Social implications of balloon kyphoplasty: prospective study from a single UK centre

Zdenek Klezl · Navjot Bhangoo ·
Jonathan Phillips · Girish Swamy ·
Denis Calthorpe · Rajendra Bommireddy

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Abstract

Purpose The incidence of osteoporotic fractures is increasing with an ageing population. This has potential consequences for health services, patients and their families. Treatment of osteoporotic vertebral compression fractures (OVCFs) has been limited to non-surgical measures so far. The social and functional consequences of balloon kyphoplasty, a recent development for the treatment of VCF, were assessed in this cohort study.

Methods Data collected prospectively from 53 patients undergoing balloon kyphoplasty for symptomatic OVCF in our hospital's spinal unit were compared with data from an historical age-matched group of 51 consecutive patients treated conservatively for symptomatic OVCF. Social functionality was recorded prior to the injury, and at 6-month and 1-year follow-up; mortality was recorded at 6 months and 1 year.

Results The mortality rate in the balloon kyphoplasty group was 11 % (6/53) at 1 year post-OVCF, versus 22 % (11/51) in the conservatively treated controls. A drift to a lower level of social functionality (defined by a lower level of independence) was observed at 1 year in 21 % of patients in the balloon kyphoplasty group versus 53 % of patients in the conservatively treated group. A drift to a

lower level of independence was noted in 67 % of the conservatively treated patients who started at a lower level of functionality versus 20 % drift in a similar group who were treated with balloon kyphoplasty.

Conclusions The reduction in mortality and drift in social functionality at 1 year following treatment with balloon kyphoplasty suggests that it is a viable option for the management of OVCFs.

Keywords Balloon kyphoplasty · Osteoporosis · Social function · Vertebral compression fractures

Introduction and objectives

With an ageing population, the incidence of osteoporosis is predicted to increase, along with its consequent impact on quality of life [1]. Vertebral fractures are common in patients with osteoporosis [2]. Constant pain, and thus interference with normal day-to-day activities, is experienced by about 40 % of patients following a vertebral fracture [3]. The treatment of osteoporotic compression fractures has in the past been limited to non-surgical modes of management, i.e. analgesia and bracing, but the outcomes associated with these management strategies are often less than satisfactory [4]. Recent advances have enabled techniques to be developed to treat these fractures, i.e. vertebroplasty and balloon kyphoplasty.

Studies generally suggest that vertebroplasty provides some relief from pain in patients with osteoporotic vertebral compression fractures (OVCFs) [5–10]. However, two recent randomized controlled studies unexpectedly failed to demonstrate a beneficial effect of vertebroplasty compared with a sham procedure in patients with painful OVCFs [11, 12]. A critical analysis of the studies indicated

Z. Klezl (✉) · N. Bhangoo · J. Phillips · G. Swamy ·
D. Calthorpe · R. Bommireddy
Department of Trauma and Orthopaedics, Spinal Unit,
Royal Derby Hospital, Uttoxeter Road,
Derby DE22 3NE, UK
e-mail: zklezl@aospine.org

Z. Klezl
3rd Medical School, Charles' University,
Srobarova 50, 100 34 Prague, Czech Republic

that some of the patients treated with vertebroplasty may not have received a sufficient volume of cement in at least one of the studies, rendering the treatment ineffective [11, 13]. The author of the analysis concluded that the studies did not conclusively prove or disprove the efficacy of vertebroplasty [13].

Balloon kyphoplasty is a relatively new procedure (developed in 1998 by ‘Kyphon Inc.’) that can be used to treat OVCFs. It was developed to address pain related to vertebral body collapse. Indeed, the pain-relieving benefits of balloon kyphoplasty have consistently been demonstrated in previous studies [5–9, 14–16]. The data from these studies were supported by a recent randomized controlled trial comparing balloon kyphoplasty with non-surgical care [17].

While balloon kyphoplasty provides relief from pain in patients with OVCF, very little data exist detailing the consequences of balloon kyphoplasty on social function. The aim of this study was to determine the social and functional consequences of balloon kyphoplasty in patients who have sustained OVCFs.

Methods

Design

In this cohort study, the data were collected prospectively from 63 patients undergoing balloon kyphoplasty for symptomatic OVCFs in our hospital’s spinal unit between October 2006 and October 2008. The case control group was an age-matched group of 55 consecutive patients who were admitted to our institution and treated conservatively for symptomatic OVCFs (primary diagnosis) prior to 2006.

Setting

The study was conducted in the spinal unit at a regional teaching hospital.

Ethics approval and patient consent

All patients who underwent balloon kyphoplasty were routinely followed up in clinic to assess their progress. This was an observational study on patients undergoing a routine surgical procedure with no additional intervention. The acquisition of study data did not interfere with clinical practice. Monitoring (completion of questionnaires) occurred during routine follow-up post-surgical clinics; therefore, it was deemed that formal ethical approval was not required for the study. All patients signed a consent form for the intervention.

Participants

All 63 patients with symptomatic OVCFs in the prospective cohort were assessed clinically and patients found suitable for kyphoplasty underwent magnetic resonance imaging (MRI) as part of pre-operative planning in assessing the oedema and adjacent segment occult fractures. Only those who had clear evidence of OVCFs on plain radiographs, when compared with previous radiographs, did not undergo MRI. Recent symptomatic fractures (radiologically active) were treated with balloon kyphoplasty. Kyphoplasty patients included inpatient admissions from other wards, outpatient referrals and emergency admissions for failure to cope or worsening pain and further collapse. All patients were routinely pre-assessed to ensure that any pre-existing medical disorders were identified. Data regarding their social mobility preceding and following their fracture were acquired.

These results were compared with data from a consecutive age-matched group of 55 patients who were admitted to our institution with a primary diagnosis of symptomatic OVCFs, and treated conservatively prior to 2006. All patients in the control group had severe pain and disability (which led to hospitalization for pain control and gentle physiotherapy). Patients with major trauma (traffic accidents, metastatic tumours or infection) were excluded.

Intervention: surgical procedure

Patients were given either a general or local anaesthesia, as decided by the anaesthetist, based on the medical fitness of the patient. All patients were placed in the prone position on a radiolucent table with appropriately placed padding to prevent the compression of abdominal contents and allow for thoracic expansion.

Bi-planar radiographic imaging was acquired by the placement of two image intensifiers perpendicular to each other. Anterior–posterior and lateral views of the vertebral bodies were deemed acceptable if the end plates of the vertebral body were parallel and the spinous process centred between the pedicles on the anterior–posterior image.

A standard protocol for the balloon kyphoplasty procedure was followed according to the manufacturer’s instructions. After routine skin preparation and draping, stab incisions at the appropriate vertebral levels were performed, and a Jamshidi® (CareFusion, San Diego, CA, USA) bone needle was inserted in such a manner as to allow access to the vertebral body on either side. Using the ‘Seldinger’ technique, the tract for the balloon was made using a blunt Kirschner wire and osseous introducers. The balloons were inserted and expanded under manometric control. With the aid of a contrast medium within the balloon the volume inserted indicated the approximate

amount of cement required. High-viscosity bone cement was inserted into the pre-formed cavity following removal of the balloon tamp. KyphX HV-R (high-viscosity radiopaque) bone cement was used in all cases (Medtronic, Inc., Minneapolis, MN, USA). Cement leakage was minimized by close observation under radiographic control during cement insertion. Blood pressure was closely monitored intra-operatively during cement injection, as was any cement leakage outside the vertebral body (into the spinal canal or surrounding tissues and vessels). Once completed, the instruments were removed and final images were taken. The stab incisions were closed in a routine manner. Post-operatively, all patients were asked to mobilize as pain allowed. Patients were discharged either on the same day or the following day.

Outcome measures

All patients treated surgically completed a questionnaire at pre-intervention, 6-week follow-up, and at 6-month and 1-year intervals. Questions were asked pertaining to their degree of mobility, accommodation and use of carers. Pain was reported on a visual analogue scale (where 0 = no pain and 10 = maximal pain). Disability was assessed using the Oswestry Disability Index, Version 2.0 [18], and anxiety and depression, using the Hospital Anxiety and Depression Scale questionnaire [19].

Patients were classified into six main groups according to their level of social functioning at the time immediately prior to their fracture and at subsequent follow-ups. Social functionality was graded as follows:

1. Fully mobile and independent (able to complete full activities of daily living [ADLs] in own home)
2. Own home with carers
3. Warden-controlled accommodation
4. Residential accommodation
5. Nursing home resident
6. Hospitalized.

Hospital notes were retrieved for patients in the age-matched control group and were analysed for the parameters above (these parameters were recorded in the notes in a standardized way). Data were available for pre-intervention and 1 year post-injury and were used to classify patients into the six social functioning groups above.

Statistical analysis

The number and percentage of patients who experienced social drift (including those who died) within a year of inclusion in the study were calculated within each group; exact 95 % confidence intervals using the Blyth–Still–Casella method were derived [20–22]. The number and

percentage of patients who died within a year of inclusion in the study were analysed in the same way. Further, an unpaired Student's *t* test was used for continuous data and a two-tailed Fisher's exact test for categorical variables. A *p* value of <0.05 was considered to be statistically significant.

Results

Surgically managed patients: balloon kyphoplasty

A total of 63 patients underwent balloon kyphoplasty for symptomatic OVCF between October 2006 and October 2008. The average age of the patients was 76 years (range 55–91 years) and most patients were females (*n* = 45). In total, 105 vertebral levels were operated upon, such that balloon kyphoplasty was performed on more than one level in some patients at any one time. No decrease in blood pressure was recorded during the procedure. Minor leakage of cement was observed outside of the vertebral body on three occasions, but had no clinical consequences.

Ten patients were excluded from the study: nine (14 %) were lost to follow-up, and one patient withdrew consent. Social mobility analysis with full data was performed for the 53 patients. Of the 53 patients, 43 (81 %) lived in their own homes prior to the fracture and were able to perform their ADL independently, six lived in their own home with carers and four lived in warden-controlled accommodation. The social drift of these patients 1 year after injury is summarized in Fig. 1.

Of the 53 surgically treated patients, 11 (20.75 %; 95 % CI: 11.59–33.30) experienced a drift to a lower status 1 year after surgery (Table 1), including six patients (11.32 %; 95 % CI: 5.05–22.31) who died during the course of the study. Nine patients who experienced a drift to a lower status were fully mobile and independent prior to the injury and lived in their own home. The other 34 (79 %) patients, who lived in their own homes prior to the fracture and were able to perform their ADL independently, maintained their social functioning at 1 year. Two of the six patients who lived in their own home with carers prior to the injury died during the study; the other four patients continued to live in the same accommodation post-balloon kyphoplasty. Patients who lived at a lower level of social functioning prior to their injury did not demonstrate any drift at 1 year following balloon kyphoplasty: the four patients who lived pre-morbidly in warden-controlled accommodation returned to their accommodation post-surgery.

Conservatively managed patients

A total of 55 consecutive patients who were seen in Emergency department and admitted for conservative

Fig. 1 Social drift occurred in 21 % patients who were treated using balloon kyphoplasty for symptomatic vertebral compression fractures. The analysis was performed on 53 patients for whom full data were available

Table 1 Summary of the social drift of patients who underwent balloon kyphoplasty for their spinal fracture

Pre-morbid social functioning	1-year follow-up	Number of patients
Fully mobile and independent, own home	Fully mobile and independent, own home	34
	Own home with carers	4
	Warden-controlled accommodation	0
	Residential home	1
	Nursing home	0
	Hospitalized	0
	Deceased	4
Own home with carers	Own home with carers	4
	Warden-controlled accommodation	0
	Residential home	0
	Nursing home	0
	Hospitalized	0
	Deceased	2
Warden-controlled accommodation	Warden-controlled accommodation	4
	Residential home	0
	Nursing home	0
	Hospitalized	0
	Deceased	0
Nursing home	Nursing home	0
	Deceased	0

The analysis was performed on the 53 patients for whom full data were available, including patients who died during the course of the study

treatment, from a total of 91 symptomatic OVCFs prior to 2006, were identified as being suitable for comparison. The average age of the patients was 80 years (range 53–90), with women, as expected, presenting as the dominant gender (46 female).

Four patients (7 %) were lost to follow-up and thus were not included in the analysis. The social function of 51 patients was analysed. Of the 51 patients, 36 (71 %) lived in their own home and were able to perform full ADL prior to the fracture, five lived in their own home with carers, six lived in warden-controlled accommodation, one needed

care in a nursing home, two lived in a residential home and one was hospitalized. The social drift of this conservatively managed group is summarized in Fig. 2.

Of the 51 conservatively managed patients, 27 (52.9 %; 95 % CI: 38.46–67.07) experienced a drift to a lower status 1 year post-OVCF (Table 2), including 11 (21.6 %; 95 % CI: 12.08–34.75) patients who died within 1 year of their fracture. The group of 36 patients who were fully mobile and independent prior to the OVCF showed a 52.8 % drift, with 10 patients requiring increased social input following their fracture and 7 patients not surviving; 19 patients were

Fig. 2 Social drift occurred in 53 % of patients with osteoporotic vertebral compression fractures that were treated non-surgically. The analysis was performed on the 51 patients for whom full data were available

able to maintain their social function at 1 year. The 15 patients with lower social function (pre-morbid social input required) demonstrated a 66.7 % drift 1 year post-OVCF, with six patients requiring increased social input following their fracture and four patients not surviving. Two of the five patients who lived in their own accommodation with the help of carers prior to their injury continued to live in the same accommodation, whereas two required care in a nursing home; one patient died. Of the six patients that lived in warden-controlled accommodation pre-morbidly, two continued to live in the same accommodation with the same social input, one required a residential home and three needed care in nursing homes. The two patients in residential homes and one hospitalized patient died during the study.

Comparative analysis between groups

There was no statistically significant difference between the two groups with relation to age ($p = 1.00$), initial place of residence pre fracture ($p = 0.064$), ambulatory and ADL status before fractures ($p = 0.26$).

94.3 % of kyphoplasty patients were fully ambulating either independently or with aid by 1 week and were discharged to destination mandating independent ADLs as compared with only 56.5 % in the control group who were ambulating at 1 week post OVCF ($p = 0.01$).

Four patients in the kyphoplasty group had subsequent OVCF in adjacent levels and three patients in the control group had similar adjacent level OVCF's. There was no statistically significant difference between the groups comparing the frequency and the number of levels involved ($p = 0.39$).

A statistically significant number of patients died within 3 months in the control group compared with the kyphoplasty group (Fig. 3). The cause of death was one or

more of the following: Left ventricular failure with pulmonary oedema, chest infection and urinary sepsis with renal failure in all patients.

Discussion

While the literature suggests that balloon kyphoplasty reduces pain related to OVCF, few studies have demonstrated its effect on social status [17]. In a multicentre randomized controlled study, Wardlaw and co-workers showed that balloon kyphoplasty improved patients' quality of life and reduced disability compared with non-surgical management. However, their study did not investigate the social status of the two groups [17]. Our results regarding social function are in keeping with previous studies, which included functional outcomes following balloon kyphoplasty [23, 24]. VCFs not only have patient-specific effects in terms of morbidity and mortality (Lau and co-workers quoted the mortality at 3 years at 46 % [25]), but are also a financial burden on society.

In our study, the mortality at 1 year in the conservative group was 22 %, compared with 11 % in the surgically treated group. This may indicate that maintenance of a higher functional status is an important factor influencing survival in these elderly patients. The study has demonstrated that the functional drift of patients who underwent balloon kyphoplasty was lower when compared with those treated non-operatively. Moreover, drift was demonstrated in only two patients (20 %) who were surgically managed and required some form of help pre-morbidly; in contrast, 11 out of the 15 (73 %) patients with a lower social status prior to injury drifted to require more social intervention in the conservatively managed group. In the opinion of the authors, it is the treatment of pain that does most to ensure an early return to function. A study by Ledlie and

Table 2 Summary of the social drift of patients whose spinal fracture was treated conservatively

Pre-morbid social functioning	1-year follow-up	Number of patients
Fully mobile and independent, own home	Fully mobile and independent, own home	19
	Own home with carers	2
	Warden-controlled accommodation	2
	Residential home	2
	Nursing home	1
	Hospitalized	3
	Deceased	7
Own home with carers	Own home with carers	2
	Warden-controlled accommodation	0
	Residential home	0
	Nursing home	2
	Hospitalized	0
	Deceased	1
	Deceased	1
Warden-controlled accommodation	Warden-controlled accommodation	2
	Residential home	1
	Nursing home	3
	Hospitalized	0
Residential home	Residential home	0
	Nursing home	0
	Hospitalized	0
	Deceased	2
Nursing home	Nursing home	1
	Hospitalized	0
	Deceased	0
Hospitalized	Hospitalized	0
	Deceased	1

The analysis was performed on the 51 patients for whom full data were available, including those who died during the course of the study

co-workers had already demonstrated that full ambulation could be achieved at 1 week in 85 % of cases; complete pain relief was achieved in 86 % of cases at 3–6 months post-surgery [26]. In our study, 94 % of surgical patients had achieved full ambulation post-operatively within 1 week.

The main limitation of this study is that comparison was made between a group who were treated prospectively with surgery and an historical cohort of conservatively treated patients, albeit at the same institute. Selection and procedural bias were reduced in the surgical group, as only a single surgeon performed the balloon kyphoplasty. To minimize confounding factors, surgical indications,

Fig. 3 A statistically significant number of patients died within 3 months in the control group as compared with the deaths in the kyphoplasty group within 1 year ($p < 0.04$)

procedural follow-up criteria and standard data collection procedures were strictly adhered to.

Conclusion

In this prospective independent analysis comparing the outcomes of patients who have undergone balloon kyphoplasty at a single centre with the outcomes of patients treated conservatively at the same institution, the principal findings suggest that balloon kyphoplasty is a viable means of managing symptomatic osteoporotic vertebral fractures and reducing the social drift that may occur following OVCF. The results also suggest that balloon kyphoplasty may contribute to reduced mortality compared with conservative management.

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