Pain Physician 2016; 19:495-506 • ISSN 1533-3159

Retrospective Study

Percutaneous Kyphoplasty Evaluated by Cement Volume and Distribution: An Analysis of Clinical Data

Xin He, MD, Hui Li, MD, YiBin Meng, MD, YunFei Huang, MD, DingJun Hao, MD, QiNing Wu, MD, and JiJun Liu, MD

From: Xi'an Jiatong University
Xi'an, Shannxi China

Address Correspondence:
Dingjun Hao, MD
Xi'an Jiaotong University
Xi'an Shannxi China
0769-22823031
NO.555, Youyi Road, Beilin
District, Xi'an Shannxi
E-mail:502156955@qq.com

Disclaimer: There was no external funding in the preparation of this manuscript.
Conflict of interest: Each author certifies that he or she, or a member of his or her immediate family, has no commercial association (i.e., consultancies, stock ownership, equity interest, patent/licensing arrangements, etc.) that might pose a conflict of interest in connection with the submitted manuscript.

Manuscript received: 08-31-2015
Revised manuscript received: 02-17-2016
Accepted for publication: 03-28-2016

Free full manuscript:
www.painphysicianjournal.com

Background: Percutaneous kyphoplasty (PKP) could achieve rapid pain relief for older patients with osteoporotic vertebral compression fractures (OVCFs). Bone cement in PKP was the key factor keeping the stabilization of the vertebral body. However, the same amount of cement can distribute differently in a vertebral body and can thereby result in different surgery outcomes. Therefore, the volume and distribution of bone cement should be considered as 2 distinct variables to evaluate the effectiveness of PKP.

Objectives: On the basis of comparing surgery outcomes between patients with different recovery states measured by visual analog scores (VAS) and exploring the relationships among bone cement, surgery outcomes, and degrees of pain relief, the objective of the study is to determine the best combination of cement volume and cement distribution for PKP.

Study Design: Retrospective study.

Methods: There were 220 patients with 220 vertebra who received PKP in our hospital from January 2011 to January 2013. According to the different pain relief degrees, patients were divided into 2 groups. The epidemiological data, surgical outcomes, and complications were compared between the 2 groups. A receiver operating characteristic curve (ROC) was used to analyze the diagnostic value of bone cement on patient recovery state. A correlation analysis was used to analyze the relationships between bone cement and surgery outcomes. Moreover, logistic regression was also used to assess the safety of cement injection.

Results: There were 77 recuperators and 143 non-recuperators in our study. There were no differences in epidemiological data between the 2 groups. However, the surgery duration, cement volume, cement distribution, restoration rate of vertebral height, and improvement of kyphotic angle in the recuperator group were all higher than those in the non-recuperator group. The area under the ROC curve of cement distribution as a predictor of pain relief was better than that of cement volume (0.77 vs. 0.65, $P < 0.05$). Cement distribution had a sensitivity of 62% and a specificity of 84% when it was at 0.49. Cement volume had a sensitivity of 49% and a specificity of 82% when it was at 3.80 mL. All patients were then divided into 4 parts based on the 2 values. Extensive cement distribution (more than or equal to 0.49) was discovered to noticeably increase the recuperative rate both for a small cement volume (less than 3.80 mL) and a large cement volume (more than or equal to 3.80 mL). A small cement volume with an extensive distribution had the same recuperative effect as a large cement volume with a confined distribution ($\chi2 = 2.880$, $P = 0.090$). When the cement volume was constant, cement distribution was positively correlated with the restoration rate of vertebral height and improvement of the kyphotic angle ($r2 = 0.207$, $P < 0.01$; $r2 = 0.159$, $P = 0.02$), but cement distribution was not a risk factor for cement leakage or adjacent vertebral fractures (OR = 35.760, 95%CI: 0.096 – 13291.207, $P > 0.05$; OR = 0.051, 95% CI: 0.011 – 1.032, $P > 0.05$). Although a large cement volume may contribute to the restoration of vertebral height ($r2 = 0.153$, $P < 0.05$), it was found to be a risk factor for adjacent vertebral fractures (OR = 1.733, 95% CI: 1.158 – 2.595, $P < 0.05$).

Limitations: The distribution of cement in fractured vertebra was not calcuated accurately.

Conclusions: The diagnostic value of cement distribution is better than that for cement volume in relieving patient pain. A cement distribution above 0.49 with a small cement volume should be suggested for PKP. An extensive cement distribution can improve the kyphotic angle and vertebral height effectively, and it does not cause cement leakage or adjacent vertebral fractures.

Key words: Psteoporotic vertebral compression fractures percutaneous kyphoplasty cement volume cement distribution

Pain Physician 2016; 19:495-506

Vertebral compression fractures (VCFs) are a major health problem. The annual incidence of VCFs is 10.7/1000 in women and 5.7/1000 in men. It is the major cause of disability and a burden for national health care budgets (1). Elderly people, especially those with osteoporosis, more easily develop VCFs (2). It is estimated that osteoporotic vertebral compression fractures (OVCFs) will develop in 8% of women older than 50 years and 27% of men and women older than 65 years (3). The consequences of OVCFs have a substantial negative impact on patient function and quality of life (4).

There are surgical and non-surgical methods for treating OVCFs. The non-surgical managements include taking painkillers, improving functional status, or preventing future fractures (5). However, they have limited effectiveness and serious side-effects (6). Compared with non-surgical methods, PKP, as a surgical method, is minimally invasive and easy to perform. PKP can reduce pain to a large extent, restore lost vertebral body height, and improve quality of life (7).

The bone cement used in PKP is made of viscous polymethylmethacrylate (PMMA). Cement augmentation results in the stabilization of micromovements and prevention of progressive collapse of the fractured vertebral body (8). However, an excessive injection of cement may cause some biomechanical changes, including endplate necrosis and leakage into the disc space, spinal canal, and vascular area (9). This may suggest that a minimal intravertebral cement volume should be used. However, few researchers have explored the amount of PMMA consumed in the process of surgery and its actual distribution in the vertebral body. Many studies have confirmed that an adequate cement proportion with a small cement volume can achieve good surgical results (10-12), which indicates that cement volume and cement distribution should be considered as 2 distinct variables to evaluate PKP. The aim of this study is to adopt the use of an x-ray method to calculate and evaluate the cement volume and distribution of PKP to provide guidance for surgeons to effectively perform surgery and to reduce as many complications as possible.

Methods

Patients

Between January 2011 and January 2013, there were 220 patients diagnosed with OVCF and having PKP surgery in our hospital. All patients had acute or chronic focal back pain, some of which was alleviated by lying on the back. Tenderness and percussion pain at a fractured vertebral body were found from physical examination.

The inclusion criteria were as follows: 1) single vertebral compression fracture; 2) fracture without any pressure in the spinal canal or nerve lesion; 3) osteoporosis (diagnosed by bone mineral density, T value ≤ -2.5); 4) intact vertebral posterior wall; and 5) repeat spinal radiographs obtained during follow-up period.

The excluding criteria were as follows: 1) patients lost to follow-up; 2) a patient history of previous percutaneous vertebroplasty (PVP) or PKP; 3) clinical or imaging evidence of metastatic bone tumor or multiple myeloma; and 4) any complications of the endocrine system (such as diabetes, thyroid dysfunction, and so on).

This study was approved by the medical ethics committee of Xi'an Jiaotong University.

Surgical Technique

PKP has been described in previous studies (13). The procedure was performed under either general or local anesthesia with a unilateral way. X-ray fluoroscopy was used throughout the procedure. A stab incision was made on the pedicle level of the skin. The correct incision site was identified with the anteroposterior (AP) view of the image intensifier. A needle pipe and pin were placed via a stab incision. The tip was lateral to the pedicle projection in the AP view and parallel to the superior endplate in the lateral view. Then, the needle pin was removed and a guide wire was introduced into two-thirds of the vertebral body. A cannula and expander were inserted into the pedicle through the wire pin. Next, the wire pin was removed and a drill was inserted through the cannula. The balloon was slowly inflated with the initial bulk pressure. Next, the operator controls the volume of the balloon to recover the damaged vertebral body with micro pressure until an adequate kyphotic angle reduction was obtained. Lastly, the balloon was deflated and withdrawn, and the resulting cavity was filled with PMMA cement.

Surgery Outcomes

The follow-up time was set every 3 months in one year postoperatively (Fig. 1). Patient physical examinations and spinal radiographs were taken at each time.

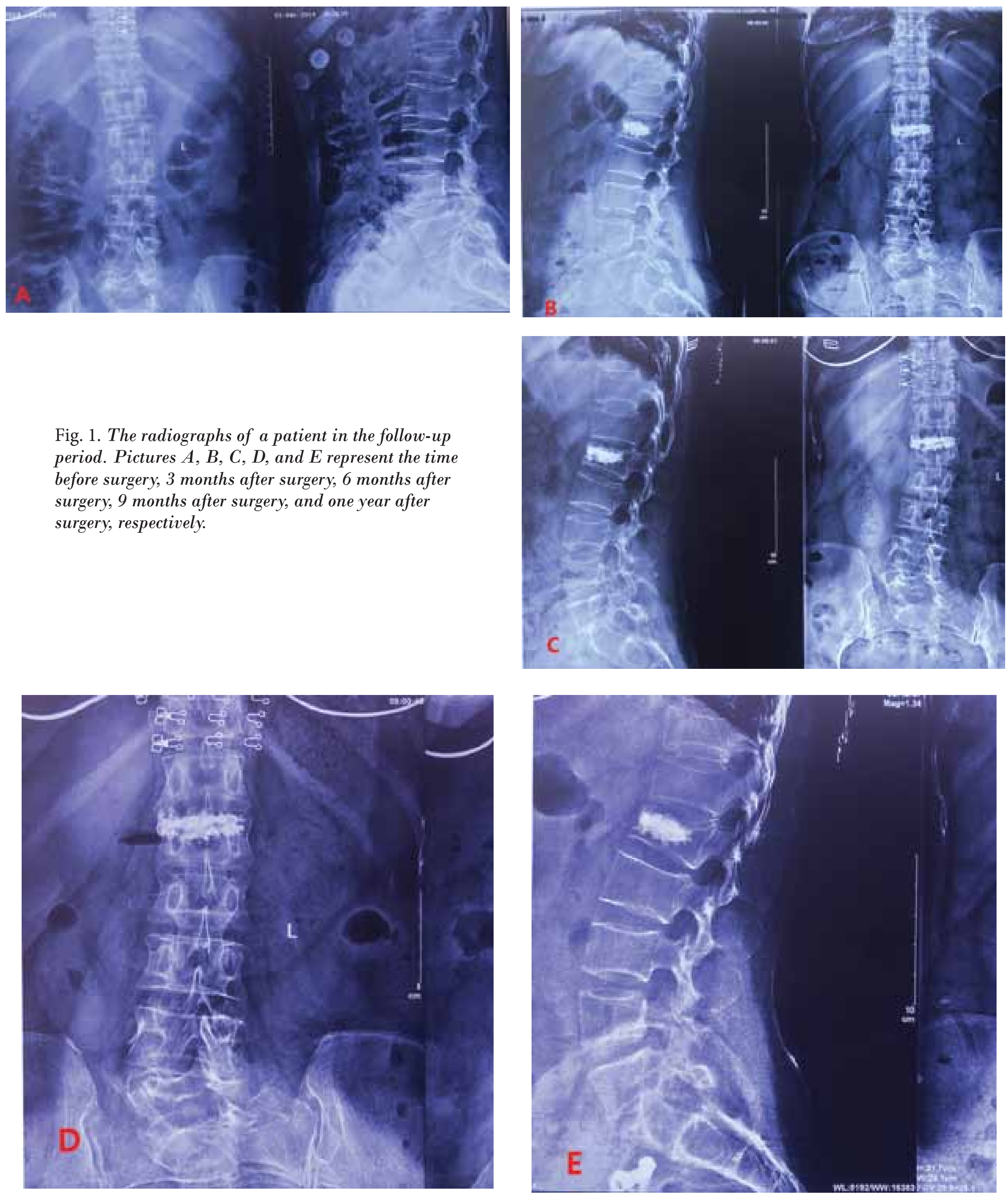

Fig. 1. *The radiographs of a patient in the follow-up period. Pictures A, B, C, D, and E represent the time before surgery, 3 months after surgery, 6 months after surgery, 9 months after surgery, and one year after surgery, respectively.*

Long-term recovery data were recorded at one year after surgery and represented the postoperative data. All preoperative data were recorded on the day before surgery. X-rays were used for clinical test.

The cement volume and surgical duration were recorded by the operators. The cement distribution was calculated as the mean ratio of bright areas to the whole fractured vertebra area both in the AP and lateral views under x-rays after surgery (Fig. 2). Bone mineral density (BMD) was measured by dual x-ray radiographic absorptiometry. The degree of focal back pain was assessed by visual analog scale (VAS) (0 = no pain, 10 = worst pain). While the VAS differences were calculated as follows: preoperative VAS-postoperative VAS. The restoration rate of vertebral height was calculated as follows: (postoperative vertebral heigh-preoperative vertebral height)/(predicted primary vertebral height-preoperative vertebral height)x100% (Fig. 3). The pre-

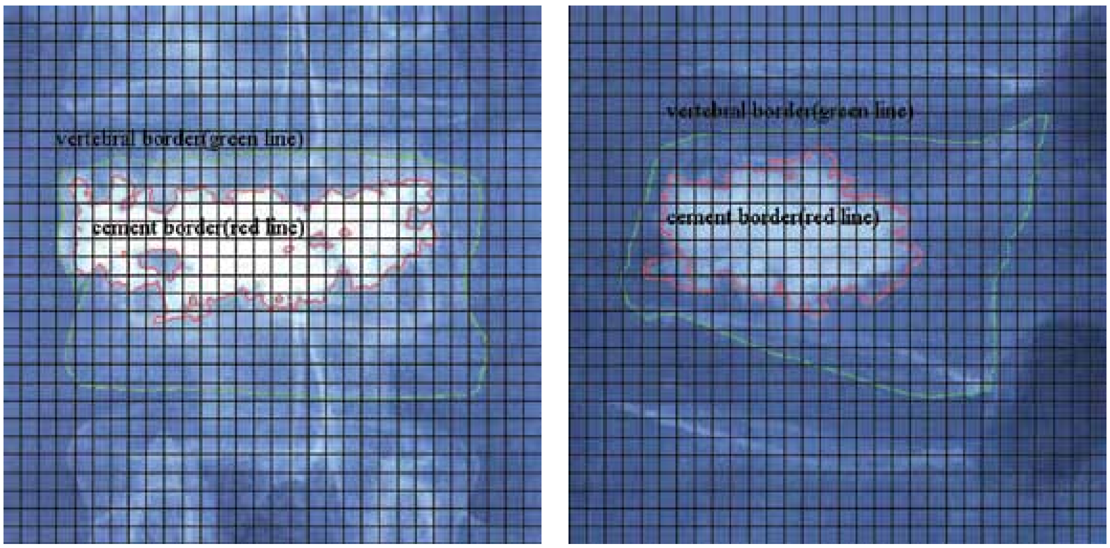

Fig. 2. *Measurement of cement distribution. We selected the portion of fractured vertebra in the picture and put it into a new 15 cm*15 cm transparent layer. The layer was divided by a number of the same sized squares. The area of each square was 0.25 mm2. Different brightness areas were automatically selected by the software. The green line represents the vertebral border and the red line represents the cement border. If the selected area covered more than half of the square, the area was calculated as 1. Otherwise, it was 0. Then, the ratio of cement area to vertebral cross-sectional area was estimated. The picture indicates that the cement distributions were 105/307 and 88/269 in the AP and lateral views, respectively. Thus, the total cement distribution was 66.92%.*

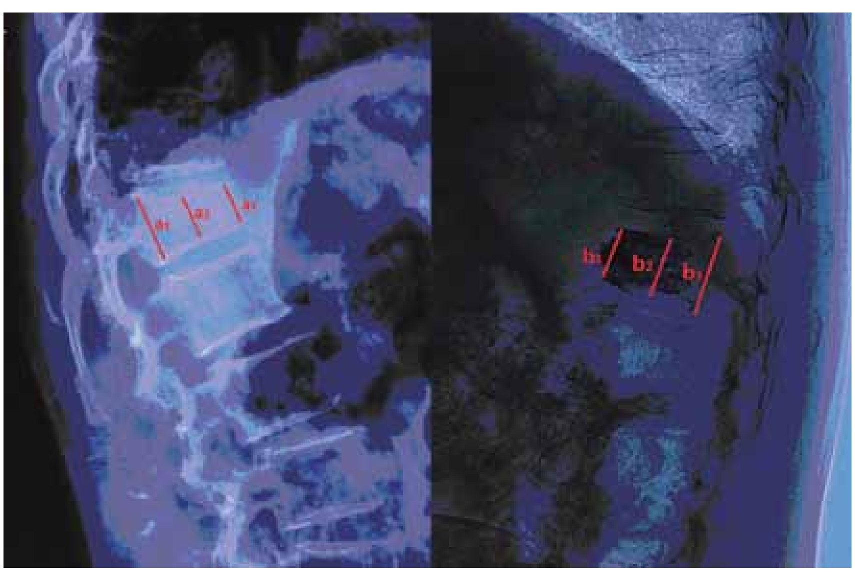

Fig. 3. *Measurement of the vertebral height. In the figure, a2 and b2, which were equal to (a1 + a3)/2 and (b1 + b3)/2, respectively, were represented as the preoperative vertebral height and postoperative vertebral height. The restoration rate of vertebral height was calculated as follows: (postoperative vertebral height - preoperative vertebral height)/(predicted primary vertebral height - preoperative vertebral height)*100%.*

dicted primary vertebral height was the mean height of 2 vertebrae adjacent to the injured vertebra. Improvement of the kyphotic angle was calculated as follows: preoperative Cobb angle-postoperative Cobb angle. Cobb angle was measured from the superior endplate of vertebra one level above the treated vertebra to the inferior endplate of the vertebral one level below the treated vertebra on the lateral x-ray image (Fig. 4). Cement leakage was defined as any presence of extravertebral high cement signal observed by x-ray. Adjacent vertebral fracture postoperatively was defined with any vertebral fracture next to the treated vertebral body.

For the purpose of this study, patients were divided into 2 groups according to VAS differences. One was recuperators group in which patient VAS differences were more than or equal to 5; the other was the non-recuperator group in which patient VAS differences were less than 5.

Clinical follow-up examinations of patients were independently performed by an orthopedic specialist and diagnostic images were independently evaluated by a radiologist.

Statistical Analysis

Data were analyzed using the SPSS18.0 software (IBM, Armonk, NY, USA). Numeric variables were expressed as means ± standard deviation (SD). Nominal variables were expressed as numbers (percentage). A ROC curve was constructed and the area-under-curve was calculated to assess which was better in evaluating patient recovery state after PKP, cement volume or cement distribution. A correlation analysis was used to analyze the relationship between bone cement and surgery outcomes. Cement leakage and adjacent vertebral fractures were used as surgery complications to evaluate the safety of bone cement in the method of logistics regression. The statistical significance was set at $P < 0.05$.

Results

General Information of Patients

A total of 164 women and 56 men with 85 thoracic vertebras and 135 lumber vertebras received PKP in our hospital. The mean age was 71.4 ± 8.7 years (range from 56 years to 91 years). There were 146 patients (66.4%) that underwent local anesthesia. The mean body mass index (BMI) and BMD were 24.26 ± 4.13 and -3.78 ± 0.94, respectively. The VAS improved from 7.0 ± 1.4 preoperatively to 2.3 ± 2.1 postoperatively (T = 26.787, $P <$ 0.001). According to VAS difference, 77 patients were recuperators and 143 patients were non-recuperators. There were no statistical differences in demographic data between the 2 groups. The details are shown in Table 1.

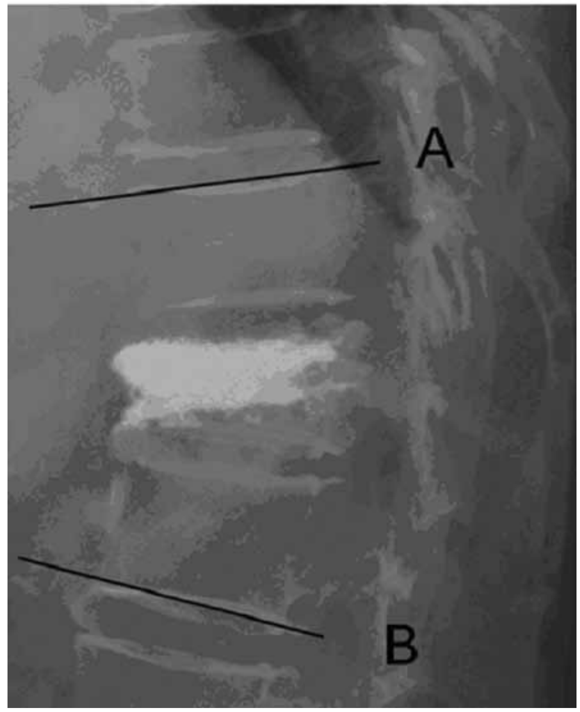

Fig. 4. *Measurement of the Cobb angle. The Cobb angle was measured based on the superior endplate of the vertebra one level above the treated vertebra (line A) to the inferior endplate of the vertebral body one level below the treated vertebra (line B) on the lateral x-ray image.*

Surgery Outcomes and Complications

All patients underwent PKP successfully. The cement volume and distribution were 3.4 ± 1.0 mL and 0.4 ± 0.1 mL, respectively. The restoration rate of vertebral height and surgical duration in the recuperators group were higher than that in the non-recuperators group (46.4 ± 10.0% vs. 41.5 ± 10.6%, $P < 0.01$; 50.90 ± 5.81 minutes vs. 49.26 ± 4.57 minutes, $P = 0.02$). There were no differences in Cobb angle between the 2 groups preoperatively and postoperatively. However, the improvement of kyphotic angle was higher in the recuperators group (4.81 ± 0.88° vs. 4.52 ± 1.20°, $P < 0.05$) (Table 2). There were still 11 (5.0%) and 41 (18.6%) patients experiencing cement leakage and adjacent vertebral fractures, respectively. However, there were no significant

Table 1. *Demographic data between the 2 groups, n (%).*

Characteristics	Recuperator group (n = 77)	Non-recuperator group (n = 143)	χ2
Sex			
female	58 (75.3%)	106 (74.1%)	0.038
male	19 (24.7%)	37 (25.9%)	$P > 0.05$
Age (years)			
<60	8 (10.4%)	14 (9.8%)	2.346
60 — 79	52 (67.5%)	107 (74.8%)	$P > 0.05$
≥ 80	17 (22.1%)	22 (15.4%)	
Fractured vertebras			
Thoracic vertebra	33 (42.9%)	52 (36.4%)	0.890
Lumber vertebra	44 (57.1%)	91 (63.6%)	$P > 0.05$
Type of anesthesia			
Local	50 (64.9%)	96 (67.1%)	0.108
General	27 (35.1%)	47 (32.9%)	$P > 0.05$
Body mass index (BMI, kg / m2)			
< 18.5	2 (2.6%)	16 (11.2%)	5.924
18.5 — 24.9	39 (50.6%)	74 (51.7%)	$P > 0.05$
25— 29.9	27 (35.1%)	42 (29.4%)	
≥ 30	9 (11.7%)	11 (7.7%)	
Bone mineral density (BMD, T value)			
< -4.5	15 (19.5%)	32 (22.4%)	0.477
-4.5 — -3.5	28 (36.4%)	46 (32.2%)	$P > 0.05$
-3.4 — -2.5	34 (44.2%)	65 (45.5%)	

Column percentage in bracket

Table 2. *The comparison of surgery outcomes between the 2 groups ($\overline{X} \pm S$).*

Surgery outcomes	Recuperators	Non-recuperators	T
The restoration rate of vertebral height (%)	46.4 ± 10.0	41.5 ± 10.6	3.332*
Preoperative Cobb angle (°)	13.6 ± 6.9	14.7 ± 7.4	-1.112
Postoperative Cobb angle (°)	9.4 ± 7.7	9.6 ± 6.2	-0.265
Improvement of kyphotic angle (°)	4.81 ± 0.88	4.52 ± 1.20	2.008*
Surgical duration (min)	50.90 ± 5.81	49.26 ± 4.57	2.308*
Cement volume (ml)	3.80 ± 1.14	3.19 ± 0.92	4.276*
Cement distribution (%)	0.50 ± 0.12	0.39 ± 0.10	7.685*

*significant difference at $P < 0.05$

Table 3. *The comparison of complications between the 2 groups, n (%).*

Complications	Recuperators	Non-recuperators	χ2
Cement leakage (No.)	3 (3.9%)	8 (5.6%)	0.052
Adjacent vertebral fractures (No.)	14 (18.2%)	27 (18.9%)	0.016

*significant difference at $P < 0.05$

differences in the amount of cement leakage and adjacent vertebral fractures between the 2 groups (Table 3).

Cement Volume and Cement Distribution

The cement volume and distribution in the recuperators group were both higher than that in the non-recuperators group (3.80 ± 1.14 mL vs. 3.19 ± 0.92 mL, $P < 0.01$; 0.50 ± 0.12 vs. 0.39 ± 0.10, $P < 0.01$). The area under the ROC curve of cement volume was 0.65 (95% CI: 0.57 – 0.73, $P < 0.01$). Cement volume at 3.80 showed a sensitivity of 49% and a specificity of 82% for the diagnosis of pain relief after PKP. The area under the ROC curve of cement distribution was 0.77 (95% CI: 0.70 – 0.84, $P < 0.01$). Cement distribution at 0.49 had a sensitivity of 62% and a specificity of 84% (Fig. 5, Cement volume and distribution reached the highest Youden index at red points). Both variables were good indicators for distinguishing the recuperators and non-recuperators. However, the diagnostic value of cement distribution was better than that of cement volume ($Z = 4.07$, $P < 0.05$).

Cement distribution had a medium positive correlation with cement volume ($r2 = 0.510$, $P < 0.01$). When cement distribution at 0.49 and cement volume at 3.80 mL were set as 2 dividing lines, all patients were divided into 4 parts (Fig. 6). Part A represented the patients with extensive cement distribution (more than or equal to 0.49) and a large cement volume (more than or equal to 3.80 mL); Part B represented the patients with extensive cement distribution and a small cement volume (less than 3.80 mL); Part C represented the patients with a confined cement distribution (less than 0.49) and a small cement volume; Part D represented the patients with a confined cement distribution and a large cement volume. The recuperative rate in each part was 69.4%, 53.3%, 18.3% and 26.7%, respectively. Extensive cement distribution could increase the recuperative rate both with the small and large cement volumes (Part A vs. Part D, $\chi2 = 8.690$, $P = 0.003$; Part B vs. Part C, $\chi2 = 15.903$, $P < 0.001$). However, cement volume could not make an improvement (Part A vs. Part B, $\chi2 = 2.064$, $P = 0.151$; Part C vs. Part D, $\chi2 = 0.613$, $P = 0.434$). Moreover, the small cement volume with an extensive distribution had the same recuperative effect as the large cement volume with a confined distribution (Part B vs. Part D, $\chi2 = 2.880$, $P = 0.090$), which meant that cement distribution and volume could affect PKP in 2 different ways.

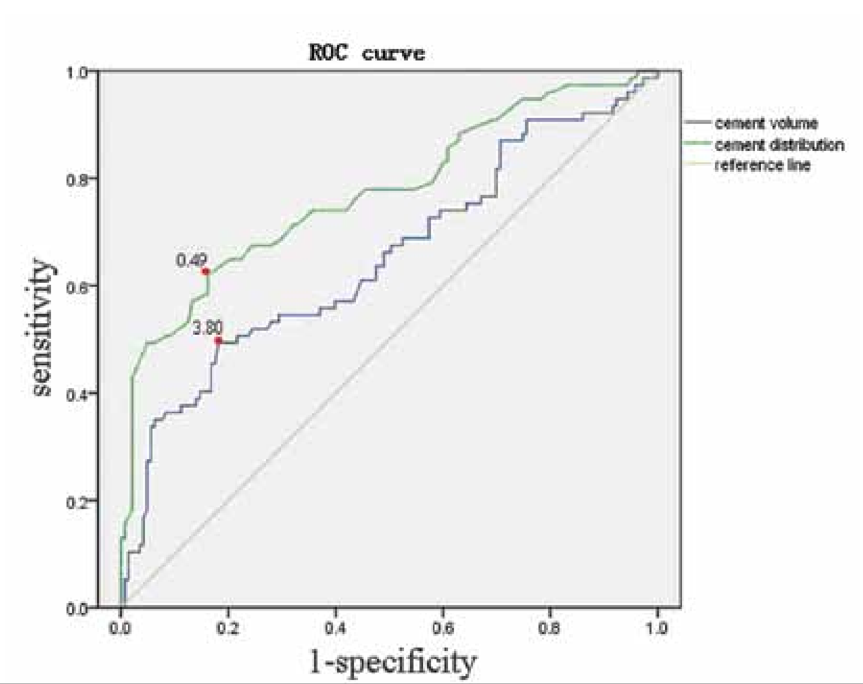

Fig. 5. *ROC curve of cement volume and distribution.*

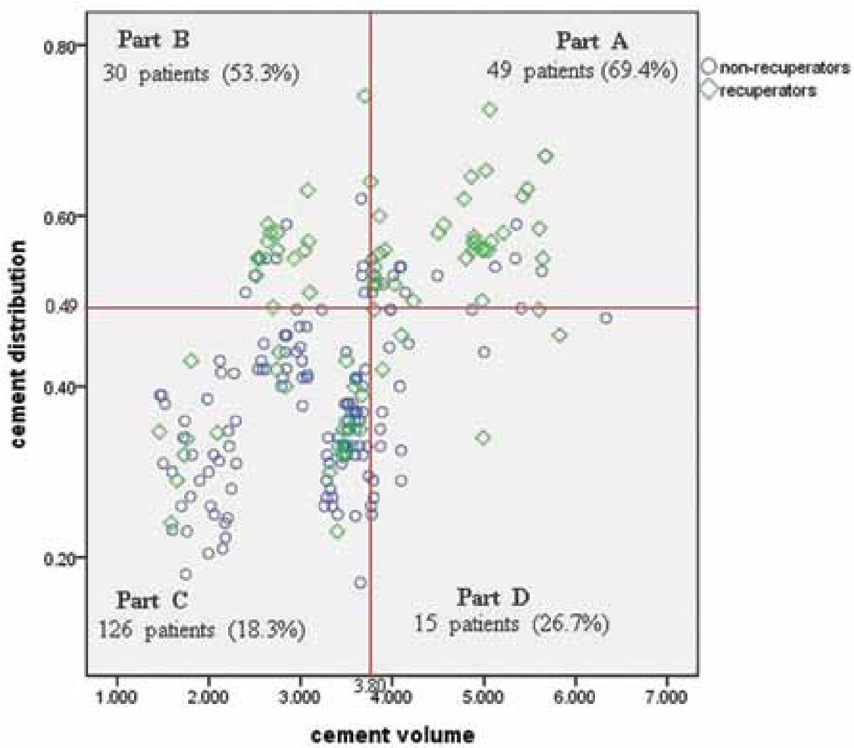

Fig. 6. Comparison of different cement volume and distribtuion.

Correlation Analysis

A correlation analysis was used for exploring the relationships between cement characteristics and clinical outcomes (Table 4). When controlled for cement volume, cement distribution was positively correlated with restoration rate of vertebral height and improvement of kyphotic angle (r2 = 0.207, *P* < 0.01; r2 = 0.159, *P* = 0.02). When controlled for cement distribution, cement volume had a positive correlation with restoration rate of vertebral height and surgical duration (r2 = 0.153, *P* = 0.02; r2 = 0.371, *P* < 0.01). A logistics regression model also showed that cement distribution and volume were not risk factors for cement leakage (OR = 35.760, 95% CI: 0.096 – 13291.207, *P* > 0.05; OR = 0.771, 95% CI: 0.392 – 1.516, *P* > 0.05). However, cement volume was a risk factor for adjacent vertebral fractures (OR = 1.733, 95% CI: 1.158 – 2.595, *P* < 0.01) (Table 5).

Discussion

The aim of the present study was to assess the cement volume and distribution in evaluating PKP and explore the relationships among cement volume, cement distribution, and surgery outcomes. According to VAS differences, all patients were divided into 2 groups. A total of 77 patients (35%) had long-term pain relief. Although there were no differences in demographic data between 2 groups, the restoration rate of vertebral height, improvement of kyphotic angle, and surgical time in recuperators group were all higher than those in non-recuperators group. The area under the ROC curve of cement distribution was better than that of cement volume as a predictor of pain relief. Cement distribution had a sensitivity of 62% and a specificity of 84% when it was 0.49. Extensive cement distribution could increase the recuperative rate both with a small or large cement volume. Moreover, a small cement volume with extensive distribution had the same recuperative effect as a large cement volume with confined distribution. When controlled for cement volume, cement distribution was positively correlated with restoration rate of vertebral height and improvement of kyphotic angle. Only cement volume was a risk factor for adjacent vertebral fractures.

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

Surgery outcomes	Cement distribution	Cement volume
Restoration rate of vertebral height	0.207*	0.153*
Improvement of kyphotic angle	0.159*	0.109
Surgical duration	0.029	0.371*

*significant difference at $P < 0.05$

Table 5. *Correlation between cement characteristics and surgery complications OR (95%CI).*

Surgery complications	Cement distribution	Cement volume
Cement leakage	35.760 (0.096 – 13291.207)	0.771 (0.392 – 1.516)
Adjacent vertebral fractures	0.051 (0.011 – 1.032)	1.733 (1.158 – 2.595)

Compared with conservative treatment, including analgesic medication, bed rest, and back braces, PKP is effective in ameliorating OVCF-associated pain by involving the percutaneous injection of cement directly into the fractured vertebra (14-15). Patients in this study showed an obvious decrease in pain from 7.0 ± 1.4 preoperatively to 2.3 ± 2.1 one year postoperatively. Yu et al (16) had shown that patients had a mean VAS at 7.7 ± 1.3 preoperatively and 2.2 ± 0.9 after surgery. The VAS differences are all around 5. Hirakawa et al (17) defined complete pain relief as a VAS score of 0 or 1 at 3 months after surgery. Ma et al (18) found that short- and long-term VAS outcomes were internally inconsistent within the subgroups from the meta-analysis. As such, we think it is incorrect to diagnose a patient as a recuperator only by his postoperative VAS outcome. If the VAS for a patient was 8 preoperatively and reached 2 after surgery, this patient would not be considered as a recuperator according to Hirakawa et al (17). However, the patient may have an improvement in vertebral height and not feel any subsequent back pain. So a decrease in VAS should be considered in the same manner as improvements of physical component summary (PCS) or numeric rating score (NRS) pain scores that are used in evaluating patient recovery (19).

In many patients, PKP appears to have the ability to partly restore vertebral height and thereby reduce kyphotic deformity (20). The change of vertebral body height and Cobb's angle are often used for assessing the efficacy of PKP (21). PKP is also superior in reducing Cobb angle in the long-term and results in higher vertebral body height (22). In this study, we used the restoration rate of vertebral height and improvement of kyphotic angle as surgery outcomes. The restoration rate of vertebral height and improvement of kyphotic angle in the recuperator group were both higher than that those in the non-recuperator group, which was also powerful evidence to support the use of our grouping method.

Cement is the key factor for stabilizing the injured vertebrae by filling the bone cavity; however, the proper cement volume is still in question. Dong (23) showed that a 2 to 3.5 cubic centimeter cement volume could repair a fractured vertebral body, and a 4 to 8 cubic centimeter cement volume could remodel vertebral stiffness. One in vivo study following PKP showed that for keeping vertebral body stiffness and strength, vertebral body cement filling degrees of 16% and 30%, respectively, are required, which correspond to approximately 3.2 mL and 6 mL in a conversion (24). Liebschner et al (25) also thought that a cement volume at approximately 3 mL could restore vertebral stiffness. In our study, cement volume in the recuperator group was higher than that in the non-recuperator group. Cement volume had a sensitivity of 49% and a specificity of 82% when it was 3.80 mL. However, a large cement volume did not increase the recuperative rate significantly. Another study has also confirmed that there is no correlation between large cement volume and patient pain relief (26). Thus, it is unnecessary to inject large amounts of cement in efforts to make the surgical outcome better.

Our use of cement distribution as an indicator in this study is an innovative approach, which is estimated as the mean ratio of bright areas to the whole vertebra area both in the AP and lateral views observed by x-ray. In our results, the cement distribution in the recuperator group was higher than that in the non-recuperator group. The results also showed that extensive cement distribution could increase the recuperative rate under the circumstance of both small and large cement volumes. Previous studies used the cemented vertebral body fraction (CVBF, calculated as ratio of intravertebral cement volume to vertebral body volume) to estimate the cement distribution. CVBF at 0.24 (27) or 0.12 (28) have both been recommended to keep the vertebral body strong and safe and could also distinguish patients with different recovery states. However, CVBF sensitivity has only been shown to reach 37%. Jin et al (29) showed that the best cement volume should be measured as 0.8 to 1 times the size of the balloon. However, their studies did not take into account the real distribution of bone cement in the vertebral body. In our study, a cement distribution at 0.49 was optimal with a sensitivity of 62% and specificity of 84%. The area under the ROC curve of cement distribution as a predictor of pain relief was bigger than that of cement volume. Although some types of fractured vertebra can restrict cement distribution, it can still be externally manipulated during surgery. Our results showed that the more extensive the cement distribution, the higher the recuperative rate. This suggests that cement distribution is a more accurate and objective evaluating indicator in comparison to cement volume.

The relation between cement volume and pain relief suggests a causative effect of the injection of cement. Our results showed that cement volume would increase restoration rate of vertebral height and surgical duration. However, it has not yet solved the problem of cement-associated complications, such as cement leakage and adjacent vertebral fractures (30). Aquarius et al (31) concluded that vertebral augmentation with clinically relevant amounts of cement contributed to stress peaks under the endplate. Jin et al (32) indicated that cement volume was considered to be the most important determinant in endplate fracture and showed that changing the stiffness of cement had a negligible effect on the stress distribution of vertebral bodies. The viscosity of cement has also been identified as an independent predictor of cement leakage (33). Hui (34) presented the idea that doses of cement correlate to intervertebral disc degeneration. In our study, too large of a cement volume was found to contribute to the occurrence of adjacent vertebral fractures. Although cement volume positively correlates with cement distribution, extensive distribution will not cause cement leakage or adjacent vertebral fractures. Because a small cement volume with an extensive distribution has the same recuperative effects as a large cement volume with a confined distribution, cement distribution can partially replace cement volume when performing a cement injection. When the cement volume remains constant, a more extensive cement distribution leads to better surgical outcomes.

The present study is not without limitations. It was a retrospective study with small sample size. The clinical outcomes included in this study did not cover a wide range of terminal results. The diagnostic values were based on the dichotomous outcomes and changed corresponding to VAS differences. Thus, the generalizability of our results needs to be further explored.

Limitations

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.

Conclusions

The diagnostic value of cement distribution is better than that of cement volume for relieving patient pain. A cement distribution above 0.49 with a small cement volume should be suggested for PKP. An extensive cement distribution can improve the kyphotic angle and vertebral height effectively and also does not cause cement leakage or adjacent vertebral fractures.

Acknowledgments

We thank Chao Sun of his data analysis for this study.

References

1. Lad SP, Patil CG, Lad EM, Boakye M. Trends in pathological vertebral fractures in the United States: 1993 to 2004. *J Neurosurg Spine* 2007; 7:305-310.
2. EPOS Group, Felsenberg D, Silman AJ, Lunt M, Armbrecht G, Ismail AA, Finn JD, Cockeril WC, Banzer D, Benevolenskaya LI, Bhalla A, Bruges Armas J, Cannata JB, Cooper C, Dequeker J, Eastell R, Felsch B, Gowin W, Havelka S, Hoszowski K, Jajic I, Janott J, Johnell O, Kanis JA, Kragl G, Lopes Vaz A, Lorenc R, Lyritis G, Masaryk P, Matthis C, Miazgowski T, Parisi G, Pols HA, Poor G, Raspe HH, Reid DM, Reisinger W, Schedit-Nave C, Stepan JJ, Todd CJ, Weber K, Woolf AD, Yershova OB, Reeve J, O'Neill TW. Incidence of vertebral fracture in Europe: Results from the European prospective osteoporosis study (EPOS). *J Bone Miner Res* 2002; 17:716-724.
3. Bonnick SL. Osteoporosis in men and women. *Clin Cornerstone* 2006; 8:28-39.
4. Yang HL, Zhao L, Liu J, Sanford CG Jr, Chen L, Tang T, Ebraheim NA. Changes of pulmonary function for patients with osteoporotic vertebral compression fractures after kyphoplasty. *J Spinal Disord Tech* 2007; 20:221-225.
5. Saad F, Lipton A, Cook R, Chen YM, Smith M, Coleman R. Pathologic fractures correlate with reduced survival in patients with malignant bone disease. *Cancer* 2007; 110:1860-1867.
6. Wardlaw D, Cummings SR, Van Meirhaeghe J, Bastian L, Tillman JB, Ranstam J, Eastell R, Shabe P, Talmadge K, Boonen S. Efficacy and safety of balloon kyphoplasty compared with non-surgical care for vertebral compression fracture (FREE): A randomised controlled trial. *Lancet* 2009; 373:1016-1024.
7. Voggenreiter G. Balloon kyphoplasty is effective in deformity correction of osteoporotic vertebral compression fractures. *Spine* 2005; 30:2806-2812.
8. Belkoff SM, Mathis JM, Jasper LE, Deramond H. The biomechanics of vertebroplasty. The effect of cement volume on mechanical behavior. *Spine (Phila Pa 1976)* 2001; 26:1537-1541.
9. Zou J, Mei X, Zhu X. The long-term incidence of subsequent vertebral body fracture after vertebral augmentation therapy: A systematic review and meta-analysis. *Pain Physician* 2012; 15:E515-E522.
10. Luo J, Daines L, Charalambous A, Adams MA, Annesley-Williams DJ, Dolan P. Vertebroplasty: Only small cement volumes are required to normalize stress distributions on the vertebral bodies. *Spine (Phila Pa 1976)* 2009; 34:2865-2873.
11. Kaufmann TJ, Trout AT, Kallmes DF. The effects of cement volume on clinical outcomes of percutaneous vertebroplasty. *AJNR* 2006; 27:1933-1937.
12. Al-Ali F, Barrow T, Luke K. Vertebroplasty: What is important and what is not. *AJNR* 2009; 30:1835-1839.
13. Hsieh MK, Chen LH, Chen WJ. Current concepts of percutaneous balloon kyphoplasty for the treatment of osteoporotic vertebral compression fractures: Evidence based review. *Biomed J* 2013; 36:334-356.
14. Cyteval C, Sarrabere MP, Roux JO, Thomas E, Jorgensen C, Blotman F, Sany J, Taourel P. Acute osteoporotic vertebral collapse: Open study on percutaneous injection of acrylic surgical cement in 20 patients. *Am J Roentgenol* 1999; 173:1685-1690.
15. Deramond H, Depriester C, Galibert P, Le Gars D. Percutaneous vertebroplasty with polymethylmethacrylate: Technique, indications and results. *Radiol Clin North Am* 1998; 36:533-546.
16. Yu CW, Hsieh MK, Chen LH, Niu CC, Fu TS, Lai PL, Chen WJ, Chen WC, Lu ML. Percutaneous balloon kyphoplasty for the treatment of vertebral compression fractures. *BMC Surgery* 2014; 14:3.
17. Hirakawa M, Kobayashi N, Ishiyama M, Fuwa S, Saida Y, Honda H, Numaguchi Y. Radiological findings as favorable predictors of pain relief in patients with osteoporotic compression fractures after percutaneous vertebroplasty: A retrospective study of 156 cases. *Jpn J Radiol* 2012; 30:407-414.
18. Ma XL, Xing D, Ma JX, Xu WG, Wang J, Chen Y. Balloon kyphoplasty versus percutaneous vertebroplasty in treating osteoporotic vertebral compression fracture: Grading the evidence through a systematic review and meta-analysis. *Eur Spine J* 2012; 21:1844-1859.
19. Berenson J, Pflugmacher R, Zonder P. Balloon kyphoplasty versus non-surgical fracture management for treatment of painful vertebral body compression fractures in patients with cancer: A multicentre, randomised controlled trial. *Lancet* 2011; 12:225-235.
20. Taylor RS, Peter F, Rebecca JT. Balloon kyphoplasty in the management of vertebral compression fractures: An updated systematic review and meta-analysis. *Eur Spine J* 2007; 16:1085-1100.
21. Yang HL, Wang GL, Niu GQ, Liu JY, Hiltner E, Meng B, Guo JJ, Tang TS. Using MRI to determine painful vertebrae to be treated by kyphoplasty in multiple-level vertebral compression fractures: A prospective study. *The Journal of International Medical Research* 2008; 36:1056-1063.
22. Chang X, Lv YF, Chen B, Li HY, Han XB, Yang K, Zhang W, Zhou Y, Li CQ. Vertebroplasty versus kyphoplasty in osteoporotic vertebral compression fracture: A meta-analysis of prospective comparative studies. *International Orthopaedics* 2014; 10:1007.
23. Kim DJ, Kim TW, Park KH, Chi MP, Kim JO. The proper volume and distribution of cement augmentation on percutaneous vertebroplasty. *J Korean Neurosurg Soc* 2010; 48:125-128.
24. Molloy S, Mathis JM, Belkoff SM. The effect of vertebral body percentage fill on mechanical behavior during percutaneous vertebroplasty. *Spine (Phila Pa 1976)* 2003; 28:1549-1554.
25. Liebschner MAK, Rosenberg WS, Keaveny TM. Effects of bone cement volume and distribution on vertebral stiffness after vertebroplasty. *Spine* 2001; 26:1547-1554.
26. Komemushi A, Tanigawa N, Kariya S, Kojima H, Shomura Y, Sawada S. Percutaneous vertebroplasty for compression fracture: Analysis of vertebral body volume by CT volumetry. *Acta Radiol* 2005; 46:276-279.
27. Rotter R, Schmitt L, Gierer P, Schmitz KP, Noriega D4, Mittlmeier T3, Meeder PJ5, Martin H2. Minimum cement volume required in vertebral body augmentation—A biomechanical study comparing the permanent SpineJack device and balloon kyphoplasty in traumatic fracture. *Clinical Biomechanics* 2015; 4:1-6.
28. Marc J, Laurens Bollen, van Erkel AR, Dijkstra PD. Optimal intravertebral cement volume in percutaneous vertebroplasty for painful osteoporotic vertebral compression fractures. *Spine* 2012; 37:1747-1755.
29. Jin YJ, Yoon SH, Park KW, Chung SK, Kim KJ, Yeom JS, Kim HJ. The volumetric analysis of cement in vertebroplasty: Relationship with clinical outcome and complications. *Spine (Phila Pa 1976)* 2011; 36:E761-E772.
30. Robinson Y, Christoph EH, Försth P,

Olerud C. Kyphoplasty in osteoporotic vertebral compression fractures-guidelines and technical considerations. *Journal of Orthopaedic Surgery and Research* 2011; 6:43.

31. Aquarius R, van der Zijden AM, Homminga J, Verdonschot N, Tanck E. Does bone cement in percutaneous vertebroplasty act as a stress riser? *Spine* 2013; 38:2092-2097.
32. Kim JM, Shin DA, Byun DH, Kim HS, Kim S, Kim HI. Effect of bone cement volume and stiffness on occurrences of adjacent vertebral fractures after vertebroplasty. *J Korean Neurosurg Soc* 2012; 52:435-440.
33. Nieuwenhuijse MJ, Muijs SP, van Erkel AR, Dijkstra SP. A clinical comparative study on low versus medium viscosity polymethylmetacrylate bone cement in percutaneous vertebroplasty-viscosity associated with cement leakage. *Spine* 2010; 35:E1037-E1044.
34. Zhao H, Ni CF, Huang J, Zhao SM, Gu WW, Jiang H, Chen L, Tan TS. Effects of bone cement on intervertebral disc degeneration. *Experimental and Therapeutic Medicine* 2014; 7:963-969.