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Original Article

Clinical analysis of vertebroplasty in the treatment of vertebral compression fractures

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Abstract: Objective: To evaluate the clinical efficacy and influencing factors of vertebroplasty with high viscosity bone cement in the treatment of vertebral compression fractures. Methods: A total of 120 elderly patients with osteopenia and osteoporotic vertebral compression fractures were enrolled in this study. They were grouped according to the surgical site and bone mineral density, and underwent vertebroplasty with high-viscosity bone cement. After operation, the dispersion range of bone cement was delineated by stratification based on Computed Tomography (CT), on which the dispersion volume of bone cement was calculated; injection volume of bone cement was recorded; postoperative vertebral height recovery and correction degree of kyphotic Cobb angle were calculated, on which pain visual analogue scale (VAS) and Oswestry disability index (ODI) of the patients were evaluated before and after operation. Furthermore, postoperative vertebral height recovery and correction degree of kyphotic Cobb angle were compared between the patients with different surgical sites and different bone mineral density; correlation between the injection volume, dispersion volume of bone cement and the vertebral height recovery was analyzed. Results: Postoperative VAS and ODI of the patients in various groups were significantly lower than those before operation. The fractured vertebral height recovery was not correlated with the injection volume of bone cement (R^2=0.004, P=0.487), but positively correlated with the dispersion degree of bone cement (R^2=0.619, P=0.000). Conclusion: For the patients with different fracture sites and different bone mineral density, vertebroplasty with high viscosity bone cement can effectively correct the kyphotic Cobb angle and recover the injured vertebral height in the treatment of vertebral compression fractures as well as relieve the patient pain quickly and effectively and improve their quality of life.

Keywords: Vertebroplasty, high-viscosity bone cement, vertebral compression fracture

Introduction

Vertebral compression fracture (VCF) constitutes the most common type of fractures in patients with osteoporosis. As China enters the aging society, incidence of VCF caused by osteoporosis is increasing year by year. VCF brings patients different degrees of low back pain, limits waist activities, reduces pulmonary function, and even leads to spinal deformity, thus limiting the function of abdominal and thoracic organs and seriously affecting their quality of life [1, 2].

Currently, several methods have been used to treat VCF, including bed rest, pain relief, support, rehabilitation or combination of these therapies. However, these methods have their own limitations. Firstly, patients, especially the elderly, are difficult to endure long-term bed rest, and a number of complications such as venous thrombosis and bedsore will be caused therefrom, threating the life safety of patients [3]. Secondly, conservative treatment can not reverse the kyphosis caused by biomechanical changes in spinal cord. Biomechanical changes may be a factor contributing to an increase in the incidence of adjacent vertebral fractures [4]. Thirdly, about 1/3 of the patients will suffer from persistent pain and progressive functional limitation [5]. In addition, the risk of conventional open operation generally increases resulting from combined medical diseases in patients. Therefore, it is urgent to find a treatment protocol that can relieve patient pain and improve functional limitations without experiencing major surgical trauma.

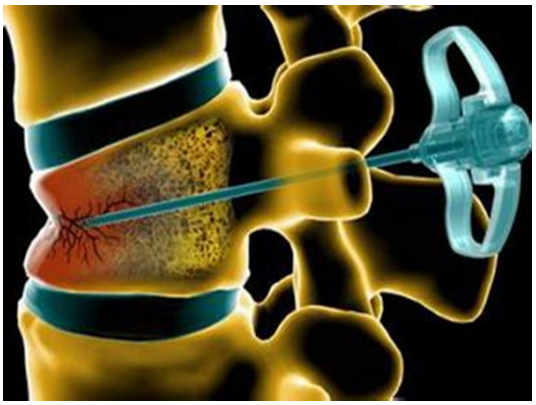

Figure 1. Injecting imaging picture.

Percutaneous vertebroplasty (PVP) is a commonly used method for minimally invasive treatment of VCF. PVP is intended to inject bone cement into the vertebral body, thereby improving the injured vertebral height and enhancing the injured vertebral strength, so as to improve the spinal stability and alleviate the pain [6, 7]. PVP was first introduced in 1980 to treat vertebral hemangioma, and so far, it has been widely used to treat the patients with back pain and VCF [8-10]. PVP as an effective surgical protocol has been extensively recognized by clinical investigators. However, a number of complications will occur, including bone cement leakage, adjacent vertebral fracture, bone cement poisoning and other serious complications such as spinal cord compression and nerve injury [11, 12]. Ideal filling materials can achieve better clinical efficacy and reduce the incidence of complications. Although high viscosity bone cement has been more and more widely used in PVP, study on the relationship between injured vertebral height recovery and dispersion degree of bone cement was seldom. Therefore, a retrospective study was conducted on the clinical data of 120 patients with VCF treated with high viscosity bone cement from October 2014 to April 2017, aiming to evaluate the role of PVP in improving vertebral height and correcting kyphosis, and analyze the relationship between injured vertebral height recovery and injection volume and dispersion degree of bone cement.

Materials and methods

Clinical materials

A total of 120 patients were enrolled in this study, including 52 males and 68 females, aged from 57-80 years and with an average age of 67.8 years.

Inclusion criteria: Imaging findings showed the spinal fractures complying with VCF diagnostic criteria; the patients were older than 55 years old; bone mineral density examination showed osteopenia or osteoporosis; the patients were able to lie prostrate above 1 h [13].

Exclusion criteria: Patients with coagulation disorders, accompanied by bleeding tendency; patients with spinal cord injury, cauda equina injury and other nerve dysfunction; patients with pathological fractures, accompanied by malignant disease or bone metastasis; patients with hypertension, diabetes and other major cardiac and pulmonary diseases, who cannot tolerate the surgery confirmed through systemic evaluation.

Surgical procedure

The patients lay in prone position; the injured vertebral body was positioned under fluoroscopy with C-arm X-ray machine; the bilateral pedicle puncture points were labeled in vitro; the 10-11 o'clock position outside of the proposed pedicle shadow on the left side was selected, and the 1-2 o'clock position on the right side was selected. The patients were disinfected and draped in the usual sterile fashion, and then received local anesthesia with 1% lidocaine from the labeled points; inserted the puncture needle into the vertebral body along the vertebral pedicle under fluoroscopy, and adjusted the puncture angle, position and depth, so as to make the needle tip enter anterior part of the pedicle, until anteroposterior film showed the needle was adjacent to the medial margin of the pedicle, indicating correct direction. Stopped puncturing when the lateral fluoroscopic puncture tip reached 1/3-1/4 of the vertebral anterior and the anteroposterior fluoroscopic puncture tip was located in the middle of medial margin of pedicle shadow and spinous process; the bone cement entering drawing period was injected into the fractured vertebral body under monitoring with C-arm X-ray machine, with about 0.3 mL bone cement injected per each rotation; stopped pressurization when the bone cement would disperse beyond the vertebral margin, and read the volume of bone cement injected through the scale on the bone cement filler. See **Figure 1**. The vital signs and neurological symptoms of both

Table 1. Comparison of vertebral height and kyphotic angle before and after PVP ($\bar{x}$ ± sd)

Group	Group L1 (n=30)	Group L2 (n=30)	Group T1 (n=30)	Group T2 (n=30)	F	P
Anterior border (mm)					0.563	0.644
Before operation	18.3±4.6	18.6±6.9	17.4±5.5	17.5±5.7		
After operation	23.9±4.4*	22.5±6.1*	22.3±4.8*	21.6±4.2*		
P	0.000	0.035	0.000	0.000		
Central height (mm)					0.396	0.767
Before operation	19.8±5.5	19.0±4.9	19.1±4.5	19.2±5.6		
After operation	24.6±4.7*	23.1±5.5*	23.9±3.8*	22.8±4.8*		
P	0.000	0.000	0.000	0.014		
Kyphotic Cobb angle (°)					0.928	0.442
Before operation	21.7±5.3	22.9±6.7	20.3±6.5	22.1±6.1		
After operation	11.8±6.7*	13.2±6.1*	12.7±4.8*	13.6±4.8*		
P	0.000	0.000	0.000	0.000		

Note: Compared with before operation, *P<0.05. PVP, percutaneous vertebroplasty.

Table 2. Comparison of VAS and ODI before and after PVP ($\bar{x}$ ± sd)

Group	VAS (score)		P	ODI (%)		P
	Before operation	After operation		Before operation	After operation	
Group L1 (n=30)	8.6±1.3	0.9±0.3*	0.000	72.3±8.9	4.6±2.1*	0.000
Group L2 (n=30)	8.1±1.1	0.8±0.3*	0.000	74.5±9.1	5.3±1.7*	0.000
Group T1 (n=30)	8.5±1.2	0.7±0.2*	0.000	69.8±8.1	5.4±1.5*	0.000
Group T2 (n=30)	8.6±1.0	0.8±0.2*	0.000	74.6±9.1	5.1±1.9*	0.000
F	1.986			2.543		
P	0.125			0.062		

Note: Compared with before operation, *P<0.05. VAS, visual analogue scale; ODI, Oswestry disability index; PVP, percutaneous vertebroplasty.

lower limbs were observed closely during the injection of bone cement. The patients lay in supine position for 2 h after operation. In addition, anti-osteoporosis drugs were taken for long term, supplemented with calcium and vitamin D.

Outcome measures

Bone mineral density (BMD) of all patients was determined with dual X-ray absorptiometry (DXA) before operation; the patients were divided into group L1, L2, T1 and T2 according to the surgical sites and BMD, of which group L1: $T_{\text{lumbar vertebra}} \leq -2.5$ (T=(detected value-peak bone mass in normal adults with the same gender and race)/BMD standard deviation of normal adults); group L2:-1>$T_{\text{lumbar vertebra}}$>-2.5; group T1:$T_{\text{thoracic vertebra}} \leq -2.5$; group T2:-1>$T_{\text{thoracic vertebra}}$ >-2.5. After operation, all patients received ultra-thin thickness computed tomography (CT) or positron emission tomography (PET) for injured vertebral body, and the acquired images were imported into PACS workstation. Dispersion range of bone cement was delineated by stratification, and corresponding volume was calculated, namely the volume of bone cement dispersed. Intraoperative injection volume of bone cement was recorded. Kyphotic Cobb angle was measured on the preoperative and postoperative lateral X-ray films of the injured vertebral body. Postoperative vertebral recovery height and correction degree of kyphotic Cobb angle were calculated. The data were measured independently by two spinal surgeons, and mean of the measurements was statistically analyzed. Subjective feelings of the preoperative and postoperative pain and disability in patients were evaluated with visual analogue scale (VAS) and Oswestry disability index (ODI).

Statistical treatment

The measurement data were analyzed with SPSS16.0, expressed in ($\bar{x}$ ± sd). The variable

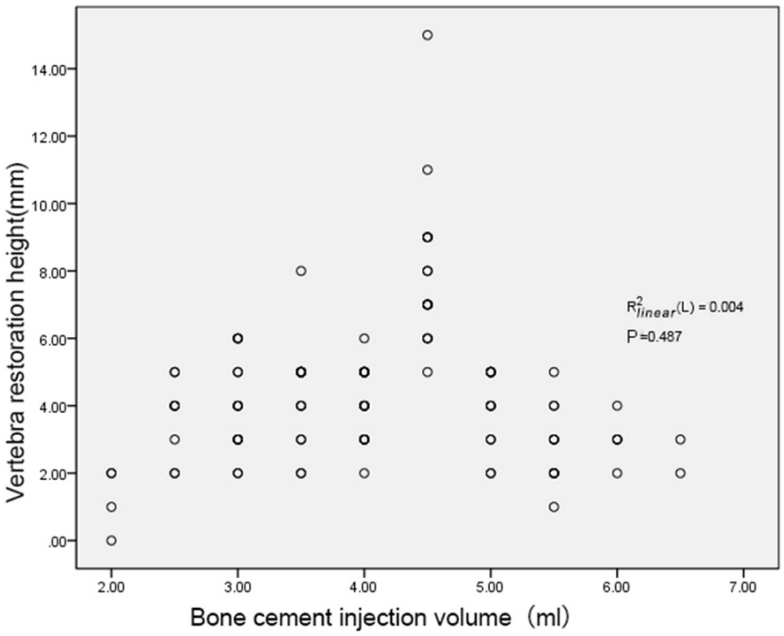

Figure 2. Scatter plot of linear correlation between fractured vertebral height recovery and injection volume of bone cement.

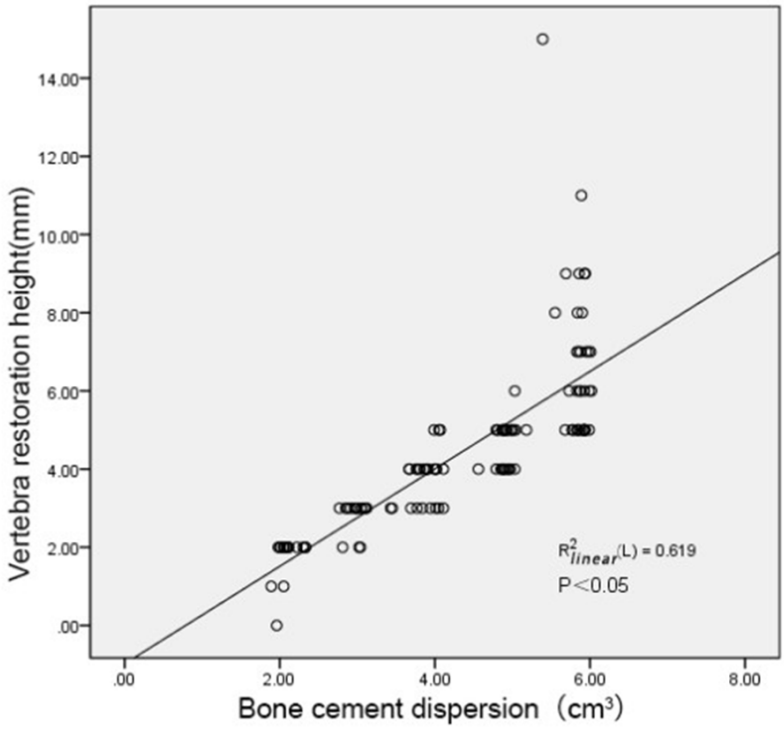

Figure 3. Scatter plot of linear correlation between fractured vertebral height recovery and dispersion volume of bone cement.

data of four groups (such as anterior border, central height, kyphotic Cobb angle, VAS and ODI) were compared by paired *t* test before and after operation, and the four groups were compared using Analysis of Variance (ANOVA). Correlation among bone cement injection volume, bone cement dispersion volume and fractured vertebral recovery height was analyzed using linear correlation and regression analysis, and the linear regression equation was established. P< 0.05 represents statistically significant difference.

Results

Evaluation of patients' subjective feelings of PVP in vertebral height recovery, degree of pain and disability

After operation, the vertebral anterior border and mean central height increased in the four groups compared with those before operation, and the kyphotic Cobb angle decreased, all of which presented statistically significant differences, but the vertebral recovery height presented no statistical difference before and after operation between the four groups (P>0.05). See **Table 1**.

VAS and ODI decreased in the four groups after operation compared with those before operation, but there was no significant difference between the four groups in postoperative VAS and ODI. See **Table 2**.

The relationship between vertebral height recovery and injection volume and dispersion volume of bone cement was analyzed

The fractured vertebral height recovery was not correlated with the injection volume of bone cement (R^2=0.004, P=0.487), but positively correlated with the dispersion volume of bone

cement (R^2=0.619, P=0.000). See **Figures 2** and **3**.

The postoperative complications of PVP were evaluated

All patients were followed up for an average of 12 months (3 to 17 months) after operation. Cauda equine syndrome occurred in one patient, and adjacent vertebral compression fractures occurred in two patients, accounting for 1.6%. No surgical site infection, pulmonary embolism and other complications occurred in all patients.

Discussion

As the application of PVP in the treatment of VCF is studied deeply, the scholars have gradually realized the shortcomings of PVP in vertebral height recovery. For instance, the spinal fixation is unable to restore the normal spinal sequence in the case of deformity. Some scholars expect to solve the problem with percutaneous kyphoplasty (PKP). Similar to PVF, PKP can relieve the patient pain, while it also presents more obvious advantages in long-term improvement of kyphotic angle and bone cement permeability. Nevertheless, PKP presents longer length of operation and higher material cost than those of PVP [14]. As far as the current study is concerned, PVP has more advantages and has been widely used clinically.

Studies have shown that PVP can improve the patient pain. Kim et al. reviewed the clinical data of 673 patients with VCF treated with PVP, and found that PVP presented excellent pain relief in single-stage and multistage surgeries [15]. Some scholars believed that PVP mainly reduces the patient pain clinically rather than recovers the injured vertebral height [16]. However, Hiwatashi et al. study has shown that PVP could recover the injured vertebral height, and nearly 85% of patients increased the vertebral height by an average of 2 mm [17]. Baroud et al. compared the efficacy of bone cements with different viscosity in the treatment of VCF, and found that both can alleviate the patient pain and reduce the Cobb angle, and the postoperative VAS and Cobb angle in high viscosity bone cement group were significantly lower than those of conventional bone cement group [18]. Our study results showed that the vertebral height recovered in different degrees after VCF was treated with high viscosity bone cement compared with that before operation, with an average of 4.41±2.10 mm, and the preoperative BMD and fracture site generated no impact on the operative efficacy. Meanwhile, the patient pain was alleviated and functional limitation was improved after operation. We speculated that such effect was achieved because of special physical and chemical properties of high viscosity bone cement. The high viscosity bone cement is characterized by instantaneous high viscosity, low fluidity and relatively low polymerization temperature, causing less thermal damage to the tissues.

More and more clinical trials have shown that there is no direct correlation between the clinical efficacy and injection volume of bone cement. It has been reported that only a small amount of bone cement (about 3 mL) could achieve pain relief [19, 20]. However, the dispersion area of bone cement in vertebral body cannot be used as an index to evaluate the therapeutic effect. These findings indicated that the injection volume and dispersion area of bone cement in vertebral body were of little significance in evaluating the therapeutic effect [20]. Therefore, the concept of dispersion volume of bone cement was proposed, namely a three-dimensional space formed by binding trabecular bone and its wrapping space after the bone cement is injected into the vertebral body and disperses stretching the space between the fracture line in the vertebral body and trabecular bone [21]. This evaluation highlights the specific bone cement setting at the vertebral fracture site rather than the absolute injection volume of bone cement. In this study, correlation between the injection volume, dispersion volume of bone cement and fractured vertebral height recovery was analyzed, and the findings showed that the fractured vertebral height recovery was positively correlated with the dispersion degree of bone cement (R^2= 0.619, P=0.000), but not correlated with the injection volume of bone cement, supporting the literature conclusion [22].

For safety evaluation, the most common complications such as bone cement leakage and cauda equine syndrome were analyzed. Relevant literature reported that the incidence of bone cement leakage in patients underwent PVP was up to 8% [23]. However, bone cement

leakage does not cause any clinical symptoms generally [24]. In this study, one patient suffered from cauda equine syndrome and two patients from adjacent vertebral compression fractures, with the incidence lower than that reported in literature. This may be attributed to the application of high viscosity bone cement. The postoperative complications may be related to early postoperative activities of patients. Although a number of studies have reported the incidence of bone cement leakage, few reports have reported the cases suffered from spinal stenosis and pulmonary embolism due to bone cement leakage.

In sum up, this study demonstrated that application of high viscosity bone cement can improve the pain of VCF patients, recover the vertebral height and improve kyphosis. The PVP with high viscosity bone cement is of great clinical significance in vertebral height recovery, improvement of the quality of life for the patients with osteopenia or osteoporotic compression fractures.

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Disclosure of conflict of interest

None.

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