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Efficacy and safety of unilateral and bilateral percutaneous balloon kyphoplasty for AOspineA3/A4 osteoporotic thoracolumbar burst fractures

Ruijie Wan, MD, Shaofan Liu, MD*

Abstract

To retrospectively evaluate the efficacy and safety of unilateral and bilateral percutaneous balloon kyphoplasty (PKP) in the treatment of osteoporotic thoracolumbar burst fractures.

Retrospectively collected clinical data of 138 patients with osteoporotic thoracolumbar burst fractures who underwent unilateral (n=70) and bilateral (n=68) PKP in our hospital from March 2015 to December 2018. The general conditions, operation time, radiation exposure time, intraoperative blood loss, bone cement dosage, hospitalization expenses, and complications were collected from the two groups. Visual analog scale (VAS) values, Cobb's angle changes, average vertebral height changes, and Oswestry Dysfunction Index (ODI) values before treatment, 1 month, and 6 months after treatment were collected.

There was no significant difference in gender (male: 28 vs 22; female 42 vs 46) and age (70.25 ± 7.10 vs 69.82 ± 8.20, $P > .05$) distribution between the two groups. The VAS score (7.38 ± 1.34 vs 2.52 ± 0.99, $P < .05$), ODI (77.24 ± 6.98 vs 23.11 ± 3.54, $P < .05$), vertebral mean height (16.71 ± 2.18 vs 17.05 ± 1.94, $P < .05$) and Cobb's angle (20.26 ± 3.21 vs 11.58 ± 3.20, $P < .05$) of the two groups were significantly improved after operation, but there was no significant difference between the two groups ($P > .05$). There was no significant difference in the rate of cement leakage (10.29% vs 11.42%, $P > .05$), incision swelling (30.88% vs 19.71%, $P > .05$) and incidence of adjacent vertebrae (4.41% vs 5.71%, $P > .05$) between the two groups. Compared with bilateral PKP group, operation time (50.88 ± 7.38 vs 62.18 ± 8.01), intraoperative blood loss (14.54 ± 3.16 vs 22.03 ± 5.92), radiation exposure time (23.74 ± 3.41 vs 15.22 ± 3.70), bone cement dosage (4.36 ± 0.81 vs 5.16 ± 0.77) and hospitalization costs (2.38 ± 0.08 vs 2.74 ± 0.07) were significantly lower in the unilateral PKP group ($P < .05$).

Bilateral PKP and unilateral PKP have the same efficacy and safety in the treatment of osteoporotic thoracolumbar burst fractures. However, the unilateral PKP has the characteristics of short operation time, small trauma, low cost and short radiation exposure time, and has clinical application value.

Abbreviations: CT = computed tomography, MRI = magnetic resonance imaging, ODI = Oswestry Dysfunction Index, PKP = Percutaneous balloon kyphoplasty, PLC = posterior longitudinal ligament complex, QCT = quantitative computed tomography, VAS = visual analog scale.

Keywords: bilateral, efficacy, osteoporosis, percutaneous balloon dilatation kyphoplasty, safety, thoracolumbar burst fracture, unilateral

1. Introduction

Osteoporotic thoracolumbar fractures are the most common pathological changes in spinal fractures. They are more common in middle-aged and elderly population, In Europe, the incidence of osteoporotic fracture is 18% to 26% and the cost of managing osteoporosis was estimated at €37 billion and notably the costs of treatment and long-term care of patients with fractures were considerably higher than the costs for pharmacological prevention.[1,2] osteoporotic fracture main clinical manifestations are chronic back pain, limited mobility, severe kyphosis and neurological dysfunction, which seriously affect the quality of life of middle-aged and elderly patients.[1,2] Owing to the decrease of bone strength, loss of bone mass and enhancement of bone fragility, osteoporotic spinal fractures can occur in middle-aged and elderly patients during their daily activities. Because the type of fracture is low energy injury, it is mostly compressive fracture and mild burst fracture.[3,4] At present, percutaneous balloon kyphoplasty (PKP) not only can quickly stabilize the vertebral body, significantly reduce back pain after injury, correct

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

Department of Orthopedics, Traditional Chinese Medicine Hospital, Chongqing, China.

** Correspondence: Shaofan Liu, Department of Orthopedics, Traditional Chinese Medicine Hospital, Chongqing 400013, China (e-mail: doctorwzl123@sina.com).*

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kyphosis, prevent spinal deformity, but also have lower leakage rate of bone cement and higher safety. It has become a definite and safe minimally invasive treatment for the treatment of osteoporotic thoracolumbar vertebral compression fractures and has been widely carried out clinically.[5,6]

However, with the increase of traffic accidents and outdoor activities, coupled with the aging of the social population, the incidence of osteoporotic thoracolumbar burst fracture shows an increasing trend. How to choose a relatively minimally invasive, safe and effective treatment for this kind of fracture has become a research hotspot of spine surgeons. It has been previously believed that osteoporotic thoracolumbar burst fractures are due to the destruction of the posterior wall integrity of the vertebral body and partial osseous occupancy of the spinal canal. PKP treatment of osteoporotic thoracolumbar burst fractures has an increased probability of leakage of cement in the spinal canal, and the risk of spinal cord and nerve injury increases. Therefore, PKP is a relative contraindication for osteoporotic spinal burst fracture and has not been widely developed clinically.[7] But, in recent years, some experienced spine surgeons have used PKP to treat mild to moderate osteoporosis thoracolumbar burst fractures, and achieved good results.[8,9] PKP surgical approach is divided into bilateral and unilateral. The efficacy and safety of unilateral and bilateral PKP surgery for mild to moderate osteoporosis thoracolumbar burst fractures are rarely reported. This study retrospectively collected 138 patients with osteoporotic thoracolumbar burst fractures who underwent unilateral (n=70) and bilateral (n=68) PKP procedures from March 2015 to December 2018. Clinical data were analyzed to explore the efficacy and safety of unilateral and bilateral PKP in the treatment of osteoporotic thoracolumbar burst fractures.

2. Methods and clinical data

2.1. Clinical data collection

The clinical data of 138 patients with osteoporotic thoracolumbar burst fractures who underwent unilateral (n=70) and bilateral (n=68) PKP in our hospital from March 2015 to December 2018 were retrospectively collected. The inclusion criteria were as follows:

1. middle-aged and elderly patients;
2. have weight-bearing or spontaneous low back pain;
3. spinal quantitative computed tomography (QCT) examination confirmed a single-segment osteoporotic thoracolumbar burst fracture;
4. X-ray, computed tomography (CT) and magnetic resonance imaging (MRI) examination of the thoracolumbar spine were performed before operation to confirm the fracture site and diagnosis;
5. intraspinal space occupancy <25% and no symptoms of nerve injury;
6. vertebral body leading edge height collapse ≤2/3;
7. AOspine is classified as A3/A4.

The diagnostic criterion of osteoporosis proposed by WHO is QCT <80 mg/cm^3. The exclusion criteria were as follows:

1. burst fracture with associated symptoms and signs of nerve root, cauda equina and spinal cord injury;
2. accompanied by severe damage or fracture and dislocation of the posterior longitudinal ligament complex (PLC);
3. with serious diseases such as heart, liver, kidney, and other important organs;
4. with severe blood system diseases;
5. with high blood calcium or hypocalcemia, parathyroid dysfunction and other diseases affecting bone metabolism;
6. people with serious infectious diseases;
7. with primary or metastatic spinal tumors.

This study was approved by the ethics committee of Traditional Chinese Medicine Hospital (Local ethical committee approval, 2015–012). All patients and their families were informed of the operation and signed consent.

2.2. Treatment measures

All operations were performed by two senior orthopaedic surgeons. Bilateral PKP was performed as previously reported.[10,11] The patient was in prone position and was localized by conventional C-arm X-ray. The skin at the projection site of the lateral upper edge of the pedicle at the left 10 points and the right 2 points was cut 5 mm, and the direction of the sagittal plane 15 to 25 degrees was punctured through the pedicle to the anterior 5 mm of the posterior edge of the vertebral body. The working passage was established, the intravertebral passage was established by hand drill, the balloon vertebroplasty apparatus was placed unilaterally, the contrast medium was slowly injected through the balloon, and the balloon was dilated under X-ray fluoroscopy to achieve the reduction of the vertebral body. The opposite side was treated with the same method. Bone cement polymethyl methacrylate (PMMA, Heraeus, Germany) to viscous state. Under the fluoroscopy of C-arm X-ray machine, bilateral bone cement injectors inject the bone cement slowly, evenly and uniformly into the diseased vertebral body until it is well distributed. After the bone cement is solidified, the rotary bone cement injector is given and pulled out together with the working passage to suture the wound. Postoperative anti-osteoporosis treatment, guidance of rehabilitation exercise and other treatment.

Unilateral PKP: prepare the same two-sided group before surgery, puncture is unilateral (left or right) and individualized puncture is used. Due to the high puncture angle and position requirements, the puncture path was simulated on CT or MRI images before surgery (the anatomy of the pedicle may be located outside the pedicle), and the puncture introversion angle is 35° to 45°. The position of the tip of the puncture needle is required: the X-ray positive position is located in the middle of the vertebral body, and the lateral position piece is located slightly in front of the center of the vertebral body (generally about 3 mm). At the same time, according to the specific conditions of the vertebral body, the puncture side is selected and the puncture angle is appropriately adjusted so that the position of the balloon is slightly biased toward the compression side. In addition to the injection of bone cement, the tip of the cement syringe requires the positive position to be located outside the center of the vertebral body, and the other operations are the same as the bilateral group. After the operation, the wound was sutured, the anti-osteoporosis drug treatment was performed and the rehabilitation exercise was guided.

2.3. Clinical data collection of two groups of patients

All test indicators were collected using previously reported indicators.[8–13] Visual analog scale (VAS) was used to assess pain

Table 1

Comparison of general clinical data of two groups of patients.

Basic information	Unilateral group (n=70)	Bilateral group (n=68)	P
Age	70.25±7.10	69.82±8.20	.747
Male	28	22	.154
Female	42	46	.123
Total vertebral body (Number)	70	68	.348
First lumbar spine (L1, %)	18 (25.7%)	18 (26.5%)	
Second lumbar spine (L2, %)	10 (14.3%)	10 (14.7%)	
Third lumbar spine (L3, %)	2 (0.28%)	2 (0.29%)	
Eleventh thoracic vertebrae (T11, %)	10 (14.3%)	12 (17.6%)	
Twelfth thoracic vertebrae (T12, %)	24 (34.2%)	18 (26.5%)	
Seventh thoracic vertebrae (T7, %)	2 (0.28%)	0 (0%)	
Eighth thoracic vertebrae (T8, %)	0 (0%)	2 (0.29%)	
Ninth thoracic vertebrae (T9, %)	4 (0.57%)	4 (0.58%)	
Tenth thoracic vertebrae (T10, %)	0 (0%)	4 (0.58%)	
AOSpine typing			
Type A3	40	36	.304
Type A4	30	32	.275
IBM	24.77±1.91	24.21±2.24	.329
Preoperative QCT bone mineral density (mg/cm^3)	41.5±8.91	40.5±9.24	0.653

*P is <.05, with statistical significance representative.

scores before and 3 days after surgery. The Oswestry Dysfunction Index (ODI) was used to assess the degree of dysfunction in patients before, 1 and 6 months after surgery. X-ray was used to measure the change of the height of the vertebral body and the Cobb's angle before and after surgery. The general conditions, operation time, radiation exposure time, intraoperative blood loss, bone cement dosage, hospitalization expenses, and complications were collected from the two groups.

2.4. Statistical analysis

Statistical analysis was performed with SPSS 20.0. Measurement data are expressed as mean±standard deviation (x±s), using t test. The count data is expressed in terms of rate, and the χ^2 test is used for comparison. $P<.05$ considered a statistically significant difference.

3. Result

3.1. Characteristics of the patients included in the study

As shown in Table 1, there was no significant difference in age, fracture site, sex, AOSpine classification, body mass index and preoperative QCT bone mineral density between the two groups ($P>.05$), which indicated that the two groups were comparable.

3.2. Unilateral and bilateral PKP in a representative case of preoperative puncture point positioning, intraoperative puncture, postoperative effect

As shown in Figures 1 and 2, preoperative MRI and CT showed vertebral burst fractures in both unilateral and bilateral PKP cases. Puncture point localization was performed by CT before operation, and precise unilateral and bilateral PKP operation was performed under X-ray guidance during operation. Postoperative CT showed a relatively good distribution of bone cement in the unilateral and bilateral groups.

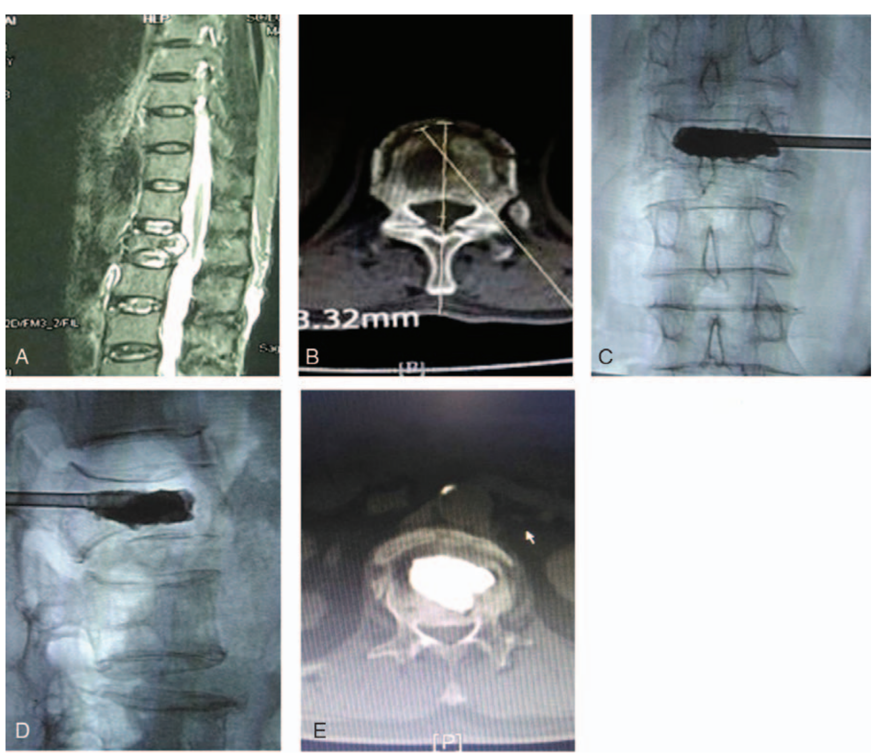

Figure 1. Schematic diagram of the unilateral PKP surgery. (A) Preoperative MRI; (B) puncture path; (C) intraoperative orthotopic X-ray; (D) intraoperative lateral X-ray; (E) postoperative CT changes.

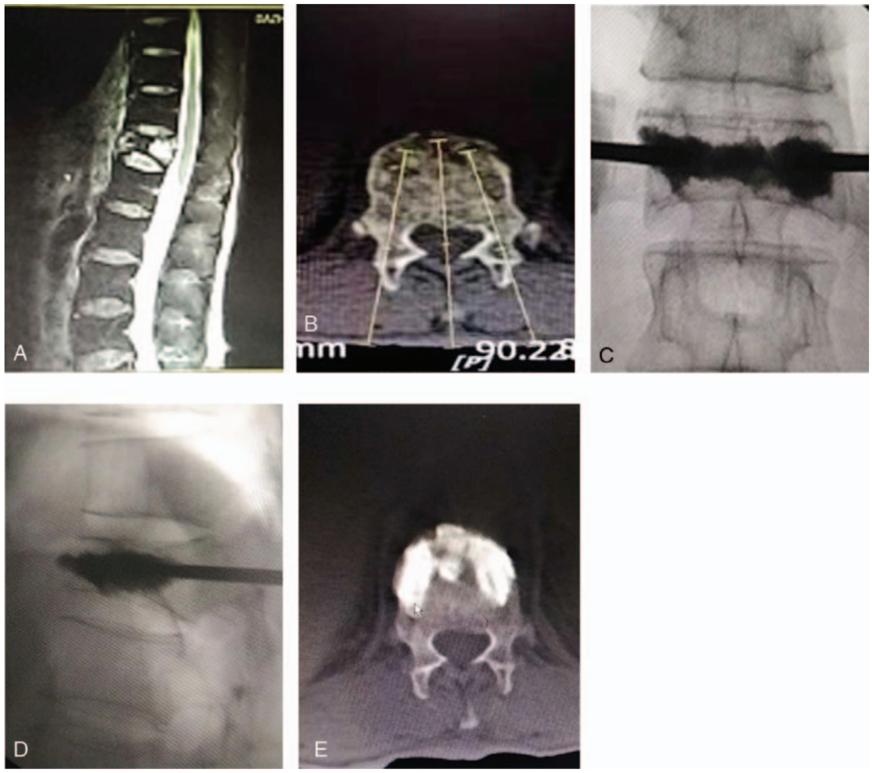

Figure 2. Schematic diagram of the bilateral PKP surgery. (A) Preoperative MRI; (B) puncture path; (C) intraoperative orthotopic X-ray; (D) intraoperative lateral X-ray; (E) postoperative CT changes.

3.3. Comparison of operation time, X-ray exposure time, intraoperative blood loss, bone cement dosage, and hospitalization cost in the two groups

Table 2 shows that compared with the bilateral PKP group, the operative time, X-ray exposure time, intraoperative blood loss, bone cement dosage, and hospitalization cost were significantly lower in the unilateral PKP group, with statistical difference ($P > .05$).

3.4. Analysis of VAS score, average height of vertebral body, and Cobb's angle before and after treatment in two groups of patients

Table 3 shows that there was no significant difference in preoperative VAS score, mean height of vertebral body, and Cobb's angle between the two groups ($P > .05$). The VAS scores of the two groups were significantly lower ($P < .05$), but the VAS scores of the unilateral group were significantly lower than those of the bilateral group ($P < .05$). The average height of the vertebral body was significantly increased in the two groups ($P < .05$), but there was no significant difference between the unilateral group and the bilateral group ($P > .05$). The Cobb's angle was significantly lower in the two groups ($P < .05$), but there was no significant difference between the unilateral group and the bilateral group ($P > .05$).

Table 2

Comparisons of operation time, radiation exposure time, intraoperative blood loss, bone cement dosage and hospitalization costs between the two groups.

Parameter	Bilateral group (n=68)	Unilateral group (n=70)	Adjusted P-
Operation time (min)	62.18±8.01	50.88±7.38*	.002
Radiation exposure time (min)	23.74±3.41	15.22±3.70*	.001
Intraoperative blood loss (mL)	22.03±5.92	14.54±3.16*	.001
Hospitalization costs (yuan)	2.74±0.07	2.38±0.08*	.021
Bone cement dosage (mL/vertebra)	5.16±0.77	4.36±0.81*	.015

* Postoperative comparison between unilateral group and bilateral group, $P < .05$.

Table 3

Analysis of VAS score, average vertebral height and Cobb angle before and after treatment in two groups.

Parameter	Bilateral group (n=68)	Unilateral group (n=70)	Adjusted P
VAS			
Before treatment	7.38±1.34	7.48±1.06	
After treatment	2.52±0.99#	2.03±0.75#,*	.021
Adjusted P-value	0.001	0.001	
Vertebral mean height (mm)			
Before treatment	16.71±2.18	17.05±1.94	
After treatment	20.23±2.17#	19.60±1.82#	
Adjusted P-value	0.008	0.013	
Cobb angle (°)			
Before treatment	20.26±3.21	19.25±3.46	
After treatment	11.58±3.20#	11.02±3.06#	
	0.007	0.011	

Representatives of each group after surgery compared with before surgery, $P < .05$.
* Postoperative comparison between unilateral group and bilateral group, $P < .05$.

Table 4

Comparison of ODI scores between the two groups before and after treatment (%).

Parameter	Bilateral group (n=68)	Unilateral group (n=70)
Before treatment	77.24±6.98	78.24±7.85
One month after treatment	27.20±4.83#	27.61±4.36#
Adjusted *P*-value	0.001	0.001
Six months after treatment	23.11±3.54#	24.12±4.27#
Adjusted *P*-value	0.001	0.001

#Represents the comparison between the groups after operation and before operation, $P<.05$; *Representing 1 month after operation, the unilateral group was compared with the bilateral group ($P<.05$); and representing 6 months after operation, the unilateral group was compared with the bilateral group ($P<.05$).

3.5. Comparison of ODI scores between the two groups before and after treatment

Table 4 shows that the ODI scores of the two groups before treatment were basically similar, and there was no statistical difference ($P>.05$). At 1 month and 6 months after surgery, the patient's ODI score was significantly lower ($P<.05$). However, there was no statistically significant difference between the unilateral group and the bilateral group at 1 month and 6 months after surgery ($P>.05$).

3.6. Comparison of complications between the two groups

Table 5 shows that compared with the bilateral PKP group, the incidence of complications (bone cement leakage, incision swelling, and wound infection) in the unilateral PKP group was similar to that in the bilateral group, and there was no statistical difference ($P>.05$).

4. Discussion

For thoracolumbar burst fractures, due to the damage of the anterior column, the stability is worse, and it is more likely to cause secondary spinal deformity and neurological dysfunction. Therefore, posterior minimally invasive or open pedicle screw system is widely used in the treatment of thoracolumbar burst fractures.[13,14] However, for the majority of AOSpine type A3/A4 elderly osteoporotic thoracolumbar burst fractures without nerve injury, there are many shortcomings such as high anesthesia risk, great trauma, vertebral shell fracture changes, internal fixation loosening, internal fixation loosening and falling off, and the need for second-stage removal and internal fixation surgery, which not only increases the trauma, prolongs the operation time, but also increases medical costs.[15–18] Exploring minimally invasive and effective treatment for AOSpine type A3/A4 elderly osteoporotic thoracolumbar burst fractures has important clinical significance. At present, some scholars have applied PKP to the treatment of osteoporotic burst fracture without nerve compression. It has been proved that PKP has better reduction effect, lower cement leakage rate and higher safety.[8,9,19–22]

At present, the clinical PKP surgical approach is bilateral and unilateral, respectively. The efficacy and safety of the two procedures are currently controversial. In general, the optimal distribution of bone cement in the vertebral body requires bilateral puncture, but some studies have suggested that the bilateral puncture needle tip is close to the cortical bone of the vertebral body burst, but it is easy to cause bone cement leakage. Kim et al believe that after the needle tip is placed in a proper position by precise puncture, a bone cement can be obtained by a single-sided puncture injection of bone cement.[23] Current studies suggest that unilateral PKP is similar to bilateral PKP in the treatment of osteoporotic spinal compression fractures, and unilateral PKP has the advantages of short operation time, less injury and low incidence of local pain after operation.[24] The traditional one-sided PKP puncture method cannot ensure that the bone cement is distributed over the midline to the opposite side, causing the bone cement to be distributed on one side. Although it has little effect on the axial compressive strength, under the lateral pressure load, the non-piercing side stiffness is significantly lower than the puncture side.[25] Some scholars have solved this problem better by combining the three-point puncture method with the controllable direction balloon technique or the navigation puncture technique.[26,27] However, this technology has high requirements on equipment and cannot be widely used in primary hospitals. Under the experience of unilateral PKP puncture, we improved the pedicle, combined with preoperative X-ray and CT/MRI, simulated the puncture path under the computer and adopted individualized puncture. In this way, the needle tip can be punctured to reach the first 1/3 of the center of the vertebral body, and the balloon can be accurately implanted in the front 2/3 of the center of the vertebral body, so that the bone cement can be distributed along both sides of the midline. This study found that the improved unilateral puncture was distributed along both sides of the vertebral body, confirming that the unilateral and conventional bilateral puncture PKP can ensure that the bone cement is distributed over the midline to the contralateral side.

This study found that compared with bilateral PKP, the operative time, X-ray exposure time, bone cement dosage, intraoperative blood loss, hospitalization cost, postoperative VAS score, and incision swelling rate were significantly lower in patients with unilateral PKP. However, the incidence of Cobb's angle, average height of vertebral body, cement leakage rate and adjacent vertebral fractures were basically the same after treatment. However, the Cobb's angle, the average height of the vertebral body, the rate of cement leakage, and the incidence of adjacent vertebral fractures were similar in the two groups. This suggests that unilateral PKP can effectively shorten the operation time, reduce X-ray exposure time, reduce hospitalization hospitalization costs, reduce intraoperative injury, relieve local pain and swelling after surgery, and have no significant effect on treatment efficacy and safety. Clinically, bilateral PKP can distribute bone cement along both sides and diffuse to the center by bilateral puncture, which can better maintain bone stability. However, the time spent on bilateral puncture is increased, and the trauma is increased, which may lead to local

Table 5

Comparisons of complications between two groups.

Parameter	Bilateral group (n=68)	Unilateral group (n=70)	Adjusted *P*-value
Bone cement leakage	7 (10.29%)	8 (11.42%)	.785
Incision swelling	21 (30.88%)	18 (25.7%)	.095
Adjacent vertebral fracture	3 (4.41%)	4 (5.71%)	.681
Bone cement leakage	7 (10.29%)	8 (11.42%)	.367

*Represents the comparison between the two groups ($P<.05$).

incision swelling after operation, postoperative pain relief is slow, and postoperative experience is reduced. However, unilateral PKP surgery cannot only effectively promote the distribution of bone cement along the center to both sides, but also shorten the time of surgery and radiation exposure, reduce intraoperative trauma, reduce postoperative pain time, and improve postoperative experience.

The cement leakage of PKP technology has always been the focus of scholars' research.[27] There was no statistical difference in bone cement leakage between the unilateral PKP group and the bilateral PKP group in this study. No leakage of bone cement in the two groups of patients caused nerve and organ compression. Regarding the prevention of bone cement leakage, we believe that through reasonable selection of patients, X-ray monitoring of bone cement injection, gelatin sponge filling, high-viscosity bone cement technology, etc, can basically control the leakage of bone cement. Regarding the adjacent vertebral fractures after PKP, some scholars believe that the incidence is related to the stiffness and strength of bone cement, and some scholars believe that it is mainly related to bone cement distribution and leakage. In addition, the intraoperative balloon over-reduction and severe osteoporosis can also cause fractures of the adjacent vertebrae.[28,29] Unilateral PKP reduces the amount of bone cement and improves the distribution of bone cement, theoretically reducing the incidence of adjacent vertebral fractures. However, there was no significant difference in the incidence of adjacent vertebral fractures between the two groups ($P > .05$). It may be related to the following interference factors:

1. most osteoporotic fractures occur in the thoracolumbar region;
2. The natural course of osteoporotic diseases is also an important reason for the high incidence of adjacent vertebral fractures;
3. The research sample size is too small and other interference factors.

In this study, we evaluated the ODI scores of 1 and 6 months after unilateral and bilateral PKP. The evaluation results showed that the ODI scores of unilateral PKP were similar to those of bilateral PKP, suggesting that unilateral PKP and bilateral PKP have similar therapeutic effects in the treatment of osteoporotic spinal burst fractures. This study suggests that unilateral PKP can effectively fill the intervertebral space of the lesion, maintain fracture stability, avoid the contralateral vertebral re-compression fracture and scoliosis caused by inadequate injection of bone cement, and can effectively restore the vertebral function of patients and ensure the significant improvement of vertebral dysfunction. Although this study found that unilateral PKP has obvious advantages for osteoporotic burst fracture, there are still some limitations in this study. First, the pathological changes of osteoporotic burst fracture are changeable, and some patients are complicated, so the treatment should be combined with the specific conditions of patients. Secondly, the sample size of this study is too small to fully represent the actual situation of all cases. Thirdly, different surgical operators have different proficiency in precise positioning of puncture points, balloon dilatation and reduction, bone cement injection and other details, and there are deviations in clinical practice. Fourthly, this study has all limitations and risk of bias inherent to study design. Finally, this paper results and conclusions cannot be generalized to different populations.

In conclusion, this study suggests that, compared with bilateral PKP, unilateral PKP has the same therapeutic effect and safety in the treatment of osteoporotic thoracolumbar burst fracture. However, unilateral PKP can effectively reduce the time of operation and radiation exposure, reduce the cost of operation, reduce surgical trauma, and help to quickly relieve the pain of patients after operation. It has certain clinical popularization value.

Author contributions

Conceptualization: Ruijie Wan, Shaofan Liu.
Data curation: Ruijie Wan, Shaofan Liu.
Formal analysis: Ruijie Wan, Shaofan Liu.
Funding acquisition: Ruijie Wan, Shaofan Liu.
Investigation: Ruijie Wan, Shaofan Liu.
Methodology: Ruijie Wan, Shaofan Liu.
Project administration: Ruijie Wan, Shaofan Liu.
Resources: Ruijie Wan, Shaofan Liu.
Software: Ruijie Wan, Shaofan Liu.
Supervision: Ruijie Wan, Shaofan Liu.
Validation: Ruijie Wan, Shaofan Liu.
Visualization: Ruijie Wan, Shaofan Liu.
Writing – original draft: Ruijie Wan, Shaofan Liu.
Writing – review & editing: Ruijie Wan, Shaofan Liu.

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