Summary

✓ Percutaneous vertebroplasty (PV), a procedure where bone cement is injected into a partially collapsed vertebral body, is used to relieve pain and provide mechanical stability in cases of osteoporosis or tumour infiltration.

✓ PV provided rapid pain relief and increased mobility in most patients according to the results from 15 uncontrolled studies in 882 persons where over 1,500 vertebrae were treated. Serious complications from bone cement leaks and adjacent vertebral fractures were rare.

✓ Despite the increasing use of PV there are no controlled prospective studies on safety and efficacy with long-term follow-up.

✓ Physician and supply costs range from C $300 - 600 per vertebra treated. This figure excludes hospital or investigational costs.

The Technology

PV is a minimally invasive procedure commonly performed on an outpatient basis under local or general anesthesia. Different techniques exist and have evolved based on European and North American experiences.1 The primary goal is to provide pain relief and improve mobility, with a secondary goal of stabilizing the vertebral body by providing movement between bone fragments.1

The mechanism of pain relief remains unclear.3 Necrosis of a tumour or destruction of nerve endings in adjacent healthy tissue may be caused by mechanical, vascular, chemical, and or thermal changes due to heat produced during polymethylmethacrylate (PMMA) hardening.3 PMMA is the principle component of bone cement. Mechanical stabilization of the vertebral body is another possible explanation.3

A multidisciplinary team, including a spinal surgeon, may be involved in the decision to perform PV since many factors require consideration, including: local and systemic disease spread, vertebral level, pain severity, neurological status, life expectancy and other treatments being considered (surgery, radiation therapy, pharmacotherapy or a combination of these methods).2 Diagnostic testing pre-procedures may include bone scanning, MRI imaging and/or CT scanning which screen for contraindications, and determine the acuity or state of fracture healing.2

PMMA is injected into the vertebral body. Fluoroscopy and/or CT guidance is used to visualize the cement during injection and is required for the safe performance of PV.3

Regulatory Status

Bone cement is regulated as a device in Canada, although it is not authorized for sale in the treatment of PV (Nancy Shadeed, Health Canada, Ottawa: personal communication, 2002 Feb 18). In the U.S. the bone cement used in PV does not have Food and Drug Administration approval; its use is "off-label".5

Patient Group

Approximately 1.4 million Canadians suffer from osteoporosis (OP); 1 in 4 women and 1 in 8 men over the age of 50.6 Vertebral compression fractures (VCF), a complication of OP, may present clinically with severe back pain, but may also be asymptomatic and remain undetected.7

There is limited information in Canada about the prevalence and incidence of VCF. In a population of 4,816 Canadian men and women 50 years and older, a prevalence rate of 0.8% (n=40) was reported for clinically recognized VCF.1 International studies estimate the prevalence rate of VCF to be between 20-25% depending on the definitions and methods of evaluation.9
Recent studies show that VCF are as great in men as in women but since women live longer, the lifetime risk of VCF from age 50 onward is 16% in white women and 5% in white men. VCF are associated with pain, disability, deformity, expense, and often lead to a decreased quality of life.

**Current Practice**

Current treatment of VCF is nonoperative and is often less than adequate (e.g., vitamins, minerals, antiresorptive agents, analgesics, anti-inflammatory agents, bed rest, physical therapy and bracing). Persons suffering from severely debilitating pain have restricted mobility and are at an increased risk for major complications from immobility.

**Administration and Cost**

Physician and supply costs range from C $300 - 600 per vertebra treated (excluding hospital and investigational costs). Many manufacturers make bone cement. Supply costs include the cost of cement (approximately C $66 per vertebra level) (Johanne J. Touchette, Zimmer of Canada Ltd., Mississauga (ON): personal communication, 2002 Mar 02). Also included is the cost of a single-use biopsy needle (Cook Canada Inc - C $69) (Kevin Kotowich, Cook Canada Inc., Stouffville (ON): personal communication, 2002 Feb 18). Stryker Percutaneous Cement Delivery Systems contain all the components necessary to do a one to two level injection at a cost of C $450 per procedure (Diana Howard, Stryker Canada, Hamilton (ON): personal communication, 2002 Mar 08). The cost is increased when multiple levels of vertebrae are treated.

There may be a potential cost savings by hospitals due to reduced length of hospital stay and a potential reduction in costly complications that may arise from prolonged immobilization in elderly persons.

Many provinces do not have specific physician fee items to allow billing for the procedure. However, Ontario physicians have an OHIP fee for the initial treatment of $148.10 and $74.05 for each additional vertebrae level (maximum of three levels). (Dr. Henry Phillips, Ontario Ministry of Health, Kingston (ON): personal communication, 2002 May 07).

**Rate of Technology Diffusion**

PV has gained wide popularity in the U.S. since its introduction in France in 1984. The magnitude of the clinical problem has generated high interest in this procedure. It is difficult to estimate the continued rate of diffusion in Canada, since long-term safety and effectiveness are unknown. Since VCF is a problem in an aging population, wider use of PV may be anticipated if the procedure were found to be safe and effective.

**Concurrent Developments**

Kyphon (Santa Clara, CA) has developed a new procedure called kyphoplasty to help restore vertebral body height. This may be combined with PV. A device, called a bone tamp, is inflated following placement in the vertebral body. Bone is compressed and a space is created for cement to be inserted following tamp removal. Kyphoplasty has been successfully performed in several industry-sponsored, uncontrolled studies in human subjects. Kyphoplasty is a more expensive procedure as compared to PV; product costs are approximately US $3,400. Kyphoplasty is not currently performed in Canadian hospitals.

**The Evidence**

In the largest reported study, Gangi and colleagues performed 287 PVs in 187 patients with an average follow-up of 2.7 years. Reduced analgesic use was reported in 78% of cases with OP, 83% of cases with tumour lesions, and 73% of cases with hemangioma. Persons lost to follow-up during the nine-year time frame of the study were not reported.

Studies have reported increased mobility, decreased medication use, and decreased pain. Pain has been subjectively and objectively measured using validated tools.

Zoarski and colleagues evaluated the safety and efficacy of PV in a prospective study of 30 patients with 54 symptomatic VCF. A validated tool to test quality of care for musculoskeletal conditions, the Musculoskeletal Outcomes Data Evaluation and Management Scale (MODEMS), was administered by mail to all patients pre-intervention and two weeks post-intervention. Paired t-tests confirmed significant
improvements in satisfaction, pain and disability, and physical and mental function in all patients at two weeks. The durability of the procedure was evaluated 15-18 months post-intervention. Twenty-three (76.7%) of the 30 patients responded and 96% remained satisfied and expressed diminished back pain. With the exception of sleep, statistically significant improvements in the quality of life of persons undergoing PV were also reported by Cortet and colleagues19 in a prospective study (n=16) using the Nottingham Health Profile. In another study (n=97), 74% of persons reported that PV had enhanced their quality of life while 26% reported no change.

### Adverse Effects

In a series of 258 patients treated with PV, a high risk of nerve root or spinal cord compression with leaks in the epidural space or in the intervertebral foramina was reported.29 In a retrospective study cement was detected by CT scan in the epidural space in 92 (26.5%) of 347 treated vertebrae in 64 (40.3%) of 159 patients.28 In this study no patients had neurological abnormalities. In 13 of 15 studies, approximately 226 cement leaks were reported in 1,441 procedures.

PMMA that is insufficiently polymerized at the time of injection may migrate into major blood vessels and cause pulmonary embolism (PE). One documented case of symptomatic PE30 and two cases of asymptomatic PE have been reported.16 In a third study, three patients were diagnosed with PE of acrylic cement after the cement migrated through the paraspinal veins.17 No deaths related to PE from cement migration were reported in the studies.

Although PV may be able to prevent vertebral collapse at the level of the treated vertebrae, one study suggests that there may be an increase in the incidence of fracture adjacent to a cemented vertebra. In an uncontrolled, retrospective study of 25 (67%) of 40 patients with symptomatic osteoporotic VCF, the odds ratio (OR) of a VCF adjacent to a cemented vertebra was 2.27 (95% CI: 1.11-4.56) compared with 1.44 (95%CI: 0.82-2.55) for a VCF adjacent to an un cemented VCF (mean duration of follow-up was 48 months, range 12-84 months).24 During follow-up, 13 patients (52%) developed at least one new VCF and 34 VCFs were reported.24 In another uncontrolled retrospective study of 97 patients, a total of 258 PV procedures were performed and 21 patients were found to have VCFs.17

Information about the timing and location of new VCF post-intervention was not consistently reported. Experts have suggested that the risk of adjacent collapse is low and may occur in any patient at all vertebral levels during the follow-up of osteoporotic disease.17,20 Further evaluation in prospective randomized trials comparing PV with conservative therapy are needed to determine whether vertebrae adjacent to treated vertebrae are at increased risk for fracture.

Complications may arise from inappropriate patient selection, poor visualization owing to inadequate fluoroscopic equipment, poor patient co-operation, operator error; lack of patient monitoring, and improper aseptic technique.

### Implementation Issues

Studies are limited by small sample sizes with heterogeneous populations, subjects lost to follow-up, short-term follow-up, and biases that are inherent in retrospective observational studies. None of the studies had a control group for comparison. These limitations place restrictions on the ability to generalize the findings. Long-term safety and effectiveness remain unknown.

### References


