

Original Article

Clinical application of controllable bone cement injection during percutaneous vertebroplasty

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Abstract: Objectives: To compare the clinical efficacy and safety of controllable versus conventional cement injection during percutaneous vertebroplasty (PVP) for vertebral fractures, and to explore the factors associated with poor cement dispersion and leakage. Methods: This single-center retrospective study enrolled 200 patients with vertebral fracture who underwent PVP between Apr 2022 and Mar 2023. Patients were divided into the conventional cement injection group and controllable cement injection group. Visual analogue scale (VAS) scores were evaluated at baseline, postoperative day 1, and 3 months after surgery. In the controllable cement group, leakage rates were compared between the low- and standard-volume cement injection subgroups. Radiological and bone quality-related parameters were further analyzed according to cement dispersion patterns. Multivariate Logistic regression was used to identify independent risk factors for poor cement dispersion and leakage. Results: VAS scores decreased significantly at postoperative day 1 and month 3 compared with baseline values in both groups (all $P < 0.05$). Compared with the conventional injection group, the controllable bone cement injection group demonstrated shorter operation time, reduced intraoperative blood loss, lower cement injection volume, and shorter hospital stay (all $P < 0.05$). The two groups had similar preoperative VAS scores, whereas the controllable cement injection group presented significantly lower postoperative VAS scores (all $P < 0.05$). In the controllable cement injection group, patients with good cement dispersion achieved greater pain relief than those with poor dispersion ($P < 0.05$). In addition, the low-volume subgroup exhibited a lower cement leakage rate than the standard-volume subgroup ($P < 0.05$). Multivariate Logistic regression identified low bone mineral density, posterior vertebral cortical defects, and large cement injection volume as independent risk factors for poor cement dispersion and leakage. Conclusions: Controllable bone cement injection during PVP provides superior perioperative outcomes and improved postoperative pain relief compared with conventional cement methods for vertebral fractures.

Keywords: Percutaneous vertebroplasty, controllable bone cement, bone cement leakage, bone cement dispersion, pain score

Introduction

With the growth of the aging population, osteoporotic vertebral compression fractures (OVCFs) have become one of the most prevalent spinal disorders among older adults [1]. Reduced bone mineral density (BMD) and deterioration of trabecular structure render vertebrae susceptible to collapse following minor trauma or even daily activities, leading to severe pain, functional impairment, and prolonged recovery [2]. Although conservative treatment, including bed rest, analgesics, anti-osteoporosis drugs, remains an option for selected patients, its clinical efficacy is often limited and may cause complications such as

pressure ulcers and venous thrombosis [3]. In contrast, percutaneous vertebroplasty (PVP) has become a widely adopted minimally invasive intervention for OVCFs, providing rapid pain relief and reliable vertebral stabilization with minimal trauma [4, 5].

Conventional PVP typically involves manual injection of bone cement, during which injection pressure, flow rate, and cement volume are difficult to precisely regulate [6]. Consequently, uneven cement dispersion, characterized by unilateral or localized filling patterns, may occur, potentially compromising biomechanical balance and increasing the risk of adjacent vertebral refractures [7, 8]. Moreover, uncontrolled

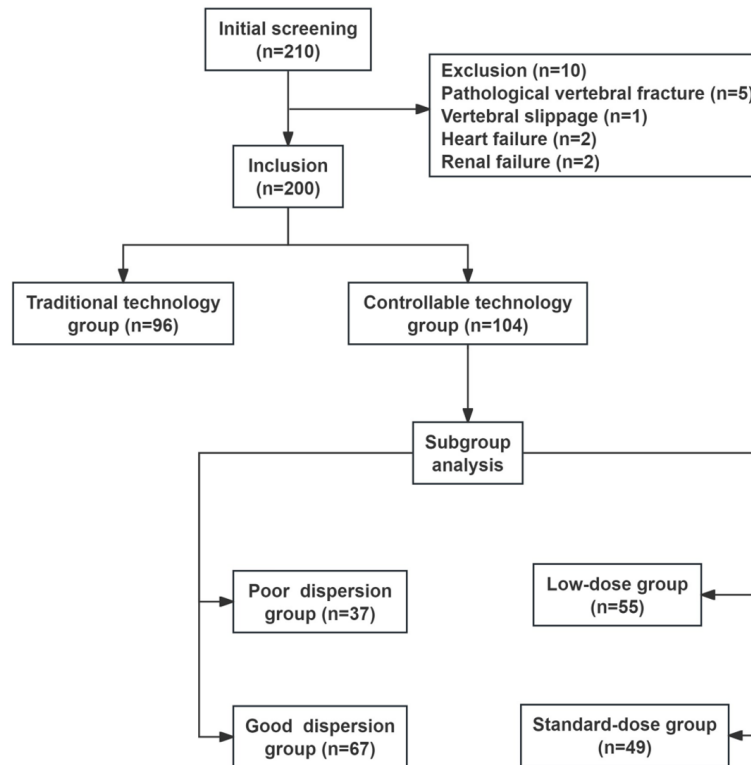


Figure 1. Flow chart of patient selection.

cement injection may generate transiently elevated intravertebral pressure, causing cement extravasation through cortical defects into paravertebral tissues, venous plexus, or the spinal canal. Cement leakage rates after PVP have been reported to range from 10% and 30%, and severe leakage can cause neurological complications or pulmonary embolism [9, 10]. These drawbacks highlight the need for improved cement delivery strategies.

To address these limitations, the controllable cement injection technique, which utilizes specialized delivery systems to regulate injection pressure, flow rate, and cement volume, has been developed [11]. By enabling steady, targeted filling, this approach facilitates more homogeneous cement distribution and reduces the risk of leakage [12]. Preliminary small-sample studies have shown potential benefits regarding injection precision and postoperative recovery; however, large-scale comparative data remains insufficient [13, 14]. Furthermore, the risk factors associated with suboptimal dispersion and leakage during controllable injection, especially the effects of BMD, cortical integrity, and cement

volume, remain insufficiently investigated [15, 16].

Therefore, this single-center retrospective study enrolled 200 patients with osteoporotic vertebral compression fractures who underwent PVP and compared conventional versus controllable cement injection techniques across multiple perioperative and clinical outcomes. Within the controllable injection group, subgroup analyses were performed to investigate the associations between cement volume and leakage risk, as well as between cement dispersion patterns and postoperative pain relief. Multivariate logistic regression analysis was used to identify independent risk factors for poor cement dispersion and leakage. This study aimed to clarify the potential clinical advantages of controllable cement

injection and provide evidence-based guidance for optimizing surgical safety and efficacy.

Patients and methods

Study design

This single-center retrospective cohort study consecutively screened 210 patients with vertebral fractures who underwent PVP between April 2022 and March 2023. After excluding 10 ineligible cases, a final cohort of 200 patients was included for subsequent study. According to the cement injection technique used during PVP, patients were divided into the conventional cement injection group (n=96) and the controllable cement injection group (n=104).

Two subgroup analyses were further conducted within the controllable injection group. First, patients were stratified into the low-volume subgroup (n=55) and the standard-volume subgroup (n=49) according to the injected cement volume. Then, patients were categorized into the satisfactory dispersion subgroup (n=67) and the poor dispersion subgroup (n=37) according to cement distribution patterns (**Figure 1**).

Inclusion criteria

(1) Osteoporotic vertebral compression fracture (OVCF) confirmed by imaging examinations, including X-ray, computed tomography (CT), and magnetic resonance imaging (MRI), with definite vertebral height loss and cortical disruption, with or without intravertebral cleft or posterior vertebral wall defect [17].

(2) Age >18 years, with clear indications for PVP, absence of absolute surgical contraindications, and availability of complete clinical records.

(3) Persistent thoracolumbar pain aggravated by physical activity as the primary complaint, with complete preoperative assessments, including visual analogue scale (VAS), BMD, routine blood tests, coagulation function tests, liver/kidney function assessments, and electrocardiography.

(4) Availability of complete documentation, including medical records, operative notes, cement injection parameters, imaging examinations, postoperative re-examinations, and follow-up data, allowing the extraction of baseline characteristics and perioperative variables, including operation time, intraoperative blood loss, cement volume, and length hospital stay.

(5) Completion of regular follow-up evaluations at postoperative 1 day and 3 months, including pain assessment and imaging re-examination.

(6) Underwent PVP at our hospital between April 2022 and March 2023, using either traditional or controllable cement injection techniques.

Exclusion criteria

(1) Pathological vertebral fractures due to tumors, multiple myeloma, tuberculosis, or pyogenic spondylitis.

(2) Severe spinal deformity, critical spinal canal stenosis, spondylolisthesis, prior spinal fracture surgery, or revision spinal surgery.

(3) Severe dysfunction of vital organs (heart, brain, lung, liver, kidney), severe coagulation disorders, or systemic infection.

(4) Psychiatric disorders or cognitive impairment affecting clinical assessment or follow-up compliance.

(5) Incomplete medical records or imaging data, loss to follow-up, or lack of valid follow-up data.

(6) Requirement for additional auxiliary spinal procedures during surgery, conversion to another surgical approach, or intraoperative termination of surgery.

(7) Long-term use of hormones, immunosuppressants, or other medications that may influence bone metabolism [18].

Surgical protocols

Conventional (non-controllable) bone cement injection group: Local infiltration anesthesia was achieved with 2% lidocaine hydrochloride injection (5 mL: 0.1 g; Shandong Hualu Pharmaceutical Co., Ltd., Shandong, China). Under fluoroscopic guidance using C-arm X-ray machine (HF-5000; Nanjing Perlove Medical Equipment Co., Ltd., Jiangsu, China), unilateral transpedicular puncture was performed using a PVP puncture needle (PVP-13G; Changzhou Baikangte Medical Devices Co., Ltd., Jiangsu, China). The needle was advanced gradually until its tip reached the junction of the anterior and middle thirds of the vertebral body.

After confirming the appropriate needle position, polymethyl methacrylate (PMMA) bone cement (FLAGSHIP; Triumphant Medical Co., Ltd., Shanghai, China) was prepared according to the manufacturer's instructions. When the cement reached the appropriate doughy phase, manual injection was performed using a standard syringe. Injection pressure and flow velocity were determined by the surgeon's tactile sensation, without quantitative pressure regulation. Real-time fluoroscopy was applied to monitor cement distribution throughout the procedure. Injection was halted immediately once extravasation was observed. After completion of injection, the puncture needle was maintained in position for 3 to 5 minutes. Following initial cement hardening, the needle was withdrawn, and compression hemostasis was applied at the puncture site before dressing coverage [19].

Controllable technology group: Anesthesia method, surgical positioning, puncture approach, and criteria for needle placement were identical to those adopted in the conventional injection group. After successful puncture, a controllable cement injection system (YKG-01; Beijing

Bangsai Technology Co., Ltd., Beijing, China) was connected to the puncture needle. Injection was implemented using a graded, constant-pressure, low-speed, and quantitative delivery protocol. Injection pressure was maintained within 0.2-0.4 MPa, and the flow rate was controlled at 0.2-0.4 mL/s. Each single injection volume was limited to 0.5-1.0 mL, and cement was delivered intermittently in multiple small aliquots. The same PMMA bone cement (FLAGSHIP, Triumphant Medical, Shanghai, China) was used as that in the conventional injection group.

The injection parameters and total injection volume were adjusted according to real-time fluoroscopic findings of cement distribution. A continuous low-pressure and stable delivery mode was maintained during the whole process to minimize transient pressure elevation and reduce the risk of cement leakage through cortical defects or intravertebral clefts. Participants in this group were further divided into the low-volume group (total injection volume ≤ 4.0 mL) and the standard-volume group (> 4.0 mL) based on actual total cement volume injected [20]. Cement solidification management and postoperative care were consistent with those in the conventional injection group.

Outcome measures

Intraoperative general parameters: The operative time, intraoperative blood loss, and total injection volume were recorded for all patients in both groups. Operative time was defined as the interval from skin puncture to needle removal after completion of cement injection. Intraoperative blood loss was estimated using the gauze weighing method. The weight difference between preoperative dry gauze and postoperative used gauze was measured using an electronic analytical balance (FA2004; Shanghai Liangping Instrument Co., Ltd., Shanghai, China), and the corresponding blood volume was calculated accordingly. The total cement volume injected was determined based on the built-in scale of the controllable injection system and the graduation mark of disposable medical syringes (5 mL; Jiangxi Hongda Medical Devices Group Co., Ltd., Jiangxi, China).

Pain severity assessment: Pain intensity was assessed using the visual analogue scale (VAS) preoperatively, and postoperative 1 day and 3

months. The VAS score ranges from 0 to 10 points, with 0 representing no pain and 10 the most severe pain [21]. All assessments were performed using standard paper VAS rulers (15 cm; Nantong Sanxin Medical Products Co., Ltd., Jiangsu, China).

BMD parameters: Before surgery, lumbar BMD was assessed using a dual-energy X-ray absorptiometry scanner (Dexa Pro-I; Suzhou Bosimei Medical Technology Co., Ltd., Jiangsu, China). During examination, patients were positioned supine and instructed to remove external metallic objects. The scanning region included the L1-L4 vertebral bodies, and the T-score values were automatically generated. The severity of osteoporosis was then classified based on the obtained T-scores [22].

Imaging evaluation indicators: Preoperative and postoperative imaging examinations were performed using a digital radiography system (DX-9500; Shenzhen Anjian Technology Co., Ltd., Guangdong, China), a 16-slice spiral CT scanner (NeuViz 16; Neusoft Medical Systems Co., Ltd., Liaoning, China), and a 1.5-T MRI system (uMR 560; United Imaging Healthcare Group Co., Ltd., Shanghai, China). The observed imaging parameters included the presence of intravertebral cleft sign, cortical defects on posterior vertebral wall, cement distribution pattern, and cement leakage. Cement dispersion was assessed according to postoperative imaging findings. Cases with cement evenly distributed within the vertebral body with continuous peripheral extension and without obvious voids were classified into the satisfactory cement dispersion group. In contrast, cases presenting localized cement aggregation and distinct vacant areas within the vertebral body were categorized into the poor dispersion group. Bone cement leakage was defined as the extravasation of cement beyond vertebral cortical boundaries into adjacent structures, including paravertebral soft tissues, intervertebral discs, vertebral venous plexus, and other surrounding tissues [23].

Postoperative hospital stay: Postoperative hospital stay was defined as the duration from the day of surgery completion to the day of discharge after fulfillment of clinical discharge criteria [24]. The admission and discharge dates were automatically recorded by the hospital electronic medical record system (V6.5;

Winning Health Technology Group Co., Ltd., Shanghai, China).

Data collection

All baseline data were systematically collected within 24 hours after patient admission, covering demographic characteristics, bone imaging findings, and laboratory examination results. Intraoperative parameters were extracted immediately after surgery. VAS pain scores were assessed at three predefined time points: preoperatively, postoperative day 1, and the 3-month follow-up visit. Postoperative imaging data were acquired during the first postoperative day re-examination, while hospital stay length and postoperative complications were recorded at discharge. Two orthopedic physicians who did not participate in surgical operations independently extracted and cross-checked all study data. Any discrepancies were resolved through re-evaluation of the original medical records and imaging files by a third assessor.

Ethical statement

This study was approved by the Ethics Committee of Longchang people's Hospital (Approval No.: 2022-03-001). The study was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki.

Sample size calculation

In this single-center retrospective controlled study, the incidence of bone cement leakage was selected as the primary endpoint for sample size estimation. Based on previously published studies on PVP [25, 26], the estimated leakage rates were assumed to be 22.0% in the conventional injection group and 8.0% in the controllable injection group. The significance level (α) was set at 0.05, the statistical power ($1-\beta$) was set at 0.8, and the allocation ratio between the two groups was set at 1:1. The formula for comparing two independent proportions was $n = \frac{2\bar{P}(1-\bar{P})(Z_{\alpha/2} + Z_b)^2}{(P_1 - P_2)^2}$, where P_1

and P_2 represent the estimated leakage rates in the two groups, respectively, and $\bar{P}$ represents the pooled leakage rate. Based on the assumed leakage rates and pooled proportion, the minimal required sample size was 86 cases per group. Considering the possibility of incom-

plete data in retrospective research, an additional 15% of patients were reserved. Ultimately, a total of 200 patients were included in the study, including 96 cases in the traditional injection group and 104 cases in the controllable injection group, which satisfied the pre-specified sample size requirements. After all data collection was completed, post-hoc power analysis was performed using G*Power 3.1 software. Based on the observed cement leakage rates in the two groups, a two-tailed test with $\alpha=0.05$ was conducted. The effect size (ϕ) was -0.207, and the actual statistical power $1-\beta$ was 0.86, higher than the conventional threshold of 0.8. This result indicates an adequate sample size and robust statistical performance. The risk of type II error was low, and the overall data possessed satisfactory statistical reliability.

Statistical analysis

All statistical analyses were performed using SPSS 26.0 software (IBM Corporation, USA). The distribution of continuous variables was assessed using normality tests. Normally distributed continuous variables were presented as mean $\pm$ standard deviation (SD) and compared between groups using the independent-samples t-test. For repeated measures analysis of variance was applied to compare data collected at different time points within the same group. Non-normally distributed continuous variables were described as median and interquartile range [M (Q1, Q3)], and intergroup comparisons were conducted using the Mann-Whitney U test. Categorical data were expressed as frequencies and percentages [n (%)] and compared using the chi-square test or Fisher's exact test, as appropriate.

To identify independent risk factors associated with poor cement dispersion and cement leakage, variables with $P<0.05$ in univariate analyses were entered into multivariate binary logistic regression models. Odds ratio (OR) and 95% confidence interval (CI) were calculated accordingly. All statistical tests were two-tailed, and a P value <0.05 was considered statistically significant.

Results

Comparison of baseline characteristics

Table 1 summarizes the baseline clinical data of the 200 enrolled patients, including 96

Table 1. Comparison of baseline clinical data between the two groups

Indicators	Total (n=200)	Conventional injection group (n=96)	Controllable injection group (n=104)	P	OR	95% CI for OR
Age (years)	69.72±6.52	69.70±6.48	69.73±6.59	0.972	1.001	0.959, 1.044
Sex (n %)				0.252	0.707	0.390, 1.280
Male	65 (32.5)	35 (36.5)	30 (28.8)			
Female	135 (67.5)	61 (63.5)	74 (71.2)			
BMI (kg/m ²)	23.22±2.88	23.15±2.96	23.29±2.81	0.727	1.017	0.924, 1.121
BMD T-score	-3.15±0.78	-3.24±0.76	-3.06±0.80	0.106	1.350	0.938, 1.941
Intravertebral cleft sign (n %)	73 (36.5)	32 (33.3)	41 (39.4)	0.372	1.302	0.730, 2.321
Posterior vertebral cortical defect (n %)	54 (27.0)	26 (27.1)	28 (26.9)	0.980	0.992	0.531, 1.853
Fracture segment (n %)				0.630	0.871	0.496, 1.528
T-segment	84 (42.0)	42 (43.8)	42 (40.4)			
L-segment	116 (58.0)	54 (56.2)	62 (59.6)			
Fracture type (n %)				0.497	1.233	0.673, 2.260
Compressive	140 (70.0)	65 (67.7)	75 (72.1)			
Burst	60 (30.0)	31 (32.3)	29 (27.9)			
Time from injury to operation (days)	6.36±2.82	6.13±2.62	6.56±2.99	0.277	1.057	0.957, 1.168

Note: OR: odds ratio; 95% CI: 95% confidence interval; SD: standard deviation; BMI: body mass index; BMD: bone mineral density; T: thoracic; L: lumbar.

cases in the conventional injection group and 104 cases in the controllable injection group. No significant differences were observed between the two groups in terms of age (69.70±6.48 years vs. 69.73±6.59 years, $P=0.972$), sex distribution (males: 36.5% vs. 28.8%; females: 63.5% vs. 71.2%, $P=0.252$), body mass index (BMI) (23.15±2.96 kg/m² vs. 23.29±2.81 kg/m², $P=0.727$) and lumbar BMD T-score (-3.24±0.76 vs. -3.06±0.80, $P=0.106$). There were also no intergroup differences in the positive rate of intravertebral cleft sign (33.3% vs. 39.4%, $P=0.372$), incidence of posterior vertebral cortical defect (27.1% vs. 26.9%, $P=0.980$), distribution of fracture segments (thoracic vertebrae: 43.8% vs. 40.4%; lumbar vertebrae: 56.2% vs. 59.6%, $P=0.630$), or fracture type classification (compression fracture: 67.7% vs. 72.1%; burst fracture: 32.3% vs. 27.9%, $P=0.497$). In addition, the interval between injury and surgery was also comparable between groups (6.13±2.62 days vs. 6.56±2.99 days, $P=0.277$). Overall, no significant differences were identified in baseline characteristics between the two groups, indicating adequate comparability for subsequent analyses.

Comparison of intraoperative parameters

The operative time was markedly longer in the controllable injection group than in the

traditional injection group (48.27±10.29 vs. 37.00±8.33 min, $P<0.001$). The Cohen's d value was -1.199, with a 95% CI for the mean difference ranging from -13.90 to -8.65 min. No significant difference was observed in intraoperative blood loss between the two groups (16.31±5.20 mL vs. 15.22±5.43 mL, $P=0.150$). The effect size was small (Cohen's $d=-0.205$), and the 95% CI of the mean difference ranged from -2.57 to 0.40 mL. The total injected volume of bone cement was significantly greater in the controllable injection group compared with the conventional injection group (5.04±1.01 vs. 4.48±1.07 mL, $P<0.001$; Cohen's $d=-0.542$; 95% CI: -0.85 to -0.27 mL). These findings demonstrated that the controllable cement injection technique required a longer operative time and was associated with a higher cement volume, while intraoperative blood loss was comparable between the two groups (Table 2).

Comparison of postoperative hospital stay

The controllable injection group showed a notably shorter postoperative hospital stay than the conventional injection group (3.89±0.97 vs. 4.83±1.29 days, $P<0.001$). The corresponding Cohen's d value was 0.829, and the 95% CI for the mean difference ranged from 0.62 to 1.26 days (Table 3).

Table 2. Comparison of intraoperative parameters between the two groups

Indicators	Total (n=200)	Conventional injection group (n=96)	Controllable injection group (n=104)	P	Effect size (Cohen's D)	t	95% CI of the difference
Operation time (min)	42.86±10.95	37.00±8.33	48.27±10.29	<0.001	-1.199	-8.472	-13.90, -8.65
Intraoperative blood loss (mL)	15.79±5.33	15.22±5.43	16.31±5.20	0.150	-0.205	-1.445	-2.57, 0.40
Injected volume of bone cement (mL)	4.77±1.08	4.48±1.07	5.04±1.01	<0.001	-0.542	-3.829	-0.85, -0.27

Note: 95% CI: 95% confidence interval; SD: standard deviation.

Table 3. Comparison of postoperative hospital stay between the two groups

Indicators	Total (n=200)	Conventional injection group (n=96)	Controllable injection group (n=104)	P	Effect size (Cohen's D)	t	95% CI of the difference
Postoperative hospital stay (days)	4.34±1.23	4.83±1.29	3.89±0.97	<0.001	0.829	5.791	0.62, 1.26

Note: 95% CI: 95% confidence interval; SD: standard deviation.

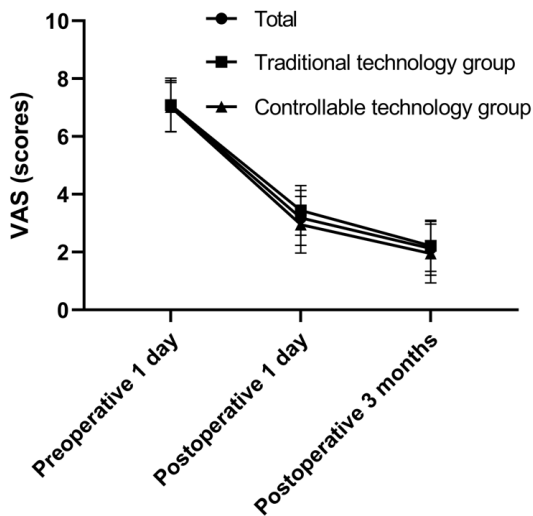


Figure 2. VAS score changes in all patients, conventional injection group, and controllable injection group. Note: VAS: visual analogue scale.

Comparison of VAS scores

As illustrated in **Figure 2**, VAS scores were relatively high before surgery in all included patients. No significant between-group difference was observed in preoperative VAS scores ($P=0.592$). The scores decreased significantly on postoperative day 1 and further decreased at the 3-month follow-up in both groups, showing sustained postoperative pain relief. Nevertheless, the conventional injection group exhibited significantly higher VAS scores than the controllable injection group on postoperative day 1 and 3 months after surgery ($P<0.001$; $P=0.007$). These findings demonstrate that the controllable cement injection provides more favorable and stable pain control after surgery.

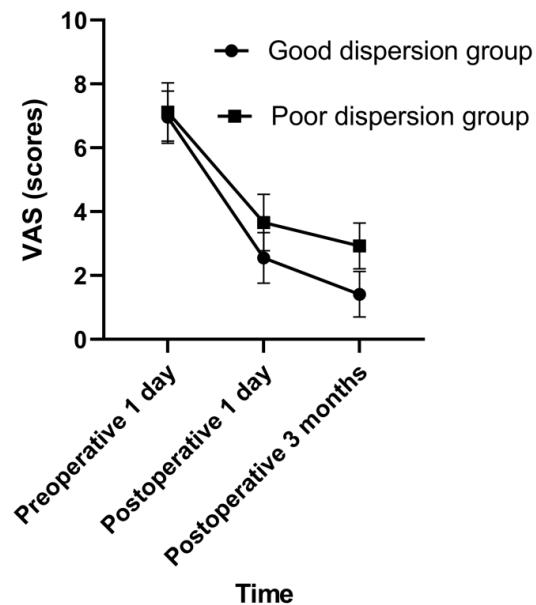


Figure 3. Changes in VAS scores in the satisfactory and poor cement dispersion subgroups. Note: VAS: visual analogue scale.

Comparison of VAS scores between the good and poor dispersion group in controllable injection group

Figure 3 presents the dynamic changes in VAS scores at three time points (preoperatively, postoperative day 1 and 3 months postoperatively) between patients with satisfactory dispersion (67 cases) and poor dispersion (37 cases) within the controllable cement injection group. The two subgroups showed comparable preoperative VAS scores ($P=0.365$). VAS values dropped remarkably in both groups on postoperative day 1, with a more prominent reduction

Table 4. Comparison of cement leakage rates between the low- and standard-volume subgroups

Indicators	Low-volume group (n=55)	Standard-volume group (n=49)	P	Effect size (Phi)	χ^2
Bone cement penetration (n %)	11 (20.0)	19 (38.8)	0.035	-0.207	4.451

Table 5. Multivariate logistic regression analysis of factors associated with poor bone cement dispersion during controllable cement injection

Indicators	B	P	OR	95% CI for OR
Age	0.060	0.580	1.061	0.859, 1.311
Gender	-1.898	0.150	0.150	0.011, 1.992
BMI	-0.094	0.694	0.910	0.570, 1.454
BMD T-score	-3.939	0.024	0.019	0.001, 0.589
Intravertebral cleft sign	2.167	0.220	8.731	0.273, 279.380
Posterior vertebral cortical defect	6.517	0.006	676.285	6.459, 70807.189
Fracture segment	1.759	0.246	5.809	0.298, 113.400
Fracture type	0.903	0.592	2.467	0.090, 67.298
Time from injury to operation	-0.110	0.639	0.896	0.567, 1.418
Operation time	0.019	0.788	1.020	0.885, 1.175
Intraoperative blood loss	0.149	0.231	1.160	0.910, 1.480
Injected volume of bone cement	2.224	0.033	9.241	1.195, 71.449

Note: OR: odds ratio; 95% CI: 95% confidence interval; BMI: body mass index; BMD: bone mineral density.

observed in the satisfactory dispersion group ($P<0.001$). The intergroup difference became more pronounced at the 3-month follow-up ($P<0.001$). In general, patients with satisfactory cement dispersion exhibited significantly lower postoperative VAS scores compared with those with poor dispersion at all follow-up time points.

Cement leakage rates with different injection volumes in the controllable injection group

Table 4 presents the comparison of cement leakage rates across different injection volume subgroups in patients undergoing controllable cement injection. In the low-volume group (<4 mL, $n=55$), cement leakage occurred in 11 cases, corresponding to a leakage rate of 20.0%. In the standard-volume group (≥ 4 mL, $n=49$), leakage was detected in 19 cases, with a leakage rate of 38.8%. The difference between the two groups was statistically significant ($\chi^2=4.451$, $P=0.035$), with a Phi coefficient of -0.207. These results indicate that a higher cement volume was associated with an increased risk of cement leakage in patients undergoing controllable cement injection.

Independent factors associated with poor cement dispersion in the controllable cement injection group

Table 5 summarizes the results of multivariate binary logistic regression analysis for risk factors associated with poor cement dispersion among patients treated with the controllable injection technique. A total of 12 candidate variables were included in the regression model. Lumbar spine BMD T-score was identified as a protective factor for poor dispersion ($B=-3.939$, $P=0.024$, $OR=0.019$, 95% CI: 0.001-0.589). This finding suggests that higher BMD was associated with a lower probability of poor cement dispersion. Conversely, posterior vertebral cortical defect ($B=6.517$, $P=0.006$, $OR=676.285$, 95% CI: 6.459-70807.189) and bone cement injection volume ($B=2.224$, $P=0.033$, $OR=9.241$, 95% CI: 1.195-71.449) were identified as independent risk factors.

No significant associations were observed between poor cement dispersion and intravertebral cleft sign ($P=0.220$), fracture segment ($P=0.246$), or fracture type ($P=0.592$). Likewise, age, sex, BMI, interval from injury to surgery, operative time, and intraoperative blood loss showed no significant correlation with poor

Table 6. Multivariate logistic regression analysis of factors associated with cement leakage during controllable cement injection

Indicators	B	P	OR	95% CI for OR
Age	0.052	0.597	1.053	0.870, 1.275
Sex	-0.312	0.494	0.732	0.300, 1.789
BMI	0.089	0.426	1.093	0.878, 1.361
BMD T-score	-1.856	0.003	0.156	0.046, 0.531
Intravertebral cleft sign	0.524	0.203	1.689	0.753, 3.789
Posterior vertebral cortical defect	1.734	0.001	5.654	1.970, 16.234
Fracture segment	0.318	0.425	1.374	0.630, 2.998
Fracture type	0.456	0.364	1.578	0.590, 4.221
Time from injury to operation	0.067	0.452	1.069	0.898, 1.273
Operation time	0.012	0.724	1.012	0.946, 1.083
Intraoperative blood loss	0.034	0.543	1.035	0.927, 1.155
Injected volume of bone cement	0.892	0.002	2.440	1.389, 4.286

Note: OR: odds ratio; 95% CI: 95% confidence interval; BMI: body mass index; BMD: bone mineral density.

cement dispersion (all $P > 0.05$). Overall, lower BMD, posterior vertebral cortical defects, and greater cement injection volume were independent influencing factors for poor bone cement dispersion during controllable cement injection.

Independent correlates of bone cement leakage in the controllable technology group

Table 6 presents the results of multivariate binary logistic regression analysis for factors associated with cement leakage in the controllable injection group. A total of 12 variables were included in the regression model. Lumbar BMD T-score was identified as a protective factor against cement leakage ($B = -1.856$, $P = 0.003$, $OR = 0.156$, 95% CI: 0.046-0.531). This finding indicated that higher BMD (more negative T-score) was associated with an increased risk of cement leakage. Posterior vertebral cortical defect ($B = 1.734$, $P = 0.001$, $OR = 5.654$, 95% CI: 1.970-16.234) and greater cement injection volume ($B = 0.892$, $P = 0.002$, $OR = 2.440$, 95% CI: 1.389-4.286) were independently associated with an increased likelihood of cement leakage.

No significant correlations were found between cement leakage and intravertebral cleft sign ($P = 0.203$), fracture segment ($P = 0.425$), or fracture type ($P = 0.364$). Similarly, age, gender, BMI, interval from injury to surgery, operation time and intraoperative blood loss were not associated with cement leakage (all $P > 0.05$).

Discussion

This retrospective study enrolled 200 patients who underwent PVP for vertebral fractures. We systematically compared the clinical outcomes of the controllable bone cement injection technique with those of the conventional injection method, and further explored the independent factors related to poor cement dispersion and cement leakage in patients treated with the controllable technique. The results demonstrated that although the controllable technique was associated with a longer operation time and greater cement volume, it achieved superior postoperative pain relief and a shorter hospital stay, indicating higher surgical efficiency and rehabilitation benefits. This advantage may be attributed to the precise regulation of injection pressure, flow rate, and volume by the controllable injection system. Such controlled delivery may facilitate more uniform three-dimensional cement dispersion within the vertebral body, thereby effectively restoring the biomechanical stability of the injured vertebra and providing a solid structural foundation for pain relief [27]. Notably, this study indicates an association between cement dispersion quality and postoperative pain outcomes in patients receiving controllable cement injection. Compared with patients with poor dispersion, patients with satisfactory dispersion exhibited significantly lower VAS scores at postoperative day 1 and 3-month follow-up. These findings suggest that achieving uniform cement dispersion may be more

clinically relevant than simply increasing cement volume during vertebral augmentation [28].

In the controllable injection group, the low-volume subgroup (≤ 4.0 mL) had a significantly lower cement leakage rate than the standard-volume subgroup (> 4.0 mL), suggesting the potential importance of cement volume control in reducing leakage risk. Excessive injection volumes significantly increase intravertebral pressure, driving cement to extravasate along low-resistance pathways such as cortical fissures and the basivertebral venous plexus [29]. Our subgroup analysis further demonstrated that even under pressure-controllable conditions, cement volume remains an independent factor affecting leakage, highlighting the need for simultaneous optimization of injection parameters and total cement volume. Therefore, clinicians should not rely solely on pressure regulation but should also carefully adjust cement volume according to vertebral characteristics to achieve an appropriate balance between mechanical stabilization and procedural safety [30]. Multivariate logistic regression analysis consistently identified lower BMD, posterior vertebral cortical defects, and greater cement injection volume as common independent risk factors for both poor cement dispersion and cement leakage. These findings have important clinical implications for preoperative risk assessment, as these variables reflect three key aspects of the procedure: bone quality, structural integrity of the vertebral body, and surgical operation intensity. Lower BMD reflects compromised trabecular architecture and reduced mechanical containment capacity, making cement more prone to irregular cement migration within the vertebral body and increase the likelihood of extravasation into surrounding structures [31, 32]. In the present study, the overall cement leakage rate in the controllable bone cement injection group was 28.8%. Although this rate was higher than the 7%-15% leakage rate reported for percutaneous kyphoplasty (PKP) in previous literature, it was significantly lower than the range of 10%-65% documented for conventional PVP. Notably, the observed leakage rate in the low-volume subgroup (20.0%) was markedly lower than that in the standard-volume subgroup (38.8%). More importantly, all leakage events were confined to low-risk areas such as the

paravertebral space and intervertebral disc space. This finding indicates that the controlled regulation injection pressure and flow rate may help limit bone cement migration patterns and reduce the occurrence of clinically significant leakage during vertebral augmentation.

In terms of risk factors for bone cement leakage, a retrospective study involving 120 patients with OVCs [25] reported that BMD, cortical defects and cement injection volume were independent risk factors for cement leakage after PVP, which is highly consistent with our findings. That study further identified BMD T-score as an important predictor of leakage risk and proposed that patients with a T-score below -3.0 may represent a higher-risk subgroup. For such patients, the use of higher-viscosity cement and a slower injection rate was recommended during surgery. A meta-analysis [33] investigating risk factors for cement leakage after percutaneous vertebral augmentation (PVA) demonstrated that impaired cortical integrity, intravertebral vacuum clefts, and vertebral basilar venous foramina were major anatomical risk factors associated with leakage, while cement injection volume represented a crucial procedure-related factor. Notably, the analysis highlighted that cement distribution characteristics may provide additional information regarding postoperative pain outcomes beyond cement volume alone. Another study focusing on cement distribution patterns in unilateral PVP [34] divided patients into satisfactory and poor dispersion groups. Although no significant differences were found between groups in baseline characteristics, operation time, cement volume, or leakage rate, patients with satisfactory dispersion showed lower VAS scores at 1 month and 1 year postoperatively, as well as a lower incidence of refracture of the injured vertebra. The study proposed that an H-type cement distribution pattern between the vertebral endplates may provide more favorable biomechanical support, whereas O-type distribution patterns (poor dispersion) may result in localized support and uneven stress transmission, which aggravated microfracture activity and undermined vertebral stability. These findings are consistent with our finding that favorable cement dispersion was associated with better pain relief. The discrepancy between previous studies and our findings regarding the correlation between cement vol-

ume and leakage rate may be attributed to different diagnostic criteria for good dispersion and varied cement viscosity adopted across studies.

Limitations and future research directions

Several limitations in this study should be acknowledged. First, as a single-center retrospective study, it was inevitably subject to potential selection bias and information bias. Variations in surgical experience and technical proficiency among different surgeons may have influenced the observed outcomes. Second, the overall sample size was relatively limited, particularly in the poor cement dispersion subgroup (n=37) in the controllable injection group, which may have reduced the statistical stability of regression analyses. Third, cement dispersion was assessed based on postoperative X-ray and CT findings without three-dimensional quantitative reconstruction or automated volumetric analysis. Accordingly, the grouping criteria may have involved certain observer subjectivity. Fourth, the follow-up period was limited to 3 months, preventing assessment of the long-term effects of cement distribution on vertebral height maintenance, adjacent vertebral fractures, and other delayed complications. Fifth, key parameters of the controllable injection technique, including injection pressure, flow rate, and cement viscosity, were not systematically stratified or analyzed, and their individual contributions to cement distribution outcomes remain unclear. Sixth, standardized functional outcome measures, such as the Oswestry Disability Index (ODI), were not included in this study. In addition, although cement leakage location was assessed using postoperative two-dimensional radiographs and plain CT scans, the absence of three-dimensional volumetric quantitative analysis may have limited the accurate evaluation of leakage severity and its clinical relevance.

Future studies should include multicenter, prospective, randomized controlled trials with larger sample sizes to further validate the clinical effectiveness and generalizability of the controllable cement injection technique. Three-dimensional CT-based quantitative evaluation should be developed to provide more objective evaluation of cement dispersion patterns. In addition, individualized models incorporating

cement injection volume, vertebral morphology, and BMD may help optimize injection strategies. Additionally, longer-term follow-up is also warranted to assess the impact of cement distribution characteristics on delayed outcomes, including adjacent segment fractures and vertebral recompression.

Conclusions

This study demonstrates that the controllable bone cement injection technique may provide favorable clinical outcomes in patients undergoing PVP. In clinical practice, preoperative assessment of BMD and posterior vertebral integrity may help identify patients at higher risk of poor cement dispersion and cement leakage. Individualized cement injection strategy is recommended to balance adequate vertebral augmentation with procedural safety. Further multicenter prospective studies are warranted to validate these findings and establish standardized protocols for individualized application of the controllable cement injection technique.

Disclosure conflict of interest

None.

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