Quality Improvement Guidelines for Percutaneous Vertebroplasty

Mark O. Baerlocher, MD, Wael E. Saad, MD, Sean Dariushnia, MD, John D. Barr, MD, J. Kevin McGraw, MD, and Boris Nikolic, MD, MBA, for the Society of Interventional Radiology Standards of Practice Committee

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.

From the Department of Radiology (M.O.B.), Royal Victoria Hospital, Barrie, Ontario, Canada; Department of Radiology, Division of Vascular and Interventional Radiology (W.E.S.), University of Michigan Medical Center, Ann Arbor, Michigan; Department of Radiology (S.D.), Emory University School of Medicine, Atlanta, Georgia; California Center for Neurointerventional Surgery (J.D.B.), La Jolla, California; Riverside Radiology and Interventional Associates (J.K.M.), Riverside Methodist Hospital, Columbus, Ohio; and Department of Radiology (B.N.), Stratton Medical Center, Albany, New York. Received July 31, 2013; final revision received September 7, 2013; accepted September 9, 2013. **Address correspondence to** M.O.B., c/o SIR, 3975 Fair Ridge Dr., Suite 400 N., Fairfax, VA 22033; E-mail: mark.baerlocher@alumni.utoronto.ca

None of the authors have identified a conflict of interest.

An earlier version of this article first appeared in *J Vasc Interv Radiol* 2003; 14:827–831.

J Vasc Interv Radiol 2014; 25:165–170

http://dx.doi.org/10.1016/j.jvir.2013.09.004

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.