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Clinical Article

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Efficacy and Safety of Balloon Kyphoplasty in the Treatment of Osteoporotic Vertebral Body Compression Fractures : Compared with Vertebroplasty

Objective : Kyphoplasty and vertebroplasty are two minimally invasive procedures for osteoporotic vertebral compression fractures. The purpose of this retrospective study was to compare the radiological findings and clinical outcomes between two procedures.

Methods : Osteoporotic vertebral fractures were treated in 76 vertebrae, using kyphoplasty (n=35 vertebrae) and using vertebroplasty (n=41 vertebrae). Fractured vertebral bodies were diagnosed by correlating the clinical symptoms with radiologic study. The responses of pain symptoms were measured by a self-reported Visual Analog Scale (VAS) score. Plain X-rays were checked preoperatively and postoperatively at admission and 6 months. The vertebral body height and kyphotic angle were measured to assess the reduction of the sagittal alignment.

Results : The mean pain scores were decreased significantly for both procedures postoperatively, but there were no significant differences between two groups. Kyphoplasty led to a significant reduction of the vertebral body height and improvement of kyphotic angle. There were no neurological deficits after kyphoplasty, but one patient experienced paraparesis after vertebroplasty. During the 6 months follow-up both procedures provided stabilization of the sagittal alignment.

Conclusion : Kyphoplasty and vertebroplasty are considered effective minimally invasive techniques for the stabilization of osteoporotic vertebral body fractures, leading to a statistically significant reduction in pain. Kyphoplasty significantly restore sagittal alignment. Also, complications and the incidence of bone cement leakage are significantly lesser than vertebroplasty. Therefore, kyphoplasty seems to be reasonable procedure for osteoporotic vertebral body compression fractures when medical treatment fail.

KEY WORDS : Osteoporosis · Vertebroplasty · Kyphoplasty · Kyphosis · Vertebral height · Spinal compression fracture.

INTRODUCTION

Vertebral body compression fractures (VBCFs) are common in the elderly[17,19] and occur when the vertebral body is too weak to support the loads of everyday activities. In the USA, approximately 700,000 vertebral fractures annually are attributable to osteoporosis. For a 50-year-old woman, the lifetime risk of clinically evident spine fracture is 15.6%[17]. Because the primary cause of osteoporosis is aging, the incidence of the vertebral body compression fractures-related sequelae is expected to increase as the populace ages and longevity continues to advance[7]. Whether or not acutely painful, the resulting spinal deformity can lead to chronic back pain, reduced physical and social functioning, depression, a loss of independence, decreased lung capacity, and malnutrition caused by early satiety[19].

Vertebroplasty is a minimally invasive procedure for osteoporotic VBCFs. Although vertebroplasty is currently being used successfully for relief of pain in osteoporotic VBCFs, this technique potentially has serious complications related with extravasation of the bone cement. Importantly, the leakage of the cement into the epidural space may cause neurological deficit[17]. Kyphoplasty is a newly introduced technique that has many potential advantages such as better restoration of vertebral body height, sagittal alignment correction and a lower risk of cement leakage[7,8,13,14]. We compared the results of these two procedures with regards to pain improvement, complication, and postoperative reduction of vertebral body height and kyphotic angle.

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MATERIALS AND METHODS

Population

A total of 76 vertebrae compression fractures were treated by percutaneous vertebroplasty or balloon kyphoplasty in 72 patients. Mean age of the patients was 70.8 years (range 45-88 years). All patients had single vertebral body fracture. Of the 72 patients, 38 patients underwent vertebroplasty, and 34 kyphoplasty. New fractures developed in 4 patients 6 to 9 weeks after first operation; two kyphoplasty and two vertebroplasty. We considered the second procedure as a separate procedure because the intervals were more than one month apart. The level of fractures distributed between T7 and L4 and was most prevalent at thoracolumbar junction. Mean follow-up period was 7.44 months (range 1-40 months).

Patient selection

Patients with acute fractures, which had been demonstrated on magnetic resonance imaging (MRI) or computerized tomography (CT) with bone scan that were concordant with pain at the site of fracture, were considered candidates for vertebroplasty or kyphoplasty. Preoperatively, patients were treated medically with narcotics and bed rest for 2 weeks. Additionally, some patients required brace application. Only patients in whom medical management failed underwent surgery. We excluded following cases to be contraindication for this procedure; pregnancy, bleeding disorders, high-velocity fractures, burst fracture with retropulsed bone, pain unrelated to vertebral body collapse, and circumstances precluding the technical feasibility. Multi-level vertebral body fractures were not included in this study.

Fig. 1. Compression ratio and kyphotic angle. Compression ratio=(1-B/A)×100, Kyphotic angle=C.

Assesment of sagittal alignment

Plain radiographs were checked pre- and postoperatively in all patients. Anterior vertebral body height was measured in the fractured and nearest normal vertebral body. Compression ratio of the fractured vertebral body was recorded as a percentage of predicted height based on the nearest normal vertebral body. And kyphotic angle was obtained by the angle between inferior endplate of the fractured body and one level above (Fig. 1).

Assesment of outcome

Visual Analog Scale (VAS) scores (from 0; no pain to 10; worst imaginable pain) were determined by questionnaire. The preoperative and postoperative compression ratios were assessed to calculate the body height reduction ratio (Reduction ratio=postoperative compression ratio - preoperative compression ratio). The kyphotic angle reductions were calculated to compare preoperative kyphotic angle with postoperative angle. Assesments were made preoperatively and postoperatively at one day and 6 months after surgery. Statistical analysis was done using the paired-sample t test.

RESULTS

During the period between April 2002 and September 2006, 76 vertebrae compression fractures were treated by percutaneous vertebroplasty or balloon kyphoplasty in 72 patients. Forty-one vertebrae were treated by percutaneous vertebroplasty in 38 patients. Mean age of the patients was 71 years (range 45-87 years) and mean bone mineral density (BMD) was -2.91. 35 vertebrae underwent a balloon kyphoplasty in 34 patients. Mean age of the patients was 70 years (range 51-88 years) and mean BMD was -2.63 (Table 1).

Table 1. Summary of patients

	Vertebroplasty	Kyphoplasty
No. of patients	38	34
Sex : male/female	6/32	5/29
No. of vertebrae	41	35
No. of patient for		
1 procedure only	35	33
2 procedures	3	1
Age (year)	71 (45-87)	70 (51-88)
Mean BMD	-2.91	-2.63

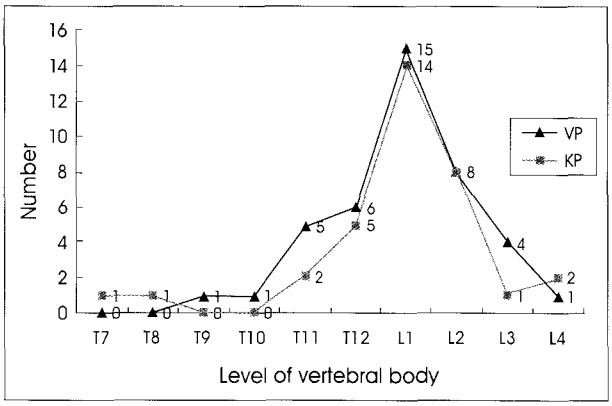

Fig. 2. Distribution of compression fractures.

WHO T-score under -2.50 with fracture was considered as severe osteoporosis. Thus, mean BMDs of both groups were categorized as severe osteoporosis. The fractures had occurred between T7 and L4. The fracture distribution is shown in (Fig. 2). The most prevalent level was thoracolumbar junction in both groups. There were no significant differences between two groups in age, BMD and distribution of fracture level.

Table 2. Changes in body height reduction

	Preoperative CR	Postoperative CR at one day	Postoperative CR at 6 months	p*
Vertebroplasty (n)	24.2% (41)	21.6% (41)	22.4% (38)	0.300
Kyphoplasty (n)	28.1% (35)	14.7% (35)	15.1% (30)	0.000

CR : compression ratio, p : Paired *t* test compared with preoperative compression ratio, * : comparison of preoperative and postoperative CR

Compression ratio

The preoperative mean compression ratio was 24.2%, and it was decreased to 21.6% after vertebroplasty at one day after surgery. At 6 months follow-up, compression ratio was 22.4%. In kyphoplasty group, the initial mean compression ratio was 28.1%, and it was decreased to 14.7% at one day after surgery. At 6 months follow-up, it was 15.1% (Table 2). There was no statistical difference between initial compression ratio and postoperative compression ratio at one day and 6 months in vertebroplasty group (p-value$>$0.05) and postoperative compression ratio at one day and 6 months in kyphoplasty group (p-value$>$0.05). However, there was significant difference between initial compression ratio and postoperative compression ratio at one day in kyphoplasty group (p-value $<$0.001). There was a positive relationship between initial compression ratio and body height reduction, and it was much more remarkable after kyphoplasty than vertebroplasty (Fig. 3). This was more dramatic if the initial compression ratio is over 20% in kyphoplasty group (Fig. 4).

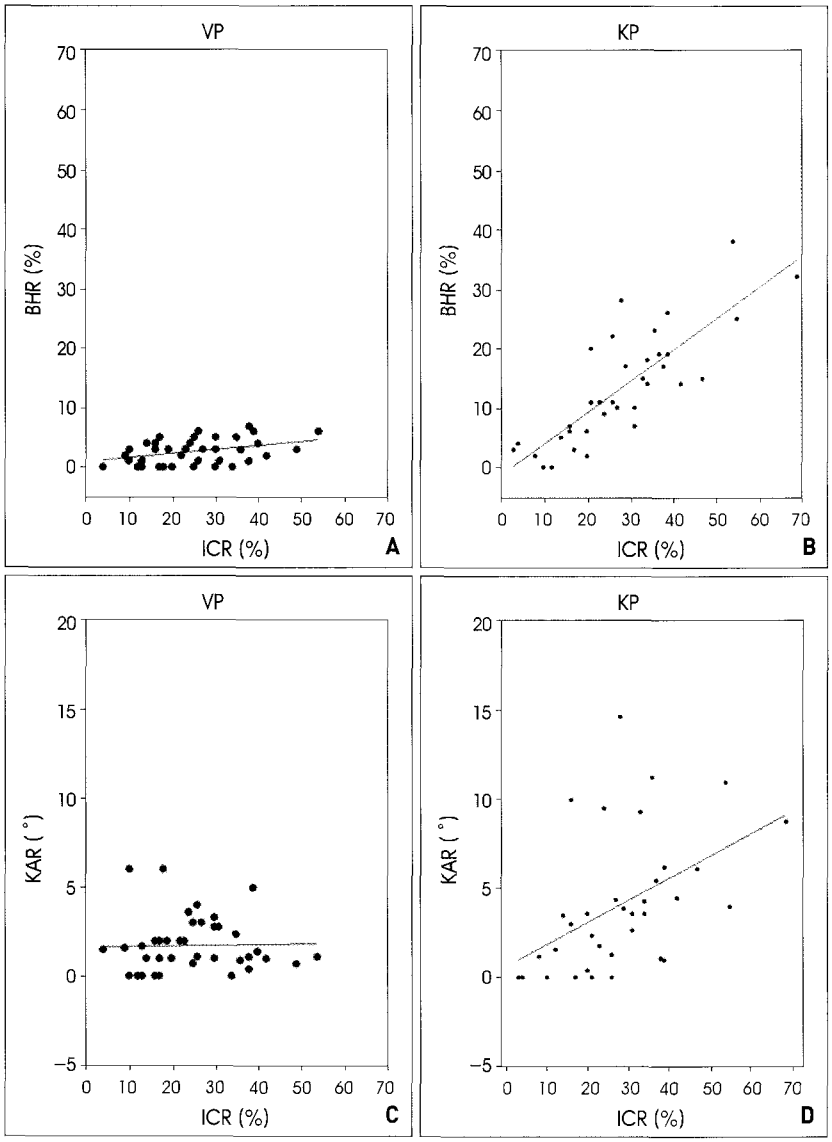

Fig. 3. Scatter diagram of vertebroplasty and kyphoplasty. A, B : There is a positive relationship between initial compression ratio and postoperative body height reduction at one day and this is much more remarkable in kyphoplasty group than vertebroplasty group. C, D : There is little difference of KAR whether or not ICR is high in vertebroplasty group, but the more ICR is high, the more degree of KAR we can be gained in kyphoplasty group. ICR : Initial compression ratio, BHR : Body height reduction, KAR : Kyphotic angle reduction.

Kyphotic angle

The initial mean kyphotic angle was 5.65° (range -7-16°), and was corrected to 3.92° (range -7-15°) after vertebroplasty at one day. At 6 months, angle was 4.01° (range -5-13°) (Table 3). There was no statistical difference between preoperative kyphotic angle and postoperative kyphotic angle at one day and 6 months postoperatively (p-value$>$0.05). But, in kyphoplasty group, the preoperative mean kyphotic angle was 9.47° (range 0-28°), and was corrected to 5.35° (range 0-24°) at postoperative one day. At 6 months, the angle was 5.41° (range 2-25°) (Table 3). There was significantly statistical difference between preoperative kyphotic angle and postoperative kyphotic angle at one day ($p$$<$0.05). In scatter diagram, there was little difference of reduction

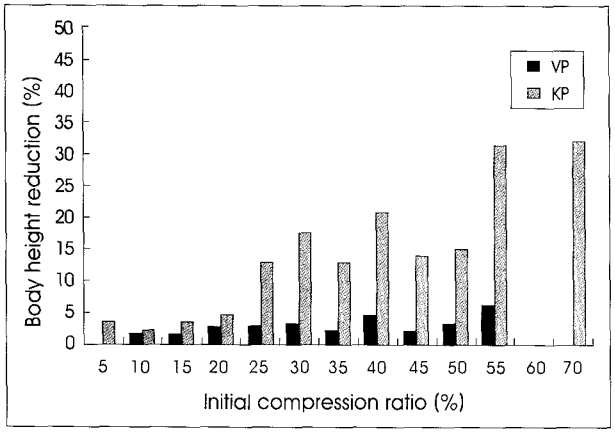

Fig. 4. Relationship between initial compression ratio and body height reduction. When initial compression ratio is over 20%, kyphoplasty can be expected to provide better body height reduction ratio.

Table 3. Changes in kyphotic angle reduction

	Preoperative KA	Postoperative KA at one day	Postoperative KA at 6 months	p*
Vertebroplasty (n)	5.65°(41)	3.92°(41)	4.01°(38)	0.111
Kyphoplasty (n)	9.47°(35)	5.35°(35)	5.41°(30)	0.004

KA : kyphotic angle, p : Paired *t* test compared with preoperative kyphotic angle, * : comparison of preoperative and postoperative KA

Table 4. Changes in VAS score after vertebroplasty and kyphoplasty

	Preoperative VAS	Postoperative VAS at one day	Postoperative VAS at 6 months	p*
Vertebroplasty (n)	8.07 (41)	2.78 (41)	2.65 (38)	0.000
Kyphoplasty (n)	8.25 (35)	2.63 (35)	2.60 (30)	0.000

p : Paired *t* test compared with preoperative kyphotic angle, * : comparison of preoperative and postoperative VAS

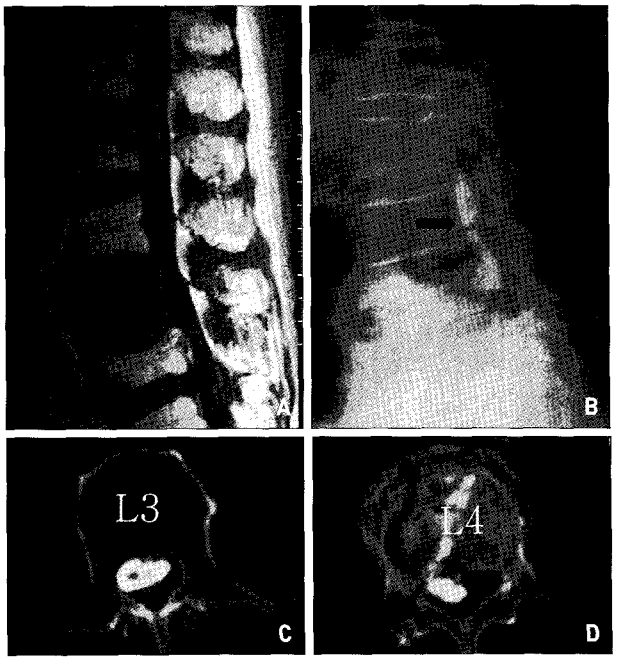

Fig. 5. Case of cement leakage. A : T1 weighted image showing low signal intensity on 4th lumbar vertebral body, B : Immediate postoperative plane film indicating cement extravasation extending from L3 to L4(arrow), C,D : Immediate postoperative computerized tomography scan, demonstrating confirm leakage of the cement to epidural space.

Table 5. Incidence of cement leakage after vertebroplasty and kyphoplasty

	Epidural	Intravenous	Discal	Paravertebral	%
Vertebroplasty	3	4	5	5	41.4%
Kyphoplasty	0	0	1	3	11.4%

of kyphotic angle whether or not initial compression ratio was high in vertebroplasty group, but the higher the initial compression ratio was, the more reduction of kyphotic angle was gained in kyphoplasty group. (Fig. 3).

VAS score

The preoperative mean VAS score was 8.07, and it was reduced to 2.78 at postoperative one day in vertebroplasty group. At 6 months, it was 2.65. In kyphoplasty group, the preoperative mean VAS score was 8.25, and it was reduced to 2.63 postoperative at one day. At 6 months, it was 2.60 (Table 4). There were no significant difference between both groups.

Complication

There were no medical complications, such as myocardial infarction or pulmonary embolism. Twenty-one cases of cement extravasation were evidenced by postoperative CT scan and plane film. Twenty cases were asymptomatic, decompressive surgery was needed in one patient (Fig. 5). The incidence of cement leakage was 41.4% (17 of 41) in vertebroplasty, and 11.4% (4 of 35) in kyphoplasty. Immediate postoperative CT scan revealed that PMMA leaked into the epidural and intravenous space in 3 (7.3%) of 41 and 4 (9.8%) of 41 after vertebroplasty, but there was no leakage into the epidural and intravenous space after kyphoplasty (Table 5).

DISCUSSION

Osteoporotic vertebral body compression fractures usually lead to severe back pain, limited mobility and spinal deformity in elderly patients. In most cases, conservative treatments including bed rest, analgesics and occasionally external bracing is sufficient. But, osteoporotic vertebral body compression fractures can result in severe and persistent pain that may fail to conservative treatment[1]. Two minimally invasive surgical options for these persistent painful vertebral body compression fractures that is unresponsive to conservative therapy are currently available. One is percutaneous vertebroplasty and the other is balloon kyphoplasty.

The result of this study show that vertebroplasty and

kyphoplasty were well-tolerated procedures for the treatment of painful osteoporotic vertebral body compression fractures. In many other studies of vertebroplasty and kyphoplasty, postoperative VAS score decreased significantly from 8.25 (range 7.2-8.6) to 2.1 (range 0.6-3.4)[1,6,12,20]. In our study, postoperative VAS score decreased from 8.07 to 2.65 in vertebroplasty and from 8.25 to 2.60 in kyphoplasty. Regarding to degrees of pain relief, both procedures are known to provide excellent pain relief. However, our results showed the difference between two techniques on the basis of reduction of spinal deformity and risk of cement extravasation. Our study results indicate that kyphoplasty is more effective in reduction of spinal deformity than vertebroplasty. Substantial improvements were documented for vertebral body height and kyphotic angle. The reduction of vertebral body height and kyphotic angle were significantly more effective in kyphoplasty than vertebroplasty. In addition, the higher initial compression ratio and kyphotic angle, the more reduction ratio we obtained in kyphoplasty group.

In other studies of kyphoplasty, Voggenreiter et al.[20] reported effectiveness of reduction of vertebral deformity. First, the Cobb angle improved significantly from 17.0±8.1° (range 6-38°) before surgery to 10.5±9° (range 2-32°). Vertebral body height improved significantly from 0.59±0.24 (range 0.2-1.06) to 0.08±0.16 (range 0.38-1.0). Phillips et al.[13] noted a mean of 8.8° (range 0-29°) of correction of local spinal kyphosis was achieved with kyphoplasty. Thirty of 52 fractures were considered reducible and had more than 5° of correction, with a mean improvement in sagittal alignment of this population of 14.2°. But, Yoon et al.[21] reported overall mean kyphotic angle change in thoracic vertebral fractures was 1.0° and in lumbar vertebral fractures was 2.1°, that were not statistically significant.

Vertebral body compression fractures lead to progressive sagittal spine deformity and changes in spinal biomechanics and are believed to contribute to a fivefold increased risk of further fracture by virtue of force transmission to weak vertebrae above or below[5,8]. Bouza[1] demonstrated that the incidence of new vertebral fractures was 16% in kyphoplasty. But, our results indicated that the incidence of new vertebral fractures was 7.9% (3 of 38) in vertebroplasty group and 2.9% (1 of 34) in kyphoplasty group.

The results of this study indicate that the incidence of cement extravasation was less in kyphoplasty group than vertebroplasty group. This support the hypothesis that injection of high-viscosity cement into a previously formed cavity is much safer over the injection of low-viscosity liquid cement into the unreduced vertebral body[8]. During the vertebroplasty or kyphoplasty, polymethylmethacrylate (PMMA) has been the most widely used bone filler, and most of the serious complications reported are related to leakage of PMMA outside of the vertebral body during injection[2-4,10,12]. The PMMA may exit the vertebral body through fractures in the vertebral cortex or by injection of cement into the vertebral venous system[6,10]. Leakage of cement through the vertebral cortex may result in direct injury to or compression of adjacent structures such as the spinal cord or nerve root. When injected cement enters the venous system, there is the potential for cement to fill the epidural veins and cause spinal cord or nerve root compression, or for pulmonary embolism[6,10]. In addition, high-pressure intraosseous injection of cement may lead to embolization of methylmethacrylate monomer and bone marrow contents of the lungs, with negative cardiopulmonary sequelae[9,11,12,15,16,18]. In this study, there were 3 epidural leakages, 4 venous leakages, 5 intradiscal leakages and 5 paravertebral leakages in 41 cases (41%) treated with vertebroplasty. In one epidural leakage, leaked cement compressed nerve root that required decompressive surgery. However, neurological deficit was not improved (Fig. 7).

Kyphoplasty has the advantage of ability to correct spinal deformity and low-pressure injection of cement into the fractured vertebral body versus vertebroplasty. During kyphoplasty, the creation of an intravertebral cavity with the Inflatable Bone Temps (IBTs) allows for a range of filler options, with placement under lower pressure. In addition, the IBT compacts the trabecular bone, which may seal potential osseous or venous leak paths[14]. In this study, the cement leakage was seen in 17 of 41 (41%) patients in vertebroplasty group and 4 of 35 (11%) in kyphoplasty group. There was significantly statistical difference in the incidence of cement leakage to the spinal canal, epidural vein and intradiscal space except for paravertebral body. Fortunately, there was no cement leakage into the spinal canal and epidural vein in kyphoplasty. Voggenreiter et al.[20] reported extravertebral leakages in 9 of 39 vertebral fractures treated with kyphoplasty. In 5 cases, cement leaked into the adjacent intervertebral disc; in 2 cases, leakages occurred lateral to the vertebral body; and in 2 patients, cement leaked into paravertebral veins. No cement leaked into the spinal canal or neural foramens. None of the cement leakage caused any apparent clinical consequences.

CONCLUSION

Kyphoplasty and vertebroplasty are very effective techniques for the stabilization of osteoporotic vertebral body compression fractures leading to a statistically significant reduction in pain. Both procedures are minimally invasive technique that provide immediate effect as evidenced by our findings. In our

study, kyphoplasty significantly restored sagittal alignment that lasted for at least 6 months. Also, there were fewer complications and the incidence of bone cement leakage was significantly lesser in kyphoplasty than vertebroplasty. Therefore, despite the short mean follow-up period of 6 months, authors recommend kyphoplasty to the patients with painful osteoporotic compression fractures that fail to medical treatment.

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