Observational Study

Development of Symptomatic Adjacent and Remote Level Compression Fractures Following Balloon-assisted Kyphoplasty in a Series of 1,318 Patients

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Background: Balloon-assisted kyphoplasty (BAK) is a minimally invasive procedure to treat vertebral compression fractures (VCF). BAK not only restores vertebral height and corrects kyphotic deformity by cement augmentation, but it also may alter spinal biomechanics, leading to subsequent adjacent level VCFs.

Objectives: This study aims to investigate the timing, location, and incidence of new VCFs following BAK and identify the risk factors associated with their occurrence.

Study Design: Single-institution observational study.

Methods: A prospectively collected cohort of 1,318 patients who underwent BAK by a single-surgeon from 2001 through 2022 was analyzed. The patients had pain that was unresponsive to nonsurgical management and a VCF secondary to osteoporosis, trauma, or neoplasm. The time between the index and subsequent fracture, fracture level, number of initial fractures, age, body mass index (BMI), tobacco use, and chronic corticosteroid use were recorded.

Results: Of 1,318 patients, 204 (15.5%) patients underwent a second BAK procedure an average of 373 days following BAK (range: 2–3,235 days). Third, fourth, and fifth procedures were less common (45, 12, and 6 patients, respectively). A total of 142 patients (69.6%) developed a subsequent fracture adjacent to the index level; adjacent and remote level fractures developed at different times (mean: 282 vs 581 days, $P = 0.001$). Patients treated for multiple VCFs in a single surgery were more likely to develop subsequent VCFs ($P = 0.024$) and at adjacent levels ($P = 0.007$). Subsequent VCFs were associated with older age ($P < 0.001$), women ($P = 0.045$), osteoporosis ($P < 0.001$), and chronic corticosteroid use ($P < 0.001$). A subgroup analysis of 812 (61.6%) patients who underwent BAK for degenerative indications revealed that osteoporosis ($\beta = 0.09$; 95% CI, 0.03–0.16; $P = 0.005$) and chronic corticosteroid use ($\beta = 0.06$; 95% CI, 0–0.11; $P = 0.055$) were associated with adjacent level fracture. For the entire cohort, almost every patient treated for both a thoracic and lumbar fracture (92.3%) developed an adjacent level second fracture ($P = 0.005$).

Limitations: The true incidence of post-BAK fractures may be underestimated as surveillance is not routine in asymptomatic or osteoporotic patients.

Conclusions: Symptomatic post-BAK VCFs are infrequent and may occur long after the initial procedure. Nearly two-thirds of subsequent fractures in our study occurred adjacent to the initially treated level; almost every patient who suffered thoracic and lumbar fractures at the same time developed an adjacent level second fracture. Additionally, osteoporosis and chronic corticosteroid use were associated with adjacent level fractures in patients who underwent surgery for degenerative indications.

Key words: Kyphoplasty, balloon-assisted kyphoplasty, cement augmentation, osteoporosis, spine fracture, compression fracture, adjacent level fracture

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Osteoporosis is a worldwide disease characterized by reduced bone mass and altered bone architecture, resulting in increased fragility and fracture risk (1). Vertebral compression fracture (VCF) is the most common type of osteoporotic fracture with an estimated 700,000 cases per year in the United States (2). VCF symptoms range from pain, disfigurement, and height loss, to pneumonia, psychological distress, and impaired activities of daily living (3).

Guidelines for managing osteoporotic VCFs are limited; there is no standard for treatment (4). More than two-thirds of patients with VCFs are asymptomatic and are incidentally diagnosed radiographically (5). Conservative treatment includes bracing and physical therapy. Minimally invasive interventional procedures include nerve root blocks and epidural injections. Operative treatment, such as vertebral augmentation or open surgical fixation, are utilized for symptomatic and severe cases.

Balloon-assisted kyphoplasty (BAK) aims to restore vertebral height and correct focal kyphotic deformity through cement augmentation. This procedure is typically performed through a unipedicular or bipedicular approach, in which cannulas are placed percutaneously adjacent to each collapsed vertebral body (6). Since its approval by the US Food and Drug Administration in 1998, BAK has been shown to treat intractable pain secondary to VCF, as well as improve patient function, disability, and quality of life (6-9). However, why post-BAK VCFs occur is not fully understood. Many postulate that vertebral augmentation leads to biomechanical alteration of the osteoporotic spine (10). These fractures can occur in vertebral levels adjacent to the index level or at remote levels (11).

We performed our study in order to examine the timing, location, and incidence of post-BAK VCFs in a large patient cohort with adequate follow-up. As a result, risk factors associated with the development of subsequent VCFs were established.

Methods

Patient Selection

In our study, 1,318 patients with VCFs underwent BAK at a single regional referral center from 2001 through 2022. The median follow-up time was 920 days; 917 (69.6%) patients received a one-year follow-up. A total of 2,573 fractures were treated during this period. The indication for BAK treatment was pain unresponsive to nonsurgical management and VCF secondary to osteoporosis, trauma, or neoplasm. Patient demographics were recorded, including patient age, gender, body mass index (BMI; kg/m^2), a previous diagnosis of osteoporosis by a physician prior to surgery, current or former tobacco use, and chronic corticosteroid use defined by therapy ≥ 3 months before surgery (Table 1).

Surgical Procedure

In this study, the Kyphon Balloon Kyphoplasty System (Medtronic) was utilized in all patients and performed by this study's senior author. The technique has been previously described in detail (11) (Fig. 1).

Statistical Analysis

Statistical analysis was carried out using Microsoft Excel Version 2022 (Microsoft Corporation) and R version 4.2.1 (The R Foundation) for MacOS 10.11.6 (Apple Inc.). Kaplan-Meier analysis was performed on Prism 9 (GraphPad Software). Descriptive statistics including mean, medians, ranges, and SD were calculated. Independent-sample t tests or χ^2 analyses were performed to determine statistical significance. Logistic regression univariate and multivariate analyses were performed using R version 4.2.1. For outcomes that exhibited significance after univariate analysis, multivariate regression analysis was performed to account for potential confounding factors. The median value for continuous variables was used as the cutoff for prognostic factor analyses. In all tests, a P value < 0.05 was deemed statistically significant.

Results

A total of 204 patients (15.5%) including 147 (72.1%) women and 57 (27.9%) men were identified who developed a total of 340 symptomatic second compression fractures. All 204 patients underwent another BAK at either an adjacent or remote level from the index procedure. Third, fourth, and fifth procedures were treated in 45, 12, and 6 patients, respectively. Patient demographics, fracture level, indication for BAK, time between index and subsequent fracture, and number of initial fractures were recorded (Table 2).

Patients that developed a subsequent symptomatic VCF underwent a second BAK procedure on an average of 373 days following the initial procedure (median 91 days, range: 2–3,235 days). From these patients, 142 of 204 (69.6%) suffered a fracture at a vertebral level immediately adjacent to the index level. For patients that developed multiple symptomatic VCFs, 45 (22.1%)

Table 1. *Patient demographics for the 1,318-patient series.*

Characteristic	Value
Age (years)	67.3 ± 15.0 (69 [16–99])
Gender (no. of pts.)	
Men	450 (34.1%)
Women	868 (65.9%)
BMI (kg/m^2)	27.6 ± 6.6 (26.6 [13.4–61.1])
Previous Osteoporosis Diagnosis (no. of pts.)	947 (71.9%)
Tobacco Use (no. of pts.)	612 (46.4%)
Chronic Steroid Use (no. of pts.)	244 (18.5%)
Indication for Kyphoplasty (no. of pts.)	
Degenerative	812 (61.6%)
Trauma	185 (14.0%)
Malignancy	321 (24.4%)

Values are reported as mean ± SD (median [range]) or number (%)
Abbreviations: BMI, body mass index; no., number; pts., patients

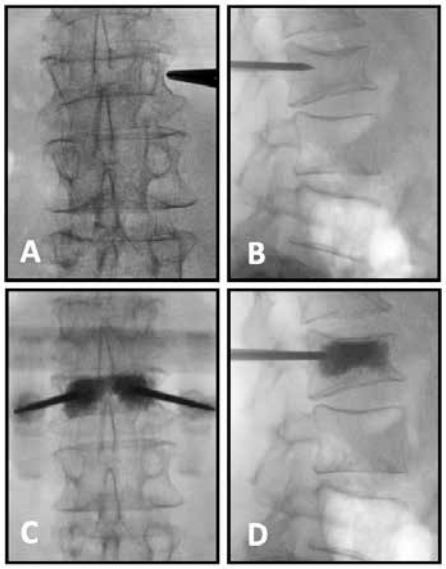

Fig. 1. *Intraoperative fluoroscopic images of the balloon-assisted kyphoplasty procedure. A) The lateral aspect of the pedicle is localized. B) A trochar is passed into the vertebral body through the pedicle. C) A balloon is inflated to restore vertebral height and create a cavity for the bone cement. D) The bone cement is injected slowly to avoid extravasation.*

underwent a third, 12 (5.8%) underwent a fourth, and 6 (2.9%) underwent a fifth BAK procedure. These fractures were treated at a mean of 448, 406, and 262 days post the index procedure, respectively (Fig. 2).

An analysis of the number of levels treated per procedure was conducted. Compared to single-level

Table 2. *Demographics and clinical characteristics for the 204 patients who developed a subsequent symptomatic vertebral compression fracture.*

Characteristic	Value
Age (years)	67.6 ± 12.9 (73 [28–99])
Gender (no. of pts.)	
Men	57 (27.9%)
Women	147 (72.1%)
BMI (kg/m^2)	27.7 ± 6.1 (26.2 [15.6–50.4])
Previous Osteoporosis Diagnosis	181 (88.7%)
Tobacco Use (no. of pts.)	95 (46.4%)
Chronic Corticosteroid Use (no. of pts.)	38 (18.5%)
Indication for Kyphoplasty (no. of pts.)	
Degenerative	167 (81.9%)
Trauma	7 (3.4%)
Malignancy	30 (14.7%)
Days Between First and Second BAK	372.9 ± 604.0 (91 [2–3,235])
Days Between Second and Third BAK	448.4 ± 694.9 (219 [16–3,413])
Days Between Third and Fourth BAK	405.6 ± 497.0 (106 [13–1,393])
Days Between Fourth and Fifth BAK	261.5 ± 318.0 (192.5 [23–881])

Values are reported as mean +/- SD (median [range]) or number (%)
Abbreviations: BAK, balloon-assisted kyphoplasty; BMI, body mass index; no., number; pts., patients

BAK procedures, patients who were treated for more than one VCF were more likely to develop a subsequent compression fracture (P = 0.024) especially at an adjacent level (P = 0.007) (Table 3).

Our analysis revealed differences in patients who did and did not develop subsequent post-BAK VCFs. Patients with subsequent VCFs were associated with older age (P < 0.001), women (P = 0.045), a previous osteoporosis diagnosis (P < 0.001), and chronic corticosteroid use (P < 0.001) (Table 4).

A subgroup analysis for the 812 patients who underwent kyphoplasty for degenerative indications was then performed using logistic regression analysis (Table 5). Using univariate analysis, a previous diagnosis of osteoporosis (β = 0.12; 95% CI, 0.04–0.19; P = 0.002) and chronic corticosteroid use (β = 0.1; 95% CI, 0.03–0.17; P = 0.004) were significantly associated with a subsequent fracture. On multivariate analysis, osteoporosis (β = 0.11; 95% CI, 0.03–0.18; P = 0.005) and chronic corticosteroid use (β = 0.09; 95% CI, 0.02–0.15, P = 0.012) continued to remain significant. A univariate analysis

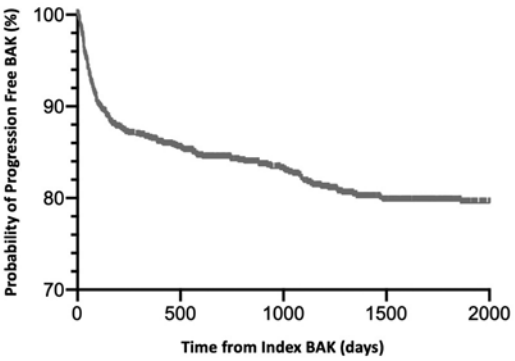

Fig. 2. *Kaplan-Meier analysis describing the probability of patients that did not develop a subsequent vertebral compression fracture after balloon-assisted kyphoplasty (BAK) as a function of time, referred to as progression-free BAK.*

Table 3. *Comparison of patients who developed a subsequent vertebral compression fracture by the number of initial levels treated.*

Initial No. of Levels Treated	1	≥ 2	*P*
No. of Treated Fractures	249 (73.2%)	91 (26.8%)	
Development of Subsequent Fracture (no. of pts.)	106 (13.6%)	98 (18.2%)	0.024*
Subsequent Adjacent Level VCF (no. of pts.)	65 (61.3%)	77 (78.6%)	0.007*
Subsequent Remote Level VCF (no. of pts.)	41 (38.7%)	21 (21.4%)	0.007*

Values are reported as mean +/- SD (median [range]) or number (%)
Abbreviations: No., number; pts., patients
*statistically significant

of patients that developed adjacent level fractures also revealed a significant association between a previous diagnosis of osteoporosis (β = 0.1; 95% CI, 0.03–0.16; *P* = 0.003) and chronic corticosteroid use (β = 0.07; 95% CI, 0.01–0.12; *P* = 0.02). For patients with an adjacent level fracture, both a previous diagnosis of osteoporosis (β = 0.09; 95% CI, 0.03–0.16; *P* = 0.005) and chronic corticosteroid use (β = 0.06; 95% CI, 0–0.11; *P* = 0.055) remained significant after a multivariate analysis. However, no tested prognostic value was associated with remote level fracture following a logistic regression analysis (Table 6).

A further analysis of patients who developed subsequent adjacent or remote level fractures did not reveal predictive factors between them. There was no statistical difference in age (*P* = 0.902), gender (*P* = 0.819), BMI (*P* = 0.683), previous osteoporosis diagnosis (*P* = 0.148), tobacco use (*P* = 0.606), or chronic corticosteroid use (*P* = 0.937). Adjacent fractures were treated at a mean time of 282 days. In comparison, remote fractures were less common (30.4%) and treated at a mean time of 581 days (*P* < 0.001). Patients who were treated for VCFs in the thoracic spine were not more likely to develop adjacent level fractures (*P* = 0.529). However, an adjacent level fracture was more common in patients treated only in the lumbar spine (*P* = 0.011). Additionally, almost every patient (92.3%) who was treated for both a thoracic and lumbar fracture in the same initial, index procedure developed a subsequent fracture at an adjacent level (*P* = 0.005) (Table 7).

Discussion

BAK is a routine and widely utilized procedure to treat symptomatic VCFs. To the best of our knowledge, ours is the largest single-institution study to date that addresses the incidence of symptomatic post-BAK VCFs

Table 4. *Comparison of patients who did and did not develop post balloon-assisted kyphoplasty vertebral compression fractures (VCFs).*

Characteristic	No Subsequent VCF (n = 1,114)	Subsequent VCF (n = 204)	*P*
Age (years)	67.1± 15.3 (69 [16–99])	71.4 ± 12.9 (74 [28–99])	< 0.001*
Gender (no. of pts.)			0.045*
Men	392 (35.2%)	57 (27.9%)	
Women	722 (64.8%)	147 (72.1%)	
BMI (kg/m^2)	27.8 ± 6.7 (26.6 [13.6–61.1])	27.0 ± 6.1 (26.2 [15.6–50.4])	0.128
Osteoporosis (no. of pts.)	766 (68.8%)	181 (88.7%)	< 0.001*
Tobacco Use (no. of pts.)	504 (45.2%)	103 (50.5%)	0.167
Chronic Corticosteroid Use (no. of pts.)	188 (16.9%)	60 (29.4%)	< 0.001*

Values are reported as mean +/- SD (median [range]) or number (%)
Abbreviations: BAK, balloon-assisted kyphoplasty; BMI, body mass index; no., number; pts., patients
*statistically significant

and investigates precipitating risk factors. This study is also unique in that subsequent VCFs were stratified into adjacent and remote level fractures. In patients who developed subsequent symptomatic VCFs, there was a large variation in time between fractures. However, patients who developed adjacent level fractures did so sooner than patients who developed fractures at remote levels. This suggests an there is an alternation of spinal local biomechanics at adjacent levels following BAK; cement augmentation may induce degenerative changes in adjacent vertebrae and lead to both an increased endplate bulge and an altered load transfer to proximal vertebrae (12-14). Remote level fractures may occur naturally as osteoporosis advances with age.

It is important to note that the annual incidence of VCF has been reported to be 1.1% in women and 0.6% in men. Our study adds to the existing body of literature and is consistent with the natural history of VCF by reporting an incidence rate of subsequent fracture at 15.5%. The incidence rate of subsequent fracture in smaller patient cohorts has previously been investigated, ranging from 11.5%–25.9% in recent studies (15-19). However, the comparison between studies is confounded by differences in patient demographics, surgical decision-making pertaining to conservative or operative treatment, surgeon-specific techniques, and

Table 5. *Demographics and clinical characteristics for 812 patients who underwent kyphoplasty for degenerative indications.*

Characteristic	Value
Age (years)	72.6 ± 13.6 (74 [18–99])
Gender (no. of pts.)	
Men	236 (29.1%)
Women	576 (70.9%)
BMI (kg/m^2)	27.2 ± 6.4 (26.0 [14.8–51.0])
Previous Osteoporosis Diagnosis (no. of pts.)	673 (82.9%)
Tobacco Use (no. of pts.)	381 (46.9%)
Chronic Corticosteroid Use (no. of pts.)	182 (22.4%)

Values are reported as mean +/- SD (median [range]) and number (%)
Abbreviations: BMI, body mass index; no., number; pts., patients

Table 6. *Risk factors for a subsequent vertebral compression fracture (VCF) in patients who underwent kyphoplasty for degenerative indications.*

Development of Subsequent Fracture	β	95% CI	*P*	β	95% CI	*P*
Age > 74.1 years	0.03	-0.03 to 0.09	0.3	-	-	-
Women	-0.04	-0.1 to 0.02	0.2	-	-	-
BMI > 26.0 (kg/m^2)	0.03	-0.04 to 0.09	0.4	-	-	-
Previous Osteoporosis Diagnosis	0.12	0.04 to 0.19	0.002*	0.11	0.03, 0.18	0.005*
Tobacco Use	0.03	-0.03 to 0.08	0.4	-	-	-
Chronic Corticosteroid Use	0.1	0.03 to 0.17	0.004*	0.09	0.02, 0.15	0.012*
Adjacent Level Subsequent VCF						
Age > 74.1 years	0.03	-0.02 to 0.08	0.2	-	-	-
Women	-0.03	-0.09 to 0.02	0.2	-	-	-
BMI > 26.0 (kg/m^2)	0.05	-0.01to 0.1	0.091	-	-	-
Previous Osteoporosis Diagnosis	0.1	0.03 to 0.16	0.003*	0.09	0.03, 0.16	0.005*
Tobacco Use	0	-0.05 to 0.05	> 0.9	-	-	-
Chronic Corticosteroid Use	0.07	0.01 to 0.12	0.022*	0.06	0, 0.11	0.055*
Remote Level Subsequent VCF						
Age > 74.1 years	0	-0.04 to 0.03	0.9	-	-	-
Women	-0.01	-0.04 to 0.03	0.8	-	-	-
BMI > 26.0 (kg/m^2)	-0.02	-0.06 to 0.02	0.3	-	-	-
Previous Osteoporosis Diagnosis	0.02	-0.02 to 0.07	0.4	-	-	-
Tobacco Use	0.02	-0.01 to 0.06	0.2	-	-	-
Chronic Corticosteroid Use	0.03	-0.01 to 0.07	014	-	-	-

Abbreviations: BMI, body mass index; no., number; pts., patients
*statistically significant

Table 7. *Comparison of patients who developed subsequent adjacent and remote level vertebral compression fractures (VCF)s.*

Characteristic	Subsequent Adjacent Level VCF (n = 142)	Subsequent Remote Level VCF (n = 62)	*P*
Age (years)	71.5 ± 13.3 (74.5 [35–99])	67.3 ± 12.1 (73 [28–90])	0.902
Gender (no. of pts.)			0.819
Men	39 (27.5%)	18 (29.0%)	
Women	103 (72.5%)	44 (71.0%)	
BMI (kg/m^2)	27.1 ± 6.0 (26.4 [15.6–50.4])	26.7 ± 6.3 (25.2 [17.4–45.7])	0.683
Osteoporosis (no. of pts.)	129 (90.8%)	52 (83.9%)	0.148
Tobacco Use (no. of pts.)	70 (49.3%)	33 (53.2%)	0.606
Chronic Corticosteroid Use (no. of pts.)	42 (29.6%)	18 (29.0%)	0.937
Time from Index BAK (days)	281.9 ± 521.6 (71.5 [5–2,976])	581.4 ± 722.3 (247 [2–3,235])	0.001*
Index Level(s) Treated at Surgery (no. of pts.)			
Thoracic Only	64 (45.1%)	25 (40.3%)	0.529
Lumbar Only	53 (37.3%)	35 (56.5%)	0.011*
Both Thoracic and Lumbar	25 (17.6%)	2 (3.2%)	0.005*

Values are reported as mean +/- standard deviation (median [range]) or number (%)
Abbreviations: BAK, balloon-assisted kyphoplasty; BMI, body mass index; no., number; pts., patients
*statistically significant

differing follow-up periods. Regarding subsequent adjacent level fracture, a meta-analysis published in 2022 of 16 studies and 2,549 patients found a rate of 14.7% (20). In our study, with a single-surgeon single-institution, had an adjacent level fracture rate of 10.8%.

There have been limited studies that investigate risk factors attributed to developing subsequent VCFs after kyphoplasty. Our study found that patients who developed subsequent fractures were associated with old age, women, a previous diagnosis of osteoporosis, and chronic corticosteroid use. In patients who underwent BAK for degenerative indications, osteoporosis and chronic corticosteroid use were associated with subsequent fractures at adjacent levels. This is consistent with previous literature (12,15-17,20-23). Older patients may suffer from more advanced osteoporosis and lower bone mineral densities, in turn leading to postsurgical fractures (24). However, controversy remains regarding the association between adjacent level fracture and bone mineral density. Although they were not found to be significant in this study, a lower BMI (P = 0.128) and a past history of tobacco use (P = 0.167) may be risk factors for post-BAK VCF as well. A low BMI is thought to be related to increased postmenopause bone loss (25).

Our study's important finding is that a post-BAK VCF is not frequent (15.5%) and occurs long after the initial procedure (mean 373 days, range: 2–3,235 days). Patients who develop multiple post-BAK fractures are even more rare (≥ 3 fractures, 4.8%). Of subsequent fractures, adjacent level fracture was found to be more common than remote level fracture (69.6% vs 30.4%, P = 0.001).

Limitations

This was a single-surgeon single-institution study that lacked broad representation. Patients without one-year follow-up were assumed to not have developed a symptomatic subsequent fracture. Additionally, patients were followed clinically, given that the standard of care for evaluating postoperative compression fractures does not require repeat radiographs. Since surveillance is not routine in patients who are asymptomatic or osteoporotic, the literature as a whole may underestimate the incidence of subsequent fractures. Future multicenter, international, and randomized controlled studies are needed to better assess the rate of post-BAKVCFs.

Conclusion

BAK is an effective, minimally invasive procedure for stabilizing VCFs. Symptomatic post-BAK compression fractures are relatively infrequent and may occur long after the initial procedure. Risk factors for developing any post-BAK fracture were age, gender, a previous diagnosis of osteoporosis, and chronic corti-

costeroid use. In patients who did develop subsequent fractures that required intervention, two-thirds did so at a level immediately adjacent to the index level. Osteoporosis and chronic corticosteroid use were associated with subsequent fractures at adjacent levels in patients with degenerative fractures.

Author Contributions

SA, ST, RKS, XZ, and PCG contributed to the design and implementation of the research; SA, ST, AT, VRW to data collection; SA and ST to the analysis of the results, and SA, ST, AT, VRW, RKS, XZ, and PCG to the writing of the manuscript.

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