



## Early versus late percutaneous kyphoplasty for treating osteoporotic vertebral compression fracture: A retrospective study

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### ABSTRACT

**Objective:** Osteoporotic vertebral compression fracture (OVCF) is a common disease in the aged population that can greatly affect the quality of life. Percutaneous kyphoplasty (PKP) has become a mainstream approach for treating OVCF, but the optimal surgical timing for treating OVCF with PKP remains controversial. In the current study, we retrospectively studied patients with OVCF that underwent PKP, and aimed to find out whether surgical timing could affect the clinical and radiological outcomes.

**Patients and methods:** We retrospectively studied 62 patients who underwent PKP for OVCF. Patients were divided into 2 groups based on the timing of PKP: operation within 4 weeks (group A) and operation later than 4 weeks (group B). VAS, ODI, height of fracture vertebra, restored height rate, local kyphosis angle and complications were assessed preoperatively and throughout the follow-up.

**Results:** There were 36 cases (58 fracture vertebra) in the group A and 26 cases (40 fracture vertebra) in the group B. There was no significant difference between the two groups regarding to the demographic data before surgery. In terms of the VAS and ODI, no statistical difference was observed before operation, after operation and at the 6th month follow-up between the two groups. The HRR after operation and at the 6th month follow-up in the group A was  $17.5 \pm 5.3\%$  and  $10.5 \pm 3.7\%$ , and that in the group B was  $7.2 \pm 3.2\%$  and  $3.6 \pm 1.1\%$ , and there is significant difference between the two groups ( $p < 0.05$ ). The LKA (preoperatively / post-operatively / 6th month follow-up) was  $-12.7^\circ$ ,  $-7.3^\circ$ ,  $-11.4^\circ$  in the group A and  $-17.6^\circ$ ,  $-14.4^\circ$ ,  $-16.1^\circ$  in the group B. There was significant difference between the two groups at all the time points for local kyphosis angle ( $p < 0.01$ ), with a lower rate of subsequent vertebral fracture in the group A ( $p < 0.05$ ).

**Conclusion:** Both surgical timings of PKP showed similar outcomes in terms of the VAS and ODI. Early PKP could result in better restoration of vertebral body height and reduced rate of subsequent fracture compared to late PKP.

### 1. Introduction

Osteoporotic vertebral compression fracture (OVCF) is a common disease in the aged population, which can cause both acute and chronic back pain, substantial spinal deformity and functional disability and greatly affect the quality of life [1,2]. OVCF is increasing exponentially with the advancing of age, and there are approximately 1.7 million cases of OVCF in America and in Europe annually [1,3].

Conservative treatment and vertebral cement augmentation are two most common treatments for OVCF. As conservative treatment requires long time of bedrest, which could accelerate the progress to osteoporosis, increase the risk of pneumonia, pressure ulcers and deep vein thrombosis, and cause approximately 50% of fracture related deaths [4,5]. Vertebral cement augmentation including percutaneous

vertebroplasty (PVP) and percutaneous kyphoplasty (PKP) has become a mainstream approach for treating OVCF, which can achieve pain relief and vertebral height restoration [6,7]. Until 2015, 1443 hospitals from 22 provinces in China have reported more than 50,976 cases that were performed with PKP [8].

Many patients are initially treated with conservative measures for several weeks, and then indicated for vertebral cement augmentation if they show little improvement. The characteristics of OVCFs differ markedly along the disease course, with increasing sagittal deformity and chronic pain over time. However, few studies have paid attention to the timing of vertebral augmentation. Phillips et al. reported that early operation could yield good degree of correction of local spinal kyphosis [9]. In Minamide's study [10], patients that underwent early operation demonstrated better alignment, better low back pain scores,

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and reduced rate of subsequent fracture. While in Nieuwenhuijse's study [11], they found there was an immediate and sustainable improvement in the level of back pain and HRQoL after vertebral cement augmentation, and which was independent of the time from fracture. The optimal surgical timing for treating OVCF with PKP remains controversial. In the current study, we retrospectively studied patients with OVCF that underwent PKP, and aimed to find out whether surgical timing could affect the clinical and radiological outcomes.

## 2. Patients and methods

### 2.1. General information

We retrospectively studied OVCF patients that admitted to the hospital and underwent PKP from Jan 2017 to Jun 2018, who were divided into 2 groups according to the timing of PKP: early operation group with operation within 4 weeks (group A) and late operation group with operation later than 4 weeks (group B). Approval was obtained from the institutional review board of our hospital.

Inclusion criteria were as follows: (1) age  $\geq 55$ ; (2) OVCF segment below T4 involved; (3) the affected vertebral body showing a confined high signal intensity on T2-weighted MR imaging, a diffused low signal intensity on T2-weighted MR imaging, or a diffused low signal intensity on T1-weighted MR imaging [12]; (4) back pain associated with OVCF interfering daily activities.

Exclusion criteria were as follows: (1) multiple myeloma, metastatic bone disease, (2) neurological deficit, (3) severe physical diseases such as respiratory and heart dysfunction; (4) follow-up less than 6 months.

### 2.2. Surgical intervention

All the patients before surgery were suggested with bed rest, and analgesic and anti-osteoporosis drug therapy. All surgical procedures were performed under general anaesthesia in a single institution by one experienced spine surgeon. In all the cases, a 11-gauge Jamshidi needle was placed percutaneously through the transpedicular or peripedicular approach route on unilateral side into the posterior part of the vertebral body. A deflated balloon (KMC, Shanghai, China) was inserted into the vertebral body and inflated to restore the height of the collapsed vertebral body and create an internal cavity under manometric control. After withdrawing the balloon, polymethylmethacrylate (PMMA) cement was injected into the cavity of the involved vertebra under fluoroscopic guidance. The injection speed was adjusted according to the cement diffusion speed, and the depth of the needle and injection pressure were adjusted constantly to maintain an even cement distribution. The process was stopped timely when the bone cement reached the posterior wall of the vertebral body or extraosseous space. The patients were advised to walk 24 h after operation. Orthosis brace was applied for 3 months after the surgery and anti-osteoporosis therapy lasted for a minimum of 1 year.

### 2.3. Clinical outcomes data

Visual analogue scale (VAS) was applied to assess the improvement in pain, with scale 0 representing no pain and 10 representing extreme pain. Oswestry disability index (ODI) was applied to assess the improvement in the ability to daily function. It assessed the aspects including pain intensity, lifting, walking, sleeping social life, etc. [13] 0.0% stands for minimal disability while 100% stands for extreme disability and the patients may be bed bound or with exaggerating symptoms.

### 2.4. Radiological outcomes data

Radiological parameters included: height of normal vertebra (HN), height of fractured vertebra (H), restored height of the fractured

vertebra (RH), height restoration rate (HRR) and local kyphosis angle (LKA), which were assessed by plain X-ray. HN was accepted as the average of the height of the normal vertebral bodies above and below the fractured vertebra. HFV was measured at the most compressed point (anterior or middle) of the vertebral endplate using lateral X-ray radiographs, and the RH was measured at the same point of the vertebral endplate. HRR represented the percentage restored from the preoperative height, it can be calculated as:  $HRR = (RH - H) / HN$ . The local kyphosis angle was defined as the angle formed by lines drawn parallel to the caudal and cranial fractured endplates.

### 2.5. Complications

Following complications were recorded: local cement leakage, pulmonary embolism, radiculopathy, infection, and fracture in adjacent levels.

The results of clinical, radiological outcomes data and complications were recorded by two independent authors before operation, immediately after operation, at the 6<sup>th</sup> month after operation and at the last follow-up.

### 2.6. Statistical analysis

Statistical analysis was carried out with SPSS 19.0 software. Independent *t*-test was applied to compare the age, bone density, intraoperative bone cement injection volume, restoration rate, VAS score and ODI index between the two groups. Chi-square test was applied to compare the gender distribution and fracture segment between the two groups. One-way ANOVA was applied to compare the VAS score and ODI index at different time points within the group. A *p* value  $< 0.05$  is considered to be statistically significant.

## 3. Results

There were 62 OVCF cases (83 fracture vertebra ranging from T5 to L5) in this study, including 4 males and 58 females, with an average age of 71.6 (55–84) years old. There were 36 cases (58 fracture vertebra) in the group A and 26 cases (40 fracture vertebra) in the group B. The average interval between symptom onset and PKP was  $13.3 \pm 6.5$  (3–27) days in the group A and  $34.3 \pm 4.4$  (28–50) days in the group B ( $p < 0.05$ ). All the cases were followed up for 6 months. There was no significant difference between the two groups regarding to the demographic data before operation, as shown in Table 1.

### 3.1. Clinical outcomes

In terms of the VAS and ODI between the two groups, no statistical difference was observed before operation. In the group A, the average preoperative VAS score was  $7.3 \pm 1.3$ , which significantly decreased to  $2.4 \pm 0.7$  at 1 day after operation and  $2.3 \pm 0.5$  at the 6<sup>th</sup> month after operation ( $p < 0.01$ ). In the group B, the VAS score significantly decreased from  $6.9 \pm 1.1$  preoperatively to  $2.3 \pm 0.6$  postoperatively and to  $2.2 \pm 0.5$  at the 6<sup>th</sup> month after operation (Table 2). The ODI score improved from an average of  $52.6 \pm 5.2$  preoperatively to  $17.3 \pm 2.3$  postoperatively ( $p < 0.01$ ) in the group A, and improved from  $50.5 \pm 4.8$  preoperatively to  $18.8 \pm 3.4$  postoperatively ( $p < 0.01$ ) in the group B, and the postoperative ODI score showed no significant difference between the two groups. There was no significant difference between the two groups at different time points, as shown in Table 2.

### 3.2. Radiological results

The patients in both groups showed significant restoration of vertebral body height 1 day after operation, but at the 6th month follow-up, height of fracture vertebra loss occurred in both groups. The HRR in

**Table 1**  
Comparison of baseline data between groups.

	Early operation (Group A, 36 patients, 56 segments)	Late operation (Group B, 26 patients, 40 segments)	P
Age, years (mean, SD)	70.2(7.6)	73.6(8.4)	0.18
Female (%)	34(94.4)	24(92.3)	0.32
Disease duration, days (mean, SD)	13.3(6.5)	34.3(4.4)	< 0.001
BMD (mean T-score)	-2.8(0.8)	-2.9(1.1)	0.42
Vertebral bodies (n, %)	58	40	
one-level procedures	20(34.5)	14(35)	0.11
two-level procedures	11(18.9)	10(25)	
three-level procedures	4(6.9)	2(5)	
Four-level procedures	1(1.7)	0	
Segment of fracture (n, %)			
T5-T10	7(12.1)	5(12.5)	0.23
T11-L2	37(63.8)	26(65)	
L3-L5	14(24.1)	9(22.5)	

BMD: bone mineral Density.

**Table 2**  
Clinical outcomes between the groups.

	Early operation (Group A, 36 patients, 56 segments)	Late operation (Group B, 26 patients, 40 segments)	P
VAS(mean, SD)			
Postoperation	7.3(1.3)	6.8(1.1)	0.25
6 months	2.4(0.7)	2.3(0.6)	0.31
Preoperation	1.8(0.5)	2.2(0.5)	0.35
ODI(mean, SD)			
Preoperation	52.6(5.2)	50.5(4.8)	0.42
Postoperation	17.3(2.5)	18.8(3.4)	0.29
6 months	15.6(2.1)	17.6(2.7)	0.27

VAS: visual analogue scale; ODI: Oswestry Disability Index.

**Table 3**  
Radiological outcomes between the groups.

	Early operation (Group A, 36 patients, 56 segments)	Late operation (Group B, 26 patients, 40 segments)	P
H, cm(mean, SD)	2.1(0.5)	1.9(0.7)	0.08
RH, cm(mean, SD)			
Postoperation	2.6(0.8)*	2.1(0.6)*	< 0.01
6 months	2.4(0.4)*	2.0(0.5)	0.04
HRR, %(mean, SD)			
Postoperation	17.5(5.3)	7.2(3.2)	< 0.01
6 months	10.5(3.7)	3.6(1.1)	< 0.01
LKA, °(mean, SD)			
Preoperation	12.7(4.5)	17.6(5.8)	< 0.01
Postoperation	7.3(2.9)*	14.4(4.5)*	< 0.01
6 months	11.4(7.3)	16.1(8.1)	< 0.01

H: height of fractured vertebra, RH: restored height of the fractured vertebra, HRR: height restoration rate, LKA: local kyphosis angle. \* compared with pre-operation, P < 0.05.

the group A was  $17.5 \pm 5.3\%$ ,  $10.5 \pm 3.7\%$  and  $7.2 \pm 3.2\%$   $3.6 \pm 1.1\%$  in the group B after operation and at the 6<sup>th</sup> month follow-up, and there was significant difference in HRR between the two groups

**Table 4**  
Complications of the two groups.

	Early operation (Group A, 36 patients, 56 segments)	Late operation (Group B, 26 patients, 40 segments)	P
Cement leakage(%)	6/56(10.7)	5/40(12.5)	0.57
Intradiscal	4	3	
Anterior vertebra	2	2	
Subsequent vertebral fracture	3/36(8.3)	9/26(34.6)	< 0.01
Adjacent vertebral fracture	2/36(5.6)	7/26(26.9)	0.04
Away vertebral fracture	1/36(2.7)	2/26(7.7)	0.28
Reoperation	2/36(5.6)	3/26(3.8)	0.35

(p < 0.05) (Table 3).

The LKA (preoperatively / post-operatively / 6<sup>th</sup> month follow-up) was  $-12.7^\circ / -7.3^\circ / -11.4^\circ$  in the group A and  $-17.6^\circ / -14.4^\circ / -16.1^\circ$  in the group B (Table 2). The mean LAA (Cobb angle) improved significantly in both groups 1 day after operation (p < 0.05). There was significant difference between the two groups at all the time points in terms of local kyphosis angle (p < 0.01).

### 3.3. Complications

According to the X-ray radiographs of the spine, there were 6 vertebra (6/56, 10.7%) of bone cement leakage in the group A, and 5 vertebra (5/40, 12.5%) in the group B. All the cases of cement leakage into the disc space or anterior vertebra showed no symptom. 3 patients (8.3%) in the group A and 9 (34.6%) in the group B showed subsequent vertebral fractures (p < 0.01). The occurrence of adjacent vertebral fracture was significantly higher in the group B, but the away fracture rate showed no significant difference. 2 patients in the group A and 3 patients in the group B received a second PKP due to adjacent vertebral fracture. There was no case of infection or pulmonary embolism (Table 4).

## 4. Discussion

OVCF is a major health problem of the aged population, which requires constant and systematic treatment. There are several treatment methods for OVCF, including conservative treatment, PVP, and PKP, which could achieve pain relief and functional improvement [4,6,14,15]. A most recent meta analysis compared non-surgical treatment, PVP and PKP for treating for OVCF [16], and the results showed that PKP could significantly improve pain, functional status, and quality of life, and was the optimal intervention for decreasing the risk of subsequent vertebral fracture and re-fracture at the treated level. But little is known about the optimal timing of PKP. In this study, we focused on how different timings of cement augmentation could affect clinical and radiographic outcomes.

In this study, the timing of PKP was determined as the interval from

symptom onset to surgical intervention. And we suppose the reasons for late surgical interventions could be: (1) the patients with back pain may take rest as their first choice, and it may delay the diagnosis of OVCF and hence delaying surgical interventions; (2) we recommend early PKP surgery once a diagnosis of OVCF is made, but due to reasons like economic burden, patients may choose conservative treatment first and only consider surgical interventions when they are not palliative. In the current study, we found that VAS and ODI reduced significantly after PKP, and there was no difference between early and late PKP, which is consistent with previous studies. In Guan's study [17], both early (< 2 weeks) and late (2–4 weeks) operations of PKP could achieve satisfactory VAS and ODI. In Erkan's study [18], early operation (< 10 weeks) and delayed (> 16 weeks) could yield similar clinical improvement in VAS and ODI. But in another study, patients treated with early PKP (< 4 weeks) demonstrated significantly better VAS scores, but they did not give the explanation of such difference. As cement could immobilize the micromovement and destroy the terminal nerve endings in the fractured vertebral body, it could result in pain reduction [19–21]. It could be the reason why early or late PKP yield similar VAS or ODI improvement.

PKP has a potential advantage to partially reestablish vertebral height and thereby restore stability to the spine [22], and our results showed that postoperative height of the fractured vertebra restored significantly, and early PKP could lead to better restored vertebra height and restoration rate than late PKP. Our finding was consistent with the study of Crandall [22] and Erkan [23], and they believe that the timing of PKP affects restoration rate more in acute fractures than in chronic fractures. Spontaneous height correction at the fresh fracture stage is easy, while fibrous tissue and bone healing at the late fracture stage could hinder the positioning correction. It could be the main reason of the difference in the restored vertebral body height and restoration rate between the early and late group. In this study, at the 6<sup>th</sup> month after PKP, we observed post-operative vertebral body height recollapse, and in the late group, the vertebra height recollapsed similar to the preoperative one. The underlying mechanism of the vertebra recollapse remains unclear. Low perfusion rate of bone cement, the bone absorption and collapse of articular surface could be the main causes of the post-operative vertebral body height recollapse [24,25]. The late stage healing after fracture, local tissue organization could impede the even distribution of bone cement, leading to the recollapse difference in the two groups. The LKA in the early group was lower than the late group, it could be due to that the patients might ignore their fracture and perform daily life walk before they were confirmed with fracture diagnosis. Although post-operative LKA was reduced significantly compared to the preoperative LKA in both groups, at the 6<sup>th</sup> month follow-up, the LKA was similar to the preoperative one. PKP could halt the progression of kyphosis after OVCF, but cannot effectively improve the long-term sagittal alignment [10,26].

For complications, leakage of the bone cement is one of the most common complications of PKP with an incidence of 4.8%–39% [8]. We found that the bone cement leakage rate between the two groups (10.7% vs 12.5%) showed no statistical difference, and the cement leakage to the disc or the paravertebral tissue was asymptomatic after the operation. As the cement injection was conducted with the assistance of X-ray exposure, the experienced surgeons could adjust the phase of the cement, injection time and pressure to avoid cement leakage, which could effectively reduce the incidence of cement leakage. There was more adjacent vertebral fracture in late PKP, and this phenomenon is likely to be related to alterations in the local biomechanical environment due to more vertebra height lose and LKA of fracture vertebra [10]. And the away fractures showed no difference in early and late PKP in this study, which could be a result of a natural progression of osteoporosis [27].

There are several limitations of the current study. Firstly, this is a retrospective study, and there were inherent limitations due to the study design, although the groups showed similar biographical data.

Secondly, the actual time that a fracture occurred cannot be accurately established and the onset of the patient's symptoms was an estimation of the time from fracture. Furthermore, this study included a small sample size, a limited follow-up duration, and a lack of control group (kyphoplasty versus non-surgically). Nonetheless, we plan to increase the sample size and include more subgroups like whether different genders could affect the outcomes and continue to follow these cohorts of patients in the future.

## 5. Conclusions

Both early and late surgical timing of PKP showed similar effect on the VAS and ODI, and the early PKP could result in better restoration of vertebral body height and reduced rate of subsequent fracture as compared to a delayed procedure.

## Conflicts of interest

None.

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