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Incidence of symptomatic adjacent vertebral fractures after percutaneous balloon kyphoplasty in osteoporotic vertebral fractures

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Abstract

To investigate the long-term outcome of 203 patients with osteoporotic vertebra fractures who were treated with percutaneous kyphoplasty (PKP) technique under local anesthesia. Magnetic resonance and Computed Tomography Image results were used and correlated with clinical presentations to identify the symptomatic vertebral acute fracture levels. Percutaneous kyphoplasty was performed under local anesthesia/sedation technique in these patients. During the follow-up, pain symptoms were recorded on a self-reported visual analog scale (VAS). 203 patients (78 males and 125 females) with traumatic osteoporotic vertebral fractures in our clinic between 2015 and 2020. Patients' VAS scores significantly decreased from 8.48±1.1 to 3.30±1.89 after 10 days of treatment ($p<0.0001$). This clinical improvement was consistent over three years of follow up (2.92±1.73, $p<0.0001$). 15 patients were lost at-follow-up and adjacent or distant adjacent level symptomatic fractures occurred in 11 patients. All the symptomatic re-fractures were also treated with PKP technique. Percutaneous kyphoplasty displayed very good long-term efficiency and safety in patients with osteoporotic vertebral fractures over 3 years of follow-up. This method can be safely performed under local anesthesia with a low rate of newly formed symptomatic adjacent level fractures.

Keywords: Kyphoplasty, osteoporosis, adjacent fractures

Introduction

There is globally growing concern about osteoporosis and vertebral compression fractures are common manifestations of osteoporosis, due to bone mineral loss, especially at elderly females. These fractures lead to severe chronic pain and reduced pulmonary function, decreased mobility, with huge negative effect on emotional wellbeing of many patients [1-5]. The mortality risk is two-fold higher in patients with osteoporotic vertebral fractures. Furthermore, patients with one VCF are five times more likely to develop another spinal fragility fracture [1].

Painful osteoporotic fractures can be treated with two minimally invasive vertebral augmentation procedures, percutaneous vertebroplasty (PVP) and percutaneous kyphoplasty (PKP) techniques, in people who have severe ongoing pain after a recent, unhealed vertebral fracture despite optimal pain management [1]. Advantages of PKP over PVP in terms of sagittal balance improvement, cement leakage, improved mortality rates have been reported [1]. These methods of treatment achieve immediate stabilization of the affected vertebral body with acute pain relief.

Most effective and safe treatment of these fractures have still been discussed in the literature. Several publications addressed catastrophic complications like neurologic deficit due to cement leakage [2]. There has been also debate on the topic that cement augmentation of osteoporotic vertebra can result in adjacent-level fractures in the thoracic and lumbar spine, but long-term results are not limited to the best of our knowledge which makes long-term results mandatory. The goal of this study was to report old term results of PKP to analyze the success rate and safety of this treatment method.

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Materials and Methods

All protocols were approved by Bursa City Hospital Ethics Committee (16.07.20-2020-3/7).

Patients

A total of 241 balloon kyphoplasty operations were performed in 203 patients (125 females, 78 males) between October 2015 and October 2020. Mean age was 70.8 years (58 to 89 years). All patients had severe local pain refractory to analgesia.

All patients had osteoporosis diagnosed by radiographic evaluation and clinical examination. In addition, some of these patients were receiving osteoporosis treatment. Before operation, all patients were examined using computed tomography (CT) scan and X-rays. In order to confirm acute vertebral fractures, bony edema in magnetic resonance imaging (MRI) in short tau inversion recovery (STIR) sequences were taken. Visual Analog Scale (VAS) was used to assess the level of pain.

Surgical methods

Balloon kyphoplasty was performed in all patients under local anesthesia. The mean time for surgical procedure at each level was 20 minutes.

After conscious sedation by intravenous (IV) fentanyl 0.5 mcg/kg and IV propofol 1 mg/kg, spontaneously breathing patients were put in prone position. In addition, 5 ml (2%) of local anesthetic prilocaine was used for each incision. SpO2 and pulse rate were obtained by a pulse oximeter. Heart rate was continuously monitored by ECG Electrocardiogram and oxygen saturation levels were continuously monitored. Oxygen (5L/min) was delivered during the procedure through a mask.

The cannula was inserted into the posterior of the pedicle with bilateral approach in the prone position. During the whole procedure, biplanar fluoroscopy was used to insert tools. A 3 mm skin incision was made around the fractured vertebral body pedicle at needle insertion point using biplanar C-arm fluoroscopic monitoring. Two 11-gauge Jamshidi needles were inserted into the pedicle through the skin. Through the Jamshidi needles, two 1.5 mm guide pins were inserted into the fractured vertebral bodies, followed by two inflatable bone tamps. The balloons were simultaneously dilated under C-arm fluoroscopic guidance. The balloon pressures were kept under 200 pounds per square inch. After forming a balloon cavity (3–4 cm3/cavity) in the vertebral body, bone cement containing 1.5 mL of polymethyl methacrylate (PMMA) (Mendec® Spine, Verona, Italy) was injected through the bone filler. 2–4 mL of PMMA was bilaterally injected into target vertebra. After hardening of PMMA, bone filler was removed. The same procedure was performed for other cannula at contralateral pedicle [Changmei Medtech® (Kyphoplasty Balloon Catheter-Kyphoplasty Tool Kit), Jiangsu, China].

Postoperative treatment

All patients were mobilized six hours after the operation. After completing the X-ray examination, the patients were discharged on the same day (Figure 1).

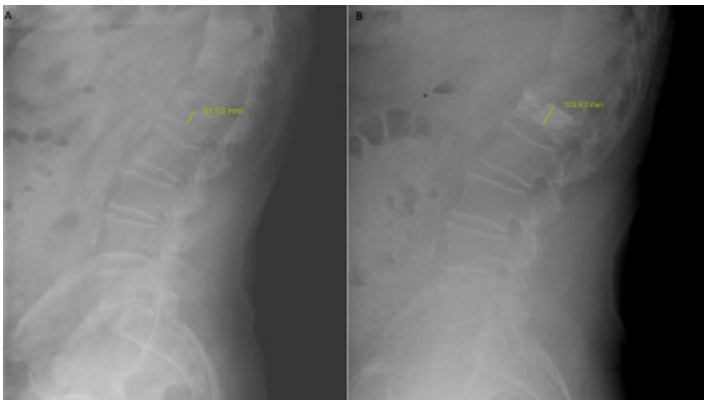

Figure 1. a, b. Pre-kyphoplasty (a) and Post-kyphoplasty (b) lateral x-ray images of patient. The height recovery of the fractured vertebra has been measured and illustrated on the figures

Clinical and radiological assessments

Clinical examinations were performed preoperatively, ten days and one month after the surgery. A 10-point VAS was used to measure the level of back pain. X-ray imaging was performed before, one day and one month after the surgery. CT and MRI scans were performed before the surgery to evaluate the symptomatic acute fractured vertebra level. During follow-up, the level of pain was recorded and for the patients that did not perform clinical visits, pain scores were recorded through the phone call. The patients were followed-up for a mean period of 36 months (ranging between 12-60 months).

Statistical Analysis

The data were compared using one-way variance analysis (ANOVA) test. Multiple comparisons were done by Fisher's LSD test. The values were presented as mean ± standard deviation. Prism v9 (USA) was used for statistical analysis.

Results

Percutaneous kyphoplasty was performed to all 203 patients under local anesthesia and sedation, including three levels in five patients, two levels in twenty-eight patients and one level in 170 patients. The most common vertebral fracture levels were L1-T12 and L2, respectively (Figure 2).

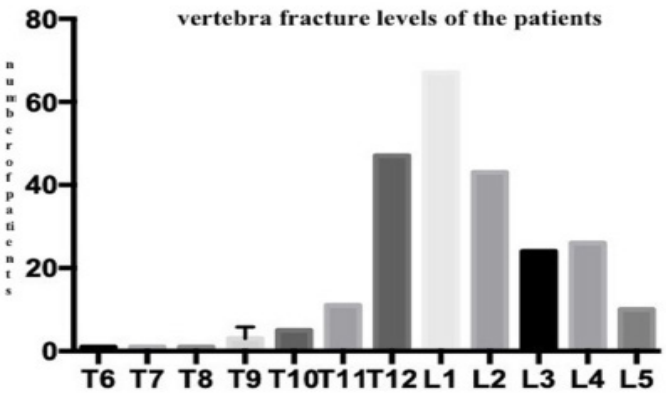

Figure 2. Vertebral level locations of patient fractures shown above

The demographic data of the patients were given in Figure 3. The mean age of the patients was 70.8 years.

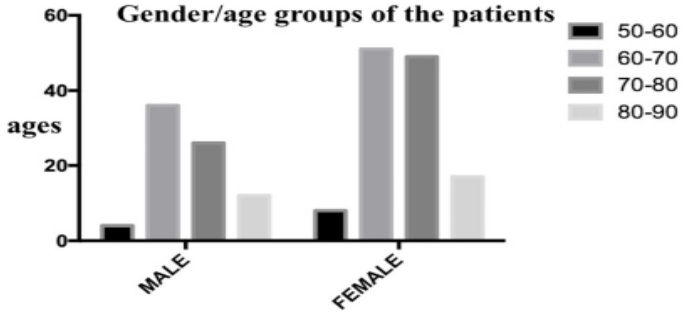

Figure 3. Demographic data of patients shown above

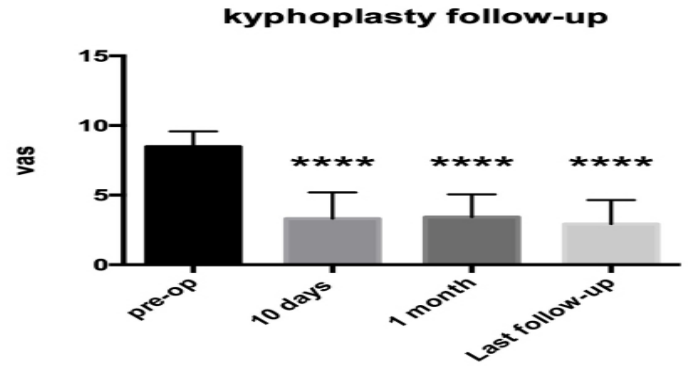

Figure 4. Mean improvement of back pain as rated on VAS pre-op, post-op ten days, one month and latest follow up after PKP

Adjacent Fractures

In 11 (four males, seven females) patients, new symptomatic re-fractures were detected (range; one month to twenty-one months) after PKP (Table 1). Four of them were adjacent level vertebral fractures and seven were distant adjacent level vertebral fractures. Vertebral re-fractures were observed at another vertebra level after one month in three patients, two months in one patient, and between 8-21 months in seven patients. During the follow-up, the adjacent level fractures were detected in 2% of the patients after an average of seven months, and at distant level in 3.4% of the patients after an average of 11.5 months. The re-fracture rate was 5.4%. No adjacent level fractures were observed for the third time in any patient (Table 1).

During the follow-up, fifteen patients (2 to 36 months) were dead. The mean follow-up period of the deceased patients was 16.6 months. Adjacent level fracture was observed in only one of the deceased patients. The patient had an adjacent level fracture nineteen months after the first fracture and died eight months after the second level fracture.

Clinical Outcomes

The average scores for VAS significantly decreased from 8.48±1.1 to 3.30±1.89, 10 days after the procedure ($p<0.0001$, uncorrected Fisher's LSD test). The pain status of all patients improved within 24 hours and were discharged from the hospital. Average pain score was still significantly lower 2.92±1.72 at approximately three years of follow-up compared to pre-op ($p<0.0001$, uncorrected Fisher's LSD test). Percutaneous kyphoplasty was performed for the second fracture in all eleven patients with re-fractures, without any additional morbidity and improved clinical status (Table 1).

Table 1. Re-fracture rates and levels after the PKP has been shown. Re-fractures were classified as adjacent and distant level fractures which were observed in eleven patients during three years of follow-up

Adjacent Level Vertebral Re-Fractures

Patients	First Fracture	Follow-up time (month)	Second Fracture	Total follow-up time (month)
1	L1	8	T12	60
2	T12	19	T11	34
3	T12-L1	1	T11	25
4	L2	1	L3	25

Distant Level Vertebral Re-Fractures

Patients	First Fracture	Follow-up time (month)	Second Fracture	Total follow-up time (month)
1	L1-L2	20	L4	59
2	L2	10	T9	22
3	L3	15	L1	30
4	L5	12	T12-L2	34
5	T12	1	T7-T9	19
6	T12-L1	21	L3-L4	43
7	L2	2	L4	22

Discussion

The aim of our study was to evaluate the long-term effectiveness and safety of PKP. We analyzed the collected patient outcomes and demonstrated that PKP relieves pain acutely in osteoporotic vertebra fractures with ongoing effectiveness at long term. Balloon kyphoplasty and vertebroplasty have come on strong in recent years for treatment of osteoporotic compression fractures and acute pain relief [1-5]. Many randomized clinical studies have suggested that both procedures can be effectively used for pain relief as per conservative treatment [6-8]. While vertebroplasty has some certain advantages, balloon kyphoplasty provides advantage for restoring the vertebral height [1]. Even though these procedures are highly efficient for pain relief, they still pose a risk for subsequent new vertebral fractures [9]. The percentage of adjacent fractures varies between 1-26% [10,11]. Studies on VP have reported the rate of adjacent fractures between 12-52% and there are only a few studies on PKP with long term results [12]. Pflugmacher et al. [5] have reported the occurrence of adjacent fractures in 18.3% vertebrae in a follow-up period between three weeks and twenty-two months. This concern has also been supported by several clinical studies showing high frequency of adjacent fractures after augmentation [5].

Studies have shown that vertebral augmentation can provide more benefit when performed with balloon kyphoplasty or vertebroplasty and 75-90% of the patients report good to excellent pain relief within 7 to 10 days [13]. The fractures may repeat if the patient suffers from severe osteoporosis. A 12-month longitudinal study has documented that 12% of patients have developed adjacent level fractures within an average of 68 days and 23% have developed fractures distant from the treated vertebrae within an average of 100 days after vertebral augmentation [14]. Grados et al. [15] have reported that they have treated 34 levels with vertebroplasty in twenty-five patients. They have followed-up the patients for a mean period of 48 months and they have shown that thirty-four subsequent fractures have developed in thirteen patients. Uppin et al. [16] have treated 177 patients with VP and 32 (12.4%) new vertebral body fractures have been reported. Twelve (33%) of these fractures were at remote levels and twenty-four (67%) were at adjacent levels.

Fribourg et al. [10] have treated thirty-eight patients with balloon kyphoplasty with a mean follow-up period of eight months and they have reported that ten patients have developed seventeen subsequent fractures. Of these, four were at remote levels, four at adjacent-below levels and nine at adjacent-above levels. Harrop et al. [17] have treated 225 vertebrae in 115 patients using KP and twenty-six (11.25 %) patients have developed thirty-four subsequent fractures within a follow-up period of one month. Pflugmacher et al. [5] have shown that 21.6% of the patients have developed subsequent fractures in eleven vertebrae (18.3%) within three weeks to twenty-two months. Five of these patients were symptomatic and additional balloon KP was performed. Three of these patients had asymptomatic adjacent fractures which were treated conservatively. In our study, only eleven (5.4%) patients developed symptomatic subsequent vertebra fractures within one month to twenty-one months of follow-up which is lower compared to the discussed literature findings. All these patients were also treated with additional balloon kyphoplasty procedure.

Several hypotheses have tried to explain the factors causing adjacent level fractures after VP or KP. Baroud et al. [18] reported that cement in the augmented vertebrae functions as an upward pillar which reduces the physiological inward bulging of end plates. As a result, the pressure in the adjacent intervertebral disc is increased by 19%. In their study, based on a 3D, non-linear finite element model, Rohlmann et al. [19] claimed that vertebral body fractures in adjacent vertebrae following VP or KP are mainly because of the anterior shift of the upper body rather than increased stiffness of the treated vertebra. This model showed that the vertebral cement augmentation had a lesser effect on intradiscal pressure and end plate stress in the unfractured vertebrae.

Berleman et al. [20] reported that a vertebra adjacent to an augmented vertebra with bone cement had a 17% lower failure load compared to a vertebra adjacent a non-augmented vertebra. They claimed that increased stiffness of the treated vertebra alters the biomechanics of load transfer.

Can the number of adjacent fractures be reduced by the amount of injected cement? Kim et al. [21] suggested that new fracture risk level depends on the degree of height restoration after balloon kyphoplasty. They showed that bone cement volume was a significant factor for subsequent vertebral fracture formation following VP. In addition, stiffness increased further depending on bone cement volume which was higher than 30%, causing subsequent adjacent vertebral body fractures, possibly in the cranial direction [21,22]. Grados et al. [15] used an average amount of 9.14 ml of cement per vertebra and 12.4% of the patients had adjacent level fractures. Belkhoff et al. [23] demonstrated that the strength of an osteoporotic vertebra could be restored by using two ml of cement.

There are some limitations of our study. As there was no control group, we had to compare our results with the previously published literature. During the follow-up, asymptomatic osteoporotic vertebrae fractures of some patients may not have been discovered. In our follow-up, patients were given anti-osteoporotic medication on a regular basis, and this may have prevented the adjacent level fractures. Early mobilization with local anesthesia and sedation anesthesia technique that we are using, may also had additional benefit of early mobilization & recovery of our patients which may lead to decreased re-fracture rates compared to previously published literature.

Conclusion

In conclusion, PKP is safe method that increases life quality of patients and provides rapid pain relief by protecting against complications of general anesthesia, particularly for the elderly. This recovery was found steady at long term follow-up. The number of re-fracture rates in adjacent segments were found to be lower than the previously reported studies.

Conflict of interests
The authors declare that they have no competing interests.

Financial Disclosure
All authors declare no financial support.

Ethical approval
All protocols were approved by Bursa City Hospital Ethics Committee (16.07.20-2020-3/7).

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