

# Percutaneous Curved Kyphoplasty in the Treatment of Thoracolumbar Osteoporotic Vertebral Compression Fractures: A Randomized Controlled Trial

**Chen Wang**

Nanjing Medical University

**Yu Zhang**

Xuzhou Medical College Affiliated Hospital

**Wang Chen**

Xuzhou Medical College Affiliated Hospital

**Shi-Lei Yan**

Xuzhou Medical College Affiliated Hospital

**Kai-Jin Guo**

Nanjing Medical University

**Shuo Feng** (✉ [xzfs0561@163.com](mailto:xzfs0561@163.com))

Affiliated Hospital of Xuzhou Medical University

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## Research article

**Keywords:** Osteoporosis, thoracic and lumbar vertebral pathological compression fracture, percutaneous curved kyphoplasty, minimally invasive surgery

**Posted Date:** February 23rd, 2021

**DOI:** <https://doi.org/10.21203/rs.3.rs-257606/v1>

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# Abstract

**Background** To evaluate the clinical efficacy of percutaneous curved kyphoplasty (PCKP) in treating thoracic and lumbar osteoporotic vertebral compression fractures (OVCFs).

**Methods** Seventy-two patients with single-level thoracolumbar OVCFs were recruited and randomly divided into two treatment groups: percutaneous curved kyphoplasty (PCKP), bilateral percutaneous kyphoplasty (PKP). Bone cement dispersion in the fractured vertebrae was observed. Surgery duration, X-ray frequency, bone cement injection volume, bone cement leakage rate, Oswestry disability index questionnaire (ODI) visual analogue scale (VAS) scores, Cobb angle, and vertebral height were recorded.

**Results** Both groups of patients at postoperative 24h and 6 months in postoperative VAS score and ODI were compared with preoperative significant improvement, but no statistical difference between two groups; The operative time, intraoperative fluoroscopy times, intraoperative bone cement injection amount and intraoperative bone cement leakage in the PCKP group were significantly less than those in the traditional PKP group, and the differences were statistically significant. The anterior edge height and Cobb angle of the injured vertebra were significantly improved after operation in both groups, but the differences between the two groups were not statistically significant.

**Conclusion** PCKP has the same short-term effect as traditional bilateral PKP in the treatment of elderly osteoporotic compression fractures, both of which can significantly relieve pain and improve life function. However, PCKP is associated with reduced trauma, less complicated surgery with shorter duration, fewer X-rays, lower complication rate, and quicker postoperative recovery versus traditional bilateral PKP.

**Trial registration:** ChiCTR, ChiCTR2100042859. Registered 25 January 2021- Retrospectively registered, [http://www.chictr.org.cn/ ChiCTR2100042859](http://www.chictr.org.cn/ChiCTR2100042859)

## 1. Background

Thoracolumbar osteoporotic vertebral compression fracture (OVCF) is a common disease in elderly patients that often involves multiple fractures, and can be managed by conservative or surgical treatment. The conservative treatment with long bed time and more complications is difficult to achieve satisfactory clinical efficacy, which limits its application in clinical practice. Surgical treatment yields significantly higher clinical efficacy than conservative treatment, and has been widely applied by surgeons in the treatment of OVCF[1].

Percutaneous kyphoplasty (PKP) is a representative surgical procedure that is widely used in the clinical management of OVCF, due to the advantages of minimal invasiveness and high clinical efficacy. In practical applications, however, PKP surgical instruments are still deficient in the process of use. For example, during unilateral puncture and injection of bone cement, the bone cement cannot evenly fill the

entire vertebral body, resulting in uneven stress on the vertebral body and prone to secondary fractures [2]. In order to ensure even distribution of bone cement in the entire vertebra, the internal inclination angle during puncture can be increased can be performed, but may increase the risk of bone cement leakage, spinal cord injury. During bilateral puncture and injection of bone cement, both the operation time and the operator's radiation exposure time were prolonged, the incidence of complications in the puncture part of the patient was increased, and the "binocular" phenomenon occurred when the bone cement injected from both sides could not fuse[3]. Due to these deficiencies and challenges, a novel surgical technique known as percutaneous curved kyphoplasty (PCKP) has been introduced and applied by surgeons, which not only leads to uniform distribution of bone cement throughout the vertebral body, but also has little effect on the puncture angle[4]. Since January 2019, PCKP has been used to treat OVCF at Affiliated Hospital of Xuzhou Medical University, with the aim of reducing percutaneous puncture-related adverse events.

## **2. Methods**

### **1. Study Design**

A prospective, controlled study included researchers who analyzed patient data and were trained in study methods but did not know the patient population. This study was conducted in our orthopedic departments from January 2019 to January 2020. This study was approved by the ethics Committee of the hospital, and its design conforms to the Regulations on the Management of Medical Institutions. This trial is registered at ClinicalTrials.gov, number ChiCTR2100042859. CONSORT Flow Diagram is provided in Fig. 1.

### **2. Inclusion And Exclusion Criteria**

The inclusion criteria for this study were patients with osteoporotic vertebral compression fracture who were able to tolerate surgery and cooperate with postoperative functional exercise in our hospital from January 2019 to January 2020. Patients in the study were informed of treatment plans and surgical risks and signed informed consent forms. (1) Patients aged > 65 years, without limitation to men or women; (2) Painful osteoporotic vertebral compression fracture; (3) Sign the informed consent of the trial.

The exclusion criteria were (1) Vertebra tuberculosis and bacterial infection; (2) Bleeding and clotting dysfunction that cannot be corrected or has bleeding tendency; (3) Extensive and largely incomplete vertebral posterior margin bone destruction; (4) The compression degree of vertebral body exceeds 70%; (5) Two or more vertebral bodies compression fractures. (6) Participate in other drug or medical device clinical trials within 30 days prior to screening; (7) The researcher judged that the patient had poor compliance and could not complete the study as required.

### **3. Patient randomization**

The study included 72 patients, 22 males and 50 females, aged 66–87 years (average, 76.04 years). Preoperative routine examination, including blood routine, coagulation routine, lower limb color Doppler ultrasonography. At the time of admission, all patients were numbered consecutively according to 1–72 cases. The patients were randomly divided into study group (n = 36) and control group (n = 36) for parallel randomization using random distribution software. The selection process of patients in the two groups is shown in Fig. 1.

## 4. Surgical procedures

PCKP (Percutaneous curved kyphoplasty) group:

Percutaneous curved kyphoplasty puncture needle and bone cement high pressure perfusion instrument (Ningbo Huarun Biotechnology Co., LTD., China), acrylic resin bone cement (StrykerInstruments, France). (Fig. 2)

With patients in a prone position, preoperative C-arm X-ray, MRI and alternative auxiliary examinations were used to determine the diseased vertebral body, label the body surface markings and determine the needle sites. The left-side puncture was performed at the 10 o'clock position and the right-side puncture at the 2 o'clock position, under topical anaesthesia using 0.5 ml of 2% lidocaine. Using C-arm X-ray, a puncture needle was inserted from the unilateral pedicle to approximately 5 mm of the posterior edge of the diseased vertebrae. The position and depth of the puncture needle were adjusted according to the C arm X-ray, After the puncture needle core was pulled out, the curved catheter was placed into the vertebra along the straight cannula. The anteroposterior fluoroscopy showed that the end of the curved catheter crossed the midline of the vertebra to reach the opposite side, and the lateral fluoroscopy reached the 1/3 of the anterior middle vertebra. The working channel at the bending angle of the vertebral body was established. The vacuum-extracted vertebral dilatation balloon catheter was inserted into the vertebral body through the working channel. When the proximal black mark entered the puncture channel, the balloon had completely entered the vertebral body, then expands the balloon and the expected position of the vertebral body was observed through fluoroscopy. The bone cement was mixed evenly and injected into the established expansion channel through the injection delivery system. The bone cement was slowly infused until it reached the posterior edge of the vertebrae. C-arm X-ray was used to observe the bone cement distribution. Once the bone cement had hardened, the cannula was rotated clockwise to separate the bone cement within the cannula lumen from the intra-vertebral bone cement, in order to prevent the tailing phenomenon, and then the trocar was removed (Fig. 3).

PKP (Percutaneous kyphoplasty) group:

PKP was treated with bilateral approach, PKP apparatus and bone cement (Kyphon Corporation, USA);Preoperative localization, disinfection and anesthesia are the same as before, C-arm fluoroscopy guided down the simultaneous puncture approach of bilateral pedicles, and successively placed the expanded trocar, fine drill and expandable balloon at the collapsed position in front of the vertebral body.

After the balloon dilatation was satisfied, bone cement was prepared and injected into the diseased vertebral body at the wire-drawing stage. The injection was stopped when the bone cement was found to be filled satisfactorily, distributed to the edge of the vertebral body or spilled out of the vertebral body under fluoroscopy.

## 5. Clinical And Radiographic Assessment

The duration of surgery, C-arm X-ray frequency, bone cement injection volume, bone cement leakage rate, anterior edge height of injured vertebra before and after surgery and kyphosis Cobb Angle of vertebra were recorded in all patients. The visual analogue scale (VAS) and functional disturbance index (Oswestry disability index, ODI) was assessment record before surgery and at 24h and 6 months following surgery, in order to make clear the clinical curative effect of surgery.

## 6. Statistical Analysis

The analysis and production of data and charts were processed by IBM SPSS Statistics 19.0 statistical software (IBM, Chicago, USA) and GraphPad Prism6.0 (GraphPad Software, San Diego, USA). Continuous variables were analyzed using Wilcoxon rank-sum tests. Categorical variables were analyzed using the Pearson chi-square or Fisher exact tests. Test level was set at both sides  $\alpha = 0.05$ ,  $P < 0.05$  was considered statistically significant.

## 3. Result

### 1. Basic conditions of surgery

The operative time and intraoperative fluoroscopy times of the PCKP group were significantly lower than those of the traditional PKP group, and the differences were statistically significant ( $P < 0.05$ , Table 1); In addition, intraoperative bone cement leakage was different between the two groups, although there was no statistical difference, including 3 cases in PCKP group (1 cases in intervertebral space, 1 case in lateral position of the diseased vertebrae, and 1 cases in anterior position of the diseased vertebrae), and 8 cases in PKP group (3 cases in intervertebral space, 1 cases in paravertebral segment intravascular, 2 cases in lateral position of the diseased vertebrae, and 2 cases in anterior position of the diseased vertebrae). Among the 72 cases, there were no serious complications such as pulmonary embolism, spinal canal stenosis, spinal cord compression, nerve injury during and after operation.

### 2. Perfusion, leakage and distribution of bone cement

In the PCKP group, bone cement was injected from a single perfusion point, and the average perfusion amount was  $(3.84 \pm 0.55)$  ml. However, after bilateral balloon dilation in the vertebral body, the space to accommodate cement was significantly increased in the traditional PKP group. Therefore, the traditional PKP group had a higher bone cement perfusion amount, with an average perfusion amount of

(4.78±0.67) ml, compared with the PCKP group, and the difference was statistically significant ( $P \leq 0.05$ , Table 1). In the traditional PKP group, there were only 1 cases of paravertebral segment intravascular leakage, with a small amount, and no distant intravascular leakage. Bone cement leakage occurred in the PCKP group in the paravertebral body, without vascular leakage. Unilateral puncture was used in the PCKP group. When the puncture needle reached the ideal position in the vertebral body, bone cement could be dispersed in the anterior and middle part of the vertebral body (Figure 3), while the bone cement injected by traditional PKP after bilateral balloon dilation was mainly distributed in both sides of the vertebral body.

### 3. Radiographic Results

The anterior height of vertebral body in PCKP group and traditional PKP group was (21.93±4.05) mm and (20.95±3.34) mm before operation, which were increased by 2.79mm and 3.01mm respectively compared with (24.72±3.47) mm and (23.96±3.36) mm after operation. (Figure 4) The difference of postoperative height in PCKP group was statistically significant compared with that before operation ( $P \leq 0.05$ ), However, there was no statistically significant difference in the height of anterior vertebral body between the two groups before and after surgery ( $P \leq 0.05$ , Table 2).

Cobb angles of kyphosis of diseased vertebrae in PCKP group and traditional PKP group were 16.44° ±9.06° and 18.01°±12.00° before operation, and 10.76°±10.10° and 12.35°±13.53° after operation, respectively. Cobb angles were corrected after operation, and decreased by 5.68° and 6.01° respectively compared with those before operation. The difference of postoperative Cobb angles in PCKP group was statistically significant compared with that before operation ( $P \leq 0.05$ ). There was no significant difference in Cobb angle between the two groups before and after operation ( $P \leq 0.05$ , Table 2).

### 4. Clinical Results

The VAS score and ODI of PCKP group and traditional PKP group were significantly improved 1 day after operation, and the difference was statistically significant ( $P \leq 0.05$ ). At the last follow-up, the VAS score and ODI of PCKP group and traditional PKP group were also significantly improved compared with that of 1 day after operation, and the differences were statistically significant ( $P \leq 0.05$ ). However, there was no significant difference in VAS score and ODI before operation, 1 day after operation and the last follow-up between PCKP group and traditional PKP group (Table 2)

### 5. Postoperative complications

In this study, a small amount of bone cement leakage occurred in some patients during surgery. There were 3 patients in PCKP group (1 case in intervertebral space, 1 case in lateral position of the diseased vertebrae, and 1 case in posterior position of the diseased vertebrae, total leakage rate 8.3% (Figure 5), and 8 patients in traditional PKP group (3 cases in intervertebral space, 1 cases in paravertebral segment intravascular, 2 cases in lateral position of the diseased vertebrae, and 2 cases in anterior position of the diseased vertebrae, total leakage rate 22.2%). Most of the bone cement leakage was characterized by

leakage along the fracture line, while 1 case in the traditional PKP group had paravertebral segment intravascular leakage, because the bone cement did not enter the drawing stage and was injected prematurely. (Table 3)

In this study, during the intraoperative perfusion bone cement stage, all cases using X-ray real-time dynamic monitor the bone cement dispersion situation. The perfusion was stopped in time when vertebra leakage of bone cement was observed. If too little bone cement perfusion measure still could not reach the requirements of strengthening vertebral bodies. The perfusion should be continued after the injected bone cement has blocked the leakage path, or the perfusion should be continued after the depth or direction of the perfusion needle is adjusted. Intraoperative real-time X-ray fluoroscopy monitoring can reduce the amount of bone cement leakage, thus avoiding pulmonary embolism, spinal canal stenosis, spinal cord compression, nerve injury and other serious complications.

## 4. Discussions

Osteoporotic fracture of vertebral body is very common in the elderly, and traditional treatment requires long-term bed rest, fixation and drug treatment. Due to reduced activity, osteoporosis is further aggravated in patients, and then fractures occur repeatedly. And long-term bed prone to bed sore, deep venous thrombosis and other complications[5]. Osteoporotic fracture of vertebral body seriously affects the quality of life of the elderly and threatens their physical and mental health. Therefore, pain relief, early activity and spinal stabilization are the key points in the treatment of thoracolumbar osteoporotic compression fractures[6]. Percutaneous kyphoplasty(PKP) can reconstruct of vertebral body height, increase the stiffness of vertebral bodies, immediately stabilize vertebral body, quickly relieve back pain, make the elderly patients with early bed, reduce the complications in bed, improve cardiopulmonary function, improve the quality of life of elderly patients, is currently the treatment of vertebral osteoporotic compression fractures[1, 7].

In recent years, many scholars have proposed unilateral pedicle puncture PKP[3, 4, 8, 9]. Compared with bilateral vertebroplasty, unilateral vertebroplasty has advantages such as less trauma, shorter operation time, shorter X-ray exposure time and lower operation cost[2]. In clinical application, unilateral puncture PKP can save operation time and reduce the complications of bilateral puncture[8]. However, it may cause uneven distribution of bone cement on both sides of the vertebral body. And eventually result in wedge formation of the non-punctured vertebral body. But the idea remains controversial[10-13]. Therefore, in recent years, more and more attention has been paid to the comparative study on the filling effect of single and double piercing cement[14-17].

Unilateral approach has obvious advantages in operation time, radiation exposure, device cost and other aspects[4], but it is easy to cause uneven distribution of bone cement in the responsible vertebra. In addition, in order to improve the filling effect of bone cement and avoid lateral distribution. It is often necessary to increase the Angle of puncture needle extension, thus leading to the penetration of the inner wall of the vertebral pedicle and the increased risk of spinal cord injury and nerve root injury. Bilateral

approach does not need to increase the Angle of puncture abduction, but because it is a bilateral surgical operation, the operation time and puncture risk also increase accordingly. At the same time, some studies[2, 18] have shown that unilateral percutaneous vertebroplasty for osteoporotic vertebral compression fracture can achieve the same clinical effect as the traditional bilateral approach by grasping the intraoperative insertion Angle and using the method of multiple pushing and pushing while backing.

The advantages of unilateral bending vertebra plasty is that it does not need to overemphasize the inclination angle, but only needs to master the basic technique of transpedicle puncture to achieve the symmetry and even distribution of bone cement, ensure the continuity of bone cement distribution in the midline area, and provide stronger sagittal plane stress to support spinal injuries[4]. Compared with the traditional direct unilateral approach, which uses "single point and single time" perfusion, the angle type of bone cement injection can not only ensure the uniform distribution of bone cement, but also reduce the injection pressure of bone cement, thus helping to reduce the leakage rate of bone cement. The unilateral puncture of bending angle PKP can obtain the uniform distribution of bone cement on both sides, achieving a similar effect to the bilateral puncture. Meanwhile, in terms of operation time, puncture risk and X-ray exposure, PCKP also has the advantages of unilateral approach.

At present, the results and viewpoints of the comparative mechanical experiments of single and double piercing cement are not uniform. Tohmeh et al.[12] and Steinmann et al.[13], through in vitro mechanical experiments, found that both unilateral PVP and PKP were effective in reconstructing the stiffness and strength of injured vertebrae. There was no significant difference compared with bilateral puncture. Kim et al. [19] believed that PVP of unilateral puncture was not as effective as bilateral puncture in restoring vertebral stability. The reason lies in the unbalance of the piercing cement filling and the possible mechanical deflection. It has been reported[3]that when unilateral pedicle puncture PKP was performed, bone cement filling limited to the semi-vertebral body could basically restore the axial compression strength of the vertebral body. But under the lateral pressure load, the stiffness of the non-puncture side was significantly lower than that of the puncture side. When the bone cement filling crosses the midline, the stiffness of both sides of the vertebral body can be more evenly enhanced, so as to achieve the balanced enhancement of the vertebral physicochemical performance and reduce the risk of postoperative vertebral physicochemical deflection and wedge fractures on the non-puncture side[20]. In this study, unilateral Angle puncture was used for PCKP. When the puncture needle reached the ideal position in the vertebral body, the balloon expanded, and bone cement dispersed in the front and middle of the vertebral body, which was significantly different from that of PKP after bilateral balloon expansion, which the bone cement was mainly distributed in both sides of the vertebral body. Osteoporotic vertebral compression fractures were mainly at the collapse of the anterior, middle and endplate of the vertebral body. The amount of bone cement in poured into the PCKP group was less than that of the traditional PKP group, but the bone cement in the anterior and middle of the vertebral body was more in line with the biomechanics of the fractured vertebral body.

Bone cement leakage is a serious complication of vertebroplasty. Previous studies[7, 21] have suggested that the fracture of the perivertebral wall or endplate, the pressure of bone cement perfusion and the amount of bone cement perfusion are the main causes of bone cement leakage. Through this study, the author believes that the injection direction of bone cement is also one of the influencing factors of bone cement leakage. Conventional PKP is required to correct kyphotic deformity of the injured vertebra by injecting bone cement at the point where the puncture needle tip reaches 1/3 of the front of the vertebra. At this point, when the puncture needle is injected with bone cement toward the anterior edge of the vertebra, leakage in front and side of the bone cement is likely to occur. However, in this study, when the elbow cannula entered the front 1/3 of the vertebral body, the distal end of the cannula was toward the rear side, so the bone cement injection space was large and the bone cement injection pressure was low, which was not easy to cause leakage. Bone cement leakage occurred in only 3 of the 36 vertebral bodies in this group (8.3%), far lower than that reported in previous literature (about 14.6%)[7].

There are several limitations to our study. The results of this study may be limited by the relatively short follow-up time (6 months), the relatively small number of included study populations, and single-center studies. Therefore, the conclusions drawn from this study remain to be validated by larger prospective randomized controlled clinical trials and longer-term follow-up.

## 5. Conclusion

In conclusion, PCKP has the same short-term effect as traditional bilateral PKP in the treatment of senile osteoporotic compression fractures, both of which can obtain satisfactory clinical efficacy, significantly relieve pain and improve life function. However, compared with traditional bilateral PKP, PCKP is simple in operation, short in operation time, fewer X-rays, low in bone cement leakage rate, and can significantly reduce the surgical cost, which is worthy of wide clinical application.

## Abbreviations

PKP  
Percutaneous kyphoplasty; PCKP:Percutaneous curved kyphoplasty; OVCFs:Osteoporotic vertebral compression fractures;ODI:Oswestry disability index questionnaire □VAS□Visual analogue scale□

## Declarations

### Ethics approval and consent to participate

This study was approved by the Ethics Committee of the Affiliated Hospital of Xuzhou Medical University and conducted in accordance with the standards of the National Research Council. Written informed consent was obtained from all participants.

### Consent for publication

Not applicable.

### **Availability of data and materials**

We do not wish to share our data due to individual privacy, and according to the policy of our hospital, the data should not be shared to others without permission.

### **Competing interests**

The authors declare that they have no competing interests.

### **Funding**

The author(s) received no financial support for the research, authorship, and/or publication of this article.

### **Authors' contributions**

CW and YZ did the study, analyzed the data, and wrote the manuscript. WC, SLY, KJG, SF were involved in the design, data management, and analysis of the study. KJG, SF were involved in the study design, and data analysis. All authors read and approved the final manuscript.

### **Acknowledgements**

We would like to acknowledge the helpful comments on this paper received from our reviewers.

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# Tables

**Table 1 Comparison of basic data between the two groups**

classification	PCKP group	PKP group	P values
Number (n)	36	36	
Gender (male/female)	10/26	12/24	0.609
Age (years)	75.55±6.11	76.52±6.24	0.506
BMI (kg/m <sup>2</sup> )	22.99±2.06	23.19±1.97	0.674
BMD	2.55±0.65	2.62±0.78	0.449
operative time (min)	39.30± 7.87	48.19±9.00	0.000
X-ray frequency (n)	19.97±4.70	29.66±5.98	0.000
Infusion volume (ml)	3.84±0.55	4.78±0.67	0.000
Cement leakage (n)	3	8	0.101

**Table 2 Comparison of pain and functional efficacy between the two groups**

classification	PCKP group	PKP group	P values
<b>VAS score (score)</b>			
Pre-surgery	7.58±1.30	7.39±0.96	0.473
24h post-surgery	2.11±0.57	2.00±0.58	0.419
6-months post-surgery	1.33±0.47	1.27±0.45	0.615
<b>ODI</b>			
Pre-surgery	70.75±10.02	72.63±9.35	0.411
24h post-surgery	34.27±7.06	35.88±7.45	0.350
6-months post-surgery	23.52±4.45	23.97±4.43	0.672
<b>Anterior height of diseased vertebrae [mm]</b>			
Pre-surgery	21.93±4.05	20.95±3.34	0.268
24h post-surgery	24.72±3.47	23.96±3.36	0.353
6-months post-surgery	24.50±3.42	23.67±3.18	0.290
<b>Cobb angles [°]</b>			
Pre-surgery	16.44±9.06	18.01±12.00	0.532
24h post-surgery	10.76±10.10	12.35±13.53	0.576
6-months post-surgery	10.91±10.05	12.51±13.45	0.571

**Table 3 Comparison of postoperative adverse events between the two groups**

Classification	PCKP group	PKP group	P values
<b>Bone cement leakage</b>	3	8	0.101
Intervertebral space	1	3	
Lateral position of vertebrae	1	2	
Anterior position of vertebrae	0	2	
Posterior position of vertebrae	1	0	
Paravertebral segment intravascular	0	1	

# Figures

CONSORT 2010 Flow Diagram

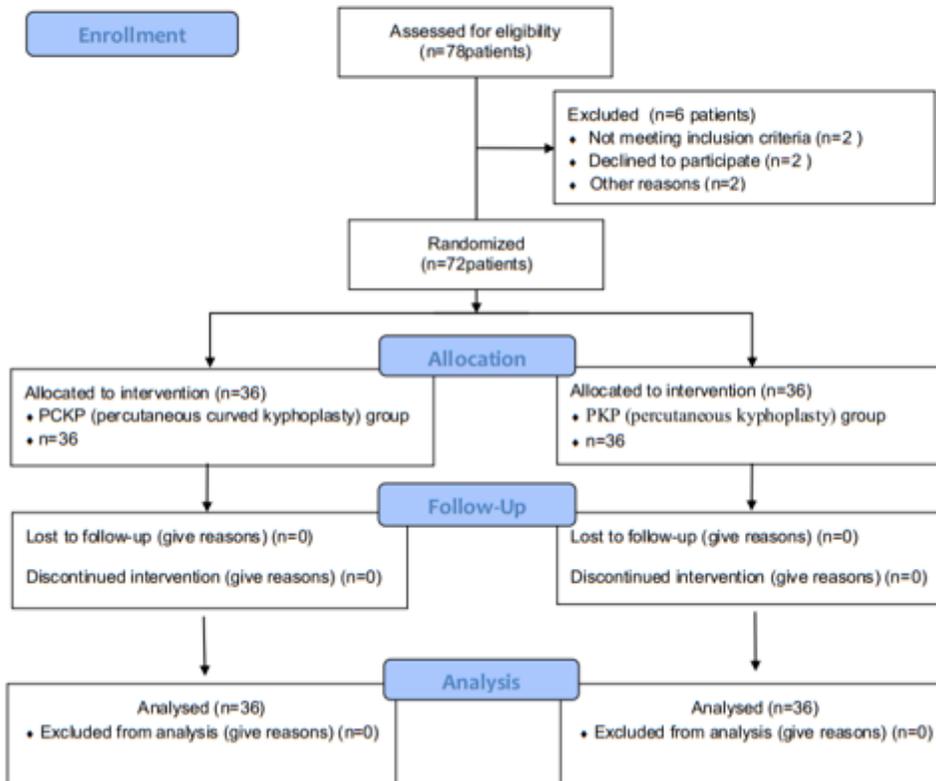
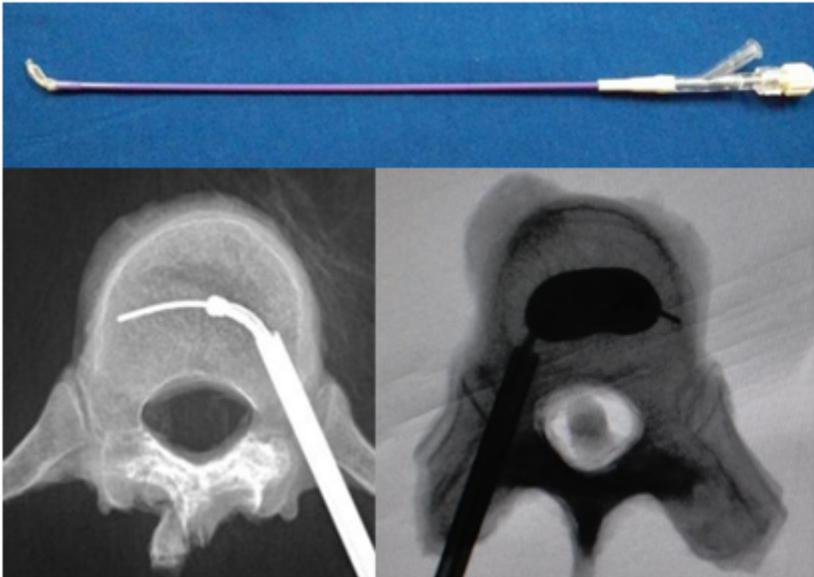


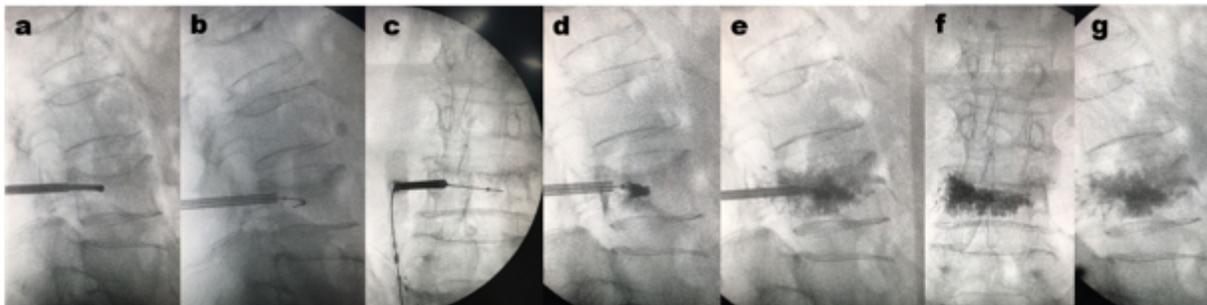
Figure 1

Flow chart of the analysis. After exclusions, a total of 72 patients were followed up.



**Figure 2**

Percutaneous curved kyphoplasty puncture needle (Ningbo Huarun Biotechnology Co., LTD., China)



**Figure 3**

Representative intraoperative fluoroscopy imaging data obtained during percutaneous curved vertebroplasty.

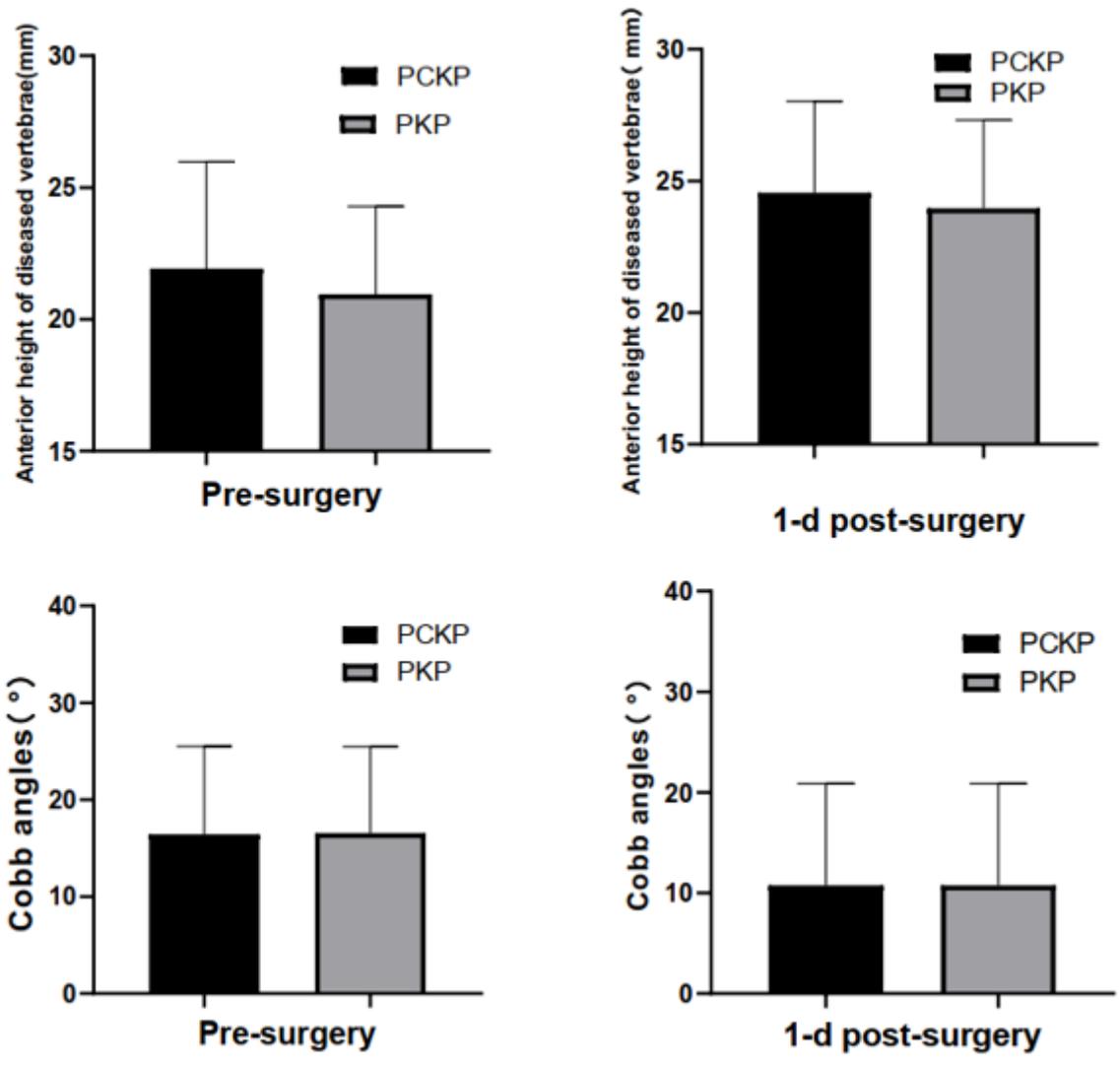
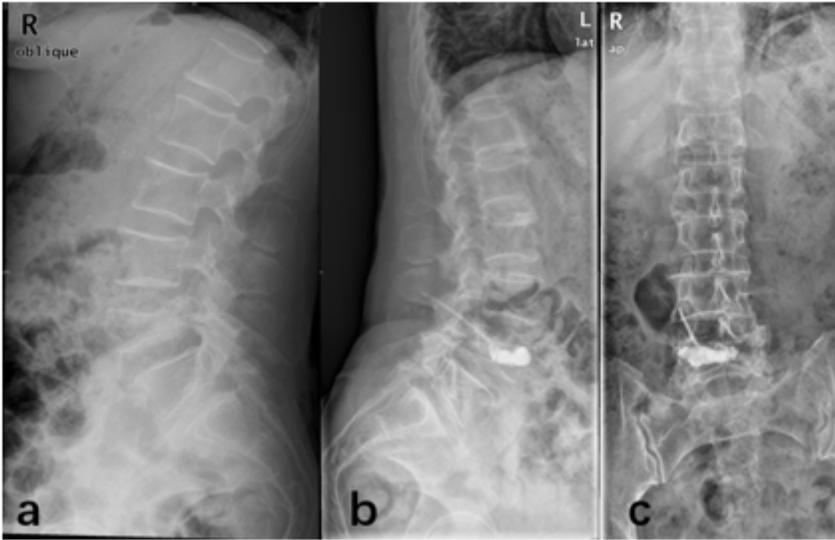


Figure 4

Comparison of the preoperative and postoperative anterior height of diseased vertebrae and Cobb angles between the two groups.



**Figure 5**

Postoperative bone cement leakage occurred in PCKP group, the patient had no symptoms.

## Supplementary Files

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- [CONSORT2010Checklist.doc](#)