Research Article

Is it necessary to approach the compressed vertebra bilaterally during the process of PKP?

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Objective: To assess the clinical and radiological outcomes following unilateral or bilateral approach in percutaneous kyphoplasty (PKP) for treatment of osteoporotic vertebral compression fractures (OVCF).

Design: Prospective comparative study.

Setting: University affiliated hospital.

Participants: From 2012 through 2016, those MRI-diagnosed single-level lumbar OVCF patients.

Interventions: They were randomly assigned for treatment with unilateral or bilateral PKP.

Outcome measures: We assessed the patient's health status with the Oswestry Disability Index (ODI) questionnaire. Anteroposterior and lateral standing radiographs were obtained to measure the vertebral height and kyphotic angle of the vertebral body in all patients.

Results: Eighty-five patients were finally enrolled in this investigation, including 42 in the unilateral and 43 in the bilateral group. The operation time, PMMA volume, radiation dose was 25.6 ± 4.2 minutes, 6.2 ± 3.5 ml and 0.88 ± 0.28 mSv in the unilateral group, while 36.6 ± 8.7 minutes, 8.5 ± 2.2 ml and 1.89 ± 1.05 mSv in the bilateral group, respectively ($P < 0.05$). The postoperative VAS and ODI were 2.7 ± 1.2 and 19.8 ± 6.4 compared to preoperative 8.7 ± 1.6 and 35.2 ± 4.3 in unilateral group, while 2.6 ± 1.3 and 19.7 ± 2.6 compared to preoperative 8.5 ± 1.3 and 36.7 ± 3.6 in bilateral group, respectively ($P > 0.05$).

Conclusion: Both bilateral and unilateral PKP are relatively safe and provide effective treatment for patients with painful OVCF. However, unilateral PKP need less radiation dose, operation time and PMMA volume.

Keywords: Percutaneous kyphoplasty (PKP), Unilateral/bilateral transpedicle approach, Osteoporotic vertebral compression fractures

Introduction

Osteoporotic vertebral compression fracture (OVCF) is a common disorder in the aged. It may result in debilitating pain and spinal deformity.¹ Although some of them may gradually improve with conservative treatment, intractable pain, decreased self-esteem, senile kyphosis, early satiety, mood disorder, and even increased mortality have been frequently reported.^{2,3} Percutaneous kyphoplasty (PKP), as a minimally invasive technique for OVCF, was first performed in 1998.^{4,5} It uses a balloon tamp inserting into the vertebral body via a transpedicular approach, followed by fixation of the fracture fragments with polymethyl methacrylate (PMMA) bone cement. Today, PKP has been a widely used vertebral augmentation procedure for treating painful vertebral compression fractures. A percutaneous bilateral approach

has been typically used to access the vertebral body. Many previous studies have reported excellent clinical results with PKP.^{6,7} In contrast, numerous complications and problems have also been reported, such as puncture difficulty and cement leakage. A recent systematic review indicated that the unilateral approach should be considered.^{8,9} However, some other studies showed that no clinically important differences were found between the unilateral and bilateral PKP.¹⁰⁻¹²

Accordingly, we designed a prospective study to compare clinical and radiographic results following unilateral or bilateral transverse process-pedicle approach in application of PKP.

Methods

Patient

From January 1, 2012 till September 31, 2016, all those MRI-diagnosed single-level lumbar OVCF patients who matched the following criteria were enrolled in this prospective investigation. With consent, these patients were

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randomly classified into the unilateral puncture group or the bilateral puncture group with SPSS software.

The inclusion criteria:

- (1) A single-level OVCF
 - (2) $15\% < \text{collapse} < 80\%$
 - (3) $2 \text{ weeks} < \text{Symptom duration} < 3 \text{ months}$
 - (4) $\text{VAS}^\# > 5$
 - (5) T score of BMD * < -2.5
 - (6) $60 < \text{age} < 80 \text{ years old.}$
- [#] Visual Analogue Scale
* bone mineral density

The exclusion criteria:

- (1) Inability to give informed consent
- (2) Poor general physical state
- (3) Caused by malignant disease
- (4) The pedicles or the back wall of the vertebra was broken
- (5) Associated with spinal stenosis or disc herniation

Surgical techniques

The PKP procedures were performed by the senior author (JZ). Under local anesthesia, the patients were placed in a prone position with C-arm installed for guidance. With a very small incision, working cannulas were inserted into the vertebra via a bipedicular or unipedicular approach. Through the working cannula, a drill was advanced to create a tunnel for the balloon. According to the size of the vertebral body (VB), a 15- or 20-mm-diameter balloon was used. The balloon was inserted into the cancellous bone of the VB and inflated manually with radio-contrast medium at a pressure of 200 psi for 3 minutes. Thereafter the balloons were deflated and removed. The void was filled with PMMA injecting under low pressure. At the end, the working cannulas were removed and the cutaneous entry points was closed with a single suture.

Intraoperatively, thermoluminescent dosimeters (Becquerel & Sievert, Taipei, Taiwan) were placed on the right flank of each patient (proximal to the iliac crest) and the upper sternum of the operator. The thermoluminescent dosimeters remained in place during the entire procedure including the first projection (checking the index level for PKP) and the last projection (after removal of the injection needle). Postoperatively, both the dosimeters were subsequently removed for dose measurements. The data of operation time, bone cement injection and radiation dose were recorded and compared. Patients were discharged at the following morning and followed up.

Outcome measures

The overall pain was evaluated using a visual analogue scale (VAS) from 0 (no pain at the base) to 10 (maximal imaginable pain at the summit). We assessed the patient's health status with the Oswestry Disability

Figure 1 Measurement of kyphotic angle. The kyphotic angle was measured between superior and inferior endplates of the fractured vertebra. In this case, the Kyphotic angle decreased from 11.0 degree preoperatively (A) to 5.6 degree postoperatively (B).

Index (ODI) questionnaire. The questionnaires were completed preoperatively and a week postoperatively as well as follow-up one year. The VAS and ODI were scored by a doctor (LX) who did not involve in the operation and was not allowed to know the patient's group.

Lateral standing radiographs were obtained to measure the vertebral height and kyphotic angle of the vertebral body in all patients (Fig. 1). The posterior height (PH) of caudal healthy vertebra, which was adjacent to OVCF, was measured and transferred as 100% on the radiograph; then, using this scale, the vertebral body anterior height (AH) and PH index of the fractured vertebral body were measured on the same radiograph. The kyphotic angle between superior and inferior endplates of the fractured vertebra was recorded. The images were assessed by a doctor (ND) who did not involve in the operation and was not allowed to know the patient's group.

Statistical analysis

The study included the following variables: age, sex, bone mineral density (BMD) T score, VAS and ODI score, AH, PH, kyphotic angle. Those measurement data were expressed as mean $\pm$ SD, and those enumeration data were expressed as percentage. Data were

Table 1 Clinical summary of patients' data.

Items	Unilateral	Bilateral	P
Age(y)	67.7 $\pm$ 7.4	70.5 $\pm$ 12.8	>0.05
Sex			>0.05
Male	15(35.7%)	17(39.5%)	
Female	27(64.3%)	26(60.5%)	
BMD T score	-3.1 $\pm$ 0.7	-3.2 $\pm$ 0.8	>0.05

BMD, bone mineral density.

Table 2 Comparisons between unilateral and bilateral punctures.

Items	Unilateral	Bilateral	P
Operation time (minute)	25.6 ± 4.2	36.6 ± 8.7	<0.05
Dosage of PMMA injected (ml)	6.2 ± 3.5	8.5 ± 2.2	<0.05
Radiation dose (mSv)			
patients	0.88 ± 0.28	1.89 ± 1.05	<0.05
operator	0.21 ± 0.12	0.24 ± 0.13	>0.05

compared between unilateral or bilateral PKP groups. Differences between groups were statistically analyzed using the *t* test or the χ^2 test depending on different variables with SAS 8.0 Software. The P value less than 0.05 was considered statistically significant.

Results

Demography

Eighty-five patients were finally enrolled in this study, 42 in unilateral group and 43 in bilateral group. For the unilateral group, there were 15 males and 27 females, with a mean age of 67.7 ± 7.4 years old. The mean bone mineral density T score was -3.1 ± 0.7 . For the bilateral group, there were 17 males and 26 females, with a mean age of 70.5 ± 12.8 years old. The mean bone mineral density T score was -3.2 ± 0.8 . In terms of demographic data of patients, there were no significant differences between the two groups (Table 1).

Intraoperative measurement

The operation time, PMMA volume, radiation dose (patients/operator) were 25.6 ± 4.2 minutes, 6.2 ± 3.5 ml and $0.88 \pm 0.28/0.21 \pm 0.12$ mSv in the unilateral group, while 36.6 ± 8.7 minutes, 8.5 ± 2.2 ml and $1.89 \pm 1.05/0.24 \pm 0.13$ mSv in bilateral group, respectively ($P < 0.05$) (Table 2).

Outcomes

For the unilateral group, the mean pain score decreased from 8.7 ± 1.6 preoperatively to 2.7 ± 1.2 postoperatively ($P < 0.01$) and to 2.6 ± 1.1 at the last follow-up

($P < 0.01$); the mean ODI score decreased from 35.2 ± 4.3 to 19.8 ± 6.4 ($P < 0.01$) and to 20.1 ± 3.5 , respectively ($P < 0.01$).

For the bilateral group, the mean pain score decreased from 8.5 ± 1.3 preoperatively to 2.6 ± 1.3 postoperatively ($P < 0.01$) and to 2.7 ± 1.1 at the last follow-up ($P < 0.01$); the mean ODI score decreased from 36.7 ± 3.6 to 19.7 ± 2.6 ($P < 0.01$) and to 19.9 ± 4.4 , respectively ($P < 0.01$) (Table 3).

No statistically significant differences were observed when mean pain scores and ODI score were compared between the groups at all time intervals.

Radiology

For the unilateral group, the AH increased from $50.1 \pm 11.2\%$ preoperatively to $79.2 \pm 12.3\%$ postoperatively ($P < 0.01$) and to $78.5 \pm 13.1\%$ at the last follow-up ($P < 0.01$), while PH increased from $81.5 \pm 14.1\%$ to $89.2 \pm 12.1\%$ ($P < 0.01$) and to $90.1 \pm 11.4\%$ ($P < 0.01$) and the Kyphotic angle decreased from $15.9 \pm 6.5^\circ$ to $9.1 \pm 4.3^\circ$ and to $9.3 \pm 5.5^\circ$, respectively ($P < 0.01$).

For the bilateral group, the AH increased from $48.9 \pm 13.2\%$ preoperatively to $77.2 \pm 11.3\%$ postoperatively ($P < 0.01$) and to $76.5 \pm 11.3\%$ at the last follow-up ($P < 0.01$), while the PH increased from $79.3 \pm 12.3\%$ to $90.2 \pm 15.1\%$ ($P < 0.01$) and to $91.3 \pm 9.4\%$ ($P < 0.01$) and the Kyphotic angle decreased from 16.2 ± 7.1 to 11.8 ± 3.8 and to 11.5 ± 3.5 , respectively ($P < 0.01$) (Table 4).

No statistically significant differences were observed when PH, AH and Kyphotic angle were compared between the groups at all time intervals.

Complications

No neurofunction deficit was observed in this study. Extra vertebral cement leakages were revealed in 3 of 42 (7.1%) in the unilateral group, while in 10 of 43 (23.3%) in the bilateral group ($P < 0.05$). During the follow-up period, 10 patients (11.8%) experienced a new fracture in 11 levels, including 5 patients (11.9%)

Table 3 Outcomes following unilateral/bilateral PKP.

Items	Unilateral			Bilateral		
	Preoperative	Postoperative	Follow-up	Preoperative	Postoperative	Follow-up
VAS	$8.7 \pm 1.6^{a,c}$	$2.7 \pm 1.2^{a,e}$	$2.6 \pm 1.1^{c,f}$	$8.5 \pm 1.3^{b,d}$	$2.6 \pm 1.3^{b,e}$	$2.7 \pm 1.1^{d,f}$
ODI	$35.2 \pm 4.3^{a,c}$	$19.8 \pm 6.4^{a,e}$	$20.1 \pm 3.5^{c,f}$	$36.7 \pm 3.6^{b,d}$	$19.7 \pm 2.6^{b,e}$	$19.9 \pm 4.4^{d,f}$

PKP, percutaneous kyphoplasty; VAS, visual analogue scale; ODI, Oswestry Disability Index.

a, b, c, d: $P < 0.05$; e, f: $P > 0.05$.

For the unilateral group, the outcome was compared between preoperatively and postoperatively (a), preoperatively and the last follow-up (c). For the bilateral group, the outcome was compared between preoperatively and postoperatively (b), preoperatively and the last follow-up (d). The outcome was compared between unilateral and bilateral group postoperatively (e) and the last follow-up (f).

Table 4 Radiography following unilateral/bilateral PKP.

Items	Unilateral			Bilateral		
	Preoperative	Postoperative	Follow-up	Preoperative	Postoperative	Follow-up
AH (%)	50.1 ± 11.2 ^{a,b}	79.2 ± 12.3 ^{a,e}	78.5 ± 13.1 ^{b,f}	48.9 ± 13.2 ^{c,d}	77.2 ± 11.3 ^{c,e}	76.5 ± 11.3 ^{d,f}
PH (%)	81.5 ± 14.1 ^{a,b}	89.2 ± 12.1 ^{a,e}	90.1 ± 11.4 ^{b,f}	79.3 ± 12.3 ^{c,d}	90.2 ± 15.1 ^{c,e}	91.3 ± 9.4 ^{d,f}
Kyphotic angle	15.9 ± 6.5 ^{a,b}	9.1 ± 4.3 ^{a,e}	9.3 ± 5.5 ^{b,f}	16.2 ± 7.1 ^{c,d}	11.8 ± 3.8 ^{c,e}	11.5 ± 3.5 ^{d,f}

AH, anterior height; PH, posterior height.

a, b, c, d: $P < 0.05$; e, f: $P > 0.05$.

For the unilateral group, the radiography was compared between preoperatively and postoperatively (a), preoperatively and the last follow-up (b). For the bilateral group, the outcome was compared between preoperatively and postoperatively (c), preoperatively and the last follow-up (d). The outcome was compared between unilateral and bilateral group postoperatively (e) and the last follow-up (f).

in 6 levels in the unilateral group and 5 patients (11.6%) in 5 levels in the bilateral group. Of these new fractured vertebrae, 1 levels in the unilateral group and 4 levels in the bilateral group were adjacent to the vertebrae previously treated ($P < 0.05$).

Discussion

The purpose for an ideal treatment for osteoporotic vertebral compression fractures is supposed to achieve a lasting improvement in symptoms, durable kyphosis deformity correction and prevention of new fractures.^{13–15} Although the benefits of bilateral percutaneous kyphoplasty regarding pain relief, low rates of cement leakage, and height restoration have been documented, several retrospective studies concluded that a unilateral percutaneous kyphoplasty might provide similar results for clinical and radiographic outcomes as bilateral percutaneous kyphoplasties.^{16–18} However, less prospective study was proceeded to compare clinical

and radiographic results between the unilateral and bilateral PKP.

Our prospective study exhibited that both unilateral and bilateral PKP markedly improved the outcome of patients with OVCF. This was reflected in considerable change in VAS and ODI scores as well as a significant improvement in the AH, PH and Kyphotic angle after treatment. However, no statistically significant differences were observed compared between the two groups at all time intervals. These results support that both unilateral and bilateral PKP were effective methods in the treatment of OVCF.

In our study, the radiation doses to the patient are significantly different between the unilateral and the bilateral groups. However, the doses to the operator were not different statistically. The dosimeter on the operator is mainly exposed to the scatter radiation, while that on the patient is partly exposed to the primary radiation. Therefore, the dose amount on the operator is less than that on the patient.

In this study, the cement leakage in the unilateral level was significantly less than the bilateral level. These complications may be related with the puncture technique. Compared with the bilateral technique, the puncture point of unilateral PKP was more lateral to the facet joint and extraversion angle was larger. Sometimes, the distribution of bone cement in the compressed vertebral body looked similar between the unilateral and bilateral PKPs (Fig. 2).

Figure 2 Bone cement distribution in the compressed vertebral body. In most unilateral puncture cases (A), the bone cement may also diffuse to the other side compared to the bilateral puncture case (B).

Conclusions

Both bilateral and unilateral PKP are relatively safe and provide effective treatment for patients with painful osteoporotic vertebral compression fracture. However, unilateral PKP need less radiation dose, operation time and volume of cement.

Disclaimer statements

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Declaration of interest The authors report no declarations of interest.

Conflicts of interest None.

Ethics approval None.

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