ORIGINAL ARTICLE

UNILATERAL PERCUTANEOUS KYPHOPLASTY IN PATIENTS WITH PAINFUL OSTEOPOROTIC VERTEBRAL COMPRESSION FRACTURES; SINGLE CENTER EXPERIENCE

Ağrılı Osteoporotik Vertebra Kompresyon Kırığı Olan Hastalarda Tek Taraflı Kifoplasti Uygulaması; Tek Merkez Deneyimi

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ABSTRACT

Objective: The objective of this study is to evaluate the outcomes of unilateral percutaneous kyphoplasty (PKP) performed in treatment-resistant patients with osteoporotic vertebral fractures.

Material and Methods: The study sample consisted of eight patients with painful osteoporotic compression fractures who did not respond to conservative treatment methods. However, the respective clinical results were evaluated based on radiological findings pertaining to 18 operated vertebrae of the said eight patients. The Oswestry Disability Index (ODI) scores and Visual Analogue Scale (VAS) scores were recorded before the procedure and at the 1st-month and 6th-month follow-up visits. Vertebral angle (VA), and anterior height (AH), central height (CH) and posterior height (PH) of the superior and inferior endplates of the vertebrae were measured before the procedure and at the 6th-month follow-up using direct radiography.

Results: Mean VAS and ODI scores decreased 70.5% and 72%, respectively, over a 6-month period. The mean vertebral height increased after kyphoplasty, as reflected by a 3.15% increase in AH, 24.6% increase in CH and 0.99% increase in PH. Additionally, VA was found to have increased by 13.6%.

Conclusion: The results of this study featuring a small patient population indicated that unilateral balloon PKP can be used safely and effectively to achieve earlier mobilization with faster pain relief and fewer complications.

Keywords: *Osteoporosis; Kyphoplasty; Pain; Fractures; Compression*

ÖZET

Amaç: Çalışmamızda medikal tedaviye dirençli osteoporotik vertebra kırığı olan hastalarda tek taraflı kifoplasti uygulamamız ile ilgili sonuçları paylaşmayı amaçladık.

Gereç ve Yöntemler: Çalışmaya ağrılı osteoporotik kompresyon kırığı olan ve konservatif tedaviye yanıt alınamayan 8 hasta dahil edildi. Klinik sonuçları hasta sayısı üzerinden değerlendirirken radyolojik sonuçları işlem yapılan 18 vertebra sayısı üzerinden değerlendirildi. İşlem öncesi,1.ay ve 6. ay kontrollerinde oswestry disability indeksi (ODİ) skorları ve vizüel analog skala (VAS) skorları, kaydedildi. Direkt radyografi kullanılarak işlem öncesi ve 6.ay kontrolünde vertebral açı (VA), vertebral üst ve alt uç plakların ön yüksekliği (AH), merkezi yüksekliği (CH) ve arka yüksekliği (PH) ölçüldü.

Bulgular: VAS skor ortalaması ve ODİ skor ortalamasında 6 aylık süreçte sırası ile %70,5 ve %72 lük bir azalma gözlendi. Ortalama vertebra yüksekliğin kifoplasti işleminden sonra AH % 3,15, CH %.24,6 ve PH %0,99 artış saptandı. VA'da %13,6 lik bir artış saptanmıştır.

Sonuç: Kısıtlı hasta popülasyonumuzla ilgili deneyimler, balon kifoplastinin hızlı ağrı kesici ve daha az komplikasyonla daha erken mobilizasyon elde etmek için etkili ve güvenli olduğunu göstermiştir.

Anahtar Kelimeler: *Osteoporoz; Kifoplasti; Ağrı; Kırık; Kompresyon*

INTRODUCTION

Osteoporosis is the most common form of metabolic bone disease and is characterized by decreased bone mineral density due to increased bone resorption and increased fracture risk. Osteoporosis is a major public health problem (1). It is estimated that more than 40% of postmenopausal women and approximately 25-33% of men will develop a fracture at some point in life (2). Vertebral compression fractures are the most common type of osteoporotic fracture (1). Magnetic Resonance Imaging (MRI) is particularly useful in demonstrating whether the fracture is acute or chronic (3). Conservative treatment of osteoporotic vertebral fractures (OPVFs) includes methods such as bed rest, corset wearing, medical therapy and physical therapy. However, at times, conservative treatments may be insufficient. In patients, where conservative treatments are insufficient, surgical treatment may also fail because of poor osteoporotic bone quality (4). Percutaneous kyphoplasty (PKP) is one of the treatment options that can be utilized in such cases where conservative and surgical treatments fall short. PKP was developed by Mark Reiley in 1998 and described by Garfin et al. in the PKP procedure, before the injection of polymethyl methacrylate (PMMA) from the pedicle, the balloon is guided through the cannula and inflated to create a cavity and raise the vertebra. Pasty PMMA is filled into the created cavity and checked with fluoroscopy (5). PKP is a minimally invasive surgical method in the treatment of OPVFs that allows mobilization and early return to normal life in a short time through pain reduction and fracture stabilization.

In the light of the foregoing, this study was carried out to evaluate the outcomes of unilateral PKP performed in treatment-resistant patients with osteoporotic vertebral fractures.

MATERIAL AND METHODS

This study was designed as a retrospective descriptive study. The study protocol was approved by the Ethics Committee of the University of Health Sciences (2023-07/2023-474). The study was carried out in accordance with the principles stated in the Declaration of Helsinki. The sample of the study consisted of 8 patients with painful osteoporotic compression fractures who did not respond to conservative treatment methods and underwent PKP in the Department of Algology, Faculty of Medicine, Akdeniz University, between 2018-2022. The physical examination of the patients revealed that their spinal movements were painful and limited. None of the patients had a neurological deficit. PKP was not planned for patients with radicular pain, uncorrectable coagulopathy disorders, PMMA allergy, myelopathy findings due to spinal stenosis, ongoing infection, benefit from conservative treatment, and patients with asymptomatic fractures.

Oswestry Disability Index (ODI) and Visual Analogue Scale (VAS) scores were recorded before the procedure, at the 1st-month and 6th-month follow-up visits. In our study, clinical and radiological findings of 18 operated vertebrae of 8 patients who underwent kyphoplasty were evaluated.

ODI is a questionnaire consisting of 10 questions measuring the severity of pain, personal care, lifting, walking, sitting, standing, social life, sleeping, travel status, and cognitive status of pain. Each question is evaluated between 0-5 points. When the total score is calculated, it is multiplied by two and expressed as a percentage. The maximum score is "100" and the minimum score is "0". It is known that as the total score increases, functional competence decreases and disability increases (6).

The pain levels of the patients were evaluated with VAS. VAS is a widely used and validated measurement tool for assessing bodily pains. In assessing pain with VAS, one end of a 100 mm (10 cm) ruler is considered to indicate zero pain level and the other end severe pain level, and patients are asked to show the point corresponding to the pain they feel on this ruler. Higher values indicate more severe pains.

The patients were evaluated with radiography and magnetic resonance imaging (MRI). The MRI, particularly short tau inversion recovery (STIR) MRI and T1-weighted (T1W) MRI, revealed fracture and bone marrow edema. Eighteen vertebrae of 8 patients included in the study who underwent kyphoplasty were evaluated radiologically. The 18 vertebrae operated on with kyphoplasty were as follows: 4 vertebrae at the L1 level, 3 vertebrae at the L2 level, 5 vertebrae at the L3 level, 3 vertebrae at the L4 level, and another 3 vertebrae at the L5 level. Radiological controls of the patients were performed at the 6th-month follow-up

Bozok Tıp Derg 2023;13(4):111-117
Bozok Med J 2023;13(4):111-117

visit in the light of the dorsolumbar radiographs. The clinical and radiological results were evaluated based on the number of examined patients and vertebrae, respectively. The vertebral angle (VA) was calculated according to the angle of intersection of the lines that intersect parallel to the superior and inferior end plates of the fractured vertebra (7). VA was calculated before the procedure and at the 6th-month follow-up visit (Figure 1). A total of three sites were defined for the measurement of anterior height (AH), central height (CH), and posterior height (PH) of the superior and inferior end plates of the vertebrae using direct radiography. Accordingly, AH, CH, and PH were measured preoperatively and at the 6th-month follow-up visit postoperatively.

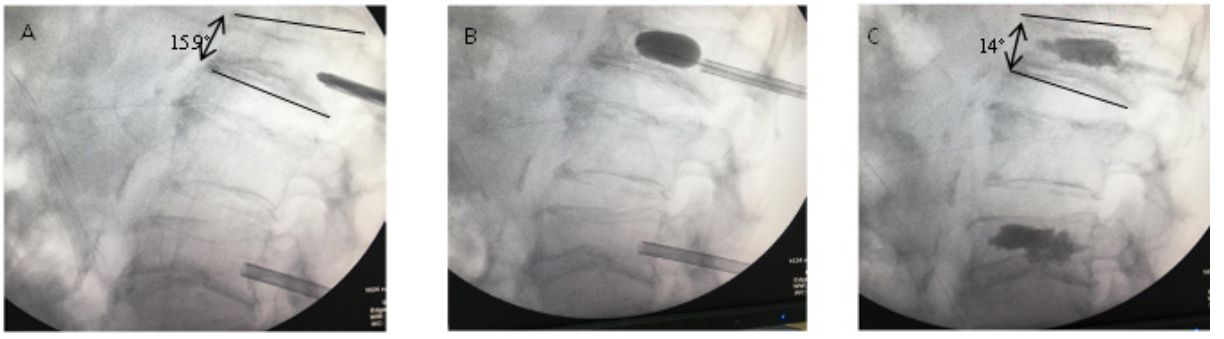
Vertebral integrity was examined in detail via MRI obtained from the sagittal and axial planes, and the entrance side and level were determined for PKP. For the PKP procedure, patients were placed on the operating table in the prone position, preferably under sedation anesthesia. With the guidance of fluoroscopy, the pedicles to be operated were determined and the end-plate view, the symmetrical base of which was not visible, was brought to the appropriate position. The fracture site was determined by fluoroscopy and local anesthesia was applied.

Transpedicular access routes were preferred. After a small skin incision made with a scalpel, the pedicle of the fractured vertebra was entered using a Jamshidi needle and a mallet, accompanied by fluoroscopy. The lateral and anterior-posterior images obtained with fluoroscopy were used to determine whether it was in the vertebral body. Under the guidance of anterior-posterior radiography, the lateral view was achieved by moving forward within the pedicle until reaching the middle of the pedicle. The needle was advanced to enter the corpus. In the meantime, whether the patients had radicular pain was checked. After checking whether it was in the bone tissue with Kirschner wire (K-wire), the needle was removed by placing the wire on the anterior lower wall of the vertebra. A working cannula was placed under the guidance of K-wire. Drilling was used to make room in the fracture. Before PMMA injection, the balloon is guided through the cannula and inflated to create a cavity and raise the vertebra. Fluidic PMMA was injected under pressure through the cannula. In the meantime, whether the vertebral body was filled or PMMA had escaped out of the fracture was checked by fluoroscopy (Figure 1). All patients were discharged after an average of 5 hours based on the results of direct radiography performed after the procedure.

Statistical Analysis

The research data were analyzed using the SPSS 21 (Statistical Package for Social Sciences for Windows, Version 21.0, IBM Corp., Armonk, NY, U.S., 2012) software package. Descriptive statistics were expressed using mean, standard deviation, minimum, and maximum. Shapiro-Wilk test was used to determine whether the variables conform to normal distribution. Subsequently, Wilcoxon test were used for statistical

Figure 1. A lateral image of the inflated balloon tamps in the fractured vertebral body (A),(B). A small volume of bone cement was injected just posterior to the bony defect to build a barrier. Lateral (C) and anterior-posterior (D) images of the bone cement that filled the cavity in the fractured vertebral body, respectively. Cement leakage was not detected.



Bozok Tıp Derg 2023;13(4):111-117
Bozok Med J 2023;13(4):111-117

analyses. The significance level was set at 0.05. software package. Descriptive statistics were expressed using mean, standard deviation, minimum, and maximum. Shapiro-Wilk test was used to determine whether the variables conform to normal distribution. Subsequently, Wilcoxon test were used for statistical analyses. The significance level was set at 0.05.

RESULTS

PKP was performed in 18 vertebrae of eight patients, 6 (75%) female and 2 male (25%), due to osteoporotic vertebral compression fractures. The mean age of the patients was 62.5 (min.55, max. 89) years. The major symptom in all cases was pain and there was no neurological deficit. The 18 vertebrae operated on with kyphoplasty were as follows: 4 (22%) vertebrae at the L1 level, 3 (17%) vertebrae at the L2 level, 5 (27%) vertebrae at the L3 level, 3 (17%) vertebrae at the L4 level, and another 3 (17%) vertebrae at the L5 level. Analysis of the types of the compression fractures in the vertebrae revealed that there was wedge fracture in 11 vertebrae, biconcave fracture in 6 vertebrae, and crush fracture in 1 vertebra. MRI revealed bone marrow edema in all operated vertebrae. Preoperative and postoperative AH, CH and PH values of the superior and inferior endplates of the vertebrae were measured and comparatively analyzed (Table 1). Complications associated with bone cement were classified according to the anatomical region. There was cement leakage minimal to the superior disc in one patient and cement leakage to the posterior soft tissues in another patient (Table 1). Accordingly, the total preoperative vertebral AH, CH and PH values of the patients were measured as 394 mm, 229.32 mm and 472.8 mm, respectively. Additionally, the total postoperative vertebral AH, CH and PH values were measured as 412.4 mm, 290.89 mm and 480.6 mm, respectively. On the other hand, the mean preoperative vertebral AH, CH and PH values of the patients were measured as 22.2 mm, 14.2 mm and 27.03 mm, respectively. In addition, the mean postoperative vertebral AH, CH and PH values were measured as 22.91 mm, 17.7 mm and 27.3 mm, respectively (Table 2). These results indicated that the

Table 1. Patients' initials, age, gender, osteoporosis fracture type and fracture level information, bone marrow edema appearance in Magnetic resonance (MR) imaging, pre- and postoperative vertebral angle (VA), anterior height (AH), central height (CH) and posterior height (PH) values, and postoperative complication data are shown in the table. The angle is specified in degrees (°). Height is specified in mm.

Patients' Initials	Age	Gender	Fracture Level	Fracture Type	Bone edema	Operated site	Preoperative VA	Postoperative VA	Preoperative AH	Postoperative AH	Preoperative CH	Postoperative CH	Preoperative PH	Postoperative PH	Complication
1-Z.Ç	63	Female	L1	Wedge	+	Left	9.1	5.3	27.4	30	17	21.7	33.8	34	-
			L2	Biconcave	+	Left	4.5	2.3	28.2	29.9	17.1	20.7	31.6	31.8	-
			L3	Wedge	+	Left	9.3	5.1	23.6	26	7.6	16.4	30.7	31.5	-
2-Y.O	65	Male	L1	Wedge	+	Right	15.9	14	18	18.8	13	16.4	26	26	-
			L3	Biconcave	+	Right	2	0.9	28.4	29.9	21	26..7	30.8	31.1	-
3-M.Ö	71	Male	L5	Crush	+	Right	3.7	3.5	24	24.7	16	18.1	27	27	Cement leakage to the posterior soft tissues
4-S.G.	74	Female	L5	Wedge	+	Right	10	9.4	20.6	21.1	14	16.6	26	27	
5-Z.U	55	Female	L1	Wedge	+	Left	5.5	5.4	18	18.3	9	11.2	23.4	23.6	
			L2	Wedge	+	Left	7.6	7.5	19.7	19.7	11.5	15.2	24.7	24.8	
			L4	Biconcave	+	Left	3.9	3.1	24	24.5	17.3	18	27.8	27.8	
			L5	Biconcave	+	Right	1	1	25	25	14.8	20.2	25.7	25.8	
6-S.M	82	Female	L3	Wedge	+	Right	11	11	17.9	18	13.6	19.3	24	25	Cement leakage minimal to the superior disc
			L4	Wedge	+	Right	9.5	9	22.7	23	19.3	20.4	27.8	28.1	
7-M.G	56	Female	L3	Wedge	+	Left	6.7	6.1	19.3	19.7	9.2	11.8	25.3	25.5	
			L4	Wedge	+	Right	5.5	5.4	18	18.3	8.3	11.2	24.4	24.6	
8-A.U	66	Female	L1	Wedge	+	Left	5.7	5.7	21.2	21.1	13.2	15.8	26.3	26.5	
			L2	Biconcave	+	Left	5.3	5	25.2	25.8	19.3	23	28.9	29.2	
			L3	Biconcave	+	Left	4	3.5	18.8	19.8.	15.5	16.3	22.5	22.9	

Bozok Tıp Derg 2023;13(4):111-117
Bozok Med J 2023;13(4):111-117

mean height increased after PKP, as reflected by a 3.15% increase in AH, 24.6% increase in CH, and 0.99% increase in PH. Furthermore, the mean preoperative and postoperative VA values were measured as 6.67 and 5.73, respectively (Table 2). Additionally, the total preoperative and postoperative VA values were measured as 120 and 103, respectively. There was a statistically significant difference between the pretreatment and posttreatment AH, CH, PH and VA scores (Table 2) (P values were 0.001, 0.001, 0.001 and 0.001 respectively).

The mean preoperative and postoperative 1st-month and 6th-month VAS scores of the patients were measured as 7.8, 2.3 and 2.3, respectively (Table 3). In addition, the mean preoperative and postoperative 1st-month and 6th-month ODI scores of the patients were measured as 65.2, 20.2 and 18.8, respectively (Table 3). Accordingly, there was a 70.5% decrease in the mean VAS scores, and a 69.4% and a 72% decrease in the mean postoperative 1st-month and 6th-month ODI scores. There was a statistically significant difference between the pretreatment and posttreatment VAS and ODİ scores

Table 2. Wilcoxon test was used for statistical analyses. Before and after the procedure; Statistics of pre- and postoperative vertebral angle (VA), anterior height (AH), central height (CH) and posterior height (PH) values, and postoperative

	BEFORE PROCEDURE		AFTER PROCEDURE		
VARIABLES	**Mean ± SD**	**Min-Max**	**Mean ± SD**	**Min-Max**	**p value**
VA	6.6 ±3.6	1 -15.90	5.7 ± 3.42	0.9-14	0.001
AH	22.2 ± 3.6	17.9 – 28.4	22.9 ± 4.1	18-30	0.001
CH	14.2±3.9	7.6-21	17.7±4.1	11.2-26.7	0.001
PH	27.03±3.08	22.50-33.80	27.3±3.08	22.90-34	0.001

SD: Standart Deviation, **Min:** Minimum, **Max:** Maximum

Table 3. Patients' initials, preoperative and postoperative 1st- and 6th-month VAS (Visual Analogue Scale) scores, and preoperative and postoperative 1st- and 6th-month ODI (Oswestry Disability Index) scores are shown in the table.

Patients' Initials	Preoperative VAS scores	Postoperative 1st-month VAS scores	Postoperative 6th-month VAS scores	Preoperative ODI scores	Postoperative 1st-month ODI scores	Postoperative 6th-month ODI scores
1-Z.Ç	8	2	2	60	17.7	13.3
2-Y.O	8	3	3	84.4	20	22.2
3-M.Ö	5	4	4	40	33.3	33.3
4-S.G	7	2	1	55.5	15.5	11.1
5-Z.U	10	1	1	93.3	11.1	8.8
6-Ş.M	9	4	4	64.4	35.5	31.1
7-M.G	8	2	2	60	20	20
8-A.U	8	1	2	64.4	8.8	11.1

Table 4. Wilcoxon test was used for statistical analyses. VAS: Visual analogue scale, ODI (Oswestry Disability Index)

Variables		**Mean ± SD**	**Min-Max**
VAS	Before Procedure	7.8 ± 1.4	5 - 10
	1st Month	2.3 ± 1.18	1- 4
	6th Month	2.3 ± 1.18	1 - 4
	p value	0.011	
ODİ	Before Procedure	65.2 ± 16.6	40 – 93.3
	1st Month	20.2 ± 9.6	8.8 – 35.5
	6th Month	18.8 ± 9.4	8.8 – 33.5
	p value	0.012	

SD: Standart Deviation, **Min:** Minimum, **Max:** Maximum

Bozok Tıp Derg 2023;13(4):111-117
Bozok Med J 2023;13(4):111-117

(Table 4) (P values were 0.011 and 0.012 respectively).

DISCUSSION

With the increase in the elderly population, OPVFs are seen more frequently, which means a significant socioeconomic burden on medical systems and society. PKP is used in the treatment of OPVFs that do not respond to conservative treatment due to its clinical efficacy and low risk of complications. Vertebral compression fractures are the most common type of osteoporotic fractures (1). On the other hand, the most common (51%) vertebral compression fractures are wedge fractures, followed by biconcave (17%) and crush (13%) fractures (8). Similarly, of the 18 fractures operated on in this study, 11 (61%) were wedge and 6 (33%) were biconcave fractures, and 1 (6%) was a crush fracture. In addition, 22%, 17%, 27%, 17% and 17% of the OPVFs were at the L1, L2, L3, L4 and L5 levels, respectively. It is known that untreated OPVFs decrease the quality of life and ultimately increase the morbidity and mortality rates (9). Balloon kyphoplasty has been a good alternative in the treatment of OPVFs in terms of pain relief, early mobilization, local anesthesia, shorter duration of the respective percutaneous surgery as well as very low surgical complication rates. In parallel, a significant difference was found in this study between the pre- and postoperative VAS scores. The relief of pain may be attributed to thermal, chemical and mechanical factors. Stabilization of the vertebra with kyphoplasty fixates the microfractures in the area and prevents micromovements, thereby preventing development of new fractures and reducing pain. It has been suggested that the heat generated by the polymerization effect of PMMA causes thermal necrosis of the nerve tissue, reducing pain (10-11). In a study conducted with 36 patients who were operated on with a unilateral approach, postoperative 1-year AH, CH, and PH values were found to be significantly increased compared to the preoperative AH, CH, and PH values (12). In comparison, the post-procedural vertebral height measurements of the patients included in this study revealed that the total postoperative AH, CH, and PH values increased by 3.15%, 24.6%, and 0.99%, respectively. The significant increase in CH values may be due to maintaining and raising the height of the middle wall by providing more bone cement to the middle section during the PKP process. It is expected that vertebral corpus angle and segmental kyphosis will improve with kyphoplasty (13). As a matter of fact, in a study by Song et al. conducted in 2015, balloon kyphoplasty was found to be effective in correcting vertebral deformity (14). In another study conducted with 54 patients in 2021, there was a marked improvement in the VAS and quality of life scores and in vertebral angle after PKP (15). In parallel, a 13.6% increase was observed in VA values in this study. The height between the endplates, which decreased after the occurrence of the fracture in the vertebral body, increased especially in the central region of the vertebrae after PKP, however no significant improvement was observed in VA. In the event of biconcave OPVFs, PKP results in an increase primarily in CH. On the other hand, in the event of more common wedge OPVFs, PKP results in an increase primarily in AH, thereby leading to a more significant improvement in VA. In contrast, although wedge OPVFs were common, no significant increase was observed in VA values in this study, suggesting that the bone cement was mostly applied to the middle region in the PKP procedure. Benyamin et al. reported that the pain in almost all cases decreased and there was a recovery of up to 80-85% in daily life activities provided that the source of the pain is diagnosed accurately (16). It has been demonstrated that performing the PKP procedure during the period when the fracture is acute or subacute positively affects the surgical outcome (17). MRI is an effective method in the assessment of the duration of the fracture. In this context, patients who were determined to have bone marrow edema on indicated MRI were included in this study.

Studies have reported significant improvement in VAS and ODI scores following PKP (18-20). Similarly, a 70.5% and 72% decrease was observed in the mean VAS and ODI scores, respectively, in this study. Bone cement-related complications observed in this study were classified according to the anatomical region. Accordingly, there was cement leakage minimal to the superior disc in one patient and cement leakage to the posterior soft tissues in another patient. Both of these complications are considered non-serious cement-related complications, as they are only radiologically significant and do not cause symptoms in the patient.

Limitation of our study was the small sample size resulting from the specificity of our inclusion criteria and the fact that it was a retrospective study.

CONCLUSION

In conclusion, application of unilateral percutaneous kyphoplasty procedure due to vertebral compression fractures significantly reduced patients' pain, improved their daily life activities, significantly reduced their life support needs, and thereby positively affected their psychological and emotional statuses. Therefore, given the recent increase in the number of vertebral compression fractures, PKP can be considered a gold standard surgical method, as it is a minimally invasive method, shortens the hospital stay, provides mobilization in a short time, corrects spinal deformity, and thus increases the quality of life of the patient.

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