Retrospective Study

Clinical Efficacy of Different Bone Cement Distribution Patterns in Percutaneous Kyphoplasty: A Retrospective Study

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Background: Bone cement distribution patterns in percutaneous kyphoplasty (PKP) is the key factor in keeping the vertebral stabilization and curative effect. However, the same cement volume can result in different bone cement distribution patterns and can thereby lead to different clinical outcomes. Therefore we investigated associations between cement distribution patterns and the occurrence rates of recompression in cemented vertebrae after PKP for patients with osteoporotic vertebral compression fractures (OVCFs).

Objectives: The study focuses attention on the influence of compact and dispersive cement distribution patterns in PKP for patients with OVCFs.

Study Design: A retrospective cohort study.

Setting: An affiliated people's hospital of a university.

Methods: According to different cement distribution patterns, patients were assigned to 4 groups. The demographic data, radiographic data, and clinical outcomes were compared between the 4 groups. The Visual Analog Scale (VAS) and Oswestry Disability Index (ODI) were evaluated before and 2 days after PKP. Moreover, the relationships between bone cement and clinical outcomes were analyzed. The epidemiologic data, clinical outcomes, and complications of the 4 groups were assessed. Comparisons of the radiologic and clinical results of the 4 groups were made pre- and postoperatively. Anterior height of fractured vertebrae (AH), the kyphotic Cobb angle, and the volumetric cubage index of the fractured vertebrae were measured.

Results: A total of 104 subjects were retrospectively analyzed and followed up (median age, 75.01 ± 8.42 years; age range, 56–94 years). The mean procedure duration was 61.26 ± 23.05 minutes (range, 30–140 minutes). The mean follow-up was 12.1 ± 2.2 months (range, 2–15 months). Statistically, there was no significant difference in terms of gender, age, body mass index, and bone mineral density ($P > 0.05$). The incidence of cement leakage was significantly lower in group A than those in the other groups. The total amount of bone cement injected into 104 cases (104 vertebral bodies in total) was 848.5 mL, and the amount of bone cement injected into a single vertebral body was 7.94 ± 1.38 mL. The amount of bone cement injection in each group was the lowest (6.80 ± 1.66 mL) in group D, followed by (7.94 ± 1.38 mL) group B, and the highest (8.96 ± 1.68 mL) in group A, with a statistically significant difference between the 4 groups ($P < 0.05$). No serious complications were observed during the follow-up periods. The AH and Cobb angle improved significantly for the 4 groups ($P < 0.05$). The VAS score decreased from 3.55 ± 0.54, 3.53 ± 0.65, 3.40 ± 0.58, and 3.40 ± 0.66 preoperatively to 0.18 ± 0.39, 0.23 ± 0.41, 0.20 ± 0.40, and 0.15 ± 0.36 at 48 hours postoperatively. The ODI score dropped from 35.65 ± 4.54, 36.45 ± 4.72, 34.12 ± 4.86, and 35.65 ± 4.34 preoperatively to 15.47 ± 1.32, 15.32 ± 1.34, 15.23 ± 1.26, and 15.73 ± 1.17 at 48 hours postoperatively.

Limitations: Our estimation of the vertebral body volume is imprecise. In addition, the number of subjects with OVCFs was small in this retrospective study. The volume of the fractured vertebra was not calculated accurately.

Conclusions: Significant associations between cement distribution patterns and bone cement leakage affected the clinical outcome in patients after PKP. A higher incidence of bone cement leakage was observed in patients with treated vertebrae exhibiting a single-dispersive or single-compact pattern.

Key words: Percutaneous kyphoplasty, osteoporotic vertebral compression fracture, bone cement distribution patterns

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Percutaneous kyphoplasty (PKP), a minimally invasive therapy, has been recommended to rapidly relieve intractable pain and regain lost function (1). Notably, the unilateral approach of PKP will lead to uneven distribution of bone cement. Insufficient cement distribution patterns in the fractured area of the index vertebra have been suggested to associate with new compression fractures in adjacent vertebrae and unrelieved pain after PKP (2,3). However, no studies are available concerning the comparison between confluent cement pattern and separated cement pattern treatment in fractured vertebral bodies.

Bone cement leakage and recompression can occur after PKP treatment, and some risk factors have been hypothesized. The representative risk factor is severe osteoporosis, and insufficient polymethylmethacrylate volume (4,5). The cement distribution pattern has been proposed to be associated with the occurrence of new compression fractures in adjacent vertebrae (6). However, no study has demonstrated the correlation between cement dispersion patterns and pain or functional improvement.

We reviewed our experience and hypothesized that different cement dispersion patterns and volumetric cubage index (VCI) in treated vertebrae affect the frequency of cement leakage. This study aims to develop propose for cement distribution patterns and to investigate the correlations between various variables in different cement distribution patterns, radiographic indices, and the occurrence rates of recompression in cemented vertebrae after PKP.

Methods

Patient Eligibility

The institutional review board of The Affiliated People's Hospital of Jiangsu University approved this study and written informed consent was received.

From December 2016 to May 2018, 104 patients underwent PKP procedures in our hospital for the treatment of osteoporotic vertebral compression fractures (OVCFs) that did not respond to conservative treatment. All patients underwent x-ray measurement and computed tomography to identify the vertebral fracture. Dual-energy x-ray absorptiometry was used to assess thoracolumbar spine bone mineral density (BMD). The study protocol was approved by the institutional ethics committee of the Affiliated People's Hospital of Jiangsu University (No. 2019-04-032) and written informed consent was obtained from all patients.

The inclusion criteria were (1) single symptomatic thoracic or lumbar VCF treated with PKP; (2) those without history of PKP surgery; (3) those regularly treated with an anti-osteoporotic during the follow-up period after PVP; (4) BMD T value ≤ –2.5; and (5) regular pre- and postoperative radiologic follow-up for more than 2 years.

The exclusion criteria were (1) patients lost to follow-up, (2) multiple-levels involved, (3) pathologic compression fractures caused by symptomatic hemangioma or metastasis, (4) unavailable preoperative magnetic resonance imaging and postoperative computed tomography scan, and (5) cannot tolerate surgery due to any internal and external diseases.

Grouping

The patients were assigned into 4 groups according to the bone cement distribution patterns observed on frontal and lateral radiographs. Group A (single compact): the vertebral body bone cement masses are spongiform dispersive masses; group B (single dispersive): the bone cement masses are compact masses; group C (bilateral compact): the bilateral bone cement masses are 2 compact and complete masses with no or only a small part of contact between them; group D (bilateral dispersive): the bilateral bone cement masses are spongy dispersive masses with no or only a small amount of contact between the 2 (Fig. 1, Table 1).

Kyphoplasty Procedure

After general anesthesia, the patient was placed in the prone position. The pedicle of the vertebral arch was punctured unilaterally or bilaterally, then the guide needle, dilated cannula, and working cannula were inserted to establish the working passage. Lateral fluoroscopy showed that the tip of the puncture needle was located at the junction of the pedicle and vertebral body. This ensured that the puncture needle passed through the pedicle and reached the first third of the vertebral body. After removing the puncture needle, bone cement was injected into the injured vertebral body at the later stage of wire drawing. After the hardening of the cement, we removed the needle and disinfected the wound, and dressed it with a sterile dressing. Intravenous antibiotics were routinely used for 2 to 3 days after the operation.

Fig. 1. *(A) Measurement of the anterior vertebral height and Cobb angle on postoperative lateral x-ray; (B) A is the length of the lower vertebral endplate on the frontal view; (C) B is the length of the lower vertebral endplate on the lateral view.*

Table 1. *Comparison of baseline characteristics of patients between different cement distribution patterns.*

Items		A (Single-compact)	B (Single-dispersive)	C (Double-compact)	D (Double-dispersive)	*P* Value
Number of cases		20	20	38	26	/
Age (yrs)		75.92 ± 8.47	73.35 ± 7.61	76.85 ± 7.93	73.60 ± 9.21	> 0.05
Gender (male/female)		11/27	2/24	7/13	3/17	< 0.05
BMI (kg/m^2)		22.6 ± 1.83	23.10 ± 2.08	21.10 ± 4.88	21.05 ± 2.93	> 0.05
BMD (T score)		–3 ± 1	–3 ± 1.2	–3 ± 1	–2 ± 2.1	> 0.05
Fracture types	Nearly normal	16	13	10	11	> 0.05
	Wedge-shaped	19	13	8	9	
	Crack	3	0	2	0	
Procedure duration (min)		58.86 ± 21.91	61.26 ± 23.05	70.78 ± 29.07	60.00 ± 23.39	< 0.05
Blood loss (mL)		4.63 ± 3.59	6.26 ± 4.23	4.61 ± 1.11	4.90 ± 3.83	< 0.05
Fracture vertebrae distribution	T11	5	3	1	1	> 0.05
	T12	9	7	2	4	
	L1	12	8	9	6	
	L2	4	5	5	3	
	L3	6	2	2	4	
	L4	2	0	1	2	
Injected cement volume (mL)		8.96 ± 1.68	7.94 ± 1.38	8.27 ± 1.23	6.80 ± 1.66	< 0.05
Cement leakage (n)		5 (25%)	5 (25%)	5 (13.15%)	3 (11.53%)	< 0.05
VCI		0.31 ± 0.08	0.26 ± 0.06	0.33 ± 0.07	0.30 ± 0.05	< 0.05

Parameters Observed

Data were collected on patient's age, gender, body mass index, bone mass density (T score), the volume of injected cement, fracture level, fracture severity grade, and procedure duration in reviewing medical records. Fracture severity grade was characterized based on the semiquantitative classification of Genant et al (7).

X-Ray Measurements

X-rays were reviewed and examined for cement leakage, anterior height of fractured vertebrae (AH), middle height of fractured vertebrae, and the kyphotic Cobb angle of the fractured vertebrae, and were taken and recorded preoperatively, 2 days postoperatively, and at the final follow-up to evaluate the extent of reduction and correction. At the last follow-up, the length of the lower vertebral endplate on the frontal view of x-ray was measured and recorded as A, the length of the lower vertebral endplate on the lateral view of x-ray was measured and recorded as B, and the height of the vertebral body was measured and recorded as H. Assuming that the vertebral body was an elliptical cylinder, the vertebral body volume can be calculated with the following formula:

$$V = \frac{\pi \times A \times B \times H}{2}$$

VCI = volume of bone cement volume/vertebral body volume. All the radiologic parameters were measured by a radiologist and a spine surgeon individually and independently to eliminate intra- and interobserver bias. All radiographs were stored in Digital Imaging and Communications in Medicine format and reviewed using the Picture Archiving and Communication System.

Assessment of Clinical Outcomes

The Visual Analog Scale (VAS) for back pain and the Oswestry Disability Index (ODI) were routinely administered to all patients (8,9). Clinical outcomes were compared between groups. Meanwhile, preoperative, immediate postoperative, 2 days postoperative, and 1-year VAS scores and ODI indices were compared.

Statistical Analyses

The statistical analysis was performed with SPSS Version 18.0 (SPSS Inc., Chicago, IL). The interrater reliability of the radiographic assessment of cement distribution patterns was assessed by the kappa analysis. The Wilcoxon rank-sum test was used to compare and analyze the patient age, weight, height, body mass index (BMI), T score of BMD, vertebral height restoration, Cobb angle correction, the anterior border of the vertebra, the volume of cement injected, and VAS scores. The differences in patient gender were evaluated by the Fisher exact test. The occurrence rate of recompression in cemented vertebrae among these groups was compared using the χ^2 test. A $P < 0.05$ was considered statistically significant.

Results

General Information of Patients

A total of 81 women and 23 men with 32 thoracic vertebras and 71 lumber vertebras received PKP treatment in our hospital. The mean age was 75.01 ± 8.42 years (range, 62–92 years). The mean BMI and BMD were 22.2 ± 3.02 and –3.0 ± 1.3, respectively. There was no significant difference between each group in terms of fracture types ($P > 0.05$). The mean blood loss in each group was 4.63 ± 3.59 mL, 6.26 ± 4.23 mL, 4.61 ± 1.11 mL, and 4.90 ± 3.83 mL, respectively. The mean procedure duration in each group was 58.86 ± 21.91 mL, 61.26 ± 23.05 mL, 70.78 ± 29.07 mL, and 60.00 ± 23.39 mL, respectively. The mean cement volume in each group was 8.96 ± 1.68 mL, 7.94 ± 1.38 mL, 8.27 ± 1.23 mL, and 6.80 ± 1.66 mL, respectively. There were still 5 (13.15%), 5 (19.23%), 5 (25.00%), and 3 (15.00%) patients experiencing cement leakage and recompression, respectively. However, there were no significant differences in the amount of cement leakage and fracture vertebrae distribution between the 4 groups (Table 2).

Radiologic and Clinical Parameters

The radiologic and clinical data documented preoperatively and 48 hours postoperatively are shown in Table 2. At the immediate postoperative period, AH, Cobb angle, VCI, VAS, and ODI at the time of preoperative point at 48 hours postoperatively were both significantly different in each group ($P < 0.05$). There were no differences in the Cobb angle between the 4 groups pre- and postoperatively. However, the improvement of the Cobb angle was higher in group C ($P < 0.05$). The VAS of groups A and B were significantly different 2 days after surgery. No significant differences were found in other parameters at the immediate postoperative period between the 4 groups ($P > 0.05$). The VAS showed significant improvement in all groups after operation ($P < 0.05$) (Table 3).

Table 2. *The functional outcomes for different cement distribution patterns.*

Group	VAS Score		*P* Value	ODI Score		*P* Value
	Preoperation	48 Hours Postoperation		Preoperation	48 Hours Postoperation	
Group A	3.55 ± 0.54	0.18 ± 0.39	< 0.05	35.65 ± 4.54	14.47 ± 1.32	< 0.05
Group B	3.53 ± 0.65	0.23 ± 0.41	< 0.05	36.45 ± 4.72	15.32 ± 1.34	< 0.05
Group C	3.40 ± 0.58	0.20 ± 0.40	< 0.05	34.12 ± 4.86	15.23 ± 1.26	< 0.05
Group D	3.40 ± 0.66	0.15 ± 0.36	< 0.05	35.65 ± 4.54	14.63 ± 1.17	< 0.05
P value	> 0.05	> 0.05		> 0.05	> 0.05	

Table 3. *Comparison of radiographic outcomes for different cement distribution patterns.*

Group	AH		*P* Value	Cobb angle		*P* Value
	Preoperation	2 Days Postoperation		Preoperation	2 Days Postoperation	
A	23.64 ± 4.71	27.18 ± 4.37	< 0.05	7.05 ± 5.05	7.7 ± 5.68	< 0.05
B	22.72 ± 3.93	26.33 ± 4.03	< 0.05	8.15 ± 6.46	8.35 ± 6.27	< 0.05
C	20.72 ± 5.42	27.05 ± 4.34	< 0.05	9.10 ± 5.57	7.05 ± 5.84	< 0.05
D	22.38 ± 4.45	26.2 ± 2.90	< 0.05	8.34 ± 5.54	7.23 ± 4.42	< 0.05
P value	> 0.05	> 0.05		> 0.05	< 0.05	

Correlation Analysis

A correlation analysis was performed to explore the relationships between cement characteristics and radiologic and clinical outcomes (Table 4). The restoration of AH was positively correlated with cement volume. VCI was correlated with the improvement of cement volume and procedure duration. Cement volume was correlated with procedure duration .

Discussion

This study aimed to evaluate the cement distribution and VCI in assessing PKP and to investigate the relationships among cement distribution, VCI, and clinical outcomes. Based on the cement distribution pattern, a total of 104 patients were assigned to 4 groups. Although baseline characteristics among the 4 groups showed no significant differences, the restoration rate of AH, improvement of Cobb angle, and procedure duration in group C were higher than those in the other 3 groups. Besides, single-extensive distribution showed the same recuperative effect as single-confined distribution. Under the condition of the same cement distribution, there are significant positive correlations between VCI, restoration rate of AH, and improvement of Cobb angle.

This study showed that VAS and ODI scores improved significantly after surgery in each group ($P <$ 0.05), confirming that PKP could effectively alleviate pain and reduce recompression rate postsurgery. Moreover, the VAS and ODI scores of the patients showed significant improvement in groups A and D than in groups B and C at the final follow-up, indicating that extensive distribution of treated vertebrae has certain advantages in long-term pain relief. The results demonstrated that all cement distribution patterns in PKP can relieve pain and reduce spinal biological curvature. Moreover, the survival analysis for VAS showed that age, cement volume, and VCI resulted in the improvement of pain. Older people were found to be more tolerant of pain after surgery than young people by Hayashi et al (10).

VAS and ODI scores showed significant improvement postoperatively in this study, indicating that PKP could relieve pain and reduce recompression after the operation. He et al (11) defined complete pain relief as a VAS score of 0 or 1 at 3 months after surgery. A meta-analysis from Mao et al (12) found that short- and long-term VAS outcomes were internally inconsistent within the subgroups. As such, we think it is incorrect to diagnose a patient as recuperated only by his or her postoperative VAS outcome. However, the VAS and ODI scores in the groups A and B were significantly higher than in the other groups at the final follow-up ($P <$ 0.05), suggesting that insufficient bone cement distri-

Table 4. *Correlation between cement characteristics and surgery outcomes.*

Clinical Outcomes		Restoration of AH	Restoration of Cobb Angel	VCI	Cement Volume	VAS Score	ODI Score	Procedure Duration	Blood Loss	Bone Leakage
Restoration of AH	R	1	−0.174	0.103	0.238*	0.078	0.128	−0.122	−0.161	−0.040
	P		0.078	0.296	0.015	0.428	0.632	0.219	0.103	0.687
Restoration of Cobb angel	R		1	−0.047	0.014	0.100	0.142	−0.018	0.062	0.035
	P			0.634	0.891	0.314	0.422	0.856	0.533	0.723
VCI	R			1	0.708**	−0.030	0.060	−0.212*	−0.134	0.083
	P				0.000	0.760	0.982	0.031	0.175	0.403
Cement volume	R				1	0.009	0.032	−0.199*	−0.103	0.024
	P					0.932	0.752	0.043	0.299	0.807
VAS score	R					1	0.683	0.167	−0.050	−0.027
	P						0.029	0.090	0.613	0.787
ODI score	R						1			
	P									
Procedure duration	R							1	0.131	−0.104
	P								0.186	0.295
Blood loss	R								1	−0.079
	P									0.423
Bone leakage	R									1
	P									

Fig. 2. *The patterns of cement distribution. (A) Single-compact pattern; (B) single-dispersive pattern; (C) double-compact pattern; (D) double-dispersive pattern.*

bution could cause serious clinical symptoms. It might have resulted from the instability in the cemented vertebrae with single and compact transform patterns and aggravation of deformity by recompression.

Yan et al (13) reported that PKP could restore vertebral height and correct kyphotic deformity. The improvement in radiographic findings, including vertebral height and Cobb angle, is adopted to assess the efficacy of PKP (14). This study reported that the restoration rate of anterior height and improvement of kyphotic Cobb angle in groups C and D were both higher than those in groups A and B.

To our knowledge, the present study is first conducted to investigate the relationship between bone cement distribution patterns and bone cement leakage in cemented vertebrae following PKP in patients with OVCFs. In addition to osteoporosis as fracture etiology, we restricted the analysis to patients with a single-level fracture and typical location of the fractured area for creating a uniform cohort and simplifying interpretation of the results.

We demonstrated that the vertebral recompression rate in group A was significantly higher than that in group B by subgroup analysis. The bone cement filling the cancellous bone helps the body load disperse homogeneously in the bone cement, cranial endplates, and caudal endplates. Liebschner et al (15) found that both bipedicular and unipedicular perfusion of bone cement could restore vertebral strength, but greater stiffness was obtained with symmetrical distribution. Besides this point, they believed that the fraction of cement volume rather than the absolute cement volume was more valuable. Besides, bone cement leakage is also closely related to vertebral refracture: (1) the uneven distribution of bone cement in the diseased vertebra leads to the uneven improvement of the strength and stiffness of each part of the vertebral body, and (2) the relative strength and stiffness of the injured vertebral body after the injection of bone cement is significantly improved compared with the adjacent vertebral body. Theoretically, the annular distribution of bone cement along the vertebral body edge can reduce the uneven stress of the adjacent vertebra, and thus reduce the risk of refracture (16).

The cemented-cement interface failure may cause vertebral height loss. However, we found no difference in the incidence of bone cement leakage in cemented vertebrae between groups A and B. No previous study reported this phenomenon and explored whether cement interlock with the surrounding cancellous portion in the single-dispersive distribution pattern was more effective than a single-compact pattern in maintaining the vertebral height.

Our results about different bone cement distribution patterns further our understanding of the relationships between bone cement leakage and cement distribution patterns after PKP (Fig. 2).

Xiang et al (17) reported that complications involving the overall incidence of cement leaks was associated with clinical complications, ranging from 6.8% to 21.9%. Hence the preoperative prediction of cement leakage would be helpful and facilitate a reduction in the incidence of cement leakage. Sun et al (18) reported that cement leakage could be limited in the case of bone nonunion and peripheral walls deficiency. In this study, the overall leakage rate was below the previously reported value, most incidences were asymptomatic, and no serious complications observed (4).

Insufficient cement distribution was associated with bone cement leakage because pressure in the vertebral body prevents bone cement from the injection and sufficient dispersion (19). Once any bone cement leaks are noted during the operation, bone cementation should be terminated immediately (20). Here we demonstrated that a significant relationship between bone cement leakage and cement distribution, although the incidence of cement leakage was higher in groups A and B (25.00% and 25.00%, respectively) than in groups C and D (13.15% and 11.53%, respectively), was consistent with previous studies that detected cement leakage by postoperative computed tomography (18).

Limitations

Several limitations existed in this retrospective study. First, although the cement area observed by x-ray was always measured by the same experienced radiologist, the cement distribution in fractured vertebra was not accurately calculated. However, manual counting would introduce inevitable errors. A new way to measure cement distribution by using x-rays should be explored. Second, it was a retrospective study having a limited number of patients and a short-term follow-up, which may alter the accuracy of conclusions. Third, the volume of the fractured vertebra was not calculated accurately for the irregular elliptical columnar vertebrae. Fourth, some other influencing factors, such as degree of kyphosis correction and fracture morphology, may exist.

Conclusions

This study indicates that the cement distribution pattern in group A was significantly related to bone cement leakage, which also had an impact on the radiologic and clinical outcomes after PKP. Also, corrections of radiologic parameters or the loss of correction during the postoperative follow-up period were not associated with pain or functional improvement. Furthermore, a higher occurrence of bone cement leakage in the cemented vertebrae was observed in vertebrae exhibiting a single-compact distribution pattern or single-dispersive distribution pattern. The single-compact distribution pattern, which has a better VCI, shows a greater therapeutic value than that of cement volume for radiologic and clinical outcomes.

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