

RESULTS OF TREATMENT OF PAINFUL VERTEBRAL FRACTURES BY KYPHOPLASTY OR ORTHOSIS: A PROSPECTIVE NONRANDOMIZED CONTROLLED STUDY

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Abstract

This study analyzed the results of treatment of painful vertebral fractures in patients with primary osteoporosis with balloon kyphoplasty compared with conventional management. Half of the patients were treated with balloon kyphoplasty and half of the patients with thoracolumbosacral orthosis (TLSO). Outcomes included back pain severity measured on visual analog scale (VAS), activity level (VAS), bed rest, SF-36 medical outcomes survey, subject satisfaction, and radiomorphology.

Patients reported severe back pain interfering with daily activities before treatment. Physical functioning and quality of life were also markedly impaired. Statistically significant ($p < 0.05$) improvements occurred in all pain and functional outcomes after treatment in the kyphoplasty group. Minor improvements were noted in the orthosis group. Clinical outcomes were significantly different between the groups ($p < 0.05$). Kyphoplasty increased midline vertebral height of the treated vertebral bodies, whereas in the orthosis group, vertebral height decreased.

INTRODUCTION

Osteoporosis is an increasing burden of an aging society, resulting in over 1 million vertebral fractures in Europe per year. Braces are frequently used in conservative treatment and may help patients to stay mobile. However, patients with vertebral fractures may have severe pain. Kyphoplasty is a minimally invasive procedure improving pain and deformity in patients with vertebral fractures (1). This paper presents prospective controlled study of kyphoplasty in patients with primary osteoporosis with painful acute vertebral compression fractures present for less than 3 months.

METHODS AND SUBJECTS

A prospective nonrandomized controlled study was undertaken in a single centre. The study population consisted of consecutive patients with painful osteoporotic vertebral fractures presenting at our department from June 2006 to September 2007.

Methods

All patients in both groups received medical treatment (standard dose of oral aminobisphosphonate + 1000 mg calcium + 1000 IE vitamin D) and a recommendation for

supervised physiotherapy once a week for 6 months. For patients undergoing kyphoplasty, two cannulae were inserted transpedicularly into the crushed vertebral body. Cavities of about 5 ml volume were created by two balloon tamps inserted through the cannulae. After removal of the balloon tamps, bone cement (polymethylmethacrylate; KyphX, Kyphon, USA) was injected into the created cavities. For patients undergoing conventional management, thoracolumbosacral orthosis (TLSO) were prescribed and were worn when patients were awake.

Clinical study of the spine was assessed by evaluation of the lateral X-rays of the spine according to standard radiological analyses and the actual measurement of midline vertebral height was performed (2). After a minimum of 6 months new vertebral fractures of the thoracic and lumbar spine and of vertebrae directly adjacent to the fractured vertebrae were assessed. Back pain was evaluated in patients by a visual analog scale (VAS). Activity level and patient satisfaction were also evaluated by VAS. Patients were additionally asked to estimate the time spent in bed in the last 28 days and to answer the SF-36 medical outcomes survey, which has been validated for Slovenian language. Kyphoplasty and TLSO group outcomes were compared at follow-up using multivariate generalized linear regression modelling. Baseline characteristics were compared using independent two-group t-test. All data analysis was undertaken using SPSS V.11.

Subjects

Patients of both genders with primary osteoporosis with one or more painful osteoporotic vertebral fractures requiring hospitalisation were eligible for participation. Vertebral fractures were presented for <3 months before inclusion. If kyphoplasty was technically feasible (absence of burst fractures, vertebra plana, and presence of clearly discernible pedicles) the patients were offered surgery or control therapy with optimal medical treatment of osteoporosis, including bracing (TLSO), physiotherapy and analgesics treatment.

RESULTS

Sixteen patients with twenty osteoporotic vertebral fractures were included. Eight patients chose to undergo kyphoplasty, whereas the remaining eight patients were taken as TLSO group.

Radiological analysis

There was no evidence of a statistically significant difference in the characteristics of the kyphoplasty and TLSO groups at entry to the study. Vertebrae treated by kyphoplasty exhibited a relatively increased midline vertebral height, whereas in the TLSO group midline vertebral height decreased, indicating further collapse of the fractured vertebral body. The midline vertebral height was significantly greater ($p < 0.001$) in the kyphoplasty group compared with the TLSO group. New vertebral fracture of the adjacent level was detected in two patients in the TLSO group at the follow-up.

Pain perception and daily activities

At the final follow-up, the kyphoplasty group exhibited a significant improvement of the VAS score compared with TLSO group ($p = 0.004$). The pain was significantly lower ($p = 0.002$) in the kyphoplasty group compared with the TLSO group. The patients in the kyphoplasty group were also more satisfied with the result of their treatment ($p = 0.001$). The beneficial effect of kyphoplasty on patients' complaints seems to be accompanied by improved health perception as determined by the SF-36 score. At final follow-up, the kyphoplasty group exhibited a significant improvement in SF36 scores as compared with controls (Physical Component Summary, $p = 0.002$; Mental Component Summary, $p = 0.18$; Fig. 1).

No patient in the kyphoplasty group spent any full day in bed because of pain in the last 28 days before final follow-up, whereas 2 patients in the TLSO group spent on average 14 full days in bed ($p = 0.75$). No patient in the kyphoplasty group spent half of a day in bed because of pain in the last 28 days, whereas 6 patients in the TLSO group spent on average 13 days half of a day in bed ($p = 0.005$).

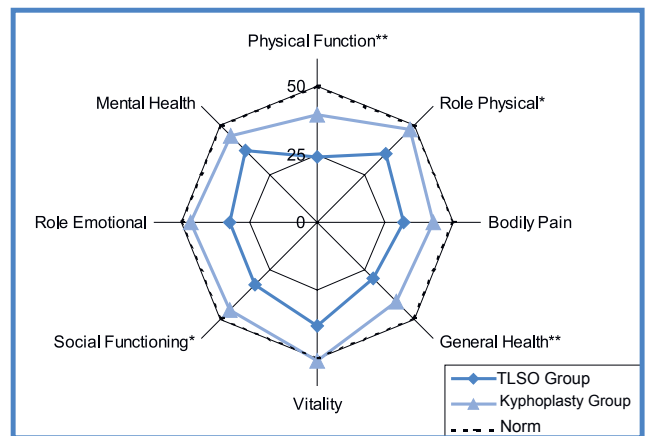


Figure 1: Norm-based scores for TLSO and kyphoplasty groups (SF-36v2).

* $p < 0.05$; ** $p < 0.01$

DISCUSSION

The results of this study support the use of kyphoplasty in addition to medical therapy as an effective method of treatment of fractured osteoporotic vertebrae, resulting in reduction of pain, improvement of daily activities, and improvement of total health perception as measured by SF-36 survey. Similar results were described by other authors (3). However, as balloon kyphoplasty is an expensive and invasive procedure, a formal cost-effectiveness study is required to confirm a potential benefit over standard brace treatment.

It has been shown that kyphoplasty may induce new vertebral fractures, particularly in adjacent vertebrae, because of the increased strength of the stabilized vertebral bodies in an osteoporotic spine. However, in our study we did not observe any such fractures in the kyphoplasty group. Moreover, two adjacent vertebral fractures occurred in the TLSO group suggesting that hyperkyphosis at the level of fractured vertebrae alters loading pattern of the spine thus increasing the risk of further vertebral fractures (4).

CONCLUSION

In this study a positive effect of kyphoplasty over standard brace treatment was observed on vertebral morphology and patient's satisfaction, pain, level of activity, and total health perception.

References:

1. Voggenreiter G. Balloon kyphoplasty is effective in deformity correction of osteoporotic vertebral compression fractures. *Spine* 2005; 30:2806-12.

2. Lieberman IH, Dudeney S, Reinhardt MK, Bell G. Initial outcome and efficacy of "kyphoplasty" in the treatment of painful osteoporotic vertebral compression fractures. *Spine* 2001; 26:1631-8.
3. Kasperk C, Hillmeier J, Noldge G, Grafe IA, DaFonseca K, Raupp D, et al. Treatment of painful vertebral fractures by kyphoplasty in patients with primary osteoporosis: a prospective nonrandomized controlled study. *J Bone Miner Res* 2005; 20:604-12.
4. Klotzbuecher CM, Ross PD, Landsman PB, Abbott TA III, Berger M. Patients with prior fractures have an increased risk of future fractures: A summary of the literature and statistical synthesis. *J Bone Miner Res* 2000; 15:721-39.