


# Comparison of efficacies of unipedicular kyphoplasty and bipedicular kyphoplasty for treatment of single-level osteoporotic vertebral compression fractures

## A STROBE-compliant retrospective study

Chung Hun Lee, MD<sup>a</sup>, Hyun Joong Kim, MD<sup>b</sup>, Mi Kyoung Lee, MD, PhD<sup>a</sup>, Hyo Sung Kim, MD<sup>a</sup>, Sang Sik Choi, MD, PhD<sup>a,\*</sup> 

### Abstract

Kyphoplasty (KP) is an effective method for treating osteoporotic vertebral compression fractures (OVCFs). Although the bipedicular approach is considered the main treatment approach, the unipedicular approach has also been shown to be effective. This study aimed to retrospectively compare the radiological and clinical outcomes of unipedicular and bipedicular KP in the treatment of single-level OVCFs.

In total, 96 patients with single-level OVCF who received KP were divided into 2 groups: the unipedicular group, in which 28 patients underwent KP via the unipedicular approach, and the bipedicular group, in which 68 patients underwent KP via the bipedicular approach. Clinical results, radiological findings, and complications were compared between the groups. The clinical results were evaluated for up to 1 year after surgery using a numerical rating scale score. The radiological findings were compared in terms of recovery of the lowest vertebral body height at the same location on radiographs taken both 1 day and 1 year after surgery. The degrees of recovery of the kyphotic angle (KA) were simultaneously compared. The surgical time, amount of cement used, and any postoperative complications were also compared.

Both groups showed significant improvements in all clinical and radiological parameters until 1 year after surgery. The unipedicular group required significantly lower amounts of cement than the bipedicular group (unipedicular:  $4.4 \pm 0.8$  mL, bipedicular:  $5.6 \pm 1.0$  mL,  $P = .00$ ), but there were no significant differences in the clinical and radiological results for up to 1 year after surgery. There were no significant differences in leakage of intradiscal cement, appearance of adjacent vertebral compression fractures within 1 year of surgery, and surgical time.

Unipedicular and bipedicular KP significantly reduced the pain experienced by patients with single-level OVCF, restored vertebral height, and corrected the KA, which remained stable for at least 1 year after treatment. Unipedicular KP required lower amounts of cement than bipedicular KP and was as effective as bipedicular KP in terms of radiological and clinical outcomes. The results of this study have level three evidence and grade B recommendation.

**Abbreviations:** AP = Anteroposterior, AVCF = Adjacent vertebral compression fracture, BMD = Bone mineral density, COPD = Chronic obstructive pulmonary disease, DM = Diabetes mellitus, HTN = Hypertension, KA = Kyphotic angle, KP = Kyphoplasty, MRI = Magnetic resonance imaging, NRS = Numerical rating scale, OVCF = Osteoporotic vertebral compression fracture, PMMA = Polymethylmethacrylate, VP = Vertebroplasty.

**Keywords:** kyphoplasty, kyphotic angle, numerical rating scale, osteoporotic vertebral compression fractures, vertebral height

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The datasets generated during and/or analyzed during the current study are publicly available.

<sup>a</sup> Department of Anesthesiology and Pain Medicine, Korea University Medical Center, Guro Hospital, Seoul, Republic of Korea, <sup>b</sup> Department of Anesthesiology and Pain Medicine, Korea University Medical Center, Ansan Hospital, Gyeonggi-do, Republic of Korea.

\* Correspondence: Sang Sik Choi, Korea University Medical Center, Guro Hospital, Gurodong Road 148, Guro-Gu, Seoul 08308, Republic of Korea (e-mail: clonidine@empal.com).

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## 1. Introduction

Osteoporotic vertebral compression fractures (OVCFs) are common in elderly patients, with 1.4 million new fractures occurring worldwide each year.<sup>[1–4]</sup> They can cause significant pain, deformation, and disability and reduce patients' quality of life.<sup>[5]</sup> Most patients with OVCFs avoid movement to reduce pain, which can cause a number of complications, such as loss of muscle strength, social isolation, decreased lung vitality, and respiratory infections. Furthermore, prolonged bed rest can increase bone demineralization and lead to additional fractures. Previous studies have reported that even a single OVCF can cause additional fractures by altering spinal biomechanics.<sup>[6]</sup> In addition, spinal deformation caused by OVCFs can lead to malnutrition, depression, and decreased lung capacity.<sup>[5]</sup> As a result, OVCFs can significantly increase morbidity and mortality in elderly patients.<sup>[7–9]</sup>

Conventional treatments for OVCFs include early conservative treatment such as bed rest, administration of analgesics, and physical support; however, some fractures exhibit progressive deformation and persistent pain. The goal of surgical treatment for such fractures is to resolve the associated morbidity by providing pain relief and early stabilization of the fracture.<sup>[10]</sup> Various techniques have been developed for vertebral body augmentation to treat unstable OVCFs.<sup>[5]</sup> A report by Galibert et al<sup>[11]</sup> on the performance of vertebroplasty (VP) in patients with hemangioma for the first time led to VP being introduced for OVCF treatment and at the time, being considered the best method for OVCF therapy. However, VP could not improve the reduced vertebral height in patients with OVCFs.<sup>[5]</sup>

Balloon kyphoplasty (KP) is a transpedicular treatment approach that involves inserting a balloon tamp to the vertebral body to repair a vertebral fracture and fix the fracture by administering polymethylmethacrylate (PMMA) bone cement into the vertebral body.<sup>[12,13]</sup> It benefits patients with OVCFs in a number of ways, including recovery of vertebral height and kyphotic angle (KA) of the spine, rapid pain relief, improvement in mobility, and significantly reduced morbidity.<sup>[14–17]</sup> Although bipedicular KP is considered a safe and effective mainstream approach,<sup>[13,18]</sup> unipedicular KP has been reported to offer benefits such as reduced surgical time, radiation exposure, and incidence of complications.<sup>[19–21]</sup>

A recent meta-analysis demonstrated that there is no consensus on whether bipedicular KP has similar efficacy to unipedicular KP,<sup>[20,22,23]</sup> or whether unipedicular KP is superior, as it has a shorter procedure time and requires less cement.<sup>[21,24–26]</sup> Therefore, this study aimed to compare the efficacies of bipedicular and unipedicular KP and determine which of the 2 methods is superior.

## 2. Methods

### 2.1. Study design

This retrospective observational study adhered to the STROBE checklist (S1, <http://links.lww.com/MD/E804> checklist) and was approved by the Institutional Review Board of the Korea University Medical Center, Guro Hospital, Seoul, Republic of Korea (2019GR0399) on November 12, 2019.

From January 2010 to August 2018, we analyzed patients with single-level OVCFs in the thoracic or lumbar spine (T5–L5) who underwent KP. The patients were divided into a unipedicular group, treated with unipedicular and extrapedicular KP, and a

bipedicular group, treated with bipedicular and transpedicular KP. All study participants were aged >50 years, underwent KP within 6 weeks of OVCF occurrence, and had bone mineral density (BMD)  $\leq -2.5$ . The inclusion criteria were having a numerical rating scale (NRS) pain score of  $\geq 4$  despite the use of conservative treatments such as drug administration after OVCF occurrence, having edematous fractures on T2-weighted chemical fat suppression images or a short tau inversion recovery sequence on magnetic resonance imaging (MRI), and possessing general records of radiography, including those of the spine at the surgical site, acquired preoperatively, 1 day postoperatively, and 12 months postoperatively.

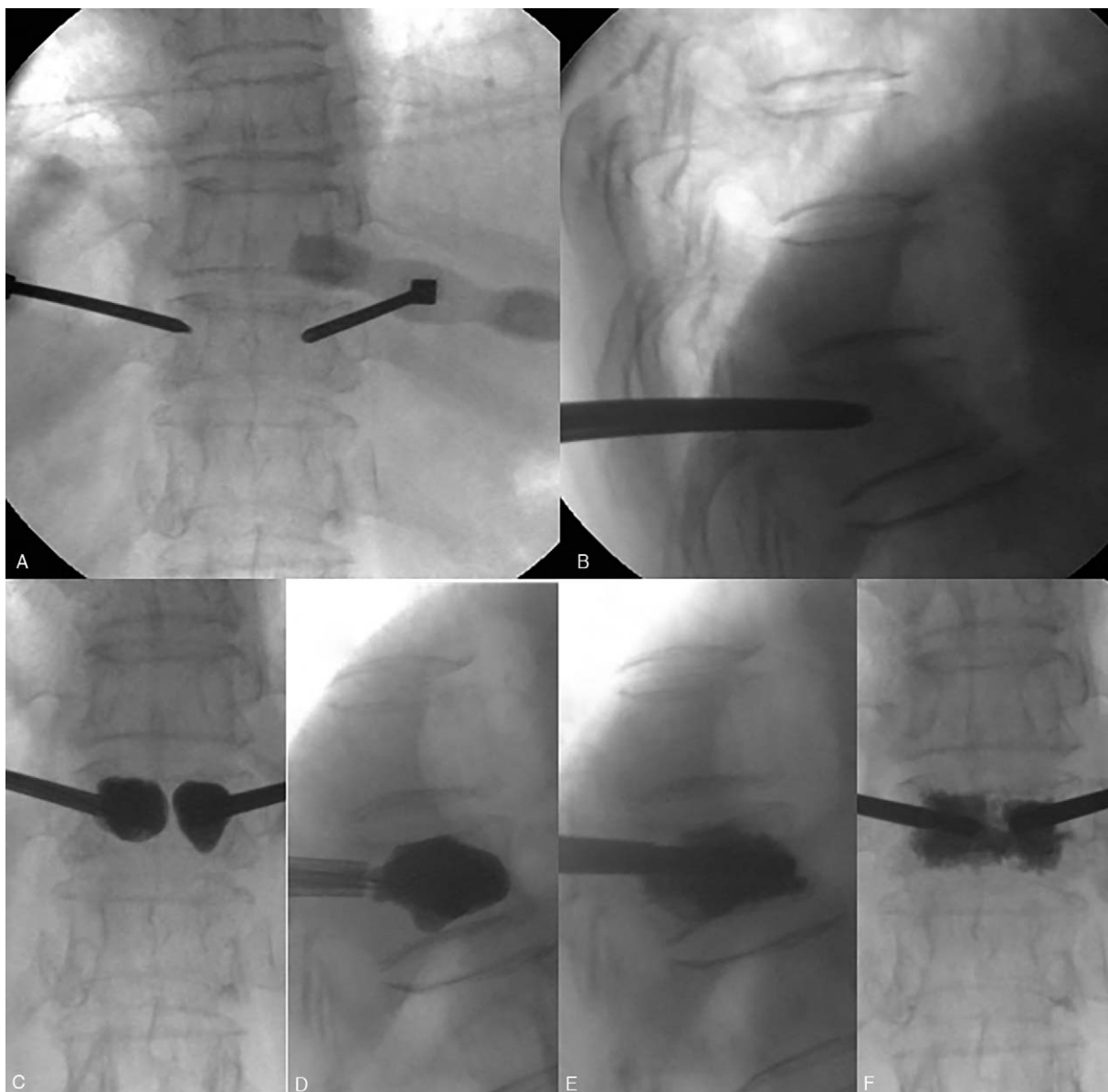
Conversely, patients with fractures that occurred >6 weeks before undergoing KP, no evidence of edematous fractures on MRI, NRS pain scores of <4 after drug treatment, evidence of bleeding disorders, asymptomatic fractures, local infections, secondary post-traumatic fractures, and a lack of general radiography records immediately and 12 months after surgery, those without osteoporosis, and those who underwent multilevel KP, underwent KP for pathologic fractures caused by cancer metastasis, those lost to clinical follow-up within 12 months, and died within 12 months were excluded from this study.

KP was performed by the same physician for all patients. All patients received continuous epidural catheterization near the fracture level to alleviate pain caused by the fracture and during the KP procedure.

### 2.2. Procedure

**2.2.1. Bipedicular group.** Patients were placed in the prone position with a bolster placed under the sternum and pelvis for kyphosis correction. An aseptic dressing was applied to the procedure site. Patients were administered 6 mL of 0.19% ropivacaine through an epidural catheter. Under fluoroscopic guidance, infiltration was performed using 1% lidocaine from the skin to the target pedicle using a 24 G spinal needle. Subsequently, under fluoroscopy, a trocar was angled obliquely to the anteroposterior (AP) axis at an angle of 10° to 20° and advanced to the center of the vertebral body via the transpedicular approach. The trocar was inserted after infiltration with 1% lidocaine on the other side of the vertebral body. After inserting a guidewire, the cannula was inserted through the guidewire so that its end was positioned lateral to the posterior third of the vertebral body. The KP balloon catheter (BALANSY balloon catheter; HAN-SONG BIOBANK, Korea) was inserted through the cannula and advanced along two-thirds of the path into the anterior vertebral body. After expanding the balloon to ensure simultaneous satisfactory cavities on both sides, the balloon was deflated, and the cavities were simultaneously filled with PMMA (Fig. 1A–F).

**2.2.2. Unipedicular group.** The patients were placed in the same position as the bipedicular group; an aseptic dressing was applied and an epidural drug was administered. Infiltration with 1% lidocaine was performed along the direction in which the pedicle was seen more clearly in the AP and oblique views. The trocar was inserted under fluoroscopy, via the extrapedicular approach at an angle of 20° to 30° with respect to the AP axis and to one side of lidocaine infiltration. After inserting the guidewire, the cannula was inserted such that it was located in the posterior third of the vertebral body in the lateral view. The same type of balloon catheter as the bipedicular group was inserted through the cannula and advanced along two-thirds of the path into the



**Figure 1.** (A) The trocar is obliquely angled to the AP axis at an angle of 15° and advanced to the center of the vertebral body via the transpedicular approach. It is also inserted in the other side of the vertebral body. (B) The end of the cannula is positioned at the lateral view in the posterior-third of the vertebral body. (C, D) The balloon is expanded to ensure a satisfactory cavity on both sides at the same time. (E, F) The balloon is deflated, and the cavity is simultaneously filled with PMMA. AP = anteroposterior, PMMA = polymethylmethacrylate.

anterior vertebral body. In the unipedicular group, the end of the cannula was positioned as centrally as possible, and the AP and lateral views were checked to determine whether the inserted balloon extended to the left and right as well as above and below the spine. Finally, the balloon was contracted, and the cavity was filled with PMMA (Fig. 2A–F).

All patients underwent close observation in the hospital for at least 24 hours after surgery, and vital signs and other complications were assessed.

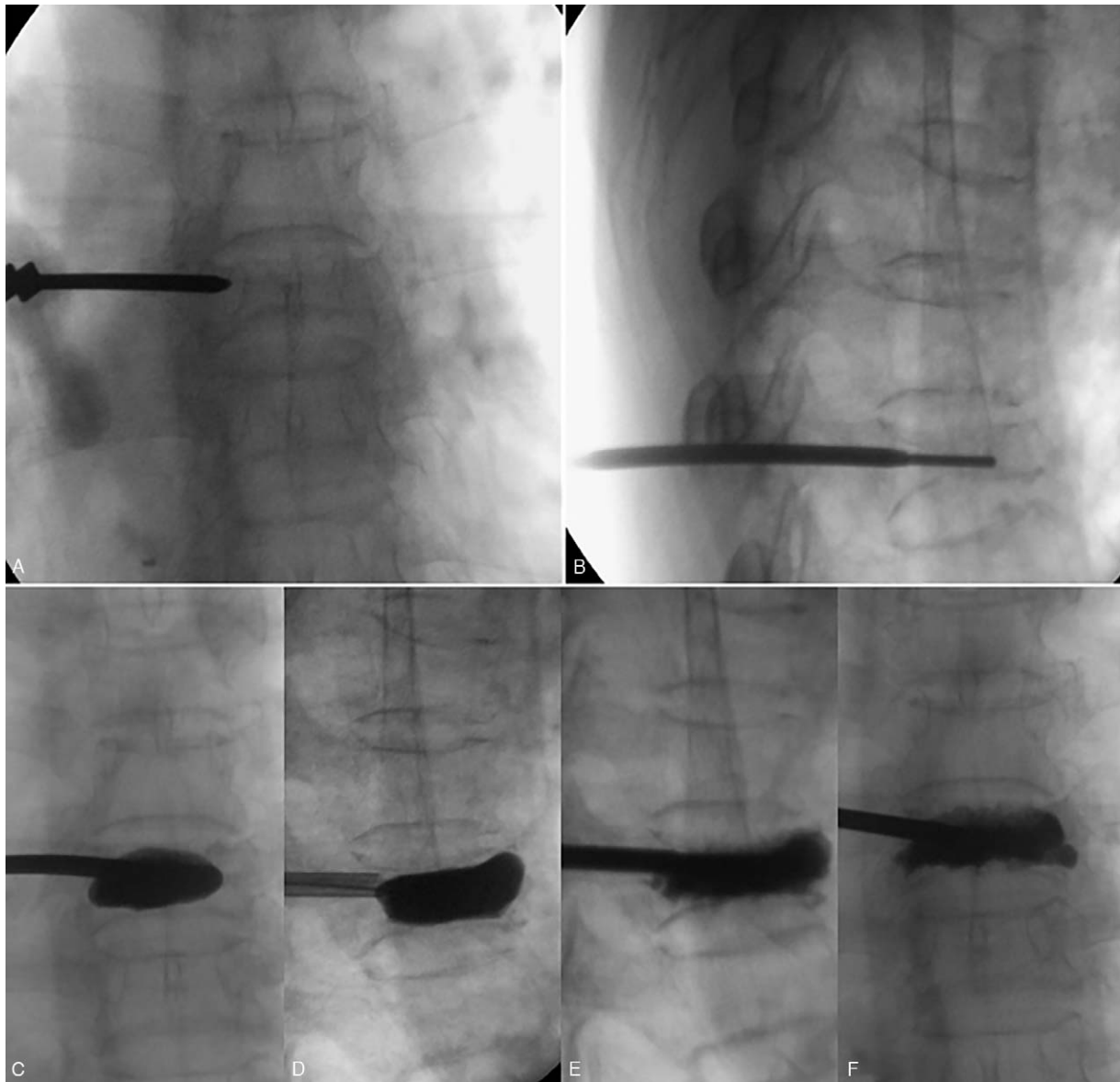
### 2.3. Data collection

The following data were collected for demographic analysis: age; sex; BMD; level of compression fracture; days from onset of pain to KP; history of cancer, hypertension (HTN) or angina, diabetes

mellitus (DM), asthma or chronic obstructive pulmonary disease (COPD), thyroid or parathyroid disease, hepatic disease, kidney disease, use of steroids, and compression ratio (Fig. 3).

**2.3.1. Clinical evaluation.** Pain scores were recorded from 0 to 10 using the NRS, with 0 indicating “no pain” and 10 indicating the “maximum amount of pain imaginable.” We collected NRS scores corresponding to the different time points, including immediately before the procedure (baseline NRS score) and 1, 3, 6, and 12 months after the procedure from the patients’ medical records.

**2.3.2. Radiological evaluation.** Radiological evaluation was performed in accordance with the following 2 criteria: level of spinal deformation and KA. Spinal deformation was assessed using quantitative morphometrics,<sup>[27,28]</sup> and the criterion for defining



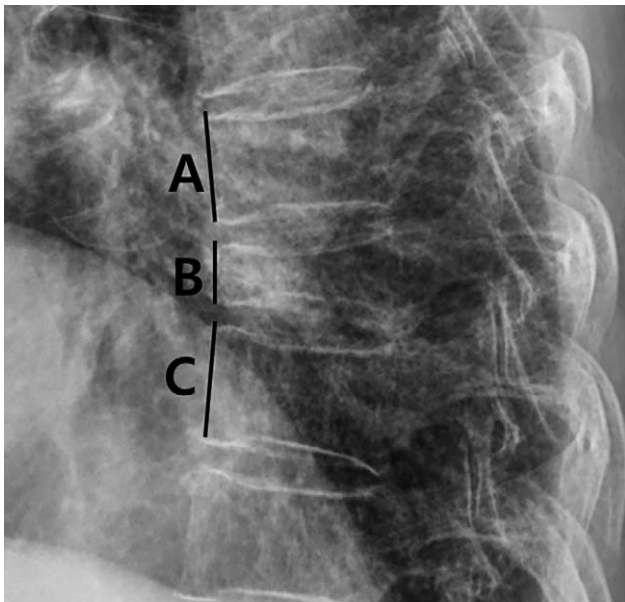
**Figure 2.** (A) The trocar is inserted via the extrapedicular approach at an angle of 25° with respect to the AP axis under fluoroscopy to one side of the lidocaine infiltration. (B) The cannula is inserted through the guidewire so that it is located in the area of the posterior-third of the vertebral body at the lateral view. (C, D) The end of the cannula is positioned as centrally as possible, and the AP and lateral views are checked to ensure that the inserted balloon is extended to the left and right as well as above and below the spine. (E, F) The balloon is contracted, and the cavity is filled with PMMA. AP = anteroposterior, PMMA = polymethylmethacrylate.

the level of spinal deformity was determined by measuring the lowest vertebral height before surgery and then evaluating the recovery of the vertebral height at the same location after surgery (Fig. 4). After evaluating the height of the lowest vertebral body before surgery, we evaluated the difference in the rate of recovery of the vertebral height at the same location on the radiograph taken 1 day after the procedure as well as the difference in the rate of recovery after 1 year of the procedure. The KA was calculated on the basis of the intersection angle of the lines running parallel to the upper and lower end plates of the fractured vertebrae (Fig. 5).<sup>[29]</sup> When compared with the preoperative evaluation of the KA, we calculated the difference and percentage change in the KA from the radiograph taken 1 day after surgery and calculated those in the same manner using the radiograph taken 1 year after the procedure.

**2.3.3. Surgical evaluation.** Surgical evaluation included assessment of the total surgical time, amount of PMMA injected, and postoperative complication ratio. The total surgical time was defined as the time between preoperative lidocaine infiltration and dressing at the end of the procedure. The postoperative complications were as follows: intradiscal cement leakage, cement leakage into the paravertebral vein or epidural space, infection, and adjacent vertebral compression fracture (AVCF) within 1 year of KP.

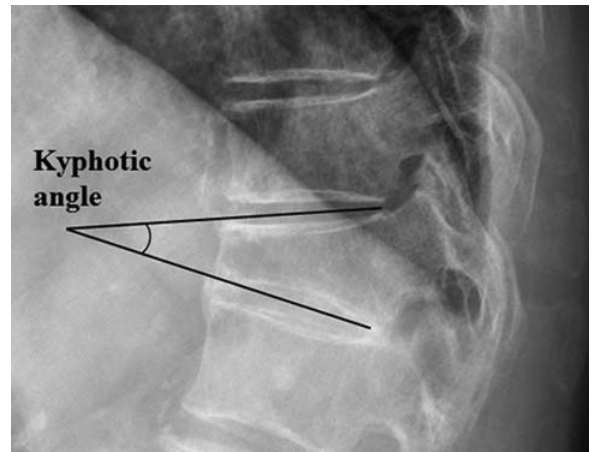
#### 2.4. Statistical analysis

Demographic data were analyzed using the Kolmogorov–Smirnov test to assess normality of the distribution. Demographic data that followed a normal distribution were compared using an



**Figure 3.** Measurement of vertebral compression ratio is done using the following formula:  $[(A + C)/2 - B]/[(A + C)/2]$ . (A) Anterior vertebral height of upper vertebra, (B) anterior vertebral height of fracture level, (C) anterior vertebral height of lower vertebra.

independent *t* test. Data that were not normally distributed were compared using the Mann–Whitney *U* test. We evaluated whether the NRS score, KA, and vertebral height improved significantly compared with those at baseline after each procedure using the post hoc Bonferroni test with repeated measures analysis of variance (ANOVA). After correcting for confounding variables (age, sex, BMD, level of compression fracture, days from onset of the pain to the procedure, and history of cancer, HTN or angina, DM, asthma or COPD, thyroid or parathyroid disease, hepatic disease, kidney disease, use of steroids, and compression ratio), we analyzed differences in the NRS score, surgical time, and amount of cement injected between the groups using an analysis of covariance (ANCOVA). The difference and ratio of KA and vertebral height recovery were also compared between the 2 groups using ANCOVA. The patients were divided into thoracic and lumbar



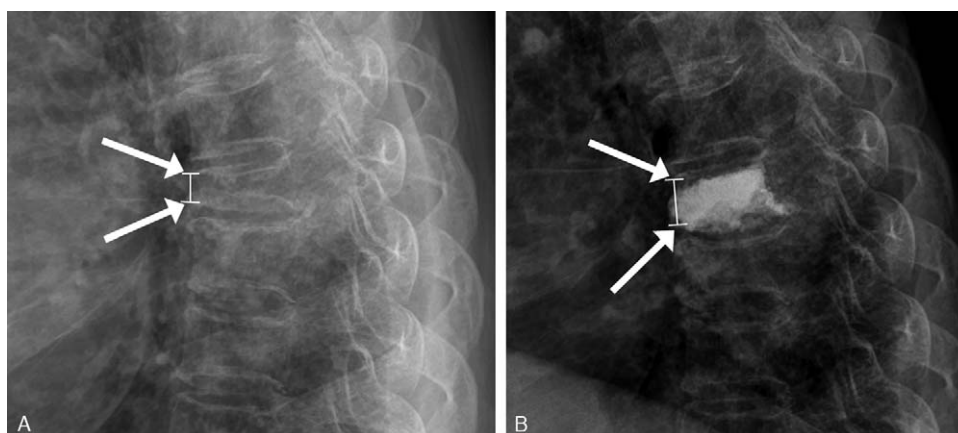
**Figure 5.** The kyphotic angle is calculated on the basis of the intersection angle of the lines running parallel to the upper and lower end plates of the fractured vertebrae.

spine OVCF groups based on the fracture location, and ANCOVA was used to determine the degree of NRS recovery, difference and percentage of KA recovery, and difference in height recovery between the unipedicular and bipedicular groups. The intradiscal cement leakage ratio and AVCF ratio within 1 year were compared using multivariate logistic regression. Data are presented as mean  $\pm$  standard deviation or median [interquartile ranges]. The Statistical Package for the Social Sciences software (version 17.0; SPSS 157 Inc., Chicago, IL) was used for analysis. All statistical tests were 2-sided, and the threshold for statistical significance was set at  $P < .05$ .

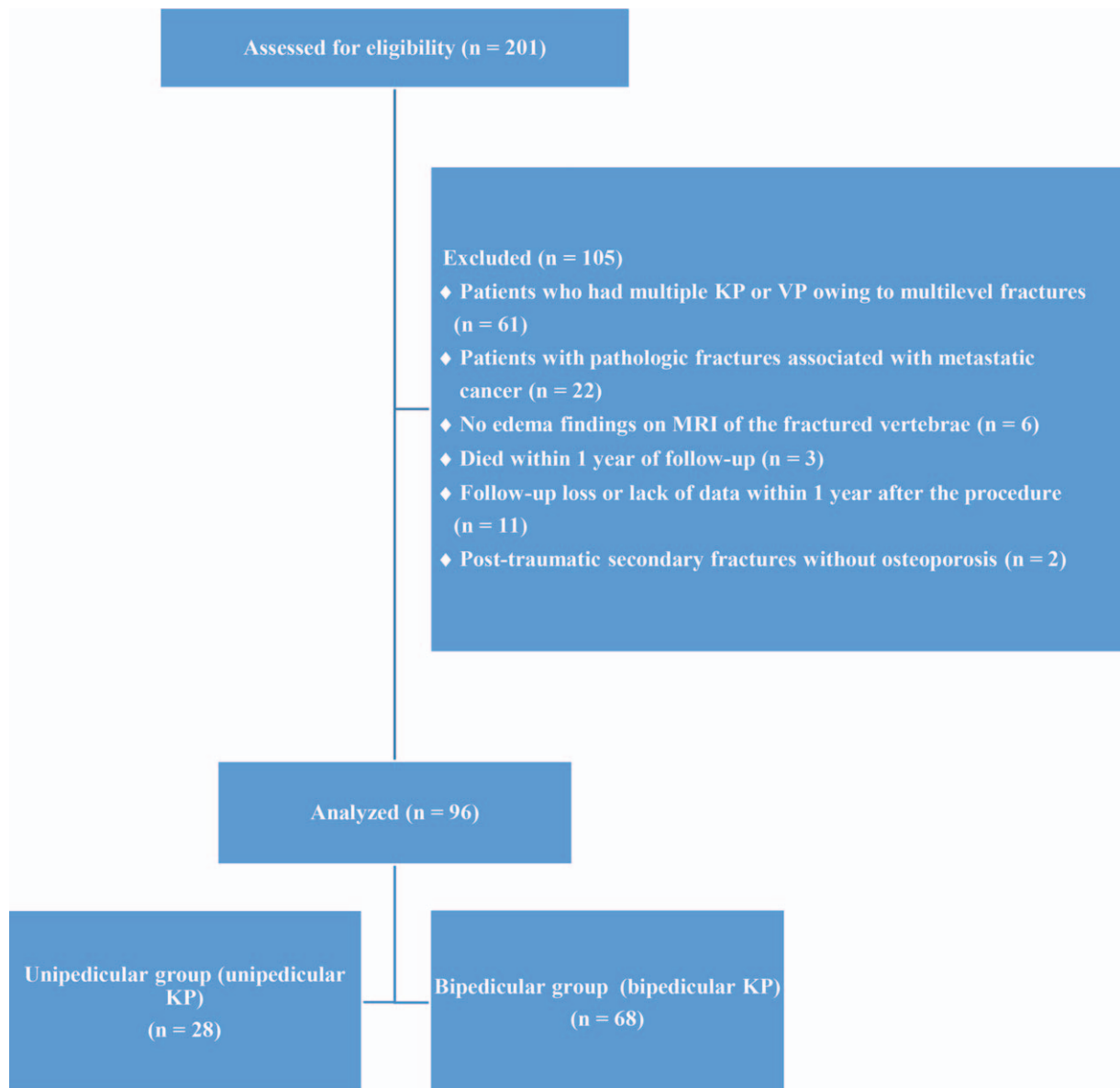
Statistical analysis was conducted after consulting with Soon Young Hwang (Korea University Medical Center, Guro Hospital), a statistical expert.

### 3. Results

We analyzed the medical records of 201 patients, 3 of whom died within 1 year of follow-up, and 11 were lost to follow-up or lacked data for 1 year after the procedure. Twenty-two patients with pathologic fractures associated with cancer metastasis, 6



**Figure 4.** The level of spinal deformity is evaluated using the lowest vertebral height before and after surgery to evaluate the recovery of the vertebral height at the same location after surgery. (A) Arrow indicates the lowest vertebral height. (B) Arrow indicates the recovery of the vertebral height at the same location after surgery.



**Figure 6.** Flow diagram showing the patient inclusion criteria. KP=kyphoplasty, MRI=magnetic resonance imaging, VP=vertebroplasty.

with no edema findings in the fractured vertebrae on MRI, 61 who underwent multiple KP or VP owing to multilevel fractures, and 2 with post-traumatic secondary fractures without osteoporosis (BMD  $>-2.5$ ) were excluded from the study. Finally, 96 patients were analyzed, with 28 in the unipedicular group and 68 in the bipedicular group (Fig. 6).

No significant differences were observed in the demographic and clinical characteristics of the patients between the 2 groups (Table 1).

### 3.1. Clinical findings

The NRS scores at 1, 3, 6, and 12 months after the procedure were significantly lower in both groups when compared with those at baseline (Table 2). In the corrected analysis of confounding variables, there were no significant differences in the NRS scores between the 2 groups at 1, 3, 6, and 12 months (Table 3). In addition, when the 2 groups were compared at the

thoracic and lumbar levels, the NRS score was not significantly different at 1, 3, 6, and 12 months (Supplementary file 2, <http://links.lww.com/MD/E805>).

### 3.2. Radiological findings

The lowest vertebral height of the vertebral body significantly increased in both groups after surgery; this increase was maintained until 1 year of follow-up (Table 4). There was no significant difference in the recovery ratio of vertebral height between the 2 groups after 1 day and after 1 year of KP (Table 5). In addition, comparison of the 2 groups at the thoracic and lumbar levels revealed no significant differences in the recovery ratio of vertebral height at both 1 day and 1 year after surgery (Supplementary file 3, <http://links.lww.com/MD/E806>).

The KA significantly improved in both groups after surgery, and this improvement was maintained for up to 1 year after surgery (Table 6). There were no significant differences in the

**Table 1****Baseline characteristics of patients.**

	Unipedicular group (n=28)	Bipedicular group (n=68)	P
Age, y	70.5±11.8	74.7±9.2	.15
Sex (M/F)	9/19	14/54	.29
Days from fracture to kyphoplasty	21.9±10.2	20.8±9.2	.71
Site of compression fracture	T: 21 L: 7	T: 37 L: 31	.07
BMD, g/cm <sup>2</sup>	-3.3±0.7	-3.3±0.7	.57
Cancer	7 [25% (18, 43%)]	18 [27% (18, 38%)]	1.0
HTN or angina	16 [57% (39, 74%)]	44 [65% (53, 75%)]	.64
DM	9 [32% (18, 51%)]	14 [21% (13, 32%)]	.29
Asthma or COPD	5 [18% (8, 36%)]	7 [10% (5, 20%)]	.50
Thyroid or parathyroid disease	4 [14% (6, 32%)]	5 [7% (3, 16%)]	.44
Hepatic disease	0 [0% (0, 12%)]	2 [3% (1, 10%)]	.58
Kidney disease	2 [7% (2, 23%)]	3 [4% (2, 12%)]	.63
Use of steroids	5 [18% (8, 36%)]	12 [18% (11, 29%)]	.98
Compression ratio	0.34±0.12	0.31±0.15	.35
Baseline NRS score	8 [7–8]	8 [7–8]	.51

Data are presented as mean ± standard deviation, median [interquartile ranges], or number [% (95% confidence intervals)].

BMD=bone mineral density, COPD=chronic obstructive pulmonary disease, DM=diabetes mellitus, HTN=hypertension, NRS=Numerical rating scale (score range, 0–10).

**Table 2****Comparison of the baseline pain scores at each time point.**

Group	Period A	Period B	Unipedicular group		Bipedicular group	
			Average difference (A–B)	P	Average difference (A–B)	P
Baseline pain score*		POD 1M	4.77	< .001	4.65	< .001
		POD 3M	4.62	< .001	4.41	< .001
		POD 6M	5.07	< .001	4.91	< .001
		POD 12M	5.18	< .001	5.05	< .001

Data were analyzed using analysis of variance (ANOVA) with the Bonferroni post hoc test. A *P* value of < .0125 was considered statistically significant.

POD 1M=Pain score 1 mo after kyphoplasty, POD 3M=Pain score 3 mo after kyphoplasty, POD 6M=Pain score 6 mo after kyphoplasty, POD 12M=Pain score 12 mo after kyphoplasty.

\*Pain score on an 11-point (0–10) numerical rating scale.

**Table 3****Comparison of the numerical rating scale scores between the groups after correction for confounding variables.**

Time of NRS score assessment after KP	Unipedicular group (n=28)	Bipedicular group (n=68)	P
Baseline	7.5±1.1	7.6±1.2	.51
1 mo	2.8±1.6	3.0±1.6	.49
3 mo	2.9±1.7	3.2±1.7	.23
6 mo	2.5±1.1	2.7±1.4	.39
12 mo	2.4±1.3	2.6±1.5	.31

KP=Kyphoplasty, NRS=Numerical rating scale (score range, 0–10).

Data are presented as adjusted mean ± standard deviation. The difference in the NRS scores between the groups was analyzed using analysis of covariance (ANCOVA). Adjustments were made for age, sex, time from fracture to KP, location of compression fracture, bone mineral density, cancer, hypertension or angina, diabetes mellitus, asthma or chronic obstructive pulmonary disease, thyroid or parathyroid disease, hepatic disease, kidney disease, use of steroids, and compression ratio.

**Table 4****Comparison of baseline vertebral heights at each time point.**

Group	Period A	Period B	Unipedicular group		Bipedicular group	
			Average difference (A–B)	P	Average difference (A–B)	P
Baseline vertebral height*, cm		(1)	2.27	< .001	2.95	< .001
		(2)	2.08	< .001	2.55	< .001

\*Vertebral height: Lowest spinal height in the vertebral body. (1) Vertebral height 1 day after kyphoplasty, (2) Vertebral height 1 year after kyphoplasty. Data were analyzed using analysis of variance (ANOVA) with the Bonferroni post hoc test. A *P* value of < .025 was considered statistically significant.

**Table 5**  
**Comparison of recovery of vertebral height between the groups after correction for confounding variables.**

	Unipedicular group (n = 28)	Bipedicular group (n = 68)	P
Baseline vertebral height* (cm) (A)	14.0 ± 4.8	16.0 ± 5.1	.08
Recovery of the vertebral height 1 d after KP, cm (B)	2.2 ± 1.4	2.9 ± 1.9	.18
(B)/(A) × 100 (%)	18.5 ± 12.4	21.1 ± 17.0	.33
Recovery of the vertebral height 1 yr after KP, cm (C)	2.0 ± 1.3	2.5 ± 1.8	.22
(C)/(A) × 100 (%)	16.2 ± 10.9	18.7 ± 16.1	.37

Data are presented as adjusted mean ± standard deviation or percentage. The difference in the vertebral height and ratio between the groups was analyzed using analysis of covariance (ANCOVA). Adjustments were made for age, sex, time from fracture to KP, location of the compression fracture, bone mineral density, cancer, hypertension or angina, diabetes mellitus, asthma or chronic obstructive pulmonary disease, thyroid or parathyroid disease, hepatic disease, kidney disease, use of steroids, and compression ratio.

\* Vertebral height: Lowest spinal height in the vertebral body, KP = kyphoplasty.

**Table 6**  
**Comparison of baseline kyphotic angles at each time point.**

Group	Period A	Period B	Unipedicular group		Bipedicular group	
			Average difference (A–B)	P	Average difference (A–B)	P
Baseline kyphotic angle*, °		(1)	3.47	< .001	3.75	< .001
		(2)	3.18	< .001	3.35	< .001

\* Kyphotic angle: Calculated angle based on the intersection angle of the lines that run parallel to the upper and lower end plates of the vertebrae. (1) Kyphotic angle 1 d after kyphoplasty, (2) kyphotic angle 1 yr after kyphoplasty. Data were analyzed using analysis of variance (ANOVA) with the Bonferroni post hoc test. A *P* value of < .025 was considered statistically significant.

difference and ratio of KA recovery between the 2 groups at 1 day and 1 year after surgery (Table 7); this absence of differences was also seen when the 2 groups were compared at the thoracic and lumbar levels (Supplementary file 4, <http://links.lww.com/MD/E807>).

### 3.3. Surgical findings

There was no significant difference in the mean surgical time between the unipedicular and bipedicular groups (36.7 ± 9.7 minutes in the unipedicular group and 39.6 ± 12.7 minutes in the bipedicular group; *P* = .53). Significantly less PMMA was injected in the unipedicular group than in the bipedicular group (4.4 ± 0.8 mL in the unipedicular group and 5.6 ± 1.0 mL in the bipedicular group; *P* = .00). Comparison of the 2 groups at the thoracic and lumbar levels showed a significant difference in the amount of PMMA injected (thoracic level: unipedicular group, 4.2 ± 0.8 mL; bipedicular group, 5.3 ± 1.1 mL; *P* = .01; lumbar level: unipedicular group, 4.9 ± 0.6 mL; bipedicular group, 6.0 ± 0.7 mL; *P* = .01).

### 3.4. Postoperative complications

Life-threatening complications such as pulmonary embolism or cement leakage into the paravertebral vein were not observed in

either group. In addition, no infection or cement leakage into the epidural space was found. Cement leakage into the intradiscal space was observed in 4 of 28 patients in the unipedicular group and in 12 of 68 patients in the bipedicular group, with no significant difference between the groups (*P* = .67) (Table 8). None of the patients with cement leakage into the intradiscal space complained of obvious clinical symptoms or developed neurological symptoms.

During the 1-year follow-up period, AVCF occurred in 4 of 28 patients in the unipedicular group and in 11 of 68 patients in the bipedicular group; the symptoms improved after undergoing an additional KP. There was no significant difference in the rate of AVCF occurrence within 1 year between the 2 groups (*P* = .84) (Table 8).

Anterior rib fracture induced by orienting the patient in the prone position during the surgery occurred in 1 patient in the bipedicular group; this was successfully treated with conservative treatment such as administration of analgesic agents.

## 4. Discussion

This study aimed to compare the clinical, radiological, and surgical findings and postoperative complications between patients who underwent unipedicular and bipedicular KP for

**Table 7**  
**Comparison of recovery of kyphotic angle between the groups after correction for confounding variables.**

	Unipedicular group (n = 28)	Bipedicular group (n = 68)	P
Baseline kyphotic angle*, ° (A)	14.2 ± 4.7	13.9 ± 6.5	.18
Recovery of the kyphotic angle 1 d after KP, ° (B)	3.4 ± 2.2	3.7 ± 2.4	.37
(B)/(A) × 100 (%)	24.4 ± 13.9	27.4 ± 14.4	.95
Recovery of the kyphotic angle 1 yr after KP, ° (C)	3.1 ± 2.2	3.3 ± 2.0	.53
(C)/(A) × 100 (%)	22.0 ± 13.1	24.5 ± 12.3	.88

Data are presented as adjusted mean ± standard deviation or percentage. The difference in the kyphotic angle and ratio between the groups was analyzed using analysis of covariance (ANCOVA). Adjustments were made for age, sex, time from fracture to KP, location of the compression fracture, bone mineral density, cancer, hypertension or angina, diabetes mellitus, asthma or chronic obstructive pulmonary disease, thyroid or parathyroid disease, hepatic disease, kidney disease, use of steroids, and compression ratio.

\* Kyphotic angle: Calculated angle based on the intersection angle of the lines that run parallel to the upper and lower end plates of the vertebrae, KP = kyphoplasty.



**Table 8****Comparison of complication rates after kyphoplasty between the groups.**

Side effects	Unipedicular group	Bipedicular group	Adjusted OR (95% CI) Reference: bipedicular group	P
Cement leakage into the intradiscal space	4/28, [14% (6, 32%)]	12/68, [18% (10, 28%)]	0.73 (0.16–3.24)	.67
Adjacent vertebral fracture after KP	4/28, [14% (6, 32%)]	11/68, [16% (9, 27%)]	0.85 (0.17–4.19)	.84

Data are presented as numbers [% (95% CIs)] and were analyzed using multivariable logistic regression analysis. Adjustments were made for age, sex, time from fracture to KP, location of the compression fracture, bone mineral density, cancer, hypertension or angina, diabetes mellitus, asthma or chronic obstructive pulmonary disease, thyroid or parathyroid disease, hepatic disease, kidney disease, use of steroids, and compression ratio.

CI = confidence interval, KP = kyphoplasty, OR = odds ratio.

single-level OVCF. In both groups, the NRS score, vertebral height, and KA after KP significantly improved after 1 year. The amount of cement injected was significantly higher in the bipedicular group than in the unipedicular group; however, there was no significant difference in the improvement of the NRS score and recovery of vertebral height and the KA. In addition, there were no significant differences in the ratio of cement leakage into the intradiscal space, ratio of AVCF within 1 year, and surgical time. The patients were divided into the groups based on the presence of a thoracic or a lumbar fracture, and the results were maintained across the 2 groups.

Balloon KP has been shown to be effective in treating OVCFs.<sup>[13,17,18]</sup> Previously, bipedicular KP was considered the main approach for OVCF treatment<sup>[30]</sup>; however, subsequent studies have shown that unipedicular KP can also yield clinical and radiological improvements.<sup>[10,31]</sup>

In this study, unipedicular KP was found to yield similar clinical and radiological improvements as bipedicular KP. Previous cadaver studies have reported no significant differences in the restoration of vertebral body strength, stiffness, and height between the unipedicular and bipedicular groups.<sup>[32,33]</sup> However, as a condition of restoration, Chen et al<sup>[34]</sup> concluded that the distribution of cement in the vertebral body is important, and an uneven distribution of cement in the unipedicular group could increase the biodynamic imbalance in the vertebral body compared with that in the bipedicular group. In addition, most studies that have reported equivalent efficiencies of both unipedicular and bipedicular KP have also suggested that the cannula used during unipedicular KP should be centered relative to that used during bipedicular KP.<sup>[5,32,35–37]</sup> Therefore, in this study, the cannula was centered as much as possible via the extrapedicular approach used in unipedicular KP so that PMMA was evenly distributed on the left and right sides of the vertebra.

Previous studies have recommended the administration of a sufficient amount of cement because administration of an amount less than the volume of the vertebral body may result in a lack of improvement of clinical symptoms.<sup>[38]</sup> Liebschner et al<sup>[39]</sup> proposed that injecting cement up to 15% of the volume of the vertebral body may be sufficient to restore strength to the damaged levels. Martinčić et al<sup>[40]</sup> also reported that filling cement up to 15% of the volume of the vertebral body did not increase the compressive stiffness of the intradiscal pressure. Specifically, the authors reported that an average of 4 to 6 mL of cement is adequate for the thoracolumbar vertebra. In the present study, we injected an average cement volume of  $4.2 \pm 0.8$  mL and  $4.9 \pm 0.6$  mL at the thoracic and lumbar levels in the unipedicular group, and  $5.3 \pm 1.1$  mL and  $6.0 \pm 0.7$  mL at the same levels in the bipedicular group, respectively. As seen in a prospective study conducted in 2013 by Rebolledo et al,<sup>[10]</sup> our study showed significant differences in the amount of cement injected in the 2

approaches. However, when a sufficient volume of cement was used, there was no significant difference in the improvement of the NRS score and spinal deformation between the 2 groups.

Chen et al<sup>[35]</sup> conducted a study in 2010 and found that bipedicular KP was more effective than unipedicular KP in improving vertebral height. However, Feng et al<sup>[21]</sup> concluded that unipedicular KP was more successful than bipedicular KP at improving the vertebral height. Unlike either of these studies, we found that neither approach was superior to other in improving vertebral height or KA. Chen et al<sup>[29]</sup> conducted another study in 2011 and reported conclusions similar to those of our study. Furthermore, Chung et al<sup>[41]</sup> reported that bipedicular KP had a greater advantage in reducing KA than unipedicular KP. The authors also reported that the greater cement leakage in the unipedicular group to the spinal canal was caused by efforts to position the bone tamp more centrally during surgery. However, unipedicular KP is generally known to reduce the risks associated with placing large-bore needles in the spine<sup>[26]</sup>; these risks include pedicle fracture, spinal canal invasion, nerve damage, cement leakage through the cannula tract, and spinal epidural hematoma. In this study, we found no significant differences in the degree of KA recovery between the 2 groups. Complications such as spinal canal invasion, nerve damage, pedicle fracture, cement leakage through the cannula tract, and spinal epidural hematoma were also not observed in either group.

Unless there is a significant difference in clinical and radiological findings and postoperative complications, it may be advisable to proceed with the unipedicular approach for thoracic segments with smaller pedicles. However, if the small size of the pedicle precludes the needle trajectory for cement injection from being close to the midline, a bipedicular approach may be considered.

Unipedicular KP has been reported to significantly reduce radiation exposure, surgical time, and cost when compared with bipedicular KP.<sup>[29,42]</sup> Although the present study did not measure radiation exposure, there was no significant difference in the surgical time between the 2 groups. This may be attributed to the fact that inserting the trocar via the extrapedicular approach and placing the needle at the center of the vertebral body in unipedicular KP are more difficult than inserting the trocar via the transpedicular approach in bipedicular KP. In addition, we used bipedicular KP to insert the balloon and inject the cement simultaneously through both needles, which may have contributed to lack of significant difference in the surgical time. From an economic point of view, it was found that a bipedicular KP required about 1.5 times the material cost as a unipedicular KP. Given a lack of significant differences in clinical and radiological findings and postoperative complications between the 2 approaches, as shown in this study and the study by Chen et al,<sup>[30]</sup> the more economical unipedicular KP may be preferable.

Cement leakage and AVCF are common complications that occur during and after KP. In studies conducted by Rebolledo et al.<sup>[10]</sup> (unipedicular KP: mean amount of 4.8 mL, bipedicular KP: mean amount of 6.3 mL,  $P=.02$ ), who used a similar amount of cement as in this study, the cement leakage rates were 7% in unipedicular KP and 25% in bipedicular KP, which were also significantly different. Yan et al.<sup>[43]</sup> also reported cement leakage rates of 7.6% in unipedicular KP and 14.6% in bipedicular KP; they were significantly different between the two groups when the average amount of cement used was 3.4 mL in unipedicular KP and 5.5 mL in bipedicular KP. However, Wang et al.<sup>[43]</sup> reported cement leakage rates of 12.9% in unipedicular KP and 16.1% in bipedicular KP, which were not significantly different between the 2 groups, when the average amount of cement used was 3.5 mL in unipedicular KP and 7.5 mL in bipedicular KP. In this study, there was also a significant difference in the injected volume of PMMA between the 2 groups. However, there was no significant difference in the leakage rate of cement into the intradiscal space (14% in the unipedicular group and 18% in the bipedicular group;  $P=.68$ ). In addition, there was no cement leakage into the vascular and epidural spaces in either group.

We did not observe any significant differences in the AVCF rates, despite noting a difference in the amount of cement injected. A 2019 report revealed that the risk factors for AVCF after VP include BMD, preoperative compression ratio, preoperative sagittal index, intradiscal cement leakage, and large cement volume-to-vertebral body ratio as per univariate analysis.<sup>[44]</sup> Significant risk factors as per multivariate analysis were BMD and intradiscal cement leakage. The lack of significant differences in the ratio of AVCF may be due to a lack of such differences in the ratio of BMD and intradiscal cement leakage between the 2 groups. In addition, despite the difference in the amount of cement injected, the appropriate amount (within 15% of the volume of the vertebral body) for either group is still comparable.

To minimize other variables in the comparison between unipedicular and bipedicular KP, this study only included patients who underwent KP for single-level fractures and excluded those who received multiple KP or VP concurrently for multilevel fractures. The latter patients were excluded because it was not possible to compare the effects of unipedicular and bipedicular KP accurately, and it may cause variations in the comparison of complications between the 2 groups, such as AVCF caused by KP.

There are some limitations to the present study. First, our measurements did not allow for blinded assessment of vertebral height or KA before and after surgery, allowing for possible biases in the radiological assessment. Second, the loss to follow-up of 14 of 201 patients may have affected the validity of our results. The inclusion of the elderly population in this study may have contributed to a higher loss rate during follow-up. Three patients died during the 1-year follow-up period, and 11 were excluded from the study owing to loss of contact during follow-up or incomplete radiological data. Third, given that this study was retrospective, it was difficult to extend the follow-up period to more than 1 year, and a longer follow-up period may have helped in the detection of additional AVCFs, if any. Fourth, because this study was not a randomized controlled one, there may have been a selection bias when assigning patients to the 2 groups. However, there was no significant difference in the baseline demographic data, preoperative NRS score, preoperative KA, and preoperative vertebral height between the 2 groups. In addition, we evaluated each result using an analytical method

(covariance and multivariable logistic regression analyses) that could correct for these variables. Fifth, it is not possible to accurately determine epidural cement leakage because cost considerations prohibit computed tomography (CT) scans if there are no abnormal symptoms (motor weakness, radiating pain, fever, unstable vital sign) after KP. Patients with neurological deficits, which may appear due to leakage of cement into the epidural space, were also not specifically reported in this study. We did not observe any images of cement passing over the posterior border of the vertebral body on the lateral view of the X-ray and therefore, noted this as “No cement leaks into the epidural space were found” in the text. Bypassing the accurate identification of cement leakage into the epidural space through CT scans may limit evaluation of the benefits of the unipedicular approach, in which significantly less cement is used. Future well-organized prospective studies will need to accurately identify epidural cement spills through CT scans.

## 5. Conclusion

Unipedicular and bipedicular KP significantly reduced the pain experienced by patients with single-level OVCFs, restored vertebral height, and corrected the KA, which remained stable for at least 1 year after treatment. In particular, unipedicular KP required lower amounts of cement than bipedicular KP and was as effective as bipedicular KP with respect to the radiological and clinical outcomes. The above findings have level III evidence and a grade B recommendation as per the Guidelines of the North American Spine Society.<sup>[45]</sup>

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## Author contributions

**Conceptualization:** Chung Hun Lee, Sang Sik Choi, Mi Kyoung Lee.

**Data curation:** Chung Hun Lee, Hyun Joong Kim, Hyo Sung Kim.

**Formal analysis:** Chung Hun Lee, Hyo Sung Kim.

**Investigation:** Chung Hun Lee, Hyun Joong Kim.

**Methodology:** Chung Hun Lee, Sang Sik Choi, Hyun Joong Kim.

**Project administration:** Chung Hun Lee, Mi Kyoung Lee.

**Resources:** Chung Hun Lee.

**Software:** Sang Sik Choi, Mi Kyoung Lee, Hyo Sung Kim.

**Supervision:** Sang Sik Choi, Mi Kyoung Lee, Chung Hun Lee.

**Validation:** Sang Sik Choi, Mi Kyoung Lee.

**Visualization:** Mi Kyoung Lee.

**Writing – original draft:** Chung Hun Lee, Sang Sik Choi.

**Writing – review and editing:** Chung Hun Lee, Sang Sik Choi, Mi Kyoung Lee.

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