Journal of Clinical Neuroscience 22 (2015) 680–684

Contents lists available at ScienceDirect

Journal of Clinical Neuroscience

journal homepage: www.elsevier.com/locate/jocn

Clinical Study

Single-balloon *versus* double-balloon bipedicular kyphoplasty for osteoporotic vertebral compression fractures

Heng Wang [a], Zhenzhong Sun [b], Zhiwen Wang [a], Weimin Jiang [a,*]

[a] Orthopedics Department, The First Affiliated Hospital of Soochow University, 188 Shizi Street, Soochow 215006, China
[b] Orthopedics Department, The Ninth People's Hospital of Wuxi, Wuxi, China

ARTICLE INFO

Article history:
Received 20 July 2014
Accepted 15 October 2014

Keywords:
Bipedicular
Kyphoplasty
Osteoporosis
Vertebral compression fracture

ABSTRACT

Twenty-eight patients with osteoporotic vertebral compression fractures (OVCF) were treated with single-balloon bipedicular kyphoplasty (Group A), and 40 patients were treated with double-balloon bipedicular kyphoplasty (Group B). Visual Analogue Scale (VAS) score, vertebral height, and kyphotic angle (KA) were evaluated pre-operatively, post-operatively (3 days after surgery) and at final follow-up. Operative time, X-ray exposure frequency and costs were recorded. The mean operative time and X-ray exposure frequency in Group A were greater than in Group B ($p < 0.05$). Significant improvement of the VAS score was noted in each group, and remained unchanged at final follow-up. Mean increases of anterior and middle height of the fractured vertebral body were 5.14 mm and 4.14 mm in Group A, respectively, and 6.22 mm and 5.06 mm in Group B, respectively, and the differences between the groups were statistically significant ($p < 0.05$). Mean reduction of KA was 6.9° in Group A and 8.8° in Group B, which was statistically significant ($p < 0.05$). No statistically significant difference was observed in terms of cement leakage between groups. The mean cost of Group A (US$4202) was significantly less than that of Group B (US$6220) ($p < 0.001$). Single-balloon bipedicular kyphoplasty is a safe and cost-effective surgical method for the treatment of OVCF. It can achieve pain relief comparable with double-balloon bipedicular kyphoplasty. However, double-balloon bipedicular kyphoplasty is more efficacious in terms of the restoration of vertebral height and reduction of KA, and the operative time and X-ray exposure frequency are lower.

1. Introduction

Osteoporotic vertebral compression fractures (OVCF) are common in the elderly, affecting around 1.4 million people each year [1]. Conservative management consists of bed rest, pain relievers, bracing, and physical therapy, but some fractures develop into a progressive deformity and cause debilitating pain [2,3]. Open surgery poses a significant risk in these patients, most of whom are elderly and frail and have only weak bone to support the instrumentation [4,5].

Kyphoplasty is a safe and effective procedure used to treat painful vertebral compression fractures [6]. It uses a balloon, also referred to as an inflatable bone tamp, to create a cavity in the fractured vertebral body into which bone cement is deposited. Traditionally, the standard technique for kyphoplasty consists of cannulating both pedicles and placing two balloons into the vertebral body (double-balloon bipedicular kyphoplasty), and both balloons are inflated simultaneously for *en masse* reduction [7]. However, bipedicular kyphoplasty with a single balloon (single-balloon bipedicular kyphoplasty) is also applied in clinical settings to reduce the financial cost to patients. To our knowledge, there have been no thorough studies that compare the two techniques of bipedicular kyphoplasty in the treatment of OVCF.

The purpose of this study is to retrospectively evaluate and compare the clinical and radiological outcomes of bipedicular kyphoplasty with a single balloon and double balloons for OVCF.

2. Materials and methods

2.1. Study population

This study included 68 patients with a single-level osteoporotic compression fracture at the thoracic and lumbar vertebrae (T6–L4) who underwent bipedicular kyphoplasty between January 2011 and October 2012.

* Corresponding author. Tel.: +86 512 6778 0111; fax: +86 512 6522 8072.
E-mail address: jwmpaper@126.com (W. Jiang).

http://dx.doi.org/10.1016/j.jocn.2014.10.014
0967-5868/

This study was approved by the Ethics Committee of the First Affiliated Hospital of Soochow University, and written informed consent was obtained from all patients.

Inclusion criteria were (1) pain lasting less than 3 months, (2) a pain region consistent with the presence of edema in the fractured vertebra found on MRI, and (3) a Visual Analogue Scale (VAS) score of five or above. Exclusion criteria were (1) a pathologic compression fracture, (2) neurologic deficits, (3) spinal cord compression syndrome, (4) previous spinal surgery, and (5) significant scoliosis.

The 68 patients were divided into two groups according to the surgical procedure: Group A (single-balloon group, who received single-balloon bipedicular kyphoplasty) and Group B (double-balloon group, who received double-balloon bipedicular kyphoplasty). Group A consisted of 28 patients (11 male and 17 female) with a mean age of 68.0 ± standard deviation (SD) of 7.7 years (range 56–81). Group B consisted of 40 patients (16 male and 24 female) with a mean age of 69.6 ± SD 9.4 years (range 55–83). There were no significant differences between the two groups regarding demographic data, as shown in Table 1.

2.2. Surgical technique

The operations were performed by the same senior surgeon (W.J.). All bipedicular kyphoplasty procedures were performed under general anesthesia using fluoroscopic guidance. Patients were placed in the prone position with a bolster placed under the sternum and pelvis. Double-balloon bipedicular kyphoplasty was performed as previously described [7]. Briefly, this procedure involves inserting KyphX Inflatable Bone Tamps (Kyphon, Sunnyvale, CA, USA) bilaterally into the fractured vertebral body. The balloons are simultaneously and slowly inflated to elevate the endplate, reduce the fracture, and create a cavity. The balloons are deflated and withdrawn, and the resulting cavity is filled with polymethylmethacrylate (PMMA) cement. In single-balloon bipedicular kyphoplasty, the single balloon is inserted into the vertebra through the working channel of one side, inflated, deflated and withdrawn, then inserted into the vertebra through the contralateral working channel. PMMA cement is then injected incrementally into the resulting cavity.

2.3. Data collection and outcome assessment

Patients' demographic data including age, sex, body weight, height and bone mineral density were recorded before surgery. Operative time, cement volume, and exposure time to the C-arm machine were recorded during the operation.

We recorded clinical and radiological evaluations pre-operatively, post-operatively (3 days after surgery), and at final follow-up.

Pain was evaluated using a VAS, with 0 = no pain and 10 = the worst pain imaginable. The anterior and middle heights of the fractured vertebra were defined as the distance between the superior and inferior endplates of the anterior vertebral wall and the center of the vertebra, respectively [8]. The kyphotic angle (KA) was measured as the intersection angle of the inferior end plate and the superior end plate of the fractured vertebral body (Fig. 1). KA reduction was calculated by subtracting the post-operative KA from the pre-operative KA [9].

From the anteroposterior projection, four points were hand-selected and marked on fractured vertebra (Fig. 2). Points *a* and *b* were placed at the most right-superior and left-superior endplate margins, respectively. Points *c* and *d* were placed at the most right-inferior and left-inferior endplate margins, respectively. To determine whether lateral wedging occurred, the absolute value of the difference between the measurements of lines *ac* and *bd* were compared post-operatively.

The outcome of cement leakage was assessed after surgery using radiographs and CT scans. The costs of the two procedures were recorded in US dollars.

2.4. Statistical analysis

Data were presented as mean ± SD. The Statistical Package for the Social Sciences software (version 16.0, SPSS, Chicago, IL, USA) was used for the analysis. Intergroup comparisons were made using *t*-test or chi-squared test. Comparisons of clinical and radiological outcomes pre and post-operatively were made using a paired *t*-test. Differences were considered statistically significant when $p < 0.05$.

3. Results

All 68 patients tolerated the operation well. The average operative time was 55 ± 13 minutes in Group A and 49 ± 9 minutes in Group B ($p = 0.033$). The average cement volume was 4.75 ± 1.07 ml in Group A and 5.31 ± 1.05 ml in Group B ($p = 0.037$) (Table 2). Patients were exposed to X-rays 64 ± 11 times in Group A and 55 ± 16 times in Group B, and this difference was statistically significant ($p = 0.012$). There was a mean difference of US$2018 in material operative costs between the two procedures, with a mean cost of US$4202 ± 133 in Group A and US$6220 ± 148 in Group B ($p < 0.001$) (Table 2).

The mean follow-up was 17.7 ± 2.7 months for Group A and 18.7 ± 3.1 months for Group B. Both groups experienced excellent pain relief. The VAS score decreased significantly in both groups, from a pre-operative value of 8.0 ± 1.7 to a post-operative value of 2.3 ± 1.5 in Group A ($p < 0.001$), and from 7.8 ± 1.8 to 2.4 ± 1.2 in Group B ($p < 0.001$). The VAS score decreased further to 1.9 ± 1.8 and 2.1 ± 1.1 at final follow-up in Group A and Group B, respectively (Table 3). There was no significant difference in post-operative VAS scores between the two groups ($p > 0.05$).

Significant increases of the anterior and middle vertebral heights were observed after surgery and the vertebral heights were maintained throughout the follow-up period in both groups (Table 3). Mean increases of anterior and middle height of the fractured vertebral body was 5.14 mm and 4.14 mm in Group A, respectively, and 6.22 mm and 5.06 mm in Group B, respectively,

Table 1
Pre-operative demographic data of patients undergoing single-balloon (Group A) and double-balloon (Group B) bipedicular kyphoplasty

	Group A	Group B	*p* value
Patients (n)	28	40	–
Male: Female	11:17	16:24	–
Age, years (range)	68.0 ± 7.7 (56–81)	69.6 ± 9.4 (55–83)	0.457
Fracture age, days (range)	32.3 ± 14.0 (7–55)	33.2 ± 17.2 (7–60)	0.819
T-score	−3.22 ± 0.48	−3.36 ± 0.55	0.279
Visual Analogue Scale score	8.0 ± 1.7	7.8 ± 1.8	0.514
Kyphotic angle	19.5 ± 5.8°	20.7 ± 4.8°	0.354

Data are presented as mean ± standard deviation unless otherwise indicated.