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Research Article

Efficacy of bone cement volume in unilateral kyphoplasty of thoracolumbar compression fractures: A clinical comparative study

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ABSTRACT

Objective: To compare the clinical and radiological efficacy of bone cement volumes injected during unilateral percutaneous balloon kyphoplasty for thoracolumbar vertebral compression fractures.

Methods: In this retrospective study, we reviewed data from 96 patients who underwent single-level unilateral kyphoplasty. The patients were categorized into 2 groups based on the cement volume injected: group 1 (cement volume ≤4 mL, minimum 3 mL; n=48) and group 2 (cement volume >4 mL, maximum 6 mL; n=48). The clinical outcomes, as assessed using the Oswestry Disability Index (ODI) and visual analog scale (VAS) scores, were evaluated preoperatively and then at the final follow-up 1 month postoperatively. The vertebral corpus height at the fracture level was measured at the anterior, middle, and posterior regions through sagittal computed tomography scanning.

Results: The mean age of the patients was 64.2 years in group 1 and 63.8 years in group 2. In group 1, the mean anterior vertebral height increased from 19.0 ± 3.3 mm preoperatively to 19.9 ± 3.2 mm postoperatively, whereas in group 2, it increased from 17.9 ± 3.8 mm to 19.6 ± 3.7 mm, respectively. The middle vertebral heights were 15.4 ± 2.5 mm preoperatively and 16.9 ± 2.8 mm postoperatively in group 1 and 16.0 ± 3.6 mm and 17.5 ± 3.2 mm, respectively, in group 2. Both groups exhibited significant improvements in ODI and VAS scores, with no significant difference between the groups. A statistically significant increase was recorded within each group for the anterior, middle, and posterior vertebral heights. However, a significantly greater increase was noted in the anterior height in group 2 compared to that in group 1 ($P < .05$).

Conclusion: Unilateral kyphoplasty is an effective procedure for managing painful vertebral compression fractures. The greatest loss of vertebral height occurred in the middle column, which also exhibited the greatest potential for restoration. Thus, a higher cement volume facilitated greater restoration of the anterior column height.

Level of Evidence: Level III, Therapeutic Study

Introduction

Vertebral compression fractures (VCFs) mostly occur due to osteoporosis, trauma, infections, and neoplasms. The majority of vertebral fractures are osteoporosis-related, typically in the thoracolumbar region of elderly women. Osteoporotic VCFs affect approximately 25% of all postmenopausal women, and more than 1.4 million new fractures are recorded annually across the world.[1,2] Percutaneous kyphoplasty is a minimally invasive technique that involves the percutaneous injection of poly-methyl methacrylate (PMMA) into the fractured vertebral corpus under C-arm fluoroscopy. The goal of kyphoplasty is to return the fractured vertebra as close as possible to its normal height, to reduce pain and to mobilize the patient earlier.[3-5] Unilateral percutaneous balloon kyphoplasty is a technique with a low risk of complications in the treatment of painful and disabling VCFs.[6,7] However, the amount of cement to be injected remains controversial. Several studies have been conducted on vertebroplasty; however, kyphoplasty is often overlooked in this regard. In this study, we compared the clinical efficacy of the cement amount injected in unilateral kyphoplasty. We also hypothesized that high-volume cement injection can provide better pain relief and vertebral height restoration.

Material and methods

Between 2017 and 2021, a total of 168 patients received kyphoplasty after thoracolumbar compression fractures at the Department of Neurosurgery, University of Health Sciences Izmir Bozyaka Education and Research Hospital Hospital. Of these, we retrospectively reviewed the data of 96 patients who underwent single-level unilateral percutaneous balloon kyphoplasty alone and included them in the study. The vertebral fracture types were determined based on the AOspine classification of thoracolumbar fractures.[8] Only patients who experienced focal back pain with no or minor neurological deficits were included in our study. Patients with posterior spinal canal compression or spinal stenosis, spine infections, and bleeding disorders were excluded from the study. Multilevel vertebral fractures were excluded from the study. All the patients were evaluated for a history of trauma, osteoporosis, malignancy, and comorbidities. The bone cement volume injected during the surgery was recorded.

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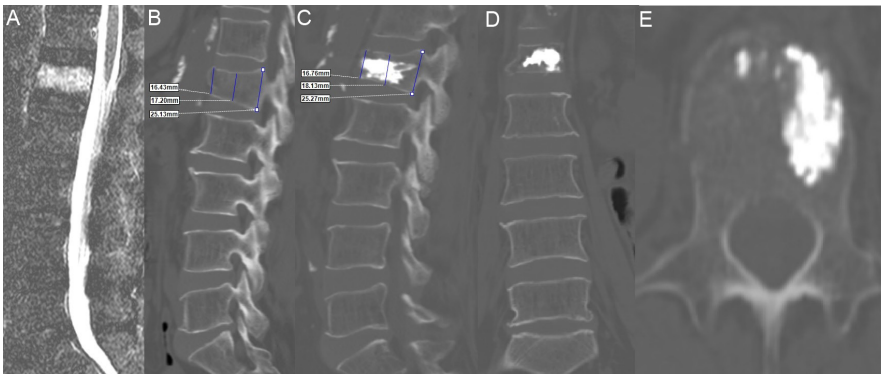

Figure 1. (A) Preoperative STIR MRI displaying bone edema of the L1 compression fracture; (B) preoperative sagittal CT scan showing the measurement of anterior (16.43 mm), middle (17.20 mm), and posterior (25.13 mm) corpus height; (C) postoperative sagittal CT scan of the patient in group 1 after 3 cm^3 bone cement injection, showing an increase of these columns (16.76 mm, 18.13 mm, and 25.27 mm, respectively); postoperative coronal (D) and axial (E) CT scans. CT, computed tomography; MRI, magnetic resonance imaging.

The patients were assigned to 2 groups based on the bone cement volume injected, as follows: (a) group 1: cement injected with ≤4 mL (min. 3 mL) (n=48; Figures 1 and 2) and (b) group 2: cement injected >4 mL (max. 6 mL) (n=48; Figures 3 and 4). The minimum amount of bone cement injected in group 1 was 3 mL, and the maximum amount of bone cement injected in group 2 was 6 mL. The clinical outcomes before the surgery and at the final follow-up appointment in the first postoperative month were evaluated using the Oswestry Disability Index (ODI) scale. The visual analog scale (VAS), ranging from 0 (no pain) to 10 (severe pain), was used to evaluate the severity of back pain. All patients underwent thoracolumbar radiography, computed tomography (CT), and magnetic resonance imaging (MRI) examinations before and after the surgery. All patients were diagnosed with apparent bone edema in the fractured vertebral corpus on short tau inversion recovery sequences MRI. Computed tomography was performed before the surgery and in the first week after surgery. The vertebral corpus height at all fracture levels was measured at the anterior, middle, and posterior body using midsagittal CT scans (Figures 1-4). Postoperative cement leakage into the anterior vertebral corpus, disc space, spinal canal, and vascular region was assessed using axial and sagittal CT scans. Written informed consent was obtained from all patients. All steps of this study were approved by the institutional ethics review committee of University Health Sciences Izmir Bozyaka Education and Research Hospital (Date: June 09, 2021, issue no. 2021/94) in accordance with the World Medical Association Declaration of Helsinki and its most recent amendments.

Kyphoplasty procedure

All surgeries included in this study were performed by the same experienced surgeons at our hospital. All patients were positioned prone under local anesthesia in addition to pseudoanalgesia. A small paramedian skin incision was made, and using simultaneous AP and lateral fluoroscopy, a guidewire was penetrated to obtain a transpedicular approach into the fractured vertebra. Under guidewire guidance, a larger cannula was placed through the pedicle into the corpus. Initially, a bone biopsy was performed in patients with suspected malignancy. The balloon was then inserted through the cannula up to approximately three-fourth of the corpus. The balloon was slowly inflated with the contrast medium. Balloon inflation was stopped when the pressure was 250-300 psi or reached the vertebral endplates. The balloon was deflated and removed after reaching the optimum balloon pressure. The semi-solid bone cement, polymethylmethacrylate, was injected slowly to fill the cavity under fluoroscopic guidance. The skin incision was then sutured and a tape was applied.

Statistical analysis

Statistical analyses were performed with the Statistical Package for the Social Science (SPSS) 20 software (IBM SPSS Corp.; Armonk, NY, USA, RRID: SCR_019096). The Mann–Whitney *U*-test was performed for the comparison of 2 independent groups. Pre- and postoperative dependent variables of each group (corpus height at anterior, middle, and posterior column, and ODI scores of the patients) were compared using the Wilcoxon signed-rank test. A *P*-value of .05 was considered to indicate statistical significance.

HIGHLIGHTS

- Vertebral compression fractures (VCFs), commonly caused by osteoporosis, trauma, infections, and neoplasms, significantly impact mobility and quality of life, particularly in postmenopausal women. This study aimed to compare the clinical efficacy of different cement volumes in unilateral percutaneous balloon kyphoplasty, evaluating their impact on pain relief and vertebral height restoration.
- Both groups showed significant improvements in ODI and VAS scores postoperatively ($P < .05$), but no significant difference was observed between them ($P > .05$). However, group 2 (higher cement volume) demonstrated greater anterior corpus height restoration ($P < .05$) but also had a higher rate of cement leakage (10 vs. 6 patients) and adjacent vertebral fractures (4 cases).
- The results indicate that both cement volumes effectively reduce pain and improve function, but higher volumes (≥4 mL) lead to greater anterior height restoration with increased cement leakage and adjacent fractures.

Results

This study included 96 patients diagnosed with AOspine type A1 thoracolumbar fractures. A total of 28 men and 68 women with a mean age of 64.0 years (range: 32-87 years) underwent unilateral percutaneous balloon kyphoplasty. Group 1 (mean age: 64.2 years; range: 32-87 years) consisted of 35 females and 13 males, while group 2 (mean age: 63.8 years; range: 41-84 years) consisted of 33 females and 15 males (Table 1). The difference in the distribution of gender between the 2 groups was not statistically significant ($P > .05$). Of the total, 69 patients were diagnosed with osteoporosis before surgery. Most patients had a history of minor trauma, such as a fall or slip. The fractures were at T11 in 6 patients, T12 in 26 patients, L1 in 35 patients, L2 in 18 patients, and L3 in 11 patients (Table 2). The mean cement volume injected into the patients was 3.6 mL (SD=0.2, range: 3.0-3.9) in group 1 and 4.9 mL (SD=0.4, range: 4.1-6.0) in group 2. The mean operative time was 28.5 minutes (range: 18-45 minutes).

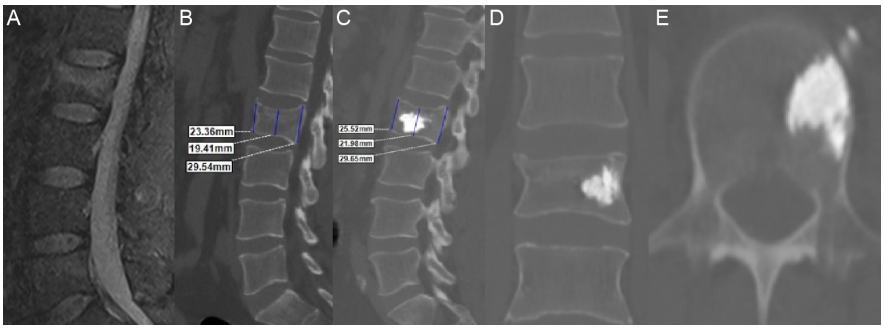

Figure 2. Preoperative STIR MRI (A) and sagittal CT (B) images of the L2 compression fracture. Postoperative sagittal CT image (C) of the patient injected with 3.5 cm^3 bone cement in group 1, shows the corpus height increase in the anterior, middle, and posterior columns. Postoperative coronal (D) and axial (E) CT scans of unilateral percutaneous balloon kyphoplasty. CT, computed tomography; MRI, magnetic resonance imaging.

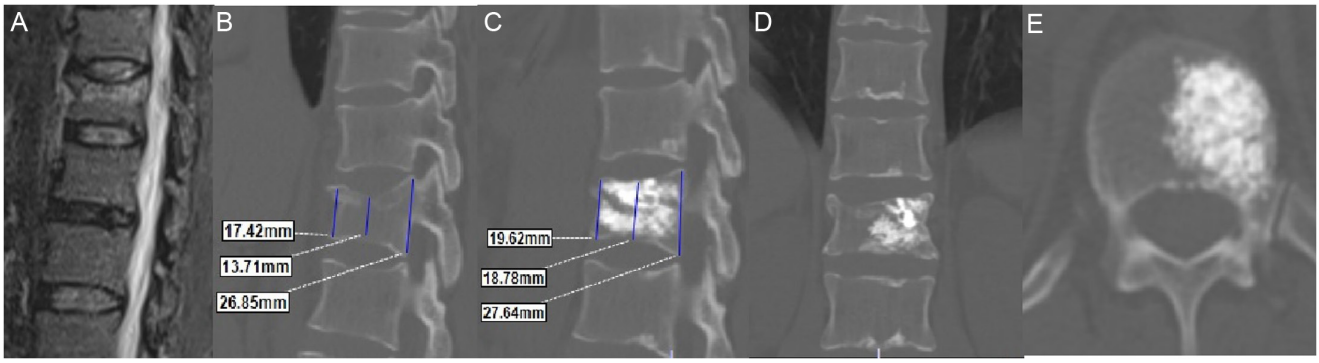

Figure 3. Preoperative STIR MRI (A) with bone edema of the T12 compression fracture and sagittal CT scan (B) with the measurements of the columns. Postoperative sagittal (C) CT scan showing an increase in the corpus heights, coronal (D) and axial (E) CT of the patient in group 2 after unilateral kyphoplasty performed with 5.5 cm^3 of PMMA. CT, computed tomography; MRI, magnetic resonance imaging; PMMA. poly-methyl methacrylate.

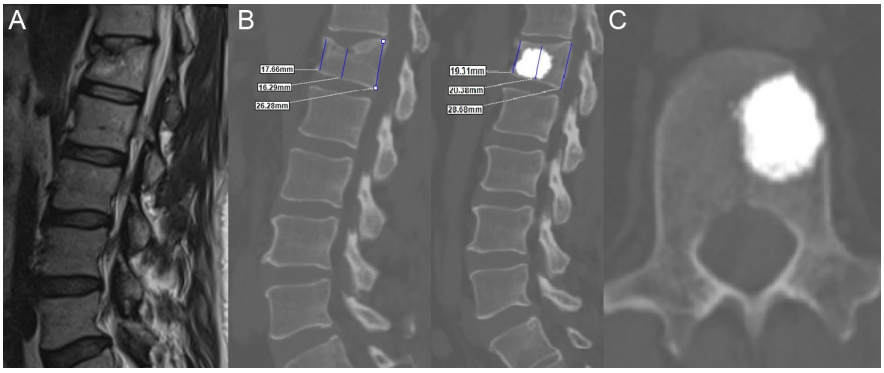

Figure 4. Preoperative sagittal MRI (A) and CT scan (B) of the L1 compression fracture. Postoperative sagittal CT scan (C) exhibiting an increase in the corpus height of 3 columns after unilateral percutaneous kyphoplasty with 5 cm^3 bone cement injected in group 2. CT, computed tomography; MRI, magnetic resonance imaging.

Clinical evaluation

The ODI scores significantly improved in both groups ($P < .05$), with the preoperative and postoperative mean scores being 72.1 ± 9.4 and 36.4 ± 6.6, respectively, in Group 1, and 73.4 ± 9.6 and 38.1 ± 6.8, respectively, in group 2. The VAS pain scores significantly decreased from 7.2 ± 0.6 preoperatively to 2.3 ± 0.7 postoperatively in group 1, while the corresponding scores in group 2 were 7.3 ± 0.7 and 2.4 ± 0.6, respectively ($P < .001$). These results indicate that both groups experienced a significant decrease in ODI and VAS scores, but no

Table 1. Demographic characteristics of patients who underwent single-level unilateral percutaneous balloon kyphoplasty

	Group 1 (Bone Cement Injected with ≤4 cm^3. Min. 3 cm^3)	Group 2 (Bone Cement Injected with >4 cm^3. Max. 6 cm^3)
Number	48	48
Gender Number of females/males	35 F/13 M	33 F/15 M
Average age At operation (years)	64.2 (range 32-87)	63.8 (range 41-84)

Table 2. Fracture levels and distribution of cases according to gender

	Group 1		Group 2		
	Male	Female	Male	Female	Total
T11	1	3	–	2	6
T12	2	11	4	9	26
L1	6	12	8	9	35
L2	2	6	3	7	18
L3	2	3	–	6	11
Total	13	35	15	33	96

Table 3. Comparison of pre- and postoperative results of the 2 groups according to the bone cement amount

	Group 1 (Bone Cement Injected with ≤4 cm^3. Min. 3 cm^3)	Group 2 (Bone Cement Injected with >4 cm^3. Max. 6 cm^3)
ODI score		
Preoperative	72.1 ± 9.4	73.4 ± 9.6
Postoperative	36.4 ± 6.6	38.1 ± 6.8
P	<.001	<.001
VAS pain score		
Preoperative	7.2 ± 0.6	7.3 ± 0.7
Postoperative	2.3 ± 0.7	2.4 ± 0.6
P	<.001	<.001
Anterior corpus height (mm)		
Preoperative	19.0 ± 3.3	17.9 ± 3.8
Postoperative	19.9 ± 3.2	19.6 ± 3.7
P	<.0001	<.0001
Increase (mm)	+0.9 mm	+1.7 mm
Middle corpus height (mm)		
Preoperative	15.4 ± 2.5	16.0 ± 3.6
Postoperative	16.9 ± 2.8	17.5 ± 3.2
P	<.0001	<.0001
Increase (mm)	+1.5 mm	+1.5 mm
Posterior corpus height (mm)		
Preoperative	23.1 ± 2.9	23.6 ± 3.0
Postoperative	23.8 ± 2.8	24.2 ± 2.9
Increase (mm)	+0.7 mm	+0.6 mm
P	<.0001	<.0001

Data are expressed as the mean ± SD.
$P \leq .05$ was considered to indicate statistical significance.
ODI, Oswestry Disability Index; VAS, visual analog scale.

significant difference was observed between the 2 groups ($P > .05$, Table 3).

Radiological evaluation

The mean anterior corpus height increased from 19.0 ± 3.3 mm preoperatively to 19.9 ± 3.2 mm in group 1 (+0.9 mm) and from 17.9 ± 3.8 mm to 19.6 ± 3.7 mm in group 2 (+1.7 mm). This increase was statistically significant ($P < .05$) in both groups; however, a significant difference in the anterior corpus height increase was observed between the 2 groups ($P < .05$) (Table 3).

The mean preoperative and postoperative middle corpus heights were 15.4 ± 2.5 mm and 16.9 ± 2.8 mm (+1.5 mm), respectively, in group 1, and 16.0 ± 3.6 mm and 17.5 ± 3.2 mm (+1.5 mm) in group 2. This increase was statistically significant in both groups ($P < .05$), although the postoperative middle corpus height increase did not differ significantly between the 2 groups (Table 3).

The mean posterior corpus height increased from 23.1 ± 2.9 mm preoperatively to 23.8 ± 2.8 mm (+0.7 mm) in group 1 and from 23.6 ± 3.0 mm to 24.2 ± 2.9 mm (+0.6 mm) in group 2. This increase was statistically significant in both groups ($P < .05$), although the postoperative posterior corpus height increase did not differ significantly between the 2 groups (Table 3).

Postoperative complications

Cement leakage was divided into 4 groups based on the location: paravertebral, intradiscal, epidural, and intravenous types. Intradiscal cement leakage was grouped into 3 categories: type I: intervertebral-extradiscal leakage, type II: intradiscal leakage, and type III: combined leakage. Leakage according to the amount of cement was classified as follows: grade I: <25% of the intervertebral space, grade II: 25%-50% of the intervertebral space, grade III: 50%-75% of the intervertebral space, and grade IV: >75% of the intervertebral space.

Asymptomatic cement leakage occurred in 17% of patients postoperatively. Of these, it occurred in the paravertebral space in 3 patients, into the intradiscal space in 8 patients, into the epidural space in 4 patients, and into the vascular region (intravenous) in 1 patient. The 8 intradiscal cement leakage patients included 5 type I patients, 2 type II patients, and 1 type III patient. Most of the patients (n=12, 75%) had grade I cement leakage. No patient developed morbidity or mortality due to these complications. The cement leakage was observed in 6 patients in group 1 and 10 patients in group 2.

High volumes of bone cement were associated with a high rate of subsequent adjacent vertebral fractures. We found that 4 patients in group 2 had subsequent adjacent vertebral fractures.

Discussion

There is no consensus on the clinical efficacy associated with a certain amount of cement volume injected in unilateral kyphoplasty for thoracolumbar compression fractures. This retrospective study is one of the largest comprehensive reviews to compare the clinical and radiological efficacy of bone cement volume in unilateral kyphoplasty. Unilateral percutaneous balloon kyphoplasty contributes to the goal of relieving pain and realigning the fractured vertebral body. In the present study, we divided the study group based on the amount of cement volume injected and evaluated the resultant pain scores, measured the corpus height after kyphoplasty in both groups, and analyzed the postoperative complications of cement leakage. Fractures involving the posterior wall of the corpus are still considered a contraindication for kyphoplasty in the literature,[9-11] which can lead to a motor deficit when leakage occurs toward the spinal canal. Therefore, we did not include these patients with burst fractures of AO spine A3 and A4.

In thisstudy, we performed unilateral kyphoplasty. Several studies have previously compared the outcomes of unilateral and bilateral kyphoplasty. Steinmann et al[12] reported similar outcomes after the biomechanical comparison of antipedicular and pedicular kyphoplasty. Cheng et al[13] observed no apparent difference in the clinical results and complications between unilateral and bilateral kyphoplasty. They found that unilateral kyphoplasty was associated with a shorter operative time and lower x-ray exposure frequency. Yin et al,[14] in their meta-analysis, noted similar satisfactory clinical outcomes via both unilateral and bilateral kyphoplasties. Accordingly, they suggested that unilateral kyphoplasty is advantageous. In addition, Yilmaz et al[15] concluded that the unilateral kyphoplasty procedure is as sufficient for pain relief as bilateral kyphoplasty.

Considering the limited literature on kyphoplasty regarding optimal intravertebral cement volume, several well-designed studies on vertebroplasty serve as a guide on this subject. However, the results of these studies regarding injected cement volume in vertebroplasty and pain relief are conflicting. Most of the studies found no association,[16-19] although, in one study, Jin et al[20] examined 96 patients with single-level VCFs who underwent percutaneous vertebroplasty and demonstrated the safe range of cement volume. Kaufmann et al[21] treated 158 patients with single-level vertebroplasty and found no significant association between the volume of cement injected and the clinical outcomes of post-procedure pain. Belkoff et al[22] stated

that, in vertebroplasty, 4-8 mL cement was required at the thoracolumbar level and 4-6 mL was required at the lumbar level. Molloy et al[23] reported that 3.5 mL of bone cement volume was sufficient in vertebroplasty; however, 7 mL was more effective for vertebral restoration. Wang et al[24] concluded that both low and high cement volumes relieved pain effectively in vertebroplasty and that high cement volumes may increase the rate of subsequent adjacent fractures. In a study on balloon kyphoplasty, Röder et al[25] suggested that cement volume was the most important modifiable predictor for pain relief. The authors observed that a cement volume of <3 mL provides less pain alleviation. In our study, we injected >3 mL of cement in each patient. In this study, we analyzed the association between cement volume and clinical outcomes. We divided our patients into 2 groups according to the cement volume injected: cement injected ≤4 mL (min. 3 mL) and >4 mL (range 3-6 mL). Both groups exhibited a significant decrease in ODI and VAS scores, but no significant difference was observed between the 2 groups. Our data confirm that this procedure could significantly improve the ODI and VAS scores in both groups, regardless of the injected cement volume (min. 3 mL). The mean difference in ODI was well above the minimal clinically important differences in the literature, which highlights the success of this procedure.

In this study, both groups showed a significant corpus height increase in the anterior, middle, and posterior columns. In group I, the highest increase of corpus height was in the middle column (+1.5 mm), followed by that in the anterior column (+0.9 mm) and the least in the posterior column (+0.7 mm). In group II, the lowest increase in the corpus height was similar in the posterior column (+0.6 mm), while the highest increase was in the anterior column (+1.7 mm), followed by the middle column (+1.5 mm). Mooney et al[26] examined 59 patients undergoing kyphoplasty and noted the greatest vertebral body height improvement in the middle, followed by the anterior and posterior locations. They reported that the greatest loss in vertebral height tended to occur in the middle and thus has the greatest potential for height restoration. In a study, de Falco and Bocchetti[27] analyzed the morphological data obtained by measuring the anterior, medial, and posterior height of the vertebra, indicating significant improvements in all parameters. Gaitanis et al[28] analyzed 32 consecutive patients in a study and recorded an increase in the anterior wall height in 87.7% of the patients, with a mean increase of 4.3 mm. In their study, they did not mention the cement amount, which differs from that in our present study. Lieberman et al[29] stated that kyphoplasty restored 47% of the lost height in 70% of the vertebral bodies. In addition to these studies, we compared the vertebral heights due to the amount of cement. Osteoporotic VCFs may cause local kyphosis due to vertebral collapse and wedging. Kyphoplasty leads to better vertebral height restoration with higher cement volume, which prevents the patients from causing local kyphosis and provides better spinal alignment. In conclusion, both low and high cement volumes relieved pain effectively; however, the volume of ≥4 mL was more effective for vertebral restoration. The greatest loss in vertebral corpus height tended to occur in the middle of the corpus. Therefore, the middle column showed the greatest potential for height restoration after kyphoplasty. With an increasing amount of cement, we obtained greater corpus restoration in the anterior column.

Limitations

This study had several limitations. First, the retrospective study design may have led to selection bias, although the same inclusion criteria were applied to both groups. The patient's habits, occupation, and comorbidities were not considered. This study does not provide the percentage of height restored, and the cement volume was calculated as a percentage of the total vertebral volume. It does not include some other possibly important variables, such as T scores.

Unilateral kyphoplasty is an effective procedure for treating painful VCFs. The greatest loss in vertebral corpus height tends to occur in the middle of the corpus. Therefore, the middle column has the greatest potential for height restoration after kyphoplasty. Although a significant increase in corpus height was achieved in the anterior, middle, and posterior columns, anterior corpus height restoration was greater with a higher number of cement injections.

Availability of Data and Materials: The data that support the findings of this study are available from the corresponding author upon reasonable request.

Ethics Committee Approval: This study was approved by the Institutional Ethics Review Committee at the University of Health Sciences Izmir Bozyaka Education and Research Hospital (dated June 09, 2021, Issue no.: 2021/94).

Informed Consent: Written informed consent was obtained from all participants who agreed to take part in the study. Additional informed consent was also collected from all individual participants whose identifying information was included in this article.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept – H.B.B., H.Y.; Design – H.B.B., T.Ü.; Supervision – E.A., H.Y.; Resources – T.Ü.; Materials – T.Ü., A.T.; Data Collection and/or Processing – H.B.B., T.Ü., A.T. C.A.; Analysis and/or Interpretation – H.B.B., A.T., C.A.; Literature Search – E.A; Writing – H.B.B., T.Ü., C.A.; Critical Review – E.A., H.Y

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