Comparison of unilateral and bilateral percutaneous kyphoplasty for the treatment of osteoporotic vertebral compression fractures associated with scoliosis

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Abstract. To assess the clinical and radiographic effectiveness of unilateral and bilateral percutaneous kyphoplasty (PKP) in the treatment of osteoporotic vertebral compression fractures (OVCF) associated with scoliosis, 52 patients with OVCF associated with scoliosis who underwent PKP were retrospectively analysed. The patients were divided into the unilateral PKP group (n=26) and the bilateral PKP group (n=26). The operation time, bone cement injection volume and frequency of intraoperative fluoroscopy were recorded and compared between the groups. Additionally, visual analogue scale (VAS) and Oswestry disability index (ODI) scores, as well as postoperative complications, including bone cement leakage and adjacent vertebral fractures, were also assessed. The operation time, bone cement injection volume and intraoperative fluoroscopy frequency were significantly lower in the unilateral compared with the bilateral group ($P<0.001$). The VAS score, ODI score, average vertebral body height and kyphotic angle (KA) were improved after surgery in each group with no difference in these clinical parameters between the two groups both before and after surgery. Furthermore, the proportion of cases with bone cement leakage in the unilateral group was significantly lower compared with that in the bilateral group ($P<0.05$). During the follow-up, there were three cases (11.5%) in the unilateral group and two cases (7.7%) in the bilateral group who suffered adjacent vertebral fractures, but there was no statistically significant difference between the two groups ($P>0.05$). For treating patients with OVCF accompanied by scoliosis, both unilateral and bilateral PKP could effectively relieve the acute back pain and correct the KA. However, unilateral PKP presents more advantages, such as a short operation duration and reduced intraoperative fluoroscopy frequency and bone cement leakage.

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Introduction

Osteoporotic vertebral compression fractures (OVCF) predominantly occur in the elderly and cause pain, dysfunction, loss of mobility, as well as a large economic burden (1). Annually, >1.4 million patients worldwide are affected by OVCF (2). Percutaneous kyphoplasty (PKP) is widely used to treat OVCF with good clinical results (3,4). The purpose of OVCF treatment is to maximize pain control and functional outcome. PKP not only provides rapid pain relief, but also restores the height of fractured vertebra and corrects the kyphosis caused by OVCF. Potential advantages of PKP over open surgery include the minimally invasive procedure, low bleeding, significant pain relief and faster return to daily life for patients (5-7).

Several patients with OVCF experience degenerative lumbar scoliosis, which is a risk factor for osteoporotic fractures. In patients with OVCF accompanied by scoliosis, the presence of spinal rotation makes it more difficult to puncture the vertebral body, thereby increasing the risk of nerve injury during the positioning of the needle (8,9).

There are two surgical approaches to PKP surgery, including unilateral PKP and bilateral PKP, both of which have equally good clinical and radiological outcomes in the treatment of OVCF (10). However, bilateral PKP results in improved distribution of bone cement and fracture reduction compared with that achieved with unilateral PKP, whereas unilateral PKP has advantages in decreasing the risk of adjacent vertebral fractures (11-13). There is no consensus regarding the optimal PKP approach, and to the best of our knowledge, only a few clinical studies have compared the effectiveness of both approaches in treating OVCF with scoliosis (12). Therefore, the present study aimed to assess the clinical and radiographic outcomes of unilateral and bilateral PKP in treating OVCF with scoliosis.

Materials and methods

General information. Data from patients with OVCF accompanied by scoliosis who underwent PKP at The First Affiliated Hospital of Soochow University (Suzhou, China) between January 2018 and December 2020 were retrospectively analysed. Since the choice between a unilateral or bilateral approach for treatment of patients with OVCF and scoliosis has always been controversial, prior to the present study, it was unclear which approach was more suitable for these patients. The patients were informed about the advantages and disadvantages of the two surgeries and the bilateral or unilateral puncture approach was selected following the patients' decision. According to the inclusion and exclusion criteria, 52 patients were included in the present study, which was approved by the Ethics Committee of The First Affiliated Hospital of Soochow University. Informed written consent was obtained from all patients. The patients were split into two groups: Unilateral PKP group (n=26; mean age, 71.7±8.1 years) and bilateral PKP group (n=26; mean age, 69.2±9.6 years). All patients were followed up for at least one year with their consent. The preoperative, intraoperative and postoperative information of these patients was gathered via radiographic and medical records and routine outpatient follow-ups.

Inclusion and exclusion criteria. Inclusion criteria were as follows: i) Patients aged ≥50 years with local tenderness, low back pain and lumbar dysfunction; ii) T-score for bone mineral density (BMD) ≤-2.5, compliant with the diagnostic criteria of osteoporosis (14); iii) radiograph showing a cobb angle >10 degrees in the coronal plane, compliant with the diagnostic criteria of scoliosis without neurological deficits or gross instability (15); iv) MRI showing a single-level vertebral body with a fresh vertebral compression fracture; and v) data integrity of the patients during preoperative, intraoperative and postoperative periods. Exclusion criteria were as follows: i) Pathological fractures ascribed to tuberculosis or tumour; ii) patients with mental illness, such as depression or Alzheimer's disease; iii) presence of coronary heart disease; iv) patients with long-term use of glucocorticoids for treating rheumatic disease and v) abnormal coagulation.

Surgical procedure. The standard procedure of PKP was performed by senior surgeons as described in a previous study (16). The patient was placed on an operating table in the prone position. In the bilateral group, according to the aforementioned surgical methods, symmetrical incisions were made at 2-2.5 cm proximal to the apical spinous process. A puncture needle was inserted at an abduction angle of 25-35 degrees into both sides of the vertebral body through the pedicle with the guidance of a C-arm. Subsequently, a working channel was established through a guidewire. An appropriate inflatable balloon was inserted into the vertebral body, which was inflated to provide space for cement injection into the compressed vertebral body. OSTEOPAL®V bone cement was used in this study. The formulation of the bone cement included the powder phase and the liquid phase. The powder phase was composed of Poly (methyl acrylate, methyl methacrylate), Zirconium dioxide, Benzoyl peroxide. The liquid phase was composed of methyl methacrylate (MMA); a peroxide decomposer, N,N-dimethyl-p-toluidine; and hydroquinone. The formulation of the bone cement was most effective when the ratio of powder to liquid was 2:1. The bone cement should be of 'tooth paste' consistency prior to injection (17). High-viscosity cement was slowly infused into the inflated vertebral body through the working channel. In the unilateral group, only one incision was made, and the puncture site was selected on the side with a clear pedicle shadow under the C-arm fluoroscopy. Under anteroposterior fluoroscopy, the tunnel was expanded to the anterior part of the vertebral body using a dilator to reach the middle of the vertebral body. The balloon was placed as deep as possible in the middle of the vertebral body. Balloon dilation and bone cement injection were performed in the same way as in the bilateral approach. After surgery, all patients received >1 year anti-osteoporosis treatment with 600 mg of supplemental calcium and 800 IU of vitamin D daily. All patients received preoperative X-ray, MRI and CT to identify the fracture segment and postoperative 1-day X-ray to assess the outcome of treatment (Figs. 1 and 2).

Evaluation parameters. The operation time, bone cement injection volume, intraoperative fluoroscopy frequency, duration of hospital stay and apical vertebral rotation were recorded. Nash-Moe classification ranged from 0 (both sides of the pedicles were symmetrical with no vertebral rotation degree) to 4 (the most severe vertebral rotation degree) and was used to reflect the vertebral rotation degree (18). The vertebral body height and local kyphotic angle (KA) were measured on a standing lateral radiograph pre- and postoperatively. The fractured vertebral body height was measured at the point of most pronounced compression (anterior or middle). The KA was calculated from the angle of intersection of the lines parallel to the upper and lower end plates of the fractured vertebrae (Fig. 3). The compression rate (CR) was calculated as the height of each fractured vertebral body divided by the height of the neighbouring normal vertebral body. Postoperatively, the restoration rate (RR) was calculated as follows: (Restored vertebral body height-original fractured vertebral body height)/adjacent normal vertebral body height (Fig. 4) (19). The visual analogue scale (VAS) and Oswestry disability index (ODI) scores were evaluated preoperatively and postoperatively. VAS ranged from 0 (no pain) to 10 (the worst pain experienced) and was used for measuring back pain. Daily life function was estimated using the ODI score (20). The ODI score system includes 10 sections: Pain intensity, personal care, lifting, walking, sitting, standing, sleeping, sexual life, social life and traveling. Each section consists of six statements with a score of 0-5. The score is calculated as follows: (Total score/5x number of questions answered) x100% (21). Calculation of the VAS and ODI was described in a previous study (22). The occurrence rates of the adjacent vertebral body fractures and bone cement leakage were calculated postoperatively at follow-up.

Statistical analysis. Statistical analysis was performed using SPSS (version 25.0; IBM Corp.). Independent sample Student's t-test was used to compare the age, BMD T-score,

Table I. Baseline characteristics of the two groups.

Characteristic	Unilateral group (n=26)	Bilateral group (n=26)	P-value
Sex, n			0.548
Male	7	9	
Female	19	17	
Age, years	71.7±8.1	69.2±9.6	0.324
BMD T-score	-2.9±0.3	-3.0±0.4	0.223
Follow-up, months	13.5±1.6	13.5±1.9	0.938
Fracture location, n			0.575
Thoracic	12	10	
Lumbar	14	16	
Scoliosis direction, n			0.165
Right	16	11	
Left	10	15	
Apical vertebral rotation (Nash-Moe grade), n			0.697
0	6	9	
1	17	15	
2	3	2	

BMD, bone mineral density.

intraoperative data, CR and RR between the two groups. A mixed ANOVA followed by Bonferroni correction was used for comparing KA and average vertebral height between the two groups at different time points and within the same group pre- and postoperatively. The Mann-Whitney U test was used to compare VAS and ODI scores between the two groups, while the Wilcoxon signed-rank test was used to compare the preoperative and postoperative VAS and ODI scores of the same group, and each test was followed by Bonferroni correction. The variables of Nash-Moe grade and adjacent vertebral fracture were analysed by Fisher's exact test, while the remaining variables of sex, fracture location, scoliosis direction and cement leakage rate were analysed using the Chi-square test. The parametric numerical data are presented as mean ± standard deviation, the non-parametric ordinal data are presented as the median (interquartile range), and the count data are shown as n (%). P<0.05 was considered to indicate a statistically significant difference.

Results

Comparison of general data. The mean BMD T-score was -2.9±0.3 in the unilateral group and -3.0±0.4 in the bilateral group. In the unilateral group, 12 patients had single thoracic fractures whereas 14 patients had single lumbar fractures. In the bilateral group, 10 patients had single thoracic fractures whereas 16 patients had single lumbar fractures. There were no significant differences between the two groups in terms of BMD and fracture location. An apical vertebral rotation was present in 76.9% (20/26) of the patients in the unilateral group and 65.3% (17/26) of the patients in the bilateral group, with no significant difference between the two groups. The direction of scoliosis also showed no significant difference between the two groups (P>0.05) (Table I).

Comparison of intraoperative data and assessment of VAS and ODI scores. The operation time in the unilateral group was shorter than that in the bilateral group (40.5±9.0 vs. 57.2±11.4 min; P<0.001). In addition, the injected cement volume was significantly lower in the unilateral group than that in the bilateral group (4.7±0.9 vs. 7.7±1.2 ml; P<0.001). Furthermore, the frequency of intraoperative fluoroscopy was lower in the unilateral group than that in the bilateral group (28.3±7.4 vs. 52.6±9.6 times; P<0.001). Regarding the duration of hospital stay, there was no significant difference between the two groups (P>0.05). The VAS and ODI scores at 1-day after surgery and final follow-up improved significantly compared with those before surgery in both groups (P<0.05). However, these scores did not vary significantly between the two groups both before and after surgery (P>0.05; Table II).

Comparison of radiographic data and postoperative complications. The CR of the vertebral body before surgery was not significantly different between the two groups (P>0.05). The average vertebral body height and KA significantly improved after surgery in both groups compared with the preoperative measurements (P<0.05). However, after surgery, RR and KA were not statistically significant between the two groups (P>0.05). During a mean follow-up of 13.5 months (range, 12-16 months) after surgery, the unilateral group included three cases (11.5%) with bone cement leakage, whereas the bilateral group included nine cases (34.6%) (P<0.05). In patients with bone cement leakage, neither clinical nor neurological signs were observed. In the unilateral group, three of 26 (11.5%) patients exhibited adjacent vertebral fractures, the first patient at 1 month, the second at 6 months and the third at 12 months postoperatively. In the bilateral group, two of 26 (7.7%) patients exhibited adjacent vertebral fractures, one patient at 8 months and the other at 14 months postoperatively. The incidence of

Table II. Comparisons of intraoperative data, VAS score and ODI between the two groups.

Characteristic	Unilateral group (n=26)	Bilateral group (n=26)	P-value
Operation time, min	40.5±9.0	57.2±11.4	<0.001
Intraoperative fluoroscopy frequency, times	28.3±7.4	52.6±9.6	<0.001
Injected cement volume, ml	4.7±0.9	7.7±1.2	<0.001
Hospital stay, days	4.9±1.3	5.0±1.5	0.844
VAS score (interquartile range)			
Preoperative	7 (6-8)	7 (7-9)	0.291
1-day postoperative	3 (3-4)[a]	3 (3-4)[a]	0.663
Final follow-up	2 (1-3)[a]	2 (2-2)[a]	0.648
ODI, % (interquartile range)			
Preoperative	58 (52-65)	57 (51-66)	0.993
1-day postoperative	30 (25-33)[a]	30 (26-33)[a]	0.971
Final follow-up	20 (19-23)[a]	20 (17-24)[a]	0.650

[a]P<0.05 vs. preoperative results. VAS, Visual Analogue Scale; ODI, Oswestry Disability Index.

Table III. Comparisons of radiographic data and postoperative complications between the two groups.

Characteristic	Unilateral group (n=26)	Bilateral group (n=26)	P-value
Average vertebral height, mm			
Preoperative	17.7±3.3	17.6±3.4	0.981
1-day postoperative	23.2±3.9[a]	24.8±3.2[a]	0.113
Final follow-up	22.3±3.8[a]	24.1±3.2[a]	0.072
Kyphotic angle, degrees			
Preoperative	15.5±5.5	13.8±4.5	0.229
1-day postoperative	8.2±4.3[a]	6.7±2.9[a]	0.146
Final follow-up	8.9±4.4[a]	7.4±2.6[a]	0.129
Compression rate, %	36.6±8.0	35.3±11.0	0.637
Restoration rate, %	21.9±6.4	26.1±13.0	0.146
Cement leakage rate, n (%)	3 (11.5)	9 (34.6)	0.048
Adjacent vertebral fracture, n (%)	3 (11.5)	2 (7.7)	1.000

[a]P<0.05 vs. preoperative results.

adjacent vertebral fractures did not vary significantly between the two groups (Table III). Preoperative X-ray, MRI and CT images of the typical cases of the both groups showed a single-level vertebral body with a fresh vertebral compression fracture in a patient with scoliosis. Postoperative 1-day X-ray showed even distribution of bone cement and partial recovery of the vertebral height and kyphotic angle (Figs. 1, 2).

Discussion

OVCF associated with scoliosis is common in clinical practice, but its treatment is still challenging. PKP is considered to be an effective treatment for OVCF associated with scoliosis (23). However, unclear pedicle projection leads to higher risk of puncture injury when performing PKP for treating OVCF associated with scoliosis. Bilateral PKP is considered the universal approach for the management of OVCF by injecting cement via both pedicles, and one important advantage of this approach is the good distribution of bone cement (19,24). By contrast, bilateral PKP has certain shortcomings, such as higher frequency of intraoperative fluoroscopy and risk of cement leakage (25). Compared with that in bilateral PKP, unilateral PKP is associated with reduced operation time and risk of puncture, but the disadvantage of uneven distribution of bone cement may lead to vertebral refracture. It is still controversial which surgical approach is more advantageous for OVCF with scoliosis (10,26).

The present study compared the clinical efficacy and safety of unilateral and bilateral PKP in treating patients with OVCF accompanied by scoliosis. The current results indicated that both unilateral and bilateral PKP had the same efficacy in restoring vertebral body height and correcting KA.

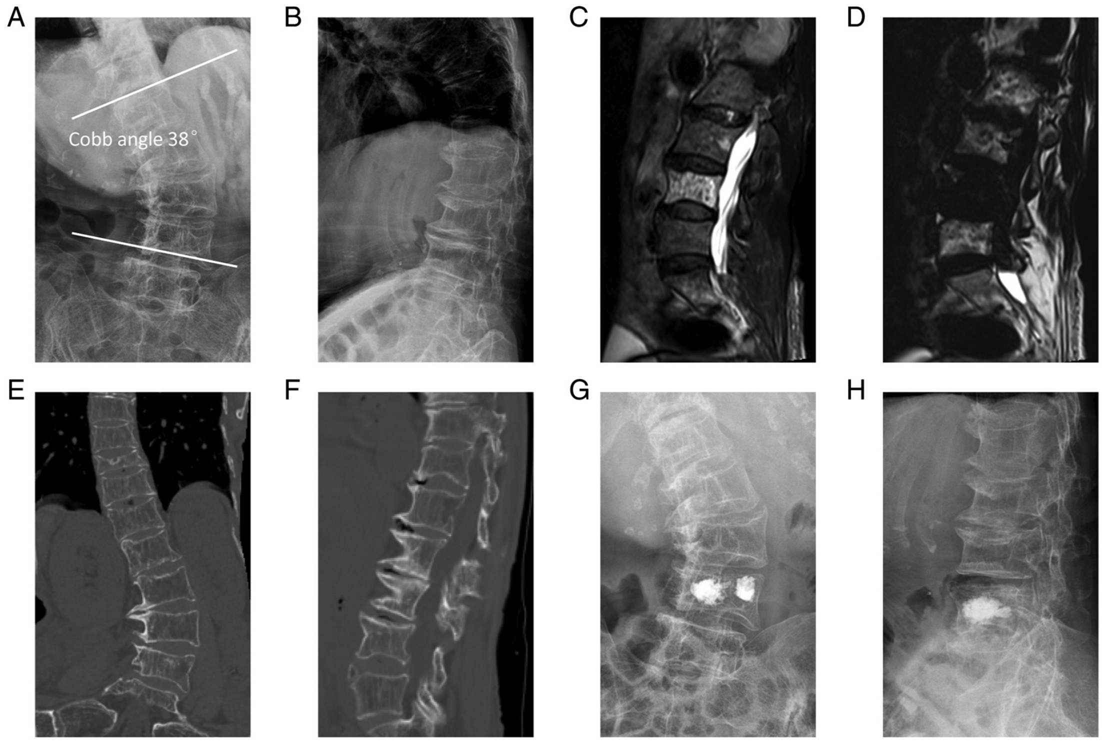

Figure 1. X-ray, MRI and CT images of a 70-year-old female patient with OVCF accompanied by spinal scoliosis treated using bilateral kyphoplasty. Preoperative X-ray at (A) anteroposterior and (B) lateral views showing the patient with scoliosis and OVCF. (C) Preoperative sagittal T2-weighted MRI showing high signal of short-TI inversion recovery sequence change on L4 vertebra. (D) Preoperative sagittal T1-weighted MRI showing low signal change on L4 vertebra. Preoperative (E) sagittal and (F) coronal CT showing OVCF of L4 with scoliosis. Postoperative 1-day X-rays at (G) anteroposterior and (H) lateral view showing accepted bilateral kyphoplasty, good positioning of the bone cement without leakage and partial recovery of the vertebral height and kyphotic angle. OVCF, osteoporotic vertebral compression fractures.

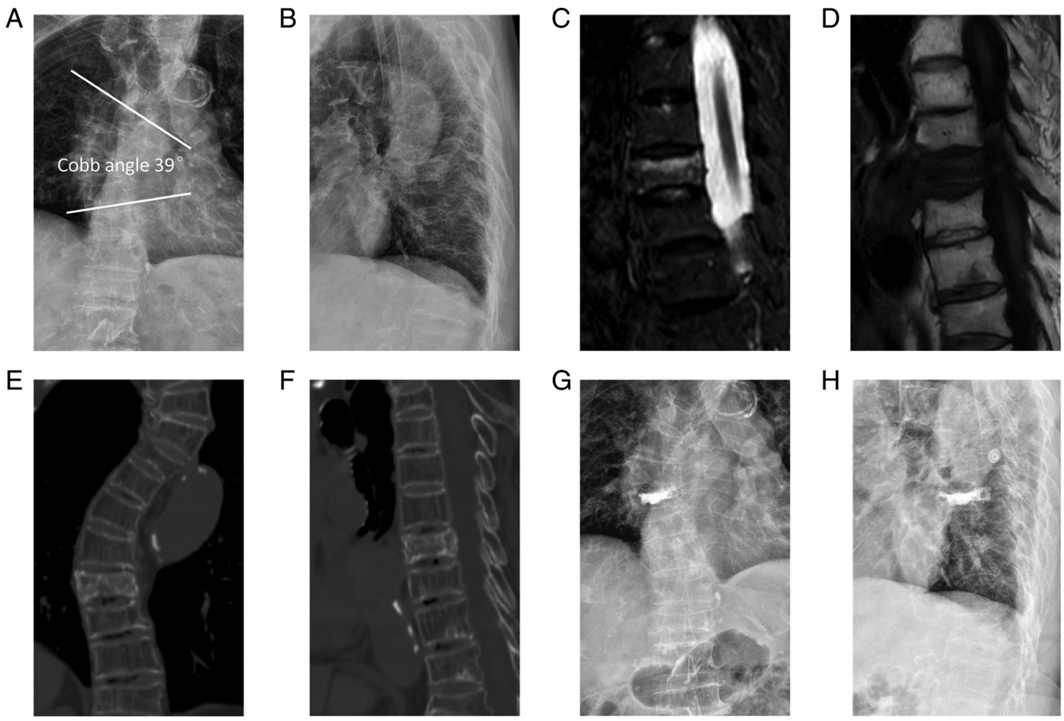

Figure 2. X-ray, MRI and CT images of an 85-year-old female patient with OVCF accompanied by spinal scoliosis treated by unilateral kyphoplasty. Preoperative X-rays of (A) anteroposterior and (B) lateral views showing scoliosis and OVCF. (C) Preoperative sagittal T2-weighted MRI showing high signal of short-TI inversion recovery sequence change on T9 vertebra. (D) Preoperative sagittal T1-weighted MRI showing low signal change on T9 vertebra. Preoperative (E) sagittal and (F) coronal CTs showing OVCF of T9 with scoliosis. Postoperative 1-day X-rays at (G) anteroposterior and (H) lateral view showing accepted unilateral kyphoplasty, good positioning of the bone cement without leakage and partial recovery of the vertebral height and kyphotic angle. OVCF, osteoporotic vertebral compression fractures.

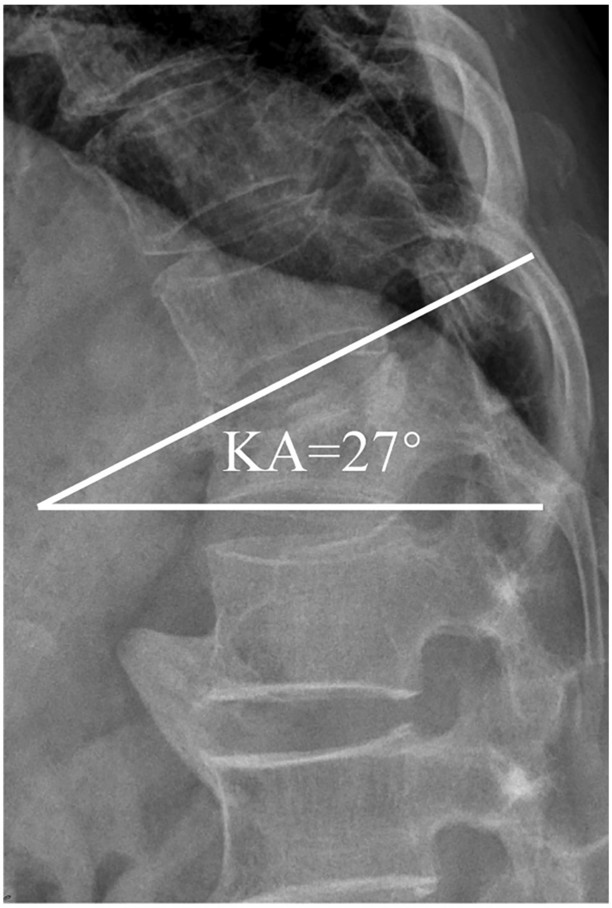

Figure 3. Radiographic evaluation of KA. KA was calculated from the angle of intersection of the lines parallel to the upper and lower end plates of the fractured vertebrae. KA, kyphotic angle.

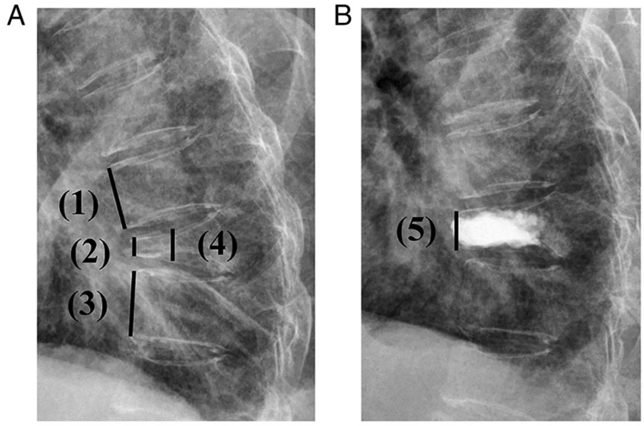

Figure 4. Compression and restoration rates. (A) Preoperative X-ray at lateral view. (B) Postoperative 1-day X-ray at lateral view. Radiographic evaluation of anterior (2) and middle (4) vertebral body height, neighbouring normal vertebral body height [(1) and (3)]. Radiographic evaluation of fractured vertebral body height (2) and restored vertebral body height (5). Compression rate=(2)/[(2)+(3)]/2 x100%. Restoration rate=[(5)-(2)]/[(1)+(3)]/2 x100%.

The VAS and ODI scores improved postoperatively in both groups, but the differences between the two groups were not statistically significant. Lee *et al* (27) reported that unilateral PKP is equally successful with bilateral PKP in terms of pain relief and restoration of the vertebra when treating single-level OVCF. A cadaver study also showed that bilateral and unilateral PKP are equally effective in restoring vertebral body strength, stiffness and height (12). Consistently, the results of the present study showed that for treating OVCF accompanied by scoliosis, unilateral PKP could achieve the same effect in relieving clinical symptoms compared with that achieved by bilateral PKP.

Bone cement leakage is one of the common complications in PKP and it is affected by the injected cement volume, fracture severity grade and puncture accuracy (28). The current study found that the incidence of bone cement leakage in the unilateral group was lower than that in the bilateral group. This finding may be attributed to the fact that in OVCF with scoliosis, level of deformity increases the difficulty of performing the standard intraoperative fluoroscopy, which elevates the risk of cement leakage when surgeons puncture through the bilateral pedicles. Moreover, the mean amount of injection volume in the bilateral group was higher than that in the unilateral group. Li *et al* (29) reported that an increase in the injection volume of polymethyl methacrylate could increase the probability of cement leakage in PKP. Additionally, the current study showed that the operation duration in the unilateral group was shorter than that in the bilateral group, which was similar to the results of previous studies (11,30). The present study also found that unilateral PKP could decrease the intraoperative fluoroscopy frequency compared with that of the bilateral PKP in the treatment of OVCF accompanied by scoliosis. Consistently, Yan *et al* (30) reported that bilateral PKP used twice the average radiation dosage per patient that was used for unilateral PKP. In brief, unilateral PKP shortened the operation time, and decreased the intraoperative fluoroscopy frequency and bone cement leakage compared with those in bilateral PKP used for the management of OVCF with scoliosis.

At present, the occurrence of adjacent vertebral fractures after PKP is gaining significant attention from researchers. Yu *et al* (31), in their meta-analysis study, showed that the incidence of adjacent vertebral fractures after PKP is 3.21-63.00%. Among several risk factors for postoperative adjacent vertebral fractures, a combination of degenerative lateral bending is an independent risk factor (32). However, when comparing the incidence of adjacent vertebral fractures after PKP between the bilateral and unilateral PKP groups, the present study found that the difference was not significant. Similarly, certain studies reported no statistically significant difference between the unilateral and bilateral PKP groups in terms of the risk ratio of postoperative adjacent segment fractures (12,27). The findings of the current retrospective analysis provided evidence that unilateral PKP may be a preferable option for treating OVCF with scoliosis and provided a direction for future research on OVCF combined with scoliosis.

However, the present study had some limitations. Firstly, the sample size was small because of the strict inclusion and exclusion criteria. A larger sample size would have helped in drawing more accurate conclusions. Secondly, the surgeries were not performed by the same surgeon, although all surgeons had vast experience in performing this type of surgery. Thirdly, this was a retrospective study, and it could be affected by selection bias. Future prospective studies must be conducted to limit the possibility of selection bias. Therefore, a large, prospective, randomized control study is warranted to further validate the present results.

Unilateral PKP was as effective as bilateral PKP in the treatment of OVCF accompanied by scoliosis. Both procedures could relieve acute back pain, improve the compressed vertebral body height and correct the KA. Nevertheless, compared with those in the bilateral PKP, unilateral PKP could reduce the intraoperative fluoroscopy and shorten the operation time. Furthermore, unilateral PKP exerted lower rates of bone cement leakage and it did not increase the risk of adjacent vertebral fractures. Altogether, unilateral PKP could be a preferable option compared with the bilateral PKP in the management of OVCF associated with scoliosis.

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Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Authors' contributions

KC, KZ and JZo designed the study. ZL wrote the manuscript, collected patient information and interpreted data. HanL and YT contributed to the clinical and radiological evaluations. JZh performed the statistical analysis and collected patient information. HaoL interpreted data and revised the article. KC and KZ confirm the authenticity of all the raw data. All authors have read and approved the final manuscript.

Ethics approval and consent to participate

All procedures involving human participants were performed in accordance with the Ethical Standards of the present institute's research committee and the 1964 Helsinki Declaration and its later amendments. The present study was approved by the Ethics Committee of the First Affiliated Hospital of Soochow University (approval no. 137; Suzhou, China). All patients signed the informed consent form about inclusion in the present study at the time of follow-up and the usual preoperative consent form prior to surgery.

Patient consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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