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Standards for the Performance of Percutaneous Vertebroplasty: American College of Radiology and Society of Interventional Radiology Guidelines

Part I STANDARD FOR THE PERFORMANCE OF PERCUTANEOUS VERTEBROPLASTY[*,†]

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The American College of Radiology will periodically define new 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 standards will be reviewed for revision or renewal, as appropriate, on their fifth anniversary or sooner, if indicated.

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* This standard (Res. 14, which became effective on January 1, 2001) has been included in its unaltered entirety. However, it should be noted that there are some errors in reference citations that are undergoing correction.

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

Standard for the Performance of Percutaneous Vertebroplasty

Developed by a collaborative panel of the American College of Radiology, the American Society of Neuroradiology, the American Society of Interventional and Therapeutic Neuroradiology, and the American Society of Spine Radiology.

I. Introduction

This Standard for the Performance of Percutaneous Vertebroplasty was developed by a consensus of recognized pioneers of the technique in the United States. Physicians from the fields of interventional neuroradiology, musculoskeletal radiology, neurosurgery, and orthopedic surgery participated in the development process. 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 were difficult to set due to the relative paucity of data and lack of uniform reporting of clinical outcomes and complications.

Percutaneous vertebroplasty is being performed with rapidly increasing frequency in the United States. We anticipate that more data regarding outcomes and complications will be collected and published

in the near future. Therefore, we recommend that this standard be reviewed and, if necessary, revised within the next 24 months in order to remain current with this rapidly progressing technique.

Developed by Galibert and colleagues in France in the late 1980s (1), percutaneous vertebroplasty entails injection of polymethylmethacrylate (PMMA) cement into the collapsed vertebra. Although this procedure does not reexpand the collapsed vertebra, reinforcing and stabilizing the fracture seems to alleviate pain.

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

Percutaneous vertebroplasty is an established, safe, and effective procedure for selected patients. Extensive experience documents the safety and efficacy of this procedure (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.

II. 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 (26,27). Vertebral compression fractures are a leading cause of nursing home admission. Open surgical fixation is rarely employed 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 percutaneous vertebroplasty for treatment of aggressive hemangiomas (1,2) and osteolytic neoplasms (3,4) led to extension of the indications to include osteoporotic compression fractures refractory to medical therapy (5–19).

III. Indications and Contraindications

A. Indications

1. Painful osteoporotic vertebral compression fracture(s) refractory to medical therapy. Failure of medical therapy is defined as minimal or no pain relief with the administration of physician-prescribed analgesics or achievement of adequate pain relief only with narcotic dosages that induce excessive and intolerable sedation, confusion, or constipation. Associated major disability such as inability to walk, transfer, or perform activities of daily living is almost always present.

2. Painful vertebral fracture or severe osteolysis with impending fracture related to benign or malignant tumor, such as hemangioma, myeloma, or metastasis.

3. Painful vertebral fracture associated with osteonecrosis (Kummell's disease).

4. Unstable compression fracture with demonstration of movement at the wedge deformity.

5. Patients with multiple compression deformities resulting from osteoporotic collapse for whom further collapse would likely result in pulmonary compromise, gastrointestinal tract dysfunction, or altered center of gravity with associated increased risk of falling as a result of deformity of the spine.

6. Chronic traumatic fractures in normal bone with nonunion of fracture fragments or internal cystic changes.

B. Absolute Contraindications

1. Asymptomatic stable fracture.
2. Patient clearly improving on medical therapy.
3. Prophylaxis in osteopenic patients with no evidence of acute fracture.
4. Osteomyelitis of target vertebra.
5. Acute traumatic fracture of nonosteoporotic vertebra.
6. Uncorrectable coagulopathy or hemorrhagic diathesis.
7. Allergy to any component required for the procedure.

C. Relative Contraindications

1. Radicular pain or radiculopathy, significantly in excess of vertebral pain, caused by a compressive syndrome unrelated to vertebral body collapse. In such circumstances, preoperative vertebroplasty may be indicated if a spinal destabilization procedure is planned.
2. Retropulsion of fracture fragment causing significant spinal canal compromise.
3. Tumor extension into the epidural space with significant spinal canal compromise.
4. Severe vertebral body collapse.
5. Stable fracture without pain and known to be more than 2 years old.
6. Treatment of more than three levels performed at one time.

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

IV. Qualifications and Responsibilities of Personnel

A. Physician

1. In general, the requirements for the performance of percutaneous vertebroplasty (see Section IV.A.3) may be met by adhering to the recommendations listed below:

a. Certification in Radiology or Diagnostic Radiology by the American Board of Radiology, the American Osteopathic Board of Radiology, or the Royal College of Physicians and Surgeons of Canada.

and

b. Completion of an Accreditation Council for Graduate Medical Education (ACGME) accredited residency or fellowship program that included 6 months training in cross-sectional imaging, including CT and MR imaging, and 4 months training in image-guided interventional radiologic techniques including percutaneous vertebroplasty, biopsy and drainage procedures, and vascular embolization. This must include performance (under the supervision of a qualified physician) of at least 10 percutaneous vertebroplasties with acceptable success and complication rates documented by a log of cases performed as described in this document (see Section VII.C).

Physicians whose residency or fellowship training did not include the above-described experience with percutaneous vertebroplasty may be considered as satisfying the qualifications for this procedure if they meet all other requirements and have performed at least 10 percutaneous vertebroplasties with acceptable success and complication rates documented by a log of cases performed as described in this document (see Section VII.C).

2. In the absence of appropriate ACGME approved residency or fellowship training (as listed in Section IV.A.1.a above) or other postgraduate training that included comparable instruction and experience, physicians may meet the requirements listed in Section IV.A.1 by adhering to the following recommendations:

a. Documentation of "hands-on" training in the performance of percutaneous vertebroplasty.

and

b. Performance and completion of at least two successful and uncomplicated percutaneous vertebroplasty procedures as principal operator under the supervision of an on-site, qualified physician with acceptable success and complication rates

and (see Section VII.C).

c. Substantiation in writing by the Director of the Department of Radiology, the Chief of the Medical Staff, or the Chair of the Credentials Committee of the institution in which the procedures were performed that the physician is familiar with all of the following:

1. Indications and contraindications for percutaneous vertebroplasty.
2. Preprocedural assessment and intraprocedural monitoring of the patient.
3. Appropriate use and operation of fluoroscopic and radiographic equipment, digital subtraction systems, and other electronic imaging systems.

4. Principles of radiation protection, hazards of radiation exposure to the patient and the radiologic personnel, and radiation monitoring requirements.
5. Anatomy, physiology, and pathophysiology of the spine, spinal cord, and nerve roots.
6. Pharmacology of contrast agents and of polymethylmethacrylate and recognition and treatment of adverse reactions to these substances.
7. Technical aspects of performing this procedure.
8. Postprocedural patient management, particularly the recognition and initial management of procedural complications.

3. Certain fundamental knowledge and skills are required for the appropriate application and safe performance of percutaneous 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 percutaneous vertebroplasty is indicated.

and

b. The physician must fully appreciate the benefits and risks of percutaneous vertebroplasty and the alternatives to the procedure.

and

c. The physician is required to be competent in the use of fluoroscopy, computed tomography (CT), and magnetic resonance imaging (MRI); modalities employed to evaluate potential patients and to guide the percutaneous vertebroplasty procedure.

and

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

and

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 pre- or postprocedural care, or who have relative contraindications to the procedure.

and

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

and

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.

4. Maintenance of competence. Maintenance of competence requires regular continuing clinical activity, including:
   a. Regular performance of imaging-guided percutaneous interventions, including sufficient numbers of percutaneous vertebroplasties to maintain success and complication rates as outlined below.
   b. Participation in a quality improvement program that monitors these rates.
   c. Participation in postgraduate courses that provide continuing education on diagnostic and technical advances in percutaneous vertebroplasty.
   d. The physician's continuing education should be in accordance with the ACR Standard for Continuing Medical Education (CME).

B. 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 considers that certification and continuing education in the appropriate subfield(s) 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 appropriate subfields in medical physics for this standard are Radiological Physics and Diagnostic Radiological Physics. The continuing education of a Qualified Medical Physicist should be in accordance with the ACR Standard for Continuing Medical Education (CME).

C. Radiological Technologist

The technologist, together with the physician and the nursing personnel, should have responsibility 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 percutaneous vertebroplasty procedure or similar interventional procedures and be certified by the American Registry of Radiologic Technologists (ARRT) or have an unrestricted state license.

D. Nursing Services

Nursing services are an integral part of the team for pre- and postprocedural patient management and education and may assist the physician in monitoring the patient during the percutaneous vertebroplasty procedure.

V. Specifications of the Procedure

A. Technical Requirements

There are several technical requirements that are necessary to ensure safe and successful percutaneous vertebroplasties. These include adequate institutional facilities, imaging and monitoring equipment, and support personnel. The following are minimum facility requirements for any institution in which percutaneous vertebroplasty is to be performed:

1. A procedure suite large enough to allow 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. A high-resolution image intensifier and video system with adequate shielding 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. Operator should be able to recognize, interpret, and act immediately on image finding.
3. Immediate access to CT and MR imaging is necessary to allow evaluation of potential complications. This may be particularly desirable if percutaneous vertebroplasty is planned in patients with osteolytic vertebral metastasis and/or with significant preexisting spinal canal compromise. CT is desirable for evaluation of the spinal canal and intervertebral foramina if significant extravasation of cement is suspected, even if the patient remains asymptomatic.
4. The facility must provide adequate resources for observing patients during and after percutaneous 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 percutaneous 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 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. Vital signs should be obtained at regular intervals during the course of the procedure, and a record of these measurements should be maintained.
b. Patients undergoing percutaneous vertebroplasty must have intravenous access in place for the administration of fluids and medications as needed.
c. If the patient is to receive conscious sedation, pulse oximetry must be used. Administration of sedation for percutaneous vertebroplasty should be in accordance with the ACR Standard 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 VII.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.

VI. 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.

VII. Quality Improvement and Documentation

A. Documentation

Results of percutaneous 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 percutaneous vertebroplasty should be followed up to detect and record any false negative and false positive results.

A permanent record of percutaneous vertebroplasty procedures should be maintained on a retrievable image storage format.

1. Image 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 percutaneous vertebroplasty procedure should include:
   a. Procedure undertaken and its purpose.
   b. Local anesthesia, if used, listing agent and amount.
   c. Conscious sedation, if used, listing medications and amounts.
   d. Listing of level(s) treated and amount of cement injected at each level.
   e. Immediate complications, if any, including treatment and outcome. Reporting should be in accordance with the ACR Standard on Communication: Diagnostic Radiology.
3. Follow-up documentation:
   a. Evaluation of long-term patient response (pain relief, mobility improvement). Standardized assessment tools such as the SF-36 and the Roland scale may be useful for both pre- 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.

B. Informed Consent and Procedural Risk

Informed consent or emergency administrative consent must be obtained and must be in compliance with state law. 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. Complication Rates and Thresholds (1–20)

While 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. Thus, indicator thresholds may be used to assess the efficacy of ongoing quality improvement programs. For the purposes of this standard, a threshold is a specific level of an indicator (e.g., complication rate) that should prompt a review. When complication rates exceed a maximum threshold, a review should be performed to determine causes and to implement changes, if necessary.

Routine periodic review of all cases having less than perfect outcomes is strongly encouraged. Serious complications of percutaneous vertebroplasty are infrequent. A review is therefore recommended for all instances of death, infection, and symptomatic pulmonary embolus.

A review may be prompted when a complication rate surpasses the threshold values outlined below (suggested thresholds are listed in parentheses):

1. *Clinical complications*
   a. Death (0%).
   b. Permanent (duration >30 days) neurological deficit (other than radicular pain):
      1. osteoporosis (0%)
      2. neoplasm (5%)
   c. Transient (duration ≤30 days) neurological deficit (other than radicular pain) or radicular pain syndrome (either permanent or transient):
      1. osteoporosis (5%)
      2. neoplasm (10%)
   d. Symptomatic pulmonary cement embolus (0%).
   e. Symptomatic epidural venous cement embolus (5%).
   f. Infection (0%).
   g. Fracture of rib or vertebra (5%)

h. Significant hemorrhage or vascular injury (0%).
i. Allergic or idiosyncratic reaction (1%)

2. *Technical/procedural complications*
   a. Failure to obtain proper informed consent (0%).
   b. Cement embolus to pulmonary vasculature without clinical sequela and estimated volume >0.25 mL (5%).
   c. Cement embolus to epidural veins without clinical sequela and producing >10% spinal canal compromise or estimated volume >0.25 mL (10%).

D. Clinical Outcomes

1. Achievement of significant pain relief and improved mobility (osteoporosis) (80%).
2. Achievement of significant pain relief and improved mobility (neoplasm) (50%) (when treatment is performed primarily for spinal stabilization, not pain relief, this threshold would not apply).

VIII. Quality Control and Improvement, Safety, Infection Control, and Patient Education Concerns

Policies and procedures related to quality, patient education, infection control, and safety should be developed and implemented in accordance with the ACR policy on Quality Control and Improvement, Safety, Infection Control, and Patient Education Concerns appearing elsewhere in this publication.

Acknowledgments

This Standard was developed according to the process described elsewhere in this publication by the Standards and Accreditation Committee of the Commission on Neuroradiology and MR in collaboration with the American Society of Neuroradiology, the American Society of Interventional and Therapeutic Neuroradiology, and the American Society of Spine Radiology.

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Part II QUALITY IMPROVEMENT GUIDELINES FOR PERCUTANEOUS VERTEBROPLASTY[*,†]

Preamble

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

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

Methodology

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

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

When the evidence of literature is weak, conflicting, or contradictory, consensus for the parameter is reached by a minimum of 12 Standards of Practice Committee members with use of a Modified Delphi Consensus Method (1,2). For the purposes of these documents, consensus is defined as 80% Delphi participant agreement on a value or parameter.

The draft document is critically reviewed by the Standards of Practice Committee members by telephone conference call or face-to-face

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[*] J. Kevin McGraw, John Cardella, John Dean Barr, John M. Mathis, Orestes Sanchez, Marc S. Schwartzberg, Timothy L. Swan, and David Sacks for the Society of Interventional Radiology Standards of Practice Committee.

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meeting. The finalized draft from the Committee is sent to the SIR membership for further input/criticism during a 30-day comment period. These comments are discussed by the Standards of Practice Committee and appropriate revisions are made to create the finished standards document. Before its publication, the document is endorsed by the SIR Executive Council.

Vertebral Fractures

Each year, more than 700,000 vertebral fractures secondary to osteoporosis are diagnosed in the United States population, resulting in 115,000 hospital admissions (3). The lifetime risk of a vertebral body compression fracture is 16% for women and 5% for men, and the incidence of osteoporotic fractures is anticipated to increase fourfold worldwide in the next 50 years (3). Other causes of painful compression fracture include malignant involvement of the spinal column (metastasis, myeloma, and lymphoma), hemangioma, and vertebral osteonecrosis. In addition to pain, spinal column instability may also be present. Regardless of etiology, treatment for compression fractures has been largely conservative and directed toward pain control, usually consisting of narcotic analgesia, bedrest, and back bracing. For osteoporosis, current preventive drug regimens, including hormonal replacement therapy, biphosphates, and calcitonin, often are not prescribed until the disease has been diagnosed by the presence of a fracture.

Percutaneous vertebroplasty is a therapeutic alternative for the treatment of pain associated with vertebral body compression fractures (4–22). The procedure entails placement of a large-caliber needle into the involved vertebral body and injection of radiopaque bone cement (e.g., polymethyl methacrylate). The injected bone cement does not reexpand the collapsed vertebra, but acts as an internal splint to reinforce and stabilize the fracture for pain alleviation.

These guidelines are written to be used in quality improvement programs to assess percutaneous vertebroplasty procedures. The most important processes of care are (1) selecting the patients, (2) performing the procedure, and (3) monitoring the patients. The outcome measures or indicators for these processes are indications, success rates, and complication rates. Outcome measures are assigned threshold levels.

Definitions

Percutaneous vertebroplasty is defined as the injection of radiopaque bone cement (e.g., polymethyl methacrylate) into a painful osteoporotic compression fracture (9,10,12–14,16,18,20–28) or painful pathologic vertebral body (e.g., multiple myeloma [7,8,29–32], metastatic disease [5–7,33], and hemangioma [4,33–38]) with use of imaging guidance. Radiologic imaging has been a critical part of percutaneous vertebro-

plasty from its inception. Most procedures are performed with use of fluoroscopic guidance for needle placement and to monitor bone cement injection. The use of computed tomography has also been described (39).

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* reference 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 percutaneous 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; e.g., 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; they may require nominal therapy or a short hospital stay for observation (generally overnight; see Appendix 1). The complication rates and thresholds described herein refer to major complications.

Indications

The major indication for percutaneous 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). Other, less common indications, are outlined in Table 14.1. Absolute and relative contraindications are outlined in Table 14.2. The indications and contraindications for percutaneous

Table 14.1. Indications for Percutaneous Vertebroplasty: Threshold 95%.

1. Painful primary and secondary osteoporotic vertebral compression fracture(s) refractory to medical therapy
2. Painful vertebrae with extensive osteolysis or invasion secondary to benign or malignant tumor (i.e., hemangioma, multiple myeloma, or metastatic disease)
3. Painful vertebral fracture associated with osteonecrosis (Kummell's disease)

Note: When fewer than 95% of percutaneous vertebroplasty in an institution are performed for one or more of the above indications, it should prompt a review of practices related to selection of patients for percutaneous vertebroplasty.

vertebroplasty may change in the future as more research and information become available.

Success Rates

When percutaneous vertebroplasty is performed for osteoporosis, success is defined as achievement of significant pain relief and/or improved mobility as measured by validated measurement tools with a threshold of 80%.

When percutaneous 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 with a threshold of 50 to 60%.

Complications

Major complications occur in less than 1% of patients treated for compression fractures secondary to osteoporosis and in less than 5% of

Table 14.2. Absolute and Relative Contraindications for Percutaneous Vertebroplasty.

Absolute contraindications
1. Asymptomatic vertebral body compression fractures
2. Patient improving on medical therapy
3. Prophylaxis in osteoporotic patients
4. Ongoing local or systemic infection
5. Retropulsed bone fragment resulting in myelopathy
6. Spinal canal compromise secondary to tumor resulting in myelopathy
7. Uncorrectable coagulopathy
8. Allergy to bone cement or opacification agent
Relative contraindications
1. Radiculopathy in excess of vertebral pain, caused by a compressive syndrome unrelated to vertebral collapse. Occasionally, preoperative percutaneous vertebroplasty can be performed before a spinal decompressive procedure
2. Asymptomatic retropulsion of a fracture fragment causing significant spinal canal compromise
3. Asymptomatic tumor extension into the epidural space

treated patients with neoplastic involvement (5–9,13,14,16,19,22,23,28, 40–49). Published complication rates and suggested thresholds are included in Table 14.3.

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, than is the published rate.

Overall procedure threshold for all complications resulting from percutaneous vertebroplasty performed for osteoporosis is 2% and performed for neoplastic indications is 10% (32).

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Table 14.3. Specific Complications for Percutaneous Vertebroplasty.

Specific Complication	Published Rates (%)	Suggested Thresholds (%)
Transient neurological deficit(<30 days)		
Osteoporosis	**1**	**1**
Neoplastic	**5**	**10**
Permanent neurological deficit (>30 days or requiring surgery)		
Osteoporosis	**0**	**<1**
Neoplastic	**2**	**5**
Fracture of rib or vertebra	**<1**	**<1**
Allergic or idiosyncratic reaction	**<1**	**<1**
Infection	**<1**	**<1**
Symptomatic pulmonary cement embolus	**<1**	**<1**
Significant hemorrhage or vascular injury	**0**	**0**
Death	**0**	**0**

MD, Mark I. Silverstein, MD, H. Bob Smouse, MD, Patricia E. Thorpe, MD, Richard B. Towbin, MD, Anthony C. Venbrux, MD, Daniel J. Wunder, MD, Thomas M. Vesely, MD, Curtis W. Bakal, MD, Elizabeth A. Drucker, MD, JD, Curtis A. Lewis, MD, MBA, Albert A. Nemcek, Jr, MD, and Kenneth S. Rholl, MD.

Appendix 1. SIR Standards of Practice Committee Classification of Complications by Outcome

Minor Complications

a. No therapy, no consequence, or
b. Nominal therapy, no consequence, includes overnight admission for observation only.

Major Complications

a. Require therapy, minor hospitalization (<48 h),
b. Require major therapy, unplanned hospitalization (>48 h),
c. Have permanent adverse sequelae, or
d. Result in death.

Appendix 2. Methodology

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

Consensus on statements in this document was obtained utilizing a modified Delphi technique (1,2).

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

Note: The clinical practice guidelines of the Society of Interventional Radiology attempt to define practice principles that generally should assist in producing high-quality medical care. These guidelines are voluntary and are not rules. A physician may deviate from these guidelines, as necessitated by the individual patient and available resources. These practice guidelines should not be deemed inclusive of all proper methods of care or exclusive of other methods of care that are reasonably directed toward the same result. Other sources of information may be used in conjunction with these principles to produce a process leading to high-quality medical care. The ultimate judgment regarding the conduct of any specific procedure or course of management must be made by the physician, who should consider all circumstances relevant to the individual clinical situation. Adherence to the SIR Quality Improvement Program will not ensure a successful outcome in every

situation. It is prudent to document the rationale for any deviation from suggested practice guidelines in the department policies and procedure manual or in the patient's medical record.

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