Vesselplasty for the treatment of osteoporotic vertebral compression fractures with peripheral wall damage: a retrospective study

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ABSTRACT

Study design: A retrospective study. Objective: The clinical efficacy of vertebroplasty and kyphoplasty treating osteoporotic vertebral compression fractures (OVCF) has been widely recognized in recent years. However, there are also disadvantages of bone cement leakage (BCL), limited correction of kyphosis and recovery of vertebral height. Nowadays, in view of these shortcomings, vesselplasty has been widely used in clinical practice. The objective of this study is to assess its clinical effect and application value for the treatment of OVCF with peripheral wall damage.

Methods: 62 patients (70 vertebrae) treated for OVCF with peripheral wall damage using vesselplasty retrospectively reviewed. The data collection included operation time, volume of bone cement, relevant surgical complications, visual analog scale (VAS), Oswestry disability index (ODI), vertebral body height and kyphosis Cobb angle.

Results: The volume of bone cement was 3–8 (5.3 ± 1.3) ml. There were 3 vertebrae of BCL (4.3%). VAS and ODI at different time points after operation were decreased compared with before operation (all p < 0.05). There were no statistical differences between VAS or ODI at different postoperative time points (p > 0.05). Vertebral body height and Cobb angle at different time points after operation were improved compared with before operation (all p < 0.05). There were no statistical differences between vertebral body height or Cobb angle at different postoperative time points (all p > 0.05).

Conclusions: Vesselplasty may reduce the risk of BCL and better control the dispersion of bone cement in the treatment of OVCF. It relieves pain, restores vertebral body height and corrects kyphosis, especially in OVCF with peripheral wall damage. Therefore, vesselplasty is safe and worthy of clinical application.

Introduction

With the aging of population, the incidence of osteoporotic vertebral compression fractures (OVCF) is significantly increasing. Considering surgical trauma and loosening of internal fixation, percutaneous vertebroplasty (PVP) and percutaneous kyphoplasty (PKP) have become the first choice for the treatment of OVCF. However, both methods have disadvantages of high incidence of bone cement leakage (BCL), limited correction of kyphosis and recovery of vertebral height. BCL can cause nerve and spinal cord injury, and other serious complications such as re-fracture of adjacent vertebra and pulmonary embolism. In PVP, the direct infusion of bone cement into vertebrae can generate high infusion pressure, which may make the cement leak. In PKP, bone cement is not injected until vertebral expansion is completed and the balloon removed. Therefore, the vertebra may collapse again before cement injection.

In view of the shortcomings of PVP and PKP, A-Spine Holding Group Corporation (Taipei, Taiwan) developed the Vessel-X bone-filling mesh container, and a new technical approach, vesselplasty (vertebral augmentation using Vessel-X bone filler) emerged. The rationale of vesselplasty is to insert a distal detachable mesh container (Vessel-X) into the injured vertebra through a working path, inject bone cement and gradually expanding the container. The Vessel-X filler is made up of 100 µm mesh, allowing the bone cement permeating from the container to get a good grip with cancellous bone, which is very suitable for the vertebral fracture with peripheral wall damage. When the permeated cement starts to solidify it forms a wolf-tooth effect with cancellous bone. The working path is then removed the container retained in the vertebral body. In the whole procedure, bone cement is always surrounded by the container, instead of being injected directly into the vertebral body, so that the container can prevent BCL. Vesselplasty is designed based on mechanics and hydrodynamics. The mesh container has a dense polymer net layered structure which can significantly reduce BCL compared with PVP/PKP. In vesselplasty, bone cement is directly injected to pressurize, and the cement dispersing outside the container can help to expand the vertebral body. Thus in theory, vesselplasty can better restore vertebral body height and correct kyphosis.

In the past decade, vesselplasty has been widely used in clinical practice, especially for patients with peripheral wall damage with no symptoms of nerve and spinal cord injury. It can improve the safety of surgery and reduce the incidence of BCL.
Affected vertebral segment covered from thoracic (34) to lumbar and 13 vertebral bodies with posterior wall damage. The range of plate damage, 10 vertebral bodies with lower endplate damage, vertebrae with lateral wall damage, 45 vertebrae with upper endplate damage.

There were 62 vertebrae with anterior wall damage, 49 vertebrae, including 19 males. Average age was 70.2 ± 9.6 years (54–82 years). There were 62 vertebrae with anterior wall damage, 49 vertebrae, including 19 males. Average age was 70.2 ± 9.6 years (54–82 years).

Nevertheless, few studies or case series with competitive number of subjects can offer reasonably strong evidence to support these views. Therefore, we aim to conduct a retrospective study using vesselplasty for the treatment of OVCF with peripheral wall damage, and evaluate its clinical effect and application value.

Materials and methods

Patient case selection and general information

Institutional review board approval was obtained from our ethics committee, and the study was conducted based on principles of Declaration of Helsinki. Patients treated for OVCF using vesselplasty in database records of our hospital were retrospectively collected and analyzed between January 1, 2017, to December 31, 2019. For inclusion in this study, all participant subjects were diagnosed as osteoporosis through bone mineral density (BMD) examination, and should have complete imaging studies including radiographs, computed tomography (CT) scans and magnetic resonance (MR) images, which were used to observe fracture and confirm the vertebral peripheral wall damage. None of the patients had symptoms and signs of nerve or spinal cord injury. Available clinical data were also necessary, including demographic characteristic, chief complaint, neurospinal function and complications.

Based on the criteria, there were 62 consecutive cases (70 vertebrae), including 19 males. Average age was 70.2 ± 9.6 years (54–82 years). There were 62 vertebrae with anterior wall damage, 49 vertebrae with lateral wall damage, 45 vertebrae with upper endplate damage, 10 vertebral bodies with lower endplate damage, and 13 vertebral bodies with posterior wall damage. The range of affected vertebral segment covered from thoracic (34) to lumbar (36) (Table 1).

Surgical procedure and postoperative management

Patients were positioned prone under anesthesia. Through a small skin incision, the vertebral body was entered with a bone access needle through a pedicle and the working channel dilated under X-ray monitoring. Then the Vessel-X bone-filling mesh container was passed to the predetermined position through the channel, and progressively filled with bone cement until it oozed out of the mesh and entered the space of cancellous bone. Finally the working channel was withdrawn and the incision sutured (Figure 1).

After the operation, patients were treated with analgesia, anticoagulation and infection prophylaxis. After 24 hours, they could mobilise under the protection of a lumbar support. Postoperative radiograph and CT scans were examined to observe the reduction of vertebrae and diffusion of bone cement. Anti osteoporosis treatment was standardized and BMD was rechecked regularly.

Data collection

Operation time and volume of bone cement injected into each vertebra were recorded. Relevant surgical complications such as BCL, infection, ectopic embolism, and systemic manifestations were also collected. Clinical symptoms including pain and dysfunction were assessed based on visual analog scale (VAS) (0–10 points, 0 points for no pain, and 10 points for the most severe pain). The Oswestry disability index (ODI) (higher score indicates severer dysfunction) was used to assess the improvement in the motor function status of patients. VAS scores and ODI were recorded routinely on admission, at 24 hours, 1 month and 3 months post-operation and at the last follow-up.

Radiographic assessment

BCL was recorded according to Intraoperative and postoperative radiograph and CT scans. The vertebral body height of affected segments was assessed based on recommendation of Pflugmacher et al. which was defined as the distance between upper and lower endplates on lateral radiographs. The kyphosis Cobb angle was measured based on the method proposed by Kuklo et al. that is, the angle between the extension line of the upper endplate of the upper vertebra and the extension line of the lower endplate of the lower vertebra, with the affected vertebra as the center. Radiographic assessments were also recorded routinely on admission, at 24 hours, 1 month and 3 months post-operation and at the last follow-up.

Statistical analysis

All statistical analyses were performed using Statistical Packages of Social Sciences (SPSS) software (version 22.0). A p value of <0.05 was considered statistical significance. Means and standard deviations (x ± s) were used to describe quantitative data including vertebral body height, Cobb angle, VAS and ODI. Normal distribution of the data was assessed by the Kolmogorov-Smirnov test and all these variables showed a normal distribution. Differences in these variables before and after the operation were analyzed with a two-tailed paired Student’s t-test.

Result

Operation time and volume of bone cement

Of the total 62 consecutive cases (70 vertebrae), vesselplasty went well, all patients tolerated the operation, and their vital signs were stable. The time of operation was 20–65 (34.5 ± 10.5) minutes, and the volume of bone cement injected into each vertebral body was 3–8 (5.3 ± 1.3) ml, as shown in Table 1.

| No. | Clinical Information               | Number |
|-----|-----------------------------------|--------|
| 1   | Sex (Male/Female)                 | 19/43  |
| 2   | Mean age (years)                  | 70.2 ± 9.6 |
| 3   | Affected vertebral segment        |        |
|     | T7                               | 1      |
|     | T8                               | 3      |
|     | T9                               | 4      |
|     | T10                              | 6      |
|     | T11                              | 9      |
|     | T12                              | 11     |
|     | L1                               | 13     |
|     | L2                               | 11     |
|     | L3                               | 8      |
|     | L4                               | 4      |
|     | Total (thoracic/lumbar)           | 70 (34/36) |
| 4   | Peripheral wall damage            |        |
|     | anterior wall damage              | 62     |
|     | lateral wall damage               | 49     |
|     | posterior wall damage             | 13     |
|     | upper endplate damage             | 45     |
|     | lower endplate damage             | 10     |
| 5   | Mean operation time (min)         | 34.5 ± 10.5 |
| 6   | Mean volume of cement to each vertebra (ml) | 5.3 ± 1.3 |
All the patients were followed up for 4-6 months, with an average of 5.1 ± 0.4 months. VAS scores and ODI at different time points after operation were decreased compared with before operation (all \( p < 0.05 \)), which indicated significant alleviation of pain and improvement of motor function. There were no statistical differences between VAS scores or ODI at different postoperative time points (all \( p > 0.05 \)) (Table 2).

### Vertebral body height and cobb angle

Similar to VAS and ODI, anterior border height of the vertebral body and Cobb angle at different time points after operation were compared with before operation (all \( p < 0.05 \)), which indicated significant fracture reduction and deformity correction. There were no statistical differences between vertebral body height or Cobb angle at different postoperative time points (all \( p > 0.05 \)) (Table 3).

### Complications

There was no nerve or spinal cord injuries. No infection, ectopic embolism, and systemic manifestations occurred. There were 3 vertebrae of postoperative BCL, among which 2 vertebrae leaked to paravertebral area, 0 vertebra leaked to upper or lower end-plate, 0 vertebra leaked into spinal canal and 1 vertebra leaked through the puncture channel, but without relevant symptoms. The incidence of BCL was 4.3% (Table 4).

### Discussion

BCL is the most common problem in PVP/PKP for the treatment of OVCF, especially in OVCF cases with peripheral wall damage. At present, Yeom’s classification of BCL is widely recognized and applied in clinical practice. It divides BCL into 3 types: type B (leakage via the basivertebral vein), type S (leakage via the segmental vein) and type C (leakage through a cortical defect). Among which type C is the most common, and can occur in any part around the vertebral body, such as intervertebral disc, paravertebral body, posterior vertebral edge, etc. Studies show that in PVP, the direct infusion of bone cement into vertebrae can generate high infusion pressure, which make the cement easy to leak, thus the incidence of BCL is as high as 19% ~ 76%, with an average of 29%.\(^{13-15}\) Later, PKP was developed, in which a balloon is used to form a cavity in the vertebral body and restore the height, then bone cement is injected under low pressure, and that reduced the incidence of BCL to about 8%.\(^{16}\) However, for those OVCF with peripheral vertebral wall damage, the fracture can be further enlarged due to the expansion of the injured vertebral body, which increases the risk of BCL. There is a high risk of spinal cord (cauda equina) or nerve injury especially in the case with posterior wall damage.\(^{17}\)

Studies indicate that PVP, PKP and vesselplasty all achieve satisfactory results in pain relief, but PKP did better in restoring vertebral body height, while vesselplasty had lower incidence of BCL.\(^{18,19}\) In our study, there were only 3 cases of BCL. None of the cases had BCL into spinal canal, 2 vertebrae had paravertebral leakage which defined as type B,\(^{12}\) and only 1 vertebra leaked through puncture channel into posterior soft tissue as type C. Those patients with BCL did not have relevant clinical
symptoms, and no special treatment was given. Therefore, our study indicated sound safety of vesselplasty and that BCL can be effectively controlled for OVCF with peripheral wall damage through vesselplasty, which was consistent with most other published data.18–20 According to our results, the postoperative ODI and VAS scores of patients decreased, indicating that their functional status and pain caused by fracture were significantly improved, which was consistent with most studies. 18,21 Our radiographic assessment showed that vertebral body height increased and Cobb angle was corrected significantly, suggesting satisfactory improvement of spinal deformity and restoration of vertebral body height through cement injection using mesh container. Since vesselplasty uses the Vessel-X container and the cement dispersing outside for vertebra distraction, it will expand more space than PKP, and can better restore vertebral body height and correct kyphosis in theory.22,23 Chen et al.24 found that vesselplasty and PKP had statistical significance compared with PVP in restoring vertebral body height, while there was no difference between the former two. As for the degree of recovering of vertebral body height, the study results are different, but all have shown significant improvement compared with before the operation. In addition, the compressed vertebral body can not only cause kyphosis, but also reduce the ability in load dispersing of upper and lower intervertebral disc, resulting in fracture of adjacent vertebra or re-fracture of injured vertebra. In the treatment of OVCF, it is necessary strengthening the injured vertebral body, as well as restoring its height.25

In summary, at present, the overall effect of vesselplasty is better than PVP and PKP. However, the ultimate choice of surgical method still depend on the compression degree of vertebral body, economic conditions of patients and other factors. For those patients suffering OVCF with peripheral wall damage and without excessive economic pressure, we tend to recommend vesselplasty.

A limitation of the study is the short follow-up period. The longest period in this study was 6 months since we initially believed that longer period of follow-up would reduce patients’ compliance and make data collection more difficult. However, longer period up to 1 or 2 years may Improve the reliability of evidence.

### Conclusion

Vesselplasty can reduce the risk of BCL and better control the dispersion of bone cement in the treatment of OVCF. It has a definite effect in relieving pain, restoring the vertebral body height and correcting the kyphosis caused by injured vertebrae, especially in OVCF with with peripheral wall damage. Therefore, vesselplasty is safe and worthy of clinical application.

### Ethics approval and consent to participate

The case was reviewed by the Changzheng Hospital Ethics Committee and ethical approval was waived as written consent was obtained from the patient.

### Patient consent

Written informed consent was obtained from the patient for publication of this study and any accompanying images.

### Consent for publication

Written patient consent was obtained for publication of all aspects of the case including personal and clinical details and images, which may compromise anonymity.

### Disclosure statement

All authors read and approved the final manuscript and declare that they have no competing interests.

### Author contributions

CJG designed the study and collected the data. XCQ did the data analysis. CJG wrote the manuscript. YJM revised the manuscript and decided to submit the manuscript for publication. All authors read and approved the final manuscript.

### Data availability statement

All supporting data can be provided upon request to the authors.
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