

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



Kiyoshi Tarukado*, Osamu Tono, Katsumi Harimaya, Toshio Doi

Department of Orthopedic Surgery, Kyushu University, Beppu Hospital, Oita, Japan

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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

* Corresponding author at: 4546 Tsurumihara, Tsurumi, Beppu, Oita 874-0838, Japan.

E-mail addresses: kt99059@hotmail.com (K. Tarukado), otohno@yahoo.co.jp (O. Tono), harimaya@ortho.med.kyusyu-u.ac.jp (K. Harimaya), toshidoi@ortho.med.kyushu-u.ac.jp (T. Doi).



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

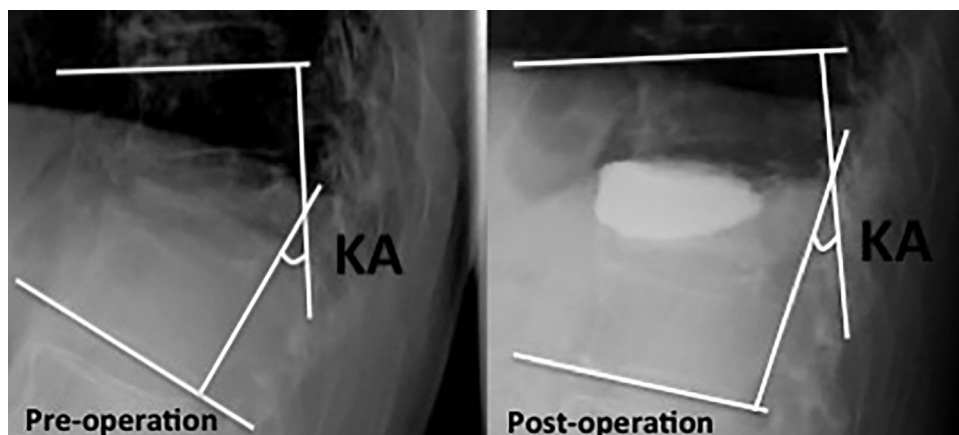


Fig. 2. X-ray films showing the method by which the focal kyphosis angle was measured. The focal kyphosis angle between the higher end plate of the upper vertebral body and the lower end plate of the lower vertebral body was measured.

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