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Can a unilateral approach replace the bilateral approach in percutaneous kyphoplasty?

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ABSTRACT

Aims: The main techniques used in balloon kyphoplasty include bilateral and unilateral approaches, but debate continues regarding their effectiveness. This study primarily aims to evaluate the clinical effects and safety profiles of unilateral and bilateral balloon kyphoplasty in osteoporotic and traumatic vertebral compression fractures and to compare patient satisfaction. The study's secondary aim is to identify the factors affecting prognosis, if any, in the general patient population. Our study compared the clinical and radiological results of patients with thoracolumbar vertebra fractures who underwent bilateral and unilateral balloon kyphoplasty operations in general and separately for patient subgroups.

Methods: Patients who underwent balloon kyphoplasty at the Neurosurgery Department of Atatürk Training and Research Hospital were investigated retrospectively and called for outpatient clinic control. Their current condition and satisfaction were evaluated. Clinically, patient satisfaction was assessed using a three-point Likert scale, Roland-Morris Disability Questionnaire, and VAS (Visual Analog Scale), and radiologically, preoperative, early postoperative, and late postoperative images in the sagittal plane, vertebral kyphosis angle, segmental kyphosis angle, Beck index, height loss, and axial canal compressions were examined and evaluated comparatively.

Results: A total of 77 patients who could be contacted and who were able to access the outpatient clinic were included in the study. Sixty-seven of the patients underwent unilateral surgery, and ten patients underwent bilateral surgery. In the final control, patients who underwent bilateral kyphoplasty had less height loss than patients who underwent unilateral kyphoplasty. There was no difference in other radiological outcomes. There was no significant difference in clinical outcomes between patients who underwent bilateral and unilateral kyphoplasty. Mean Visual Analogue Scale and Roland Morris scores at the final follow-up were significantly higher in female patients than in male patients.

Conclusion: There was no statistically significant difference in the satisfaction of patients who underwent bilateral kyphoplasty compared to unilateral kyphoplasty. This result may be due to the small number of patients in the study, and more extensive series are needed. The fact that the clinical results of female patients are worse than those of male patients may be a guide to giving realistic answers to the questions of patients' prognosis and pain expectations in the postoperative period.

Keywords: Kyphoplasty, unilateral approach, bilateral approach, vertebral compression fractures

INTRODUCTION

The balloon kyphoplasty (BKP) technique, developed for the treatment of progressive kyphotic deformity resulting from osteoporotic spinal fractures, consists of percutaneous inflation of a balloon placed in the fractured vertebral body to reduce the fracture and stabilization of the fracture by injection of a biomaterial into the body after balloon removal. Early results of this method, developed to restore sagittal balance by restoring vertebral body height in osteoporotic spinal fractures, have been reported to be quite favorable.[1-3]

Although the most common indication for BKP is painful acute and subacute osteoporotic compression fractures, traumatic compression fractures, aggressive spinal haemangiomas, multiple myeloma, and bone destructive metastases are also indications for kyphoplasty.[4-6]

Although these are widespread procedures, there is still controversy in the literature regarding the efficacy of bilateral and unilateral approaches to balloon kyphoplasty.

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METHODS

The study was initiated with approval of the Katip Çelebi University Atatürk Training and Research Hospital Ethics Committee (Date: 27.03.2019, Decision No: 131). All procedures were carried out in accordance with the ethical rules and the principles of the Declaration of Helsinki.

This study retrospectively analyzed patients who underwent balloon kyphoplasty in the Department of Neurosurgery of Atatürk Training and Research Hospital. Patients who could be reached and who came to the outpatient clinic for a control examination were included in the study. The inclusion criteria were the absence of neurological deficits and late outpatient clinic control availability.

Preoperative independent variables were age, gender, fracture site, fracture cause, level, fracture type, the time between trauma and hospitalization, the time between hospitalization and operation, and the time between operation and discharge.

Using PACS imaging software, vertebral kyphosis angle, segmental kyphosis angle, Beck index, and height loss in the sagittal plane, as well as canal compression in the axial plane, were evaluated in preoperative, early postoperative, and late postoperative images (**Figure 1, Figure 2**).

Vertebral kyphosis (α, degrees): angle between the upper and lower endplates of the fractured vertebral body

Segmental kyphosis (β, degrees): angle between the upper endplate of the vertebral body above and the lower endplate of the vertebral body below the fractured body

Beck index (%): anterior vertebral body height (a) / posterior vertebral body height (b)

Note: Segmental kyphosis was not measured if there was an additional fracture in the adjacent vertebra, above or below.

Height loss (%): average of the mid-heights of the two adjacent vertebrae (c and d) - the height at the center of the fractured vertebra (e) / average of the mid-heights of the two adjacent vertebrae (c and d)

Spinal canal compression (%): diameter of the most severe spinal canal compression (largest anteroposterior diameter of the retro pulse fragment in the spinal canal) / mean value of the spinal canal diameters at the level of two adjacent vertebrae above and below

Preoperative radiological findings were considered independent variables, and radiological findings in the early postoperative period and at the last follow-up were considered dependent variables.

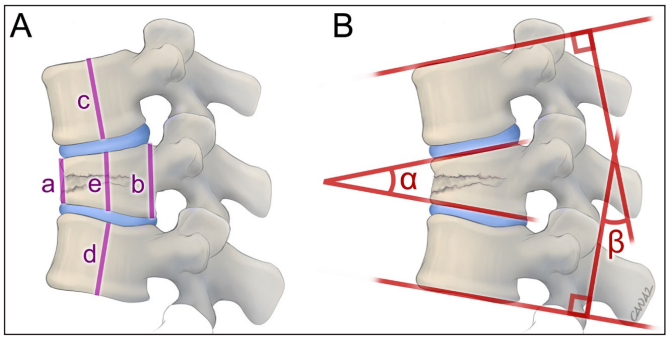

Figure 1. Schematic representation of radiological parameters (A-B). a: anterior vertebral body height. b: posterior vertebral body height. c: mid-height of the corpus of the upper adjacent vertebra. d: mid-height of the corpus of the lower adjacent vertebra. e: mid-height of the corpus of the fractured vertebra (A). α: vertebral kyphosis angle. β: Segmental kyphosis angle.

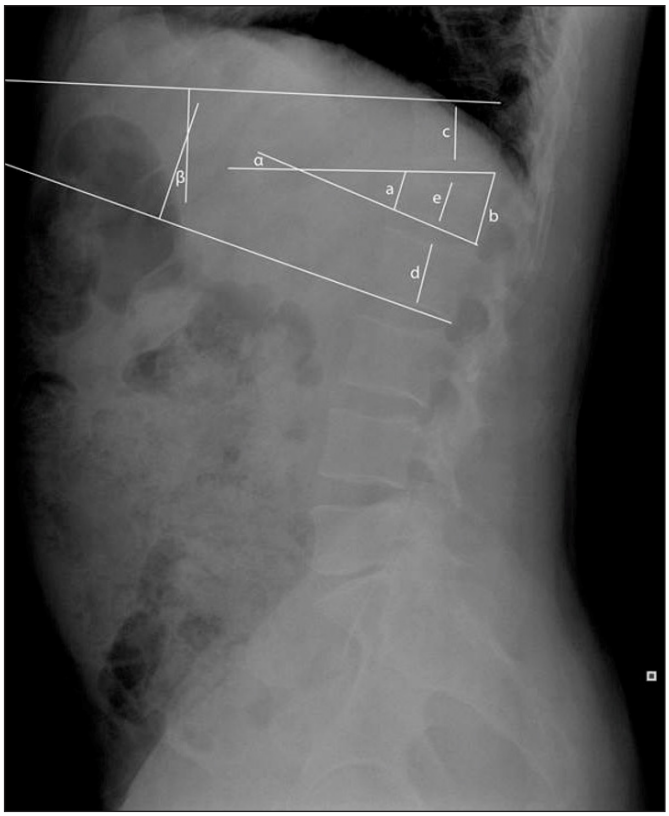

Figure 2. Representation of radiological parameters on the lateral radiograph. α: vertebral kyphosis angle (angle between the fractured vertebral body's upper and lower end plates). β: segmental kyphosis angle (angle between the upper end plate of the vertebral body above and the lower end plate of the vertebral body below the fractured body)

At the last follow-up visit, clinical evaluation was performed on three dependent variables: the Triple Likert Scale questionnaire for patient satisfaction, the Roland-Morris disability questionnaire, and the Visual Analogue Scale (VAS). While evaluating patient satisfaction, the patient was asked whether each of the three items was true for him/her. These items are: a) I am satisfied with the operation; I would have the operation again if I had the same situation. I would recommend that my relatives have surgery in the same situation. b) I was partially satisfied with the surgery; I am unsure if I would have surgery again in the same situation. I am not sure if I

would recommend that my relatives have surgery in the same situation. c) I am not satisfied with the surgery; I would not have surgery in the same situation again. I would not recommend that my relatives have surgery in the same situation.

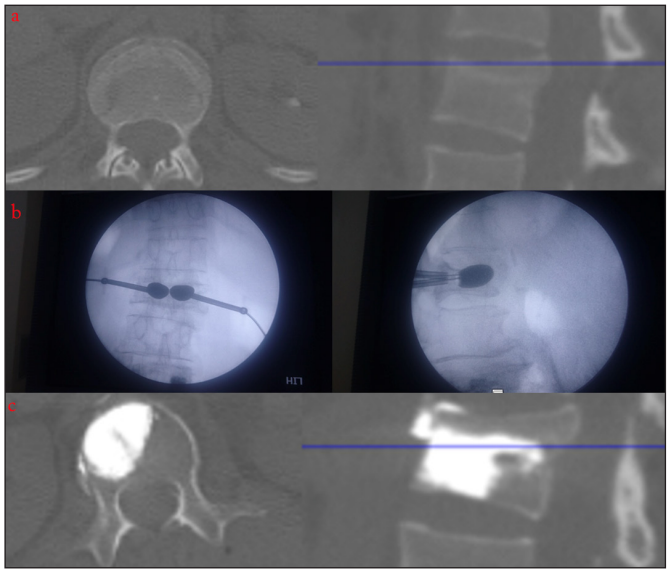

Figure 3. Preoperative, peroperative, and postoperative imaging of a patient undergoing kyphoplasty. a: preoperative tomography image, including axial and sagittal sections. b: peroperative anterior-posterior and lateral fluoroscopy images c: postoperative tomography image, including axial and sagittal sections

After the questioning of the patients, groups b and c were combined, and statistical tests were performed as the group "those who were not fully satisfied with the surgery."

The IBM SPSS Statistics 22 program was used. The chi-square test was used to compare a categorical independent variable (e.g., gender) with a categorical dependent variable (e.g., patient satisfaction). Pearson's bivariate correlation test was used to compare a numeric independent variable (e.g., age) with a numeric dependent variable (e.g., VAS). When one of the variables was categorical and the other was numerical, t-tests (independent sample or paired sample) were used.

RESULTS

Of the 77 patients who underwent kyphoplasty and were included in the study, 28 were male and 49 were female, and the mean age was 62.82 years (minimum: 16, maximum: 87, standard deviation: 15.04). A total of 100 percutaneous kyphoplasty procedures were performed in 85 sessions. All kyphoplasty procedures were performed under local anesthesia under fluoroscopic control.

One patient underwent kyphoplasty of 6 vertebrae (2+2+1+1) in 4 sessions. All kyphoplasty procedures were performed bilaterally in this patient. One patient had one kyphoplasty performed bilaterally in two sessions (2 kyphoplasty total). In addition, bilateral kyphoplasty was performed on one vertebra of 8 patients. Thus, 16 vertebrae of 10 patients underwent bilateral kyphoplasty in 14 sessions.

Additionally, unilateral kyphoplasty was performed on three vertebrae of two patients and two vertebrae of nine patients in the same session. Four patients underwent kyphoplasty in two separate sessions (2 kyphoplasty total). The remaining 52 patients underwent kyphoplasty of 1 vertebra in 1 session. Thus, unilateral kyphoplasty was performed on 84 vertebrae of 67 patients in 71 sessions. No patient underwent unilateral kyphoplasty on one vertebra and bilateral kyphoplasty on the other.

A total of 8 of these 77 patients who underwent clinical control could not undergo late follow-up CT because they refused (7 patients underwent unilateral kyphoplasty on one vertebra, and one patient underwent unilateral kyphoplasty on two vertebrae). Late radiological control was performed on 69 of the 77 patients who underwent clinical control. While the clinical results were evaluated based on the number of patients (77 patients), the radiological results were evaluated based on the number of vertebrae (91 vertebrae with late radiological control). The last radiological controls were performed after an average of 19.21 months (minimum: 2, maximum: 46, standard deviation: 10.67). Clinical controls were performed at an average of 18.26 months (minimum: 3, maximum: 46, standard deviation: 10.69).

When we analyzed the vertebrae treated, it was seen that kyphoplasty was performed on 1 Th5 vertebra, 3 Th7 vertebra, 1 Th8 vertebra, 3 Th9 vertebra, 4 Th10 vertebra, 7 T11 vertebra, 19 Th12 vertebra, 33 L1 vertebra, 12 L2 vertebra, 10 L3 vertebra, 4 L4 vertebra, and 3 L5 vertebra.

For both vertebral and segmental kyphosis angles, slight improvements without statistical significance were seen in the early postoperative period. Nevertheless, the kyphosis continued to rise following kyphoplasty, and more severe kyphosis angles were observed throughout the final follow-up in comparison to both the early postoperative and preoperative periods, with statistical significance. There was no difference between unilateral and bilateral kyphoplasty in vertebral and segmental kyphosis at any period. While there was a significant improvement in the early postop period, the mean Beck index became even lower than the preop period because of deterioration over time. There was no statistically significant difference at the last follow-up compared to the preop period. There was no difference in the Beck index between unilateral and bilateral kyphoplasty in any period. While there was a significant improvement in the mean height loss in the early postop period, it became even lower than in the preop period because of worsening over time. The values were statistically

significantly worse at the last follow-up than at the preop period. When the final control height losses were analyzed, it was noted that the height loss in unilateral kyphoplasty (0.426±0.149) was statistically significantly (P=0.042, independent sample T-test) higher than the height loss in bilateral kyphoplasty (0.309±1.91). There was no statistically significant difference in canal compression at the last follow-up compared to the preoperative period. There was no difference between unilateral and bilateral kyphoplasty in canal compression in any period (Table 1).

Prolonged hospitalization time was associated with worse preop height loss and worse early vertebral Cobb and Beck index values, while a long hospitalization-operation interval was associated with worse preop canal compression (Pearson Correlation; P, 0.05, 0.015, 0.005, 0.017, 0.008, respectively). However, there was no correlation between these intervals and the final control radiological values.

There was no difference between male and female patients regarding patient satisfaction, but female patients were worse than male patients at the last follow-up, according to both the Roland Morris scale and VAS. In addition, patients with spinal canal compression did worse than patients without compression, according to the Roland Morris scale at the last follow-up.

Although the mean age of the patients who were satisfied with the outcome (63.3±14.9) was higher than the mean age of the patients who were not satisfied (58.2±16.4), this was not statistically significant (Table 2). There was no significant correlation between age and Roland Morris and VAS values (Pearson Correlation Test, p: 0.051 and 0.122, respectively). There was no statistically significant difference between the clinical outcomes of the 67 patients who operated with the unilateral approach and the 10 patients who operated with the bilateral approach. Our study categorized fracture etiology under three headings: trauma, osteoporosis, and others, and osteoporosis and trauma groups were compared. There was no difference between the clinical results of patients who underwent single-level kyphoplasty and patients who underwent multiple-level kyphoplasty. Postoperative discharge of patients whose surgeries were delayed after admission was also delayed (Pearson Correlation, p: 0.038). However, there was no correlation between these delays and clinical outcomes. In our study, kyphoplasty was also performed in patients with A3-4 fractures, and although there was no difference in terms of patient satisfaction and VAS in the final postoperative controls of 45 patients without canal compression and 32 patients with canal compression (without neurological deficit), patients without canal compression were statistically significantly better than patients with canal compression in terms of Roland Morris score (Table 2).

Table 1. Analytical radiological results

	Preoperative (mean±SD)	Early postoperative (mean±SD)	p (preoperative/ early postoperative)	Last control (mean±SD)	p (Early postoperative/ last control; preoperative/ last control)
Vertebral Cobb	6.99±6.65	6.76±6.43	0.557	8.69±6.38	0.000; 0.003
Segmental Cobb	6.65±13.84	6.20±14.40	0.531	9.27±15.27	0.002; 0.006
Beck index	0.81±0.16	0.84±0.15	0.005	0.79±0.18	0.001; 0.260
Height loss	0.35±0.19	0.31±0.15	0.045	0.40±0.15	0.000; 0.036
Spinal canal compression	0.07±0.20	0.09±0.16	0.029	0.09±0.16	0.418; 0.077

Table 2. Clinical outcomes

	Satisfied	Unsatisfied	Roland Morris (Mean±SS)	VAS (Meana±SS)
Male (28)	25 (89.3%)	3 (10.7%)	6.85±6.88	24.11±22.56
Female (49)	42 (85.7%)	7 (14.3%)	11.68±6.75	41.28±30.42
P (Chi-square / IST/ IST)	0.654		0.004	0.013
Unilateral Approach (67)	58 (86.6%)	9 (13.4%)	10.03±7.13	36.59±28.60
Bilateral Approach (10)	9 (90%)	1 (10%)	9.20±7.58	24.90±30.08
P (Chi-square / IST/ IST)	0.763		0.735	0.236
Spinal Canal Compression (-) (45)	39 (86.7%)	6 (13.3%)	8.48±6.58	32.02±29.29
Spinal Canal Compression (+) (32)	28 (87.5%)	4 (12.5%)	11.81±7.52	38,94±28,29
P (Chi-square / IST/ IST)	0.915		0.046	0.311
Osteoporosis (23)	21 (91.3%)	2 (8.7%)	10.09±7.81	31,95±26,50
Trauma (41)	37 (90.2%)	4 (9.8%)	9.30±7.05	35,80±30,62
P (Chi-square / IST/ IST)	0.889		0.686	0.622
Single Level (60)	52 (86.7%)	8 (13.3%)	9.68±7.01	34,86±29,12
Multi-Level (17)	15 (88.2%)	2 (11.8%)	10.71±7.78	35,53±28,89
P (Chi-square / IST/ IST)	0.865		0.608	0.934

IST: Independent sample T-test, SD: Standard Deviation

DISCUSSION

Vertebral fractures are an essential health problem that may cause severe deterioration in quality of life and lead to morbidity and even mortality.[7-10] In recent years, percutaneous kyphoplasty has become the standard surgical procedure for vertebral fractures, but there is still controversy about the optimal surgical approach. It is unclear if the bilateral kyphoplasty is more effective than the unilateral kyphoplasty. For example, although the bilateral approach seems to provide better spreading of the injected cement within the bone, it is unclear to what extent this is reflected in the clinic.

In their study, Chen et al.[11] concluded that the bilateral approach was more effective in restoring the height of the vertebral body. On the contrary, there are also publications reporting that the results are not different.[12-18]

A study by Yilmaz et al.[19] looked at the differences in anterior wall vertebral height, midline height of the vertebral body, and posterior wall heights between patients who had surgery with a unilateral or bilateral approach. In the study, an increase in wall heights was observed in both approaches, and no statistically significant difference was found between the two groups. Our study revealed a statistically significant rise in the Beck index. This result may be related to increasing the height of the anterior wall and protecting it by placing the cement more anteriorly. In addition, when we compared the preoperative and early height loss, there was no statistically significant difference between the two groups.

In a study by Wang et al.[20] 203 patients with an approximate follow-up period of 12.7 months were analyzed, and it was observed that 38.9% of patients had recollapse. In the recollapse group, the mean midline vertebral height ratio and kyphotic angles changed statistically significantly during follow-up. It has been shown that pain scores decreased immediately after percutaneous kyphoplasty and generally remained low during follow-up. Our study found that late vertebral kyphosis and segmental kyphosis values worsened statistically significantly compared with preoperative values. This finding may be due to vertebral recollapse.

When the results of the patients with canal compression were analyzed, we found that early postoperative canal compression was statistically significantly increased compared to preoperative compression. Still, when we compared the early and late compression values, we found that the compression decreased statistically significantly over time. Finally, we found a statistically significant decrease when we compared the preoperative and late-postoperative compression values. We found no study comparing the early and late period data of patients with canal compression.

When the relationship between gender and the Roland Morris Disability Index was analyzed, it was found that the Roland Morris value was statistically significantly higher in women. We can say that this situation is related to the fact that osteoporosis is more common in women and comorbidities are more common. There was a correlation between age and Roland Morris. When the patients were divided into two groups, patients aged 65 years and younger and patients aged 66 years and older, the Roland Morris value was found to be 8.5 in the group of patients aged 65 years and younger and 11.8 in the group of patients aged 66 years and older. This result was statistically significant. Roland Morris's value was found to increase with increasing age. However, this result was thought to be related to the increase in additional morbidities with age.

CONCLUSION

There was no statistically significant difference in the satisfaction of patients who underwent bilateral kyphoplasty compared to unilateral kyphoplasty. However, when the pain parameters were analyzed, it was observed that the negative pain scores of female patients were higher than those of male patients in the long term. This result may be a guide for prognosis.

Although the progression to kyphosis in the early postoperative period seems to have been controlled in the early postoperative period, we observe that kyphoplasty is insufficient to prevent kyphosis progression in the final controls of the patients. Although there was no statistically significant difference in the Beck index at the last follow-up in our study, progressive worsening was noticeable. When choosing the surgical approach in either case, it is important to keep in mind that segmental and global kyphotic angulations may happen, angulations that are already there may get worse over time, and patients may have issues with their sagittal balance.

The fact that there is no significant worsening of canal compression in the long term suggests that kyphoplasty can be used as a safe method in patients without neurological findings.

The retrospective nature of our study and the small number of patients who underwent bilateral kyphoplasty are limitations in terms of evaluation. Larger series and multicenter studies with a higher level of evidence are needed to show whether there is a difference between the two methods and, if there is a difference, which method is superior in which patient group.

ETHICAL DECLARATIONS

Ethics Committee Approval

The study was initiated with approval of the Katip Çelebi University Atatürk Training and Research Hospital Ethics Committee (Date: 27.03.2019, Decision No:131).

Informed Consent

Written consent was obtained from the patients participating in this study.

Referee Evaluation Process

Externally peer reviewed.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

Financial Disclosure

The authors declared that this study has received no financial support.

Author Contributions

All the authors declare that they have all participated in the design, execution, and analysis of the paper, and that they have approved the final version.

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