CAR Standard for Performance of the Percutaneous Vertebroplasty

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Each standard, representing a policy statement by the Canadian Association of Radiologists, has undergone a thorough consensus process. The standards recognize that the safe and effective use of diagnostic and therapeutic radiology requires specific training, skills, and techniques as described in each document.

I. INTRODUCTION

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 Deramond and colleagues in France in the late 1980s (1), percutaneous vertebroplasty entails injection of polymethyl methacrylate (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 (1B 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. 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 . 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 and osteolytic neoplasms led to extension of the indications to include osteoporotic compression fractures refractory to medical therapy.

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. **PHYSICIAN QUALIFICATIONS**

That Physicians involved in the performance, supervision and interpretation of percutaneous vertebroplasty should be Diagnostic Radiologists and must have a Fellowship or Certification in Diagnostic Radiology with the Royal College of Physicians and Surgeons of Canada and/or the Collège des médecins du Québec. Also acceptable are foreign Specialist qualifications if the Radiologist so qualified holds an appointment in Radiology with a Canadian University.

As new imaging modalities and interventional techniques are developed additional clinical training, under supervision and with proper documentation, should be obtained before radiologists interpret or perform such examinations or procedures independently. Such additional training must meet with pertinent provincial/regional regulations. Continuing professional development must meet with the requirements of the Maintenance of Certification Program of the Royal College of Physicians and Surgeons of Canada.

V. **RADIOLOGIC TECHNOLOGISTS**

The medical radiation technologist must have Canadian Association of Medical Radiation Technologists certification or be certified by an equivalent licensing body recognized by the CAMRT.Under the overall supervision of the radiologists, the technologist will have the responsibility for patient comfort and safety, for examination preparation and performance, and for image technical evaluation and quality and applicable quality assurance.

The training of technologists engaged in specialty activities shall meet with applicable and valid national and provincial specialty qualifications.Continued education of technologists is encouraged by the C.A.M.R.T. and should meet pertinent provincial regulations.

VI. **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 procedural 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 B including blood pressure monitoring, pulse oximetry, and B and equipment for cardio- pulmonary electro-cardiography 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. 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. Aregistered 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. 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 am- bulation 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. **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 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. 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 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 CAR Standard on Communication: Diagnostic Radiology.

3. Followup 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 Canadian provicial 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 (<1%)
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 (<1%).
e. Symptomatic epidural venous cement embolus (5%).
f. Infection (<1%).
g. Fracture of rib or vertebra (5%).
h. Significant hemorrhage or vascular injury (<1%).
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 is performed primarily for spinal treatment stabilization, not pain relief, this threshold would not apply).

IX. **QUALITY CONTROL ANDIMPROVEMENT, 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.

X. **REFERENCES**

1. Galibert P, Deramond H, Rosat P, et al. Preliminary note on the treatment of vertebral angioma by percutaneous acrylic vertebroplasty. Neurochirurgie 1987; 33(2): 166- 168.

2. Deramond H, Darrason R, Galibert P. Percutaneous vertebroplasty with acrylic cement in the treatment ofaggressive spinal angiomas. Rachis 1989; 1: 143- 153.

3. Weill A, Chiras J, Simon JM, et al. Spinal metastases: indications for and results of percutaneous injection of acrylic surgical cement. Radiology 1996; 199: 241- 247.

4. Cotten A, Dewatre F, Cortet B, et al. Percutaneous vertebroplasty for osteolytic metastases and myeloma: effects of the percentage of lesion filling and the leakage of methyl methacrylate at clinical follow- up. Radiology 1996;
200: 525- 530.

5. Deramond H, Galibert P, Debussche- Depriester C. Vertebroplasty. Neuroradiology 1991; 33 (suppl): S177- S178.

6. Debussche- Depriester C, Deramond H, Fardellone P, et al. Percutaneous vertebroplasty with acrylic cement in the treatment of osteoporotic vertebral crush fracture syndrome. Neuroradiology 1991; 33 (Suppl): S149- S152.

7. Gangi A, Kastler BA, Dietemann JL. Percutaneous vertebroplasty guided by a combination of CT and fluoroscopy. Am J Neuroradiol 1994; 15: 83- 86.

8. Cardon T, Hachulla E, Flipo RM, et al. Percutaneous vertebroplasty with acrylic cement in the treatment of Langerhans cell vertebral histiocytosis. Clin Rheumatol1994; 13(3): 518- 521.

9. Chiras J, Deramond H. Complications des In: Saillant G, Laville C, eds. Echecs verte-broplasties. et complications de la chirurgie du rachis: chirurgie de reprise. Paris, France: Sauramps Medical, 1995: 149- 153.

10. Dousset V, Mousselard H, de Monck d=User L, et al. Asymptomatic cervical hemangioma treated by percutaneous vertebroplasty. Neuroradiology 1996; 38(4): 392- 394.

11. Jensen ME, Evans AJ Mathis JM, et al. Percutaneous polymethyl- methacrylate vertebroplasty in the treatment of osteoporotic vertebral body compression fractures: technical aspects. Am J Neuroradiol 1997; 18: 1897- 1904.

12. Deramond H, Depriester C, Toussaint P, et al. Percutaneous vertebral surgery: techniques and indications. Sem Musculoskel Radiol 1997; 1(2).

13. Chiras J, Depriester C, Weill A, et al. Percutaneous vertebroplasty. J Neuroradiol 1997; 24: 45- 59.

14. Lemley TJ, Barr MS, Barr JD, et al. Percutaneous vertebroplasty: a new technique for treatment of benign and malignant vertebral body compression fractures. Surgical Physician Assistant 1997; 3(3): 24- 27.

15. Mathis JM, Petri M, Naff N. Percutaneous treatment of steroid- induced osteoporotic verte-broplasty compression fractures. Arthritis Rheum 1998; 41(1): 171- 175.

16. Cotten A, Boutry N, Cortet B, et al. Percutaneous vertebroplasty: state of the art. Radiographics 1998; 18: 311- 320.

17. Barr MS, Barr JD. Invited commentary. Vertebroplasty: state of the art. Radiographics 1998; 18: 320-322.

18. Do HM, Jensen ME, Cloft HJ. Percutaneous vertebroplasty in the treatment of patients with vertebral osteonecrosis (Kummell=s disease). Neurosurgical Focus 1999; 7(1): article 2.
19. Barr JD, Barr MS, Lemley TJ, et al. Percutaneous vertebroplasty for pain relief and spinal stabilization. Spine 2000; 25: 923- 928.

20. Padovani B, Kasriel O, Brunner P, et al. Pulmonary embolism caused by acrylic cement: a rare complication of percutaneous vertebroplasty. Am J Neuroradiol 1999; 20: 375- 377.

21. Cooper C. The epidemiology of fragility fractures: is there a role for bone quality? Calcif Tissue Int 1993; 53(suppl 1): S23- S26.

22. Cooper C, Atkinson EJ, Jacobsen SJ, et al. study of survival after osteoporotic fractures. Population-based Am J Epidemiol 1993; 137(9): 1001- 1005.

23. Riggs BL, Melton LJ, 3d. Involutional osteoporosis. N Engl J Med 1986; 314: 1676- 1686.

24. Riggs BL, Melton LJ, 3d. The worldwide problem of osteoporosis: insights afforded by epidemiology. Bone 1995; 17 (suppl): S505- S511.

25. Wasnich RD. Vertebral fracture epidemiology. Bone 1996; 18: S179- S183.

26. Silverman SL. The clinical consequences of vertebral compression fracture. Bone 1992; 13 (suppl): S27-S31.

27. Heaney RP. The natural history of vertebral osteoporosis. Is low bone mass an epiphenomenon? Bone 1992; 13 (suppl): S23- S26.