Recompression of Augmented Vertebrae after Balloon Kyphoplasty Is a Risk of Adjacent Vertebral Fracture

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Abstract:

Introduction: This study aimed to identify factors associated with adjacent vertebral fracture (AVF) incidence after balloon kyphoplasty (BKP).

Methods: To perform the analyses, 133 vertebrae of 128 patients who underwent BKP for osteoporotic vertebral compression fracture were retrospectively investigated. According to the presence of AVF throughout a 1-year period following BKP, patients were divided into AVF (n = 22) and non-AVF (n = 111) groups. The groups were compared with respect to pre- and postoperative parameters, including the incidence of recompression of augmented vertebrae (RAV). RAV was defined as a decrease in anterior vertebral body height of at least 5 mm within the 3 months that followed BKP. To identify factors associated with AVF incidence, univariate and multivariate analyses were performed.

Results: The univariate analysis revealed that the AVF group had a lower cement augmentation ratio, greater preoperative wedge angle, lower preoperative vertebral body height, lower postoperative vertebral body height 3 months post-BKP, and a greater change in vertebral body height and rate of RAV than the non-AVF group. Multivariate analysis revealed that low preoperative vertebral body height and RAV occurrence were associated with AVF incidence.

Conclusions: To the best of our knowledge, this study is the first to indicate that RAV is a risk factor for AVF. Study findings indicate that the incidence of AVF can be decreased if RAV development is avoided.

Keywords:

adjacent vertebral fracture, balloon kyphoplasty, osteoporotic vertebral compression fracture, recompression of augmented vertebrae

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Introduction

Osteoporotic vertebral compression fractures (OVF) are a major health problem in an aging society as they cause kyphosis, back pain, restricted pulmonary function, and gastrointestinal dysfunction[1)]. The main methods used to manage symptomatic OVF are conservative treatments, such as rest, corset use, and medication. However, despite adequate conservative treatment, some cases of severe back pain or nonunion require surgery. In older patients, OVF should be treated using procedures that are as minimally invasive as possible. Minimally invasive vertebral augmentation with balloon kyphoplasty (BKP) has become very popular[2-4)]. Multiple previous studies have reported that BKP is a safe and effective technique for treating OVF and it significantly reduces back pain and improves quality of life[5-8)]. However, in some rare cases, complications, including cement extrusion into the spinal canal, infection, and pulmonary embolism, have occurred after the procedure[9)]. Relative to other complications of BKP, the incidence of adjacent vertebral fracture (AVF) is relatively high, with a postoperative rate that ranges from 6.5% to 25%[1,9-14)]. AVF has been reported to cause revision surgery and persistent pain after vertebroplasty or BKP[15-17)].

Many investigators have attempted to determine risk factors for AVF after using cement augmentation techniques, including vertebroplasty or BKP. Bone mineral density (BMD), intravertebral cleft, cement leakage into a disc, and high cement volume have been reported as risk factors of AVF after vertebroplasty[18-21)]. Preoperative compression se-

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verity, greater surgical correction, and female sex have been reported as risk factors of AVF after BKP[12,15,22]. Although many risk factors have been discussed, the precise identities of risk factors remain controversial.

Augmented vertebral body height loss after BKP has been reported[23-26]; however, its clinical significance is unknown. In this study, we referred to the height loss phenomenon after BKP as recompression of augmented vertebrae (RAV). This study aimed to identify potential risk factors of AVF after BKP.

Material and Methods

Patient selection

Clinical data of 176 patients with symptomatic OVF treated with BKP from January 2011 to October 2019 at our hospital were retrospectively collected. A total of 186 vertebrae were treated with BKP, including 164 one-level compression fractures and 11 two-level fractures. Patients who did not have X-ray follow-up data at ≥3 months post-BKP, who had missing data, and who underwent posterior instrumentation combined with BKP were excluded from the study.

Surgical procedure and postoperative care

Balloon kyphoplasty was performed using a spinal balloon device with patients under general anesthesia. Patients were placed in a prone position on a four-poster frame. A deflated balloon was inserted into the vertebral body via a bilateral transpedicular approach and inflated to restore the height of the injured vertebra and create an internal cavity. The balloon was then deflated, and the remaining cavity was filled with cement under low pressure. After surgery, patients were permitted self-ambulation as soon as possible. Back braces were applied to all patients after surgery for 1-3 months. Osteoporotic medications, including bisphosphonates, vitamin D, or parathyroid hormone, were prescribed after the procedure.

Patient data collection

Patient information, medical records, and radiological images were collected pre- and postoperatively. Patient information collected included age, sex, body mass index, conservative treatment period before BKP, and follow-up period after BKP. According to the presence of AVF within the year that followed BKP, patients were divided into AVF and non-AVF groups.

Image assessment

Plain radiographs were assessed based on lateral views in the lateral position before surgery and 1 week and 3 months postoperatively. All radiological parameters were measured twice by two orthopedic surgeons individually and independently (intraclass correlation coefficient > 0.8); the average of the two measurements was used. Fracture level was

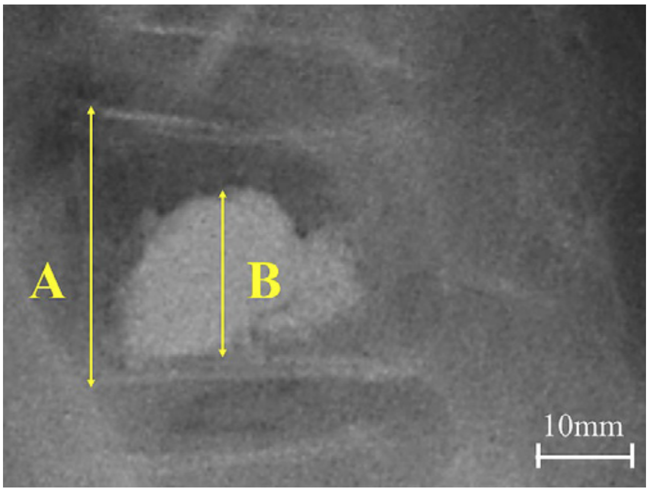

Figure 1. Calculation of cement augmentation ratio.
Anterior vertebral body height and cement height is indicated with A and B, respectively. Cement augmentation ratio was calculated via the following formula: [B/A] ×100.

classified as thoracolumbar (Th11-L2) and non-thoracolumbar (Th10, L3-5). The intravertebral cleft within the injured vertebra was defined as a radiolucent shadow on lateral radiography or computed tomography. Cement leakage was defined as cement extending into disc space and was assessed via X-ray or computed tomography. Cement augmentation ratio was calculated using the following formula: [vertebral height/augmented cement height] × 100 (Fig. 1)[21]. The wedge angle was defined as the angle between the superior and inferior endplate of the compressed vertebra considered. Vertebral body height was measured at the anterior wall of the compressed vertebra (Fig. 2). RAV was defined as a decrease in anterior vertebral body height of at least 5 mm between 1 week and 3 months post-BKP.

Statistical analysis

All analyses were conducted using SPSS 21.0. Values of $p < 0.05$ were considered statistically significant. Quantitative data are presented as a mean ± standard deviation, and a Shapiro-Wilk test was used to assess the normality of the data distribution. The differences between groups in continuous variables were examined using Student's t-test and Mann-Whitney U test for parametric and nonparametric data, respectively, while categorical data were compared using the chi-square. Indices that were significantly different in the univariate analysis were inputted into the multivariate logistic regression correlation analysis to determine factors associated with AVF incidence. A stepwise method was used in the multivariate analysis. Odds ratios (ORs) and 95% confidence intervals were calculated and assessed the goodness of fitting of logistic regression models by Hosmer-Lemeshow test.

Results

A total of 133 vertebrae of 128 patients were examined in

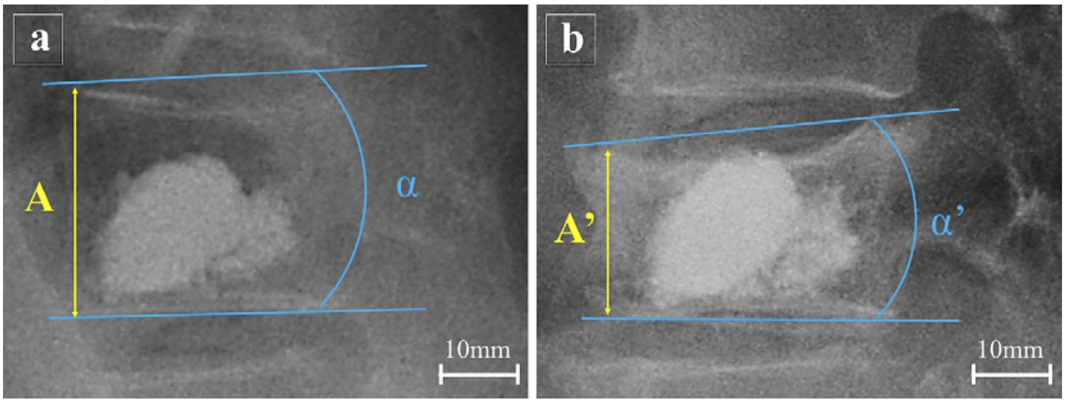

Figure 2. Measurement of vertebral body height and wedge angle.
X-rays obtained (a) 1 week postoperatively and (b) 3 months postoperatively are shown. Pre- and postoperative vertebral body height are indicated with A and A´, respectively. Pre- and postoperative wedge angle are indicated with α and α´, respectively. Change in vertebral height is A – A´ and change in wedge angle is α – α´. Recompression of augmented vertebra is defined as A – A´ ≥ 5.

Table 1. Baseline Characteristics of the AVF and Non-AVF Groups Pre- and Post-surgery.

	AVF (n=22) Mean±SD or N (%)	Non-AVF (n=111) Mean±SD or N (%)	P-value
Age, years	78.8±4.6	77.9±7.1	0.444
Sex, female	15 (68%)	82 (74%)	0.583
BMI, kg/m^2	20.1±3.6	22.1±4.0	0.126
Preoperative conservative treatment period, days	69.5±41.2	65.4±73	0.800
Postoperative follow-up period, weeks	25.5±20.2	24.5±20	0.298
Thoracolumbar fracture (Th11–L2)	21 (95%)	88 (79%)	0.057
Intravertebral cleft	1 (4.5%)	21 (19%)	0.096

AVF, adjacent vertebral fracture; BMI, body mass index; SD, standard deviation; N, number

this study. The locations and numbers of treated vertebral bodies were as follows: Th10 (n = 2), Th11 (n = 5), Th12 (n = 34), L1 (n = 45), L2 (n = 25), L3 (n = 14), L4 (n = 4), and L5 (n = 4). In 22 patients (17%), AVF was identified throughout the 3- to 12-month postoperative period. The AVF and non-AVF group consisted of 22 and 111 patients, respectively. Table 1 shows baseline characteristics of the AVF and non-AVF groups. The mean age of the AVF and non-AVF group was 78.8 and 77.9 years ($p = 0.44$), respectively. There were no significant differences between the groups regarding sex, body mass index, preoperative conservative period before BKP, postoperative follow-up period after BKP, and incidence rates of thoracolumbar fracture (Th11-L2) and intravertebral cleft.

Table 2 shows radiological measurements of the AVF and non-AVF groups before and after BKP. There were no significant differences between the groups regarding total cement volume and the incidence rate of cement leakage into a disc. There were no neurologic symptoms observed in cases with cement leakage. The cement augmentation ratio was lower in the AVF group (68.9%) than in the non-AVF group (73.7%, $p = 0.036$). The wedge angle before BKP was greater in the AVF group (15.2°) than in the non-AVF group (13.0°, $p = 0.025$), whereas there were no significant differences between groups regarding wedge angle 1 week and 3 months post-BKP. Vertebral body height before BKP and 3 months after BKP was lower in the AVF group than in the non-AVF group (16.7 mm vs. 20.3 mm, $p < 0.01$ and 17.1 mm vs. 22.1 mm, $p < 0.01$, respectively), whereas there was no significant vertebral body height difference observed between the groups 1 week after BKP. There were no significant differences observed between the groups in wedge angle change 1 week and 3 months after BKP; however, the vertebral body height change of the AVF group was greater than that of the non-AVF group (5.1 mm vs. 3 mm, respectively; $p < 0.01$). Further, the AVF group had a greater incidence rate of RAV (64%) than the non-AVF group (64% vs. 12%, respectively; $p < 0.01$). Thus, in univariate analysis, there were significant differences between the two groups in six indices: cement augmentation ratio, preoperative wedge angle, preoperative vertebral body height, vertebral body height at 3 months, postoperative difference of vertebral body height for 3 months, and incidence of RAV. When the six indices that statistically differed between groups were input into a multivariate logistic regression correlation, the multivariate analysis revealed that vertebral body height before BKP (OR = 0.82) and incidence of RAV (OR = 21.9) were associated with the incidence of

Table 2. Radiological Measurements for the AVF and Non-AVF Groups.

	AVF (n=22) Mean±SD or N (%)	Non-AVF (n=111) Mean±SD or N (%)	P-value
Total cement volume, mL	5.1±1.2	5.0±1.3	0.839
Cement leakage into a disc, N (%)	4 (18%)	14 (13%)	0.343
Cement augmentation ratio, %	68.9±10.1	73.7±9.7	0.036
Wedge angle, degrees			
Preoperatively	15.2±3.2	13.0±9.7	0.025
1 week postoperatively	10.4±3.8	9.6±6.6	0.395
3 months postoperatively	13±4.4	11.9±6.7	0.322
Postoperative difference at 1 week and 3 months	2.6±2.4	2.4±2.4	0.656
Vertebral body height, mm			
Preoperatively	16.7±4.4	20.3±5.4	0.004
1 week postoperatively	22.1±3.5	24.1±4.6	0.058
3 months postoperatively	17.1±2.7	22.1±3.5	<0.001
Postoperative difference at 1 week and 3 months	5.1±2.8	3±2.1	<0.001
Incidence of RAV, N (%)	14 (64%)	13 (12%)	<0.001

AVF, adjacent vertebral fracture; SD, standard deviation; RAV, recompression of augmented vertebra; N, number

Table 3. Multivariate Analysis of Factors Associated with AVF Incidence.

	OR	P-value	95% CI
Cement augmentation ratio		0.587	
Wedge angle, preoperatively		0.975	
Vertebral height, preoperatively	0.820	0.002	0.725–0.928
Vertebral body height, 3 months postoperatively		0.307	
Postoperative vertebral body height difference at 1 week and 3 months		0.984	
RAV	21.891	<0.001	6.219–77.058

AVF, adjacent vertebral fracture; RAV, recompression of augmented vertebra; OR, odds ratios; CI, confidence interval

AVF (Table 3). In addition, the Hosmer-Lemeshow test has a p-value of 0.932, indicating that the logistic regression analysis model has no fit problem.

Case presentation

The patient was a 78-year-old woman with an L2 vertebral fracture (Fig. 3a) who underwent BKP following conservative treatment. A postoperative radiograph showed improvement in the vertebral body height and wedge angle of L2, while the cancellous bone remained around the cement in the vertebral body (Fig. 3b). A postoperative radiograph, one month after BKP, showed loss of the augmented vertebral body height (Fig. 3c). She had an adjacent vertebral fracture, six months after BKP (Fig. 3d).

Discussion

This study retrospectively investigated risk factors that affect AVF incidence after BKP for symptomatic OVF. Via multivariate analysis, low vertebral body height before BKP and the incidence of RAV after BKP were associated with AVF incidence. Preoperative vertebral body height has previously been examined as a risk factor for AVF[12,15]. Meanwhile, the association between RAV and the incidence of AVF has not been previously examined. To the best of our knowledge, this study is the first to focus on the association between RAV and the incidence of AVF and the first to indicate that RAV is a risk factor for AVF.

Movrin et al. reported that BMD is a risk factor for the development of AVF after vertebroplasty or BKP[13]. Certainly, there is a strong relationship between bone density and bone strength, and it is reasonable to use BMD to assess AVF risk. However, there have been reports of significant differences in the prevalence of vertebral fractures among individuals with similar BMD[27,28], as well as reports of no significant differences in BMD concerning the incidence of AVF after BKP[12,15]. In this study, we excluded BMD from the analysis due to missing data to avoid reducing the statistical power of the analysis. For reference, the preoperative DXA values were 66.9 ± 11.6 g/cm^3 and 61.1 ± 11.7 g/cm^3 in the AVF (n = 16) and non-AVF group (n = 91), respectively, in this study, with no significant difference.

Several studies have indicated that preoperative compression severity is associated with AVF risk[12,15]. Compression severity has been assessed based on wedge angle or vertebral height. Civelek et al.[12] demonstrated that increased preoperative wedge angle was a risk factor of AVF after BKP

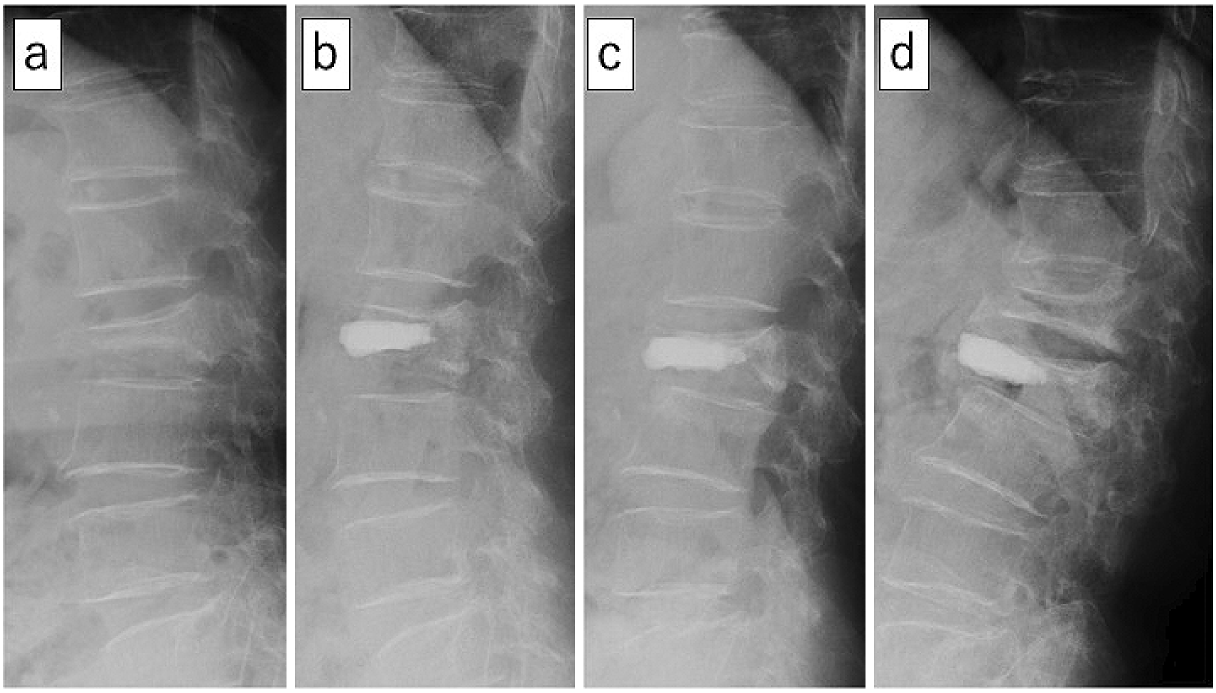

Figure 3. A 78-year-old woman with AVF after augmented vertebral body height loss following BKP.
(a) Preoperative radiograph (lateral view) showing the L2 vertebral fracture (vertebral body height=10 mm).
(b) Postoperative radiograph (lateral view), 1 week after BKP, showing cancellous bone remaining around the cement in the vertebral body.
(c) Postoperative radiograph (lateral view), 1 month after BKP, showing loss of augmented vertebral body height (RAV).
(d) Postoperative radiograph (lateral view), 6 months after BKP, showing an adjacent vertebral fracture at L1.

but did not examine preoperative vertebral height. Takahashi et al.[15] indicated that both greater preoperative wedge angle and low vertebral height were associated with AVF upon univariate analysis, but only wedge angle was identified as a significant risk factor upon multivariate analysis. Moreover, wedge angles above 25° were reported as high-risk indicators of AVF. In this study, preoperative wedge angle and vertebral height were identified as significant risk factors for AVF via univariate analysis, but only vertebral height significantly affected risk via multivariate analysis. Although wedge angle and vertebral body height are strongly correlated and are factors that indicate vertebral body collapse, when endplate deformation occurs during vertebral body collapse and the angles are not easy to measure, wedge angle measurements may not be accurate[29]. Therefore, we consider vertebral body height to be more suitable for assessing the risk of AVF after BKP than wedge angle.

RAV is a phenomenon in which vertebral body height is lost after BKP. Movrin et al.[13] showed that the average loss of augmented vertebrae height was about 5% after BKP in the first postoperative year. Several researchers have revealed that height loss of augmented vertebra is associated with persistent low back pain and the aggravation of kyphotic deformity. Further, it was reported that 10%-30% of these effects occur in the 3-month period following BKP. Moreover, older age, intravertebral cleft, low cement volume, and low cement augmentation ratio were reported as risk factors of RAV[23-26,30]. However, the association between RAV and AVF incidence has not been revealed, and there is no unified name or definition for the vertebral body height loss phenomenon. In this study, we referred to vertebral body height loss as RAV and defined it as a 5 mm height loss that occurs throughout the 3-month period following BKP.

We consider RAV to be the result of cancellous bone collapse between cement and endplates. It occurs due to load stress on the cement-augmented vertebral body. Although the causes of RAV are multifactorial, the occurrence of RAV may indicate the presence of increased stress on the anterior side of the vertebra. Furthermore, the incidence of RAV increases the kyphotic angle of cement-augmented vertebrae, which may further increase stress on adjacent vertebral bodies and create a biomechanical environment in which AVF is likely to develop[31]. Vertebral fracture has been reported to increase compressive strain in the anterior region of the adjacent vertebrae[32,33]. Luo et al.[34] investigated creep deformation change after vertebral fracture. Following fracture, creep deformation of the fractured vertebral body significantly increased, especially in the anterior region, and similar changes were observed at the adjacent level. In addition, Takano et al.[35] revealed that vertebral fracture increased stress concentration in the affected vertebrae and the adjacent vertebrae using finite element analysis. These results suggest that AVF is caused not only by bone fragility but also by the increase in stress concentration in the adjacent vertebrae. Therefore, one of the causes of AVF may be the increase in stress concentration in the adjacent vertebrae associated with the onset of RAV.

The results of this study suggest that the incidence of AVF can be decreased if RAV development is avoided. Previous studies have shown that RAV is caused by the cancellous bone that remains between the cement and the endplate[24]. Because both AVF and RAV are associated with poor postoperative outcomes, the use of an adequate cementing technique, which could prevent RAV and AVF, may improve postoperative outcomes of BKP. Kobayashi et al. suggested that augmented cement should come in contact with both endplates to avoid the incidence of RAV, especially in elderly patients[30]. Therefore, we suggest that it is appropriate to augment cement so that it contacts the endplates of compressed vertebrae.

This study has several limitations. First, it was retrospective, which can introduce bias and errors. Second, the postoperative follow-up periods considered were not consistent and ranged widely from 3 to 12 months. However, there was no significant difference in the postoperative follow-up period between groups (Table 1). Therefore, this limitation was not likely to influence findings. Third, the definition of RAV has not been determined. Finally, we did not evaluate BMD and osteoporotic medications in this study due to missing data. Despite these limitations, this study provides important information regarding the association between RAV after BKP and subsequent AVF.

Conclusion

The retrospective assessment of 128 patients with symptomatic OVF treated with BKP identified low preoperative vertebral body height and RAV occurrence as significant risk factors associated with AVF incidence. This study is the first to indicate that RAV is a risk factor of AVF and suggests that AVF can be decreased if RAV development is avoided.

Conflicts of Interest: The authors declare that there are no relevant conflicts of interest.

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Author Contributions: Yohei Yamada and Satoshi Kato wrote and prepared the manuscript, and all the authors participated in the study design.

Ethical Approval: Ethical approval was waived by the ethics committee due to the retrospective study design.

Informed Consent: Informed consent for publication was obtained by all participants in this study.

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