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Original Article

Effect of PVP with a Mesh-Hold bone-filling mesh bag and different viscosities of bone cement in the treatment of osteoporotic vertebral compression fractures

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Abstract: Objective: To investigate the effect of percutaneous vertebroplasty (PVP) with Mesh-Hold™ bone-filling mesh bag and different viscosities of bone cement in the treatment of osteoporotic vertebral compression fractures (OVCF). Methods: A total of 105 patients with OVCF were randomly divided into group A (n=35, Mesh-Hold™ bone-filling mesh bag PVP), group B (n=35, high-viscosity bone cement PVP, 7 mL), and group C (n=35, low-viscosity bone cement PVP, 3 mL). VAS was used to assess thoracolumbar pain and ODI was used to assess thoracolumbar function. The VAS and ODI scores before surgery and at 1 day, 1 month, 6 months, and 12 months after surgery, bone cement leakage, uneven cement distribution, and injection volume within 1 month after operation were compared between the two groups. Results: The VAS and ODI scores of groups A, B and C were significantly reduced at 1 day, 1 month, 6 months, and 12 months after surgery as compared with those before surgery ($P<0.05$). The leakage rates of bone cement in groups A and B were 8.57% and 11.43%, which were significantly lower than that in group C (28.57%) ($P<0.05$). The uneven distribution rates of bone cement in groups A and B were 2.86%, which were significantly lower than that in group C (17.14%) ($P<0.05$); there was no significant difference in the injection volume of bone cement among the three groups ($P>0.05$). Conclusion: PVP with Mesh-Hold™ bone-filling mesh bag and high-viscosity bone cement can quickly relieve pain, and reduce bone cement leakage and uneven distribution.

Keywords: Mesh-Hold™ bone-filling mesh bag, PVP, different viscosities of bone cement, osteoporotic vertebral compression fracture

Introduction

Fractures may occur in osteoporosis patients due to reduced bone strength and fracture thresholds when subjected to slight external forces, leading to long-term bedrest and refractory pain. The incidence of fractures is about 20%, and increases with aging [1, 2]. Osteoporotic vertebral compression fracture (OVCF) is the most common and serious complication of osteoporosis. Due to the sagittal imbalance, patients may experience severe pain in the lower back and long-term bedrest; severely affecting its quality of life [3, 4]. Studies showed that OVCF is common in the elderly, and the incidence of OVCF in women is significantly higher than that in men. Among patients aged over 65 years, the incidence of OVCF in women is about 6 times that of men. With the increase of life expectancy and aging, the incidence of OVCF in China is also increasing [5-7]. OVCF patients need to stay in bed for a long time due to pain in the back or chest. If not treated in time, various complications will result from long-term bedrest.

Traditional OVCF treatment includes external fixation, bedrest, analgesics, etc. After treatment, the patient still has severe pain, even loss of vertebral body height or a hump. Percutaneous vertebroplasty (PVP) is a minimally invasive surgery in which bone cement is injected into the vertebral cancellous bone. When it hardens into solid material, it strengthens and stabilizes the fracture, quickly relieving pain and reducing complications such as being bedridden [8]. PVP is currently commonly used in the clinical treatment of OVCF. As a minimally

invasive surgery, it has the characteristics of low trauma, high safety, and rapid analgesic effects, so it is widely recognized by surgeons and patients in clinic [9, 10]. However, since the injection of bone cement requires the assistance of a high-pressure device, PVP is prone to postoperative complications, especially the bone cement leaking. A study showed that about 66% of complications after PVP are due to bone cement leakage [11]. There are no clear symptoms when the bone cement leakage is mild, but severe leakage can lead to spinal cord injury, increase the risk of neurological complications, and even lead to disability, which causes greater pain to the patients. Nowadays, low-viscosity bone cement commonly used in clinical practice often causes leakages, compressing nerve roots and damaging soft tissues, and even causing pulmonary embolisms in patients; all of which endangers patients' life and health. Data show that incidence of bone cement leakage in PVP using low-viscosity bone cement for OVCF can be up to 25.8% to 65% [3, 12]. Therefore, it is important to reduce the leakage of bone cement after PVP treatment.

High-viscosity bone cement is a new material with high viscosity, and the bone cement material reaction temperature is low, so its curing time is relatively quick, reducing the risk of bone cement leakage [13]. PVP with the Mesh-Hold™ bone-filling mesh bag is also a newly introduced method for vertebroplasty. The Mesh-Hold™ bone-filling mesh bag has polymer network structures that can wrap most of the bone cement and reduce the bone cement leakage and extravasation [14]. This study compared the visual analogue score (VAS), dysfunction index (ODI) score, bone cement leakage rate, uneven distribution, and injection volume in the treatment of OVCF by PVP with Mesh-Hold™ bone-filling mesh bag, high-viscosity bone cement, and low-viscosity bone cement; in order to seek out a more suitable and effective method for clinical treatment of OVCF.

Materials and methods

Baseline data

A total of 105 patients with OVCF treated in our hospital from July 2016 to December 2019 were enrolled. Inclusion criteria: ① Patients were all diagnosed with OVCF by CT, X-ray, MRI and bone density examination, with vertebral bone mineral density T value less than -2.5 [15]; ② Patients over 50 years of age with a clear history of trauma; ③ Patients with obvious local pain in the lower back, which was aggravated when turning over, standing and moving, with the course of the disease less than 6 weeks; ④ Patients with less than 70% of injured vertebra compression and with no symptoms of nerve compression; ⑤ This study has been approved by the medical ethics committee of the hospital; ⑥ Informed consent was signed and provided by all patients.

Exclusion criteria: ① Patients with neurological impairment caused by cauda equina or spinal cord injury; ② Patients with spinal cord tumors and spinal stenosis; ③ Patients with diabetes, hypertension, or rheumatoid arthritis; ④ Patients with severe organ diseases; ⑤ Patients with mental illness who could not cooperate with the study; ⑥ Patients who withdrew halfway. According to a random number table method, patients were divided into group A (n=35), group B (n=35) and group C (n=35). In group A, there were 10 males and 25 females, aged 55-82 years, with an average age of (68.48±10.68) years, and 24 cases with single vertebral fracture and 11 cases with double vertebral fracture. In group B, there were 15 males and 20 females, aged 54-81 years, with an average age of (68.21±10.87) years, and 26 cases with single vertebral fracture and 9 cases with double vertebral fracture. In group C, there were 13 males and 22 females, aged 56-82 years, with an average age of (68.17±10.73) years, and 22 cases with single vertebral fracture and 13 cases with double vertebral fracture. There was no difference in baseline data among the three groups (P>0.05).

Methods

Group A received PVP using Mesh-Hold™ bone-filling mesh bag, group B received PVP using high-viscosity bone cement (7 mL), and group C received PVP with low-viscosity bone cement (3 mL). The patients were placed in a supine posture, and the chest, abdomen, and pelvis were suspended from the table. After routine disinfection and draping, local anesthesia was performed with 1% lidocaine hydrochloride. The patient's heart rate, blood pressure and other vital signs were closely monitored throughout the operation. The operation was performed under the C-arm X-ray fluoroscopy, the puncture needle was passed through the pedicle of

Table 1. Comparison of baseline data in each group

Group	Case	Gender		Age (years)	Vertebral body	
		Male	Female		Single vertebral body	Double vertebral body
Group A	35	10 (28.57)	25 (71.43)	68.48±10.68	24 (68.57)	11 (31.43)
Group B	35	15 (42.86)	20 (57.14)	68.21±10.87	26 (74.29)	9 (25.71)
Group C	35	13 (37.14)	22 (62.86)	68.17±10.73	22 (62.86)	13 (37.14)
t		1.567		0.009	1.061	
P		0.211		0.991	0.303	

the injured vertebra until it reached 2/3 into the anterior of the middle of the vertebra near the midline of the injured vertebra, and the compressed vertebra was expanded with a specialized machine. The mesh bag or injection tube is sent into the vertebral body to deliver bone cement. After the dose reached the expected level, the injection was stopped. When the bone cement hardens, the puncture needle is removed, and the injured vertebrae were bound up with a sterile dressing. Anti-venous thrombosis drugs and anti-osteoporosis drugs were given after the operation.

Outcome measurements

VAS was used to assess thoracolumbar pain and ODI was used to assess thoracolumbar function. VAS and ODI scores of each group at each time point (before surgery, 1 day, 1 month, 6 months and 12 months after surgery) were compared, and the bone cement leakage rate and uneven distribution of bone cement in each group were compared within 1 month after surgery. VAS scoring criteria: 0 is painless and 10 is the most painful. ODI scoring criteria: a lower score indicates better function.

Statistical methods

All data were analyzed using SPSS 22.0, and comparison was performed using independent sample χ^2 test. Measurement data were compared using single factor F test. Repeated measurement with post hoc LSD-t test was used for comparison of various indicators at different time points. The difference was statistically significant at P<0.05.

Results

Baseline data

In group A, there were 10 males and 25 females, aged 55-82 years, with an average age of (68.48±10.68) years, and 24 cases with single vertebral fracture and 11 cases with double vertebral fracture. In group B, there were 15 males and 20 females, aged 54-81 years, with an average age of (68.21±10.87) years, and 26 cases with single vertebral fracture and 9 cases with double vertebral fracture. In group C, there were 13 males and 22 females, aged 56-82 years, with an average age of (68.17±10.73) years, and 22 cases with single vertebral fracture and 13 cases with double vertebral fracture. There was no difference in baseline data among the three groups (*P*>0.05, **Table 1**).

VAS score

The VAS score of each group was significantly reduced at 1 day, 1 month, 6 months, and 12 months after surgery (*P*<0.05). The VAS scores of group C at 6 months (2.03±0.64) and 12 months (1.91±0.65) after surgery were significantly reduced compared with 1 day (3.21±1.11) and 1 month (3.02±0.91) after surgery (*P*<0.05). The VAS scores of groups A and B were significantly lower than those of group C at 1 day and 1 month after surgery (*P*<0.05, **Table 2**).

ODI score

The ODI scores of groups A, B, and C were significantly decreased at 1 month (15.07±5.11 vs 15.16±5.19 vs 15.07±5.38), 6 months (11.89±4.01 vs 12.39±3.81 vs 11.76±4.16), and 12 months (10.45±3.06 vs 10.32±2.92 vs 10.62±3.74) after surgery compared with 1 day (23.82±4.96 vs 23.48±4.88 vs 24.19±5.12) after surgery (*P*<0.05). The ODI score of each group was significantly reduced at 6 months and 12 months after surgery compared with 1 month after surgery (*P*<0.05), and the ODI scores of each group was significantly reduced at 12 months after surgery compared with 6 months after surgery (*P*<0.05, **Table 3**).

Table 2. Comparison of VAS score at different time points in each group ($\bar{x} \pm s$)

Index		Before surgery	1 day after surgery	1 month after surgery	6 months after surgery	12 months after surgery
VAS	Group A (35)	7.25±1.36	$2.18\pm0.67^{\Delta,*}$	$2.25\pm0.62^{\Delta,*}$	$2.08\pm0.61^{\Delta}$	$2.02\pm0.62^{\Delta}$
	Group B (35)	7.47±1.46	$2.23\pm0.63^{\Delta,*}$	$2.18\pm0.64^{\Delta,*}$	$2.13\pm0.66^{\Delta}$	$2.12\pm0.66^{\Delta}$
	Group C (35)	7.16±1.27	$3.21\pm1.11^{\Delta}$	$3.02\pm0.91^{\Delta}$	$2.03\pm0.64^{\Delta,\blacktriangle,\#}$	$1.91\pm0.65^{\Delta,\blacktriangle,\#}$
F		$F_{time\text{-}point}$=527.277, $F_{interaction}$=9.475, $F_{inter\text{-}group}$=2.399				
P		$P_{time\text{-}point}$=0.000<0.001, $P_{interaction}$=0.000<0.001, $P_{inter\text{-}group}$=0.096>0.05				

Note: Compared with group C, $^{*}P$<0.05; Compared with before surgery, $^{\Delta}P$<0.05; Compared with 1 day after surgery, $^{\blacktriangle}P$<0.05; Compared with 1 month after surgery, $^{\#}P$<0.05; Compared with 6 months after surgery.

Table 3. Comparison of ODI score at different time points in each group ($\bar{x} \pm s$)

Index		Before surgery	1 day after surgery	1 month after surgery	6 months after surgery	12 months after surgery
ODI	Group A (35)	66.02±5.07	$23.82\pm4.96^{\Delta}$	$15.07\pm5.11^{\Delta,\blacktriangle}$	$11.89\pm4.01^{\Delta,\blacktriangle,\#}$	$10.45\pm3.06^{\Delta,\blacktriangle,\#,\&}$
	Group B (35)	65.65±5.18	$23.48\pm4.88^{\Delta}$	$15.16\pm5.19^{\Delta,\blacktriangle}$	$12.39\pm3.81^{\Delta,\blacktriangle,\#}$	$10.32\pm2.92^{\Delta,\blacktriangle,\#,\&}$
	Group C (35)	66.24±4.96	$24.19\pm5.12^{\Delta}$	$15.07\pm5.38^{\Delta,\blacktriangle}$	$11.76\pm4.16^{\Delta,\blacktriangle,\#}$	$10.62\pm3.7^{\Delta,\blacktriangle,\#,\&}$
F		$F_{time\text{-}point}$=4552.519, $F_{interaction}$=0.361, $F_{inter\text{-}group}$=0.022				
P		$P_{time\text{-}point}$=0.000<0.001, $P_{interaction}$=0.940>0.05, $P_{inter\text{-}group}$=978>0.05				

Note: Compared with group C, $^{\Delta}P$<0.05; Compared with 1 day after surgery, $^{\blacktriangle}P$<0.05; Compared with 1 month after surgery, $^{\#}P$<0.05; Compared with 6 months after surgery, $^{\&}P$<0.05.

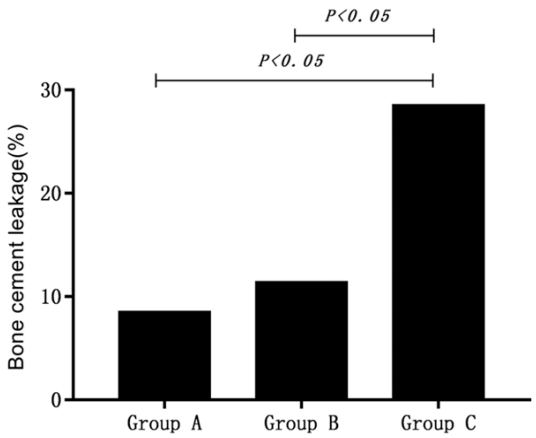

Figure 1. Comparison of bone cement leakage in each group. The bone cement leakage rate of Group A and Group B was significantly lower than that of Group C, P<0.05.

Bone cement leakage, uneven distribution, injection volume

There was 1 case of venous leakage, 1 case of paravertebral leakage, 1 case of intervertebral disc leakage in group A. There was 1 case of venous leakage, 2 cases of paravertebral leakage, 1 case of intervertebral disk leakage in group B, and there were 3 cases of venous leakage, 5 cases of paravertebral leakage and 2 cases of intervertebral disc leakage in group C. The leakage rates of bone cement in group A and group B were 8.57% and 11.43%, which were significantly lower than those in group C (28.57%) (P<0.05, **Figure 1**). The uneven distribution rates of bone cement in group A and group B were 2.86%, which was significantly lower than that of 17.14% in group C (P<0.05, **Figure 2**). There was no significant difference in the injection volume among the three groups (P>0.05, **Figure 3**).

Discussion

In traditional PVP treatment with low-viscosity bone cement, due to the short curing time of bone cement and the difficulty for the surgeon to grasp the injection time, if the surgeon has problems in surgery, the incidence of serious complications such as bone cement leakage and pulmonary embolism can increase [16, 17]. In addition, the heat generated by the polymerization of bone cement can burn surrounding tissues, especially nerve roots and spinal cords. Burns of the bone cells will delay fracture healing [18, 19]. Therefore, a safe and effective OVCF treatment is of great significance for clinical treatment.

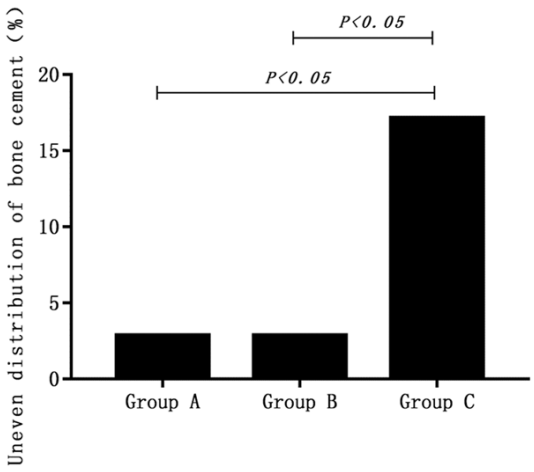

Figure 2. Comparison of uneven distribution of bone cement in each group. The uneven distribution of bone cement in Group A and Group B was significantly lower than that in Group C, $P<0.05$.

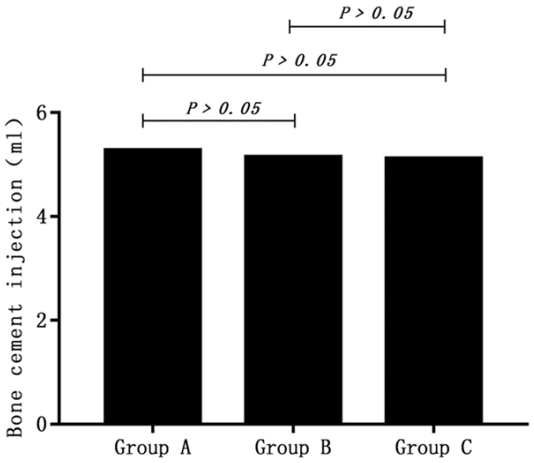

Figure 3. Comparison of injection volume of bone cement in each group. There was no difference in the injection volume of bone cement in Groups A, B and C ($P>0.05$).

As a new type of material, high-viscosity bone cement has a higher viscosity, which can cure quickly. Moreover, it has a good developing effect, strong fatigue resistance, strong compressive strength and anti-twisting characteristics, and promotes the recovery of vertebral height; so it has been applied in PVP treatment increasingly year by year. High viscosity fluids can only be injected with a low pressure, thus reducing the complications caused by the high-pressure device. The injection time of high viscosity bone cement is longer, which can improve the judgment of the injection time of the surgeon, so that the surgeon can better understand the injection time, and reduce the risk of extravasation caused by improper injection time. At the same time, the polymerization temperature of high viscosity bone cement is usually between 50°C and 60°C, which can reduce damage caused by the thermal effects of bone cement polymerization on nerve roots and other surrounding tissues, and greatly reduces the occurrence of complications, especially the risk of bone cement extravasation [20, 21]. The application of high viscosity bone cement in PVP treatment has a good effect on relieving the pain of the chest and back, and restoring the vertebral height, including the middle and front edge, and correcting convex deformities.

PVP with the Mesh-Hold™ bone-filling mesh bag is a new type of vertebralplasty widely recognized in the clinic. The mesh bag in the treatment is a dense polymer mesh layer, which can wrap most of the bone cement, allowing only a small amount of bone cement to leak out. In the meantime, the mesh bag can fix the shape, which can control and reduce the uneven distribution of bone cement when more bone cement is injected and expanded [22, 23]. During the PVP treatment with Mesh-Hold™ bone-filling mesh bag, spiral propellers were used to inject bone cement, so as to improve the collapsed vertebrae, enhance the strength of the vertebrae, and reduce the pain of patients, which is conducive to the postoperative recovery of patients. The results of this study show that the ODI score of each group gradually decreased at 1 day, 1 month, 6 months, and 12 months after surgery; and the VAS score of each group at 1 day, 1 month, 6 months, and 12 months after surgery was decreased compared with that before surgery. VAS score in group C was significantly reduced at 6 and 12 months after surgery compared with 1 day and 1 month after surgery, and the VAS scores in group A and group B were significantly lower than that of group C at 1 day and 1 month after surgery.

This study showed that PVP with a Mesh-Hold™ bone-filling mesh bag, low-viscosity bone cement and high-viscosity bone cement can all improve physical dysfunction and relieve pain; but Mesh-Hold bone-filling mesh bag and high-viscosity bone cement quickly relieved the patient's pain at one day after surgery.

Bone cement leakage is a complication of PVP treatment. The reasons for bone cement leak-

age include: [24, 25] premature injection of bone cement, high temperature of bone cement and operating room, which accelerates the hardening of bone cement and shortens the curing time so that the bone cement injection time cannot be correctly mastered during the surgery, high injection pressure or improper puncture or other operations by surgeons, as well as excessive volume of bone cement. In this study, PVP treatment is performed under fluoroscopy, so bone cement can be injected slowly and effective measures are taken to prevent leakage. In this study, there was no significant difference in the injection volume of the three groups, suggesting that the study did not blindly increase the injection volume of bone cement. The results of this study also show that the leakage rates of bone cement in groups A and B are 8.57% and 11.43%, which are significantly lower than 28.57% in group C. The uneven distribution rate of bone cement in groups A and B is 2.86%, which was lower than 17.14% of group C. The results show that Mesh-Hold™ bone-filling mesh bags and high-viscosity bone cement can effectively reduce the occurrence of bone cement leakage and uneven distribution.

In summary, patients with long-term bedrest caused by OVCF are prone to various complications, and the intractable pain resulted from OVCF seriously affects patients' quality of life. PVP, as the recommended therapy, has the characteristics of low trauma, high selectivity, and rapid analgesic effect. The traditional PVP treatment with low-viscosity bone cement has relatively short injection time and curing time, which increases the risk of bone cement leakage and pulmonary embolism.

PVP with Mesh-Hold™ bone-filling mesh bag allows only a small amount of bone cement to leak out of the mesh bag and reduces the uneven distribution of bone cement. Mesh-Hold™ bone-filling mesh bags, high-viscosity bone cement and low-viscosity bone cement can improve physical dysfunction and relieve pain in OVCF patients; however, Mesh-Hold™ bone-filling mesh bag and high-viscosity bone cement can quickly relieve pain and reduce the occurrence of bone cement leakage and uneven distribution.

Disclosure of conflict of interest

None.

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