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# Effect of unilateral vertebral cement injection into PVP for osteoporotic vertebral compression fractures

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**Abstract**

***Objective:*** To investigate the effect of PVP injection of unilateral vertebral cement on fractures in the compression of osteoporotic vertebrals.

***Methods:*** From October 2017 to October 2018, 126 patients with osteoporotic vertebral compression fractures in our hospital were selected as the research subjects, and random number expression was used to divide them into study group and control group, each with 63 cases. In the research group, unilateral vertebral bone cement was injected into PVP, and in the control group, bilateral vertebral bone cement was injected into PVP. The amount of bone cement injection, operation time, X-ray irradiation time, length of hospital stay, and bone cement leakage rate were compared between the two groups of patients. The vertebral height of the lesion before and after surgery, Cobb angle of kyphosis, and Oswestry dysfunction index (ODI) were compared. Pain visual analogue scale (VAS) was used.

***Results:*** Compared with the control group, the study group had less bone cement injection, shorter operation time, shorter X-ray irradiation time, and shorter hospital stay. The disparity were very important. There was no fully important difference between the two classes in the leakage rate of postoperative cement (P > 0,05). There was no substantial difference between the two classes in vertebral height, Cobb angle kyphosis, and ODI after surgery. The VAS scores in the two groups at 1 day and 12 months behind operation were considerably lower than those before surgery and the difference was statistically important; nevertheless, the two groups' VAS scores were at 1 day, 3, 6, and 12 months after surgery. No arithmetical importance was given.

***Conclusion:*** PVP injection of vertebral body with unilateral bone cement is effective in treating osteoporotic important solidity fractures and has the advantages of less injection of bone cement, shorter postoperative time, and X-ray irradiation time.

**Keywords:** osteoporosis; vertebral compression fracture; percutaneous vertebroplasty; unilateral；

## 1. Introduction

With the development of social aging, the incidence of osteoporosis is gradually increasing (Wu Bowen et al., 2015)(Hansen E.J. et al., 2016). The major clinical features of osteoporosis are decreased bone density, and bone structure degeneration. Fracture is a severe complication. The fracturing of the vertebral compression is a common form of osteoporotic fractures that may trigger discomfort at the fracture site, decrease the height of the vertebral body, etc. This changes the natural curvature of the spine and affects spinal stability. Clinical treatment methods include physical therapy,

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conservative therapy, and surgical treatment. Traditional physical and conservative treatment methods can increase bone loss, accelerate muscle atrophy, and limit the rate of cure of patients. The drug treatment is long and effective, with many adverse reactions and affecting the quality of life of patients (Yi H.J. et al., 2016).

Percutaneous Vertebroplasty (PVP) has become a popular surgical procedure for the treatment of osteoporotic vertebral compression fractures (Saracen A. & Kotwica Z., 2016) in recent years, with the increasing advancement of minimally invasive techniques. It has advantages of less trauma, simple operation, good pain relief effect, fewer complications, and early out of bed activities, and has been widely recognized by clinicians and patients (Zhang L.G. et al., 2015)(Yang E.Z. et al., 2016). However, the PVP technique also has problems such as re-fracture of the vertebral body and bone cement leakage after operation, which is difficult to deal with and has attracted the attention of clinicians (Zhu J.J. et al., 2017). Studies have found that age, osteoporosis, type and distribution of bone cement materials are closely related to vertebral re-fractures, but there are few reports on interventions for surgical approaches to PVP surgery (Zhong B.Y. et al., 2015). In addition, the clinical safety and effectiveness of PVP for unilateral or bilateral vertebral puncture approaches have not been unified. This study involved 126 patients with osteoporotic vertebral compression fractures in our hospital from October 2017 to October 2018 as the research object, and analyzed the effect of vertebral unilateral bone cement injection of PVP on osteoporotic vertebral compression fractures.

## 2. Materials and methods

### 2.1. General Information

From October 2017 to October 2018, our hospital reported 126 patients with osteoporotic vertebral compression fractures as the study subjects, including 43 males and 83 females, aged 50 to 76 years, with an average age (65.35 ± 3.48 years). Patients were distributed randomly to research group and control group, with 63 cases each.

### 2.2. Inclusion and exclusion criteria

Inclusion criteria: (1) measured by X-ray film and bone density meter, T value below -2.5, and fresh fracture; (2) single-segment vertebral compression fracture, posterior injured side intact; (3) age 76; (4) no nerve root damage; (5) informed consent signed by patient or family member.

Criteria for exclusion: (1) those with occupancy of the spinal canal; (2) those with contraindications to surgery; (3) those with malignant tumors; (4) those with coagulopathy; (5) insufficient compliance.

### 2.3. Methods

Take the patient in a prone position, use a C-arm to accurately locate the vertebral fracture location, and mark it. Routine disinfection and spreading towels. According to the specific location of the fracture, lidocaine (5g · L-1) was used for local anesthesia. The research group used unilateral vertebral bone cement to inject PVP. Select the puncture at the upper edge of the vertebral transverse process at 6cm. The puncture needle is inserted at an angle of 45 °. Adjust the angle, depth and position of the needle. The puncture needle point reaches the front third of the vertebra. Stop the puncture and remove the needle core. Observe the movement and sensation of both lower limbs of the patient during puncture. Inject the bone cement prepared in advance in the state of wire drawing in the diseased vertebrae, and stop the injection when the bone cement approaches the posterior edge of the vertebral body or paravertebra leakage, intervertebral space leakage, venous leakage, epidural leakage occurs. Observe the patient's vital signs closely during the operation. When the bone cement is solidified, the puncture needle is pulled out, the incision is sutured and covered with the dressing. In the control group, bilateral vertebral bone cement was injected into PVP. Select the puncture at the upper edge of the vertebral transverse process at 4cm, and cut the skin. The puncture needle is inserted at an angle of 30 °, and the needle tip reaches the front third of the vertebral body. In addition, bone cement perfusion was the same as the study group. Patients in both groups were given conventional antibiotics after surgery, and activities were performed properly after 24 hours.

### 2.4. Observation indicators

The bone cement injection volume, operation time, X-ray irradiation time, hospitalization time, and bone cement leakage rate were record. The height of the diseased vertebrae before and after surgery, and the Cobb angle of the kyphosis were recorded. Visual analog scales (VAS) (Zhao Xuehui et al., 2015) were used to assess pain before and after 1 day, and 3, 6 , and 12 months after surgery. The higher the score, the heightened the pain. The

Oswestry guide (ODI)(Xue Wei, 2017) was used for assessing the state of the patient's limb function.

The higher the index, the more severe the dysfunction of the limbs;

**2.5. Statistical methods**

The data was analyze using statistical software SPSS 22.0. The calculation data was expressed as (x ± s) and the group relation was tested; the number of cases expressed the counted data and the X2 method was used. In P < 0.05 the gap was statistically important

**3. Results**

**3.1. Comparison of two groups of general information**

There were no major differences between the two groups in age, BMI, gender, fracture-to-operation time, fracture site and medical diseases (P > 0.05; Table 1).

**3.2. Comparison of clinical indicators between the two groups of patients**

The research group had less bone cement injection, shorter working period, shorter X-ray irradiation time and shorter stay in the hospital compared with the control group. The disparities were fully important. There was no substantial difference between the control group and the research group in the yield rate of bone cement (P>0.05; Table 2).

*Table 1:* **Comparison of general information between two groups of patients**

| Clinical data | Control group（n=63） | Experimental group（n=63） | t/X2 | P |
|---|---|---|---|---|
| Age（$\bar{x}$±s） | 65.29±3.76 | 65.13±3.03 | 0.154 | 0.095 |
| BMI（kg/m2，$\bar{x}$±s） | 21.51±1.30 | 21.78±1.14 | 1.214 | 0.257 |
| Sex | | | | |
| Male | 20 | 23 | 0.345 | 0.085 |
| Female | 43 | 40 | | |
| Time from fracture to operation（d，$\bar{x}$±s） | 5.16±2.41 | 5.24±2.38 | 0.671 | 0.095 |
| Fracture site | | | | |
| 1st lumbar spine | 18 | 19 | | |
| 2nd lumbar spine | 12 | 10 | | |
| 3rd lumbar spine | 5 | 6 | | |
| 4th lumbar spine | 1 | 1 | 0.084 | 0.132 |
| 5th lumbar spine | 2 | 3 | | |
| 9th thoracic spine | 5 | 5 | | |
| 10th thoracic spine | 2 | 3 | | |
| 11th thoracic spine | 6 | 5 | | |
| 12th thoracic spine | 12 | 11 | | |
| Combined medical diseases | | | | |
| Yes | 54 | 53 | 2.615 | 0.104 |
| No | 9 | 10 | | |

*Table 2:* **Comparison of clinical indicators of patients ($\bar{x}$ ± s)**

| Clinical indicator | Experimental group (n=63) | Control group (n=63) | t/X2 | P |
|---|---|---|---|---|
| Bone cement injection volume（ml） | 3.51±0.34 | 5.64±0.56 | -5.545 | 0.002 |
| Operation time（min） | 36.74±5.36 | 57.73±4.89 | -12.324 | 0.021 |
| X-ray irradiation time（min） | 14.73±1.65 | 24.54±2.01 | -6.642 | 0.001 |
| Hospital stay（d） | 8.46±4.18 | 11.28±5.07 | -5.841 | 0.015 |

| | | | | |
|---|---|---|---|---|
| Bone cement leakage rate （%） | 4（6.35） | 5（7.94） | 0.087 | 0.648 |

**3.3. Comparison of vertebral height, kyphosis Cobb angle and ODI in two groups of patients before and after surgery**

The vertebral height, kyphotic Cobb angle, and ODI of the two groups were meaningfully improved after surgery compared with those prior to surgery, and the differences were noteworthy ( P<0.05). The above measures were, however, not statistically relevant between two classes (P>0.05; Table 3).

**3.4. Comparison of VAS scores before and after surgery in two groups of patients**

Compared to preoperative, the VAS scores were significantly reduced after operation in the two groups at 1d, 3, 6 , and 12 months and the differentiation was fully important. No statistically significant comparison of monthly VAS scores between two classes (P>0.05; Table 4).

*Table 3:* **Comparison of vertebral height, kyphosis Cobb angle, and ODI before and after surgery in two groups**

| Clinical indicators | Experimental group (n=63) | Control group (n=63) |
|---|---|---|
| Vertebral body height （mm） | | |
| Before surgery | 18.14±1.26 | 18.05±1.30 |
| After surgery | 22.25±2.01 ab | 21.98±2.58 a |
| Cobb angle of kyphosis (°) | | |
| Before surgery | 21.32±2.15 | 21.16±2.08 |
| After surgery | 13.78±1.59 ab | 14.02±1.34 a |
| ODI | | |
| Before surgery | 42.87±3.59 | 42.65±3.67 |
| After surgery | 22.41±2.25 ab | 23.13±2.03 a |

Note: Compared with before surgery, aP <0.05; compared with control group, bP> 0.05

*Table 4:* **Comparison of VAS scores before and after surgery in two groups of patients ($\bar{x}$ ± s)**

| VAS score | Experimental group (n=63) | Control group (n=63) |
|---|---|---|
| Before surgery | 7.89±0.84 | 7.67±0.76 |
| 1d after surgery | 2.94±0.76 ab | 2.83±0.59 a |
| 3 months after surgery | 2.79±0.65 ab | 2.73±0.59 a |
| 6 months after surgery | 2.56±0.42 ab | 2.50±0.39 a |
| 12 months after surgery | 3.21±0.12 ab | 3.16±0.18 a |

Note: Compared with preoperative, aP <0.05; compared with control group, bP> 0.05

**4. Discussion**

Osteoporosis is more common in postmenopausal women and the elderly (Rzewuska M. et al., 2015). Vertebral density crack is a serious complication and it is difficult to treat clinically. It often results in patients with limited mobility and affects their ability to take care of themselves (Saracen A. & Kotwica Z., 2014). According to statistics, the global incidence of osteoporotic vertebral density fractures in people over 50 years of age is 11.9% to 48.6%, and the incidence is different in different regions and between different races (McCarthy J. & Davis A., 2016). The primary objectives of treating osteoporotic vertebral compression (OVC) fractures are to correct the deformed vertebral body deformity and vertebral body height, minimize pain, and enhance muscle function. PVP is intended to create micro-channels within the vertebral body, inject bone cement into the vertebral body, to restore the height of the vertebral body, to avoid long-term compression of the vertebral body and to alleviate pain quickly. This operating technique is a minimally invasive process. While ensuring clinical efficacy, it can also make up for the lack of traditional surgery and is beneficial to patients' recovery. Over the years, the effectiveness of PVP treatment and patient satisfaction have been widely recognized (Mattie R. et al., 2016). XieJiajia et

al.(2019) compared conservative PVP treatment in the treatment of OVC fractures, and the results

showed that PVP has a clear clinical effect, can significantly reduce pain in patients, and can promote functional restoration. The heavier the vertebral osteoporosis, the more obvious the decrease of bone density, the significant voiding of the internal structure, the easier the injection of semi-solid bone cement, and the better the ratio can be achieved to restore the vertebral body height (Alhashash M. et al., 2019). PVP has been commonly used in clinical practice in the treatment of OVC fractures, but the pedicle approach to this surgical procedure is still controversial (Luo Hongtao et al., 2015).

Li Jian et al. (2015) pointed out that bilateral PVP was injected into bone cement and its distribution was more uniform, but multiple irradiations were needed during the operation, the operation time was longer, and the incidence of bone cement leakage was high. It will also cause radiation damage and affect the efficacy. Unilateral PVP bone cement is difficult to distribute uniformly, and asymmetry on both sides of the injured vertebra is easy to occur, but its leakage rate is small. The results of this study show that the amount of bone cement injected in the study group is small, and the operation time, X-ray irradiation time and hospital stay are short. This shows that unilateral approach PVP surgery can significantly alleviate the pain and safety of patients, while bilateral approach PVP surgery can increase the exposure risk. Unilateral approach is less concerned with bone cement, which can effectively control pressure during injection, ensure clinical efficacy, and reduce the risk of leakage. Bone cement leakage is one of the more common complications of PVP: bone cement leaks into the spinal canal, outside the vertebra, and the intervertebral space through the ruptured vertebral cortex, compressing the nerve roots and the spinal cord (Zhu S.Y. et al., 2016). Bone cement can even penetrate the venous plexus through the bone marrow and penetrate into the circulatory system. In severe cases, it can cause pulmonary embolism, myocardial infarction, cerebral infarction, etc. (Hatzantonis C. et al., 2017). In this analysis, bone cement leakage occurred after unilateral PVP in four cases, and bone cement leakage occurred after bilateral PVP in 5 cases. No complications occurred in both groups, such as organ embolism and neurological symptoms. It shows that the incidence of bone cement leakage is lower, and after unilateral and bilateral approaches safety is better. Feng Chaoshuai et al.(2019) observed PVP 's clinical efficacy in treating fractures of the vertebral compression with various approaches. The results showed that the incidence of bone cement leakage was not significantly related to the surgical approach. The results of this study are consistent with the results of the above studies.

The findings exposed that the two groups' vertebral height, kyphotic Cobb angle and ODI were meaningfully improved compared with those prior to surgery, but there was no noteworthy difference among the two groups in vertebral height, kyphotic Cobb angle, and ODI. This shows that unilateral along with bilateral approaches to PVP do not have any advantages or disadvantages in vertebral height, Cobb angle kyphosis, and postoperative recovery from ODI and the clinical impact is stronger. Sun Lin researches et al. (2018) showed that unilateral approach PVP can promote vertebral body recovery and restore mechanical properties, can effectively correct kyphotic deformities, and is conducive to limb function recovery. The results of this study are consistent with this study. Nonetheless, if unilateral injection of bone cement does not reach the vertebral body's midline, it can result in poor recovery of vertebral body strength, resulting in unequal force on both sides, and vulnerable to vertebral compression. If unilateral or bilateral injection of bone cement crosses the midline, the rigidity on both sides of the vertebral body is fairly stable, and the vertebral body's biomechanical equilibrium is maintained. In this study, the hip and chest were elevated before surgery, leaving a gap between the injured vertebrae to allow the bone cement to penetrate the midline and the contralateral side. The angle of abduction was used to ensure the bone cement crossed the vertebral body midline. Comparison of VAS scores in the two groups in this study found that the VAS scores were substantially lower at 1d, 3, 6 , and 12 months after surgery than before, but there was no major difference in VAS at 1d, 3, 6 , and 12 months after surgery. According to most researchers study findings (Sun H. & Li C., 2016)(Pi Haiju et al., 2017). After the bone cement solidifies, it can increase the overall stability of the vertebral body, and also increase the stability of microfractures, reduce friction between microfractures, and thereby reduce stimulation and pain. Ren Hailong et al. (2014) reported that when bone cement solidifies, it can

destroy nerve endings and prevent pain conduction, which may be its analgesic mechanism.

To sum up, PVP injection of unilateral and bilateral body cement is a safer surgical procedure for osteoporotic stress fractures in the vertebral stress. There is no major improvement in pain relief and quality of life, but PVP injection of single lateral bone cement has the advantages of less discomfort and short operating time, does not raise the risk of bone cement leakage, easy procedure, low economic cost, and is more readily embraced by clinicians and family members of patients

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