

Balloon kyphoplasty versus vertebroplasty for treatment of osteoporotic vertebral compression fracture: a prospective, comparative, and randomized clinical study

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Abstract

Summary Bone pain and spinal axial deformity are major concerns in aged patients suffering from osteoporotic vertebral compression fracture (VCF). Pain can be relieved by vertebroplasty or kyphoplasty procedures, in which the compressed vertebral body is filled with substitutes. We randomly assigned 100 patients with osteoporotic compression fracture at the thoraco-lumbar (T-L) junction into two

groups: vertebroplasty and kyphoplasty; we used polymethylmethacrylate (PMMA) as the bone filler. Pain before and after treatment was assessed with visual analog scale (VAS) scores and vertebral body height and kyphotic wedge angle were measured from reconstructed computed tomography images. More PMMA was used in the kyphoplasty group than in the vertebroplasty group (5.56 ± 0.62 vs. 4.91 ± 0.65 mL, $p < 0.001$). Vertebral body height and kyphotic wedge angle of the T-L spine were also improved ($p < 0.001$). VAS pain scores did not differ significantly between the treatment groups. The duration of follow-up was 6 months. Two patients in the kyphoplasty group had an adjacent segment fracture. In terms of clinical outcome there was little difference between the treatment groups. Thus, owing to the higher cost of the kyphotic balloon procedure, we recommend vertebroplasty over kyphoplasty for the treatment of osteoporotic VCFs.

Introduction Spinal axial deformities are major concerns in aged patients suffering from osteoporotic vertebral compression fracture. Pain may be relieved by vertebroplasty or kyphoplasty. We investigated the radiological and clinical outcomes of these procedures.

Methods One hundred cases of VCF at the thoraco-lumbar junction were randomly assigned into two groups: vertebroplasty or kyphoplasty (50 cases each). We used polymethylmethacrylate as the bone filler. Pain before and after treatment was assessed with visual analog scale scores and vertebral body height and kyphotic wedge angle were measured from reconstructed computed tomography images.

Results More PMMA was used in the kyphoplasty group than in the vertebroplasty group (5.56 ± 0.62 vs. 4.91 ± 0.65 mL, $p < 0.001$). Vertebral body height and kyphotic wedge angle of the T-L spine were also improved ($p < 0.001$). VAS pain scores did not differ significantly between the treatment groups. The duration of follow-up was

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6 months. Two patients in the kyphoplasty group had an adjacent segment fracture.

Conclusions In terms of clinical outcome there was little difference between the treatment groups. Thus, with the higher cost of the kyphotic balloon procedure, we recommend vertebroplasty over kyphoplasty for the treatment of osteoporotic VCFs.

Keywords Bone cement · Kyphoplasty · Osteoporosis · Prospective comparative randomized clinical trial · Vertebral compression fractures · Vertebroplasty

Introduction

Osteoporotic vertebral compression fractures (VCFs) constitute an important public health concern. During the last decade, two new treatments for osteoporotic VCFs have gained considerable credibility: percutaneous vertebroplasty and balloon kyphoplasty. Initially reported in 1987, vertebroplasty involves the destruction of an angioma through consolidation of the vertebral column by percutaneous injection of acrylic cement (most commonly polymethylmethacrylate/PMMA) [1]. Kyphoplasty involves the use of an inflatable bone tamp that when introduced into the vertebral body restores vertebral height and forms a space into which acrylic cement can be injected [2, 3]. However, it is currently unknown if either of vertebroplasty or kyphoplasty provides a better treatment outcome than the other.

The technical procedures, and the short-term clinical outcomes and complications, of vertebroplasty and kyphoplasty have been documented. However, there is little scientific data regarding the efficacy of these treatments. Such data may be generated with randomized controlled trials [4], but thus far there have only been prospective and retrospective uncontrolled short-term observational and case-control studies [5–7]. These studies have consistently shown favorable short-term outcomes of vertebroplasty and kyphoplasty, in terms of both pain relief and functional status. However, whether one of these treatments provides a better outcome than the other and whether the long-term outcomes are as favorable as the short-term outcomes remains unclear [6]. Moreover, fractured vertebrae treated with bone cements are stiffer than untreated vertebrae and may consequently transfer greater load to adjacent vertebral levels [8, 9]. Thus, there is concern that these procedures could lead to a heightened rate of subsequent VCFs [10, 11].

To our knowledge, there have been few reports comparing balloon kyphoplasty and percutaneous vertebroplasty for treating osteoporotic VCFs. We hypothesized that there may be different radiological outcomes or prognoses (such as pain relief or new compression fractures) between these treatments. With a prospective, comparative, and randomized

clinical study design, we compared 50 VCF patients receiving kyphoplasty with 50 VCF patients receiving vertebroplasty. Both pain relief and clinical outcomes were investigated.

Methods

Patients

The study was approved by the local Institutional Review Board. All patients provided informed written consent before participating. One hundred patients with confirmed osteoporotic VCF at the thoraco-lumbar (T-L) junction (T12–L1) were enrolled and randomly assigned (by permuted block randomization) to either a kyphoplasty or vertebroplasty group ($n=50$ in each). The kyphoplasty group was treated with the balloon kyphoplasty procedure and the vertebroplasty group with percutaneous vertebroplasty. The mean age of patients was 72.3 ± 7.6 years (57–88) in the kyphoplasty group and 74.3 ± 6.4 years (57–84) in the vertebroplasty group. Males comprised 23% of all patients (11 in the kyphoplasty group and 12 in the vertebroplasty group). Kyphoplasty or vertebroplasty was performed within 43 days of injury, with the mean duration between injury and surgery being 17.0 ± 7.7 and 15.8 ± 6.7 days, respectively. Measurements of vertebral body height and kyphotic wedge angle (to evaluate kyphosis), and pain, on a 10-point visual analog scale (VAS), were made pre- and post-operatively. Radiographic measurements were made by technicians “blind” to treatment group status, with variability controlled via inter- and intra-observer comparisons. The operation time and amount of the bone cement polymethylmethacrylate used were also recorded. The minimum follow-up period was 6 months. There were no significant differences between the treatment groups with regard to the demographic data obtained (including mean age, gender, location, and duration between injury and surgery); see Table 1.

Operating technique

The indication for balloon kyphoplasty or percutaneous vertebroplasty was the same [12]. The surgical procedures involved IV general anesthesia (Propofol) plus 2% xylocaine injected locally. A special bone biopsy needle (Angiotech, USA) was passed percutaneously and slowly through each side of the pedicle into the vertebral body. The bone filler PMMA (Zimmer) was prepared and mixed with both an antibiotic (gentamicin), to reduce the risk of infection, and a powder containing barium, allowing X-ray visualization. An optimal amount of bone filler was injected into the vertebral body via the needles on both sides. All procedures were performed under a mobile C-arm X-ray. Kyphoplasty was performed under the same anesthetic protocol as

Table 1 Patient demographic data of both kyphoplasty and vertebroplasty groups

	Kyphoplasty (<i>n</i> =50)	Vertebroplasty (<i>n</i> =50)	<i>p</i> value	Power ($\alpha=0.050$)
Age (years)	72.3±7.6	74.3±6.4	0.163	0.159
Gender (male/female)	11/39	12/38	–	–
Location (T12/L1)	19/31	19/31	–	–
Duration between injury and surgery (days)	17.0±7.7	15.8±6.7	0.405	0.050
Operation time (minutes)	46.2±4.5	44.0±4.4	0.015*	0.607
Amount of PMMA (mL)	5.56±0.62	4.91±0.65	<0.001*	1.000

Data are expressed as *n* or mean±SD

PMMA polymethylmethacrylate

**p*<0.05

vertebroplasty. Using image guidance X-rays, two small incisions were made and a probe was placed into the vertebral space at the fracture site. The bone was drilled and a balloon (VCF-X Central Medical Tech., Taiwan), called a bone tamp, was inserted on each side. The balloons were then inflated with contrast medium (to facilitate image guidance X-rays) and expanded to the desired height and removed. The spaces created by the balloons were then filled with PMMA (prepared as for vertebroplasty) to bind the fracture. All patients undertook an orally administered treatment regimen to protect their bone density after surgery.

Statistical analyses

Data are expressed as mean±SD. Independent data, including age, duration between injury and surgery, operation time, vertebral body height, amount of PMMA used, and kyphotic wedge angle, were compared between treatment groups with Student's *t*-tests. Pre- and post-operative vertebral body height and kyphotic wedge angle were evaluated with paired *t*-tests. Ranking data, including the VAS scores, were compared across groups using Mann–Whitney *U* tests. Wilcoxon signed-rank tests were used to compare pre- and post-operation ranking data. A value of *p*<0.05 was considered statistically significant.

Results

Table 1 presents demographic data and clinical characteristics for both treatment groups. The kyphoplasty and vertebroplasty groups did not differ significantly in age, gender distribution, location of osteoporotic VCFs, duration between injury and surgery, pre-operative VAS pain score, vertebral body height, or kyphotic wedge angle. Compared to the vertebroplasty group, the kyphoplasty group required a longer operation time (46.2±4.5 vs. 44.0±4.4 min, 1.05-fold, *p*<0.05) and a greater amount of PMMA (5.56±0.62 vs. 4.91±0.65 mL, 1.13-fold, *p*<0.001; Table 1). Two

patients in the kyphoplasty group had adjacent segment fractures: one patient had a fracture at T11 (41 days after surgery) and the other had a fracture at L2 (50 days after surgery).

Pre-operative vertebral body height was 1.13±0.34 cm in the kyphoplasty group and 1.01±0.22 cm in the vertebroplasty group. The post-operative vertebral body height in the kyphoplasty and vertebroplasty groups was 2.04±0.41 cm (*p*<0.001) and 1.32±0.26 cm (*p*<0.001), respectively (Fig. 1). The pre-operative kyphotic wedge angle was 17.0±7.3° in the kyphoplasty group and 15.5±4.2° in the vertebroplasty group. The post-operative kyphotic wedge angle in the kyphoplasty and vertebroplasty groups was 9.0±5.7° (*p*<0.001) and 12.2±3.6° (*p*<0.001), respectively (Fig. 2). The post-operative increase in vertebral body height and reduction in kyphotic wedge angle were both greater in the kyphoplasty group than in the vertebroplasty group (*p*<0.001).

For the kyphoplasty group, the VAS pain score was 8.0±0.8 prior to surgery, decreased to 2.6±0.6 (*p*<0.001) in the post-operative period (3 days), and remained at 2.6±0.6 (*p*<0.001) at the final follow-up (6 months). Similarly, for the vertebroplasty group, the VAS pain score was 7.9±0.7

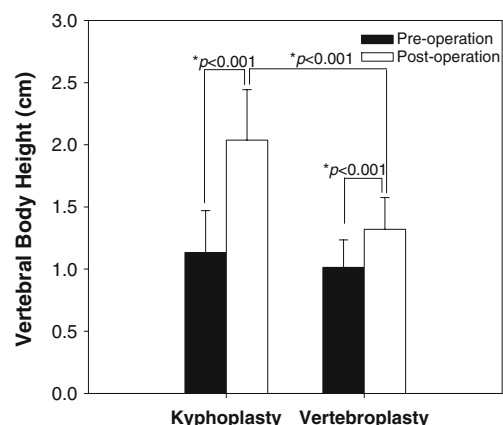


Fig. 1 Vertebral body height before and after kyphoplasty and vertebroplasty. Data are expressed as mean±SD (**p*<0.001)

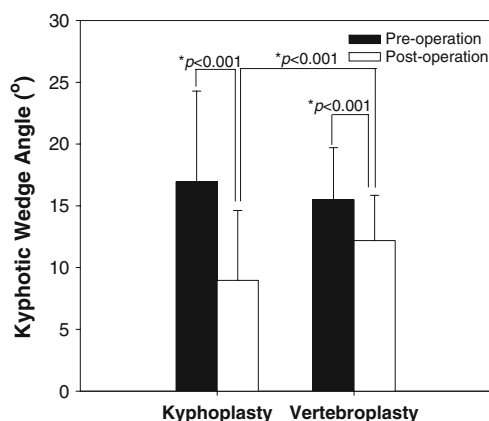


Fig. 2 Kyphotic wedge angle before and after kyphoplasty and vertebroplasty. Data are expressed as mean±SD (* $p<0.001$)

prior to surgery, decreased to 2.3 ± 0.5 ($p<0.001$) in the post-operative period (3 days), and was 2.6 ± 0.6 ($p<0.001$) at the final follow-up (6 months). There was no statistical difference in VAS pain scores between the treatment groups at any stage from the pre-operative period, through the post-operative period, to the final follow-up (Fig. 3).

Discussion

Vertebroplasty and kyphoplasty provide significant relief to patients with painful VCFs related to osteoporosis, multiple myeloma, hemangioma, or metastases [4]. Unfortunately, much of the current literature reports retrospective and case studies. There are limited data comparing balloon kyphoplasty versus vertebroplasty [4, 10, 13–16]. The present study independently performed a prospective, comparative, and randomized clinical study to determine the effectiveness of vertebroplasty and kyphoplasty in treating symptomatic VCFs as well as to assess some clinical outcomes.

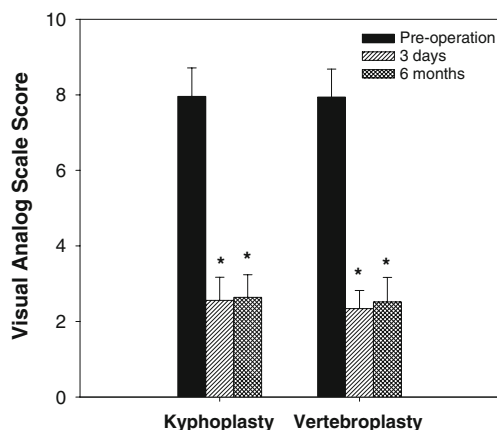


Fig. 3 Pain outcomes (VAS scores) before and after (3-day and 6-month) kyphoplasty and vertebroplasty. Data are expressed as mean±SD. Statistically significant improvements were identified for both procedures (* $p<0.001$ compared to pre-operation)

A wedge-shaped compression fracture shifts the center of gravity of the upper body anteriorly and is generally compensated for in the spine and hips. However, it is unclear how a wedge-shaped compression fracture of a vertebra increases both forces in the trunk muscles and intradiscal pressure in adjacent discs [17]. Both kyphoplasty and vertebroplasty can restore vertebral body height and kyphotic wedge angle [18]. This is in accordance with clinical studies that have shown increased height after treatment with either vertebroplasty [19–21] or kyphoplasty [2, 12]. In the present study, we found that kyphoplasty restored vertebral body height more often than vertebroplasty. This is consistent with previous results showing kyphoplasty to have a superior capability for restoring vertebral body height [22]. It is likely that the use of a balloon to expand the center of the vertebral body to create a void into which cement is injected helps restore vertebral body height. In a clinical setting, vertebroplasty has been shown to reduce wedge angle by 7.4° [21]; a 4° – 10° reduction in wedge angle after kyphoplasty has been shown [23, 24]. Our results were an 8.0° reduction in wedge angle after kyphoplasty and a 3.3° reduction after vertebroplasty ($p<0.001$).

In comparison to vertebroplasty, kyphoplasty has a potential advantage in that it may partially reestablish vertebral height and thereby restore stability to the spine [25, 26]. There has been no study assessing the extent to which the amount of height correction and degree of improvement in spinal stability are correlated [5].

Our data show that both vertebroplasty and kyphoplasty were effective in reducing pain, as measured with VAS pain scores. The percentage improvement in VAS pain scores was 67.8% after kyphoplasty and 70.5% after vertebroplasty. There was no statistically significant difference in pain scores between the vertebroplasty and kyphoplasty groups. A recent meta-analysis study had showed that vertebroplasty shows a significantly greater improvement in pain scores. Although the greater improvement achieved with vertebroplasty did reach statistically significant values, there was no clinically significant difference in pain outcomes between the treatment types [4]. Moreover, two other meta-analyses comparing vertebroplasty and kyphoplasty have each shown statistically significant improvements in VAS pain scores after both treatments [10, 13]. Patients experience an immediate improvement in quality of life when their pain is reduced [27], these data suggest that similar clinical benefits could be achieved with either treatment procedure.

Although there were significant improvements in pain after both vertebroplasty and kyphoplasty, there were also multiple complications reported. Two patients in the kyphoplasty group of our study had an adjacent segment fracture. This reflects the findings of a previous study for there is an increased risk of new VCF adjacent to level with increased height restoration after vertebroplasty [28].

Because of the superior height restoration achieved with vertebroplasty, new VCFs could be expected to occur more commonly than with kyphoplasty [29–31]. In contrast, a meta-analysis found the risk of sustaining a new VCF to be significantly greater after vertebroplasty than after kyphoplasty. Other variables, including age, gender, bone mineral density, number of procedures, number of vertebrae treated, amount of cement injected, or cement leakage into the soft tissues or veins, were not associated with an increased risk of new VCFs [4].

Also important to consider are the costs associated with each procedure. Kyphoplasty is typically performed in the operating room, using general anesthesia, and with an overnight hospital stay required. This can involve costs up to 20 times higher than for vertebroplasty, which can be performed under conscious levels of sedation on an outpatient basis [18, 32]. Limitations of the present study include selection criteria of patients. Some conditions, including metastatic malignant tumor, long-term steroid treatment for systemic disease, long-term hemodialysis, hormonal disorder, or signs of infection sign at the treatment site, could affect the outcome of compression fracture treatment. In addition, our follow-up period was 6 months, which most would consider to allow for short-term data only. However, the age of our study participants, and typical co-morbidities, mean that a 10–15-year follow-up is unlikely to be achieved. A 2–5-year follow-up would be more appropriately considered as “long-term”. Nevertheless, we still keep following the data currently.

In conclusion, in terms of clinical outcome we found little difference between vertebroplasty and kyphoplasty treatment groups. Thus, with the higher cost of the kyphotic balloon procedure, we recommend vertebroplasty over kyphoplasty for the treatment of osteoporotic VCFs. It is hoped that as these procedures become more prevalent there will be an increased number of prospective, randomized studies comparing them with each other, and with medical treatment alone. The results of such studies will help patients choose the procedure that is optimal for them in terms of pain relief, safety, and cost.

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Conflicts of interest None.

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