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Research Article

Clinical Study of Percutaneous Curved Vertebroplasty(PCVP) and Traditional Vertebroplasty for the Treatment of Osteoporotic Vertebral Compression Fractures

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ISSN: 2643-704X

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Submission: June 27, 2024

Published: July 12, 2024

Volume 5 - Issue 4

How to cite this article: Quanhe Qiu*, Weiping Xiao, Biaopeng Li*, Shunpu Wang, Jiewei Bao and Jing Jiang*. Clinical Study of Percutaneous Curved Vertebroplasty(PCVP) and Traditional Vertebroplasty for the Treatment of Osteoporotic Vertebral Compression Fractures. J Biotech Biores. 5(4). JBB. 000616. 2024.
DOI: 10.31031/JBB.2024.05.000616

Abstract

Objective: To evaluate the therapeutic effect of percutaneous curved vertebroplasty and traditional vertebroplasty for the treatment of osteoporotic vertebral compression fractures.

Methods: 261 patients (300 vertebral fractures, T11-L5) were randomly divided to 3 groups: A groups were treated with percutaneous curved vertebroplasty (83 patients, 100 vertebral fractures), B groups were treated with traditional unipedicular percutaneous vertebroplasty (90 patients, 100 vertebral fractures), and C groups were treated with traditional bipedicular percutaneous vertebroplasty (88 patients, 100 vertebral fractures). Clinical data including clinical and radiological evaluation results were performed pre- and postoperatively.

Results: Compared with preoperative data, the VAS scores, Oswestry disability index (ODI) scores, and local kyphotic angle were improved with significant differences after surgery in three groups (P<0.05). However, there were no differences between the three groups (P>0.05). The local kyphotic angle correction rate was respectively (37.9±15.7)%, (38.55±14.89)% and (37.26±16.14)% in three groups with no statistic difference (P>0.05). There were no significant differences between the three groups in the leakage rate of bone cement (group A is 26.00%, group B is 18.00%, group C is 25.00%, P>0.05). The operation time of group A (18.29±4.68min) and group B (18.04±4.20min) were less than that of group C (26.2874±4.36min) with significantly difference(P<0.05). The cement volume of group A and C were respectively 8.27±3.21ml and 8.39±2.55ml with no difference (P>0.05). The cement volume of group B (4.40±1.62ml) was obviously less than that of the other two groups(P<0.05).

Conclusion: Both percutaneous curved vertebroplasty and traditional percutaneous vertobreplasty can effectively relieve the back pain. PCVP is superior in cement dispersion and the volume of bone cement to traditional unilateral puncture, and is superior in operation time and trauma to traditional bilateral puncture. PCVP is not superior in the leakage rate of bone cement.

Keywords: Percutaneous vertebroplasty; Percutaneous curved vertebroplasty; Osteoporosis; Cement leakage; Operation time

Introduction

With the aging of the population, the improvement of medical level and the increase of people self-awareness of health, the people with osteoporosis and vertebral compression fractures were also becoming more common. Osteoporotic vertebral compression fractures (OVCFs) could cause severe back pain, restrict activity, gastrointestinal neurosis, lower the quality of life and increased case fatality rate [1-3]. Conservative treatment mainly includes bed rest, pain medication and external fixation, which has the disadvantages of great pain, prolonged treatment, uncertain curative effect and many other complications. The minimally

invasive techniques such as percutaneous vertebroplasty (PVP), which has been recognized as an effective procedure in the treatment of OVCFs was introduced to reduce these clinical problems [4-6]. Previous studies have demonstrated that PVP can immediately relieve the back pain and improve the quality of life [7]. At present, there were mainly unilateral and bilateral vertebral pedicle approaches. Compared with bilateral approaches, the unilateral approaches has the advantages of less trauma and shorter operation time, but also has the disadvantages of worse bone cement diffusion and less cement volume. Li [8] suggested that the application of a flexible bone cement injector for percutaneous unilateral vertebroplasty could achieve better long-term efficacy under the premise of not increasing the operation time, radiation exposure time and the incidence of bone cement leakage. How to achieve the outcomes of bilateral approach through unilateral approach is the direction of orthopedic surgeons to explore. In this study, 83 cases (100 vertebraes) of OVCFS were treated by percutaneous curved vertebroplasty compared to the groups of traditional unilateral and bilateral approaches (100 vertebraes respectively). The report is as follows.

Method and Materials

Study population selection

This was a prospective clinical study. A total of 261 patients (300 vertebraes) were randomly divided into 3 groups with random cross comparison grouping (group A: percutaneous curved approaches; group B: traditional unilateral approaches; group C: traditional bilateral approaches) between July 2016 and September 2020. Table 1 summarizes the detailed characteristics of the three groups of patients which are comparable.

Table 1: Patient demographics.

Variables	Total	Group A	Group B	Group C	P-Value
Age (years)[a]	74.78±6.41	74.42±5.90	75.04±6.93	74.85±6.41	0.818
Sex[b]					0.436
Men	86	30	25	31	
Women	175	53	65	57	
BMD (T-score)[a]	-3.25±1.03	-3.52±0.96	-2.99±1.09	-3.18±1.21	0.183
Operation time (minutes)[a]	19.49±8.2	18.6±4.95[c]	15.96±6.9[c]	23.72±9.6[d]	0
Cement volume (mL)[a]	6.97±2.05	8.29±0.96[c]	4.45±0.69[d]	8.16±1.32[c]	0
Cement leakage[b]	69	26	18	25	0.588

Abbreviations: BMD, bone mineral density; percutaneous kyphoplasty.

Note: a: Paired sample t test; b: chi-square test; c: No significant difference between the groups, P>0.05. d: Significant difference compared with the other two groups, P<0.05. Group A: Percutaneous curved vertebroplasty; Group B: Traditional unipedicular percutaneous vertebroplasty; Group C: traditional bipedicular percutaneous vertebroplasty.

Patients older than 60 years of age, bone mineral density T scores < -2.5, and with one or two levels of thoracolumbar OVCFs (assessed by MRI, from thoracic 11 to lumbar 5 vertebral bodies) due to osteoporosis were included in this study. OVCFs were diagnosed in patients who complained of back pain or lower back pain, had a history of low-energy trauma and tenderness in the thoracolumbar region according to the physical examination, and manifested compression of the vertebral body on magnetic resonance imaging. All patients enrolled in this study had relatively severe pain despite undergoing conservative management for 1-6 weeks (average 6.7 days). All patients underwent pathological examination through pedicle before injection of bone cement to excluded the disease of multiple myeloma or metastatic carcinoma. Also the patients who met the following criteria were excluded from this study: 1) spinal cord compression or stenosis of the vertebral canal >30% of the local canal diameter; 2) neurologic deficits; 3) systemic or local spine infections; 4) follow-up lost; 5) severe comorbidity in the heart, liver, kidney, and lung intolerance to surgery; 6) bleeding disorders. This study was conducted in accordance with the Declaration of Helsinki and approved by ethics committee of The Affiliated Hospital of Jiangxi University of Traditional Chinese Medicine. All data were collected and analyzed anonymously. All patients signed informed consent and all data were collected and analyzed anonymously.

Surgical management

Before the operation, all the patients took X-ray (lateral), and magnetic resonance imaging (MRI) scans. The same senior surgeon performed the surgery in all the patients. The surgery was performed under local infiltration anesthesia (1 case is for general anesthesia) under electrocardiographic monitoring with the patient in the prone position with the spine extended by chest and pelvic bolsters on a radiolucent operating table. All the fractures were reduced by hand compression *in vitro*. G-arm fluoroscopy(GE, USA) was used for simultaneous viewing of anteroposterior and lateral projections of the spine to identify an extra-pedicular or transpedicular entry point into the vertebral body. A puncture needle was placed percutaneously into the posterior vertebral body through transpedicular approach, and the PVP procedures were performed in the standard fashion reported in previous studies [9-10]. The procedure of PCVP was much the same as PVP except for an extra curved catheter(OSTEOPAL®V, zhejiang, China) (Figure 1-4). The injection and leakage of bone cement (Heraeus, German) were monitored using G-arm fluoroscopy during the surgery. With any

doubt of cement leakage into the spinal canal on the fluoroscopy, cement injection was stopped. Bone cement used was polymethyl methacrylate. After the operation, the patients began to walk or turn over by themselves after 3-4 hours. All the patients had the same conservative treatment of bisphosphonates, calcitonin, and vitamin D supplementation pre- and post-operation.

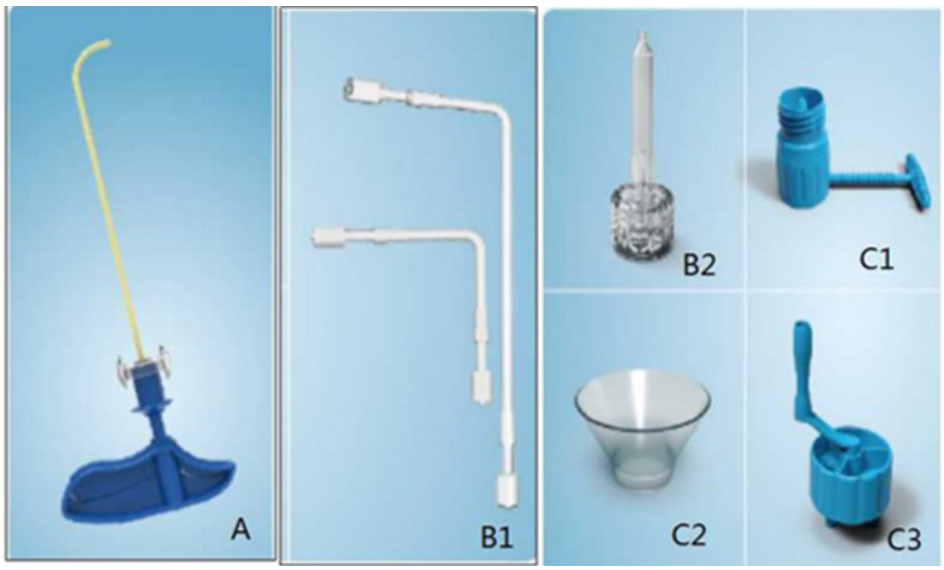

Figure 1: The surgical tool of percutaneous curved vertebroplasty. (A) The curved needles. (B) The catheter used to push bone cement. (C) The container for computing the bone cement.

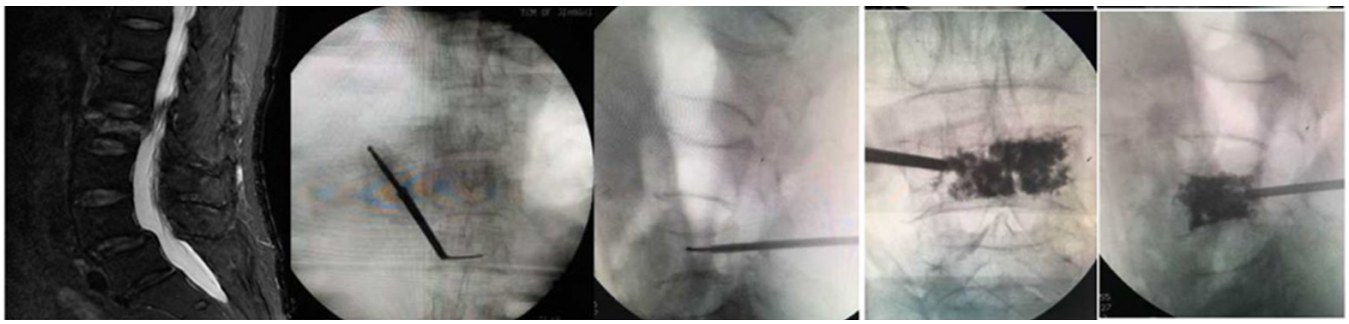

Figure 2: A 77-year-old female patient was admitted to our hospital after rough cough. (A) Preoperative sagittal MRI showed acute fracture of L2 vertebra. (B/C) Plain radiograph showed osteoporotic vertebral compression fracture of L2 vertebra with percutaneous curved kyphoplasty. (D/E) The cement were injected into vertebra body.

Figure 3: A 71-year-old female patient was admitted to our hospital after she slipped down. (A/B) Preoperative T1 and T2 sagittal MRI showed acute recent fracture of L2 vertebra. (C/D) Plain radiograph showed osteoporotic vertebral compression fracture of L2 vertebra with traditional unipedicular percutaneous kyphoplasty. The cement leaked from the anterior edge of the vertebra.

Figure 4: A 66-year-old female patient was admitted to our hospital after she slipped down. (A/B) Preoperative T1 and fat saturation sequence in MRI showed acute recent fracture of L2 vertebra. (C/D) Plain radiograph showed osteoporotic vertebral compression fracture of L2 vertebra with traditional bipedicular percutaneous kyphoplasty. The anterior local kyphotic angle improved compared to that of preoperation.

Evaluation criteria

Clinical data including clinical and radiological evaluation results were collected by two independent authors preoperatively and postoperatively. Clinical evaluation incorporated the visual analog scale (VAS) score (ranged from 0 to 10; 0: no pain, 10: worst pain) for pain evaluation and the Oswestry disability index (ODI) score for functional assessment. Local kyphotic angle was measured preoperatively and postoperatively, as were cement leakage, volume of bone cement and operation time. The local kyphotic angle correction rate was calculate according to this formula: (K1-K2)/K1×100%, k1: preoperatively, K2; postoperatively. The operation time was recorded from skin discission to incision close except closed reduction and narcosis.

Statistical analysis

All data were collected, and SPSS Version 17.0 (SPSS Inc., Chicago, IL, USA) was used for the statistical evaluation. The results were presented as mean ± SD. A Student's t-test was used to identify a significant difference between pre- and postoperative measurements of VAS score, ODI score, local kyphotic angle correction rate, cement volume and operation time for each group. The independent two-sample t-test was used to identify a significant difference between the groups. Categorical data were compared via the chi-squared test (Fisher's exact test for small samples). In all analyses, P-value <0.05 was considered statistically significant.

Result

This perspective study included 300 vetebrals (261 patients). Group A was comprised of 30 men and 53 women with a mean age at operation of 74.42 (range from 60 to 91) years. Group B was comprised of 25 men and 65 women with a mean age at operation of 75.04 (range from 61 to 96) years. Group C was comprised of 31 men and 57 women with a mean age at operation of 74.85 (range from 61 to 105) years. Figure 5 summarizes the detailed levels of the fractured vertebral bodies. The average compressive rate of fractured vertebral bodies was 56.3% (ranged from 35.7% to 84.4%). After surgery, the patients were followed up 7 days.

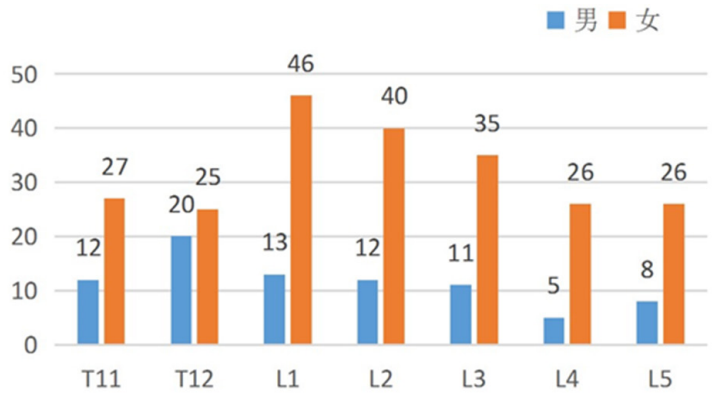

Figure 5: The detailed levels of the fractured vertebral bodies.

There were no significant differences in age, sex, BMD, vertebral compression, operative levels and follow-up between three groups (P>0.05, Table 1). The operation time of group A (18.6±4.95 minutes) and group B (15.96±6.9) were less than that of group C (23.72±9.6 minutes) with significant differences (P<0.05, Table 1). Compared with preoperative data, the VAS scores, ODI scores, and

local kyphotic angle correction rates were improved with significant differences after surgery and the last follow-up in the three groups. However, there were no significant differences between the three groups (P>0.05, Table 2). All the patients underwent the manual reduction before the operation, and the correction rate was respectively 37.9±15.7, 38.55±14.89 and 37.26±16.14 with no significant differences. Cement leakage occurred in 68 cases (26 cases in Group A, 18 cases in Group B, 25 cases in Group C), without pulmonary embolism and spinal cord injury. There were no significant differences between the three groups in the leakage rate of bone cement (Table 1). During the follow-up period, there were no adverse events such as infection, bone cement displacement, or abscission in the three groups.

Table 2: Comparison of surgical results between three groups in patients with OVCF.

	Group A		Group B		Group C	
Outcomes	**Preoperative**	**Postoperative**	**Preoperative**	**Postoperative**	**Preoperative**	**Postoperative**
VAS score	5.20±0.68	1.26±0.60[a,b]	5.56±0.90	1.24±0.59[a,b]	5.88±1.23	1.25±0.83[a,b]
ODI score	58.58±18.35	24.11±6.75[a,b]	65.12±8.29	25.69±3.21[a,b]	61.99±14.49	24.36±4.71[a,b]
LKA (°)	25.19±5.73	15.29±5.74[a,b]	25.3±5.9	15.32±4.14[a,b]	24.97±5.72	16.75±4.85[a,b]
LKA correction rate(%)	37.9±15.7[a]		38.55±14.89[a]		37.26±16.14[a]	

Abbreviations: OVCF, osteoporotic vertebral compression fracture; ODI, Oswestry disability index; VAS, visual analog scale. LKA: local kyphotic angle.

Notes: a: Significant difference between preoperative and postoperative using paired t-test; P<0.05. b Significant difference between three groups using One-Way ANOVA. P>0.05. Group A: Percutaneous curved vertebroplasty; Group B: Traditional unipedicular percutaneous vertebroplasty; Group C: traditional bipedicular percutaneous vertebroplasty.

The cement volume of group A and group C were respectively 8.29±0.96ml and 8.16±1.32ml, with no difference (P> 0.05). The cement volume of group B (4.45±0.69ml) was obviously less than that of other two groups (P<0.05). There were 3 patients in group B underwent additional PVP surgery because of little bone cement. and immediate relief of typical back pain after reoperation.

Discussion

In 1984, bone cement was first applied in the treatment of vertebral hemangioma for a good curative effect. Later, bone cement was gradually applied to palliative treatment of osteoporotic vertebral fracture and metastatic cancer. The OVCFs, which are mainly caused by osteoporosis, have become a major health problem worldwide nowadays. Most OVCFs can be healed within a few months by conservative therapy, but when the symptoms persist after conservative therapy, surgical treatment such as PVP should be regarded as a better choice. The bone cement plays a supporting role on the fracture endplate to relieve the pain, and plays a certain killing role on the peripheral nerve and tumor cells due to the local high temperature generated in the hardening process. At present, there are mainly PKP and PVP two operative methods. Compared with PVP, PKP can inject cement at relatively low pressure, which reduces the probability of bone cement leakage. It is also suspected that the corrective kyphosis effect of PKP is caused by the position during surgery and has nothing to do with balloon opening [11-12]. All the cases were treated with traditional PVP or PCVP because the ballon cannot be used in PCVP. Wang [13] considered that PCVP had the advantages of larger volume of bone cement, low leakage rate, better cement dispersion, and fewer fluoroscopy times, and there was no significant difference in VAS score. In this study, all patients were acute or subacute fractures, with an average of 6.7 days. There was no significant difference in the correction rate of kyphosis among the three groups, but the correction rate was significantly improved compared with that of preoperatively, indicating that external manual reduction could well correct the kyphosis of the vertebral body, and the height of the vertebral body was completely restored in some patients.

Compared with pre-operation, the VAS score in the three groups of patients were significantly lower after operation (3 patients were slightly lower, then lower down to 1 points after the treatment with the nonsteroidal drugs for 2 days). It is shown that the three groups of patients got a satisfied effect in pain and also proved that PVP is an effective treatment for OVCFs.

Bone cement leakage is the most common complication during surgery, which is related to the integrity of the vertebral wall and endplate, the operator's performance, the time of the cement injection, and the volume of cement. Although cement leakage is rarely symptomatic, the reported incidence of cement leakage varies from 5% to >80% [14-16]. In the present study, the incidence of cement leakage of the three groups were detected in 26%, 18% and 25% respectively with no significant difference. In the process of PCVP, we found that the pressure of the injection increased obviously at 4-5 minutes after the mixture of the cement, which greatly increased the risk of cement leakage. The long curved push rod delayed the cement entry into the vertebral body about 1-3s, which increased the risk of the cement leakage. It is difficult to adjust the position of the curved cannula in the vertebral body once the position was not good for the first time. Meanwhile, the PEEK materials around the inner needle at the corner was likely to be worn by the bone when the needle pulled out. Therefore, the position of the curved needle should be successfully placed in the vertebral body for one time as far as possible. Due to the poor adjustability of elbow needle, once cement leakage occurs during the injection of bone cement, the injection can only be suspended for tends of seconds to wait for the solidification of bone cement or withdraw the curved needle to change a position for injection. While the prolonged time increased the risk of leakage because of

the increased pressure and also affect the diffusion of the cement on the opposite side. This is the deficiency of PCVP in the prevention of cement leakage.

In this study, we found that the average amount of bone cement in group A and group C were more other than that in group B. In the process of PCVP, the cement was first diffused in the opposite vertebral body until the cement reached the posterior edge in the lateral radiograph. Then the catheter was gradually pulled out and the cement was slowly injected until the cement filled the vertebral body. The cement in anteroposterior radiograph always showed a complete piece but not the "monocular", "binocular" or "dumbbell" shape. In the traditional unipedicular groups, once the cement leakage occurred, the space to adjust is finite, so finally the total amount of the cement is significantly less than the other two groups. In group B, there was a great relationship between the cement dispersion and the obliquity angle of the puncture needle. The puncture point should be selected about 2-3mm outside of the "bull's eye" to ensure enough obliquity angle, so the tip of the needle can reach the middle of the vertebral body in anteroposterior radiograph. The vertebral above T10 were not selected in our study because it is not necessary to choose the bipedicular percutaneous kyphoplasty. At present, it is generally believed that the injection amount of bone cement can be as low as 3-5ml in the lumbar spine [17,18], while the average amount in one vertebral body exceeds 5ml in our study.

Most of the patients with OVCFs were older with cardiovascular system disease or respiratory system disease. All the patients were operated in a prone position which would increase cardiac stress, The risk of operation increased with the prolongation of operation time, especially in patients with cardiopulmonary dysfunction. Therefore, it is necessary to shorten operation time as soon as possible. The operation time was related to the number of puncture, the time of adjustment of the puncture position and needle's angle, and the number of fluoroscopy. In our study, we found that the operation time in the unilateral puncture groups was significantly shorter than the bilateral puncture groups. The shorter operation time was the advantage of PCVP and unilateral puncture, especially in patients with cardiopulmonary dysfunction.

Conclusion

In this study, all the patients can significantly relieve the pain. There was no differences in local kyphotic angle corrections. Compared with the traditional bilateral puncture, PCVP is superior in cement dispersion and the volume of bone cement than traditional unilateral puncture and is superior in operation time and trauma than traditional bilateral puncture. PCVP is not superior in the leakage rate of bone cement. The preoperative evaluation of cortical integrity around the vertebral body was extremely important to defense cement leakage due to the poor ability to adjust. However, there is still a need for a larger sample multicenter study to further confirm this result.

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