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RANDOMIZED TRIAL

Balloon Kyphoplasty *Versus* KIVA Vertebral Augmentation—Comparison of 2 Techniques for Osteoporotic Vertebral Body Fractures

A Prospective Randomized Study

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Study Design. Prospective, parallel-group, controlled comparative randomized study.

Objective. This study compares the efficacy in sagittal vertebral height and wedge deformity restoration, polymethylmethacrylate cement leakage safety, and functional outcome of balloon kyphoplasty (BK) *versus* KIVA (a novel vertebral augmentation technique) implant for the augmentation of fresh osteoporotic vertebral body fractures.

Summary of Background Data. Minimally invasive vertebral augmentation procedures have been widely used to treat vertebral compression fractures caused by osteoporosis. The results of these trials are encouraging in augmenting the vertebra and reducing the wedge deformity. However, after BK, polymethylmethacrylate leakage remains common after A3.1 AO type fractures, with a frequency per vertebra into the epidural space up to 9.8% but less common (0.03%–5.6%) in A1.1 AO type fracture. KIVA is a novel percutaneous uniportal vertebral augmentation device that is designed to restore the vertebral body and reduce polymethylmethacrylate leakage.

Methods. From a total 190 patients with osteoporotic fractures who were initially enrolled in this prospective randomized study, 10 patients were excluded (5 met exclusion criteria, 5 with evidence of metastasis). This study examined 82 patients (69 ± 11 yr) with 133 fractures who received KIVA and 86 patients (72 ± 9 yr) with 122 fractures that were reinforced with BK. Anterior (anterior vertebral body height ratio [AVBHr]), midline (midline vertebral body height ratio [MVBHr]), and posterior (posterior vertebral body height ratio [PVBHr]) vertebral body height ratio and Gardner segmental vertebral wedge deformity were measured preoperatively to postoperatively. New fractures were recorded at the final observation. The baseline anthropometric and roentgenographic parameters did not differ between the 2 groups. Any cement leakage was examined on plain roentgenograms and computed tomographic scan. All patients were followed for an average of 14 months (range, 13–15 mo) postoperatively.

Results. At the final observation, both KIVA and BK restored significantly AVBHr, PVBHr, and MVBHr. However, only KIVA device reduced significantly the Gardner angle ($P = 0.002$). Residual kyphosis of more than 5° was measured significantly more ($P < 0.001$) in the BK than in KIVA spines. KIVA showed significantly lower (0.03%, χ^2, $P \leq 0.05$) leakage) (paravertebral, intradiscal) rate per vertebra than BK (0.098%) in which because of intracanal leakage 2 patients developed acute paraplegia and were reoperated in emergency. New fracture rate was similar in both groups. Back pain scores (visual analogue scale), 36-Item Short Form Health Survey (Physical Function and Mental Health domains), and Oswestry Disability Index scores improved significantly in the patients of both groups.

Conclusion. Both KIVA and BK restored in short-term similarly vertebral body height, but only KIVA restored vertebral body wedge deformity. KIVA was followed by significantly lower and harmless always extracanal leakage rate than BK. Longer observation is needed to show whether these radiological changes have any functional impact.

Key words: osteoporotic vertebral fracture, balloon kyphoplasty, vertebroplasty, KIVA. **Spine 2013;38:292–299**

Vertebral body fracture is the most common type of osteoporotic fracture that often causes disabling pain and kyphotic deformity leading to impaired physical function and reduced quality of life.[1,2]

Most of the patients with osteoporotic vertebral fractures are treated successfully conservatively by means of pain medication, bed rest, physiotherapy, and/or a cast. When pain persists, one should consider minimally invasive vertebral body augmentation techniques, for example, vertebroplasty (VP)

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The device(s)/drug(s) that is/are the subject of this manuscript is/are being evaluated as part of an ongoing FDA-approved investigational protocol (IDE) or corresponding national protocol for the augmentation of fresh osteoporotic vertebral body fractures.

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and balloon kyphoplasty (BK).[3] Ideally, the operative treatment of osteoporotic fractures should address both fracture-related pain and the resulted kyphotic deformity.

The original treatment of osteoporotic compression fractures was VP, with forcible injection of polymethylmethacrylate (PMMA) bone cement into the compressed vertebral body, thus relieving pain caused by loss of height without restoring it. In contrast to VP, BK creates an intravertebral cavity surrounded by compacted cancellous bone resulting from balloon inflation and allows for low-pressure filling of the cavity with viscous cement.

However, there are 2 major procedural disadvantages of both BK and VP surgical techniques: incomplete fracture reduction associated with significant loss of the restored height and cement leakage during PMMA injection.

To avoid loss of height after balloon deflation, associated severe compression, or burst fractures, 2 minimal invasive techniques have been used: hybrid minimal invasive techniques using pedicle screw constructs[4] plus BK for the fractured vertebral body and expandable scaffolding devices[5] that can be implanted extra- or transpedicularly and expanded inside the vertebral body.

Extravertebral cement leakage has been reported to occur in up to 65% of vertebra treated with VP,[5] whereas BK is associated with much lower leakage rates.[6–9] The PMMA may exit the vertebral body through deficiencies or fractures in the vertebral cortex or by injection of cement into the vertebral venous system.[9] Leakage of cement through the vertebral cortex may result in direct injury to or compression of adjacent structures, such as the spinal cord, nerve roots, or PMMA pulmonary embolism.[10]

Furthermore, although PMMA is a common cement for VP or KP, disadvantages include rigidity that may lead to fractures at adjacent or remote vertebral levels.[11–15]

Because of these concerns, numerous efforts have been made to minimize these risks by searching for new types of cement,[5,16–20] improved instrumentation for cement injection,[21] and reduction of the volume of cement/monomer injected into the vertebral body to potentially minimize complication rates.

Using a novel PEEK implant (KIVA) *via* a transpedicular approach for vertebral body augmentation and height restoration with PMMA is a recent technology that has been shown to have good potential in early investigations.[22] Potential advantages of this technique were better than BK reduction of compressed vertebral body with lower cement volume and potentially lower extravasation rates plus maintenance of vertebral height over time because of the PEEK.

The null hypothesis of this study was that BK and KIVA augmentation techniques provide similar radiological results regarding vertebral body height and wedge deformity restoration and functional results and are associated with similar PMMA cement leakage rate.

PATIENTS AND METHODS

We performed a prospective, parallel-group, controlled comparative randomized study (Figure 1) to test the hypothesis that the short-term radiological and functional results of both

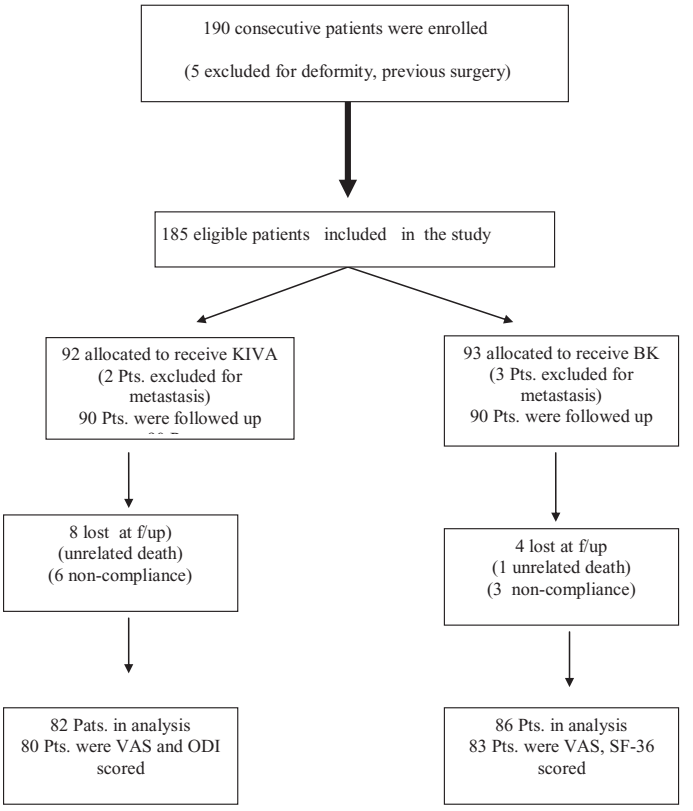

Figure 1. Prospective, parallel-group, controlled comparative randomized study. KIVA is a novel vertebral augmentation technique. BK indicates balloon kyphoplasty; VAS, visual analogue scale; ODI, Oswestry Disability Index; SF-36, 36-Item Short Form Health Survey.

KIVA and BK are similar, and both techniques are associated with similar leakage rate. The 2 augmentation devices (KIVA and BK) were compared for correcting anterior vertebral body height ratio (AVBHr), midline vertebral body height ratio (MVBHr), posterior vertebral body height ratio (PVBHr), and segmental kyphotic angle (Gardner angle) (Figure 2). AVBHr, MVBHr, and PVBHr segmental Gardner kyphotic angle were measured preoperatively to postoperatively. Although there is no evidence-based data regarding relationship between a cutoff of 5° rest kyphosis after vertebral body height restoration and pain, it is the empirical thought among spine surgeons that a post-traumatic kyphosis could at least theoretically induce back pain. On the basis of this assumption, we compared the patients of both groups in relation to this radiological parameter as well. Plain roentgenograms and computed tomographic scan were used to detect any PMMA leakage. AVBHr, MVBHr, PVBHr, and segmental Gardner kyphotic angle and cement leakage were digitally measured using the e-film software (Merge Healthcare, Chicago, IL) by an independent observer (V.V.) who did not participate in surgeries. This software has a high precision to detect even 1° differences.

Furthermore, the 2 techniques were compared for alleviating pain (visual analogue scale [VAS] score, 0–10). Significant improvement of pain score was considered a reduction of VAS score of more than 5.5 points. Furthermore, the BK and KIVA were compared for improving self-assessment quality of life

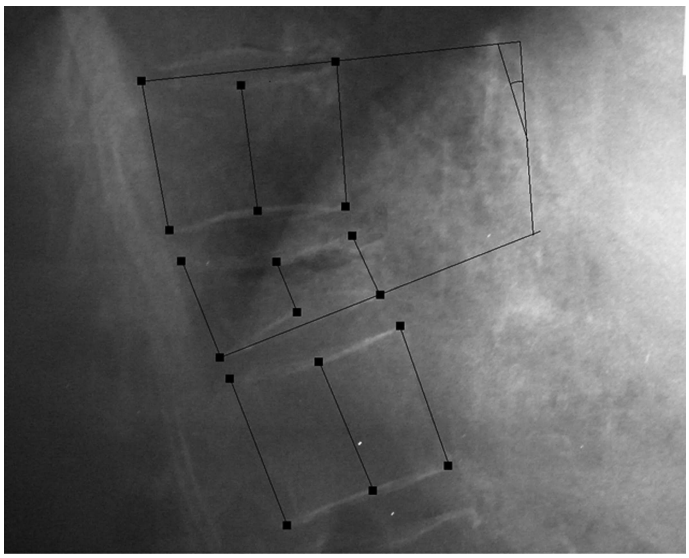

Figure 2. Schematic demonstration of radiological measurement of anterior vertebral body height ratio, posterior vertebral body height ratio, midline vertebral body height ratio, and Wedge angle.

(Physical Function and Mental Health domains of 36-Item Short Form Health Survey [SF-36] questionnaire) as well and Oswestry Disability Index (ODI). Following physical examination, the symptomatic levels were confirmed by standing long-film anteroposterior and lateral whole-spine roentgenograms, CT scan, and/or magnetic resonance image.

The participants, investigators (other than surgeons performing the procedures), and outcome assessors were unaware of the group assignments. A 1-year follow-up was planned. Enrollment commenced in May 2010 and ended in September 2010, whereas the follow-up ended in October 2011. The human research ethics committee of this institution approved the study, and all participants provided written informed consent.

Participants

Participants were recruited from our hospital inpatient and emergency department. Inclusion criteria were history of low-energy recent trauma or acute onset of back pain without evident trauma, presence of associated back pain of no more than 3 months' duration, and the imaging evidence of presence of 1 or more (1–5) simultaneous vertebral fractures (Figure 3). Osteoporotic fractures were included if they were defined as vertebral collapse of grade 1 or higher according to the grading system of Genant and Jergas[23] (Figure 4). Only 2 and 1 burst[23] fractures in KIVA and BK groups, respectively, were included in this study. Exclusion criteria were previous spinal operation, spinal infection, significant spinal deformity (*e.g.*, scoliosis), and bleeding disorders. Patients with intraoperative biopsy positive for metastasis were excluded as well. A total of 190 consecutive patients were enrolled for this study (Figure 1). Five patients were excluded from meeting the above-mentioned exclusion criteria (4 patients had spinal deformity, and 1 had previous spine operation). Furthermore, from the 185 consecutive patients who were eligible and received either

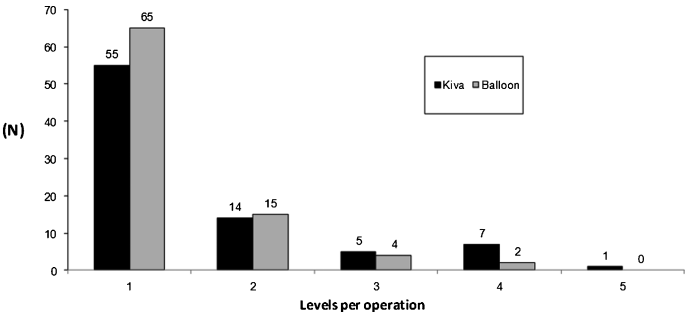

Figure 3. Levels of vertebrae augmentation. KIVA (a novel vertebral augmentation technique) *versus* balloon kyphoplasty.

KIVA (92) or BK (93), 8 patients from KIVA group and 4 from BK group were lost at the final evaluation for different reasons (Figure 1). During vertebral augmentation, metastasis was shown during needle biopsy in 2 patients of KIVA group and 3 patients of BK group. These 5 patients were excluded from the final analysis. Thus, this investigation enrolled 168 consecutive patients with 255 fractures. There were 82 patients (69 ± 11 yr) (range, 57–82 yr) with 133 fractures, who randomly received KIVA and 86 patients (72 ± 9 yr) (range, 57–83 yr) with 122 fractures, who received BK (Figure 5).

Interventions

KIVA and BK were performed under biplane fluoroscopy in the operating room and under general anesthesia and continuous neuromonitoring by a single experienced spine surgeon (P.K.). The patients were placed in the prone position on a AcroMed frame (DePuy Spine Inc., Raynhamm, MA). Biopsy was routinely done from all vertebrae prior to augmentation with either BK or KIVA. The spine surgeon who performed all surgeries was unaware of the augmentation method to be used, and only in the operation room was he informed for the method to use, resulted from randomization. The hospital stay was 24 hours, with the exception of the patients of the BK group who developed neurological impairment. The cost of Balex device and KIVA plus PMMA per augmented vertebra in our country is approximately €1450 ($1931.26).

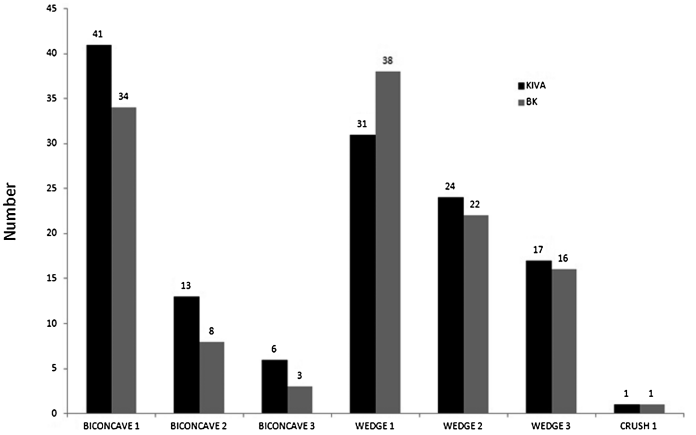

Figure 4. Vertebral fractures semiquantitative grading. KIVA is a novel vertebral augmentation technique. BK indicates, balloon kyphoplasty.[23]

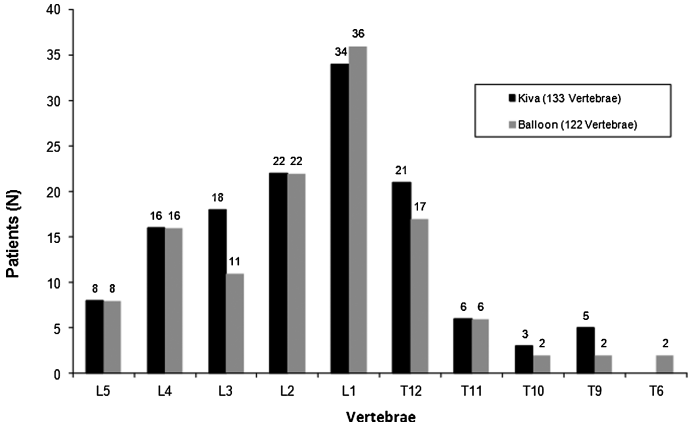

Figure 5. Number of vertebrae per level KIVA (a novel vertebral augmentation technique) *versus* balloon kyphoplasty.

KIVA Procedure

This is a unilateral percutaneous vertebral augmentation device (KIVA, VCF Treatment System; Benvenue Medical, Santa Clara, CA).[22] The KIVA system is a sterile, single-use device in which an external delivery handle is used to deploy the KIVA implant over a ninitol coil guide wire. The coil is first advanced through the deployment cannula and into the cancellous portion of the vertebral body using an external handle. The KIVA implant, which comprises PEEK-OPTIMA (Invibio Inc., West Conshohocken, PA) and loaded with 15% barium sulfate to enhance visibility under fluoroscopy, is incrementally advanced over the coil to form a nesting, cylindrical column with an *in situ* outer diameter of 20 mm. Up to 4 loops of the implant may be inserted into the vertebral body for a maximum coil stack height of 12 mm, which re-elevates the endplate, thereby providing the desired vertebral fracture reduction. After the coil is retracted, radiopaque PMMA cement (usually 1–2 mL per vertebra, depending on number of PEEK loops inserted) is injected through the lumen of the PEEK implant, thereby interlocking the implant to the vertebral body cancellous bone. In addition, the injected PMMA into the PEEK creates a uniform cylindrical column in the anterior and partially middle vertebral column that safeguards PMMA containment.

Balloon Kyphoplasty Procedure

The Balex device and technique is very similar to the classical Balloon Kyphoplasty (Kyphon, Medronic, Inc., Sunnyvale, CA). K-wires of 2-mm diameter are inserted through both pedicles of the damaged vertebra (Balex; Taeyeon Medical Co., Ltd, Incheon, Korea). Following that a cannula was inserted subsequently into both pedicles. The position of the cannulae was continuously controlled in both planes. Then an expander is inserted bilaterally and inflated. After creation of the desired void, PMMA is slowly injected after removal of the expander cannula, using cement filler and pusher under continuous fluoroscopic monitoring.

Statistics and Outcomes

Block randomization with random block size was used (nQuery; Statsol, Cork, Ireland) for the purpose of this prospective randomized study.

Paired and unpaired t test was used to compare changes of the same group or between different groups with parametric values. Chi-squared test was used for nonparametric comparisons. Pearson correlation coefficient (r) was used for correlations between different parameters. Lowest level of significance for paired and unpaired t test and χ^2 test was considered P value of less than 0.05. Pearson correlation coefficient $r > 0.45$ was considered as significant at the P value level of less than 0.001.

RESULTS

Important covariates are shown in the Table 1. This table indicates that both study groups were reasonably balanced. For this reason, we refrained from multivariable analysis. An *a priori* power analysis was not conducted. Hence, the results of this study must be interpreted with care. However, the data presented here provide an indication of the direction of measured effect as well as how much variability exists in the measured effect.

The male-to-female ratio was 1:1.8 and 1:1.4 for patients of KIVA and BK groups, respectively.

There were no statistically significant differences between the 2 groups in the preoperative baseline characteristics: age (unpaired t test, $P > 0.1$), sex (unpaired t test, $P > 0.2$), and levels plus number of fractures per individual (Figures 3 and 5).

The mean duration of KIVA and BK augmentation techniques was 8 ± 2 and 15 ± 4 minutes per level, respectively (unpaired t test, $P < 0.01$).

TABLE 1. Baseline Patients' Characteristics

Parameter	KIVA Group (n = 82)	BK Group (n = 86)
Female, N (%)	56 (68.3)	63 (71.6)
Age (95% CI), yr	69.6 (66.6–72.5)	72.3 (69.9–74.7)
BMI (95% CI), kg/cm^2	28.1 (27.2–29.1)	28.3 (27.3–29.4)
No. of augmented vertebra	133	122
ODI*	64%	62%
VAS*	8.2	7.8
PF (SF-36)*	32	28
MH (SF-36)*	42	41
Wedge angle*	13.7°	14.9°
AVBHr*	0.78	0.74
PVBHr*	0.92	0.92
MVBHr*	0.88	0.89

**Average values.*

KIVA is a novel vertebral augmentation technique. BK indicates, balloon kyphoplasty; CI, confidence interval; BMI, body mass index; ODI, Oswestry Disability Index; VAS, visual analogue scale; PF, Physical Function; SF-36, 36-Item Short Form Health Survey; MH, Mental Health; AVBHr, anterior vertebral body height ratio; PVBHr, posterior vertebral body height ratio; MVBHr, midline vertebral body height ratio.

Irrespectively of the method used, the most commonly augmented vertebra was the L_1, whereas the less common was the T_6 (Figure 5).

No cases of intraoperative hypotension, respiratory disturbance, infection, or death were observed and no blood transfusions were required.

The follow-up evaluation averaged 14 months (range, 13–15 mo) for both groups.

Patients' radiological and functional outcomes were evaluated and compared at baseline and at the maximum follow-up visit.

However, although the patients with intraoperative evidence for metastasis were excluded from the final analysis, in all these 5 patients, vertebral augmentation (BP and KIVA) was successful and relieved pain immediately postoperatively.

Radiological Results

An average of 3 ± 1 loops of PEEK were implanted in each vertebra of KIVA group. Both KIVA and BK restored significantly AVBHr at 24% and 23%, respectively (unpaired *t* test, $P = 0.97$).

PVBHr was restored only by KIVA at an average 6%; however, it was statistically marginally significant (*t* test, $P = 0.08$).

KIVA and BK significantly restored MVBHr in a similar amount at 31% and 22%, respectively (*t* test, $P = 0.45$).

The numerical reduction of segmental Gardner kyphosis angle was in KIVA at 5° ± 3.5° ($P = 0.009$) and in BK at 6° ± 5° ($P = 0.067$).

Sixty-nine (84%) and 86 (100%) spines in groups KIVA and BK, respectively, showed at the final observation a residual kyphosis of 5° or more ($\chi^2 = 14.6$, $P < 0.001$).

When comparing the amount of PMMA cement that was injected per vertebra in each group, the BK group was found to have a significantly greater amount of injected cement (2.8 ± 0.5 mL) than the KIVA group (1.8 ± 0.4 mL) ($P < 0.001$).

Cement leakage was radiologically (plain radiographs and computed tomographic scan) shown in 4 (0.03%) and 12 (0.098%) vertebrae in KIVA and BK groups, respectively ($\chi^2 = 5.05$, $P < 0.05$). No case with intracanal leakage was shown in KIVA patients. In 2 (2.3%) patients who received BK, intracanal PMMA leakage occurred in 2 vertebrae (1.6%) with intraoperative positive neuromonitoring signals. These 2 patients immediately underwent decompression under the same anesthesia. Both patients recovered neurologically and were able to walk without aids at the final follow-up (Table 2).

New fractures were observed in 10 (12.2%) patients of KIVA group and in 11 (13%) patients of BK group ($\chi^2 = 0.014$, $P > 0.2$). More specifically, adjacent vertebral body fractures were observed in 6 and 8 patients of KIVA and BK groups, respectively, whereas remote fractures were observed in 4 and 3 patients of KIVA and BK groups, respectively.

Functional Results

Significant (>5.5 points) back pain score (VAS) improvement was shown in 44 (54%) and 37 (43%) patients in KIVA and BK groups, respectively.

TABLE 2. Comparative Radiological Data Pre-to Postoperatively and KIVA *Versus* Balloon Kyphoplasty

Group	AVBHr				PVBHr				MVBHr				Wedge Angle			
	Preoperatively	Postoperatively	*P*	Correction (%)	Preoperatively	Postoperatively	*P*	Changes (%)	Preoperatively	Postoperatively	*P*	Changes (%)	Preoperatively	Postoperatively	*P*	Changes (°)
KIVA	0.78 ± 0.25	0.87 ± 0.17	0.0014	24.3 ± 45	0.92 ± 0.12	0.95 ± 0.11	0.082	5.92 ± 16	0.74 ± 0.25	0.88 ± 0.18	0.000008	30.5 ± 47	13.7 ± 7	7.80 ± 6	0.009	5 ± 3.5
BK	0.74 ± 0.23	0.89 ± 0.17	0.0019	23 ± 63	0.92 ± 0.12	0.95 ± 0.1	0.31	−1.26 ± 8	0.70 ± 0.23	0.89 ± 0.14	0.00005	21.9 ± 26	14.9 ± 8	11.5 ± 7	0.067	6 ± 5
Inter-group *P*	0.38	0.67		0.97	0.79	0.95		0.07	0.42	0.82		0.45	0.52	0.11		

All values are shown as average ± standard deviation.

AVBHr indicates anterior vertebra body height ratio; PVBHr, posterior vertebra body height ratio; MVBHr, midline vertebra body height ratio.

SF-36 (Physical Functioning domain) improved at 51% and 59% in the patients of KIVA and BK groups, respectively ($P = 0.95$). SF-36 (Mental Health domain) improved at 34% in both groups ($P = 0.64$).

ODI scores (%) improved significantly in the patients of KIVA and BK groups (Table 3).

SF-36 (Physical Function and Mental Health domains) and ODI did not significantly correlate with residual Gardner angle kyphosis in both groups (*P*: 0.2–0.1).

DISCUSSION

VP and BK are considered the "gold standards" in the percutaneous minimally invasive surgical treatment of osteoporotic compression vertebral body fractures, and each new vertebral body augmentation technique should be compared with them.

However, incomplete fracture reduction, significant loss of reduction after balloon tamp deflation prior to cement injection, and PMMA cement leakage are usually associated with BK and VP. To avoid these drawbacks associated with VP and BK, some implants have been introduced and biomechanically and clinically tested with or without PMMA and offered promising advantages compared with classical BK.[5,24–26]

This prospective randomized study was designed to test the hypothesis that BK and KIVA augmentation techniques provide similar radiological results regarding vertebral body height and wedge deformity restoration and functional results and are associated with similar PMMA cement leakage rate. This study justified the null hypothesis of this study in that both KIVA and BK reduced significantly vertebral body height, whereas solely the KIVA implant offered significant reduction of Gardner kyphosis angle and significantly reduced PMMA leakage.

KIVA is a novel technique for percutaneous unilateral vertebral body augmentation, and a single study has been published reporting short-term results in a mixed population of patients experiencing symptomatic osteoporotic fractures and osteolytic metastases.[22]

The short-term results of this prospective randomized study in 2 homogenous randomly selected populations with patients experiencing osteoporotic fractures disclosed some radiologically important advantages of the KIVA device compared with BK: lower leakage rate and better wedge deformity correction. Instead of the inflatable balloon of BK that crushes and pushes vertebral bone to create a void for PMMA cement, KIVA implant is made of PEEK that is introduced, under the upper depressed endplate without crushing but merely penetrating the osteoporotic vertebral cancellous bone, elevating simultaneously the endplate of the fractured vertebral body. The PEEK implantation augments the fractured vertebral body and eliminates at least theoretically any immediate loss of correction that is reported immediately after deflation and removal of inflatable balloon described in BK. Subsequently, PMMA is injected through the PEEK into the vertebral body in significantly smaller amounts than in BK, with low pressure forming a cement column in the anterior and partially middle vertebral column which are usually fractured and compressed.

TABLE 3. Comparative Functional Outcome Scores KIVA *Versus* Balloon Kyphoplasty (BK) Preoperatively to 1 Year Postoperatively

	VAS			SF–36							ODI		
				PF				MH					
Group	Preoperatively	Postoperatively	*P*	Preoperatively	Postoperatively	*P*	Improvement (%)	Preoperatively	Postoperatively	*P*	Improvement (%)	Preoperatively (%)	Postoperatively (%)	*P*
KIVA	8.2 ± 1.4	2.7± 3	0.001	32 ± 11	65.8 ± 15.6	0.001	51	42 ± 10	64 ± 11	0.001	34	64 ± 19	31.7 ± 19	0.001
BK	7.8 ± 1.2	2.5 ± 3	0.001	28 ± 12	68 ± 19.8	0.001	59	41 ± 9	62 ± 9.7	0.001	34	62 ± 14	26.3 ± 15.7	0.001
Between-groups *P*		0.95			0.72				0.64				0.43	

VAS indicates visual analogue scale (1–10); PF, Physical Function; SF-36, 36-Item Short Form Health Survey; MH, Mental Health; ODI, percentage of Oswestry Disability Index; KIVA, a novel vertebral augmentation technique*; BK, balloon kyphoplasty.*

The previously reported mean kyphotic angle restoration for both VP and BK was 6.6°.[22,24–28] The authors reported that not all subjects had a reduction in kyphotic angle or restoration of height (<5° change in kyphotic angle).[22,24–27] In this study, KIVA and BK reduced kyphotic angle at an average of 5° and 6°, respectively. Previous reports showed that a mean of 34% and 39% of BK and VP interventions, respectively, did not result in an appreciable restoration of height or kyphotic angle.[22,24–27] In our series, 12% and 13% of the KIVA and BK spines showed a rest-kyphosis of more than 5° at the follow-up evaluation, which, however, did not correlate with functional outcome.

In BK and VP procedures, PMMA cement may leak laterally to the soft tissues, superiorly or inferiorly into the adjacent disc space,[29] or posteriorly, where it may involve the exiting nerve root or the spinal canal. KIVA showed lower (0.03%) leakage rate per vertebra than BK (0.098%). Although leakage was located either paravertebral or intradiscal in the KIVA patients, in the BK group there were 2 (1.6%) patients (2 vertebra) with intracanal leakage who developed acute incomplete paraplegia immediately postoperatively. The latter seems to present the most important advantage of the KIVA cement containment technique compared with BK. This significantly lower leakage rate associated with KIVA system is due to the PEEK implantation that allows directional cement delivery within the PEEK loops, which helps facilitate cement containment. The leakage rate which was associated with BK in our series was within that previously reported for BK. (0.03%–9.8%).[9,29–33]

Most previously published studies reported more new fractures after BK than VP. The reported new fractures after BK and VP varies from 11.25% to 26% in a follow-up ranging from 1 month to 2 years.[12,34–37] The rate of adjacent new fractures ranges from 18% to 90%.[12,34–37] In our study, new fractures were observed in 12.2% and 11% of patients of KIVA group and BK group, respectively. Comparing 1 *versus* multilevel BK, a previous article reported a rate of 18% new fractures, all occurred in patients with more than 1-level BK.[15]

The findings of our study compare favorably with the findings from 4 separate meta-analyses of published studies of the clinical effectiveness of BK. Specifically, our average VAS score reductions were 5.5 and 5.3 for KIVA and BK, respectively, within the mean pain reductions reported in these meta-analyses (4.6–5.6).[30,31,38,39]

The authors of a recent biomechanical study[40] compared BK and vertebral body stenting and showed that the height loss after BK balloon deflation was significantly decreased by using stenting compared with BK. Although these authors support the use of this augmentation method to avoid height loss, no mention was made regarding PMMA leakage.[40] More recently, a clinical study used vertebral body stenting for osteoporotic and metastatic fractures and reported on 22.7% of cement leakage (ventral, lateral, and intracanal) without neurological findings.[41]

Although there is currently a controversy regarding the superiority of BK and VP compared with the nonprocedural conservative treatment of fresh wedge compression fractures, most related studies supported these percutaneous augmentation techniques for immediate pain relief. Because BK restores vertebral body height and is associated with less leakage rate (than VP), we considered BK as the procedural "gold standard" comparison group in our study that compares 2 percutaneous minimal invasive surgery techniques.

To date, it could not yet be established with certainty that height gain and improved realignment are clinically relevant. There is still a lack of randomized trials focusing on long-term results in VP *versus* BK and showing a significantly better outcome due to restored spinal alignment. In this study, the rest-kyphotic deformity after BK and KIVA could not be correlated with the functional score (SF-36, ODI scores not correlated with Gardner angle) at the final follow-up evaluation.

This prospective randomized study showed that both KIVA and BK restored the osteoporotic vertebral body height, but solely KIVA implant restored the post-traumatic vertebral body wedge deformity safely and in greater amount than BK. In addition, KIVA was associated with significantly lower, always extracanal, harmless leakage rate than BK.

Based mostly on the safety in significantly reducing cement leakage, we support KIVA implant as a reliable alternative technique to BK for treating fresh (<3 mo) osteoporotic fractures. Longer observation period is necessary in order to prove whether the provided by the KIVA better radiographical reduction of post-traumatic wedge deformity, improves self-reported functional results or not.

➢ Key Points

- ❑ Both KIVA and BK restored significantly AVBHr, PVBHr, and MVBHr 12 months postoperatively.
- ❑ Only KIVA reduced the Gardner kyphotic angle ($P = 0.002$) significantly. Residual kyphosis of more than 5° was measured significantly more ($P < 0.001$) in the BK than in the KIVA spines.
- ❑ KIVA showed significantly ($P < 0.05$) lower (0.03%) extracanal PMMA leakage rate per vertebra than BK (0.098%).
- ❑ New fracture rate was similar in both groups in the short-term follow-up. Back pain scores (VAS), SF-36 (Physical Function and Mental Health domains), and ODI scores improved significantly in the patients of both groups.
- ❑ The better radiological reduction of post-traumatic kyphosis associated with KIVA may at least theoretically influence the medium- and long-term results (less back pain, less frequent adjacent segment fractures).

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