

Clinical Outcomes of Fracture Haemorrhage Aspiration for Percutaneous Vertebroplasty in Treating Osteoporotic Vertebral Compression Fractures

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Background: A retrospective study aimed to introduce a new method for improving the diffusion degree of bone cement and to observe its clinical efficacy in percutaneous vertebroplasty treating osteoporotic vertebral compression fractures (OVCFs).

Methods: From January 2019 to March 2020, a total of 83 patients were enrolled and reviewed. The patients were divided into two groups according to the operation method. The clinical and radiographic parameters were recorded and compared between these two groups. Those who received percutaneous vertebroplasty with haemorrhage aspiration were recorded as group A (n=42). In group A, the haemorrhage in the vertebral fracture was aspirated compared with conventional percutaneous vertebroplasty. Patients who underwent conventional percutaneous vertebroplasty were classified as group B (n=41).

Results: Visual analogue scale (VAS) values and Oswestry Disability Index (ODI) scores showed no significant difference between the two groups preoperatively, postoperatively or at the final follow-up (FU) ($P>0.05$). The intraoperative VAS score (bone cement injection) in group A was significantly lower than that in group B (3.83 ± 0.79 vs 5.44 ± 1.32 , $P<0.01$). The local kyphotic angle (LKA) (final follow-up), LKA loss, fractured vertebral anterior height loss (FVAHL) and anterior vertebral height loss ratio (AVHLR) were significantly lower in group A than in group B. The anterior vertebral height ratio (AVHR) at the final FU in group A was higher than that in group B ($P=0.013$). The distribution of bone cement was significantly different ($P=0.034$). By analysing the distribution pattern of bone cement, it was found that the values of LKA loss, FVAHL and AVHLR were superior in the type A bone cement distribution to those in types B and C.

Conclusion: Compared with traditional surgical methods, bone haemorrhage aspiration could improve the diffusion degree of bone cement and reduce the height loss and deformity of injured vertebrae. This method provides a feasible new scheme for improving the dispersion of bone cement.

Keywords: osteoporotic vertebral compression fractures, percutaneous vertebroplasty, bone cement distribution, fracture haemorrhage aspiration

Background

Osteoporotic vertebral compression fractures (OVCFs) are the most common fractures in senior citizens, and the incidence of OVCFs increases with age.¹⁻⁴ OVCFs cause back pain, neurological symptoms, functional limitations, malformations and a reduction in quality of life. Percutaneous vertebroplasty (PV) is a commonly used surgical treatment for patients with OVCFs. This treatment can effectively

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strengthen the compressed vertebral body, relieve the pain caused by thoracolumbar fractures, improve the quality of life of patients, and avoid the complications caused by long-term bedrest.^{5–7} Recent studies have found that the distribution of bone cement may affect vertebral body height restoration and local kyphosis, and a better dispersion distribution may indicate better clinical recovery.^{1,3,8,9} However, the existing articles do not reveal the factors affecting bone cement distribution patterns of the vertebral body, and we believe that bleeding inside the fracture occupies part of the space in the vertebral body. Therefore, during PV surgical puncture, the fracture haemorrhage was aspirated and then filled with bone cement to improve the distribution pattern of bone cement. Additionally, this method was compared with traditional surgical methods.

Methods

Patient Selection

The study was approved by the Institutional Review Board of The First Affiliated Hospital of Chongqing Medical University and was conducted according to the principles of the Declaration of Helsinki. All the patients provided their written informed consent to participate in our study prior to the storage of their data in the hospital database. Patients who received PV treatment from January 2019 to March 2020 were reviewed. The inclusion criteria were as follows: the average bone mineral density (BMD) (T score < -2.5) preoperatively, single thoracic or lumbar vertebral fractures, without history of PK or neurological symptoms, failed to conservative treatment (bed rest, anti-osteoporosis treatments, non-steroidal anti-inflammatory drugs etc), the bone cement was injected through the pedicles bilaterally, the follow-up (FU) time was at least than 1 year, no history of trauma during the FU. The exclusion criteria were as follows: pathological vertebral lesions such as vertebral metastatic carcinoma etc, fractures of adjacent vertebral bodies, patients who were lost FU. 83 consecutive patients who underwent PV treatment for OVCFs were investigated and were randomly assigned to choose one of the two treatments. Those who received PV with haemorrhage aspiration were recorded as group A (n=42). Patients who underwent conventional PV were classified as group B (n=41). All patients were admitted 1 day before surgery for preoperative preparation and management. During this time, All patients were treated with non-steroidal anti-inflammatory drugs (NSAIDs) for

symptomatic relief and calcium (1000 to 1500 mg per day) and vitamin D (400 to 1200 IU per day) supplement.

Surgical Technique

All operations were performed by the same experienced spine surgeon. The procedure was performed with the patient under local anaesthesia with adequate preoperative analgesia. A C-arm X-ray was used to capture standard anteroposterior and lateral images for the operative vertebral bodies, and safety puncture techniques for the vertebral body (baseline positioning, puncture point positioning, puncture direction adjustment, step-by-step insertion) were used. The bilateral pedicle puncture approach was used to reach the front of the posterior margin of the vertebral bodies for approximately 3 mm guide wires, expansion cannulae, and working cannulae were then sequentially utilized. Two working 10mL empty needles are connected to the working cannula, one of the empty needles is used for blood aspiration, and the other is kept under pressure without blood aspiration. Approximately 3–5 mL of haemorrhage in the fractured vertebra were aspirated from one pedicle with a needle in the experimental group but not in the control group (Figure 1). The prepared bone cement was slowly injected into the vertebral body through the working cannulas, accompanied by perspective monitoring until the vertebral body was filled with bone cement. The cannula was then pulled out. The patients were allowed to walk 4 hours postoperatively. Standard anti-osteoporosis treatment was performed after the operation. X-ray films were rechecked within 1 day after the operation to assess the filling of bone cement, and X-ray films were rechecked 1 month, 6 months and 12 months after the operation.

Assessed Parameters

The study indicators were divided into three parts: treatment information, curative effect assessment and radiologic assessment. Treatment information: hospitalization duration, intraoperative blood loss, operation time, and bone cement volume. Preoperative and postoperative treatment information of the patients was recorded. Clinical outcomes were assessed using the Oswestry disability index (ODI) and visual analogue scale (VAS). ODI scores were assessed before and after surgery as well as at the final follow-up, and VAS scores were assessed before the operation, during the operation (after cementing), after the operation and at the final FU. Radiologic assessments: fractured vertebral anterior height (FVAH); and anterior vertebral height ratio (AVHR) = $FVAH / (\text{sum of vertebral anterior height of adjacent vertebral body}) \times 2$. The anterior vertebral height recovery ratio (AVHRR) was defined as postoperative



Figure 1 Fracture haemorrhage aspiration. Two working 10mL empty needles are connected to the working cannula, one of the empty needles is used for blood aspiration, and the other is kept under pressure without blood aspiration.

AVHR - preoperative AVHR. The anterior vertebral height loss ratio (AVHLR) was defined as postoperative AVHR - final FU AVHR. Local kyphotic angle (LKA)/region kyphotic angle (RKA) recovery = preoperative LKA/RKA - postoperative LKA/RKA, LKA/RKA loss = the final FU LKA/RKA - postoperative LKA/RKA. Fractured vertebral anterior height recovery (FVAHR) = postoperative FVAH - preoperative FVAH. Fractured vertebral anterior height loss (FVAHL) = postoperative FVAH - final FU FVAH. The distribution pattern of bone cement was evaluated as follows. The upper and lower endplates of the injured vertebrae were used as a reference to evaluate the longitudinal distribution of bone cement, and the midline of the coronal position of the radiologic film was used as a reference to evaluate the horizontal distribution of bone cement. A: Bone cement is connected to the upper and lower endplates on both sides of the midline. B: Bone cement is connected to the upper and lower endplates on one side of the midline. C: Bone cement is not connected to the

upper or lower endplates on either side of the midline (Figure 2).

The assessment of studies was performed by 2 independent assessors, with any disagreement between assessors was resolved through discussion.

Statistical Analysis

SPSS 23.0 software was used to analyse the data. Continuous variables are expressed as the mean \pm standard deviation, and independent sample t-tests or variance analyses (ANOVAs) were used. The chi-square test was adapted to analyse the categorical variables. Significant differences were defined as $p < 0.05$.

Results

A total of 83 patient medical records were included in this study; there were 42 patients in experimental group A and 41 patients in control group B. There were no significant

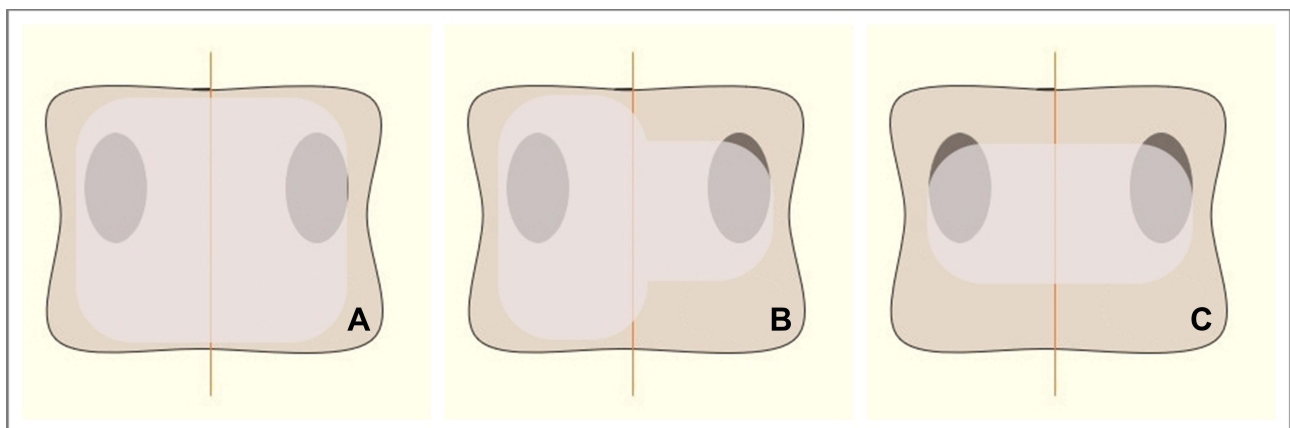


Figure 2 (A) Bone cement is connected to the upper and lower endplates on both sides of the midline. (B) Bone cement is connected to the upper and lower endplates on one side of the midline. (C) Bone cement is not connected to the upper or lower endplates on either side of the midline.

differences in age, sex, BMI or follow-up time between the two groups ($P>0.05$) (Table 1). There was no significant difference in the hospitalization duration, intraoperative blood loss (do not contain blood loss in aspiration) or operation time between the two groups ($P > 0.05$). The bone cement dosage in group B was 5.98 ± 1.45 mL, which was significantly lower than that in group A (4.80 ± 1.14 mL, $P<0.01$).

The VAS and ODI scores showed no significant difference between the two groups preoperatively, postoperatively or at the final FU ($P>0.05$). The intraoperative VAS score (bone cement injection) in group A was significantly lower than that in group B (3.83 ± 0.79 vs 5.44 ± 1.32 , $P<0.01$). The LKA (final follow-up), LKA loss, RKA loss, FVAHL and AVHLR were significantly lower in group A than in group B (11.53 ± 6.23 vs 14.95 ± 7.12 , $p=0.022$; 1.66 ± 2.97 vs 3.32 ± 3.07 , $p=0.014$; 0.95 ± 3.40 vs 2.62 ± 4.14 , $p=0.048$; 0.94 ± 1.74 vs 2.69 ± 2.45 , $p<0.01$; 2.86 ± 6.58 vs 10.00 ± 9.48 , $p<0.01$). The AVHR (final follow-up) in group A was higher than that in group B (79.38 ± 17.38 vs 70.83 ± 12.74 , $P=0.013$) (Table 2). The distribution of bone cement was significantly different ($P=0.034$). By analysing the distribution pattern of bone cement, it was

Table 1 Basic Information of the Patients

Indexes	Group A	Group B	P value
Age (y)	72.86 \pm 10.22	70.17 \pm 9.13	0.211
Sex			
Male	12	11	
Female	30	30	
BMI (kg/m ²)	22.26 \pm 3.19	22.62 \pm 2.97	0.591
Hospitalization duration (d)	4.93 \pm 1.69	4.46 \pm 1.47	0.185
Blood loss (mL) (aspiration)	4.48 \pm 0.74		
Intraoperative blood loss (mL) (do not contain blood loss in aspiration)	4.33 \pm 3.21	5.37 \pm 1.96	0.082
Operation time (mins)	33.21 \pm 10.69	37.37 \pm 14.08	0.134
Fracture segment			
Thoracic (T1–10)	4	2	
Thoracolumbar (T11–L2)	33	33	
Lumbar (L3–5)	5	6	
Vertebral compression degree			
I (< 33%)	15	10	
II (33 ~ 66%)	17	25	
III (> 66%)	10	6	
Bone cement distribution			
A	25 (59.52%)	15 (36.59%)	0.034
B	12 (28.57%)	12 (29.27%)	
C	5 (11.90%)	14 (34.15%)	
Bone cement volume (mL)	4.80 \pm 1.14	5.98 \pm 1.45	<0.01*
Follow-up time (months)	16.43 \pm 2.78	15.56 \pm 2.83	0.162

Table 2 Analysis of Outcomes Between Different Groups

Indexes	Group A	Group B	P value
LKA (pre-op)	14.78 \pm 7.16	15.31 \pm 8.11	0.753
LKA (24 h post-op)	9.87 \pm 6.65	11.63 \pm 6.47	0.225
LKA (final FU)	11.53 \pm 6.23	14.95 \pm 7.12	0.022*
LKA recovery	4.91 \pm 5.16	3.68 \pm 4.42	0.248
LKA loss	1.66 \pm 2.97	3.32 \pm 3.07	0.014*
RKA (pre-op)	10.71 \pm 14.70	11.66 \pm 17.22	0.786
RKA (24 h post-op)	8.23 \pm 14.46	10.28 \pm 16.73	0.551
RKA (final FU)	9.18 \pm 14.42	12.90 \pm 16.41	0.275
RKA recovery	2.48 \pm 5.14	1.38 \pm 5.15	0.333
RKA loss	0.95 \pm 3.40	2.62 \pm 4.14	0.048*
FVAH (pre-op)	19.69 \pm 6.84	19.66 \pm 5.08	0.979
FVAH (24 h post-op)	22.89 \pm 5.51	22.49 \pm 4.05	0.709
FVAH (final FU)	21.95 \pm 5.11	19.80 \pm 4.19	0.040
FVAHR	3.20 \pm 4.08	2.83 \pm 4.08	0.686
FVAHL	0.94 \pm 1.74	2.69 \pm 2.45	<0.01*
AVHR (pre-op)(%)	70.86 \pm 25.09	72.63 \pm 17.12	0.708
AVHR (24 h post-op)(%)	82.24 \pm 18.91	80.83 \pm 14.16	0.702
AVHR (final FU)(%)	79.38 \pm 17.38	70.83 \pm 12.74	0.013*
AVHRR (%)	11.38 \pm 14.32	8.20 \pm 15.83	0.339
AVHLR (%)	2.86 \pm 6.58	10.00 \pm 9.48	<0.01*
VAS (pre-op)	5.57 \pm 1.04	5.61 \pm 0.89	0.857
VAS (op)	3.83 \pm 0.79	5.44 \pm 1.32	<0.01*
VAS (24 h post-op)	1.71 \pm 0.74	1.56 \pm 0.63	0.315
VAS (final FU)	0.64 \pm 0.58	0.56 \pm 0.50	0.493
ODI (pre-op)	47.81 \pm 12.12	49.90 \pm 9.22	0.379
ODI (24 h post-op)	19.14 \pm 2.87	17.80 \pm 3.40	0.056
ODI (final FU)	6.14 \pm 2.84	5.90 \pm 2.28	0.672
Bone cement leakage	21.43%	17.07%	0.615

Note: * $P<0.05$.

found that the LKA loss, FVAHL and AVHLR were superior in the type A bone cement distribution to those in types B and C (Table 3).

Case Presentation

Case 1 A 63-year-old female underwent lumbar fracture (L1) percutaneous vertebroplasty of bone cement distribution type: A, with no significant recompression of the fractured vertebral body at the last follow-up. (FVAH (pre-op): 21.37mm; FVAH (24h post-op): 21.95mm; FVAH (final FU): 21.57mm) (Figure 3)

Case 2 A 64-year-old female underwent thoracic vertebra fracture (T12) percutaneous vertebroplasty of bone cement distribution type: B, with slight recompression of the fractured vertebral body at the last follow-up. (FVAH (pre-op): 16.09mm; FVAH (24h post-op): 18.69mm; FVAH (final FU): 17.01mm) (Figure 4)

Case 3 A 68-year-old female underwent lumbar fracture (L1) percutaneous vertebroplasty of bone cement

Table 3 Analysis of Bone Cement Distribution Group

Indexes	A	B	C	P value
LKA loss	1.41±3.02	3.59±3.33	3.35±2.31	0.004*
RKA loss	1.74±4.46	1.69±3.24	1.97±3.31	0.215
FVAHL	1.15±2.46	1.84±1.77	3.14±1.96	0.001*
AVHLR (%)	4.15±8.08	5.67±9.38	12.00±7.63	0.002*
VAS (pre-op)	5.40±0.96	5.79±0.98	5.74±0.93	0.203
VAS (24 h post-op)	1.50±0.68	1.79±0.72	1.74±0.65	0.160
VAS (final FU)	0.33±0.47	0.79±0.51	0.95±0.40	<0.01*
ODI (pre-op)	47.30±11.41	50.83±10.45	49.58±9.79	0.516
ODI (24 h post-op)	17.80±3.07	19.25±3.00	18.95±3.55	0.099
ODI (final FU)	4.70±2.24	7.25±2.19	7.26±2.33	<0.01*

Note: *P<0.05.

distribution type: C, with obvious recompression of the fractured vertebral body at the last follow-up. (FVAH (pre-op): 16.04mm; FVAH (24h post-op): 19.34mm; FVAH (final FU): 16.22mm) (Figure 5)

Discussion

OVCFs are a major public health problem that has afflicted most elderly people. Bone cement strengthens the compressed vertebral body to treat OVCFs, and the prognosis of PVP is affected by BMD, bone cement distribution, etc.^{1,2,9,10} It was reported that the patients with

thoracic and lumbar compressed fractures according to the type of diffusion of bone cement and found that the vertebral body with poor diffusion of bone cement may have unstable spines, leading to postoperative re-compression of the fractured vertebral body and aggravating clinical symptoms.¹¹ Previous studies have pointed out that pre-operative severe kyphotic deformities, solid lump cement distribution patterns, and larger reduction angles are risk factors for the development of recollapse; among these risk factors, the solid lump cement distribution pattern is the most significant. Due to the lack of or rare occurrence

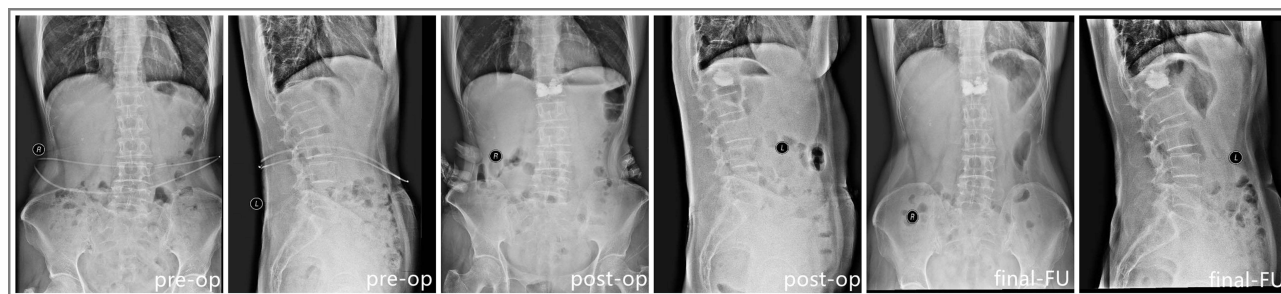


Figure 3 A 63-year-old female underwent lumbar fracture (L1) percutaneous vertebroplasty of bone cement distribution type: A, with no significant compression of the fractured vertebral body at the last follow-up.

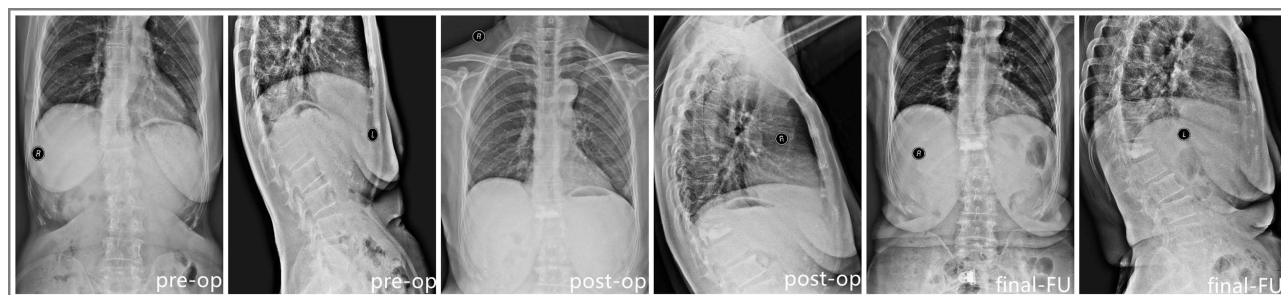


Figure 4 A 64-year-old female underwent thoracic vertebra fracture (T12) percutaneous vertebroplasty of bone cement distribution type: B, with slight recompression of the fractured vertebral body at the last follow-up.

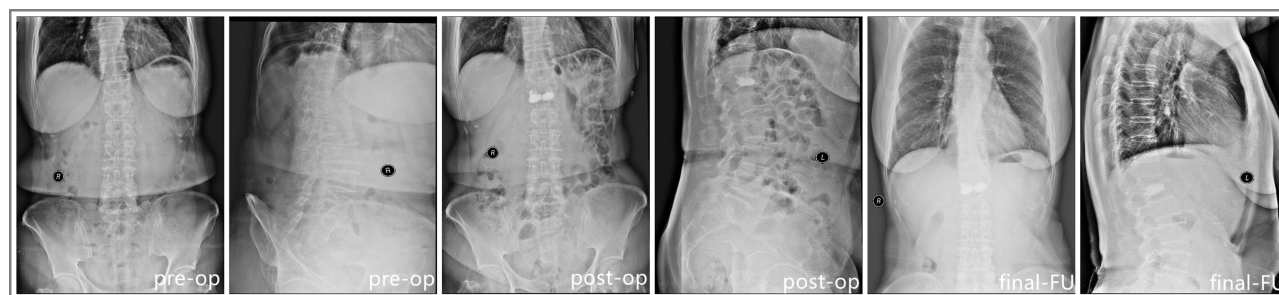


Figure 5 A 68-year-old female underwent lumbar fracture (L1) percutaneous vertebroplasty of bone cement distribution type: C, with obvious retraction of the fractured vertebral body at the last follow-up.

of contiguous interdigitation with surrounding cancellous bones, the stress may concentrate on the surrounding fragile cancellous bone, resulting in recollapse.¹² Once the bone cement diffuses to the surrounding cancellous bone, the stress load can be transmitted from the upper endplate to the lower endplate via the bone cement. However, the weaker cancellous bone was not loaded in series as it was if the bone cement mass was not dispersive but consisted of 1 or 2 solid masses, resulting in greater height loss and kyphotic deformity.^{13,14}

The distribution pattern of bone cement has been studied previously. It was conducted grouping studies on the distribution of bone cement according to whether the bone cement touched the upper and lower endplates and found that when the bone cement touched the upper and lower endplates, the vertebral strength could better recover to maintain the height of the vertebral body and reduce the risk of vertebral retraction.^{10,11} It has been reported that when there is bone cement distribution around the upper and lower endplates, the rate of vertebral retraction may be lower than that of endplates without bone cement distribution.¹⁵ In a finite element analysis of bone cement distribution, it was found that if only one side of the endplate was surrounded by bone cement, the vertebral stiffness only increased 2 fold, with almost no change in strength. However, when bone cement contacted the upper and lower endplates, the vertebral stiffness and strength could increase by a maximum of 8 fold and 11 fold, respectively.^{16,17}

Although previous studies have shown that simultaneous contact of bone cement with upper and lower endplates reduces the compression of fractured vertebrae and is beneficial for improving prognosis,¹⁷ obtaining a better distribution of bone cement when PV is performed remains a problem for surgeons. There are still few studies concerning how to improve the distribution mode of bone

cement. Some scholars believe that increasing the amount of bone cement injected may improve the distribution of bone cement, while others point out that increasing the amount of bone cement injected may increase the risk of bone cement leakage. Many studies proposed that if the intraoperative diffusion of bone cement on one side of the endplate was not satisfactory, the puncture position could be adjusted for secondary injection to improve the diffusion of bone cement.^{8–11} In a cadaver study, researchers administered lumbar lavage to reduce fat and bone marrow in the vertebrae for decompression within the vertebrae to reduce cement leakage and improve cement distribution.^{11–18} Obviously, this technique of removing fat and bone marrow from part of the vertebral body is not suitable in the clinic, but reducing the internal pressure of the vertebral body provides guidance. Based on this, we proposed a novel ideal to improve the distribution of bone cement by reducing internal haemorrhage in the fractured vertebral body, which removes the barriers of diffusion. In this study, the distribution of bone cement was significantly different ($P=0.034$). And the distribution rate of type A as well as the FVAHL, AVHR and AVHLR in the experimental group were all superior to those in the control group ($P<0.05$). After analysis of the distribution mode of bone cement, it was found that once the bone cement contacted the upper and lower endplates, its LKA loss, RKA loss, FVAHL and AVHLR were significantly better than those of other distribution modes ($P<0.05$), which supports the results of previous studies.

Some scholars have found that the distribution pattern of bone cement has no significant effect on the short-term relief of clinical symptoms in patients. We believed that this is because the thermal effect of bone cement leads to the degeneration and necrosis of teloneurons in the vertebral body,^{17–19} while vertebral body retraction has not yet occurred, so the clinical symptoms of patients are well

relieved in a short postoperative period. Patients with better cement distribution were found to obtain significant clinical relief during long-term FU. In this study, there was no significant difference in VAS or ODI scores between the experimental group and the control group preoperatively, postoperatively or at the final follow-up. However, a short follow-up may not powerfully reflect the long-term improvement of prognosis. Besides, the intraoperative VAS score in the experimental group was significantly lower than that in the control group. One reason to explain this phenomenon is that the internal pressure of the vertebral body was reduced when blood haemorrhage was aspirated from the fractured vertebral body when bone cement perfusion occurred. Therefore, the VAS score in the experimental group was better than that in the control group intraoperatively. The VAS (last follow-up) and ODI (last FU) scores of the type A distribution mode were better than those of the other distribution modes.

The bone cement dosage affects prognosis. Increasing the bone cement perfusion measure optimizes injured vertebral height restoration and improves the degree of bone cement dispersion, but more leakage may occur. In addition, the injection amount of bone cement was not associated with pain relief, so increasing the amount of bone cement to improve the diffusion of bone cement is not an ideal method.^{19–21} Based on biomechanical research in the laboratory, it was found that the stiffness and strength of vertebrae recovered to 70% and 64%, respectively, when the perfusion amount of bone cement reached 2 mL, and they recovered to 94% and 100%, respectively, when the perfusion amount reached 6 mL.^{22,23} Other studies have shown that large bone cement dosages do not show greater benefits and lead to asymmetrical cement distribution and excessive vertebral stiffness.^{6,8,20,21} In some cases, even if the injection volume of bone cement was increased, bone cement was an uncertainly connected endplate, indicating that the amount of bone cement is not the decisive factor in improving the distribution pattern.^{23,24} Based on these findings, we explored a new approach. In our study, the experimental group obtained better diffusion of bone cement. It is believed that the diffusion of bone cement could be improved by reducing blood accumulation in fractured vertebrae without increasing the amount of bone cement and that the bone cement leakage caused by excessive amounts of bone cement could be avoided. Albers et al²⁵ reported that the vertebral body lavage reduces hemodynamic response to vertebral body augmentation with PMMA, most likely resulting from decreased amounts of bone marrow substance displaced into the

circulation thereby decreasing the risk of pulmonary fat embolism syndrome. However, our team tried the technique of vertebral body lavage but we are still improving related tools to achieve a higher success rate.

Conclusions

Compared with traditional surgical methods, bone haemorrhage aspiration can improve the diffusion degree of bone cement and reduce the height loss and deformity of injured vertebrae. This method provides a feasible new scheme for improving the dispersion of bone cement. This study is a single-centre retrospective study with a short follow-up time. We will continue to follow these patients, and a large sample multicentre study will solve this problem.

Abbreviations

OVCFs, osteoporotic vertebral compression fractures; PV, percutaneous vertebroplasty; VAS, visual analogue scale; ODI, Oswestry Disability Index; PK, percutaneous kyphoplasty; PMMA, polymethylmethacrylate; BMD, bone mineral density; BMI, body mass index; MRI, magnetic resonance imaging; FU, follow-up; FVAH, fractured vertebral anterior height; AVHR, anterior vertebral height ratio; AVHRR, anterior vertebral height recovery ratio; AVHLR, anterior vertebral height loss ratio; LKA, local kyphotic angle; RKA, region kyphotic angle; FVAHR, fractured vertebral anterior height recovery; FVAHL, fractured vertebral anterior height loss.

Data Sharing Statement

The datasets generated and/or analysed during the current study are not publicly available due to the data is confidential patient data but are available from the corresponding author on reasonable request.

Ethics Approval and Consent to Participate

The Institutional Review Board of the First Affiliated Hospital of Chongqing Medical University approved this study and conducted in accordance with the Declaration of Helsinki. All participants provided written informed consent before their data were stored in our hospital database and used for study purposes.

Author Contributions

WYZ designed the study. JMP collected the data. TJH, JQ, XJL and ZXQ performed the statistical analysis and drafted

and revised the manuscript. JMP wrote the manuscript and WYZ revised the manuscript. All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

The authors declare that they have no competing interests.

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