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Percutaneous curved vertebroplasty in the treatment of thoracolumbar osteoporotic vertebral compression fractures

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Abstract

Objective: To evaluate the clinical efficacy of percutaneous curved vertebroplasty (PCVP) in treating thoracic and lumbar osteoporotic vertebral compression fractures (OVCFs).

Methods: Patients with thoracolumbar OVCFs were recruited and randomly divided into three treatment groups: PCVP, unilateral percutaneous vertebroplasty (PVP) or bilateral PVP. Bone cement dispersion in the fractured vertebrae was observed. Surgery duration, X-ray frequency, bone cement injection volume, bone cement leakage rate and visual analogue scale (VAS) scores were recorded.

Results: Among 78 patients included, surgery duration and X-ray frequency were significantly lower in the PCVP and unilateral PVP groups versus bilateral PVP group. Bone cement injection volume was significantly higher in the bilateral PVP group (6.3 ± 1.4 ml) versus unilateral PVP (3.5 ± 1.1 ml) and PCVP groups (4.6 ± 1.2 ml). VAS scores at 24 h and 3 months post-surgery were significantly decreased versus baseline in all groups. The bone cement leakage rate was lowest in the PCVP group (8.8% [3/34 patients]).

Conclusion: PCVP is associated with reduced trauma, less complicated surgery with shorter duration, fewer X-rays, lower complication rate, and quicker postoperative recovery versus unilateral and bilateral PVP.

Keywords

Osteoporosis, thoracic and lumbar vertebral pathological compression fracture, percutaneous curved vertebroplasty, minimally invasive surgery

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Introduction

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 safety of conservative treatment is relatively high, but it is difficult to achieve satisfactory clinical efficacy, which limits its application in clinical practice.[1] Surgical treatment yields significantly higher clinical efficacy than conservative treatment, and has been widely applied by surgeons in the treatment of OVCF.[1]

Percutaneous vertebroplasty (PVP) 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, the clinical efficacy of PVP is intimately correlated with the distribution of bone cement within the vertebral body.[2] If a unilateral percutaneous puncture approach is adopted, the bone cement is merely distributed on the unilateral side of the vertebra. In order to obtain high clinical efficacy and ensure even distribution of bone cement in the entire vertebra, either the internal inclination angle during puncture can be increased or bilateral percutaneous puncture can be performed, which may increase the risk of bone cement leakage, spinal cord injury[2] and surgical trauma to the patients.[3] Due to these deficiencies and challenges, a novel surgical technique known as percutaneous curved vertebroplasty (PCVP) 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 2016, PCVP has been used to treat OVCF at the Third Affiliated Hospital of Anhui Medical University, with the aim of reducing percutaneous puncture-related adverse events.

In the present study, the clinical efficacy and surgical safety of PCVP and unilateral and bilateral PVP, in treating patients with OVCF, were evaluated and statistically compared to identify the optimal technique in the surgical management for OVCF.

Patients and methods

Study population

This prospective single-centre study included patients diagnosed with thoracic and lumbar OVCF who were admitted to the Third Affiliated Hospital of Anhui Medical University, Hefei, China between March 2016 and February 2017. Criteria for inclusion into the final analyses comprised the following: diagnosis of osteoporosis according to bone mineral density criteria determined by dual-energy X-ray absorptiometry (DXA); fresh compression fracture of the thoracolumbar vertebrae diagnosed by magnetic resonance imaging (MRI) and other imaging examinations; and complete postoperative follow-up data.

Patients with posterior wall rupture of the thoracolumbar vertebrae or traumatic thoracic and lumbar pedicle fractures; patients with symptoms and signs of spinal cord or nerve root compression; patients with pathological fractures caused by metastatic tumours and haemangiomas; and patients lost to postoperative follow-up were excluded from the study.

Patients were randomised into three different treatment groups using a random number table method.

This study was approved by the Institutional review board of the Third Affiliated Hospital of Anhui Medical University and written informed consent was obtained from all included patients.

Surgical procedures

Unilateral PVP. With patients in a prone position, preoperative G-arm X-ray (Siemens Healthcare, Erlangen, Germany), MRI (Siemens Healthcare) 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 (Sigma; St. Louis, MO, USA). Using G-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 G arm X-ray, then a flat-head drill was inserted into the cannula, and slowly drilled into the junction of the anterior 1/3 of the vertebrae using the lateral G arm X-ray. The flat drill was then removed, and the bone cement (polymethylmethacrylate; Sigma) was slowly infused until it reached the posterior edge of the vertebrae. G-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.

Bilateral PVP. All surgical procedures were identical to those described for unilateral PVP, except that the bone cement was infused into bilateral pedicles.

PCVP. The procedures for percutaneous puncture and placement of the cannula were identical to those described for unilateral PVP. Following placement of the puncture needle (Figure 1a), the bending-angle injector (Figure 1b) was inserted into the cannula. Using G-arm X-ray for guidance,

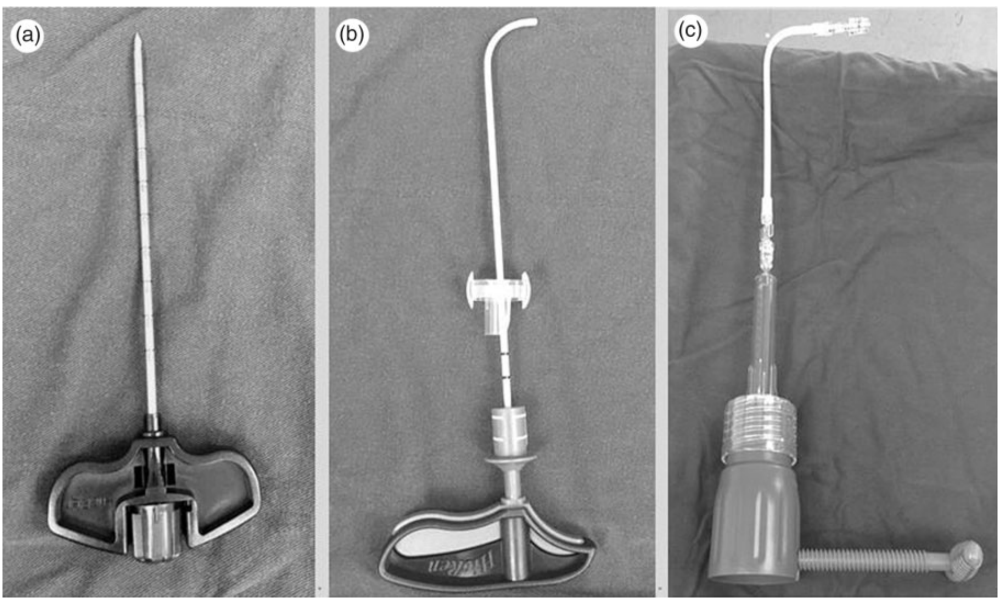

Figure 1. Representative images of surgical instruments using in percutaneous curved vertebroplasty, showing: (a) puncture trocar; (b) bending-angle injector; and (c) cement screw injector.

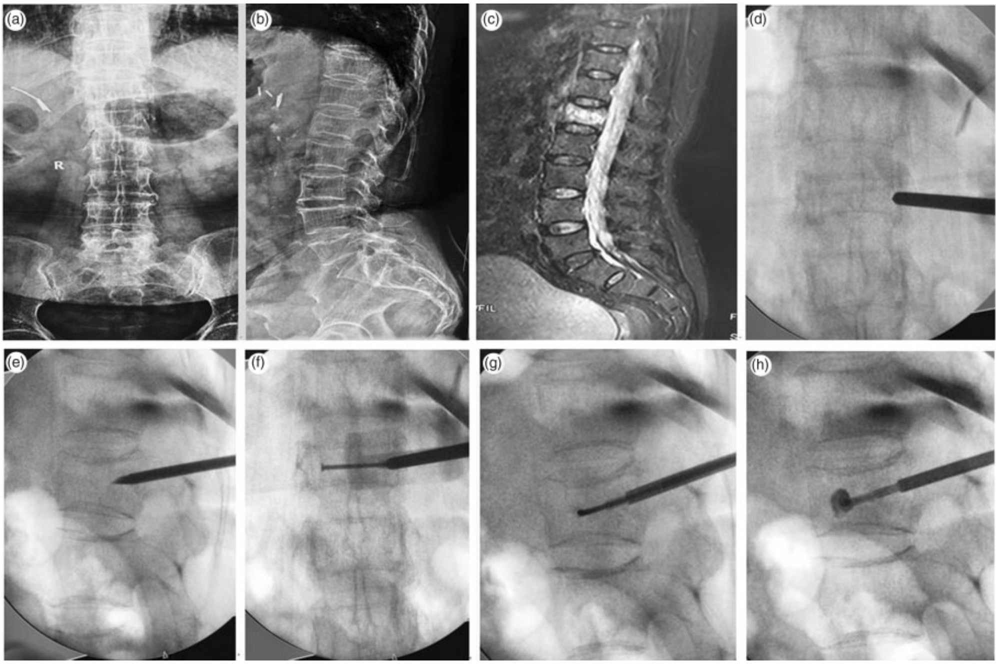

Figure 2. Representative preoperative and intraoperative fluoroscopy imaging data obtained during percutaneous curved vertebroplasty, showing: (a) Preoperative anteroposterior X-ray, L1 vertebral compression fracture; (b) Preoperative lateral X-ray, L1 vertebral compression fracture; (c) Preoperative sagittal magnetic resonance imaging, L1 fresh vertebral compression fracture; (d) Anteroposterior X-ray, the puncture needle has not broken through the medial pedicle wall of the L1 vertebral arch; (e) Lateral X-ray, the puncture needle was inserted from the unilateral pedicle of the vertebral arch to 5 mm from the posterior edge of the L1 vertebral body; (f) Anteroposterior X-ray, the bending-angle injector was inserted into the cannula, and the tip is across the L1 vertebral midline; (g) Lateral X-ray, the bending-angle injector has reached the anterior 1/3; and (h) Lateral X-ray, during bone cement infusion, 3-point injection was performed while the bending-angle injector was removed; the bone cement is well diffused with no obvious bone-cement leakage.

the tip of the bending-angle injector was placed exceeding the midline of the vertebrae and adjacent to the inner wall of the contralateral pedicle. A cement screw injector (Figure 1c) was used to slowly infuse the prepared bone cement into the junction of the anterior 1/3 of the vertebrae until it reached the posterior edge of the vertebrae. Subsequently, 3-point injection of the bone cement was performed while simultaneously retracting the bending-angle injector. The distribution of bone cement was observed using the G-arm X-ray. Once the bone cement had hardened, the cannula was rotated clockwise to separate the cannula from the intra-vertebral bone cement, and the cannula was removed (Figure 2).

Evaluation parameters

Following surgery, the patients in all three groups were kept in a supine position. Vital signs, and sensation and movement status of the bilateral lower extremities were observed. At 6 h following surgery, patients were allowed to walk with thoracolumbar braces. The duration of surgery, G-arm X-ray frequency, bone cement injection

Table 1. Baseline demographic and clinical data among patients with thoracolumbar osteoporotic vertebral compression fractures, divided into three treatment groups.

Study group	Male/ Female	Age, years	Bone density, T-score	Distribution of diseased vertebrae T10	T11	T12	L1	L2	L3	L4	L5
Unilateral PVP group ($n = 26$)	10/16	68.9 ± 11.9	–2.8 ± 0.3	1	6	9	8	1	2	1	2
Bilateral PVP group ($n = 22$)	10/12	69.8 ± 12.1	–2.9 ± 0.4	0	7	9	10	2	2	1	1
PCVP group ($n = 30$)	12/18	71.8 ± 11.2	–2.9 ± 0.3	1	6	10	8	3	2	2	2

Data presented as *n* prevalence or mean ± SD.
PVP, percutaneous vertebroplasty; PCVP, percutaneous curved vertebroplasty.
No statistically significant between-group differences ($P > 0.05$; Student's paired *t*-test).

volume, bone cement leakage rate (assessed by conventional MRI at 1 day following surgery), and visual analogue scale (VAS) scores before surgery and at 24 h and 3 months following surgery, were recorded.

Statistical analyses

Continuous data are presented as mean ± SD and categorial data are presented as *n* prevalence, and all data analyses were performed using SPSS software, version 19.0 (SPSS Inc., Chicago, IL, USA). Between-group differences were statistically analysed using Student's paired *t*-test. A P value < 0.05 was considered to be statistically significant.

Results

Baseline data

A total of 78 patients diagnosed with thoracic and lumbar OVCF (comprising 96 vertebrae) and who had complete follow-up records, were included in the study, comprising 32 male and 46 female patients aged 60–87 years, (mean, 70.9 ± 11.2 years) (Table 1). Overall mean preoperative bone mineral density T-score was –3.0 ± 0.5 (range, –2.5 to –3.5). Surgical treatment groups comprised PCVP ($n = 30$), unilateral PVP ($n = 26$) and bilateral PVP ($n = 22$). Baseline data including age, sex, bone density and distribution of the diseased vertebrae did not significantly differ between the three treatment groups (all $P > 0.05$; Table 1).

Overall postoperative outcomes

All patients in all three groups successfully completed surgical treatment. No bone cement embolism or pulmonary embolism occurred during or after surgery. There were no adverse cardiac and cerebral vascular events, no spinal cord or nerve root injuries, and no epidural haematoma or cementation. Bone cement leakage occurred in 18 vertebrae, located in the intervertebral space, in the anterior or lateral position of the diseased vertebrae. MRI at postoperative day 1 demonstrated a small quantity of bone cement leakage within the canal and adjacent to the posterior edge of three diseased vertebrae, but no neurological symptoms were reported. At the 3-month postoperative follow-up assessment, no adjacent vertebral stress fractures were observed in any of the three groups (Figure 3).

Comparison of surgical parameters

The duration of surgery, G-arm X-ray frequency, bone cement injection volume,

Figure 3. Representative post-treatment images from a 74-year-old female patient in the percutaneous curved vertebroplasty group: (a) Anteroposterior X-ray, showing good bilateral diffusion of bone cement; (b) Lateral X-ray, showing no obvious bone cement leakage; (c) Sagittal MRI, showing no obvious bone cement leakage; and (d) Cross-sectional MRI, showing no obvious bone cement leakage and good diffusion of bone cement.

bone cement leakage rate and VAS scores before and at 24 h and 3 months following surgery, are summarized in Table 2. Surgery duration was significantly longer in the bilateral PVP group compared with the unilateral PVP and PCVP groups (both $P < 0.05$), whereas the duration of surgery did not significantly differ between the unilateral PVP and PCVP groups ($P > 0.05$). Frequency of G-arm X-rays were significantly higher in the bilateral PVP group versus the unilateral PVP and PCVP groups (both $P < 0.05$), but there was no statistically significant difference between the unilateral PVP and PCVP groups ($P > 0.05$). The volume of bone

Table 2. Comparison of surgical parameters, and VAS scores before and after surgery, among patients with thoracolumbar osteoporotic vertebral compression fractures, divided into three treatment groups.

Study group	Surgery duration, min	X-ray frequency, n	Infusion volume, ml	Cement leakage rate ($n = 96$ vertebrae)	VAS score		
					Presurgery	24 h postsurgery	3-months postsurgery
Unilateral PVP group ($n = 26$)	20.7 ± 10.6*	9.3 ± 3.9*	3.5 ± 1.1*	9/30 (30)*	7.9 ± 0.8	$2.6 \pm 0.7^{\Delta}$	$1.6 \pm 0.3^{\Delta}$
Bilateral PVP group ($n = 22$)	37.9 ± 6.9	18.0 ± 3.1	6.3 ± 1.6	6/32 (18.8)	8.3 ± 0.7	$2.7 \pm 0.7^{\Delta}$	$1.7 \pm 0.8^{\Delta}$
PCVP group ($n = 30$)	21.9 ± 8.9*	8.6 ± 4.1*	$4.6 \pm 1.2^{*\#}$	3/34 $(8.8)^{*\#}$	8.0 ± 1.1	$2.3 \pm 1.3^{\Delta}$	$1.2 \pm 0.5^{\Delta}$

Data presented as mean $\pm$ SD or *n* (%) prevalence.
VAS, visual analogue scale; PVP, percutaneous vertebroplasty; PCVP, percutaneous curved vertebroplasty.
$^{\Delta}P < 0.05$, compared with the same group before surgery; $^{\#}P < 0.05$, compared with the unilateral group; $^{*}P < 0.05$, compared with the bilateral group (all Student's paired *t*-test).

cement injection into the vertebral bodies differed significantly between all three groups (all $P < 0.05$), with the lowest injection volume in the unilateral PVP group, followed by the PCVP group and lastly the bilateral PVP group. The bone cement leakage rate also differed significantly between all three groups (all $P < 0.05$), and was found to be lowest in the PCVP group, followed by the bilateral PVP group, and highest in the unilateral PVP group.

Comparison of VAS scores

Postoperative pain symptoms were significantly reduced compared with preoperative symptoms in all of the study groups. Mean VAS scores at 24 h and 3 months postoperatively were significantly lower than preoperative VAS scores in all three groups (all $P < 0.05$). The were no statistically significant differences in mean VAS scores between 24 h and 3 months postoperatively in any of the treatment groups (all $P > 0.05$). In addition, there were no statistically significant between-group differences in mean VAS scores at any of the measured time-points (all $P > 0.05$) (Table 2).

Discussion

Problems associated with an aging population are gradually emerging, such as increases in the quantity and type of age-related diseases.[5] Osteoporosis has become a major disease in the elderly population[5] that not only causes evident clinical symptoms, but is also associated with serious complications. Thoracic and lumbar OVCF is one of the severe complications of osteoporosis, with high morbidity and mortality rates. Surgical intervention remains the standard treatment for OVCF,[6] with PVP being the conventional surgical treatment, as it can quickly alleviate pain and is associated with reduced risk of postoperative complications.[7]

Percutaneous vertebroplasty was first applied to treat cervical haemangiomas, and thoracic and lumbar OVCF in 1987.[8] As a minimally invasive surgical technique, PVP involves percutaneous injection of bone cement into the vertebral body through the pedicle or the lateral approach, and can stabilize bone fractures, restore bone stiffness and mechanical strength, prevent compression progression and relieve surgical pain and trauma.[8] The potential mechanism underlying pain relief is that the injected bone cement shares the trabecular pressure and enhances bone strength via entering the trabecular space of the diseased vertebra to stabilize the trabecular bone. In addition, the resulting thermal effect can destroy peripheral nerves of the vertebra and relieve pain.[9] PVP is mainly unilateral and bilateral, and the process of selecting which approach to take remains controversial.[10] Unilateral PVP possesses multiple advantages, such as reduced trauma, fewer intraoperative X-rays and shorter surgery duration.[11] Bilateral PVP is more conducive to promoting the even dispersion of bone cement in the diseased vertebrae, and uniform bone cement distribution is correlated with the extent of pain relief.[12] However, bilateral PVP prolongs the duration of surgery, and is less likely to be tolerated by elderly patients. Due to the problems mentioned above, it is vital that the uniformity of bone cement distribution is enhanced in unilateral PVP. A current method involves increasing the puncture angle during unilateral PVP, to allow the bone cement to distribute evenly into the vertebrae. Due to the impact of patient posture and other factors, however, this procedure is likely to injure the inner wall of the pedicle and damage the nerves.[12] The emergence of PCVP may resolve this issue by applying the specialised bending-angle vertebroplasty device during unilateral PVP. Intraoperatively, it is unnecessary to excessively enlarge the internal inclination angle of puncture, and the bending-angle puncture needle can reach more positions compared with the right-angled metal cannula, leading to more uniform bone cement distribution in the diseased vertebrae.[10,11]

In the present study, bone cement was more evenly distributed in the diseased vertebrae in the PCVP group compared with the unilateral and bilateral PVP groups, and postoperative pain was significantly alleviated. Postoperative VAS scores were significantly reduced at 24 h and 3 months in all three treatment groups, with no statistically significant difference between the treatments, indicating that the symptoms were effectively alleviated and the three approaches yielded similar clinical efficacy. In the PCVP group, the frequency of G-arm X-ray and duration of surgery were reduced compared with the bilateral PVP group, and PCVP was shown to have significant advantages in terms of bone cement distribution, bone cement injection volume and bone cement leakage rate over unilateral PVP.

Although PVP is a minimally invasive approach, surgical risk and complications, such as bone cement leakage, nerve root or spinal cord injury, and adjacent vertebral fractures, are unavoidable.[13] Bone cement leakage is the most common complication of PVP, with an incidence rate ranging between 3% and 75%.[14] Leakage can occur along the puncture needle path, or into the fracture gap, the anterior vertebra, intervertebral space, paravertebral tissues, or even the spinal canal and paravertebral vessels.[15] Leakage primarily results from percutaneous puncture by unskilled surgeons, repeated punctures, excessively rapid bone cement injection or excessive force, or early removal of the puncture needle, amongst other factors.[15] The excessive compression force on the diseased vertebrae induces a large injection resistance force. The greater the amount of bone cement injection, the higher the risk of bone cement leakage.[16] In a previous study,[17] the highest rate of bone cement leakage occurred in the unilateral PVP group because the internal inclination angle of puncture was enlarged, the bone cement injection volume was increased and the pressure on the diseased vertebrae was elevated, leading to bone cement leakage. In terms of bilateral PVP, the injection pressure was less and the injection volume was smaller, thereby the cement leakage rate was lower.[17] Another study showed that during PCVP,[18] a curved injection route was created to the contralateral side. The bending-angle injector was withdrawn during the infusion of bone cement, which formed 3-point injection to gradually disperse the bone cement to the middle region of the diseased vertebrae. The bone cement dispersion could be dynamically adjusted by the G-arm X-ray. All these measures collectively reduced the risk of bone cement leakage during PCVP.[18]

Nerve root or spinal cord injury is frequently caused by excessive depth of percutaneous needle penetration, too large an inclination angle or cement leakage into the spinal canal.[19] To achieve a wide and even distribution of bone cement in the vertebrae, the inclination angle of needle insertion is constantly increased during unilateral PVP, which inevitably increases the risk of injuring and damaging the internal wall of the pedicle, the nerve root or even the spinal cord.[19] Although it is unnecessary to elevate the inclination angle during bilateral PVP, bilateral surgical procedures can increase the risk of surgical trauma and injury.[19] The introduction of PCVP can effectively resolve these problems without increasing the inclination angle, and thus minimize the risk of injury. During PCVP, a specialised bending-angle device can reach the contralateral side of the vertebral body, yielding an identical effect to bilateral PVP in terms of bone cement injection, and reduces the frequency of punctures and G-arm X-ray.[20] In the present clinical trial, no nerve root or spinal cord injuries occurred following surgery in any of the three treatment groups. However, the frequency of G-arm X-ray and surgery duration in the PCVP and unilateral PVP groups were significantly lower than those in the bilateral PVP group. Following PVP, there is a significant increase in the incidence of stress fractures in the diseased and adjacent vertebrae.[20] During PCVP, a bending-angle device is utilized to form a three-point injection, which allows the bone cement to distribute widely and evenly in the vertebrae, providing a favourable biomechanical environment and effectively reducing the risk of fracture in the diseased and adjacent vertebrae.

It should be noted that the results of the present study may be limited by the relatively short duration of follow-up (3 months), the small study population and the fact that this was a single centre study. Thus, the conclusions drawn from this investigation remain to be validated by subsequent larger clinical trials with longer-term follow-up.

In conclusion, PCVP was found to be efficacious in the treatment of thoracic and lumbar OVCF, as it is conducive to uniform bone cement distribution in the fractured vertebrae, and is associated with only slight trauma, short surgery duration, low G-arm X-ray frequency and low risk of postoperative complications. The unique advantages support the widespread application of this minimally invasive technique in the management of OVCF in clinical practice.

Declaration of conflicting interest

The authors declare that there is no conflict of interest.

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