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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.

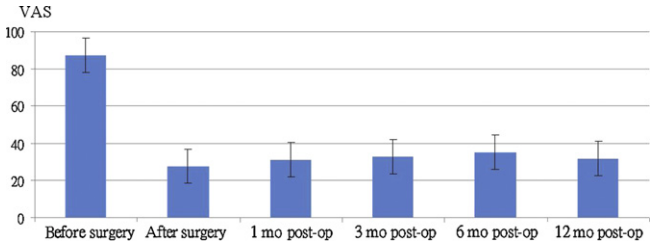

Fig. 1. The VAS scores decreased from 87 ± 18 before surgery to 28 ± 23 on 1 day after surgery, 31 ± 22 at 1 month, 33 ± 26 at 3 months, 35 ± 25 at 6 months, and 32 ± 20 at 12 months follow-up visits. VAS = visual analog scale.

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

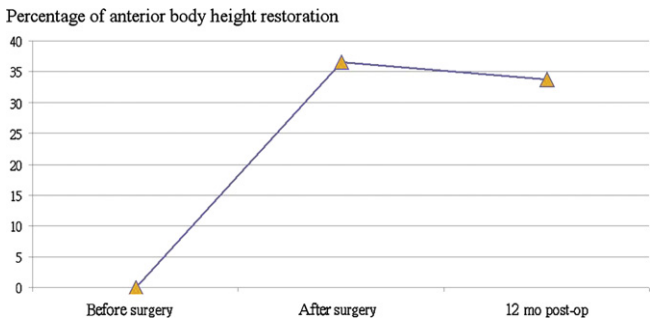

Fig. 2. The average restoration of the fractured vertebral body height was 36.5% and slightly decreased to 33.8% at final follow-up.

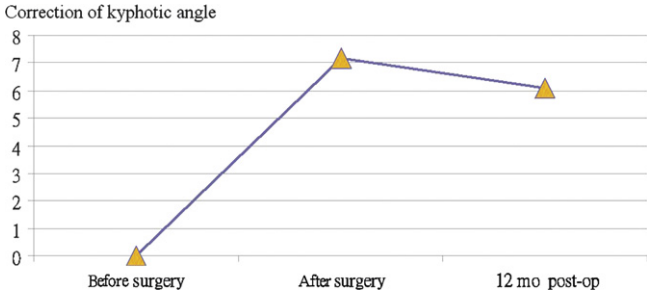

Fig. 3. The average correction of the sagittal alignment was 7.2° and slightly decreased to 6.1° at final follow-up.

vertebrae (95.4%) in this study were treated via a unipedicular approach, which consisted of left unipedicular puncture in 97 vertebrae and right unipedicular puncture in 27 vertebrae. The remaining vertebrae were treated using a bipedicular approach.

The VAS scores decreased from 87 ± 18 before surgery as a baseline 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 (Fig. 1, $p < 0.001$, statistically significant by paired t test). Eight-six patients returned to their preinjury activities of daily living and achieved better quality of life than their preoperative status, whereas the remaining 14 patients had back relief but with no significant difference in daily activities ($p < 0.001$, statistically significant by Wilcoxon signed rank test). The average restoration of the fractured vertebral body height was 36.5% as determined by comparing the fractured vertebra to the anterior body height of the adjacent vertebral segments (Fig. 2, $p < 0.001$, statistically significant by paired t test). The average body height restoration slightly decreased to 33.8% at final follow-up. The average correction of the sagittal alignment was 7.2° when measuring the relative kyphotic angle of one level vertebra above and below (Fig. 3, $p < 0.001$, statistically significant by paired t test). The average kyphotic correction slightly decreased to 6.1° at final follow-up.

No major surgery-related complications were observed during after at least 12 months of follow-up (Fig. 4). Nineteen (19%) patients who had new adjacent fractures underwent another PV or BK. One patient experienced postoperative superficial wound infection, which responded well to oral antibiotics treatment. There

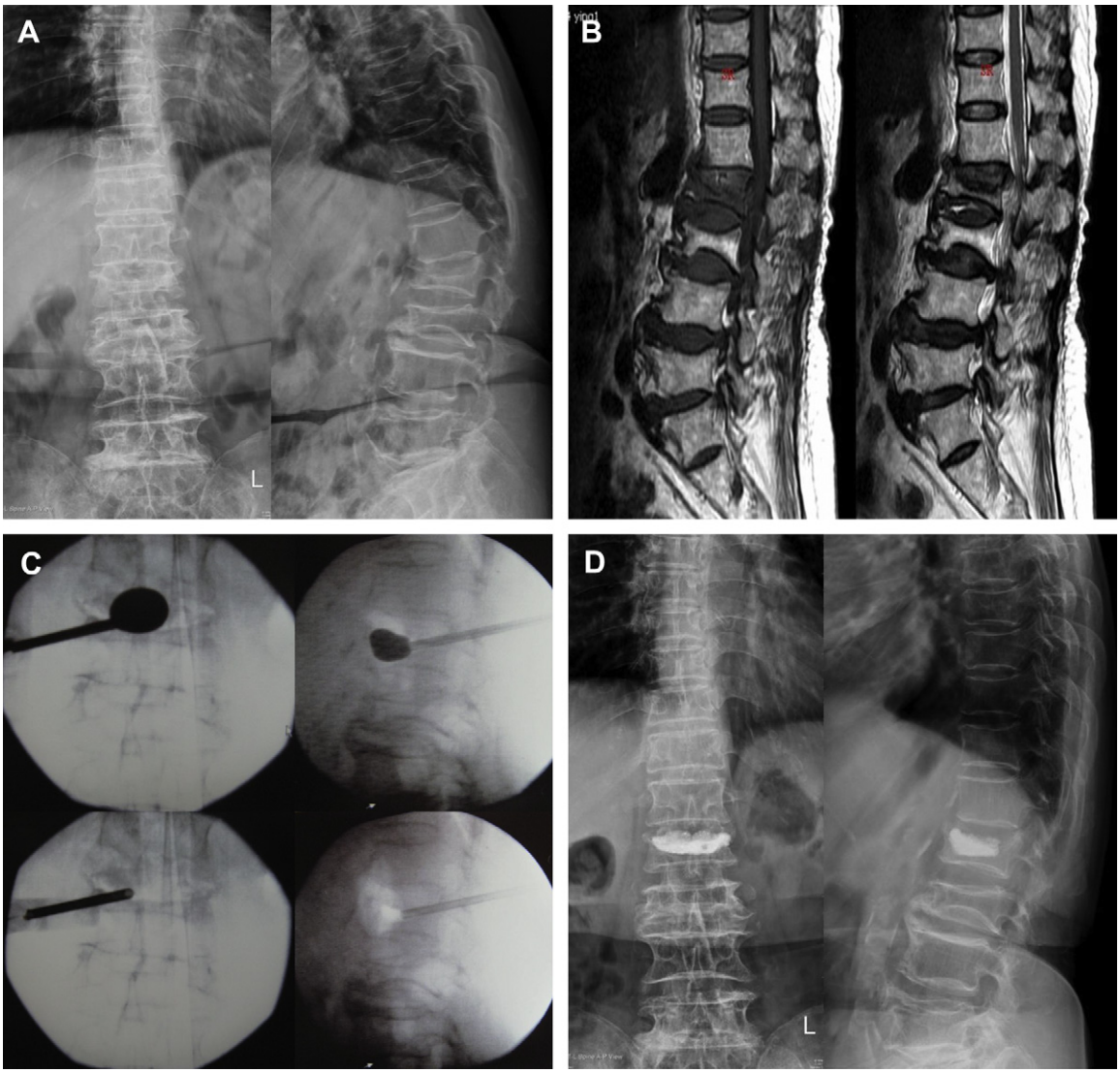

Fig. 4. A 78-year-old female suffered from intractable back pain with buttocks radiation after falling. (A) The preoperative radiography showed multiple-level osteoporotic vertebral compression fractures. (B) The preoperative magnetic resonance imaging clearly indicated the accurate lesion site. (C) The intraoperative pictures demonstrated good reduction of L2 vertebral body height with an iatrogenic vacuum cleft. (D) The postoperative radiography revealed good augmentation of the fractured vertebral body after cement pouring.

were 20 (15.4%) balloons that ruptured with Telebrex contrast medium extravasation, which could obscure the visual field of intraoperative fluoroscopy (Fig. 5). Of 19 (14.6%) treated vertebrae with PMMA bone cement leakage, 7 cement leakages with balloon rupture and 12 with balloon integrity were noted. All these cement leakage, including 17 leakage into paraspinal soft tissue and 2 into intervertebral disc, presented as asymptomatic and could be treated conservatively. The difference in number of cement leakages between the balloon rupture with contrast medium extravasation and those balloon integrity without contrast medium extravasation was statistically significant (Table 2, $p = 0.005$, statistically significant by chi-square test).

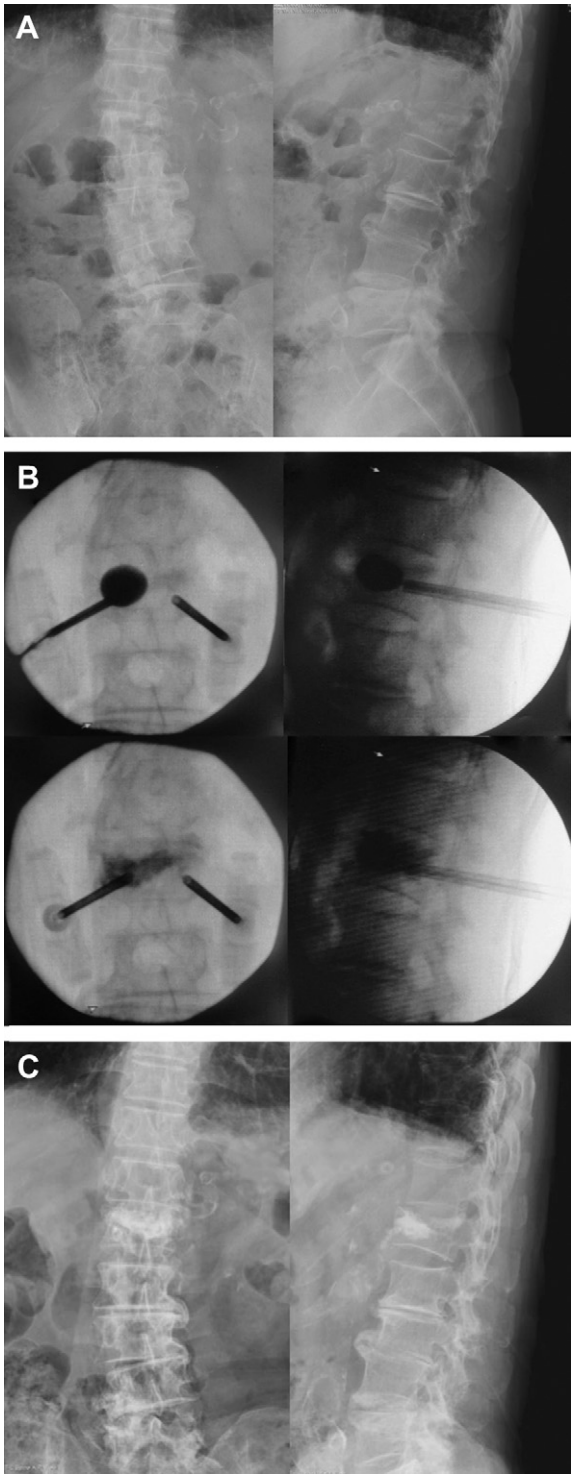

Fig. 5. A 69-year-old female suffered from intractable back pain after trauma. (A) The preoperative radiography showed L1 osteoporotic vertebral compression fracture. (B) The intraoperative pictures demonstrated the balloon rupture or tear with Telebrex contrast medium extravasation. (C) The postoperative radiography revealed little cement leakage outside the treated vertebra.

Table 2
Cement leakage outside the treated vertebrae in relationship to balloon rupture during the procedure of balloon kyphoplasty.

Balloon	Cement leakage	No cement leakage	Total
Rupture	7	13	20
Integrity	12	98	110
Total ($p = 0.005$)[a]	19	111	130

[a] Analyzed using a chi-square test.

4. Discussion

Both PV and BK are minimally invasive therapeutic procedures developed for the management of symptomatic osteoporotic VCFs. With PV, PMMA bone cement is usually suggested to fill the clefts or gaps between fracture fragments in a more liquid form or paste-like consistency, which makes it easier to penetrate through fracture defects in the cortex and results in cement leakage outside the treated vertebrae.[10,12] BK is another percutaneous vertebral augmentation procedure and has experienced rapid growth in recent years. The procedure involves fluoroscopically guided introduction of an inflatable balloon tamp into the fractured vertebral body to create a cavity and expand the collapsed vertebra. After withdrawal of the balloon tamp, the cavity is then filled with thicker PMMA bone cement under lower pressure to reduce the risk of cement leakage. In addition, the impaction of the trabecular bone against the surrounding cortical bone by the inflatable balloon can provide a bony shell to reduce the risk of cement leakage.[8–12] The mechanism of pain relief in percutaneous vertebral augmentation remains unclear, but it is generally believed to result from the stabilization of the fractured vertebrae and the elimination of microscopic and/or macroscopic motion at the fracture site. Other postulated mechanisms of pain relief include a chemical neurolytic effect of PMMA and the thermal neurolytic effect of the PMMA exotherm.[13,14]

This study had limited radiographic and functional results. No standardized outcome measure was obtained other than a VAS score and modified MacNab system. The radiographic results were reviewed by one investigator (Y.S.C.) who was the treating surgeon. This could introduce some bias when assessing radiographs. Similar to most studies in the related literature, the VAS scores of our patients undergoing BK improved significantly from 87 before surgery to 28 one day after surgery, and 32 at 12-month follow-up visit. Eight-six patients recovered to their preinjury normal daily activities and experienced better quality of life. However, there were no other functional scores available in this study because most patients were farmers or heavy labors who refused the complicated questionnaires. Regarding the restoration of the vertebral body height and the correction of the sagittal alignment, the extent of these improvements varies widely from study to study. This may be a consequence of using different measurement methods for some aspects of the populations in the different studies. In general, it has been suggested that the shorter the time interval between the diagnosis of osteoporotic VCF and the performance of BK, a substantial body height restoration can be reached. Furthermore, the bipedicular approach seems to achieve better fracture reduction than the unipedicular approach.

Either VP or BK generally is done via a bipedicular approach. In a biomechanical study, Liebschner et al[15] suggested that

unipedicular PV may not be as effective in providing vertebral body stability as bipedicular or posterolateral PV. In contrast, Tohmeh et al[16] used cadaveric spines to compare the biomechanical efficacy of unipedicular versus bipedicular approach for managing osteoporotic VCFs. They concluded that unipedicular cement injection is adequate and could be considered as an alternative when a bipedicular cement injection is obviated. In a clinical study, Chen et al[17] reported that VCFs with vacuum clefts can be treated successfully using a unipedicular approach. Twenty-six of 27 patients had adequate filling and all patients were satisfied with their treatment. A vacuum cleft is relatively common in patients who are senile. Thirty-eight (29.2%) vertebrae in our study revealed an intraosseus vacuum cleft on initial radiographic examination. The vacuum phenomenon may be accentuated on hyperextension or even in a prone position, which occurred in several patients of our series. This situation can also be produced while BK reduces the collapsed vertebral body through a unipedicle. Most vertebrae in this study were treated via a unipedicular approach, which saves time and is considered less traumatic for the patient. The patients tolerated the procedure well under local anesthesia with slight sedation.

The term “kyphoplasty” was introduced by Kyphon Inc. to describe balloon-assisted vertebroplasty using a specific fracture reduction system. The so-called fracture reduction equipment we used in this study was VCFX, which was produced by Central Medical Technologies in Taiwan with similar efficacy and lower cost than KyphX. Cement leakage outside the vertebral body was observed in 19 (14.6%) of the treated vertebrae in this study, which was within the standard range regarding prevalence based on a search of the related literature. Several previously published reviews and meta-analyses indicated that BK appears to be more safe and effective than PV in the treatment of osteoporotic VCFs.[8–12] It can reduce the loss of body height and the degree of kyphotic deformity and generates a lower cement leakage rate while affording similar responses in terms of pain relief and improvement in patients’ functional quality of life.

The incidence of cement leakage during BK has been reported to vary from 8.6% to 33%.[18–24] The proposed reasons for decreased cement leakage compared with PV include (1) balloon tamping to create a cavity that is surrounded by a shell of impacted cancellous bone; (2) ability to determine proper amount of cement needed to be poured because of the calculated volume of fluid used to inflate the balloon; and (3) thicker cement viscosity and lower injection pressure during bone cement introduction. However, it always remains a possibility for bone cement to leak from the receiving vertebral body despite the repeated precautions taken during this procedure and the above-mentioned advantages of BK.

There are some factors that may contribute to cement leakage using VCFX BK, such as biomaterial manufacturing of unqualified balloon tamp, immature surgical technique, incorrect manipulation of instruments and equipments, and acute fracture with sharp bone chip, which results in balloon rupture or tear with extravasation of Telebrex contrast medium. The remaining dye will mask the visual field of intraoperative fluoroscopy and preclude early detection of cement leakage during the cement pouring procedure. In our study, the rupture of 20 balloons was noted during practice, and cement leakage was found in 19 (14.6%) treated vertebrae after surgery. We therefore identified a statistically significant increase in the incidence of cement leakage whenever balloon rupture or tear with Telebrex contrast medium extravasation. Fortunately, no further revision surgery was required because of no clinical symptoms or complaints being noted related to cement leakage.

In conclusion, BK is an effective and low-risk method to treat painful osteoporotic VCFs. It does have value to restore vertebral body height and correct kyphotic deformity, which leads to a more physiological spinal alignment. However, balloon rupture or tear with contrast medium extravasation is troublesome, which can obscure the visual field of the treated vertebra intraoperatively under fluoroscopy and influence the following injection of bone cement. A significant level of caution should be applied by the surgical team throughout the BK procedure to preclude cement leakage from the damaged vertebral body.

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