Society of Interventional Radiology Quality Improvement Guidelines for Percutaneous Vertebroplasty

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PREAMBLE

THE membership of the Society of Interventional Radiology (SIR) Standards of Practice Committee represents experts in a broad spectrum of interventional procedures from 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 content, rates, and thresholds.

When the evidence of literature is weak, conflicting, or contradictory, consensus for the parameter is reached by a minimum of 12 Standards of Practice Committee members with use of a Modified Delphi Consensus Method (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 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

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preventive drug regimens, including hormonal replacement therapy, biphosphonates, 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 (eg, 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 (i) selecting patients, (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.

Table 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 (ie, hemangioma, multiple myeloma, or metastatic disease).
3. Painful vertebral fracture associated with osteonecrosis (Kummell 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 or practices related to selection of patients for percutaneous vertebroplasty.

Table 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

DEFINITIONS

Percutaneous vertebroplasty is defined as the injection of radiopaque bone cement (eg, polymethyl methacrylate) into a painful osteoporotic compression fracture (9,10,12–14,16, 18,20–28) or painful pathologic vertebral body (eg, multiple myeloma [7,8,29–31], metastatic disease [5–7, 33], and hemangioma [4,33–38]) with use of imaging guidance. Radiologic imaging has been a critical part of percutaneous vertebroplasty 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 (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 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; 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; 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

Table 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

intolerable sedation, confusion, or constipation). Other indications are less common and outlined in **Table 1**. Absolute and relative contraindications are outlined in **Table 2**. The indications and contraindications for percutaneous vertebroplasty may change in the future as more research and information becomes 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%–60%.

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 (5–9,13,14,16,19,22,23,28,40–49). Published complication rates and suggested thresholds are included in **Table 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, eg, 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.

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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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

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

APPENDIX 2: METHODOLOGY

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

Consensus on statements in this document was obtained 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 upon request from SIR, 10201 Lee Highway, Suite 500, Fairfax, VA 22030.

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