Rezultati zdravljenja bolečih vretenčnih zlomov: prospektivna, ne-randomizirana primerjava med kifoplastiko in simptomatskim zdravljenjem

Results of treatment of painful vertebral fractures by kyphoplasty or conservative symptomatic management: a prospective nonrandomized controlled study

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Izvleček

Namen: *S pričujočo študijo smo želeli primerjati rezultate zdravljenja bolečih vretenčnih zlomov pri bolnikih s primarno osteoporozo. Zdravljenje z balonsko kifoplastiko smo primerjali z zdravljenjem na konzervativen način.*

Metode: *Polovico bolnikov smo zdravili z balonsko kifoplastiko, polovico pa simptomatsko (analgetiki, mirovanje, torako-lumbo-sakralna ortoza). Rezultate smo ovrednotili z merjenjem bolečine po vizualni analogni lestvici (VAS), oceno stopnje aktivnosti (VAS), potrebo po počitku v postelji, točkovnim sistemom SF-36, zadovoljnostjo bolnika s prejetim zdravljenjem in z rentgenskimi spremembami.*

Rezultati: *Pred zastavljenim zdravljenjem so vsi bolniki imeli hude bolečine v hrbtenici, ki so jih v vsakdanjih aktivnostih omejevale. V skupini, zdravljeni s kifoplastiko, smo ugotovili statistično pomembno izboljšanje (P<0,05) v oceni*

Abstract

Purpose: *This nonrandomised study analyzed the results of treatment of painful vertebral fractures in patients with primary osteoporosis with balloon kyphoplasty and compared them with conventional management (control group).*

Methods: *Consecutive patients were enrolled from an outpatient orthopaedic department over a four month period. Eight patients were treated with balloon kyphoplasty and eight with a symptomatic approach (analgesics, bed rest, thoracolumbosacral orthosis). Outcome measures included back pain severity measured on a visual analog scale (VAS), activity level measured on a VAS, bed rest, the SF-36 medical outcomes survey, subject satisfaction, and radiomorphology.*

Results: *Patients reported severe back pain interfering with daily activities before treatment. Physical functioning and quality of life were also markedly impaired. Statisti-*

bolečine in funkcionalnih parametrih. V skupini, zdravljeni na konzervativen način, smo opazili zgolj blago izboljšanje. V skupini, zdravljeni s kifoplastiko, smo opazili povečano višino telesa zdravljenega vretenca, v skupini, zdravljeni konzervativno, pa se je višina telesa vretenca v opazovalnem obdobju zmanjšala.

Zaključek: *S kifoplastiko lahko, v primerjavi s konzervativnim načinom zdravljenja, pričakujemo boljši izhod zdravljenja v smislu morfologije zlomljenega vretenca, bolnikovega zadovoljstva, bolečine, stopnje aktivnosti in splošne percepcije zdravja.*

cally significant ($P < 0.05$) improvements in pain and functional outcomes occurred after treatment in the kyphoplasty group. Minor improvements were noted in the control group. Clinical outcomes were significantly different between the groups ($P < 0.05$). Kyphoplasty increased the midline vertebral height of the treated vertebral bodies, whereas in the control group vertebral height decreased.

Conclusion: *A positive effect of kyphoplasty over conventional treatment was observed on vertebral morphology and patient satisfaction, pain, level of activity, and overall health perception.*

INTRODUCTION

Osteoporosis is producing an increasing burden on an aging society. There are over 1 million vertebral fractures in Europe per year [1] and, as the population continues to age, the estimated incidence of osteoporotic vertebral compression fracture (VCF) is likely to increase 4-fold during the next 50 years [2].

Traditional treatment for patients with VCF includes analgesics, initial bed rest, anti-osteoporotic medication, and rehabilitation. Braces are also frequently used in conservative treatment and may help patients to stay mobile [3]. However, symptomatic treatment is only partly effective and about a third of patients suffers from intractable pain and loss of mobility [4]. Symptomatic treatment does not address the spinal malalignment, and the lack of mobility leads to further demineralization [5] which may predispose to additional fractures.

Balloon kyphoplasty is a minimally invasive procedure developed for the management of symptomatic VCFs. It is designed to address the fracture-related pain by internally stabilizing the fractured vertebra and to restore vertebral body height, thereby reducing the kyphotic deformity. Balloon kyphoplasty, it has been suggested, has the lowest complication rate of the currently available surgical options [6, 7].

This paper presents a prospective non-randomized non-blinded controlled study of kyphoplasty in patients with primary osteoporosis with painful acute vertebral compression fractures present for less than 3 months and compares the results of treatment with those of conservative management.

MATERIAL AND METHODS

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

PATIENTS

Patients of either gender with primary osteoporosis with one or more painful osteoporotic vertebral fractures requiring hospitalization were eligible for participation. Inclusion criteria were: 1) osteoporo-

tic VCF, 2) pain lasting < 3 months, 3) localized spinal pain that worsened with percussion over the spinal process of the fractured vertebra, 4) no technical reasons why kyphoplasty could not be performed, 5) suitability for general anesthesia and 6) informed written consent. Patients with malignancy-associated VCF, retropulsed bone, pedicle fracture or neurologic deficits were excluded from the study.

Suitable patients were offered kyphoplasty and were informed of risks and benefits of kyphoplasty and conservative management. Given sufficient information, patients then decided whether they wanted to undergo kyphoplasty (kyphoplasty group) or conventional treatment (control group).

METHODS

Physical examination combined with standing radiographs, bone scintigraphy (^{99m}Tc), computerized tomography and, if needed, magnetic resonance imaging were used to diagnose vertebral fractures. All patients in both groups received medical treatment (standard doses of an oral aminobisphosphonate + 1000 mg calcium + 1000 IE vitamin D) and a recommendation for supervised physiotherapy once a week for 6 months.

For patients undergoing conventional management, optimized analgesic treatment and thoracolumbosacral orthoses (TLSO), worn when patients were awake, were prescribed. For patients undergoing kyphoplasty, a standard operative procedure was undertaken. Patients were positioned prone with a bolster placed under the sternum and pelvis. General anesthesia was used in all cases. Two cannulae were inserted transpedicularly into the crushed vertebral body. Cavities of about 5 mL volume were created by two balloon tamps (KyphX Xpander Inflatable Bone Tamp, Kyphon Inc., USA) inserted through the cannulae. After removal of the balloon tamps, bone cement (polymethylmethacrylate; KyphX, Kyphon Inc., USA) was injected into the created cavities.

Standing lateral X-rays of the spine were evaluated pre- and post-treatment. The vertical heights of all fractured vertebrae were measured both before treatment and during the follow-up period. Vertebral height was defined as the distance (endplate to endplate) at the center of the vertebral body on the lateral radiograph. An estimate of the pre-fracture height was calculated as an average of the vertebral body heights above and below the fractured vertebra. To minimize possible magnification effects and inter-radiographic precision errors of different tube-to-film distances, relative heights and height differences were calculated as follows: relative pretreatment height = measured pretreatment height / estimated pretreatment height, relative follow-up height = measured follow-up height / estimated follow-up height, height difference = relative follow-up height – relative pretreatment height, percentage of regain-of-lost-height (height lost that is restored at the follow-up) = height difference / (1 - relative pretreatment height) x 100 [8].

A standard examination protocol at a minimum of 6-month follow-up was applied for both groups. New vertebral fractures of the thoracic and lumbar spine and of vertebrae directly adjacent to the fractured vertebrae were assessed on standing radiographs at follow-up. Back pain was evaluated by the patients using 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 in the Slovenian language.

All data analysis was undertaken using the software package SPSS (version 15, SPSS Inc., USA). Central tendencies of non-normally distributed parameters are represented as median values with ranges in parenthesis. Non-parametric tests were used to compare the differences between and within the groups. Differences were considered statistically significant for p values < 0.05.

RESULTS

Sixteen patients with twenty osteoporotic vertebral fractures were included. Eight patients chose to undergo kyphoplasty, and the remaining eight patients served as the control group. There were no demographic differences between the groups (Table 1).

The median follow-up was 12 months (range, 6–14 months) in the kyphoplasty group and 13 months (range, 6–22 months) in the control group (P = 0.401). No patients were lost to follow up.

Table 1. *Demographics*

	Kyphoplasty group	Control Group	P
Number of patients	8	8	
Number of VCF	10	10	
M:F (n:n)	4:6	0:10	0.087[a]
Age (years)	74 (70 – 79)	77.5 (66 - 83)	0.111[b]
Duration of symptoms (weeks)	4.5 (2 -7)	5 (2 – 12)	0.508[b]
Levels treated			
T9	1	0	
T10	0	1	
T11	1	1	
T12	1	2	
L1	2	2	
L2	3	1	
L3	1	2	
L4	1	1	

[a] Fischer's test, [b] Mann-Whitney U test

Table 2. *Efficacy outcome comparison*

	Kyphoplasty group	Control Group	P
Pain pretreatment (VAS)	10 (5 – 10)	9 (5 – 10)	0.207[a]
Pain follow-up (VAS)	0 (0 – 4)	5.5 (2 – 8)	0.002[a]
P (pretreatment vs. follow-up)	0.026[b]	0.018[b]	
Activity level pretreatment (VAS)	0 (0 – 3)	3.5 (0 – 6)	0.069[a]
Activity level follow-up (VAS)	7 (5 – 10)	5 (0 – 9)	0.041[a]
P (pretreatment vs. follow-up)	0.026[b]	0,181[b]	
Satisfaction (VAS)	10 (8 – 10)	5 (2 – 9)	0.001[a]
Relative pretreatment height (%)	65.5 (43 – 83)	76 (41 – 91)	0.570[a]
Regain-of-lost-height (%)	67 (50 – 100)	-37 (-87 – -9)	<0.001[a]

[a] Mann-Whitney U test, [b] Wilcoxon signed ranks test

RADIOLOGICAL ANALYSIS

Two patients from each group had a VCF on two levels. The levels treated ranged from T9 to L4 (Table 1). Vertebrae treated by kyphoplasty exhibited a relatively increased midline vertebral height (67%, median), whereas in the control group midline vertebral height decreased (−37%, median), indicating further collapse of the fractured vertebral body (Table 2). The midline vertebral height at follow-up compared to the expected vertebral height (relative follow-up height) was significantly greater ($P < 0{,}001$) in the kyphoplasty group (median 89.5%, range 76–100%) compared with the control group (median 38%, range 31–78%). A new vertebral fracture at the adjacent level was detected in two patients in the control group and no patients in the kyphoplasty group at the follow-up (Figure 1).

PAIN PERCEPTION AND DAILY ACTIVITIES

At the final follow-up, the kyphoplasty group exhibited a significant improvement in satisfaction and in the VAS scores for pain and activity level (Table 2).

The beneficial effect of kyphoplasty on patient symptoms was accompanied by an improved health perception as determined by the SF-36 score. Specifically, when compared to the control group, the kyphoplasty group exhibited a significantly better result in the following domains: Physical Function, Role Physical, General Health and Social Functioning (Figure 2). The Physical Component Summary parameter, which combines the physical attributes of the SF-36 questionnaire, was significantly better in the kyphoplasty group ($P = 0.002$). The Mental Component Summary parameter showed no significant difference between the groups ($P = 0.18$).

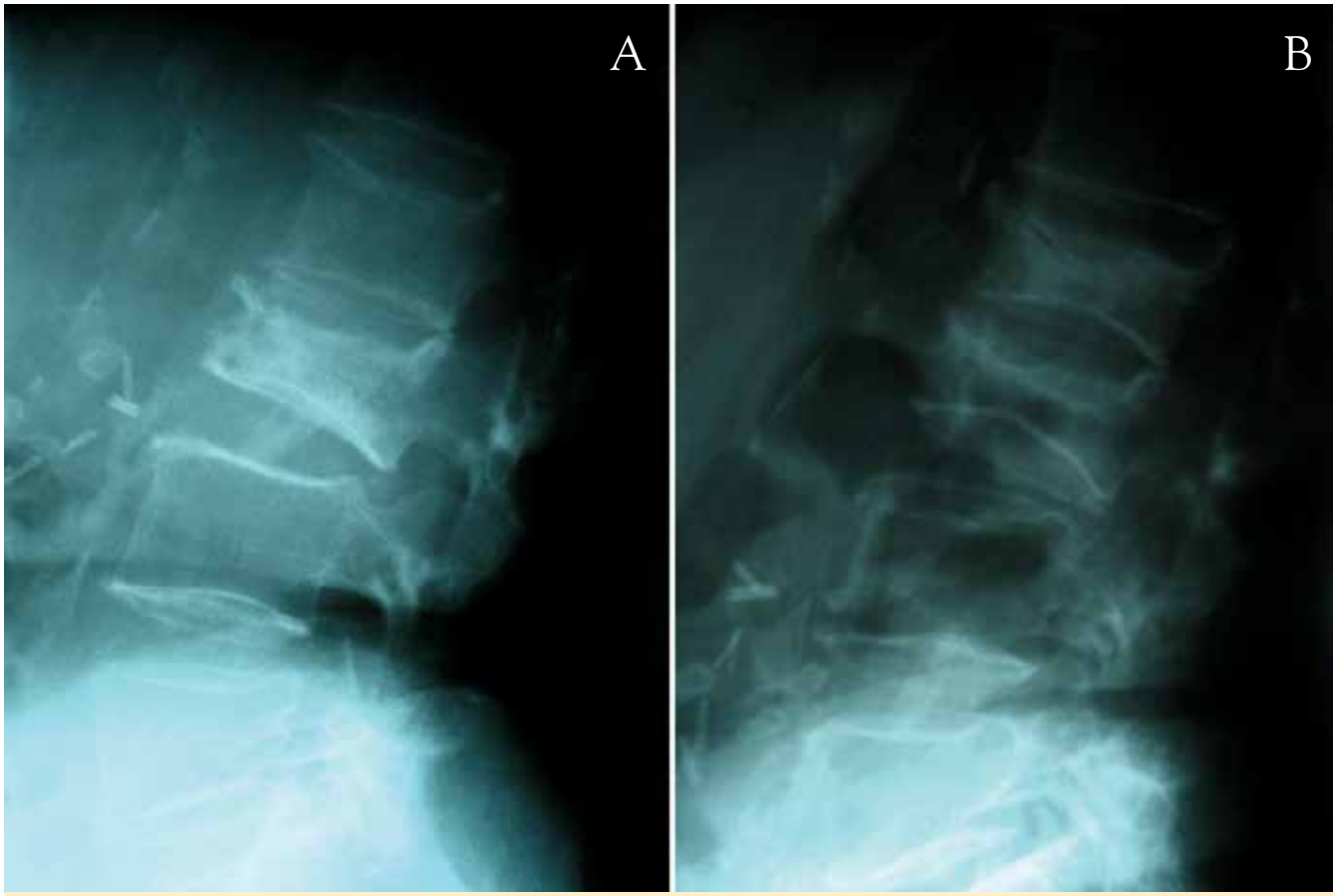

Figure 1. *Fracture of L2 and L3 vertebra in a 82-year old woman. A. Before treatment. B. One year after conventional management.*

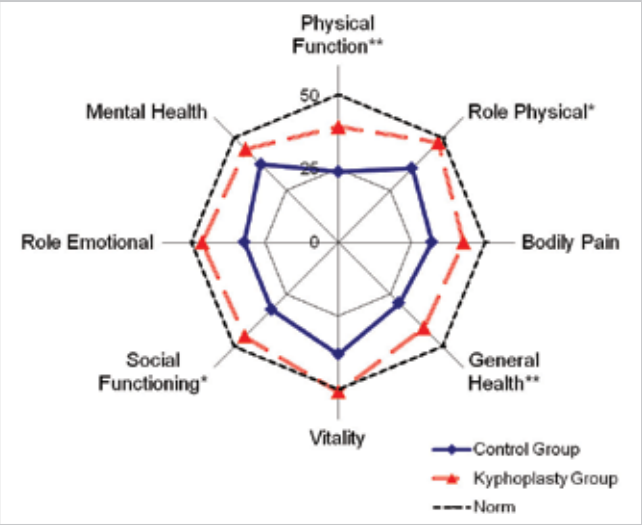

Figure 2. *Norm-based scores for control and kyphoplasty group (SF-36v2).*

** P<0.05; **P<0.01*

No patient in the kyphoplasty group spent any full day in bed because of pain in the 28 days before the final follow-up, whereas two patients in the control group had spent on average 14 full days in bed (Fisher's exact test, $P = 0.233$). No patient in the kyphoplasty group spent half of a day in bed because of pain in the last 28 days, whereas six patients in the control group had spent on average of 13 half-days in bed (Fischer's exact test, $P = 0.003$).

DISCUSSION

The results of this study support the use of kyphoplasty in addition to medical therapy as an effective treatment method of fractured osteoporotic vertebra. Reduction of pain and improvements in daily activities and patient satisfaction were significantly better in the kyphoplasty group during a follow-up period of at least 6 months. Total health perception in the kyphoplasty group, as measured by the SF-36 survey, was near that of a healthy population. On the other hand, the control group displayed lower values in all SF-36 parameters, especially in the parameters describing physical attributes.

Similar results have been described by other authors [9, 10]. In our study, a positive effect of kyphoplasty over conventional treatment was observed in patients with acute fractures (less than 3 months). However, rapid and marked improvement can also be expected in patients with chronic fractures [11]. Immediate pain relief in the majority of patients and avoidance of the side effects of long-term analgesic medication are some of the benefits of an early intervention. Another advantage of kyphoplasty is a sustained (for at least 2 years) improvement of symptoms [12].

Most patients with a vertebral fracture do not require operative treatment, as the symptoms tend to resolve with conservative management. At present, no formal cost-effectiveness study is available to confirm a potential benefit over conventional treatment in either acute or chronic cases. The question of when to treat operatively will remain unresolved until we can predict which patients will develop chronic vertebral instability and, hence, intractable pain.

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 otherwise osteoporotic spine [13, 14]. However, we did not observe any such fractures in the kyphoplasty group. Moreover, two adjacent vertebral fractures occurred in the control group, suggesting that hyperkyphosis at the level of fractured vertebrae alters the loading pattern of the spine, thus increasing the risk of further vertebral fractures [15].

The principle limitations of this study were the small number of VCFs and the non-randomized and non-blinded design, which may have allowed bias and confounding. Additionally, small number of patients and the lack of a formal sample size calculation may have decreased the statistical power of the study. However, even with a small sample size, we managed to detect differences in important outcomes between the kyphoplasty and control group. Given that the patients themselves selected the treatment method, the differences between the groups may

have occurred on account of non-measured confounders. Although the differences in the baseline characteristics were not significant, pre-treatment activity level neared significance, suggesting that patients with better activity levels tended to opt for conventional treatment.

CONCLUSION

In conclusion, a positive effect of kyphoplasty over conventional treatment was observed on vertebral morphology and patient satisfaction, pain, level of activity and total health perception.

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