Original Article

Outcomes of Balloon Kyphoplasty for the Treatment of Osteoporotic Vertebral Compression Fracture in Rheumatoid Arthritis: A Case–control Study

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Abstract

Background: Patients with rheumatoid arthritis (RA) have higher rate of osteoporosis and vertebral fracture than individuals without RA. This study aimed to compare the outcomes of balloon kyphoplasty (KP) performed to treat osteoporotic vertebral compression fracture (OVCF) in RA patients with the outcomes in non-RA patients. **Materials and Methods:** The patients who received KP for OVCF and could be followed up at least 1 year were included in the study. These patients were divided into RA group and non-RA group. For clinical outcomes, the visual analog scale for back pain (VAS-BP) and Korean version of the Oswestry Disability Index (K-ODI) were assessed before and after the procedure and at the 1-year followup. For radiological outcomes, the anterior vertebral height and change in local kyphotic angle were measured. Complications were also examined. **Results:** Twenty three RA patients (31 vertebral bodies) and 107 non-RA patients (124 vertebral bodies) were analyzed. In two groups, postoperative VAS-BP and K-ODI decreased significantly to similar extents. There was a similar recovery of vertebral height and kyphotic angle in two groups. However, in terms of complications, adjacent segment fracture and recollapse were more frequent in the RA group than in the non-RA group. **Conclusions:** The use of KP to treat OVCF in RA group exhibited similar outcomes to non-RA group in terms of pain reduction, vertebral height restoration, and kyphosis correction. However, RA group had significantly higher rate of complications involving adjacent segment fracture and recollapse. Therefore, careful followup after KP in patients with RA is required to monitor for high complication rate.

Keywords: *Balloon kyphoplasty, osteoporotic vertebral compression fracture, rheumatoid arthritis*

Introduction

Individuals with rheumatoid arthritis (RA) have a rate of osteoporosis more than twofold greater than individuals without RA, which increases the risk of osteoporotic vertebral compression fracture (OVCF) more than sixfold.[1-5] It is reported that kyphoplasty (KP) is better than conservative treatment in patients with OVCF.[6] However, to our knowledge, there have been no published studies on the comparison results of KP treatment of OVCF for patients with RA and those for patients without RA. We hypothesized that the outcomes of balloon KP in patients with RA would be poorer, as their overall bone strength is decreased by various factors.

Materials and Methods

This study was approved by our Institutional Review Board. We conducted a retrospective comparative study of patients who received balloon KP to treat OVCF in Hanyang University Medical Center between August 2011 and May 2017 and could be followed up at least 1 year. Patients who were followed up at the department of rheumatology in our hospital for RA or who were diagnosed RA with the American College of Rheumatology criteria were classified as the RA group.[7] Other patients were classified as the non-RA group. The age, gender, body mass index, and bone mineral density (BMD) measured using dual-energy X-ray absorptiometry at the time of procedure were reviewed from electronic medical records. In the case of RA patients, the medications for RA were also identified. We defined OVCF as low-energy trauma resulting in lumbago and focal tenderness at thoracolumbar or lumbar vertebra observed during physical examination and compression of the anterior vertebral body on plain radiographs. Acute

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fractures were confirmed by magnetic resonance image or bone scan. Patients with a vertebral fracture due to high-energy trauma and those with a suspected pathological fracture due to infection or tumors were excluded from the study. Patients who described severe pain in everyday living, even after receiving 3 weeks of conservative treatment, and with a 30% or higher anterior vertebral compression rate on a simple radiograph, were considered eligible for KP.

KP procedure was performed by one surgeon (CNK) using a conventional bilateral transpedicular approach, with the patient in the prone position after local anesthesia and sedation. The bone cement injection area and cement leakage were monitored through a C-arm fluoroscope during the procedure. The bone cement injection time was defined as the time between the start of polymerization and the start of the injection, and the cement volume was measured by adding up the volume of cement injected on both sides. Patients began to walk independently immediately after the operation.

Clinical results were evaluated using a visual analog scale for back pain (VAS-BP) and the Korean version of the Oswestry Disability Index (K-ODI), all of which were measured before and after the procedure and at the 1-year followup. The radiological results were evaluated twice, at intervals of 2 weeks by a spine fellow and a chief resident from the orthopedic department who received the same training. The anterior height of the fractured vertebral body and the local kyphotic angle were measured before and after the procedure and at the 1-year followup. Complications, including cement leakage, recollapse of the cemented vertebral body, and adjacent segment fractures, were checked during followup period. The vertebral height was calculated from a simple radiograph taken in standing position and was defined a ratio of the vertebral height of the collapsed vertebral body to the average of the adjacent upper and lower anterior vertebral heights, converted into a percentage. The local kyphotic angle was measured by calculating the Cobb's angle formed by the superior end plate of the upper vertebral body and the inferior end plate of the lower vertebral body of the fractured vertebral body. Recollapse was defined when the height of vertebral body decreased >5% during 1 year of followup compared with the height of vertebral body immediately after the procedure, and bone absorption around the inserted polymethylmethacrylate was noticeable. Cement leakage was confirmed through anteroposterior and lateral simple radiographs, and if necessary, a computed tomography scan was used.[8]

Statistical analysis

All statistical analyses were performed using the Statistical Package for the Social Sciences version 19.0 (SAS Institute, Cary, North Carolina, USA). A paired *t*-test was used to compare the changes in the vertebral compression rate and kyphotic angle before and after the procedure and after 1 year of followup. The correlation between recollapse, adjacent segment fracture, and cement leakage was examined using the Chi-squared test. The Student's *t*-test was used for the comparative analysis of continuous data, and Cohen's kappa statistic was used for the analysis of intraobserver and interobserver reliabilities. $P < 0.05$ was considered statistically significant.

Results

Of the patients enrolled in this study, 23 had been diagnosed with RA (the RA group) affecting 31 vertebral bodies. In total, 4 patients were male and 19 were female, with a mean age of 70.7 (55–82) years. The non-RA group included 107 patients and 124 involved vertebral bodies. In total, 23 were male and 84 female, with a mean age of 71.7 (58–90) years. There were no statistically significant differences between the RA versus non-RA groups in terms of demographics, except for BMD. In the BMD test (performed before the KP), the RA group had a mean T-score of −3.41 (−4.7 to −2.5) and the non-RA group had a mean T-score of −2.94 (−4.0 to −2.5). RA patients had significantly lower BMD than non-RA patients ($P = 0.002$) [Table 1].

After a diagnosis of RA, duration of pharmacotherapy until the balloon KP procedure was a mean of 9.95 (1–41) years. Twenty three patients (100%) were receiving steroids, 23 patients (100%) were receiving nonsteroid anti-inflammatory drugs, and 18 patients (78%) were receiving methotrexate.

The mean volumes of cement injected into patients in the RA group and the non-RA group during the balloon KP procedure were 6.4 (4.5–10) cc and 6.6 (4.5–10) cc, and the mean injection times were 10.5 (8.5–13) min and

Table 1: Demographic data

Patient data	RA group	Non-RA group	*P*
Patients (*n*)	23	107	
Fractured vertebrae (*n*)	31	124	
Age (years)	70.7 (55-82)	71.7 (58-90)	0.611
Gender (female:male)	19:4	84:23	0.783
BMI (kg/m^2)	24.4 (14.4-30.3)	23.6 (15.5-33.3)	0.256
BMD (T-score)	−3.41 (−4.7-−2.5)	-2.94 (−4.0-−2.5)	0.002
BMD (g/cm^2)	0.50 (0.30-0.55)	0.56 (0.32-0.52)	0.028
Number of involved vertebrae, *n* (%)			
T11	2 (6.5)	13 (10.5)	0.068
T12	3 (9.7)	31 (25.0)	
L1	13 (41.9)	51 (41.1)	
L2	6 (19.4)	21 (16.9)	
Other (not thoracolumbar junction)	7 (22.5)	8 (6.5)	

BMD=Bone mineral density, BMI=Body mass index, L=Lumbar, T=Thoracic

10.1 (7.5–13.5) min. There were no significant differences between the two groups ($P = 0.472$ and $P = 0.558$).

For the entire cohort, there was a statistically significant improvement in all clinical and radiologic outcomes, except for 1-year postoperative local kyphotic angle.

For the measurements of vertebral height and local kyphotic angle made from preoperative and postoperative radiographs, the kappa coefficients for intraobserver reliability were 0.89 (0.78–0.99) and 0.89 (0.79–0.99) and the kappa coefficients for interobserver reliability were 0.77 (0.62–0.91) and 0.75 (0.64–0.87). The kappa coefficients were good, suggesting good interobserver and intraobserver reliabilities.

In the RA group, the mean vertebral height of the fractured body was restored from 56.3 (29.3–67.2)% before the balloon KP procedure to 74.5 (60.2–96.6)% after the procedure ($P < 0.001$). Furthermore, the vertebral height was maintained at the 1-year followup than before the procedure ($P < 0.001$). In the non-RA group, the mean vertebral height of the fractured body was restored from 55.7 (27.9–66.6)% before the balloon KP procedure up to 73.4 (50.3–95.1)% after the procedure ($P < 0.001$). Again, the vertebral height was higher at the 1-year followup than before the procedure ($P < 0.001$). In the RA group, the local kyphotic angle displayed approximately 3.9° of deformity correction after the procedure relative to that prior to the procedure ($P < 0.001$); however, a 4.0° correction loss of kyphotic angle was also noted at the 1-year followup ($P = 0.225$). In the non-RA group, the local kyphotic angle improved from 4.1° after the procedure ($P < 0.001$); however, there was also a 3.2° correction loss at the 1-year followup ($P = 0.340$) [Table 2].

The degree of clinical improvement in the two groups was examined. After KP, in the RA group, the VAS-BP and K-ODI improved by 5.7 (4–7) and 16.1 (11–25), and in the non-RA group, they improved by 5.3 (4–9) and 19.9 (14–27) ($P = 0.313$ and $P = 0.085$). However, at the 1-year followup, VAS-BP and K-ODI declined. In the RA group, they were 0.4 (0–4) and 0.4 (0–15). In the non-RA group, they were 0.3 (0–3) and 1.7 (0–12) ($P = 0.854$ and $P = 0.157$).

The change of vertebral height and local kyphotic angle was compared in the two groups, and in the RA group, they were 18.2 (13.4–40.5)% and 3.9 (2.3–11.4)°. In the non-RA group, they were 17.7 (11.3–32.9)% and 4.1 (2.9–13.7)°; there were no significant differences between the two groups ($P = 0.468$ and $P = 0.734$). However, at the 1-year followup, vertebral height and local kyphotic angle worsened. In the RA group, they were 4.1 (1.1–11.2)% and 4.0 (1.9–10.7)°. In the non-RA group, they were 2.9 (0.9–10.4)% and 2.8 (0.7–12.5)° ($P = 0.628$ and $P = 0.812$) [Table 3].

Cement leakage is a complication that can occur after the balloon KP procedure; 14 patients (45.1%) were affected in the RA group and 40 (32.2%) in the non-RA group ($P = 0.108$). Recollapse [Figure 1] occurred in six patients (19.3%) in the RA group and in five patients (4.0%) in the non-RA group; collapse occurred significantly more frequently in the RA group ($P < 0.001$). Adjacent segment fracture [Figure 2] occurred in three patients (9.6%) in the RA group and in six patients (4.8%) in the non-RA group ($P = 0.026$) [Table 4].

Recollapse occurred at a mean of 3.42 (0.5–11) months after the procedure in the RA group and a mean of 7.25 (0.25–31) months in the non-RA group; there was no statistically significant difference between the two groups ($P = 0.841$) [Table 5]. The adjacent segment fracture took place a mean of 5 (2–7) months after the balloon KP procedure in the RA group and a mean of 4 (1–7) months (range 1–7 months) in the non-RA group; there was no

Table 2: Clinical and radiological outcomes

Outcomes	Preoperative	Postoperative	1-year postoperative	*P* (preoperative vs. postoperative/ preoperative vs. 1-year postoperative)
Clinical outcomes				
VAS-BP				
RA	8.1 (6-10)	2.4 (0-4)	2.8 (1-5)	<0.001/<0.001
Non-RA	7.4 (6-10)	2.1 (0-4)	2.4 (1-5)	<0.001/<0.001
K-ODI				
RA	38.1 (35-44)	22.0 (17-25)	22.4 (15-29)	<0.001/<0.001
Non-RA	37.0 (34-47)	17.1 (15-26)	18.8 (15-29)	<0.001/<0.001
Radiological outcomes				
Vertebral height (%)				
RA	56.3 (29.3-67.2)	74.5 (60.2-96.6)	70.1 (50.1-91.3)	<0.001/<0.001
Non-RA	55.7 (27.9-66.6)	73.4 (50.3-95.1)	70.5 (49.4-94.3)	<0.001/<0.001
Local kyphotic angle (°)				
RA	16.9 (11.4-22.3)	13.0 (9.4-15.1)	16.0 (11.2-14.4)	<0.001/0.225
Non-RA	15.6 (12.2-25.8)	11.5 (10.3-17.7)	14.3 (11.5-16.9)	<0.001/0.340

RA=Rheumatoid arthritis, VAS-BP=Visual analog scale for back pain, K-ODI=Korean version of the Oswestry Disability Index

Table 3: Comparison of clinical and radiological outcomes

Difference	RA group	Non-RA group	*P*
Preoperative - postoperative			
VAS-BP	5.7 (4-7)	5.3 (4-9)	0.313
K-ODI	16.1 (11-25)	19.9 (14-27)	0.085
Vertebral height (%)	18.2 (13.4-40.5)	17.7 (11.3-32.9)	0.468
Local kyphotic angle (°)	3.9 (2.3-11.4)	4.1 (2.9-13.7)	0.734
Postoperative - 1-year postoperative			
VAS-BP	0.4 (0-4)	0.3 (0-3)	0.854
K-ODI	0.4 (0-15)	1.7 (0-12)	0.157
Vertebral height (%)	4.1 (1.1-11.2)	2.9 (0.9-10.4)	0.628
Local kyphotic angle (°)	4.0 (1.9-10.7)	2.8 (0.7-12.5)	0.812

RA=Rheumatoid arthritis, VAS-BP=Visual analog scale for back pain, K-ODI=Korean version of the Oswestry Disability Index

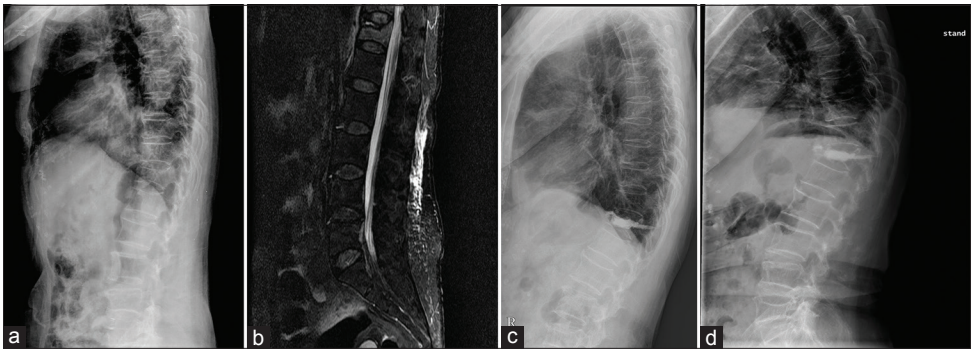

Figure 1: A T12 osteoporotic vertebral compression fracture in a patient with rheumatoid arthritis (case number 3). (a) Preoperative radiograph. (b) Preoperative magnetic resonance image. (c) Postoperative radiograph showing cement filling without leakage. (d) Recollapse after 11 postoperative months

Figure 2: L2, L3 osteoporotic vertebral compression fractures in a patient with rheumatoid arthritis (case number 18). (a) Preoperative radiograph. (b) Preoperative magnetic resonance image. (c) Postoperative radiograph showing cement filling without leakage. (d) Adjacent segment fracture at L1 after 2 postoperative months

statistically significant difference between the two groups ($P = 0.712$) [Table 6].

Discussion

RA is a chronic, systemic, inflammatory disease that causes continuous synovitis and progressive destruction of the joints. RA reduces bone density through the interaction of various factors.[1-3] According to Hauser *et al*., 26.5% of RA patients have osteoporosis, which is high in comparison to the control group at 17.4%.[9] Considering high osteoporotic morbidity and the risk of vertebral fracture in RA patients, a relatively small number of studies have investigated OVCF. We previously reported that balloon KP delivered improved results for the restoration of vertebral height in RA patients than conservative management.[10] To date, however, there have been no studies on the outcomes and complications following percutaneous balloon KP performed on RA patients for OVCF. In the current study, we performed a comparative analysis between a group of patients with RA and a control group of patients through 1 year of followup after balloon KP for OVCF. We observed that the RA group had a significantly higher rate

Table 4: Postoperative complications

Complications	RA group (%)	Non-RA group (%)	*P*
Cement leakage	14 (45.1)	40 (32.2)	0.108
Recollapse	6 (19.3)	5 (4.0)	0.001
Adjacent segment fracture	3 (9.6)	6 (4.8)	0.026

RA=Rheumatoid arthritis

Table 5: Time of recollapse

RA group case number	Month of recollapse	Non-RA group case number	Month of recollapse
3	11	17	0.25
5	1	19	31
8	2	23	1
9	0.5	30	1
15	1	74	3
23	5		
Mean	3.42		7.25

P=0.841. RA=Rheumatoid arthritis

Table 6: Time of adjacent segment fracture

RA group case number	Month of adjacent segment fracture	Non-RA group case number	Month of adjacent segment fracture
1	7	4	7
4	6	47	2
18	2	61	1
		76	7
		82	4
		86	3
Mean	5.0		4.0

P=0.712. RA=Rheumatoid arthritis

of recollapse and adjacent segment fracture compared with the non-RA group.

Previous studies have reported various rates of adjacent segment fractures following percutaneous balloon KP, ranging between 6.5% and 25%.[11-13] There is still debate about whether adjacent segment fracture after balloon KP is part of the natural progression of the disease or due to the increased load transfer to the adjacent segment following cement reinforcement. In a biomechanical study using cadavers, Kayanja *et al*.[14] reported that bone cement reinforcement did not increase the load transferred to the adjacent segment, but rather the fracture occurs naturally when there is a serious external force that the osteoporotic vertebral body cannot endure. Rho *et al*.,[15] however, stated that low BMD and cement leakage are the major factors likely to cause a new fracture after balloon KP. Rohlmann *et al*.[16] stated that if a large amount of cement is injected, it will flatten the end plate of the vertebral body, thereby increasing the pressure inside the adjacent disc and increasing the load transferred, which also increases the risk of adjacent segment fracture. The rate of overall adjacent segment fracture in the current study is 5.8%, which was not remarkably different from the results of previous studies, but the RA group showed a significantly higher rate of adjacent segment fracture compared with the non-RA group. There were no differences between the two groups in terms of the amount of bone cement injected, the rate of cement leakage, or the degree of kyphotic correction; however, the RA group had lower BMD, and it is likely that this caused the difference in the rate of adjacent segment fracture between the two groups.

According to Spross *et al*., the risk of adjacent segment fracture in the 6 months after balloon KP procedure is high when the local kyphotic angle before the procedure is >30° or when RA or cardiovascular disease is present. Other factors that can increase the risk of adjacent segment fracture include the relative inactivity of RA patients, steroid treatment for RA, and the fact that RA patients are at greater risk of osteoporosis, which causes invasion and weakening of the adjacent disc and vertebral body.[17]

Steroid treatment for patients in the early stages of RA causes secondary osteoporosis. Harrop *et al*.[18] and Syed *et al*.[19] reported that, among patients who received percutaneous vertebroplasty, recollapse was reported twice as often in patients who were treated with steroids. Harrop *et al*. reported an 11.25% recollapse rate in patients with primary osteoporosis and 48.6% in patients with secondary osteoporosis.[18] This difference is attributed to the fact that the continuous use of steroids restricts osteogenesis, reduces calcium absorption through the intestines, and reduces the differentiation of osteogenic precursors.[20] In the current study, the RA group had lower BMD than the non-RA group, which is probably due to the direct effects of RA and secondary osteoporosis caused by the use of steroids, which is common.

The current study is the first to undertake a comparative analysis of balloon KP performed on RA patients for OVCF using a control group. Although both groups showed statistically significant clinical improvements, the rate of recollapse of the cemented vertebral body and the rate of adjacent segment fracture after the balloon KP procedure were significantly increased in the RA group.

The limitations of our study were as follows: first, the number of participants was small due to a low rate of disease prevalence; second, the study was performed retrospectively; and third, no compensations were made in relation to the period, in which steroids and other drugs were administered to patients with RA.

Conclusion

Percutaneous balloon KP for patients with RA and OVCF showed results similar to the control group in terms of the early reduction of pain and the restoration of vertebral height. However, the BMD of the RA group was significantly lower than that of the control group before the procedure, and the rate of recollapse of the cemented

vertebral body and the rate of adjacent segment fracture were significantly higher in the RA group than in the control group. Therefore, careful followup is required to monitor for recollapse and adjacent segment fracture after percutaneous balloon KP in patients with RA and OVCF.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patients have given their consent for their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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