

## Pogostost zlomov sosednjih vretenc po osteoporotičnem zlomu vretenca: prospektivna, ne-randomizirana primerjava med perkutano vertebroplastiko in konzervativnim zdravljenjem

### Prevalence of adjacent-level fractures after osteoporotic vertebral compression fractures: a prospective non-randomized trial comparing percutaneous vertebroplasty with conservative therapy

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#### Izvleček

**Namen:** Namen predstavljene prospektivne nerandomizirane študije je bil oceniti pogostost in možne dejavnike tveganja za zlom sosednjega vretenca po opravljeni perkutani vertebroplastiki (PVP) v primerjavi s konzervativnim zdravljenjem.

**Metode:** V študijo so bili vključeni bolniki s kliničnimi in rentgenskimi znaki osteoporotičnega zloma vretenca (starost zloma < 6 tednov) in vztrajanjem hujše bolečnosti kljub protibolečinski terapiji. Vsem bolnikom, ki so izpolnjevali vključitvene kriterije, je bila kot možnost zdravljenja predstavljena metoda PVP. Bolnike, ki se za operativno zdravljenje niso odločili, smo ob njihovem soglasju dalje zdravili konzervativno in so predstavljali kontrolno skupino bolnikov.

**Rezultati:** V skupini bolnikov po opravljeni PVP je v 1 letu prišlo do zloma sosednjega vretenca pri 2 od 27

#### Abstract

**Purpose:** The purpose of this prospective non-randomized study was to analyze the prevalence and possible risk factors of adjacent-level fractures comparing percutaneous vertebroplasty (PVP) with conservative therapy.

**Methods:** Consecutive patients satisfying the inclusion criteria of acute vertebral fracture pain (occurring within 1–6 weeks of the event and not relieved by oral analgesia) and imaging criteria of acute fracture activity were enrolled. All patients meeting the inclusion criteria were offered PVP. Patients who declined PVP and agreed to longitudinal evaluation were treated conservatively and constituted the control group.

**Results:** In 2 of 27 patients (7.4%) treated with PVP and in 10 of 61 patients treated conservatively (16.4%), adjacent-level fractures oc-

bolnikov (7,4 %). Med bolniki, zdravljenimi konzervativno, je v 1 letu zlom sosednjega vretenca utrpelo 10 od 61 bolnikov (16,4 %). Ugotovili smo možno povezavo med pogostostjo zlomov sosednjega vretenca s stopnjo lokalne kifoze ter mineralno kostno gostoto.

**Zaključek:** Pridobljeni rezultati kažejo, da je PVP metoda z nizkim tveganjem za zlom sosednjega vretenca. Obstaja možna povezava med pogostostjo zlomov sosednjega vretenca in stopnjo osteoporoze ter pogostostjo zlomov sosednjega vretenca in spremenjeno biomehaniko hrbtnice kot posledico lokalne kifoze. Pri bolnikih, zdravljenih s PVP, smo v primerjavi s konzervativno zdravljenimi bolniki po 1 letu ugotavljali v povprečju manjšo deformiranost vretenc, manj zlomov sosednjih vretenc in boljšo odpravo bolečin.

curring within 1 year. The degree of local kyphosis and bone mineral density (BMD) were identified as possible predictive factors for adjacent-level fractures.

**Conclusion:** These results indicated that PVP carries a low risk of adjacent-level fractures. Lower BMD values and altered biomechanics in the treated area of the spine due to resistant kyphosis are possible predictive factors for adjacent-level fractures. A positive effect of PVP over conventional treatment was observed upon reduction of the prevalence of adjacent-level fractures, vertebral morphology, and pain reduction.

## INTRODUCTION

Vertebral compression fractures (VCFs) constitute a major healthcare problem worldwide. This is because of their high incidence as well as direct and indirect negative consequences on patient health-related quality-of-life (QoL) and costs to the healthcare system (1).

Percutaneous vertebroplasty (PVP) has been shown to provide benefit to patients with painful VCFs in terms of pain control and disability resolution (2, 3). Despite the demonstrated benefit, whether PVP also increases fracture morbidity by inducing or facilitating subsequent vertebral fractures is controversial. Investigators have attempted to explore this issue through clinical and biomechanical studies. In the literature, there are conflicting clinical data regarding the incidence of subsequent fracture. Moreover, the risk of adjacent vertebral fractures has not been well established because comparison data with conservatively treated control groups are limited.

## MATERIALS AND METHODS

The study protocol was approved by the National Medical Ethics Committee of Slovenia. Written informed consent was obtained from all participating individuals.

In this prospective non-randomized, non-blinded, controlled study, undertaken between January 2007 and December 2008, 88 consecutive patients with painful osteoporotic VCFs were enrolled.

Male and female patients with painful osteoporotic VCFs requiring hospitalization were considered for study enrolment. Inclusion criteria were: osteoporotic VCF; pain lasting <6 weeks; localized spinal pain that worsened with percussion over the spinal process of the fractured vertebra; no technical reasons why PVP could not be done; and suitability for general anaesthesia. Exclusion criteria were: presence of a neurological deficit; an osteoporotic vertebral collapse >90%; an uncooperative patient; bleeding disorders; unstable fractures due to involvement of posterior elements; malignant diseases; and systemic or spinal infection.

Patients with kyphotic deformity >30°, subsequent sintering at follow-up (progressive loss of vertebral height), and pain resistance to analgesics (assessed by a visual analog scale (VAS) score of >5 points) were offered PVP (after being informed of the risks and benefits of PVP and conservative management). Given sufficient information, patients then decided whether they wanted to undergo PVP or conventional treatment. Patients who declined PVP and who agreed to longitudinal evaluation constituted the control group.

The diagnosis of VCF was established by clinical examination and radiographic evaluation. All patients underwent radiographic evaluation and CT. If needed, the activity of osteoporotic VCF was additionally confirmed by evaluation of bony oedema in fat-suppressed sequences (STIR) of MRI. Concomitant laboratory analyses and bone biochemical markers were used to exclude other bone diseases.

Patients were evaluated for pain using the VAS score, i.e., a scale of 0–10 (with 10 indicating the most pain). VAS score was evaluated by all patients at the time of hospital admission and in the PVP group on the first day after the procedure to evaluate their clinical response to the procedure. The final assessment of the VAS score was done at 1 year after study inclusion.

The height of the fractured vertebral body and kyphotic angle were measured before treatment and during follow-up for all patients. In the fractured vertebral body, vertical heights at their most compressed site were measured and compared with the vertical heights at the same site of both the nearest normal vertebral bodies. We thus calculated the compression rate. We used Cobb's technique to calculate the segmental kyphotic angle across the fractured level. The measurement was taken from the superior endplate of the vertebra one level above the treated vertebra to the inferior endplate of the vertebral body one level below the treated vertebra (4).

Conservative treatment consisted of a period of relative bed rest and analgesia, with application of a thoraco-lumbar extension orthosis while standing. The duration of bed rest was restricted to that necessary to achieve reasonable control of pain upon mobilization.

For patients undergoing PVP, a standard preoperative procedure was undertaken. PVP procedures were done under local anesthesia using a Jamshidi needle to cannulate the pedicle with the aid of fluoroscopy. Needles were advanced to the anterior third of the vertebral body under fluoroscopic guidance. Then, bone cement containing 1.5 cm<sup>3</sup> of polymethylmethacrylate

(PMMA) cement was injected through the filler. From each side, 2–4 cm<sup>3</sup> of PMMA was injected into most patients. After the PMMA hardened, the bone filler was removed.

The follow-up was at 24 h, 6 weeks, 12 weeks and 1 year after therapy. These times were calculated from the day of PVP or the day of enrolment into the study in the control group. Visits during the 6<sup>th</sup> and 12<sup>th</sup> weeks were not considered in the present analysis.

At the final follow-up examination 1 year after study inclusion we measured bone mineral density (BMD) at the lumbar spine (L1–L4) by dual-energy radiographic absorptiometry. A mean value of BMD was calculated for each subject by averaging values from L1–L4, excluding those vertebrae where the augmentation procedure had been carried out. Osteoporosis was defined according to the World Health Organization (WHO) (5) as a BMD >2.5 standard deviations (SDs) below the mean of a young healthy reference population of the same sex (T score).

New vertebral fractures of the thoracic and lumbar spine adjacent to the treated vertebrae were assessed on standing radiographs at follow-up. New vertebral fractures were defined as a decrease (compared with baseline radiographs) of  $\geq 20\%$  and  $\geq 4$  mm in any of the three vertebral heights (anterior, middle, posterior) on follow-up.

To investigate the relationship between possible predictors of new vertebral body fracture and the incidence of new vertebral fractures, we included the factors of age, sex, BMD, kyphotic deformity and, in the BK group, also the amount of PMMA injected per vertebral body (cement volume) and extravasation of cement (cement leakage).

### Statistical analyses

Basic demographic and clinical numerical data are mean  $\pm$  SD. Outcome measures are mean  $\pm$  standard error, and analyzed by the unpaired *t*-test. Categorical data are expressed as proportions and analyzed by Pearson's chi-squared test or Fisher's exact test.

Changes in VAS score, compression rate and kyphotic angle from pre-treatment to postoperative status and to 1 year after VCF status were analyzed by matched-pair *t*-tests or repeated measures analysis of variance. For *post-hoc* comparisons, the Bonferroni correction (at the alpha level) was used.

The relationship between possible risk factors and adjacent-level fractures was analyzed using Pearson's chi-squared test or Fisher's exact test. For the purpose of analyses, the variables of patient age, cement volume, pre-treatment kyphotic angle, postoperative kyphotic angle, improvement in kyphotic angle, and BMD were dichotomized according to the second quartile.  $P < 0.05$  was considered significant. Data were analyzed using PASW 18 software (SPSS Inc., Chicago, IL, USA).

## RESULTS

Out of 88 patients suffering symptomatic osteoporotic VCF, 27 patients with 32 levels were treated surgically with PVP and 61 patients with 64 levels were treated conservatively (control group). Among patients in the PVP group, 23 (85.2%) had a single vertebral fracture, and 4 (14.8%) had multiple lesions. The level of frac-

ture was distributed between ThV1 and L4, and was most prevalent at the thoracolumbar junction. Of 61 patients treated conservatively, 58 (95.1%) had a single vertebral fracture, and 3 (4.9%) had multiple fractures. Fractures were distributed between Th7 and L4 and were most prevalent at the thoracolumbar junction.

Table 1 summarizes the demographic and baseline characteristics of treated patients. Significant differences between PVP and control group were not observed when comparing the mean age and sex. However, patients in the control group had, on average, lower vertical body height deformity (mean pre-treatment compression value 71.4% vs. 55.5%), lower pre-treatment local kyphotic angle (6.0° vs. 11.3°) and lower pre-treatment VAS score (6.7 vs. 8.7) compared with the PVP group.

The clinical and radiological characteristics of patients after PVP are presented in Table 2. The mean ( $\pm$  standard error) volume of PMMA cement per body was  $5.8 \pm 0.33$  mL. The proportion of cases with cement extravasation was 25.9% and intra-disk cement leakage was detected in 3 of 7 patients with cement extravasation. We found a significant improvement in mean compression immediately after PVP (55.5% vs. 65.0,  $p < 0.001$ ). A similar trend was seen for the

**Table 1.** Comparison of demographic and baseline characteristics between patients treated by percutaneous vertebroplasty (PVP) and patients treated conservatively (control group)

	PVP group (n=27)	Control group (n=61)	P
Age, years	72.9 $\pm$ 5.6 (62–82)	73.8 $\pm$ 7.5 (56–86)	0.604
Sex			0.899
Women, n (%)	22 (81.5)	49 (60.3)	
Men, n (%)	5 (18.5)	12 (19.7)	
Pre-treatment compression value, %	55.5 $\pm$ 8.2 (42–72)	71.4 $\pm$ 11.8 (39–92)	<0.001
Pre-treatment local kyphotic angle, degrees	11.3 $\pm$ 4.2 (4–21)	6.0 $\pm$ 3.0 (2–13)	<0.001
Pre-treatment VAS score	8.7 $\pm$ 0.8 (7–10)	6.7 $\pm$ 1.3 (4–9)	<0.001

<sup>a</sup> Data are mean and standard deviation (min–max), unless otherwise specified.

VAS=visual analog scale

**Table 2.** Clinical and radiological characteristics of patients at 1 day after percutaneous vertebroplasty(PVP).

	PVP group (n=27)
Cement volume, mL	5.8 ± 0.33
Cement leakage, n (%)	7/27 (25.9)
Intradiscal cement leakage, n	3/7
Postoperative compression, %	65.0 ± 1.52
Improvement in compression value, %	9.5 ± 1.20
Postoperative local kyphotic angle, degrees	8.9 ± 0.86
Postoperative improvement in local kyphotic angle, degrees	2.3 ± 0.44
Postoperative VAS score	2.3 ± 0.14

<sup>a</sup> Data are mean and standard error, unless otherwise specified. VAS=visual analogue scale

mean kyphotic angle (11.3° vs. 8.9°,  $p < 0.001$ ). The mean VAS score fell dramatically from the baseline (preoperative) mean value of  $\approx 9$  to the mean value of  $\approx 2$  immediately after surgery ( $p < 0.001$ ).

After 1 year, the mean VAS score was slightly lower in the PVP group compared with the control group (2.4 vs. 3.8, respectively) (Table 3).

No significant difference was found in the mean BMD in the PVP and control group (2.8 vs. 2.6 kg/m<sup>2</sup>, respectively), measured 1 year after the procedure. At

the same final visit, patients were examined for new vertebral fractures. In the PVP group, two fractures developed in 2 patients (7.4%). Both subsequent fractures were asymptomatic and both were found in patients with a BMD T-score  $\geq -3.2$  SD (mean T score,  $-3.4$  SD) below the mean of a young healthy reference population of the same sex. Postoperative local kyphosis in these patients was 9° and 12°, respectively.

In the control group, new vertebral fractures at adjacent levels were detected in 10 (16.4%) patients. In 2 patients, adjacent vertebral fracture was symptomatic, making the patients come to control earlier (4 and 7 month after onset of treatment). For the other 8 patients, adjacent vertebral fractures were asymptomatic and detected on routine follow-up (in 3 patients after 3 months and in 5 patients at the final visit after 1 year).

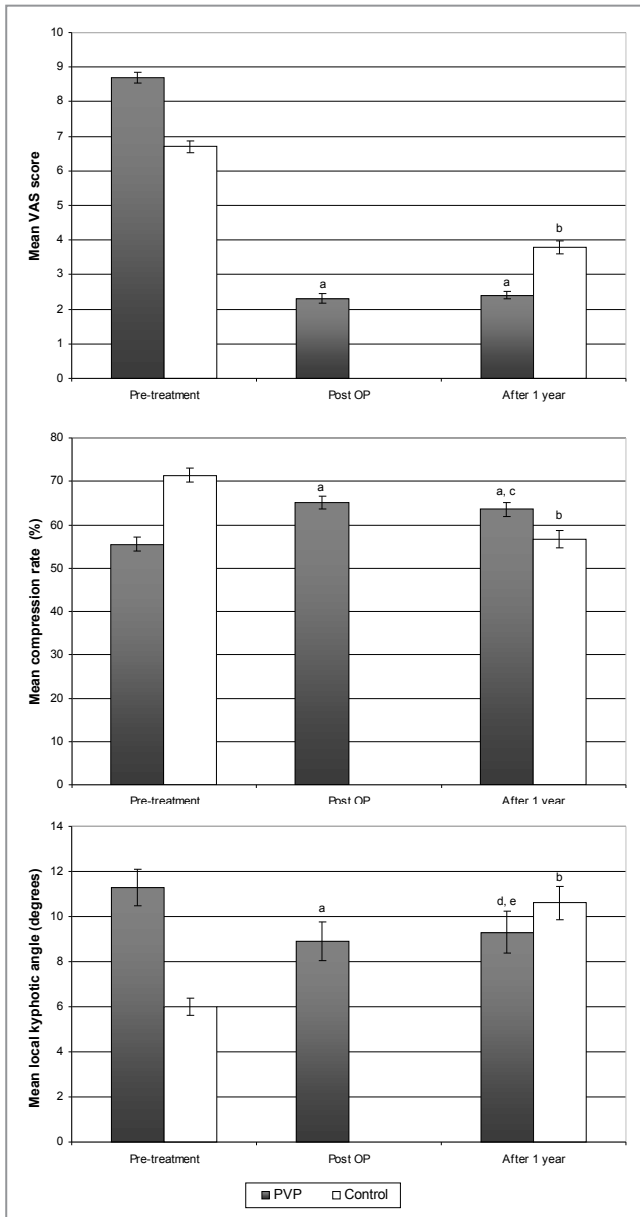
The changes in VAS score, compression, and local kyphotic angle through the follow-up period are shown for both groups in Figure 1. In the PVP group, the mean VAS score fell dramatically from the baseline (preoperative) mean value of  $\approx 9$  to the mean value of  $\approx 2$  immediately after surgery. After 1 year, the VAS score was lower in the PVP group compared with the control group (2.4 vs. 3.8,  $p < 0.001$ ), respectively. At 1 year, the mean increase in local kyphotic angle was

**Table 3.** Outcome of treatment and clinical status of patients 1 year after VCF <sup>a</sup>

	PVP group (n=27)	Control group (n=61)	P
Compression value after 1 year, %	63.5 ± 1.60	56.7 ± 2.05	0.010
Deterioration in compression value in 1 year, %	1.5 ± 0.34	14.7 ± 1.18	<0.001
Local kyphotic angle after 1 year, degrees	9.3 ± 0.92	10.6 ± 0.72	0.308
Increase in local kyphotic angle in 1 year, degrees	0.4 ± 0.11	4.7 ± 0.49	<0.001
VAS score after 1 year	2.4 ± 0.11	3.8 ± 0.19	<0.001
BMD after 1 year, T-score	2.8 ± 0.09	2.6 ± 0.07	0.122
Adjacent vertebral fracture after 1 year, n (%)	2 (7.4)	10 (16.4)	0.257

<sup>a</sup> Data are mean and standard error, unless otherwise specified.

BMD=bone mineral density; PVP=percutaneous vertebroplasty; VAS=visual analogue scale; VCF=vertebral compression fracture



**Figure 1.** Mean VAS score, mean compression, and mean local kyphotic angle in the PVP and control group at first visit (pre-treatment), after the surgical procedure (post OP) and at final visit (after 1 year). Mean values  $\pm$  standard error are shown. a 'Post OP' and 'after 1 year' compared with 'pre-treatment' in the PVP group ( $p < 0.001$ ); b 'after 1 year compared with 'pre-treatment' in the control group ( $p < 0.001$ ); c 'after 1 year' compared with 'post OP' in the PVP group ( $p < 0.001$ ); d 'after 1 year' compared with 'pre-treatment' in the PVP group ( $p = 0.001$ ); e 'after 1 year' compared with 'post OP' in the PVP group ( $p = 0.001$ ). PVP=percutaneous vertebroplasty; VAS=visual analog scale.

significantly lower in patients treated with PVP compared with the control group ( $0.4^\circ$  vs.  $4.7^\circ$ ,  $p < 0.001$ ).

The relationship between possible risk factors and adjacent-level fractures for both study groups is presented in Table 4. In the control group, preoperative local kyphotic angle and BMD seemed to be related to adjacent-level fractures ( $p = 0.079$  and  $p = 0.044$ , respectively) whereas, in the PVP group, only BMD showed a possible relationship to adjacent-level fractures ( $p = 0.080$ ).

Adjacent-level fractures occurred in 9 of 39 (23%) conservatively treated patients with local kyphosis  $\geq 5.0^\circ$  after the first vertebral fracture and only in 1 out of 22 (5%) patients with local kyphosis  $< 5.0^\circ$  after the first vertebral fracture ( $p = 0.079$ ). Among patients with  $BMD \geq -2.6$ , 8 out of 31 (26%) patients had an adjacent-level fracture, whereas among patients with  $BMD < -2.6$ , only 2 out of 30 (7%) patients had an adjacent-level fracture ( $p = 0.044$ ).

## DISCUSSION

Whether new compression fractures are the result of the natural progression of osteoporosis or they should be regarded as the consequence of stiffness by augmentation with bone cement is controversial (6–10).

In general, the literature suggests that the percentage of fractures is higher in patients after one of these procedures than in a subject who has osteoporosis but no fractures (11, 12). This comparison may not be justified because the presence of one osteoporotic fracture can increase the risk of developing another fracture by up to 12.6-fold (13). Therefore the observed prevalence of fracture may reflect the natural history of the disease.

There are several explanations for adjacent fractures after augmentation of the vertebral body. Rigid cement fixation could theoretically induce degenerative changes in adjacent bone, and the augmented vertebra is probably much stiffer than the adjacent vertebra (14). It has been suggested that relatively stiff

**Table 4.** Relationship between possible risk factors to adjacent-level fractures in the PVP and control group

Risk factors	PVP group (n=27)		Control group (n=61)	
	Adjacent-level fracture, n (%)	P	Adjacent-level fracture, n (%)	P
Sex		0.999		0.187
Women	2/22 (9.1)		10/49 (20.4)	
Men	0/5 (0)		0/12 (0)	
Age		0.481		0.321
≥73 (PVP), ≥74 (control) years	2/14 (14.3)		7/34 (20.6)	
<73 (PVP), 74 (control) years	0/13 (0)		3/27 (11.1)	
Cement volume		0.499		–
≥6.0 mL	2/16 (12.5)		–	
<6.0 mL	0/11 (0)		–	
Cement leakage		0.459		–
Yes	1/7 (14.3)		–	
No	1/20 (5.0)		–	
Preoperative local kyphotic angle		0.499		0.079
≥11.0° (PVP), ≥5.0° (control)	2/16 (12.5)		9/39 (23.1)	
<11.0° (PVP), <5.0° (control)	0/11 (0)		1/22 (4.5)	
Local kyphotic angle at 1 day after surgery		0.481		–
≥9.0°	2/14 (14.3)		–	
<9.0°	0/13 (0)		–	
Improvement in local kyphotic angle 1 day after surgery		0.516		–
≥2.0°	2/17 (11.8)		–	
<2.0°	0/10 (0)		–	
BMD		0.080		0.044
≥3.0 (PVP), ≥2.6 (control)	2/8 (25.0)		8/31 (25.8)	
<3.0 (PVP), <2.6 (control)	0/19 (0)		2/30 (6.7)	

BMD=bone mineral density; PVP= percutaneous vertebroplasty

bone cement injected into osteoporotic bone causes stress peaks on the endplates, leading to fractures at adjacent levels (15). Baroud et al. (16) developed biomechanical models to examine cement augmentation on loading in adjacent vertebrae. In-depth analyses of the model demonstrated that the cement in the treated vertebra acts as a “pillar”, reducing the physi-

ologic inward bulge of the endplates. As a result of this effect, the pressure in the adjacent intervertebral disk increases by ≤19%. The authors theorized that this shift in adjacent loading is one of the reasons for adjacent fractures.

It has been found that, given a prevalent osteoporotic fracture treated with conservative medical therapy, the

chance of having an incident fracture within 1 year is 19.2% (11). Only 23% of these second fractures were symptomatic. Hence, 5% of women with an untreated compression fracture are expected to sustain a symptomatic subsequent vertebral fracture within 1 year.

In a study by Grados et al. (17) two-thirds of vertebral fractures after vertebroplasty were identified at levels adjacent to the vertebroplasty and the remainder at remote levels.

In this comparative study, during follow-up, patients treated conservatively had a higher prevalence of fracture (16.4%) of adjacent vertebra than patients treated with PVP (7.4%). Therefore, it can be reasonably assumed that fractures that occurred after PVP would have occurred if a percutaneous vertebral augmentation procedure had not been done. It also seems that, without an augmentation procedure, adjacent fractures would be more frequent because vertebral fractures change the biomechanics of the spine (18), which might increase the risk of additional vertebral fractures (11). This risk increases with the severity of the deformity (19) and therefore the surgical correction of a deformity and prevention of further deterioration of local kyphosis can reduce morbidity and mortality in these patients.

Our data indicate that one of the most important factors for a vertebral fracture adjacent to augmented vertebra is the degree of osteoporosis. These results suggest that the procedure is usually done in a part of the spine that is already weakened. Hence, adjacent vertebrae are more likely to fail even if the percutaneous augmentation procedure had not been done. It also seems that the occurrence of new VCFs after the percutaneous augmentation procedure is due to altered biomechanics in the treated area of the spine (15, 20).

Studies have reported a fourfold greater risk of developing additional VCFs after the initial VCF than in the population without VCFs (21). Hence, the combination of a low lumbar spine BMD and prevalent fractures is a good predictor of an increased fracture risk for adjacent-level fractures.

A kyphotic deformity of the vertebral body after sustained VCF increases the anterior stresses in adjacent levels by changing biomechanical loads as they are transferred through the spine. Therefore, a vertebral fracture is a potential increased risk for subsequent fracture in adjacent vertebrae (22). Hence, height restoration has the potential benefit of reducing post-fracture kyphosis, decreased pulmonary-related mortality, and possibly decreasing the incidence of adjacent-level fractures (7).

We found a mean improvement in the kyphotic angle of  $2.3^\circ$  in the PVP group. What has often been neglected in the controversy regarding height restoration with balloon kyphoplasty is that PVP can, in selected patients, also restore vertebral body height. Hiwatashi et al. (23) showed that vertebral body height can be augmented with VP by hyper-extending the affected spinal segment. Similarly, McKiernan et al. (24) demonstrated dynamic fracture mobility in 35% of 65 VCFs they treated. Using PVP alone, they reported that the mean anterior vertebral height increased 106% compared with the initial fracture height (an absolute mean increase of 8.4 mm) in patients with mobile fractures. The reduction in the kyphotic angle in their study was 40% (24).

The mechanism behind the restoration of height during vertebroplasty is probably due to two factors. First, it is well-known that improvement in fracture height can be achieved by simply by placing the patient prone. Second, the pressure and volume of injected PMMA helps to preserve positional changes and may further restore fracture height (20).

At the one-year follow-up, we noticed progress in local kyphosis in the control group in comparison with the PVP group (where the local kyphosis remained practically unchanged).

A serious complication of all vertebral augmentation techniques is leakage of PMMA cement. It was reported (25) that cement leakage into the disk increased the risk of new fractures in adjacent vertebral bodies. In the present study, cement extravasation into the



spinal canal or the neural foramen did not occur. We found radiographically confirmed cement leakage in 25.9% of all patients treated with PVP. We found cement leakage to be within the disk in 3 of 7 patients with cement leakage. Komemushi et al. (26) found cement leakage into the disk to be a significant predictor of adjacent VCF. In the present study, in cases with intra-disk cement leakage, we did not find new adjacent fractures. Therefore, we did not find a connection between disk leakage and new adjacent compression fractures.

The mechanism of pain relief after percutaneous augmentation of VCF with PMMA is most commonly through fracture stabilization (although thermal and chemical ablation of nerve endings in the vertebral body may also contribute to pain relief). Pain relief is expected within 24 h after the procedure. Our results confirmed a clear decrease in pain within 24 h after PVP. Typically, patients in the PVP group experienced improved mobility within 24 h, and most could bear weight soon after the procedure. The amount and type of pain medication could be reduced or stopped. It appears that the magnitude of pain relief after a percutaneous augmentation procedure is higher in individuals with acute fractures, as well as shorter periods of fracture-related pain compared with patients with older fractures or long duration of pain. Significant improvement in pain relief in most patients and avoidance of the side effects of long-term analgesic medication are some of

the benefits of an early intervention. However, there were no additional significant improvements with regard to pain after 1 year, and differences in improvement between PVP and control group diminished in 1 year.

The drawbacks of the present study included the non-randomized and non-blinded design, which may have allowed bias and confounding. There were an unequal number of subjects in the two groups, recruited on the basis of consenting or refusing to have PVP and a relatively short follow-up period. Another limitation was that only patients who had a new compression fracture on radiography received MRI in the follow-up period. Asymptomatic new compression fractures with only changes in MRI signal intensity may have been missed.

Comparing PVP with non-surgical management, the present study indicated that the most important factors for adjacent-level fractures after an osteoporotic vertebral fracture were the degree of osteoporosis and altered biomechanics of the spine due to local kyphosis. Correction of the vertebral morphology and prevention of further deterioration achieved with PVP probably has a positive effect on the spinal biomechanics and thus reduces the incidence of subsequent fracture. Starting anti-osteoporosis therapy is essential and is the one of the most effective measures in reducing the occurrence of further fractures.

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