

Study of Unilateral Extrapedicular and Bilateral Pedicle Approach Percutaneous Kyphoplasty for Osteoporotic Vertebral Compression Fracture

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ABSTRACT

Objective: To determine the efficacy and complication of unilateral extrapedicular approach (UEA) and bilateral pedicle approach (BPA) percutaneous kyphoplasty (PKP) in treating thoracolumbar osteoporotic compression fractures.

Study Design: A descriptive study.

Place and Duration of Study: Department of Orthopaedics, Bazhou district people Hospital, Sichuan, China, from December 2016 to March 2021.

Methodology: Patients with single-level thoracolumbar osteoporotic compression fractures, who underwent BPA and UEA PKP, were divided into the UEA (n=47) and BPA group (n=42). Index was recorded including operation duration, bone cement volume, intraoperative X-ray times, complication, visual analogue scale (VAS), Cobb angle, Oswestry dysfunction index (ODI), the recurrence rate of the injured vertebra and adjacent vertebral fractures within 12 months after operation.

Results: There were significant differences in operation duration, bone cement volume, and intraoperative X-ray time between the two groups ($p < 0.05$). VAS, Cobb angle, and ODI significantly improved at 3 days and 12 months after the surgery in each group ($p < 0.05$), but no significant statistical difference was found at each time point between the groups ($p > 0.05$). Bone cement leaked 2 cases in UEA and 8 cases in the BPA group ($p < 0.05$). No pulmonary embolism, neurovascular injury, and infection occurred. No significant difference was found in fracture recurrence rate within 12 months after operation ($p > 0.05$).

Conclusion: Unilateral extrapedicular percutaneous kyphoplasty is an effective and safe way in treating thoracolumbar osteoporotic fractures with relatively less duration of surgery, intraoperative X-ray exposure, bone cement volume, and leakage rate.

Key Words: Thoracolumbar osteoporotic compression fractures, Unilateral extrapedicular approach, Percutaneous kyphoplasty, Bilateral pedicle approach.

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INTRODUCTION

Osteoporosis has a high incidence disease among the elderly, and osteoporotic vertebral compression fracture (OVCF) is its common complication.¹ The thoracolumbar segment (T₁₁-L₂) is more prone to OVCF.² Percutaneous kyphoplasty (PKP) is a common and popular way in treating OVCF.³ Previously, the bilateral pedicle approach (BPA) was commonly used in PKP. Recently, PKP by unilateral approach has been reported for its advantages.⁴ However, the routine unilateral pedicle approach has problems of uneven bone cement distribution, thin pedicle condition, and so on. Therefore, the unilateral extrapedicular approach (UEA) was adopted in clinical application.

The aim of this study was to evaluate the efficacy and complications in treating thoracolumbar OVCF.

METHODOLOGY

This descriptive study was conducted at the Department of Orthopaedics, Bazhou District People Hospital, Sichuan, China, from December 2016 to March 2021. Inclusion criteria were age older than 65 years with bone density less than -2.5, single-segment fracture of the T11-L2 vertebral body with a compression degree less than 75%, without PKP operation contraindication and with any other fracture and history of lumbar surgery, or previous spinal neurovascular injury, preoperative CT scanning should have demonstrated intact posterior wall and pedicle of the injured vertebra, and MRI indicated fresh fracture.

Exclusion criteria were concomitant vertebral injuries; the previous history of lumbar spinal pathology with posterior column fracture, mental illness precluding cooperation with the treatment and postoperative follow-up, patients with the likelihood of severe complications who could not tolerate the surgery or with blood coagulation dysfunction; Vertebrae old fracture

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(more than 3 weeks and STIR sequence of MRI images showing no hyperintensity signal) or with a spinal neurovascular symptom. All participants signed the informed consent form for surgery before the PKP operation. This study was approved by the Hospital Medical Ethics Committee.

In the UEA group, patients were placed with a prone position. The patient's ilium and chest were supported by a soft pillow to suspend the abdomen. The fluoroscopy project tube position was adjusted so that it could be projected on the standard anteroposterior and lateral position of the injured vertebrae. The pedicles of both sides of the injured vertebrae were symmetrically marked with elliptical pedicle shadows on the anteroposterior position, and the endplate of the injured vertebrae with integrity on the lateral position showed a linear shadow. Pedicle shadow and preoperative skin marker (preoperative plan according to horizontal CT) were verified. Ten ml local anesthesia medicine (Lidocaine and saline were diluted in a ratio of 1:1) in a syringe was injected from skin to the pedicle base (Junction of pedicle and vertebrae) with a long needle under fluoroscopy. About a 5-mm incision was made on the skin marker point (entry point). A puncture needle with working sleeve was advanced syringe long needle from the skin to the pedicle base. Once the abduction and inclination angles were right, the puncture needle was advanced to vertebrae under fluoroscopy. When the apex of the puncture needle was 5mm ahead of the vertebrae posterior wall, the puncture needle was removed, and the working sleeve was fixed there. After the balloon was placed, a contrast medium was injected to expand the balloon. The balloon was withdrawn after the satisfactory reduction was performed. Subsequently, bone cement with the appropriate period was injected into the vertebrae. During this procedure, fluoroscopy was used to monitor the cement distribution, and the injection stop immediately once the out leakage happened.

The sleeve was taken out when the bone cement became solidified. The skin incision was closed with a dressing (Figure 1).

In the BEA group position, anesthesia, and fluoroscopy positioning before disinfection were as it was in the early steps of the UEA group. The puncture needle advanced from the skin to the 10 and the 2 o'clock position of the left and right pedicle shadow. Both sides were operated simultaneously including puncture. Balloon application and bone cement injection were the same with the UEA group (Figure 2).

Operation time, bone cement volume, intraoperative X-ray times, complication, bone cement out leakage rate, preoperative and postoperative VAS, ODI, Cobb angle (Upper and lower endplate line of injured vertebrae angle), and recurrence rate of adjacent vertebral fractures within 12 months after operation were observed and compared in both groups.

SPSS 19.0 software was used to analyse the data in this study. Measurement data were shown by mean \pm SD format and compared by t-test. Count data were compared using chi-squared test $p < 0.05$ was considered as statistically significant.



Figure 1: (a) L1 fresh OVCF; (b) Arrow revealed unilateral extrapedicular approach; (c) Postoperative lateral X-ray showed vertebral body reduction; (d) Postoperative CT horizontal view showed bone cement distribution.

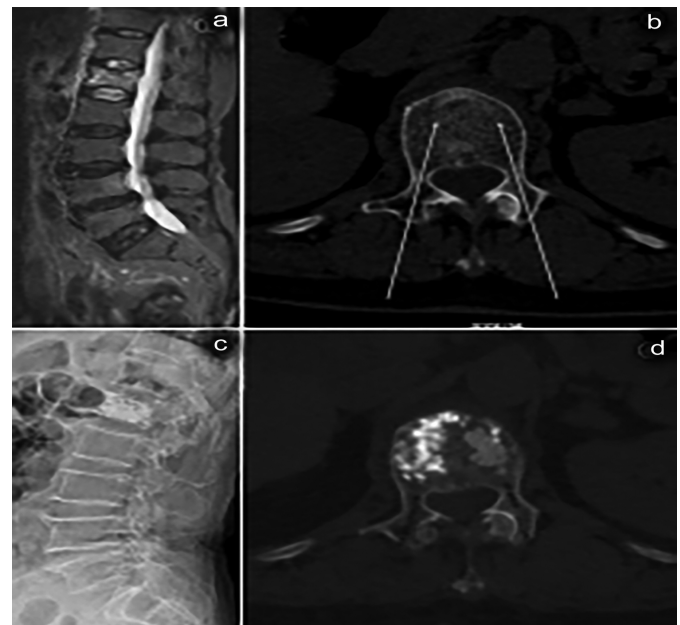


Figure 2: (a) L1 fresh OVCF; (b) Arrow revealed bilateral pedicle approach; (c) Postoperative lateral X-ray showed vertebral body reduction; (d) Postoperative CT horizontal view showed bone cement distribution.

RESULTS

In the UEA group ($n=47$) injured vertebral bodies involved T_{11} in 5, T_{12} in 12 and L_2 in 12 cases each, and L_1 in 18 cases. BPA group ($n=42$) had vertebral bodies involved as T_{11} in 6, L_2 in 9, T_{12} in 12, and L_1 in 15 cases. Bone cement leakage occurred in 2 cases of UEA (4.26%) and 8 cases in the BPA (19.05%) group ($\chi^2=3.284$, $p=0.07$). No segmental artery injury, pulmonary embolism, nerve injury, and infection occurred during and after surgery.

Table I: VAS ODI and Cobb angle improvement in UEA and BEA groups.

| | | UEA group | BPA group | t | p |
|-------------|-------------------------|------------|------------|------|------|
| VAS | Preoperative | 7.06±1.17 | 6.67±0.75 | 1.88 | 0.06 |
| | Postoperative 3 days | 2.96±1.00 | 2.69±0.78 | 1.39 | 0.17 |
| | Postoperative 12 months | 1.36±0.80 | 1.55±0.83 | 1.08 | 0.28 |
| ODI | Preoperative | 70.32±6.64 | 68.69±4.75 | 1.32 | 0.19 |
| | Postoperative 3 days | 25.13±5.49 | 23.57±3.99 | 1.51 | 0.13 |
| | Postoperative 12 months | 22.19±3.16 | 20.86±4.30 | 1.68 | 0.09 |
| Cobb angle° | Preoperative | 35.32±2.21 | 34.64±2.27 | 1.42 | 0.16 |
| | Postoperative 3 days | 20.00±3.18 | 19.17±2.88 | 1.29 | 0.20 |
| | Postoperative 12 months | 20.60±3.09 | 19.50±3.03 | 1.69 | 0.10 |

The mean operation duration was 25.97 ± 9.03 minutes in the UEA group and 30.08 ± 5.21 minutes in the BPA group. The used bone cement volume was 4.19 ± 0.60 ml in the UEA group and 5.94 ± 0.18 ml in the BPA group. The intraoperative number of X-ray was 8.57 ± 1.17 times in the UEA group and 12.00 ± 2.32 times in the BPA group. The differences between unilateral and BPA groups were statistically significant respectively ($t=2.59$, $p=0.01$; $t=9.51$, $p < 0.001$; $t=7.78$, and $p < 0.001$ respectively). VAS scores, ODI, and Cobb angle improvement were shown in Table I. There was no significant difference in the recurrence rate of vertebra refracture between the bilateral (3 cases, 7.14%) and the UEA (4 cases, 8.51%) group in 12 months after surgery ($X^2=0.057$, $p=0.811$).

DISCUSSION

Osteoporosis is the most common bone metabolic disease among the elderly patient. Thoracolumbar OVCF is one of the common complications of osteoporosis.⁵ Percutaneous kyphoplasty (PKP) is a common and popular way of treating OVCF around the world, and it not only has less trauma but also can avoid fixation failure due to osteoporosis.⁶ In the past, bilateral pedicle approach PKP was the common application. Recently, the unilateral approach (especially for UEA) has obtained the concerns. This retrospective comparative analysis between BPA and UEA PKP methods was carried out in the authors' department to evaluate the efficacy. In this study, the VAS and ODI significantly improved in both group after the operation, but there were no significant differences about VAS and ODI between both groups after surgery, which revealed that UEA and BPA PKP could effectively reduce pain and improve function. The bilateral pedicle approach could almost symmetrically provide cement distribution in the vertebrae but increase surgical cost, duration of surgery and radiation exposure.⁷

The routine unilateral pedicle approach PKP could overcome the above shortcomings, but its refracture rate because of bone cement one side distribution receives concern.⁸ In this study, the refracture rate has been improved when UEA was adopted for its improved puncture approach.

The amount of injected bone cement and the recurring fracture of the vertebrae (including adjacent vertebrae) are two important care aspects after PKP.⁹ Positive correlation was reported between the injected bone cement volume and

leakage rate.¹⁰ In this study, the bone cement leakage rate is higher in the BPA (19.05%) group ($p \leq 0.05$). Additionally, an over amount of bone cement filling could increase the leakage rate.¹¹ The bone cement and vertebrae volume ideal ratio was 0.24, which was about 4ml in the thoracolumbar region.¹² In this study, the average volume of bone cement in the UEA group was 4.19 ± 0.60 ml, which was significantly lower than 5.94 ± 0.18 ml in the BPA group. There was no statistical difference in VAS and ODI at different time points between the groups after surgery. It suggested that even a corresponding less amount of bone cement could also achieve the pain relief and lumbar function improvement as that of the BPA group. The routine unilateral pedicle approach PKP injected bone cement with uneven distribution for the limited abduction angle, which could significantly increase the possibility of re-fracture.¹³ In this study, the tabduction angle of the puncture needle was appropriately increased during UEA, which was beneficial to the bone cement distribution. During the follow-up period, no statistically different of incidence of re-fracture (the operative and adjacent vertebrae) was found in the UEA group as compared with that in the BPA group (8.51% vs. 7.14%, $p > 0.05$).

Prevention of re-fracture is a vital concept for PKP surgery.¹⁴ The restoration and maintenance of Cobb angle of vertebrae is of clinical significance for spinal mechanical recovery in the long-term.¹⁵

This study showed that UEA was similar to BPA in terms of recovery and maintenance of Cobb's angle. Satisfied reduction and spinal stress distribution could decrease the possibility of the re-fracture from the injured and adjacent vertebra. Additionally, the elastic modulus improvement of injury vertebrae was noticed after PKP surgery for decades.¹⁶ Some scholars focused on the biological bone cement. In the authors' opinion, relative less bone cement filled in the injured vertebra can provide more capacity for osteoporotic vertebral bone recovery under subsequent reasonable anti-osteoporosis treatment. In this study, the recurrence rate of vertebra refracture revealed no significant difference between the two groups (4 cases in UEA and 3 cases in the BPA group $p \leq 0.05$) in 12 months after surgery.

CONCLUSION

UEA PKP had the similar efficacy as BPA. No significant differ-

ence was found between these two ways in the recovery of injured vertebrae Cobb angle and the refracture rate after the operation. UEA PKP was characterised by less operation duration, intraoperative radiation exposure and amount of bone cement injection, and leakage rate. UEA is a safe and effective minimally invasive method for OVCF.

ETHICAL APPROVAL:

The study was approved by the Research Ethics Committee of Medical Service of Bazhou District People Hospital (Decision date: 1/12/2016, Decision No.BZHRECTCM20161201).

PATIENTS' CONSENT:

The authors have obtained patients' consent to publish the data concerning this study. Patients understand that efforts will be made to conceal their identity.

COMPETING INTEREST:

The authors declared no competing interest.

AUTHORS' CONTRIBUTION:

YT, SY, CZ: All authors contributed to the study conception and design. Performed material preparation, data collection, and analyses were performed.

XL: Performed operations.

HH: Designed the surgery plan and wrote the manuscript.

All authors read and approved the final version of the manuscript.

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