Balloon Kyphoplasty for Acute Osteoporotic Compression Fractures

T. YANG, S. LIU, X. LV*, Z. WU*

The Hospital Affiliated to Changchun University of Chinese Medicine; Changchun, China

** Beijing Neurosurgical Institute, Beijing Tiantan Hospital, Capital Medical University; Beijing, China*

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Summary

We reviewed the effectiveness of balloon kyphoplasty in the treatment of acute symptomatic vertebral compression fractures.

We assessed radiographic and functional outcome in 11 patients with a 24.3 month follow-up from a retrospectively monitored series of 11 patients who underwent balloon kyphoplasty (BKP). A visual analogue scale (VAS) and the short McGill questionnaire (MPQ) were used to assess average symptoms.

Eleven patients with 19 treated vertebrae completed the study. The VAS showed significant improvement after treatment: the initial score was 9.1 ± 0.6 (mean $\pm$ SD), falling to 2.7 ± 1.07 by 24.3 months ($P < 0.001$). The MPQ also showed a significant improvement ($P < 0.001$) at follow-up. A new fracture was seen in one patient affecting two vertebrae adjacent to the treated level. On CT following the procedure, there was cement leakage in the disc in 9% of cases.

BKP is a minimally invasive procedure that has been shown to be effective in the treatment of acute symptomatic vertebral compression fractures. It appears that BKP is associated with a low incidence of procedure-related complications and cement extravasation.

Introduction

Percutaneous vertebroplasty was described by Deramond et Al in 1987¹. The procedure was used initially to treat aggressive hemangiomas, but it was then extended to the treat-

ment of osteolytic metastases and myeloma and currently osteoporotic compression fractures refractory to medical therapy². With good training and equipment, balloon kyphoplasty is increasingly used in the treatment of painful malignant and osteoporotic fractures and is usually performed via a posterior percutaneous transpedicular approach by use of catheters with inflatable bone tamps placed inside the affected vertebral body³. Our purpose was to assess the effectiveness and safety of BKP using polymethylmethacrylate (PMMA) in patients who agreed at acute phase to test BKP for increased improvement in quality of life.

Materials and Methods

We initiated a retrospective study of 11 consecutive patients with osteoporotic compression fractures between July 2004 and July 2007. Specific inclusion criteria were: 1) painful osteoporotic compression fractures, 2) inability to walk or perform activities of daily living, and 3) pain localized to the fracture level. Patients were excluded if they had: 1) uncorrected coagulopathy, 2) tumor extensions into the epidural space, 3) spinal canal compromise greater than 20%, 4) vertebra plana, 5) back pain longer than one year, and 6) pedicle or pars fracture. We performed percutaneous vertebroplasty on 19 vertebrae. During the study, we analysed the radiographic and functional outcome in 11 patients. The average clinical and radiographic follow-up was 24.3 months (range 19–37 months).

This group comprised three men and eight women. The mean age was 67.3 years (range, 43–83 yrs). Fracture levels included T7–L5. Evaluations were one or more collapsed vertebrae on plain x-rays of the entire spine and CT scan as well as MRI. Three patients had multiple vertebral fractures due to severe osteoporosis. We decided which vertebrae to treat using only MRI data. Clinical and radiological assessment was performed at follow-up. We used a visual analogue scale (VAS) and the short McGill questionnaire (MPQ) to assess each patient's average symptoms. The questionnaire includes: a verbal pain scale (VS) with six levels ranging from zero (no pain) to five (excruciating pain) and a pain descriptor scale (PD) which sums the number of words chosen from a list of adjectives frequently used to describe pain⁴. At each follow-up visit, anteroposterior and lateral radiographs of the spine were obtained to assess the morphology of the vertebrae treated and new vertebral collapse. The outcome assessment and the radiographic evaluation were done by the authors who performed the vertebroplasty. Statistical analysis was performed using SPSS 9.0 software. The Wilcoxon paired test was used to assess any significant difference between baseline and post-vertebroplasty data.

Table 1 Patient clinical data.

Patient No.	Age/sex	Duration (hours)	Levels treated	Follow-up (months)
1.	43/F	30	T7-9, T11-L1	24
2.	50/M	5	L1	24
3.	71/F	24	L2,3,5	19
4.	80/M	26	L1	31
5.	50/M	16	L1	26
6.	71/F	26	L1	21
7.	83/F	5	L1	19
8.	67/F	36	T12	19
9.	68/F	48	L1	37
10.	78/F	8	L1,3	27
11.	79/F	12	L3	20

M, male; F, female; T, thoracic; L, lumbar.

Technique

All procedures were performed in the prone position under local anesthesia with mild sedation. After a 1 cm skin incision was made over the planned site of access under biplane fluoroscopic guidance, a needle (11 or 8-G) was advanced through midportion of the vertebral body. The kyphoplasty balloon was then inserted into the vertebral body under fluoroscopic guidance and was safely inflated. After removal of the balloon, the space progressively filled with high viscosity cement under low pressure (Figures 1 and 2). We usually place one needle. The total amount of PMMA is 1.5 to 5 ml. Because of concern for toxicity associated with PMMA until it has cured⁵, we do not inject more than 20 ml at one session and will therefore only treat three vertebral levels per session. On completion of the procedure, patients were permitted to stand the day after the procedure and were discharged in 24–48 h. Pain related to compression fractures usually markedly decreases in 24 to 72 hours, allowing the tapering of any preprocedure narcotic medications. The patient is instructed not to lift any heavy objects. Patient 1 was treated in two different sessions with a one month interval. X-ray examination and CT scans were obtained immediately after each procedure. Plain x-rays were repeated when each patient returned to the clinic at follow-up. CT scans were evaluated for extravasation of methylmethacrylate outside the confines of the cortical margins of the vertebral body.

Results

From July 2004 to July 2007, 11 patients with 19 treated vertebrae completed the study (Table 1). All fractures were at acute phase and patients had persistent pain of 5–48 hours duration (mean 21 h). All sites of compression undergoing treatment involved thoracic and/or lumbar spine. Five treatments were performed via a bipedicular technique, except at 14 treatment levels in which there was sufficient filling across the midline to obviate the need for contralateral injection. Injection volumes ranged from 1.5 to 5 ml per level. At the six week follow-up most patients remained stable. The mean VAS decreased from a preoperative score of 9.1 to 2.7 ($P < 0.01$) (Table 2). The VAS and MPQ showed significant improvement af-

Figure 1 Patient 5. Lateral radiographs of a patient with vertebral fractures. There are fractures of L1. Cement was injected at L1. When seen 26 months later there was no further collapse of the injected vertebrae.

ter treatment: the average pain VAS and VP measures of pain intensity revealed a significant reduction after the intervention ($P < 0.001$) maintained at 24.3 months (19-37 months). PD showed a significant improvement after treatment.

On radiological examination, no new or further collapse of the injected vertebral bodies was seen during follow-up. The shape of the cement was constant and no fragmentation or mi-

gration was seen. One patient (9%) developed a new fracture at two levels during follow-up, adjacent to the treated vertebra. We treated this patient by further vertebroplasty. The procedure was well tolerated and no major complications were observed. Cement leakage outside (5.3%) occurred in one of the 19 vertebrae treated and the leakage was within the intervertebral disc. No patients had radicular neuritis after the procedure.

Table 2 Outcomes of patients.

	Outcome score (standard deviation)		
	Score at presentation	Score at follow-up (mean)	Pa
Visual analogue scale	9.1 (0.6)	2.7 (1.07)	< 0.001
Verbal pain scale	4.4 (0.7)	0.6 (0.6)	< 0.001
Pain descriptor scale	24.0 (4.5)	2.6 (2.6)	< 0.001
<i>a, paired t-test or Wilcoxon signed rank test compared with baseline</i>

Figure 2 Patient 10. There are fractures of L1 and L3. Anteroposterior (left) and lateral (right) radiographs after treatment. When seen 27 months later there was no further collapse of the injected vertebrae.

Discussion

Compression fractures of the spine are especially common in elderly women as a result of post-menopausal osteoporosis^{6,7}. This is the leading cause of osteoporotic compression fracture in patients undergoing vertebroplasty. Other causes noted have been corticosteroid-induced osteoporosis, secondary osteoporosis (Cushing's disease, hyperthyroidism, hypogonadism) or idiopathic causes. Although the subgroups are small, there seems to be uniform response of each of these groups to treatment with vertebroplasty. Initial treatment includes bed rest, pain management with local and systemic analgesia, bracing to improve comfort, and reassurance⁸. However, 35% of patients may develop persistent severe pain with an im-

paired quality of life which may require narcotics⁹. Previous studies have demonstrated that used in patients with persistent pain, refractory to conservative treatment, vertebroplasty produces significant pain relief^{2,9,10}. The study showed that balloon kyphoplasty provided rapid, marked and sustained (for at least two years) improvements in pain, function and quality of life. A kyphoplasty consists of injection of cement into the fractured vertebral body, creating a cavity. This treatment not only prevents cement leakage, but also avoids the potential complications of migration of the cement¹¹. BKP can be done under general anaesthesia or conscious sedation, either as a day case, or with an overnight stay, depending on medical needs. Although investigators have reported reduced pain and improved function af-

ter kyphoplasty treatment, there are no data from randomized trials assessing its efficacy and safety¹².

Vertebral fractures change the biomechanics of the spine, which might increase the risk of additional vertebral fractures. The effect of kyphoplasty treatment on this risk has been unclear. A non-randomised study reported fewer subsequent fractures after kyphoplasty than non-surgical care, whereas other uncontrolled studies have suggested that kyphoplasty might heighten the risk¹³. However, a recently published concurrently controlled study comparing balloon kyphoplasty with nonoperative care found that balloon kyphoplasty significantly reduced the number of subjects with incident (subsequent) fractures at six months compared to a matched cohort managed nonoperatively; a second similar study showed the same trend¹². In our study, 9% of patients developed new fractures adjacent to the treated vertebra in a two year period. The incidences of asymptomatic and symptomatic cement leakage are significantly higher with VP than with KP (75% vs. 14%, $P < 0.05$)^{7,13,14}. When examining prospective-only studies, this difference continued to be statistically significant (56.2% vs. 13.6%, $P < 0.001$)³. Although the difference between the incidences of symptomatic leakage per patient was not statistically significant, the difference in the ratios of symptomatic leaks per levels treated was statistically significant ($P > 0.05$)¹⁶. There were two serious adverse events related to kyphoplasty treatment (hematoma and urinary tract infection)^{3,4}. To date, we have not experienced post-procedural complications in our series, although such complications have been reported.

Vertebroplasty (VP), an alternative treatment for vertebral fractures, involves the injection of less viscous cement into the fractured vertebra^{5,15-17}. BKP, on the other hand, involves the inflation of a balloon to restore vertebral height followed by the injection of more viscous cement under lower pressure. Percutaneous kyphoplasty has several benefits over vertebroplasty including a decreased risk of cement leakage. Compared to a rate of up to 65% with vertebroplasty, kyphoplasty has an extravasation rate of less than 10%, theoretically leading to fewer complications than vertebro-

plasty^{7,18}. The majority of complications from vertebral augmentation arise from extravasation of cement and consequently any technique that decreases this event would be beneficial^{19,20}. The choice of kyphoplasty over vertebroplasty in this series was largely based upon a decreased extravasation rate with kyphoplasty. Therefore, the added benefit is potentially restoring vertebral height when compared to vertebroplasty. The number of patients in our study is too small to draw any statistical conclusions, and although we were unable to show a major increase in the risk of new vertebral fractures, further studies are necessary. Additional studies are needed to evaluate the potential benefits of balloon kyphoplasty on these outcomes.

In contrast, the negative consequences of bed rest on elderly patients, including rapid deconditioning and further bone loss, are well documented⁴. Patients with fracture-related spinal deformities have impaired pulmonary function, digestive disturbances, diminished physical performance, altered gait and balance, clinical depression, and excess mortality. The safety and immediate benefits of balloon kyphoplasty shown in this study are consistent with those reported in previous studies, indicating that balloon kyphoplasty should be considered for pain relief, functional improvement, and/or anatomic alignment restoration for all older patients diagnosed with a painful compression fractures.

Conclusions

BKP has been demonstrated to provide osseous stability and pain relief in association with osteoporotic compression fractures. Most patients experience rapid relief of pain within three days, and relief is long-term. The results of the treatment seem to be durable with the primary concern being that of adjacent vertebral body injury, especially in view of the increased mobility of the patients after treatment.

There is even greater promise in the future to be able to restore vertebral body height to precompression values. Balloon kyphoplasty is an effective and safe procedure for patients with acute vertebral fractures.

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Xianli Lv, MD
 Beijing Neurosurgical Institute
 No. 6, Tiantan Xili
 Beijing, 100050
 P.R.China
 BE-mail: lvxianli000@163.com