Comparison of early results of Vesselplasty and percutaneous vertebroplasty in the treatment of elderly patients with osteoporotic vertebral compression fracture

CURRENT STATUS: UNDER REVIEW

Journal of Orthopaedic Surgery and Research  BMC

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DOI: 10.21203/rs.3.rs-17452/v1

SUBJECT AREAS
Orthopedics

KEYWORDS
Osteoporotic vertebral compression fractures, Percutaneous vertebroplasty, Vesselplasty, Early efficacy
Abstract

Objective
To investigate the early clinical effect of vesselplasty and percutaneous vertebroplasty in the treatment of elderly patients osteoporotic vertebral compression fractures.

Methods
A retrospective analysis was performed on 22 patients (10 males and 12 females, aged 60~85 years old [73.1±9.6] with osteoporosis fracture treated by vesselplasty in Shanxi Bethune Hospital from March 2017 to December 2018. During the same period, 56 patients (20 males and 36 females, aged 60-80 years (70.3±9.4) were treated with percutaneous vertebroplasty (PVP) for osteoporosis fractures. Preoperative and postoperative Visual Analogue Score (VAS), operative time, intraoperative bone cement leakage, preoperative and postoperative vertebral body anterior margin height were recorded to evaluate the clinical efficacy.

Results
In the vesselplasty group, preoperative VAS score was 7.9±0.9, postoperative VAS score was 3.8±0.8, postoperative recovery rate of vertebral height was 19.9%±19.1%, operative time (33.6±6.2)min, and bone cement leakage was observed in 3 cases. In the PVP group, preoperative VAS score was 7.9±0.9, postoperative VAS score was 3.7±0.8, postoperative recovery rate of vertebral height was 18.8%±18.2%, operative time (35.8±6.6)min, and bone cement leakage was observed in 15 cases. Compared with the PVP group [26.8%, the bone cement leakage rate of the vesselplasty group [13.6%] was significantly reduced, and the difference was statistically significant, but there was no significant difference in other data.

Conclusion
Both vesselplasty and percutaneous vertebroplasty can achieve satisfactory early clinical efficacy in the treatment of senile osteoporosis vertebral compression fractures. Bone cement leakage rate of vesselplasty is smaller and it is safer.

Background
Osteoporotic vertebral compression fractures (OVCFs) are common fracture types in elderly patients
with osteoporotic spine. After the fracture, the waist and back were painful and the movement was limited. The patient could not complete daily life and was forced to stay in bed. Patients undergoing non-surgical treatment stay in bed for a long time, and are prone to complications such as bedsores, epidemic pneumonia, urinary infections, deep vein thrombosis, and even life-threatening conditions. Therefore, restoring spinal stability, timely pain relief, and early getting out of bed are the key to the treatment of osteoporotic compression fractures in the elderly [1-2]. Percutaneous vertebroplasty (PVP) and percutaneous kyphoplasty (PKP) are commonly used clinically minimally invasive treatment methods for senile osteoporotic vertebral compression fractures. The clinical results are satisfactory, but a common disadvantage is the high rate of bone cement leakage.

Bone-filled mesh bag balloon vertebroplasty (Vesselplasty) is a minimally invasive surgical technique for the treatment of senile osteoporotic vertebral compression fractures. The wrapping effect of the mesh bag can effectively prevent the extravasation of the bone cement, reduce the complications caused by the extravasation of the bone cement, improve the safety of the operation, and can also stabilize the vertebral body. Compared with PVP, the treatment of osteoporotic fractures in the elderly with mesh bag balloon vertebroplasty is relatively few, and comparative studies between the two are rarely reported [3-4].

This study used a systematic case review to analyze the case data of elderly osteoporotic vertebral compression fractures treated with Vesselplasty and PVP from March 2017 to December 2018 in Shanxi Bethune Hospital. The clinical application characteristics, complications and clinical efficacy of the two methods were compared to provide a reference for clinical treatment.

Materials And Methods

**Inclusion and exclusion criteria**

Inclusion criteria:

1. Age ≥60 years of age;
2. Thoracolumbar pain after no obvious inducement or low-energy injury, physical examination showed obvious tenderness and throbbing pain in the thoracic or lumbar spine;
3. The imaging examination clearly diagnosed a fresh fracture (usually within 3 weeks);
4. Bone mineral density (BMD) ≤ -2.5;
5. Although there are many basic diseases in the past, they can be adjusted to the tolerance range of the operation, and the patient has a strong subjective surgical
intention.
exclusion criteria ① Patients with pathological vertebral fractures caused by malignant bone tumors; ② High energy
Patients with injury combined with spinal cord and nerve root compression symptoms; ③ Patients with mental illness who cannot cooperate with surgery; ④ Clotting dysfunction and bleeding tendency; ⑤ Severe heart, lung, liver, kidney and other important organ dysfunction that cannot tolerate surgery; ⑥ Persons with severe allergies or rejection of bone cement components; ⑦ Old fractures and others who do not want surgery.

General Information

Vesselplasty was used to treat 22 patients with osteoporotic fractures, 10 males and 12 females, aged 60 to 85 years [73.1 ± 9.6 years]. A total of 25 vertebrae, 21 single vertebrae, and 2 double vertebrae. In the same period, 56 patients with osteoporotic fractures were treated with percutaneous vertebroplasty (PVP), including 20 males and 36 females, aged 60 to 80 years [(70.3 ± 9.4) years]. In total, there are 70 vertebrae, 36 single vertebrae, 11 double vertebrae, and 4 vertebrae.

Surgical method

1. Preoperative preparation

Routine preparation: Routine laboratory tests for routine blood tests, blood coagulation, liver and kidney function tests, etc; improve electrocardiogram, cardiac color Doppler ultrasound, chest X-ray examination to assess cardiopulmonary function; X-ray films, CT of thoracolumbar spine, and MRI to confirm injury and diagnosis of spine, prone position training; Preoperative risk assessment and psychological counseling.

Equipment preparation: vertebroplasty kit (Shandong Guanlong Medical Technology Co., Ltd.), bone cement (Heraeus Medical GmbH, Germany), G-arm, iodine contrast agent.

2. Surgical steps (Figure 1): The patient is placed in a prone position with the abdomen suspended. Position the injured vertebra under G-arm perspective. The unilateral pedicle approach is adopted, generally the spinous process is opened about 1.5-2 cm laterally and laterally, and 20% lidocaine is used for local anesthesia. After the anesthesia is effective, a 0.5 cm incision is taken, and a
percutaneous pedicle is punctured under the monitoring of a G-arm, and a working sleeve is placed so that the front end of the sleeve is located about 0.5 cm in front of the posterior edge of the vertebral body. Use the drill through the pedicle working sleeve to enter the anterior 1/3 of the vertebral body, remove the drill, insert the expansion orthosis, and place it in the anterior 1/3 of the vertebral body. The orthoses are placed in a bone-filled mesh bag, and the bone cement is adjusted. After the wire drawing period, the bone cement is injected through a working sleeve under the monitoring of a G-arm. Generally, about 3-4.5ml is injected. During the operation, the bone cement was diffused and there was no obvious exudation. After the bone cement was solidified, the working sleeve was removed by micro-motion drilling to prevent tailing of the bone cement, bandaging the wound, and returning to the ward.

3. Postoperative treatment: The patient lies supine for 4 to 6 hours. After 6 hours, the ECG monitoring is stable and the thoracolumbar X-rays are reviewed. After 12 hours, the patient wears waist circumference and walks down. The VAS score is used to evaluate the patient’s pain. Postoperative regular anti-osteoporosis treatment.

4. Efficacy evaluation: The visual analogue pain score (VAS) was used to evaluate the quality of life of patients before and 12 hours after surgery; the imaging rate was compared with the recovery rate of the anterior margin of the injured vertebral body after surgery; the operation time and bone cement were recorded. Leakage evaluates the effect of surgery. The vertebral height recovery rate of injured vertebrae is evaluated using the ratio (the recovery rate of vertebral height of injured vertebrae = (the height of the anterior edge of the injured vertebral body-the height of the anterior edge of the vertebral body before the operation) / the anterior edge of the vertebral body before the injury Height) X100%.

5. Statistical method: SPSS 20 software was used for statistical analysis, and measurement data consistent with the normal distribution were expressed by Mean ± SD. The homogeneity of variance test was performed using independent sample t test, and the comparison of bone cement leakage was performed by chi-square test. P <0.05 indicates that the difference is statistically significant.

Results
1. Comparison of VAS scores between two groups

Vesselplasty for patients with osteoporotic fractures had a preoperative VAS of (7.9 ± 0.9) points and a postoperative VAS of (3.8 ± 0.8) points; the preoperative VAS of the PVP group was (7.9 ± 0.9) points, and the postoperative VAS score was (3.7 ± 0.8) points; the postoperative VAS scores were significantly reduced in both groups, indicating that the curative effect of the operation was satisfactory, and the patient's lower back pain improved significantly. However, there was no significant difference between the two groups (P> 0.05, Table 1). The operation time of Vesselplasty was (33.6 ± 6.2) min, and the operation time of PVP group was (35.8 ± 6.6) min. There was no significant difference between the two groups (P> 0.05).

2. Comparison of vertebral height recovery between the two groups

The vertebral height recovery rate of patients with osteoporotic vertebral compression fractures treated with bone-filled mesh balloon vertebroplasty was 19.9% ± 19.1%, and the vertebral height recovery rate of PVP group was 18.8% ± 18.2%. The imaging results showed that the vertebral height was restored to different degrees by both surgical methods, but there was no statistical significance between the two groups (Table 1).

3. Comparison of bone cement leakage between the two groups

Compared with the PVP group (26.78%), the leakage rate of bone cement (13.64%) in the bone-filled mesh bag balloon vertebroplasty group was significantly reduced, indicating that the bone-filled mesh bag balloon vertebroplasty was used to treat osteoporotic vertebral compression. Patients with fractures are safer (Table 1).

Table 1
| Subject                          | Vesselplasty | PVP     | P value |
|--------------------------------|-------------|---------|---------|
| Case (n)                        | 22          | 56      |         |
| Operative vertebra n            | 25          | 70      |         |
| Age year                        | 73.05±9.55  | 70.25±9.40 | 0.866 |
| Operating time (min)             | 33.64±6.21  | 35.82±6.56 | 0.356 |
| Pre-op VAS (score)               | 7.91±0.87   | 7.88±0.89 | 0.324 |
| After 12 h VAS (score)           | 3.77±0.81   | 3.67±0.82 | 0.165 |
| Pre-op height of anterior edge of vertebral body (mm) | 22.91±5.74 | 23.16±6.82 | 0.583 |
| Post-op height of anterior edge of vertebral body (mm) | 26.68±4.94 | 27.13±5.68 | 0.462 |
| Recovery rate of vertebral height (%) | 19.85±19.09 | 18.78±18.20 | 0.694 |
| Leakage rate of bone cement (%)  | 13.64       | 26.78   | 0.043   |

P<0.05 Difference was statistically significant

Discussion
China has entered an aging society, and the process of population aging has continued to deepen. The incidence of vertebral compression fractures caused by osteoporosis has gradually increased. Such fractures have become a common cause and cause of death in elderly fracture patients [5-8]. The thoracolumbar region of the human body is in the area of excessive physiological flexion, which bears most of the pressure of the human body. Therefore, more than 50% of spine fractures are located in the thoracolumbar segment [9]. After the fracture, there are back pain, limited mobility, kyphosis, nerve compression seriously, that affects the quality of patients' daily lives. Restoring spinal stability, timely pain relief, and early getting out of bed are the keys to treating osteoporotic compression fractures in the elderly. At present, the commonly used surgical treatments in the clinic
include PVP, PKP, and spinal fixation [10-15]. The common disadvantages of PVP and PKP are the high leakage rate of bone cement, the trauma of spinal internal fixation surgery, and the elderly patients should not tolerate it. Bone-filled mesh bag balloon vertebroplasty (Vesselplasty) is a minimally invasive surgical technique for the treatment of senile osteoporotic vertebral compression fractures. The wrapping effect of the mesh bag can effectively prevent the extravasation of the bone cement, reduce the complications caused by the extravasation of the bone cement, improve the safety of the operation, and can also stabilize the vertebral body.

1. The feasibility and effect of the treatment of osteoporotic vertebral compression fracture with bone filling mesh balloon vertebroplasty. In 1987, French doctor galibert [16] first publicly reported PVP technology in the treatment of cervical vertebral hemangioma. In 1990, deramond [17] applied PVP technology to the treatment of osteoporotic vertebral compression fractures (OVCFs). Since then, it has gradually developed into a common treatment for osteoporotic vertebral compression fracture in the elderly. The main risk of PVP is the leakage of bone cement. The highest incidence of PVP reported in the literature is 81% [18-20]. Compared with PVP, the probability of cement leakage in PKP was significantly reduced, but the incidence was still greater than 20% [21]. Spinal internal fixation technology can achieve immediate stability of fracture, satisfactory reduction and other clinical effects, but the number of operative bleeding is significantly higher than that of minimally invasive surgery, and patients still need to stay in bed for a long time after operation. Osteoporosis leads to screw loosening and bone graft non fusion. Because the elderly patients have many and complex basic diseases, the ability of compensation of important organs such as heart, brain and kidney is reduced in varying degrees, and the risk of spine internal fixation is large, so its application in the elderly patients with osteoporosis fracture is obviously limited. Flors [22] and Klingler [23] reported the satisfying clinical effect, using the vesselplasty to treat osteoporotic vertebral compression fracture, hemangioma and metastatic cancer. The advantage of the design is that the bone cement is limited in the mesh bag, which greatly reduces the occurrence of leakage. Tanghai [24] through retrospective case analysis, it is pointed out that bone filling mesh bag technology can safely and effectively treat osteoporotic vertebral fracture and vertebral metastasis, which not only
has satisfactory analgesic effect, partially restores the height of fracture vertebral body, but also reduces the risk of bone cement leakage, and provides a new scheme and selection for minimally invasive treatment of spine. Xie Yaming [25] through a retrospective case-control study, it was pointed out that the treatment of OVCFs with mesh bag plasty can rapidly relieve the pain of patients, improve the ability of activity, and restore the height of vertebral body. Compared with PKP, it can reduce the occurrence of bone cement leakage. He Chunjing [26] through the comparative study, it is shown that both mesh bag forming and PKP can effectively relieve the pain after fracture and improve Cobb angle, and mesh bag forming can reduce the probability of bone cement leakage. In the treatment of osteoporotic vertebral compression fractures in the elderly, the VAS scores of the two groups were significantly reduced, which indicated that the surgical effect was satisfactory and the quality of life of the patients was significantly improved. The imaging results showed that the height of vertebral body was restored in different degrees by the two operation methods, but there was no significant difference between the two groups. Compared with PVP group (26.78%), the leakage rate of bone cement (13.64%) in the group of bone filled balloon vertebroplasty was significantly reduced, indicating that the safety of bone filled balloon vertebroplasty in the treatment of osteoporotic vertebral compression fracture was higher.

2. The leakage of bone cement often occurs in intervertebral disc, intervertebral space, venous plexus and spinal canal. The leakage of spinal canal and compression of spinal cord or nerve root cause symptoms, and pulmonary embolism easily occurs along the venous plexus to systemic circulation, with no serious clinical consequences [27-30]. Sarah et al. [31] through the analysis of 1512 single center and retrospective cases, it was found that the probability of cement embolism in PVP operation was 3.9%, and the proportion with clinical symptoms was 0.3%. Besharat et al. [32] suggested that patients with bone cement pulmonary embolism should be treated conservatively in other cases unless the embolic range is wide and hemodynamic changes are caused. The leakage of bone cement is related to many factors. Marc et al. [33] believed that fracture severity and cement viscosity were risk factors for cement leakage. Xie Weixing et al [34] proposed that high bone density and cortical bone defect were independent risk factors of cement leakage. According to Ding Jie et al. [35], the
leakage of bone cement is related to the severity of fracture, the defect of endplate and the viscosity of bone cement. Yang Lei et al. [36] conducted a biomechanical evaluation on the corpse and found that the selection of PKP surgical cement materials affected the leakage of bone cement and postoperative complications, and pointed out that degradable calcium phosphate bone cement can reduce the leakage of bone cement and avoid postoperative complications caused by non degradable materials, which is a potential alternative material. In addition, the leakage of bone cement is closely related to the dilution of cement and the ambient temperature. Yang Huilin [2] believed that the reason of leakage was that the injection of bone cement was too early, the injection speed was too fast, and the bone cement was diluted. If the bone cement reaches the drawing stage, it will significantly reduce the leakage rate. It is recommended to inject it during drawing stage. At the same time, there is a significant positive correlation between the solidification of bone cement and temperature. High temperature will accelerate the solidification of bone cement, and low temperature will prolong the solidification time. Therefore, the clinical needs to make an accurate choice based on the local hospital operating room conditions. Yang Huilin used temperature gradient perfusion technology and plugging perfusion technology, which significantly reduced the leakage rate of bone cement [2]. In this study, there was no intraspinal leakage or pulmonary embolism in the two groups, and there was no obvious clinical symptoms in the small amount of leakage in the intervertebral space or paravertebral. The author believes that the following aspects should be satisfied in order to obtain satisfactory clinical effect. (1) Before the operation, the X-ray film, CT, MRI and even bone scan should be improved, and the severity of the responsible vertebral body and fracture should be determined in combination with the detailed physical examination; (2) the bone density examination should be improved to fully evaluate the osteoporosis degree of the patients, and the anti osteoporosis treatment should be strictly carried out during the perioperative period; (3) the performance of different bone cement materials should be mastered, and the time of bone cement solidification and injection should be well controlled Injection speed; (4) the injection should be gradually completed under the dynamic monitoring of g-arm, and should not be in a hurry to achieve success; (5) a surgical puncture segment ≤ 3 vertebrae.
The effect of the dosage of bone cement on the improvement of vertebral strength, the relief of postoperative pain and the increase of the risk of adjacent segment fracture has been a topic of discussion for spine surgeons. Jin et al [37] put forward that injecting 3.5ml bone cement into the injured vertebra can restore the normal stress distribution of vertebra and achieve the purpose of relieving pain after the biomechanical study of the corpse. Liebschner et al. [38] through finite element analysis, believed that filling 15% volume bone cement in the vertebral body can restore the strength of the vertebral body, and the strength increased significantly after filling 30%, but over filling may increase the risk of adjacent vertebral body fracture. Liang de [39] proposed that the volume ratio of bone cement to vertebral body can reflect the relationship between the amount of bone cement injected and the leakage of bone cement, and the average volume ratio of bone cement to vertebral body was 24.88%. Zheng Yusong et al. [40] believed that with the increase of the injection dose of bone cement in the vertebral body, the injection pressure of bone cement increased, further increasing the risk of leakage of bone cement. Cho et al. [41] through the analysis of five models of osteoporosis finite element model, it was proposed that strengthening the excessive hardness of bone cement increased the risk of adjacent vertebral fracture after vertebroplasty. Gao et al. [42] believed that a large amount of bone cement was a potential risk factor for spinal cord compression and paralysis. If the preoperative bone density of patients was low and the bone cortex of the responsible vertebral body was interrupted, the amount of bone cement infusion should be reduced. The author believes that too little bone cement perfusion can not restore the stiffness and strength of the injured vertebrae, and too much perfusion will increase the risk of bone cement leakage and adjacent vertebrae fracture. Therefore, the dosage of intraoperative bone cement infusion should be individualized according to the actual situation. Injection of 1.5ml of bone cement into the injured vertebrae can obviously relieve the pain of the patients, but in order to recover the height of the injured vertebrae and obtain sufficient strength of the vertebrae, it is generally recommended to inject 4.5ml of bone cement. The results of this study showed that the height of vertebral body was restored in different degrees in the group of Vesselplasty (19.9% ± 19.1%) and PvP (18.8% ± 18.2%). In vesselplasty group, the preoperative VAS was (7.9 ± 0.9) score, the
postoperative VAS was 3.8 ± 0.8. In PVP group, the preoperative VAS was (7.9 ± 0.9) score, and the postoperative VAS was 3.7 ± 0.8. There was no significant difference between the two groups in VAS score, but the VAS scores of the two groups were significantly reduced, indicating that there were satisfied effect of surgery, and the patients' back pain was significantly improved.

To sum up, bone filling mesh balloon technique and percutaneous vertebroplasty can achieve satisfactory early effect in the treatment of osteoporotic compression fractures in the elderly. Vesselplasty technique has a smaller incidence of cement leakage and is safer to use. It can be used as a feasible option for OVCFs. In practical work, we need to evaluate the severity of fracture and osteoporosis in detail, and formulate a detailed operation plan in combination with the age, basic diseases, daily living ability and operation demands of the patients. During the operation, we need to operate in strict accordance with the technical specifications of bone cement. The satisfactory clinical effect is closely related to the clinical experience and surgical techniques of the surgeons.

Declarations
The article is the author's original manuscript and has not been submitted for publication or submission in any journal. The data and results of the paper are the author's true view.

Funding: There is no funding for this article.

Competing interests: All authors agree to submit the article without any competing interest.

Ethics approval and consent to participate: It has passed the ethical review of the author's unit. The approval number of ethical review is YALL-2U1V-050.

Authors' contributions: Jun Mei and Qiang Liu : Research Design, write Paper. Dou Wu: Research Guidance, Surgery Technical Support; Xiaoxu Song: Data Collection, statistical analysis.

Acknowledgements: Thanks to Professor Qiang Liu for his guidance, the team members for their efforts, and the patients for their trust.

Abbreviations
OVCFs: Osteoporotic vertebral compression fractures
Vesselplasty: Bone-filled mesh bag balloon vertebroplasty
PVP: Percutaneous vertebroplasty
PKP: percutaneous kyphoplasty

VAS: Visual analogue score

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Figures
Figure 1

Puncture procedure of A-F bone filling mesh bag plasty