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Clinical efficacy of modified percutaneous kyphoplasty (PKP) *vs.* conventional PKP for osteoporotic vertebral compression fractures: a single-center retrospective study

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Abstract. – OBJECTIVE: To investigate the clinical efficacy of using a standardized modified percutaneous kyphoplasty (transverse process-pedicle approach to percutaneous kyphoplasty, TPKP) approach for the treatment of osteoporotic vertebral compression fractures (OVCFs) and to explore the possibility that it may become the preferred option in the future.

PATIENTS AND METHODS: A retrospective analysis was conducted on a total of 81 patients (TPKP group, 43 cases; PKP group, 38 cases) with OVCFs who underwent TPKP and PKP at the Department of Spine Surgery, Wuhan Fourth Hospital, from May 2021 to October 2021. We evaluated the patients' demographic information, intraoperative data (volume of cement injection and, duration of surgery), clinical outcomes at different time points (Visual Analog Scale, Oswestry Dysfunction Index), and radiographic data (Cobb angle, anterior vertebral body height). Statistical analysis was performed to assess the efficacy of the procedure, both within and between the two groups before and after surgery.

RESULTS: The difference in preoperative general information between the two groups of patients was non-statistically significant (p>0.05), and they were comparable. Additionally, no statistically significant difference (p>0.05) was found between the TPKP and PKP groups in terms of operative time, length of hospital stay, recovery of injured spine height, Cobb angle, and cement leakage rate. However, significant statistical differences (p<0.05) were noted between the two groups regarding cement volume, distribution pattern, 1-day postoperative VAS scores, 1-day postoperative ODI scores, and loss of height of the injured spine. TPKP demonstrated superior performance compared to PKP in these specific areas.

CONCLUSIONS: TPKP offers the same surgical safety as the conventional approach, with better cement distribution and better pain relief, as well as the advantage of maintaining the height of the operated vertebral body. The technique is easy to master and use when guided by standard puncture procedures.

Key Words:
Modified percutaneous kyphoplasty, Transverse process-pedicle approach, Osteoporotic vertebral compression fractures, Clinical outcome.

Introduction

Worldwide, the number of people over 60 has doubled since 1980, signaling the beginning of an aging society. By 2050, 22% of the world's population, or 5%, will be over the age of 60, according to estimates[1,2]. Aging-related disorders of the skeletal and muscular systems are the most prevalent of these[3]. Osteoporosis is frequently closely associated with these disorders and now affects more than 20 billion patients worldwide[4,5]. A common side effect of osteoporosis is osteoporotic vertebral compression fractures (OVCFs). The prevalence of osteoporosis in China is similar to that in Western countries[6,7]. Approximately 750,000 OVCFs are reported annually in the United States, according to the National Osteoporosis Foundation.

Percutaneous kyphoplasty (PKP) is currently a common surgical option for treating such fractures. It can effectively alleviate pain, improve patients' quality of life, and quickly maintain the strength of the injured vertebral body[8-10]. Unilateral and bilateral punctures are the most common types. Although bilateral puncture improves diffusion, it necessitates a longer operating time,

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more X-ray exposure, and more money spent at the hospital[11,12]. Although the unilateral approach is shorter and less expensive, the distribution of the injected cement must cross the midline of the vertebral body in order to achieve postoperative biomechanical equilibrium[13,14]. The first third of the vertebral body in the midline is the ideal target point for the unilateral approach[15]. The greater external deflection angle frequently causes the internal arch wall to break, causing damage to the nerve roots and bone cement to leak into the spinal canal. As a result, we set out to discover a more cost-effective surgical option that would combine the advantages of unilateral and bilateral PKP procedures.

It has been shown through several studies[16,17] on anatomy and imaging that a transverse process-pedicle approach can be used for PKP, allowing for greater abduction angles and relative safety by puncturing through the transverse process and lateral part of the pedicle. To our knowledge, although the transverse process-pedicle approach has been used by some surgeons, no standardized puncture protocol has been developed and the literature on its clinical outcome is scarce. The purpose of this study was to compare and analyze the clinical effectiveness of TPKP with conventional PKP for the treatment of OVCFs.

Patients and Methods

All patients signed a preoperative informed consent form. The research proposal was approved by the Ethics Committee of Wuhan No. 4 Hospital (No. KY2022-081-01).

Patient Population

This retrospective study investigated a group of patients who received conventional unilateral PKP surgery and TPKP surgery at the Department of Spine Surgery, Wuhan Fourth Hospital, from May to October 2021. Among the 103 patients with OVCFs treated during this 6-month period, 81 met the inclusion criteria. Among the eligible patients, 43 underwent TPKP, while the remaining 38 underwent conventional PKP treatment.

Selection Criteria

Inclusion criteria: (1) age ≥60 years; (2) a whole-body BMD test suggests osteoporosis (T<-2.5); (3) fresh single-segment vertebral compression fracture confirmed by X-ray, CT, MRI; (4) duration of disease <2 weeks; (5) postoperative follow-up was at least 1 year.

Exclusion criteria: (1) combination of spinal tuberculosis, spinal metastases, or spinal infection; (2) combination of hematological disorders; (3) patients who are unable to cooperate with surgery, such as mental disorders or impaired consciousness; or refuse surgery and request conservative treatment (4) two or more vertebral fractures; (5) patients with symptoms of spinal cord compression; (6) patients who have already undergone PKP or PVP surgery.

Patients were excluded from the data if they died within 1 year of surgery for non-surgical reasons, or if other reasons not attributable to the test factors prevented continued follow-up.

Materials

The surgical equipment for both groups of patients with OVCFs was manufactured by Shandong Guanlong Medical Supplies Co Ltd (Shandong, China); while the bone cement material used as polymethyl methacrylate (PMMA) was manufactured by Heraeus Medical GmbH, Germany (Hanau, Germany). The iohexol injection was manufactured by Yangtze River Pharmaceutical Group Ltd (Jiangsu, China).

Surgical Procedures

Prior to surgery, all patients provided informed consent, and the surgical procedures were carried out by experienced spinal surgeons (X.W. and ZG.Z.). All surgeries were conducted under the supervision of a C-arm imaging system, and the operating room was equipped to perform prompt decompression surgery if needed.

TPKP Group

Patients were positioned in a prone posture with the assistance of two soft cushions placed under the breast and the pelvis to elevate the patient's abdomen, which helps to minimize abdominal compression. Using C-arm X-ray guidance, the affected vertebral body was identified, and the puncture site on the patient's body surface was marked after fluoroscopy. Standard disinfection was performed using a surgical towel, and local anesthesia was administered with 1% lidocaine infiltration. The choice of needle for surgical puncture entry is made by entering the needle on the side of the primary patient where vertebral compression is more pronounced, or pain is more severe. In cases where compression is similar on both sides of the vertebrae and there is no significant difference in pain between the two sides, the side that is easier to puncture is selected for the procedure. The puncture point was selected laterally to the vertebral arch projection, typically on the left and right sides relative to the "cat's-eye" sign. Subsequently, the puncture point was laterally adjusted by a distance equivalent to the diameter of one transverse arch (the patient's transverse arch diameter was measured preoperatively using CT 3D) (Figure 1). The puncture point is confirmed using fluoroscopy and the angle of puncture (10-30° of lateral inclination) is determined. Once the anteroposterior radiograph indicates that the puncture needle has reached the outer wall of the vertebral arch, the lateral image should show it reaching halfway up the arch. In the lateral view, the puncture needle should reach the posterior edge of the vertebral body when the anteroposterior radiograph indicates that it has reached the medial wall of the arch. Continuing further, the puncture needle enters the anterior 1/3 of the vertebral body. On intraoperative lateral fluoroscopy, when the tip of the needle was found to be located in the anterior middle 1/3 of the vertebral body, and on simultaneous orthogonal x-ray fluoroscopy, when the head of the puncture needle was located near the midline, the puncture needle was removed, and a guide needle was placed. Establish the working channel and balloon expansion system, and place the working sleeve step by step. The balloon is slowly dilated by injecting a contrast agent under fluoroscopic monitoring. Injections were discontinued once the spinal body was satisfactorily repositioned and/or the balloon was dilated to the superior and inferior endplates of the injured vertebral body. Subsequently, the balloon system is removed. The entire injection phase is performed under strict fluoroscopy. Injections from anterior 1/3 of the vertebrae and each injection of 0.5-0.75 ml of cement are observed fluoroscopically from front and side views. If there is a cement leakage, the position of the injector in the vertebrae is adjusted, usually by setting the injector back 1 centimeter and continuing the injection until the cement reaches the posterior third of the vertebral body. When satisfactory cement filling was monitored under intraoperative fluoroscopy, the puncture needle was gradually removed, and the wound was stitched. Figure 2 illustrates a schematic diagram of the anatomy of the peri-vertebral nerves and blood vessels involved in the TPKP puncture. Figure 3 displays a diagram illustrating the simulated puncture route and the position of the puncture needle at various stages of the procedure.

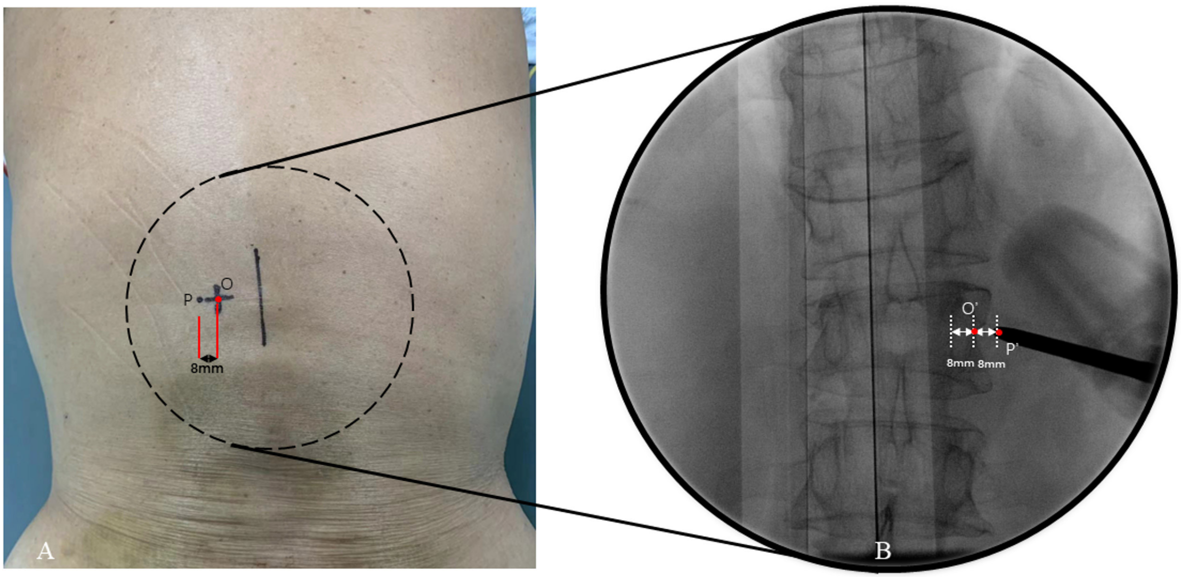

Figure 1. Schematic diagram of needle insertion point selection for TPKP operation. **A,** Point O corresponds to the point on the body surface where the lateral edge of the vertebral arch is located. Point P is the skin entry point. Pre-operative CT measurement of the patient's pedicle width of 8 mm. **B,** Intraoperative anteroposterior radiograph of the lumbar spine at the point of puncture. Point O' is the lateral edge of the vertebral arch; point P' is the point of entry on imaging. Point P' has O' displaced outward a distance of one times the width of the vertebral arch.

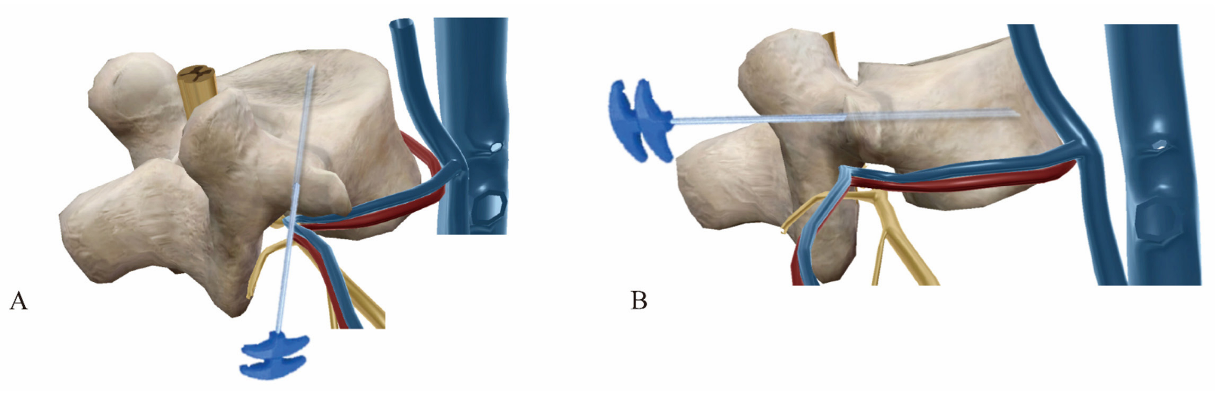

Figure 2. Schematic diagram of the anatomy of the lumbar spine (L1) as punctured by TPKP. **A,** Oblique position schematic; (**B**), Lateral schematic.

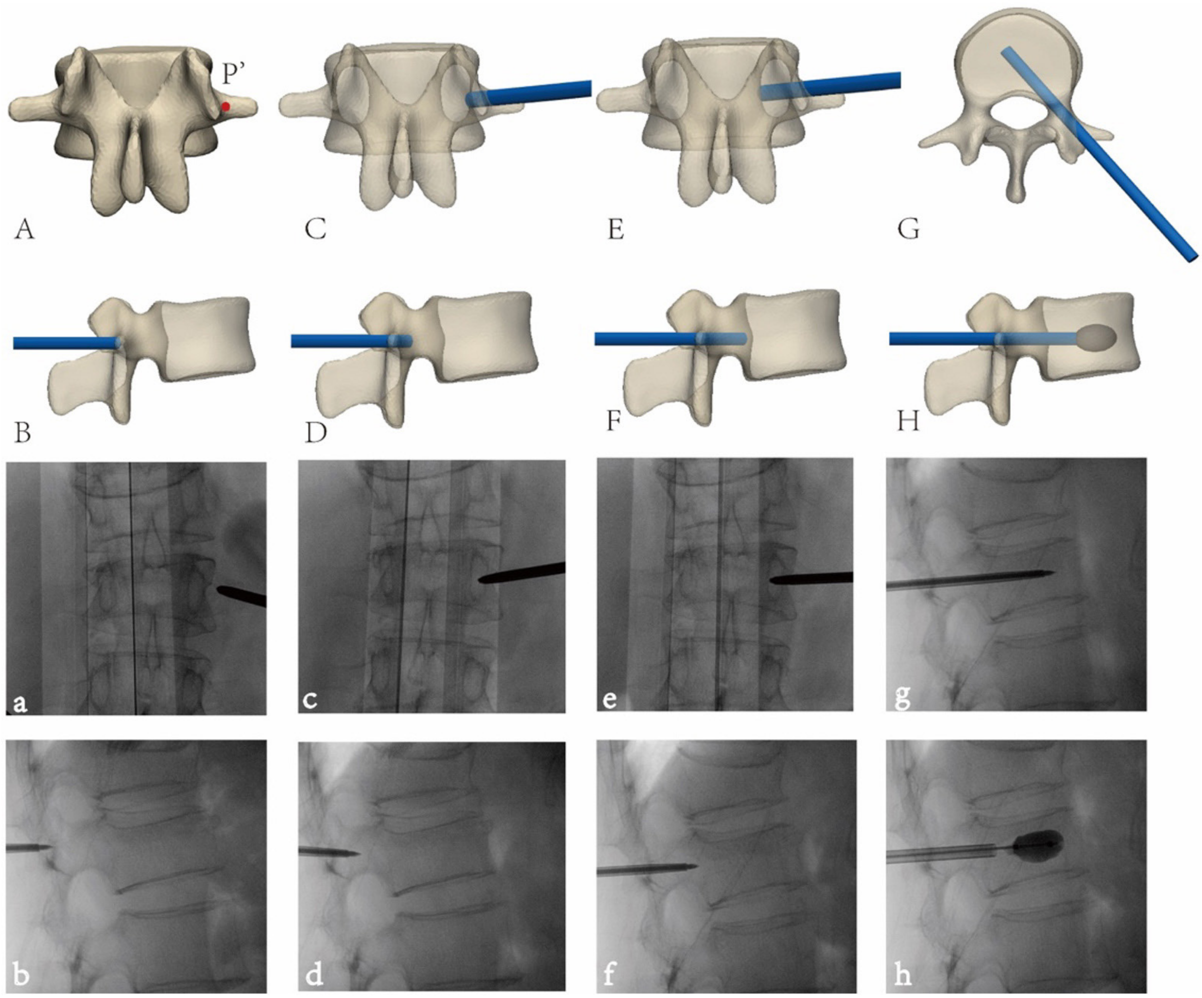

Figure 3. TPKP puncture path simulation and intraoperative imaging. Point P' is the location of the puncture point on the vertebral body. **A-H,** Simulated puncture path; **a-h,** x-rays of the puncture needle in each intraoperative position. **A, B (a, b)** The puncture point was selected as the puncture needle to move one pedicle width outside the pedicle. **C, D (c, d)** When the puncture needle is seen in the AP X-ray to reach the outer wall of the arch, the puncture needle in the lateral X-ray should reach half of the vertebral pedicle. **E, F (e, f)** When the puncture needle reaches the inner wall of the arch in the AP X-ray, the puncture needle in the lateral position should reach the posterior edge of the vertebra. **G, H (g, h)** The puncture needle continues to advance and in the lateral position reaches the anterior 1/3 of the vertebral body and passes the midline of the vertebral body.

All patients rested in bed on the day of surgery and started wearing the lumbar brace down to the floor on the next day for 4-6 weeks and continued to wear the brace depending on the patient's evaluation one month after surgery. All patients received a personalized anti-osteoporosis treatment plan after surgery, and their medication was adjusted by our professional staff during the follow-up period, according to their indicators.

PKP Group

Specific surgical operations were performed according to the Expert Consensus on the standardization of percutaneous kyphoplasty and related issues (2018 version).

Outcome Measurements

All patients are assessed preoperatively using the thoracolumbar osteoporotic fracture score assessment system (TLOFSAS)[18]. The assessment score serves as the basis for selecting the appropriate treatment approach. Non-surgical treatment is considered for patients with a total score of ≤3. For patients with a total score of 4, the decision to pursue non-surgical or surgical treatment depends on factors such as the patient's vital signs, surgical tolerance, and willingness to undergo surgery, as well as their quality-of-life requirements. Surgical treatment is recommended for patients with a total score of ≥5 (Table I). In our study, all enrolled patients scored ≥4 according to the TLOFSAS criteria, with the maximum score being 7. Moreover, all enrolled patients met the indications for surgical intervention[18].

Table I. Thoracolumbar Osteoporotic Fracture Scoring Assessment System (TLOFSAS).

Item	Score
Morphology	
Normal	0
Compression fractures: single concave or double concave	1
Burst fracture	2
MRI	
Normal	0
Long T1 and T2 signal change	1
Vacuum or effusion phenomenon	2
Bone mineral density	
T>-2.5	0
-2.5>T>-3.5	1
T<-3.5	2
Clinical manifestations	
No significant pain	0
Low back pain: postural changes induced pain	1
Sustained pain/spinal cord injury	2
Total points	0-8

The operative time, volume of bone cement injected, intraoperative bleeding and number of intraoperative fluoroscopies were analyzed in both groups.

Two questionnaires, the visual analog scale (VAS) and the Oswestry Disability Index (ODI), were used to assess patients' pain and function, at various time points. Specifically, the VAS and ODI assessments were conducted preoperatively, 1 day, 6 months, and 1 year postoperative. However, due to factors such as age and lifestyle, the ODI score pertaining to sexuality was excluded from this particular study. Consequently, the ODI questionnaire comprised a total of 9 items out of the original 45. The ODI score was calculated using the following formula: total score=(score/45) x 100%.

Patients underwent routine radiographic imaging (X-rays) at three-time points: preoperatively, 1 day after the procedure, and during the period of each follow-up visit. The X-rays documented the changes in anterior vertebral body height (AH) and the Cobb angle of the patient. Additionally, the distribution and leakage of the bone cement were recorded 1 day after the surgery. In our study, we categorized bone cement distribution into three types: type I represented unilateral distribution, where the bone cement was biased towards one side without crossing the midline; type II denoted central distribution, where the bone cement extended beyond the midline but did not reach the contralateral vertebral body; and type III indicated bilateral distribution, where the bone cement was present on both sides of the midline (Figure 4)[19].

Two senior spinal surgery residents independently measured each patient's imaging, and the mean of the two surgeons' measurements was ultimately included for analysis.

Statistical Analysis

Statistical analysis was performed on all measures using SPSS 26.0 statistical software (IBM Corp., Armonk, NY, USA). Measures were expressed as mean±SD. Comparisons between groups were made using the independent samples *t*-test and within-group comparisons were made using the paired *t*-test. Statistical data were analyzed using the χ^2 test and Fisher exact test. $p<0.05$ means statistically significant.

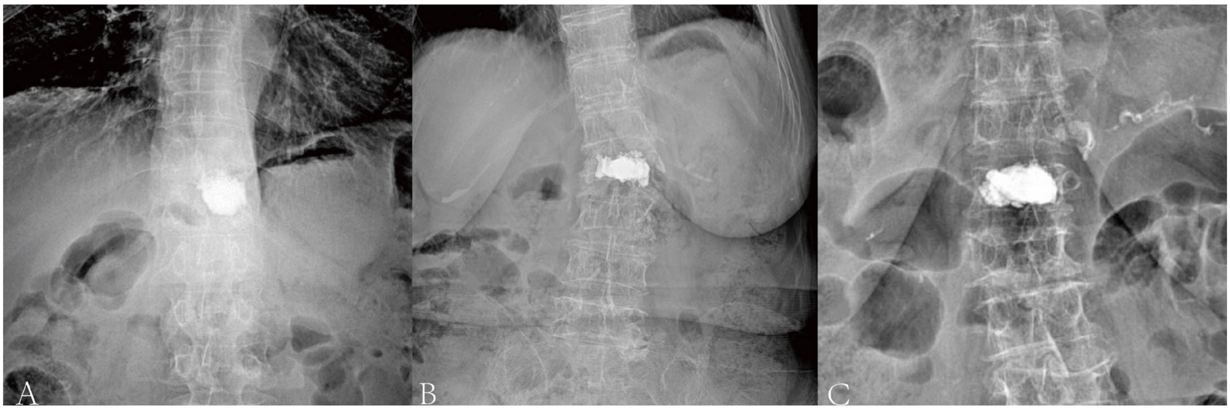

Figure 4. Typical imaging of bone cement distribution. **A,** I type: unilateral distribution, where the bone cement was biased to one side and did not cross the midline; (**B**), II type: central distribution, where the bone cement exceeded the midline and did not reach the contralateral vertebral body; (**C**), III type: bilateral distribution, where the bone cement was distributed on both sides of the midline.

Results

Patient Characteristics

Forty-three sufferers were included in the TPKP group, including 36 females and 7 males, with an average age of 74.05 years (74.05±8.48 years). There were 38 patients in the PKP group, 29 females and 9 males, with an average age of 72.65 years (72.65 ± 9.53 years). Fracture sites in both groups included T10 (4 cases), T11 (7 cases), T12 (11 cases), L1 (23 cases), L2 (18 cases), L3 (11 cases), and L4 (7 cases). In the TPKP group, there were 13 patients with thoracic fractures and 30 patients with lumbar fractures, while there were 9 thoracic and 29 lumbar fractures in the PKP group.

No statistically significant differences were found between the TPKP and PKP groups in terms of gender, age, BMI, T Scores, TLOFSAS score, and fracture site (p>0.05) (Table II).

Basic Surgical Data

In the TPKP group, the average operation time was 39.3±8.01 min, with 21.6±3.19 intraoperative radiations. The amount of bone cement injected was 7.08±0.96 ml, while the intraoperative bleeding was 12.65±2.98 ml, and patients in this group had an average hospital stay of 4.95±1.1 days. Comparatively, the PKP group had an average operation time of 43.6±6.7 minutes, with 23.5±3.65 intraoperative radiations. The amount of bone cement injected averaged 6.28±0.79 ml, while the intraoperative bleeding measured 11.15±3.03 ml. Patients in this group had an average length of stay of 5.05±0.89 days. Among the evaluated indicators, there was only a statistically significant difference in the amount of bone cement injected between the two groups (p<0.05, Table II), while the remaining indicators were not significantly different (p>0.05, Table II).

Clinical Efficacy

Significant improvements in postoperative VAS scores and ODI indices were observed in both the TPKP and PKP groups; the VAS score in the TPKP group decreased from 7.15±0.93 preoperatively to 2.9±0.85 postoperatively and fell to 0.45±0.51 at the final follow-up; the VAS score in the PKP group was 7.05±0.76 preoperatively and decreased to 3.45±0.76 postoperatively and was 0.55±0.51 at the final follow-up. The difference was statistically significant only at 1 day postoperatively (p<0.05, Figure 5A), but not at any other time point. The same phenomenon was seen in the ODI index, which changed from 78.15±6.97 preoperatively to 43.55±4.68 (1 day postoperatively) in the TPKP group and decreased from 79.25±5.74 preoperatively to 49.15±4.23 in the PKP group, with a statistically significant difference between the two groups at 1 day postoperatively (p<0.05, Figure 5B).

On imaging, vertebral height and Cobb angle were effectively restored in both groups postoperatively, but at the last follow-up measurement, it was found that the TPKP group lost less height than the PKP group (p<0.05), meaning that the TPKP group was better able to maintain vertebral height over a longer period than the PKP group (Figure 5C-D).

Table II. The general data on PKP and TPKP patients.

	PKP	TPKP	*p*-value
No. patients	38	43	
Age (y)	72.65±9.53	74.05±8.48	0.626
Gender (n, %)			0.404
Male	9 (23.68)	7 (16.28)	
Female	29 (76.32)	36 (83.72)	
BMI (kg/m^2)	22.84±3.76	23.49±3.52	0.573
T scores	-2.99±0.26	-3.04±0.27	0.553
Fracture site (n, %)			0.508
Thoracic vertebra	9 (23.68)	13 (30.23)	
Lumbar vertebra	29 (76.32)	30 (69.77)	
TLOFSAS Score	5.35±1.04	5.60±0.94	0.430
Intraoperative bleeding (ml)	11.15±3.03	12.65±2.98	0.123
Operation time (min)	43.6±6.7	39.3±8.01	0.073
Cement volume (ml)	6.28±0.79	7.08±0.96	**0.007***
Radiation frequency	23.5±3.65	21.6±3.19	0.087
Length of stay (d)	5.05±0.89	4.95±1.1	0.753
Bone cement distribution types (n, %)			**0.005***
I type	17 (44.74)	6 (13.95)	
II type	14 (36.84)	19 (44.19)	
III type	7 (18.42)	18 (41.86)	

*Significant difference at $p<0.05$ compared with the PKP group. I type: unilateral distribution. Bone cement is biased to one side not crossing the midline. II type: central distribution. Bone cement exceeds the midline without reaching the contralateral vertebral body. III type: bilateral distribution. Bone cement distributed on both sides of the midline.

Safety

No significant postoperative adverse effects, such as wound infection or incision swelling, were observed in any of the 81 cases. The histocompatibility of the bone cement was deemed satisfactory. In total, 7 cases of bone cement leakage were identified across both groups, with 4 cases occurring in the TPKP group (9.30%) and 3 cases in the PKP group (7.89%). Importantly, 7 cases instances of leakage were asymptomatic and did not require additional intervention ($p>0.05$).

Discussion

The conventional unilateral transforaminal approach, which has been utilized in clinical practice for several

decades, is the typical puncture route for PKP. However, this approach has been associated with various reported complications and issues, including suboptimal postoperative pain relief, uneven cement distribution, and the potential for postoperative vertebral recollapse[20,21]. In contrast, the transverse process-pedicle approach to puncture pathway bone cement gives better dispersion and has been used by some surgeons in clinical practice, but there are few systematic studies and a standard puncture procedure has not been developed, so it is not widely used.

In the conventional approach, the puncture point is situated near the inner wall of the vertebral arch on the articular eminence, resulting in a limited abduction angle. Conversely, in TPKP, the puncture point is located on the transverse process, allowing for a greater angle of abduction. This positioning enables the puncture needle tip to reach, and even surpass, the midline, facilitating easier access to the best target location in the anterior middle third of the body of the vertebrae. Consequently, there is a higher likelihood of bone cement diffusion to the contralateral side, as evidenced by the distribution pattern of bone cement observed in the TPKP group in this study. Wang et al[22] also demonstrated a significantly higher rate of successful puncture in the TPKP group (87.7%) compared to the conventional approach (51.7%). The maximum, intermediate, and mini-

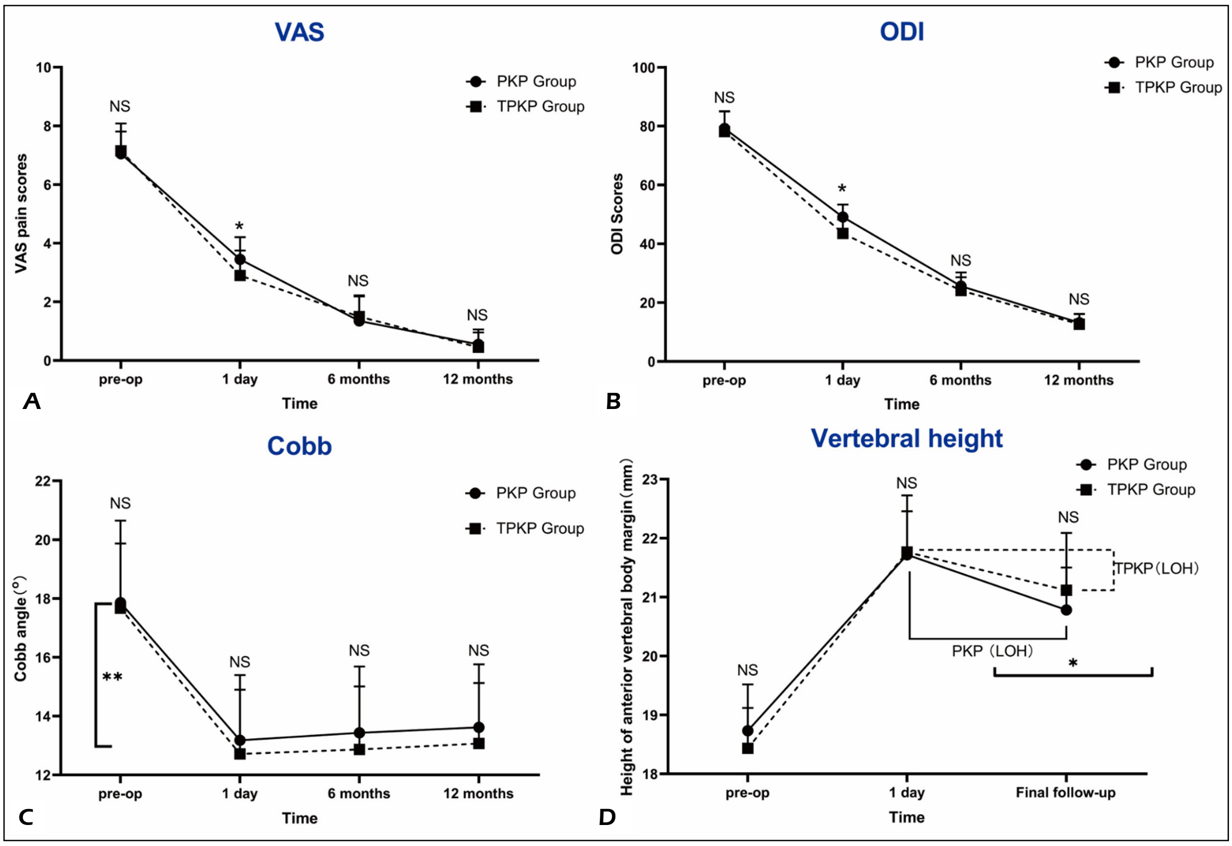

Figure 5. Preoperative and postoperative clinical outcome scores and imaging measurements for patients in the PKP and TPKP groups. **A, B,** VAS and ODI of patients in both groups. VAS indicated a visual analog scale. ODI indicated Oswestry Disability Index. * Significant difference in VAS and ODI between the two groups 1 day postoperatively (p<0.05). **C,** Different periods of Cobb angle in two groups of patients. **Significant difference (p<0.05) between both groups 1 day postoperatively compared to preoperatively. **D,** Postoperative change in the height of the anterior vertebral body margin in both groups. LOH: Difference in height of the anterior vertebral body margin between the last follow-up and 1d after surgery. *There was a significant difference in vertebral height loss between the TPKP and PKP groups (p<0.05).

mum camber angles were all greater in the TPKP group than in the conventional PKP group, and the angles tended to increase from L1 to L5. The safest puncture angles (median camber) were also all significantly greater in TPKP at L1-L5 compared to conventional PKP.

The findings of this study revealed a significant improvement in postoperative VAS and ODI scores for patients in both the TPKP and PKP groups. At the 6-month and 12-month follow-up visits, no statistically significant difference was observed between the two groups. However, the difference in VAS and ODI scores between the two groups was statistically significant at the 1-day postoperative evaluation (p>0.05). Notably, patients in the TPKP group exhibited a more substantial improvement in VAS and ODI scores compared to those in the PKP group. This outcome may be associated with the amount of bone cement injected. Furthermore, our results indicated that the TPKP group received a greater quantity of bone cement compared to the PKP group, and the distribution of bone cement in the TPKP group tended to lean towards the type II or III distribution. A broader spread of bone cement within the spinal body correlates with alleviated pain relief, improved patient function, and reduced loss of vertebral height. This appears to be supported by other studies, with Lv et al[23] finding that the distribution pattern of the bone cement can influence the patient's pain relief. Tao et al[24] divided 447 patients with OVCFs into three groups and performed TPKP, conventional unilateral PKP, and conventional bilateral PKP, and also demonstrated that TPKP achieved similar symptomatic relief and functional recovery to conventional bilateral PKP, with a higher proportion of bilateral cement distribution in TPKP.

Both the TPKP and PKP groups demonstrated significant restoration of vertebral height based on imaging results. However, there appeared to be no statistically significant difference in the postoperative follow-up comparison between the TPKP and PKP groups. However, noteworthy findings emerged as the TPKP group exhibited significantly less vertebral height loss at 12 months postoperatively compared to the 1-day postoperative measurements ($p<0.05$). This implies that TPKP has an advantage in preserving vertebral height when compared to conventional PKP. It suggests that the type of bone cement distribution is associated with vertebral height loss in the injured vertebrae. Increasing the volume of injected cement, without raising the risk of cement leakage, may enhance injection pressure and facilitate optimal cement distribution. An ideal cement distribution pattern proves beneficial for maintaining vertebral height. Lin et al[25] also found a positive correlation between the "left-right range" of cement and the rate of vertebral height restoration, which aligns with our study's results. Tan et al[26] demonstrated that allowing full contact of the cement with the upper and lower endplates is an ideal distribution, which better maintains the height of the fractured vertebrae and reduces the risk of distant neighboring vertebral fractures. Similarly, a study by Zhuo et al[27] found that the needle trajectory of a modified transverse process-pedicle approach, planned precisely using fluoroscopic guidance and clear anatomical landmarks, facilitated an adequately homogeneous distribution of bone cement and provided significant pain relief.

In our study, a total of 7 cases of cement leakage were observed in the TPKP and PKP groups. Seven cases were categorized as intervertebral disc space or paravertebral area leakage, and interestingly, all cases were asymptomatic and did not require specific management. The occurrence of cement leakage was 9.30% (4/43) and 7.89% (3/38) in the two groups, respectively, and the difference was not statistically significant. These results are in accordance with previous studies[28-30], suggesting that increasing the volume of bone cement pumped does not lead to a higher leakage rate. Furthermore, the safety profile of TPKP was confirmed to be similar to that of PKP. Based on our experience, there are several measures that can be implemented to avoid cement leakage, including (1) Preoperative use of imaging tools (e.g., CT and 3D reconstruction) to assist in determining the condition and severity of the rupture of the injured vertebral body, (2) initiating cement injection during the extraction phase and continuing the injection after the initial set, (3) during the procedure, the cement injection site is placed as close as possible to the posterior third of the vertebral body, avoiding blood vessels in the spinal canal, (4) intraoperative monitoring of bone cement injection using a c-arm and (5) utilizing a gelatin sponge to seal vertebral cortical bone defects and reduce bone cement leakage during fractionated injection[31].

The occurrence of vertebral re-fractures following vertebroplasty has been reported[32,33] in previous literature, with rates ranging from 2.9% to 27.6%. Low bone mineral density is widely recognized as a significant risk factor for recurrent fractures. Consequently, there has been an increasing emphasis by orthopedic surgeons on prioritizing anti-osteoporosis treatment for patients with OVCFs[34]. A large-scale clinical trial conducted by Bawa et al[35] demonstrated a 40% reduction in the risk of re-fracture among patients who received anti-osteoporosis treatment compared to those who did not. In our study, a total of 5 patients from both the TPKP and PKP groups experienced re-fracture at the 1-year follow-up (TPKP: 2 cases; PKP: 3 cases, $p>0.05$). This result may be attributed to the increased emphasis on anti-osteoporosis treatment by orthopedic surgeons nowadays and may also be related to the fact that the follow-up period of our study population was not long enough.

Limitations

There are limitations to this study: (1) the number of patients was small due to the strict inclusion criteria of this study; (2) the classification of cement distribution type was only done with anteroposterior X-ray and fine structures were not observed; (3) as only T10 to L4 vertebrae were involved in the injured vertebrae in this study, there is an insufficient experience in puncturing the upper thoracic vertebrae, so OVCFs for the upper thoracic vertebrae are not recommended for the time being; (4) although we observed the recovery and loss of height in the operated vertebrae, it is important to note that the follow-up period was relatively short, and the evaluation regarding postoperative re-fracture was not comprehensive.

Conclusions

This study demonstrates that TPKP is safe, feasible, and effective in treating OVCFs. Good clinical outcomes were achieved at the one-year follow-up. TPKP allows for a better distribution of the bone cement than conventional unilateral PKP. It is also more effective at relieving postoperative pain and facilitating functional recovery, as well as maintaining vertebral height for a year after surgery. There was no statistically significant leakage of bone cement compared to conventional PKP and TPKP proved to be sufficiently safe. The modified PKP we performed, which has a more standardized procedure, is easier for specialist spinal surgeons to master and has a shorter learning curve. As a result, TPKP may be the preferred treatment for OVCFs patients over conventional PKP.

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Authors' Contributions
Y.Q., X.W., and ZG.Z. designed the study. Y.Q., J.H., and Y.L. acquired the data. Y.Q., X.W., J.H., and FH.Y. conducted a statistical analysis of the data. Y.Q., X.W., and Y.L. wrote the manuscript. FH.Y. and ZG.Z. reviewed and supervised the work. Final approval of the published version; the agreement has been reached on the journal to which the article is to be submitted, and responsibility for all aspects of the work has been agreed upon.

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Conflict of Interest
The authors declared no conflict of interest.

Informed Consent
Patients' informed consent was waived because the study was retrospective.

Ethics Approval
All processes have been approved by the Ethics Committee of Wuhan Fourth Hospital (No. KY2022-081-01).

Data Availability
All patient clinical data were obtained from the Department of Spine Surgery, Wuhan Fourth Hospital, Wuhan, China, and no data copyright issues were involved. Data are available upon reasonable request.

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