Immediate and early postoperative pain relief after kyphoplasty without significant restoration of vertebral body height in acute osteoporotic vertebral fractures

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Object. Painful osteoporotic vertebral compression fractures (VCFs) are a significant cause of disability in the elderly population. Kyphoplasty, a recently developed minimally invasive procedure, has been advocated for the successful management of these fractures in terms of immediate pain relief, and also for restoration of the premorbid level of daily activities. In this retrospective study the authors report on their experience with the early management of VCFs with kyphoplasty.

Methods. A retrospective analysis was conducted in 13 patients (seven women and six men) whose ages ranged from 48 to 87 years (mean age 71.5 ± 11 years [mean $\pm$ standard deviation]). The interval between onset of symptoms and surgical intervention ranged from 4 to 9 weeks. Twenty levels (12 thoracic, eight lumbar) were treated in this cohort. Immediate and early postoperative (1-month follow-up visit) visual analog scale (VAS) pain scores, activity levels, and restoration of vertebral body (VB) height were assessed.

The mean preoperative VAS score was 8 ± 1 , whereas the immediate and early postoperative scores were 1 ± 1 . These findings reflected a resolution of 90 to 100% of preoperative pain. All patients resumed routine activities within hours of the procedure, although improvement in VB height was not accomplished in this cohort. No major complications were encountered in this clinical series.

Conclusions. Kyphoplasty is a safe and effective method for the treatment of osteoporotic VCFs. Failure to restore VB height does not seem to interfere with the excellent pain management and good functional outcome provided by this procedure.

KEY WORDS • osteoporosis • vertebral compression fracture • pain • kyphoplasty • polymethyl methacrylate

Osteoporosis is the most common metabolic disorder of the bones, affecting approximately 28 million people in the US.¹⁶ It is estimated that 35% of all women older than 65 years of age suffer from this disorder,⁵ which predominantly affects postmenopausal women. Because age is the most important risk factor for osteoporosis, the number of affected individuals is anticipated to increase substantially in the coming years, as a result of the increase in life expectancy in the population of the industrialized countries.^{7,34} In the US alone, approximately 1.5 million fractures occur annually as a result of primary or secondary osteoporosis, and almost half of those (700,000) involve the spine.^{7,16,25,35}

Osteoporotic VCFs are a significant cause of morbidity and mortality in postmenopausal women and elderly men.

Abbreviations used in this paper: PMMA = polymethyl methacrylate; VAS = visual analog scale; VB = vertebral body; VCF = vertebral compression fracture.

Fracture-related acute or chronic pain as well as gradual destruction of the VB with subsequent development of spinal kyphosis and abdominal protuberance interferes with the patient's daily activities and severely impairs their quality of life. Depression, poor nutritional status, decreased appetite, and impaired pulmonary function have been reported in patients who sustain VCFs.^{7,14,23,24} The impact on the patient's life increases with the number of vertebrae involved. The presence of one osteoporotic VCF leads to a fivefold increase in the risk of sustaining a second vertebral fracture,¹⁷ possibly due to altered biomechanical relationships in the spine as well as disease progression. Kado, et al.,²⁰ reported a 23% increase in the mortality risk in women with one VCF and a 34% increase when multiple VCFs are present.

In the last few years, balloon kyphoplasty, a minimally invasive procedure, has been developed for the treatment of painful VCFs, with quite promising results. This technique involves the percutaneous insertion and inflation of

a bone tamp in the VB and subsequent low-force injection of a high-viscosity substance (PMMA), aiming to achieve pain relief and restoration of vertebral height. Nevertheless, the importance of the timing of the intervention and of the restoration of VB height has not been well established. In this communication, we present our experience with early management of this entity by using balloon kyphoplasty in 13 patients with osteoporotic VCFs.

CLINICAL MATERIAL AND METHODS

This is a retrospective clinical study of 13 patients (seven women and six men) whose ages ranged from 48 to 87 years; the mean age was $71.5 \text{ years} \pm 11 \text{ years}$. The time interval between onset of symptoms and surgical treatment ranged from 4 to 9 weeks. All procedures were performed after induction of general anesthesia, with intraoperative somatosensory evoked potentials, motor evoked potentials, and electromyographic monitoring used for every case. In this cohort we attempted to restore a total of 20 levels (12 thoracic, eight lumbar) with a percutaneous surgical method in which a unilateral extrapedicular approach was used on the thoracic levels and a bilateral transpedicular approach on the lumbar levels. All the procedures were performed with the aid of fluoroscopic guidance. We routinely used PMMA as a filling agent in these procedures. In no case was more than 3 ml of PMMA used, to prevent delayed adjacent VCFs.³¹

Immediate and 1-month postoperative VAS pain scores were obtained; also, activity levels and restoration of VB height were assessed independently for each case.

RESULTS

The pre- and postoperative VAS scores were calculated and were found to be 8 ± 1 and 1 ± 1 , respectively. These immediate and early postoperative findings demonstrated resolution of 90 to 100% of the preoperative pain (Fig. 1). All patients resumed their routine activities within hours of the procedure and were discharged within 24 hours. No significant improvement in VB height was accomplished in this cohort (Figs. 2 and 3). No major complications were encountered.

DISCUSSION

Osteoporotic VCFs constitute an increasing source of morbidity and disability among the elderly popula-

Fig. 1. Bar graph showing pre- and postoperative VAS scores in patients with VCFs.

Fig. 2. Graph showing pre- and postoperative VB height in patients undergoing kyphoplasty.

tion.^{4,30,32} The negative impact of these entities on the ability to perform daily activities is of paramount importance; approximately 50% of patients with more than one VCF are in need of daily self-care assistance.²⁸ Treatment of VCFs has traditionally been conservative, consisting of bed rest, analgesic drugs, and back braces²⁹ in severe cases, along with other pain-relieving methods such as massage and heat therapy.^{21,24} Immobilization, however, is a well-known predisposing factor for further bone loss, resulting in an increased tendency to sustain additional osteoporotic fractures, and reinforcing an already existent vicious cycle. Additionally, prolonged therapy with pain medication may lead to confusion and gastrointestinal and addiction problems.

In an effort to prevent further fractures and to achieve early pain relief and mobilization of these patients, vertebroplasty, a minimally invasive technique, was developed. Vertebroplasty was first described by Galibert, et al., in 1987¹¹ for the treatment of VB tumors, and its use has since been expanded to include osteoporotic VCFs. This procedure entails the high-force injection of low-viscosity PMMA in the VB. Vertebroplasty achieves excellent pain relief; 60 to 100% of treated patients experience a significant improvement within a few days.^{1,5,6,10,28} Nevertheless, the injection of PMMA under high pressure carries a substantial risk of extravertebral cement leakage; Cortet, et al.,⁶ reported that leakage was observed in 65% of their patients. Depending on the extent and the exact location of the leakage, a variety of complications may develop. Perivertebral venous migration of the cement might lead to pulmonary embolism³ and death, and foraminal or epidural cement extravasation may cause nerve root or spinal cord compression with subsequent neurological symptoms that require surgical intervention.^{8,21,26} Furthermore, vertebroplasty fails to achieve restoration of VB height and spinal realignment.^{7,9,18} The kyphotic deformity is "frozen," and this is believed to correlate with an increased risk of adjacent VCFs and impaired functional outcome.

The recently developed percutaneous balloon kyphoplasty procedure is aimed at addressing the shortcomings of vertebroplasty, and has been gaining popularity, especially among physicians in the surgical subspecialties. Kyphoplasty results in immediate relief of the fracture pain, comparable to vertebroplasty.^{2,13,18,22} Lieberman, et al.,²⁴

Fig. 3. Postoperative plain intraoperative fluoroscopic views showing minimal restoration of VB height after kyphoplasty.

found that all of their patients treated with kyphoplasty noted a marked reduction in the intensity of pain after the procedure. Garfin, et al.,¹² reported similar results in a retrospective study, with 90% of patients in their cohort experiencing significant pain relief within 2 weeks. Our results confirm those of previously published reports. The exact mechanism of pain relief by vertebral augmentation procedures remains unknown; postulated mechanisms include a chemical or thermal effect of PMMA resulting in the destruction of nerve endings transmitting pain signals, as well as a mechanical stabilization of microfractures.^{6,15,19}

Extravasation of cement appears to occur much less frequently with kyphoplasty in comparison with vertebroplasty. The low-force injection of a higher-viscosity material along with the packing and hardening of the cancellous bones accomplished by the balloon inflation seem to confine PMMA effectively inside the vertebra. Coumans, et al.,⁷ reported only a 2.7% risk of material leakage per treated level in a cohort including patients with osteoporosis as well as those with multiple myeloma, who are generally considered more prone to intraoperative complications such as cement leakage. Lieberman, et al.,²⁴ and Ledlie and Renfro,²² reported cement extravasation rates of 8.6 and 9%, respectively. No cement leakage was noted in our cohort, which further supports the safety of this procedure.

In several series, kyphoplasty has been indicated to achieve partial VB height restoration, which is considered important for correction of the kyphotic deformity.^{2,13,22,24} Lieberman, et al.,²⁴ reported a 47% increase in midline VB height in 70% of the treated levels, although they stated that longer follow-up duration is required before definite conclusions can be made. Similarly, Berlemann, et al.,² noted a 47.7% correction of local osseous kyphosis. They also observed a relationship between the age of the frac-

ture, the amount of preoperative kyphosis, and the location of the vertebra in terms of the potential for height restoration; recent fractures (< 6 weeks old) that are caudally located with a severe kyphotic deformity are more likely to show significant restoration of VB height after kyphoplasty.² Improvement of local sagittal alignment in the region of the fracture has also been reported in the literature.^{27,33,34}

In our series, no statistically significant increase in VB height was noted, despite early intervention. Nevertheless, all patients resumed normal daily activities within hours after the procedure, and their functional level has remained unchanged throughout the entire follow-up period. This indicates that early management of osteoporotic VCFs with kyphoplasty may lead to a desirable functional outcome and marked improvement in the quality of life, even without restoration of the VB height.

CONCLUSIONS

The treatment of osteoporotic VCFs with kyphoplasty appears to provide significant pain reduction and restores patients to their premorbid level of daily activities. Complications associated with this procedure seem to be minimal. Nevertheless, large, long-term, clinical randomized prospective studies need to be conducted for an adequate assessment of the life-long results as well as the eventual shortcomings of kyphoplasty. For instance, the exact behavior of PMMA several decades after its placement remains to be elucidated.

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