# ORIGINAL ARTICLE

# Incidence and risk factors for early adjacent vertebral fractures after balloon kyphoplasty for osteoporotic fractures: analysis of the SWISSspine registry

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### Abstract

Purpose The SWISSspine registry (SSR) was launched in 2005 to assess the safety and effectiveness of balloon kyphoplasty (BKP). In the meantime, repeated reports on high rates of adjacent vertebral fractures (ASF) after BKP of vertebral insufficiency fractures were published. The causes for ASF and their risk factors are still under debate. The purpose of this study was to report the incidence and potential risk factors of ASF within the SSR dataset.

Methods The SSR data points are collected perioperatively and during follow-ups, with surgeon- and patient-based information. All patients documented with a monosegmental osteoporotic vertebral insufficiency fracture between March 2005 and May 2012 were included in the study. The incidence of ASF, significant associations with co-variates (patient age, gender, fracture location, cement volume, preoperative segmental kyphosis, extent of kyphosis correction, and individual co-morbidities) and influence on quality of life (EQ-5D) and back pain (VAS) were analyzed.

Results A total of 375 patients with a mean follow-up of 3.6 months was included. ASF were found in 9.9 % (n=37) and occurred on average 2.8 months postoperatively. Preoperative segmental kyphosis >30° (p=0.026), and rheumatoid arthritis (p=0.038) and cardiovascular disease (p=0.047) were significantly associated with ASF. Furthermore, patients with ASF had significantly

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higher back pain at the final follow-up (p = 0.001). No further significant associations between the studied co-variates and ASF were seen in the adjusted analysis.

Conclusions The findings suggest that patients with a preoperative segmental kyphosis >30° or patients with comorbidities like rheumatoid arthritis and a cardiovascular disease are at high risk of ASF within 6 months after the index surgery. In case of an ASF event, back pain levels are significantly increased.

Level of evidence IV.

**Keywords** Balloon kyphoplasty · Adjacent segment fracture · SWISSspine registry · Risk factors · Rheumatoid arthritis

# Introduction

Vertebral compression fractures (VCF) are an increasingly prevalent disease in the aging population and may cause pain, limited physical function, decreased mobility, reduced quality of life (QoL) and increased mortality as well as a resulting heavy economic burden on society [1–4]. Technical advances in minimal invasive spine surgery have offered new treatment possibilities.

Balloon kyphoplasty (BKP) of VCF was first described by Garfin et al. [4]. With the transpedicular insertion of two inflatable balloons into the fractured vertebral body, a void can be created which is subsequently filled with polymethyl methacrylate bone cement (PMMA) to realign and stabilize the fractured and often kyphotic vertebra (kyphoplasty).

The Swiss Federal Office of Health mandated a nationwide health technology assessment registry for BKP to assess its benefits and to determine the reimbursement of this procedure. Therefore, the SWISSspine registry (SSR)



was launched in March 2005. In 2010, first results of the registry were published [5] indicating that BKP is a safe and effective procedure in the treatment of vertebral fractures with a significant and clinically relevant reduction of back pain as well as improvement of QoL. This was in accordance with previous studies [6–8]. SSR data also showed that within the first postoperative year 20 % of all patients sustained new fractures, 72 % adjacent to the cemented levels [5]. The adjacent segment fracture (ASF) seems to be a non-negligible complication of BKP in osteoporotic vertebral fractures. This requires further investigation, especially since the incidence is still controversial [9–14], and potential risk factors are not well studied.

The aim of our study was hence to analyze the early ASF after kyphoplasty for osteoporotic fractures within the SSR.

### Materials and methods

The registry

SSR data are collected perioperatively and during followups. Main follow-up intervals are at 3 and 6 months, 1 year and annually thereafter. The documentation forms and outcome instruments are: (1) primary intervention form (surgeon-administered), (2) follow-up form (surgeonadministered), (3) comorbidity questionnaire (patient assessment), (4) EQ-5D questionnaire (patient assessment), (5) North American Spine Society outcome instrument (NASS) (patient assessment) between 2005 and 2009. In 2009, the evaluation obligation was released and the NASS patient assessment was replaced by the Core Outcome Measures Index (COMI Back). The main reason to change to the COMI instrument was a better comparability of SSR BKP results with those of the international Spine Tango registry [15, 16]. Both outcome instruments, NASS and COMI, have a visual analog scale (VAS 0-10) for pain assessment, which was used as one of the outcome measures in the study.

The EQ-5D is one of the most frequently used generic QoL instruments in health economic and outcome studies today. The instrument includes a global visual analog scale (VAS), anchored in worst and best imaginable health status, and the EQ-5D descriptive system which is subdivided into five dimensions; (1) mobility, (2) self-care, (3) usual activities, (4) pain/discomfort and (5) anxiety/depression [17]. The EQ-5D score ranges from -0.6 to 1, where 1 is the best imaginable health and 0 represents a state of death.

All patients sign an informed consent form agreeing with data collection in the registry and regular follow-ups. Patient questionnaires are completed before surgery and at all follow-ups, except for the preoperative comorbidity

form. Surgeons complete the primary form at the time of surgery and the follow-up form at each follow-up.

Sample characteristics

From March 2005 to May 2012, 817 surgeries and 1,797 follow-ups were documented. The Swiss Society for Spinal Surgery recommends the following criteria for BKP: (a) the VCF is responsible for the symptoms, (b) the pain level on VAS is persistently above five points, (c) the segmental kyphosis for thoracic vertebrae needs to be at least 15°, (d) the segmental kyphosis for lumbar vertebrae needs to be at least 10°, (e) height reduction of the fractured vertebra is larger than 1/3 of the height of the adjacent vertebrae.

Patients with an osteoporotic vertebral fracture and at least one follow-up within the first 6 postoperative months were included in the study. To simplify the interpretation of our study results, patients with more than one vertebral body fracture were excluded. The in- and exclusion criteria resulted in a sample of 375 patients (91 males and 284 females) with an average age of 72.7 years for females and 73.1 years for males. A total of 44 single surgeons were involved in the treatment of these 375 patients (8–9 patients per surgeon on average; range 1–44 cases). Detailed demographic characteristics of the sample are shown in Table 1 and co-morbidities in Table 2.

### Statistical analysis

Patients with and without ASF were compared regarding their demographic and clinical characteristics. Wilcoxon signed-rank test was used for comparisons of continuous variables such as pain on VAS between patients with and without ASF. When comparing proportions, the Chi-square test was used.

A multivariate logistic regression model was built to search for significant associations for ASF after BKP treatment. The binary outcome was the occurrence of ASF (yes/no). Co-variates considered in the analysis were: patient age, gender, fracture location (Th4–Th11, Th12, L1, L2–L5), volume of injected cement (<4.5 ml, ≥4.5 ml), preoperative segmental kyphosis (none, 10–20°, 21°–30°, >30°), and extent of achieved correction of segmental kyphosis immediately after surgery (worsening, no change, 1 category, 2 categories, >2 categories improvement—see below).

The registry contains information on segmental kyphosis. The preoperative categories are: none,  $10^{\circ}-15^{\circ}$ ,  $16^{\circ}-20^{\circ}$ ,  $21^{\circ}-25^{\circ}$ ,  $26^{\circ}-30^{\circ}$  and  $>30^{\circ}$ . Postoperatively, the categories are the same, except for an extra category of  $5^{\circ}-10^{\circ}$ . For the adjustment in the multivariate regression models the four possible changes of the postoperative segmental kyphosis category relatively to the perioperative were used: worsening of kyphosis category, no change, 1



 Table 1
 Demographic and clinical characteristics of the patients with and without adjacent fractures

	Adjacent segment fracture		Total $(n = 375)$	Compariso (p value)	
	Yes $(n = 37)$	No (n = 338)			
Ø age	75.2	72.5	72.8	0.010	
% <60 years	5.4	10.4	9.9	0.323	
% 60–69 years	21.6	26.9	26.4		
% 70-79 years	37.9	40.2	40.0		
% ≥80 years	35.1	22.5	23.7		
% female	73.0	76.0	75.7	0.680	
Ø length of stay	7.1	7.0	7.0	0.829	
% Th4–Th11	16.2	11.4	11.9	0.700	
% Th12	19.0	25.2	24.5		
% L1	29.7	32.3	32.1		
% L2–L5	35.1	31.2	31.5		
% A1.1 fracture type	5.4	12.1	11.5	0.591	
% A1.2 fracture type	48.7	43.2	43.7		
% A 3.1 fracture type	35.1	31.1	31.5		
% other fracture type	10.8	13.6	13.3		
% no segmental kyphosis preop	20.0	30.4	29.4	< 0.001	
% 10°–20° segm. kyphosis preop	40.0	47.3	46.6		
% 20°-30° segm. kyphosis preop	17.1	17.9	17.8		
% >30° segm. kyphosis preop	22.9	4.4	6.2		
% no segm. kyphosis postop	67.7	73.0	72.5	0.656	
% 10°–20° segm. kyphosis postop	19.4	18.8	18.9		
% 20°-30° segm. kyphosis postop	12.9	8.2	8.6		
% of worsening of segm. kyphosis after correction	3.0	9.6	8.9	0.310	
% of no change in segm. kyphosis after correction	21.2	31.7	30.7		
% of 1 category improvement after correction	30.3	19.5	20.6		
% of 2 categories improvement after correction	24.2	18.1	18.7		
% of >2 categories improvement after correction	21.2	21.2	21.2		

Table 1 continued

	Adjacent segment fracture		Total $(n = 375)$	Compariso (p value)	
	Yes $(n = 37)$	No (n = 338)			
% fracture age ≥8 weeks	11.8	16.4	15.9	0.488	
% no pain medication preop	8.6	5.0	5.4	0.375	
% NSAIDs preop	60.0	72.7	71.3	0.117	
% weak opiates preop	42.9	30.7	31.9	0.143	
% strong opiates preop	17.1	20.0	19.7	0.688	
% <4.5 ml cement injected	22.2	30.0	29.2	0.332	
% ≥4.5 ml cement injected	77.8	70.0	70.8		
Ø preop back pain (SD)	78 (18)	70 (25)	71 (25)	0.124	
Ø postop back pain (SD)	40 (24)	25 (23)	27 (23)	0.001	
Ø back pain relief (SD)	39 (27)	45 (32)	44 (31)	0.190	
% achieved 18 VAS points	81.3	81.5	81.5	0.969	
Ø preop EQ-5D score (SD)	0.089 (0.42)	0.227 (0.42)	0.213 (0.43)	0.114	
Ø postop EQ-5D score (SD)	0.624 (0.27)	0.713 (0.26)	0.704 (0.26)	0.072	
Ø EQ-5D score change (SD)	0.535 (0.46)	0.486 (0.45)	0.491 (0.45)	0.549	
% achieved 0.25 points EQ-5D score improvement	67.7	62.0	62.6	0.519	

Wilcoxon signed-rank test was used for continuous variables and Chi square test for proportions, n.s. not significant

category improvement, 2 categories improvement, >2 categories improvement. The extra category (5°-10°) together with the category "none" on the follow-up form was thereby equalized to the category "none" on the surgery form.

 $\alpha$  was set to 0.05 throughout the study. All statistical analyses were conducted using SAS 9.3 (SAS Institute, Inc., Cary, NC, USA).

# Ethics

Ethical approval was not needed as anonymized data were collected and evaluated within a mandated registry based on informed written patient consent.



Table 2 Proportions of individual co-morbidities in patients with and without adjacent fractures

Co-morbidity	Adjacent segment fracture		Total	Univariate comparison			
	Yes $(n = 37)$	No $(n = 338)$	(n = 375)	Odds ratio	Lower 95 % CI	Upper 95 % CI	p value
Cardiovascular disease (%)	78.4	51.5	54.1	0.293	0.13	0.659	0.003
Other disease (%)	32.4	32.3	32.3	0.992	0.48	2.048	0.98
Osteoarthritis (%)	21.6	21.6	21.6	0.999	0.438	2.277	0.99
Liver, kidney and/or stomach disease (%)	13.5	13.9	13.9	1.033	0.383	2.785	0.95
Depression (pharmacologically treated) (%)	8.1	11.8	11.5	1.521	0.447	5.182	0.50
Diabetes (%)	5.4	10.1	9.6	1.957	0.451	8.498	0.37
Lung disease (%)	16.2	8.6	9.3	0.485	0.187	1.258	0.14
Rheumatological arthritis (%)	21.6	8.3	9.6	0.327	0.137	0.784	0.012
Anemia (%)	5.4	3.6	3.7	0.644	0.139	2.996	0.57

95 % CI 95 % confidence intervals

### Results

A total of 37 patients (9.9 %) showed an ASF, in 72 % the cranial and in 28 % the caudal adjacent vertebra was involved. The average follow-up was 3.6 months (range 0.8–6.6 months). The adjacent new fracture was detected on average 2.8 months (range 1.2–6.6 months) postoperatively.

### Univariate analysis

The non-adjusted comparisons between the patients with and without ASF as shown in Table 1 revealed significant difference regarding preoperative segmental kyphosis (p < 0.001). Furthermore, comparison of back pain characteristics demonstrated that patients with and without ASF have significantly different postoperative back pain (p = 0.001). The latter was higher in patients with ASF. The average back pain relief, however, was not significantly different between the patient groups, differing by only 6 VAS points on the 100 points scale. Regarding EQ-5D score characteristics, no significant differences were observed.

The proportions of individual co-morbidities for patients with and without ASF were compared in Table 2. Cardiovascular disease and rheumatoid arthritis were significantly more frequently observed in patients with ASF.

### Multivariate analysis

The multivariate logistic regression revealed preoperative segmental kyphosis to be significantly associated with an early postoperative ASF (p=0.026). According to the model, patients with preoperative segmental kyphosis higher than 30° had an 8.36-times (95 % CI 1.61–43.5) higher likelihood for an ASF than those without segmental kyphosis ("no segmental kyphosis preoperative"). In addition, rheumatoid arthritis (OR 2.96, 95 % CI

1.07–8.21; p = 0.038) and cardiovascular disease (OR 2.66, 95 % CI 1.01–7.0; p = 0.047) as comorbidity were associated with higher likelihood for an ASF. Patient age (p = 0.24), gender (p = 0.78), fracture location (p = 0.70), volume of injected cement (p = 0.55) and extent of achieved correction of segmental kyphosis (p = 0.53) were non-significant co-variates.

### Discussion

This study presents the analysis of the so far largest cohort of patients treated with BKP, focusing specifically on early incidence of adjacent segmental fractures and their association with surgical and patient characteristics. In this analysis, a collective of patients with osteoporotic fractures and short-term follow-up up to 6 months was considered. Prior studies reported ASF after BKP to mainly occur within the first 3 months postoperatively and most often in patients with osteoporosis as cause of the primary vertebral fracture [12, 18–20]. In addition to osteoporosis as fracture etiology, we restricted the analysis to patients with a single level fracture for creating a uniform cohort and simplifying interpretation of results. In our sample nearly each tenth patient developed an early ASF. A preoperative segmental kyphosis >30° was significantly associated with the occurrence of ASF both in the univariate and multivariate analyses. We could demonstrate that patients with ASF had a significantly higher risk of persistent back pain in the univariate model.

In the literature, ASF rates after BKP vary between 6.5 and 25 % [12, 19–22]. Our observed rate of nearly 10 % is well within this reported range. The higher rates of adjacent fractures in other studies may be explained by inclusion of patients treated on multiple segments and having long-term follow-ups [12, 18, 22]. The cumulative



incidence of new vertebral fractures at any spine level within 1 year after an incident vertebral fracture has been found to be 6.6 % in postmenopausal women [13]. This percentage seems to be well comparable to the 10 % seen in the BKP treated cohort.

The natural cause of ASF after insufficiency fractures is still unknown. Evidence exists that rather the primary disease (osteoporosis) and secondary malalignment of the vertebral column may be the reason for further fractures [11, 13, 23, 24] rather than the cement augmentation itself. Primary and secondary osteoporosis [18, 19, 25] are already identified risk factors for ASF after BKP [19, 25]. Our results, in terms of significant association of the segmental kyphosis prior to surgery for the occurrence of ASF, also support this thesis. However, the extent of achieved correction of segmental kyphosis did not result in a significant association with the incidence of ASF.

Both univariate and multivariate analyses showed a significant association of cardiovascular disease and rheumatoid arthritis with ASF. Those associations were not previously reported and it is difficult to explain them. One may speculate that advanced cardiovascular disease, rheumatoid arthritis or their combination (with or without other co-morbidities) may be associated with less mobility and, therefore, a potentially higher degree of osteoporosis. Furthermore, in patients with rheumatoid arthritis, an involvement and weakening of the adjacent discovertebral joints and steroid treatments may contribute to the higher rate of ASF. However, those are hypotheses that require further studies.

The extent of achieved correction of segmental kyphosis was not significant in the statistical model. In our opinion, the amount of preoperative kyphosis may reflect the severity of the underlying disease, i.e., osteoporosis. Another possible explanation could be the residual kyphotic deformity due to surgical difficulties in fully realigning such a high preoperative kyphosis angle. The sagittal malalignment due to an increased segmental kyphosis may lead to potentially higher load through the anterior column and consequent higher incidence of ASF [26, 27]. Movrin et al. [19] reported a decreased risk of ASF in patients with a kyphotic angle lower than 9° postoperatively in comparison with kyphosis higher than 9°.

# Weaknesses and strengths

Some limitations of the present study require a further explanation. A potential under-reporting of surgeon-based outcomes like ASF cannot be completely excluded in this observational unmonitored study. All surgeons participating in the documentation are accredited by the Swiss Spine Society for BKP procedures. To get accredited each surgeon has to participate in an advanced training including a cadaver lab. Furthermore, they need an adequate

infrastructure to conduct the procedure in their hospital. An audit or any other control mechanism in a national registry would need strong financial and organizational resources and was considered as not feasible by the stakeholders of the project.

No direct treatment comparator is included in the SSR documentation. A complete documentation of a comparator procedure like non-surgical treatment in a national registry would need additional and substantial administrative and financial efforts, which were considered even less feasible. Therefore, it is impossible to distinguish between ASF due to BKP and adjacent "natural" vertebral insufficiency fractures in this study. Controlled studies of non-surgical treatment versus BKP are needed.

The mean follow-up of 3.6 months in our study is relatively short and the incidence of ASF might even be higher with longer follow-up. However, most ASF usually occur within the first 3 months after BKP [12, 18, 19, 28], the vast majority of the BKP-associated ASFs should, therefore, be included in our study sample. One of the main reasons for considering early follow-ups was the goal to minimize the basic influences of patient's primary disease such as osteoporosis on the incidence of ASFs.

Also, the analysis did not include data on bone mineral density (BMD) and data on sagittal alignment, as it was not part of the SSR dataset. Impaired sagittal balance may potentially be associated with a mechanical risk of further fractures.

Finally, the registry uses predefined categories for preor postoperative segmental kyphosis, which were grouped into four categories for the current analysis. The relation between the segmental kyphosis at follow-ups and occurrence of ASF could be more accurately studied in linear multivariate regression models considering kyphosis angle as a continuous variable.

On the other hand, this is the first study of ASF after BKP based on a national registry, and thus less dependent on a single treating institution or individual surgeon and related experience. The real-life data enable a more objective analysis with higher external validity, which is the major strength of the current study. Furthermore, the analysis contains the so far largest collective of patients treated with BKP for osteoporotic VCF.

# Conclusions

A preoperative segmental kyphotic angle >30°, rheumatoid arthritis and cardiovascular disease are significantly associated with an early ASF and increased back pain after BKP in patients with mono-segmental osteoporotic insufficiency fractures. Controlled trials are required to compare non-surgical treatment and BKP regarding their incidence of ASFs.



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