

Kyphoplasty for Osteoporotic Vertebral Compression Fractures: Outcomes and Intradiscal Cement Leakage Type

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Abstract

Background: Kyphoplasty (KP) has been widely applied to treat painful osteoporotic vertebral compression fractures (VCFs). However, knowledge about sequelae is still inadequate. This study aimed to assess outcomes following balloon KP in patients with osteoporotic VCFs.

Methods: A total of 251 patients were included and classified into two groups: group A included 31 patients with braces for one month after KP, and group B contained 220 patients without braces. Patients with intradiscal bone cement leakage were divided into two groups according to spinal X-ray imaging with Round-type (n = 2) and Spike-type (n = 9). Operating efficacy was evaluated via a comparison of the visual analog scale (VAS) and Oswestry Disability Index (ODI) before and after KP. Complications such as adjacent vertebral fractures (AVFs) and remote vertebral fractures (RVFs) were observed.

Results: 361 vertebral bodies, including 153 thoracic vertebrae (42.4%) and 208 lumbar vertebrae (57.6%) were treated. Mean age of patients was 73.3 [standard deviation (SD) = 6.4] years and 72.9% were women. Mean follow-up duration was 22.8 (SD = 13.2) months. Operation average time was 35.2 (SD = 9.3) minutes. Average intraoperative fluoroscopy was 23.6 (SD = 9.8) times. Average volume of bone cement injected into each vertebral body was 3.7 (SD = 0.9) ml. We observed 18 AVFs and nine RVFs within 1-31 months of surgery. The remote fracture was 0% in group A and 4.1% in group B, which was also a statistically significant difference (P < 0.05). The AVFs were 78% in group of Spike-type and 0% in group of Round-type, which shows a significant difference between the groups (P < 0.05). All groups had significantly improved VAS and ODI at each follow-up time.

Conclusion: KP is an effective treatment for the management of osteoporotic VCFs, but it seems that intra-disc leakage with Spike-type increases the risk of AVFs. We recommend patients wear braces for at least one month after KP to reduce pain and new fractures.

Keywords: Kyphoplasty; Compression Fractures; Osteoporotic Fractures

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Background

Osteoporosis is a public health problem that is contributing to a growing number of osteoporotic vertebral compression fractures (VCFs). Every year, approximately 1 to 1.5 million osteoporotic VCFs occur in the United States (US), with an incidence rate of 40% in women over 80 years old (1). VCFs increase patient morbidity and reduce the quality of life, and there are controversies about the optimal timing and treatment methods. The standard treatment choices for osteoporotic VCFs consist of conservative therapies including analgesics, external orthosis, physical therapy, and bed rest (2). Due to failure to respond to conservative treatment, there is a trend toward combined treatment consisting of kyphoplasty (KP)/vertebroplasty with cement augmentation and percutaneous dorsal instrumentation (3).

KP is a minimally invasive surgical technique that effectively relieves back pain caused by a VCF. During this technique, cement, most commonly polymethylmethacrylate (PMMA), is injected into the fracture under image guidance (4). Depending on individual case characteristics, it can be executed in either an inpatient or outpatient setting (4). KP appears to be safe and effective for treating a large group of patients with VCFs. However, knowledge of risk factors and

complications remains limited (3). The risk of a new fracture, such as adjacent vertebral fractures (AVFs), after KP remains unanswered (5, 6). This study aims to (I) describe our experiences with KP on osteoporotic VCFs, (II) compare the risk of AVFs between patients without and with a brace after KP, and (III) investigate the risk of AVFs after KP in patients with intradiscal bone cement leakage.

Methods

This retrospective study was conducted on 251 patients with osteoporotic VCFs who had undergone KP at Shahid Beheshti University of Medical Sciences, Tehran, Iran, from July 2013 to June 2021. Data were collected through a review of the cases' records and relevant imaging. Patients were diagnosed with osteoporotic VCFs on clinical and radiological evaluation.

Cases with no neurological deficit and no other associated fractures were included. All cases included in this study had a trial of conservative management and were candidates for KP after the failure of conservative treatment. Each case was followed up for at least 6 months.

AVFs were identified when VCFs happened directly above or below the cement-treated vertebra.



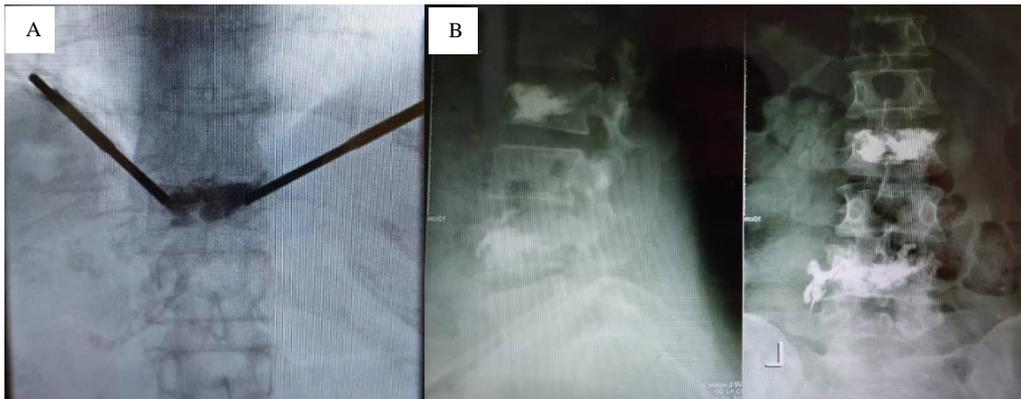


Figure 1. A) Fluoroscopic image, intradiscal cement leakage during percutaneous kyphoplasty (KP) (Spike type); B) Anteroposterior (AP) and lateral lumbar X-ray showing Spike-type intradiscal cement leakage in another patient

In addition, remote VCFs could be diagnosed when VCFs occurred in a vertebra at least one normal segment distance. The patients were divided into two groups: group A received a brace for one month after KP, and group B did not receive a brace. In addition, patients with intradiscal bone cement leakage were divided into two groups of Spike-type and Round-type based on their spinal X-ray imaging (Figures 1 and 2).

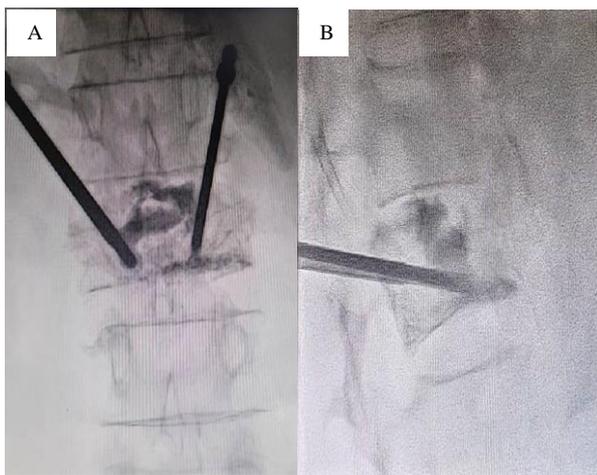


Figure 2. A and B) Anteroposterior (AP) and lateral fluoroscopic images showing Round-type intradiscal cement leakage

Pre-operation, all the patients underwent clinical assessment including conventional X-ray, computed tomography (CT), magnetic resonance imaging (MRI), visual analog scale (VAS) for the severity of pain (on a scale of 0-10; 0: no pain, 10: worst pain), and Oswestry Disability Index (ODI) for difficulty in daily routine activities (on a scale of 0-50; 0: no disability, 50: completely disabled). Post-operative clinical assessment included VAS, ODI, and radiological outcomes. Complications such as remote vertebral fracture (RVFs), AVFs, and risk of cement leakage were evaluated and compared in both study groups. Comparison of data before and one month after KP, and at the last follow-up was performed.

Surgical Technique: KP procedures were performed under local anesthesia in a prone position. Under the fluoroscopy guide, the PMMA was injected into the vertebral body through the uni- or bilateral transpedicular approach. During the injection of PMMA, the spread of bone cement in the vertebral body was carefully observed.

When the bone cement spread to the posterior wall of the vertebral body or the paravertebral venous plexus, the injection was stopped to avoid the bone cement leakage into the spinal canal and the blood vessels. After the PMMA hardened, the working cannula was removed.

Statistical analysis of the data was performed using SPSS (version 18, SPSS Inc., Chicago, IL, USA). For continuous values, the characteristics of cases and fractured vertebrae, and cement volume were analyzed using a t-test or Mann-Whitney U test. Grouped values were assessed by a Pearson chi-square test; values of ≤ 0.05 were considered significant.

Ethics: The Ethics Committee of Shahid Beheshti University of Medical Sciences accepted the study. All cases and/or their legal guardians gave written informed consent to participate in this study.

Results

In the 251 cases with osteoporotic VCFs, 361 vertebral bodies were treated. KP was performed in 153 thoracic vertebrae (42.4%) and 208 lumbar vertebrae (57.6%), including T6, T7, T8, T9, T10, T11, T12, L1, L2, L3, L4, and L5 [8 (2.2%), 8 (2.2%), 19 (5.2%), 8 (2.2%), 10 (2.8%), 31 (8.6%), 69 (19.2%), 88 (24.4%), 70 (19.4%), 33 (9.1%), 13 (3.6%), and 4 (1.1%), respectively]. Characteristics of patients and complications are shown in table 1. Cement leakage was observed in the superior disc space (n = 7) and the inferior disc space (n = 4). All of the patients had significantly improved VAS and ODI ($P < 0.05$).

Characteristics	Values	Ranges
Age (year)	73.3 ± 6.4	49-93
Gender (women)	183 (72.9)	-
Pre-op VAS	9.1 ± 0.6	8-10
Post-op VAS	1.6 ± 0.7	1-3
Pre-op ODI	32.3 ± 3.6	25-45
Post-op ODI	13.1 ± 2.0	8-20
Volume of bone cement injected into each vertebra (ml)	3.7 ± 0.9	1.5-7.5
Follow-up (year)	1.9 ± 1.1	0.5-8.0
Operation time (minute)	35.2 ± 9.3	20-55
Fluoroscopy times (number)	23.6 ± 9.8	12-55
Kyphoplasty level		
One	168 (66.9)	-
Two	63 (25.1)	-
Three	15 (6.0)	-
Four	3 (1.2)	-
Five	2 (0.8)	-
Complications		
Remote fracture	9 (3.6)	-
AVF	18 (7.2)	-
Intradiscal bone cement leakage	11 (4.4)	-
Anterior vertebral bone cement leakage	34 (13.5)	-

Values are mean ± standard deviation (SD) or number (percentage) or ranges. VAS: Visual analog scale; ODI: Oswestry Disability Index; AVF: Adjacent vertebral fracture

Table 2. Clinical outcome comparison of patients with and without brace after kyphoplasty (KP)

Characteristics	Post-operative (n = 251)		P-value
	Group A: With brace (n = 31)	Group B: Without brace (n = 220)	
Age (year)	74.9 ± 5.6	73.1 ± 6.4	0.138
Gender			
Men	9 (29.0)	59 (26.8)	0.791
Women	22 (71.0)	161 (73.2)	0.868
Pre-op VAS	9.3 ± 0.4	9.1 ± 0.6	0.105
Post-op VAS	1.3 ± 0.5	1.6 ± 0.6	0.019
Pre-op ODI	32.1 ± 2.3	32.4 ± 3.8	0.669
Post-op ODI	12.5 ± 1.9	13.1 ± 2.0	0.117
Follow-up time (year)	1.1 ± 0.3	2.1 ± 1.2	0.001
Volume of bone cement injected into each vertebra (ml)	3.5 ± 0.7	3.8 ± 0.9	0.094
Patients with AVFs	1 (3.2)	17 (7.7)	0.132
Patients with remote fracture	0 (0)	9 (4.1)	0.046
Kyphoplasty level			
One	17 (54.8)	151 (68.6)	-
Two	12 (38.7)	51 (23.2)	-
Three	2 (6.5)	13 (5.9)	-
Four	0 (0)	3 (1.4)	-
Five	0 (0)	2 (0.9)	-

Values are mean ± standard deviation (SD) or number (percentage)
 VAS: Visual analog scale; ODI: Oswestry Disability Index; AVFs: Adjacent vertebral fractures

We observed 18 AVFs within 1-14, and 9 RVFs within 1-31 months of surgery. Patients with multiple vertebrae treated did not have a higher risk of AVFs or RVFs. Two patients had intracanal bone cement leakage and underwent emergency laminectomy, and both were significantly improved. No other complications were observed.

Table 2 depicts the demography and clinical outcomes of the groups. There was a statistically significant difference ($P < 0.05$) between the patients who experienced RVF in group B (4.1%) compared to group A (0%). The post-operative pain level in group A was significantly lower than in group B. There were no statistical differences concerning gender, age, operation time, intraoperative fluoroscopy times, pre-operative ODI score, pre-operative VAS score, and cement amount between the two groups (Table 2).

Intra-disc leakage was found in 4.4% (11/251) of the cases. The AVFs were presented in 7.2% (18/251) of the patients, and 38.9% (7/18) of them had intradiscal bone cement leakage (Figure 3). The association of AVFs with contributing risk factors in patients with intradiscal bone cement leakage after KP is shown in table 3.

The AVFs were 78% in group of Spike-type, and 0% in group of Round-type, which was significantly different between the groups ($P < 0.05$). However, there was no significant difference in study parameters between both the study groups (Table 3) ($P > 0.05$). In addition, the cement leaked into the adjacent intervertebral disc but did not cause neurological symptoms.



Figure 3. Sagittal T1-weighted (T1W) lumbo-sacral magnetic resonance imaging (MRI) in a 75-year-old female patient showing L5 kyphoplasty (KP) with L4/L5 Spike-type intradiscal cement leakage. Five months after KP, adjacent vertebral fracture (AVF) was observed at L4 vertebra

Discussion

This study showed that KP was an effective and minimally invasive operation for patients with osteoporotic VCFs. Overall, the efficacy of surgical management with a brace after KP was better than that without the brace. Moreover, in this study, for the first time, a practical approach of using spinal X-ray imaging in patients with intradiscal bone cement leakage is proposed for AVFs prognosis. However, additional research will be required to confirm the findings. Therefore, our results should be interpreted and applied cautiously.

Table 3. Clinical outcome comparison of patients with intra-disc leakage types after kyphoplasty (KP)

Characteristics	Patients with intra-disc leakage (n = 11)		P-value
	Spike type (n = 9)	Round type (n = 2)	
Age (year)	78.4 ± 6.8	73.5 ± 6.4	0.377
Gender			
Men	0 (0)	1 (50.0)	-
Women	9 (100)	1 (50.0)	-
Pre-op VAS	8.7 ± 0.6	9.0 ± 0.1	0.558
Post-op VAS	1.7 ± 0.7	1.5 ± 0.7	0.726
Pre-op ODI	32.7 ± 4.5	32.0 ± 1.4	0.838
Post-op ODI	13.6 ± 2.1	12.5 ± 0.7	0.498
Follow-up time (year)	1.8 ± 0.9	1.3 ± 0.3	0.505
Volume of bone cement injected into each vertebra (ml)	4.2 ± 1.0	4.3 ± 0.3	0.896
Patients with AVFs	7 (78.0)	0 (0)	< 0.050
Patients without AVFs	2 (22.0)	2 (100)	< 0.050
Kyphoplasty level			
One	7 (77.8)	2 (100)	-
Two	1 (11.1)	-	-
Three	1 (11.1)	-	-

Values are mean ± standard deviation (SD) or number (percentage)
 VAS: Visual analog scale; ODI: Oswestry Disability Index; AVFs: Adjacent vertebral fractures

KP is safe, and severe complications are extremely rare, but side effects such as AVFs are not rare and often require surgical intervention. In the literature, rates of AVFs after KP are reported to be around 3-25 percent (5, 7-13). The rate of 7.2% observed in our study is concordant with that of the literature. The higher rates of AVFs in other studies are multifactorial, including comorbidity, functional status, and having long-term follow-ups. Recently, Do et al. reported that KP was an effective pain-relieving treatment for cases with VCFs. They presented that 3.1% of patients had new VCFs post-augmentation within the first two-month period post-injection. It was also concluded that KP would pose no threats to subsequent VCFs (13). The results of the present study confirm this finding.

A systematic review and meta-analysis comparing KP procedures to non-operative management of osteoporotic VCFs showed greater pain outcomes for patients receiving KP (14). Although KP has been reported to be a safe procedure in the literature, it causes complications such as cement leakage into the intervertebral disc space (5, 6, 15). There is still controversy regarding risk factors for AVFs after KP (5, 6). In patients with intradiscal cement leakage, a high AVF rate has been presented due to mechanical pressure on the endplate in the adjacent vertebral bodies (6, 15-17). The rate of AVFs has been reported > 50% (16) and 69% (6), which is consistent with our study's rate. In the present study, intra-disc leakage was found in 4.4% of the patients, and it was found that 63.6% of them had AVFs.

Besides, 77.8% of patients with Spike-type intra-disc leakage had AVFs, which is statistically high, and therefore, there is a significant difference in variation between patients. It should be noted that the risk of cement leakage into the intradiscal space is decreased by the use of X-ray or appropriate imaging guidance with proper technique to ensure the correct placement of the cement (18). Our technical experience is that, during cement injection, if the cement moves in the endplate, we pull back the trocar 2-3 mm. Then, after the injected cement hardens a bit, more cement is injected.

Consistent with the former study (6), our study found that patients without a brace after KP had more pain and more new fractures than those with the brace. There is a biomechanical and psychological issue in the use of a brace. KP provided significant spinal pain relief in patients with osteoporotic VCFs. Some patients expedite their return to normal daily activity, which may negatively impact their spine and cause AVFs. Patients need to wear a brace after KP to decrease spine motion and reduce the risk of AVFs. The idea is that patients will be more careful in their activities after removing their braces. On the other hand, the shortest period to wear braces in patients who received KP is still a point of discussion. Ko et al. reported that patients might need to wear braces for up to 3 months (6), but our experience suggests one month. It should be noted that the time that the brace should be worn varies depending on the patient. Thus, future high-quality studies are needed to determine the required time to use the brace.

The current study had limitations. First, the study design was retrospective, which means that selection bias was inevitable. Second, our sample size of patients with intradiscal bone cement leakage was small; future large-scale prospective studies should be conducted to confirm our novel findings. Third, the effect of osteoporosis medication and comorbidities was not considered as an inclusion criterion. However, the strength of the study includes a long-term follow-up.

Conclusion

This study shows that KP can reduce complications and relieve pain in patients with osteoporotic VCFs. Patients should wear braces for at least one month after KP to reduce pain and new fractures. It also presents that spinal X-ray imaging with Round-type in patients with osteoporotic VCFs with intra-disc leakage may reduce AVFs. The incidence of AVFs also correlated with comorbidities. Thus, further prospective randomized studies, such as large multicenter clinical trials, should be performed to confirm our results.

Conflict of Interest

The authors declare no conflict of interest in this study.

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