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A study on the relationship between the rate of vertebral body height loss before balloon kyphoplasty and early adjacent vertebral fracture

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Abstract.
BACKGROUND: The number of patients with an osteoporotic vertebral compression fracture, which is often accompanied by lower back pain and restrained activities, is growing. Balloon kyphoplasty involves the inflation of a balloon to restore height and reduce kyphotic deformity before stabilization with polymethylmethacrylate. However, there is a great deal of debate about whether balloon kyphoplasty also increases fracture morbidity by either inducing or facilitating subsequent adjacent vertebral fractures.
OBJECTIVE: To evaluate the relationship between the rate of vertebral body height loss before balloon kyphoplasty and the etiology of early adjacent vertebral fracture after augmentation.
METHODS: A total of 59 patients with osteoporotic vertebral compression fractures who underwent kyphoplasty were enrolled. This study defined early adjacent segmental fractures as new fractures occurring within three months after surgery. This study included the rate of vertebral body height loss.
RESULTS: Early adjacent vertebral fractures were diagnosed in nine (15%) of the 59 patients. The patients were divided into two groups, with and without adjacent vertebral fractures. There was no significant difference in terms of age, body mass index, bone mineral density, local kyphotic angle, Cobb's angle, cement volume, cement leakage, and percent height restored between the groups with fractures and without fractures. There was a statistically significant difference between the two groups in the rate of vertebral body height loss. The rate of vertebral body height loss was significantly higher in the fracture group than in the without fracture group.
CONCLUSIONS: A high rate of vertebral body height loss increased the risk of early adjacent vertebral fractures after balloon kyphoplasty.

Keywords: Osteoporotic vertebral compression fracture, adjacent vertebral fracture, balloon kyphoplasty, vertebral body height loss

1. Introduction

With the aging of the global population, the incidence of osteoporosis increases every year. The number of patients with osteoporotic vertebral compres-

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sion fractures (OVCF), which is often accompanied by lower back pain and restrained activities, has also increased, creating an important public health problem. Some authors reported that balloon kyphoplasty was rarely used for osteoporotic vertebral compression fractures, but may be used in the presence of obvious vertebral height loss [1]. However, to relieve the pain caused by OVCF, balloon kyphoplasty (KP) is widely performed as a surgical intervention. Balloon KP, which was first developed by Garfin et al., involves the inflation of a balloon within an OVCF to restore height and reduce kyphotic deformity before stabilization with polymethylmethacrylate [2,3]. Balloon KP is a safe and minimally invasive technique for patients with neoplastic, traumatic, or osteoporotic lesions of the vertebra to achieve rapid pain relief, restore bone height and vertebral realignment, and thus stabilize the vertebra [4,5].

However, this procedure has several potential complications, including extrusion of the cement into the spinal canal, infection, failure to relieve pain, subsequent spinal cord injury, hematoma formation, pulmonary embolus, and osteomyelitis [6]. Also, there is a great deal of debate about whether balloon KP also increases fracture morbidity by either inducing or facilitating adjacent vertebral fracture (AVF). Bone mineral density (BMD) and the kyphotic angle before surgery or correction are well-known independent risk factors for osteoporotic AVFs [7].

According to the literature, the majority of AVFs occurred within two or three months after the procedure. If early adjacent vertebral fractures occur within three months after surgery, it is difficult for the patient to accept. However, the imminent risk factors for early adjacent vertebral fractures after balloon KP are controversial. This study aimed to evaluate the relationship between the rate of vertebral body height loss before balloon KP and the etiology of early adjacent vertebral fractures after augmentation.

2. Materials and methods

2.1. Subjects

This was a retrospective cohort study that enrolled a total of 59 consecutive patients with painful OVCF who underwent KP performed by a single surgeon (H.K.S.) between January 2015 and January 2018, following approval by the Intuitional Review Board. The inclusion criteria for the present study were (1) complete medical records and related radiographic data, including the bone cement volume and bone mineral density (BMD), (2) a minimum of 12 months of follow-up, and (3) patients who experienced severe back pain due to acute (fracture age < 2 weeks) or subacute (fracture age between 2 and 8 weeks) osteoporotic VCF. The exclusion criteria were (1) the presence of a neurological deficit, (2) an osteoporotic vertebral collapse greater than 90%, an uncooperative patient, (3) bleeding disorders, (4) unstable fractures due to posterior element involvement, (5) the presence of malignant disease, (6) the presence of any systemic or spinal infection, and (7) severe deformity of the spine in the sagittal plane. Considering the above options, 59 patients were divided into the group with early adjacent vertebral fractures after kyphoplasty (group A, $n = 9$) and the group without early adjacent vertebral fractures after kyphoplasty (group B, $n = 50$) (Fig. 1).

2.2. Variables

Vertebral compression fractures were diagnosed using computed tomography (CT) and magnetic resonance imaging (MRI). Early adjacent vertebral fractures were defined as new fractures that had developed within three months after surgery. Fractures that occurred three months after surgery were not included. The average BMD was calculated by averaging the values from L1 to L4.

The kyphotic deformity was measured four times (a few weeks before, just before, just after, and three months after the patients underwent KP) by two different methods (Fig. 2). One was Cobb's angle, from the superior endplate of the vertebral body one level above the fractured vertebra to the inferior endplate of the vertebral body one level below the treated vertebra. The other was the local kyphotic angle, from the superior endplate of the fractured vertebral body to the inferior endplate of the fractured vertebral body. The vertebral body height loss before the kypoplasty was calculated by two surveyed methods (Fig. 2): (1) the anterior vertebral body compression percentage (AVBC%), consisting of the percentage of anterior vertebral body compression with respect to the average height of the anterior vertebral bodies immediately cephalad and caudad to the injury level (formula: V2/[(V1 + V3)/2] $\times$ 100%) and (2) the anterior/middle column vertebral body compression ratio (VBCR), i.e., the ratio of the anterior vertebral height (AV09H) to the posterior vertebral height (PVH) by the formula VBCR = AVH/PVH. Moreover, the rate of vertebral body height loss was defined as the height loss difference between the X-ray

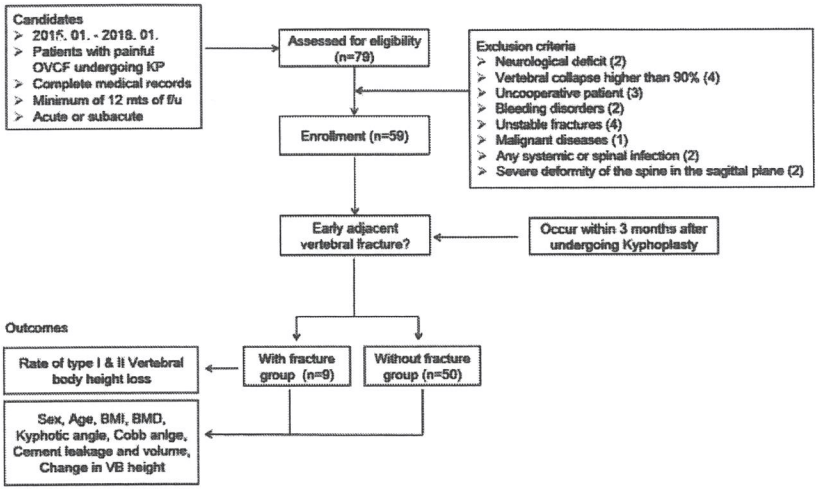

Fig. 1. Flowchart showing the selection of subjects in the current study.

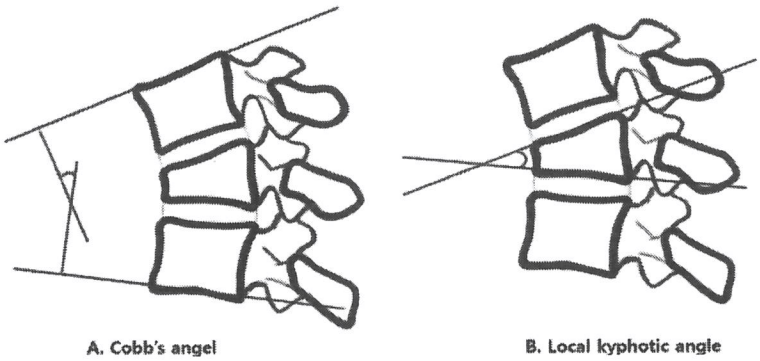

Fig. 2. Surveyed measurement techniques for assessing kyphotic deformity by two different methods. Method 1 was Cobb's angle, from the superior endplate of the vertebra body one level above the fractured vertebra to the inferior endplate of the vertebral body one level below the treated vertebra. Method 2 was the local kyphotic angle, from the superior endplate of the fractured vertebra body to the inferior endplate of the fractured vertebra body.

taken a few weeks before the patient underwent KP and just before the patient underwent KP divided by the period in weeks. Thus, the rate of type I vertebral body height loss (%/week) was calculated by: ([V2α/{(V1α + V3α)/2} × 100%] − [V2β/{(V1β + V3β)/2} × 100%])/period in weeks). The rate of type II vertebral body height loss (%/weeks) was calculated by the formula: (AVHα/PVHα − AVHβ/PVHβ) × 100%/period in weeks.

2.3. Surgical technique

The indications for KP included recent fractures that were resistant to relief by painkillers for at least three weeks, a visual analog scale (VAS) score of > 5 points, and a kyphotic deformity of > 15°. The patients were treated with local anesthesia while lying on their faces on a fluoroscopy table without excessively reduction of kyphosis. Two 13-gauge long spinal needles were inserted into the pedicle and advanced to the anterior third of the vertebral body under C-arm fluoroscopic guidance. Then, a contracted balloon was inserted into the vertebral body through two canals to create cavity. The purpose of local kyphosis angle can be recovered to the pre-fracture levels. Using a small amount of cement to minimize the risk of leakage resulted in an insufficient volume of cement being injected. About 2–8 mL of PMMA bone cement was injected depending on the the size of vertebral body. After surgery, the patients with fractures were fitted with a tailor-made corset for 2–3 months after the procedure.

Table 1
Comparison of patient characteristics in groups with and without early adjacent vertebral fracture after kyphoplasty

Characteristics	Group A ($n = 9$)	Group B ($n = 50$)	p-value
Sex (female:male)	2:7	6:44	0.767
Age (years)	77.89 ± 7.94	75.18 ± 8.32	0.370
Body mass index (kg/m^2)	23.50 ± 4.09	23.06 ± 3.91	0.758
L-spine BMD (g/m^2)	−2.24 ± 0.90	−2.43 ± 1.22	0.655
Cement leakage	4 (44.4)	15 (30.0)	0.403
Cement volume	6.2 ± 1.8	6.4 ± 1.6	0.350

Data are presented as mean ± standard deviation or n (%). Group A: the group with early adjacent vertebral fracture after kyphoplasty. Group B: the group without early adjacent vertebral fracture after kyphoplasty. BMD: bone mineral density.

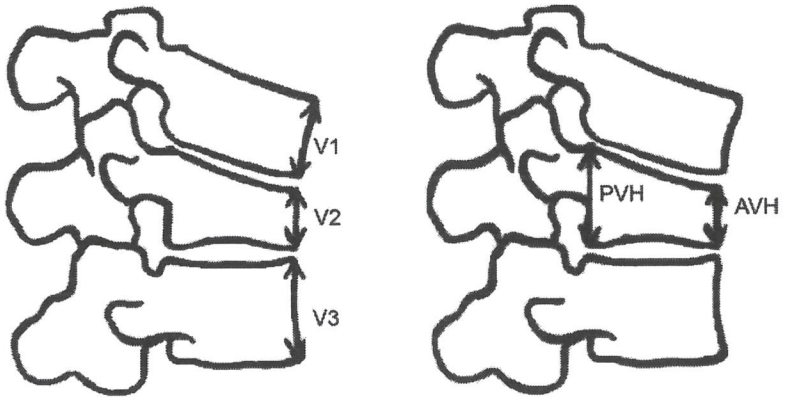

Fig. 3. Surveyed measurement techniques for assessing vertebral body height loss. Anterior vertebral body compression percentage (AVBC%) = V2/[(V1 + V3)/2] × 100% and anterior/middle column vertebral body compression ratio (VBCR) = AVH/PVH. AVH: anterior vertebral height, PVH: posterior vertebral height.

2.4. Statistical analyses

All the variables in this study are expressed as means ± standard deviation, depending upon the characteristics of the parameters. All data were statistically analyzed using the Student's t-test. The Chi-squared test was used to compare the categorical data. All p-values < 0.05 were considered statistically significant. In this study, IBM SPSS ver. 25.0 (IBM Corp., Armonk, NY, USA) was used as the statistical program.

3. Results

In the 59 patients with painful OVCF, 62 vertebral bodies were treated with KP. Early adjacent vertebral fractures were occurred in nine (15.2%) of the 59 patients who underwent KP, including in the cranial adjacent vertebra in eight patients and caudal adjacent vertebra in one patient. The level of adjacent vertebral fracture was distributed between T12 and L2, with the most common vertebra being L1. Of the 59 patients, 56 (95.0%) had a single vertebral fracture and three (5.0%) had multiple vertebral fractures. The average follow-up was 12.8 months (range, 3–26.2 months), and an adjacent vertebral fracture was identified at an average of 1.5 months (range, 0.8–3 months) after the KP.

There were no statistical differences according to sex, age, BMI, lumbar spine BMD, cement leakage, and percent height restored between the fracture and the control groups (Table 1). Cement leakage into the disc space was confirmed in 19 of the 59 patients after surgery. Of these, four patients had adjacent vertebral fractures and 15 patients had cement leakage without adjacent vertebral fractures. Cement leakage was identified in patients (55%) in the fracture group and the control group (30%). As shown in Fig. 5, the average percent change in the anterior, middle, and posterior vertebral body heights was 22.2, 25.6, and 6.5 in group A and 18.2, 22.6, and 7.9 in group B, respectively. No correlations or associations were found between the anterior, middle, or posterior vertebral body height im-

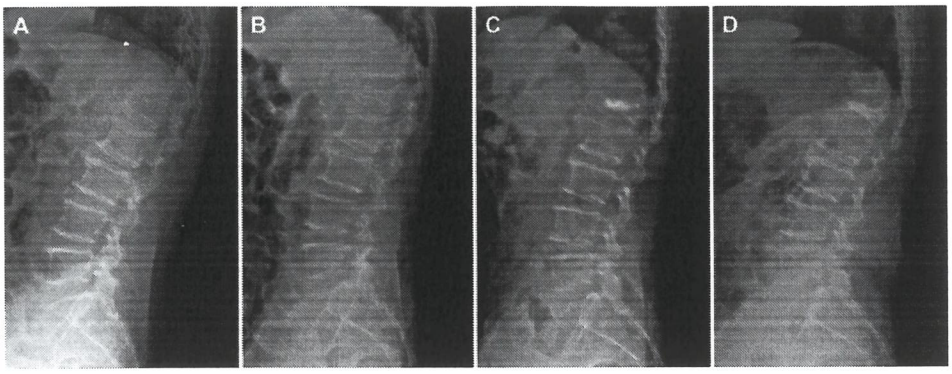

Fig. 4. An 88-year-old male with a painful osteoporotic compression fracture. (A) Plain radiograph taken a few weeks before the patient underwent kyphoplasty, revealing an osteoporotic compression fracture at L1. (B) Plain radiograph taken just before the patient underwent KP, revealing more vertebral body height loss. (C) Plain radiograph taken just after the patient underwent KP. (D) Early adjacent vertebral fracture at T12 that developed three months after balloon kyphoplasty.

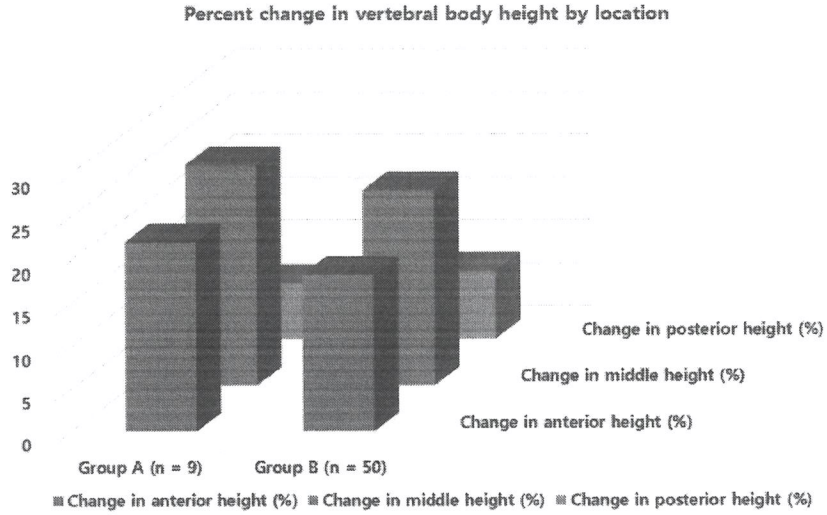

Fig. 5. Percent change in vertebral body height by location.

provements and early adjacent vertebral fractures (anterior, $p = 0.213$; middle, $p = 0.431$; and posterior, $p = 0.325$).

There was one statistical difference in kyphotic deformity measured four times (a few weeks before the patient underwent KP, preoperatively, postoperatively, and three months after the patient underwent KP) by two different methods (Table 2). The mean local kyphotic angle measured a few weeks before the patients underwent KP was 13.62 ± 6.58 in the fracture group and 10.88 ± 5.39 in the control group ($p = 0.179$). The mean Cobb's angle measured a few weeks before the patients underwent KP was 19.90 ± 9.2 in the fracture group and 15.09 ± 8.94 in the control group ($p = 0.144$). The mean local kyphotic angle measured preoperatively was 17.49 ± 7.36 in the fracture group and 13.48 ± 5.72 in the control group ($p = 0.069$). The mean Cobb's angle measured preoperatively was 24.92 ± 11.95 in the fracture group and 18.08 ± 8.17 in the control group ($p = 0.036$). The mean local kyphotic angle measured postoperatively was 11.20 ± 4.99 in the fracture group and 13.56 ± 5.77 in the control group ($p = 0.253$). The mean Cobb's angle measured postoperatively was 23.83 ± 10.79 in the fracture group and 19.39 ± 9.89 in the control group ($p = 0.226$). The mean local kyphotic angle, measured three months after the patients underwent KP was 11.20 ± 4.99 in the fracture group and 13.56 ± 5.77 in the control group ($p = 0.253$). The mean Cobb's angle, measured three months after the patients underwent KP was 23.83 ±

Table 2
Comparison of kyphotic deformity measured four times in patients with and without early adjacent vertebral fractures

Characteristics	Group A ($n = 9$)	Group B ($n = 50$)	p-value
A few weeks before, local kyphotic angle (°)	13.62 ± 6.58	10.88 ± 5.39	0.179
A few weeks before, Cobb's angle (°)	19.90 ± 9.2	15.09 ± 8.94	0.144
Preoperative local kyphotic angle (°)	17.49 ± 7.36	13.48 ± 5.72	0.069
Preoperative Cobb's angle (°)	24.92 ± 11.95	18.08 ± 8.17	0.036
Postoperative local kyphotic angle (°)	11.20 ± 4.99	13.56 ± 5.77	0.253
Postoperative Cobb's angle (°)	23.83 ± 10.79	19.39 ± 9.89	0.226
3 months after, local kyphotic angle (°)	11.12 ± 3.53	13.62 ± 4.21	0.187
3 months after, Cobb's angle (°)	24.13 ± 8.14	19.52 ± 7.62	0.272

Group A: the group with early adjacent vertebral fracture after kyphoplasty. Group B: the group without early adjacent vertebral fracture after kyphoplasty.

Table 3
Comparison of patient characteristics in groups with and without early adjacent vertebral fractures after kyphoplasty

Characteristics	Group A ($n = 9$)	Group B ($n = 50$)	p-value
Rate of type I vertebral body height loss (%/week)	8.80 ± 4.94	3.43 ± 3.65	0.000
Rate of type II vertebral body height loss (%/week)	8.515 ± 4.65	1.62 ± 2.43	0.002

Data are presented as mean ± standard deviation or n (%). Group A: the group with early adjacent vertebral fracture after kyphoplasty. Group B: the group without early adjacent vertebral fracture after kyphoplasty.

10.79 in the fracture group and 19.39 ± 9.89 in the control group ($p = 0.226$).

Between the two groups, there was statistically significant difference in the type I and II vertebral body height loss ratio (Table 3). The mean type I vertebral body height loss ratio (%) was −8.80 ± 4.94%/week in the fracture group and −3.43 ± 3.65%/week in the control group. The mean type II vertebral body height loss ratio (%) was −8.52 ± 4.65%/week in the fracture group and −1.63 ± 2.43%/week in the control group. The ratio of the loss in the two types of vertebral body height was significantly higher in the fracture group than in the non-fracture group.

4. Discussion

The incidence of adjacent vertebral fractures after ballooning KP in the literature is between 6.5% and 25% [6,8–11]. Friborg et al. [10] treated 38 patients at 47 levels with balloon KP. Ten of these patients had 17 adjacent vertebral fractures. Harrop et al. [11] treated 225 levels in 115 patients with balloon KP. Thirty-four adjacent vertebral fractures occurred in 26 patients within the mean follow-up period of one month. In this study, similar to the previous study, adjacent vertebral fractures occurred in about 16% after the KP.

Researchers have attempted to explore this problem through clinical and biomechanical studies. It is unclear whether these should be considered a result of bone cement augmentation or new vertebral body fractures are simply the result of the natural progression of osteoporosis. Also, the fractured vertebral body loses its former shape and shows kyphotic deformity, which causes the vertical load to shift to the front of the vertebral body [5]. In patients who already have osteoporosis, a slight force may cause an AVF [7,9]. Moreover, there are no well-established standards to quantify the percentage of vertebral height regained following kyphoplasty. Other investigators have quantified spinal deformity as the percent restoration of VB height previously lost and the percent VB height increase or degree in the correction of the resultant angular deformity [12–14].

In our study, no associations were found between anterior, middle, or posterior vertebral body height improvement and early adjacent vertebral fracture but one meaningful outcome was found with kyphotic deformity. The mean Cobb's angle, measured just before the patient underwent KP was 24.92 ± 11.95 in the fracture group and 18.08 ± 8.17 in the control group ($p = 0.036$). This was the same finding reported in previous studies [15], but there was no significant difference measured a few weeks before the patient underwent KP and three months after undergoing KP. It appears that the high rate of vertebral body height loss increased Cobb's angle, eventually causing higher mechanical pressure and injury to the endplate in the adjacent vertebral bodies.

Further, BMD is a well-known independent risk factor for osteoporotic AVFs [11,16,17]. The dual X-ray

absorptiometry (DXA) T-score is correlated with fracture risk and can indicate the progression or remission of osteoporosis [18,19]. BMD may be a confounding factor increasing the risk of adjacent fractures after VCF treatment, but has not yet been investigated in this context.

Our study demonstrated that BMD was not a risk factor for early adjacent vertebral fractures after KP, because we compared early adjacent vertebral fractures that occurred within three months. However, if we compared the long-term adjacent vertebral fractures, the finding would be as relevant to BMD as in previous studies.

AVF risk has also been shown to increase based on independent risk factors such as increased cement volume [20], vertebral body height restoration [21,22], and the location of the fracture at the thoracolumbar junction [16,23–25]. The imminent risk factors for early adjacent vertebral fractures after balloon KP are still controversial.

There is consistent evidence that kyphoplasty can achieve height restoration of the fractured vertebrae [15, 26,27]. Pumberger et al. [28] reported the local kyphotic angle and Cobb's angle were significantly restored after kyphoplasty.

Most adjacent vertebral fractures occur within three months of KP. Although KP reduces postoperative back pain and improves the patient's daily life, it can increase the mechanical pressure applied to the end plates of adjacent vertebral bodies [20,25]. Therefore, in the case of a high rate of vertebral body height loss, the risk of early adjacent vertebral fracture can be reduced by wearing a rigid brace for few months after surgery.

This study had several limitations. First, the retrospective nature of this study had inherent selection bias. Second, we enrolled a small number of patients and only identified fractures that occurred within three months, so there is a limit to comparisons with AVFs that occurred three months after surgery and subsequent studies are required. Third, we could not examine simple radiographs immediately after the fractures. Therefore, we could not determine the rate of vertebral height reduction between the fracture and KP. Fourth, it was not possible to investigate whether the patient was taking osteoporosis medication before the procedure. Therefore, this study did not consider the effects of osteoporosis drugs. A larger study population may be needed to discover the significant associations between the rate of vertebral body height loss before balloon kyphoplasty and early adjacent vertebral fracture.

5. Conclusions

Balloon KP is a minimally invasive procedure for stabilizing vertebral compression fractures and is effective in reducing pain. However, early adjacent vertebral fractures were present in 16% of the patients within three months after surgery. The most important risk factor for fractures was the rate of vertebral body height loss. Thus, careful attention should be paid to determining whether a high rate of vertebral body height loss occurs before KP.

Conflict of interest

No potential conflicts of interest relevant to this article were reported.

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