REFERENCE COMMITTEE II

Reference Committee II met on Monday, May 22, 2017 in the Washington Marriott Wardman Park Hotel in Washington, D.C. The members of this committee were Kenneth W. Chin, MD, FACR, Chair, Debra S. Dyer, MD, FACR, Alexander Goehler, MD, Grant J. Linnell, DO, Suresh K. Mukherji, MD, FACR, Rajeev Suri, MBBS.

The session was attended by approximately 600 members.

The Reference Committee recognizes the following reports as informational and I recommend that they be filed.

COMMISSIONS, COMMITTEES & TASK FORCES:

Commission on Economics
Commission on Government Relations

Commission on Human Resources
Commission on Interventional & Cardiovascular

Commission on Neuroradiology
Journal of the American College of Radiology

Commission on Leadership & Practice Development
Commission on Patient & Family Centered Care

The Committee was assigned the following resolutions for consideration:

Resolution Sponsor

12. Ten Year Extension of Policies: CSC
(a) Education
(b) Technologists and Allied Health Professions
(c) Technologists and Allied Health Professions
(d) Technologists and Allied Health Professions
(e) Testimony
(f) Third Party Carriers and Compensation
(g) Third Party Carriers and Compensation
(h) Third Party Carriers and Compensation
(i) Third Party Carriers and Compensation
(j) Third Party Carriers and Compensation
(k) Third Party Carriers and Compensation
(l) Third Party Carriers and Compensation

13. ACR–SIR Practice Parameter for Endovascular Management of the Thrombosed or Dysfunctional Dialysis Access CSC
14. ACR–SIR–SPR Practice Parameter for Performance of Arteriography
15. ACR–SIR–SPR Practice Parameter for the Creation of a Transjugular Intrahepatic Portosystemic Shunt (TIPS)
18. ACR–ASNR–SPR Practice Parameter for the Performance of Computed Tomography (CT) Perfusion in Neuroradiologic Imaging
21. ACR–NASCI–SPR Practice Parameter for the Performance of Quantification of Cardiovascular Computed Tomography (CT) and Magnetic Resonance Imaging (MRI)
22. ACR Practice Parameter for Performing and Interpreting Diagnostic Computed Tomography (CT)
23. Role of Patients in the American College of Radiology Georgia Radiological Society

THE REFERENCE COMMITTEE RECOMMENDS THE FOLLOWING CONSENT CALENDAR FOR ACCEPTANCE:

RECOMMENDED FOR ADOPTION:

Resolution No. 12 Ten Year Extension of Policies

BE IT RESOLVED,

that the following policy of the American College of Radiology be extended for an additional ten year period:

(a) EDUCATION

1. CREDENTIALING AND TRAINING

   d. Percutaneous Transluminal Angioplasty: Credentials Criteria

   The American College of Radiology endorses the Position Statement for Maintenance of Privileges for Image-Guided Interventions (which replaces Guidelines for Percutaneous Transluminal Angioplasty developed by the Society of Interventional Radiology); adopted 1987, 1997, 2007 (Res. 1-a).

   CREDENTIALS CRITERIA FOR PERIPHERAL, RENAL AND VISCERAL PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY

   Percutaneous transluminal angioplasty (PTA), without or with stents, has become established as effective therapy for selected patients with peripheral and renal vascular occlusive diseases. Extensive literature now documents the safety and efficacy of this procedure in the management of atherosclerotic stenoses and occlusions, as well as other arterial pathologies such as fibromuscular dysplasia and the intimal proliferative lesions that occasionally complicate surgical anastomoses. As with any invasive therapy, the patient is most likely to benefit only when the procedure is performed in an appropriate environment by experienced physicians. The Society of Cardiovascular and Interventional Radiology proposes the following guidelines for physicians, hospital
administrators and health planners who plan for and develop the optimal conditions under which these procedures should be performed.

THE PHYSICIAN

Physicians who perform angioplasty of the peripheral and renal vessels should have a thorough understanding of the clinical manifestations and natural history of peripheral and renovascular occlusive disease. They should be knowledgeable in the alternative therapies that are available including their risks and benefits. They should be competent to interpret diagnostic peripheral and renal angiographic examinations and competent to perform arteriographic procedures via either femoral (retrograde and antegrade), auxiliary axillary, radial and translumbar approaches. In addition, the complex nature of angioplasty procedures requires further training beyond that necessary for routine diagnostic angiography. To assure the experience and competence needed to perform successful angioplasty, the physician should meet the following minimal criteria:

Completion of an approved residency program which includes:

- Experience performing and interpreting peripheral arteriography and selective and sub-selective diagnostic vascular procedures, or in lieu of residency training criteria, the performance of a substantial number of peripheral and selective angiographic procedures for at least five years with acceptable complication rates.
- Training and experience in percutaneous interventions including a substantial number of peripheral and visceral arterial as well as venous endovascular recanalization procedures.
- Expertise in vascular diagnostic procedures including diagnostic angiography, CTA, MRA and vascular ultrasound.
- Instruction in radiation physics, radiation effects and protection with successful completion of a formal examination on these subjects, and additional experience including one of the following:
  - 1 or 2 year post-residency training in percutaneous interventions, which includes participation in a substantial number of peripheral and renal angioplasty procedures, or
  - 200 peripheral and renal angiograms performed within the previous 3 years, with documented success and complication rates within accepted limits, and participation in a minimum of 25 peripheral and/or renal angioplasty procedures under the direct supervision of a physician who already meets these criteria, or

Both trainees and practicing physicians should keep a log of the performance of a substantial number of peripheral and renal angioplasties for a period of at least three years— with documented success and complication rates within accepted limits. Participation in registries (when available) is encouraged to assist with documentation of outcomes.

The physician Physicians who perform angioplasty should be competent in the recognition and initial management of complications specific to peripheral and renal angioplasty. The physician should participate in continuing medical education activities, including demonstration courses and visiting fellowships on an annual basis.
In lieu of residency training criteria, the physician should have performed a substantial number of peripheral and selective angiographic procedures and PTA/stent procedures for at least five years with acceptable complication rates and have expertise in vascular diagnostic procedures including diagnostic angiography, CTA, MRA and vascular ultrasound.

THE ANGIOGRAPHIC FACILITY
The angiographic examination required to assess a patient’s suitability for percutaneous transluminal angioplasty should be equal to or exceed in quality to that required for diagnostic angiography performed for vascular surgery. The angiographic facility should have the following:

- High-resolution image intensifier and television imaging chain.
- Physiologic monitoring devices including ECG and intra-arterial pressures.
- Facilities to manage and resuscitate unstable patients.
- A film changer capable of obtaining rapid serial films of at least 14 inches in diameter. Digital subtraction angiography is an adjunct to conventional filming which may reduce patient discomfort and provide increased safety in patients with reduced renal function.
- Personnel trained to provide proper safe patient care, conscious sedation and operation of the equipment.
- Equipment necessary to diagnose and treat complications possibly arising from endovascular recanalization procedures.

SURGICAL SUPPORT
The safe performance of peripheral and renal angioplasty requires a strong cooperative effort between the physician performing the procedure and a vascular surgery team. Although complications of peripheral and renal angioplasty only rarely require urgent surgery, these procedures should be performed in an environment where operative repair can be instituted promptly.

TECHNOLOGISTS AND ALLIED HEALTH PROFESSIONS

1. ACR ENDORSEMENT OF THE AMERICAN REGISTRY OF DIAGNOSTIC MEDICAL SONOGRAPHY AND THE AMERICAN REGISTRY OF RADIOLOGIC TECHNOLOGISTS
The American College of Radiology endorses the American Registry of Diagnostic Medical Sonography (ARDMS) and the American Registry of Radiologic Technologists (ARRT) as the most appropriate agencies for the certification of ultrasound technologists; adopted 1987, 1997, 2007 (Res. 23-a).

5. FLUOROSCOPY
The American College of Radiology approves of the practice of certified and/or licensed radiologic technologists performing fluoroscopy in a facility or department as a positioning or localizing procedure only, and then only if monitored by a supervising physician who is personally and immediately available*. There must be a written policy or process for the positioning or localizing procedure that is approved by the medical
director of the facility or department/service and that includes written authority or policies and processes for designating radiologic technologists who may perform such procedures; adopted 1987, 1997, 2007 (Res. 12-m).

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

(d) TECHNOLOGISTS AND ALLIED HEALTH PROFESSIONS

19. SUPERVISION OF RADIOLOGIC TECHNOLOGISTS

The policy of the American College of Radiology is to seek and/or support appropriate legislation that provides that certified and/or licensed radiologic technologists may use equipment emitting ionizing or non-ionizing radiation for diagnostic or treatment only by prescription of and under the direct supervision of a fully licensed physician. A student radiologic technologist must be under the supervision of a certified and/or licensed radiologic technologist in an accredited allied health educational program; adopted 1987, 1997, 2007 (Res. 12-n).

(e) TESTIMONY

1. TESTIMONY GUIDELINES

The American College of Radiology adopted the following statement setting forth guidelines for testimony by College officers, commission and committee members and employees.

AMERICAN COLLEGE OF RADIOLOGY GUIDELINES

Testimony by College Officers, Commission and Committee Members and Employees

An individual holding an official capacity with the College who gives evidence for use in litigation must exercise great care to distinguish between his or her personal opinion on the merits of the matter at issue and the policy positions of the College.

The policies of the College are a matter of public record and, if relevant, may be appropriately cited in testimony. Also, the fact that an individual holds an official position with the College may be an appropriate part of his or her qualifications as an expert witness. However, the College, except pursuant to specific action by the Board of Chancellors, does not take a position on the merits of particular cases. A witness who holds an official capacity with the College must therefore be at pains to make clear that his or her testimony expresses his or her personal views, and must not state or imply in a written opinion or deposition or trial testimony that he or she is speaking as a representative of the College or is testifying to the views of the College on the merits of a particular case; adopted 1987, 1997, 2007 (Res. 36-v).

(f) THIRD PARTY CARRIERS AND COMPENSATION

5. CENTRAL ACR RESOURCE FOR MEDICARE REIMBURSEMENT POLICIES

The American College of Radiology (ACR) should continue to develop the mechanism whereby all Medicare reimbursement policies, both implemented and under development, related to radiology and radiation oncology, be made available to all
radiologists who serve as Carrier Advisory Committee members and the general membership for reference and comment; adopted 1997, 2007 (Res. 1-d).

(g) THIRD PARTY CARRIERS AND COMPENSATION

7. COMPENSATION

Radiology should be regarded and compensated on the same basis as are the services of all other physicians. Radiologists should be treated in the same manner as other physicians in all matters, including the prerogative to bill patients directly for their professional services in any practice setting; adopted 1973, 1987, 1997, 2007 (Res. 1-e).

(h) THIRD PARTY CARRIERS AND COMPENSATION

9. CPT CODE REVISIONS

The American College of Radiology, through its CPT advisory committee, shall maintain an active role in insuring that future editions of CPT include codes for all current radiological procedures; adopted 1987, 1997, 2007 (Res. 1-i).

(i) THIRD PARTY CARRIERS AND COMPENSATION

18. MEDICARE/MEDICAID PROGRAMS

The ACR joins the American Medical Association in condemning and deploring all acts of fraud and wrong doing in the Medicare and Medicaid programs. If the ACR can be of assistance to federal agencies in this area, it will be pleased to do so; 1977, 1987, amended 1997, 2007 (Res. 1-f).

(j) THIRD PARTY CARRIERS AND COMPENSATION

19. MEDICARE REIMBURSEMENT

The American College of Radiology, through appropriate commissions, committees, members and staff, will continue to respond to the membership in gathering and disseminating information designed to identify and correct regional inconsistencies in the interpretation and implementation of reimbursement policies by Medicare carriers and intermediaries, and continue to actively seek revision of these policies; adopted 1985, 1997, 2007 (Res. 1-g).

(k) THIRD PARTY CARRIERS AND COMPENSATION

21. OUTPATIENT REIMBURSEMENT

The American College of Radiology supports the principle that reimbursement for any outpatient radiologic procedure should be made based upon medical validity and necessity for a given examination whether performed in a hospital or non-hospital setting; adopted 1987, 1997, 2007 (Res. 1-h).

(l) THIRD PARTY CARRIERS AND COMPENSATION

31. RETROACTIVE DENIAL OF REFERRED SERVICES

Retroactive denial of referred services is an inappropriate method to control utilization of radiologic services; adopted 1973, 1987, 1997, 2007 (Res. 36-w).
Resolution No. 13  ACR–SIR Practice Parameter for Endovascular Management of the Thrombosed or Dysfunctional Dialysis Access


Resolution No. 18  ACR–ASNR–SPR Practice Parameter for the Performance of Computed Tomography (CT) Perfusion in Neuroradiologic Imaging

Resolution No. 19  ACR–ASNR–SPR Practice Parameter for the Performance of Intracranial Magnetic Resonance Perfusion Imaging

Resolution No. 20  ACR–ASNR–SPR Practice Parameter for the Performance of functional Magnetic Resonance Imaging (fMRI) of the Brain

Resolution No. 21  ACR–NASCI–SPR Practice Parameter for the Performance of Quantification of Cardiovascular Computed Tomography (CT) and Magnetic Resonance Imaging (MRI)

Resolution No. 22  ACR Practice Parameter for Performing and Interpreting Diagnostic Computed Tomography (CT)

Resolution No. 23  Role of Patients in the American College of Radiology

BE IT RESOLVED,

That the American College of Radiology will explore the feasibility of additional direct roles that patients and patient stakeholders can play in the ACR, such as conference attendee, conference presenter, member, and Board of Chancellor member.

RECOMMENDED FOR ADOPTION AS AMENDED (amended lines noted):

Resolution No. 14  ACR–SIR–SPR Practice Parameter for Performance of Arteriography (Lines 230, 256)

The SIR and SPR representatives affirm that in their best judgement the proposed changes would be acceptable to SIR and SPR; subject to ratification by SIR and SPR.

Resolution No. 15  ACR–SIR–SPR Practice Parameter for the Creation of a Transjugular Intrahepatic Portosystemic Shunt (TIPS) (Line 202)

The SIR and SPR representatives affirm that in their best judgement the proposed changes would be acceptable to SIR and SPR; subject to ratification by SIR and SPR.

The ASNR, ASSR, SIR and SNIS representatives affirm that in their best judgement the proposed changes would be acceptable to ASNR, ASSR, SIR and SNIS; subject to ratification by ASNR, ASSR, SIR and SNIS.

Reference Committee II wishes to thank the Councilors and visitors for their valuable input in these deliberations.

Respectfully Submitted:

Kenneth W. Chin, MD, FACR, Chair
Debra S. Dyer, MD, FACR
Alexander Goehler, MD
Grant J. Linnell, DO
Suresh K. Mukherji, MD, FACR
Rajeev Suri, MBBS
### COMMISSIONS, COMMITTEES & TASK FORCES:

- Commission on Economics
- Commission on Human Resources
- Commission on Neuroradiology
- Commission on Interventional & Cardiovascular
- Commission on Leadership & Practice Development
- Commission on Patient & Family Centered Care

### RESOLUTIONS

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**ACR STAFF:**
- **Director:** Dina Hernandez
- **Assistant:** Ashraful Azim
- **Moderator:** Lavonne Robbins
- **Attorney:** Tom Hoffman
- **Recorder:** Dee Salem
NOT FOR PUBLICATION, QUOTATION, OR CITATION

RESOLUTION NO. 14

BE IT RESOLVED, that the American College of Radiology adopt the ACR–SIR–SPR Practice Parameter for Performance of Arteriography

Sponsored By: ACR Council Steering Committee

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

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

Each practice parameter and technical standard, representing a policy statement by the College, has undergone a thorough consensus process in which it has been subjected to extensive review and approval. The practice parameters and technical standards recognize that the safe and effective use of diagnostic and therapeutic radiology requires specific training, skills, and techniques, as described in each document. Reproduction or modification of the published practice parameter and technical standard by those entities not providing these services is not authorized.

Revised 2012 (Resolution 5)*

ACR–SIR–SPR PRACTICE PARAMETER FOR PERFORMANCE OF ARTERIOGRAPHY

PREAMBLE

This document is an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. Practice Parameters and Technical Standards are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care. For these reasons and those set forth below, the American College of Radiology and our collaborating medical specialty societies caution against the use of these documents in litigation in which the clinical decisions of a practitioner are called into question.

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

1 Iowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing, ___ N.W.2d ___ (Iowa 2013) Iowa Supreme Court refuses to find that the ACR Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures (Revised 2008) sets a national standard for who may perform fluoroscopic procedures in light of the standard’s stated purpose that ACR standards are educational tools and not intended to establish a legal standard of care. See also, Stanley v. McCarver, 63 P.3d 1076 (Ariz. App. 2003) where in a concurring opinion the Court stated that “published standards or guidelines of specialty medical organizations are useful in determining the duty owed or the standard of care applicable in a given situation” even though ACR standards themselves do not establish the standard of care.
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 the guidance in this document will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The sole purpose of this document is to assist practitioners in achieving this objective.

I. INTRODUCTION

This parameter was revised collaboratively by the American College of Radiology (ACR), the Society of Interventional Radiology (SIR), and the Society for Pediatric Radiology (SPR) [1].

For purposes of this parameter, the term “arterial intervention” refers to all catheter-based procedures performed on arteries, and it may be referred to elsewhere as “interventional procedure” or “endovascular surgery”.

Diagnostic arteriography is an established, safe, and accurate method of evaluating vascular disease. It is considered the diagnostic gold 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 [2]. 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 parameter was developed to help practicing angiographers 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. It is intended to provide guidance in both 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 [3] and the cervicocerebral circulation (see the ACR–ASNR–SIR–SNIS Practice Parameter for the Performance of Diagnostic Cervicocerebral Catheter Angiography in Adults [4]). Patients will benefit when appropriate selection criteria, preprocedure 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 parameter may be necessary and appropriate depending on the specific clinical circumstances.

II. DEFINITIONS

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

Diagnostic arteriography 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 digital imaging or serial film systems

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

Moderate sedation – defined by the ACR–SIR Practice Parameter for Sedation/Analgesia [5]

Success – the completion of the arteriogram, including gaining access to the artery, obtaining a set of complete images together with other pertinent data (eg, hemodynamics) sufficient to support further medical decision-making, and the timely and accurate interpretation of the findings. Successful arteriogram arteriography does not
necessarily imply that the procedure is complication free; one may have successful arteriogram arteriography 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 entire arterial circulation of a lower extremity, including the arterial supply to the foot.

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.

III. ALTERNATIVE DIAGNOSTIC STUDIES, INDICATIONS, AND CONTRAINDICATIONS

The lists below summarize most of the appropriate 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). In addition, for diagnostic arteriogram arteriography to be considered 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 magnetic resonance angiography)
3. Computed tomography (including computed tomography angiography)
4. Nuclear medicine, including positron emission tomography
5. Functional and perfusion imaging
6. Physiologic testing (eg, pulse volume recording)
7. Segmental blood pressure measurements

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 diagnostic arteriography.

Some of these alternative tests may be used as an adjunct to diagnostic arteriography. 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 [6-14]
   a. Suspected acute pulmonary embolus, in particular when other diagnostic tests are inconclusive or discordant with clinical findings
      i. High-probability ventilation-perfusion imaging study when there is a contraindication to anticoagulation
      ii. Indeterminate ventilation-perfusion imaging study or nondiagnostic CT scan in a patient suspected of having a pulmonary embolus
      iii. Low-probability ventilation-perfusion imaging study in a patient with a high clinical suspicion of pulmonary embolus
      iv. Ventilation-perfusion imaging study or CT pulmonary angiography scan cannot be performed.
   b. Known or suspected chronic pulmonary thromboembolism embolus
   c. Other suspected pulmonary abnormalities, such as vasculitis, congenital and acquired vascular anomalies, tumor encasement, and vascular malformations
d. Foreign body retrievals within the pulmonary vasculature

e. Prior to, during, or after arterial intervention

f. Spontaneous hemorrhage

2. Spinal arteriography [15,16]
a. Spine and spinal cord tumors
b. Vascular malformations
c. Spinal trauma
d. Preoperative evaluation prior to open or endovascular aortic or spinal surgery
e. Prior to, during, or after arterial intervention

f. Spontaneous hemorrhage

3. Bronchial arteriography [9,10,17-19]
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, during, or after arterial intervention
e. Bronchial artery aneurysm
f. Spinal arteriovenous malformations

4. Aortography [17,20]
a. Abnormalities including acute traumatic injury, dissection, aneurysm, occlusive disease, aortitis, and congenital anomaly
b. Evaluation of the aorta and its branches prior to selective studies
c. Prior to, during, or after arterial intervention
d. Spontaneous hemorrhage

5. Abdominal visceral arteriography [21-27]
a. Acute or chronic gastrointestinal hemorrhage
b. Blunt or penetrating abdominal trauma
c. Intra-abdominal tumors
d. Acute or chronic intestinal ischemia
e. Evaluation of mesenteric, splenic, and portal vein patency in the setting of suspected portal hypertension
f. Primary vascular abnormalities, including aneurysms, vascular malformations, occlusive disease, and vasculitis
g. Preoperative evaluation prior to open surgical procedures
h. Preoperative and postoperative evaluation of organ transplantation
i. Iatrogenic vascular injury
j. Prior to, during, or after arterial intervention

k. Spontaneous hemorrhage

6. Renal arteriography [28,29]
a. Renovascular occlusive disease (eg, 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. Preoperative and postoperative evaluation for renal transplantation
g. Iatrogenic vascular injury
h. Prior to, during, or after arterial intervention
NOT FOR PUBLICATION, QUOTATION, OR CITATION

i. Spontaneous hemorrhage

7. Pelvic arteriography [24,30]
   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. Benign prostatic hyperplasia
   h. Uterine leiomyoma; adenomyosis
   i. Postpartum hemorrhage
   j. Iatrogenic vascular injury
   k. Prior to, during, or after arterial intervention
   l. Spontaneous hemorrhage
   m. Assessment of arterial anatomy, such as in prior to free flap harvesting or organ transplantation

8. Extremity arteriography [31-37]
   a. Atherosclerotic vascular disease, including aneurysms, emboli, occlusive disease, and thrombosis
   b. Vascular trauma
   c. Preoperative planning and postoperative evaluation
   d. Evaluation of surgical bypass grafts and dialysis grafts and fistulas
   e. Other primary vascular abnormalities, such as vascular malformations, vasculitis, entrapment syndrome, and thoracic outlet syndrome
   f. Extremity tumors
   g. Iatrogenic vascular injury
   h. Prior to, during, or after arterial intervention
   i. Spontaneous hemorrhage

There may be circumstances where arteriography prior to, during, or after arterial intervention is justified on other vessels not cited above.

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. These indications apply to both adult and pediatric patients unless otherwise specified.

C. Contraindications

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

1. Severe hypertension
   2. Uncorrectable coagulopathy or thrombocytopenia
   3. Clinically significant sensitivity to iodinated contrast material
   4. Renal insufficiency based on the estimated glomerular filtration rate (eGFR).
   5. Congestive heart failure
   6. Certain connective tissue disorders (reported complications at the puncture site)

For optimum patient management, these relative contraindications should be addressed 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 with the patient’s history, physical findings, and prior imaging studies. Therefore, the physician must be clinically informed and understand the specific questions to be answered by diagnostic arteriography prior to the procedure in order to plan and perform it safely and effectively.

The physician performing a diagnostic angiogram must fully appreciate the benefits, alternatives, and risks of the procedure. He or 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), the American Osteopathic Board of Radiology, the Royal College of Physicians and Surgeons of Canada, or the Collège des Médecins du Québec and has performed (with supervision) a sufficient number of arteriography procedures to demonstrate competency as attested by the supervising physician(s). A sufficient number of peripheral, visceral, or neurovascular diagnostic arteriograms, 50 as primary operator, with acceptable success and complication rates within the quality assurance threshold rates laid out in this parameter [38,39].

2. Successful completion of radiology residency training program approved by the Accreditation Council for Graduate Medical Education (ACGME), the Royal College of Physicians and Surgeons of Canada (RCPSC), the Collège des Médecins du Québec, or the American Osteopathic Association (AOA) to include interventional radiology residency program and/or interventional/vascular radiology fellowship, and must have a minimum of 12 months training in a service that is primarily responsible for the performance of percutaneous peripheral, visceral, and neurovascular diagnostic arteriography. Documented formal training in the performance of invasive catheter angiographic procedures must be included. During this training, the physician should have performed (with supervision) a sufficient number of arteriography procedures to demonstrate competency as attested by the supervising physician(s). A sufficient number of peripheral, visceral, or neurovascular diagnostic arteriograms, 50 as primary operator. 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 parameter [38].

3. Successful completion of an ACGME-approved nonradiology residency or fellowship training, and must have a minimum of 12 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 100\(^2\) peripheral, visceral, or neurodiagnostic arteriograms, 50 as 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 parameter [38].

and

4. Physicians meeting any of the qualifications in 1, 2, or 3 above must also have written substantiation that they are familiar with all of the following:

a. Indications and contraindications for the procedure.

b. Periprocedural and intraprocedural assessment, monitoring, and management of the patient and complications. For pediatric cases, this includes dedicated training in pediatric angiography and training of the underlying causes of pediatric causes for vascular disease as well as knowledge of age-based normal ranges for vital signs, and signs and symptoms of complications; or the availability of team members with such expertise (such as pediatric sedation and monitoring personnel). This also includes knowledge of the normal amounts of fluids that can be administered during the procedure (including fluids going through sheaths) to prevent volume overload.

c. Pharmacology of drugs used for sedation and analgesia, and recognition and treatment of adverse reactions and complications. For pediatric cases, this includes knowledge of weight based pediatric dosages, age-based normal values for vital signs, contraindications and signs and symptoms of adverse reactions and complications.

d. Appropriate use and operation of fluoroscopic and radiographic equipment, mechanical injectors, digital subtraction, and other electronic imaging systems.

e. Principles of radiation protection, the hazards of radiation, and radiation monitoring requirements as they apply to patients and personnel, including appropriate dose-reduction strategies for children [40].

f. Pharmacology of contrast agents and recognition and treatment of potential adverse reactions.

g. Percutaneous needle and catheter introduction techniques. Ultrasound guidance may be used for access, most often in children. For newborns neonates this also implies the potential use of the umbilical artery as a possible catheter access site for angiographic procedures. In an attempt to spare the femoral arteries from subsequent limb threatening complications due to hypoperfusion of the lower extremity from the presence of the catheter or sheath in the femoral artery.

h. Technical aspects of performing the procedure, including the use of alternative catheter and guide-wire systems, invasive monitoring devices such as pressure transducers, selective angiographic methods, appropriate injection rates and volumes of contrast media (weight-based in children), and imaging sequences [41].

i. Recognition of periprocedural complications and knowledge of treatment options for these complications (eg, stenting, embolization, thrombolysis, suction embolectomy, surgery).

j. Anatomy, physiology, and pathophysiology of peripheral and visceral arterial vasculature, including normal variants.

k. Interpretation of diagnostic arteriographic studies including common artifacts (eg, standing wave, bone subtraction artifact).

The written substantiation should come from the chief of interventional radiology, the chief of neuroradiology, the chief of interventional neuroradiology, or the chair of the department of the institution in which the physician will be providing these services\(^3\). Substantiation could also come from a prior institution in which the physician provided the services, but only at the discretion of the current interventional, neurointerventional, or neuroradiology chief, or the chair who solicits the additional input.

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\(^2\) When these numbers are used for credentialing, they apply to a complete patient encounter regardless of the number of vessels selected or treated during a given encounter [35].

\(^3\) At institutions in which there is joint (dual) credentialing across departments doing like procedures, this substantiation of experience should be done by the chairs of both departments to ensure equity of experience among practitioners when their training backgrounds differ (43).
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 parameter. Continued competence should depend on participation in a quality improvement program that monitors these rates.

Continuing Medical Education

The physician’s continuing education should be in accordance with the ACR Practice Parameter for Continuing Medical Education (CME) [42].

B. Nonphysician Practitioners

Physician assistants and nurse practitioners can be valuable members of the interventional radiology team. Their participation in angiography procedures should be specifically under the supervision of appropriately qualified and credentialed physicians. See the ACR–SIR–SNIS–SPR Practice Parameter for Interventional Clinical Practice and Management [43].

C. Qualified Medical Physicist

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

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

The appropriate subfield of medical physics for this parameter is Diagnostic Medical Physics (including medical physics certification categories of Radiological Physics, Diagnostic Radiological Physics, or Diagnostic Imaging Physics.)

D. Registered Radiologist Assistant

A registered radiologist assistant is an advanced level radiographer who is certified and registered as a radiologist assistant by the American Registry of Radiologic Technologists (ARRT) after having successfully completed an advanced academic program encompassing an ACR/ASRT (American Society of Radiologic Technologists) radiologist assistant curriculum and a radiologist-directed clinical preceptorship. Under radiologist supervision, the radiologist assistant may perform patient assessment, patient management and selected examinations as delineated in the Joint Policy Statement of the ACR and the ASRT titled “Radiologist Assistant: Roles and Responsibilities” and as allowed by state law. The radiologist assistant transmits to the supervising radiologists those observations that have a bearing on diagnosis. Performance of diagnostic interpretations remains outside the scope of practice of the radiologist assistant. (ACR Resolution 34, adopted in 2006)
E. 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 the patient for the arteriographic procedure and, together with the nurse, monitor the patient during the procedure. The technologist should obtain the imaging data in a manner prescribed by the supervising physician. The technologist should also perform the regular quality control testing of the equipment under the 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.

F. Nursing Services

Nursing services are an integral part of the team for periprocedural and intraprocedural 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 flat-panel detector or image intensifier and television chain with standard arteriographic filming capabilities, including large-format image intensifiers (14 inch or greater) with minimum 1,024-image matrix. Smaller image intensifiers may be used in primarily pediatric settings. Digital angiographic systems are strongly recommended, as they allow for reduced volumes of contrast material, reduced examination times, and reduction of radiation dose. Features such as last image hold, pulsed fluoroscopy, and road mapping capabilities are strongly recommended for dose reduction. Imaging and image recording must be consistent with the “as low as reasonably achievable” radiation safety guidelines. Appropriate shielding for the operator should be available on all angiographic systems [44]. The use of cineradiography or small-field mobile image intensifiers is inappropriate for the routine recording of noncoronary noncardiac angiography because they cause an unacceptably high patient and operator radiation dose.

2. The equipment should be capable of recording the radiation dose received by the patient so it can be made part of the patient’s permanent medical record [45].

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4 The American College of Radiology approves of the practice of certified and/or licensed radiologic technologists performing fluoroscopy in a facility or department as a positioning or localizing procedure only, and then only if monitored by a supervising physician who is personally and immediately available.* There must be a written policy or process for the positioning or localizing procedure that is approved by the medical director of the facility or department/service and that includes written authority or policies and processes for designating radiologic technologists who may perform such procedures. (ACR Resolution 26, 1987 – revised in 2007, Resolution 12m)

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

PRACTICE PARAMETER

Arteriography

2017 Resolution No. 14
3. Adequate angiographic supplies such as catheters, guidewires, needles, and introducer sheaths

4. An angiographic injector capable of varying injection volumes and rates, with appropriate safety mechanisms to prevent overinjection

5. An angiography suite that is large enough to allow safe 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.

6. An area for preprocedural preparation and postprocedural observation and monitoring of the patient. At this location, there should be personnel to provide care as outlined in section V.E below (patient care), and there should 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 receives sedation, the ACR–SIR Practice Parameter for Sedation/Analgesia should be followed [5].

2. Appropriate emergency equipment and medications must be immediately available to treat adverse reactions associated with administered medications and/or procedural complications. The equipment should be maintained and medications inventoried for drug expiration dates on a regular basis. The equipment, medications, and other emergency support must also be appropriate for the range of ages and sizes in the patient population.

3. If peripheral or pulmonary arteriography is regularly performed, physiologic pressure monitors should be available for determining intra-arterial pressures.

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 sedation, a member of the procedural team should be assigned to periodically assess the patient’s status. If the patient undergoes sedation, a nurse or other appropriately trained individual should monitor the patient as his or 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 sedation (see the ACR–SIR Practice Parameter for Sedation/Analgesia [5]). For pediatric cases, personnel should be experienced and qualified in pediatric sedation, monitoring, and airway maintenance. Having Pediatric Advanced Life Support (PALS) training and current certification is recommended. Children may easily slip between depths of sedation during the case. Therefore, there must be experienced and qualified personnel available to manage the airway and rescue children from deep sedation or apnea should this occur (see the ACR–SIR Practice Parameter for Sedation/Analgesia [5]). Anesthesia team support should be considered as an alternative to sedation in patients if nursing staff is uncomfortable with sedation of patients or if there are extensive comorbidities.

D. Surgical Support

For additional information, see the ACR–SIR–SNIS–SPR Practice Parameter for Interventional Clinical Practice and Management [43].
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 freestanding center, detailed protocols for the rapid transport or admission of patients to an acute care hospital should be formalized in writing. It is preferred that pediatric angiography be performed at institutions with appropriate pediatric subspecialty and supportive care.

E. Patient Care

1. Preprocedural care

The indications for elective arteriographic studies should be documented as described below. For emergency procedures, a note should be written summarizing the indications 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–SIR Practice Parameter on Informed Consent for Image-Guided Procedures [46].

2. Procedural care

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

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

b. All patients 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 receives sedation, pulse oximetry should be used in addition to 2b above. Carbon dioxide capnography is strongly recommended. A registered nurse or other appropriately trained personnel should be present, and his or 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.

g. In all patients, an ongoing tally of contrast material administered should be performed to avoid contrast nephropathy.
3. Postprocedural care

a. The operating physician or a qualified designee should evaluate the patient after the procedure, and these findings should be summarized in a progress note. If sedation was administered prior to and during the procedure, safe and adequate recovery from 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, a physician assistant, or a nurse. See the ACR–SIR Practice Parameter for Sedation/Analgesia [5]. Postprocedure documentation should be in accordance with the ACR–SIR–SPR Practice Parameter for the Reporting and Archiving of Interventional Radiology Procedures [47].

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 will be available within a few hours. However, if the official interpretation is not likely to be in the medical record 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 vascular access, the means by which hemostasis was achieved, puncture-site stability, 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 circulation.

d. The patient should be monitored for urinary output, cardiac symptoms, pain, and other indicators of systemic complications that may need to be addressed further.

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 of vascular access requires manipulation in the ascending or transverse thoracic aorta or brachiocephalic vessels, neurologic status should be assessed periodically and changes from baseline reported immediately.

g. Additional sedation and postprocedural observation may be indicated and necessary for the safety of pediatric patients, depending on age and morbidities.

F. Selection Criteria for Short-Term Observation

The duration of postprocedure observation must be individualized. Arteriography 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 be considered only when all of the following conditions can be met:

1. A patient capable of independent ambulation prior to the procedure demonstrates stable, independent ambulation after the procedure. Alternatively, nonambulatory patients should have adequate assistance after discharge to provide care as needed.

2. Prior to discharge, the patient’s mental status has returned to baseline, with the patient, guardian, or supervising adult capable of following instructions and detecting changes in symptomatology.

3. The patient, guardian, or supervising adult is provided with instructions on how to recognize potential complications (eg, 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 information regarding recognition of potential complications and is available to transport the patient and be in attendance during the initial night after discharge.

5. The patient is free of concurrent serious medical illness that might contribute to a significantly increased risk of complication.
6. The patient has recovered from the effects of the sedation to a level as defined in the ACR–SIR Practice Parameter for Sedation/Analgesia [5].

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. Complications occurring during or after arteriography, including large hematoma, anuria, persistent nausea, vomiting, or unexpected alteration in neurological status compared to baseline, 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 1 hour from where the patient is to spend the first postprocedure night.

8. For pediatric patients, inadequate parent or guardian ability or availability for monitoring for early postprocedure or postanesthesia complications, in addition to the patient’s inability to follow instructions, potentially places the patient at higher risk.

The decision regarding 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 ACR–SIR–SPR Practice Parameter for the Reporting and Archiving of Interventional Radiology Procedures [47].

VII. RADIATION SAFETY IN IMAGING

Radiologists, medical physicists, registered radiologist assistants, radiologic technologists, and all supervising physicians have a responsibility for safety in the workplace by keeping radiation exposure to staff, and to society as a whole, “as low as reasonably achievable” (ALARA) and to assure that radiation doses to individual patients are appropriate, taking into account the possible risk from radiation exposure and the diagnostic image quality necessary to achieve the clinical objective. All personnel that work with ionizing radiation must understand the key principles of occupational and public radiation protection (justification, optimization of protection and application of dose limits) and the principles of proper management of radiation dose to patients (justification, optimization and the use of dose reference levels).

Nationally developed guidelines, such as the ACR’s Appropriateness Criteria®, should be used to help choose the most appropriate imaging procedures to prevent unwarranted radiation exposure.

Facilities should have and adhere to policies and procedures that require varying ionizing radiation examination protocols (plain radiography, fluoroscopy, interventional radiology, CT) to take into account patient body habitus (such as patient dimensions, weight, or body mass index) to optimize the relationship between minimal radiation dose and adequate image quality. Automated dose reduction technologies available on imaging equipment should be used whenever appropriate. If such technology is not available, appropriate manual techniques should be used.

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

Radiation exposures or other dose indices should be measured and patient radiation dose estimated for representative examinations and types of patients by a Qualified Medical Physicist in accordance with the applicable ACR technical standards. Regular auditing of patient dose indices should be performed by comparing the facility’s dose information with national benchmarks, such as the ACR Dose Index Registry, the NCRP Report No. 172, Reference Levels and Achievable Doses in Medical and Dental Imaging: Recommendations for the United States or the Conference of Radiation Control Program Director’s National Evaluation of X-ray Trends. (ACR Resolution 17 adopted in 2006 – revised in 2009, 2013, Resolution 52).

Radiation safety deserves particular attention when fluoroscopically guided procedures are performed on children [45,48]. The Image Gently coalition has provided useful guidance in this regard, including the Step Lightly campaign [49]. The Image Wisely campaign has been formed to provide similar guidance for radiation safety in adult patients.

As noted in the ACR–AAPM Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures [50]: “If the cumulative air kerma at the reference point exceeds the substantial radiation dose level (SRDL), which is typically set at 5 gray (Gy), provisions should be made for patient follow-up to allow for detection and management of possible radiation effects [45,48,51]. (For specific classes of procedures, if a higher or lower SRDL is chosen it should be supported by published literature or data collected by the facility [52].) If follow-up for possible radiation injury is indicated, the patient should be advised of the potential for radiation injury to the skin and be given instructions for proper follow-up, and these steps should be documented in the medical record [45]. When potentially high-dose procedures are repeated, (eg, TIPS, or for neuroembolization), previous skin exposure should be considered [53].” The SIR–CIRSE Cardiovascular and Interventional Radiological Society of Europe guidelines for patient radiation dose management recommend that follow-up should be performed if the cumulative air kerma at the reference point exceeds 5 Gy [48,50].

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

Policies and procedures related to quality, patient education, infection control, and safety should be developed and implemented in accordance with the ACR Policy on Quality Control and Improvement, Safety, Infection Control, and Patient Education appearing under the heading Position Statement on QC & Improvement, Safety, Infection Control, and Patient Education on the ACR website (http://www.acr.org/guidelines).

These data should be used in conjunction with the thresholds described in section IX below to assess diagnostic arteriography procedural efficacy and complication rates and to trigger institutional review when those thresholds are exceeded.
IX. QUALITY IMPROVEMENT

These parameters are 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.

Although 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. 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 QI programs.

For the purpose of these parameters, a threshold is a specific level of an indicator that, when reached or crossed, should prompt a review of departmental policies and procedures. Procedure thresholds or overall thresholds refer to a group of outcome measures for a procedure (eg, major complications for diagnostic arteriography). Individual complications may also be associated with complication-specific thresholds (eg, 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 QI 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 refer to major complications, unless otherwise noted.

A. Measure 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 [54]. Arteriographic complications may be divided into 3 groups: puncture site, systemic, and catheter induced. Puncture site complications such as arterial spasm, thrombosis, and hematoma may be more frequent in infants and small children, given the small size of their vessels relative to the size of sheaths and catheters.

By far, the most frequent puncture site complication is hematoma. Although the incidence of minor hematomas is quite variable and may be as high as 10%, major hematomas are unusual [54-56]. 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 [57]. Other puncture-site problems, including dissection, thrombosis, pseudoaneurysm, and 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 [56]. For example, a small hematoma at an axillary puncture site may cause neural injury and require surgical evacuation earlier than a similar femoral hematoma.
Vascular closure devices (VCDs) have been developed to reduce the cost of a hospital stay as well as complications [58]. The use of VCDs is currently indicated for retrograde femoral arterial access. Some studies have shown that there is a higher risk of pseudoaneurysm and hematoma with VCDs, as well as an increased risk of complications in patients with peripheral arterial disease [58,59]. There are other studies, however, showing either noninferiority or a decreased rate of major complications of VCDs compared to manual compression for peripheral arterial interventions or cardiac interventions [60,61]. VCDs can be used to improve patient satisfaction, decrease hospital stay, and encourage patient mobilization without prolonged bed rest [58,61,62]. VCDs are not approved for use in pediatric patients and their use should be cautioned [41].

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 endovascular procedures. Although antibiotic prophylaxis is not generally required for diagnostic arteriography [63,64], it may be warranted in patients who are at risk for infection (eg, diabetic, immunocompromised) or who undergo vascular closure placement or in patients subjected to lengthy procedures [65].

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 [66]. 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 1 other major risk factor [67-70]. See the ACR–SPR Practice Parameter for the Use of Intravascular Contrast Media [71] and the ACR Manual on Contrast Media [72].

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 [73-76]. Preexisting renal insufficiency is a risk factor for the development of contrast media–induced nephrotoxicity. Other 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 [54]. Low-osmolar contrast medium has a small but definite benefit over high-osmolar contrast media for patients with preexisting azotemia [77]. Preprocedural hydration may have a protective effect in high-risk patients. Some newer drugs and hydration protocols may also have a role in protection from contrast media–associated nephrotoxicity, but they require further study. In pediatric angiography, knowledge of weight-based contrast media volume limits and familiarity of alternative contrast media such as carbon dioxide are useful to minimize complications.

For the purposes of this parameter, contrast media–associated nephrotoxicity as a major complication is 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% for contrast media–associated nephrotoxicity requiring renal replacement therapy, such as dialysis, 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% [54,56,78].
Pediatric angiography holds additional unique potential complications, including arterial stenosis and occlusion due to vasospasm, which may lead to limb length discrepancy. In recent years, these types of complications have decreased in frequency, in part because of advances in guidewire, sheath, and catheter technology. For pediatric complication rates, detailed discussion is available elsewhere [41].

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 QI program.

Indicators and thresholds for complications in diagnostic arteriography are listed in Table 1 [41]. 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, the procedure mix, and the skills of the physicians involved. The departmental indicators should be used for all procedures performed within the department. 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 QI program summary.

### Table 1

<table>
<thead>
<tr>
<th>Department Indicators</th>
<th>Reported Rates</th>
<th>Major Adverse Event Threshold</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Puncture-site complications</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hematoma (requiring transfusion, surgery, or delayed discharge)</td>
<td>0.0% to 0.68%</td>
<td>0.5%</td>
</tr>
<tr>
<td>Occlusion</td>
<td>0.0% to 0.76%</td>
<td>0.2%</td>
</tr>
<tr>
<td>Pseudoaneurysm or arteriovenous fistula</td>
<td>0.04% to 0.3%</td>
<td>0.2%</td>
</tr>
<tr>
<td><strong>Vascular closure device–associated complications</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Access site infection</td>
<td>0.5% to 2.4%</td>
<td>2.0%</td>
</tr>
<tr>
<td><strong>Catheter-induced complications in the aorta or principal branches (other than puncture site)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Distal emboli</td>
<td>0.0% to 0.10%</td>
<td>0.2%</td>
</tr>
<tr>
<td>Arterial dissection / subintimal passage</td>
<td>0.43%</td>
<td>0.5%</td>
</tr>
<tr>
<td>Subintimal injection of contrast media</td>
<td>0.0% to 0.44%</td>
<td>0.5%</td>
</tr>
<tr>
<td><strong>Other procedure-related complications</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Major contrast media reactions</td>
<td>0.0% to 3.58%</td>
<td>0.5%</td>
</tr>
<tr>
<td>Contrast media–induced nephrotoxicity requiring renal replacement therapy (such as dialysis)</td>
<td>0.2% to 3.0%</td>
<td>0.2%</td>
</tr>
<tr>
<td><strong>Overall procedure threshold for major complications</strong></td>
<td>1.0%</td>
<td>1.0%</td>
</tr>
</tbody>
</table>

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

\[
\text{Threshold} = \left( \frac{\text{number of patients with major complications undergoing diagnostic arteriography only}}{\text{total number of patients undergoing diagnostic arteriography only}} \right) \times 100
\]
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 number of patients (e.g., early in a QI program). In this situation, the overall procedure threshold is more appropriate for use in a QI program.

ACKNOWLEDGEMENTS

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REFERENCES


PRACTICE PARAMETER Arteriography
2017 Resolution No. 14


Minor Complications

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

Major Complications

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

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

Development Chronology for this Parameter
1993 (Resolution 8)
Amended 1995 (Resolution 14)
Revised 1997 (Resolution 5)
Revised 1999 (Resolution 9)
Revised 2002 (Resolution 12)
Amended 2004 (Resolution 25)
Amended 2006 (Resolution 16, 17, 34, 35, 36)
Revised 2007 (Resolution 9)
BE IT RESOLVED,  
that the American College of Radiology adopt the ACR–SIR–SPR Practice Parameter for the Creation of a Transjugular Intrahepatic Portosystemic Shunt (TIPS)  

Sponsored By: ACR Council Steering Committee  

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

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

Each practice parameter and technical standard, representing a policy statement by the College, has undergone a thorough consensus process in which it has been subjected to extensive review and approval. The practice parameters and technical standards recognize that the safe and effective use of diagnostic and therapeutic radiology requires specific training, skills, and techniques, as described in each document. Reproduction or modification of the published practice parameter and technical standard by those entities not providing these services is not authorized.

Revised 2012 (Resolution 4)*

ACR–SIR–SPR PRACTICE PARAMETER FOR THE CREATION OF A TRANSJUGULAR INTRAHEPATIC PORTOSYSTEMIC SHUNT (TIPS)

PREAMBLE

This document is an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. Practice Parameters and Technical Standards are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care. For these reasons and those set forth below, the American College of Radiology and our collaborating medical specialty societies caution against the use of these documents in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the physician or medical physicist in light of all the circumstances presented. Thus, an approach that differs from the practice parameters, 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 practice parameters when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of the practice parameters. However, a practitioner who employs an approach substantially different from these practice parameters is advised to document in the patient record information sufficient to explain the approach taken.

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

PRACTICE PARAMETER  

TIPS  

2017 Resolution No. 15
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 practice parameters 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 practice parameters is to assist practitioners in achieving this objective.

**I. INTRODUCTION**

This practice parameter was revised collaboratively by the American College of Radiology (ACR), the Society of Interventional Radiology (SIR), and the Society for Pediatric Radiology (SPR) [1].

A transjugular intrahepatic portosystemic shunt (TIPS) is a percutaneous method used to treat the complications of portal hypertension. During the TIPS procedure, a channel, which shunts blood from the portal vein to a hepatic vein, is created through the hepatic parenchyma, reducing the portosystemic pressure gradient. Although TIPS has proven effective as a treatment for uncontrolled variceal hemorrhage, refractory ascites, and hepatic hydrothorax and as a bridge to liver transplant, it is not useful as a means to preserve liver function, with a possible exception in the treatment of Budd-Chiari syndrome [2-5].

Creating a TIPS involves several steps:

1. Catheterization of a hepatic vein
2. Wedge or balloon occluded hepatic venography to visualize the portal vein (CO₂ portography) [56] or intravascular/transabdominal ultrasound to visualize the portal vein and to guide the needle pass [57-62]
3. Passage of a long curved needle from the hepatic vein through the liver parenchyma into an intrahepatic branch of the portal vein
4. Direct portal venography to confirm proper location within the portal vein
5. Direct measurement of baseline systemic and portal vein pressures
6. Balloon dilation of the tract between the hepatic and portal veins
7. Deployment of a bare metal stent or self-expanding stent graft within the portosystemic tract to maintain it against the recoil of the surrounding liver parenchyma and prevent tissue ingrowth
8. Angiographic and hemodynamic assessment of the shunt tract
9. Dilation of the endoprosthesis until a satisfactory portosystemic pressure gradient has been reached, typically less than 12 mmHg [63-66]
10. Embolization of varices may be considered if opacification of the varices persists on portography following TIPS creation or in treating gastric varices or esophageal varices to prevent recurrent variceal bleeding [67,68].

The practice parameters that follow are to be used in quality improvement (QI) programs to evaluate the safety and effectiveness of the TIPS procedure. The most important processes of care are 1) proper patient selection, 2) performance of the procedure, and 3) post-TIPS surveillance. The major outcome measures for TIPS include improvement or resolution of the clinical indications for the procedure, early- and long-term reduction of portal hypertension, and the incidence of adverse events. Outcome measures are assigned threshold levels based on literature review and expert opinion. When the evidence of literature was weak, conflicting, or contradictory, consensus for the parameter was reached by a minimum of 12 committee members using a modified Delphi consensus method [69].

Although practicing physicians should strive to achieve perfect outcomes (eg, 100% success, 0% complications), in practice all physicians will fall short of this ideal. Thus, in addition to QI case reviews customarily conducted...
after individual procedural failures or complications, outcome measure thresholds should be used to assess TIPS efficacy in ongoing QI programs. Failing to achieve technical success in 95% and hemodynamic success in 90% of cases or exceeding the thresholds for major or minor complications (see Appendices B and C) should prompt a review of departmental policies and procedures. Patient referral patterns and selection factors may dictate a different threshold value for a metric at a particular institution. Thus, setting universal thresholds is very difficult, and each department is urged to alter the thresholds to higher or lower values to meet its own QI program needs.

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, 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 below refer to major complications unless otherwise noted.

Note: Treatment measures (including clinical, hemodynamic, and anatomic success), patient descriptors, measures of shunt patency, and encephalopathy grading based on the reporting standards defined by the Technology Assessment Committee of the SIR are incorporated into this document by reference [70].

II. INDICATIONS AND CONTRAINDICATIONS

A. Indications

TIPS creation is indicated for:

1. Uncontrollable variceal hemorrhage
2. Current or prior variceal hemorrhage that is not amenable to initial or continued endoscopic therapy
3. Prophylaxis against recurrent variceal bleed in high-risk patients
4. Portal hypertensive gastropathy or intestine-opathy
5. Refractory ascites
6. Hepatic hydrothorax
7. Budd-Chiari syndrome [71]
8. Hepatopulmonary syndrome
9. Hepatorenal syndrome [72]
10. Decompression of portosystemic collaterals prior to abdominal surgical 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.

B. Contraindications

The patients under consideration for a TIPS procedure are generally severely ill. Sometimes they require intervention as a potentially life-saving measure, acknowledging that the procedure itself entails significant risks. Although there are no absolute contraindications to creating a TIPS, the following are relative contraindications:

1. Elevated right or left heart pressures
2. Heart failure or cardiac valvular insufficiency
3. Rapidly progressive liver failure
4. Clinically significant refractory hepatic encephalopathy
5. Uncontrolled systemic infection or sepsis
6. Unrelieved biliary obstruction
7. Extensive primary or metastatic hepatic malignancy
8. Severe, uncorrectable coagulopathy
9. Marked pulmonary arterial hypertension
Although polycystic liver disease is frequently listed as a contraindication to TIPS, this is an unsubstantiated historic contraindication [73]. TIPS has been successfully performed in the setting of polycystic liver disease [73-75]. The use of a hybrid cross-sectional/angiographic imaging suite may facilitate successful placement [76].

It should be noted that in the setting of emergent variceal bleeding, TIPS can be performed in the presence of severe coagulopathy, although every effort should be made to safely correct the coagulopathy before, during, and after the procedure.

III. SUCCESS AND COMPLICATIONS

A. Measures of Success

Success should be classified as technical, hemodynamic, and clinical [70]. Note that success rates are not currently available for the pediatric population because of the lack of large series focusing on them. Because of the smaller size of their anatomic structures and other factors, success rates may be lower for them than for adults.

Technical success – Technical success describes the successful creation of a shunt (stent bridging) between the hepatic vein and intrahepatic branch of the portal vein. In the case of parallel shunt placement, technical success is reported for individual shunts.

Hemodynamic success – Hemodynamic success refers to the successful post-TIPS reduction of the portosystemic gradient below a threshold chosen for that study. A common hemodynamic end point, particularly when managing bleeding varices, is a portosystemic gradient of 12 mmHg [63-66,77]. Some authors have reported that in patients with bleeding varices, cessation of variceal filling during hand-injected splenic (or, in the case of intestinal varices, mesenteric) venography is a useful marker of successful decompression. This sign can be more difficult to standardize because different injection rates can lead to differences in the appearance of variceal flow. Although it can be argued that endoscopic confirmation of variceal decompression may be the gold standard for confirming hemodynamic success, this is impractical and probably unnecessary. Hemodynamic success can also be reported at follow-up shunt revisions. Absolute portal and right atrial pressures and the calculated portosystemic gradient, in millimeters of mercury and/or centimeters of water, should be recorded at the start and completion of the procedure.

Clinical success – Numerous studies have documented the efficacy and complications of TIPS for treatment of variceal bleeding and refractory ascites. Although much has been written about the unpredictable initial patency of TIPS, this has become less of an issue with more widespread use of stent grafts [78-87]. The 2-year primary patency rates of 76% to 84% and primary assisted patency rates of 93% are significantly improved because of the use of polytetrafluoroethylene (PTFE) stent grafts [87-93]. A recent meta-analysis demonstrated improved shunt patency with PTFE covered stents without increasing the risk of hepatic encephalopathy and with a trend towards longer survival [94]. The long-term management of patients after their first episode of variceal bleeding will depend on the actual outcomes of differing treatments and less on the absolute patency of a TIPS. Therefore, clinical success is perhaps the most important parameter in longitudinal studies of TIPS patients.

In the case of actively bleeding patients, early clinical success is determined by prompt arrest of acute variceal hemorrhage. This is indicated by cessation of demonstrable gastrointestinal bleeding, transfusion requirements, pharmacologic support, or balloon tamponade and by return of hemodynamic stability with or without performance of adjunctive variceal embolization when indicated. Because nonvariceal bleeding can coexist in upward of one-third of patients with varices, it is essential to verify endoscopically the causes of continued or recurrent bleeding after shunt placement or revision [95,96].

Clinical success is also reflected in the interval of time during which the patient remains free of the symptoms alleviated by the TIPS. For patients treated for variceal hemorrhage, this is the period between TIPS and the recurrence of a bleeding episode. For patients with ascites, this is the period between improvement or resolution
of ascites and recurrence of ascites. This is best described in terms of “event-free survival” intervals after TIPS placement. For variceal bleeding, it is recognized that this measure will greatly underestimate shunt stenosis or occlusion because TIPS patients may remain asymptomatic for prolonged periods despite having highly stenotic or occluded shunts. Furthermore, the outcomes after TIPS may differ depending on the types of varices (for example, gastric versus esophageal varices) [97].

B. Success Rates

Success rates for creation of TIPS in patients with patent hepatic and portal veins are given in Appendix B. Successful shunt creation has been reported in cases of hepatic and/or portal vein thromboses. These situations are relatively infrequent and may require considerably more technical expertise than shunt creation in patients with patent portal and hepatic veins. Accordingly, it is recognized that lower success rates can be anticipated in patients with these anatomic conditions. Of note, encouraging data are now available in a large, retrospective study involving Budd-Chiari patients, demonstrating technical success rates of up to 93% and 1-, 5-, and 10-year transplant-free survival rates of 88%, 78%, and 69%, respectively [71]. It is presently difficult, however, to define threshold levels for success in such cases. Similarly, TIPS in transplanted livers may have different clinical outcomes compared to native (nontransplanted) livers [98].

C. Complications [26,75,99-142]

Although major complications can occur during or as a result of TIPS, they are generally uncommon and are reduced with operator experience (Appendix C). 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 number of patients, for example, early in a QI program. In this situation, the overall procedure threshold is more appropriate for use in a QI program. Note that expected complication rates are not currently available for the pediatric population because of the relatively small number of cases.

Major complications occur in 5% of patients.

Participation by the radiologist in patient follow-up is an integral part of TIPS and will increase the durable efficacy of the procedure. Close follow-up with monitoring of shunt function and patency is necessary and appropriate for the radiologist. Appropriate methods include Doppler sonography in a validated laboratory or shunt venography.

IV. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Physician

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

1. Certification in Radiology or Diagnostic Radiology by the American Board of Radiology (ABR), the American Osteopathic Board of Radiology, the Royal College of Physicians and Surgeons of Canada, or the Collège des Médecins du Québec and has performed (with supervision) a sufficient number of TIPS procedures to demonstrate competency as attested by the supervising physician(s). The physician must have performed a minimum of 100 diagnostic angiograms, 50 angioplasties (25 as primary operator), 10 vascular stents, and 5 embolization procedures with documentation of success and complication rates as described in the appropriate ACR practice parameters, technical standards, or
2. Successful completion of a radiology or interventional radiology residency training program approved by the Accreditation Council for Graduate Medical Education (ACGME), the Royal College of Physicians and Surgeons of Canada (RCPSC), the Collège des Médecins du Québec, or the American Osteopathic Association (AOA) and a minimum of 12 months’ training and experience in vascular/interventional radiology and/or in an interventional/vascular radiology fellowship program, and have performed (with supervision) a sufficient number of TIPS procedures to demonstrate competency as attested by the supervising physician(s). 100 diagnostic angiograms, 50 angioplasties (25 as primary operator), 10 vascular stents, and 5 embolization procedures with documentation of success and complication rates as described in the appropriate ACR practice parameter, technical standard, or policy [143,144]. In addition, a minimum of 5 TIPS procedures must have been performed or supervised with documented success and complication rates that meet the threshold criteria listed in Appendix B and C.

3. In the absence of either an appropriate ACGME recognized residency training as outlined in IV.A.2 above or of a formal fellowship training in a Radiology Residency Review Committee (RRC) accredited vascular/interventional radiology fellowship program or of other postgraduate training that included comparable instruction and experience in interventional and vascular angiography, the physician must have at least 2 years’ experience with demonstrated competency as primary operator in diagnostic angiography under the supervision of an on-site qualified physician during which a minimum of 100 diagnostic angiograms, 50 angioplasties (25 as primary operator), 10 vascular stents, and 5 embolization procedures were performed with documentation of success and complication rates as described in the appropriate ACR practice parameter, technical standard, or policy [143,144]. The operator must have performed a minimum of 5 TIPS procedures with documented success and complication rates that meet the threshold criteria listed in Appendix B and C.

4. Physicians meeting any of the qualifications in 1, 2, or 3 above must also have written substantiation that they are familiar with all of the following:
   a. Indications and contraindications for the procedure.
   b. Periprocedural and intraprocedural assessment, monitoring, and management of the patient and complications. For pediatric cases, this includes knowledge of age-based normal ranges for vital signs, and signs and symptoms of complications; or availability of team members with such expertise (such as pediatric sedation and monitoring personnel).
   c. Pharmacology of drugs used for sedation and analgesia, and recognition and treatment of adverse reactions and complications. For pediatric cases, this includes knowledge of weight-based pediatric dosages, age-based normal values for vital signs, and signs and symptoms of adverse reactions and complications.
   d. Appropriate use and operation of fluoroscopic and radiographic equipment, mechanical injectors, digital subtraction equipment, and other electronic imaging systems.
   e. Principles of radiation protection, hazards of radiation, and radiation monitoring requirements as they apply to both patients and personnel, including appropriate dose-reduction strategies for children [145].
   f. Pharmacology of contrast agents and recognition and treatment of their potential adverse reactions.
   g. Percutaneous needle and catheter introduction techniques.
   h. Technical aspects of performing the procedure, including the use of multiple catheter and guidewire systems, selective angiographic methods, vascular embolization and thrombolytic methods, appropriate injection rates and volumes of contrast media (weight-based in children), and imaging sequences.
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i. Knowledge of potential intraprocedural complications and appropriate treatment options regarding these complications.

j. Anatomy, physiology, and pathophysiology, including pressure monitoring of gastrointestinal and hepatic vasculature, as well as normal variants.

k. Interpretation of gastrointestinal, hepatic, arterial, and venous vascular studies.

l. Postprocedural patient management, especially recognition and initial management of complications.

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

Maintenance of Competence

Physicians must perform a sufficient number of TIPS procedures to maintain their skills, with acceptable success and complication rates as laid out in this document (Appendix B and C). Continued competence should depend on participation in a QI program that monitors these rates.

Continuing Medical Education

The physician’s continuing education should be in accordance with the ACR Practice Parameter for Continuing Medical Education (CME) [146].

B. Nonphysician Practitioners

Physician assistants and nurse practitioners can be valuable members of the interventional radiology team. Their participation in TIPS procedures should be specifically under the direct supervision of appropriately qualified and credentialed physicians. See the ACR–SIR–SNIS–SPR Practice Parameter for Interventional Clinical Practice and Management [147].

C. Qualified Medical Physicist

A Qualified Medical Physicist should have the responsibility for overseeing the equipment quality control program and for monitoring fluoroscopy and other cross-sectional imaging studies, both upon installation and routinely on an annual basis. Qualified Medical Physicists assuming these responsibilities should meet the following qualifications:

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

A Qualified Medical Physicist should meet the ACR Practice Parameter for Continuing Medical Education (CME). (ACR Resolution 17, 1996 – revised in 2012, Resolution 42) [146]

The appropriate subfield of medical physics for this practice parameter is Diagnostic Medical Physics. (Previous medical physics certification categories including Radiological Physics, Diagnostic Radiological Physics, and Diagnostic Imaging Physics are also acceptable).
D. Registered Radiologist Assistant

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

E. 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 the patient for the procedure and together with the nurse, monitor the patient during the procedure. The technologist should obtain the imaging data in a manner prescribed by the supervising physician. The technologist should also perform the regular quality control testing of the equipment under supervision of the physicist.

Technologists should be certified by the American Registry of Radiologic Technologists (ARRT) or have an unrestricted state license with documented training and experience in the imaging modality used for the imaging-guided percutaneous procedure.

F. Anesthesiologist

In certain circumstances, the primary operator may determine that anesthesiology support may be required.

G. Nursing Services

Nursing services are an integral part of the team for periprocedural and intraprocedural 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 TIPS creation. These include adequate arteriographic equipment and institutional facilities, physiologic monitoring equipment, and support personnel.
A. Angiographic Equipment and Facilities

1. A high-resolution flat panel detector or image intensifier and television chain with standard angiographic filming capabilities. Digital subtraction angiographic systems with high spatial resolution are recommended, as they allow for reduced volumes of contrast material and reduced examination times. These digital acquisition systems are sufficient to offer an alternative to conventional film systems and are more flexible and therefore preferable for safe and accurate TIPS creation. Use of last image hold and pulsed fluoroscopy is recommended for dose reduction. The equipment should be capable of displaying to the operator the radiation dose received by the patient at the operator’s normal working position and recording the radiation dose received by the patient so it can be made part of the patient’s permanent medical record [148]. 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, stents, balloons, needles, pressure measurement equipment, and introducer sheaths

3. An angiography suite large enough to allow easy transfer of the patient from the bed to the table and to allow room for the procedure table, monitoring equipment, and other hardware such as intravenous pumps, ventilator, 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 for preprocedural preparation and postprocedural observation and monitoring of the patient. At this location, there should be personnel to provide care as outlined in section V.E. below (Patient Care), and 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. For facilities using moderate sedation, a pulse oximeter or an end-tidal carbon dioxide monitor should be available. (See the ACR-SIR Practice Parameter for Sedation/Analgesia [149].) For facilities using general anesthesia, the patient is typically intubated and additional monitoring, such as direct arterial line blood pressure monitoring, may be considered.

2. Appropriate emergency equipment and medications must be immediately available to treat adverse reactions associated with administered medications and/or procedural complications. The equipment should be maintained and medications inventoried for drug expiration dates on a regular basis. The equipment, medications, and other emergency support must also be appropriate for the range of ages and sizes in the patient population.

3. Equipment for invasive pressure monitoring should be readily available. In addition to conventional physiologic monitoring, the equipment must be capable of measuring the portal and systemic venous pressures obtained during creation of the TIPS.
C. Support Personnel

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

2. It would be unusual for the patient to not receive sedation or general anesthesia. However, if that were the case, one of the staff members assisting the procedure should be assigned to periodically assess the patient’s status. If the patient is to undergo sedation, a nurse or other appropriately trained individual should monitor the patient as his or 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 sedation. (See the ACR–SIR Practice Parameter for Sedation/Analgesia. [149].) For pediatric cases, sedation and recovery personnel should be experienced and qualified in pediatric sedation, monitoring, and airway maintenance. Children may easily slip between depths of sedation during the procedure. Therefore, there must be experienced and qualified personnel available to manage the airway and rescue children from deep sedation or apnea should this occur. Health professionals who provide sedation for TIPS procedures should comply with the recommendations of the ACR–SIR Practice Parameter for Sedation/Analgesia [149].

3. For unstable patients, additional support may be necessary to ensure the safe performance of TIPS. The primary operator may be engaged in the details of the proper performance of the TIPS. Therefore, appropriate personnel should be available to attend to the ongoing care and resuscitation of critically ill patients. Such personnel might include anesthesiologists; operating room, ICU, and/or ER trained nurses; or other physicians. The nurses may be radiology nurses and/or the same personnel responsible for monitoring and maintaining moderate sedation as discussed immediately above. Alternatively, the nurses may be supplied from other patient care units in the facility.

All such additional personnel should work in concert with and under the overall supervision of the primary operator performing the TIPS but within the scopes of service as defined by their professions, state regulations, and institutional guidelines.

D. Surgical Support

Although surgical or other emergency treatment is needed infrequently for serious complications after TIPS creation, there should be prompt access to surgical and interventional equipment and to specialists familiar with the management of patients with complications in the unlikely event of a life-threatening complication.

E. Patient Care

For additional information see the ACR–SIR–SNIS–SPR Practice Parameter for Interventional Clinical Practice and Management [147].

1. Preprocedure care

In addition to having demonstrated competence in performing the TIPS procedure and having been granted institutional privileges to perform the procedure, the physician performing the procedure must have knowledge of the following:
a. Clinically significant history, including indications for the procedure
b. Clinically significant physical or diagnostic examination, including knowledge and awareness of
   other clinical or medical conditions that may necessitate specific care, such as the presence of
   patent portal vein or massive ascites, and certain diagnostic laboratory results
c. Relative contraindications and factors that will lead to increased risk of complication
d. Possible alternative methods, such as surgical, endoscopic, or medical treatments, to obtain the
   desired therapeutic result

Informed consent must be in compliance with state laws and the ACR–SIR Practice Parameter on
Informed Consent for Image-Guided Procedures [150].

2. Procedural care

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

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

b. TIPS creation carries a substantial likelihood of clinically significant patient radiation dose [151].
   Therefore, the physician performing the procedure should have knowledge of radiation exposure
   factors, including kVp, mA, magnification factor, and fluoroscopic/angiographic fluorographic
   frame rate. The operator should also consider additional parameters such as collimation, field of
   view, last image hold, and geometry (especially the patient’s proximity to the lateral source). The
   fluoroscopic equipment should be capable of displaying the radiation dose received by the patient
   to the operator at the operator’s normal working position and recording the radiation dose received
   by the patient. The radiation dose should be recorded and made part of the patient’s permanent
   medical record [148].

c. The physician creating the TIPS should have knowledge of physiologic parameters that would
   indicate developing problems or complications and be able to interpret changes in heart rate or
   rhythm, changes in blood pressure, and changes in oxygen saturation. These are essential for
   successful intraprocedural care of the patient.

d. Nursing personnel, technologists, and those directly involved in the care of patients undergoing
   TIPS creation should have protocols for use in standardizing care. These should include, but are not
   limited to, the following:
   i. Equipment needed for the procedure
   ii. Patient monitoring
   iii. Protocols should be reviewed and updated periodically.

3. Postprocedure care

a. The operating physician or a qualified designee should evaluate the patient after the procedure, and
   these findings should be summarized in a progress note. If sedation was administered prior to and
   during the procedure, safe and adequate recovery from 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, a midlevel practitioner, or a nurse. (See
   the ACR–SIR Practice Parameter for Sedation/Analgesia [149].) Postprocedure documentation
   should be in accordance with the ACR–SIR–SPR Practice Parameter for the Reporting and
   Archiving of Interventional Radiology Procedures [152].
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 patient’s medical condition.

c. During the initial postprocedure period, skilled nurses or other appropriately trained personnel should periodically monitor the puncture site for bleeding or hematoma.

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 operating physician or a qualified designee 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, a midlevel practitioner, or a nurse.

Although not part of the TIPS procedure, a baseline study (eg, ultrasound) to evaluate the shunt’s functional status should be obtained prior to or shortly after discharge. This study can be delayed for several days or until an early outpatient clinical visit, particularly in patients who receive TIPS stent grafts. Unlike bare metal stents, expanded PTFE (e-PTFE) TIPS stent grafts typically prevent successful TIPS sonography within the first several days or week until graft incorporation begins because of an acoustic barrier thought to be secondary to microbullae embedded within the e-PTFE [153] or possibly pockets of gas between the e-PTFE and the wire mesh of the stent or between the hepatic parenchyma and the e-PTFE [154].

VI. DOCUMENTATION

Reporting should be in accordance with the ACR–SIR–SPR Practice Parameter for the Reporting and Archiving of Interventional Radiology Procedures [152].

VII. RADIATION SAFETY IN IMAGING

Radiologists, medical physicists, registered radiologist assistants, radiologic technologists, and all supervising physicians have a responsibility for safety in the workplace by keeping radiation exposure to staff, and to society as a whole, “as low as reasonably achievable” (ALARA) and to assure that radiation doses to individual patients are appropriate, taking into account the possible risk from radiation exposure and the diagnostic image quality necessary to achieve the clinical objective. All personnel that work with ionizing radiation must understand the key principles of occupational and public radiation protection (justification, optimization of protection and application of dose limits) and the principles of proper management of radiation dose to patients (justification, optimization and the use of dose reference levels)


Nationally developed guidelines, such as the ACR’s Appropriateness Criteria®, should be used to help choose the most appropriate imaging procedures to prevent unwarranted radiation exposure.

Facilities should have and adhere to policies and procedures that require varying ionizing radiation examination protocols (plain radiography, fluoroscopy, interventional radiology, CT) to take into account patient body habitus (such as patient dimensions, weight, or body mass index) to optimize the relationship between minimal radiation dose and adequate image quality. Automated dose reduction technologies available on imaging equipment should be used whenever appropriate. If such technology is not available, appropriate manual techniques should be used.
Additional information regarding patient radiation safety in imaging is available at the Image Gently® for children (www.imagegently.org) and Image Wisely® for adults (www.imagewisely.org) websites. These advocacy and awareness campaigns provide free educational materials for all stakeholders involved in imaging (patients, technologists, referring providers, medical physicists, and radiologists).

Radiation exposures or other dose indices should be measured and patient radiation dose estimated for representative examinations and types of patients by a Qualified Medical Physicist in accordance with the applicable ACR technical standards. Regular auditing of patient dose indices should be performed by comparing the facility’s dose information with national benchmarks, such as the ACR Dose Index Registry, the NCRP Report No. 172, Reference Levels and Achievable Doses in Medical and Dental Imaging: Recommendations for the United States or the Conference of Radiation Control Program Director’s National Evaluation of X-ray Trends. (ACR Resolution 17 adopted in 2006 – revised in 2009, 2013, Resolution 52).

In addition, manual techniques (adjusting the fluorographic angiographic and fluoroscopic frame rates, increasing the patient’s distance from the source, minimizing the distance between the patient and the image receptor, limiting the use of digital subtraction angiography, use of last image hold and video fluoroscopy chips, etc.), should be used to optimize the radiation dose. In other words, the technique employed should be tailored to the task at hand [155-157].

Radiation safety deserves particular attention when fluoroscopically guided procedures are performed on children. The Image Gently® coalition has provided useful guidance in this regard [158].

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

Policies and procedures related to quality, patient education, infection control, and safety should be developed and implemented in accordance with the ACR Policy on Quality Control and Improvement, Safety, Infection Control, and Patient Education appearing under the heading Position Statement on QC & Improvement, Safety, Infection Control, and Patient Education on the ACR website (http://www.acr.org/guidelines) and other published practice parameters and recommendations [3,159-161].


This information should be used in conjunction with the thresholds described in section II and Appendices B and C below to assess TIPS procedural efficacy and complication rates and to trigger institutional review when the thresholds defined in those sections are exceeded.

APPENDIX A

Society of Interventional Radiology
Standards of Practice Committee

Classification of Complications by Outcome

Minor Complications

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

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

Success Rates for TIPS

Type of Success

Technical
Creation of a patent TIPS between the hepatic vein and a branch of the portal vein in the presence of patent portal and hepatic veins 95%

Hemodynamic
Reduction of the portosystemic gradient to a level targeted by the operator. In general, the target portosystemic gradient is ≤12 mmHg [63-66,77]. The authors recognize that the final portosystemic gradient may vary depending on the treated indication (eg, ascites versus gastric or esophageal variceal hemorrhage). 90%

Clinical Success for Variceal Bleeding
Acute clinical success for variceal bleeding [164,165]. When feasible, the event-free survival interval should be recorded by the primary operator or the patient’s primary physician. 90%

Clinical Success for Ascites
Complete or partial response with intention to treat [28,39,44,166,167] 50% to 90%

Clinical Success for Refractory Hydrothorax
Complete or partial response [18,23,46,50,168-170] 42% to 80%

APPENDIX C

TABLE C1. SPECIFIC COMPLICATIONS OF TIPS

<table>
<thead>
<tr>
<th>Major Complications (overall)</th>
<th>Reported Rate</th>
<th>Suggested Complication-Specific Threshold</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemoperitoneum+</td>
<td>0.5%</td>
<td>&lt;5%</td>
</tr>
<tr>
<td>Stent malposition**</td>
<td>1%</td>
<td>&lt;5%</td>
</tr>
<tr>
<td>Hemobilia</td>
<td>2%</td>
<td>&lt;5%</td>
</tr>
<tr>
<td>Radiation skin burn</td>
<td>0.1%</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>Hepatic infarction</td>
<td>0.5%</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>Renal failure requiring chronic dialysis</td>
<td>0.25%</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>Hepatic artery injury</td>
<td>1%</td>
<td>2% [113]</td>
</tr>
<tr>
<td>Accelerated liver failure***</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Severe or uncontrolled encephalopathy****</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Refractory encephalopathy [142,171-173]</td>
<td>3% to 8%</td>
<td>10%</td>
</tr>
<tr>
<td>Death*****</td>
<td>1%</td>
<td>&lt;5%</td>
</tr>
</tbody>
</table>

Minor Complications (overall)

<table>
<thead>
<tr>
<th>Reported Rate</th>
<th>Suggested Complication-Specific Threshold</th>
</tr>
</thead>
<tbody>
<tr>
<td>4%</td>
<td>8%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Minor Complications (overall)</th>
<th>Reported Rate</th>
<th>Suggested Complication-Specific Threshold</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transient contrast-induced renal failure</td>
<td>2%</td>
<td>5%</td>
</tr>
<tr>
<td>Encephalopathy controlled by medical therapy [142]</td>
<td>5% to 35%</td>
<td>40%</td>
</tr>
<tr>
<td>Fever</td>
<td>2%</td>
<td>5%</td>
</tr>
<tr>
<td>Transient pulmonary edema</td>
<td>1%</td>
<td>1%</td>
</tr>
<tr>
<td>Transcapsular puncture [142]</td>
<td>5% to 30%</td>
<td>10%</td>
</tr>
<tr>
<td>Procedure</td>
<td>Rate</td>
<td></td>
</tr>
<tr>
<td>-------------------------------</td>
<td>------</td>
<td></td>
</tr>
<tr>
<td>Biliary duct puncture</td>
<td>&lt;5%</td>
<td></td>
</tr>
<tr>
<td>Gallbladder puncture</td>
<td>&lt;10%</td>
<td></td>
</tr>
<tr>
<td>Right kidney puncture</td>
<td>1.5%</td>
<td></td>
</tr>
</tbody>
</table>

- Hemoperitoneum warranting blood transfusion

**A major stent malposition includes conditions such as free stent migration within the portal or systemic venous circulations or ones resulting in vascular perforation or caval occlusion (due to excessive extension of a stent graft into the inferior vena cava or to the right atrium).

***The rate of accelerated liver failure after TIPS is highly dependent upon patient selection, final shunt diameter, and comorbid factors (eg, pre-existing multiorgan system failure, high MELD score, elevated APACHE II scores, high Child-Pugh scores). Part of this risk is not specific to the creation of a TIPS, but is shared by surgical forms of portosystemic diversion as well. Thus a specific threshold for this complication cannot be assigned.

****Encephalopathy rates are directly dependent on patient selection, as with any form of portosystemic diversion. For example, patients with severe or refractory ascites may manifest severe encephalopathy (requiring hospitalization) in 30% to 40% of cases [17,23,24,53]. In contrast, elective patients with Child-Pugh class A or B hepatocellular disease may manifest severe, uncontrolled encephalopathy in 3% to 10% of cases [25,26,52,130,135,136,141].

*****Death refers to 30-day mortality directly related to a complication of TIPS creation. As with accelerated liver failure after TIPS (see **), the majority of deaths after TIPS are dependent on preexisting comorbid factors such as elevated APACHE II scores, Child-Pugh class or scores, and multiorgan system failure. The existence of these pre-TIPS conditions can greatly increase the rate of 30-day mortality after TIPS or surgical forms of portosystemic diversion. Proper patient selection and minimization of procedural complications can greatly reduce death rates.

ACKNOWLEDGEMENTS

This practice parameter was revised according to the process described under the heading The Process for Developing ACR Practice Parameters and Technical Standards on the ACR website (http://www.acr.org/guidelines) by the Committee on Practice Parameters – Interventional and Cardiovascular Radiology of the ACR Commission on Interventional and Cardiovascular Radiology and the Committee on Practice Parameters – Pediatric Radiology of the ACR Commission on Pediatric Radiology, in collaboration with the SIR and SPR.

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**Development Chronology for this Practice**

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Amended 2004 (Resolution 25)

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Revised 2007 (Resolution 8, 12m)

Amended 2009 (Resolution 11)

Revised 2012 (Resolution 4)

Amended 2014 (Resolution 39)
BE IT RESOLVED, that the American College of Radiology adopt the ACR–ASNR–ASSR–SIR–SNIS Practice Parameter for the Performance of Vertebral Augmentation

Sponsored By: ACR Council Steering Committee

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

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Revised 2012 (Resolution 6)*

ACR–ASNR–ASSR–SIR–SNIS PRACTICE PARAMETER FOR THE PERFORMANCE OF VERTEBRAL AUGMENTATION

PREAMBLE

This document is an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. Practice Parameters and Technical Standards are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care. For these reasons and those set forth below, the American College of Radiology and our collaborating medical specialty societies caution against the use of these documents in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the physician or medical physicist in light of all the circumstances presented. Thus, an approach that differs from the practice parameters, 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 practice parameters when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of the practice parameters. However, a practitioner who employs an approach substantially different from these practice parameters 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

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1 Iowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing, 721 N.W.2d 805 (Iowa 2006) (Iowa Supreme Court refuses to find that the ACR Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures (Revised 2008) sets a national standard for who may perform fluoroscopic procedures in light of the standard’s stated purpose that ACR standards are educational tools and not intended to establish a legal standard of care. See also, Stanley v. McCarver, 63 P.3d 1076 (Ariz. App. 2003) where in a concurring opinion the Court stated that “published standards or guidelines of specialty medical organizations are useful in determining the duty owed or the standard of care applicable in a given situation” even though ACR standards themselves do not establish the standard of care.
I. INTRODUCTION

This practice parameter was revised collaboratively by the American College of Radiology (ACR), the American Society of Neuroradiology (ASNR), the American Society of Spine Radiology (ASSR), the Society of Interventional Radiology (SIR), and the Society of NeuroInterventional Surgery (SNIS).

This document addresses vertebral augmentation, which includes all percutaneous techniques used to achieve internal vertebral body stabilization. Vertebral augmentation encompasses a variety of procedures for treating pathologically weakened vertebral bodies. The more common ones are vertebroplasty and acrylic vertebroplasty, which involves injecting surgical bone cement; balloon kyphoplasty (also called balloon-assisted vertebroplasty), which involves inflation of a balloon in the weakened fractured vertebral body to attempt fracture reduction before cement is injected; and/or radiofrequency ablation (RFA) and coblation techniques.[1] Other less common procedures include mechanical void creation (also called mechanical cavitation) with an osteotome, injection of bone graft material or bone substitutes, and insertion of materials and/or implants in an attempt to restore the patient’s vertebral height or attempt to decrease the possibility of extravasation.[2,3]. The field is evolving rapidly and this document also applies to any new methods for achieving the same end: vertebral augmentation.

A thorough review of the literature was performed. When published data were felt to be inadequate, data from the expert panel members’ own quality assurance programs were used to supplement. Thresholds for quality assurance have been updated in accordance with available data in the literature.

Introduced by Galibert and Deramond et al in France in 1987[4], vertebroplasty entails injection of material into the weakened vertebra. Radiologic imaging has been a critical part of vertebroplasty from its inception. Most procedures are performed using fluoroscopic guidance for needle placement and material injection or placement. The use of computed tomography (CT) has also been described for these purposes.[5,6]

Vertebral augmentation is an established and safe procedure[4,5,7-24]. The New England Journal of Medicine published 2 blinded, randomized controlled trials that failed to demonstrate an advantage in their study populations for vertebroplasty over a control sham intervention for either pain reduction or disability improvement involving the paraspinal injection of anesthetic.[25,26] However, later larger blinded, randomized controlled trials (RCTs) demonstrated statistically significant benefits in pain and functional improvement following vertebroplasty compared to sham treatments [Ref: Clark W, Bird P.J.

Furthermore, larger non-blinded, prospective randomized controlled studies and other studies of vertebral augmentation other studies of vertebral augmentation, systematic reviews and meta-analyses of the randomized controlled trials have shown its efficacy[27-46] [Ref: 27-46; Anderson PA]. As with any invasive procedure, the patient is most likely to benefit when the procedure is performed in an appropriate environment by qualified physicians.

These practice parameters are intended to be used in quality improvement programs to assess vertebral augmentation procedures. The most important processes of care are (1) patient selection, (2) performing the procedure; and (3) monitoring the patient and (4) appropriate patient follow-up. The outcome measures or indicators for these processes are indications, success rates, and complication rates. Outcome measures are assigned threshold levels.
Use of other technologies to treat patients for the same indications should yield similar or better success rates and complication profiles.

II. DEFINITIONS

Vertebral augmentation includes all percutaneous techniques used to achieve internal vertebral body stabilization.

Vertebroplasty is a minimally invasive surgical or interventional image-guided procedure, performed by percutaneously injecting radiopaque bone cement, osteoinductive substance, or other therapeutic material into a painful osteoporotic or neoplastic compression fracture or a painful vertebral body weakened by any other etiology.

Kyphoplasty is an image-guided procedure in which a device such as a balloon or osteotome is employed to create a cavity within the vertebra, which is then filled with material. Balloon inflation may sometimes be employed to attempt vertebral height restoration.

Other similar vertebral augmentation techniques involving the adjunctive implantation of devices in conjunction with bone filling materials have been described as well. These techniques may possibly effect vertebral height restoration and/or potentially decrease extravasation of the filler material.

Kyphoplasty is an image-guided percutaneous procedure that creates a cavity within the bone that is then filled with material.

Failure of medical therapy is defined as:

1. A patient rendered nonambulatory because of pain from a weakened or fractured vertebral body; pain persisting at a level that prevents ambulation despite 24 hours of analgesic therapy
2. A patient with sufficient pain from a weakened or fractured vertebral body that physical therapy is intolerable; pain persisting at that level despite 24 hours of analgesic therapy
3. Any patient with a weakened or fractured vertebral body and unacceptable side effects such as excessive sedation, confusion, or constipation due to the analgesic therapy necessary to reduce pain to a tolerable level

III. OVERVIEW

Vertebral compression fractures are a common and often debilitating complication of osteoporosis [47-51]. Although most fractures heal within a few weeks or months, a minority of patients continue to suffer pain that does not respond to conservative therapy [52-54]. Vertebral compression fractures are a leading cause of nursing home admission and mortality [Ref: Lange A, Kasperk C]. Open surgical fixation is rarely used to treat these fractures unless there is neurological compromise. The poor quality of bone at the adjacent unfractured levels does not provide a good anchor for surgical hardware, and the advanced age of most affected patients increases the morbidity and mortality risks of major surgery.

Initial success with vertebroplasty for treating aggressive hemangiomas [4,15] and osteolytic neoplasms [13,24] led to extension of the indications to include osteoporotic compression fractures refractory to medical therapy [5,7-12,14,16-22]. Vertebral augmentation is currently being used to treat a wide variety of osteolytic metastases and multiple myelomas [39,55-58].
Perioperative imaging that identifies the painful vertebral body in concordance with the clinical examination is considered essential for the safe and effective performance of vertebral augmentation.

IV. INDICATIONS AND CONTRAINDICATIONS

The major indication for vertebral augmentation is the treatment of symptomatic osteoporotic vertebral body fracture(s) refractory to medical therapy or vertebral bodies weakened because of neoplasia. Currently, there is no indication for prophylactic vertebral augmentation for prophylaxis against future to prevent future osteoporotic fracture. The indications and contraindications for vertebral augmentation may change in the future as more research and information become available.

A. Indication Threshold—95%

1. Painful osteoporotic vertebral fracture(s) refractory to medical therapy
2. Vertebral bodies weakened by neoplasm
3. Symptomatic vertebral body microfracture (as documented by magnetic resonance imaging [MRI] or nuclear imaging, and/or lytic lesion seen on computed tomography [CT]) without obvious loss of vertebral body height

When fewer than 95% of vertebral augmentations in an institution are performed for the above indications, it should prompt a review of practices related to selection of patients for this procedure.

B. Absolute Contraindications

1. Septicemia
2. Active osteomyelitis of the target vertebra
3. Uncorrectable coagulopathy
4. Allergy to bone cement or opacification agent

C. Relative Contraindications

1. Radiculopathy in excess of local vertebral pain, caused by a compressive syndrome unrelated to vertebral collapse. Occasionally preoperative vertebroplasty can be performed before a spinal decompressive procedure.
2. Retropulsion of a fracture fragment causing severe spinal canal signs and symptoms of neurological compromise
3. Epidural tumor extension with significant encroachment on the spinal canal
4. Ongoing systemic infection
5. Patient improving on medical therapy
6. Prophylaxis in osteoporotic patients (unless being performed as part of a research protocol)
7. Myelopathy or cauda equina syndrome originating at the fracture level

V. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Physician

In general, the requirements for physicians performing vertebral augmentation may be met by adhering to the recommendations listed below:

1. Certification in Radiology or Diagnostic Radiology by the American Board of Radiology, the American Osteopathic Board of Radiology, the Royal College of Physicians and Surgeons of Canada, or the Collège des Médecins du Québec, and has performed (with supervision) a sufficient number of vertebral augmentation procedures to demonstrate competency as attested by the supervising physician(s), must include performance of successful vertebral augmentation procedures in at least 5
patients as the primary operator, under the supervision of a qualified physician, and without major complications.

or

2. Completion of an approved residency or fellowship program by the Accreditation Council for Graduate Medical Education (ACGME), the Royal College of Physicians and Surgeons of Canada (RCPSC), the Collège des Médecins du Québec, or an American Osteopathic Association (AOA) approved residency program and has performed (with supervision) a sufficient number of vertebral augmentation procedures to demonstrate competency as attested by the supervising physician(s), that included 6 months of training in cross-sectional imaging, including CT and MR imaging, and 4 months of training in image-guided interventional radiological techniques, including vertebral augmentation, biopsy and drainage procedures, and vascular embolization. This must include performance of successful vertebral augmentations in at least 5 patients as the primary operator, under the supervision of a qualified physician, and without major complications.

or

3. A physician who did not successfully complete an ACGME approved radiology residency or fellowship program that included the above may still be considered qualified to perform vertebral augmentation provided the following can be demonstrated: the physician must have at least 1 year of experience in performing percutaneous image-guided spine procedures, during which the physician was supervised by a physician with active privileges in these spine procedures. During this year he or she must have performed a minimum of 5 vertebral augmentations as primary operator with outcomes within the quality improvement thresholds of this practice parameter.

and

4. Physicians meeting any of the qualifications in 1, 2, or 3 above must have written substantiation that they are familiar with all of the following:

a. Indications and contraindications for vertebral augmentation.

b. Periprocedural and intraprocedural assessment, monitoring, and management of the patient, and particularly the recognition and initial management of procedural complications.

c. Appropriate use and operation of fluoroscopic and radiographic equipment, digital subtraction systems, and other electronic imaging systems.

d. Principles of radiation protection, hazards of radiation, and radiation monitoring requirements as they apply to both patients and personnel.

e. Anatomy, physiology, and pathophysiology of the spine, spinal cord, and nerve roots.

f. Pharmacology of contrast agents and implanted materials and recognition and treatment of potential adverse reactions to these substances.

g. Technical aspects of performing this procedure.

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

and

5. Physicians must possess certain fundamental knowledge and skills that are required for the appropriate application and safe performance of vertebral augmentation:

a. In addition to a basic understanding of spinal anatomy, physiology, and pathophysiology, the physician must have sufficient knowledge of the clinical and imaging evaluation of patients with spinal disorders to determine those for whom vertebral augmentation is indicated.

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2At institutions in which there is joint (dual) credentialing across departments doing like procedures, this substantiation of experience should be done by the chairs of both departments to ensure equity of experience among practitioners when their training backgrounds differ [43].
b. The physician must fully appreciate the benefits and risks of vertebral augmentation and the alternatives to the procedure.

c. The physician is required to be competent in the use of fluoroscopy, CT, and MRI or interpretation of images in the modalities used to evaluate potential patients and guide the vertebral augmentation procedure.

d. The physician should be able to recognize, interpret, and act immediately on image findings.

e. The physician must have the ability, skills, and knowledge to evaluate the patient’s clinical status and to identify those patients who might be at increased risk, who may require additional perioperative care, or who have relative contraindications to the procedure.

f. The physician must be capable of providing the initial clinical management of complications of vertebral augmentation, including administration of basic life support, treatment of pneumothorax, and recognition of spinal cord compression.

g. Training in radiation physics and safety is an important component of these requirements. Such training is important to maximize both patient and physician safety. It is highly recommended that the physician have adequate training in and be familiar with the principles of radiation exposure, the hazards of radiation exposure to both patients and radiologic personnel, and the radiation monitoring requirements for the imaging methods listed above.

Some methods of vertebral augmentation may require specialized training and experience, and such needs should be assessed before a physician contemplates using any method.

Maintenance of Competence

Physicians should perform a sufficient number of vertebral augmentation procedures to maintain their skills, with acceptable success and complication rates as laid out in this practice parameter. Continued competence depends on participation in a quality improvement program that monitors these rates. Regular attendance at postgraduate courses that provide continuing education on diagnostic and technical advances in vertebral augmentation is necessary.

Continuing Medical Education

The physician’s continuing education should be in accordance with the ACR Practice Parameter for Continuing Medical Education (CME) [59].

B. Nonphysician Practitioners

Physician assistants and nurse practitioners can be valuable members of the interventional radiology team but not as primary operator. These nonphysician practitioners can function as independent members of the team but not as primary operator. See the ACR–SIR–SNIS–SPR Practice Parameter for Interventional Clinical Practice and Management [60].

C. Qualified Medical Physicist

A Qualified Medical Physicist is an individual who is competent to practice independently one or more of the subfields in medical physics. The American College of Radiology (ACR) considers certification, continuing education, and experience in the appropriate subfield(s) to demonstrate that an individual is competent to practice one or more of the subfields in medical physics and to be a Qualified Medical Physicist. The ACR strongly recommends that the individual be certified in the appropriate subfield(s) by the American Board of Radiology (ABR), the Canadian College of Physics in Medicine, or the American Board of Medical Physics (ABMP).
A Qualified Medical Physicist should meet the ACR Practice Parameter for Continuing Medical Education (CME) (ACR Resolution 17, 1996 – revised in 2012, Resolution 42) [59].

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

D. Registered Radiologist Assistant

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

E. Radiologic Technologist

The technologist, together with the physician and the nursing personnel, should be responsible for patient comfort. The technologist should be able to prepare and position the patient for the vertebral augmentation procedure and, together with the nurse, monitor the patient during the procedure. The technologist should obtain the imaging data in a manner prescribed by the supervising physician. The technologist should also perform regular quality control testing of the equipment under the supervision of the Qualified Medical Physicist.

The technologist should have appropriate training and experience in the vertebral augmentation procedure and be certified by the American Registry of Radiologic Technologists (ARRT) and/or have an unrestricted state license.

F. Nursing Services

Nursing services are an integral part of the team for perioperative patient management and education and may assist the physician in monitoring the patient during the vertebral augmentation procedure.

VI. SPECIFICATIONS OF THE PROCEDURE

A. Technical Requirements

Vertebral augmentation may be performed with either fluoroscopy or CT imaging guidance. The choice is a matter of operator preference and patient characteristics. In either case, there are several technical requirements to ensure safe and successful vertebral augmentations. These include adequate institutional facilities, imaging and monitoring equipment, and support personnel. The following are minimum requirements for any institution in which vertebral augmentation is to be performed:

1. A procedural suite large enough to allow safe and easy, straightforward transfer of the patient from bed to procedural table with sufficient space for appropriate positioning of patient monitoring equipment, anesthesia equipment, respirators, etc. There should be adequate space for the operating team to work...
unencumbered on either side of the patient and for the circulation of other staff within the room without contaminating the sterile conditions.

2. The majority of these procedures are performed under fluoroscopic guidance. A high-resolution image intensifier or flat-panel detector and video system with adequate shielding, capable of rapid imaging in orthogonal planes and with capabilities for permanent image recording, is strongly recommended. The fluoroscope should be compliant with IEC 601-2-43 [61]. Imaging findings are acquired and stored either on conventional film or digitally on computerized storage media. Imaging and image recording must be consistent with the as low as reasonably achievable (ALARA) radiation safety guidelines.

3. Immediate Prompt access to CT and rapid (within 30 or 45 minutes) access to MRI is necessary to evaluate potential complications. This may be particularly important if vertebral augmentation is planned in patients with osteolytic vertebral metastasis and/or with significant pre-existing spinal canal compromise.

4. The facility must provide adequate resources for observing patients during and after vertebral augmentation. Physiologic monitoring devices appropriate to the patient’s needs—including blood pressure monitoring, pulse oximetry, and electrocardiography—and equipment for cardiopulmonary resuscitation must be available in the procedural suite.

B. Surgical and Emergency Support

Although serious complications of vertebral augmentation are infrequent, there should be prompt access to surgical, interventional, and medical management of complications.

C. Patient Care

1. Preprocedural care
   a. The clinical history and findings, including the indications for the procedure, must be reviewed and recorded in the patient’s medical record by the physician performing the procedure. Specific inquiry should be made with respect to relevant medications, prior allergic reactions, and bleeding/clotting status.
   b. The vital signs and the results of physical and neurological examinations must be obtained and recorded.
   c. The indication(s) for the procedure, including (if applicable) documentation of failed medical therapy, must be recorded.
   d. The indication(s) for treatment of the fracture should have documentation of imaging correlation and confirmation.

2. Procedural care
   a. Adherence to the Joint Commission’s current Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™ is required for procedures in non-operating room settings, including bedside procedures.
      The organization should have processes and systems in place for reconciling differences in staff responses during the “time-out.”
   b. Vital signs should be obtained at regular intervals during the course of the procedure, and a record of these measurements should be maintained.
   c. Patients undergoing vertebral augmentation must have intravenous access in place for the administration of fluids and medications as needed.
   d. If the patient receives sedation, pulse oximetry must be used. Administration of sedation for vertebral augmentation should be in accordance with the ACR–SIR Practice Parameter for Sedation/Analgesia [62]. A registered nurse or other appropriately trained personnel should be present and have primary responsibility for monitoring the patient. A record of medication doses and times of administration should be maintained.
3. Postprocedural care
   a. A procedural note should be written in the patient’s medical record summarizing the course of the procedure and what was accomplished, any immediate complications, and the patient’s status at the conclusion of the procedure (see section VIII.A.2 below). This note may be brief if the formal report will be available within a few hours. This information should be communicated to the referring physician in a timely manner. A more detailed summary of the procedure should be written in the medical record if the formal typed [transcribed] report will not be on the medical record within the same day.
   b. All patients should be at bed rest and observed during the initial postprocedural period. The length of this period will depend on the patient’s medical condition.
   c. During the immediate postprocedural period, skilled nurses or other appropriately trained personnel should monitor the patient’s vital signs, urinary output, sensorium, and motor strength. Neurological status should be assessed frequently at regular intervals. Initial ambulation of the patient must be carefully supervised.
   d. The operating physician or a qualified designee (another physician or a nurse) should evaluate the patient after the initial postprocedural period, and these findings should be summarized in a progress note on the patient’s medical record. The physician or designee must be available for continuing postprocedural care during hospitalization at the facility and after discharge.

VII. EQUIPMENT QUALITY CONTROL

Each facility should have documented policies and procedures for monitoring and evaluating the effective management, safety, and proper performance of imaging and interventional equipment. The quality control program should be designed to maximize the quality of the diagnostic information. This may be accomplished as part of a routine preventive maintenance program.

VIII. QUALITY IMPROVEMENT AND DOCUMENTATION

A. Documentation

Results of vertebral augmentation procedures should be monitored on a continuous basis. Records should be kept of both immediate and long-term results and complications. The number of complications should be documented. Any biopsies performed in conjunction with vertebral augmentation should be followed up to detect and record any false negative and false positive results.

A permanent record of vertebral augmentation procedures should be maintained in a retrievable image storage format.

1. Imaging labeling should include permanent identification containing:
   a. Facility name and location
   b. Examination date
   c. Patient’s first and last names
   d. Patient’s identification number and/or date of birth.

2. The initial progress note and final report should include:
   a. Procedure undertaken and its purpose
   b. Type of anesthesia used (local, moderate, deep, or general)
   c. Listing of level(s) treated and amount of cement injected at each level
   d. Evaluation of injection site and focused neurologic examination
   e. Immediate complications, if any, including treatment and outcome
   f. Radiation dose estimate (or fluoroscopy time and the number of images obtained on equipment that does not provide direct dosimetry information) [63-65]
3. Follow-up documentation:
   a. Postprocedure evaluation to assess patient response (pain relief, mobility improvement). Standardized assessment tools such as the SF 36 and the Roland-Morris disability scale may be useful for both preoperative and postoperative patient evaluation
   b. Evaluation of injection site and focused neurologic examination
   c. Delayed complications, if any, including treatment and outcome
   d. Pathology (biopsy) results, if any
   e. Record of communications with patient and referring physician
   f. Patient disposition

Reporting should be in accordance with the ACR–SIR–SPR Practice Parameter for the Reporting and Archiving of Interventional Radiology Procedures [66].

B. Informed Consent and Procedural Risk

Informed consent or emergency administrative consent must be obtained and must comply with the ACR–SIR Practice Parameter on Informed Consent for Image-Guided Procedures [67]. Risks cited should include, but may not be limited to, infection, bleeding, allergic reaction, rib or vertebral fracture, vessel injury, pneumothorax (for appropriate levels), and implanted material displacement, into the adjacent epidural or paravertebral veins resulting in worsening pain or paralysis, spinal cord or nerve injury, or pulmonary complication, or death. The potential need for immediate surgical intervention should be discussed. The possibility that the patient may not experience significant pain relief should also be discussed.

C. Success and Complication Rates and Thresholds [4,5,7-24]

Although practicing physicians should strive to achieve perfect outcomes (i.e., 100% success, 0% complications), in practice, all physicians will fall short of this ideal to a variable extent. Therefore, indicators of practice parameters may be used to assess the efficacy of ongoing quality improvement programs. For the purposes of these practice parameters, a threshold is a specific level of an indicator that should prompt a review. Procedure thresholds or overall thresholds refer to a group of indicators for a procedure, for example, major complications. Individual complications may also be associated with complication-specific thresholds. When measures such as indications or success rates fall below a minimum threshold or when complication rates exceed a maximum threshold, a review should be performed to determine causes and to implement changes if necessary. For example, if the incidence of fracture of rib or other bone is one measure of the quality of vertebral augmentation, values in excess of the defined threshold (in this case <1%) should trigger a review of policies and procedures within the department to determine the causes and to implement changes to lower the incidence of the complication.

Thresholds may vary from those listed herein; 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 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 but may require nominal therapy or a short hospital stay for observation (generally overnight; see Appendix A). The complication rates and thresholds described herein refer to major complications.
Routine periodic review of all cases having less than perfect outcomes is strongly encouraged. Serious complications of vertebral augmentation are infrequent. A review is therefore recommended for all instances of death, infection, or symptomatic pulmonary embolus.

**Success Rates**

When vertebral augmentation is performed, success is defined as achievement of significant pain relief, reduced disability, and/or improved quality of life. These should be measured by at least 1 of the relevant and validated measurement tools, such as the 10-point numerical pain rating scale score or a visual analogue scale score (Roland-Morris Back Pain score, Oswestry Disability Index, The Short Form (36) Health Survey, or similar outcome tool to measure pain, disability, and/or quality of life). For osteoporosis, procedure outcomes can be defined using the criteria by Hodler et al [68] with patients categorized as worse, same, better, or pain/disability gone. For the purpose of this document, pain/disability gone is defined as improved. Therefore patients should be categorized as either improved, the same, or worse. This categorization should be determined with the use of a validated measurement tool.

When vertebral augmentation is performed for neoplastic involvement, success is defined as achievement of significant pain relief and/or improved mobility as measured by validated measurement tools.

**Table 1: Vertebral Augmentation Success Rates [69-76]** [Ref: 69-76; Beall D, Chambers]

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<thead>
<tr>
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<th>Published Success Rates</th>
<th>Threshold for Review</th>
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<tbody>
<tr>
<td>Neoplastic, all causes</td>
<td>70% to 92%</td>
<td>&lt;60%</td>
</tr>
<tr>
<td>Osteoporosis, all causes</td>
<td>80% to 98%</td>
<td>&lt;70%</td>
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**Complications**

Major complications occur in less than 1% of patients treated for compression fractures secondary to osteoporosis and in less than 5% of treated patients with neoplastic involvement. Published complication rates and suggested thresholds are given below.

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, for example, early in a quality improvement program. In this situation, the suggested threshold is more appropriate for use in a quality improvement program than is the published rate.

**Table 2: Specific Complications for Vertebral Augmentation [70,71,77-82]**

<table>
<thead>
<tr>
<th>Specific Complication</th>
<th>Published Rates</th>
<th>Thresholds for Review</th>
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<tbody>
<tr>
<td>Transient neurological deficit (within 30 days of the procedure)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Osteoporosis</td>
<td>1%</td>
<td>&gt;2%</td>
</tr>
<tr>
<td>Neoplasm</td>
<td>10%</td>
<td>&gt;10%</td>
</tr>
<tr>
<td>Permanent neurological deficit (within 30 days of the procedure or requiring surgery)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Osteoporosis</td>
<td>&lt;1%</td>
<td>&gt;1%</td>
</tr>
<tr>
<td>Neoplasm</td>
<td>2%</td>
<td>&gt;5%</td>
</tr>
<tr>
<td>Fracture of rib, sternum, or vertebra</td>
<td>1%</td>
<td>&gt;2%</td>
</tr>
<tr>
<td>Allergic or idiosyncratic reaction</td>
<td>&lt;1%</td>
<td>&gt;1%</td>
</tr>
</tbody>
</table>
Table 2: Specific Complications for Vertebral Augmentation [70,71,77-82]

<table>
<thead>
<tr>
<th>Specific Complication</th>
<th>Published Rates</th>
<th>Thresholds for Review</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infection</td>
<td>&lt;1%</td>
<td>&gt;0%</td>
</tr>
<tr>
<td>Symptomatic pulmonary embolus</td>
<td>&lt;1%</td>
<td>&gt;0%</td>
</tr>
<tr>
<td>Significant hemorrhage or vascular injury</td>
<td>&lt;1%</td>
<td>&gt;0%</td>
</tr>
<tr>
<td>Symptomatic hemothorax or pneumothorax</td>
<td>&lt;1%</td>
<td>&gt;0%</td>
</tr>
<tr>
<td>Death</td>
<td>&lt;1%</td>
<td>&gt;0%</td>
</tr>
</tbody>
</table>

The overall procedure threshold for all complications resulting from vertebral augmentation performed for osteoporosis is 2%, and when performed for neoplastic indications it is 10%.

IX. RADIATION SAFETY IN IMAGING

Radiologists, medical physicists, registered radiologist assistants, radiologic technologists, and all supervising physicians have a responsibility for safety in the workplace by keeping radiation exposure to staff, and to society as a whole, “as low as reasonably achievable” (ALARA) and to assure that radiation doses to individual patients are appropriate, taking into account the possible risk from radiation exposure and the diagnostic image quality necessary to achieve the clinical objective. All personnel that work with ionizing radiation must understand the key principles of occupational and public radiation protection (justification, optimization of protection and application of dose limits) and the principles of proper management of radiation dose to patients (justification, optimization and the use of dose reference levels).


Nationally developed guidelines, such as the ACR’s Appropriateness Criteria®, should be used to help choose the most appropriate imaging procedures to prevent unwarranted radiation exposure.

Facilities should have and adhere to policies and procedures that require varying ionizing radiation examination protocols (plain radiography, fluoroscopy, interventional radiology, CT) to take into account patient body habitus (such as patient dimensions, weight, or body mass index) to optimize the relationship between minimal radiation dose and adequate image quality. Automated dose reduction technologies available on imaging equipment should be used whenever appropriate. If such technology is not available, appropriate manual techniques should be used.

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

Radiation exposures or other dose indices should be measured and patient radiation dose estimated for representative examinations and types of patients by a Qualified Medical Physicist in accordance with the applicable ACR Technical Standards. Regular auditing of patient dose indices should be performed by comparing the facility’s dose information with national benchmarks, such as the ACR Dose Index Registry, the NCRP Report No. 172, Reference Levels and Achievable Doses in Medical and Dental Imaging: Recommendations for the United States or the Conference of Radiation Control Program Director’s National Evaluation of X-ray Trends. (ACR Resolution 17 adopted in 2006 – revised in 2009, 2013, Resolution 52).
X. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION

Policies and procedures related to quality, patient education, infection control, and safety should be developed and implemented in accordance with the ACR Policy on Quality Control and Improvement, Safety, Infection Control, and Patient Education appearing under the heading Position Statement on QC & Improvement, Safety, Infection Control, and Patient Education on the ACR website (http://www.acr.org/guidelines).

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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
A. Require therapy, minor hospitalization (<48 hours)
B. Require major therapy, unplanned increase in level of care, prolonged hospitalization (>48 hours)
C. Have permanent adverse sequelae
D. Result in death

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

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Amended 2004 (Resolution 25)
Revised 2005 (Resolution 44)
Amended 2006 (Resolution 16g, 17, 34, 35, 36)
Revised 2009 (Resolution 25)
Revised 2011 (Resolution 40)
Revised 2012 (Resolution 6)
Amended 2014 (Resolution 39)