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Original Article

The clinical comparative study on high and low viscosity bone cement application in vertebroplasty

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Abstract: Objective: To investigate the clinical effect of high and low viscosity bone cement in vertebroplasty for treatment of osteoporotic vertebral compression fractures. Methods: 40 cases of patients with osteoporotic thoracolumbar compression fractures admitted into department of orthopeadics in our hospital were reviewed. All patients were divided into high viscosity bone cement group (20 cases) and low viscosity bone cement group (20 cases). Visual Analog Score (VAS), Oswestry Dability Index (ODI), injured vertebral height restoration (Cobb Angle) and bone cement leakage rate, subsequent fracture rate of vertebrae body with or without surgical treatment were measured. Results: Compared with the low viscosity bone cement group, the VAS score, ODI score and Cobb angle of high viscosity bone cement group had a statistical difference ($P<0.05$). The postoperative complications in high viscosity bone cement group were lower than those in low viscosity bone cement group ($P<0.05$). Conclusion: Compared with low viscosity bone cement, bone cement leakage rate reduced obviously in high viscosity bone cement with good clinical effect and prognosis in vertebroplasty for treatment of osteoporotic thoracolumbar compression fractures.

Keywords: Vertebroplasty, high viscosity bone cement, osteoporosis, spinal fracture, compression fracture

Introduction

Recent years, with the development of minimally invasive surgery and emergence of new methods and concept, percutaneous vertebroplasty (PVP) is applied in treatment of pain and malformation induced by fracture to improve life quality, which is one of most successful treatment for osteoporotic vertebral compression fracture as a new technique [1, 2]. However, postoperative cement leakage is really a problem that orthopedic surgeon have struggle to solve because of cement leakage rate up to 30%-70% [3, 4]. Cement leakage into great vessels or nerve pedicle will cause severe complications like spinal cord compression, nerve damage, blood vessels thermal damage and pulmonary embolism while little cement leakage is complicated without clinical manifestation. At present, there is no consensus about how to reduce or avoid cement leakage effectively [5]. Postoperative vertebrae re-fracture also troubles orthopedic surgeons. Moreover, adjacent vertebrae fracture (AVF) is most and the mechanism is not clear with morbidity at 8%-52% [6] for complex factors. Whether novel bone cement can decrease the risk of AVF is needed to be validate.

Some studies [7-9] reported that high viscosity bone cement was applied in the treatment of osteoporotic vertebrae compression fracture with relatively satisfactory clinical effect. Compared with conventional PVP, there is no statistical difference about postoperative pain relief rate in treatment with high viscosity bone cement and the main complication bone cement leakage decrease significantly. Li Chunhai [10] reported that only two case of bone cement leakage adjacent vertebrae body in all 31 case of vertebrae compression fracture treated with high viscosity cement (leakage rate 6.45%). Although high viscosity bone cement had a potential application prospect, related studies were absent currently. More clinical application studies and summary were needed to further to improve and complete the application. Therefore, the data of thoracolumbar osteoporotic compression fracture treated with PVP recently were reviewed to compare the clinical effect of

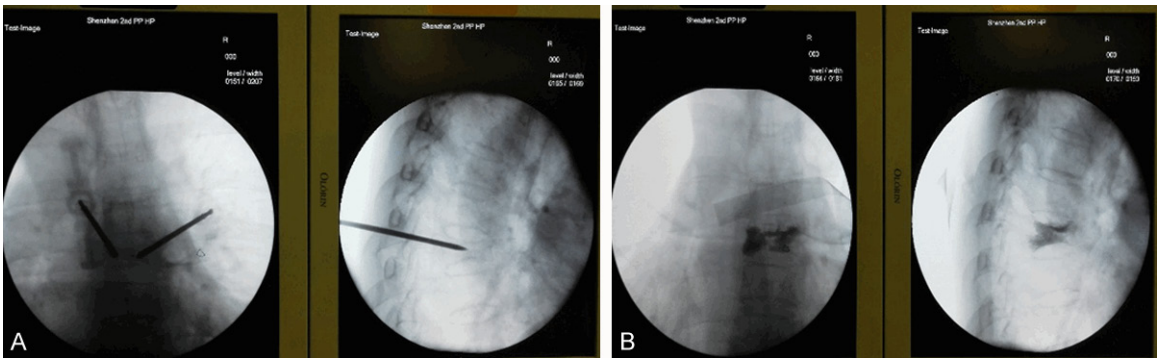

Figure 1. A: The satisfactory puncturing passage intraoperatively. B: High viscosity bone cement 3 days postoperatively.

high viscosity bone cement and low viscosity bone cement treating osteoporotic vertebrae compression fracture.

Materials and methods

General data

From January 2009 to August 2014, 40 patients with vertebrae compression fracture who were admitted into Shenzhen Bao'an district Shiyan people's hospital were reviewed. There were 18 in male and 22 in female with mean age 66.4±9.8 years old (from 59 to 88 years old). The time of follow-ups in high viscosity group and low viscosity group were 0.8~3.0 year (mean 2.0±0.6) and 1.0~3.0 year (2.0±0.5) respectively. Some patients had low back pain, and pain when turning over with unable to stand up. Besides, pain released when supine and worsened when bending over. Physical examination showed that there were obvious tenderness and percussion pain at thoracic vertebrae or lumbar fracture site. Inclusion criteria: 1. Vertebrae compression fracture confirmed by international recognized imaging (X plain film, CT, MRI) and clinical examination; 2. Osteoporosis diagnosed by bone mineral density (BMD), BMD was less than 2.5 SD suggested the possibility of osteoporosis; 3. Obvious acute pain induced by vertebrae compression fracture (<3 month); 4. Chronic pain complicated with bone nonunion; 5. Thoracic vertebrae or lumbar fracture without symptom and signs of spinal cord damage or pedicle damage. Exclusion criteria: 1. Blood coagulation dysfunction with bleeding tendency; 2. Injury of neural function including spinal cord damage or cauda enquina injury; 3. Patient complicated with nerve compression, spinal stenosis, spinal tuberculosis, spinal tumor or rheumatoid arthritis; 4. Patients complicated with hypertension, diabetes and major disease involving heart, brain, lung, liver or kidney; 5. Complicated with malignant disease or bone metastasis disease. 6. Unable to undergo related examinations; 7. Poor compliant patients or loss to follow up during follow-ups. According to treatment measures, all patients were divided into low viscosity group (n=20) and high viscosity group (n=20). This study was approved by independent ethics committee and written informed consent forms were provided prior participation. There was no statistical difference between compare of clinical basic data including follow-up time, which were comparable.

Procedures

Patients were in prone position on four-point support frame of spine surgery to keep chest and abdomen hung with head fixed by head frame. The entry point was confirmed by C-arm X-ray machine and marked, after that regular skin disinfection and sterile towels were applied. 1% lidocaine was used in subcutaneous local anesthesia at fractured vertebrae skin, and puncture needle was inserted into superior outer edge and the needle direction was determined under fluoroscopy. The puncture needle was inserted in to ventral a third of vertebrae body slowly and C-arm X-ray machine was used to confirm the needle in satisfactory position (**Figure 1A**). Adjusted bone cement was injected into vertebrae body under C-arm X-ray machine fluoroscopy and bone cement spread out gradually. Pathological examination was made on vertebrae body bone tissue to

Figure 2. High viscosity bone cement injected by injection syringe and special hydraulic propulsion pump.

exclude the pathological fracture induced by tumors during operation.

High viscosity bone cement was used in high viscosity bone cement group, and high viscosity bone cement was adjusted to wiredrawing stage following directions, which was injected into vertebrae body with injection syringe and special hydraulic propulsion pump (**Figure 2**). Low viscosity bone cement was used in low viscosity bone cement group, and low viscosity bone cement was adjusted following directions. Patients were in supine position and were under close observation postoperatively. The blood pressure, heart rate and oxygen saturation were checked per 15 min in the postoperative first hour. Specific treatment was applied to osteoporotic patients. According to rehabilitation condition of patients, patients were guided to exercise the function of low back muscle, and patients were helped to walk under protection of lumbar brace. Imaging examination including X plain film was applied 3d postoperatively (**Figure 1B**).

Observation indexes

1. Evaluation of distribution and leakage of bone cement: spine X-ray plain film at first day postoperatively and spine CT were read by two independent radiologists to check whether bone cement contacted both upper and lower endplate simultaneously and there was bone cement side distribution. Bone cement leakage included vein effusion, para-vertebral leakage and intervertebral disc leakage. 2. Pain relief assessment: VAS was used to assess pain preoperatively and at the final follow-up. 3. Evaluation for improvement of spinal function: ODI were used to assess spinal function preoperatively and at the final follow-up. 4. Evaluation for height rehabilitation of fractured vertebrae: Cobb angle measured in vertebral lateral X plain film to assess the front height of fracture vertebral body and rehabilitation of kyphosis deformity. 5. Rate of bone cement pulmonary embolization postoperatively. 6. The postoperative vertebrae re-fracture of surgical vertebrae body or non- surgical vertebrae body evaluated by X-ray plain film and CT.

Statistical analysis

Package SPSS 17.0 was applied in statistical analysis. All data were showed by mean ± SD. The VAS, ODI and Cobb angle preoperative and at final follow-up was analyzed by t test, leakage rate, bone cement pulmonary embolism and rate of adjacent fracture was analyzed by chi-square test. $P<0.05$ was regarded as significance.

Results

Compare of quantity of cement injected

All surgeries were completed successfully. The injected volume of high viscosity bone cement and low viscosity bone cement were 2.0~5.0 ml (mean 2.7±0.8 ml) and 2.0~5.0 ml (2.6±0.7 ml) respectively. There was no statistical difference about injected volume of bone cement ($P>0.05$).

Compare of VAS, ODI and Cobb angle between two groups

There was no significance about preoperative VAS, ODI and Cobb angle between two groups. The compare of VAS, ODI and Cobb angle at final follow-up had statistical difference (**Table 1**).

Compare of leakage rate of bone cement and bone cement distribution inside vertebrae body

In high viscosity bone cement group, no vein leakage of bone cement was found during

Table 1. Comparison of VAS, ODI and Cobb angle between two groups

No. of Group	n	VAS		ODI		Cobb angle	
		Preoperative	The final follow-up	Preoperative	The final follow-up	Preoperative	The final follow-up
High viscosity bone cement group	20	8.6±1.1	2.0±0.6*	35.6±4.6	15.0±4.1*	26.6±5.1	13.8±2.6*
low viscosity bone cement group	20	8.8±1.2	2.8±0.9	35.4±4.5	22.5±5.7	26.7±5.2	16.6±3.1

Note: compare with low viscosity bone cement, *P<0.05.

Table 2. Leakage rate of bone cement between two groups

No. of Group	n	Treated segment	Vein leakage	Intervertebral disc leakage	Para-vertebrae leakage	Intracranial leakage	Total leakage rate
High viscosity bone cement group	20	26	0/26 (0%)*	1/26 (3.8%)	1/26 (3.8%)*	0/26 (0%)*	2/26 (7.7%)*
low viscosity bone cement group	20	24	1/24 (4.2%)	1/24 (4.2%)	3/24 (12.5%)	1/24 (4.2%)	6/24 (25.0%)

Note: compare with low viscosity bone cement, *P<0.05.

operation. However, there were one case of intervertebral disc leakage and one case of para-vertebral leakage with no clinical symptoms. Besides, three case of side distribution of bone cement and five case of bone cement contacting with upper and lower endplate simultaneously were found. There was no vein leakage of bone cement confirmed by CT and one case of intervertebral disc leakage, three case of para-vertebral leakage and one case of intracranial leakage confirmed by X plain film postoperatively. No obvious clinical symptom was found except that intracranial leakage was complicated with mild low back pain. There were six cases of side distribution of bone cement and 9 case of bone cement contacting with upper and lower endplate simultaneously. No statistical difference was found about postoperative intervertebral disc leakage between two groups. There were statistical differences about vein leakage rate, para-vertebrae leakage rate, intracranial leakage rate and total leakage rate between two groups. Compared with low viscosity bone cement group, statistical difference about side distribution and bone cement contacting upper and lower endplate simultaneously were found, which suggested that high viscosity bone cement distributed more uniformly and was better than low viscosity bone cement (**Table 2**).

The postoperative re-fracture rate of surgical vertebrae body or non-surgical body and rate of bone cement pulmonary embolism between two groups

There was no re-fracture of surgical vertebrae body in both high viscosity bone cement group and low viscosity bone cement group during follow-up. One elder patient with severe osteoporotic vertebrae body compression fracture (T12) in high viscosity bone cement group had distal vertebrae fracture (L4) after walking on the second day postoperatively. One case of postoperative adjacent vertebrae fracture was found in low viscosity bone cement group. There was no statistical difference about re-fracture rate of surgical vertebrae body or non-surgical vertebrae body in both groups. No patients in both group had pulmonary embolism of bone cement postoperatively.

Discussions

Osteoporosis had become a kind of common disease with severe damage to elderly health [11]. A female had a risk of osteoporotic fracture at 30%~40% worldwide. The rate of osteoporosis was approximately 60% for the aged over 60 years old, 80% of who were female. China was one of countries with high incidence of osteoporosis, there were approximately 8.2 million osteoporotic patients accounting for 70% of population [12]. Some studies reported that 40% of osteoporotic patients would have osteoporotic vertebrae fracture [13, 14]. With the increasing aging, the patients with osteoporotic vertebrae fracture were prone to increase gradually, especially for menopausal women. About 20% of the elderly over 70 years old suffered from osteoporotic vertebrae compression fracture [15], all of who had severe low back pain, kyphosis deformity, disability even life can't oneself management, which decreased life quality severely [16]. Fracture including osteoporotic vertebrae fracture was the main severe complication of osteoporosis [17, 18].

PVP was the one of clinical common operation treatment with severe complication of bone cement leakage. Some studies showed that low viscosity bone cement had a higher rate of vein leakage and para-vertebrae leakage than high viscosity bone cement [19, 20]. Low viscosity bone cement was easy to happen leakage and diffuse to vein to induce pulmonary embolism with disadvantage of short solidification time and inconvenient operation. Bone cement polymerization would produce heat to induce thermal damage to surrounding tissue, especially nerve pedicle and spinal cord, as well as bone cells inside vertebrae body having influence on bone union.

Some studies demonstrated that viscosity of bone cement was the main influence factor of bone cement leakage and high viscosity bone cement could reduce postoperative rate of leakage significantly. Habib [19] reported that high viscosity bone cement had a more uniform distribution than low viscosity bone cement, which might account for decreased rate of bone cement leakage. Bhatia [21] reported that high viscosity bone cement had a short injection time and lower rate of vein leakage without increase of operating procedure. This study showed that high viscosity bone cement group had a lower rate of postoperative leakage because high viscosity bone cement was improved on basis of low viscosity bone cement, which could improve the liquid phase in the process of bone cement mixing and decrease the leakage rate and other complication rate to enhance the safety of PVP. The VAS, ODI, Cobb angle at final follow-up in high viscosity bone cement group were obviously lower than lower viscosity bone cement group. High viscosity bone cement had less irreversible thermal damage to surrounding tissue and nerve damage due to advantages of instant high viscosity, long injection time, low solidification temperature and low polymerization temperature.

However, there were no statistical difference about postoperative vertebrae body re-fracture of surgical vertebrae body or nonsurgical vertebrae body between high viscosity bone cement group and low viscosity bone cement group in this study. Because the reasons of subsequent fracture of surgical vertebrae body or nonsurgical vertebrae body were complex, Fan Shunwu [22] had a review on that. The main risk factors of postoperative vertebrae body re-fracture of PVP were necrosis of surgical vertebrae, intracranial fissure change and no bone cement region, excessive rehabilitation of vertebrae height and hypokyphosis. The main risk factors of surgical vertebrae re-fracture were low bone density, intervertebral disc leakage of bone cement, low BMI, excessive rehabilitation of vertebrae body height, age and drug therapy. Although there was no study suggested that high viscosity bone cement could obviously reduce postoperative re-fracture rate of surgical vertebrae body or nonsurgical vertebrae body, we believed that high viscosity bone cement could partially reduce postoperative re-fracture risk of vertebrae body. The reasons were as following: High viscosity bone cement had a more uniform distribution, lower postoperative leakage rate, enough mechanical strength and better ability to rehabilitate the load capacity. If the use of high viscosity bone cement and the operation in PVP procedure were standardized on the basis of fully assessment on severity of osteoporosis, anti-osteoporosis drug was used in perioperative and postoperative and postoperative bed rest time and activity level on the ground was vary from person to person, the postoperative re-fracture risk of vertebrae body would reduce.

Above all, high viscosity bone cement could significantly decrease the bone cement leakage rate in PVP, in which high viscosity bone cement had a better effect on osteoporotic vertebrae compression fracture than low viscosity bone cement. Therefore, adopting high viscosity bone cement in PVP could be a more effective and safe method to treating osteoporotic thoracolumbar vertebrae compression fracture.

Disclosure of conflict of interest

None.

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