

Percutaneous vertebroplasty with high- versus low-viscosity bone cement for osteoporotic vertebral compression fractures

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Abstract

Background: There is no consensus on the best choice between high- and low-viscosity bone cement for percutaneous vertebroplasty (PVP). This study aimed to compare the clinical outcomes and leakage between three cements with different viscosities in treating osteoporotic vertebral compression fractures.

Methods: This is a prospective study comparing patients who were treated with PVP: group A (n = 99, 107 vertebrae) with high-viscosity OSTEOPAL V cement, group B (n = 79, 100 vertebrae) with low-viscosity OSTEOPAL V cement, and group C (n = 88, 102 vertebrae) with low-viscosity Eurofix VTP cement. Postoperative pain severity was evaluated using the visual analog scale. Cement leakage was evaluated using radiography and computed tomography.

Results: There was no significant difference in the incidence of cement leakage between the three groups (group A 20.6%, group B 24.2%, group C 20.6%, $P = 0.767$). All three groups showed significant reduction in postoperative pain scores but did not differ significantly in pain scores at postoperative 2 days (group A 2.01 ± 0.62 , group B 2.15 ± 0.33 , group C 1.92 ± 0.71 , $P = 0.646$). During the 6 months after cement implantation, significantly less reduction in the fractured vertebral body height was noticed in group B and group C than in group A (group A 19.0%, group B 8.1%, group C 7.3%, $P = 0.009$).

Conclusions: Low-viscosity cement has comparable incidence of leakage compared to high-viscosity cement in PVP for osteoporotic vertebral compression fractures. It also can better prevent postoperative loss of vertebral body height.

Background

Polymethyl methacrylate (PMMA) bone cement is used in percutaneous vertebroplasty (PVP) for the treatment of osteoporotic vertebral compression fractures. It is injected into the fractured vertebral body to achieve immediate augmentation, relief of the pain, and patient mobility improvement. However, cement leakage into the paravertebral space or blood vessels constitutes a potentially severe complication of PVP and can result in neurological deficit [1] or even paralysis, and pulmonary [2] or heart embolism [3–6], which can be fatal.

Bone cement is prepared by mixing the polymer powder and the monomer liquid of PMMA. The viscosity of the cement paste increases with advancement of polymerization of PMMA and finally solidify. The cement is implanted into the fractured vertebra using an injection gun immediately after mixing, when it still has a low viscosity and is easy to aspirate. It has been worried that low-viscosity cement is prone to leak from the vertebra. However, use of high-viscosity cement does not completely prevent the occurrence of leakage [7–11]. In our practice, it was noticed that cement leakage mostly occurs in the late phase of injection, when the cement viscosity is increasing. Increased viscosity requires higher injection pressure and may lead to more leakage. In addition, increased injection pressure causes more intraoperative pain. We speculate that low-viscosity cement requires lower injection pressure, which may reduce the risk of

leakage. It may also have better filling in the vertebral trabeculae and thus prevent postoperative loss of vertebral height.

The present study aimed to compare the three cements (high-viscosity OSTEOPAL V, low-viscosity OSTEOPAL V, and low-viscosity Eurofix VTP) in terms of leakage incidence and clinical outcomes for treating osteoporotic vertebral compression fractures using PVP.

Materials And Methods

Patients

This is a prospective study with 266 patients with osteoporotic vertebral compression fractures (309 vertebrae) treated at our hospital during March 2015 to February 2018. The inclusion criteria were: 1) osteoporotic vertebral compression fracture confirmed by imaging examination; 2) back pain evaluated by visual analog scale above 4 points; 3) bone edema in the fractured vertebra on magnetic resonance imaging (MRI): high signal in T2-weighted images and short tau inversion recovery sequences, and low signal in T1-weighted images; 4) age over 50 years; 5) decreased bone mineral density (T scores < -1).

The exclusion criteria included: 1) spinal malignancy, infection or angioma; 2) spinal cord compression or vertebral canal stenosis more than 30%; 3) neurologic deficits; 4) uncorrectable bleeding disorders; 5) severe comorbidities of the heart, liver, kidney, or lung. This study was approved by the ethics committee of our hospital.

The patients were divided into three groups: group A (n = 99, 107 vertebrae) with high-viscosity OSTEOPAL V cement (Heraeus Medical GmbH, Germany), group B (n = 79, 100 vertebrae) with low-viscosity OSTEOPAL V cement, and group C (n = 88, 102 vertebrae) with low-viscosity Eurofix VTP cement (Synimed, France).

Surgical procedure

The patients were in the prone position. Parecoxib sodium 40 mg and dezocine 5 mg were intravenously administered 30 minutes before the surgery. Infiltration anesthesia was performed using 0.8–1% lidocaine along the puncture pathway. All surgeries were performed under fluoroscopy by two senior surgeons, Xiaojun Zeng and Wei Wang. The destination of the vertebroplasty needle point was the vertebral edema shown by MRI. During the procedure, the needle was stopped and readjusted if severe pain or nerve root irritation occurred. The needle point was advanced to the position medial to the pedicle and near to the base of the spinous process (anteroposterior view), and the anterior one-third borderline of the vertebra (lateral view).

Cement preparation and implantation

The cement was prepared by mixing the polymer powder and the monomer liquid of PMMA in a dry, clean stainless-steel bowl at an ambient temperature of 22 °C. The high-viscosity OSTEOPAL V cement and the

low-viscosity Eurofix VTP cement were prepared exactly according to the manufacturer's instruction. The low-viscosity OSTEOPAL V cement was prepared by reducing the amount of the polymer powder by 1–2 g. The cement paste was loaded into the injection gun immediately after the preparation process. At around 2 minutes 5 seconds after the mixing, the cement was injected into the fractured vertebra under fluoroscopy. The volume of injected cement was recorded.

Assessment of outcomes

Antiosteoporotic therapy was continued postoperatively. No analgesics were used postoperatively. The patients were encouraged to ambulate with a wide wrist belt at postoperative 24 hours. Cement leakage and filling were evaluated using X-ray and computed tomography (CT) within postoperative 3 days before the patients were discharged at postoperative 2–3 days. All patients were followed up for at least 6 months with radiography. Pain severity was evaluated preoperatively, intraoperatively, and at postoperative 2 days using the visual analog scale.

In the axial CT images, the cement border and the vertebral border were manually outlined using the PASC software (Fig. 1). Then the cement diffusion volume and the vertebral volume were automatically calculated by the software by combining the image layers. Cement filling percentage and cement diffusion rate were calculated using the following formulas.

cement filling percentage = cement diffusion volume / vertebral volume × 100%

cement diffusion rate = cement diffusion volume / cement injection volume

The anterior vertebral body height was measured in the lateral X-ray images. The percentage of further height loss at 6 months was calculated using the following formulas.

percentage of further height loss at 6 months = percentage of height loss at 6 months - percentage of height loss immediately after the surgery

percentage of height loss = (estimated original height – measured height) / estimated original height × 100%

estimated original height = (height of the superior vertebral body + height of the inferior vertebral body) / 2

Statistical analysis

Continuous data are presented as means and standard deviations and compared using the one-way analysis of variance followed by the Tukey's post hoc test. Categorical data are presented as percentages and compared using the chi-square test. All statistical analyses were performed using the SPSS 25.0 (IBM, US).

Results

There was no significant difference in the general characteristics between the three groups (Table 1). There three groups showed no significant difference in the incidence of cement leakage (Table 2). No leakage-associated spinal cord injury, nerve root injury, or embolism occurred.

All three groups showed significant reduction in postoperative pain sores (Table 3). The three groups did not differ significantly in preoperative and postoperative pain scores. However, high-viscosity OSTEOPAL V cement was associated with significantly higher pain scores compared to low-viscosity OSTEOPAL V cement and low-viscosity Eurofix VTP cement.

The volume of injected cement per vertebral body was significantly higher in group B and group C than in group A (Table 4). These two groups also had significantly higher cement filling percentage and cement diffusion rate than group A. At 6 months, there were 12 patients with 12 vertebrae in group A, 10 patients with 11 vertebrae in group B, and 16 patients with 16 vertebrae in group C. The percentage of further height loss at 6 months was significantly lower in group B and group C compared to group A.

Discussion

Our study found that there was no significant difference in the incidence of leakage and postoperative pain between high-viscosity OSTEOPAL V cement, low-viscosity OSTEOPAL V cement, and low-viscosity Eurofix VTP cement for the treatment of osteoporotic vertebral compression fractures with PVP. The two cements of low-viscosity were associated with significantly less intraoperative pain compared to the high-viscosity OSTEOPAL V cement. They also had significantly higher filling percentage and diffusion rate and significantly less further height loss than the high-viscosity OSTEOPAL V cement.

Viscosity of PMMA can be decreased with extended working time by increasing the liquid-to-powder ratio during the mixing, decreasing the ambient temperature, or chilling the liquid monomer [12]. It has also been reported that increased liquid-to-powder ratio may decrease the mechanical strength of the cement by 24% [13]. However, the clinical impact of this effect is unclear. Two brands of cement were used in our study, OSTEOPAL V and Eurofix VTP. We have tested the low-viscosity OSTEOPAL V cement before our study, which was prepared by reducing the amount of the powder PMMA, and found it had similar mechanical strength to that prepared using the normal liquid-to-powder ratio. Low viscosity of the cement may postpone the solidification and provide more time for cement injection.

Our study found that PVP with either high- or low-viscosity cement significantly reduced postoperative pain with comparable incidence of leakage. In addition, the two low-viscosity cements were associated

with significantly less intraoperative pain compared to the high-viscosity cement. We noticed that there was no pain or very mild pain during advancement of the vertebroplasty needle. The patients experienced pain when the cement was injected, especially during the last phase of injection, when the viscosity is increasing and the cement solidify. Cement implantation increases pressure inside the vertebral body and results in pain during cement injection. Despite the significantly higher volumes of the low-viscosity cements injected, they still resulted in significantly less intraoperative pain compared to the high-viscosity cement without increasing the incidence of leakage. Further investigation is needed to explain this counterintuitive effect.

The two low-viscosity cements had significantly less further height loss than the high-viscosity cement. This may be associated with the significantly higher filling percentage and diffusion rate of the low-viscosity cement, and the significantly higher volumes of the low-viscosity cements injected. Lower viscosity may increase the cement infiltration and filling in the vertebral trabeculae, which may also increase the injection volume. It has been suggested that higher volume of injected cement in the vertebra is associated with better vertebral augmentation and pain relief [14, 15] and less further loss of the vertebral body height [16–18].

Our study has limitations. First, the cement viscosity was not measured. The relativity of high and low viscosity in our study was determined by altering the liquid-to-powder ratio. Second, only 38 (14.3%) of the patients completed the follow-up at 6 months. This may compromise the reliability of the results of vertebral height loss.

Conclusions

PVP with low-viscosity cement and high-viscosity has similar incidence of leakage. Low-viscosity cement is associated with significantly less intraoperative pain compared to high-viscosity cement. It can also better prevent the postoperative loss of vertebral height, which may reduce the risk of future refracture.

Abbreviations

| | |
|-----------------------------|------|
| percutaneous vertebroplasty | PVP |
| Polymethyl methacrylate | PMMA |
| magnetic resonance imaging | MRI |
| computed tomography | CT |

Declarations

Ethics approval and consent to participate: This study was approved by tRenmin Hospital, Hubei University of Medicine. Wriitten informed consent was obtained from all the study subjects before

enrollment.

Consent for publication: Not applicable.

Availability of data and material: The datasets generated and analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests: The authors declare that they have no competing interests.

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Authors' contributions: FM and XZ contributed to the conception and design of the study; WW and ZZ performed the experiments, collected and analyzed data; FM and XZ wrote the manuscript; All authors reviewed and approved the final version of the manuscript.

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Tables

Table 1 Patient general characteristics

| | Group A (n = 99) | Group B (n = 79) | Group C (n = 88) | P value |
|---|------------------------------|-----------------------------|------------------------------|---------|
| Cement type | High-viscosity OSTEOPAL V | Low-viscosity OSTEOPAL V | Low-viscosity Eurofix VTP | |
| Female/male (n) | 73/26 | 59/20 | 65/23 | 0.989 |
| Age (year) | 72.38 ± 9 | 70.1 ± 7.87 | 71.5 ± 8.05 | 0.870 |
| Bone mineral density (T score) | -2.36 ± 0.67 | -2.89 ± 0.94 | -2.48 ± 0.81 | 0.659 |
| Number of fractured vertebrae (thoracic/lumbar) | 107 (61/46) | 100 (56/44) | 102 (56/46) | 0.954 |
| Total number of vertebral bodies with fissures found in preoperative CT | 82 | 79 | 80 | 0.858 |
| Endplate fissure | 13 | 15 | 16 | 0.732 |
| Front or lateral wall fissure | 71 | 61 | 73 | 0.326 |
| Back wall fissure | 17 | 19 | 20 | 0.746 |

Table 2 Cement leakage assessment

| | Group A (n = 99) | Group B (n = 79) | Group C (n = 88) | P value |
|--|------------------|------------------|------------------|---------|
| Total number of vertebral bodies with cement leakage | 22 | 24 | 21 | 0.767 |
| Through endplate | 5 | 6 | 5 | 0.892 |
| Through front or lateral wall | 9 | 10 | 9 | 0.909 |
| Through back wall | 5 | 4 | 4 | 0.959 |
| Through blood vessels | 3 | 4 | 3 | 0.863 |
| Incidence of cement leakage (%) | 20.6 (22/107) | 24 (24/100) | 20.6 (21/102) | 0.767 |

Table 3 Visual analog scale pain scores

| | Group A (n = 99) | Group B (n = 79) | Group C (n = 88) | P value |
|---------------------------|------------------|------------------|------------------|---------|
| Preoperative | 8.31 ± 0.76 | 8.25 ± 0.57 | 8.18 ± 0.27 | 0.872 |
| Intraoperative | 8.01 ± 1.51 | 4.01 ± 1.21 | 4.20 ± 1.16 | 0.021 |
| Immediately postoperative | 2.11 ± 0.53* | 2.01 ± 0.69* | 2.18 ± 0.35* | 0.735 |
| Postoperative 2 days | 2.01 ± 0.62* | 2.15 ± 0.33* | 1.92 ± 0.71* | 0.646 |
| P value | 0.012 | 0.011 | 0.009 | |

*vs preoperative

Table 4 Cement filling and vertebral height loss

| | Group A (n = 99) | Group B (n = 79) | Group C (n = 88) | P value |
|--|------------------|------------------|------------------|---------|
| Injected cement volume per vertebral body (ml) | | | | |
| Through unilateral approach | 4.52 ± 2.7 | 6.92 ± 1.7 | 6.57 ± 1.9 | 0.025 |
| Through bilateral approach | 7.24 ± 3.1 | 11.75 ± 2.64 | 11.41 ± 3.2 | 0.021 |
| Cement filling percentage (%) | 20.78 | 48.53 | 49.12 | 0.017 |
| Cement diffusion rate (%) | 4.98 | 9.55 | 9.71 | 0.020 |
| Percentage of further height loss at 6 months* | 19.01 ± 0.53 | 8.12 ± 0.13 | 7.35 ± 0.71 | 0.009 |

There were 12 patients with 12 vertebrae in group A, 10 patients with 11 vertebrae in group B, and 16 patients with 16 vertebrae in group C.

Figures



Figure 1

Manually outlining the cement border and the vertebral border in the axial CT images