Prospective Study

The Effect of Early Limited Activity after Bipedicular Percutaneous Vertebroplasty to Treat Acute Painful Osteoporotic Vertebral Compression Fractures

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Background: Although percutaneous vertebroplasty (PVP) can effectively relieve the pain for patients with acute osteoporotic vertebral compression fractures (OVCFs), many patients still complain of mild back pain in the early postoperative period.

Objectives: The aim of this study was to assess the effect of early limited activity (LA) on prognosis after bipedicular small-cement-volume (i.e., PVP) to treat single-segment acute OVCFs.

Study Design: A prospective study and retrospective observations were performed on 125 patients with a minimum of 1 year of follow-up.

Setting: A university hospital orthopedics and pathology departments.

Methods: All patients were allocated into an LA group (n = 64) and an unlimited activity group (ULA group, n = 61). Patients in the LA group were suggested to keep time of off-bed activity < 4 hours per day in the first 3 weeks postoperatively. Patients in the ULA group did not limit activity. The demographic, clinical, and radiologic outcomes were assessed, such as pain intensity Numeric Rating Scale (NRS-11) and vertebral height ratio (i.e., fractured vertebral height/adjacent nonfractured vertebral height). Based on outcomes following surgery, all patients were classified as responders (NRS-11 score 1-day postoperation < 50% of preoperative NRS-11 score) or low responders (NRS-11 score 1-day postoperation ≥ 50% of preoperative NRS-11 score).

Results: The demographic results and complications were similar. In the LA group, NRS-11 scores at 1 and 3 months postoperation respectively were 2.23 ± 0.42 and 1.46 ± 0.40, and corresponding scores respectively were 2.85 ± 0.80 and 1.73 ± 0.77 in the ULA group, and there was a difference in the 2 groups in both time points ($P < 0.05$). At 12 months postoperation, anterior and middle vertebral height ratio respectively were 78.42% ± 3.52% and 82.37% ± 3.49% in the LA group, which were higher than 76.87% ± 3.68% and 81.10% ± 3.31% in the ULA group ($P < 0.05$). Thirty-two cases were low responders. Among those, NRS-11 scores at 1 and 3 months postoperation respectively were 2.29 ± 0.45 and 1.53 ± 0.46 in the LA group, which were lower than 3.67 ± 0.80 and 2.56 ± 0.79 in the ULA group ($P < 0.05$), and at 12 months postoperation, anterior vertebral height ratio was 79.81% ± 3.25% in the LA group and 75.60% ± 3.50% in the ULA group ($P < 0.05$).

Limitations: First, some patients lacked the results of bone mineral density during follow-up; second, the limited time in our study was chosen from our previous working experience, which may lack an objective basis; third, NRS-11 is solely used as an indicator of clinical outcomes in our study; finally, our next studies can increase the sample size to improve the clinically difference.

Conclusions: LA in the early period after PVP can help patients achieve more pain relief postoperatively and maintain better vertebral shape, especially for low responders.

Key words: Osteoporotic vertebral compression fractures, percutaneous vertebroplasty, Numeric Rating Scale, vertebral height, responders, low responders, limited activity, complications

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Percutaneous vertebroplasty (PVP) and percutaneous kyphoplasty (PKP) are 2 minimally invasive procedures that involve radiographically guided injection of bone cement directly into the vertebral bodies. They are widely applied to treat osteoporotic vertebral compression fractures (OVCFs). PKP has obvious advantages in the recovery of the vertebral shape and correction of the spinal kyphosis compared with PVP (1,2). However, PVP requires simpler operating procedures and lower cost than PKP. Therefore, PVP is more acceptable to operators and patients when the vertebral compression degree is not very serious.

Many authors have suggested that more bone cement should be injected into vertebral bodies, which would help OVCF patients achieve better pain relief by maintaining vertebral stability and increasing strength of the injured vertebral bodies (3,4). However, injection with a large volume of bone cement may be associated with an increased risk of complications, such as cement leakage and new, adjacent vertebral fractures (5-7). In contrast, some authors have suggested that injection with a small volume of bone cement (2 to 4 mL) could help OVCF patients achieve satisfactory pain relief as well (8,9). No matter how much bone cement is used in OVCF patients, some patients still only achieve weak pain relief, and almost all patients feel various degrees of mild back pain in the early period postoperatively (10).

Acute OVCF patients with vertebral compression ratio under 50% were always treated with bilateral PVP by using a small volume of bone cement in our spinal operative group in this hospital. In our previous works, we found that some acute OVCF patients could obtain satisfactory outcomes by reducing the time of off-bed activity in the early period after PVP. By comparing the clinical data between 2 groups of patients, treated with limited activity (LA) and unlimited activity (ULA), in the early period after PVP, the aim of this study was to investigate whether early limited off-bed activity could help patients recover better.

Methods

Patient Population

Between April 2014 and December 2016, 129 patients diagnosed with single-segment acute OVCFs from T10 to L5 with vertebral compression ratio under 50% were treated in our spinal operative group. The vertebral compression ratio was assessed from lateral radiographs of the spine using the equation: vertebral compression ratio = 1- (anterior vertebral height/posterior vertebral height). The basic data were recorded in all patients, including age, gender, causes of fracture, preexisting comorbidities, T-score, type of fracture, cement leakage examined by postoperative computed tomography (CT) scan, complications and adverse events.

All patients received x-ray, CT, and magnetic resonance imaging (MRI) before PVP treatment. The inclusion criteria in this study were as follows: (1) single-segment OVCFs; (2) vertebral compression ratio < 50%; (3) aged above 60 years; (4) segments of OVCFs from T10 to L5; (5) history of back trauma < 5 days; and (6) low signal on T1-weighted and high signal on short inversion time inversion recovery sequences in the fractured vertebra, and no evidence of posterior ligamentous complex injury on MRI. Exclusion criteria were as follows: (1) multiple-segment OVCFs; (2) pathologic fractures; (3) long-term chronic low back pain; (4) thoracolumbar and lumbar burst fractures; and (5) long-term use of hormone therapy or chemotherapy. The study protocol was approved by the ethics committee of our hospital and written informed consent for this study design was obtained from all patients.

Patients were allocated into 2 groups according to the admission time. Briefly, patients hospitalized in odd-numbered months were allocated into the LA group, and patients hospitalized in even-numbered months were allocated into the ULA group. In the LA group, in the first 3 weeks after PVP, patients were encouraged to undergo more bed rest, and off-bed activity was recommended to be < 4 hours per day and to last no more than 30 minutes per time. After 3 weeks postoperatively, these patients were encouraged to gradually perform more daily activity. In the ULA group, if patients could tolerate pain after PVP, they were encouraged to perform daily activity without limited time. The off-bed activity time per day in the first 3 weeks postoperatively was recorded in all patients. Based on their outcomes following surgery, all patients were subsequently classified as responders (Numeric Rating Scale [NRS-11] score 1-day postoperation < 50% of preoperative NRS-11 score) or low responders (NRS-11 score 1-day postoperation ≥ 50% of preoperative NRS-11 score).

Surgical Techniques

All PVP procedures were performed by 2 surgeons in all patients. All procedures were performed under local anesthesia using intermittent C-arm fluoroscopic

guidance. The patients were placed in the prone position on the operating table. The hyperextension position of the lumbar vertebra with a chest and iliac cushion under the body helped reduce fractures. After bilateral marking on the skin and local anesthesia with fluoroscopic guidance, a small incision was made with a scalpel blade. To reduce the radiation dose, all patients were chosen for the bilateral puncture approach in the same amount of time. Two 10G bone-puncture needles (Kynetyc, Shanghai, China) were placed transpedicularly in the fractured vertebra simultaneously. The defined volume of polymethylmethacrylate bone cement (Tecres S.P.A., Verona, Italy) in each side was approximately 1.5 mL at the T10 to L5 segments. The cement was injected between the anterior one-third and posterior one-third vertebrae in the lateral view. When cement had infiltrated into the anterior one-fourth or posterior one-fourth of vertebrae in the lateral view, the needle was repositioned to further inject, or the injection operation was stopped (typical perspective images are shown in Fig. 1). All patients were observed in the supine position for 4 hours after PVP operation, and an overnight hospital stay was required. They were discharged the next day. All patients were prescribed calcium carbonate, vitamin D3 granules, and salmon calcitonin (nasal spray) for at least 3 months. According to the expert consensus and guidelines in our country, the use of the earlier mentioned drugs was allowed in the clinic, especially for patients who suffered from acute fracture (11,12). The operative time, perspective times, operative segments, and volume of bone cement were recorded in all patients. The perspective times meant the frequency (number of times) that the C-arm was used during the operation.

Clinical and Radiologic Assessments

Back pain was assessed by a 0 to 10 cm NRS-11 at preoperation and 1 day, 1 month, 3 months, 6 months, and 12 months after PVP. The signal intensity of paravertebral tissues was observed on preoperative T2-weighted MRI images. In addition, imaging follow-up consisted of anterior-posterior and lateral spinal radiograph examinations at 1 day, 1 month, 3 months, and 12 months after PVP, and the anterior and middle vertebral heights were measured from lateral radiographs for the treated vertebra and for the adjacent nonfractured vertebrae. The anterior vertebral height ratio (AVHR) was determined by dividing the anterior height of the fractured (treated) vertebra by the mean anterior height of the adjacent superior and inferior nonfractured vertebrae. The middle vertebral height ratio (MVHR) was similarly calculated based on the midvertebral heights of the fractured and adjacent vertebrae. The cement leakage was examined by postoperative CT scan. Complications and adverse events were recorded in all patients.

Statistical Analysis

All data were analyzed by SPSS Version 19.0 (IBM Corporation, Armonk, NY), and the results are expressed as the mean ± standard deviation. The data of demographics, off-bed time, surgical parameters, complications, vertebral height, and NRS-11 scores between the LA group and the ULA group were analyzed by the independent sample t test, and the NRS-11 scores and vertebral height between the preoperation and postoperative 1 day were analyzed by the paired samples t test. Significance was set at $P < 0.05$.

Results

Demographics and Surgical Parameters

Demographic data and surgical parameters are summarized in Table 1. There were no statistically significant differences between the LA and ULA groups except that the mean off-bed time per day was greater in the ULA group ($P < 0.001$). Four patients were lost to follow-up, so the follow-up rate was 96.90% (125 of 129 patients). Sixty-four patients were allocated into the LA group, and 61 patients were allocated into the ULA group. The number of patients suffering from preexisting comorbidities was similar between the 2 groups. In addition, 32 cases were classified as low responders: 15 cases in the LA group and 17 cases in the ULA group. Ninety-three cases (49 in the LA group and 44 in the ULA group) were classified as responders, and the remainder (15 in the LA group and 17 in the ULA group) were classified as low responders. In responders, the causes of OVCFs included traffic accident (12), low falling (2), flat falling (40), and no obvious trauma (39), and in low responders they included traffic injury (15), low falling (7), and flat falling (10).

Clinical Assessment

The mean off-bed time per day in the first 3 weeks postoperatively was 3.89 ± 0.60 hours in the LA group and 10.87 ± 2.31 hours in the ULA group ($P < 0.01$) (Table 1). The outcomes of NRS-11 score are shown in Tables 2 and 3. At 1 day postoperation, both groups showed similar levels of pain relief, indicated by the fall in NRS-11, but at 1 and 3 months postoperation, NRS-11 scores

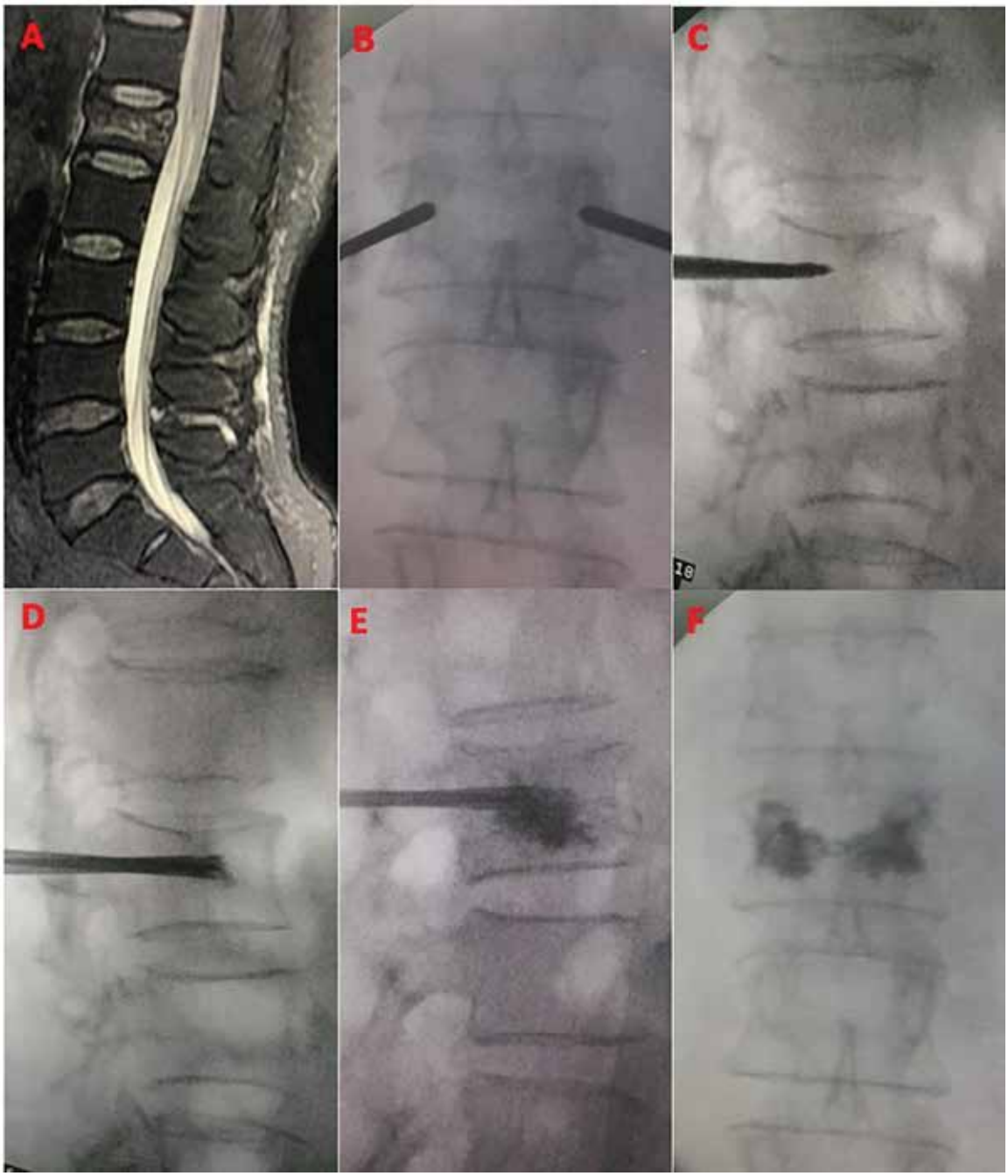

Fig. 1. *Preoperation MRI and intraoperation and postoperation perspective images from a woman aged 71 years who underwent bipedicular PVP. (A) The high-signal intensity of L1 vertebral body and back soft tissues on T2-weighted MRI. (B,C) Bilateral puncture approach under an anterior-posterior and lateral perspective guide. (D) The major cement injective position. (E,F) Three milliliters of cement injection into L1 fractured vertebra under anterior-posterior and lateral perspective guidance.*

Table 1. *Demographics, surgical parameters and complications data.*

Variable	Total	LA group	ULA group	*P* value
Number of patients (n)	125	64	61	
Age (year)	72.38 ± 6.06	72.36 ± 6.10	72.41 ± 6.06	$P = 0.963$
Sex (male/female)	46/79	22/42	24/37	$P = 0.568$
Pre-existing comorbidities (n)				
Hypertension	36	20	16	
Diabetes	29	13	16	
Coronary disease	16	7	9	
Respiratory disease	20	8	12	
Cerebrovascular disease	16	9	7	
Mean T-score	-3.11 ± 0.21	-3.13 ± 0.20	-3.09 ± 0.23	$P = 0.252$
Mean operative time (min)	38.47 ± 5.85	38.28 ± 5.71	38.67 ± 6.04	$P = 0.710$
Mean perspective times	12.84 ± 1.79	12.92 ± 1.82	12.75 ± 1.78	$P = 0.603$
Mean off-bed time per day (h)	7.30 ± 3.88	3.89 ± 0.60	10.87 ± 2.31	$P < 0.001$
Type of fracture (n)				
Wedge-shape	48	25	23	
Biconcave-shape	35	18	17	
Crushed-shape	42	21	21	
Level (n)				
T10-L2	98	50	48	
L3-L5	27	14	13	
Volume of injected cement (mL)				
T10-L2	2.84 ± 0.40	2.81 ± 0.36	2.88 ± 0.43	$P = 0.340$
L3-L5	3.50 ± 0.26	3.51 ± 0.27	3.48 ± 0.25	$P = 0.826$
T10-L5	2.98 ± 0.46	2.96 ± 0.45	3.01 ± 0.47	$P = 0.528$
Asymptomatic cement leakage (n)	25	13	12	
Lateral venous	9	4	5	
Lateral fracture	7	4	3	
Prevertebral	9	5	4	
New vertebral fracture (n)	9	4	5	
Adjacent	3	1	2	
Nonadjacent	6	3	3	
Urinary system infection (n)	1	1	0	

LA = Limited activity; ULA = Unlimited activity. Values = Mean ± SD

Table 2. *Changes in the NRS scores during follow-up.*

Groups	Pre-operation	Postoperative 1 day	Postoperative 1 month	Postoperative 3 months	Postoperative 6 months	Postoperative 12 months
LA group	8.15 ± 0.57	3.74 ± 0.50	2.23 ± 0.42**	1.46 ± 0.40*	1.09 ± 0.31	0.80 ± 0.33
ULA group	8.21 ± 0.55	3.79 ± 0.54	2.85 ± 0.80	1.73 ± 0.77	1.22 ± 0.43	0.87 ± 0.37

LA = Limited activity; ULA = Unlimited activity. ** $P < 0.01$ vs ULA group; * $P < 0.05$ vs ULA group. Values = Mean ± SD

Table 3. *Changes in the NRS scores during follow-up among the low responders and responders.*

Groups		Pre-operation	Postoperative 1 day	Postoperative 1 month	Postoperative 3 months	Postoperative 6 months	Postoperative 12 months
Low responders	LA group (n=15)	7.88 ± 0.63	4.26 ± 0.32	2.29 ± 0.45**	1.53 ± 0.46**	1.19 ± 0.33**	0.84 ± 0.37
	ULA group (n=17)	8.18 ± 0.54	4.42 ± 0.43	3.67 ± 0.80	2.56 ± 0.79	1.68 ± 0.31	1.03 ± 0.42
Responders	LA group (n=49)	8.23 ± 0.52	3.59 ± 0.43	2.21 ± 0.41**	1.44 ± 0.39	1.06 ± 0.31	0.79 ± 0.32
	ULA group (n=44)	8.22 ± 0.56	3.55 ± 0.35	2.54 ± 0.54	1.40 ± 0.46	1.04 ± 0.33	0.81 ± 0.33

LA = Limited activity; ULA = Unlimited activity. ** $P < 0.01$ vs ULA group; * $P < 0.05$ vs ULA group. Values = Mean ± SD

Table 4. *Changes in the vertebral height ratio during follow-up.*

Groups	Pre-operation		Postoperative 1 day		Postoperative 1 month		Postoperative 3 months		Postoperative 12 months	
	AVHR	MVHR	AVHR	MVHR	AVHR	MVHR	AVHR	MVHR	AVHR	MVHR
LA group	72.20 ± 2.35%	76.95 ± 2.75%	84.97 ± 3.30%	88.51 ± 3.40%	83.14 ± 3.23%	86.87 ± 3.36%	79.71 ± 3.28%*	83.52 ± 3.43%	78.42 ± 3.52%*	82.37 ± 3.49%*
ULA group	72.17 ± 2.42%	76.21 ± 2.93%	84.78 ± 3.01%	87.88 ± 3.11%	82.67 ± 3.12%	85.96 ± 3.08%	78.50 ± 3.30%	82.61 ± 3.21%	76.87 ± 3.68%	81.10 ± 3.31%

LA = Limited activity; ULA = Unlimited activity . AVHR= Anterior vertebral height ratio; MVHR= Middle vertebral height ratio. * $P < 0.05$ vs ULA group. Values = Mean ± SD

were significantly lower in the LA group compared with the ULA group (Table 2). When low responders were considered separately from responders, NRS-11 values were again lower in the LA group than the ULA group at 1 month postoperation for both responders and low responders. However, in low responders, NRS-11 scores continued to remain lower in the LA group at 3 and 6 months postoperation (Table 3).

Six patients in the LA group and 14 patients in the ULA group complained of pain at points of the lateral back muscle away from the fractured vertebra at 1 month postoperatively, and 2 patients in the LA group and 6 patients in the ULA group complained of similar pain at 3 months postoperatively. All of these patients were low responders.

Radiologic Assessment

Radiologic measures for the LA and ULA groups are shown in Table 4. The mean AVHR and MVHR were significantly increased after PVP compared with preoperation in both groups ($P < 0.01$). At 3 months postoperatively, the AVHR was 79.71% ± 3.28% in the LA group and 78.50% ± 3.30% in the ULA group ($P < 0.05$). At 12 months postoperatively, the AVHR and MVHR respectively were 78.42% ± 3.52% and 82.37% ± 3.49% in the LA group, which were significantly higher than that in the ULA group ($P < 0.05$). Radiologic measures in low responders and responders are shown in Tables 5 and 6, respectively. In low responders, AVHRs in the LA group were significantly higher than in the ULA group at 3 and 12 months postoperatively ($P < 0.05$), but no such differences were observed for the responders. MRI revealed varying degrees of high-signal intensity in the soft tissues of the back on T2-weighted images. These were observed in 29 of 32 (90.6%) low responders compared with 14 of 93 (15.1%) responders.

Complications

Complications are shown in Table 1. Cement leakage was observed in 13 patients in the LA group and 12 patients in the ULA group. However, none of these patients suffered symptomatic leakage that caused neurologic deficit, embolism, or death. A total of 9 patients (4 in the LA group and 5 in the ULA group) suffered from new vertebral fractures during 12 to 30 month follow-up (mean follow-up time 22 months), and in 3 of these cases the new fracture occurred adjacent to the previously fractured (and treated) vertebra. The cause of new vertebral fractures was sudden fall in 4 patients, traffic accident in 3 patients, and slight injury in 2 patients. All 3 patients who suffered from new adjacent fractures had a relatively lower AVHR (64%, 67%, 69%) counted by the equation in the Methods section, and the anterior vertebral height of the adjacent treated vertebrae was measured from lateral radiograph at last follow-up before the new fracture. One patient in the LA group had urinary system infection. No patients had deep vein thrombosis, muscle atrophy, joint stiffness, hypostatic pneumonia, or decubitus.

Discussion

This study found that bipedicular PVP treatment with a small volume of bone cement could help single-segment acute OVCF patients achieve significant pain relief with low risk of cement leakage and new adjacent vertebral fractures, which agreed with most previous reports about PVP with small volumes of bone cement (8,13). Limiting the time of off-bed activity in the first 3 weeks postoperatively helped patients achieve more pain relief in the first 1 to 3 months after PVP and

Table 5. *Changes in the vertebral height ratio during follow-up among the low responders.*

Groups	Pre-operation		Postoperative 1 day		Postoperative 1 month		Postoperative 3 months		Postoperative 12 months	
	AVHR	MVHR	AVHR	MVHR	AVHR	MVHR	AVHR	MVHR	AVHR	MVHR
LA group (n=15)	71.45 ± 2.85%	76.14 ± 3.63%	84.63 ± 3.62%	87.25 ± 4.43%	83.09 ± 3.35%	86.12 ± 4.38%	80.50 ± 3.00%*	82.91 ± 4.86%	79.81 ± 3.25%**	81.54 ± 4.66%
ULA group (n=17)	72.29 ± 2.16%	76.46 ± 2.79%	85.16 ± 2.63%	87.86 ± 2.79%	82.96 ± 2.79%	86.11 ± 2.73%	77.50 ± 3.23%	82.58 ± 2.80%	75.60 ± 3.50%	80.24 ± 2.69%

LA = Limited activity; ULA = Unlimited activity. AVHR= Anterior vertebral height ratio; MVHR= Middle vertebral height ratio. ** $P < 0.01$ vs ULA group; * $P < 0.05$ vs ULA group. Values = Mean ± SD

Table 6. *Changes in the vertebral height ratio during follow-up among the responders.*

Groups	Pre-operation		Postoperative 1 day		Postoperative 1 month		Postoperative 3 months		Postoperative 12 months	
	AVHR	MVHR	AVHR	MVHR	AVHR	MVHR	AVHR	MVHR	AVHR	MVHR
LA group (n=49)	72.42 ± 2.16%	77.20 ± 2.42%	85.07 ± 3.23%	88.90 ± 2.97%	83.16 ± 3.22%	87.11 ± 3.00%	79.46 ± 3.35%	83.71 ± 2.90%	78.00 ± 3.52%	82.62 ± 3.06%
ULA group (n=44)	72.12 ± 2.54%	76.12 ± 3.00%	84.63 ± 3.16%	87.89 ± 3.25%	82.56 ± 3.27%	85.90 ± 3.23%	78.88 ± 3.28%	82.62 ± 3.39%	77.35 ± 3.67%	81.43 ± 3.49%

LA = Limited activity; ULA = Unlimited activity . AVHR= Anterior vertebral height ratio; MVHR= Middle vertebral height ratio. ** $P < 0.01$ vs ULA group; * $P < 0.05$ vs ULA group. Values = Mean ± SD

maintain better vertebral shape in the long term, and benefits were greater in the low responders.

Mechanical stabilization is regarded as the most probable reason for pain relief after PVP. The pain is mainly related to the motion of the endplate and the micromotion of the trabecular fractures (14,15). When patients undergo PVP treatment with a small volume of bone cement, we speculate that there still is some micromotion of the trabecular fractures, which may result in mild pain, and it is easy to understand why LA would improve pain relief by decreasing micromotion of trabecular fractures in the first few weeks after PVP (14). In this study, better pain relief was found in the LA group at 1 and 3 months postoperatively, especially in lower responders. We think that 2 causes could account for this phenomenon. First, because stability contributes to the union of vertebral fractures, LA in the LA group afforded relatively more stability than in the ULA group, which promoted the fast union of fractures. Second, because vertebral fractures might be associated with soft-tissues injury around the spine, LA can help injured soft tissues recover, further relieving pain caused by above injured tissues (16). In this study, at 1 and 3 months postoperatively, some patients complained that there was still some pain at points of the lateral back muscle away from the fractured vertebra, and these complaints all belonged to low responders. Many patients suffered from traffic accident, or fall from low level to ground, and those traumas might lead to back soft-tissue injury, which was evaluated by preoperative MRI showing paravertebral high-signal intensity on T2-weighted images that was an effective tool to evaluate the soft-tissue injury around the spine (17,18). Therefore, we suggested that the incidence rate and degree of back soft-tissue injury was higher among low responders than that among responders, which could explain why the pain relief after PVP was worse in low responders for partial pain caused by soft-tissue injury, which could not be relieved by stability of vertebral bodies (16). Further, for low responders LA could improve the recovery of injured soft tissues and reduce the pain after PVP.

Vertebral height loss is a common phenomenon after a period of PVP treatment (19,20). There was more loss of vertebral height at 3 and 12 months postoperatively in the ULA group than in the LA group, which indicated that LA in the acute period was better for vertebral shape maintenance. Although 3 weeks are not enough time for complete union of fractures, limited off-bed activity can reduce vertical pressure on vertebral fractures and micromotion of fractures, which may afford a benefit for the union of fractures and

restoration of vertebral height. However, a significant difference in the AVHR between the 2 groups appeared at 3 months postoperatively in this study. We speculate that more activity in the ULA group may have resulted in an increase in vertebral clefts. When vertebral clefts collapse after several months activity, vertebral height is gradually altered. In addition, among low responders the results showed that there was more loss of vertebral height at 3 and 12 months postoperatively in the ULA group than that in the LA group, but the outcome showed no significant difference among responders. We considered that the relatively higher energy of trauma might result in poor stability of vertebral bodies among low responders than that among responders, for the trauma rate was 58% (54 of 93) in responders and 100% (32 of 32) in low responders. Therefore, the PVP treatment was enough to maintain the stability of vertebral bodies for responders but might not be enough for low responders, and LA might be a good complementary treatment for those patients. Although vertebral height loss does not often result in serious complications, some authors have reported that better vertebral height restoration was related to lower risk of new adjacent vertebral fractures (21-23). In this study, only 3 patients had new adjacent vertebral fractures, and all 3 of those patients suffered from a relatively bad vertebral shape with anterior vertebral height restoration ratio < 70%.

Obviously, limited off-bed activity may increase patients' inconveniences. In this study, the LA group were prescribed < 4 hours per day of off-bed activity, which could allow them to do necessary daily life activities, including eating, going to the toilet, and taking a walk. Therefore, this type of LA can easily be accepted by most patients. In particular, if patients still feel mild-moderate pain, they would be inclined to accept LA. Of course, more time on bed rest would increase the risk of bed-ridden complications, such as deep vein thrombosis, muscle atrophy, pneumonia, and urinary tract infection. However, the bed rest was not continuous, and simple regular extremity activities in bed were encouraged in this study, such as active ankle movement, so there was a very low incidence of bed-ridden complications (24,25).

PVP with a small volume of bone cement has the clear advantage of a low risk of complications, especially in terms of cement leakage and new adjacent vertebral fracture. In this study, the incidence of cement leakage shown by CT scan was only 20%, which was much lower than that in many previous reports with a large volume of cement (5). Because PVP is always guided by lateral view in most hospitals, 2 important types of bone cement leakage, intraspinal leakage and disc leakage, can often be avoided by reducing the volume of bone cement. However, the lateral leakage is still easy to ignore. In this study, cement leakage occurred from a lateral fracture or via the lateral venous supply in 16 of 25 patients in whom cement leakage was identified, and this was difficult for the surgeons to find intraoperatively. The incidence of new adjacent vertebral fractures was < 3% after a mean of 22 months follow-up in this study, which was much lower than that in other reports with a large volume of bone cement (26,27). The low levels of cement leakage in this study might have been related to a lower risk of new adjacent vertebral fractures (28-30). In addition, we thought that small volume of cement used in PVP could decrease the alteration of elastic modulus of the fractured vertebral bodies, which might be an important reason for the low rate of subsequent fractures in our study.

Many authors have reported that there is no difference in the outcomes of PVP treatment between bipedicular and unipedicular approaches (31,32). However, some studies have reported the distribution of bone cement affected the outcomes of PVP treatment, and the bipedicular approach shows lower cement leakage and better outcomes (33,34). The asymmetric distribution of bone cement is considered to affect the stiffness and biomechanical balance of compressive fractured vertebrae (9,34). In addition, a unipedicular approach usually needs a larger external oblique angle, which may increase the risk of puncturing the medial pedicular wall (33). It is true that the bilateral approach may increase radiation exposure. However, because of simultaneous bipedicular operation under the guidance of the C-shaped arm x-ray perspective, a small volume of cement, and the low puncturing angle required, the mean perspective times for puncture and injection were very low in this study.

There were some limitations to this study. First, because bone mineral density (BMD) was not routinely tested in our outpatients, some patients lacked the results of BMD during follow-up. Therefore, we did not show the effect of rest time on BMD, even though LA might influence BMD. Second, there is no standard for the time of LA, and the limited time in our study was chosen from our previous working experience, which may lack an objective basis. More future studies should be designed to assess the best limited time for patients. Third, NRS-11 is solely used as an indicator of clinical

outcomes in our study, so that the study has limitations in reflecting functional outcomes. Finally, the difference of results might be clinically small for the small sample size. However, our aims were to preliminarily investigate the influence of early LA on pain relief and vertebral shape maintenance for OVCFs patients after PVP treatment. A future study with a bigger sample size may be helpful to improve not only a statistically significant but a clinically worthwhile difference between the groups.

Conclusions

In summary, we considered that bipedicular PVP treatment with a small volume of bone cement was a good choice for single-segment acute OVCF patients, which could help patients relieve pain with a lower risk of complications. Three weeks of limited off-bed activity after PVP could help patients achieve more pain relief in the early period postoperatively and maintain a better vertebral shape in the long term, especially for low responders.

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Author contributions: All authors have read and approved the manuscript. Wenjie Jin and Kangping Shen conceived and designed the study; Xin Sun, Xingzhen Liu, and Jia Wang acquired and analyzed the data and interpreted the results; Xin Sun, Xingzhen Liu, Jia Wang, Hairong Tao, Tong Zhu, and Wenjie Jin wrote and revised the manuscript.

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