging (including angiography).
3. Computed Tomography (CT) (including helical CT and CT angiography).
4. Nuclear medicine including positron-emission tomography (PET).
5. Functional and fusion imaging.

It is incumbent upon the physician to determine the relative benefit and risk of diagnostic arteriography compared with the alternative diagnostic techniques for each patient prior to suggesting and/or performing any diagnostic study, and diagnostic arteriography in particular.

Some of these alternative tests may be used as an adjunct to diagnostic arteriography or an alternative. The use of serial tests in medical decision-making is well recognized and, in appropriate clinical circumstances, is justified. Such appropriate use of serial testing should be documented in the medical record.

## B. Indications

1. Pulmonary Arteriography [3-9]
  - a. Suspected acute pulmonary embolus, in particular when other diagnostic tests are inconclusive or discordant with clinical findings.
    - i. High-probability ventilation-perfusion scan when there is a contraindication to anticoagulation.
    - ii. Indeterminate ventilation-perfusion scan in a patient suspected of having pulmonary embolus.
    - iii. Low-probability ventilation-perfusion scan in a patient with a high clinical suspicion of pulmonary embolus.
    - iv. Ventilation-perfusion scan cannot be performed.
    - v. Helical (spiral) CT is inconclusive or cannot be performed.
  - b. Suspected chronic pulmonary embolus.
  - c. Other suspected pulmonary abnormalities, such as vasculitis, congenital and acquired anomalies, tumor encasement, and vascular malformations.
  - d. Prior to pulmonary artery interventions.
2. Spinal Arteriography [10]
  - a. Spine and spinal cord tumors.
  - b. Vascular malformations.
  - c. Spinal trauma.
  - d. Preoperative evaluation prior to aortic or spinal surgery.
  - e. Prior to interventional procedures.
3. Bronchial Arteriography [7,9,11]
  - a. Hemoptysis.
  - b. Suspected congenital cardiopulmonary anomalies.
  - c. Assessment of distal pulmonary artery circulation (through collaterals) in patients who are potential candidates for pulmonary thromboendarterectomy.
  - d. Prior to interventional procedures.
4. Aortography [11,12]
  - a. Intrinsic abnormalities, including transection, dissection, aneurysm, occlusive disease, aortitis, and congenital anomaly.
  - b. Evaluation of aorta and its branches prior to selective studies.
  - c. Prior to interventional procedures.
5. Abdominal Visceral Arteriography [13-19]
  - a. Acute or chronic gastrointestinal hemorrhage.
  - b. Blunt or penetrating abdominal trauma.
    - c. Intra-abdominal tumors.
    - d. Acute or chronic intestinal ischemia.
    - e. Portal hypertension and varices.
    - f. Primary vascular abnormalities, including aneurysms, vascular malformations, occlusive disease, or vasculitis.
    - g. Pre- and postoperative evaluation of portosystemic shunts.
    - h. Preoperative evaluation.
    - i. Pre- and postoperative evaluation of organ transplantation.
    - j. Preliminary procedure for intra-arterial computed tomographic portography.
    - k. Prior to interventional procedures.
6. Renal Arteriography [20-21]
  - a. Renovascular occlusive disease (e.g., for hypertension or progressive renal insufficiency).
  - b. Renal vascular trauma.
  - c. Primary vascular abnormalities, including aneurysms, vascular malformations, and vasculitis.
  - d. Renal tumors.
  - e. Hematuria of unknown cause.
  - f. Pre- and postoperative evaluation for renal transplantation.
  - g. Prior to interventional procedures.
7. Pelvic Arteriography [13,22]
  - a. Atherosclerotic aortoiliac disease.
  - b. Gastrointestinal or genitourinary bleeding.
  - c. Trauma.
  - d. Primary vascular abnormalities, including aneurysms, vascular malformations, and vasculitis.
  - e. Male impotence caused by arterial occlusive disease.
  - f. Pelvic tumors.
  - g. Prior to interventional procedures.
8. Extremity Arteriography [23-29]
  - a. Atherosclerotic vascular disease, including aneurysms, emboli, occlusive disease, and thrombosis.
  - b. Vascular trauma.
  - c. Preoperative planning and postoperative evaluation for reconstructive surgery.
  - d. Evaluation of surgical bypass grafts and dialysis grafts and fistulas.
  - e. Other primary vascular abnormalities, including vascular malformations, vasculitis, entrapment syndrome, thoracic outlet syndrome, etc.
  - f. Tumors.
  - g. Prior to interventional procedures.

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

### C. Contraindications

There are no absolute contraindications to diagnostic arteriography. Relative contraindications include:

1. Severe hypertension.
2. Uncorrectable coagulopathy.
3. Clinically significant sensitivity to iodinated contrast material.
4. Renal insufficiency.
5. Congestive heart failure.
6. Certain connective tissue disorders (reported complications at the puncture site).

Patient management should address these relative contraindications prior to the procedure. Every effort should be made to correct or control these clinical situations before the procedure, if feasible.

## IV. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

### A. Physician

Image-based diagnosis and treatment planning require integrating the angiographic findings within the context of 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 arteriography prior to the procedure to plan and perform it safely and effectively.

The physician performing a diagnostic arteriogram must fully appreciate the benefits, alternatives, and risks of the procedure. He/she must have a thorough understanding of vascular anatomy (including congenital and developmental variants and common collateral pathways), angiographic equipment, radiation safety considerations, and physiologic monitoring equipment and have access to an adequate supply of catheters, guidewires, and personnel to perform the procedure safely.

Diagnostic arteriography examinations must be performed under the supervision of and interpreted by a physician who has the following qualifications pertinent to the scope of services to be provided and the specific privileges sought:

1. Certification in Radiology or Diagnostic Radiology by the American Board of Radiology (ABR), American Osteopathic Board of Radiology, the Royal College of Physicians and Surgeons of Canada, or Le College des Medecins du Quebec and has performed 50 peripheral,

visceral, or neurodiagnostic arteriograms as primary operator.

or

2. Successful completion of an Accreditation Council for Graduate Medical Education (ACGME) approved radiology residency training program or an American Osteopathic Association (AOA) approved residency program and/or interventional/vascular radiology fellowship, and must have a minimum of 6 months training on a service that is primarily responsible for the performance of percutaneous peripheral, visceral, and neurodiagnostic arteriography and vascular/interventional radiology. Documented formal training in the performance of invasive catheter angiographic procedures must be included. During this training, the physician should have performed 50 peripheral, visceral, or neurodiagnostic arteriographic procedures as the primary operator, and these cases must be documented so that the director of the training program can certify that the physician is proficient in the performance of the procedures, with acceptable success and complication rates within the quality assurance threshold rates laid out in this guideline [30].

or

3. Successful completion of an ACGME approved nonradiology residency or fellowship training and must have a minimum of 6 months of training on a service that is primarily responsible for the performance of percutaneous peripheral, visceral, or neurodiagnostic arteriography and vascular/interventional radiology. Documented formal training in the performance of invasive catheter arteriographic procedures must be included. During this training the physician should have performed 50 peripheral, visceral, or neurodiagnostic arteriography procedures as the primary operator and these cases must be documented so the director of the training program can certify that the physician is proficient in the performance of the procedures, with acceptable success and complication rates within the quality assurance threshold rates laid out in this guideline [30].

and

4. Substantiation in writing by the director of interventional radiology or the chief of the department of the institution in which the physician will be providing these services that the physician is familiar with all of the following:
  - a. Indications and contraindications for the procedure.
  - b. Preprocedural assessment and intraprocedural monitoring of the patient.

- c. Pharmacology of moderate sedation medications and recognition and treatment of complications and reactions associated with them.
- d. Fluoroscopic and radiographic equipment, mechanical injectors, rapid film changers, digital subtraction, and other electronic imaging systems.
- e. Principles of radiation protection, the hazards of radiation exposure both to patients and radiologic personnel, and monitoring requirements.
- f. Pharmacology of contrast agents and recognition and treatment of adverse reactions to them.
- g. Percutaneous needle and catheter introduction techniques.
- h. Technical aspects of performing the procedure, including the use of alternative catheter and guide-wire systems, selective angiographic methods, appropriate injection rates and volumes of contrast media, and filming sequences.
- i. Recognition of periprocedural complications and knowledge of treatment options for these complications (e.g., stenting, embolization, thrombolysis, suction embolotomy, surgery).
- j. Anatomy, physiology, and pathophysiology of peripheral and visceral arterial vasculature.
- k. Interpretation of peripheral, pulmonary, and visceral arteriographic studies.
- l. Postprocedural patient management, especially recognition and initial management of complications.

#### Maintenance of Competence

Physicians must perform a sufficient number of diagnostic arteriographic procedures to maintain their skills, with acceptable success and complication rates as laid out in this guideline. Continued competence should depend on participation in a quality improvement program that monitors these rates. Appropriate attendance at postgraduate courses that provide continuing education on diagnostic advances, newer techniques, and equipment is necessary.

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 ACR considers

certification and continuing education 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 recommends that the individual be certified in the appropriate subfield(s) by the American Board of Radiology (ABR) or for MRI, by the American Board of Medical Physics (ABMP) in magnetic resonance imaging physics.

The appropriate subfields of medical physics for this guideline are Radiological Physics and Diagnostic Radiological Physics. The continuing education of a Qualified Medical Physicist should be in accordance with the [ACR Practice Guideline for Continuing Medical Education \(CME\)](#), 2006 (Res. 16g)

#### C. Radiologist Assistant

A 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. 2006 (Res. 34)

#### D. Radiologic Technologist

The technologist, together with the physician and nursing personnel, should have responsibility for patient comfort and safety. The technologist should be able to prepare and position<sup>1</sup> the patient for the arteriographic procedure and, together with the nurse, monitor the patient during the examination. The technologist should obtain the imaging data in a manner prescribed by the supervising physician.

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<sup>1</sup>The American College of Radiology approves of the practice of certified and/or licensed radiologic technologists performing fluoroscopy only as a positioning or localizing procedure and then only if monitored by a supervising physician who is personally and immediately available, and the positioning or localizing procedure must have prior written approval by the medical director of the radiology department/service and there be written authority, policy and procedures for designating radiologic technologists who perform such procedures. 1987, 1997 (Res. 1-E)

The technologist should also perform the regular quality control testing of the equipment under supervision of the physicist.

The technologist should be certified by the American Registry of Radiologic Technologists (ARRT) or have an unrestricted state license with documented training and experience in the diagnostic arteriography procedure.

#### E. Nursing Services

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

### V. SPECIFICATIONS OF THE EXAMINATION

Several technical requirements are necessary to ensure safe and successful diagnostic arteriograms. These include adequate arteriographic equipment, institutional facilities, physiologic monitoring equipment (including intravascular pressure measurement systems), and personnel.

#### A. Arteriographic Equipment and Facilities

The following are considered the minimal arteriographic equipment required for obtaining diagnostic arteriograms. In planning arteriographic facilities, equipment and facilities more advanced than those outlined below may be desired to produce higher-quality studies with reduced risk and time of study. In general, the facility should include at a minimum:

1. A high-resolution image intensifier and television chain with standard arteriographic filming capabilities including serial 14-inch film changers and/or large-format image intensifiers (14-inch or greater) with minimum 1,024-image matrix. Long-leg film changers are sufficient for lower-extremity arteriography when digital subtraction arteriographic systems or 14-inch serial film changers are available for supplemental views. Digital angiographic systems are recommended, as they allow for reduced volumes of contrast material and reduced examination times. Images 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. The use of cineradiography or small-field mobile image intensifiers is inappropriate for the routine recording of noncoronary angiography, because these methods have an

unacceptably high patient and operator radiation dose.

2. Adequate angiographic supplies such as catheters, guidewires, needles, and introducer sheaths.
3. An angiographic injector capable of varying injection volumes and rates, with appropriate safety mechanisms to prevent overinjection.
4. An angiography suite that is large enough to allow easy transfer of the patient from the bed to the table and allow room for the procedure table, monitoring equipment, and other hardware such as intravenous pumps, respirators, anesthesia equipment, and oxygen tanks. 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 observation of patients after the procedure. This might be within the radiology department, in a short-stay unit, or in a routine nursing unit. At this location there should be personnel to provide care as outlined in the Patient Care Section below. There should also be immediate access to emergency resuscitation equipment.

#### B. Physiologic Monitoring and Resuscitation Equipment

1. Sufficient equipment should be present in the arteriography suite to allow for monitoring the patient's heart rate, cardiac rhythm, and blood pressure. If the patient is to receive moderate sedation, a pulse oximeter should be available (see the ACR Practice Guideline for Adult Sedation/Analgesia).
2. There should be ready access to emergency resuscitation equipment and drugs, to include the following: an emergency defibrillator oxygen supply and appropriate tubing and delivery systems, suction equipment, tubes for endotracheal intubation, laryngoscope, ventilation bag-mask-valve apparatus, and central venous line sets. Drugs for treating cardiopulmonary arrest, contrast reaction, vasovagal reactions, narcotic or benzodiazepine overdose, bradycardia, and ventricular arrhythmias should also be readily available.
3. If peripheral or pulmonary arteriography is regularly performed, physiologic pressure monitors should be available for determining intra-arterial pressure gradients as needed.

### C. Support Personnel

1. Radiologic technologists properly trained in the use of the arteriographic equipment should assist in performing and imaging the procedure. They should be able to demonstrate appropriate knowledge of patient positioning, arteriographic image recording, angiographic contrast injectors, angiographic supplies, and the physiologic monitoring equipment. Certification as a vascular and interventional radiologic technologist is one measure of appropriate training. Technologists should be trained in basic 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 nurse or other appropriately trained individual should monitor the patient as his/her primary responsibility. This person should maintain a record of the patient's vital signs, time and dose of medications given, and other pertinent information. Nursing personnel should be qualified to administer moderate sedation (see the ACR Practice Guideline for Adult Sedation/Analgesia).

For a more comprehensive description of the arteriographic facility, see: Cardella JF, Casarella WJ, DeWeese JA, et al. Optimal resources for the examination and endovascular treatment of the peripheral and visceral vascular systems. AHA Intercouncil report on peripheral and visceral angiographic and interventional laboratories in *Circulation* 1994; 89:1481-1493 [49].

### D. Surgical Support

Although complications of diagnostic arteriography only rarely require urgent surgery, these 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 free-standing center, detailed protocols for the rapid transport or admission of patient to an acute-care hospital should be formalized in writing.

### E. Patient Care

The written or electronic request for a diagnostic arteriography examination should provide sufficient information to demonstrate the medical necessity of the examination and allow for the proper performance and interpretation of the examination.

Documentation that satisfies medical necessity includes 1) signs and symptoms and/or 2) relevant history (including known diagnoses). The provision of 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 state scope of practice requirements. 2006 (Res. 35)

#### 1. Preprocedure care

The indications for elective arteriographic studies should be documented as described below. 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.

- a. Clinically significant history, including indications for the procedure.
- b. Clinically significant physical examination, including an awareness of clinical or medical conditions that may necessitate specific care. For most patients with chronic lower-extremity atherosclerotic disease, ankle/brachial systolic pressure ratios should be measured prior to arteriography. However, there are instances, such as in patients with advanced multilevel disease, when ankle/brachial systolic pressure ratios are of less value than objective physical findings. In selected cases, measurement of segmental pressures or pulse-volume recordings may help define the level of disease and assist in planning the arteriographic approach.
- c. Laboratory evaluation may be indicated, including measurement of hemoglobin, hematocrit, creatinine, electrolytes, and coagulation parameters.

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

#### 2. Procedural care

- a. Adherence to the JCAHO Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™ is required for procedures in non-operating room settings including bedside procedures. "Time out" must be conducted in the

location where the procedure will be done, just before starting the procedure and must:

- Involve the entire operative team.
- Use active communication.
- Be briefly documented, such as in a checklist, and
- At the least, include:
  - Correct patient identity.
  - Correct side and site.
  - Agreement on the procedure to be done.
  - Correct patient position.
  - Availability of correct implants and any special equipment or special requirements.

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

- b. All patients should have cardiac monitoring continuously during the procedure, with intermittent blood pressure monitoring. A record of vital signs should be maintained.
- c. All patients should have intravenous access for the administration of fluids and medications as needed.
- d. If the patient is to receive moderate sedation, pulse oximetry should be used. A registered nurse or other appropriately trained personnel should be present, and his/her primary responsibility should be to monitor the patient. A record should be kept of medication doses and times of administration.
- e. In certain circumstances, intra-arterial pressure measurements are very helpful in the assessment of peripheral vascular disease, in pulmonary arteriography, and in other diagnostic vascular procedures. Their use is encouraged when indicated.
- f. A physician should be available during the immediate postprocedure period to ensure that there is adequate hemostasis at the puncture site and that the patient is stable prior to transfer to the postprocedure care area.

### 3. Postprocedure care

- a. A procedure note should be written in the patient’s chart summarizing the major findings of the study and any immediate complications. This note may be brief if an official interpretation<sup>2</sup> is available within a

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<sup>2</sup>The ACR Medical Legal Committee defines official interpretation as that written report (and any supplements or amendments thereto) that attach to the patient’s permanent record. In healthcare facilities with a privilege delineation

few hours. The immediate note should include at a minimum: indications, operative procedure and imaging findings, date and time, operator(s), complications, medications and/or contrast used, and conclusions. However, if the official interpretation is not likely to be on the chart the same day, a more detailed summary of the study should be written in the chart at the conclusion of the procedure. 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, skilled nurses or other appropriately trained personnel 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 overnight care.
- e. The initial ambulation of the patient must be supervised. Vascular perfusion, puncture-site stability, and independent patient function and mobility must be ensured.
- f. When the treatment or vascular access requires manipulation in the ascending or transverse thoracic aorta or brachiocephalic vessels, neurologic status should be assessed periodically.
- g. The operating physician or a qualified designate should evaluate the patient after the procedure, and these findings should be summarized in a progress note. If moderate sedation was administered prior to and during the procedure, recovery from moderate sedation must be documented. The physician or 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 must be individualized. Diagnostic arteriography can be performed on many patients with a short period of postprocedure observation (less than 8 hours) prior to

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system, such a written report is prepared only by a qualified physician who has been granted specific delineated clinical privileges for that purpose by the facility’s governing body upon the recommendation of the medical staff.

discharge to home; others require overnight care. Short-term observation should only be considered when all of the following conditions can be met:

1. Patients should be capable of independent ambulation prior to the procedure and have demonstrated stable independent ambulation after the procedure. Alternatively, non-ambulatory patients should have adequate assistance after discharge to provide care as needed.
2. Mental status should be intact, with the patient capable of following instructions and detecting changes in symptomatology. Alternatively, patients with impaired mental 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, neurologic deficit, decreased urinary output, pain and discoloration distal to the puncture site) and how to obtain medical assistance in the event of such complications.
4. A responsible adult is provided with the information regarding recognition of potential complications and be available to transport the patient and be in attendance during the initial night after discharge.
5. The patient should be free of concurrent serious medical illness that might contribute to a significantly increased risk of complication.
6. The patient must have recovered from the effects of the sedation to a level as defined in the ACR Practice Guideline for Adult Sedation/Analgesia.

#### G. Relative Contraindications to Short-Term Observation

Several factors must be considered when determining the length of postprocedure skilled nursing care. 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 overnight admission.

1. Patients with poorly controlled hypertension, in whom there appears to be increased risk of hematoma formation, may benefit from overnight 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 should be hospitalized until stable.
4. Insulin-dependent diabetics who have labile serum glucose levels in the periprocedure period should be hospitalized until stable.
5. Complication occurring during or after arteriography, including large hematoma, anuria, persistent nausea, and vomiting, should prompt observation until symptoms resolve.
6. Patients who exhibit hemodynamic instability or significant arrhythmia during or after the procedure should be hospitalized until stable.
7. Travel time to the hospital or to another acute care facility should be less than one hour 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 decision in each case must be made by the operating physician and the referring physician after review of all pertinent data.

## VI. DOCUMENTATION

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

## VII. RADIATION SAFETY IN IMAGING

Radiologists, 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 is the concept "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 or manual techniques should be used to moderate the exposure while maintaining the necessary diagnostic image quality. Patient radiation doses should be periodically measured by a medical physicist in accordance with the appropriate ACR Technical Standard, 2006 (Res. 17)

## **VIII. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION CONCERNS**

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

These data should be utilized in conjunction with the thresholds described in Section VIII below to assess diagnostic arteriography procedural efficacy and complication rates and, as defined in that section to trigger institutional review when those thresholds are exceeded.

## **IX. QUALITY IMPROVEMENT**

These guidelines are written to be used in quality improvement (QI) programs to assess diagnostic arteriography. The most important processes of care are patient selection, performance of the procedure, and monitoring the patient. The major outcome measures for diagnostic arteriography include complete imaging of the pathology, success rates, and complication rates. Outcome measures are assigned threshold levels.

While practicing physicians should strive to achieve perfect outcomes (e.g., 100% success, 0% complications), in practice all physicians will fall short of this ideal to a variable extent. Thus, in addition to QI case reviews customarily conducted after individual procedural failures or complications, outcome measure thresholds should be used to assess diagnostic arteriography in ongoing quality improvement programs. For the purpose of these guidelines, a threshold is a specific level of an indicator which, when reached or crossed, should prompt a review of departmental policies and procedures. Procedure thresholds or overall thresholds reference a group of outcome measures for a procedure, e.g., major complications for diagnostic arteriography. Individual complications may also be associated with complication-specific thresholds, e.g., fever or hemorrhage. When outcome measures such as success rates or indications fall below a minimum threshold, or when complication rates exceed a maximum threshold, a departmental 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 department is urged to alter the

thresholds as needed to higher or lower values to meet its own quality improvement program needs.

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

### **A. Measures of Success**

The rate for successful completion of a diagnostic arteriogram is 95%.

### **B. Complication Rates and Thresholds**

Complications from diagnostic arteriography are uncommon. Digital subtraction angiography may allow reduced contrast load and reduced time of study, and it may result in lower incidence of complications [31]. Arteriographic complications may be divided into three groups: puncture site, systemic, and catheter induced.

By far, the most frequent puncture site complication is hematoma. While the incidence of minor hematomas is quite variable and may be as high as 10%, major hematomas are unusual [31-33]. A major hematoma, defined as one requiring transfusion, surgical evacuation, or delay in discharge, occurs in 0.5% of femoral punctures and 1.7% of axillary punctures [34]. Other puncture-site problems, including dissection, thrombosis, pseudoaneurysm, or arteriovenous fistula, are also rare, occurring in less than 1% of femoral punctures. There is some variation in the number of complications, depending on the puncture site chosen [33]. For example, a small hematoma at an axillary puncture site may cause neural injury and require surgical evacuation earlier than a similar femoral hematoma. Clinically significant infection at the puncture site with bacteremia is very rare, occurring most often in repeated punctures of the same artery over a short period of time or with long-term sheath access, as in interventional procedures. Therefore antibiotic prophylaxis is not generally recommended for diagnostic arteriography [35,36].

Systemic complications occur in less than 5% of cases. Among the most common are nausea, vomiting, and vasovagal syncope. Minor nausea, without associated vomiting, occurs more frequently but usually with mild symptoms that pass in a few moments. This generally is not listed as a complication, as the episode is self-limited, is not associated with changes in pulse or blood pressure, and does not require specific therapy. Nausea may also be

a symptom of vasovagal hypotension, which is usually characterized by lightheadedness, bradycardia, diaphoresis, and hypotension. Idiosyncratic (allergic) contrast reactions, which include urticaria, periorbital edema, wheezing, etc., complicate less than 3% of arteriographic procedures [37]. Most reactions are mild: more than half require no therapy, and less than 1% necessitate hospitalization. There are fewer reactions with lower-osmolality agents particularly for patients with a history of a previous contrast reaction or more than one other major risk factor [38-41]. See the ACR Practice Guideline for the Use of Intravascular Contrast Media [42].

The incidence of contrast-media-associated nephrotoxicity is difficult to determine from a review of the literature, in part due to the varying definitions that have been used [43-46]. It is generally agreed that pre-existing renal insufficiency is a risk factor for its development. Other possible predisposing risk factors include insulin-dependent diabetes, possibly dehydration, and large contrast volume. Digital subtraction arteriographic systems have allowed lower contrast doses and, as a result, may lower the risk of renal injury [31]. Low-osmolar contrast medium has a small but definite benefit over high-osmolar contrast media for patients with pre-existing azotemia [47]. Preprocedural hydration may have a protective effect in high-risk patients and some newer drugs may also have a role in protection from contrast-media-associated nephrotoxicity.

For the purposes of this guideline, contrast-media-associated nephrotoxicity as a major complication will be clinically defined as an elevation of serum creatinine requiring care that unexpectedly delays discharge or results in unexpected admission, readmission, or permanent impairment of renal function. This definition focuses on the outcome of renal impairment, which is the central issue in any monitoring program. The threshold chosen is 0.2% and is based on consensus and a review of the pertinent literature. It is very dependent on the patient population, and practitioners are encouraged to modify this threshold to reflect the circumstances of their practice.

Complications related to catheter manipulation are the third group of complications in arteriography. These include subintimal passage of the guidewire or catheter and dissections or emboli caused by catheter manipulation or contrast injection. These have been reported to occur in 0.5% to 2.0% of cases, with the most recent series reporting a frequency of less than 0.5% [31,33,48,49]. In recent years, these types of complications have decreased in frequency, in part due to advances in guidewire and catheter technology.

Other complications can be stratified on the basis of outcome. Major complications may result in admission to a hospital for therapy (for outpatient procedures), an unplanned increase in the level of care, resulting in prolonged hospitalization, permanent adverse sequelae, or death. Minor complications result in no sequelae; they may require nominal therapy or a short hospital stay for observation (generally overnight) (see Appendix A). The complication rates and thresholds listed below refer to major complications unless otherwise noted. Any death within 24 hours of the procedure or a puncture-site infection should be reviewed as part of the institution-wide quality improvement program.

Indicators and thresholds for complications in diagnostic arteriography are listed in Table 1. The thresholds listed were determined by consensus after review of the pertinent literature. The thresholds are recommendations only and may require alteration to meet the needs of each institution after consideration of the patient population, procedure mix, and the skills of the physicians involved. The departmental indicators should be used for all procedures performed within the department, regardless of the physician operator. Each physician should be appropriately monitored. The actions taken when the thresholds are exceeded should be set by each department and stated in the department's quality improvement program summary.

**TABLE 1: Indicators and Thresholds for Complications in Diagnostic Arteriography (31-48)**

<u>Department Indicators</u>	<u>Reported Rates</u>	<u>Major Adverse Event Threshold</u>
<b>Puncture site complications</b>		
Hematoma (requiring transfusion, surgery, or delayed discharge)	0.0%-0.68%	0.5%
Occlusion	0.0%-0.76%	0.2%
Pseudoaneurysm/arterio-venous fistula	0.04%-0.2%	0.2%
<b>Catheter-induced complications (other than puncture site)</b>		
Distal emboli	0.0%-0.10%	0.5%
Arterial dissection/subintimal passage	0.43%	0.5%
Subintimal injection of contrast	0.0%-0.44%	0.5%
Major contrast reactions	0.0%-3.58%	0.5%
Contrast-media-associated nephrotoxicity	0.2%-1.4%	0.2%

Overall procedure threshold for major complication 1.0%  
 The overall procedure threshold for major complications is determined by the following formula:

$$\frac{\text{\# of pts with major complications undergoing diagnostic arteriography only}}{\text{\# of pts undergoing diagnostic arteriography only}} \times 100$$

Published rates for individual types of complications are highly dependent on patient selection and are based on series comprising several hundred patients, which is a volume larger than most individual practitioners are likely to treat. It is also recognized that a single complication can cause a rate to cross above a complication-specific threshold when the complication occurs in a small volume of patients (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.

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## 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.