Vertebroplasty versus kyphoplasty: a comparative study of safety and cost-effectiveness and tips to improve outcomes of vertebroplasty

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Background
Vertebroplasty (VP) has been found to be effective in treating persistent pain resulting from osteoporotic vertebral fractures. It brings rapid and significant pain relief but shows high rates of cement leakage (CL) and does not restore lost vertebral height. Kyphoplasty (KP) can partially restore vertebral height with minimal risk for CL but is very expensive, time consuming, and exposes surgeons to higher radiation risk.
Patients and methods
Thirty-one patients who underwent either VP or KP were included in the study. VP technique was refined to minimize complications and maximize outcome. VP was performed unipedicularly, whereas KP was performed usually bipedicularly (except for two patients). Pain relief and functional outcome were evaluated using the Visual Analogue Scale and the Oswestry Disability Index. Radiographs were used to evaluate CL, vertebral height restoration, and cemented vertebral body fraction.
Results
Twenty patients underwent VP and 11 patients underwent KP. The mean duration was 45.5 and 70.9 min for VP and KP, respectively. The mean number of C-arm images was 46 and 163 images for VP and KP, respectively. The mean reduction in Visual Analogue Scale was 7.2 and 7.6 points for VP and KP, respectively. The mean reduction in the Oswestry Disability Index was 66.3 and 72.1 points for VP and KP, respectively. The mean regain in vertebral height was 19.7 and 42.5% after VP and KP, respectively. Symptomatic adjacent level fractures occurred in two VP patients and one KP patient.
Conclusion
KP is more effective compared with VP in terms of vertebral height restoration, but is very expensive, time consuming, and entails more radiation exposure to surgeons compared with VP. Both techniques are equally effective as regards pain relief. CL can be minimized by refining VP technique.

Keywords:
kyphoplasty, vertebral augmentation, vertebral compression fractures, vertebroplasty

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Introduction

Osteoporotic vertebral compression fracture (VCF) is a common presentation in outpatient clinics and emergency departments. They affect 25% of postmenopausal women and up to 40% of women aged 80 and older, whereas its prevalence is less common in older men [1–3].

Although two-thirds VCF patients will gradually improve with conservative treatment [4], patients will still have an increased risk for early and late morbidity, including decreased activity, increasing kyphosis, adjacent level fractures (ALFs), pulmonary dysfunction, withdrawal from society, and depression [1–5].

Vertebral augmentation (VA) procedures using poly-methyl-meth-acrylate (PMMA) have been shown to be useful in treating refractory pain after VCFs. Although VA techniques such as vertebroplasty (VP) and kyphoplasty (KP) have been suggested to decrease the duration of early confinement to bed and to improve short-term and long-term results, controversy still exists in the literature about which technique is safer and more efficient [1,3,6–10].

VP was described to treat pain, restore patient mobility, and prevent further vertebral collapse [11,12]. KP was designed to restore the vertebral height using inflatable balloon tamps. This was assumed to elevate the end-plate with compression of cancellous bone around the inflated tamp, which can minimize the kyphotic deformity and cement leakage (CL), respectively [13].

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In Egypt, the high cost of KP became an obstacle to popularizing KP use. This urged the authors of the current study to modify and refine their VP technique and to compare between VP and KP as regards clinical improvement, vertebral height restoration (VHR), complication rates, and cost-effectiveness.

Patients and methods

Between January 2008 and January 2011, 31 patients underwent cemented VA using PMMA after presenting with subacute/chronic pain due to osteoporotic VCFs. This study approved by the Ethical committee of Department of Orthopedic and Spinal Surgery, Faculty of Medicine, Ain Shams University, Cairo, Egypt. All patients were refractory to brief periods of bed rest, Miacalcic 100 IU daily injections, and potent analgesics for at least 3 weeks. Diagnosis was confirmed using radiographs, computed tomography (CT) scans, and MRI. The target vertebra was localized according to site of pain and tenderness, collapse on lateral radiographs, and edema on MRI sagittal images.

Technique

VA was performed under local anesthesia and intravenous conscious sedation (for VP) or under general anesthesia (for KP) under intravenous antibiotic coverage. Patients were positioned prone keeping a hyperlordotic attitude. Radiography guidance using C-arm was used throughout the procedure (Fig. 1).

Through a 0.5 cm stab incision, a stylet was used to feel the margins of the transverse process, and then it was moved medially until the facet joint. Bilateral stylets were inserted for KP and a unilateral stylet (with higher medial inclination) for VP was inserted on the more collapsed side. In VP, the stylet was advanced short of the anterior one-fourth of vertebra. In KP, the stylets were replaced with wider cannulae (over K wires) followed by drill bit application to drill tracks for the bone tamps. The balloon tamps were then introduced bipedicularly (unipedicularly in two cases) until the markers reached within 5 mm from the anterior cortex. The balloons are inflated simultaneously (with a radio-opaque dye) to create voids and elevate the endplate if possible while pressure on the pump monitor was observed. C-arm images were used to assess height restoration if any. The balloons were then deflated and removed (Figs. 2 and 3).

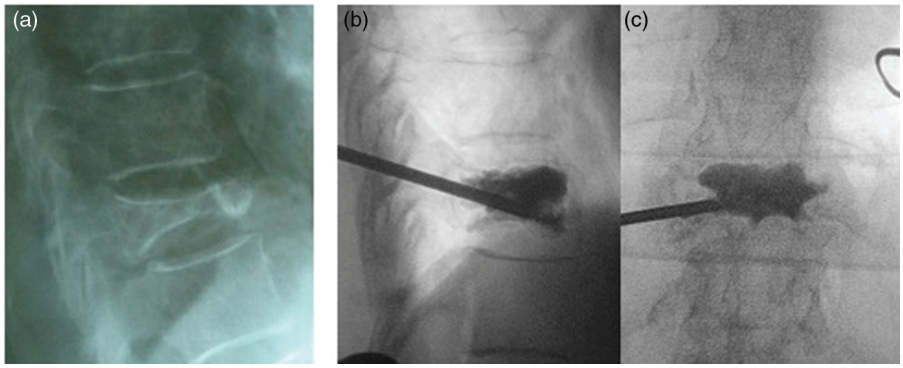
During VP, the fluid and powder were divided into two identical portions using graduated plastic syringes, and the first portion was mixed for unipedicular VP. Cement was not injected until having tooth-paste-like consistency or even heavier to minimize leakage and embolism. Regardless of the integrity of the posterior cortex, the injection was stopped when cement reached the posterior fourth of the vertebral body. On the anteroposterior (AP) view, if cement did not reach the contralateral third of the vertebral body, another stylet was inserted through the contralateral pedicle and the second cement portion was used.

The PMMA cement used was specific for VA. It had lower viscosity and longer setting time as well as higher content of barium-sulphate (at least 22%) when compared with the traditional bone cement used in arthroplasty.

Postoperative evaluation

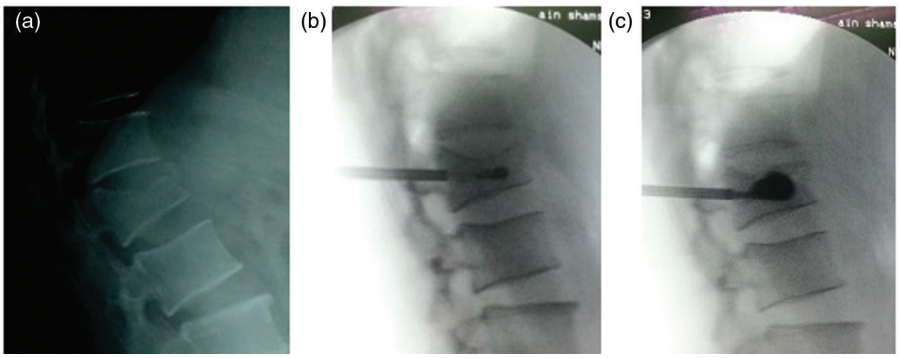
Postoperative evaluation included Visual Analogue Scale (VAS) for pain relief, plain radiographs for the assessment of VHR, and CL and symmetrical cement distribution within the vertebra (Fig. 4). Patients were discharged within 36 h of the procedure with oral analgesics and antibiotics (for 3–5 days) and

Figure 1



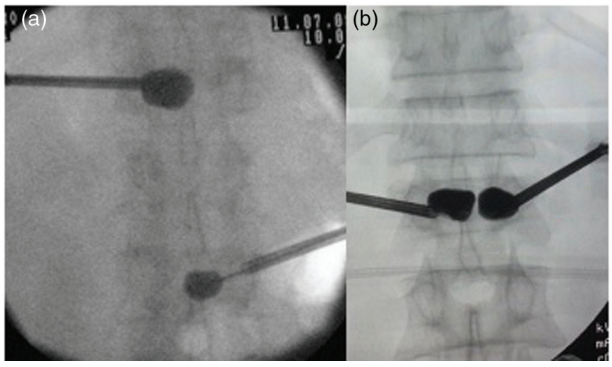
(a) Collapsed vertebral body. (b) Same vertebra after positioning in hyperlordosis with partial height restoration followed by cement injection. (c) Cement filled body symmetrically despite unipedicular injection.

Figure 2



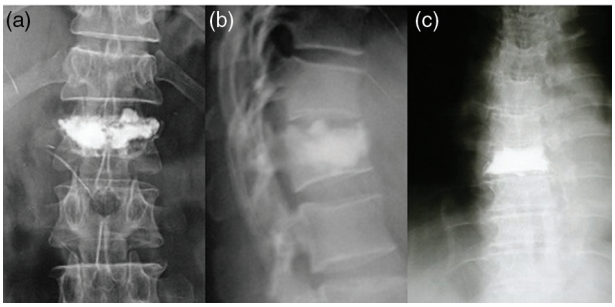
(a) 50% collapse of vertebral body height. (b) Balloon tamp inserted before inflation. (c) Balloon tamp inflated with elevation of the anterior part of the fractured endplate.

Figure 3



(a) Unipedicular kyphoplasty (KP) for two nonadjacent VCFs. (b) Bipedicular KP for a single level KP.

Figure 4



(a, b) Postoperative anteroposterior (AP) radiography of kyphoplasty showing intradiscal cement leakage. (c) Postoperative AP radiography showing symmetrical cement distribution after unipedicular vertebroplasty.

osteoporosis medications. They were referred for physiotherapy for back muscle strengthening and postural/balance training for 8 weeks.

Follow-up visits were scheduled at the end of second week when a Becker muscular dystrophy (BMD) Dual-energy X-ray Absorptiometry (DEXA) scan was performed if not previously carried out. Later follow-up visits were scheduled at 6, 12, and 18 months. The VAS and the Oswestry Disability Index were used for pain and functional assessment at 6 months. Radiographs were performed every 6 months.

Results

Twenty patients underwent VP, whereas 11 patients underwent KP. There were 21 female and 10 male patients with variable comorbidities (Table 1). The mean duration from time of VCF until VA was 24.4 (range: 3–42) weeks. The mean duration of a single level procedure was 45.5 (range: 35–75) min and 70.9 (range: 50–85) min for VP and KP, respectively ($P<0.05$). The mean number of radiographs images taken was 46 (range: 32–56) images and 163 (range: 120–201) images for VP and KP, respectively. The mean duration of hospital stay was 22.4 (range: 8–30) h and 24.5 (range: 7–32) h for VP and KP, respectively ($P>0.05$). The mean duration of follow-up period was 10.3 (range: 4–19) months for both groups.

All patients showed early significant pain relief and regained ambulation and ability to sit and turn in bed without significant pain within the first 24 h after either procedure. The mean reduction in VAS was 7.2 (range: 5–7.5) and 7.6 (range: 4.5–8) points for VP and KP, respectively ($P>0.05$). The mean reduction in the Oswestry Disability Index was 66.3 (range: 40–78) points and 72.1 (range: 58–84) points for VP and KP, respectively ($P<0.05$). The mean reduction in analgesic dose (within 2 weeks) was 72.5 and 79.1% for VP and KP, respectively ($P>0.05$).

Comparison of preoperative and postoperative lateral view radiographs showed that the mean regain in vertebral height was 19.7 (range: 0–40)% and 42.5

Table 1 Patients' demographics and comorbidities

	Number of patients	Sex distribution	Comorbidity (controlled)	Number of VCFs mean/patient
VP	20	14 female and 6 male	3 hepatic, 1 renal, 4 diabetic, 5 hypertension	Total=28Mean=1.4 (1–3)
KP	11	7 female and 4 male	2 diabetic, 2 hypertension	Total=15Mean=1.4 (1–3)
Total	31		17/31 with comorbidities	43 vertebrae

KP, kyphoplasty; VCF, vertebral compression fracture; VP, vertebroplasty.

(range: 10–65)% after VP and KP, respectively ($P<0.05$). This was calculated based on the average of vertebral body height of the adjacent two vertebrae. Radiographs (AP/lateral) showed a mean cemented vertebral body fraction (CVBF) of 58 and 52% for VP and KP, respectively ($P>0.05$). Symptomatic ALFs occurred in two VP patients and one KP patient ($P>0.05$) and they all occurred within 8 months of VA and were treated conservatively.

Discussion

VP was the first type of VA introduced to treat refractory pain resulting from osteoporotic VCFs [14], after being primarily used in 1980 to treat vertebral angiomas causing back pain [14,15]. It has demonstrated success but often with worrying complications [7,16,17]. With time, VP underwent marked evolution to minimize complications such as cement extravasation and/or embolization [14]. In VP, PMMA is injected at a relatively high pressure due to the minimal void present for cement injection [18]. KP theoretically elevates the endplates and restores some lost height. Cement is then injected at a much lower pressure [14]. This reduces the risk for CL [19].

Vertebral augmentation versus conservative treatment

In 2009, two sham-controlled studies [20,21] questioned the effectiveness of VP in treating VCFs. As a result, VP and KP use declined by 10% [3]. In 2010, VERTOS II randomized trial [22], which met strict criteria – pain for less than 6 weeks, VAS score greater than or equal to 5, and edema on MRI – showed that VA patients had significantly better pain control at 1 month and 1 year (VAS reduction higher by 2.3) [22]. Other randomized controlled studies showed marked pain relief on short-term and long-term basis after VP and KP with a much lower incidence of new VCFs after 2 years [23,24]. A delay of a year was seen as a cause of the absence of VA benefit in the studies of Buchbinder *et al.* [20] and Kallmes *et al.* [21].

Vertebroplasty versus kyphoplasty

Although the indications for VP and KP are similar [25], KP ought to be safer when the integrity of vertebral body cortex is questionable [26,27]. Moreover, as most VA complications are related to CL, many surgeons preferred KP to VP. Furthermore, the belief that KP can restore vertebral body height and thus reduce refracture risk makes it more attractive [26,28–31]. As a result, KP use showed considerable growth from 2004 to 2008, whereas VP use remained relatively stagnant. This discrepancy lacked sound clinical basis as there was conflicting evidence as to which procedure is safer [3].

Clinical outcome: pain relief and vertebral height restoration

There has been only one randomized controlled study comparing VP with KP for osteoporotic VCFs. Liu *et al.* [32] reported that in VCFs treated within 6 months using either technique, there was excellent analgesic effect with no significant difference. A reduction in the kyphosis angle was observed in both groups, but it was significantly greater in the KP group. More PMMA was injected in KP than in VP (5.6 vs. 4.9 ml). After 6 months, two new VCFs occurred in the KP group [32]. However, three case series comparing VP with KP [10,33,34] showed that less PMMA was injected in KP than in VP (3.2 vs. 3.5 ml).

Buchbinder *et al.* [20] reported that the quantity of cement injected per vertebra was 2.0±1.2 ml. Some case series reported that the mean CVBF was significantly smaller in weak responders than in those with pain relief (15 vs. 21%), being a more important parameter compared with the amount of injected cement [20]. However, injecting a bigger volume of PMMA increases the risk for CL, embolism, and ALFs [35,36].

VHR after KP, even if partial, suggests an increased quality of life (less kyphosis and less ALFs). The case series initially published were all very encouraging, but the results of recent randomized studies have been very mixed.

Complications

Complications after VA include CL, ALFs, and cardiopulmonary complications, and their risk was found to be 3.9 and 2.2% after VP and KP, respectively. CL is much less frequent with KP than with VP and it occurs in 70% of patients regardless

of the procedure [19,37,38]. In VERTOS II, asymptomatic pulmonary embolisms were detected through chest CT screening in 25% of patients. CL into the azygos vein was the only risk factor identified for pulmonary embolism [39].

The risk for new VCFs was not analyzed in the first few studies on VP/KP because VCFs were in themselves a strong risk factor for refracture. Recent studies reported that new VCF risk was 20–24%, 50–70% occurred adjacent to VA, 60–70% occurred within 2 months after VA, and that adjacent ones occurred earlier than nonadjacent ones (58 vs. 127 days).

The incidence of late ALFs is commonly reported as higher after KP, but some studies report otherwise. Degree of osteoporosis and altered biomechanics are better than VA type as predictors of ALFs. Reported incidences of ALFs after VP range from 4.2 to 13.5% and that after KP range from 6.5 to 36%. Although CL statistics indicate KP as the safer procedure, most studies of ALFs suggest otherwise [3].

In 2011, the American Academy of Orthopaedic Surgeons strongly recommended against VP use in neurologically intact patients with VCFs. They weakly recommended KP as an alternative, which was a reflection of inconsistent results in studies comparing KP and VP [40]. With more proper patient selection criteria and surgeons getting more experienced, complication rates (e.g. CL) became less frequently reported in more recent studies.

Cost-effectiveness

Few cost-effectiveness analysis studies have been conducted, and all are in favor of VP or KP compared with conventional treatment [6]. The results of cost-effectiveness analyses comparing VP with KP have not shown much difference in terms of pain relief, functional benefits, or risks for refracture rates. KP limits vertebral height loss and kyphosis, but has no effect on clinical results after 1 year of VA. Nevertheless, it remains extremely expensive when compared with VP (seven to eight times the cost).

Refining our technique

Before 2008, we have performed many VPs. Our experience showed marked patient satisfaction with low complication rates. Nevertheless, radiographic CL and lack of VHR were of concern. We considered shifting to KP but the elevated cost represented an obstacle. This urged us to modify and refine our technique of VP to approach the results of KP.

Hyperlordotic position was observed to distract the vertebral endplates apart if any mobility existed. Soft pillows under the thighs and chest with the hips extended were used.

During VP, the stylet was more convergent to increase the CVBF and minimize asymmetrical cementation, which could increase pain relief and decrease refracture risks. Satisfactory CVBF indicated that cement has reached the contralateral third of vertebral body.

In KP, we used the bipedicular approach in all but two cases in which we used a unipedicular approach. The mean duration of KP was at least 1.6 times that of VP, and the mean radiation exposure was at least 3.5 times that of VP. We assume that using unipedicular approach for KP will be more economic and time saving but the unavailability of single KP balloon kit may be an obstacle. Nevertheless, unipedicular KP can be performed in patients with multilevel fractures.

Sometimes during VP, cement is injected in a low viscosity state to allow more time for multilevel/bipedicular injections. This increases the risk for CL. We divided the fluid and powder into two portions using graduated plastic syringes and one portion is initially mixed. This maneuver allowed time for delayed cement injection with higher viscosity. When unipedicular VP is found to be unsatisfactory (low CVBF on AP view), a contralateral pedicle stylet can be applied and the second portion can be mixed.

In some VCFs, posterior cortical breaching was expected or confirmed with CT. Cement injection was delayed and was stopped when reaching the posterior fourth of the vertebral body.

In our study intradiscal cement leakage occurred irrespective of the VA procedure. It was more related to a pre-existing fracture of the endplate.

We referred our patients for physiotherapy for postural/balance training and back muscle strengthening. We believed that good posture and low frequency of falls can reduce ALFs and even improve patient satisfaction. All patients received medical treatment for osteoporosis. Physiotherapy and osteoporosis treatment are important contributors to the low incidence of new VCFs [three (10.7%) patients].

Conclusion

The authors conclude that both VP and KP are effective procedures that can treat refractory pain after osteoporotic

VCFs. When patient selection criteria are respected, the outcomes are at least good to excellent, and complications are minimal. Osteoporosis treatment together with back muscle rehabilitation and balance training programs can significantly improve outcomes and minimize the eminent risk for ALFs. KP is relatively more beneficial compared with VP. Nevertheless, when VP technique is refined, it can compete with KP as regards radiological and clinical outcomes, patient safety, and, most of all, financial burdens. Trials that use unipedicular KP are needed in a step toward lowering its cost.

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Nil.

Conflicts of interest
There are no conflicts of interest.

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