

Efficacy and safety of high-viscosity cement in percutaneous vertebroplasty for treatment of Osteoporotic vertebral compression fractures

A retrospective cohort study

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Abstract

To evaluate the efficacy and safety of high viscosity bone cement in the percutaneous vertebroplasty (PVP) for treatment of single-level osteoporotic vertebral compression fractures.

Eighty patients were enrolled in this study. All patients were received PVP, and they were divided into 2 groups according to the viscosity of bone cement, either high viscosity bone cement (HV group) or low viscosity cement (LV group). Oswestry Disability Index questionnaire and visual analog scale as clinical assessments were quantified. The operative time and injected bone cement volume were recorded. The anterior vertebral height (AVH) and bone cement leakage were evaluated in the radiograph.

No significant difference was observed in the operative time. Both groups showed significant improvements in pain relief and functional capacity status (visual analog scale and Oswestry disability index scores) after surgery. Less bone cement volume was injected into the the injured vertebra in the HV group and statistical significance was found between both groups. In the HV group, there was lower leakage rate and less patients of severe leakage compared with the LV group. However, the correction of AVH showed no significant differences between the 2 groups and no significant loss of AVH was observed in 2 groups.

High-viscosity and low-viscosity PVP have the similar effects in improving quality of life and relieving pain. There were lower cement leakage rate and less patients of severe leakage in the PVP with high-viscosity bone cement.

Abbreviations: AVH = anterior vertebral height, ODI = Oswestry disability index, OVCF = osteoporotic vertebral compression fracture, PMMA = polymethylmethacrylate, PVP = percutaneous vertebroplasty, SD = standard deviation, VAS = visual analog scale.

Keywords: cement leakage, complication, high viscosity cement, osteoporotic vertebral compression fractures, percutaneous vertebroplasty

1. Introduction

Osteoporotic vertebral compression fracture (OVCF) is an important health issue in ageing populations, approximately 20% of individuals over 70 years.^[1] The fractures can cause

persistent pain, unable to perform the activities of daily life, and significant decrease in quality of life.^[2,3] Traditionally, conservative treatment including bed rest, analgesic medication, back bracing, and muscle relaxants was adopted to alleviate pain. The comorbidities of long-term bed included deep venous thrombosis, acceleration of osteopenia, loss of height, and respiratory problems.^[4] In recent years, however, percutaneous vertebroplasty (PVP) has gained worldwide acceptance as an effective treatment option for back-pain due to OVCFs. PVP, initially developed in France by radiologist Harve Deramond and colleagues for symptomatic vertebral angioma, and then expanded to osteoporotic fractures, is a minimally invasive technique involving the injection of polymethylmethacrylate (PMMA) cement into the fractured vertebral body to relieve pain, reinforce the bone, and prevent further vertebral compression.

Despite the high success rate of PVP in the treatment for OVCFs, several studies have reported some major complications following the vertebroplasty.^[5-7] The most frequent is cement leakage, which may lead to serious complications such as spinal cord or nerve compression, pulmonary cement, and in some rare cases, possibly causing death when occurred into the spinal canal or peripheral veins. Baroud and his colleagues in their experimental study found that the leakage of bone cement reduced when the viscosity of the injected cement increased, and there was a strong relationship between them.^[8] Recently, a series of laboratory testing and clinical trials demonstrated that the

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All data generated or analyzed during this study are included in this published article [and its supplementary information files].

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high-viscosity in the PVP could reduce the leakage of bone cement when compared to low-viscosity, however, these studies were limited to comparison of high-viscosity cement vertebroplasty and balloon kyphoplasty with low-viscosity cement.^[9–11]

The purpose of this retrospective study was to evaluate and compare the efficacy and safety (especially the cement leakage) of high viscosity bone cement in the PVP for treatment of single-level OVCFs.

2. Material and methods

2.1. Patient population

This was a retrospective trial conducted between June 2014 and September 2016. In this study, we reviewed 80 patients, who met the following inclusion criteria: 1. Single-level OVCF of thoracic and lumbar vertebrae (T10-L5), and without neurological deficit; 2. Osteoporosis diagnosed by dual-energy X-ray absorptiometry, and bone mineral density was less than 2.5 SD suggesting osteoporosis; 3. Acute back pain resulting from vertebral fracture; The exclusion criteria were as follow: age <55 years, traumatic fracture, infection, tuberculosis, and bone metastases, and a history of previous vertebroplasty and other thoracic or lumbar surgery.

All patients were scanned using magnetic resonance imaging, which indicated obvious bone edema in the fractured vertebra. The study was approved by the Ethics Committee of our Hospital and all patients provided written informed consent. Patients were divided into 2 groups according to the cement viscosity (high-viscosity cement, HV group or low-viscosity cement, LV group).

2.2. Surgical procedure

All procedures were carried out under local anesthesia. Each patient was positioned prone on a radiolucent operating table for spine surgery. The patient's heart rate, blood pressure, PO₂, and level of consciousness were measured with electronic monitors throughout the procedure. The position of fractured vertebra was fixed by using C-arm fluoroscopy. Fluoroscopic images were obtained in the anteroposterior and lateral planes to ensure that the pedicles could be adequately visualized. The unilateral approach was adopted in all patients in this study. Injected landmarks for pedicle access were drawn on the skin. An approximately 5 mm incision was made at the skin entry point, after which the PVP needles were used to access the back muscle to reach the vertebral body. The needle was inserted in to the anterior and middle 3/4 of vertebrae body slowly and C-arm fluoroscopy was used to confirm the needle in satisfactory position. Then the position of the needle was fixed to enable injection of the bone cement into the vertebrae body. The high viscosity or low viscosity bone cement was selected for each patient according to the plan. However, high viscosity was injected into vertebrae body with injection syringe and special hydraulic propulsion pump. The entire surgery proceeding was guided by C-arm fluoroscopy and bone cement spread out gradually. The volume of bone cement per vertebrae was recorded. The same group of doctors performed all operations.

2.3. Postoperative managements

Patients routinely remained supine in bed for 24 hours after the procedure and were encouraged to start out-of-bed activities with

lumbar brace within 1 week postoperatively. However, excessive and heavy activities were forbidden. All patients were referred for treatment with calcium and vitamin D supplements, and antiresorptive or anabolic agents. Following discharge from the hospital, all patients were clinically and radiologically assessed in the orthopedic outpatient clinic every 3 months.

2.4. Observation index

The operation time and volume of bone cement per vertebrae were recorded. Visual analog scale (VAS) score and Oswestry disability index (ODI) questionnaire were used to assess clinical outcome.

The anterior vertebral height (AVH), were measured in the lateral radiographic preoperatively and postoperatively. AVH of the injured vertebra and the normal vertebrae above and below the injured vertebrae was measured. The percentage of AVH was calculated as described.^[12] Assessment of cement leakage was based on radiographs, supplemented by postoperative computed tomography scans. The location of the leakage was recorded.

The following locations were subject to leakage:

- (1) the disk space,
- (2) the epidural space,
- (3) the paravertebral areas, and
- (4) the peripheral veins.

The amount of leakage was then characterized postoperative as mild, moderate, or severe according to Georgy.^[13] All the data were reviewed by an independent observer with no involvement in their treatment.

2.5. Statistical analyses

The SPSS statistical package, Windows V17.0 (SPSS, Chicago, IL) was used to perform statistical analyses. The 2-sample *t* test, Chi square test, and ANOVA analysis were used for data analyses. Data were presented as the mean ± standard deviation. For all analyses, a *P* value <.05 was considered statistically significant.

3. Results

In this study, 80 patients were included, 24 male and 56 female, with a mean age of 67.8 years (range, 56–82 years). After division, the HV group and LV group enrolled 40 patients respectively. Baseline demographic and fracture level in both groups are shown in Table 1. There were no significant differences observed between HV group and LV group.

Table 1

Characteristics of the patient cohort in both groups.

Parameter	HV group	LV group	<i>P</i> value
Number of patients	40	40	
Age, yr	68.2 ± 6.4 (56–82)	67.4 ± 6.9 (55–80)	.617
Gender, males/females	11/29	13/27	.626
Fracture level			.653
Thoracic	17	19	
Lumbar	23	21	
Operative time (min)	31.2 ± 7.5	33.3 ± 8.0	.223
Cement volume (mL)	3.2 ± 0.6	4.1 ± 0.8	<.001

HV = high viscosity bone cement, LV = low viscosity cement.

Table 2
The change of VAS in the pre-and post-operative period.

Group	Preop	2d postop	6m postop	1y postop
HV	7.2±1.2	3.2±1.0	1.8±0.7	1.7±0.6
LV	6.9±1.1	3.2±0.9	1.9±0.6	1.8±0.6
P value	.318	.724	.726	.371

HV = high viscosity bone cement, LV = low viscosity cement, VAS = visual analog scale.

The operative time in the high-viscosity group was 31.2 ± 7.5minutes, and 33.3 ± 8.0min in the low-viscosity group. No significant difference was observed between the 2 groups, suggesting that PVP using high-viscosity bone cement required equal time during the operation (*P* >.05). The injected bone cement volume was 3.2 ± 0.6ml and 4.1 ± 0.8 mL in the control and fractured groups respectively. Statistical difference was detected significantly between both groups (*P* <.001) Table 1.

3.1. Clinical outcomes

Preoperatively, VAS scores were 7.2 ± 1.2 and 6.9 ± 1.1 points in the HV and LV groups respectively, and these were significantly decreased in both groups during the postoperative period (*P* <.05). However, there was no significant difference of VAS score at the follow-up periods between the 2 groups (*P* >.05) (Table 2).

At 2 days, 6 months, and 1 year after surgery, ODI scores in both groups were more significantly improved than those before surgery (*P* <.05). However, no significant difference was observed between the HV and LV groups, which is consistent with the change of VAS scores (Table 3).

3.2. Radiological evaluation

The preoperative AVH was 42.5 ± 11.1% in the HV group and 41.4 ± 12.6% in the LV group (*P* =.672). There was no significant difference between the 2 groups. After surgery, the AVH was 45.2 ± 11.8% and 44.2 ± 13.7% in 2 groups respectively, with no difference observed between them. Similarly, there was no significant difference of AVH between preoperatively and postoperatively in 2 groups respectively (*P* = .297 and *P* = .340), indicating that PVP with high-viscosity or low-viscosity bone cement could not effectively restore the anterior vertebral body height. At 1 year follow-up, there was no significant loss of AVH in 2 groups (Table 4).

4. Leakage rates and locations

Leakage rates and locations are presented in Table 5. The overall rate of cement leakage was 15.0% (6 of 40 patients) in the HV group, which was lower than 37.5% (15 of 40 patients) in the LV group. There was statistical difference between 2 groups

Table 3
The change of ODI (%) in the pre- and post-operative period.

Group	Preop	2d postop	6m postop	1y postop
HV	77.2±7.5	29.5±7.1	27.3±6.0	26.8±5.5
LV	75.7±8.1	28.2±6.5	25.6±5.7	25.3±5.3
P value	.393	.403	.184	.226

ODI = Oswestry disability index.

Table 4
The change of AVH (%) in the pre- and post-operative period.

Group	Preop	2d postop	1y postop
HV	42.5±11.1	45.2±11.8	41.6±10.2
LV	41.4±12.6	44.2±13.7	40.3±10.7
P value	.672	.730	.581

HV = high viscosity bone cement, LV = low viscosity cement, AVH = anterior vertebral height.

(*P* =.022). In the HV group, no patient had severe leakage (5 patients with mild leakage; 1 patient with moderate leakage). However, in the LV group, there are 2 patients of severe leakage, 4 moderate leakages, 9 mild leakages. The cement leakage occurred most commonly in the disc space (Figs. 1–3).

4.1. Complications

No significant clinical complications or postprocedural clinical sequelae were encountered. There were 2 cases of new nonadjacent fracture in HV group and 1 case in LV group respectively, within 6 months postoperatively.

5. Discussion

As we know, a great deal of clinical trials and systematic reviews have shown that PVP was a safe and effective choice for pain relief and quality of life improvement in the osteoporotic patients or in malignancy.^[14,15] And in some published reports, it was demonstrated that the analgesic drug consumption and external brace support decreased in patients of OVCFs after PVP.^[16,17] PVP has gained popularity as a treatment modality for OVCFs for providing nearly immediate pain relief and mechanical strengthening of the vertebral body.

The efficacy of PVP in the patients of OVCFs was confirmed in this current study. In our study, all the patients underwent PVP using high-viscosity or low-viscosity bone cement. The results showed clear improvement after surgery. The average ODI score decreased to 28.9 ± 6.8 from 76.5 ± 7.8, and VAS to 3.1 ± 0.9 from 7.1 ± 1.1, respectively, and there were significant differences observed after surgery. However, no difference was observed in terms of VAS and ODI between 2 groups, which indicated that PVP using high-viscosity bone cement could obtain equally better outcome in pain relief and quality of life improvement, compared to the low viscosity bone cement. Presently, the mechanism of pain relief due to PVP is still not clear. Some authors proposed the calorogenic effect, the injected PMMA cement reached a high temperature in the process of concreting procedure, which can damage the nerves around the cement in the fractured body.^[18,19] Moreover, the chemical neurolytic effect of PMMA cement and local anesthesia may also contribute to the pain relief.^[20] Additionally, we recorded the operation time of all patients and compared that of HV group with LV group. There was slightly but not significantly shorter in the HV group, and no statistical difference between them. It could be interpreted by the same unilateral approach and a single-level thoracic or lumbar spine fracture.

Despite the favorable outcome, the complications resulting from PVP had gained more and more attentions. Cement leakage is 1 of the most serious complications of traditional low-viscosity cement PVP since it can lead to many severe outcomes, including spinal cord and nerve root compression, paraplegia, cement

Table 5
The leakage location and grade in 2 groups.

Group	Leakage rate	Grade of leakage		
		Mild	Moderate	Severe
HV	6/40	5	1	0
LV	15/40	9	4	2
<i>P</i> value	.022			

Group	Location of leakage			
	Disc space	Epidural space	Paravertebra	Peripheral vein
HV	3	1	1	1
LV	8	3	2	2

HV = high viscosity bone cement, LV = low viscosity cement.

pulmonary embolisms, and even death. Some previous reports showed that the bone cement leakage of PVP varies from 5% to more than 80%.^[21] In our study, the incidence of cement leakage was 23.8% (37.5% in the LV group and 15.0% in the HV group), which is consistent with the previous studies.

There were many factors associated with the bone cement leakage, such as injection approach (unilateral or bilateral), injected cement volume, fracture level and severity, and cement viscosity.^[22,23] Anselmetti reported that the cement leakages in the PVP were due to the low viscosity of bone cement, when PVP



Figure 1. Preoperative and postoperative films of a 65-yr-old woman with OVCFs of L1 vertebral body, treated with high-viscosity cement PVP. Preoperative anterior-posterior and lateral films showing slight loss of the anterior vertebral body height at the L1 level (A) (B). Sagittal MR image of the L1 vertebral body confirming the compression fracture (C) (D). Postoperative anterior-posterior and lateral films showing no leakage of bone cement after PVP (E) (F). OVCFs = Osteoporotic vertebral compression fractures, PVP = percutaneous vertebroplasty.

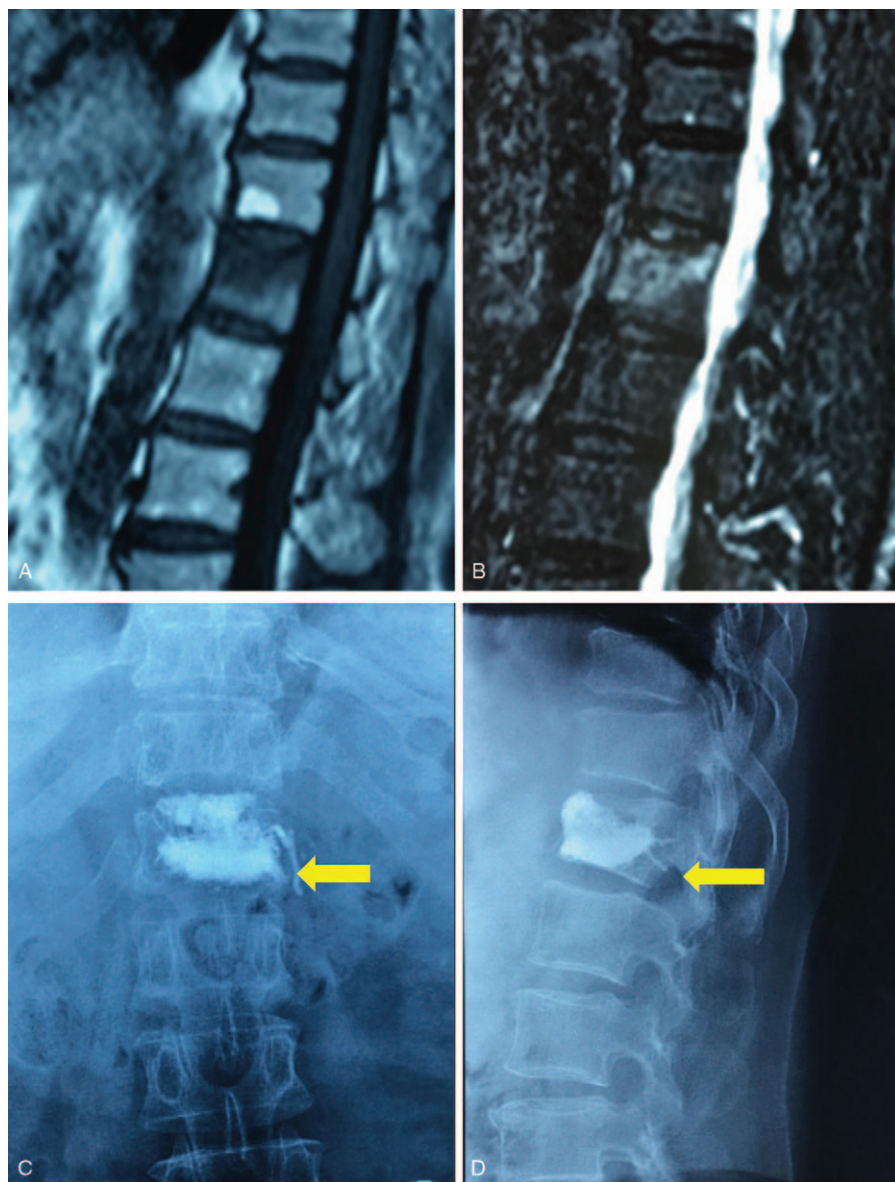


Figure 2. Preoperative and postoperative films of a 60-yr-old woman with OVCs of T12 vertebral body, treated with low-viscosity cement PVP. Preoperative MR image showing the compression fracture at the T12 level (A) (B). Postoperative anterior-posterior and lateral film showing the leakage of bone cement in the Peripheral vein after PVP (C) (D). PVP = percutaneous vertebroplasty.

technique and radiological equipment are optimal.^[24] The impact of cement viscosity on leakage rate was recently evaluated in vitro by Baroud et al,^[8] whose study demonstrated that higher viscosity cements were shown to result in significantly lower leakage rates in their laboratory model of vertebral fracture. In the current study, the incidence of bone cement leakage was 15% in the HV group, lower than 37.5% in the LV group, and there was significantly statistical difference between both groups, which indicated that the use of high viscosity could clearly reduce the cement leakage in PVP. Habib^[9] showed that the filling uniformity increased and the cement leakage reduced in all high-viscosity groups compared to the low-viscosity groups, and concluded that the uniform cement filling of high-viscosity system was responsible for reducing cement leakage for vertebral body augmentation procedures.

Zhu et al^[23] demonstrated in their report that volume of injected bone cement was determined to be most strongly associated with bone cement leakage, and the volume of cement in PVP was associated with cement viscosity. The similar result was confirmed in our study. In the high-viscosity group, the volume of cement was 3.2 ± 0.6 mL, lower than that of low-viscosity group (4.1 ± 0.8 mL), with less cement leakage. High-viscosity cements may alleviate the need for bone tamps and cavity creation within the vertebral body, thus significantly reducing the volume of injected cement, which maybe attribute to reduce cement leakage using the high-viscosity bone cement.

A recent study reported that neither extension of cement to the endplate nor leakage into the disk space was found to have significant impact on postprocedural pain or function or subsequent fracture rate at 2 years.^[25] This was confirmed by our

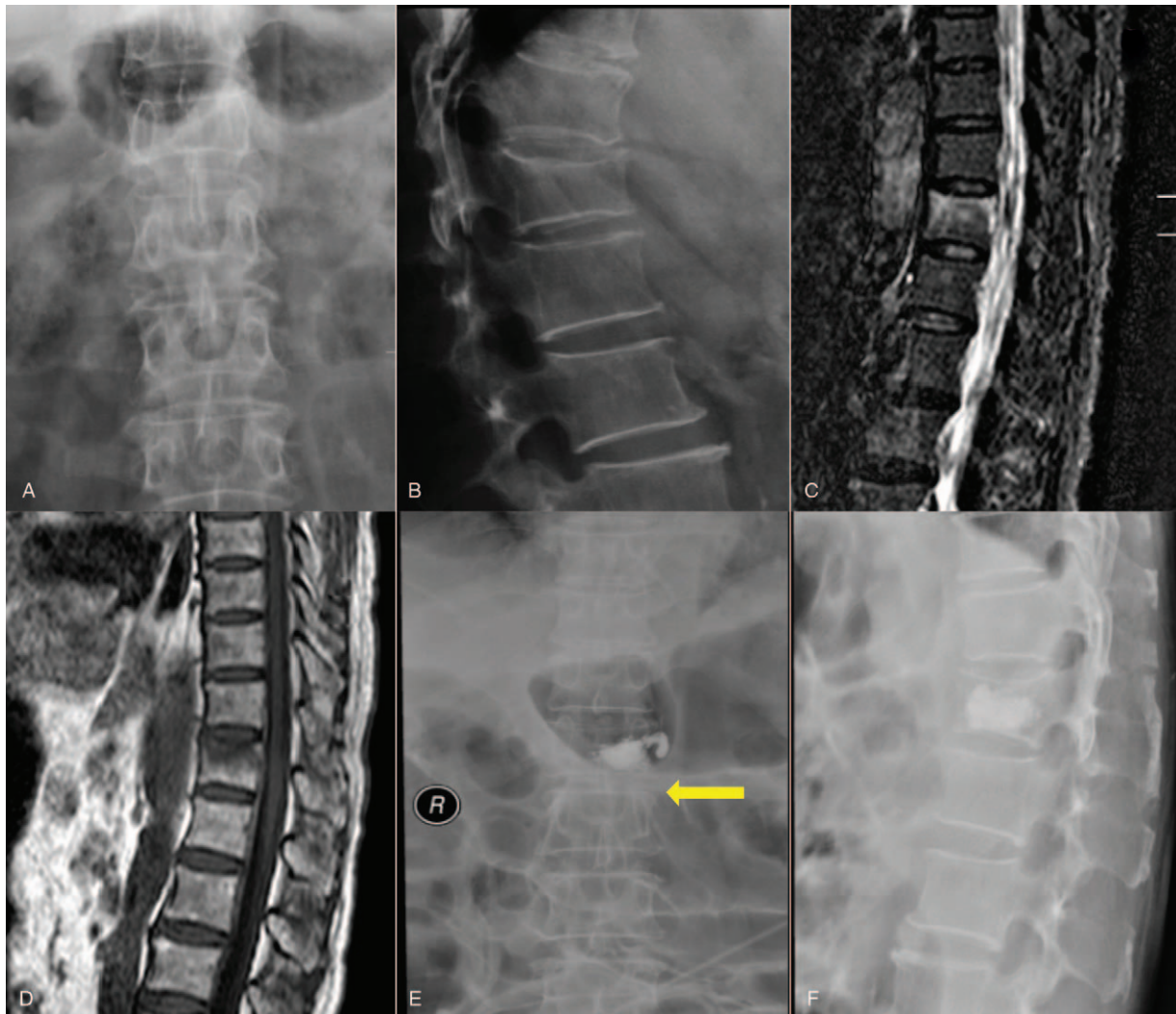


Figure 3. Preoperative and postoperative films of a 75-yr-old man with OVCFs of T12 vertebral body, treated with high-viscosity cement PVP. Preoperative anterior-posterior and lateral films showing a kyphotic deformity and loss of the anterior vertebral body height at the T12 level (A) (B). Sagittal MR image of the T12 vertebral body confirming the compression fracture (C) (D). Postoperative anterior-posterior film showing the mild leakage of bone cement in the paravertebral area after PVP, and lateral film indicating slight correction of AVBH (E) (F). OVCF = osteoporotic vertebral compression fracture, PVP = percutaneous vertebroplasty.

trial. However, the result from our study showed that the high viscosity bone cement could also reduce the incidence of cement leakage in peripheral vein and epidural space, and therefore could lower the rate of potential severe complication such as spinal cord and nerve root compression, and cement pulmonary embolisms.

The restoration of vertebral body height and kyphotic deformity was very important for some OVCFs patients. For PVP with high-viscosity cement, the injection of cement was pushed with the high pressure pump. The power of cement delivered into the fractured vertebra to brace the compressed bone trabecular restored the height loss of the collapsed vertebra and corrected the kyphotic deformity. In our study, there was no significant improvement in restoration of vertebral height after surgery, either using low viscosity or high viscosity bone cement. It was not consistent with previous report,^[11] which showed that high-viscosity cement vertebroplasty could effectively restore the vertebral height.

In term of the postoperative vertebrae body refracture, there was no case of adjacent re-fracture in 2 groups and no significant difference between both groups in this study. It indicated that

PVP using high-viscosity bone cement would not increase the re-fracture risk of adjacent vertebrae body and nonadjacent vertebrae body in single-level OVCFs.

The chief limitations of this study were the relatively small sample size, short follow-up in a single center and only focus on the patients of single-segment OVCFs. Another limitation was that the analysis of the relationship between cement leakage and injection pressure or the severity of osteoporosis was missing in this retrospective study. In the future, prospectively randomized controlled trial in the multicenter, enrolling more patients (not limited to single-level OVCFs) and long-term follow-up period, will be necessary to evaluate the safety and efficacy of high viscosity bone cement in the PVP.

6. Conclusion

The results of this study confirmed that PVP was a safe and effective treatment in improving the quality of life and relieving pain for patients of OVCFs. Based on this study, high-viscosity

cement PVP had the comparable effects, with lower cement leakage rate, less patients of severe leakage and injected cement volume compared to low-viscosity cement. High-viscosity cement was recommended using in PVP for the treatment of OVCFs.

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