Original Article

Does an osteoporotic vertebral fracture treated by balloon kyphoplasty successfully achieve bone union during the follow-up? A retrospective study with a minimum 2-year follow-up

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ABSTRACT

Objective: To investigate whether bone union is achieved in osteoporotic vertebral fracture (OVF) patients who undergo balloon kyphoplasty (BKP).

Methods: Thirty-six vertebrae, which were followed-up for more than two years after BKP, were evaluated in the present study. Bone union was assessed by using CT scans and lateral X-ray films obtained in the sitting and supine positions.

Results: Twenty-seven vertebrae exhibited bone union at the final follow-up. The VAS scores improved in all cases.

Conclusions: Unstable vertebrae after treatment may develop complications; thus special attention should be paid to the treated vertebrae until bone union has been achieved.

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1. Introduction

There are many reports on the clinical results of balloon kyphoplasty (BKP) for the treatment of osteoporotic vertebral body fractures (OVF) that include information about the alignment, pain, safety, efficacy and complications.^{1–9} In these studies, good results were achieved in almost all cases. However, because the stabilization of the fractured vertebrae is generally considered to be the mechanism underlying the pain relief observed following BKP, these past studies did not examine the dynamics of instability after BKP. Past literature previously reported that instability of the vertebrae persists after BKP,¹⁰ and some reports have described the recompression of the treated vertebral body after BKP.¹¹ Furthermore, paraparesis has been reported to occur due to instability after BKP.¹² We also observed one case with delayed palsy after BKP in our institution that needed additional decompression and fusion surgery. In other words, the instability that occurs because of the OVF remains after BKP (Fig. 1). In spite of the fact that BKP is used as a treatment for OVF with instability, the achievement of bone union after BKP has never been discussed. In the present study, we

investigated whether bone union of the OVF is achieved after BKP with a minimum 2-year follow-up.

2. Methods

Between April 2011 and August 2015, 95 BKP procedures that were performed at our institution were retrospectively reviewed. The cases that were followed up for more than two years after BKP were included in the present study. The cases that were followed up for less than two years after BKP and those that required reoperation at the operated site during the follow-up period were excluded. The indication for BKP is persistent back pain due to OVF with instability that is resistant to conservative treatments (including medication, bed rest and immobilization). This study was reviewed and approved by the institutional review board of Kyushu University.

An OVF is diagnosed based on the clinical symptoms and imaging findings. Lower back pain with body movement was considered to be a representative medical finding in OVF patients. The primary imaging assessment was performed using lateral X-ray films with the patient in the sitting and supine positions in order to assess the instability of the fractured vertebrae. Instability was defined by a change in the shape of the vertebral body or the existence of an intravertebral cleft on the lateral X-ray films. An OVF was diagnosed when the representative imaging findings and clinical symptoms were present at the same time. All of the

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Fig. 1. A cleft between the cement and the end plate was observed on an X-ray film taken with the patient in the supine position that disappeared in the sitting position. This condition is referred to as instability after balloon kyphoplasty (BKP).

patients eventually underwent computed tomography (CT) and MRI to confirm the diagnosis and for surgical planning.

The evaluation of the imaging findings, including the lateral X-ray films that were obtained in the sitting and the supine positions, CT and a visual analog scale (VAS) were carried out at the time, more than two years after the patient underwent BKP. Bone union has never occurred between cement and bone. Consequently, bone union was defined using the two following criteria: 1) the absence of a cleft between the cement and the endplate of the vertebra and a change in the shape of the vertebral body on lateral X-ray films obtained in the sitting and supine positions; 2) a bridging callus surrounding the treated vertebral body and the disappearance of the intravertebral cleft were present on a CT scan taken at the final follow-up examination. Bone union was only judged to have occurred in the cases that fulfilled both of these criteria in the final assessment. The imaging findings were independently evaluated by three orthopedic surgeons. The final decisions were in the cases in which the three surgeons agreed on the findings. The presence of back pain before BKP and at the final follow-up examination was evaluated using a VAS. The difference in the mean VAS scores between the bone union group (UG) and the non-union group (NUG) was analyzed using a *t*-test. In addition, the patient's age, sex, duration of symptoms, cement volume, kyphosis angle (at pre-operation, post-operation and the final follow-up) (Fig. 2) and the follow-up period were compared between the two groups.

3. Results

Thirty-six vertebrae that had been followed up for more than two years after BKP were ultimately included in the present study (males: 5; females: 31). Twenty-five vertebrae were followed up for less than two years. Three vertebrae required reoperation during the follow-up period because of infection or paraparesis

due to persistent instability. Five patients died due to cancer or heart failure during the follow-up period. Twenty-six vertebrae of 20 patients were lost to follow-up. The mean age at surgery was 80 years (range: 67–97 years). The average duration from the onset of pain to surgery was 5.5 months (0.5–29). BKP was performed at T7–10 in 3 cases, T11–L2 in 27 cases and L3–5 in 6 cases. Two patients received treatment for two vertebral bodies and one patient received treatment for three vertebral bodies. The mean follow-up period was 31 months (range: 24–48 months).

Twenty-seven vertebrae (75%) exhibited bone union at the final follow-up examination. As a matter of course, all cases had instability before BKP. At immediately after BKP, 20 of 36 cases had instability, and 16 of 36 cases got stability. At final follow-up, 14 of 20 cases got bone union, 6 of 20 cases remained instability, 13 of 16 cases got bone union, and 3 of 16 cases had new instability. The bone union morphology was divided into two types (Fig. 3): bone union in the treated vertebral body itself was observed in 16 cases, while bone union with the adjacent vertebral body by a bridging callus surrounding the cement was observed in 11 cases. With the exception of the kyphosis angle (at pre-operation, post-operation and the final follow-up), no significant differences were observed in the VAS scores or the other examination items of the UG and NUG (Table 1). No significant differences were also observed regarding the patients' age and sex.

4. Discussion

After the first vertebroplasty was reported in 1987,¹³ the cement augmentation technique gradually spread to the treatment of spinal tumors and OVF. The first kyphoplasty operation with an inflatable bone tamp was reported in 2001.^{14,15} Many previous studies have reported the effectiveness of BKP and have also included substantial debates on the complications, mainly with

Fig. 2. X-ray films showing the method by which the focal kyphosis angle was measured. The focal kyphosis angle between the higher end plate of the upper vertebral body and the lower end plate of the lower vertebral body was measured.

Fig. 3. Detailed X-ray films and computed tomography (CT) scans showing the types of bone union. These conditions are referred to as bone union. A: No cleft was observed between the cement and the end plate of the vertebra on lateral X-ray films in the sitting and supine positions. The cement was completely surrounded by the bone of the vertebral body itself on CT. B: A bridging callus between the adjacent vertebral bodies and the disappearance of the intravertebral cleft were seen on CT. No cleft was observed on lateral X-ray films in the sitting and supine positions.

regard to adjacent fractures and spinal alignment.^{8,16–21} BKP is now widely used because of its safety, efficacy and its low level of invasiveness. Although the detailed mechanisms underlying the pain relief following BKP are still unknown, it is generally considered that they involve the fixation of the fractured vertebrae. The presence of persistent instability after BKP and how bone union is achieved in vertebral bodies with remaining instability have never been discussed. Past literature previously reported that instability remains after balloon kyphoplasty.¹⁰ Ohba et al.¹² reported that instability of the treated vertebrae after balloon kyphoplasty caused paraparesis. In addition, Kim et al.¹¹ reported that the incidence of recompression in treated vertebrae was 12.5%. In other words, fixation is not immediately provided for all fractured vertebral bodies, and the fixed state is not necessarily permanent, even if the OVF is fixed immediately after BKP. Of note, although BKP was used as a treatment for unstable OVF, no evaluations of bone union have been reported in studies with long follow-up periods. We therefore investigated whether the treatment of OVF by BKP achieved bone union in a minimum 2-year follow-up. It was previously reported that instability of the vertebrae remained in 45% of cases immediately after BKP.¹⁰ In this study, 9 vertebrae (25%) exhibited instability at the final follow-up examination. Attention should be paid to this finding in order to avoid the development of complications due to remaining instability. Taking the form and rate of bone union at the follow-up examinations into consideration, two different courses

of bone union were presumed to have occurred. First, it is likely that some vertebral bodies were somewhat stabilized by BKP and developed a bridging callus between the adjacent vertebrae, leading to the bone union of the treated vertebral body. This type of bone union might be involved in the natural process of ageing spine. Second, other vertebral bodies were involved in achieving strong stabilization immediately after BKP in the treated vertebrae – after which the bones around the cement fused during follow-up. If instability remained after BKP, 70% of the cases with instability have a possibility to obtain the bone union during follow-up.

In the present study, significant differences were recognized in the kyphosis angle (at pre-operation, at post-operation and at the final follow-up) between the UG and the NUG. Bone union was observed to have been achieved at the final follow-up examination of all 6 of the cases that involved lumbar-level vertebrae. It is thought that a significant difference in the kyphosis angle appeared because numerous lumbar vertebrae with physiological lordosis were included in the UG. However, this remains a matter of speculation due to the small number of cases and because the lumbar vertebrae might have advantages with regard to the achievement of bone union due to the volume of cancellous bone in comparison to the vertebrae at other levels. As a result, bone union could be achieved in all of the lumbar-level OVFs.

The effectiveness of BKP was also recognized in the present study. Bone union did not significantly affect the VAS scores for pain. The mechanism underlying the pain relief appears to not only

Table 1
Comparison of examination items between UG and NUG.

Examination items	Union group (mean $\pm$ SE)	Non-union group (mean $\pm$ SE)	P-value
Preoperative VAS	66.7 $\pm$ 3.4	68.4 $\pm$ 6.8	0.82
VAS at the final follow-up	23.2 $\pm$ 5.4	21.8 $\pm$ 5.7	0.86
Disease duration(month)	4.9 $\pm$ 0.9	7.4 $\pm$ 3.2	0.48
Cement volume(ml)	7.8 $\pm$ 0.6	7.7 $\pm$ 1.3	0.94
Follow-up period(month)	31.0 $\pm$ 1.3	32.8 $\pm$ 3.1	0.61
Kyphosis angle at pre-operation(deg)	23.0 $\pm$ 3.7	39.2 $\pm$ 5.0	0.02
Kyphosis angle at post-operation(deg)	12.2 $\pm$ 3.8	29.3 $\pm$ 5.2	0.02
Kyphosis angle at final follow-up(deg)	14.8 $\pm$ 3.9	37.9 $\pm$ 5.1	0.002

include a reduction of the instability of the vertebral body, but also other factors, including the alignment, soft tissue damage, muscle fatigue, facet joint arthritis, the chemical neurolytic effect of polymethyl methacrylate (PMMA) and the thermal neurolytic effect of PMMA.

These results indicate that bone union was not achieved after BKP for OVF in one-quarter of the treated cases over the long follow-up period of the present study. Questions therefore remain regarding of the procedure, including why bone union is achieved in some cases but not in others, and why the VAS for pain improves in patients even when bone union is not achieved. Although there were no significant differences between UG and NUG regarding disease duration, the disease duration did tend to be shorter in the UG. If the number of cases increases, then significant differences might appear.

To the best of our knowledge, this is one of the worthwhile reports that contains important findings that mention bone union of BKP-treated vertebrae over a long follow-up period. However, the present study is associated with some potential limitations. First, our cases included a mixture of fracture types (wedge deformity, biconcave deformity or crush deformity).²² Second, the disease duration (acute, subacute, delayed union, pseudoarthrosis) varied. Third, this study included only a small number of cases and the patients' pain was only evaluated by the VAS scores. Finally, because many of the patients in the present study were of advanced age, it was very difficult to sustain the follow-up for two years.

It will therefore be necessary to add to these cases and to subdivide the cases into different fracture types. Furthermore, these cases need to be divided according to the time when they were treated by BKP, and should be evaluated by other, more precise, evaluation tools in the future.

Bone union was not successfully achieved in one-quarter of the cases that were treated by BKP. Vertebrae that are unstable after treatment may develop complications; thus special attention should be paid to the treated vertebrae until bone union has been achieved. However, BKP was effective for reducing the VAS score in patients suffering from OVF-related back pain.

Ethics approval

The study was reviewed and approved by the institutional review board of Kyushu University.

Conflict of interests

None.

Authors' contributions

KT contributed to the conception and design of the study, acquisition of the data, analysis and interpretation of the data, and drafting the manuscript. OT and OT aided in the acquisition of the data. TD participated in the design and coordination and helped in drafting the manuscript. All authors read and approved the final manuscript.

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