

Clinical Outcomes of Patients with Osteoporotic Thoracolumbar Fracture Treated with Percutaneous Vertebroplasty and Balloon Kyphoplasty

Perkütan Vertebroplasti ve Balon Kifoplasti ile Tedavi Edilen Osteoporotik Torakolomber Kırığı Olan Hastaların Klinik Sonuçları

¹Güray BULUT, ²Aziz ÇATALTEPE

¹Department of Neurosurgery, Medipol University, Istanbul, Türkiye

²Department of Orthopedic Surgery and Traumatology, Medipol University, Istanbul, Türkiye

Güray Bulut: <https://orcid.org/0000-0002-9318-4800>

Aziz Çataltepe: <https://orcid.org/0000-0001-9785-9062>

ABSTRACT

Objective: We aimed to evaluate the clinical outcomes of vertebroplasty (VP) or kyphoplasty (KP) in patients with vertebral body fractures due to osteoporosis.

Materials and Methods: We retrospectively analysed 26 patients who underwent VP and KP for thoracolumbar osteoporotic fracture. Two groups were formed according to the procedure. While VP was applied to 14 cases, KP was applied to 12 cases. The cases were evaluated radiologically with Magnetic Resonance Imaging (MRI), Computed Tomography (CT), and X-ray radiography. Before and after treatment, the Oswestry Disability Index (ODI) was used to compare daily activities, while the visual analogue scale (VAS) measured resting pain.

Results: VP and KP were applied to 22 female and 4 male cases. Preoperative VAS scores were similar in both groups and were not statistically significant ($p=0.995$). Preoperative ODI scores were similar in both groups and were not statistically significant ($p=0.842$). Cement leakage without the neurological deficit was observed in 5 patients.

Conclusions: The effects of VP and KP procedures on VAS and ODI scores are similar. However, economically, the cost of KP is relatively high compared to VP. The study suggests using VP due to its low cost and clinically similar results on VAS and ODI scores compared to KP.

Keywords: Kyphoplasty, osteoporosis, pain, vertebral compression fracture, vertebroplasty

ÖZ

Amaç: Bu çalışma ile osteoporozla bağlı olarak vertebra korpus fraktürü gelişmiş hastalara uygulanan vertebroplasti (VP) veya kifoplastinin (KP) klinik sonuçlarını değerlendirmeyi amaçladık.

Materyal ve Metot: Kliniğimizde torakolomber osteoporotik kırık nedeniyle VP ve KP uygulanan 26 hasta retrospektif incelendi. Yapılan yonteme göre iki grup oluşturularak VP 14 olguya ve KP 12 olguya uygulandı. Olgular radyolojik olarak Magnetik Rezonans Görüntüleme (MRG), Bilgisayarlı Tomografi (BT) ve X-ray radyografi ile değerlendirildi. Hastaların istirahat ağrıları visual analog skala (VAS) kullanılarak; günlük yaşam aktiviteleri ise Oswestry Disabilite İndeksi (ODİ) kullanılarak tedavi öncesi ve tedavi sonrası karşılaştırıldı.

Bulgular: Torakolomber vertebra korpus kırığı olan 22 kadın ve 4 erkek vakaya VP ve KP uygulandı. Ameliyat öncesi VAS skorları her iki grupta da benzerdi ve istatistiksel olarak anlamlı değildi ($p=0,995$). Ameliyat öncesi ODI skorları her iki grupta da benzerdi ve istatistiksel olarak anlamlı değildi ($p=0,842$). 5 hastada nörolojik defisit yapmayan sement kaçağı görüldü.

Sonuç: VP ve KP prosedürlerinin VAS ve ODİ skorları üzerindeki etkileri benzerdir. Ancak ekonomik olarak KP'nin maliyeti VP'ye göre nispeten oldukça yüksektir. Mevcut çalışma, VP'nin KP ile karşılaştırıldığında düşük maliyeti ve VAS ve ODI skorlarında klinik olarak benzer sonuçlara sahip olması nedeniyle VP'nin uygulanmasını önermektedir.

Anahtar Kelimeler: Ağrı, kifoplasti, osteoporoz, vertebral kompresyon kırığı, vertebroplasti

Sorumlu Yazar / Corresponding Author:

Aziz Çataltepe
Department of Orthopedic Surgery and Traumatology, Medipol University, 34214, Istanbul, Türkiye
Tel: +905325182093
E-mail: aziz.cataltepe@medipol.edu.tr

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INTRODUCTION

Osteoporotic fractures generally affect patients over 65 and are frequently seen at the thoracolumbar junction and lower levels.¹ The treatment aims to provide anatomical reduction, prevent spinal deformity, reduce pain, restore vertebral height, and enable the patient to return to daily activities early with early mobilisation.^{2,3}

The management options for spinal fractures are limited.^{4,5} Cement augmentation of painful osteoporotic compression fractures consists of percutaneous stabilisation of the vertebral bodies with polymethyl methacrylate, an alternative treatment to open surgery.⁶ Percutaneous vertebroplasty (VP) and percutaneous balloon kyphoplasty (KP) are the strengthening of the vertebrae that have weakened due to various reasons and lost their height by percutaneous injection of polymethylmethacrylate (PMMA).^{7,8} While VP is performed with cement augmentation, KP is performed with cement augmentation and an inflatable balloon tamp. These minimally invasive techniques have become widely used by many spine surgeons. Both VP and KP might enhance bone strength, effectively relieve fracture pain, and allow rapid mobilisation of the patient in the elderly, often high-risk patient population for anaesthesia.⁹⁻¹¹ VP was first applied to the C2 vertebra by Galibert and Deramond in 1987.¹² Later, it was involved in compression fractures due to various pathologies.¹³ It has developed over time and has begun to be used in materials that contribute to the restoration and alignment of the corpus, such as KP.¹³⁻¹⁶

Both VP and KP are applied in painful osteoporotic and osteolytic thoracolumbar vertebral fractures, in osteoporotic vertebral fractures whose pain does not go away after 3 weeks of non-surgical treatment, in patients with early mobilisable pneumonia, deep vein thrombosis, and analgesic intolerance. They are applied in diagnosing and treating osteolytic primary vertebral tumours and metastatic vertebral tumours.¹³⁻¹⁶

In the current study, patients with osteoporotic vertebral corpus fracture in the thoracolumbar region

underwent VP or KP for various reasons (trauma, weight lifting, sudden flexion). The clinical and radiological results before and after the operation were evaluated. We aimed to assess the effectiveness of both methods on clinical outcomes.

MATERIALS AND METHODS

Ethical Status: Ethics committee approval was obtained from the Medipol University Faculty of Medicine Ethics Committee (Date: 10.08.2023, decision no: 655). The study was conducted in accordance with the principles of the Declaration of Helsinki.

Design: This study prospectively collected data in an institutional database between February 2017 and May 2022. In the current study, all patients were selected consecutively. A cohort of 26 consecutive patients who underwent VP or KP due to thoracolumbar osteoporotic fractures that occurred owing to various reasons (trauma, weight lifting, sudden flexion) were evaluated retrospectively. Two groups were formed according to the procedure in which VP was applied to 14 cases, and KP was applied to 12 cases.

Procedure: The cases were evaluated radiologically with Magnetic Resonance Imaging (MRI), Computed Tomography (CT), and X-ray radiography (Figure 1a). All surgeries were performed by the same surgeon. Operations were performed under local anaesthesia and sedation in operating room conditions. The patients were positioned to prone and the surgical area was covered with sterile drapes after positioning, images were taken with C-arm fluoroscopy, and the application was performed bilaterally transpedicularly. An amount of cement ranging from 4 to 10 cc was injected into the vertebral body (Figure 1b). The cases were mobilised 6 hours after the operation. Control radiographs were taken routinely (Figure 1c). All patients underwent radiological evaluation. All patients who should be quickly mobilized with physical therapy were referred to the relevant departments to treat general osteopenia and osteoporosis.

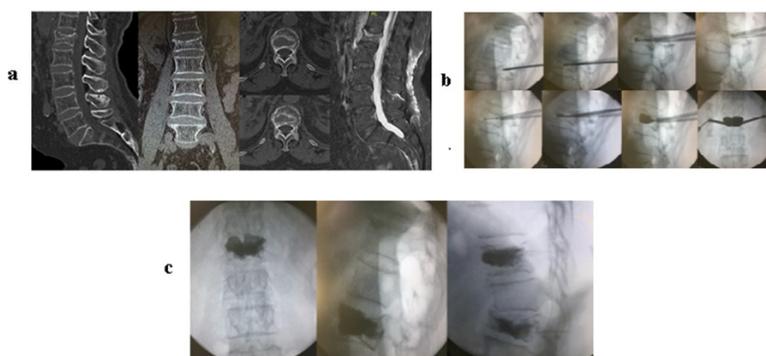


Figure 1. Procedures.

a: Preoperative CT and MRI images of L1 fracture;
b: The stages of the Kyphoplasty operation with C-arm fluoroscopy images;
c: X-ray images of the case who underwent Vertebroplasty

Outcome Measures: The visual analogue scale (VAS) values for resting pain of the patients and the evaluations using the Oswestry Disability Index (ODI) for activities of daily living were compared using preoperative and postoperative scores. The ODI has ten sections: pain, personal care, lifting, walking, sitting, standing, sleeping, sex life, social life, and travelling.¹⁷

Statistical Analysis: CSS (Number Cruncher Statistical System) 2007 Statistical Software (Utah, USA) program was used for statistical analysis. We expressed nominal data as frequencies or percentages and quantitative data as mean ± SD. The Shapiro-

Wilk test was performed to test the normality of study data. Groups were compared using the independent t-test for normally distributed continuous variables. The Chi-square test was used to analyse qualitative comparative parameters. A P-value of ≤ 0.05 was considered statistically significant.

RESULTS

VP and KP procedures were performed on 26 patients with thoracolumbar vertebral corpus fractures. The mean follow-up period was 16 months (12-30). The mean time between trauma and surgery was 1.1 months (1 week-2 months) (Table 1).

Table 1. The mean follow-up period and procedure time.

Period	Time
Follow-up period, month	16 (12-30)
Procedure time, month	1.1 (1 week-2 months)

VP was applied to 14 cases, and KP was applied to 12 cases. The mean age of the cases in VP was 72±6,51 years. The mean age of the cases in KP was 73.38±5.23 years. In the thoracic region, there were 4 (28.6%) fractures in VP and 4 (33.3%) in KP procedure. In the lumbar region, there were 10 (71.4%) fractures in VP and 8 (66.7%) in KP procedure. Of the patients who underwent VP, 12 were female (85.7%) and 2 were male (14.3%). Of the patients who underwent KP, 10 were female (83.3%), and 2 were male (16.7%). The main symptoms of the cases were low back and back pain, and were evaluated with VAS. Preoperative VAS scores were similar in both groups and were not statistically significant (p=0.995). The comparison of the VAS scores of both groups at the postoperative 1st, 3rd, and 12th months was not statistically significant (p=0.131,

p=0.994, p=0.314, respectively). However, the preoperative VAS values of the groups were 1st, 3rd, and 12th month comparisons showed statistically significant improvement (VP: p=0.001 and KP: p=0.001). Preoperative ODI scores were similar in both groups and were not statistically significant (p=0.842). The comparison of the ODI scores of both groups at the postoperative 1st, 3rd, and 12th months was not statistically significant (p=0.210, p=0.501, p=0.189, respectively). Nevertheless, the preoperative ODI scores of the groups were 1st, 3rd, and 12th month comparisons demonstrated statistically significant improvement (VP: p=0.001 and KP: p=0.001) (Table 2).

As a complication, cement leakage without neurological deficit was observed in 5 patients (Figure 2). Preoperative mean VAS values of cases with cement

Table 2. Comparison of cases who underwent vertebroplasty and kyphoplasty.

Parameters	VP (n=14)	KP (n=12)	p
Age, mean±SD	72±6,51	73.38±5.23	0.274
Sex, n (%)			
Female	12 (85.7)	10 (83.3)	0.544
Male	2 (14.3)	2 (16.7)	0.544
Region n (%)			
Thoracic	4 (28.6)	4 (33.3)	0.492
Lumbar	10 (71.4)	8 (66.7)	0.519
VAS, mean±SD			
Preoperative	8.6±1.6	8.6±1.0	0.995
1st month	3.5±1.0	3±1.0	0.131
3rd month	3±1.0	2±2.0	0.994
12th month	1.5±2.0	1±2.0	0.314
p	0.001	0.001	
ODI, mean±SD			
Preoperative	47.33±22.34	45.08±17.35	0.842
1st month	28.5±9.42	21.42±15.38	0.210
3rd month	21.83±8.63	16.5±7.13	0.501
12th month	11.5±8.14	9.82±4.93	0.189
p	0.001	0.001	

VAS: Visual analogue scale; ODI: Oswestry Disability Index; VP: Vertebroplasty; KP: Kyphoplasty.

leakage were 8.3 ± 1.2 , and ODI values were 46.8 ± 19.2 . At 1 month postoperatively, VAS was recorded as 2.2 ± 0.8 ($p=0.001$) and ODI as 27.2 ± 6.8 ($p=0.001$) (Table 3). It was observed that cement leakage did not affect the VAS value and ODI

scores.

DISCUSSION AND CONCLUSION

The major finding of this study was that VP or KP can be preferred as a minimally invasive procedure



Figure 2. Leakage along the tube in the area where cement was placed.

Table 3. Cases that encounter cement leakage.

Parameters	Preoperative	1st month	p
Cement leakage VAS, mean \pm SD	8.3 ± 1.2	2.2 ± 0.8	$p=0.001^*$
Cement leakage ODI, mean \pm SD	46.8 ± 19.2	27.2 ± 6.8	$p=0.001^*$

VAS: Visual analogue scale; ODI: Oswestry Disability Index; *: Statistically significant.

in treating patients with osteoporotic vertebral fractures. The effects of both procedures on VAS and ODI scores are similar. These applications can increase patients' quality of life and enable them to return to their daily activities quickly. Performing the procedures with local anaesthesia is advantageous for the advanced age group.

Vertebral fractures are usually seen after accelerated movement based on trauma and osteoporosis. Fractures may also be secondary to primary or metastatic cancer or rarely seen due to hemangiomas.^{11,13-16} Some researchers have reported that STIR sequences effectively detect acute and subacute fractures in MRI imaging.¹⁸ We performed VP and KP procedures after seeing acute and subacute fractures in preoperative MRI images in all our patients.

VP and KP are minimally invasive surgical techniques that can increase the mechanical stability of the vertebral lesion by injecting filling materials into the fractured vertebra.²⁰⁻²³ Filling materials used in VP and KP include injectable PMMA, composite bone cement, biodegradable bone cement, calcium phosphate cement (CPC), and others.⁷ Different filling materials affect the biomechanical properties of vertebral bodies and cause various biomechanical effects on adjacent vertebral bodies.^{7,19} PMMA was applied in the present study.

Treatment with VP or KP operations applied to patients who complain of pain due to vertebral fracture but do not have neurological loss is quite effective.^{24,25} The procedure can be performed with local or general anaesthesia.^{9,14,16} In the current study, all patients were operated under local anaesthesia and sedation. Therefore, complications that may arise from general anaesthesia are avoided. In addition, nerve monitoring, especially in thoracic vertebra applications, will help us to detect possible complications more quickly.

Vertebroplasty is not an uncomplicated procedure.^{24,26} Mild complications from VP and KP procedures; a temporary increase in pain and transient hypotension, moderate; severe infection and leakage of cement into the foraminal, epidural, or dural space; It is severe like cement leakage in paravertebral vessels and can lead to pulmonary embolism, cardiac perforation, cerebral embolism, and even death.²⁶⁻³⁰ In the present study, cement leaked into the disc space in four patients, and there was a procedural cannula trace in one patient. Control with C-arm fluoroscopy at every stage of the procedure and checking with contrast material before cement application will minimise possible complications. In addition, the amount and consistency of cement is also important. An experimental study showed that high-

viscosity cement used in VP is less prone to leakage than KP made with low-viscosity cement.⁶ Although special attention is paid to the time required for the cement to begin to solidify, it should not be forgotten that cement leakage may occur depending on the structure and aetiology of the fracture.²⁹ These leaks that might impact clinical outcomes can be seen in VP and KP.¹⁵ The present study demonstrated that VAS and ODI scores obtained from cases with cement leaks did not affect clinical improvement.

VP or KP has been reported as a low-risk procedure that increases physical movement capacity and significantly reduces pain. However, some studies indicate that both methods give the same results, and some results report that one is better than the other.^{5,8,13,24,25} The current study demonstrated that the values of VAS and ODI scores for preoperative and postoperative months were similar in both groups and were not statistically significant. However, according to the preoperative values, we found that both methods caused statistically significant improvements. It would be right to remember that the present study was on osteoporotic fractures, and the results may be different in oncological fractures. According to the current study, both methods of treating osteoporotic vertebral corpus fractures effectively increase the quality of life and rapidly meet daily needs.

Clinical success has yet to be achieved in cases of KP performed more than 6 months later. Publications suggest that VP should be preferred instead of KP in patients with a fracture age of over 3 months.^{22,23} Studies report that the effect of procedures performed for 6 weeks or longer is the same as placebo as the application period gets longer.¹⁰ Conversely, studies report that KP is successful in patients with painful osteoporotic spine fractures whose fracture age is at least 12 months.²¹ In the present study, the patient group who applied between 1 week and 2 months after the onset of the complaints and the procedures performed in an average of 1.1 months may affect successful and good results.

Some studies in the literature showed that patients treated with VP or KP are less likely to die after treatment than patients treated without surgery.¹⁶ The advanced age of the patient group and the high incidence of complications due to immobilisation necessitate treatment for osteoporotic vertebral corpus compression fractures.⁴ Therefore, VP and KP performed under local anaesthesia with the percutaneous method allow rapid mobilisation and effective pain control.¹⁻⁶ In the current study, the patient was discharged in 1.5-2 days due to mobilisation 6 hours after the procedure and an average of 1 night's observation unless there was another health problem preventing mobilisation.

In the literature, some reports demonstrated that VP proved the procedure's lower cost than KP.^{2,3} The cost of KP in minimally invasive procedures in treating patients with osteoporotic vertebral fractures was found to have higher values when we compared it with the low cost of VP management in the present study.

In conclusion, the effects of VP and KP procedures on VAS and ODI scores are similar. However, economically, the cost of KP is relatively high compared to VP. The study suggests using VP due to its low cost and clinically similar results on VAS and ODI scores compared to KP. There were several limitations to this study. The first one is that the follow-up period of 16 months is relatively short for assessing the clinical outcomes. Moreover, the present study did not search for the value of the injected cement during the procedure in either method.

Ethics Committee Approval: This study was planned following the Helsinki Principles, and ethical approval was obtained from the Medipol University Non-Interventional Research Ethics Committee (Date:10/08/2023, decision no: 655).

Conflict of Interest: No conflict of interest was declared by the authors.

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