

Impact of Kyphoplasty Treatment for Vertebral Compression Fractures on Pain and Function in 105 Patients

Vliv léčby kyfoplastikou na bolest a funkci u kompresních zlomenin páteře u 105 pacientů

Z. KLEZL^{1,2}, J. A. *CLAMP¹, J. BECKER³, M. JONES¹, D. CALTHORPE¹, R. BOMMIREDDY¹

¹ Royal Derby Hospital, NHS Foundation Trust, Derby, United Kingdom

² Ortopedická klinika 3. LF UK, Praha 10, Vinohrady, Czech Republic,

³ Charing Cross Hospital, Imperial College NHS Trust, London, United Kingdom

ABSTRACT

PURPOSE OF THE STUDY

Vertebral compression fractures are very common. Symptomatic relief with conservative therapy is often difficult to achieve. Balloon kyphoplasty is a relatively new technique which stabilises the vertebral body and restores spinal alignment in recent fractures, it achieves significant pain relief and improved functional outcome is reported.

The aim of this prospective study was to determine the level of pain relief and functional outcome in patients who were initially treated conservatively for 4-6 weeks and if symptoms did not have tendency to resolve, then had kyphoplasty surgery.

MATERIAL AND METHODS

105 patients underwent balloon kyphoplasty between April 2006 and August 2010 and had 1 year follow up. Total 170 levels were augmented, 65% (n=68) of patients were female and the average age was 74 years. Pain relief was assessed using visual analogue score (VAS) and functional outcome using Oswestry Disability Index (ODI).

RESULTS

Results showed decrease of the average pre-operative VAS from 8.2 to 4.4 in the immediate postoperative period ($p=0.000$). This dramatic improvement remained and was 4.1 at 6 weeks, 3.3 at 6 months and 3.6 at 1 year. The average pre-operative ODI was 58. This improved to 47 in the immediate post-operative period ($p=0.002$). At 6 weeks this had improved further to 40 and further improvements were seen at 6 months (ODI 37) and 1 year (ODI 38). The average screening time was 2 minutes and 20 seconds. The average volume of cement used per level was 5.5cm³. Radiographic measurements were performed by independent radiologist. The average pre-operative vertebral angle was 11.6° and 10.9° post-operatively. This was maintained throughout the follow up. This represented a negligible 6% improvement in vertebral body angle. We did not experience any clinically significant complications, we have encountered 11 minor complications which did not require any additional measures (cement leaks, penetration of the vertebral body margins by balloons or K wires and rib fractures).

DISCUSSION

Pain relief and improvement of functional outcome was sustained after one year. Limited number of patients who had 2 year follow up showed trend of minimal deterioration of both parameters (VAS and ODI). This can be explained by incidence of few adjacent segment fractures and progressive overall osteoarthritic changes in this aging population. Radiological evaluation showed maintenance of achieved alignment which did not deteriorate over time. Complication rate was low and did not require any further surgical interventions and did not have any effect on final good clinical outcome.

CONCLUSION

Balloon kyphoplasty proved to be safe surgical technique and should be considered in patients with ongoing pain following an acute vertebral compression fracture that does not improve with initial conservative treatment. It significantly improves pain and functional status in elderly patients.

Key words: cement augmentation, osteoporotic fracture, kyphoplasty.

INTRODUCTION

Low energy vertebral compression fractures are common and are principally due to osteoporosis. In the United States 250,000 are diagnosed annually and 80% are caused by osteoporosis (3). They can occur secondary to other pathological processes that reduce bone density or disturb bone architecture such as myeloma or bone metastasis (4). An ageing population has contributed to an increased prevalence. Reports suggest 25%-33% of women and 1 in 8 men over the age of 50 have osteoporosis (3, 4).

40% of vertebral compression fractures are clinically insignificant when they occur (4). They may be apparent as progressive kyphosis. Patients who seek medical treatment usually present with more or less intensive pain. This is often sufficient to impact on quality of life and performance of activities of daily living. A reduction in functional level, the concept of social drift, may result.

Pain relief to allow function is often difficult to achieve with conventional analgesia. Bracing is poorly tolerated and has potential problems e.g. pressure sores. Open reconstructive surgery, with significant morbidity, is often inappropriate in a frail group of patients with significant co-morbidity and poor bone quality.

Balloon kyphoplasty using percutaneous instrumentation, first performed in 1998, creates a cavity in the vertebral body using an inflatable bone tamp, which may restore vertebral height in recent fractures. Vertebral body height is maintained by bone cement and can afford significant pain relief (4). The concept, although not fully understood, is based principally on restored stability and normalising biomechanics but chemical and thermal theories have also been postulated (8).

MATERIALS AND METHODS

All patients receiving balloon kyphoplasty treatment at our hospital from April 2006 to August 2010 were entered prospectively onto a database. Visual Analogue Score (VAS) for pain and Oswestry Disability Index (ODI) for function were recorded pre-operatively, immediately post-operatively, at 6 weeks, 6 months, 1 and 2 years. Technical data including number of levels, cement volume, screening time and vertebral angle correction was recorded. The procedures were carried out by 2 consultant spinal surgeons (ZK, RB).

No attempt was made to accumulate missing data in order that the series remains prospective.

Kyphoplasty was performed using prone positioning on a Montreal mattress. General anaesthesia was used most commonly. Local anaesthesia and sedation was used if general anaesthesia was considered inappropriate by the anaesthesiologist. Bi-planar imaging was used routinely in all the cases. Kyphon instrumentation and bi-pedicular (T8-S1) and bi-extrapedicular or uni-extrapedicular approach was used (T5-T8).

In case of posterior wall involvement, egg shell technique was utilized. In these cases, cavity was created by inflating of the balloon, which was then deflated and

removed and the cavity was filled with less viscous cement. Balloons were reinserted and reinflated expressing the liquid cement around the cavity walls. This "barrier" then contained the main bulk of highly viscous cement, which was injected into the vertebral body. Fig. 1. Patients were routinely mobilised on the first post-operative day and discharged when comfortable. Radiographs of the operated area were taken routinely.

Patients were only considered for intervention if they had significant pain for at least 4–6 weeks not responding to conventional treatment with analgesia or physiotherapy. Fitness for surgery was decided by the anaesthesiologist. Evidence of recent fracture was required either with MRI scans demonstrating high marrow signal on T2 weighted or STIR sequences and low signal on T1 weighted images or comparison of new radiographs demonstrating a fracture with recent radiographs not demonstrating a fracture (Fig. 2. Fig. 3. Fig. 4).

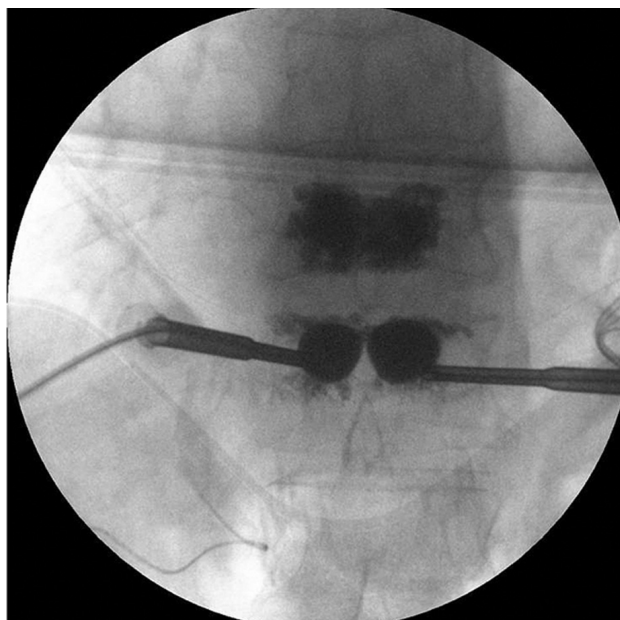


Fig. 1. Balloons were inserted into the vertebral body, expanded with contrast, deflated and removed. 1,5 cc of fairly liquid cement was injected and balloons were re-inserted into the vertebral body and re-inflated expressing the cement outside in controlled way.

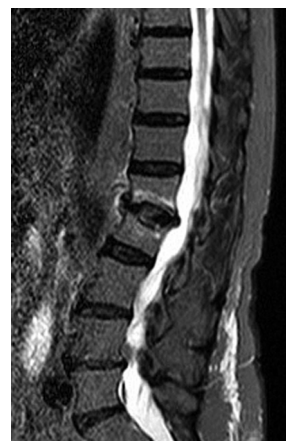


Fig. 2. MRI STIR sequence film demonstrating recent osteoporotic fractures of L1 and L2.

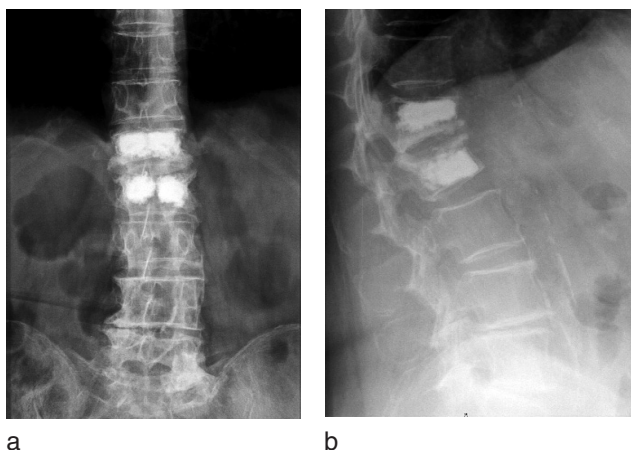


Fig. 3a and 3b. Follow up AP (a) and lateral (b) views showing good symmetrical fill of the vertebrae with bone cement.

RESULTS

198 patients underwent balloon kyphoplasty between April 2006 and August 2010. Some data was incomplete. 105 patients had sufficient data for meaningful analysis. 170 levels were operated on in 105 patients. 65% (n=68) of patients were female and the average age was 74 years.

Table 1 shows that most cases involved either a single level or 2 levels were augmented. No more than 4 levels were instrumented at any one procedure. Most procedures were concentrated around the thoraco-lumbar junction. Table 2 shows the distribution of levels instrumented.

Tab. 1. Frequency with which different numbers of levels was augmented

Number of levels augmented	Frequency
1	58
2	33
3	11
4	3

Tab. 2. Frequency with which each level was augmented

Vertebral Level	Frequency
T5	3
T6	3
T7	7
T8	9
T9	11
T10	7
T11	23
T12	32
L1	34
L2	13
L3	14
L4	8
L5	4
Sacrum	2

The average screening time was 2 minute and 20 seconds. The average volume of cement used per level was 5.5cm³.

The average pre-operative visual analogue score (VAS) was 8.2. This decreased to 4.4 in the immediate postoperative period (p=0.000). This dramatic improvement remained and was 4.1 at 6 weeks, 3.3 at 6 months and 3.6 at 1 year. Only 18 patients had data recorded at the 2 year stage with slight worsening value of 3.8. The average first recorded post-operative VAS was 4.2 (p=0.000). Table 3 below details at what point the first VAS was recorded in each patient.

The average pre-operative Oswestry disability index (ODI) was 58. This improved to 47 in the immediate post-operative period (p=0.002). At 6 weeks this had improved further to 40 and further improvements were seen at 6 months (ODI 37) and 1 year (ODI 38). 16 patients who had data recorded at 2 years follow up reached ODI of 40. The average first recorded post-operative ODI was 44 (p=0.000). Table 4 below details at what point the first ODI was recorded in each patient.

Radiographic measurements were performed by independent radiologist.

Tab. 3. Time point at which first VAS was recorded

	Pre-op	Post-op	6/52	6/12	1 year
VAS	n=105	n=75	n=14	n=14	n= 68

Tab. 4. Time point at which first ODI was recorded

	Pre-op	Post-op	6/52	6/12	1 year
ODI	n=90	n= 71	n=13	n=15	n= 67

The average pre-operative vertebral angle (Figure 4) was 11.6°. The average post-operative vertebral angle was 10.9° and was maintained throughout the follow up. This represents a negligible 6% improvement in vertebral body angle.

Complications were infrequent. Cement leakage occurred in three patients. In two patients the anterior cortex was breached, lateral wall breach was seen in 1 patient and in a further patient the end plate was breached. No clinical consequences were subsequently

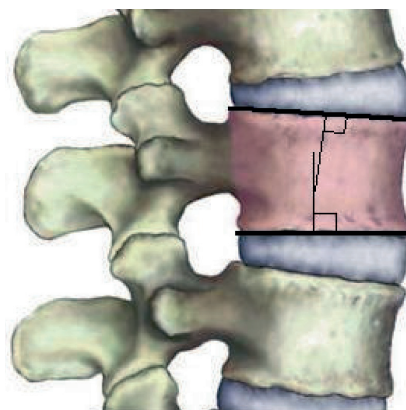


Fig. 4. Method used to measure vertebral angle.

identified. In two patients the anterior wall was breached with the K-wire but no complications occurred. In 6 patients there was collapse at other levels. In 3 of these patients the collapse was at the adjacent level. In 1 patient there was subsequent further collapse of the instrumented level. There was a technical problem in a single patient when two balloons burst with no consequences. 1 superficial infection resolved with antibiotic therapy. Two patients had rib fractures during transfer from supine to prone position.

DISCUSSION

Patients in this study had an almost 50% reduction in pain scores immediately post-operatively with VAS decreasing from 8.2 to 4.4. The average first postoperative score was 4.2. This demonstrates the rapid and effective pain relieving effect of vertebral body stabilisation. The VAS remained below 4 at the 1 year stage (3.3 at 6 months, 3.6 at 1 year) confirming the sustained benefit of balloon kyphoplasty. Insufficient data at 2 year follow up is available for useful interpretation, although the trend is of slight deterioration. It is possible that deterioration may occur from osteoporotic collapse of other vertebral bodies as it is well documented that frequency of this increases with increasing age. This improvement is similar to other published series (1, 4, 11). A systematic review suggests 92% of patients receiving balloon kyphoplasty treatment will experience some pain relief (2). A recent randomised controlled multicentre trial showed that kyphoplasty improved quality of life, function, mobility and pain faster than non-operative treatment at 1 month but the difference was not evident at 1 year due to the continual steady improvement in the non-operated group (12).

At 6 weeks post-operatively an almost 20 point improvement in ODI was observed. This demonstrates a significant increased functional ability. This improvement was sustained at 1 year. The ODI recorded on day 1 post-operatively only showed a 10 point improvement. In order to demonstrate the improved level of function the patient must be active and thus a marked improvement immediately post-operatively is unlikely to be observed.

Published evidence suggests the mortality rate doubles in patients who suffer a vertebral compression fracture. A review of 97,142 patient records showed that only 10% of these patients survived beyond 7 years following their first documented vertebral compression fracture. Improved pain relief and function in treated patients may reduce this alarming statistic (3).

Average cement volume injected was 5.5cm³. Cadaveric studies suggest 3.5cm³ of cement is required to restore near normal stress distributions to fractured and adjacent vertebral bodies (7). Reports have suggested percentage fill correlates poorly with mechanical strength (8). Experimental data suggests overfilling may cause uneven load distribution and be less biomechanically favourable (6).

In our patients the improvement in vertebral body angle of 6% (average 0.7°) was negligible. There was the-

refore no significant improvement in sagittal alignment and this does not explain the marked improvement in pain level. Previous studies have demonstrated between 40% and 70% improvement in vertebral body height and 50%–60% reduction in kyphosis (4). Studies have suggested that as little as 3.5cm³ is required to restore normal stresses across end plates of the stabilised vertebral body (7) and following compression of the cancellous bone with an inflatable bone tamp this volume is unlikely to yield significant improvements in kyphosis correction. Our study therefore suggests restoration of sagittal profile is not the principle explanation for improved pain.

Radiation exposure is a growing concern in current spinal surgery with rising number of minimally invasive or percutaneous procedures. Our fluoroscopy intra-operative time was 2 minutes and 20 seconds which was a result of bi-planar setup in the operating room and sequential (non-continuous) screening during cement injection. Mroz et al reported 5.7 minutes (+/- 2) for single level, 3.8 minutes (+/-0.8) for two levels and 2.9 minutes (+/-1.2). They set occupation hazard at 300 procedures per year and stressed the importance of wearing appropriate protective gear (thyroid shields, lead lined glasses, aprons) and keeping hands out of the radiation beam. (9)

The complication rate was minimal. Cement leakage is a recognised problem. Severe sequelae have been reported in the literature and symptomatic cement leakage occurs in 0.04% (5). Neurological compromise is the usual consequence of cement leakage into the spinal canal, cement pulmonary emboli are also reported (10, 11). Asymptomatic cement leakage only occurred in 3% of our patients. Reports have suggested similar findings with minor cement leakage without complications in up to 14% (1, 4, 5). No neurological complications were identified in our study. Although asymptomatic cement leakage is considered by some to be insignificant if leakage is through the end plate this may predispose to adjacent level collapse (5). In one patient further collapse at the augmented level was identified. This patient had excellent improvement in VAS from 8 re-operatively to 0 at 6 months which was maintained at 12 months.

Further collapse at adjacent levels occurred in 6 patients. This may well have been a consequence of the disease process. It has been suggested that kyphoplasty increases the risk of adjacent level collapse. A meta-analysis of complications reported a 17% risk of further fracture and 75% of these were at adjacent levels (5). A systematic review has suggested that further osteoporotic collapse is more frequent in patients following kyphoplasty but is similar to that expected in patients with osteoporosis and a previously documented fracture (2).

In one patient bleeding occurred during access to the vertebral body. The procedure was completed unilaterally and a bone wax plug was inserted on the side where bleeding was identified. No hemodynamic compromise occurred and an immediate CT scan identified

a small haematoma adjacent to the right hemiazygous vein. The patient had no ill effects and was discharged home on the second postoperative day.

Conservatively treated vertebral compression fractures incur large healthcare costs (4). Kyphoplasty treatment requires costly instrumentation. It is likely the treatment is cost-effective as patients should remain at a higher functional level requiring less social support. This requires further analysis.

Data collection for this study did not involve any research or specifically dedicated personnel. Consequently a significant number of patients did not receive direction in outpatient department to complete outcome measure forms and thus had to be discounted. Although this loss to follow-up potentially creates bias it is reasonable to assume that considering these patients had sought attention for pain initially they would have re-presented if they were still symptomatic.

CONCLUSION

This prospective study confirms that balloon kyphoplasty affords excellent pain relief and improves function in patients with vertebral compression fractures. Complication rates are small. Balloon kyphoplasty should be considered for all patients with vertebral compression fractures that fail to respond to an initial period of conservative treatment.

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Corresponding author:

Mr. Zdenek Klezl, Ph.D.
Consultant orthopaedic and Spinal Surgeon
Royal Derby Hospital
Uttoxeter road
Derby, DE22 3NE, United Kingdom
E-mail: zklezl@aospine.org