Retrospective Analysis

Causes of Residual Back Pain at Early Stage After Percutaneous Vertebroplasty: A Retrospective Analysis of 1,316 Cases

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Background: Percutaneous vertebroplasty (PVP) is now well accepted in the treatment of painful osteopathic vertebral compression fractures (OVCF), providing early pain relief and strengthening of the bone of the vertebrae. However, some patients still experienced severe back pain after PVP.

Objectives: To analyze the possible reason for unsatisfactory back pain relief (UBPR) after PVP at early stage.

Study Design: Retrospective analysis.

Setting: Hong-Hui Hospital in Xi'an.

Methods: Between March 2013 and January 2015, a total of 1,316 patients with OVCF were treated by PVP at our Hospital. Demographics, clinical data, and surgical data were collected to analyze the factors associated with UBPR after PVP.

Results: Sixty cases complained of UBPR, and the prevalence was 4.6%. Univariate analyses showed that preoperative bone mineral density (BMD), number of fractures, cement distribution and volume injected per level, lumbodorsal fascia contusion, and depression were associated with UBPR after PVP ($P < 0.001$). Multivariate analysis revealed that preoperative BMD (odds ratio [OR], 3.577; $P = 0.029$), lumbodorsal fascia contusion (OR, 3.805; $P = 0.002$), number of fractures (OR, 3.440; $P < 0.001$), cement volume injected per level (OR, 0.079; $P < 0.001$), cement distribution (OR, 3.009; $P = 0.013$), and depression (OR, 3.426; $P = 0.028$) were independently associated with UBPR after PVP at the early postoperative stage.

Limitations: A further prospective controlled study is needed to explore the association between the different degrees of the aforementioned factors and UBPR after PVP.

Conclusions: Preoperative low BMD, lumbodorsal fascial injury, multiple segment PVP, insufficient cement injected volume, unsatisfactory cement distribution, and depression were strong risk factors associated with UBPR after PVP in patients with OVCF.

Key words: Unsatisfactory back pain relief, residual back pain, percutaneous vertebroplasty

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Osteopathic vertebral compression fractures (OVCF) can cause severe back pain with associated morbidity and prolonged hospitalization. Percutaneous vertebroplasty (PVP), an internationally performed procedure consisting of the injection of polyethylene into a vertebral body lesion under direct radiologic guidance, has demonstrated advantages in terms of pain relief, bone strengthening, and early mobilization. Two randomized, controlled trials compared the benefit in terms of pain relief between PVP and nonsurgical management: the studies by Buchbinder et al (1) and Kallmes et al (2) came to opposing conclusions. Evidence-based guidelines (3) and systematic reviews (4) concluded that there is moderate evidence for the use of PVP in the management of patients with symptomatic OVCF refractory to conventional treatment. In a systematic review, a large proportion of patients (87%) had some pain relief, whereas a small but significant proportion of patients experienced residual pain after vertebral augmentation procedures. In other publications, the percentage of patients who experienced unsatisfactory back pain relief (UBPR) ranged from 5% to 22% (5-12). Thus, residual back pain after PVP is not rare, but can substantially impair the quality of life (13,14).

Factors associated with residual back pain after PVP have not been adequately described in previous case studies. Infections, rib fracture, cement leakage compressing the spinal cord or radicular nerves, new symptomatic compression fracture, nonhealing bone-cement interface, increased pressure in the intertrabecular space, cement-related inflammatory reaction, and transitory thoracolumbar fascia injury (Fig. 1) were identified as possible risk factors (9,15-17). However, no studies have extensively and comprehensively analyzed these risk factors. The aim of the present study was to explore factors that may affect residual back pain in patients with OVCF treated with PVP. This could help to identify patients at higher probability of residual back pain, allowing for proper intervention and improved clinical outcome.

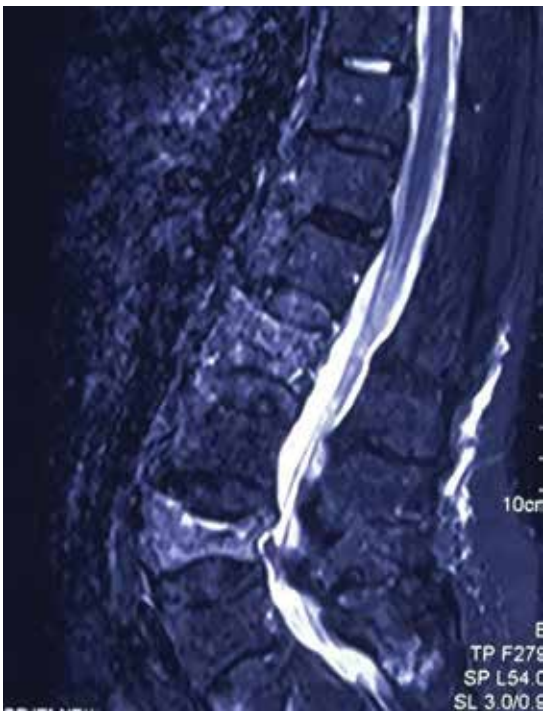

Fig. 1. *Thoracolumbar fascia injury was visible at the short time inversion recovery sequences of MRI*

Methods

This study was approved by the medical ethics committee of Xi'an Honghui Hospital in accordance with relevant guidelines and regulations, and informed consent was obtained from all patients. Between March 2013 and January 2016, a total of 1,316 patients with osteoporotic thoracic or lumbar vertebral fractures were treated by PVP at Xi'an Honghui Hospital, including 613 thoracic vertebrae and 863 lumbar vertebrae fractures. There were 842 female patients and 474 male patients. The mean age was 69.3 years (range, 61-87 years). Inclusion and exclusion criteria are described in Table 1.

Surgical Technique

PVP was performed under fluoroscopic guidance. An 11-gauge Jamshidi needle was placed percutaneously into the posterior vertebral body through either a unilateral transverse process-pedicle process or bilateral transpedicular approach. The detailed puncture technique has been described in our previous study (18). A bone drill was inserted into the anterior vertebral body to facilitate injecting the polymethylmethacrylate (PMMA, Via Andrea Doria, Verona, Italy) cement at a slightly deep position. The injection was terminated when there was satisfactory distribution of the cement or if there was any cement leak into an adjacent structure. The whole process of cement injection was always monitored with intermittent fluoroscopic evaluation

Table 1. *Inclusion and exclusion criteria.*

Indication criteria
1. Severe back pain (VAS score of back pain was > 6). 2. Back pain that was exacerbated on palpation and related to the location on x-ray in which bone marrow edema was visible on MRI short time inversion recovery sequences. 3. In the BMD examination, T value was ≤ –2.5. 4. The posterior wall of vertebral body was intact without any compression in the spinal canal.
Exclusion criteria
1. Defined cement leakage into spinal canal. 2. Rib fracture. 3. New facture at the nonoperative level. 4. Infection. 5. Pathological fracture owing to an old fracture or malignancy.

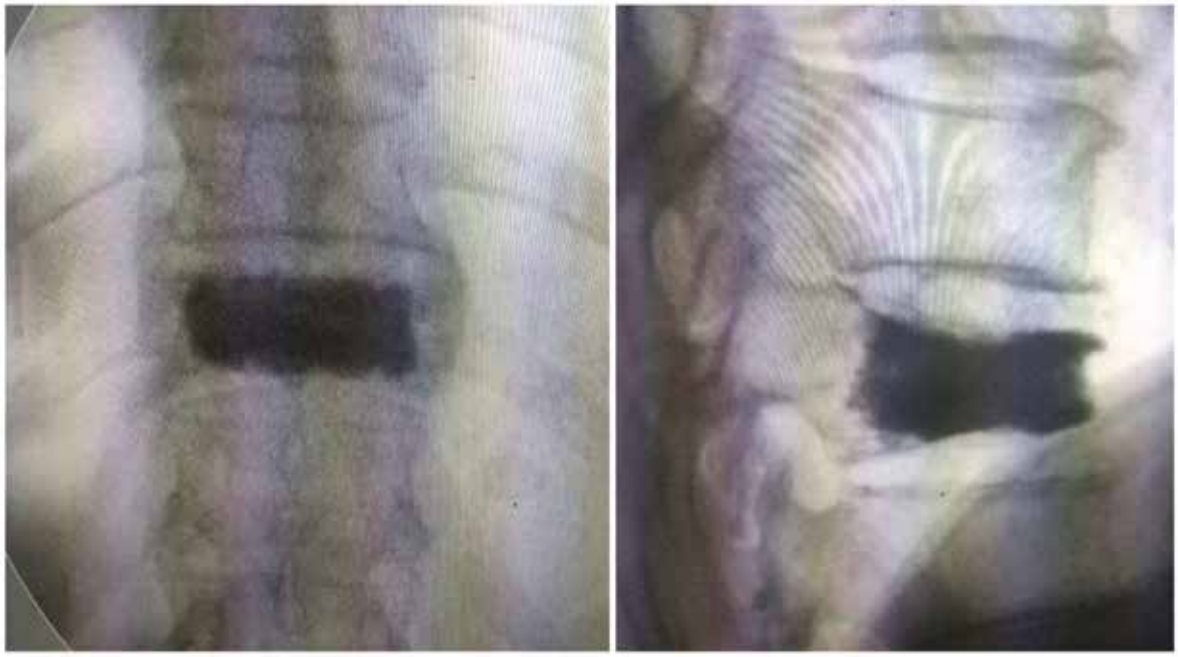

Fig. 2. *Satisfactory cement distribution was detected at the anteroposterior (left) and lateral (right) views of radiography.*

of the lateral projection. The trocar was not removed until the cement hardened. The incision was covered by water-impermeable dressing.

Postoperative Treatment and Follow-up

All patients received standard supplementation of calcium (1,000 mg daily) and vitamin D (2,000 IU daily) and antiosteoporosis therapy. All patients were scheduled for follow-up at 1 day, 1 week, 1 month, 3 months, and 1 year postoperatively, during which radiography and magnetic resonance imaging (MRI) (T1-weighted, T2-weighted, and short time inversion recovery sequences) were recommended to detect the existence of secondary OVCF. Visual Analog Scale (VAS) and Oswestry Disability Index (ODI) scores were recorded. We defined UBPR after PVP as a VAS score of > 4 both immediately postoperatively and one month postoperatively; satisfactory cement distribution was defined as cement spread from the superior to the inferior end plate, from the medial cortex of the pedicle to the medial cortex of the contralateral pedicle, and from the anterior cortex of the vertebral body to the posterior third of the vertebral body (Figs. 2 and 3).

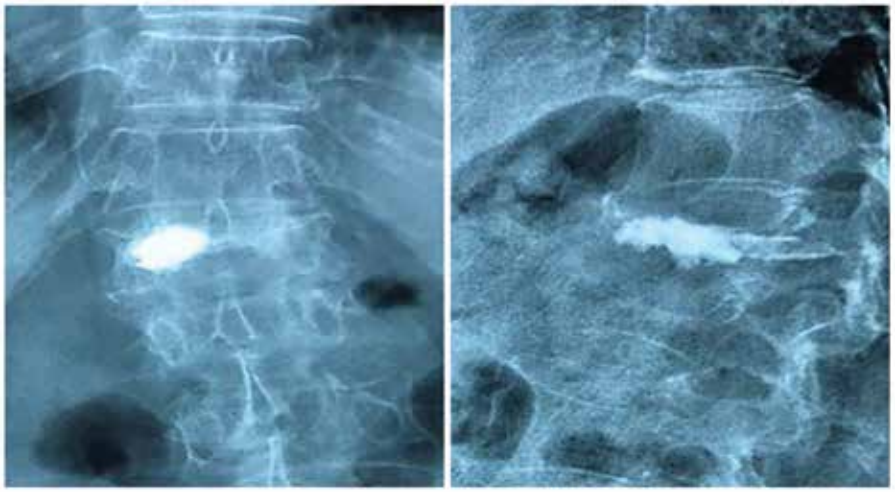

Fig. 3. *Unsatisfactory cement distribution was detected at the anteroposterior (left) and lateral (right) views of radiography.*

Table 2. *Changes of preoperative and postoperative VAS scores of back pain (x ± s).*

Groups	Preoperation	Immediately after operation	Postoperation1 month	Postoperation 3 months	Postoperation 12 months
Unsatisfactory group	7.1 ± 0.5	5.1 ± 0.5*	4.6 ± 0.4*	3.1 ± 0.3*	1.5 ± 0.3
Satisfactory group	7.3 ± 0.4	3.4 ± 0.5	2.8 ± 0.6	2.2 ± 0.3	1.3 ± 0.2

*$P < 0.05$

Table 3. *Changes of preoperative and postoperative ODI scores (x ± s).*

Groups	Preoperation	Immediately after operation	Postoperation 1 month	Postoperation 3 months	Postoperation 12 months
Unsatisfactory group	68.1 ± 6.5	55.3 ± 4.5*	51.6 ± 5.8*	43.4 ± 4.1*	32.4 ± 4.3
Satisfactory group	67.7 ± 5.7	45.4 ± 5.4	38.4 ± 5.5	35.1 ± 4.2	31.4 ± 3.2

*$P < 0.05$.

Data Collection

Factors that might have an influence on the efficacy of pain relief were evaluated, including demographic data (gender, age, height, and weight), surgical data (surgical approach, anesthesia, number of OVCF, cement volume injected per level), imaging data (cement distribution, thoracolumbar fascia injury, and preoperative bone mineral density [BMD]), and comorbidities (hypertension, diabetes, depression, and chronic obstructive pulmonary disease [COPD]). The definition of thoracolumbar fascia injury referred to in a previous article (16), which was based on the MRI finding of fascia edema and focal tenderness on physical examination in relation to the level of fascia edema.

Statistical Analysis

Data were analyzed using SPSS 22.0 software (IBM Corporation, Armonk, NY) and are presented as means ± standard deviation. Independent sample t test and the chi-square test were used to compare the difference between the 2 groups. Factors associated with residual pain were evaluated using logistic regression analysis, according to the inspection level, with $P < 0.05$ defined as statistically significant.

Results

Among 1,316 patients who underwent PVP successfully, a total of 60 cases (41 male patients and 19 female patients; age range, 68-85 years) reported UBPR and were classified in the unsatisfactory group; this represented 4.6% of the patient population. We randomly selected 60 patients with satisfactory back pain relief and assigned them to the satisfactory group. The VAS

Table 4. *Univariate analyses for all factors associated with residual back pain after PVP.*

Parameter	Satisfactory group (n = 60)	Unsatisfactory group (n = 60)	t/x^2	*P*
Age	69.19 ± 5.74	69.38 ± 4.30	0.299	0.766
Gender			0.246	0.620
Male	21 (35.0)	19 (31.7)		
Female	39 (65.0)	41 (68.3)		
Height	156.16 ± 6.78	156.40 ± 6.47	0.249	0.804
Weight	59.02 ± 4.34	59.10 ± 4.73	0.123	0.902
BMD	3.04 ± 0.25	3.29 ± 0.33	5.554	0.000
Surgical approach			0.143	0.706
Unilateral	29 (48.3)	27 (45.0)		
Bilateral	31 (51.7)	33 (55.0)		
Lumbodorsal fascia contusion			42.549	0.000
No	43 (71.7)	17 (28.3)		
Yes	17 (28.3)	43 (71.7)		
Depression			2.506	0.113
No	54 (90.0)	49 (81.7)		
Yes	6 (10.0)	11 (18.3)		
Cement distribution			7.414	0.006
Satisfactory	41 (68.3)	30 (50.0)		
Unsatisfactory	19 (31.7)	30 (50.0)		
Anesthesia			0.009	0.924
Local	27 (45.0)	27 (45.0)		
General	33 (55.0)	33 (55.0)		
Hypertension			0.827	0.363
No	24 (40.0)	28 (46.7)		
Yes	36 (60.0)	32 (53.3)		
Diabetes			0.446	0.504
No	34 (56.7)	37 (61.7)		
Yes	26 (43.3)	23 (38.3)		
COPD			0.392	0.531
No	47 (78.3)	45 (75.0)		
Yes	13 (21.7)	15 (25.0)		
Number of fractures	1.37 ± 0.60	2.17 ± 0.78	8.891	0.000
Cement volume injected per level	5.55 ± 0.46	4.75 ± 0.65	–9.062	0.000

and ODI scores of both groups are reported in Tables 2 and 3. Significant differences were observed at 1 week, 1 month, and 3 months postoperatively.

There was no statistically significant difference in the demographic characteristics (gender, age, body mass index, and vertebral height); unilateral or bilateral approach; local or general anesthesia; and comorbidities, such as hypertension, diabetes, and COPD between the 2 groups (Table 4). BMD (T-score) in the unsatisfactory group was –3.29 ± 0.33, which was worse than that in the satisfactory group (–3.04 ± 0.25; $P < 0.0001$). The cement volume injected per level was 4.75 ± 0.65 mL in the unsatisfactory group, which was lower than that in the satisfactory group (5.55 ± 0.46 mL; $P < 0.0001$). The number of OVCF was 2.17 ± 0.78 in the unsatisfactory group, which was higher than that in the satisfactory group

(1.37 ± 0.60; $P < 0.0001$). The presence of thoracolumbar fascia injury, depression, and cement distribution were significantly different between groups ($P < 0.01$).

Multivariate Analysis

A multivariate logistic model was used to test for factors independently associated with UBPR. Results showed that preoperative BMD (odds ratio [OR], 3.577; 95% confidence interval [CI], 1.138-11.25; $P = 0.029$), thoracolumbar fascia injury (OR, 3.805; 95% CI, 1.661-8.717; $P = 0.002$), number of fractures (OR, 3.440; 95% CI, 1.907-6.206; $P < 0.0001$), cement distribution (OR, 3.009; 95% CI, 1.264-7.1630; $P = 0.013$), cement volume injected per level (OR, 0.079; 95% CI, 0.036-0.172; $P < 0.0001$), and depression (OR, 3.426; 95% CI, 1.145-10.2550; $P = 0.028$) were independently associated with UBPR after PVP at the early postoperative stage (Table 5).

Discussion

PVP is currently accepted as a satisfactory and minimally invasive surgery, and it is becoming the standard procedure for pain relief in the management of OVCF. Although the rate of significant pain relief was reported to be as high as 78% to 95% among patients suffering from OVCF (5-12), residual back pain after PVP is not rare and can be clinically intractable, which can substantially impair quality of life (13,14). The findings of the current study are consistent with previous published literature, in which satisfactory pain relief was observed in 95.3% (1,256 of 1,316) at the early postoperative stage. A few studies have elaborated on the possible risk factors for residual back pain after PVP, including rib fracture, cement leakage compressing the spinal cord or radicular nerves, transitory and thoracolumbar fascia injury, infections, new symptomatic compression fracture, nonhealing bone-cement interface, increased pressure in the intertrabecular space, and cement-related inflammatory reaction (9,15-17). We defined a VAS > 4 as a cutoff to distinguish whether pain was unsatisfactorily relieved. According to the VAS score system, a pain of VAS > 4 is classified as moderate pain that can affect sleep, leading to impaired quality of life, and can usually be controlled with oral analgesics.

Rib fracture is a rare and overlooked complication after PVP. In published studies, the rate of rib fracture is < 7%. Layton et al (19) reported 7 cases among 673 procedures (1%); Evans et al (20) reported 7 cases in 245 patients (2.9%); and Jensen et al (6) reported 2 cases in 29 patients (6.9%, highest rate). Owing to compression of the thoracic wall during the process of dorsal puncture and the prone position maintained by the patient during the procedure, the fracture may be localized to the anterolateral aspect of the anterior chest wall for patients with osteoporosis. The types of fractures are often linear or minor and nondisplaced, and radiography may not identify the lesion. However, focal pain is detected at the rib fracture site on physical examination.

In our case series, C-reaction protein and erythrocyte sedimentation rate levels were routinely screened preoperatively to exclude the possibility of infectious spondylitis. Additionally, in some patients with occult infection, abnormal imaging signal can be detected in the intervertebral disc adjacent to the level of the vertebral fracture. Although cement leakage is a common complication of PVP, symptomatic leakage occurs in only a small proportion of patients, when the cement leaks into the spinal canal over the limit of compensation of epidural space. Eck et al (21) performed a meta-analysis and found that among 9,330 vertebral bodies treated with cement injection, cement leakage out of the vertebral body could be identified in 1,838, representing a prevalence of 19.7%. However, symptomatic cement leakage accounted for only 65 of 4,125 cases

Table 5. *The multifactor logistic regression analysis for the factors associated with residual back pain after PVP.*

	B	SE	Wald	P	OR	OR (95%) CI	
						Lower	Upper
BMD	1.275	0.585	4.755	0.029	3.577	1.138	11.25
Lumbodorsal fascia contusion	1.336	0.423	9.983	0.002	3.805	1.661	8.717
Cement distribution	1.102	0.443	6.197	0.013	3.009	1.264	7.163
Number of fractures	1.235	0.301	16.836	0.000	3.440	1.907	6.206
Cement volume injected per level	–2.542	0.400	40.383	0.000	0.079	0.036	0.172
Depression	1.231	0.559	4.846	0.028	3.426	1.145	10.255

Abbreviations: B, baseline; SE, standard error

(1.6%), which was manifested as nerve root irritation (radiculopathy) and/or spinal cord compression (myelopathy). Radiography or computed tomography are valuable tools to evaluate the extent and severity of the leakage. New compression fractures are another complication leading to worse long-term outcome. In the meta-analysis reported by Eck et al (21), the prevalence of new compression fractures after PVP was 565 among 3,159 cases (17.9%). However, new compression fractures are seldom encountered during the one month postoperative period; the risk gradually increases with the extension of follow-up. Additionally, new compression fractures were not observed on MRI at one month postoperatively. Thus, the residual pain originating from rib fracture, infection, leakage into the spinal canal, or new compression fractures can be recognized and excluded from the study.

Thoracolumbar fascia injury is common among patients with OVCF. In the prospective cohort study reported by Yan et al (16), the prevalence of fascial injury was as high as 42.1%, and the association between thoracolumbar injury and residual back pain after PVP was addressed (12). As pain originating from the micromovement of the vertebral fracture can be prevented with the elimination of microfractures after vertebral augmentation, soft-tissue injury, such as thoracolumbar fascia injury, could be an alternative cause of residual back pain. Our study showed that thoracolumbar fascia injury is a strong risk factor for UBPR after PVP, with an OR of 3.805.

For patients with low BMD, the quality of the vertebral bodies was poor, resulting in a greater probability of multilevel OVCF. Collapse of the multisegment vertebral body can lead to sagittal imbalance of the entire spine. Patients must compensate via retroversion of the pelvis and increased kyphosis of the thoracic spine. The abnormal alignment in the sagittal plane explains why the combination of low BMD and multilevel PVP were associated with UBPR after PVP. Additionally, the trabecular bone of the vertebral bodies was fragile, which was easily compressed by the mild axial loading force. New vertebral fractures often reappeared on the basis of old ones. Thus, vertebral collapse was usually more severe in these patients; the compressed trabeculae can affect the distribution of cement, further impairing the efficacy of surgery.

Whether PVP with the unilateral or bilateral approach can provide equal efficacy has been controversial. In a recent systematic review (22), no difference in radiologic and clinical outcome between the unilateral and bilateral approaches was observed in PVP treatment of OVCF. This conclusion was consistent with the findings of the present study. We believe that the amount and distribution of cement are the key factors associated with the analgesic mechanism of PVP. Sufficient cement injection with satisfactory distribution can induce a better effect to stabilize micromovements and fill the gap between microfractures. Thus, a better analgesic effect can be obtained after cement injection. Fu et al (23) performed a study to investigate the possibility of a dose–response correlation between cement volume and pain relief after vertebroplasty and reported a positive dose–response association between cement volume and degree of pain relief after PVP. Our study showed that in addition to cement volume injected per level, cement distribution is also a factor associated with UBPR after PVP. The OR of cement distribution was higher than that of cement volume injected per level, indicating that the degree of cement distribution can be a more direct factor in the elimination of microfractures and relief of pain generated from micromovement. The injection of bone cement is usually along the fracture cracks and is dispersed under pressure perfusion. However, OVCF usually represents compression fractures characterized by collapse of the end plate. The compressed trabeculae can form a hardened layer that affects the dispersion of cement (Fig. 4). Gaughen et al (14) and He et al (24) performed repeat vertebroplasty at the vertebral body of the initial cement injection to treat patients with UBPR. They considered that a satisfactory analgesic effect was achieved with adequate filling of the cement in the unstable fractured areas.

Several studies (25-28) have indicated that depression was negatively associated with postoperative pain and functional outcomes, and pretreatment with antidepressants preoperatively was beneficial for improvement in pain relief and functional ability. This conclusion was also supported by our study. Different from other comorbidities, such as hypertension, diabetes, or COPD, depression is another strong risk factor associated with UBPR after PVP, with an OR of 3.426.

Significant differences in VAS and ODI were observed at the early stage postoperatively, including postoperative 1 week, 1 month, and 3 months. We considered that the pain originating from soft-tissue injury can be eliminated with resolution of oedema of the thoracolumbar fascia and the underlying muscles. Additionally, intraosseous oedema resulting from the microfractures that were not bonded by cement can also be improved with conservative therapy intraosse-

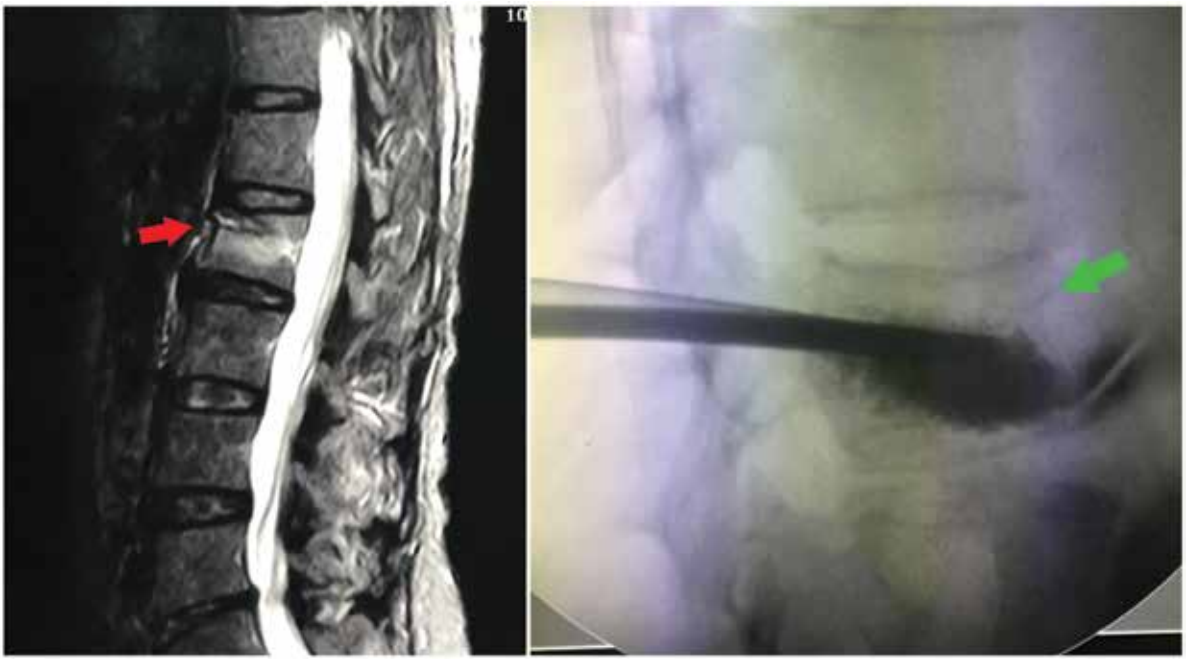

Fig. 4. *The compressed trabeculae can form a hardened layer (left, red arrow) that affects the dispersion of cement (right, green arrow).*

ous oedema meant the intervertebral trabeculae edema. Among the discussed factors, only malalignment at the sagittal plane is a factor affecting long-term efficacy. However, different from the acute pain generated from the vertebral body or soft tissue, pain due to sagittal imbalance is dull. The impact on quality of life is lower than that of the first 2 factors. This can explain why the clinical outcome was comparable at one year postoperatively. Although long-term follow-up can be performed for exploring the influence of sagittal imbalance on clinical outcome, with an extended duration of follow-up, other confounding factors, such as nonunion or secondary vertebral fractures, can increase the complexity of multifactorial analysis.

There are several limitations to this study. Pain in OVCF is associated with multiple factors. Only the common factors associated with pain relief were included in this analysis. We included patients with unrelieved pain during the first month postoperatively; the long-term complications such as nonunion or secondary vertebral fractures were not included. A further prospective controlled study is needed to explore the association between the different degrees of the aforementioned factors and UBPR after PVP.

Conclusions

Preoperative low BMD, lumbodorsal fascial injury, multiple segment PVP, insufficient cement injected volume, unsatisfactory cement distribution, and depression were strong risk factors associated with UBPR after PVP in patients with OVCF, which should be addressed during preoperative communication and postoperative management. Intraoperatively, sufficient cement injection with satisfactory distribution should be achieved for improved clinical outcome.

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