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Predictive Factors for Health-Related Quality of Life Post-Balloon Kyphoplasty in Patients with Osteoporotic Vertebral Compression Fractures

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Study Design: Retrospective cohort study.

Purpose: Balloon kyphoplasty (BKP) is a minimally invasive surgical treatment for osteoporotic vertebral compression fractures (OVCFs), with good clinical outcomes reported in short-term investigations. However, the impact of BKP on health-related QOL in the long term remains unclear. This study aimed to evaluate the effects of BKP on global sagittal balance and alignment and to determine the association between predictive factors before BKP and health-related QOL in the long term.

Methods: A longitudinal cohort study was conducted on 62 patients (13 men and 49 women) diagnosed with OVCF who underwent BKP and were followed up for more than 12 months. Spinopelvic parameters, including sagittal vertical axis (SVA), thoracic kyphosis (TK), pelvic incidence (PI) minus lumbar lordosis (LL), and low back pain (LBP) severity, were measured preoperatively, at 3 months post-BKP, and at final follow-up. Multivariate logistic regression analysis was performed to identify predictive factors for unhealthy condition after BKP, with adjustment for age, sex, and duration from onset of back pain to BKP.

Results: The mean follow-up duration was 20.7 months. The mean SVA values were 7.42 cm preoperatively, 7.62 cm at 3 months post-BKP, and 8.01 cm at final follow-up. The mean self-reported numerical rating scale scores for LBP were 8.4 preoperatively, 0.4 post-BKP, 0.6 at 3 months post-BKP, and 1.0 at final follow-up. Imbalanced spine (SVA ≥5.0 cm) and PI-LL mismatch (PI-LL ≥20°) before BKP were significantly associated with unhealthy condition (EuroQol 5 dimensions 5-level <0.65) (odds ratio and 95% confidence intervals: imbalanced spine, 4.76 and 1.32–17.2; PI-LL mismatch, 3.78 and 1.18–12.1, respectively).

Conclusion: BKP did not improve global spinopelvic parameters or health-related QOL in imbalanced patients. Higher SVA measurements and PI-LL mismatch before BKP were associated with lower health-related QOL after BKP.

Keywords: osteoporotic vertebral compression fracture, balloon kyphoplasty, global sagittal alignment, health-related quality of life

Background

Osteoporotic vertebral compression fractures (OVCFs) represent a globally significant medical and socioeconomic burden, with approximately 1.4 million new OVCFs occurring yearly.[1] Long-term consequences of OVCFs include chronic back pain, decline in physical function, decreased quality of life (QOL), and depression.[2–5] Furthermore, a single OVCF increases the risk for new vertebral fractures five-fold in the first year, and two or more fractures increase the risk up to 12-fold.[6]

Balloon kyphoplasty (BKP) is a newly-developed, minimally-invasive surgical treatment for OVCFs.[7] This technique aims to address fracture-related pain and associated spinal deformities. The deformity is corrected by inserting an inflatable bone tamp (IBT) into the fractured vertebral body. The IBT is subsequently inflated, increasing the height of the vertebral body, and cement is deposited into the cavity.[7–12] Good clinical outcomes have been reported after kyphoplasty in short-term investigations.[8–12] Kanayama et al[8] found that BKP contributed to immediate pain relief; however, BKP for OVCFs did not impact global spinal alignment and balance, and few clinical studies have investigated changes in global

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spinal alignment after BKP.[9,10] Therefore, BKP is considered to contribute greatly to the maintenance and recovery of activities of daily living (ADL) in older patients after OVCFs.[12,13] However, in our clinical experience, some patients have had low health-related QOL after BKP. No previous studies have focused on the impact of BKP on health-related QOL in the long term.

This study aimed to evaluate the effects of BKP on global sagittal balance and alignment by assessing spinopelvic parameters preoperatively, at 3 months after BKP, and at the final follow-up consultation more than 12 months later, and to determine the association between predictive factors before BKP and health-related QOL in the long term.

Materials and Methods

Patients and Eligibility Criteria

Sixty-two patients with symptomatic OVCFs were enrolled in this prospective cohort study conducted from April 2018 to June 2021. The inclusion criteria were (1) age >65 years and (2) computed tomography (CT) diagnosis of a new OVCF with magnetic resonance imaging (MRI) confirmation. The exclusion criteria were (1) pathological fractures as a result of underlying malignancy, (2) a diagnosis of more than one new OVCF, (3) severe dementia, (4) high-energy injuries, and (5) the patient was unable to answer these questionnaires by themselves.

Diagnosis of a new OVCF was made based on abnormal intensity and signal change in the vertebral body on CT scan and MRI. After confirmation of an OVCF diagnosis, patients were immediately admitted to the hospital and placed in a lumbosacral corset. Demographic data and data for the time of back pain onset were collected retrospectively by questioning the patients and their families.

Radiographic Evaluation

To obtain lateral radiographs of the whole spine and pelvis, the patients were asked to stand upright in a relaxed and natural manner, avoiding a forced position, and to look forward with both feet placed together on a flat surface, maintaining a horizontal gaze.[14,15] Radiographs were taken preoperatively, 3 months postoperatively, and at the final follow-up consultation. We analyzed the following spinopelvic parameters: (1) sagittal vertical axis (SVA), the horizontal distance between a plumb line, originating from the middle of the body of the C7 vertebrae, and the posterior superior endplate of S1; we divided the imbalanced spine group (SVA ≥5.0 cm) and balanced-spine group (SVA <5.0 cm) as per a previous report;[8] (2) thoracic kyphosis (TK) based on angle between the upper endplate of T1 and the lower endplate of T12; (3) pelvic incidence (PI) based on the angle between a line perpendicular to the sacral plate at its midpoint and a line connecting the same point to the center of the bicoxofemoral axis; (4) lumbar lordosis (LL) based on the Cobb angle from the upper endplate of L1 to the upper endplate of S1. Moreover, PI-LL mismatch was divided by more than 20 degrees or not based on the demographic mean, based on the protocol of a previous report.[16]

Questionnaire

The severity of pain was assessed using a self-reported numerical rating scale (NRS) in which patients provided a score from 0 to 10, based on the severity of low back pain (LBP) experienced during activity. Self-reported NRS of LBP were obtained preoperatively, immediately postoperatively, at 3 months after BKP, and the final follow-up consultation.

QOL assessments were completed for each participant using locally validated questionnaires with EuroQol 5 dimensions 5-level (EQ-5D-5L). The EQ-5D-5L is a self-administered questionnaire and descriptive system comprising five dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression), each with five levels of severity (no problems, slight problems, moderate problems, severe problems, and extreme problems). The responses for the five dimensions can be combined into a 5-digit number describing the respondent's health state (from "11111", meaning no problems at all, to "55555", meaning extreme problems in all five dimensions).[17] We defined the cut-off value of the EQ-5D-5L index as <0.65 for low health-related QOL for the patients after BKP, based on the mean score in this study.

Indication of BKP

Preoperative assessment of the patients was conducted by examining plain radiography, CT, and MRI of the spine. Endplate deficit and posterior wall injury on a lateral view of the CT scan were indications for BKP, as these were associated with prolonged LBP.[18] The patterns of signal changes within the fractured vertebral bodies on MRI were classified based on midsagittal T1-weighted images (T1WI) and T2-weighted images (T2WI). Diffuse low-intensity and confined high-intensity signals on T2WIs were also indications for BKP, as these are associated with an increased risk for non-union.[19]

Statistical Analyses

All statistical analyses were performed using JMP 16 (SAS Institute Japan, Tokyo, Japan). We examined the spinopelvic parameters, SVA, TK, PI- LL, and NRS of LBP preoperatively, at 3 months after BKP, and at the final follow-up consultation.

All patient data were examined for associations between the spinopelvic parameters and sex, age, average duration of the first consultation after the onset of LBP, average duration of BKP after onset of LBP, follow-up periods, preoperative bone mineral density (lumbar/femur young adult mean), presence and number of pre-existing OVCFs, and presence of subsequent fractures after BKP.

Preoperative demographic data and spinopelvic parameters of the low health-related QOL and high health-related QOL groups were compared using the two-sample *t*-test (for age, lumbar and femoral bone mineral density, average duration of the first consultation after onset of LBP, average duration of BKP after onset of LBP, number of pre-existing OVCFs, and preoperative SVA and PI-LL) and Fisher's exact tests (for sex and presence of pre-existing OVCF).

Furthermore, the utility of unhealthy conditions after BKP as a predictive risk factor was examined using multivariate logistic regression logistic analysis after adjustment for age, sex, and average duration of BKP after onset of LBP. The following variables were included as independent variables: the presence of pre-ex vertebral fracture, imbalanced spine (SVA ≥5.0 cm), and PI-LL mismatch (PI-LL ≥20°). Results are presented as mean and standard deviation (SD); the threshold for statistical significance was set at $P < 0.05$, and the corresponding 95% confidence intervals (CIs) were assessed.

Results

The study included 62 patients (13 male, 49 female) with a mean age of 78.9 years (range 63–94). On average, patients sought initial consultation 14.7 days after the onset of back pain, with BKP performed 23.8 days after the onset of back pain. The mean follow-up period was 20.7 months. Half of the cases presented with pre-existing OVCFs, and 19.7% experienced subsequent fractures after BKP. The majority of OVCFs were located in the thoracolumbar junction (T12-L2) (Table 1).

When comparing patients with low and high health-related QOL after BKP, no significant differences were found in age, bone mineral density, or time to consultation and treatment. However, the low health-related QOL group demonstrated significantly higher SVA (9.6 vs 5.8, $p<0.01$) and PI-LL (31.8 vs 19.4, $p<0.05$) compared to the high health-related QOL group (Table 2).

Table 1 Case Characteristics

Cases (male / female)	62 (13/ 49)
Age (yrs)	78.9 (63–94)
Average duration of first consultation after onset of back pain (SD) (days)	14.7 (23.2)
Average durationaverage duration of BKP after onset of back pain, (SD) (days)	23.8 (30.4)
Follow-up periods (avg) (Months)	20.7 (12–44)
Lumbar Bone mineral density (YAM, SD)	74.7 (16.6)
Femoral bone mineral density (YAM, SD)	75.5 (15.0)
Presence of pre-ex OVCFs (Cases) (%)	31 (50.0%)
Number of pre-ex OVCFs (avg)	0.95 (1.31)
Presence of subsequent fracture after BKP (Cases) (%)	12 (19.7%)
Level of OVCFs	
Thoracic (T8-T11)	3
Thoracolumbar junction (T12-L2)	48
Lumbar (L3-5)	11

Abbreviations: SD; standard deviation, NRS; numeric rating scale. OVCFs; osteoporotic vertebral fracture. BKP; balloon kyphoplasty. SD; standard deviation, YAM; young adult mean.

Table 2 Preoperatvie Demographic Data and Spinopelvic Parameter Between Low Health-Related QOL Group and High Health-Related QOL Group After BKP

	Low Health-Related QOL Group	High Health-Related QOL Group	P value
Cases (male / female)	4/ 22	9/ 26	0.37
Age (SD) (yrs)	80.7 (8.5)	77.9 (5.7)	0.13
Lumbar Bone mineral density (YAM, SD) (%)	73.3 (15.2)	75.0 (17.4)	0.71
Femoral bone mineral density (YAM, SD) (%)	71.9 (12.6)	77.8 (16.3)	0.14
Average duration of first consultation after onset of back pain (SD) (days)	11.5 (9.9)	13.2 (18.6)	0.67
Average duration of BKP after onset of back pain (SD) (days)	19.3 (10.4)	21.4 (19.1)	0.62
Presence of pre-ex OVCFs (%)	16/ 26 (61.5%)	15/36 (41.7%)	0.2
Number of pre-ex OVCFs	1.1 (1.2)	0.9 (1.4)	0.58
Spinopelvic parameter			
SVA (SD)	9.6 (5.8)	5.8 (4.9)	< 0.01
PI-LL (SD)	31.8 (24.4)	19.4 (16.4)	< 0.05

Abbreviations: QOL, quality of life; BKP, balloon kyphoplasty; SVA, sagittal vertical axis; PI, pelvic incidence; LL, lumbar lordosis; OVCFs, osteoporotic vertebral fractures; SD, standard deviation; YAM, young adult mean.

Table 3 Predictive Risk Factor of Low Health-Related QOL After Balloon Kyphoplasty After Adjustment of Age, Sex and Duration from Onset Back Pain to BKP

	Odds Ratio	95% CI	P value
Presence of pre-ex vertebral OVCFs	1.86	0.64–5.4	0.26
Imbalanced spine (SVA ≥ 5cm)	4.76	1.32 −17.2	< 0.05
PI-LL mismatch (PI-LL ≥ 20°)	3.78	1.18–12.1	< 0.05

Abbreviations: QOL, quality of life; BKP, balloon kyphoplasty; SVA, sagittal vertical axis; PI, pelvic incidence; LL, lumbar lordosis; 95% CI, 95% confidence index.

Table 3 shows that multivariate analysis, adjusted for age, sex, and average duration of BKP after onset of LBP, revealed that an imbalanced spine (SVA ≥ 5cm) was a significant risk factor for low health-related QOL (OR 4.76, 95% CI 1.32–17.2, p<0.05). Similarly, PI-LL mismatch (PI-LL ≥ 20°) was also identified as a significant risk factor (OR 3.78, 95% CI 1.18–12.1, p<0.05). Interestingly, the presence of pre-existing vertebral OVCFs was not found to be a significant predictor of low health-related QOL outcomes (OR 1.86, 95% CI 0.64–5.4, p=0.26).

Figure 1A shows the change in self-reported NRS score of LBP afrom preoperative assessment, to post-operation, to 3 months after BKP, and to final follow-up (p<0.05). Figure 1B shows the change in global spinopelvic parameters from

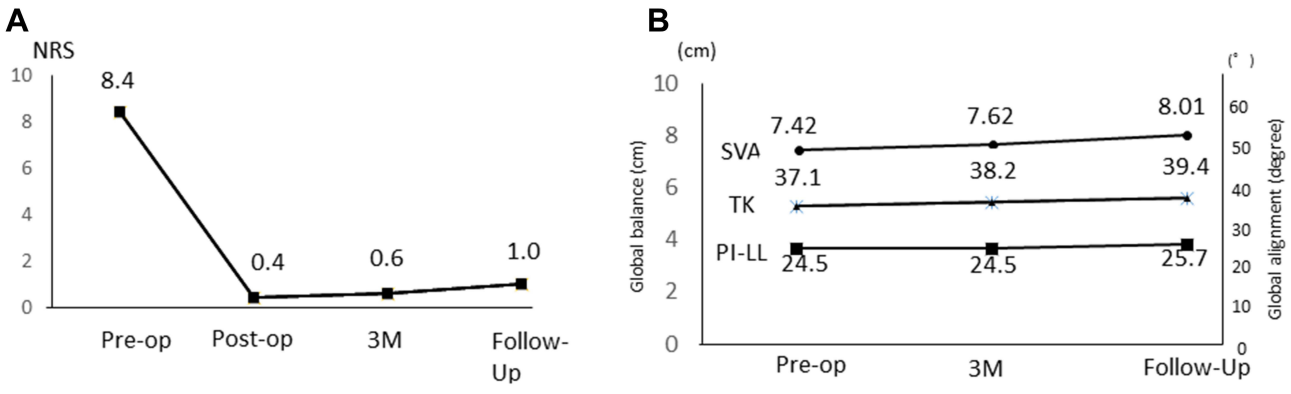

Figure 1 (**A**) Change in self-reported numerical rating scales of low back pain from preoperative assessment to postoperative, three months after BKP, and final follow-up consultation.(**B**) Changes in sagittal vertical axis, thoracic kyphosis, and pelvic incidense minus lumbar lordosis from preoperative assessment to three months after BKP and final follow-up consultation.

preoperative assessment, to 3 months after BKP, and at final follow-up. There was no significant difference between the parameters at each consultation.

Discussion

In this study, we observed that BKP improved self-reported LBP severity during the follow-up period until the final consultation. However, spinopelvic parameters were not influenced by BKP in the longitudinal study for longer than 12 months. Further, imbalanced spine and PI-LL mismatch before BKP were associated with low health-related QOL at the final follow-up consultation. Excellent early relief of pain after BKP has been previously reported, suggesting that BKP can contribute to improved post-OVCF recovery and ADL in older patients.[11,13,20,21] A previous study suggested that BKP should be indicated only in patients with painful OVCFs in the acute phase identified by CT.[18] Few reports have focused on the impact of timing on surgical outcomes for OVCFs.[20–22] Minamide et al[20] reported that early BKP results in better long-term alignment and lower subsequent OVCFs rates than a delayed procedure. Kaufmann et al[22] suggested that vertebroplasty for OVCFs is highly effective for pain relief and improvement of patient mobility, regardless of fracture age. Lieberman et al[11] reviewed the outcomes of BKP procedures in 30 patients with painful OVCFs and found that BKP restores 35% of the lost vertebral height. Phillips et al[12] conducted a prospective cohort study of 29 patients who underwent BKP for OVCFs, revealing an immediate correction of local spinal kyphosis of 8.8° on average, and significant pain reduction within the first postoperative week. Thus, the efficacy of BKP in providing pain relief and local vertebral alignment has been well established; however, there a limited number of articles have highlighted the effects of BKP on global spinal balance and alignment. In our prospective cohort study, spinopelvic balance and alignment were not significantly different after long-term follow-up. Kanayama et al[8] retrospectively reviewed 56 patients who had undergone BKP for symptomatic OVCF with a mean follow-up period of 32 months. They concluded that BKP could not restore global sagittal alignment, which is consistent with our results. Since Dubousset et al[23] proposed the concept of the "cone of economy"; the SVA and other spinopelvic parameters have been recognized as important for assessing the outcomes of LBP-related disability and health-related QOL.[14,15] Teraguchi et al[14] reported that LBP-related disability is influenced by an imbalanced spine and reciprocal change due to compensatory mechanisms in the lower extremity. Therefore, our clinical hypothesis was that the patients with an imbalanced spine might have low health-related QOL after BKP, despite relief from the pain of OVCFs. The results of our study revealed a significant association between imbalanced spine and PI-LL mismatch and low health-related QOL after BKP. For the SVA, we used a threshold of ≥5.0 cm to define an imbalanced spine. This decision aligns with previous research, including the work of Kanayama et al,[8] which has shown that an SVA of 5.0 cm or greater is associated with poorer clinical outcomes and reduced QOL in patients with spinal deformities. While our study focuses specifically on OVCFs, we believe this threshold remains relevant due to the impact of OVCFs on overall spinal alignment. Further, the PI-LL mismatch threshold of ≥20° was based on our demographic mean and supported by the protocol used in Sakuma et al.[16] In the context of OVCFs, this mismatch can indicate a substantial alteration in spinal sagittal balance, potentially affecting patient outcomes. For the EQ-5D-5L, we defined a score of <0.65 as indicating low health-related QOL. This cut-off was determined based on the mean score in our study population. While this approach might raise questions about generalizability, it allows for a more context-specific interpretation of QOL in our OVCF patients undergoing BKP. The significant associations we found between preoperative spinopelvic parameters and post-BKP QOL have important clinical implications. The present study highlights the need for comprehensive preoperative assessment and potentially more aggressive management strategies for patients with severe sagittal imbalance.

Previous studies investigating the relationship between spinopelvic parameters and patients' QOL have shown that restoring normal sagittal alignment is a critical objective in achieving favorable outcomes and preventing mechanical complications in patients with adult spinal deformity.[6,7] Lindsay et al[6] commented that the incident OVCF increases the risk of future OVCFs, which appears to be highest during the first year after fracture (4% with 0 OVCFs vs 24% with ≥2 OVCFs). Hu et al[24] reported a negative correlation between the number and severity of OVCFs and global sagittal alignment parameters. Global sagittal alignment had a better discriminative value in identifying patients with OVCF. However, the present study did not show a significant association between pre-existing OVCFs and QOL because the number of pre-existing OVCFs might have been small in each group.

Limitations

The limitations of our study should be considered. First, the sample size of 62 patients was relatively small. Further evaluations with larger and more diverse groups of patients are necessary. The average post-procedural follow-up in this study exceeded 1 year, and this should be a sufficient follow-up period to ensure the optimal potential for clinical and radiographic improvement. Nonetheless, we plan to continue following-up the patients in this cohort to further explore clinical and radiographic outcomes over longer periods. Finally, the quality of preoperative questionnaires, such as EQ-5D-5L, is questionable due to the extreme pain experienced by patients after acute vertebral compression fractures. This made health-related QOL during the pre-fracture period was difficult to measure.

Conclusions

The results of this study demonstrated that BKP relieved the LBP caused by OVCFs; however, the spinopelvic parameters were not improved by BKP after long-term follow-up. Imbalanced spine and PI-LL mismatch before BKP were associated with low health-related QOL at the final follow-up consultation after BKP. Therefore, we highlight the importance of preventing an imbalanced spine in a middle-aged population.

Ethical Approval

This study was approved by the institutional review board of Wakayama Medical University (approval number: 2898). This study complies with the Declaration of Helsinki.

Informed Consent

Informed consent was obtained from all individual participants included in the study.

Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

The authors have no competing interests to declare that are relevant to the content of this article.

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