

# Quality Improvement Guidelines for Diagnostic Arteriography

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## PREAMBLE

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

## METHODOLOGY

SIR produces its Standards of Practice documents with use of the follow-

ing process: Standards documents of relevance and timeliness are conceptualized by the Standards of Practice Committee members. A recognized expert is identified to serve as the principal author for the document. Additional authors may be assigned depending on the magnitude of the project.

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

When the evidence of literature is weak, conflicting, or contradictory, consensus for the parameter is reached by a minimum of 12 Standards of Practice Committee members with use of a Modified Delphi Consensus Method (see Appendix 2). For the purpose of these documents, consensus is defined as 80% Delphi participant agreement on a value or parameter.

The draft document is critically reviewed by the Standards of Practice Committee members, in either a telephone conference call or face-to-face meeting. The finalized draft from the Committee is sent to the SIR membership for further input/criticism during a 30-day comment period. These comments are discussed by the Standards of Practice Committee and appropriate revisions are made to create the

finished standards document. Before its publication, the document is endorsed by the SIR Executive Council.

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 but definite risk of complications. Because of 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 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 arteriography have been previously published (1). This standard is intended to define both a minimal standard of care and the indications for arteriography in vessels other than the coronary or cervicocerebral circulation. A similar document has been published for the coronary arteries (2). Please also refer to the Standard for the Performance of Diagnostic Cervi-

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cocerebral Angiography in Adults (see ACR Standards at [www.acr.org](http://www.acr.org)). Patients will likely benefit when appropriate selection criteria, pre- and post-procedural 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.

## DEFINITIONS

*Diagnostic arteriogram:* For the purposes of this standard, a diagnostic arteriogram 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 with use of serial film or digital imaging systems.

*Indicator:* For the purposes of this document, 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 document, 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 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:* For the purposes of this document, success is defined as the successful completion of angiography, including gaining access to the artery, choosing the appropriate catheter, obtaining a complete set of images, and the timely and accurate interpretation of the findings. A complete set of images in the lower extremity is defined to include 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. (See the American

College of Radiology's Standard on Diagnostic Arteriography at [www.acr.org](http://www.acr.org)). In the kidney, it is defined as imaging from the abdominal aorta to the renal parenchyma.

These guidelines are written to be used in quality improvement programs to assess diagnostic arteriography. The most important processes of care are (i) patient selection, (ii) performance of the procedure, and (iii) 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 (eg, 100% success, 0% complications), in practice, all physicians will fall short of this ideal to a variable extent. Therefore, in addition to quality improvement 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; for example, major complications for diagnostic arteriography. Individual complications may also be associated with complication-specific thresholds, such as 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. Therefore, setting universal thresholds is very difficult and each department is urged to alter the thresholds as needed to higher or lower values, to meet its own quality improvement program needs.

Complications can be stratified on the basis of outcome. Major complications 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 1). The complication rates and thresholds below refer to major complications unless otherwise noted.

## INDICATIONS

The lists below represent a summary of the indications for diagnostic arteriography. The threshold for the department and for each individual is 95% (ie, 95% of procedures should be performed for one of the indications listed below).

### Pulmonary Arteriography (3-9)

- Suspected acute pulmonary embolus, in particular, when other diagnostic tests are inconclusive or discordant with clinical findings; for example:
  - High-probability ventilation-perfusion scan when there is a contraindication to anticoagulation;
  - Indeterminate ventilation-perfusion scan in a patient suspected of having pulmonary embolus;
  - Low-probability ventilation-perfusion scan in a patient with a high clinical suspicion of pulmonary embolus;
  - Ventilation perfusion scan cannot be performed;
  - Spiral computed tomography is inconclusive or not able to be performed;
- Suspected chronic pulmonary embolus;
- Other suspected pulmonary abnormalities, such as vasculitis, congenital and acquired anomalies, tumor encasement, and vascular malformations;
- Before pulmonary artery interventions.

**Spinal Arteriography (10)**

- Spine and spinal cord tumors;
- Vascular malformations;
- Spinal trauma;
- Preoperative evaluation before aortic or spinal surgery;
- Before interventional procedures.

**Bronchial Arteriography (7,9,11)**

- Hemoptysis;
- Suspected congenital cardiopulmonary anomalies;
- Assessment of distal pulmonary artery circulation (through collaterals) in patients who are potential candidates for pulmonary thromboendarterectomy;
- Before interventional procedures.

**Aortography (11,12)**

- Intrinsic abnormalities, including transection, dissection, aneurysm, occlusive disease, aortitis, and congenital anomaly;
- Evaluation of aorta and its branches before selective studies;
- Before interventional procedures.

**Abdominal Visceral Arteriography (13–19)**

- Acute or chronic gastrointestinal hemorrhage;
- Blunt or penetrating abdominal trauma;
- Intra-abdominal tumors;
- Acute or chronic intestinal ischemia;
- Portal hypertension and varices;
- Primary vascular abnormalities, including aneurysms, vascular malformations, occlusive disease, or vasculitis;
- Pre- and postoperative evaluation of portosystemic shunts;
- Preoperative evaluation;
- Pre- and postoperative evaluation of organ transplantation;
- Preliminary procedure for computed tomographic portography;
- Before interventional procedures.

**Renal Arteriography (20,21)**

- Renovascular occlusive disease (eg, for hypertension or progressive renal insufficiency);
- Renal vascular trauma;
- Primary vascular abnormalities,

- including aneurysms, vascular malformations, and vasculitis;
- Renal tumors;
- Hematuria of unknown cause;
- Pre- and postoperative evaluation for renal transplantation;
- Before interventional procedures.

**Pelvic Arteriography (13,22)**

- Atherosclerotic aortoiliac disease;
- Gastrointestinal or genitourinary bleeding;
- Trauma;
- Primary vascular abnormalities, including aneurysms, vascular malformations, and vasculitis;
- Male impotence caused by arterial occlusive disease;
- Pelvic tumors;
- Before interventional procedures.

**Extremity Arteriography (23–29)**

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

**CONTRAINDICATIONS**

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

- severe hypertension;
- uncorrectable coagulopathy;
- clinically significant iodinated contrast material sensitivity;
- renal insufficiency;
- congestive heart failure;
- certain connective tissue disor-

ders (reported complications at the puncture site).

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

**MEASURES OF SUCCESS**

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

**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 (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. Whereas 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 to 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,

Indicators and Thresholds for Complications in Diagnostic Arteriography		
Department Indicators	Reported Rates (%)	Major Adverse Event Threshold (%)
Puncture site complications		
Hematoma (requiring transfusion, surgery, or delayed discharge)	0.0–0.68	0.5
Occlusion	0.0–0.76	0.2
Pseudoaneurysm/arteriovenous fistula	0.04–0.2	0.2
Catheter-induced complications (other than puncture site)		
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

Note.—All values supported by the weight of literature evidence and panel consensus.

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). The American College of Radiology has recently issued standards for the use of contrast agents and for the treatment of contrast reactions that may be used to guide decisions in practice (42).

The incidence of contrast media-associated nephrotoxicity is difficult to determine from a review of the literature, in part because of the varying definitions that have been used (43–46). It is generally agreed that preexisting renal insufficiency is a risk factor for its development. Other possible predisposing risk factors include insu-

lin-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 preexisting 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 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 arteriography. These include subintimal passage of the guide wire or catheter and dissections

or emboli caused by catheter manipulation or contrast injection. These have been reported to occur in 0.15%–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 because of advances in guide wire 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 1). The complication rates and thresholds in the Table 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 arteriography are listed in the Table. 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.

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 (eg, early in a quality improvement pro-

gram). In this situation, the overall procedure threshold is more appropriate for use in a quality improvement program.

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

$$\frac{\text{No. of pts. with complications undergoing diagnostic arteriography only}}{\text{No. of pts. undergoing diagnostic arteriography only}} \times 100$$

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## APPENDIX 1

### SIR STANDARDS OF PRACTICE COMMITTEE CLASSIFICATION OF COMPLICATIONS BY OUTCOME (1)

#### Minor Complications

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

#### Major Complications

- C. Require therapy, minor hospitalization (<48 h),
- D. Require major therapy, unplanned increase in level of

care, prolonged hospitalization (>48 h),

- E. Have permanent adverse sequelae, or
- F. Result in death.

## APPENDIX 2

### METHODOLOGY

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

Consensus on statements in this document was obtained with use of a modified Delphi technique (49,50).

Technical documents specifying the exact consensus and literature review methodologies, as well as the institutional affiliations and professional credentials of the authors of this document, are available upon request from SCVIR, 10201 Lee Highway, Suite 500, Fairfax, VA 22030.

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