



Quality Improvement Guidelines for Percutaneous Vertebroplasty

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ABBREVIATION

ACR = American College of Radiology

PREAMBLE

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

Technical documents specifying the exact consensus and literature review methodologies as well as the institutional affiliations and professional credentials of the authors of this document are available upon request from SIR, 3975 Fair Ridge Dr., Suite 400 N., Fairfax, VA 22033.

METHODOLOGY

SIR produces its Standards of Practice documents by using 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 by using electronic medical literature databases. Then, a critical review of peer-reviewed articles is performed with regard to the study methodology, results, and conclusions. The qualitative weight of these articles is assembled into an evidence table, which is used to write the document such that it

contains evidence-based data with respect to content, rates, and thresholds.

When the evidence of literature is weak, conflicting, or contradictory, consensus for the parameter is reached by a minimum of 12 Standards of Practice Committee members by using a modified Delphi consensus method ([Appendix A](#)) (1,2). For 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 Revisions Subcommittee members of the Standards of Practice Committee by telephone conference calling or face-to-face meeting. The finalized draft from the Committee is sent to the SIR Standards Committee for further input/criticism during a 30-day comment period. These comments are discussed by the subcommittee, 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

This document is adapted from the American College of Radiology (ACR)–American Society of Neuroradiology–American Society of Spine Radiology–SIR–Society of NeuroInterventional Surgery Practice Guideline for the performance of vertebral augmentation (3). The document has been updated for relevant evidence published in the interim since the 2011 ACR document. Significantly, data from the Vertebroplasty versus Conservative Treatment in Acute Osteoporotic Vertebral Compression Fractures (VERTOS) trial, a large randomized controlled trial, have become available and included in this revision.

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 the treatment of pathologically weakened vertebral bodies. The more common procedures are vertebroplasty and acrylic vertebroplasty, which involve injecting surgical bone cement; balloon kyphoplasty (also called balloon-assisted vertebroplasty), which involves inflation of a balloon in the weakened vertebral body to attempt fracture reduction before cement is injected; and radiofrequency ablation and coblation techniques. 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 in an attempt to restore the patient's vertebral body height. The present document also applies to any new methods for achieving the same end, vertebral augmentation.

A thorough review of the literature was performed by using Ovid Medline (1980 to present). When published data were believed to be inadequate, data from the expert panel members' own quality assurance programs were used as supplementation, as were conference proceedings. Thresholds for quality assurance have been updated in accordance with available data in the literature.

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Introduced by Galibert and Deramond et al in France in 1987 (4), vertebroplasty entails injection of material into the weakened vertebra(e). Vertebroplasty is an image-guided procedure. Most procedures are performed by 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). Two recent blinded randomized controlled trials (25,26) failed to demonstrate an advantage in their respective study populations for vertebroplasty over a placebo intervention for pain reduction or disability improvement. However, these two trials were argued to suffer from significant flaws (27–29).

The preponderance of data published to date, including a subsequently published larger randomized controlled trial, as well as subsequent metaanalyses, demonstrate a significant benefit of vertebral augmentation (30–46).

As with any invasive procedure, the patient is most likely to benefit when the procedure is performed in an appropriate environment by qualified physicians for appropriate indications.

The present guidelines are written to be used in quality improvement programs to assess percutaneous vertebroplasty procedures. The most important processes of care are (i) patient selection, (ii) performing the procedure, and (iii) 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.

DEFINITIONS

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

1. For a patient rendered nonambulatory as a result of pain from a weakened or fractured vertebral body, pain persisting at a level that prevents ambulation despite 24 hours of analgesic therapy;
2. For 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; or
3. For any patient with a weakened or fractured vertebral body, unacceptable side effects such as excessive sedation, confusion, or constipation as a result of the analgesic therapy necessary to reduce pain to a tolerable level.

OVERVIEW

Vertebral compression fractures are a common and often debilitating complication of osteoporosis (47–51), and are the most common fracture type associated with osteoporosis (52). Although most fractures heal within a few weeks or months, a minority of patients continue to experience pain that does not respond to conservative therapy (53–55). 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 nonfractured levels does not provide an adequate anchor for surgical hardware, and the advanced age of the majority of affected patients increases the morbidity and mortality risks of major surgery.

Initial success with vertebroplasty for the treatment of 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 fractures secondary to osteolytic metastases and myelomatous disease.

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. Depending on practice, this may include CT, magnetic resonance (MR) imaging, x-ray and/or fluoroscopic imaging, and/or bone scans.

INDICATIONS AND CONTRAINDICATIONS

The most common indications for vertebral augmentation are the treatment of (i) symptomatic osteoporotic vertebral body fracture(s) refractory to medical therapy and (ii) vertebral bodies weakened as a result of neoplasia. Currently, there is no indication for the use of vertebral augmentation for prophylaxis against future fracture.

Indication Threshold: 95%

1. Painful osteoporotic vertebral fracture(s) refractory to medical therapy or with unacceptable medical therapy side effects.
2. Vertebral bodies weakened by neoplasm.
3. Symptomatic vertebral body microfracture(s) as documented by MR imaging or nuclear imaging, and/or lytic lesions identified on CT without obvious loss of vertebral body height.

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

Absolute Contraindications

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

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 (motor and/or neurosensory loss including symptoms of cauda equina syndrome).
3. Epidural tumor extension with significant encroachment on the spinal canal.
4. Ongoing bacteremia.
5. Patient's condition improving with medical therapy.
6. Prophylaxis in osteoporotic patients (unless being performed as part of a research protocol).
7. Myelopathy originating at the fracture level.

QUALITY IMPROVEMENT AND DOCUMENTATION

Documentation

Results of vertebral augmentation procedures should be monitored on a continual basis. Records should be kept of 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) (56–58).
3. Follow-up documentation:
 - a. Postprocedure evaluation to assess patient response (pain relief, mobility improvement). Standardized assessment tools such as the Short Form 36 and the Roland–Morris disability scale may be useful for preoperative and postoperative patient evaluation.
 - b. Evaluation of injection site and focused neurologic examination.
 - c. Delayed complications, if any, including treatment and outcome.
 - d. Pathologic (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 Practice Guideline for the Reporting and Archiving of Interventional Radiology Procedures (59).

Informed Consent and Procedural Risk

Informed consent or emergency administrative consent must be obtained and must comply with the ACR–SIR Practice Guideline on Informed Consent for Image-guided Procedures (60). Risks cited should include infection, bleeding, allergic reaction, rib or vertebral fracture, vessel injury, pneumothorax (for appropriate levels), risks associated with radiation exposure, 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. 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.

Success and Complication Rates and Thresholds

Complications can be stratified on the basis of outcome (4,5,7–24). 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; Appendix B). The complication rates and thresholds discussed here refer to major complications unless otherwise specified.

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. 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 (eg, 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 permanent neurologic deficit is one measure of the quality of percutaneous vertebroplasty, values in excess of the defined threshold (in this case, > 1% or > 5%, depending on whether the procedure was performed for an osteoporotic or neoplastic compression fracture; Table 1) (61–68) should trigger a review of policies and procedures within the department to determine the causes and to implement changes to lower the incidence for the complication.

Thresholds may vary from those listed here; for example, patient referral patterns and selection factors may dictate a different threshold value for a particular indicator at a particular institution. Therefore, setting universal thresholds is very difficult, and each department is urged to alter the thresholds as needed to higher or lower values to meet its own quality improvement program needs.

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.

Participation by the interventional radiologist in patient follow-up is an integral part of percutaneous vertebroplasty and will increase the success rate of the procedure. Close follow-up, with monitoring and management of percutaneous vertebroplasty outcomes is appropriate for the interventional radiologist.

SUCCESS RATES

When vertebral augmentation is performed for osteoporosis, procedure outcomes can be defined by using the criteria of Hodler et al (69), with

Table 1. Specific Complications for Vertebral Augmentation (61–68)

Specific Complication	Published Rates (%)	Threshold for Review (%)
Transient neurologic deficit (\leq 30 d of procedure)		
Osteoporosis	1	> 2
Neoplasm	10	> 10
Permanent neurologic deficit (\leq 30 d of 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	> 1
Symptomatic pulmonary material embolus	< 1	> 1
Significant hemorrhage or vascular injury	< 1	> 1
Symptomatic hemothorax or pneumothorax	< 1	> 1
Death	< 1	> 0

Table 2. Vertebral Augmentation Success Rates (61,62,70–75)

Indication	Published Success Rates (%)	Threshold for Review (%)
Neoplastic, all causes	70–92	< 60
Osteoporosis, all causes	80–95	< 70

patients categorized as worse, same, better, or pain/disability gone. For the purpose of the present document, pain/disability gone is defined as improved. Therefore, patients should be categorized as improved, the same, or worse. This categorization should be determined with the use of a validated measurement tool. Published success rates are provided in **Table 2** (61,62,70–75).

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.

COMPLICATIONS

Major complications occur in fewer than 1% of patients treated for compression fractures secondary to osteoporosis and in fewer than 5% of patients treated who have neoplastic involvement. Published complications rates and suggested thresholds are provided in **Table 1**.

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 larger volume than most individual practitioners are likely to treat. Generally, the complication-specific thresholds should be set higher than the complication-specific reported rates listed earlier. It is also recognized that a single complication can cause a rate to cross above a complication-specific threshold when the complication occurs within a small patient series (eg, early in a quality improvement program). In this situation, an overall procedural threshold is more appropriate for use in a quality improvement program. In **Table 1**, all values are supported by the weight of literature evidence and panel consensus.

Perivertebral cement leakage is a common occurrence, and can be observed on CT in as many as 88% of cases (76). The majority of cases are asymptomatic, and late cement migration to the lungs is rare. As a result, routine postprocedural CT is unnecessary (76).

There is some controversy whether vertebral augmentation predisposes patients to subsequent vertebral fractures at adjacent levels, and question whether this may be related to the amount of cement injected and/or the presence and morphology of leakage into the adjacent disc spaces (77–81). Data from the VERTOS II trial found no increased risk of new vertebral fracture after vertebral augmentation (82).

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

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APPENDIX A: CONSENSUS 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 members' 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).

APPENDIX B: SIR 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 h)
- D. Require major therapy, unplanned increase in level of care, prolonged hospitalization (> 48 h)
- E. Result in permanent adverse sequelae
- F. Result in death.

SIR DISCLAIMER

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