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ORIGINAL STUDY

Effect of shape and severity of vertebral fractures on the outcomes of kyphoplasty

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The aim of this retrospective study was to evaluate the effect of shape and severity of osteoporotic vertebral fractures on the clinical and surgical outcomes of kyphoplasty. Ninety-four patients with single level vertebral fractures were enrolled. Fractures were divided into two types according to the shape of the fractured vertebrae : wedge type (n = 54) or biconcave type (n = 40). All fractures were further classified into 3 grades (grade 1-3) according to their severity. The Visual Analog Score for back pain improved significantly in the "wedge" and in the "biconcave" group : there was no significant difference between groups. Wedge type fractures had a significantly greater correction of anterior vertebral height and kyphotic angle than biconcave type fractures ($p < 0.01$). Biconcave type fractures had a significantly greater correction of the middle vertebral height ($p < 0.01$), but had a higher risk of intradiscal cement leakage ($p = 0.03$). Rates of cement leakage in grade 1, grade 2, and grade 3 fractures were 12.8%, 25.8%, and 50.0%, respectively : there was a gradually higher risk of cement leakage as the severity of compression increased ($p < 0.01$). Conclusion : assessing the shape and severity of fractured osteoporotic vertebrae gives an idea of the potential correction of body height and kyphosis, and of the risk of cement leakage.

Keywords : osteoporotic ; vertebral fracture ; wedge ; biconcave ; kyphoplasty ; cement leakage.

INTRODUCTION

Osteoporotic vertebral compression fractures (OVCFs) are the most common fractures among older people with osteoporosis. These OVCFs lead to progressive sagittal spine deformity and changes in spinal biomechanics ; they are believed to contribute to an increased risk of further fracture (*20*). Whether acutely painful or not, OVCFs are associated with height loss, deformity, impaired mobility, decreased quality of life, and sometimes chronic pain. Traditional treatment for patients with OVCFs includes bed rest, analgesics, and bracing. This type of medical management cannot restore spinal alignment or relieve pain immediately. In recent years,

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vertebroplasty (VP) and kyphoplasty (KP) have become accepted options. As a minimally invasive procedure, vertebroplasty is being used successfully for pain relief (*21*), but this technique makes no specific attempt to restore the height of the collapsed vertebral body. On the other hand, kyphoplasty is designed to restore the vertebral body back toward its original height (*3,11,15*). Several previous studies have shown that this surgical procedure has a significant advantage over vertebroplasty in terms of kyphosis correction, vertebral height restoration, and cement leakage prevention through the use of an inflatable bone tamp (*2,13,24*).

Forms of fractured vertebrae vary from person to person. The authors hypothesized that the clinical and radiological outcomes of kyphoplasty may be associated with morphological structures of the fractured vertebrae. To the best of their knowledge, though various morphometric investigations have been made to detect OVCFs (*4,7,17*). relatively few studies have reported surgical outcomes of kyphoplasty according to the morphology of the affected vertebrae (*9*). The authors made an effort to investigate if the shape and the severity of the compression would affect clinical and surgical outcomes of kyphoplasty in the treatment of OVCFs.

PATIENTS AND METHODS

Inclusion and exclusion criteria

Were included in this study all patients older than 55, who had a kyphoplasty between May 2008 and January 2011 for a single level vertebral compression fracture due to primary osteoporosis. Were excluded : pathologic fractures due to metastasis or myeloma, active infections, patients with uncorrected therapeutic anticoagulation, cases with severe compression or even destruction of the posterior wall, or with major retropulsion of bony fragments into the spinal canal. The study was approved by the institutional review board.

This led to a total of 94 (71 females, 23 males) cases : 54 wedge type fractures and 40 biconcave, all between T6 and L4. Demographic data and results of classification are presented in Table I : the two groups were similar with regard to age, gender, age of fracture, BMI, spinal BMD, location of fractured vertebrae, and severity of compression. Pain complaints never exceeded 3 months.

Surgical technique

Surgery was performed under local anaesthesia with the patient in the prone position. Biplane fluoroscopy was used throughout the procedure. Kyphoplasty was carried out as previously described (*6*). Briefly, two 11- or 13-gauge needles were inserted into the posterior part of the fractured vertebral body, percutaneously and transpedicularly. Subsequently, two appropriate inflatable bone tamps (IBTs) (Kyphon Inc., Sunnyvale, CA, USA) were slid through the needles into the anterior two-thirds of the vertebral body. They were then inflated under fluoroscopic and manometric control. Inflation was continued until the vertebral body height was restored. The balloon was then deflated and withdrawn, and the cavity within the fractured vertebra was filled up with bone cement. Most patients were discharged the next day. All patients were treated with bisphosphonates, calcitonin and vitamin D. They were followed-up at 3, 6 and 12 months.

Outcome measures

A visual analog scale (VAS) from 1 to 10 (10 : worst possible pain) was used to quantify pain before surgery, one day after surgery and at each follow-up appointment.

Imaging

All patients in this retrospective study underwent preoperative magnetic resonance imaging (MRI) to determine the presence of compression fractures, and to check if the back pain was related to the location of the OVCFs on MRI. Routine anteroposterior and lateral radiographs of the spine were obtained with the patient in the supine position before and after surgery. Preoperative and postoperative radiographs were compared to assess radiological outcomes.

Kyphosis. The kyphotic angle was formed by the superior and inferior endplates of the fractured vertebra (Fig. 1). The preoperative kyphotic angle minus the postoperative kyphotic angle equaled the kyphosis correction.

Height. Six points were used to derive the anterior height (Ha), the middle height (Hm) and the posterior height (Hp) of the vertebral body (Fig. 1). This allowed to calculate :

Vertebral height as a percentage of normal = (height of the affected vertebra/mean height of the upper and lower vertebrae) ×100%

Classification of fractured vertebrae. According to the shape of the fractured vertebrae on preoperative

Table I. — Characteristics of the study population

	Wedge type	Biconcave type	*P*-value
No. patients	54	40	
Age (year) (range)	68.4 ± 7.2 (55-85)	67.7 ± 8.0 (55-88)	0.66
Sex (male:female)	14:40	9:31	0.81
Age of fracture (day) (range)	11.0 ± 6.8 (3-28)	11.8 ± 6.5 (3-28)	0.55
BMI (kg/m^2) (range)	22.3 ± 3.5 (17.0-32.5)	22.8 ± 2.7 (17.6-30.4)	0.42
Spinal BMD (T-score) (range)	-3.1 ± 0.8 (-5.1--1.4)	-3.0 ± 1.0 (-5.3--1.1)	0.82
Location of fractured vertebrae			0.20
Thoracic (T6-T9)	4	8	
Thoracolumber (T10-L2)	42	27	
Lumber (L3-L4)	8	5	
Severity of compression			0.41
Grade 1	24	23	
Grade 2	19	12	
Grade 3	11	5	

BMI = body mass index ; BMD = bone mineral density.

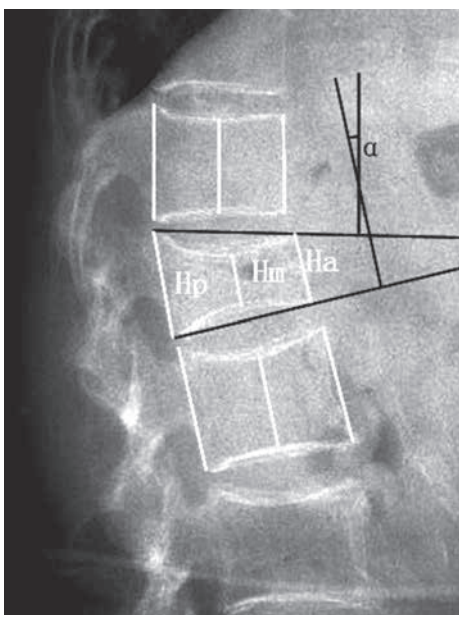

Fig. 1. — Anterior (Ha), middle (Hm), and posterior (Hp) heights (white lines). Kyphotic angle α : between superior and inferior endplates of the affected vertebra (black lines).

radiographs, all fractures were divided into two types : wedge type fractures (Hm > Ha, Fig. 2A) and biconcave type fractures (Hm < Ha, Fig. 2B). Besides, to assess the severity of compression, all fractures were also classified into 3 grades according to the most severely compressed vertebral height in Ha or Hm : grade 1, 20-25% reduction in height ; grade 2, 26-40% reduction in height ; and grade 3, > 40% reduction in height.

Cement leakage. The occurrence of cement leakage outside the treated vertebra was recorded with fluoroscopy during the operation. After the procedure, radiographs and computed tomography (CT) scans of the treated vertebra were used to identify possible extra cement leakage that might have been missed under fluoroscopy. Even minor cement extrusions were recorded as leakages. Three different anatomic compartments were defined to classify the sites of possible cement leakages : through the anterolateral wall of the vertebral body (= anterolateral) ; into the intervertebral disc space (= intradiscal) ; into the spinal canal (= intraspinal).

New fractures. At 12-month follow-up, additional radiographs or MRI were performed in patients who complained of a new onset of back pain. New fractures, including adjacent segment fractures, remote fractures, and refracture of the treated vertebral body, were diagnosed if plain radiographs revealed a definite decrease in the vertebral body height or if MRI showed bone marrow edema at the corresponding anatomic level.

Statistical analysis

For quantitative variables, comparisons before and after the intervention in the same group were assessed using a paired Student's *t* test, other comparisons using

Fig. 2A. — Wedge type fracture : Hm > Ha

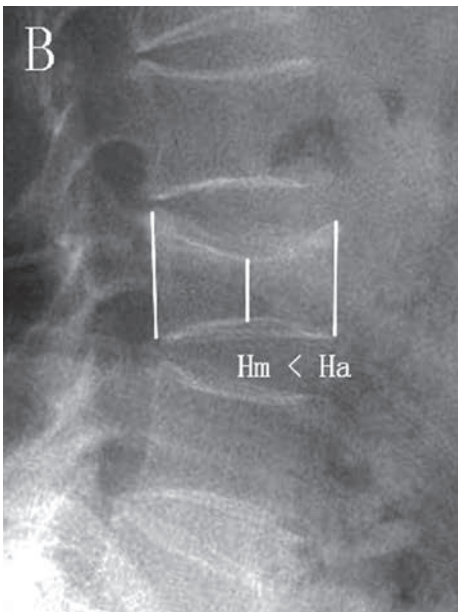

Fig. 2B. — Biconcave type fracture : Hm < Ha

an independent Student's *t*-test. For categorical variables, differences between two groups were evaluated by Fisher's exact test. Pearson's chi-square test was used to detect differences among three groups. Statistical comparisons were carried out using SPSS version 13.0 (SPSS Inc., Chicago, IL, USA). A p-value < 0.05 was considered to be statistically significant.

RESULTS

VAS for back pain

The VAS decreased significantly in both groups. In the wedge type group from 7.9 ± 1.1 before surgery to 3.2 ± 0.9 ($p < 0.01$) one day after surgery, and to 2.5 ± 0.9 at the 12-month follow-up ($p < 0.01$). In the biconcave group from 8.0 ± 1.0 before surgery to 3.2 ± 1.1 ($p < 0.01$) one day after surgery, and to 2.7 ± 0.9 ($p < 0.01$) at the 12 month follow-up. There were no significant differences between the preoperative and the postoperative values in the two groups.

The average preoperative VAS scores were 8.0 ± 1.0, 7.9 ± 1.1, and 7.8 ± 1.0 in grade 1, grade 2, and grade 3 fractures, respectively. One day after surgery, the mean VAS scores were 3.4 ± 1.0, 3.1 ± 1.0, and 3.1 ± 1.1, respectively. And at the 12-month follow-up, the mean VAS scores were 2.5 ± 0.8, 2.9 ± 0.9, and 2.5 ± 1.0, respectively. Thus VAS scores showed no significant differences among the 3 groups at preoperative or postoperative assessment.

Correction

In the wedge type group the mean correction (table II) of Ha, Hm, and Hp of the fractured vertebrae was 25.5 ± 5.0%, 18.5 ± 3.2% and 8.8 ± 2.5%, respectively. In the biconcave type group 14.0 ± 3.8%, 30.2 ± 6.4% and 8.6 ± 2.6%. The wedge type group had a significantly greater correction of Ha than the biconcave type group ($p < 0.01$), but the biconcave type group had a significantly greater correction of Hm ($p < 0.01$). The correction of Hp was not significantly different between both groups. The mean correction of the kyphotic angle (Table II) was 7.1 ± 2.9 degrees in the wedge type group and 3.4 ± 1.6 degrees in the biconcave type group : the difference between the two groups was significant ($p < 0.01$).

Table II. — Intergroup differences in vertebral height restoration and kyphosis correction

	Vertebral height restoration (%)			Kyphosis Correction (degree)
	Ha	Hm	Hp	
Wedge type	25.5 ± 5.0	18.5 ± 3.2	8.8 ± 2.5	7.1 ± 2.9
Biconcave type	14.0 ± 3.8	30.2 ± 6.4	8.6 ± 2.6	3.4 ± 1.6
P-value	$P < 0.01$	$P < 0.01$	$P = 0.60$	$P < 0.01$

Ha indicates the anterior height ; Hm, the middle height ; Hp, the posterior height.

Table III. — The leakage site of each type fractures

	Wedge type	Biconcave type	*P*-value
Anterolateral leakage	7	3	0.51
Intradiscal leakage	2	7	0.03
Intraspinal leakage	1	2	0.57
Total number	10	12	0.22

Cement leakage

As to cement leakage of all types (Table III), the total numbers were not significantly different between both groups. Similarly, no significant differences existed in anterolateral leakage or intraspinal leakage. However, intradiscal leakage was significantly more prevalent in the biconcave type group than in the wedge type group ($p = 0.03$). None of the patients with cement leakage, especially intraspinal ones, suffered from procedure-related new neurological deficits.

All fractures were classified into three grades according to their severity. There were 47 grade 1, 31 grade 2, and 16 grade 3 fractures. The overall cement leakage rate of KP in 94 treated vertebrae was 23.4%. The incidence of cement leakage in grade 1, grade 2, and grade 3 fractures was 12.8%, 25.8%, and 50.0%, respectively. There was thus a gradually higher risk of cement leakage as the severity of compression increased ($p < 0.01$) (Fig. 3).

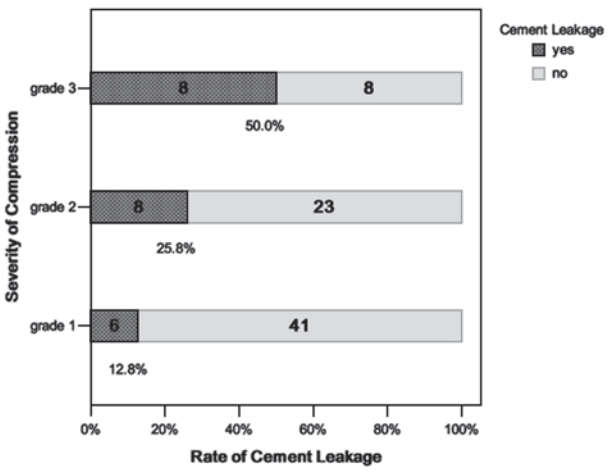

Fig. 3. — Rates of cement leakage and corresponding cases numbers in grade 1, 2, and 3 fractures.

New fractures

At the 12-month follow-up, there were 11 (20.4%) new vertebral fractures in the wedge group : 3 refractures, 3 adjacent segment fractures, and 5 remote segment fractures. In the biconcave group there were only 5 (12.5%) new fractures : one refracture, 2 adjacent segment fractures, and 2 remote segment fractures. However, the difference between groups was not significant ($p = 0.41$).

DISCUSSION

OVCFs are the most common fractures in the elderly with osteoporosis. They are painful and lead to progressive spinal deformity. Various morphometric approaches have been explored and

employed to detect OVCFs (*4,5,7,17*). Among those approaches, the semiquantitative classification of Genant *et al* (*7*) serves as a fast and reliable system in assessment of vertebral body collapse and is widely used especially in clinical drug trials for osteoporosis treatment and in the epidemiologic evaluation of populations at risk for osteoporosis. The authors attempted at first to investigate surgical outcomes of KP according to this classification. However, this semiquantitative classification of fracture shape and severity of compression is visual, and thus arbitrary. Therefore a quantitative method was used in the current study to measure the exact extent of vertebral height reduction and fracture shapes. Besides, the semiquantitative classification identifies three types of fractures : wedge type, biconcave type, and crush type. Actually, the number of cases in crush type is quite small. Only wedge type and biconcave type fractures were analyzed in this study.

Pain relief

Kyphoplasty provides significant pain relief in patients with OVCFs (*3,11,15*). The current study led to the same conclusion. However, the morphology of the fractures had no prognostic value as to pain relief.

Correction

According to the literature, vertebral body height and local kyphosis are more efficiently corrected by kyphoplasty than by vertebroplasty (*2,13,24*). In the current study, kyphoplasty led to significantly different results in the "wedge" and in the "biconcave" groups, as to the correction of local kyphosis. So the morphological aspects of the fractures help the surgeon to foresee the potential correction.

Leakage

Leakage is the most common complication of kyphoplasty. The incidence is variable and depends on the definition and on the radiological technique (*12,16,23*). In the current study a significantly higher risk of intradiscal cement leakage was revealed in biconcave type fractures. A possible reason could be that these fractures are usually associated with severe cortical disruption of the upper endplate.

The severity of the fractures was identified as a risk factor for the occurrence of cement leakage. This confirms the findings of Nieuwenhuijse *et al* (*18*). Thus, special measures must be taken in patients with severe vertebral fractures, especially those with more than 40% reduction in vertebral height. The risk of cement leakage and its potential sequelae can be reduced by positioning the needle tip away from the cortical disruption and using the appropriate viscosity of bone cement (*1,8*).

New fractures

Though most leakages are clinically asymptomatic, it has been suggested that cement leaks into the adjacent intervertebral disc space affect the mechanical loading of either the disc or adjacent vertebra, which may predispose the patient to adjacent segment fracture (*10,14,19*). However, Syed *et al* (*22*) have reported that a small amount of cement into the disc does not increase the incidence of adjacent segment fractures.

At final follow-up the authors noted 3 adjacent segment fractures in the wedge type group, and 2 in the biconcave type group : numbers too small to draw conclusions.

More striking, in the assessment of the total number of new fractures, there was a tendency toward a higher rate in the wedge type group. The authors hypothesized that wedge type fractures had a better restoration of anterior vertebral height, which may increase soft-tissue tension around the vertebral body, lead to an increased load on the vertebra, and result in new vertebral fractures at last. However, this conclusion could not be drawn confidently, as the difference between the two groups was not statistically significant due to the relatively small number of new fractures. The authors hope to confirm this speculation by conducting a study on new fractures in a larger group. If a better restoration of Ha indicates a higher incidence of new fractures, it seems that the amount of deformity correction is not as important as was thought, and surgeons may not need to aim for perfect radiographic improvement.

Limitations

In the first place this study was retrospective. In addition, functional outcomes such as the Short form-36 or the Oswestry Disability Index were not used. The follow-up period was only 12 months. Finally, in the assessment of new fractures, only symptomatic fractures were considered, and the actual new fracture rate might be higher than the observed rate.

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