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Original Article

Clinical and radiographic evaluation of balloon kyphoplasty using VCFX for osteoporotic vertebral compression fracture☆

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ABSTRACT

Objective: In response to the major concerns of cement leakage and associated neurological injuries with regards to percutaneous vertebroplasty, balloon kyphoplasty (BK) was devised and introduced in 1998. This study retrospectively evaluated the clinical outcomes and radiological findings of the first 100 patients receiving BKs because of osteoporotic vertebral compression fractures (VCFs) at our institute.
Materials and Methods: A total of 100 patients (85 female and 15 male) with 130 osteoporotic VCFs undergoing BKs from January 2007 to July 2009 were enrolled. BK using VCFX (Central Medical Technologies, Taiwan) and associated polymethylmethacrylate augmentation was performed on these patients with symptomatic VCFs that responded poorly to conservative therapy. All patients received preoperative magnetic resonance imaging to determine which level needed BK. Radiographies were used for preoperative and postoperative imaging studies. A Huskisson's visual analog scale was used to compare the clinical result of pain relief before and after surgery.
Results: The rupture of 20 (15.4%) balloons was noted during the operations. Nineteen (14.6%) cement leakages were found postoperatively, 7 cement leakages with balloon rupture and 12 with balloon integrity. No neurological complications occurred for either balloon rupture or integrity postoperatively. The visual analog scale scores improved from 87 preoperatively to 32 at final follow-up visit. Eighty-six patients returned to their preinjury activities of daily living and achieved better quality of life than their preoperative status. The average restoration of the fractured vertebral body height was 36.5%. The average correction of the sagittal alignment was 7.2°.
Conclusions: BK is an effective and low-risk method to treat painful osteoporotic VCFs. However, balloon rupture with Telebrex contrast medium extravasation is troublesome and can obscure the visual field of intraoperative fluoroscopy influencing the following injection of bone cement.

1. Introduction

Management of symptomatic osteoporotic vertebral compression fractures (VCFs) using percutaneous vertebroplasty (PV) with polymethylmethacrylate (PMMA) gained widespread use because of its simplicity and effectiveness. Although PV is considered as a minimally invasive procedure, several acute complications (such as bleeding at the puncture site; local infection; leakage of cement into the spinal canal, adjacent discs, paravertebral soft tissues, or perivertebral venous system; and pulmonary embolism) or delayed sequelae (such as adjacent vertebral fracture, cement dislodgement or fragmentation, and pyogenic spondylitis) have been reported in the related literature.[1–5] Most of these complications can be resolved by conservative treatment.[6,7] Cement leakage outside the vertebral body during PV is one of these complications and is usually clinically asymptomatic. Because of the fear that the posterior extravasation of the cement could have devastating neurological consequences and the concern that the high pressures used to introduce the cement could potentially lead to bolus thromboembolism through the vertebral venous system migration to the lung or vital organs, PV using PMMA bone cement in a less viscous form for injection was still worrisome to spine surgeons. The balloon kyphoplasty (BK) technique was devised and first used in 1998. The procedure claimed not only to secure fracture fixation and stabilization but also to reconstruct the vertebral anatomy and correct the spinal deformity, with the aim of avoiding the dreadful complications of PVs.[8–12] The purpose of this study was to evaluate the clinical outcomes and radiological findings for the first 100

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patients treated using BKs in one institute and to analyze the collected data of evidence regarding the efficacy and safety of BKs in the treatment of osteoporotic VCFs.

2. Materials and methods

The study population was comprised of 106 consecutive patients who underwent BK for the treatment of osteoporotic VCFs from January 2007 to July 2009 at our institution. Among this group, six (5.7%) patients were lost to follow-up. The remaining 100 patients who could be followed up regularly comprised the patient cohort in this study, and their medical records were reviewed. There were 85 women and 15 men with a mean age of 72.5 years (range, 62–99 years). All patients suffered from intractable back pain with no response to conservative therapy for at least 6 weeks. After a comprehensive survey and diagnostic radiography, eligible patients received a preoperative magnetic resonance imaging to determine which level needed BK. In addition to intravertebral edema, some form of bone defect or nonunion, such as vacuum cleft, osteonecrosis, or mineral defect, revealing an abnormal magnetic resonance imaging signal intensity were also indicated for BK. The surgical procedure, benefits, risks, and possible complications of BK were clearly explained to the patients and their families.

Local anesthesia or intravenous sedation was used for all patients who underwent this procedure. The patient was placed in a prone position. The skin was prepared and draped in a standard sterile fashion. The fracture level was visualized fluoroscopically using biplane C-arm and the needle entry site overlying its pedicle was localized. A small skin incision was made just lateral to the pedicle of the vertebral body to be treated. Using a combination of light malleting and manual pressure, a specialized BK needle (VCFX, Central Medical Technologies, Taiwan) was inserted and passed through the pedicle into the vertebral body. Frequent fluoroscopic images were used to confirm the location. Once the needle reached the optimal position, the needle was replaced by a working cannula to create a tract into the fractured vertebral body. The balloon tamps were introduced and then inflated until either the fracture was reduced or it was unable to be continued. After the balloon tamp was deflated and removed, a mixture of PMMA bone cement and barium contrast medium was poured into the created cavity, using a hand plunger system supplied by the manufacturer.

After the procedure, the patient could ambulate wearing a thoracolumbar brace for support and protection. Clinical outcomes were evaluated by asking patients to quantify their degree of pain on Huskisson's visual analog scale (VAS: 0 mm means no pain and 100 mm means the most pain possible) on several separate occasions: before BK; 1 day after BK (usually at discharge); and at 1 month, 3 months, 6 months, and 12 months follow-up visits. As an overall assessment of well being, the patients were asked whether they thought that the procedure had significantly improved their quality of life, no difference, or even worse. The ranking of the postoperative recovery was simply based on a modified MacNab outcome scale, which consisted of three categories compared with the preoperative status. Radiological examination was also performed to evaluate restoration of the fractured vertebral body height and correction of the sagittal alignment before surgery, 1 day after surgery, and at 12-month follow-up visit. The restoration of the fractured vertebral body height was calculated based on the following equation: $2 \times$ (postoperative anterior vertebral body height − preoperative anterior vertebral body height)/(cephalic anterior vertebral body height + caudal anterior vertebral body height) $\times$ 100%. The correction of the sagittal alignment was defined as the increase of the lordotic angle, which was formed by the intersection of two lines, one drawn tangent to the superior endplate of the cephalic vertebral body and the other tangent to the inferior endplate of the caudal vertebral body.[13,14] The Wilcoxon signed rank test and paired *t* test were used to compare the clinical outcomes and radiological findings before and after surgery. The chi-square test was used to assess the risk of cement leakage in relation to balloon rupture or tear with Telebrex contrast medium extravasation. Telebrex was a solution used for intravascular injection and indicated for angiocardiography, digital subtraction angiography, intravenous urography, computed tomography, and BK. A value of $p < 0.05$ was considered to be statistically significant.

Table 1
Osteoporotic vertebral compression fracture with or without intraosseous vacuum cleft treated by BK.

Level of BK	Without vacuum	With vacuum	Total
T7	1	0	1
T8	1	0	1
T9	1	0	1
T10	1	0	1
T11	8	3	11
T12	20	12	32
L1	20	15	35
L2	19	6	25
L3	14	2	16
L4	5	0	5
L5	2	0	2
Total	92	38	130

BK = balloon kyphoplasty; L = Lumbar spine; T = Thoracic spine.

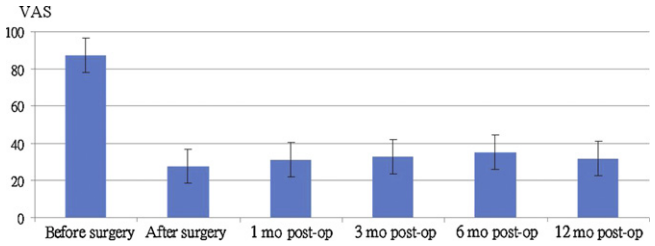

Fig. 1. The VAS scores decreased from 87 ± 18 before surgery to 28 ± 23 on 1 day after surgery, 31 ± 22 at 1 month, 33 ± 26 at 3 months, 35 ± 25 at 6 months, and 32 ± 20 at 12 months follow-up visits. VAS = visual analog scale.

3. Results

Of 100 patients with 130 symptomatic osteoporotic VCFs, one level BK was performed in 77 patients, two levels in 19 patients, three levels in 2 patients, four levels in 1 patient, and five levels in 1 patient, respectively. The fractured vertebrae extended from T7 to L5 and were predominantly located around the thoracolumbar junction. The most common fracture level was L1, which consisted of 20 fractured vertebrae and 15 vertebrae with vacuum cleft (Table 1). The mean quantity of PMMA bone cement injected per vertebral body was 6.3 mL (range, 3.5–15 mL). One hundred twenty-four

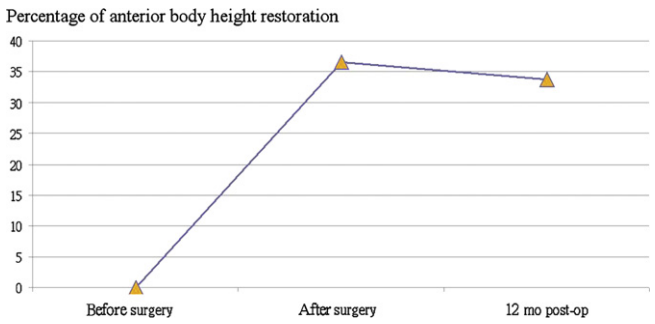

Fig. 2. The average restoration of the fractured vertebral body height was 36.5% and slightly decreased to 33.8% at final follow-up.