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Treating osteoporotic vertebral compression fractures with intraosseous vacuum phenomena using high-viscosity bone cement via bilateral percutaneous vertebroplasty

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Abstract

Osteoporotic vertebral compression fractures with intraosseous vacuum phenomena could cause persistent back pains in patients, even after receiving conservative treatment. The aim of this study was to evaluate the efficacy of using high-viscosity bone cement *via* bilateral percutaneous vertebroplasty in treating patients who have osteoporotic vertebral compression fractures with intraosseous vacuum phenomena.

Twenty osteoporotic vertebral compression fracture patients with intraosseous vacuum phenomena, who received at least 2 months of conservative treatment, were further treated by injecting high-viscosity bone cement *via* bilateral percutaneous vertebroplasty due to failure of conservative treatment. Treatment efficacy was evaluated by determining the anterior vertebral compression rates, visual analog scale (VAS) scores, and Oswestry disability index (ODI) scores at 1 day before the operation, on the first day of postoperation, at 1-month postoperation, and at 1-year postoperation.

Three of 20 patients had asymptomatic bone cement leakage when treated *via* percutaneous vertebroplasty; however, no serious complications related to these treatments were observed during the 1-year follow-up period. A statistically significant improvement on the anterior vertebral compression rates, VAS scores, and ODI scores were achieved after percutaneous vertebroplasty. However, differences in the anterior vertebral compression rate, VAS score, and ODI score in the different time points during the 1-year follow-up period was not statistically significant ($P > 0.05$).

Within the limitations of this study, the injection of high-viscosity bone cement *via* bilateral percutaneous vertebroplasty for patients who have osteoporotic vertebral compression fractures with intraosseous vacuum phenomena significantly relieved their back pains and improved their daily life activities shortly after the operation, thereby improving their life quality. In this study, the use of high-viscosity bone cement reduced the leakage rate and contributed to their successful treatment, as observed in patients during the 1-year follow-up period.

Abbreviations: MRI = magnetic resonance imaging, ODI = Oswestry disability index, STIR = short tau inversion recovery, VAS = visual analog scale.

Keywords: bone cement, osteoporotic, vertebral compression fractures, vertebroplasty

1. Introduction

Vertebral bodies can be fractured due to various causes such as osteoporosis, excessive pressure, or/and physical injuries. Osteoporotic vertebral fractures are one of most common complications of osteoporosis.[1] It has been reported that 40% of osteoporotic patients had osteoporotic vertebral fractures. Osteoporotic vertebral compression fractures can be induced by minor trauma or even minor stress such as bending forward. The prevalence of osteoporotic vertebral fractures has been reported to be 7% to 19% for women and 4% to 17% for men in the age group of 50 to 80 years old.[2] Its prevalence increases with age for both women and men.[3] For example, a recent report from Norway revealed that its prevalence was approximately 3% for women and 7.5% for men in the age group of <60 years old, and this increased to 19% for women and 20% for men in the age group of 70+ years old.[3] The occurrence of 1 vertebral fracture indicates a significantly high risk for a second vertebral fracture if left untreated.[4,5] As society continues to age, osteoporotic vertebral fractures are becoming an increasing public health problem.

Osteoporotic vertebral compression fractures lead to the loss of vertebral body height and cause kyphotic deformity. These would eventually produce chronic back pains due to muscle spasm, stress on ligaments, and/or nerve-root irritation. Osteoporotic vertebral compression fractures were frequently treated using conservative management with external bracing, analgesics, and/or bed rest.[2,3] Conservative management is intended to prevent any further bone loss and relieve back pains by increasing the bone mass, achieving fracture union and assisting its rapid rehabilitation. In general, conservative management impairs the

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daily life activities of a patient and lowers their life quality. Furthermore, conservative treatment is not often efficacious. Some of these treated patients continuously suffer from persistent back pains, and progress toward functional limitations and loss of mobility. Long-term bed rest could also lead to the further demineralization of bones, which might cause further fractures. Therefore, in most cases, osteoporotic vertebral fractures are the onset of the long-lasting deterioration of a patient's health.

Minimally invasive surgical techniques have been proposed and used in clinic for treating chronic back pains, neurological deficits, and/or spinal deformities due to osteoporotic vertebral fractures.[2,4,6–8] Kyphoplasty was introduced in 2001 with the aim restoring lost vertebral body height due to the collapsed vertebrae.[9] During the kyphoplasty operation, a cavity is created in the fractured vertebral body by inflating balloons, and bone cement is used to fill the created cavity. Kyphoplasty stabilizes the vertebra and eliminates the kyphosis caused by osteoporotic vertebral fractures. This technique has rapidly gained widespread acceptance for treating osteoporotic vertebral fractures. However, the cost of the equipment required for kyphoplasty is 7 to 10 folds higher than that for vertebroplasty. However, the average in-patient charge for patients undergoing surgical procedures such as kyphoplasty is approximately US$ 6000 more than that for nonoperative care in China.

Vertebroplasty is a minimally invasive surgical procedure introduced in 1989 to treat vertebral fractures caused by neoplasia or osteoporosis.[10] During the vertebroplasty operation, a needle is percutaneously inserted into the fractured vertebra, and bone cement is injected to stabilize the fracture site.[10] Vertebroplasty has been proven as an effective treatment for osteoporotic vertebral compression fractures, with a high success rate and relatively less complications.[10] However, bone cement leakage has been reported as a main concern in previous studies. This leakage could enter the spinal cavity, intervertebral foramen, vertebral vein, and inferior vena cava *via* channels caused by the trauma, leading to severe local or systemic complications, or even death. Furthermore, other limitations and disadvantages have been observed for vertebroplasty. For example, fractures might occur to the adjacent vertebra, and the height of the vertebra could not be completely restored after a vertebroplasty operation.[11] For patients with severe osteoporosis, the injected cement might shift its position after some time, causing further complications.[11] Therefore, there is a need to improve existing vertebroplasty procedures for treating osteoporotic vertebral compression fractures in clinic.

From January 2013 to December 2014, we adopted percutaneous vertebroplasty to treat 20 patients who experienced treatment failures after completion of their respective treatments. These patients visited North Jiangsu People's Hospital due to unrelieved back pains after receiving at least 2 months of conservative treatment for vertebral compression fractures. The diagnosis conducted in North Jiangsu People's Hospital confirmed that all 20 patients had osteoporotic vertebral compression fractures with intraosseous vacuum phenomena. High-viscosity bone cement was used for these patients to minimize the chance of bone cement leakage. In this report, we present the treatment outcomes of these cases.

2. Methods

2.1. Patients

This study was approved by the institutional ethics committee, and complied with the World Medical Association Declaration of Helsinki on Ethical Principles for Medical Research Involving Humans. From January 2013 to December 2014, 20 patients, who visited North Jiangsu People's Hospital due to unrelieved back pain after receiving at least 2 months of conservative treatment for vertebral compression fractures, were consecutively recruited into this study. Each enrolled patient provided a signed informed content approved by the Institutional Ethics Committee. The age of these patients ranged within 62 to 85 years old (mean: 72.9 years old). Among these patients, 5 patients were male and 15 patients were female. The conservative treatments[12] received by these patients before visiting North Jiangsu People's Hospital included bed rest, Caltrate D, nonsteroidal analgesics, and other treatments for minor trauma caused by falls or lumbar sprain. However, the thoracic back pains of these patients were not relieved, which even worsened when standing and/or walking.

Enrollment criteria: persistent back pains after at least 2 months of conservative treatment, which worsened when standing and/or walking; significant vertebral deformities confirmed through x-ray (GE) films, and intraosseous vacuum phenomena with bone sclerosis around cavities in the vertebra confirmed by computed tomography (CT) (GE Lightspeed 64 row spiral CT); hyperintense signals in the vertebra *via* magnetic resonance imaging (MRI) (GE 1.5T MR360) T2-weighted images and fat suppressed short tau inversion recovery (STIR) images. Osteoporosis (T-score less than –2.5) was confirmed by bone mineral density measurement (GE Prodigy Advance). Patients were excluded from the study when they have any of the following conditions: inconsistencies on the location of the physical pain and radiographic data, back pains caused by inflammation or cancer, multiple vertebral fractures, damages at the spinal cord or nerve root, and surgical contraindications such coagulation disorders. The vertebral fractures of these patients were located at T11 (1 patient), T12 (11 patients), L1 (8 patients), or L2 (4 patients). All patients received percutaneous vertebroplasty to relieve their persistent back pains, and were followed up for 1 year. However, these enrolled patients were not further sub-classified due to the small patient population and the technical limitation at the hospital.

2.2. Treatment of percutaneous vertebroplasty

Bilateral percutaneous vertebroplasty was performed under stringent sterile conditions and fluoroscopic guidance using a C-arm x-ray. Patients were placed in the prone position[10] with the abdomen suspended. Some vertebral height was first restored through body positioning. The fractured vertebra and vertebral pedicle were located and confirmed using C-arm fluoroscopy. Marks were made on the skin as insertion sites, and the needle was inserted toward the vacuum area of the injured vertebra. Patients were placed under general anesthesia prior to the insertion of the needle under the guidance of C-arm fluoroscopy, in order to reach the rear edge of the fractured vertebra along the pedicle. Then, the needles were withdrawn, guide pins were inserted, and working tubes (3.0 mm) were placed. Through these working tubes, customized fine drills were used to drill fine holes to a depth of 1.8 cm, without penetrating the anterior edge of the fractured vertebral body. After the fine drills were withdrawn, low viscosity bone cement (OSTEOPAL V; Heraeus Medical GmbH, Germany) were freshly prepared according to manufacturer's instructions and was injected into the sites of bone fractures using bone cement pushers (AND ZT-II, China) with the aid of C-arm fluoroscopy. The injection should be steady and gentle, in order to avoid rapid bolus.

During the operation, the diffusion of the bone cement and vital signs were closely monitored. The injection of bone cement was stopped when the bone cement diffused to the edge of the vertebral body or when bone cement leakage was observed. After the operation, patients received oral Caltrate D and Rocaltrol, and were given an intravenous injection of zoledronic acid (Aclasta) for anti-osteoporosis therapy.

2.3. Clinical evaluation

Anterior vertebral compression rates were determined through x-ray films taken 1 day before the operation, on the first day post-operation, at 1-month post-operation, and at 1-year post-operation using Equation (1):

$$Rate = 1 - 2 \times H_1/(H_2 + H_3) \quad (1)$$

where H_1, H_2, and H_3 are the anterior heights of the fractured vertebra, the vertebra above the fractured vertebra, and the vertebra below the fractured vertebra, respectively. VAS scores were used to evaluate the pain experienced by these patients, with 0 indicating no pain and 10 indicating severe pain.[13] ODI scores were used to evaluate the function disorders of patients in their daily life activities, with 0 representing no difficulty in daily life activities and 100 for patients who are completely unable to take care of themselves or participate in their daily life activities. These evaluations were conducted 1 day before the operation, on the first day postoperation, at 1-month postoperation, and 1-year post operation.

2.4. Statistical analysis

Numerical data were managed for analysis using SPSS 15.0 statistical software. The paired *t*-test was used to determine any statistically significant difference between 2 data points. A P-value <0.05 was considered statistically significant.

3. Results

All cases in this study had osteoporotic vertebral compression fractures with intraosseous vacuum phenomena. Figure 1 shows

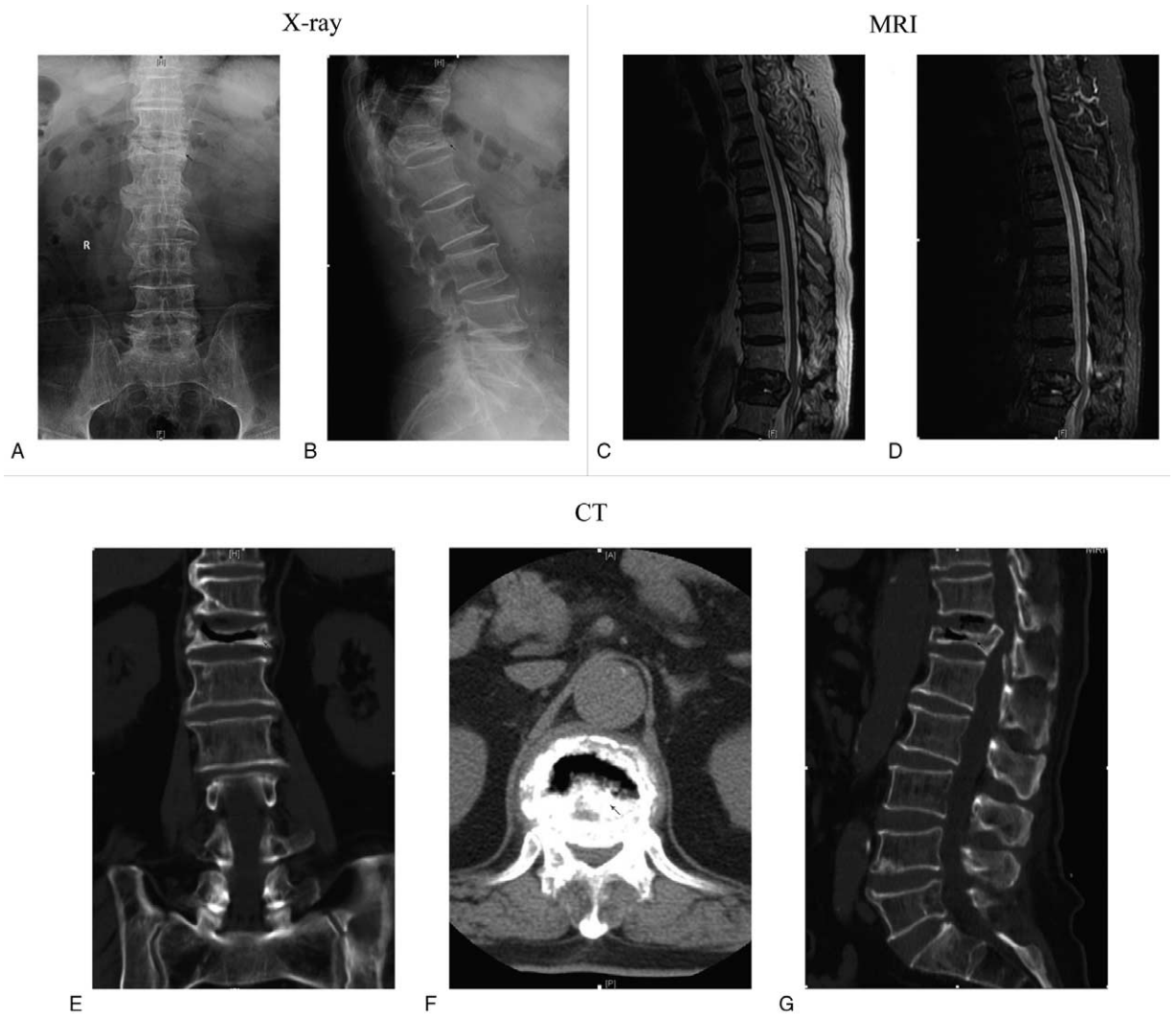

Figure 1. An 81-year-old male with a compression fracture at the T12 vertebral body due to trauma: anteroposterior x-ray film (a) and lateral x-ray film (b) revealed apparent deformities at the T12 vertebral body, anterior vertebral compression rate was approximately 60%, and the intraosseous vacuum phenomenon was observed. MRI T2-weighted image (c) and MRI STIR fat-suppressed image (d) revealed a hyperintense signal in T12; coronal CT scan (e), axial CT scan through T12 (f), and sagittal CT scan (g). This was confirmed intraosseous vacuum phenomenon, and bone sclerosis was observed around the vacuum sites. CT = computed tomography, MRI = magnetic resonance imaging, STIR = short tau inversion recovery.

Table 1

Clinical evaluation of the anterior vertebral compression rates, ODI scores, and VAS scores of patients before and after the operation.

Time	1 day before the operation	First day postoperation	1 month postoperation	1 year postoperation
ODI score	83.8±7.5	24.8±11.2	25.5±8.2	26.7±8.5
Compression rate, %	35.0±13.4	22.0±7.3	22.6±7.2	23.0±7.3
VAS score	7.5±1.1	2.7±1.2	2.2±1.0	2.3±1.3

ODI = Oswestry disability index, VAS = visual analog scale.

the x-ray, MRI, and CT images obtained for an 81-years-old male patient with a T12 fracture and intraosseous vacuum phenomena. This patient received conservative treatment of bed rest for 5 months before visiting our hospital. However, his back pain persisted for 5 months and was worsening. The patient could not walk or stand for long periods, and could not perform common daily life activities. The VAS score and anterior vertebral compression rate for this patient before the operation was 6% and 60%, respectively. Bone mineral density measurement indicated that this patient had a T score of −2.7.

In the present study, the percutaneous vertebroplasty procedure lasted for 25 to 45 minutes, with a mean duration of 33.8 minutes. Blood loss during the operation was 5.0 to 15.0 mL, with a mean volume of 7.1 mL. The bone cement injected for each fractured vertebra varied from 4.0 to 7.0 mL, with a mean volume of 5.4 mL. Furthermore, the bone cement leaked to the front of vertebral body in 2 cases, and the bone cement leaked to the intervertebral disc spaces in 1 case. Consistent with earlier reports,[10] placing the patients in the prone position with the abdomen suspended helped with some restoration of the vertebral body height.

All incisions healed well, and no serious complications such as infection, nerve damage, pulmonary embolism, and/or death were observed during the 1-year follow-up period. All 20 patients completed the follow-ups. Furthermore, all patients had good activities out of bed when wearing a waist brace on the first day postoperation. In addition, these revealed a statistically significant decrease in the ODI score (from 83.3±7.5 before the operation to 24.8±11.2 on the first day postoperation, Table 1). Moreover, their back pains were relieved to various extents, as evidenced by the statistically significant decrease in VAS scores (from 7.5±1.1 before the operation to 2.7±1.2 on the first day postoperation, Table 1). X-ray films taken after the surgery revealed that anterior vertebral compression rates (22.0±7.3%) improved, compared to that before the surgery (35.0±13.4%) (Table 1, $P=0.001$). In particular, significant improvement was observed with a VAS of 0 (vs 6 before the operation) and an anterior vertebral compression rate of 50% (vs 60% before the operation) on the first day postoperation for the patient in Fig. 1 (Fig. 2). In all 20 cases, differences in compression rate, VAS scores, and ODI scores before surgery and at any timepoint during the follow-up period were statistically significant ($P=0.001$, Table 1). However, there were no statistically significant differences between any 2 timepoints after the surgery ($P=0.9$, Table 1).

Figure 2. Anteroposterior x-ray film (a) and lateral x-ray film (b) were taken at 1 day post-operation. For the patient in Fig. 1, this shows that the anterior vertebral compression rate was approximately 50%.

4. Discussion

Vertebral compression fractures present an increasing challenge to the health care system as society continues to age. In clinic, conservative treatments have been continuously used as the first of choice for treating osteoporotic vertebral compression fractures.[4,5,14–17] However, as evidenced by the 20 patients presented in this study, conservative treatment does not always show good efficacy for treating vertebral compression fractures.[18] This was consistent with earlier reports on the poor clinical outcome of nonoperative treatments for some patients with osteoporotic vertebral fractures.[18,19]

When these 20 patients visited our hospital for unrelieved back pains after at least 2 months of conservation treatment, our diagnosis for them was that all patients had osteoporotic vertebral compression fractures with intraosseous vacuum phenomena. The intraosseous vacuum phenomena presented as emerged cavities within the fractured vertebral body, which might be filled with fluid or gas.[20] Some common characteristics were observed in these patients: >60 years of age; back pains with or without an apparent history of trauma; vertebral fractures confirmed by x-ray and MRI; pain that did not alleviate after more than 2 months of conservative treatment such as wearing a waist brace, bed rest, painkillers or other nonsurgical treatment; pains that seriously affected the daily life activities of the patient; osteoporosis confirmed by bone mineral density measurements; apparent vertebral body deformities detected by CT and x-ray; vertebral fractures with bone sclerosis detected by CT and x-ray scans; hyperintense signals within the vertebral bodies via MRI T2 weighted images and STIR fat suppressed images.

At present, there is no consensus on the surgical treatment for osteoporotic vertebral compression fractures with intraosseous vacuum phenomena. The principle guidance is to restore the stability of the vertebrae and improve the balance of the spine.[12] Open surgery has been attempted to treat osteoporotic vertebral compression fractures.[12] However, the osteoporotic bone could not hold the instrumentation used for internal fixation. Thus, it does not fuse well. In consideration to the overall health conditions of these patients and the affordability of expenses, vertebroplasty appears to be a good treatment option compared with open surgery[21,22] and kyphoplasty, due to its minimal invasion and low cost.

All operations performed for these 20 patients went smoothly without any failure. Furthermore, clinical evaluation results obtained during the 1-year follow-up period revealed that all 20 patients had statistically significant improvements ($P=0.001$) on vertebral body height, back pain, and daily life activities. This was reflected by reduced anterior vertebral compression rates, VAS scores, and ODI scores, when compared with corresponding values before the operation (Table 1, $P=0.001$). However, no further improvements were observed during the whole follow-up period after the operation (Table 1, $P=0.9$).

These clinical outcomes or observations might be attributed to the mechanism on how vertebroplasty works. It has been generally recognized[10,23–25] that the injected bone cement could block the local blood supply, thereby damaging the nerve endings. Bone cement is chemically toxic to nerve cells. The heat generated by bone cement polymerization can damage the surrounding nerve endings, but enhance vertebral strength and reduce pressure in the collapsed vertebra to eliminate pains. All these could be achieved within a relatively short period after the bone cement is injected. Once the bone cement solidifies, no further effects can be induced. Some of these 20 patients did feel less severe pains after the operation. This observation revealed that the injected bone cement did not completely fill the cavities within the vertebral bodies, or there were other cracks surrounding the filled cavities. Thus, these vertebral bodies were not able to obtain enough effective support, leading to fracture fretting caused the persistence of pain symptoms.[26]

Compared with the significant improvements on back pains and daily life activities after the operation, the improvement on the anterior vertebral compression rate was relatively lesser (Table 1). This is consistent with other reports,[27] which shows that vertebroplasty could not completely restore the lost vertebral body height.

For treating fresh vertebral compression fractures, bone cement injections should always be avoided at the site of the bone fracture, in order to reduce the chance of bone cement leakage.[28,29] However, for patients who have osteoporotic vertebral compression fractures with intraosseous vacuum phenomena, the fractured vertebrae is significantly deformed, which causes it to lose its normal relative structures for both the vertebral pedicle and the body. Furthermore, significant bone sclerosis occurred around the emerged cavities. All these made it difficult to perform an accurate puncture. In addition, conventional methods for the needle approach and placement could not be used for the puncture, in order to avoid further severe damage to the vulnerable vertebrae due to repeated punctures to the same vertebrae. Therefore, it is extremely important to achieve an accurate puncture at the first attempt. The bone cement should be directly injected into the vertebral fracture sites, and the cement should be evenly distributed in the cavities. This contributes to the re-establishment of vertebral body stability and pain relief after bone cement solidification. Moreover, this will prevent further loss on the vertebral body and prevent fractures at the other vertebral bodies.

However, it has been noticed that injecting too much bone cement might increase the fracture risk for the adjacent vertebrae.[30] In addition, there was a number of vertebral bone sclerosis and tissue re-growth around the fractures, and it was challenging for the injected bone cement to diffuse and evenly fill the cavities. In order to overcome these challenges, bone comment at the pre-drawing stage should be used for injection via percutaneous vertebroplasty. The bone cement should be injected gently and steady, in order to avoid any problems. Furthermore, the injection should be closely observed using intra-operative C-arm fluoroscopy. The injection has to be stopped once the injection pressure drops for the bone cement or leakage is noticed for the bone cement.

In our study, only 3 cases of bone cement leakage occurred among these 20 cases. Furthermore, no clinical complications were noticed during the 1-year follow-up period. The bone cement leakage rate was significantly lower than those reported in some earlier studies.[10,29,31] Jung et al[29] reported a cement leakage rate of 55.5% (20 of 36 cases) in patients who were treated via percutaneous vertebroplasty for osteoporotic compression fractures with intervertebral vacuum clefts, whereas a leakage rate of 75% was reported by Ha et al.[31] The significantly less occurrence rate of leakage in this study should be attributed to the high viscosity of the bone cement used,[12,32] and the close intra-operative monitoring conducted with the C-arm. Bone cement leakage could lead to various clinical complications.[33] The low leakage rate in this study contributed to the successful treatment observed in the patients during the 1-year follow-up period.

However, this study had inherent limitations. Due to the reluctance of patients to participate in this study, only 20 patients were enrolled in this retrospective study. In turn, due to the small enrollment size of this cohort, control groups were not used to compare the efficacy of different treatments including open operation, vertebroplasty with low viscosity bone cement, and other therapies.

In conclusion, the injection of high-viscosity bone cement via bilateral percutaneous vertebroplasty for patients who have osteoporotic vertebral compression fractures with intraosseous vacuum phenomena significantly relieved their back pains and improved their daily life activities shortly after the operation, thereby improving their life quality. The leakage rate of 3 among 20 patients might be attributed to the use of high-viscosity bone cement in this study, contributing to the successful treatment observed in patients during the 1-year follow-up period. No clinical complications were observed in these treated patients during the 1-year follow-up period. The outcomes from this study warrant further studies with larger patient populations, and negative and positive control groups.

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