Randomized Trial

Comparison of the Efficacy and Safety of Bone-filling Mesh Container and Simple Percutaneous Balloon Kyphoplasty in the Treatment of Osteoporotic Vertebral Compression Fractures

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Background: Bone cement leakage in patients with vertebral fracture limits the use of percutaneous kyphoplasty (PKP) and percutaneous vertebroplasty (PVP). Finding a method to reduce bone cement leakage is clinically rather important.

Objective: To compare the efficacy and safety of bone-filling mesh containers (BFMCS) and simple percutaneous balloon kyphoplasty in the treatment of osteoporotic vertebral compression fractures.

Study Design: A randomized controlled clinical study discussing the effect of 3 methods in the treatment of vertebral fractures.

Methods: From October 2014 to August 2015, 80 patients with single osteoporotic vertebral compression fractures were admitted in our hospital, including 31 men and 49 women with an average age of 76.2 years (range, 63-82 years). Patients were divided into a percutaneous balloon kyphoplasty group (Group A) and a PVP with dilated balloon placement group (Group B), with 40 cases in each group. The visual analog scale (VAS), Oswestry disability index (ODI), height of the vertebral body and Cobb's angle of the injured vertebrae were observed before operation and at 1 day, 1 month, and 6 months after the operation. Bone cement leakage and postoperative complications were also observed.

Results: Operations were successfully completed in all 80 patients without pulmonary embolism and without spinal cord or nerve root injury. The operation time was (32.6 ± 6.1) minutes in Group A and (31.8 ± 5.8) minutes in Group B. Operation time did not significantly differ between the 2 groups ($P > 0.05$). Both groups differed significantly when comparing the results with those measured before treatment. In Group A, the ODIs before operation and at 1 day, 1 month, and 6 months after the operation were 84.125 ± 8.821, 29.300 ± 8.951, 16.175 ± 6.748, and 11.400 ± 6.164, respectively, and those in Group B were 84.300 ± 8.768, 29.200 ± 9.121,15.975 ± 6.811, and 11.575 ± 6.460, respectively. Cobb's angle values in Group A before and after treatment were (19.225 ± 5.881)° and (13.900 ± 3.720)°, respectively, and those in Group B were (19.275 ± 6.210)° and (14.225 ± 4.016)°, respectively.

Conclusion: Both bone-filling mesh bag and simple percutaneous balloon kyphoplasty for treating osteoporotic vertebral compression fractures can relieve pain effectively and correct the Cobb angle. The bone-filling mesh container can effectively prevent bone cement leakage and reduce the incidence of bone cement leakage.

Limitations: The study has limitations due to the small number of cases and short period of follow-up time. Further studies are needed to determine whether the mesh bag can limit the distribution of bone cement within the vertebral body.

Keywords: Bone-filling mesh container, kyphoplasty, osteoporosis, vertebral compression fracture

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Percutaneous vertebroplasty (PVP) and percutaneous kyphoplasty (PKP) have become important means of treating vertebral compression fractures (1-4) and can immediately relieve pain, improve the patient's motor function, and have been widely used in clinical practice. However, the complications caused by bone cement leakage in patients with vertebral fracture, especially in patients with posterior vertebral cortical bone damage, limit the use of vertebroplasty (5). To reduce the rate of bone cement leakage and better elevate vertebral height, percutaneous vertebral kyphoplasty is improved by PKP. However, in the treatment of bone cement leakage, no significant difference was found between PKP and PVP (6-8), and both methods do not markedly reduce bone cement leakage. Hence, researchers have attempted to improve surgical instruments, and instruments such as balloons, the sky bone expansion system, the JACK expansion system, stents and the Kiva VCF system are used in clinics. However, due to issues related to the metal materials used, poor biocompatibility or failure to reduce bone cement leakage, these methods are not widely applied in clinics (9-16). Bone-filling mesh container (BFMCs) is a newly used surgical instrument. After implanting the BFMC into a space formed by balloon dilatation, bone cement is filled into the BFMC, and the vertebral body is elevated using the BFMC; bone cement is prevented from leaking outside, so that a small amount of bone cement can be infiltrated into the trabecular space through the mesh to form a microscopic twist lock and to strengthen the vertebral body. This study aims to compare the risk and efficacy of BFMC and simple percutaneous balloon kyphoplasty for the treatment of vertebral compression fractures.

Methods

Inclusion criteria: single osteoporotic vertebral compression fracture; compression degree > 25%; patients' pain site and percussion pain site consistent with imaging data. Exclusion criteria: patients with coagulation dysfunction, severe cardiopulmonary disease, acute infection; CT scan and magnetic resonance imaging (MRI) suggest fracture healing; patients with asymptomatic vertebral bone sclerosis.

A total of 80 patients were included, comprising 31 men and 49 women with ages ranging from 63 to 82 years old (mean age 76.2 years). Patients were randomly divided into 2 groups, with 40 cases in each Group. Group A comprised 16 men and 24 women with a mean age of 76.3 years, including 3 cases with hormone application history, 3 cases of diabetes, 9 cases of trauma history, and 7 cases of varying degrees of vertebral cortical bone damage. Group B comprised 15 men and 25 women with a mean age of 75.8 years, including 4 cases with hormone application history, 3 cases of diabetes, 8 cases of trauma history, and 8 cases of varying degrees of vertebral cortical bone damage. The injured vertebrae in Group A were distributed as follows: T8 in 2 cases, T9 in 3 cases, T10 in 3 cases, T11 in 4 cases, T12 in 5 cases, and L1 in 6 cases. In Group B, the injured vertebrae were distributed as follows: T8 in 3 cases, T9 in 3 cases, T10 in 2 cases, T11 in 5 cases, T12 in 6 cases, and L1 in 5 cases. The vertebral compression degree was greater than 25%, and the time from disease occurrence to surgery was from 3 days to 6 months. Age, gender, and fractured vertebra distribution did not significantly differ between the 2 groups ($P > 0.05$). The study was approved by the Medical Ethics Committee of Guizhou Provincial People's Hospital.

Surgical Methods

Group A

The patient was placed in the prone position, and the position of the needle was selected according to preoperative measurement. The upper edge of the pedicle was taken as the needle point under the guidance of a C-arm (Artis zeego digital subtraction angiography DSA system, Germany). One percent lidocaine was used for local anesthesia, the puncture needle was inserted into the upper edge of the pedicle, the puncture needle was maintained in an outreach direction with the needle tail directed to the cephalic tilt, and needle direction and depth were positively and laterally monitored. When a satisfactory position was reached, hollow drilling was used to obtain a biopsy; the solid vertebral body was used to drill to the anterior 1/3 of the vertebral body, and a balloon was then inserted for expansion. After the balloon was removed, the polymethylmethacrylate cement was blended to the "drawing stage," and the bone cement was injected using an injector. Under continuous lateral monitoring, perfuse polymethylmethacrylate cement was injected until the area was satisfactorily filled with bone cement or bone cement overflowed; the needle was then removed, and local pressure was applied. Bone cement distribution was positively laterally monitored; the needle was removed after finishing the operation, and the wound was covered with a sterile applicator. The patients were rested in bed

for 6 hours, and their vital signs were monitored; the activities of both lower extremities were observed.

Group B

The patients were placed in the prone position, and the position of the needle was selected according to preoperative measurement. The upper edge of the pedicle was taken as the needle point under the guidance of a C-arm (Artis zeego digital subtraction angiography DSA system, Germany). One percent lidocaine was used for local anesthesia, the puncture needle was inserted into the upper edge of the pedicle, the puncture needle was maintained in an outreach direction with the needle tail directed to the cephalic tilt, and needle direction and depth were positively and laterally monitored. When a satisfactory position was reached, hollow drilling was used to obtain a biopsy; the solid vertebral body was used to drill to the anterior 1/3 of the vertebral body, and a balloon was then inserted for expansion. After the balloon was removed, a BFMC (Shandong Guanlong Medical Products Co., Ltd.) and special kyphoplasty equipment (including a puncture device and inflatable balloon) were inserted; polymethylmethacrylate cement was blended to the "drawing stage," and the bone cement was injected using a propeller. Controlled pressure injection was performed under continuous lateral monitoring. Bone cement continued to be perfused when the BFMC was expanded to the cavity edge. The bone cement gradually exuded under the pressure, and a small amount of bone cement was released into the trabecular space through the mesh. When the bone cement was satisfactorily diffused, the BFMC was removed. Filling was stopped and appropriately withdrawn if the bone cement outreached during the injection process, and local pressure was applied after needle removal.

Bone cement distribution was positively laterally monitored; the needle was removed after finishing the operation, and the wound was covered with a sterile applicator. The patients were rested in bed for 6 hours, and their vital signs were monitored; the activities of both lower extremities were observed.

Observation Indices and Follow-up

Operation time, VAS score before the operation and at 1 day, 1 month, and 6 months after operation, as well as Oswestry disability index (ODI) and preoperative and postoperative Cobb's angle were recorded. Bone cement leakage, the rate of bone cement leakage and the leakage site were observed. Type I represents bone cement leaks to the spinal canal, type II represents bone cement leaks to the paraspinal vein, type III represents bone cement leaks to the adjacent vertebral soft tissue, and type IV represents bone cement leaks to the adjacent disc. The occurrence of postoperative neuralgia and vertebral fractures were recorded.

Statistical Analysis

SPSS 16.0 software was used for statistical analysis. Measurement data were expressed as the means ± standard deviation. Preoperative and postoperative VAS and ODI score were analyzed by variance analysis, Cobb's angle changes were analyzed using the t test, and grade data were detected using the chi-square test. $P < 0.05$ was considered to indicate statistical significance.

Results

Operation Time

The operation time was (32.6 ± 6.1) minutes in Group A and (31.8 ± 5.8) minutes in Group B. No significant difference was found in the operation time between the 2 groups ($P > 0.05$). VAS and ODI at Each Time Point

Postoperative VAS scores at each time point was remarkably decreased when comparing the results with those measured before the operation, and no significant difference in VAS score was observed between the 2 groups at each time point. The ODI was lower than before the operation, and the difference was statistically significant. No significant difference was found in the ODI between the 2 groups.

Postoperative Cobb's Angle Changes

Postoperative Cobb's angle measured lower than before the operation, and the difference was statistically significant. There was no significant difference in Cobb's angle between the 2 groups before and after the operation (Table 1-3).

Bone Cement Leakage

In Group A, 9 cases of cement leakage occurred to disc and adjacent vertebral soft tissue during the vertebroplasty, including 3 cases of type II, 2 cases of type III, and 4 cases of type IV; the leakage rate was 22.5%. Patients with leakage had no clinical symptoms. The bone cement leakage rate in Group B was significantly lower than that in Group A, and the difference was statistically significant (Table 4).

Table 1. *VAS changes before and after operation in both groups.*

Group (n = 40)	T1	T2	T3	T4	F value	*P* value
Group A	7.475 ± 0.905	2.050 ± 1.085a	1.200 ± 0.564a	1.375 ± 0.628a	527.752	0.000
Group B	7.475 ± 0.933	2.075 ± 1.047a	1.325 ± 0.656a	1.300 ± 0.608a	512.059	0.000
T value	0.000	-0.105	-0.914	0.543		
P value	1.000	0.917	0.364	0.589		

Compared with T1, $P < 0.05$a was considered indicate a significant difference.
T1 = one day; T2 = one month, T3 = 6 months; T4 = after operation.

Table 2. *ODI changes before and after the operation in both groups.*

Group (n = 40)	T1	T2	T3	T4	F value	*P* value
Group A	84.125 ± 8.821	29.300 ± 8.951a	16.175 ± 6.748a	11.400 ± 6.164a	741.518	0.000
Group B	84.300 ± 8.768	29.200 ± 9.121a	15.975 ± 6.811a	11.575 ± 6.460a	725.141	0.000
T value	-0.089	0.049	0.132	-0.124		
P value	0.929	0.961	0.895	0.902		

Compared with T1, $P < 0.05$a was considered to indicate a significant difference.
T1 = one day; T2 = one month, T3 = 6 months; T4 = after operation.

Table 3. *Cobb changes before and after the operation in both groups.*

Group (n =40)	T1	T2	T value	*P* value
Group A	19.275 ± 6.210	14.225 ± 4.016a	4.319	4.804
Group B	19.225 ± 5.881	13.900 ± 3.720a	0.000	0.000
T value	0.037	0.376		
P value	0.971	0.708		

Compared with T1, $P < 0.05$a was considered to indicate a significant difference.
T1 = one day; T2 = one month, T3 = 6 months; T4 = after operation.

Table 4. *Bone cement leakage in both groups.*

Group (n = 40)	I	II	III	IV	Average leakage rate
Group A	0	0.3	0.2	0.4	0.225
Group B	0	0	0	0	0

Compared with Group A, $P < 0.05$ was considered to indicate a significant difference ($P = 0.034$, F = 7.500)
Type I leakage = leaks to spinal cord; Type II leakage = leaks to paraspinal vein; Type III leakage = adjacent vertebral soft tissue; Type IV leakage = adjacent disc

Complications

In Group A, one case of intercostal neuralgia occurred at 2 days after the operation, and the symptom disappeared completely after nerve block treatment; 2 cases of adjacent vertebral fracture reoccurred at 3 months and 8 months after the operation, and the symptoms disappeared completely after vertebroplasty. In Group B, one case of adjacent vertebral fracture occurred at one month after operation, and the symptoms disappeared completely after vertebroplasty.

Typical Cases

Case 1

An 84-year-old woman was hospitalized because of back pain for 6 months. Her vertebral bone was longitudinally interrupted, and bone cement was injected while applying the BFMC. The longitudinally interrupted site was filled with bone cement, and no bone cement leakage was observed. VAS scores before operation and at 1 day, 1 month, and 6 months were 7, 2, 1, and 1 points, respectively. ODI scores before operation and at 1 day, 1 month, and 6 months were 84, 12, 9, and 8, respectively (Fig. 1).

Case 2

An 87-year-old man was hospitalized because of back pain for 15 days. After admission, he was diagnosed as having an L2 fracture. The vertebral body was punctured using the unilateral pedicle approach, a BFMC was inserted, and bone cement was injected

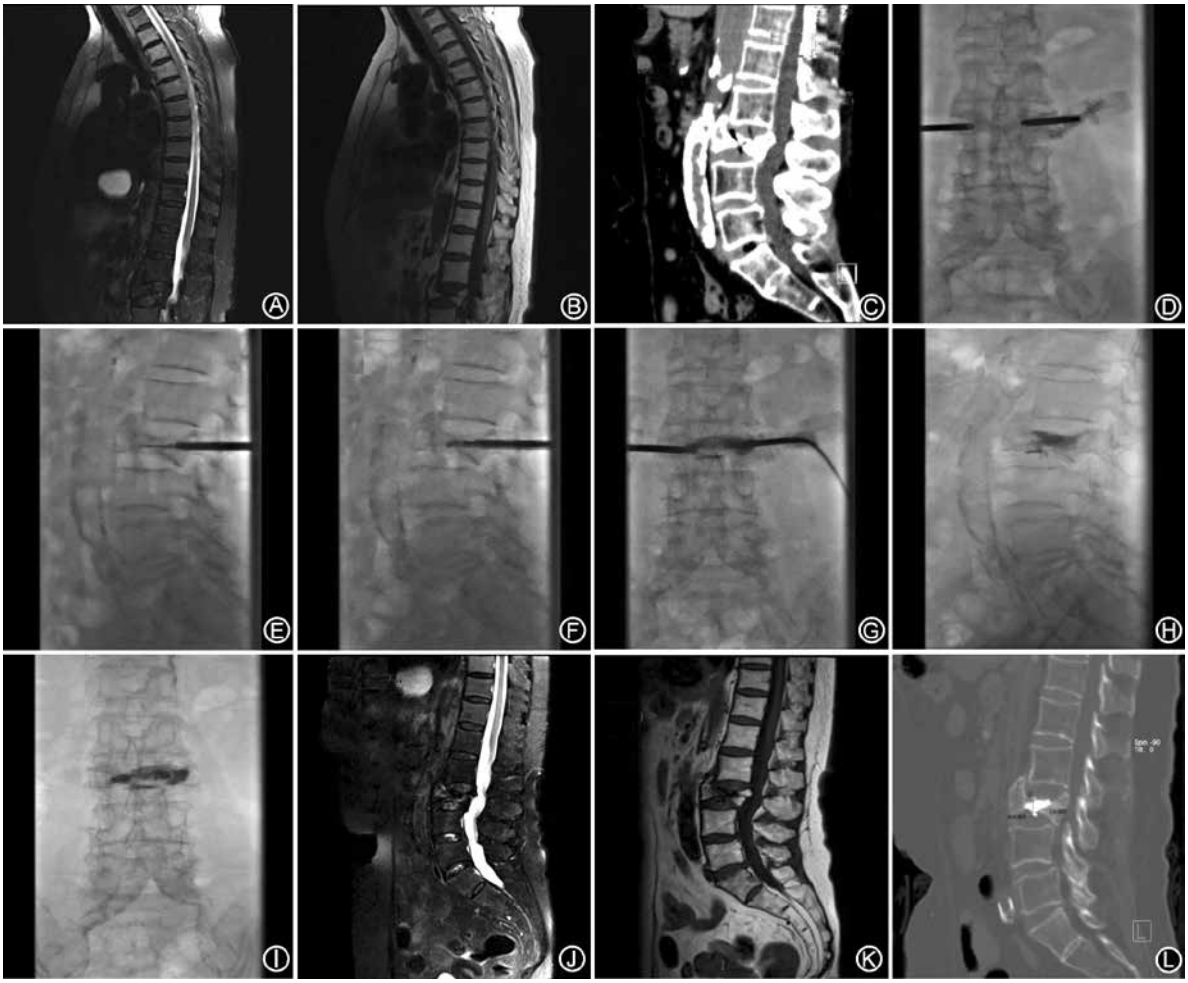

Fig. 1. An 84-year-old female was admitted to the hospital due to having back pain for 6 months with a VAS score of 7 and an Oswestry dysfunction index of 84. The VAS scores at postoperative 1 d and at 1 and 6 months were 2, 1, and 1, respectively, and the Oswestry dysfunction index values at postoperative 1 d and at 1 and 6 months were 12, 9, and 8, respectively.
A-C. MRI showed an L3 vertebral wedge, central depression and no abnormal signal within the vertebral body, suggesting an old wedge change. CT showed an L3 vertebral wedge change, the central depression, and bone longitudinal interruption, and a gas shadow was observed in the corresponding disc.
D-I. During operation, the vertebral body was punctured through the bilateral vertebral pedicle approach, the mesh bag was implanted, and bone cement was injected after balloon expansion. The volume of bone cement injection was approximately 3 ml, and the bone cement filled well without leakage.
J-L. After operation, the L3 vertebra showed a long T1 and T2 signal changes and the central depression showed a long T1 and short T2 signal filling. CT showed that the bone cement filled well without leakage.

after balloon expansion. Approximately 5 mL of bone cement was injected. The bone cement filled well without leakage. VAS scores before operation and at 1 day, 1 month, and 6 months were 8, 2, 1, and 1 points, respectively. ODI scores before operation and at 1 day, 1 month, and 6 months were 86, 13, 9, and 7, respectively (Fig. 2).

Discussion

PVP has been applied in clinical practice since 1987, and is widely used to treat vertebral compression fractures because of its advantages, which include good efficacy, less trauma, rapid recovery and few complications (17-19). Bone cement leakage is the main complication of PVP, and the reduction of the bone cement leakage

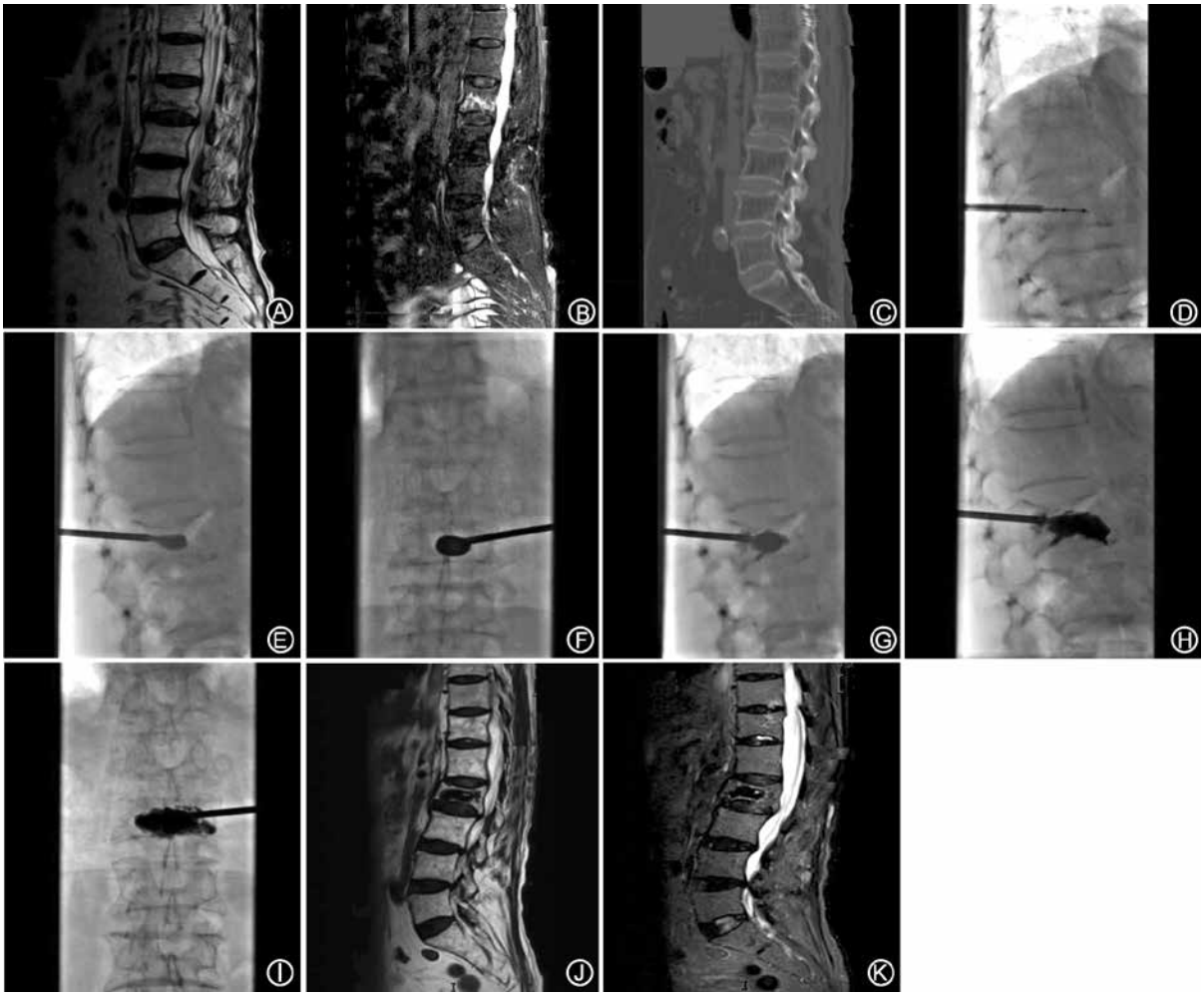

Fig. 2. *An 87-year-old male was admitted to hospital due to having back pain for 15 days with a VAS score of 8 and an Oswestry dysfunction index of 86. The VAS scores at postoperative 1 d and at 1 and 6 months were 2, 1, and 1, respectively, and the Oswestry dysfunction index values at postoperative 1 d and at 1 and 6 months were 13, 9, and 7, respectively.*
A-C. Preoperative thoracic MRI T1WI, T2WI, and STIR showed L2 vertebral compression; T1WI and T2WI showed low signal; and STIR showed high signal.
D-I. During operation, the vertebral body was punctured through the lateral vertebral pedicle approach, the mesh bag was implanted, and bone cement was injected after balloon expansion. The volume of bone cement injection was approximately 5 ml, and the bone cement filled well without leakage.
J-K. At one year after operation, the L2 vertebra showed long T1 and T2 signal changes with long T1 and short T2 signal filling.

rate to improve the safety of this surgery has become a common concern for doctors. Early simple vertebroplasty involved the direct injection of bone cement within vertebrae through a needle under high injection pressure; bone cement permeability of 11-76% was achieved (20,21). Balloon expansion kyphosis involved the formation of a cavity using balloon dilatation, after which bone cement is injected under low pressure; using this technique, the bone cement leakage rate can be decreased to 8.4% (22,23). However, after removing the balloon, the bone cement directly contacts the vertebrae and can diffuse to any site through the fracture gap, triggering serious consequences or even causing vertebra to collapse again. The use of a stent or a Kiva VCF system can avoid the loss of bone cement, but does not solve the problem of bone cement leakage. The

implanted silicone balloon cannot completely fix the bone cement; therefore, this technique is no longer used in clinics (24). Rotter et al (25) used a metal mesh stent combined with bone cement to treat vertebral compression fractures; permanent metal stents were implanted, and bone cement was then perfused to enhance the intensity and restoration of vertebral height. However, because the elastic modulus of the metal implant differs greatly from that of bone, vertebral fractures can easily occur; therefore, this technique is not widely applied in clinical practice. This study used a BFMC and simple percutaneous balloon kyphoplasty to treat osteoporotic vertebral compression fractures, and the results show that the use of a BFMC can effectively prevent bone cement leakage and reduce the rate of bone cement leakage.

Previous studies have reported that PVP is superior to conservative treatment in relieving pain (26). Hence, operative treatment is more suitable for elderly patients who have had ineffective conservative treatment, have obvious pain, or cannot lie in bed for a long time (27). Filling bone cement into the injured vertebra to achieve mechanical stability not only can lead to early walking, but can also relieve pain and has been widely accepted (28,29). Although the mechanism of pain relief after bone cement strengthening has not been clarified, most scholars believe that the heat released during the polymerization of bone cement can cause the necrosis of nerve endings in tissues adjacent to the implant, thus increasing stability after strengthening the vertebral bone cement (30). In this study, the VAS scores at each postoperative time point were significantly lower than those before operation in the 2 groups; however, VAS scores did not significantly differ at any time point between the 2 groups. Postoperative ODI did not significantly differ at each time point between the 2 groups. Postoperative ODI at each time point was lower than before the operation, and the difference was significant. Postoperative Cobb's angle was lower than before the operation, and the difference was significant. Cobb's angle did not significantly differ between the 2 groups before and after the operation. The results showed that using the BFMC and a simple percutaneous balloon expansion vertebroplasty achieved a satisfactory outcome and effectively relieved pain and improved motor function.

Balloon kyphoplasty is an improved technique based on PVP. Compared with PVP, balloon kyphoplasty has the advantages of increasing the height of the compressed vertebral body, correcting kyphosis, and recovering normal spine mechanical properties. In addition, because balloon kyphoplasty forms cavities within the vertebral body, bone cement can be injected under low pressure, and the bone cement leakage rate can be reduced to 1 to 8% (22). However, the problem of bone cement leakage has not been completely solved. In addition, the balloon dilator is not left in the vertebral body, and a loss of the vertebral height can result after withdrawing the balloon, leading to a failure of the good reconstruction of vertebral body biomechanical properties and increasing the risk of a long-term occurrence of secondary vertebral fractures. At the same time, balloon dilatation compresses the trabecular bone, thus hindering the cross-linking between the bone cement and the trabecular bone and resulting in a reduced micro-twist lock and decreased resistance to shear capacity, thus causing vertebral fractures. In the present study, no bone cement leakage was observed in the vertebroplasty group involving the use of a BFMC. The BFMC used in this study is a recently developed inflatable bag-like bone material filler that is used in clinical practice. The system consists of a transporting device and a filling bag. The material of the bag body is 75D/36F high-strength wire comprising 100% polyethylene terephthalate (PET) with a fineness of 166.5 dtex and a strength of 6.75 CN/dtex. The single-layer bag is made of a relatively thick high-strength wire that exhibits good biocompatibility. The bag is columnar when it is not inflated and can be inserted into the vertebral body through a percutaneous puncture. In the process of bone cement perfusion during vertebral reinforcement, some bone cement can be fully diffused within the cancellous bone through the mesh, and the mesh bag is used to control bone cement distribution in the vertebral body to reduce the risk of bone cement leakage. The recovery of vertebral height in compressed fractures and the correction of kyphosis deformity can reduce the pathological load of the anterior column of the spine and muscle contraction imbalance, which may help to reduce back pain and the incidence of further fractures.

Conclusion

In summary, the use of a BFMC and simple percutaneous balloon kyphoplasty to treat osteoporotic vertebral compression fractures can effectively relieve pain, restore vertebral body height, and decrease kyphosis and pain. The use of a domestic inflatable mesh bag filler material for PVP can significantly reduce the leakage of bone cement when compared with traditional

percutaneous balloon dilatation vertebroplasty and can also be used for benign and malignant vertebral lesions with cortical destruction.

However, the study has limitations due to the small number of cases and short period of follow-up time. Further studies are needed to determine whether the mesh bag can limit the distribution of bone cement within the vertebral body.

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