

Kyphoplasty and Vertebroplasty for the Treatment of Osteoporotic Vertebral Compression Fractures

Karen Beattie, BSc, PhD Candidate and Dr. A. Papaioannou, MSc, MD, FRCP(C), Associate Professor of Medicine; Department of Geriatrics, McMaster University, Hamilton, ON.

Dr. P. Boulos, MD, FRCP(C) and Dr. J.D. Adachi, MD, FRCP(C), Professors of Medicine; Department of Rheumatology, McMaster University, Hamilton, ON.

Osteoporosis is a major health concern in Canada, affecting 25% of women and 12% of men. Vertebral compression fractures, the most common of all osteoporotic fractures, are clinically diagnosed only 30% of the time. Treatment for such fractures is primarily pharmacological. However, newer, non-invasive methods of treatment, namely vertebroplasty and kyphoplasty, stabilize compression fractures, provide pain relief and even improve posture and functional ability. While vertebroplasty involves the injection of a cement product into one or more compressed vertebrae, kyphoplasty adds another step of inserting a balloon into the vertebra to re-establish original vertebral height. Clinical studies of these procedures suggest kyphoplasty provides better symptomatic relief and is associated with fewer complications than vertebroplasty. However, further randomized, controlled evidence comparing these procedures is required.

Key words: kyphoplasty, vertebroplasty, osteoporosis, vertebral fracture, compression fracture.

Introduction

It is estimated that 25% of Canadian women and 12% of Canadian men have osteoporosis.¹ With approximately one-quarter of the population reaching 65 years of age and older in the next 35 to 40 years, the prevalence of osteoporosis will only continue to significantly increase.² It has been said that vertebral body compression fractures are the most commonly experienced consequence of osteoporosis.³ However, because the diagnosis of vertebral compression fractures relies on patients reporting back pain severe enough to elicit a radiograph, it is estimated that only 30% of compression fractures are actually clinically diagnosed.⁴ Of those presenting with a clinical vertebral fracture, approximately 75% suffer from chronic pain.^{5,6} Between the ages of 50 and 54 years, the prevalence of radiographically-identified vertebral deformities is approximately 5%, increasing to 50% in individuals between 80 and 84 years of

age.⁷ Canadian data suggest that the prevalence of vertebral deformity in men is approximately one in five, while in women it is nearly one in four.⁸ The treatment regimen of vertebral compression fractures traditionally has involved the management of the clinical consequences of fractures in addition to the provision of physical rehabilitation and prevention of subsequent fractures. However, newly developed, minimally invasive techniques referred to as vertebroplasty and kyphoplasty not only stabilize compressed vertebra, but also provide significant pain relief and improve the functional abilities of people with these painful, debilitating fractures. This paper will review these procedures, as well as the results and complications of these treatments observed in clinical studies.

Management of Vertebral Fractures

Osteoporotic vertebral compression fractures can be a significant burden to both

patients and their families in terms of direct physical pain and disability and associated complications (Table 1). In addition to relieving the symptoms of these fractures, acute therapy usually involves initiation of medication for osteoporosis and physiotherapy. Chronic pain, depression, loss of sleep and loss of independence can result directly from vertebral compression fractures, and medications associated with these consequences may lead to further mood or mental alterations that can exacerbate the underlying problem.⁹ Evidence from randomized controlled trials suggests that future fracture risk can be reduced by 40–50% with the use of pharmacological treatments.¹⁰ However, such medications are usually geared towards the long-term management of osteoporosis and often can take up to one year to achieve efficacy, during which time other fractures can occur.¹¹ In addition, these agents do not deal with symptoms associated with vertebral fractures. This suggests there is an important place for the treatment of vertebral compression fractures that provides patients with pain relief combined with the opportunity to improve functional capabilities. The new, minimally invasive vertebroplasty and kyphoplasty procedures may be ideal management techniques that can potentially accomplish both these goals.

Vertebroplasty and Kyphoplasty

Initially developed in France in the mid-1980s, vertebroplasty was performed in patients with pathological fractures due to malignancy. Since then, this procedure gradually has been adopted as a treatment for osteoporotic compression fractures, and it was first used for this indication in North America in the mid-1990s.¹¹ Usually performed under local anesthesia with the assistance of fluoroscopy, vertebroplasty involves the percutaneous

Symptoms	Signs	Function	Future Risks
Back pain (acute, chronic)	Height loss	Impaired activities of daily living (e.g., bathing, dressing)	Future fractures
Sleep disturbance	Kyphosis	Difficulty fitting clothes due to kyphosis, protuberant abdomen	Mortality
Anxiety	Reduced lumbar lordosis	Difficulty bending, lifting, descending stairs, cooking	
Depression	Protuberant abdomen		
Reduced self-esteem	Reduced lung function		
Fear of future fracture & falling	Weight loss		
Reduced quality of life			
Early satiety			

transpedicular (preferred method) or extrapedicular injection of bone cement or polymethylmethacrylate (PMMA) into one or more sites of vertebral body fractures.^{3,9,11} Using one or two bone biopsy needles guided to the correct location so as to ensure the needles are not in line with an exiting vein, 1–4mL of PMMA (low viscosity) per side is injected into the cancellous bone matrix under high pressure. Vertebroplasty has the potential to stabilize the spine while increasing mobility and decreasing fracture-associated pain. However, despite the high pressure under which the bone cement is injected, vertebroplasty does not have potential to correct either spinal compression deformity or kyphosis associated with morbidity.^{9,11}

Kyphoplasty, a modified version of vertebroplasty, has been used in the United States only for the past five years since FDA approval of the inflatable bone tamp in 1998.⁹ The differences between this

procedure and vertebroplasty are presented in Table 2.

During kyphoplasty, one or two balloons or bone tamps are transpedicularly inserted into the vertebral body under image guidance (Figure 1, page 50). Gently and carefully, the balloon is inflated with the use of a radiocontrast medium for visualization, thereby compressing the cancellous bone and re-expanding the endplates of the body without lateral or posterior displacement of the fractured vertebrae.⁹ The working cavity created by the balloon is then injected with 2–6mL (per side) of viscous PMMA under low pressure via a cannula.⁹ This procedure has had a significant amount of success both in providing immediate pain relief and in restoring vertebral structure that was initially altered by compression fractures.^{3,11}

Following both vertebroplasty and kyphoplasty, patients remain supine for approximately 1–2 hours, allowing time

for the PMMA to solidify. In most cases, patients are discharged a few hours following the procedure, while those with possible neurologic complications or uncontrolled pain, or who are otherwise unstable, are required to stay overnight in hospital.³

Risks and Benefits

It appears that the best candidates for vertebroplasty and kyphoplasty are those who have focal, intense back pain and who have radiographically defined new or progressive compression fractures that are confirmed upon physical examination. The procedure is contraindicated in individuals who have complete loss of vertebral body height, pressure of bone fragments on the spinal cord, fracture through or destruction of the posterior vertebral wall, coagulation disorders or osteoblastic metastases.³

Although the best and most effective time for intervention has not yet been determined, most studies have involved patients who had failed to experience pain relief after several weeks or months of conventional medical management.^{3,12,13} It has been suggested that the probability of improvement in symptoms and functional ability may decrease progressively over time, with a low likelihood of positive results occurring in fractures that occurred six months or more before the intervention.³

To date, no randomized controlled trials have been published that compare vertebroplasty to kyphoplasty, or either

Vertebroplasty	Kyphoplasty
Cement injected under higher pressure (cement is less viscous)	Cement injected under lower pressure (cement is more viscous)
No potential to correct vertebral deformity	Greater potential to reverse vertebral deformity
No bone tamp involved	Bone tamp used to increase space for cement
Greater potential risk of extravasation of cement	Limited potential risk of extravasation of cement

to medical management alone. However, retrospective and prospective studies have been conducted on each of the procedures, and overall data show that patients experience significant pain relief following both procedures. In addition, kyphoplasty studies demonstrate significant improvements in reducing kyphosis and improving vertebral body height. There are, however, risks associated with both types of procedures.

Vertebroplasty

It is evident from published studies on vertebroplasty that patients who undergo the procedure generally experience significant back pain relief almost immediately following completion of the procedure. Table 3 highlights three such studies, the results of which are confirmed in other studies not discussed here.^{14,15} Although significant pain relief is observed in these patients, vertebroplasty does not address the ver-

tebral deformity or kyphosis in many of these cases. In addition, despite the positive results in symptomatic relief, there are risks associated with vertebroplasty, particularly those involving the foraminal or epidural leakage of the cement used in the procedure.^{3,11} While such leaks were reported in fewer than 10% of cases, radiculopathy and cord compression also have been observed in this procedure, although at very low incidences.¹⁶ Cases of pulmonary emboli also are potential consequences of vertebroplasty, although these have been observed more frequently in patients undergoing vertebroplasty for the treatment of malignant spinal tumours than for osteoporotic compression fractures.¹⁷

Kyphoplasty

Evidence from kyphoplasty studies suggests that it is a well-tolerated procedure for the indication of painful vertebral

compression fractures. In addition to providing significant pain relief (most studies report ≥ 90% relief almost immediately following the procedure), kyphoplasty also significantly improves vertebral body height, decreases kyphosis and improves patient function and mobility (Table 4). The risks of the procedure appear to be less frequent and less severe than those observed with vertebroplasty. This may be at least partially attributed to the lower pressure under which the cement is injected into the vertebral body and the higher viscosity of the cement itself.¹³

Caution

It should be noted that in October 2002, the FDA issued a report regarding complications related specifically to the leakage of bone cement that had occurred during vertebroplasty and kyphoplasty procedures. The FDA notification stated that it was working together with manufacturers and

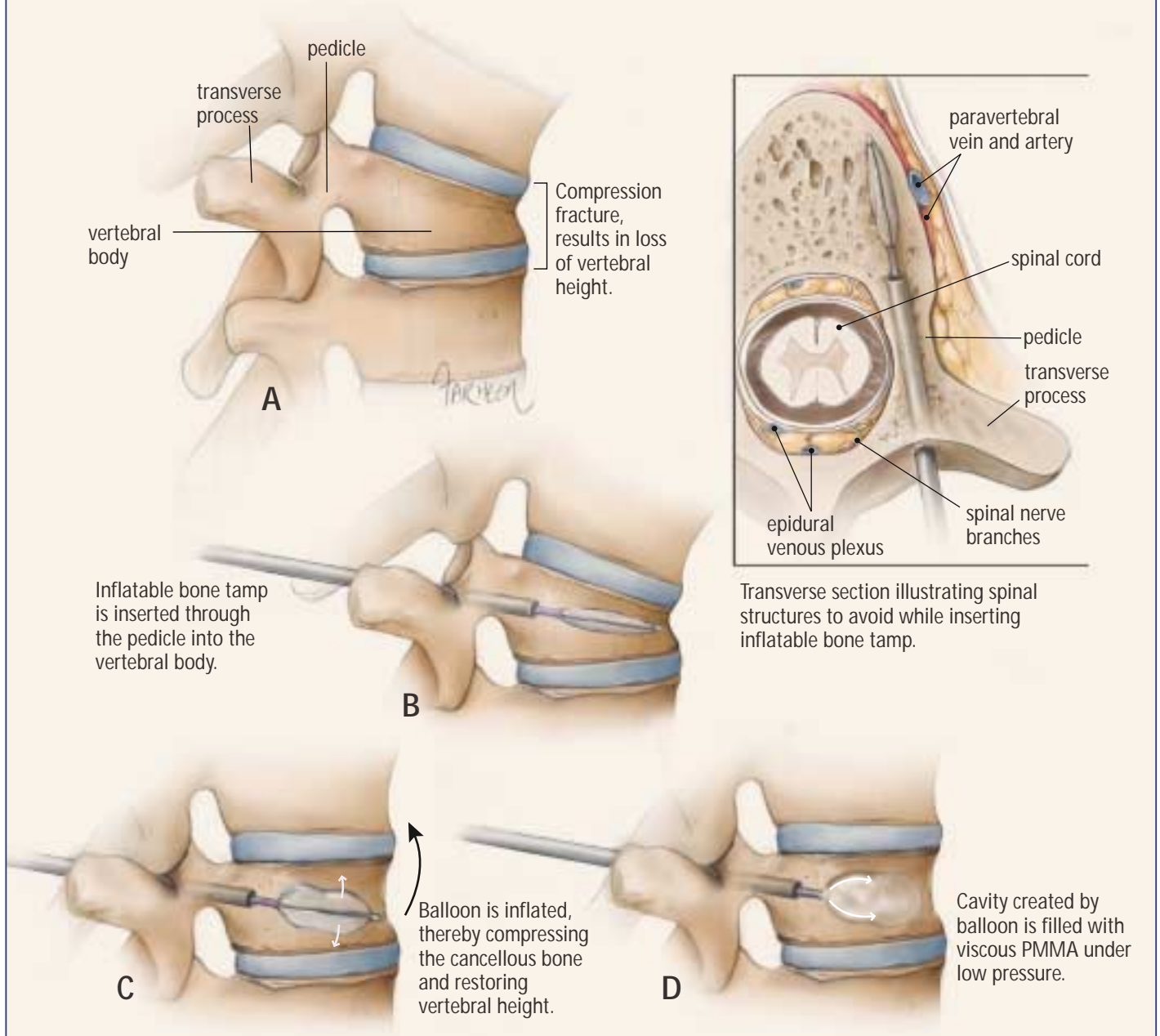
Table 3

Summary of Results from Vertebroplasty Studies*

	N Mean age (range)	Mean follow-up (range)	Results	Consequences
Barr <i>et al.</i> ¹⁹	n=38 ages not reported	18 months (2–42)	– 95% of patients had moderate (32%) to complete (63%) pain relief	– One case of nerve root and foraminal compromise two years post-treatment – One case of new fracture 10 days post-vertebroplasty, patient treated with pain relief (initial fracture secondary to oral steroid treatment)
Grados <i>et al.</i> ²⁰	n=25 66 years (48–78)	48 months (12–84)	– Focal pain reduced approximately 50% one-month post-treatment – Long-term results similar to one-month results	– During follow-up, 52% of patients had ≥ 1 new fracture – Patients were 2.27 times more likely to have vertebral fracture in vicinity of cemented vertebra vs. 1.44 times in uncemented vicinity
McGraw <i>et al.</i> ²¹	n=100 73.7 years (37–91)	21.5 months (6–44)	– 97% had significant pain relief 24 hours post-treatment – 93% had significant pain relief during follow-up – 93% improved ambulatory ability – 91% reduced amount of daily medications	– One case of sternal fracture before treatment – One case of transient radiculopathy from treated lumbar body

* These studies did not provide data on types or amounts of osteoporotic medications patients may have been taking prior to and/or after the procedures.

Figure 1: The Kyphoplasty Procedure for Treatment of Osteoporotic Vertebral Compression Fractures



professional organizations to evaluate the safety and efficacy of the cement products currently in use. In addition, it encouraged physicians to be aware of the recommendations and considerations that should be made regarding patient selection, techniques, complications and patient monitoring for these procedures.¹⁸

Conclusions

Vertebroplasty and kyphoplasty are effective methods of stabilizing osteo-

porotic compression fractures and managing the associated back pain. Kyphoplasty provides additional benefits through the insertion of a balloon tamp which re-establishes vertebral body height and decreases kyphosis. Studies involving kyphoplasty also suggest that it results in fewer, less severe side effects compared to vertebroplasty. However, until randomized controlled trials of these procedures are published and the safety of the cement

products used in these procedures is re-evaluated, reported research should be reviewed with caution. When considering these treatments for a patient with vertebral compression fractures, it is important for physicians to obtain all pertinent information regarding the complication rate and long-term follow-up at local centres where the procedure will take place. ◆

No competing financial interests declared.

Table 4

Summary of Results from Kyphoplasty Studies*

	N Mean age (range)	Mean follow-up	Results	Consequences
Theodorou <i>et al.</i> ¹³	n=15 75 years (41-86)	6-8 months	- 100% experienced dramatic pain relief post-treatment - Vertebral body height improvement to average of 90% normal height (average increase of 13% height) - Kyphosis improved by 62%	- None reported - Cases of chronic obstructive lung disease improved - 3/15 patients returned for kyphoplasty in subsequent vertebral fractures
Garfin <i>et al.</i> ¹⁰	n=340 ages not reported	≤ 18 months	- 90% symptomatic and functional improvement rate - Vertebral body height improvement to average of 90% normal height (average increase of 16% height)	- Four cases of complications related to needle insertion, not balloon tamps
Lieberman <i>et al.</i> ¹²	n=30 68.6 years (48-86)	6.7 months	- 100% reported pain relief post-treatment - 35% increase in vertebral body height - Kyphosis improved by 15% - Physical function, vitality, mental health, social functioning improved significantly	- At follow-up, no injuries to spinal or extraspinal tissues - Two cases of rib fractures related to positioning - One case perioperative pulmonary edema and myocardial infarction secondary to intraoperative fluid overload

* These studies did not provide data on types or amounts of osteoporotic medications patients may have been taking prior to and/or after the procedures.

References

- Hanley DA, Josse RG. Prevention and management of osteoporosis: consensus statements from the Scientific Advisory Board of the Osteoporosis Society of Canada. 1. Introduction. *CMAJ* 1996;155:921-3.
- Papadimitropoulos EA, Coyte PC, Josse RG, et al. Current and projected rates of hip fracture in Canada. *CMAJ* 1997;157:1357-63.
- Watts NB, Harris ST, Genant HK. Treatment of painful osteoporotic vertebral fractures with percutaneous vertebroplasty or kyphoplasty. *Osteoporos Int* 2001;12:429-37.
- Cooper C, Melton LJ. Vertebral fractures. *BMJ* 1992;304:793-4.
- Rapado A. General management of vertebral fractures. *Bone* 1996;18(3 Suppl):191S-196S.
- Huang C, Ross PD, Wasnich RD. Vertebral fracture and other predictors of physical impairment and health care utilization. *Arch Intern Med* 1996;156:2469-75.
- Melton LJ, III, Kan SH, Frye MA, et al. Epidemiology of vertebral fractures in women. *Am J Epidemiol* 1989;129:1000-11.
- Jackson SA, Tenenhouse A, Robertson L. Vertebral fracture definition from population-based data: preliminary results from the Canadian Multicenter Osteoporosis Study (CaMos). *Osteoporos Int* 2000;11:680-7.
- Garfin SR, Yuan HA, Reiley MA. New technologies in spine: kyphoplasty and vertebroplasty for the treatment of painful osteoporotic compression fractures. *Spine* 2001;26:1511-5.
- Papaioannou A, Watts NB, Kendler DL, et al. Diagnosis and management of vertebral fractures in elderly adults. *Am J Med* 2002;113:220-8.
- Lin JT, Lane JM. Nonmedical management of osteoporosis. *Curr Opin Rheumatol* 2002;14:441-6.
- Lieberman IH, Dudeney S, Reinhardt MK, et al. Initial outcome and efficacy of "kyphoplasty" in the treatment of painful osteoporotic vertebral compression fractures. *Spine* 2001;26:1631-8.
- Theodorou DJ, Theodorou SJ, Duncan TD, et al. Percutaneous balloon kyphoplasty for the correction of spinal deformity in painful vertebral body compression fractures. *Clin Imaging* 2002;26:1-5.
- Cortet B, Cotten A, Boutry N, et al. Percutaneous vertebroplasty in the treatment of osteoporotic vertebral compression fractures: an open prospective study. *J Rheumatol* 1999;26:2222-8.
- Maynard AS, Jensen ME, Schweickert PA, et al. Value of bone scan imaging in predicting pain relief from percutaneous vertebroplasty in osteoporotic vertebral fractures. *AJNR Am J Neuroradiol* 2000;21:1807-12.
- Chiras J, Depriester C, Weill A, et al. Percutaneous vertebral surgery. Technics and indications. *J Neuroradiol* 1997;24:45-59.
- Jang JS, Lee SH, Jung SK. Pulmonary embolism of polymethylmethacrylate after percutaneous vertebroplasty: a report of three cases. *Spine* 2002;27:E416-E418.
- U.S. Food and Drug Administration. FDA Public Health Web Notification: Complications related to the use of bone cement in vertebroplasty and kyphoplasty procedures, 2002. <http://www.fda.gov/cdrh/safety/bonement.html>.
- Barr JD, Barr MS, Lemley TJ, et al. Percutaneous vertebroplasty for pain relief and spinal stabilization. *Spine* 2000;25:923-8.
- Grados F, Depriester C, Cayrolle G, et al. Long-term observations of vertebral osteoporotic fractures treated by percutaneous vertebroplasty. *Rheumatology (Oxford)* 2000;39:1410-4.
- McGraw JK, Lippert JA, Minkus KD, et al. Prospective evaluation of pain relief in 100 patients undergoing percutaneous vertebroplasty: results and follow-up. *J Vasc Interv Radiol* 2002;13:883-6.