

Vertebral augmentation by kyphoplasty and vertebroplasty: 8 years experience outcomes and complications

ABSTRACT

Background and Context: Minimally invasive percutaneous vertebral augmentation techniques; vertebroplasty, and kyphoplasty have been treatment choices for vertebral compression fractures (VCFs). The purpose of this study is to evaluate the outcomes of the patients who underwent vertebroplasty or kyphoplasty regarding complications, correction of vertebral body height, kyphosis angle and pain relief assessment using visual analog score (VAS) for pain.

Materials and Methods: A retrospective review of the hospital records for 100 consecutive patients treated with kyphoplasty or vertebroplasty in our department database. Patients with osteoporotic compression fractures, traumatic compressions, and osteolytic vertebral lesions, including metastases, hemangiomas, and multiple myeloma, were included in the study. Preoperative and postoperative VAS pain scores, percentages of vertebral compression and kyphotic angles were measured and compared as well as demographic characteristics and postoperative complications. Mobilization and length of stay (LOS) were recorded.

Results: One hundred patients were treated by 110 procedures. 64 patients were operated on due to osteoporosis (72 procedures). Twelve patients were operated on because of metastasis (13 procedures), 8 patients were operated on because of multiple myeloma (9 procedures). Five patients had two surgeries, 1 patient had 3 surgeries, and 1 patient had 5 surgeries. The mean preoperative VAS was 74.05 ± 9.8 . In total, 175 levels were treated, 46 levels by kyphoplasty and 129 by vertebroplasty. The mean postoperative VAS was 20.94 ± 11.8 . Most of the patients were mobilized in the same day they of surgery. Mean LOS was 1.83 days. Six patients had nonsymptomatic leakage of polymethylmethacrylate, and patient had epidural hematoma, which was operated on performing hemi-laminectomy.

Conclusions: Percutaneous vertebroplasty and balloon kyphoplasty are both effective and safe minimally invasive procedures for the stabilization of VCFs. However, complications should be kept in mind during decision making.

Key words: Kyphoplasty; vertebral compression fractures; vertebroplasty.

Introduction

Vertebroplasty and kyphoplasty are minimally invasive procedures used in the treatment of painful vertebral compression fractures (VCFs).^[1-4] VCFs constitute a major health problem that affects more than 1.4 million people each year worldwide.^[3] Nonsurgical management may not relieve pain, frequently leads to prolonged immobilization, and may lead to pulmonary deterioration, persistent pain, progressive kyphotic deformity, weight loss, depression, and overall decrease in quality of life.^[5] Frequently seen metastatic diseases of vertebral bodies can cause pain and deformity.^[6]

The technique of vertebroplasty was originally developed by Galibert *et al.*, a French radiologist and a French neurosurgeon,

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respectively in 1984 and published in 1987,^[7] and it uses a percutaneous transpedicular approach to introduce polymethylmethacrylate (PMMA) cement into the vertebral body. Percutaneous balloon kyphoplasty is a modification of this technique, which was developed by Belkoff *et al.*^[8] Vertebroplasty and kyphoplasty can help in preventive and corrective management of VCFs of metastatic and primary oncologic diseases of vertebrae. A number of reviews have recently shown kyphoplasty to be efficacious, providing rapid pain relief, reducing need for pain medication, improving functional ability and enhancing health-related quality of life.^[2,3] This study is a retrospective analysis of the outcomes of patients who underwent vertebroplasty or kyphoplasty in our institution by the senior author in this study between 2007 and 2015. The purpose of this study is to evaluate the outcomes of the patients who underwent vertebroplasty or kyphoplasty regarding procedure complications, correction of vertebral body height, kyphosis angle, mobilization, length of stay (LOS), and pain relief procedural.

Materials and Methods

Study design and cohort

A retrospective review of the hospital records of 100 consecutive patients treated with kyphoplasty or vertebroplasty between 2007 and 2015, (110 operations). Patients who underwent vertebroplasty or kyphoplasty procedures for acute or sub-acute symptomatic vertebral wedge compression; osteoporotic compression fractures, traumatic compressions, and osteolytic vertebral lesions, including metastases, hemangiomas, and multiple myeloma, were included. Demographic characteristics, preoperative visual analog scale (VAS) scores for pain assessment, number of operated segments, percentages of vertebral compression and kyphotic angles were measured in the 1st week as control radiographs and then were compared to postoperative parallel variables.

Patient selection

The ages of patients with fractures ranged from 1 to 16 weeks and were either severely disabling or persistently symptomatic, showing no relief by means of conservative management, which consisted of activity modification, bracing (corset), and medications (nonsteroidal anti-inflammatory drugs and other analgesics) for at least 2 weeks. After diagnosing the VCF using X-ray or computerized tomography (CT), activity modification, bracing and medical management started. After 3 weeks of starting the treatment magnetic resonance imaging (MRI) studies were obtained and reviewed to assess persistence of edema in the fractured vertebra(e), which implies an acute or nonhealed state. The MRI studies were also used to evaluate other causes

of symptoms, and ensure that the middle and posterior columns were not compromised. All burst fractures were excluded. Osteoporotic fractures were carefully evaluated. Patients were classified according to pain existence period; If the pain was <1 month, conservative treatment was initiated if the patient showed no improvement of pain relief based on whether the vertebral body compression degree; vertebroplasty (>30°) or kyphoplasty (<30°) was performed. If the patients complaints were more than 1–3 months vertebroplasty or kyphoplasty was performed. If complains were more than 3 months, vertebroplasty was performed. For metastatic (multiple myeloma, carcinoma metastasis) or hemangioma, vertebroplasty was performed for vertebral compression or after transpedicular biopsy to prevent compression fractures.

Radiographic measurements

For all patients, X-ray and CT were used for diagnosis of the VCF. MRI was used to assess for the persistence of edema in the fractured vertebrae bone marrow, which implies an acute or nonhealed state, and also to evaluate the other causes of symptoms and to ensure the posterior column was intact. Different MRI sequences, T2-weighted with fat suppression and short tau inversion recovery (STIR) images were very informative, if the fracture was acute or sub-acute and associated with edema. Anteroposterior (AP) and lateral standing X-ray radiographs were done postoperatively during follow-up to measure the spinal sagittal alignment correction.

The ventral walls, mid-corpuscular body heights and kyphotic angles were measured for radiological evaluation. The kyphotic angle and vertebral body height loss was measured on lateral radiographs. The ventral and mid-vertebral heights were measured as the distance between the upper and lower end plates at the ventral wall and in the center of the vertebral body. The normal heights for the ventral wall and mid-vertebral region were defined as the sum of the measurement of the corresponding heights of the adjacent superior and inferior nonfractured vertebrae divided by two. Kyphotic angles were measured using Cobb's technique.

Surgical technique

After giving detailed information about the intervention, patient gave consent. Preoperative blood tests such as blood picture and bleeding profiles were performed. All patients were operated on under sedation and local anesthesia in a prone position, given 1 dose of a prophylactic antibiotic, cefazolin sodium (1 g). A C-arm fluoroscopy machine was used in the procedure. The fractured level is centered in both the AP and lateral projections before the skin is prepared and the patient draped. Using fluoroscopic guidance, 2 13-gauge bone biopsy needles were introduced to the ventral third

of the vertebral body bilaterally on the lateral view and reaching each side until the midline on the AP view, by using the bilateral transpedicular or extrapedicular approach for thoracic vertebra. Oblique view (approximately 20°) was also used for better visualization of the pedicle. The guide wires and working cannulas were then placed and the vertebral body was tapped. An intraoperative bone biopsy was performed as a routine step of the procedure, when needed, especially in suspicious lesions. For kyphoplasty, the balloons were then slowly inflated with dye-containing fluid to reduce the compression fracture and create a void for cement injection. Balloon inflation was done in an alternating manner between the 2 sides, under fluoroscopic imaging guidance. The inflation was stopped when the pressure exceeded 220 PSI, or if the balloon reached the endplates, or if any middle column fragment started to displace posteriorly, undetected previously in the imaging studies. The balloons were then deflated and removed from the vertebral bodies and cannulas. At this point for kyphoplasty, PMMA mixed with barium sulfate, was prepared and allowed to harden to an appropriate high viscosity and injected in the void created by the balloons. For vertebroplasty, the ventral third of the vertebrae is injected with bone filling devices till reaching the posterior one third of the vertebra, and then withdrawn. At the end a regular fluoroscopic imaging check is performed to ensure no extravasation occurs. Ideally, the cement stays in the ventral two thirds of the vertebral body and connects across the midline on the AP projection. After the procedure, patient remained in supine position for 1 h and before discharge, patients were given a soft corset for 2–4 weeks.

Patients' outcomes

Mobilization and LOS were recorded. Patients were called for routine follow-ups at 15 days for neurological assessment. At the 2nd month, routine checks were made by AP and lateral vertebral X-rays. Patients were evaluated comparing VAS preoperatively and early postoperatively and at the follow-up.

Statistical analyses

Data were presented as mean \pm standard deviation statistical analyses were performed using the Wilcoxon signed rank test according to the distribution of the data. $P < 0.01$ were considered statistically significant.

Results

Mean age was 67.81 (± 14.38). About 44 were male (44%), and 56 were female (56%). Around 100 patients were treated by 110 procedures. In total, 175 segments were treated. Nearly, 66 patients were operated on for single level, 4 patients were operated on for 4 levels in same

session. About 64 patients (64%) were operated because of osteoporotic fracture following a mild trauma or spontaneous fracture (72 procedures), 12 patients (12%) were operated on because of vertebral body metastasis (13 procedures), 8 patients (8%) were operated on because of multiple myeloma (9 procedures) [Figure 1]. Five patients had 2 surgeries, 1 patient had 3 surgeries, and 1 patient had 5 surgeries.

The mean preoperative VAS was 73.9 (± 9.7). About 171 levels were treated in 46 levels (30 procedures) kyphoplasty and 129 levels (80 procedures) were treated with vertebroplasty. The mean postoperative VAS was 20.9 (± 11.69) [Figure 2]. Mean postoperative VAS was 18 (± 9.6) in the kyphoplasty group, and 22 (± 12.2) in vertebroplasty group. There was no significant difference between kyphoplasty and vertebroplasty regarding postoperative VAS ($P = 0.220$).

The mean preoperative kyphotic angle was 16.43° (± 6.31), whereas the mean postoperative kyphotic angle was 12.83° (± 5.29) [Figure 3]. An average of 3.57° of improvement in the kyphotic angle was seen after the procedure. The mean kyphosis angle correction was 8.7 (± 2.3) in the kyphoplasty group and 1.65 (± 1.63) in the vertebroplasty group ($P < 0.001$).

The percentage of the vertebral compression improved from 27.8% (± 2.4) to 16.6% (± 1.8) after the procedure, and this was statistically significant ($P = 0.001$, paired *t*-test) [Figure 4]. The percentage of the compression corrected between kyphoplasty and vertebroplasty showed that vertebral body height correction was 15.26% (± 3.96) in the kyphoplasty group and 1.91% (± 2.05) in the vertebroplasty group ($P < 0.001$). Multilevel kyphoplasty has significantly better correction in kyphosis angle ($P < 0.001$).

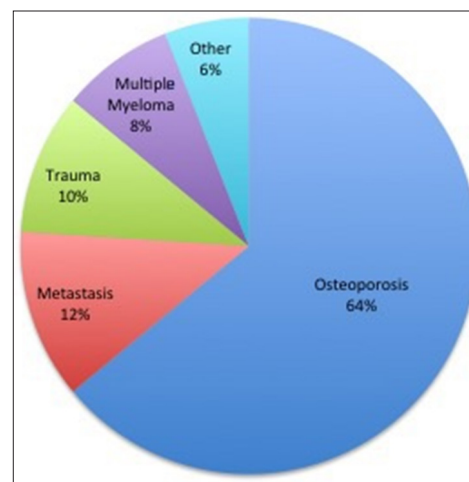


Figure 1: Etiology of vertebral compression fracture in percentage graph

Six patients had nonsymptomatic PMMA leakage, and one patient had epidural hematoma and dense paraplegia, which was operated by hemi-laminectomy as an emergency procedure after MRI showed the hematoma. For the other, 6 patients had asymptomatic intradisc space cement leakage, which was seen during the procedure, only meticulous clinical follow-up was enough. Seven patients had adjacent level compression fractures during follow-up. These 7 patients were all treated by vertebroplasty, and then all of them were re-treated again by vertebroplasty. Vertebroplasty had a higher risk for adjacent level compression fractures.

Most of the patients were mobilized in the same day of surgery representing 84% of study cohort. Mean length of hospital stay was 1.83 days [Figure 5].

Discussion

Indications and management

Vertebroplasty and kyphoplasty were used for the treatment of painful VCFs. The procedures were indicated for painful VCFs due to osteoporosis or malignancy, and for painful hemangiomas.^[6,9-11] These procedures may be efficacious

in treating painful vertebral metastasis and traumatic VCFs.^[12-15] In our study, 64 patients (64%) were operated because of osteoporotic fracture following mild trauma or spontaneous fracture (72 procedures), 12 patients (12%) were operated on because of vertebral body metastasis (13 procedures), 8 patients (8%) were operated on because of multiple myeloma (9 procedures). All patients had been diagnosed by CT scan or X-ray, then for intervention planning, MRI was done. MRI has very important role in diagnosis as Benz *et al.* confirmed that for vertebroplasty or kyphoplasty. MRI can help to differentiate acute and sub-acute from chronic fractures, as hyper-intensity in T2-weighted with fat suppression or STIR favor a good pain relief outcome especially with in the first 6 months.^[16,17] Acute and sub-acute fractures exhibit low signal intensity on T1-weighted sequences and high signal intensity on T2-weighted sequences such as STIR sequences. In addition, it is helpful to find out the underlying pathology, which causes VCF such as metastatic lesions.

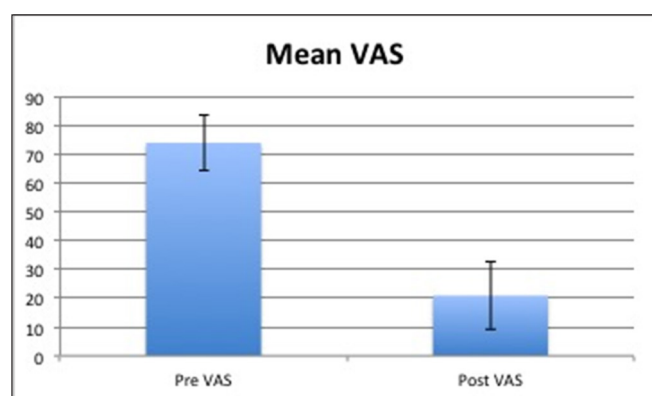


Figure 2: Preoperative and postoperative mean values of visual analog scores for pain, for all patients in study cohort

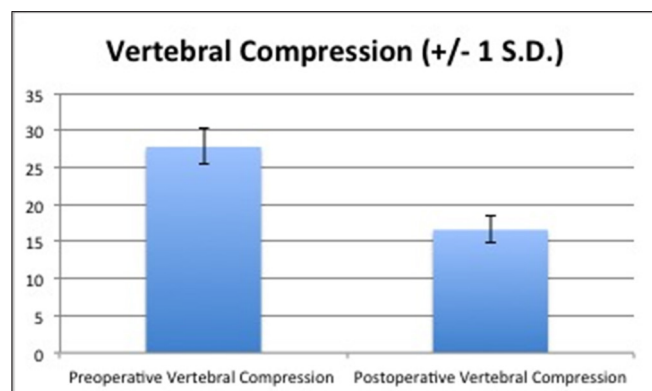


Figure 4: Preoperative and postoperative mean values of vertebral compression for all patients in study cohort

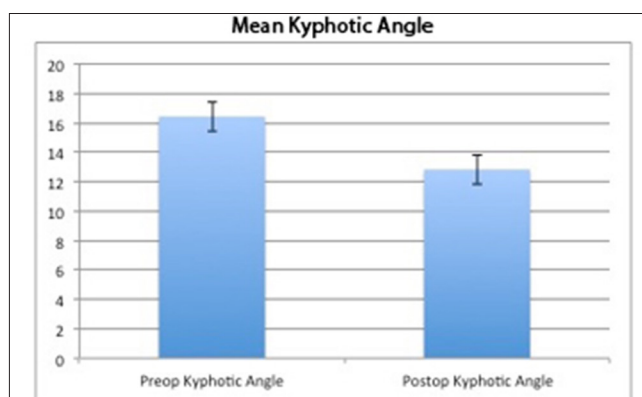


Figure 3: Preoperative and postoperative mean values of kyphotic angles for all patients in study cohort

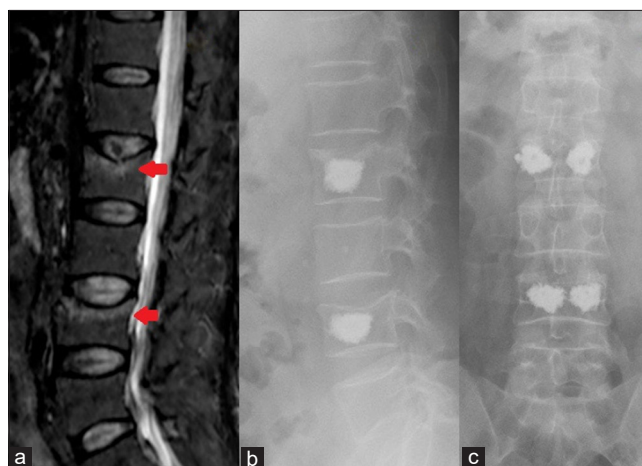


Figure 5: (a) Preoperative T2-weighted sagittal images revealed L2-L4 acute vertebral compression fracture with edema (red arrows). (b and c) Bilateral vertebroplasty for both levels were showed in postoperative anteroposterior and lateral X-rays revealed no leakage

Being a minimally invasive technique, both were effective in decreasing intraoperative blood loss in hypervascular tumors particularly in associated co-morbidities patients.^[14] In our series, all patients were operated on under sedation and local anesthesia. Local anesthesia can be a better option, especially for elderly patients.^[18]

Pain relief

In our study, preoperative and postoperative VAS scores were compared by performing the Wilcoxon test. Results were statistically better in postoperative VAS group ($P < 0.001$) in the whole study cohort. When both groups were compared, mean postoperative VAS was 18 (± 9.6) in the kyphoplasty group and 22 (± 12.2) in the vertebroplasty group. There was no significant difference between kyphoplasty and vertebroplasty regarding postoperative VAS ($P = 0.220$). In many studies, vertebroplasty and kyphoplasty are both effective in pain management, and there were not any significant differences.^[19-22] Vertebroplasty was favored by Frankel *et al.* reporting that vertebroplasty appears to offer a comparable rate of postoperative pain relief as kyphoplasty while using less bone cement more often via a unilateral approach and without the risk of adjacent level fracture,^[23] but also had statistically greater risk of cement leakage and new fracture.^[2] Taylor *et al.* reported that balloon kyphoplasty to be more effective than medical management of osteoporotic VCFs and as least as effective as vertebroplasty,^[3] which was also confirmed by Eck *et al.* that both vertebroplasty and kyphoplasty provided statistically significant improvement in VAS.^[2] Lee *et al.* reported that kyphoplasty significantly improved the degree of pain, restored the ventral vertebral height, and maintained the kyphotic angle^[24] [Table 1].

Angle correction and vertebral height correction

It was reported that kyphoplasty has better vertebral compression correction rate and kyphosis angle correction.^[20,30,33,36] When we compared kyphotic angle differences in kyphoplasty and vertebroplasty group, an average 3.57° of improvement in the kyphotic angle was seen after the procedure in both groups. Mean kyphosis angle correction was 8.7 (± 2.3) in kyphoplasty group and 1.65 (± 1.63) in vertebroplasty group ($P < 0.001$). Kyphoplasty has significantly better correction in kyphosis angle in our study [Table 1].

Mean vertebral body height restoration at 1 year follow-up was significantly higher in the kyphoplasty group in many studies.^[29,32] However, Kim *et al.* reported that under repetitive loading conditions, fractured vertebral bodies treated with kyphoplasty were initially taller, but because of a progressive loss of height during axial loading, the resulting constructs were shorter after 100,000 cycles than those treated with vertebroplasty^[37] [Table 1].

In our study, all of the procedures were bilateral. Chen *et al.* compared the patients who were treated unilaterally versus bilaterally and reported that the stiffness of nonaugmented side was statistically significantly lower than the augmented side, which might lead to an imbalance of stress on the vertebral body in unilateral group. However, when cement augmentation crosses the midline, stiffness of both sides increase comparatively and biomechanical balance is thus achieved.^[38]

Complications

The risks associated with both procedures are rare to be seen, but serious complications can occur. These risks include spinal cord compression, nerve root compression, venous embolism, and pulmonary embolism including cardiovascular collapse.^[12,39] Multiple studies showed that kyphoplasty has increased risk of adjacent level fractures and cardiac mortalities but low complication rates and leakage risk.^[19,22,27,29]

On the other hand, Röllinghoff *et al.*^[36] and Lee *et al.* reported that vertebroplasty was found to have a statistically significantly increased rate of procedure-related complications than kyphoplasty in his study.^[24] Vertebroplasty also appears to have a statistically significantly higher rate of symptomatic and asymptomatic cement leakage than kyphoplasty, which was mentioned also by Papanastassiou *et al.*^[40] [Table 1]. In our series, cement leakage and adjacent level compression risk were higher in vertebroplasty group when compared to kyphoplasty group. Of 7 patients who had adjacent level compression fractures, all of them were in the vertebroplasty group. None of the patients had superficial or deep infection in routine follow-ups.

Vertebroplasty versus kyphoplasty

Compared with conventional medical management, kyphoplasty afforded significant improvement in pain intensity and mobility,^[39] a significant reduction was observed in vertebral collapse, kyphotic deformity, the development of new vertebral fractures, and hospital stay. When kyphoplasty compared with vertebroplasty, the kyphoplasty technique reduced the loss of height, the degree of kyphotic deformity, and afforded a statistically significantly lower leakage rate more than vertebroplasty, which could be seen in our results [Table 1].

Hulme *et al.* reviewed 69 clinical studies and reported no difference between vertebroplasty and kyphoplasty on vertebral height restoration and pain relief, but cement leakage risk was less in vertebroplasty group.^[41] Ma *et al.* reported kyphoplasty may be superior to vertebroplasty in patients with large kyphotic angles, vertebral fissures, fractures in the

Table 1: Literature review of previous studies showing the results when vertebroplasty was compared to kyphoplasty

Author	Study design	Number of patients	Complications	Favored KP or VP	Height restoration percentage	Pain improvement VAS	Cement leakage
Phillips et al. 2002 ^[25]	Clinical series (prospective)	20 KP 20 VP	Cement leakage was significantly higher in VP	KP	NA	NA	Cement leakage is high in VP
Nussbaum et al. 2004 ^[26]	Meta-analysis	16,000 KP 38,000 VP	Pedicle fracture and cement leakage risk were higher in KP	VP	NA	NA	Cement leakage is high in KP
Grohs et al. 2005 ^[27]	Clinical series (prospective)	28 KP 23 VP	4 Cement leakages were noted in VP group	KP	5.8 (0-10.6) 0.0 (0.0-0.0)	Better in KP group in 1 year, after that it's similar	2 epidural, 2 segmental vessel, 4 intradiscal cement leakage
Frankel et al. 2007 ^[23]	Clinical series (retrospective)	20 KP 26 VP	Asymptomatic cement leakage in 5 patients 5 adjacent level fractures in KP group	VP	NA	Similar in both groups	Asymptomatic cement leakage in 5 patients
Zhou et al. 2008 ^[28]	Clinical series (retrospective)	42 KP 56 VP	3 cement leakages were observed in KP at the anterior border	VP-KP	0.8 5.4	Similar in both groups	3 cases had cement leakage to anterior border
Röllinghoff et al. 2009 ^[29]	Clinical series (retrospective)	90 VP/KP	2 spinal canal leakages seen in VP, 4 adjacent level fractures in VP 7 adjacent level fractures in KP	KP	Better in KP	Similar in both groups	NA
Schofer et al. 2009 ^[30]	Clinical series (retrospective)	30 KP	Cement leakage seen in 2 KP, 10 VP patient	KP	Better in KP	Similar in both groups	Cement leakage is high in VP
Hiwatashi et al. 2009 ^[31]	Clinical series (retrospective)	40 KP 66 VP	Cement leakage seen in 14 KP and 62 in VP	KP	2.2 1.8	Similar in both groups	Cement leakage is high in VP
Lovi et al. 2009 ^[4]	Clinical series (prospective)	36 KP 118 VP	Cement leakages seen in 30 in VP group	KP	7 0	Similar in both groups	Cement leakage is high in VP
Cagli et al. 2010 ^[18]	Clinical series (prospective)	64 KP 48 VP	Cement leakage in 5 KP 12 new adjacent fractures	NA	NA	Similar in both groups	Cement leakage is high in KP
Movrin et al. 2010 ^[22]	Clinical series (retrospective)	46 KP 27 VP	7 cement leakages, 3 adjacent level fractures	KP	4.9±4.5 1.5±1.7	Postoperative VAS 2.3 Postoperative VAS 2.0	7 (3 intradiscal) 4 (1 intradiscal)
Santiago et al. 2010 ^[21]	Clinical series (retrospective)	30 KP 30 VP	7 intradiscal, 2 paravertebral leakages in KP 6 intradiscal, 8 paravertebral leakages in VP	VP-KP	1.8 (statistically same) 0.5	Similar in both groups	7 intradiscal, 2 paravertebral leakages in KP 6 intradiscal, 8 paravertebral leakages in VP
Kumar et al. 2010 ^[32]	Clinical series (prospective)	24 KP 28 VP	8 cement leakage and 2 in KP group 2 adjacent level fractures in VP, 10 cement leakages	VP-KP	NA	Similar in both groups	Cement leakage is high in VP
Liu et al. 2010 ^[33]	Clinical series (retrospective)	50 KP 50 VP	2 adjacent level fractures in KP group	VP-KP	Better in KP	Similar in both groups	NA
Folman and Shabat 2011 ^[34]	Clinical series (retrospective)	31 KP 14 VP	None	KP	25 12	Similar in both groups	None
Yan et al. 2011 ^[20]	Clinical series (retrospective)	98 KP 94 VP	3 cases in KP and 9 in VP had cement leakages 22 patients had adjacent level fractures	KP	21.46 11.13	Similar in both groups	12 cases of cement leaking into the adjacent intervertebral disc (9 cases in portal venous phase and 3 cases in KP, and the rate was 9.6 vs. 3.1%, $P=0.01$)
Du et al. 2014 ^[35]	Clinical series (retrospective)	44 KP 42 VP	5 of KP, 13 of VP had cement leakages	KP	6.5 4.3	Similar in both groups	5 of KP, 13 of VP had cement leakages
Goz et al. 2015 ^[19]	Meta-analysis	225,259 KP 81,790 VP	KP had higher cardiac mortalities	KP	NA	Similar in both groups	NA

VAS - Visual analog score; VP - Vertebroplasty; KP - Kyphoplasty; NA - Not available

posterior edge of the vertebral body or significant height loss in the fractured vertebrae.^[42] Kyphoplasty can be a useful approach in patients with a ventral vertebral compression ratio of more than 70%^[43] [Table 1].

Limitations of the study

Short-term follow-up, as we believe more follow-up period, is required, especially for assessment of pain improvement and quality of life between the two groups. Small number

of patients in the study cohort, which may be affected the significance of many variables were studied.

Conclusions

Good patient selection for kyphoplasty showed better correction rates and lower risk of cement leakage and adjacent level fractures than vertebroplasty. However, both techniques have shown effectiveness in terms of pain relief. The complication rates for both were very low, but they could be serious and should be closely monitored, especially in the first 6 h after the procedure.

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Conflicts of interest

There are no conflicts of interest.

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