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PRACTICE GUIDELINE FOR THE PERFORMANCE OF VERTEBROPLASTY

PREAMBLE

These guidelines are an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. They are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care. For these reasons and those set forth below, the American College of Radiology cautions against the use of these guidelines in litigation in which the clinical decisions of a practitioner are called into question.

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

The practice of medicine involves not only the science, but also the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment. Therefore, it should be recognized that adherence to these guidelines will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action

based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The sole purpose of these guidelines is to assist practitioners in achieving this objective.

I. INTRODUCTION

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

This document deals with vertebroplasty (also known as acrylic vertebroplasty, cement vertebroplasty, percutaneous vertebroplasty, and 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 [1], vertebroplasty entails injection of polymethyl methacrylate (PMMA) cement into the collapsed vertebra. The injected bone cement acts as an internal splint to reinforce and stabilize the fracture for pain alleviation. Re-expansion of collapsed vertebrae or height restoration may be achieved during the process of vertebroplasty.

Radiologic imaging has been a critical part of vertebroplasty from its inception. Most procedures are performed using fluoroscopic guidance for needle placement and to monitor cement injection. The use of computed tomography (CT) has also been described for these purposes.

Vertebroplasty is an established, safe, and effective procedure for selected patients. Extensive experience documents its safety and efficacy [1-20]. 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 guidelines are intended to be used in quality improvement programs to assess vertebroplasty procedures. The most important processes of care are 1) selecting patients, 2) performing the procedure, and 3) monitoring the patient. 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. DEFINITION

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

III. OVERVIEW

Vertebral compression fractures are a common and often debilitating complication of osteoporosis [21-25]. 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 [26-28]. Vertebral compression fractures are a leading cause of nursing home admission. Open surgical fixation is rarely used to treat these fractures. 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 risk of major surgery.

Initial success with vertebroplasty for treating aggressive hemangiomas [1,10] and osteolytic neoplasms [8,20] led to extension of the indications to include osteoporotic compression fractures refractory to medical therapy [2-7,9,11-18]. Vertebroplasty is currently being used to treat a wide variety of osteolytic metastases and multiple myeloma.

Perioperative imaging that defines the region is considered essential for the safe performance of vertebroplasty with concordance with the clinical examination.

IV. INDICATIONS AND CONTRAINDICATIONS

The major indication for vertebroplasty is the treatment of symptomatic osteoporotic or neoplastic vertebral body compression fracture(s) refractory to medical therapy. Failure of medical therapy is defined by minimal or no pain relief with the administration of prescribed analgesics or adequate pain relief with narcotic dosages that produce undesirable side effects (excessive and intolerable sedation, confusion, or constipation). Currently, there is no indication for the use of vertebroplasty for prophylaxis against future fracture. The indications and contraindications for vertebroplasty may change in the future as more research and information become available.

A. Indication Threshold 95%

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

When fewer than 95% of vertebroplasties 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. Asymptomatic vertebral body compression fractures.
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 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 originating at the fracture level.

V. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Physician

In general, the requirements for physicians performing vertebroplasty 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 Le College des Medecins du Quebec, and must include performance of successful vertebroplasties in at least 5 patients as the primary operator, under the supervision of a qualified physician, and without complications.

or

Completion of an Accreditation Council for Graduate Medical Education (ACGME) approved residency or fellowship program or an American Osteopathic Association (AOA) approved residency program that included 6 months training in cross-sectional imaging, including CT and MR imaging, and 4 months training in image-guided interventional radiological techniques, including vertebroplasty, biopsy and drainage procedures, and vascular embolization. This must include performance of successful vertebroplasties in at least 5 patients as the primary operator, under the supervision of a qualified physician, and without complications.

or

A board eligible physician or one who did not complete an ACGME approved residency or fellowship training program (as listed above) or other postgraduate training that included comparable instruction and experience may meet the requirements by having documented “hands on” training in the performance of vertebroplasty. This must include performance of successful vertebroplasties in at least 5 patients as the primary operator, under the supervision of a qualified physician, and without complications.

and

2. For the above, substantiation in writing by the chair of the department or the chair’s designee, in accordance with the institution’s policies, or from a prior institution in which the physician provided the services, only at the discretion of the current chair to solicit the additional input that the physician is familiar with all of the following:
 - a. Indications and contraindications for vertebroplasty.

- 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 exposure to the patient and the radiologic personnel, and radiation monitoring requirements.
- e. Anatomy, physiology, and pathophysiology of the spine, spinal cord, and nerve roots.
- f. Pharmacology of contrast agents and polymethyl methacrylate and recognition and treatment of potential adverse reactions to these substances.
- g. Technical aspects of performing this procedure.

and

3. Possess certain fundamental knowledge and skills that are required for the appropriate application and safe performance of vertebroplasty:
 - 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 vertebroplasty is indicated.
 - b. The physician must fully appreciate the benefits and risks of vertebroplasty and the alternatives to the procedure.
 - c. The physician is required to be competent in the use of fluoroscopy, CT, and MRI, and in the modalities used to evaluate potential patients and guide the vertebroplasty 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 vertebroplasty, 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.

Maintenance of Competence

Physicians should perform a sufficient number of vertebroplasties to maintain their skills, with acceptable success and complication rates as laid out in this guideline. 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 vertebroplasty is necessary.

Continuing Medical Education

The physician's continuing education should be in accordance with the [ACR Practice Guideline for Continuing Medical Education \(CME\)](#).

B. Qualified Medical Physicist

A Qualified Medical Physicist is an individual who is competent to practice independently one or more of the subfields in medical physics. The American College of Radiology (ACR) considers certification and 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 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 for MRI, by the American Board of Medical Physics (ABMP) in magnetic resonance imaging physics.

The appropriate subfields in medical physics for this guideline are Radiological Physics and Diagnostic Radiological Physics.

A Qualified Medical Physicist should meet the [ACR Practice Guideline for Continuing Medical Education \(CME\)](#). (ACR Resolution 17, 1996 – revised in 2008, Resolution 7)

C. 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)

D. 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 vertebroplasty 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 medical physicist.

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

E. 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 vertebroplasty procedure.

VI. SPECIFICATIONS OF THE PROCEDURE

A. Technical Requirements

Vertebroplasty may be performed with either fluoroscopy or CT imaging guidance. The choice is a matter of operator preference and patient characteristics. In either case, several technical requirements are necessary to ensure safe and successful vertebroplasties. These include adequate institutional facilities, imaging and monitoring

equipment, and support personnel. The following are minimum requirements for any institution in which vertebroplasty is to be performed:

1. A procedural suite large enough to allow safe and easy 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. In that case, a high-resolution image intensifier or flat-panel detector and video system with adequate shielding and capable of rapid imaging in orthogonal planes and capabilities for permanent image recording is essential. 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 access to CT and rapid (within 30 or 45 minutes) access to MRI is necessary to allow evaluation of potential complications. This may be particularly desirable if vertebroplasty 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 vertebroplasty. 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 vertebroplasty 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 Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™ is required for procedures in non-operating room settings including bedside procedures. "Time out" must be conducted in the location where the procedure will be done, just before starting the procedure and must:
 - Involve the entire operative team.
 - Use active communication.
 - Be briefly documented, such as in a checklist, and include at least:
 - Correct patient identity.
 - Correct side and level(s).
 - Agreement on the procedure to be done.
 - Correct patient position.
 - Availability of correct devices and any special equipment or requirements.
 - The correct level(s) must be determined with intraprocedural imaging prior to instrumentation.

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 vertebroplasty must have intravenous access in place for the administration of fluids and medications as needed.
- d. If the patient is to receive moderate sedation, pulse oximetry must be used. Administration of sedation for vertebroplasty should be in accordance with the [ACR Practice Guideline for Adult Sedation/Analgesia](#). 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 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 care during hospitalization 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 vertebroplasty 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 vertebroplasty should be followed up to detect and record any false negative and false positive results.

A permanent record of vertebroplasty 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 physician's report of a vertebroplasty procedure 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. Immediate complications, if any, including treatment and outcome.
 - e. Radiation dose estimate (or fluoroscopy time on equipment that does not provide direct dosimetry information) [29,30].
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 scale may be useful for both preoperative and postoperative patient evaluation.
 - b. Delayed complications, if any, including treatment and outcome.
 - c. Pathology (biopsy) results, if any.
 - d. Record of communications with patient and referring physician.
 - e. Patient disposition.

Reporting should be in accordance with the [Practice Guideline for the Reporting and Archiving of Interventional Radiology Procedures](#).

B. Informed Consent and Procedural Risk

Informed consent or emergency administrative consent must be obtained and must be in compliance with all state laws and should comply with the [ACR Practice Guideline on Informed Consent for Image-Guided Procedures](#). Risks cited should include infection; bleeding; allergic reaction; fracture; pneumothorax (for appropriate levels); and extravasation of cement into the adjacent epidural or paravertebral veins resulting in worsening pain or paralysis, spinal cord or nerve injury, or pulmonary compromise. 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 [1-20]

Although practicing physicians should strive to achieve perfect outcomes (e.g., 100% success, 0% complications), in practice, all physicians will fall short of this ideal to a variable extent. Therefore, indicator thresholds may be used to assess the efficacy of ongoing quality-improvement programs. For the purposes of these guidelines, 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, e.g., 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 vertebroplasty, 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 vertebroplasty are infrequent. A review is therefore recommended for all instances of death, infection, or symptomatic pulmonary embolus.

Success Rates

When vertebroplasty is performed for osteoporosis, procedure outcomes can be defined using the criteria by Hodler et al [31] 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 by the use of a validated measurement tool.

When vertebroplasty 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: Vertebroplasty Success Rates [32-36]

	Published Success Rates	Threshold for Review
Neoplastic, all causes	70% to 92%	<60%
Osteoporosis, all causes	80% to 95%	<70%

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 complications 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, e.g., 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 Vertebroplasty [33,34,37-40]

Specific Complication	Published Rates	Thresholds for Review
Transient neurological deficit (within 30 days of the procedure)		
Osteoporosis	1%	>2%
Neoplasm	10%	>10%
Permanent neurological deficit (within 30 days of the procedure or requiring surgery)		
Osteoporosis	<1%	>1%
Neoplasm	2%	>5%
Fracture of rib, sternum or vertebra	1%	>2%
Allergic or idiosyncratic reaction	<1%	>1%
Infection	<1%	>0%
Symptomatic pulmonary cement embolus	<1%	>0%
Significant hemorrhage or vascular injury	<1%	>0%
Symptomatic hemothorax or pneumothorax	<1%	>0%
Death	<1%	>0%

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

IX. RADIATION SAFETY IN IMAGING

Radiologists, medical physicists, radiologic technologists, and all supervising physicians have a responsibility to minimize radiation dose to individual patients, to staff, and to society as a whole, while maintaining the necessary diagnostic image quality. This concept is known as “as low as reasonably achievable (ALARA).”

Facilities, in consultation with the medical physicist, should have in place and should adhere to policies and procedures, in accordance with ALARA, to vary examination protocols to take into account patient body habitus, such as height and/or weight, body mass index or lateral width. The dose reduction devices that are available on imaging equipment should be active; if not manual techniques should be used to moderate the exposure while maintaining the necessary diagnostic image quality. Periodically, radiation exposures should be measured and patient radiation doses estimated by a medical physicist in accordance with the appropriate ACR

Technical Standard. (ACR Resolution 17, adopted in 2006 – revised in 2009, Resolution 11.)

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 elsewhere in the ACR Practice Guidelines and Technical Standards book.

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Collaborative Committees

Facilitator: John Cardella, MD, FACR

ACR

Christine P. Chao, MD
Walter S. Lesley, MD, FACR

ASNR

Gregg H. Zoarski, MD
A. Orlando Ortiz, MD, MBA, FACR

ASSR

Jeffrey A. Stone, MD
Allan L. Brook, MD

SIR

John D. Barr, MD
J. Kevin McGraw, MD

SNIS

Joshua A. Hirsch, MD
Lee Jensen, MD

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Walter S. Lesley, MD, FACR
Harjit Singh, MD
Timothy L. Swan, MD
Matthew A. Mauro, MD, FACR, Chair, Commission

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Suggested Reading

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Appendix A

Society of Interventional Radiology Standards of Practice Committee Classification of Complications by Outcome

Minor Complications

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

Major Complications

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

*Guidelines 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 guidelines and standards published before 1999, the effective date was January 1 following the year in which the guideline or standard was amended, revised, or approved by the ACR Council.

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