

Comparison of the Clinical Outcomes of Percutaneous Vertebroplasty Using Different Surgical Approaches and Bone Cement Distribution

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Abstract: *Objective:* To compare clinical outcomes of percutaneous vertebroplasty (PVP) through different surgical approaches and bone cement distribution in the treatment of osteoporotic vertebral compression fractures (OVCF). *Methods:* The clinical data of 231 patients with OVCF who underwent PVP from June 2020 to June 2022 were retrospectively analyzed. Clinical characteristics and surgical data were collected for statistical analysis. The total patients were divided into a unilateral approach group (Group UA) and a bilateral approach group (Group BA) according to different surgical approaches. Then, patients in Group BA were divided into a continuous bone cement group (Group CBC) and a discontinuous bone cement group (Group DBC) according to the distribution of bone cement. *Results:* In each group, the postoperative visual analog scale (VAS) score and Oswestry disability index (ODI) score were significantly decreased ($P < 0.001$). The operation time and fluoroscopy times of Group UA were less than those of Group BA ($P < 0.001$). However, compared with Group BA, Group UA had a lower mean VAS score ($P = 0.013$) and ODI score ($P = 0.004$) at the last follow-up. The VAS ($P = 0.032$) and ODI ($P = 0.024$) scores in the CBC group were significantly lower than those in the DBC group at the last follow-up. *Conclusions:* Unilateral PVP presented several advantages over bilateral PVP, particularly in terms of shorter surgery time, less fluoroscopy frequency, and less trauma. Continuous bone cement was closely related to good clinical outcomes. In clinical practice, we suggest unilateral PVP is performed for patients and ensure the continuity of bone cement for better clinical outcomes.

Keywords: Osteoporotic vertebral compression fractures; Bone cement; Minimal surgical procedure; Treatment outcome

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1. Introduction

Osteoporotic vertebral compression fractures (OVCF) were one of the common spinal injuries with small external force in middle-aged and elderly people ^[1]. Patients suffered from back pain caused by OVCF, especially when they rolled over, coughed, or breathed deeply. Traditional conservative treatment was a long

and painful process with various complications such as deep venous thrombosis, hypostatic pneumonia, and amyotrophia^[2]. Compared with traditional conservative treatment, surgical intervention was preferred by surgeons and patients^[3,4].

As a minimally invasive surgery of bone cement injection, percutaneous vertebroplasty (PVP) strengthens the compressed vertebral and quickly relieves the pain, moreover, the surgery prevents the injured vertebrae from further compression^[5]. There are two approaches to bone cement injection, unilateral and bilateral. The surgical path of the unilateral approach started from the lateral pedicle to the vertebral body, while the surgical path of the bilateral approach passed through the whole pedicle, of which the better approach remains controversial.

Although PVP achieved relatively good clinical outcomes and was widely applied all over the world, there were still some patients suffering from residual or unrelieved pain after the surgery^[6,7]. A series of correlative factors of poor outcomes after PVP were proposed by previous studies, however no consensus was gained. Our study compares the clinical outcomes of two surgical approaches and discusses the connection between bone cement continuity and the degree of pain relief. The results of our study provide evidence for PVP clinical outcomes and guide the clinical practice.

2. Material and methods

2.1. Patients

The Institutional Ethics Board of the Third Hospital of Hebei Medical University approved this study. All participants provided informed consent for the measurement and evaluation of their data. The clinical data of 231 patients with OVCF who underwent PVP in the Third Hospital of Hebei Medical University from June 2020 to June 2022 were retrospectively analyzed. All patients had no obvious surgical contraindications before the operation and successfully completed PVP. No serious adverse reactions were observed during follow-up, and all patients were diagnosed by X-ray or MRI. The inclusion criteria included: (1) The vertebral bodies met the diagnostic criteria of OVCF, and the T value of bone mineral density measured by dual-energy X-ray was lower than -2.5. (2) The vertebral bodies met the diagnostic criteria of vertebral compression fracture by X-ray, vertebral CT, MRI, and other imaging examinations. (3) Patients underwent single-level PVP; (4) Patients were followed up for more than 12 months with complete clinical data. The exclusion criteria included: (1) Symptoms of spinal cord or nerve root compression; (2) Vertebral infection, tumor, and other diseases (3) Patients having other fractures; (4) Patients with new spinal compression fractures after the current operation and before the last follow-up.

The enrolled patients included 190 females and 41 males, with a mean age of 71.62 ± 7.73 years, and a mean follow-up time of 16.96 ± 7.64 months.

2.2. Data analysis

Preoperative demographic and clinical characteristics including age, gender, body mass index (BMI), bone mineral density (BMD), smoking and drinking, history of trauma or symptoms, followed-up period, surgical segment, local kyphosis angle (LKA), lumbar lordosis (LL), and thoracic kyphosis (TK), were documented for subsequent statistical analysis. Bone mineral density (BMD) was measured through the utilization of dual-energy X-ray absorptiometry (DEXA). If a history of trauma was present, the recorded timespan extended from the onset of the trauma to the surgical day, whereas in the absence of trauma history, the recorded timespan extended from the onset of symptoms to the surgical day.

The surgical segment, surgery time, and fluoroscopy frequency during surgery were documented. The

surgical segments were divided into three regions T7–10, T11–L2, and L3–5. During the surgeries, a G-arm fluoroscopy instrument provided assistance for accurate visualization. In this context, it is important to note that each posterior-anterior or lateral X-ray taken during the surgery was considered as one time of fluoroscopy frequency. It is crucial to understand that simultaneous posterior-anterior and lateral X-rays were recorded at two times of fluoroscopy frequency.

The visual analog scale (VAS) score, ranging from 0 to 10, assessed preoperative and final follow-up pain levels. The Oswestry disability index (ODI) score, ranging from 0 to 50, assessed lumbar function before the operation and at the final follow-up.

The measurement of TK was defined as the angle between the upper endplate of the T4 vertebral body and the lower endplate of the T12 vertebral body. LL was defined as the angle between the upper endplate of the L1 vertebral body and the lower endplate of the L5 vertebral body. In addition, LKA was defined as the angle between the upper endplate of the upper vertebral body of the compressed vertebra and the lower endplate of the lower vertebral body of the compressed vertebra.

2.3. Classification method

The 231 patients were divided into two groups according to different surgical approaches: unilateral approach and bilateral approach. There were 128 patients in the unilateral approach group (Group UA) and 103 in the bilateral approach group (Group BA). In addition, the patients who underwent bilateral PVP (Group BA) were further divided into a continuous bone cement group (Group CBC) and a discontinuous bone cement group (Group DBC) according to the distribution of postoperative cement. Cement continuity (**Figure 1**) was defined as no gap between the two bone cements on postoperative anteroposterior X-ray films, and cement discontinuity was defined as a significant gap between the two bone cements.

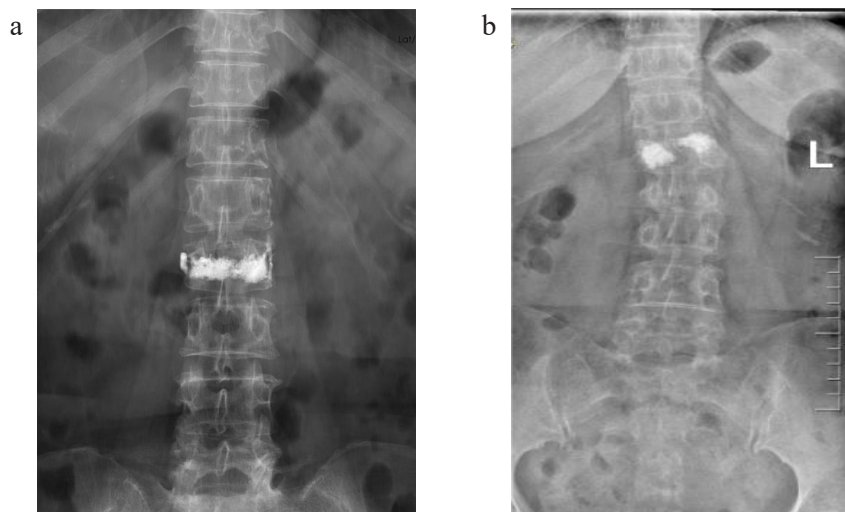


Figure 1. Bone cement continuity. (a) The continuous bone cement group with no gap between the two sides of the bone cement. (b) The discontinuous bone cement group with an obvious gap between the two sides of the bone cement.

2.4. Statistical analysis

SPSS program (version 27.0; SPSS Inc., Chicago, IL, USA) was used for statistical analysis. $P < 0.05$ was considered statistically significant. Quantitative data was tested by student's *t*-test or Mann–Whitney U-test according to data distribution. Qualitative data was tested by the chi-square test. Paired *t*-test or Wilcoxon was used for the comparison of preoperative data and last follow-up data.

3. Results

3.1. Comparison of Group UA and Group BA

A total of 231 patients were enrolled, including 128 patients in the Group UA and 103 patients in the Group BA. There were no significant differences in age ($P = 0.162$), gender ($P = 0.429$), BMI ($P = 0.266$), BMD ($P = 0.420$), smoking ($P = 0.553$), drinking ($P = 0.258$), history of trauma or symptoms ($P = 0.453$), followed-up period ($P = 0.524$) and surgical segment ($P = 0.563$) between the two groups. In Group UA, the mean surgery time was 26.17 ± 7.97 min, and the times of intraoperative fluoroscopy were 34.06 ± 7.27 . The mean surgery time of Group BA was 37.77 ± 10.86 min, and the times of intraoperative fluoroscopy was 51.91 ± 12.52 . The operation time ($P < 0.001$) and fluoroscopy times ($P < 0.001$) of Group UA were less than those of Group BA, and the differences were statistically significant.

The mean preoperative VAS score of Group UA was 7.17 ± 1.02 and the mean follow-up VAS score decreased to 1.44 ± 0.87 ($P < 0.001$). Similarly, the mean preoperative ODI score of Group UA was 34.73 ± 4.74 and the mean follow-up ODI score was 10.29 ± 3.49 ($P < 0.001$). The Group BA had a mean preoperative VAS score of 7.36 ± 1.25 and a mean follow-up VAS score of 1.75 ± 1.01 ($P < 0.001$). The mean preoperative ODI score of Group BA was 35.37 ± 4.98 , and the mean follow-up ODI score was 11.63 ± 2.91 ($P < 0.001$). Notably, both groups experienced a statistically significant decrease in VAS and ODI scores at the final follow-up assessment ($P < 0.001$), suggesting that both unilateral and bilateral approach procedures effectively alleviated pain in patients with OVCF. However, compared with the Group BA, the Group UA had a lower mean VAS score ($P = 0.013$) and ODI score ($P = 0.004$) at the last follow-up. The results are shown in **Tables 1** and **2**.

Table 1. Comparison of patient characteristics between Group UA and Group BA

Variable	Group UA (n = 128)	Group BA (n = 103)	t/z/c ²	P value
Age	72.19 ± 8.08	70.77 ± 7.13	1.397	0.162
Gender (male/female)	25/103	16/87	0.625	0.429
BMI	24.91 ± 4.62	24.33 ± 5.80	1.112	0.266
BMD	-3.14 ± 0.41	-3.21 ± 0.49	0.807	0.420
Smoking	21	14	0.352	0.553
Drinking	41	26	1.277	0.258
History of trauma or symptoms (days)	16.75 ± 16.02	14.41 ± 13.62	0.781	0.435
Followed up period	17.36 ± 7.95	16.46 ± 7.25	0.637	0.524
Surgical segment			1.148	0.563
T7–10	19	20		
T11–L2	66	47		
L3–5	43	36		
Surgery time (min)	26.17 ± 7.97	37.77 ± 10.86	7.626	< 0.001
Fluoroscopy frequency	34.06 ± 7.27	51.91 ± 12.52	10.925	< 0.001
LKA	9.06 ± 6.03	10.68 ± 7.25	1.629	0.103
LL	26.13 ± 10.82	24.24 ± 10.01	1.260	0.208
TK	40.73 ± 11.36	43.52 ± 11.51	1.415	0.157

BMI, body mass index; BMD, bone mineral density; LKA, local kyphosis angle; LL, lumbar lordosis; TK, thoracic kyphosis

Table 2. Analysis of VAS and ODI between Group UA and Group BA

Variable	Group UA (n = 128)	Group BA (n = 103)	t/z	P value
VAS				
Preoperative	7.17 ± 1.02	7.36 ± 1.25	0.991	0.331
Follow-up visit	1.44 ± 0.87	1.75 ± 1.01	2.479	0.013
t/z	9.906	8.864		
P	< 0.001	< 0.001		
ODI				
Preoperative	34.73 ± 4.74	35.37 ± 4.98	1.005	0.315
Follow-up visit	10.29 ± 3.49	11.63 ± 2.91	2.891	0.004
t/z	9.824	8.817		
P	< 0.001	< 0.001		

VAS, visual analogue scale; ODI, Oswestry Disability Index

3.2. Comparison of Group CBC and Group DBC

A total of 103 patients were enrolled, including 65 patients in the Group CBC and 38 patients in the Group DBC. There were no significant differences between the two groups in terms of patient demographics. There was also no statistically significant difference in surgery time ($P = 0.315$) and fluoroscopy frequency ($P = 0.581$) between the two groups.

In the analysis of the study participants, the Group CBC showed that the mean preoperative VAS score was 7.27 ± 1.26 and the mean follow-up VAS score was 1.55 ± 0.94 ($P < 0.001$). Additionally, the mean preoperative ODI score of Group CBC was 34.97 ± 4.99 , with a mean follow-up ODI score of 11.14 ± 2.78 ($P < 0.001$). The mean preoperative VAS score of Group DBC was 7.50 ± 1.25 , which decreased to 2.08 ± 1.05 at follow-up ($P < 0.001$). Similarly, the mean preoperative ODI score of Group DBC was 36.05 ± 4.95 , and at follow-up, it decreased to 12.47 ± 2.97 ($P < 0.001$). The VAS ($P = 0.032$) and ODI ($P = 0.024$) scores in Group CBC were significantly lower than those in Group DBC at the last follow-up. The results are presented in **Tables 3** and **Table 4**.

Table 3. Comparison of patient characteristics between Group CBC and Group DBC

Variable	Group CBC (n = 65)	Group DBC (n = 38)	t/z/c ²	P value
Age	70.49 ± 7.23	71.24 ± 7.02	0.438	0.661
Gender (male/female)	9/56	7/31	0.383	0.536
BMI	23.79 ± 5.42	25.26 ± 6.38	1.070	0.285
BMD	-3.18 ± 0.47	-3.25 ± 0.47	0.426	0.514
Smoking	7	7	1.195	0.274
Drinking	14	12	1.281	0.258
History of trauma or symptoms (days)	15.15 ± 13.49	13.13 ± 13.92	1.325	0.185
Followed up period	15.92 ± 6.75	17.39 ± 8.05	0.735	0.462
Surgical segment			2.700	0.259
T7–10	13	7		

Table 3 (Continued)

Variable	Group CBC (n = 65)	Group DBC (n = 38)	t/z/c ²	P value
T11–L2	33	14		
L3–5	19	17		
Surgery time (min)	38.54 ± 11.03	36.45 ± 10.58	1.004	0.315
Fluoroscopy frequency	52.48 ± 13.09	50.98 ± 11.57	0.551	0.581
LKA	10.12 ± 7.08	11.63 ± 7.53	0.949	0.343
LL	23.38 ± 9.40	25.71 ± 10.96	1.075	0.282
TK	42.03 ± 12.01	46.08 ± 15.59	1.409	0.235

BMI, body mass index; BMD, bone mineral density; LKA, local kyphosis angle; LL, lumbar lordosis; TK, thoracic kyphosis

Table 4. Analysis of VAS and ODI between Group CBC and Group DBC

Variable	Group CBC (n = 65)	Group DBC (n = 38)	t/z	P
VAS				
Preoperative	7.27 ± 1.26	7.50 ± 1.25	0.750	0.453
Follow-up visit	1.55 ± 0.94	2.08 ± 1.05	2.148	0.032
t/z	7.049	5.427		
P	< 0.001	< 0.001		
ODI				
Preoperative	34.97 ± 4.99	36.05 ± 4.95	0.731	0.465
Follow-up visit	11.14 ± 2.78	12.47 ± 2.97	2.252	0.024
t/z	5.378	7.014		
P	< 0.001	< 0.001		

VAS, visual analogue scale; ODI, Oswestry Disability Index

4. Discussion

Osteoporosis is a systemic skeletal disease characterized by low bone mass, decreased bone strength, destruction of bone microstructure, increased bone fragility, and susceptibility to fracture. The prevalence of osteoporosis in the elderly in the world is 21.7%, and the prevalence of osteoporosis in the elderly in Asia is the highest (24.3%)^[8]. OVCF is a serious complication of osteoporosis, and its incidence increases with the aggravation of global population aging. Osteoporotic fractures contribute to 0.83% of the worldwide burden of noncommunicable diseases^[9]. The main symptom is persistent low back pain, which seriously affects the quality of life of patients. The treatment of OVCF includes conservative treatment and surgical treatment. Conservative treatment mainly includes medical treatment, such as the use of anti-osteoporosis drugs, and calcium and vitamin D supplementation^[10]. In terms of surgical treatment, minimally invasive surgery is favored because of its small trauma, rapid recovery, and significant effect. Surgical intervention is superior to conservative treatment for pain relief in OVCF^[11,12]. Among them, PVP has become the preferred treatment for OVCF^[13,14]. The clinical efficacy of PVP is influenced by various factors. These factors include the professional expertise and skill level of the surgeon, the extent of damage to the vertebral body, the specific segment affected, the severity of osteoporosis in the patient, as well as considerations such as the viscosity, dosage, and

distribution of the bone cement used during the procedure^[15]. This study mainly explored the effect of different surgical approaches of PVP and the distribution of bone cement in the diseased vertebrae after PVP.

Both unilateral and bilateral approaches effectively relieve the pain symptoms of OVCF. Studies^[16] have shown that bilateral PVP is better than unilateral PVP in balancing the stress of the vertebral body, reducing the maximum stress and stability of the intervertebral disc. Bilateral PVP makes the distribution of bone cement injected into the vertebral body more uniform, and the structure and stiffness of the vertebral body more symmetrical, so as to produce a balanced stress distribution on the vertebral body, and significantly reduce the incidence of fracture re-compression^[17]. However, other studies^[18] have shown that unilateral PVP injected an adequate and more optimized volume of bone cement than bilateral PVP without increasing the risk of intradiscal leakage. Our results are consistent with the results of Chen *et al.*^[19] and Liu *et al.*^[20], which showed that the operation time of unilateral PVP was shorter than that of bilateral PVP, and the surgery time, X-ray fluoroscopy frequency, and bone cement injection volume were lower than those of bilateral PVP. At the one-year follow-up, our study found that patients in the unilateral group exhibited greater pain relief and spinal function recovery than those in the bilateral group. This superior outcome may be explained by factors such as the unilateral surgical approach leading to reduced trauma, shorter operation time, and decreased intraoperative fluoroscopy usage.

The distribution of bone cement in the vertebral body also affects the clinical efficacy of patients^[21,22]. Bone cement injected into the vertebral body will form a different cement distribution depending on the surrounding pressure. When the distribution of bone cement is limited to one side of the vertebral body, it is easy to cause uneven local force on the injured vertebra, which increases the risk of spinal instability and the probability of collapse of the injured vertebra^[23]. At present, there is no unified classification standard for the distribution of bone cement in the vertebral body. Based on anteroposterior radiographs of the vertebral body, Zhou *et al.*^[24] divided the vertebral body into one to four regions by drawing three vertical lines in the middle of the central spinous process and the inner edge of the pedicle on both sides. Subsequently, they classified the distribution pattern of bone cement into five types based on the location of cement distribution in the vertebral body. The study revealed that the clinical outcomes of bone cement distribution following PVP were more favorable in types I, II, and III compared to types IV and V. Bao *et al.*^[25] categorized patients into two groups, O-shaped and H-shaped, based on the cement shape observed on postoperative X-rays. In the O-shaped group, the bone cement exhibited a concentrated mass distribution within the affected vertebrae, whereas in the H-shaped group, the bone cement displayed a diffuse honeycomb distribution in the affected vertebrae. Importantly, regardless of whether the bone cement distribution was classified as O-shaped or H-shaped, the study found that both groups achieved positive clinical outcomes with similar prognostic effects. According to Li *et al.*^[26], the vertebral body with local dense and solid bone cement distribution on the anteroposterior and lateral X-ray films taken 24 hours after surgery was labeled as the blocky group. On the other hand, the vertebral bodies exhibiting diffuse, fibrous, and spongy bone cement distribution on the anteroposterior and lateral X-ray films were categorized as the spongy group. Both groups were observed to have a positive immediate analgesic effect. However, it was noted that the spongy group outperformed the blocky group in terms of maintaining vertebral body height, correcting local kyphosis, enhancing functional outcomes, and reducing the risk of postoperative adjacent vertebral fracture. Our study was divided into continuous and discontinuous groups according to the presence or absence of a significant gap between the cement on both sides. In both groups, we observed a decrease in postoperative VAS and ODI scores, suggesting that pain related to OVCF was alleviated irrespective of the cement distribution. However, the one-year follow-up revealed that the continuous group exhibited lower VAS and ODI scores compared to the discontinuous group, underscoring the superior mid-term

efficacy of the continuous group. This disparity in outcomes indicates that maintaining continuous and gap-free bilateral bone cement placement following bilateral PVP offers greater benefits for patient prognosis.

Our study has several limitations that need to be acknowledged. Firstly, it is important to note that our study is a retrospective one with a relatively small sample size and limited data sources. This increases the risk of bias, particularly in terms of subjectivity, as patients fill in the forms. Secondly, our study is confined to a single center, which introduces geographical limitations to the generalizability of the findings. Additionally, the mean duration of patient follow-up in our study was deemed insufficient. Consequently, it is crucial that the results of this study are replicated and validated through a more extensive, multi-center, prospective study with a larger sample size.

5. Conclusion

Unilateral PVP presented several advantages over bilateral PVP, particularly in terms of shorter surgery time, less fluoroscopy frequency, and less trauma. Continuous bone cement was closely related to good clinical outcomes. In clinical practice, we suggested unilateral PVP was performed for patients and ensured the continuity of bone cement for better clinical outcomes.

Disclosure statement

The authors declare no conflict of interest.

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