



Standards for the Performance of Diagnostic Angiography

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The standards of the Canadian Association of Radiologists (CAR) are not rules, but are guidelines that attempt to define principles of practice that should generally produce radiological care. The physician and medical high-quality physicist may modify an existing standard as determined by the individual patient and available resources. Adherence to CAR standards will not assure a successful outcome in every situation. The standards should not be deemed inclusive of all proper methods of care or exclusive of other methods of care reasonably directed to obtaining the same results. The standards are not intended to establish a legal standard of care or conduct, and deviation from a standard does not, in and of itself, indicate or imply that such medical practice is below an acceptable level of care. The ultimate judgment regarding the propriety of any specific procedure or course of conduct must be made by the physician and medical physicist in light of all circumstances presented by the individual situation.

I. INTRODUCTION

Diagnostic angiography is an established, safe, and accurate method of evaluating vascular disease. Angiography is considered the diagnostic standard by which the accuracy of other vascular imaging modalities should be judged. However, diagnostic angiography is an invasive procedure with a small but definite risk of complications. Due to the varying skill levels and training of physicians performing angiographic procedures, the potential exists for variation in success rates, complication rates, and diagnostic study quality. The indications for angiography have developed over time, and there may be considerable variation in practice. This standard was developed to provide a guide to practicing angiographers to ensure that patients undergo arteriography 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 adequate to answer the clinical questions that prompted them. The qualifications for physicians performing angiography have been previously published. This standard is intended to define both a minimal standard of care and the indications for angiography in vessels other than the coronary or cervicocerebral circulation. Patients will likely benefit when appropriate selection criteria, pre- and postprocedure 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 standard may be necessary and appropriate depending on the specific clinical circumstances.

II. DEFINITIONS

Diagnostic angiogram: For the purposes of this standard, a diagnostic angiogram is defined as 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.

Conscious sedation: For the purposes of this standard, conscious sedation is defined as a state of cortical depression in which the patient is calm, tranquil, and drowsy. The patient may even close his/her eyes but must be able to respond to a verbal command. Protective reflexes should be intact.

Indicator: For the purposes of this standard, an indicator is defined as 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: For the purposes of this standard, a threshold is 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 one measure of the quality (indicator) of angiography, 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.

III. INDICATIONS AND CONTRAINDICATIONS

In developing a set of indications for a diagnostic test, limitations and difficulties become apparent. Unusual clinical conditions often require exhaustive testing, and the rare manifestations of more common diseases

occasionally must be excluded. In addition, the patient population of a given hospital or geographic area may require testing for clinical problems not seen in other areas. Similarly, certain specialists may develop practices that skew their "typical" patient population with the result that requests for unusual tests become commonplace. All these variables must be considered in developing a list of indications for a diagnostic procedure. A set of guidelines helps to focus on the primary indications for a procedure or study and thereby helps avoid unnecessary testing. However, the physicians caring for the patient and 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 records. Table 1 represents a summary of the 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 in Table 1). These indications are discussed in greater detail below.

All imaging facilities should have policies and procedures to reasonably attempt to identify pregnant patients prior to the performance of any diagnostic examination involving ionizing radiation. If the patient is known to be pregnant, the potential radiation risks to the fetus and clinical benefits of the procedure should be considered and those risks discussed with the patient and the referring physician before proceeding with the study.

A. Pulmonary and Bronchial Angiography

Pulmonary angiography remains the gold standard for the diagnosis of pulmonary embolus. Properly utilized, pulmonary angiography and ventilation-perfusion scanning have complementary roles in making the diagnosis of pulmonary embolus. In most circumstances, when there is no contraindication to anticoagulation, a high-probability ventilation-perfusion scan is sufficient to justify treatment of pulmonary embolus. Angiography may be used to confirm the diagnosis in a patient with a high-probability ventilation-perfusion scan, when anticoagulation is contraindicated. A low-probability scan is not sufficient to exclude the diagnosis when there is a high clinical suspicion of embolus. In this circumstance, an angiogram is necessary to exclude the diagnosis. Angiography is generally not necessary when there is a normal perfusion scan. Indeterminate scans cannot confirm or exclude the diagnosis of pulmonary embolus; angiography may be necessary to resolve the question. Whenever possible, a ventilation-perfusion scan should be obtained before pulmonary angiography to exclude those patients who do not require further study. In addition, the scan reveals the regions of abnormal perfusion, allowing a more tailored angiography examination. It may not be possible to obtain a ventilation-perfusion scan in certain circumstances, particularly when the patient is hemodynamically unstable, and angiography should not be delayed in such an emergency situation. In limited situations, an alternative to pulmonary angiography in patients who have indeterminate VQ scans is spiral computed tomography (CT) of the central pulmonary arteries.

Pulmonary angiography is also indicated in the diagnosis of chronic emboli and is required in the preoperative planning for pulmonary thromboembolectomy. Unusual indications include the evaluation of pulmonary arteriovenous malformations, congenital anomalies, preoperative evaluation of pulmonary malignancies, and for the diagnosis of vasculitis and other primary abnormalities of the vessels.

Bronchial angiography is indicated when severe hemoptysis occurs, the bleeding is not self-limited, and embolization may be required. Bronchial angiography is often preceded by bronchoscopy to localize the portion of the lung that is responsible for the bleeding. It may also be necessary for the complete evaluation of congenital anomalies of the pulmonary vasculature. In addition, bronchial angiography is used in screening patients for pulmonary thromboendarterectomy.

B. Spinal Angiography

The most common indications for spinal angiography are evaluation of vascular malformations and less frequently for evaluation of primary and metastatic tumors. Other indications include preoperative evaluation prior to aortic or spinal surgery and after spinal trauma (see Table 1). A follow-up study is often needed to evaluate the results of therapeutic procedures.

C. Thoracic and Abdominal Aortography

The aorta may be studied for intrinsic disease or as a preliminary study to evaluate the origins of branch vessels. The decision to perform aortography prior to a selective study of the aortic branches depends on the pathologic process to be studied as well as the likelihood of coincident atherosclerosis.

In the thoracic aorta, the most common intrinsic abnormalities evaluated are traumatic transection, dissection, and aneurysm. In the case of dissection, the diagnosis may be made by noninvasive imaging studies, but angiography is often required for surgical planning. Less frequently, thoracic aortography is needed to diagnose congenital anomalies, vasculitis, and vascular manifestations of systemic diseases. Thoracic aortography may be required in the preoperative planning of endovascular or surgical bypass procedures.

The most common reasons to study the abdominal aorta are aneurysmal and occlusive vascular disease. While noninvasive imaging has greatly reduced the need for aortography, detailed evaluation of aortic branches, their location in relation to abnormal segments, and the complete extent of the abnormalities still often require angiography.

D. Abdominal Visceral Angiography

Study of the abdominal visceral organs remains one of the primary indications for angiography. These studies can be divided into evaluation for hemorrhage and tumors, preoperative planning, and diagnosis of primary vascular abnormalities.

Although fewer cases of gastrointestinal hemorrhage are seen primarily by the angiographer secondary to the increased use of endoscopy and nuclear imaging, gastrointestinal hemorrhage, either acute or chronic, remains one of the most common indications for emergency angiography. Angiography provides an accurate means of localizing acute bleeding and is required prior to any transcatheter therapy to stop the bleeding. It may be the only means of diagnosing vascular abnormalities that cause chronic or recurrent hemorrhage. Radionuclide bleeding studies may be helpful in detecting active bleeding and may assist in directing arteriography. Tumors of the solid organs are most commonly imaged and staged by noninvasive imaging studies. Angiography's primary role is in the preoperative evaluation to determine resectability, vascularity, vessel anatomy, and the need for preoperative or chemotherapeutic embolization.

Diagnostic arterial portography is important in the diagnosis and grading of portal hypertension, the evaluation of varices, and the preoperative planning and postoperative evaluation of transjugular intrahepatic portosystemic shunt (TIPS) and surgically created portosystemic shunts. Chronic ischemia (abdominal angina) and acute mesenteric ischemia often require angiography for accurate diagnosis. Angiography is useful in the evaluation of blunt and penetrating abdominal trauma particularly in the planning of transcatheter or surgical intervention. Finally, angiography is used to diagnose a variety of primary vascular abnormalities, including vasculitis, aneurysms, and miscellaneous vascular pathology.

E. Renal Angiography

Renal angiography is commonly indicated for the evaluation of renovascular hypertension, renal insufficiency, trauma, and renal tumors and for the screening of renal transplant donors. Renal artery stenosis is most accurately diagnosed by angiography, which is required in preoperative planning for angioplasty or surgery. For studies performed for the evaluation of renal artery stenosis, aortography should be performed prior to selective renal angiography to evaluate for multiple renal arteries and to avoid vascular trauma in those patients with severe aortic and renal vascular disease. While renal tumors are usually diagnosed by other studies, angiography may be requested for preoperative embolization or surgical planning. Angiography also has a central role in evaluating patients with blunt or penetrating trauma. Less frequently, angiography is requested to diagnose vasculitis or to evaluate hematuria when previous workup has been negative.

F. Pelvic Angiography

Isolated pelvic angiography (i.e., evaluation of the pelvic organs and the branches of the hypogastric [internal iliac] arteries) is performed less frequently than abdominal studies. There is a degree of overlap with abdominal studies, and pelvic studies may be combined with abdominal visceral studies (e.g., in the evaluation of gastrointestinal or genitourinary bleeding). Benign and malignant tumors, trauma, arteriovenous malformations, uterine bleeding, and postpartum hemorrhage all may require angiographic evaluation and possibly embolotherapy. Male sexual dysfunction is another indication for angiography of the hypogastric vessels, as occlusive disease of the internal pudendal arteries is one cause of impotence. There is also overlap with the evaluation of the lower extremities for vascular disease, and pelvic angiography without a lower extremity study is occasionally indicated for the evaluation of atherosclerotic occlusive or aneurysmal disease.

G. Extremity Angiography

The indications for angiography of the upper and lower extremities fall into similar pathologic groups. These include atherosclerotic occlusive or aneurysmal disease, vascular trauma, entrapment syndromes, tumors, preoperative evaluation prior to reconstructive and plastic surgery, evaluation of prior vascular bypass grafts or arteriovenous grafts and fistulas, and the evaluation of vasculitis and other primary vascular abnormalities. To understand these disease processes, the entire vasculature of the affected extremity(ies) must be imaged. In the lower extremity, this includes the vessels down to the level of the foot. In the upper extremity, the entire extremity from the origin of the great vessels from the thoracic aorta should be imaged. Certain aspects of the diagnostic evaluation of upper- and lower-extremity vascular disease are different, and these are discussed below.

By far, the most common indication for angiography of the lower-extremity vessels in adults is the evaluation of the extent and severity of atherosclerotic vascular disease (25,26). This may include occlusive, thrombotic, aneurysmal, or embolic disease. The clinical manifestations of these processes include intermittent claudication, rest pain, skin ulceration, gangrene, and blue toe syndrome. In certain circumstances, such as acute ischemia, embolism, aneurysm, and trauma, angiography is often the first diagnostic test performed after obtaining the history and performing a physical examination. For symptoms of chronic occlusive disease, noninvasive testing may be indicated to confirm the diagnosis of vascular insufficiency and to determine the vessel segments involved. In most instances, ankle/brachial systolic pressure ratios should be obtained prior to performing lower-extremity angiography for the evaluation of chronic occlusive disease. These measurements may be obtained in the noninvasive laboratory or in the angiography suite immediately prior to the procedure. They serve to determine the severity of disease and provide a baseline for postprocedure follow-up as well as for the evaluation of suspected complications. In patients with mild to moderate claudication, pulse-volume recording both before and after exercise testing is often required to categorize the severity of the problem accurately. Further pre-angiography testing may be indicated, but the evaluation should be limited to those studies that will alter subsequent management decisions.

Upper-extremity angiography is commonly performed to evaluate the extent of atherosclerosis and the secondary effects of atherosclerosis, such as emboli. Other indications for upper-extremity angiography include extremity claudication, acute or chronic arterial trauma, thoracic outlet obstruction, certain vasculitides, and subclavian steal.

Finally, dysfunction of dialysis fistulas and grafts, which may be manifested by abnormal physical examination, low intra-access flow, high venous pressures, inadequate dialysis, or thrombosis, is an indication for angiography of the shunt itself, including the arterial inflow and venous outflow. There are no absolute contraindications to diagnostic angiography. Relative contraindications include hypotension, severe hypertension, coagulopathy, clinically significant iodinated contrast material sensitivity, renal insufficiency, and congestive heart failure. 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 requires 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 angiography prior to the procedure in order to plan and perform it safely and effectively.

The physician performing the diagnostic angiogram 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 safely perform the procedure.

Diagnostic angiography examinations must be performed under the supervision of and interpreted by a physician who has the following qualifications:

Physicians involved in the performance, supervision and interpretation of diagnostic angiography should be Diagnostic Radiologists and must have a Fellowship or Certification in Diagnostic Radiology with the Royal College of Physicians and Surgeons of Canada and/or the Collège des médecins du

Québec. Also acceptable are equivalent foreign Radiologist qualifications if the Radiologist is certified by a recognized certifying body and holds a valid provincial license.

As new imaging modalities and interventional techniques are developed additional clinical training, under supervision and with proper documentation, should be obtained before radiologists interpret or perform such examinations or procedures independently. Such additional training must meet with pertinent provincial/regional regulations. Continuing professional development must meet with the requirements of the Maintenance of Certification Program of the Royal College of Physicians and Surgeons of Canada.

B. Radiologic Technologist

The medical radiation technologist must have Canadian Association of Medical Radiation Technologists certification or be certified by an equivalent licensing body recognized by the CAMRT. Under the overall supervision of the radiologists, the technologist will have the responsibility for patient comfort and safety, for examination preparation and performance, and for image technical evaluation and quality and applicable quality assurance.

The training of technologists engaged in specialty activities shall meet with applicable and valid national and provincial specialty qualifications. Continued education of technologists is encouraged by the C.A.M.R.T. and should meet pertinent provincial regulations.

C. 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

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

A. Angiographic Equipment and Facilities

The following are considered the minimal angiographic equipment required for obtaining diagnostic arteriograms. In planning angiographic 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 angiographic filming capabilities including serial 14-inch film changers and/or large-format image intensifiers (14 inch or greater) with minimum 1024 image matrix. Longleg film changers are sufficient for lower-extremity angiography when digital subtraction angiographic 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.

3. 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.

4. 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, a short-stay unit, or in a routine nursing unit. At this location there should be personnel to provide care as outlined in Section V.E. below. There should be immediate access to emergency resuscitation equipment.

B. Physiologic Monitoring and Resuscitation Equipment

1. Sufficient equipment should be present in the angiography suite to allow for monitoring the patient's heart rate, cardiac rhythm, and blood pressure. If the patient is to receive conscious sedation, a pulse oximeter should be available.

2. There should be ready access to equipment and drugs for emergency resuscitation. The equipment should include an emergency defibrillator with paper recorder and quick-view capability, oxygen supply and appropriate tubing and delivery systems, suction equipment, tubes for endotracheal intubation, laryngoscope, ventilation bag-maskvalve 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 angiography 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 angiographic equipment should assist in performing and imaging the procedure. They should be able to demonstrate appropriate knowledge of patient positioning, angiographic image recording, angiographic contrast injectors, angiographic supplies, and the physiologic monitoring equipment. Technologists should be trained in basic cardiopulmonary resuscitation and in the function of the resuscitation equipment.

2. If the patient does not receive conscious sedation, one of the staff assisting the procedure should be assigned to periodically assess the patient's status. If the patient is to undergo conscious 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 conscious sedation.

D. Surgical Support

Although complications of diagnostic angiography 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 freestanding center, detailed protocols for the rapid transport or admission of patient to an acute-care hospital should be formalized in writing.

E. Patient Care

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. Informed consent is recommended for these procedures.
- d. Laboratory evaluation may be indicated, including measurement of hemoglobin, hematocrit, creatinine, electrolytes, and coagulation parameters.

2. Procedural care

- a. All patients should have cardiac monitoring continuously during the procedure, with intermittent blood pressure monitoring. A record of vital signs should be maintained.
- b. All patients should have intravenous access for the administration of fluids and medications as needed.
- c. If the patient is to receive conscious 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.
- d. In certain circumstances, intra-arterial pressure measurements are very helpful in the assessment of peripheral vascular disease, pulmonary arteriography, and other diagnostic vascular procedures. Their use is encouraged when indicated.
- e. A physician should be available during the immediate postprocedure period to ensure that there is adequate compression of the puncture site and that the patient is stable prior to transfer to the postprocedure care area.

3. Postprocedure care

- a. 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.
- b. 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.
- c. The patient should be monitored for urinary output, cardiac symptoms, pain, and other indicators of systemic complications that may necessitate overnight care.
- d. The initial ambulation of the patient must be supervised. Vascular perfusion, puncture-site stability, and independent patient function and mobility must be ensured.
- e. When the treatment or vascular access requires manipulation in the thoracic aorta or brachiocephalic vessels, neurologic status should be assessed periodically.
- f. 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 conscious sedation was administered prior to and during the procedure, complete recovery from conscious 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 angiography can be performed on many patients with a short period of postprocedure observation (less than 8 hours) prior to 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, nonambulatory 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, 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 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.

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

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

VII. QUALITY IMPROVEMENT

A. Success Rates and Thresholds

In most situations the angiographic study should be completed during one procedure. While this usually occurs, failure may be due to a number of causes, including limited vascular access, failure to understand the extent of the information required by the referring physician, error in interpretation discovered after the procedure has ended, poor patient condition and cooperation, and contrast material dose limit. The purpose of monitoring the success of arteriographic procedures is to improve the quality of the information obtained.

To perform a complete angiogram, there must be appropriate preprocedure evaluation and planning, with a clear understanding by the operating physician of the questions that need to be answered by the study. Once the procedure has been planned, a technically adequate diagnostic study is necessary, with proper catheter placement by the physician and appropriate physician supervision of contrast injection rate, filming technique, and patient positioning. Hemodynamic studies should be obtained when appropriate. To be considered successful, an angiogram should provide a complete and adequate evaluation of the clinical problem, be appropriately and permanently recorded on film, and be judged diagnostic by others with skill in interpreting arteriograms. The arteriogram should be followed by an electronic or printed report summarizing the findings of the study, its major technical aspects, and any immediate complications. The report should be available for review by the referring physician in a timely manner. The threshold for successful arteriograms for each physician is 95%, with 5% or fewer requiring repeat or further arteriographic study during another procedure.

B. Complication Rates and Thresholds

Complications from diagnostic arteriography are uncommon. Digital subtraction angiography may allow reduced contrast load, reduced time of study, and may result in lower incidence of complications. Angiographic 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. A major hematoma, defined as one requiring transfusion, surgical evacuation, or delay in discharge, occurs in 0.5% of femoral punctures to 1.7% of axillary punctures. 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. 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 angiography.

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 angiographic procedures. Most reactions are mild: more than one-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.

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. 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. Low-osmolar contrast medium has a small but definite benefit over high-osmolar contrast media for patients with pre-existing azotemia.

For the purposes of this standard, 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 angiography. 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%. 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 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 in Table 2 refer to major complications. 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 angiography are listed in Table 2. 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 individual 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.

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Table 1.

Indications for Diagnostic Angiography. Ninety five percent (95%) of angiographic procedures should be performed for one of the indications listed below.

Pulmonary Angiography

- o High-probability ventilation-perfusion scan when there is a contraindication to anticoagulation.
- o Indeterminate ventilation-perfusion scan in a patient suspected of having pulmonary embolus.
- o Low-probability ventilation-perfusion scan in a patient with a high clinical suspicion of pulmonary embolus.
- o Suspected chronic pulmonary embolus.
- o Other suspected pulmonary abnormalities, such as vasculitis, congenital and acquired anomalies, tumor encasement, and vascular malformations.
- o Suspected pulmonary embolus when a ventilation perfusion scan cannot be performed.
- o Prior to pulmonary embolus interventions. Spinal Arteriography
- o Spine and spinal cord tumors.
- o Vascular malformations.
- o Spinal trauma.
- o Preoperative evaluation prior to aortic or spinal surgery.

Bronchial Angiography

- o Hemoptysis.
- o Suspected congenital cardiopulmonary anomalies.
- o Assessment of distal pulmonary artery circulation (by shunting) in patients who are potential candidates for pulmonary thromboendarterectomy.

Aortography

- o Intrinsic abnormalities, including transection, dissection, aneurysm, occlusive disease, aortitis, and congenital abnormality.
- o Evaluation of aorta and its branches prior to selective studies.

Abdominal Visceral Angiography

- o Acute or chronic gastrointestinal hemorrhage.
- o Intra-abdominal benign or malignant tumors.
- o Blunt or penetrating solid organ trauma.
- o Portal hypertension and varices.
- o Chronic or acute intestinal ischemia.
- o Primary vascular abnormalities, including aneurysms, vascular malformations, occlusive disease, or vasculitis.
- o Pre- and postoperative evaluation of portosystemic shunts.
- o Preoperative evaluation.
- o Preliminary procedure for computed tomographic portography.
- o Prior to chemoembolization of tumor.

Renal Angiography

- o Renal tumors.
- o Renovascular occlusive disease.
- o Renal vascular trauma.
- o Primary vascular abnormalities, including aneurysms, vascular malformations, and vasculitis.
- o Hematuria of unknown cause.
- o Preoperative evaluation for solid organ transplantation.
- o Renal insufficiency.
- o Prior to embolization procedures.

Pelvic Angiography

- o Gastrointestinal or genitourinary bleeding.
- o Male impotence caused by arterial occlusive disease.
- o Atherosclerotic aortoiliac disease.
- o Primary vascular abnormalities, including aneurysms, vascular malformations, and vasculitis.
- o Prior to embolization procedures.

Extremity Angiography

- o Atherosclerotic vascular disease, including aneurysms, emboli, occlusive disease, and thrombosis.
- o Other primary vascular abnormalities, including vascular malformations, vasculitis, entrapment syndrome, thoracic outlet syndrome, etc.
- o Vascular trauma.
- o Tumors.
- o Preoperative planning and postoperative evaluation for reconstructive surgery.
- o Evaluation of surgical bypass grafts and dialysis grafts and fistulas.
- o Prior to interventional procedures.

Overall procedure threshold for major complications 1.0%

The overall procedure threshold for major complications is determined by the following formula:

of patients with complications undergoing diagnostic angiography only X100

of patients undergoing diagnostic angiography only

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.

Table 2: Thresholds for Major Complications in Diagnostic Angiography.

The department thresholds should be used when reviewing all the procedures for the department. The thresholds indicated below are ONLY for diagnostic peripheral arteriography studies in adults.

Thresholds for Major
Department Indicators Adverse Events
Puncture site complications
Hematoma (requiring transfusion,
surgery, or delayed discharge) 0.5%
Occlusion 0.2%
Pseudoaneurysm/arteriovenous
fistula 0.2%
Catheter-induced complications
(other than puncture site)
Distal emboli 0.5%
Arterial dissection/subintimal
passage 0.5%
Subintimal injection of contrast 0.5%
Major contrast reactions 0.5%
Contrast-media-associated nephrotoxicity 0.2%
Total puncture site or catheter-induced
complications <5.0%

Appendix A

Society of Cardiovascular and 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.