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Clinical Article

Postoperative Results of Kyphoplasty for Osteoporotic Vertebral Compression Fractures

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Objective : We analyze pain relief, deformity correction and complication rate after percutaneous kyphoplasty for osteoporotic vertebral compression fractures.

Methods : The authors retrospectively reviewed medical records and radiological findings of 32 patients who underwent percutaneous kyphoplasty for osteoporotic vertebral compression fractures.

Results : The patients had significant pain improvement with the procedure. The visual analogue scale score reduced from 8.6 to 3.4 significantly after the procedure. The midline vertebral body height significantly increased postoperatively, but mean kyphotic angle did not. There was no serious complication except one case of epidural cement leakage without neurological impairment.

Conclusion : Balloon kyphoplasty safely can reduce severe back pain and returned geriatric patients to higher activity levels. The midline vertebral height is restored significantly. However kyphotic deformity correction is not significant as contrary to what we expected from the present study before it was carried out.

KEY WORDS : Kyphoplasty · Vertebral compression fracture · Kyphosis · Vertebral height.

Introduction

Osteoporosis is a systemic disease afflicting old aged person, and the number of patients with osteoporosis is likely to rise as the population ages. The disease results in progressive bone mineral loss and concurrent changes in bone architecture that leave bone vulnerable to fracture, often after minimal or no trauma. Among the various vulnerable sites to osteoporotic fracture, the spine is the most common site of osteoporotic compression fracture. And vertebral compression fractures have been shown to be associated with quality of life, physical function, mental health and survival[3,6,11,14].

Percutaneous vertebroplasty is a minimally invasive method that involves the percutaneous injection of polymethylmethacrylate into a collapsed vertebral body to stabilize the vertebra. This procedure is commonly used for osteolytic metastasis, myeloma, hemangioma and osteoporotic vertebral fractures[4]. This procedure generally results in quick, effective pain relief with relatively low complication rate[9,12,13,20]. However, the percutaneous vertebroplasty does not expand the collapsed vertebra locking the spine in a kyphotic posture and is also associated with possible cement extravasation causing neurologic deficit or rare case of pulmonary embolism[2,18].

In contrast to the vertebroplasty, the kyphoplasty is a new technique that has a number of potential advantages, including better restoration of vertebral body height, sagittal alignment correction and a lower risk of cement extravasation and procedure related complications[8,10,15,16]. We retrospectively analyzed the clinical data of 32 osteoporotic compression fracture patients treated with kyphoplasty and evaluated postoperative results of pain improvement, deformity correction and complication rate.

Materials and Methods

A total of 40 vertebral compression fractures were treated by balloon kyphoplasty in 32 patients. Mean age of the patients was 67.8years (range 49~81years). Eighty four percent, 27 among 32 patients were women. Of the 32 patients, 24 patients had single vertebral fracture, and 8 had multiple vertebral fractures (two adjacent vertebrae fractures). The level of fractures distributed between T7 and L4 and was most prevalent at thoracolumbar junction (Fig. 1). The fractures were sustained within a mean of 3 months (range 1~360 days) of the procedure. Mean postoperative follow-up period was about 5 months (range 1~11 months).

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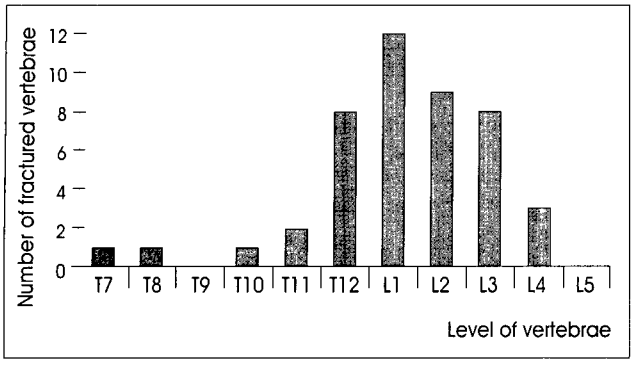

Fig. 1. Distribution of fractured vertebrae

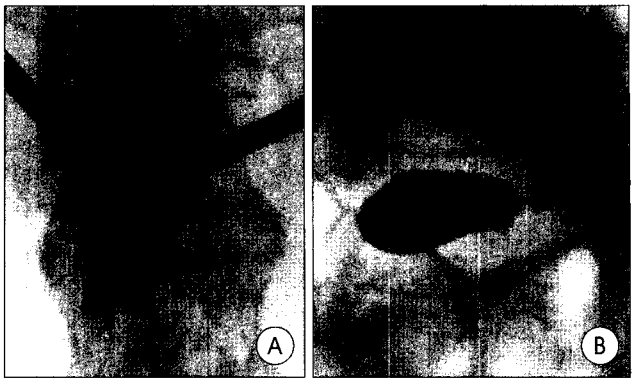

Fig. 2. Anterior(A) and lateral (B)fluoroscopic images of kyphoplasty. The Inflatable Bone Tamps are inserted into the fractured vertebral body through working canula via bilateral transpedicular approach. They are inflated, reducing the fracture, then deflated and withdrawn, leaving a cavity within the vertebral body, in which polymethylmethacrylate cement is filled.

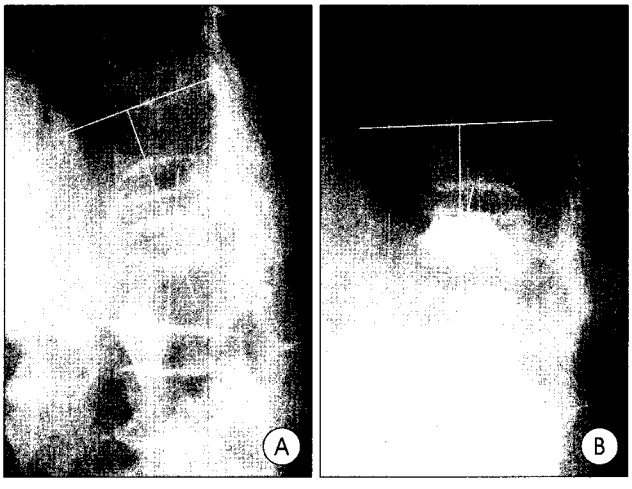

Fig. 3. A 76-year-old woman with T12 vertebral compression fracture treated with kyphoplasty four weeks after fracture. The local kyphosis is corrected from 25° (A) to 13° (B).

All patients had persistent back pain from osteoporotic vertebral compression fractures that were not responsive to nonoperative treatment, and there was no case with neurological impairment. The fracture was confirmed as the likely pain generator by correlating physical findings with the identification of edema in the fractured vertebra with Magnetic Resonance Imaging(MRI) and hot uptake of radioisotope in bone scan.

All balloon kyphoplasty procedures were performed under local anesthesia with light sedation. An 11-gauge Jamshidi needle was placed percutaneously into the posterior vertebral body through transpedicular approach. The needle was exchanged over a guide wire for a working cannula. The KyphX Inflatable Bone Tamps(IBT) (Kyphon, Inc., Sunnyvale, CA, USA) were placed bilaterally into the vertebral body through working cannula. The IBT were inflated using visual (fluoroscopic) and manometric parameters. Inflation continued untill the IBT contacted a vertebral endplate or the IBT pressure reached 220psi (Fig. 2). The IBTs were deflated and then withdrawn, and partially cured polymethylmethacrylate (PMMA) cement, CMW 1 Original (DePuy, Johnson & Johnson Co., Lancashire, England) mixed with additional barium was placed into the cavity within the fractured vertebral body.

The authors analyzed clinical and radiological data retrospectively. Clinical information was obtained in 30 patients while the rest 2 patients who were included in radiographic analysis were lost to follow-up for the evaluation of pain and ambulation. Visual analogue scale(VAS) score of back pain and ambulatory status were measured by questionnaire done preoperatively and at the last follow-up (Table 1, 2).

Preoperative and postoperative x-rays were analyzed for improvement in sagittal alignment and vertebral height restoration. Sagittal alignment was calculated using the Cobb technique; measurement was taken from the superior endplate of the vertebra one level above the treated vertebra to the inferior endplate of the vertebra one level below the treated vertebra[1,7,15,17,19] (Fig. 3). Anterior and midline vertebral height were measured in the fractured and two nearest one level above and one level below normal vertebral bodies on lateral x-ray. Each height of the fractured vertebral body was recorded as a percentage of predicted height based on the mean of the two nearest normal vertebral bodies[8,10]. Postoperative x-rays and CT scans were used to monitor cement extravasation from all treated vertebral levels.

Statistical analyses were done using the paired-samples *t* test and the Wilcoxon signed-rank test.

Results

The patients had significant pain improvement with the procedure. Preoperative mean VAS score was 8.6, and postoperative VAS score at the last follow-up was 3.4 (Table 1).

Table 1. Postoperative decrease in pain

	Preoperation	Last follow-up
Total no. of responses	30	30
Mean pain *	8.6	3.4 (P<0.001**)

* Visual analogue scale ranging from 0 to 10 (0=no pain, 10=most severe pain) ** Paired *t* test compared with preoperative pain score

Pain aggravated in 1 patient and there was no symptomatic change in 4 patients. Of the 30 patients whose ambulatory statuses were recorded preoperatively, 10 patients could not ambulate due to severe back pain, 8 patients required assistance and 12 patients could walk independently. After kyphoplsty, all patients became ambulatory; 2 patients required assistance and 28 patients could walk independently at their last follow-up (Table 2).

The mean anterior vertebral body height changed from 74.5% of the predicted height preoperatively to 80.3% of the predicted height at the last follow-up. The midline height increased from 58.9% of predicted height preoperatively to 81.2% of predictive height postoperatively. The increase of anterior body height was not statistically significant, but the increase in the midline body height was statistically significant (Table 3).

Preoperative and postoperative Cobb angle measurements were obtained in 32 patients and these were analyzed by spinal region (thoracic or lumbar). The authors could observe significant kyphosis correction and height restoration in some patients. But overall mean kyphotic angle change in thoracic vertebral fractures was 1.0°. And in lumbar fractures, overall mean lordotic angle change was 2.1°. Both of these changes were not statistically significant (Table 4).

Figure 3 provides preoperative lateral x-ray of an 76-year-old woman with a T12 osteoporotic compression fracture. The local angulation caused by the fracture was 25°. Seven months later after balloon kyphoplasty, lateral x-ray demonstrated that the local angulation was corrected to 13°.

Complications were infrequent. There was no medical complication, such as myocardial infarction or pulmonary embolism. Cement leakage into spinal canal occurred in 1 of 40 treated levels, but there was no neurologic deficit after the procedure.

Discussion

Osteoporotic vertebral compression fractures usually cause severe back pain and mobility impairment in elderly patients. Traditional nonoperative management includes long term bed rest, analgesics and bracing. This type of medical management however, fails to restore spinal alignment and vertebral height, and the lack of mobility itself can result in secondary complications, including worsening osteoporosis, atelectasis, pneumonia, deep vein thrombosis, decubitus ulcer and pulmonary embolism in old patients[3,6,11,14].

Historically, the only alternative to nonoperative management for symptomatic vertebral fractures was open surgical decompression and stabilization by internal fixation hardware and bone grafting, and this was usually reserved for patients with gross spinal deformity or neurological impairment. The reason for this surgical caution was the adverse risk/benefit ratio in this elderly population which is characterized by poor bone quality and multiple comorbid condition.

Minimal invasive percutaneous vertebroplasty involving the injection of cement directly into the fractured vertebral body has been reported to be effective in improving pain associated with vertebral compression fractures. Limitations of vertebroplasty include the inability of the procedure to address the kyphotic deformity

Table 2. Comparison of ambulatory status, preoperation and postoperation

	*Not Ambulatory** (%)	*Assisted Ambulation** (%)	Fully Ambulatory** (%)
Preoperation (n=30)	10(33.3%)	8 (26.7%)	12 (40.0%)
Postoperation (n=30)	0	2 (6.7%)	28 (93.3%)
P value***	<0.001	<0.001	<0.001

* the cause of inability to ambulate independently was the back pain, not neurologic deficits ** Not Ambulatory : bed ridden or wheelchair ambulation Assisted Ambulation : requiring walking aid (cane or walker) Fully Ambulatory : walking unassisted ***Paired *t* test and Wilcoxon signed-rank test compared with preoperation data

Table 3. Changes of mean predicted vertebral body heights *

	Preoperative height (mm)	Postoperative height (mm)	Change in height (mm)	*P* value
Anterior body height	74.5 % (19.6mm)	80.3 % (22.9mm)	5.8 % (3.2mm)	>0.05
Midline body height	58.9 % (13.7mm)	81.2 % (16.8mm)	22.3 % (3.1mm)	<0.001

* The estimated height (100%) for each level treated is based on the mean height measurement of the closest, unfractured vertebrae above and below the treated level

Table 4. Changes in spine sagittal alignment

	n (Fractures/ Patients)	Mean Preoperative Cobb angle (range)	Mean Postoperative Cobb angle(range)	Mean Change in Cobb angle(range)	*P* value*
Thoracic	12/12	16.3°(7~29°)	15.3°(4~23°)	1.0°(−10~13°)	>0.05
Lumbar	28/20	−14.4°(2~42°)	−16.5°(2~42°)	2.1°(−13~21°)	>0.05

* Wilcoxon signed-rank test

and the substantial risk of extravertebral cement leakage that results from the high-pressure cement injection required by this technique[2,9,12,13,18,20]. In contrast, kyphoplasty attempts to restore spinal alignment and allows for lower pressure placement of cement into the cavity created in the vertebral body by balloon expansion[4,5,8,15,16].

In our series, pain relief after kyphoplasty was evident with significant reduction of VAS score postoperatively. Despite the short mean follow-up period of 5 months, 83.3% of 30 patients reported improvement in pain, which was presented by decrease of VAS score. And this reduction in pain may contribute to the ability to move independently.

Ambulatory status was also effectively improved after kyphoplasty. Preoperatively, 33.3% of 30 patients were bed-ridden and 26.7% of the patients could walk with assistance due to back pain. After kyphoplsty, all the nonambulatory patients became ambulatory, and there remained only 2 patients who required assistance after procedure. Percentage of fully ambulatory patients was 93.3% at the last follow-up after kyphoplasty. The ability to ambulate is important because this may reduce the cost of care and complications in this elderly population, and will rapidly improve quality of life. But because this study is designed to report the preliminary results of kyphoplasty for the treatment of osteoporotic compression fractures in a short-term period, longer-term follow-up and more cases seems to be required to determine the clinical course of the pain relief and ambulatory function.

The consequences of kyphotic deformity associated with osteoporotic vertebral compression fractures have been shown to correlate with mortality, morbidity and functional difficulty[3,11]. Some authors reported kyphoplasty might restore normal spine alignment by correcting kyphosis, which would prevent respiratory and digestive problems, and protect vulnerable vertebral levels above or below the treated site or sites by minimizing force transfer[10,15]. In our series, the mean anterior height seemed to be increased from 74.5% to 80.3%, but it was not statistically significant. And the mean midline height was increased significantly toward the predicted height (Table 3). Overall mean changes of regional Cobb angle in thoracic and lumbar region were 1.0° and 2.1°, respectively. With regard to sagittal alignment, the mean Cobb angle seemed to be improved after procedure. But it was not statistically significant (Table 4).

There are a few literatures that reported about the sagittal angle improvement after kyphoplasty. Philips et al[15] reported significant kyphotic angle change after kyphoplasty which was performed on 61 osteoporotic vertebral compression fractures of 29 patients. They reported that overall kyphotic deformity improvement was mean of 8.8° and it was statistically significant. Lieberman et al[10] and Ledlie et al[8] reported one case illustration of sagittal angle improvement. In the present study, there were some cases which showed fair degree of correction of kyphotic deformity. But the overall mean improvement was not statistically significant. Although we do not know, therefore cannot explain exactly the reason for the difference between the results of ours and previous reports, there might have been several possible explanation. Firstly, there might have been measurement errors during x-ray evaluation because the vertebral bodies in patients with osteopenia can be difficult to image, particularly in the thoracic spine. Secondly, even though there was some restoration of vertebral height, there might have been no change in kyphosis angle because deformed intervertebral disc could absorb the expanded portion of vertebral body. Thirdly, surgeon's bias, patient indication and technical difference might have the possible role for the difference. The authors think that more experiences and more reports should be followed to clarify the reason of this different result and controversy.

During 40 procedures performed in 32 patients, there were no device-related adverse events and no procedure related medical complications. We recorded one PMMA leak that resulted in no clinical consequence. This was considerably lower than the leakage rates of PMMA reported for vertebroplasty[8,10,12,13,16]. As the kyphoplasty procedure evolved, it has become apparent that the low-pressure cement deposition as a result of the creation of an intravertebral cavity allows for longer working times with the cement. This time period allows for the placement of more viscous cement and may further lower the risk of extravertebral cement extravasation[15].

Conclusion

Balloon kyphoplasty safely reduced severe back pain, and returned geriatric patients to higher activity levels. The midline vertebral height was restored significantly. But kyphotic deformity correction was not significant as contrary to what we expected from the present study before it was carried out. The authors think that more experiences and more reports should be followed to clarify the relative advantages of kyphoplasty over the previous procedures.

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