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Percutaneous vertebroplasty and balloon kyphoplasty in the treatment of osteoporotic vertebral fractures: a prospective randomized comparison

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Abstract

Purpose The purpose of this study is to compare the efficacy and safety of percutaneous vertebroplasty (PVP) and balloon kyphoplasty (BKP) in the treatment of osteoporotic vertebral compression fractures.

Materials and methods Patients with osteoporotic vertebral body fractures (T4–L5) were randomized and not blinded to kyphoplasty ($n = 69$) or vertebroplasty ($n = 70$). The postoperative pain score (VAS) at 12 months was the primary end point. The radiographic results were evaluated in relation to the resolution of the fracture and the possible onset of further osteoporotic fractures during follow-up.

Results A total of one hundred and thirty-nine patients were eligible for randomization ($n = 70$ for PVP group and $n = 69$ for BKP), and twenty-six patients (twenty in the BKP group and six in the PVP group) were excluded. The mean average age of patients was 73 years, and 82% of the patients were females. VAS pain score was significantly reduced after surgery in both groups, and there were no significant differences between the two groups in postoperative VAS score. There was a significant reduction in kyphotic wedge angle and improvement of the sagittal index in both groups, but there was no significant difference between the two groups. There was a significant higher risk incidence of adjacent level fractures in the vertebroplasty group.

Conclusions In terms of clinical outcomes, there were no differences between the two groups. Both showed a significant clinical improvement, vertebral body height restoration and reduction in the kyphotic angle. There was a significant higher risk of adjacent level fractures in the vertebroplasty group.

Keywords Balloon kyphoplasty · Vertebroplasty · Vertebral compression fracture · Quality of life · Pain measurement · Height restoration

Introduction

Vertebral compression fracture (VCF) is a common complication in people with osteoporosis, because of the low bone density leading to fragile bones. Osteoporotic

VCFs will develop in 27% of men and women older than 65 years. The occurrence rate of osteoporotic VCFs was estimated 1.4 million new patients a year [1–3]. Consequently, osteoporotic VCFs are a significant cause of morbidity resulting in pain, spinal deformity, impaired mobility, reduced pulmonary function, clinical depression and even patient mortality [4]. While some patients are treated conservatively with activity modification, analgesics and bracing, percutaneous vertebroplasty (PVP) or balloon kyphoplasty (BKP) are the most common applied surgical treatments for those patients with severe and refractory pain. Some studies demonstrated that both kyphoplasty and vertebroplasty showed promising results in the treatment of osteoporotic vertebral body compression fractures [5–8]. These two procedures improved quality of life of

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patients with osteoporotic VCF by pain reduction and partially restoration of the vertebral height [9, 10]. As such, the utilization of both of these interventions has increased in the past 10 years [11]. However, there is no consensus in the literature as to which of the procedures leads to superior pain reduction and had the best long-term results. The purpose of this multicentre, prospective and randomized trials is to compare the efficacy of BKP and PVP in terms of pain control, fracture reduction and incidence of new fractures.

Materials and methods

Patient characteristics

The study was designed as a multicenter prospective randomized unblinded trial. According to the study protocol, all one hundred and thirty-nine participants were 55 years of age or older and had pain for at least 4 weeks attributable to one or more osteoporotic vertebral compression fractures below the fourth thoracic vertebra. The criteria for operating were:

- No pain control by brace and analgesics;
- Still evidence of bone marrow edema of the fractured vertebra;
- A shared decision between physician and patient based also on the patient's tolerance of the brace.

Patients who signed the informed consent for the study were randomized to either a vertebroplasty or a balloon kyphoplasty procedure. Subjects were assigned at random in a 1:1 ratio after eligibility and baseline assessments by an external collaborator working at the Pharmacy service of the Hospital, where a randomization sequence was allocated. The sequence was computer-generated by the website: www.randomization.com.

All fractures were detected on plain radiographs. Conventional lateral radiographic image and MRI were routinely performed. Exclusion criteria included oncological treatment at the affected level, infection, stenosis of the vertebral canal at the affected level, coagulation alterations, allergy to iodinated contrast medium, pregnancy. IRCCS Istituto Ortopedico Rizzoli (Bologna, Italy) and IRCCS Istituto Ortopedico Galeazzi (Milano, Italy) were the involved centers. The study was planned according to Consolidated Standards of Reported Trials (CONSORT) and approved by the local Ethics Committees of each center. Written consent was obtained from each participating patient before starting treatment. The study started in 2011 and was finished in 2015 when the final patient completed the 12 months follow-up.

Research parameters

The primary end point was pain reduction post-treatment measured by a 10-point visual analog scale (VAS) pain score. This scale was proposed to all the participants pre-treatment and during the follow-up period, at 1 month, 6 months and 12 months postoperatively. Secondary outcome measures administrated included World Health Organization Quality of Life (WHOQoL5D) test and Oswestry Disability Index (ODI). Standing lateral plain radiographs were performed at baseline, postoperative and after 12 months. Radiographic images were used to detect new radiographic fractures, defined as 20% height reduction, and evaluate anatomical fracture reduction post-treatment by measuring the kyphotic angulation and the sagittal index. All radiographic images were assessed centrally by a radiologist not involved in the study.

Surgical procedure

Both vertebral augmentation procedures were performed according to standard practice. PVP was performed according to local practice with Confidence-DePuy Spine PMMA, and BKP was performed with a bilateral approach as previously described using the Kyphon Osteo Introducer system manufactured by Medtronic Spine, Italia.

Statistical power analysis

With a significant level of α 0.05 and a power of 80%, equivalence limits between the groups of 0.5 points (VAS from 0 to 10) and standard deviation of the VAS score at follow-up at 12 months of 1 point, the estimated sample size was 139 patients.

Statistical methods

Statistical analysis was performed using SPSS 20.0 software. Baseline demographic and clinical characteristics of participants were described as mean for continuous variables and percentages for categorical variables. Statistical significance was set on $p < 0.05$ with hypothesis testing using a two-tailed test of significance. The data analysis was done with the missing data coded as absent. Independent continuous data were compared between the groups with Student's *t* tests, and the Fisher exact test was used to compare categorical data. Analysis of variance (ANOVA) was used to compare pre- and postoperative radiographic data between PVP group and BKP group.

The Shapiro–Wilk test was used to assess the normality of the distribution, and the Levene test was used to assess the homogeneity of variances.

Results

Patients were randomized between 2011 and 2015. The demographic statistics for the patients included in this prospective study are reported in Table 1. One hundred and thirty-nine patients were eligible for randomization ($n=70$ for PVP group and $n=69$ for BKP), and twenty-six patients (twenty in the BKP group and six in the PVP group) were excluded. A total of three patients were lost at follow-up after twelve months (Fig. 1). The mean average age of patients was 73 years, and 82% of the patients were females. Thirty-nine patients had a fracture in two or three levels. In particular, 22% of all fractures affected T4–T10 levels, 45% affected the thoraco-lumbar junction (T11–L1) and 33%

were at L2–L5 levels (Fig. 2). VAS pain score was significantly reduced after surgery in both groups, and there were no significant differences between the two groups in postoperative VAS score. ODI scores were significantly decreased in both groups after intervention, and there were no significant differences between the two groups. QoL score significantly increased after both surgical procedures, and there were no statistically significant differences between the two groups (Figs. 3, 4).

Radiographic outcomes

The analysis of preoperative and postoperative radiographic measurements for PVP and BKP groups is reported in Table 2. The postoperative reduction in kyphotic wedge angle ($p=0.890$) and sagittal index ($p=0.720$) was not significantly different between the two groups (Table 2).

Complications

The rate of cement leakage in our study was 4.5% and not significantly different between the two groups. Fifteen of 64 patients (23%) had new fractures and reintervention after vertebroplasty compared to two of 49 patients (4%) after kyphoplasty ($p=0.0043$). Eight patients had only one fracture, while the other patients had multiple fractures. Three of them were admitted and surgically treated twice during the follow-up period. During follow-up, we registered a total of forty new fractures in 113 patients (3.5%), and among these,

Table 1 Patients' characteristics

	Vertebroplasty	Kyphoplasty
Surgery as randomized	64	49
Number of levels treated	87	59
Age (mean)	72 ± 6.4	75 ± 8.6
Gender (male/female)	11/53	9/40
Prevalent fractures	1.4 (range 1–3)	1.2 (range 1–3)

Fig. 1 Patient accountability

Fig. 2 Distribution of fracture level for patients randomized to the PVP and BKP group

Fig. 3 Pain outcomes score (VAS), ODI score and EuroQoL score in kyphoplasty group before surgery and 12 months after surgery. Statistically significant improvements were identified ($p < 0.001$ compared to preoperative)

Fig. 4 Pain outcomes score (VAS), ODI score and EuroQoL score in vertebroplasty group before surgery and 12 months after surgery. Statistically significant improvements were identified ($p < 0.001$ compared to preoperative)

twelve have fractures on the level adjacent to the treated level. Eleven cases of adjacent fractures occurred in the PVP group and one case in the BKP group ($p = 0.0096$) (Table 3).

Discussion

There are few randomized studies comparing PVP and BKP [12–16]. This is a large prospective randomized trial comparing BKP and PVP with long-term follow-up. Significant pain reduction and improvement of quality of life were achieved by BKP and PVP. Our study data suggest that vertebroplasty and kyphoplasty are equally effective in substantially reducing pain and disability and improving both

Table 2 Comparison of pre- and postoperative radiographic data between PVP group and BKP group

	PVP	BKP	<i>p</i> value
Kyphotic wedge angle preoperative	10.8 ± 5.8	9.3 ± 6.5	0.228
Kyphotic wedge angle postoperative	8.8 ± 5.1	7.5 ± 4.3	0.202
Sagittal index preoperative	0.63 ± 0.18	0.66 ± 0.20	0.414
Sagittal index postoperative	0.71 ± 0.16	0.73 ± 0.18	0.502

Table 3 Patients with new radiographic fractures

	Vertebroplasty (<i>n</i> = 64)	Kyphoplasty (<i>n</i> = 49)
Total new fractures	15	2
Adjacent level fractures	11	1
Cement extravasation	3	2

mental and physical health. These findings were statistically significant but not different between the two groups. These results are consistent with the literature comparing PVP and BKP [5, 7, 12, 17].

The impact of lumbar spinal surgery is commonly evaluated with three patient-reported outcome measures: Oswestry Disability Index (ODI), Short Form of the Medical Outcomes Study (SF-36) and pain scales. A minimum clinically important difference (MCID) is a threshold used to measure the effect of clinical treatments [18, 19]. Improvement from baseline in the ODI scale was > 20 points, and there was an improvement of more than 3 points on the VAS back pain score. Both estimated the minimum clinically important difference.

There are several RCTs and meta-analysis demonstrating that kyphoplasty and vertebroplasty had a better outcome in patients with osteoporotic VCFs, compared to non-surgical management [5, 7, 8, 17, 20–23]. There are also some studies showing that these surgical treatments are cost-effective [24, 25]. Recently, a Cochrane review concluded that vertebroplasty was as effective as the sham procedure with local anesthetics [26]; however, this conclusion is based on the results of two RCTs with several limitations, for example, inclusion of chronic fractures, small sample size and high rate of crossover [27, 28].

According to our opinion, even if the conservative treatment with brace and bed rest is effective in the healing of osteoporotic fractures, it requires a long time and a strong limitation of activities for the patient. The surgical procedure (vertebroplasty or kyphoplasty) is therefore a good option to reduce healing time and improve the patient's quality of life.

Radiographic outcomes

It is in accordance with the literature that both vertebroplasty and kyphoplasty can restore the height of the vertebral body [29–33]. In our current study, we showed that there was no difference between vertebroplasty and kyphoplasty in restoring vertebral body height; however, previous studies showed a superior capability of kyphoplasty in restoring body height. However, the differences are mostly small and it is not clear if these differences have any clinical significance.

To our knowledge, there is only one other retrospective study showing no difference between the two techniques [34].

We explain the absence of significant difference in correction between vertebroplasty and kyphoplasty in the light of the data reported by Verlaan et al. [35] who observed that the endplate fracture reduction gained by inflation of the bone tamps could not be maintained after deflation.

Cement leakage

The efficacy of PVP and BKP treatments is coupled with the risk of some complications. The major complications arising from vertebral augmentation are related to cement leakage. Although most leaks are clinically asymptomatic, they could increase the risk of neurological complications and pulmonary embolism [36, 37]. Rates reported in the studies are variable, ranging from 9–72% for vertebroplasty and 7–59% for BKP [7, 38]. The rate of cement leakage in our study was 4.5%, lower than reported in the literature.

Risk of new fractures

Recent reports have shown that both procedures are associated with an increased risk of new fractures [14, 39, 40].

There is no consensus in the literature in considering this event as a complication of the previous surgical procedure or, first, a consequence of the altered spine mechanics due to the adjacent fracture and/or, second, the aggravation of the metabolic disease.

The subsequent fractures are mostly adjacent to the initial operative level because of bone cement augmentation and the transfer of greater load to adjacent vertebral levels, which leads to collapse of the adjacent vertebrae [41]. Patients from the PVP group experience significantly more adjacent level fractures at the end of the study compared to patients of the BKP group; this is in accordance with a recent meta-analysis [42]. There are several reasons that can be responsible for this complication. First, vertebra treated with cement are stiffer and thereby transfer an increased load to the adjacent vertebra. Another reason could be that there was more cement leakage in the space of the intervertebral disk in the PVP group, and this is associated with a four times higher risk of adjacent level fractures in the literature. An increased height restoration is associated with a higher risk of adjacent level fractures according to the literature [43]; however, this data did not result from this study.

Limitations

The limitations of our current study include the lack of blinding of patient and the loss at follow-up of some patients. Both treatments were not standardized between the two hospitals, and also the cement volumes were not reported and

standardized. So this lack of standardization can be seen as a limitation. These unknown differences are maybe responsible for the significant differences in adjacent level fractures between the two groups. Another limitation is the lack of data about pharmacological therapy for osteoporosis during the study period.

However, the strength of this study is the randomized and multicenter character and the relative long-term follow-up. The results of this study confirm the effectiveness of both vertebroplasty and kyphoplasty in patients with osteoporotic vertebral compression fractures.

Conclusion

Both augmentation procedures appear equally effective at restoring vertebral body height. Both treatments had similar significant effect on the clinical improvement of pain and disability. Vertebroplasty had a significant higher risk of new adjacent level fractures after treatment. The lower cost of vertebroplasty compared to kyphoplasty is also a factor to be taken into consideration in the decision-making process for the surgical treatment.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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