Article

Therapeutic Efficacy of Percutaneous Vertebroplasty Combined With Gelatin Sponge Filling in Treating Thoracolumbar Fractures: A Retrospective Analysis

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AIM: Percutaneous vertebroplasty (PVP) effectively treats thoracolumbar fractures (TLF) but is plagued by post-operative bone cement leakage. Placing a gelatin sponge in the spinal canal can enhance bone cement viscosity and reduce its fluidity, potentially lowering leakage risks. This study explores the clinical efficacy of PVP combined with gelatin sponge implantation in treating TLF and assesses its role in reducing bone cement leakage and associated postoperative complications.

METHODS: This retrospective analysis included 120 TLF patients who underwent PVP treatment at the Anji Traditional Chinese Medicine Hospital between January 2022 and September 2024. Based on the use of gelatin sponges during the procedure, patients were divided into a control group, which underwent conventional PVP (n = 67), and an observation group, which received PVP combined with gelatin sponge filling (n = 53). The Visual Analog Scale (VAS) score, Oswestry Disability Index (ODI), anterior edge height and Cobb angle of the injured vertebra, and Beck index were comparatively analyzed between the two groups at three-time points: before the operation, 1 day after surgery, and 3 months postoperatively. Furthermore, the rates of bone cement leakage, adjacent vertebral fractures, adverse reactions, and the Generic Quality of Life Inventory-74 (GQOLI-74) scores were compared between the two groups.

RESULTS: Compared to the preoperative values, the VAS scores and ODI were significantly improved in both groups at 1 day and 3 months after the procedure ($p < 0.001$). The anterior edge height, Cobb angle, and Beck index were significantly recovered ($p < 0.001$). However, these indicators showed no significant differences between the two groups before the operation, 1 day and 3 months after the procedure ($p > 0.05$). Within one year postoperatively, the incidence rates of bone cement leakage and adverse reactions were substantially reduced in the observation group than in the control group ($p < 0.05$). However, there was no statistically significant difference in the incidence rate of adjacent vertebral fractures between the two groups ($p > 0.05$). Furthermore, no difference was observed in the scores of each dimension of GQOLI-74 between the two groups before operation ($p > 0.05$). One year after the operation, the scores of each dimension of GQOLI-74 elevated in both groups ($p < 0.001$), with higher scores observed in the observation group ($p < 0.05$).

CONCLUSIONS: Compared to PVP alone, PVP combined with gelatin sponge implantation in treating TLF can effectively reduce the incidence of bone cement leakage and associated postoperative adverse reactions while improving overall quality of life one year after surgery.

Keywords: percutaneous vertebroplasty; gelatin sponge; thoracolumbar fractures; bone cement leakage; quality of life

Introduction

Thoracolumbar fracture (TLF) is the most common type of spinal injury [1,2]. The thoracolumbar region lies between the relatively fixed, kyphotic thoracic vertebrae and the more mobile, lordotic lumbar vertebrae [3]. This transitional area of the spine is biomechanically vulnerable due to the concentration of mechanical stress, making it more prone to injuries [4]. TLF can lead to potential complications, including pain, functional loss, spinal deformities, and, in severe cases, even paralysis [5].

Percutaneous vertebroplasty (PVP) is a commonly used method for treating TLF [6]. It offers rapid pain relief, restores vertebral body height, and improves patient function and mobility, thereby reducing the risk of death and alleviating complication rate [7]. PVP is a minimally invasive technique performed under the guidance of C-arm fluoroscopy, during which polymethyl methacrylate (PMMA) or calcium phosphate bone cement is percutaneously injected into the fractured vertebra [7]. Despite its advantages, one of the most common complications of PVP is bone cement leakage [8]. If the cement leaks into the spinal canal, it may compress the spinal cord or nerve roots, leading to radiculopathy or neurological dysfunction, and in severe cases, may need surgical decompression [9]. Additionally, leakage into the paravertebral veins may cause serious outcomes such as pulmonary embolism, cardiac perforation, cerebral embolism, or even death [10]. Further-

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more, bone cement leakage into the intervertebral disc may accelerate disc degeneration and increase the risk of adjacent vertebral fracture [11].

To reduce bone cement leakage during percutaneous vertebroplasty (PVP) for thoracolumbar fractures (TLF), various techniques, such as balloon kyphoplasty and bone-filling mesh bag vertebroplasty, have been adopted in previous studies, achieving promising outcomes [12–14]. However, the high cost of these techniques has limited their widespread application [15]. In comparison, gelatin sponge, a widely available and cost-effective material commonly used in clinical practice, offers a valuable alternative [15]. Gelatin sponge, primarily composed of collagen, has excellent volume-filling ability, mechanical strength, and enhanced absorbability, making it a preferred option in hemostatic and vascular embolization surgeries [16–18]. In spinal surgery, gelatin sponge is widely used due to its excellent hemostatic properties, and ability to prevent adhesions between neurons and soft tissues [19]. For example, in patients with vertebral hemangiomas undergoing vertebroplasty, administration of absorbable gelatin sponge is safe and effective, reducing blood loss during surgery and shortening operation time [20].

Biomechanical experiments conducted by Meng *et al.* [21] demonstrated that gelatin sponge can reduce the incidence of bone cement leakage by increasing the viscosity of cement and decreasing its fluidity. However, a previous study reported a limited effect of gelatin sponge on bone cement leakage [22]. Currently, research on applying gelatin sponges in PVP for TLF is limited. Therefore, this retrospective study analyzed TLF patients who underwent either conventional PVP surgery alone or PVP combined with gelatin sponge treatment. This analysis evaluated the clinical efficacy of this combined treatment method and its impact on the rate of bone cement leakage.

Materials and Methods

Research Participants

This retrospective study included 120 TLF patients treated at the Anji Traditional Chinese Medicine Hospital between January 2022 and September 2024. Based on the use of gelatin during PVP, patients were divided into the control group, which received conventional PVP (n = 67), and the observation group, which received PVP combined with gelatin sponge filling (n = 53).

This study was approved by the Anji Traditional Chinese Medicine Hospital Ethics Review Committee (Approval number: 2025-001) and strictly adheres to the principles outlined in the Declaration of Helsinki. All patients included in the study provided written informed consent.

Inclusion and Exclusion Criteria

The inclusion criteria for patient selection were as follows: (1) Patients with recent fractures, an intact posterior vertebral wall, and a normal spinal canal, without significant spinal cord/nerve roots compression; (2) Patients with no cognitive, language, or intellectual disorders; (3) Patients with diagnosis consistent with the "Chinese Expert Consensus on the Diagnosis of Osteoporosis by Imaging and Bone Mineral Density" [23] and the "Guidelines for the Treatment of Osteoporotic Vertebral Compression Fractures (OVCF)" [24]; (4) Patients who agreed to participate in a 1-year follow-up, including telephone-based follow-up assessments; (5) Patients with no prior non-surgical treatments such as pain relief, anti-osteoporotic therapy, physical therapy, or bracing; (6) Those with good compliance, regular follow-up, and complete follow-up data; and (7) Those aged 60 years or above.

Exclusion criteria included: (1) Preoperative computed tomography (CT) scan showing vertebral body collapse exceeding 75% or symptoms of nerve damage; (2) Patients with history of brain trauma and chest injury; (3) Patients known allergies to bone cement or contrast materials; (4) Patients with severe open fractures; (5) Patients with cancer, infectious disease, hematologic diseases, or other serious systematic illnesses; (6) Patients with history of previous TLF; (7) Those not requiring surgical treatment; and (8) Those known allergic predisposition or psychological disorders.

Therapeutic Intervention Protocols

Preoperative CT scans were performed using a C-arm machine (Philips BV 29, Philips Medical Systems, Best, Netherlands) and compared with preoperative imaging studies to identify the target vertebral body for the procedure. The operation was conducted under local infiltration anesthesia. Patients were placed in a prone position, with soft pads placed under the chest and iliac regions to allow the abdomen to hang freely. Gentle pressure was applied to the injured vertebral area to facilitate postural reduction.

The puncture site was determined to be approximately 3 cm lateral to the spinous process of the affected vertebra, corresponding to the fluoroscopic projection of the pedicle. After routine disinfection and draping of the surgical area, local anesthesia was administered, and a 0.3 cm longitudinal skin incision was made using a scalpel. Then, a puncture needle was inserted percutaneously. With the aid of the C-arm machine, the puncture trajectory was carefully adjusted to ensure accurate needle placement, with the needle tip positioned at the anterior 1/3 of the vertebral body. After this, the puncture needle was removed, and a hand drill was inserted through the guide needle to gradually establish the working channel under the guidance of the C-arm machine.

Gelatin sponge blocks (Dimensions: 60 mm $\times$ 20 mm $\times$ 5 mm; National Medical Device Registration: 20163642299, Jiangxi Xiangen Medical Technology Development Co., Ltd., Nanchang, China) were cut into small fragments of about 3 mm $\times$ 3 mm $\times$ 3 mm. Between five to ten of these pieces were placed through one side of the working sleeve, and then a pusher rod was used to advance the gelatin sponge blocks through the working channel to the anterior part of the vertebral body, where they were compacted (the gelatin sponge filling step was omitted in the control group).

Under C-arm fluoroscopy, the position of the tip of the pusher rod indicated the location of the gelatin sponge. When the pusher rod reached the vertebral fissure, fluoroscopy confirmed that the gelatin sponge had been delivered to the anterior wall fissure of the affected vertebra. After that, bone cement (OSTEOPAL V, Heraeus Medical GmbH, Hanau, Germany) in a filamentous state was slowly injected into the affected vertebral body under dynamic fluoroscopic monitoring using the same pusher rod.

When the cement injection pressure increased without exceeding the anterior cortical boundary of the vertebral body, it was determined that the anterior fissure had been effectively blocked by the gelatin sponge. Injection was stopped once the bone cement had evenly dispersed in the vertebra. The working channel was rotated to detach the bone cement, and then the channel was carefully retracted. Finally, the puncture site was disinfected with iodophor solution, and sterile pressure dressing was applied using gauze.

Observation Indicators

Baseline Data Collection

Baseline data were collected for all patients, including gender, age, body mass index (BMI), degree of osteoporosis (T value), time from injury to operation, fracture location and pattern, bone mineral density (BMD), surgical approach (unilateral or bilateral), operation duration, and the volume of bone cement injected. Additionally, the presence of comorbidities, such as hypertension, diabetes, or chronic obstructive pulmonary disease (COPD) was recorded. BMD was measured using a dual-energy X-ray absorptiometry (DEXA) scanner (AKDX-09 W-I, Shenzhen XRAY Electric Co., Ltd., Shenzhen, China). The T value was calculated using the formula: T value = (Individual BMD measurement – Young healthy adult average BMD)/Reference population standard deviation. The average BMD and standard deviation of young healthy adults are sourced from the reference database specific to Hologic devices: Lumbar spine BMD measurements use the Hologic lumbar spine reference database; Femoral neck and total hip BMD measurements use the Hologic National Health and Nutrition Examination Survey (NHANES) III Caucasian female population reference database [25,26].

Visual Analog Scale (VAS) Score and Oswestry Disability Index (ODI)

Pain levels were measured using the VAS scores at three-time points: before the procedure, one day after the operation, and 3 months after the operation. During VAS assessment, a 10 cm horizontal line was drawn, with one end marked as 0 representing no pain, and the other as 10 indicating severe pain. The intermediate part of the horizontal line represents different degrees of pain successively [27]. Patients were asked to mark a point on the line that best corresponded to their perceived pain level, and the distance from the 0 point indicated the VAS score. The functional status of the patient was assessed using the Oswestry Disability Index (ODI) at the same three-time points. The ODI scale contains 10 items assessing pain and various daily activities, with a total score ranging from 0 to 100. Higher scores show more severe functional impairment and disability [28].

Assessing Anatomical Structure Recovery of the Injured Vertebra

X-ray measurements of the injured vertebra were collected at three-time points: before the operation, one day postoperatively, and 3 months postoperatively. These data included the height of the anterior and posterior edges of the vertebral body, the sagittal Cobb angle, and the calculation of the Beck index to evaluate the recovery of the vertebral anatomy. The sagittal Cobb angle is defined as the angle formed by the intersection of the extended lines of the upper endplate of the injured vertebra and the lower endplate of the adjacent vertebra [29]. The Beck index is determined based on the ratio of the height of the anterior vertebral body to the height of the posterior vertebral body [30].

Observing Bone Cement Leakage and Adjacent Vertebral Fracture and Recording Adverse Reactions

The occurrence of bone cement leakage was assessed by reviewing postoperative anteroposterior and lateral X-ray images taken within one year. Additionally, the occurrence of adjacent vertebral fractures during the one-year follow-up period was collected. Any adverse events, including spinal nerve injury, rib fracture, pulmonary embolism, and pneumothorax, were also documented.

Quality of Life

The Generic Quality of Life Inventory-74 (GQOLI-74) scores were collected for all patients before surgery and one year after the procedure. This inventory evaluates four dimensions: psychological function, physical function, social function, and material life status. Each dimension is scored on a scale ranging from 0 to 100, with higher scores indicating a better quality of life [31].

Statistical Analysis

Data were statistically analyzed using SPSS (Version 21.0, IBM, Armonk, NY, USA). The Kolmogorov-Smirnov test was used to analyze the normality of continuous variables ($n \geq 30$). Variables following a normal distribution were expressed as mean $\pm$ standard deviation ($\bar{x} \pm s$), while non-normally distributed data were displayed as median and interquartile range [M (P25–P75)]. For normally distributed continuous variables, between-group comparisons were analyzed using independent-sample *t*-test, and within-

Table 1. Comparison of baseline data between the two groups [$\bar{x} \pm$ s, n (%)].

Characteristics/Group	Control group (n = 67)	Observation group (n = 53)	t/χ^2 value	p-value
Gender			0.155	0.694
Male	12 (17.91)	11 (20.75)		
Female	55 (82.09)	42 (79.25)		
Age (years)	75.52 $\pm$ 5.73	74.51 $\pm$ 6.43	0.908	0.366
BMI (kg/m^2)	23.28 $\pm$ 2.64	22.95 $\pm$ 2.47	0.699	0.486
Degree of osteoporosis (T value)	–(3.45 $\pm$ 0.49)	–(3.51 $\pm$ 0.51)	0.661	0.510
Time from injury to surgery (day)	2.30 $\pm$ 0.74	2.45 $\pm$ 0.75	1.096	0.275
Fracture site			1.041	0.594
Middle thoracic	20 (29.85)	13 (24.53)		
Lower thoracic	15 (22.39)	16 (30.19)		
Lumbar	32 (47.76)	24 (45.28)		
Fracture pattern			0.017	0.897
Endplate impaction fracture	17 (25.37)	14 (26.42)		
Wedge impaction fracture	50 (74.63)	39 (73.58)		
BMD (mg/cm^2)	725.63 $\pm$ 80.52	731.28 $\pm$ 72.41	0.399	0.691
Surgical approach			0.099	0.753
Unilateral	31 (46.27)	23 (43.40)		
Bilateral	36 (53.73)	30 (56.60)		
Operation duration (min)	35.18 $\pm$ 4.58	36.47 $\pm$ 5.61	1.386	0.168
Volume of bone cement injected (mL)	5.41 $\pm$ 0.39	5.35 $\pm$ 0.62	0.612	0.542
Hypertension, yes	41 (61.19)	33 (62.26)	0.014	0.905
Diabetes, yes	26 (38.81)	18 (33.96)	0.299	0.585
COPD, yes	16 (23.88)	10 (18.87)	0.438	0.508

Note: BMI, body mass index; BMD, bone mineral density; COPD, chronic obstructive pulmonary disease.

group comparisons (pre- vs. post-treatment) were assessed with paired-samples t-test. For non-normally distributed continuous variables, the Mann-Whitney U test was used for between-group comparisons, and the Wilcoxon signed-rank test was applied for within-group comparisons (pre- vs. post-treatment). Categorical data were presented as frequencies and percentages [n (%)], with differences between categorical variables analyzed using the chi-square test. For the χ^2 test, the Pearson chi-square test was applied when all expected frequencies (T) were $\geq$5 and the total sample size (n) was $\geq$40. A p-value of <0.05 was considered statistically significant.

Results

Comparison of Baseline Information Between the Two Groups

As detailed in Table 1, no significant differences were observed between the two groups in terms of gender distribution, age, BMI, degree of osteoporosis, time from injury to operation, fracture site, fracture pattern, BMD, surgical approach (unilateral or bilateral), operation duration, volume of bone cement injected and comorbidities such as hypertension, diabetes, and COPD, with comparable outcomes ($p > 0.05$).

Functional Recovery Outcomes of Injured Vertebra Treatment

Compared to preoperative values, VAS scores and ODI significantly reduced in both groups at 1 day and 3 months after the procedure ($p < 0.001$). However, no significant differences were observed in VAS scores or ODI between the two groups at either preoperative time point, 1 day and 3 months after the surgery ($p > 0.05$, Table 2).

Comparison of Treatment Outcomes Between the Two Groups

Compared to preoperative values, significant improvements in the Cobb angle, anterior vertebral body height, and Beck index of the injured vertebrae were observed in both groups at 1 day and 3 months postoperatively ($p < 0.001$). However, these parameters showed no statistically significant differences before the surgery or at 1 day and 3 months postoperatively ($p > 0.05$, Table 3).

Postoperative Cement Leakage and Adjacent Vertebral Fracture

Within one year after the procedure, the incidence of bone cement leakages in the observation group was 9.43%, significantly lower than the 25.37% in the control group ($p < 0.05$). However, there was no statistically significant dif-

Table 2. Comparison of VAS score and ODI between the two groups [$\bar{x} \pm$ s, M (P25–P75)].

Characteristics/Group	Control group (n = 67)	Observation group (n = 53)	*t*-value/*Z*-value	*p*-value
VAS score (point)				
Before operation	7 (6, 8)	7 (6.5, 8)	1.293	0.196
1 day postoperative	3 (2, 3)**	3 (2, 3)**	0.305	0.761
3 months postoperative	2 (2, 2)**	2 (2, 2)**	0.991	0.322
ODI (point)				
Before operation	71.37 ± 7.16	72.64 ± 8.80	0.870	0.386
1 day postoperative	40.82 ± 5.17**	40.17 ± 5.21**	0.683	0.496
3 months postoperative	31.22 ± 4.17**	31.94 ± 4.77**	0.881	0.380

Note: Compared to preoperative treatment in the same group, **$p < 0.001$. VAS, Visual Analog Scale; ODI, Oswestry Disability Index.

Table 3. Comparisons of Cobb angle, vertebral anterior margin height and Beck index of injured vertebra between the two groups [M (P25–P75)].

Characteristics/Group	Control group (n = 67)	Observation group (n = 53)	*Z*-value	*p*-value
Cobb angle (°)				
Before operation	17 (13, 19)	16 (13, 19.5)	0.228	0.819
1 month postoperative	12 (11, 13)**	13 (11, 13.5)**	1.299	0.194
3 months postoperative	13 (11, 13)**	13 (11.5, 15)**	0.549	0.583
Height of the anterior margin of the vertebral body (mm)				
Before operation	17 (14, 18)	17 (15, 18)	0.091	0.928
1 month postoperative	21 (18, 22)**	20 (18, 22)**	0.316	0.752
3 months postoperative	20 (18, 22)**	20 (18, 22)**	0.153	0.878
Beck index				
Before operation	0.71 (0.63, 0.78)	0.73 (0.65, 0.78)	0.273	0.785
1 month postoperative	0.91 (0.82, 0.96)**	0.91 (0.83, 0.92)**	0.301	0.764
3 months postoperative	0.90 (0.82, 0.92)**	0.88 (0.82, 0.92)**	0.202	0.840

Note: Compared to preoperative treatment in the same group, **$p < 0.001$.

ference between the two groups regarding the occurrence of adjacent vertebral fractures during one-year follow-up period ($p > 0.05$, Table 4).

Postoperative Adverse Reaction

Within one year after the operation, the incidence of adverse reactions in the observation group was lower than in the control group ($p < 0.05$, Table 5).

Quality of Life

Before the operation, there were no significant differences in the scores of each dimension of GQOLI-74 between the two groups ($p > 0.05$). One year postoperative, the scores of each dimension of GQOLI-74 in both groups increased, and the observation group had higher scores than the control group in all dimensions ($p < 0.05$, Table 6).

Discussion

In this study, using a gelatin sponge during PVP significantly reduced the incidence of postoperative bone cement leakage and associated adverse reactions in TLF patients, without affecting the clinical efficacy of the procedure.

The findings showed that the cement leakage rate in the control group after conventional PVP was 25.37%. Conversely, the observation group had a significantly lower bone cement leakage rate than the control group, indicating that the gelatin sponge effectively reduces the risk of leakage without negatively affecting the clinical outcomes. Under the guidance of C-arm X-ray fluoroscopy, gelatin sponges were accurately positioned in the anterior wall area of the vertebral body during PVP. The proposed mechanisms involving cement leakage prevention include: (1) Physical plugging effect: These sponges fill the cracks and trabecular pores in the anterior vertebral wall, effectively blocking the diffusion path of bone cement into perivertebral soft tissue [32]. (2) Rheological regulation: Gelatin sponge absorbs the monomeric components of bone cement, increasing its viscosity and resistance to flow, thus reducing its leakage [33]. (3) Thermal barrier protection: The sponge acts as an insulating layer between the bone cement and adjacent blood vessels and nerve tissues, reducing the risk of thermal injury during the polymerization [32]. A previous study also underscores the protective effect of gelatin sponge in patients with posterior wall damage of the vertebral body [20]. Our results further support that a gelatin sponge is a viable adjunctive strategy to reduce bone cement leakage during PVP. Importantly, the insertion of a gelatin sponge did not increase the duration

Table 4. Comparison of postoperative bone cement leakages and adjacent vertebral fractures between the two groups.

Characteristics/Group	Control group (n = 67)	Observation group (n = 53)	χ^2 value	p-value
Cement leakage (total)	17 (25.37)	5 (9.43)	5.021	0.025
Leakage of the superior vertebral endplate	5	2		
Anterior vertebral leakage	7	0		
Lateral vertebral leakage	4	3		
Posterior vertebral leakage	1	0		
Adjacent vertebral fracture	11 (16.42)	4 (7.55)	2.129	0.145

Table 5. Comparison of postoperative adverse events between the two groups [n (%)].

Characteristics/Group	Control group (n = 67)	Observation group (n = 53)	χ^2 value	p-value
Spinal nerve injury	2 (2.99)	1 (1.89)		
Rib fracture	5 (7.46)	1 (1.89)		
Pulmonary embolism	4 (5.97)	2 (3.77)		
Pneumothorax	3 (4.48)	0 (0)		
Total	14 (20.90)	4 (7.55)	4.135	0.042

Table 6. Comparison of quality of life between the two groups ($\bar{x} \pm$ s).

Characteristics/Group	Control group (n = 67)	Observation group (n = 53)	t-value	p-value
Mental function score (point)				
Before operation	59.25 ± 2.55	58.96 ± 2.39	0.636	0.526
1 year postoperative	69.31 ± 3.22**	74.40 ± 4.82**	6.914	<0.001
Body function score (point)				
Before operation	60.21 ± 2.35	60.45 ± 2.11	0.581	0.562
1 year postoperative	72.15 ± 3.12**	77.30 ± 3.58**	8.412	<0.001
Social function score (point)				
Before operation	57.57 ± 4.79	57.08 ± 4.54	0.569	0.570
1 year postoperative	66.27 ± 3.40**	72.34 ± 4.16**	8.796	<0.001
State of material life score (point)				
Before operation	59.00 ± 3.41	58.57 ± 3.60	0.669	0.505
1 year postoperative	64.90 ± 5.59**	69.15 ± 5.91**	4.033	<0.001

Note: Compared to preoperative treatment in the same group, **$p < 0.001$.

of surgery or alter the quantity of bone cement injected. This observation is consistent with Zhou *et al.* [15], who demonstrated no significant impact on cement volume with gelatin sponge insertion. In current clinical settings, PVP continues to be widely used than vertebral balloon kyphoplasty or bone-filling mesh approaches, due to its procedural simplicity, less resource consumption, and comparatively lower treatment costs [34,35]. Moreover, vertebral balloon kyphoplasty has certain technical challenges, such as the need to retract the balloon before injecting the bone cement, which can cause vertebral rebound, loss of vertebral height, and difficulty in creating a cavity, ultimately increasing the risk of bone cement leakage if the injection is repeated [36]. Given the above clinical considerations, our study proposes that the method of pre-filling gelatin sponge is relatively simple, cost-effective, and feasible to improve PVP in treating thoracolumbar fractures. This approach provides a promising enhancement to clinical practice by effectively reducing the rate of bone cement leakage while preserving the therapeutic efficacy of PVP.

Compared to the preoperative period, the VAS scores and ODI in both groups showed significant improvements after surgery, indicating that PVP effectively alleviates pain and improves functional status [37]. However, no statistically significant differences were observed in postoperative VAS scores and ODI between the two groups. These results are consistent with previous study on the treatment of osteoporotic vertebral compression fractures with endplate injury using PVP combined with gelatin sponge composite compared with PVP alone [38]. This suggests that using a gelatin sponge during PVP does not impair analgesia or functional recovery [15,39].

In terms of anatomical recovery, both groups showed significant postoperative improvement. This enhancement can be due to the uniform distribution of bone cement within the vertebral body during PVP, which improves vertebral stability, increases symmetrical load distribution across vertebrae, promotes early fracture healing, and makes the fracture configuration more stable [40]. The lack of significant differences in anatomical recovery between the two groups confirms that gelatin sponge filling does not affect the vertebral reduction process in PVP and may help reduce stress concentrations associated with bone cement masses by improving more uniform structural support [15].

Previous studies have demonstrated that bone cement leakage into the intervertebral space increases the risk of fractures in adjacent vertebral bodies [41,42]. Meta-analyses have further revealed that bone cement leakage during PVP significantly increases the incidence of secondary vertebral fractures [43]. Additionally, bone cement infiltration into the intervertebral disc or annulus fibrosus can accelerate local tissue degeneration, impairing the biomechanical cushioning function of the disc and significantly enhancing the "pillar effect", thereby decreasing the disc's ability to buffer mechanical stress [44,45]. Additionally, bone cement leakage may cause mechanical damage to adjacent endplates, alter normal stress distribution patterns between vertebral bodies, and reduce the ability of vertebrae to withstand abnormal external forces [43]. These pathological changes may synergistically deteriorate the biomechanical environment of the affected and adjacent vertebrae, thereby increasing the risk of re-fracture. In this study, the bone cement leakage rate was significantly lower in the observation group than in the control group. However, the incidence of adjacent vertebral fractures was also lower in the observation group, with no statistical significance. This result may be due to the small sample size of the study, which could have reduced its statistical power, making it difficult to obtain statistical significance despite clinically relevant trends. Therefore, it is recommended to conduct large-scale prospective studies to further validate these findings.

Complications associated with PVP are closely related to bone cement leakage [46]. Bone cement leakage can lead to adverse outcomes such as pulmonary embolism, rib fractures, pneumothorax, and spinal nerve compression, which remain significant clinical concerns [47,48]. This study found that the total incidence of adverse reactions in the observation group was significantly lower than in the control group. The use of a gelatin sponge showed several protective effects. Its physical plugging effect, effectively blocks the intravertebral venous sinuses, reducing the risk of venous bone cement leakage and decreasing the probability of pulmonary embolism [49]. Additionally, by guiding the distribution pattern of bone cement, it prevents localized stress concentration, which then reduces the occurrence of rib fractures [50]. Furthermore, the physical barrier formed by a gelatin sponge along the spinal canal can significantly reduce the risk of bone cement leakage into the spinal canal, thereby preventing potential compression injuries to the spinal cord and nerve roots [51]. Additionally, its pre-reinforcement effect on the vertebral body structure may reduce the risk of pleural injury caused by repeated puncture adjustments during surgery, providing an operational protective mechanism for reducing the incidence of pneumothorax [16]. In summary, gelatin sponges have significant advantages in reducing adverse reactions associated with bone cement leakage, thereby enhancing the overall safety profile of PVP.

In this study, no significant differences were found between the observation and control groups in the four dimensions of preoperative quality of life, such as physical function, psychological function, social function, and material living status. However, in one year postoperatively, the observation group showed significantly better performance in all four dimensions. This improvement was attributed to the significantly reduced incidence of postoperative complications in the observation group, which significantly promoted the recovery of physical functions [52]. Patients in the observation group had better postoperative psychological function, which may be closely related to improved treatment safety, particularly the reduced incidence of bone cement leakage, which helped alleviate postoperative anxiety and fear [53]. Additionally, significant improvement in physical function further relieved patients' negative emotions, creating a positive feedback loop that enhanced patients' confidence and satisfaction with the treatment and positively improved overall mental health [54]. Regarding social function, the postoperative scores were significantly higher in the observation group than in the control group, indicating a quicker return to work and social activities [55]. This change shortened the rehabilitation period and significantly improved social reengagement, which plays a crucial role in restoring social functionality.

From an economic perspective, the observation group reported a better material living status one year postoperatively, mainly due to reduced medical costs. This might be because the observation group reduced the need for secondary surgery and decreased long-term rehabilitation expenses, lowering indirect medical expenses and reducing the economic burden on patients' families and the health care system. These observations further underscore the cost-effectiveness and practical advantages of the treatment method used in the observation group.

This study has certain limitations that should be addressed in subsequent research. Firstly, the retrospective design led to a limited sample size and some selection biases. Cases were selected based on hospital record archives rather than through random sampling, and cases with lost follow-up or incomplete data were excluded. These factors may affect the universality of the findings. Secondly, there are technical bottlenecks in the intraoperative positioning of the gelatin sponge. The current sponge injection method relies on the surgeon's empirical judgment for determining the injection site without real-time imaging verification, which may cause operational variability and potential biases.

Future research should consider adopting a prospective cohort design involving collaboration among multiple medical institutions. An expanded sample size based on stratified random sampling would help reduce heterogeneity and improve the generalizability of the results. Furthermore, using radiopaque gelatin sponges or employing advanced imaging technologies such as multi-directional fluoroscopy could help identify fracture sites more accurately and improve gelatin sponge positioning during the procedure.

Conclusions

Compared to PVP alone, combining PVP with gelatin sponge implantation offers more advantages in treating TLF by effectively reducing the incidence of bone cement leakage and related postoperative adverse complications while improving quality of life one year after surgery.

Availability of Data and Materials

The data analyzed are available from the corresponding author upon reasonable request.

Author Contributions

JZ and QL designed the research study and wrote the first draft. QL performed the research. JZ analyzed the data. Both authors have been involved in revising it critically for important intellectual content. Both authors gave final approval of the version to be published. Both authors have participated sufficiently in the work to take public responsibility for appropriate portions of the content and agreed to be accountable for all aspects of the work in ensuring that questions related to its accuracy or integrity.

Ethics Approval and Consent to Participate

This study was approved by the Anji Traditional Chinese Medicine Hospital Ethics Review Committee (Approval number: 2025-001) and strictly adheres to the principles outlined in the Declaration of Helsinki. All patients included in the study provided written informed consent.

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Conflict of Interest

The authors declare no conflict of interest.

References

[1] Fang Y, Zhang S, Ye Y, Chen K, Ling G, Wang Q, *et al*. Analysis of factors influencing the intravertebral shell phenomenon after posterior reduction internal fixation of thoracolumbar fracture: a retrospective study. BMC Musculoskeletal Disorders. 2024; 25: 49. https://doi.org/10.1186/s12891-024-07168-9.

[2] Luo ZW, Liao WJ, Sun BL, Wu JB, Zhang N, Zhang Y, *et al*. Short-segment fixation and transpedicular bone grafting for the treatment of thoracolumbar spine fracture. Frontiers in Surgery. 2023; 9: 1039100. https://doi.org/10.3389/fsurg.2022.1039100.

[3] Han L, Yang H, Li Y, Li Z, Ma H, Wang C, *et al*. Biomechanical Evaluation of the Cross-link Usage and Position in the Single and Multiple Segment Posterior Lumbar Interbody Fusion. Orthopaedic Surgery. 2022; 14: 2711–2720. https://doi.org/10.1111/os.13485.

[4] Wood KB, Li W, Lebl DR, Ploumis A. Management of thoracolumbar spine fractures. The Spine Journal: Official Journal of the North American Spine Society. 2014; 14: 145–164. https://doi.org/10.1016/j.spinee.2012.10.041.

[5] Cook E, Booth A, Coleman E, Scantlebury A, McDaid C, Hewitt C, *et al*. Pragmatic randomised evaluation of stable thoracolumbar fracture treatment outcomes (PRESTO): study protocol for a randomised controlled feasibility trial combined with a qualitative study and survey. Pilot and Feasibility Studies. 2020; 6: 38. https://doi.org/10.1186/s40814-020-00574-5.

[6] Wang R, Xu Y, Ma X. Risk factors and strategies for recovery quality, postoperative pain, and recurrent fractures between percutaneous kyphoplasty and percutaneous vertebroplasty in elderly patients with thoracolumbar compression fractures: a retrospective comparative cohort study. Annals of Translational Medicine. 2023; 11: 122. https://doi.org/10.21037/atm-22-6475.

[7] Wang M, Li B, Wang Y, Jiang S, Wen G, Jiang L, *et al*. The Effects of Bone Cement Volume in Percutaneous Vertebroplasty for Thoracolumbar Junction Vertebral Compression Fractures: A Clinical Comparative Study. Mediators of Inflammation. 2022; 2022: 4230065. https://doi.org/10.1155/2022/4230065.

[8] Lu X, Shen Y, Zhao W, Wang X. Endovascular treatment of a large bone cement pulmonary embolism: Case report. SAGE Open Medical Case Reports. 2024; 12: 2050313X241277136. https://doi.org/10.1177/2050313X241277136.

[9] Jing Z, Li L, Song J. Delayed neurological deficits caused by cement extravasation following vertebroplasty: a case report. The Journal of International Medical Research. 2021; 49: 3000605211019664. https://doi.org/10.1177/03000605211019664.

[10] Zhang K, She J, Zhu Y, Wang W, Li E, Ma D. Risk factors of postoperative bone cement leakage on osteoporotic vertebral compression fracture: a retrospective study. Journal of Orthopaedic Surgery and Research. 2021; 16: 183. https://doi.org/10.1186/s13018-021-02337-1.

[11] Wang T, Si F, Zang L, Fan N, Yuan S, Du P, *et al*. Radiographic adjacent segment degeneration and risk factors for osteoporotic vertebral compression fractures treated with percutaneous kyphoplasty. International Orthopaedics. 2022; 46: 2619–2628. https://doi.org/10.1007/s00264-022-05510-1.

[12] Duan ZK, Zou JF, He XL, Huang CD, He CJ. Bone-filling mesh container versus percutaneous kyphoplasty in treating Kümmell's disease. Archives of Osteoporosis. 2019; 14: 109. https://doi.org/10.1007/s11657-019-0656-4.

[13] Tang C, Liu F. Effectiveness of bone-filled mesh bag technology and angle vertebroplasty in the treatment of osteoporotic thoracic vertebral compression fractures in the elderly. American Journal of Translational Research. 2024; 16: 3289–3297. https://doi.org/10.62347/GHNQ5649.eCollection2024.

[14] He CJ, Liu GD. Comparison of the Efficacy and Safety of Bone-filling Mesh Container and Simple Percutaneous Balloon Kyphoplasty in the Treatment of Osteoporotic Vertebral Compression Fractures. Pain Physician. 2018; 21: 259–268.

[15] Zhou C, Huang S, Liao Y, Zhang F, Meng X, Tang Z, *et al*. Feasibility Analysis of the Bone Cement-Gelatine Sponge Composite Intravertebral Prefilling Technique for Reducing Bone Cement Leakage in Stage I and II Kümmell's Disease: A Prospective Randomized Controlled Trial. Orthopaedic Surgery. 2023; 15: 1763–1771. https://doi.org/10.1111/os.13764.

[16] Renier H, Gérard L, Lamborelle P, Cousin F. Efficacy of the tract embolization technique with gelatin sponge slurry to reduce pneumothorax and chest tube placement after percutaneous CT-guided lung biopsy. Cardiovascular and Interventional Radiology. 2020; 43: 597–603. https://doi.org/10.1007/s00270-019-02387-3.

[17] Ehab K, Abouldahab O, Hassan A, Fawzy El-Sayed KM. Alvogyl and absorbable gelatin sponge as palatal wound dressings following

epithelialized free gingival graft harvest: a randomized clinical trial. Clinical Oral Investigations. 2020; 24: 1517–1525. https://doi.org/10.1007/s00784-020-03254-z.

[18] Zhao J, Honda Y, Tanaka T, Hashimoto Y, Matsumoto N. Releasing Behavior of Lipopolysaccharide from Gelatin Modulates Inflammation, Cellular Senescence, and Bone Formation in Critical-Sized Bone Defects in Rat Calvaria. Materials (Basel, Switzerland). 2019; 13: 95. https://doi.org/10.3390/ma13010095.

[19] Nallakumarasamy A, Jain M, Panigrahi S, Sahoo A, Naik S. Gelatin Sponge-induced Early Onset Quadriparesis after the Posterior Decompression for Cervical Myelopathy Due to Ossification of a Posterior Longitudinal Ligament - A Case Report. Journal of Orthopaedic Case Reports. 2022; 12: 70–73. https://doi.org/10.13107/jocr.2022.v12.i06.2870.

[20] Xu W, Lan Z, Huang Y. Intraoperative injection of absorbable gelatin sponge (AGS) mixed with cement followed by spinal decompression to treat elderly with vertebral hemangiomas. BMC Musculoskeletal Disorders. 2020; 21: 125. https://doi.org/10.1186/s12891-020-3143-6.

[21] Meng B, Qian M, Xia SX, Yang HL, Luo ZP. Biomechanical characteristics of cement/gelatin mixture for prevention of cement leakage in vertebral augmentation. European Spine Journal: Official Publication of the European Spine Society, the European Spinal Deformity Society, and the European Section of the Cervical Spine Research Society. 2013; 22: 2249–2255. https://doi.org/10.1007/s00586-013-2886-2.

[22] Oh JS, Doh JW, Shim JJ, Lee KS, Yoon SM, Bae HG. The Effectiveness of Gelfoam Technique before Percutaneous Vertebroplasy: Is It Helpful for Prevention of Cement Leakage? A Prospective Randomized Control Study. Korean Journal of Spine. 2016; 13: 63–66. https://doi.org/10.14245/kjs.2016.13.2.63.

[23] Zhang ZH, Liu ZH, Li N, Zhang MM, Huang QR, Ma YZ, *et al*. Chinese Expert Consensus on Diagnostic Criteria for Osteoporosis (Third Edition·2014). Chinese Journal of Osteoporosis. 2014; 20: 1009–1014. (In Chinese)

[24] Yin P, Ma YZ, Ma X, Chen BH, Hong Y, Liu BY, *et al*. The clinical guideline for osteoporotic compression fractures. Chinese Journal of Osteoporosis. 2015; 21: 643–648. (In Chinese)

[25] Mullin BH, Walsh JP, Zheng HF, Brown SJ, Surdulescu GL, Curtis C, *et al*. Genome-wide association study using family-based cohorts identifies the WLS and CCDC170/ESR1 loci as associated with bone mineral density. BMC Genomics. 2016; 17: 136. https://doi.org/10.1186/s12864-016-2481-0.

[26] Kanis JA. Diagnosis of osteoporosis and assessment of fracture risk. Lancet (London, England). 2002; 359: 1929–1936. https://doi.org/10.1016/S0140-6736(02)08761-5.

[27] Katz J, Melzack R. Measurement of pain. The Surgical Clinics of North America. 1999; 79: 231–252. https://doi.org/10.1016/s0039-6109(05)70381-9.

[28] Fairbank JC, Couper J, Davies JB, O'Brien JP. The Oswestry low back pain disability questionnaire. Physiotherapy. 1980; 66: 271–273.

[29] Phillips FM, Ho E, Campbell-Hupp M, McNally T, Todd Wetzel F, Gupta P. Early radiographic and clinical results of balloon kyphoplasty for the treatment of osteoporotic vertebral compression fractures. Spine. 2003; 28: 2260–2265; discussion 2265–2267. https://doi.org/10.1097/01.BRS.0000085092.84097.7B.

[30] Beck E. Radiographic measuring methods in vertebral fractures. Hefte Zur Unfallheilkunde. 1971; 108: 36–37.

[31] Li LJ, Yang DS. Generic Quality of Life Inventory (GQOLI-74). In Wang XD, Wang XL, Ma H (eds.) Manual of the Mental Health Rating Scale (Suppl) (pp. 88–100). Chinese Mental Health Press: Beijing. 1999.

[32] Zhang SL, Xu B, Lao YJ, Sheng HF. Clinical observation of gelfoam in preventing cement leakage via the anterior vertebral wall in Kümmell's patients treated with percutaneous kyphoplasty. Zhongguo Gu Shang = China Journal of Orthopaedics and Traumatology. 2021; 34: 738–742. https://doi.org/10.12200/j.issn.1003-0034.2021.08.009.

[33] Wang CH, Ma JZ, Zhang CC, Nie L. Comparison of high-viscosity cement vertebroplasty and balloon kyphoplasty for the treatment of osteoporotic vertebral compression fractures. Pain Physician. 2015; 18: E187–94.

[34] Kobayashi N, Noguchi T, Kobayashi D, Saito H, Shimoyama K, Tajima T, *et al*. Safety and efficacy of percutaneous vertebroplasty for osteoporotic vertebral compression fractures: a multicenter retrospective study in Japan. Interventional Radiology (Higashimatsuyama-shi, Japan). 2021; 6: 21–28. https://doi.org/10.22575/interventionalradiology.2020-0032.

[35] Rose LD, Bateman G, Ahmed A. Clinical significance of cement leakage in kyphoplasty and vertebroplasty: a systematic review. European Spine Journal: Official Publication of the European Spine Society, the European Spinal Deformity Society, and the European Section of the Cervical Spine Research Society. 2024; 33: 1484–1489. https://doi.org/10.1007/s00586-023-08026-3.

[36] Wang Z, Li G, He J, Huang H, Zhao A. Clinical Effect of Bone Filling Mesh Container Vertebroplasty in Osteoporotic Compression Fracture. Disease Markers. 2022; 2022: 5029679. https://doi.org/10.1155/2022/5029679.

[37] Gao M, Zeng Z, Jiang X, Ge J, Song J. Long-term quality of life and influencing factors in elderly patients after vertebroplasty based on the EQ-5D-3L Chinese utility scoring system: a retrospective study. BMC Geriatrics. 2024; 24: 686. https://doi.org/10.1186/s12877-024-05249-x.

[38] Wang YQ, Qiao L, Wang B, Tang XB, Liao YF, Zhou CQ, *et al*. Percutaneous Vertebroplasty with the Polymethyl Methacrylate - Gelatin Sponge Complex in the Treatment of Patients with Osteoporotic Vertebral Compression Fractures Accompanied by Superior Endplate Injurie. Turkish Neurosurgery. 2024; 34: 74–80. https://doi.org/10.5137/1019-5149.JTN.41797-22.2.

[39] Zhang Y, Lu M, Min L, Wang J, Wang Y, Luo Y, *et al*. Three-dimensional-printed porous implant combined with autograft reconstruction for giant cell tumor in proximal tibia. Journal of Orthopaedic Surgery and Research. 2021; 16: 286. https://doi.org/10.1186/s13018-021-02446-x.

[40] Zhang G, Zhu J, Zhang Q, Tang J, Nie M. Effects of high viscosity bone cement percutaneous vertebroplasty on pain, bone specific alkaline phosphatase, Type-I collage cross-linked-telopeptide and Boneglaprotein levels in patients with osteoporotic vertebral compression fractures. Pakistan Journal of Medical Sciences. 2022; 38: 1552–1556. https://doi.org/10.12669/pjms.38.6.5828.

[41] Zhang T, Wang Y, Zhang P, Xue F, Zhang D, Jiang B. What Are the Risk Factors for Adjacent Vertebral Fracture After Vertebral Augmentation? A Meta-Analysis of Published Studies. Global Spine Journal. 2022; 12: 130–141. https://doi.org/10.1177/2192568220978223.

[42] Xie S, Cui L, Wang C, Liu H, Ye Y, Gong S, *et al*. Contact between leaked cement and adjacent vertebral endplate induces a greater risk of adjacent vertebral fracture with vertebral bone cement augmentation biomechanically. The Spine Journal: Official Journal of the North American Spine Society. 2025; 25: 324–336. https://doi.org/10.1016/j.spinee.2024.09.021.

[43] Zhai G, Li A, Liu B, Lv D, Zhang J, Sheng W, *et al*. A meta-analysis of the secondary fractures for osteoporotic vertebral compression fractures after percutaneous vertebroplasty. Medicine. 2021; 100: e25396. https://doi.org/10.1097/MD.0000000000025396.

[44] Komemushi A, Tanigawa N, Kariya S, Kojima H, Shomura Y, Komemushi S, *et al*. Percutaneous vertebroplasty for osteoporotic compression fracture: multivariate study of predictors of new vertebral body fracture. Cardiovascular and Interventional Radiology. 2006; 29: 580–585. https://doi.org/10.1007/s00270-005-0138-5.

[45] Rho YJ, Choe WJ, Chun YI. Risk factors predicting the new symptomatic vertebral compression fractures after percutaneous verte-

broplasty or kyphoplasty. European Spine Journal: Official Publication of the European Spine Society, the European Spinal Deformity Society, and the European Section of the Cervical Spine Research Society. 2012; 21: 905–911. https://doi.org/10.1007/s00586-011-2099-5.

[46] Wu XF, Ping Y, Zeng XQ, Feng Y, Wang Z, Li T, *et al*. Percutaneous Vertebroplasty with Side-Opening Cannula or Front-Opening Cannula in the Treatment of Kummell Disease? Orthopaedic Surgery. 2020; 12: 1190–1198. https://doi.org/10.1111/os.12730.

[47] Hu YL, Wang PY, Xie ZY, Ren GR, Zhang C, Ji HY, *et al*. Interpretable Machine Learning Model to Predict Bone Cement Leakage in Percutaneous Vertebral Augmentation for Osteoporotic Vertebral Compression Fracture Based on SHapley Additive exPlanations. Global Spine Journal. 2025; 15: 689–701. https://doi.org/10.1177/21925682231204159.

[48] Noguchi T, Yamashita K, Kamei R, Maehara J. Current status and challenges of percutaneous vertebroplasty (PVP). Japanese Journal of Radiology. 2023; 41: 1–13. https://doi.org/10.1007/s11604-022-01322-w.

[49] Bhatia C, Barzilay Y, Krishna M, Friesem T, Pollock R. Cement leakage in percutaneous vertebroplasty: effect of preinjection gelfoam embolization. Spine. 2006; 31: 915–919. https://doi.org/10.1097/01.brs.0000209307.03930.38.

[50] Chen JB, Xiao YP, Chen D, Chang JZ, Li T. Clinical observation of two bone cement distribution modes of percutaneous vertebroplasty in the treatment of thoracolumbar Kümmell's disease. Journal of Orthopaedic Surgery and Research. 2020; 15: 250. https://doi.org/10.1186/s13018-020-01774-8.

[51] Wang L, Zhang C, Liang H, Huang T, Zhong W, Zhao Z, *et al*. Cement leakage in percutaneous vertebroplasty for spinal metastases: a retrospective study of risk factors and clinical outcomes. World Journal of Surgical Oncology. 2022; 20: 112. https://doi.org/10.1186/s12957-022-02583-5.

[52] Li SF, Li XY, Bai XH, Wang YL, Han PF, Li HZ. A meta-analysis comparing the efficacy of mineralized collagen-polymethylmethacrylate and polymethylmethacrylate bone cements in the treatment of vertebral compression fractures. PloS One. 2024; 19: e0299325. https://doi.org/10.1371/journal.pone.0299325.

[53] Schwarz F, Klee E, Schenk P, Katscher S, Schnake KJ, Bäumlein M, *et al*. Impact of Anxiety During Hospitalization on the Clinical Outcome of Patients With Osteoporotic Thoracolumbar Vertebral Fracture. Global Spine Journal. 2025; 15: 417–424. https://doi.org/10.1177/21925682231192847.

[54] COPE Investigators. Cognitive Behavioural Therapy to Optimize Post-Operative Fracture Recovery (COPE): protocol for a randomized controlled trial. Trials. 2022; 23: 894. https://doi.org/10.1186/s13063-022-06835-3.

[55] Wang J, Xu X, Wang L, Huang W. Prognostic factors for patient-reported satisfaction after percutaneous lumbar endoscopic discectomy at a minimum of two years' follow-Up. Scientific Reports. 2024; 14: 22194. https://doi.org/10.1038/s41598-024-73366-z.