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Clinical Article

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Segmental Deformity Correction after Balloon Kyphoplasty in the Osteoporotic Vertebral Compression Fracture

Objective : Balloon kyphoplasty can effectively relieve the symptomatic pain and correct the segmental deformity of osteoporotic vertebral compression fractures. While many articles have reported on the effectiveness of the procedure, there has not been any research on the factors affecting the deformity correction. Here, we evaluated both the relationship between postoperative pain relief and restoration of the vertebral height, and segmental kyphosis, as well as the various factors affecting segmental deformity correction after balloon kyphoplasty.

Methods : Between January 2004 and December 2006, 137 patients (158 vertebral levels) underwent balloon kyphoplasty. We analyzed various factors such as the age and sex of the patient, preoperative compression ratio, kyphotic angle of compressed segment, injected PMMA volume, configuration of compression, preoperative bone mineral density (BMD) score, time interval between onset of symptom and the procedure, visual analogue scale (VAS) score for pain rating and surgery-related complications.

Results : The mean postoperative VAS score improvement was 4.93±0.17. The mean postoperative height restoration rate was 17.8±1.57% and the kyphotic angle reduction was 1.94±0.38°. However, there were no significant statistical correlations among VAS score improvement, height restoration rate, and kyphotic angle reduction. Among the various factors, the configuration of the compressed vertebral body (p=0.002) was related to the height restoration rate and the direction of the compression (p=0.006) was related with the kyphotic angle reduction. The preoperative compression ratio (p=0.023, p=0.006) and injected PMMA volume (p<0.001, p=0.035) affected both the height restoration and kyphotic angle reduction. Only the preoperative compression ratio was found to be as an independent affecting factor (95% CI : 1.064-5.068).

Conclusion : The two major benefits of balloon kyphoplasty are immediate pain relief and local deformity correction, but segmental deformity correction achieved by balloon kyphoplasty does not result in additional pain relief. Among the factors that were shown to affect the segmental deformity correction, configuration of the compressed vertebral body, direction of the most compressed area, and preoperative compression ratio were not modifiable. However, careful preoperative consideration about the modifiable factor, the PMMA volume to inject, may contribute to the dynamic correction of the segmental deformity.

KEY WORDS : Balloon kyphoplasty · Compression fracture · Deformity · Restoration.

INTRODUCTION

Vertebral compression fractures are common in old ages and are occurring more frequently in developed countries[21,22]. A compressed vertebral body can sometimes lead to vertebral body collapse, kyphosis, chronic back pain and disability later. Furthermore, the reduced physical activity after longterm bed rest for chronic back pain after compression fractures can result in the deterioration in the quality of life for the patient themselves as well as their families[4,22]. Augmentation of the vertebral body by percutaneous polymethylmethacrylate (PMMA) injection was introduced by Galibert, et al.,[9] in 1987. Since the introduction of this procedure, many authors have reported that vertebroplasty results in firmative vertebral deformity correction and relief of back pain[1,2,6-8,10,12]. However, the vertebroplasty has not been completely satisfactory because of potent complications such as the leakage of the bone cements into the spinal canal, minimal reduction of the kyphotic posture, and some rare cases of pulmonary embolism[2,20].

In contrast to vertebroplasty, balloon kyphoplasty (BKP) is a new technique which has many advantages including better restoration of the vertebral body and a lower risk of extravasation of the cements[15,16,18,19].

To determine the effectiveness of balloon kyphoplasty on a compressed vertebral body, we retrospectively analyzed the relationship between postoperative pain relief and restoration of

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vertebral height and segmental kyphosis as well as the various factors that affect segmental deformity correction after balloon kyphoplasty.

MATERIALS AND METHODS

Patient population

Patients with compression fractures in the thoracic or lumbar vertebrae were evaluated to determine their suitability for balloon kyphoplasty. The patients who showed acute fractures upon magnetic resonance imaging or computerized tomography with bone scan and who had concordant pain at the fracture site were considered candidates for kyphoplasty. We excluded patients who had a severe compression ratio of over 60 percent and burst fracture or canal encroachment. Also, the bone mineral density was checked before the procedure and the mean data was -3.24±0.84.

For the comparisons among categorical variables, the patients' postoperative VB (Vertebral Body) height restoration rate was classified into three types : 1) Good restoration rate over 20%, 2) Moderate between 0-20%, and 3) Poor restoration with a negative rate. Patients were divided into 2 groups according to their sex and age (above and below 60 years old). The patients were grouped into 4 categories according to the time interval between the trauma and the procedure : 1) within a week, 2) between 8 and 30 days, 3) between 31 and 60 days, and 4) over 61 days and according to BMD : 1) BMD over -2.0, 2) BMD from -3.0 to -2.1 3) BMD under -3.0, 4) BMD unchecked.

Balloon kyphoplasty procedure

The procedures were performed under local anesthesia with minimal sedation. Patients were placed in a prone position and monitored by electro cardiography and oxygen saturation during the procedures. First, 2% lidocaine was injected subcutaneously at the needle insertion site, and a 0.5 cm-sized skin incision was made around the fractured vertebral body pedicle under C-arm fluoroscopic guidance. Two 11-gauge Jamshidi® needles were inserted into the pedicle percutaneously. Two 1.5 mm diameter guide pins were inserted through the Jamshidi needles, and then two inflatable bone tamps were inserted into the fractured vertebral bodies. The balloons were dilated simultaneously under C-arm fluoroscopic monitoring. Ballooning pressures did not exceed 200 psi, and a balloon cavity was made in the vertebral body with 3 to 4 cc per cavity. Then bone cement containing 1.5 cc of PMMA was injected through the filler. From each side, 2 cc to 4 cc of PMMA was injected into most patients. After the PMMA became hard, the bone filler was removed.

Patients were instructed to ambulate carefully with a hard brace on the first post-operative day, and most patients were discharged within a week after the procedure.

Measuring of vertebral body height and kyphotic angle

Preoperative and postoperative plain radiographs were reviewed to measure the restoration of the vertebral body height and kyphotic angle. Most compressed vertical heights were measured in the fractured vertebral body and compared to the same site for both of the nearest normal vertebral bodies (Fig. 1)[20]. We used Cobb's technique to calculate the segmental kyphotic angle across the fractured level and the measurement was taken from the superior endplate of the vertebra one level above the treated vertebra to the inferior endplate of the vertebral body one level below the treated vertebra[14] (Fig. 2). When nonadjacent levels were treated in a patient, separate Cobb angles were measured

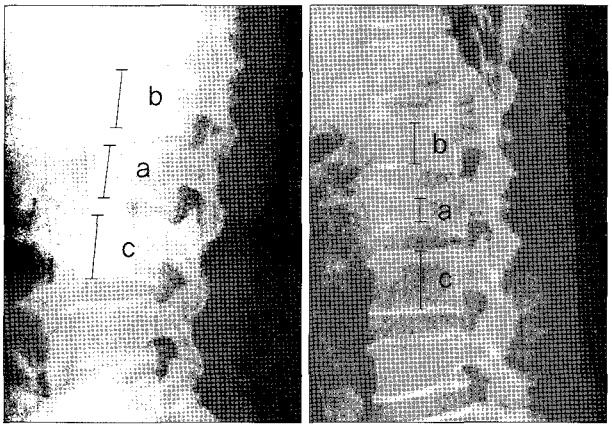

Fig. 1. Assessment of compressed vertebral body height : Most compressed vertical heights are measured in the fractured vertebral body as compared to the same site of both nearest normal vertebral bodies (Compression Ratio : a/[(b+c)/2]×100%).

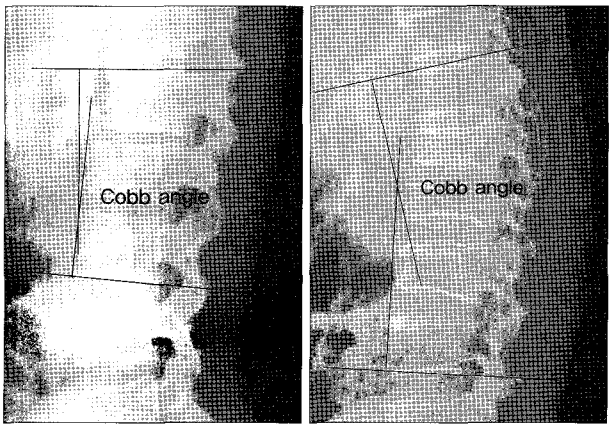

Fig. 2. Assessment of kyphotic angle : Determination of the Cobb angle measurements are taken from the superior endplate of the vertebra one level above the treated vertebra to the inferior endplate of the vertebral body one level below the treated vertebra (Cobb's technique).

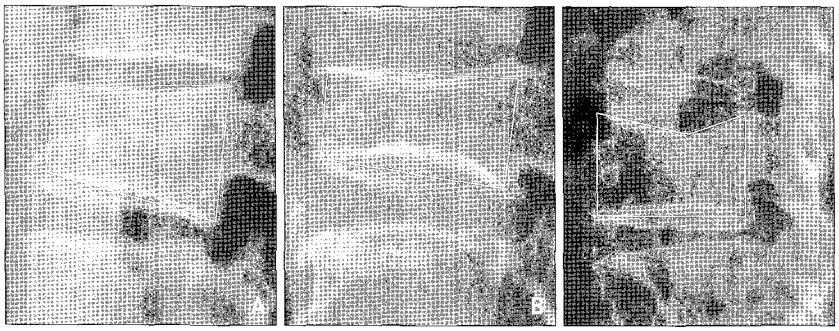

Fig. 3. Configuration of compressed vertebral body. A : Wedged type, B : Flat type, C : V-shaped type.

Table 1. Characteristics of treated levels

Characteristics	Data
Number of patients	137 (158 fractured levels)
Mean patient age	69.10±0.99 (22 to 88 yrs)
>60 years old	136 (86.1%)
<60 years old	22 (13.9%)
Sex	
Male	52 (32.9%)
Female	106 (67.1%)
Preoperative compression ratio	24.97±1.88%
Preoperative kyphotic angle	3.24±0.84 degrees
Bone marrow mineral density	−3.24±0.84
1) >−2.0	19 (12.0%)
2) between −2.1 and −3.0	14 (8.9%)
3) <−3.0	88 (55.7%)
4) not checked BMD	37 (23.4%)
Preoperative VAS* score	7.96
Postoperative VAS score	2.76
Symptom duration	76.1±17.66 days
1) less than 1 week	75 (47.5%)
2) 8−30 days	41 (25.9%)
3) 31−60 days	13 (8.2%)
4) >60 days	29 (18.4%)
Height restoration	
1) good (>20%)	72 (45.5%)
2) moderate (0−20%)	56 (35.4%)
3) poor (<0%)	30 (19.0%)
Configuration of VB†	
1) Wedge shaped	82 (51.9%)
2) Flat type	25 (15.8%)
3) V−shaped	51 (32.3%)
Direction of the compression	
1) Anterior	32 (20.3%)
2) Posterior	–
3) Superior	108 (68.4%)
4) Inferior	18 (11.4%)
Total injected PMMA Vol.	
1) < 5cc	20 (12.7%)
2) > 5cc	138 (87.3%)

*VAS : Visual Analogue Scale †VB : Vertebral body

for each treated level. If adjacent level vertebral fractures were treated, a single Cobb angle measurement across the treated levels was performed.

Configurations of the compressed vertebral body were categorized into three groups : 1) Wedge shaped, 2) Flat type, and 3) V shaped (Fig. 3). The position of the most compressed part of the vertebral body was divided into 4 areas: 1) Anterior part, 2) Posterior part, 3) Superior part, and 4) Inferior part.

Functional outcome

We periodically checked the visual analogue scale (VAS) score of back pain in the outpatient clinic and retrospectively analyzed these data. The scores ranged from 1 [no pain] to 10 [worst imaginable pain].

Statistical analysis

Data were analyzed using a commercially available statistical software package (SPSS for Windows, version 12.0. 2003; SPSS, Inc., Chicago, IL, USA). Categorical variables were compared using the Pearson chi-square test or the test for linear trend. Continuous variables were compared by multiple linear regression. Univariate association of continuous variables was tested using Spearman rank correlation coefficients (r_s). Univariate and multivariate odd ratios and 95% confidence intervals for factors affecting the segmental deformity correction were analyzed with multivariate logistic regression. A p-value less than 0.05 was considered statistically significant.

RESULTS

A total of 137 patients underwent the procedure and the total compressed level was 158. The mean age of the patients was 69.10±0.99 years (ranging from 22 to 88 years) and 106 patients (67.1%) were women (Table 1). Of the 137 patients, 116 patients had a single vertebral fracture, and 21 had multiple lesions. The level of the fracture was distributed between T4 and L5 and was most prevalent at the thoracolumbar junction (Fig. 4). The preoperative mean compression ratio of the compressed vertebral body was 24.97±1.88%, the kyphotic angle was 3.24±0.84 and the VAS score was 7.96. The postoperative vertebral body mean height restoration rate was 17.8±1.57% ($p<0.001$). The postoperative mean kyphotic angle was improved 1.94°±0.38° ($p<0.001$) and the mean VAS score dramatically fell from 7.96 to 2.76. Minor PMMA leakeage was detected in 14 cases, but there were no associated

clinical symptoms. During the 158 procedures in 137 patients, there were no device-related complications, embolism, or infection.

Based on the Pearson correlation test, there was no statistically significant difference between VAS improvement and segmental deformity correction (vertebral body height restoration rate, kyphotic angle reduction rate) after the procedure (p=0.495, p=0.822), (Table 2).

As a result of the categorical comparison with the vertebral body restoration, the configuration of the compressed vertebral body (p=0.002), the total injected PMMA volume ($p<0.001$) and the preoperative compression ratio (p=0.023) significantly affected the height restoration (Table 3). Other factors including age, sex, symptom duration, BMD and compressed site of the VB were not correlated with height restoration. In the analysis of the kyphotic angle reduction, the direction of the most compressed area (p=0.006), the preoperative compression ratio (p=0.006), and the total volume of the injected PMMA (p=0.035) were correlated with postoperative kyphotic angle reduction (Table 3).

Using a multivariate logistic regression test to analyze the different factors, we determined that the preoperative compression ratio was the only significant factor independently affecting the kyphotic angle reduction (95% confidence interval between 1.064 and 5.068), (Table 4).

DISCUSSION

Vertebral compression fractures usually cause severe back pain and motion restriction. The biggest concern with untreated compression fractures is the deterioration of compressed vertebral body, occurrence of kyphosis and neurologic changes[5,13,17]. Traditional nonoperative management includes long term bed rest, pain relievers, and functional rehabilitation with braces[3]. Open decompressive surgery was the traditional approach to restore sagittal alignment and was the only option before vertebroplasty was introduced.

Kyphoplasty is a minimally invasive procedure that can stabilize the compressed vertebral body by percutaneous injection of PMMA, reduce the pain, and restore the vertebral body heights and kyphotic angles. Lieberman et al.[16], and Garfin et al.[11], have reported that kyphoplasty improved the early outcomes in more than 300 patients with acute compression fractures. Our clinical result was similar with their results. The post-operative height restoration rate, kyphotic angle reduction and VAS score showed a great improvement after the surgery. Improvements in vertebral height in our study were in the slightly lower range (from 75% to 93%). These results are similar to those demonstrated by Garfin et al.,[11] who reported mean increases in vertebral height from 83% of the postoperative predictions to 99% after surgery. Lieberman et al.,[16] reported a mean vertebral height restoration of 46.8% (midline measurement) in 70% of 70 treated levels. The mean vertebral height restoration of 17.8±1.57% in the 158 treated levels in our study was

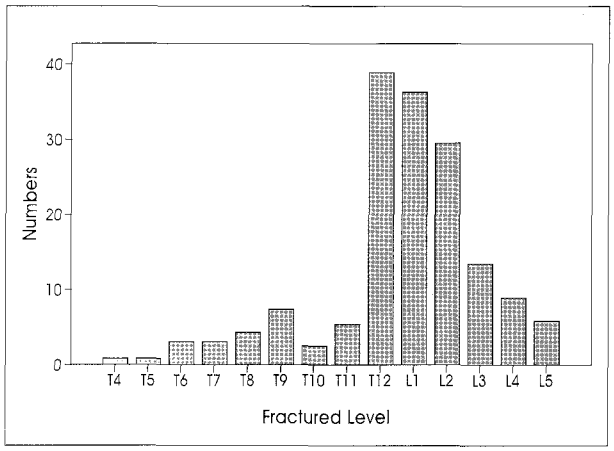

Fig. 4. Fracture distribution.

Table 2. *Correlation between VAS improvement and deformity correction*

	Unstandardized coefficients		Standardized coefficients	t	Sig.
	B	Std.Error	Beta		
Constant	4.959	.259	–	19.128	.000
Restoration Rate	.001	.009	.015	.155	.877
Kyphotic angle reduction	.005	.039	.014	.142	.888

*Dependent Variable : Postoperative VAS improvement

Table 3. Various factors affecting height restoration rate and kyphotic angle reduction

Factors	Height restoration		Kyphotic angle	
	Pearson chi-square	p-value	Pearson chi-square	p-value
Age	2.890	0.236	0.497	0.481
Sex	4.610	0.100	0.140	0.708
BMD	12.541	0.051	1.721	0.632
Symptom duration	9.677	0.139	3.574	0.311
Direction of most compressed VB	5.155	0.272	10.349	0.006*
Configuration of the compression	16.922	0.002*	4.000	0.135
Total injected PMMA Vol.	7.523	0.023*	4.461	0.035*
Preoperative compression ratio	51.173	0.000*	7.471	0.006*
Preoperative kyphotic angle	4.770	0.092	2.090	0.148

*p-value < 0.05

slightly lower than that in previous studies. These differences may be caused by the strict indications determined by the surgeons and the different methods used to analyze the patients.

We predicted that old age, osteo-porosis and a long interval bet-ween the trauma and the procedure would be the most concerning factors, but we did not find a correlation with these factors. This discordance might be limited by the number of cases and age group restriction of our analysis. The methodology used to measure the bone mineral density may contribute to this result, because the compressed osteoporotic vertebral body as well as the wide range of the normal vertebral body were included when measuring the bone mineral density.

The relationship between the compressed vertebral body configuration and the height restoration was contrary to our expectations. We expected that the configuration of the compressed vertebral body itself would have no correlation with the height restoration, but we found that this factor showed a statistically significant correlation with height restoration. (p=0.002). This association may be due to the simple prevalence of anterior wedge type of compression fracture in the spinal biomechanic etiological point of view. Further study to evaluate these factors would be valuable.

Our regressional analysis for the injected PMMA volume and segmental deformity correction showed interesting results. The kyphotic angle reduction showed a proportional and positive increase with the total injected PMMA volume. In contrast, the height restoration rate showed a negative linear regression with the total injected PMMA volume (Fig. 5). This suggests that the PMMA augmented vertebral body could reduce the kyphosis from the compression fracture. Nevertheless, a larger volume of PMMA did not further reduce the vertebral height. The result of our statistical analysis of the preoperative compression ratio and segmental deformity correction suggests that a more severely compressed vertebral body needs a larger volume of PMMA injection for the correction. Further research is necessary to determine the most suitable volume to use for the deformity correction.

Table 4. Factors affecting segmental deformity correction

Factors	Height restoration			Kyphotic angle		
	p-value	95% CI		p-value	95% CI	
Good (>20% Restoration)	.000	–	–	–	–	–
Wedge shape	.093	.108	1.188	–	–	–
Flat shape		.276	8.120	–	–	–
<25% compression ratio	–	.011	.131	–	–	–
Mod (0~20% Restoration)	.028	–	–	–	–	–
Wedge shape	.661	.294	2.173	–	–	–
Flat shape	.176	.036	1.841	–	–	–
<25% compression ratio	.248	.161	1.601	–	–	–
Reduction +	–	–	–	.193	–	–
Ant compression	–	–	–	.010	.038	.646
Sup compression	–	–	–	.002	.041	.491
<25% compression*	–	–	–	.034	1.064	5.068
<5cc injection	–	–	–	.106	.071	1.289

CI : confidence interval

CONCLUSION

Balloon kyphoplasty is an effective treatment strategy for osteoporotic compression fractures. Two major benefits of balloon kyphoplasty are the immediate pain relief and the local segmental deformity correction.

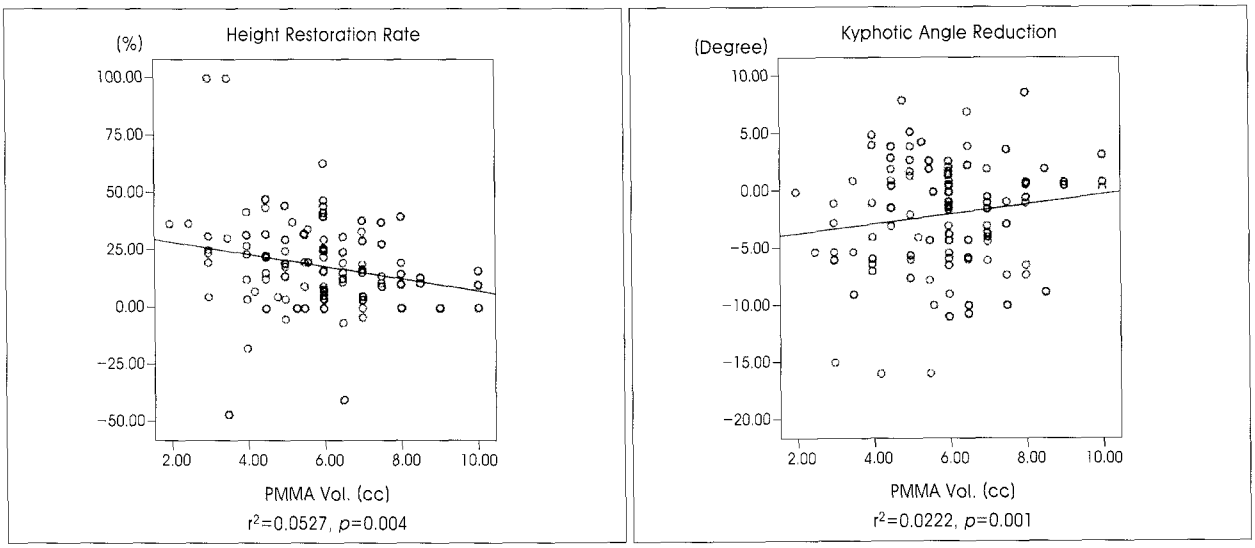

Fig. 5. Regression line analysis of injected total PMMA volume and segmental deformity correction.

However, the segmental deformity correction achieved by balloon kyphoplasty did not result in additional pain relief. Among the factors that affected the segmental deformity correction, the configuration of the compressed vertebral body, the position of the most compressed area, and the preoperative compression ratio were not modifiable. Our clinical analysis suggests that this procedure can be widely used for the treatment of osteoporotic compression fractures. However, careful preoperative consideration of the independent modifiable affecting factor, the volume of injected PMMA may contribute to the dynamic correction of the segmental deformity. Furthermore, these results serve as the first step towards designing long term follow-up studies in large populations, which will help in the designing of effective treatment strategies and clinical studies.

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