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Kyphoplasty *vs* conservative treatment: a case-control study in 110 post-menopausal women population. Is kyphoplasty better than conservative treatment?

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Abstract. – OBJECTIVE: Osteoporosis is a highly prevalent disease worldwide. Consequences of vertebral osteoporotic fractures include pain and progressive vertebral collapse resulting in spinal kyphosis, decreased quality of life, disability and mortality. Minimally invasive procedures represent an advance to the treatment of osteoporotic VCFs. Despite encouraging results reported by many authors, surgical intervention in an osteoporotic spine is fraught with difficulties. Advanced patients age and comorbidities are of great concern.

PATIENTS AND METHODS: We designed a retrospective case-control study on 110 postmenopausal women consecutively visited at our institution. Study population was split in a surgical and a conservative cohort, according to the provided treatment.

RESULTS: Kyphoplasty treated patients had lower back pain VAS scores at 1 month as compared with conservatively treated patients ($p < 0.05$). EQ5D validated questionnaire also showed a better quality of life at 1 month for surgically treated patients ($p < 0.05$). SF-12 scores showed greater improvements at 1 month and 3 months with statistically significant difference between the two groups just at 3 months ($p < 0.05$). At 12 months, scores from all scales were not statistically different between the two cohorts, although surgically treated patients showed better trends than conservatively treated patients in pain and quality of life. Kyphoplasty was able to restore more than 54.55% of the original segmental kyphosis, whereas patients in conservative cohort lost 6.67% of the original segmental kyphosis on average.

CONCLUSIONS: Kyphoplasty is a modern minimal invasive surgery, allowing faster recovery than bracing treatment. It can avoid the deformity in kyphosis due to VCF. In fact, the risk to develop a new vertebral fracture after the first one is very high.

Key Words:
Osteoporosis, Vertebral compression fractures, Conservative treatment, Kyphoplasty, Clinical outcomes.

Introduction

Osteoporosis is a highly prevalent and one of the most debilitating and costly chronic diseases worldwide. In 2000, there were 1.4 million osteoporotic VCFs worldwide, and Europe and Americas accounted for 51% of them[1,2]. VCFs are a leading cause of disability and morbidity in postmenopausal women[3]. The consequences of these fractures include pain and, in many cases, progressive vertebral collapse with resultant spinal kyphosis. Most of patients experiencing osteoporotic VCFs remain asymptomatic or minimally symptomatic; however, a large part of these patients do experience significant pain, resulting in decreased quality of life, disability and mortality[4]. Conventional medical treatment for these patients includes pain medication, pharmacological treatment, activity limitation and bracing[5-7]. Some authors suggest that could be possible to predict a new VFC using a risk scoring system based on factors that are potentially significant predictors of fragility VCFs. It would be very essential for clinicians to gauge accurately the risk of vertebral fragility fractures. According to these authors, patients with higher scores should be assigned to more strict follow-up programs and to more intensive risk-reduction programs[8]. Minimally invasive procedures, namely kyphoplasty and vertebroplasty, represent a recent advance to the treatment of

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osteoporotic VCFs. Minimally invasive surgical techniques had been developed with the purpose to give a mechanical support to the vertebral plate, to obtain an immediate fracture stabilization, to mobilize the patient the day after, to reduce disability and costs related to VCFs[9]. The two main objectives of minimally invasive procedures are to address pain and deformity associated with these fractures[10]. Despite encouraging results reported by many authors, surgical intervention in an osteoporotic spine is fraught with difficulties. Advanced patients age and the presence of comorbidities are of great concern. Moreover, kyphoplasty does not come without increasing in risks for patients and costs for health care systems[11-13]. Some authors claimed for more risk-benefit and efficacy assessment studies[14-16].

The aim of this study is to compare effects in terms of recovery and quality of life and to compare deformity prevention efficacy of kyphoplasty and conservative treatment in post-menopausal women with an osteoporotic VCF and to provide an efficacy assessment of kyphoplasty as compared with standard conservative treatment in post-menopausal women (bracing immobilization).

Patients and Methods

Data for this study were obtained from our institutional patient database. One-hundred ten consecutive post-menopausal women who visited our outpatient clinic for spinal osteoporosis from September 2010 to December 2012 were enrolled. Enrollment criteria were the following: (1) diagnosis of post-menopausal osteoporosis according to National Osteoporosis Foundation (NOF) guidelines, (2) presence of a recent (< 2 weeks) symptomatic fragility VCF at the enrollment time treated either by means of kyphoplasty or conservative treatment, (3) no more than 2 (if any) old VCFs with no resultant kyphotic deformity, (4) treatment start no later than 15 days from the VCF time. Exclusion criteria were: (1) any cause of secondary osteoporosis (including neoplastic diseases and multiple myeloma), (2) present or past steroid and/or immunosuppressive therapy, (3) primary or secondary chronic (> 6 months) back pain, (4) any previous spine surgery, (5) any other chronic pain syndrome (Table I). Enrollment criteria were designed to select patients who were unlikely to have chronic back pain or any other confounding factor overlapping with back pain due to a recent VCF. Patient's medical records and previous spinal imaging studies were thoroughly reviewed for demographical and clinical data. A VCF was defined as a vertebral endplate wedge or crush deformity based on lateral radiographs and a reduction of vertebral body height > 20%. Recent fractures were confirmed by MRI findings of marrow signal changes as previously described. Data from VAS, SF-12, and EQ5D questionnaires were also obtained from our database. All patients were asked to fill in questionnaires before treatment starting (either kyphoplasty or conservative treatment), and at 1 month, 3 months, 6 months and 12 months after treatment. Fractured vertebrae height and segmental kyphosis were also measured as depicted in Figure 1 in all patients before treatment starting and at 12 months after treatment. Standing lateral spine X-ray was taken

Table I. Inclusion and exclusion criteria for enrolment.

Enrolment criteria
Post-menopausal osteoporosis
Recent (< 2 weeks) osteoporotic vertebral compression fracture
Kyphoplasty or conservative treatment started < 15 days after fracture time
No more than 2 (if any) previous osteoporotic vertebral compression fractures
Exclusion criteria
Secondary osteoporosis
Present or past steroid and/or immunosuppressive therapies
Primary or secondary chronic (> 6 months) back pain
Any previous spine surgery
Any other chronic pain syndrome

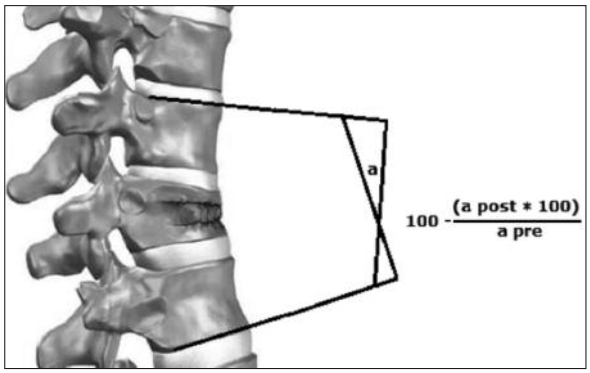

Figure 1. Schematic picture showing standard Cobb method for calculating segmental kyphosis after a vertebral compression fracture.

at baseline and at 12 months and segmental kyphosis was measured as showed in Figure 1. Kyphoplasty procedures (Medtronic Spine LLC, Sunnyvale, CA, USA) were performed through a percutaneous bilateral transpedicular approach following standard protocols. Most patients had deep sedation with local anaesthesia, whereas thirteen patients had their procedures under general anesthesia. Patients were dismissed from the hospital the same day and were told to avoid lifting heavy weights. No braces were used in the kyphoplasty treated patients. All patients enrolled in the conservative cohort were told to use a thoraco-lumbar brace (thoraco-lumbar spinal orthosis, TLSO) for 4 months. The patients must wear the brace 24 hours a day. After 4 months period all patients were told to remove the brace and go back to their usual life, all patients were also checked for compliance and patients who wore the brace for less than 85% of the whole treatment period were excluded.

Statistical Analysis

Patient population was split in a kyphoplasty cohort (52 patients; median age, 68.9 years; range 64-80 years) and a conservative treatment cohort (58 patients; range 62-84 years, mean age 70.2). Cohorts were checked for statistical homogeneity at baseline. The Student *t*-test for unpaired data was used for comparison of continuous data between cohorts. The χ^2 method or Fisher test was used to compare categorical variables, as appropriate. The repeated measures analysis of variance test (ANOVA) was used to detect any overall differences between the two treatment cohorts. We also used the *t*-test to compare the calculated means at each time point. Data were analyzed with SPSS statistic software, version 17 (SPSS, Chicago, IL, USA).

Results

One-hundred ten osteoporotic postmenopausal women were enrolled in the study. The mean age of the patient population was 69.5 years, range 62-84 years; a total of 52 kyphoplasty procedures were performed on a total of 52 patients (ange 64-80 years, mean age 68.9 years); 58 patients received conservative treatment (range 62-84 years , mean age 70.2). Table II shows demographic and clinical characteristics of the two cohorts, Figure 2 shows fractures level distribution among patients in the surgery and conservative cohorts. The two cohorts had similar baseline characteristics, as showed by *p* values in Table II. Both groups show a peak distribution at thoracolumbar junction. Back pain, as assessed by VAS score, decreased 5.52 points in kyphoplasty group at 1 month, whereas patients in conservative group had a 2.13 points decrease in the same time period ($p < 0.01$). Figure 3 also shows a decreasing trend of VAS scores for both treatment groups at later time points up to

Table II. Demographic and clinical characteristics of patients in the kyphoplasty and conservative treatment cohorts.

Variable	Kyphoplasty cohort (n = 52)	Conservative treatment cohort (n = 58)	*p* value
Age	68.9 (5.98)	70.2 (5.69)	0.21
BMI (kg/m^2)	24.25 (3.15)	23.91 (4.35)	0.11
Smoking habit (yes/no), no. (%)	24 (46.1)	26 (44.8)	0.14
Alcohol consumption (> 2 units/week), no. (%)	7 (13.4)	10 (17.2)	0.76
Patients with previous old fractures			
One (percentage)	32 (61%)	34 (58%)	
Two (percentage)	11 (21%)	13 (22%)	
Old fractures location			
Thoracic (T5-T9) (percentage)	4 (9.6%)	5 (Table I. Inclusion and exclusion criteria for enrolment 10.6%)	
Thoracolumbar junction (T10-L2) (percentage)	25 (58.1%)	28 (59.6%)	
Lumbar (L3-L5) (percentage)	14 (32.5%)	14 (29.7%)	

Results are shown as mean (SD) unless stated otherwise.

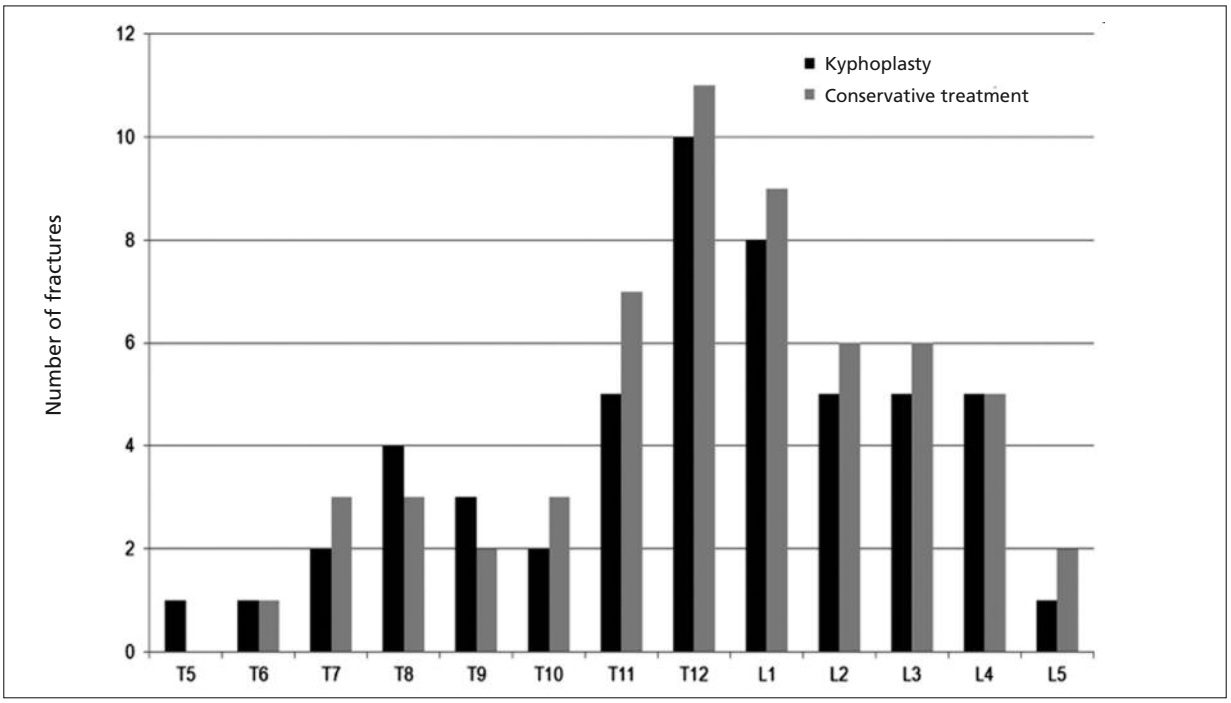

Figure 2. Fractures distribution in kyphoplasty treated and conservative treatment cohorts.

12 months. No statistically significant difference was observed between the two groups in VAS scores at 12 months, although kyphoplasty treated patients showed lower scores than conservative treated patients. Group calculated means and standard deviations are shown for kyphoplasty and conservative treatments. Compared with controls, the kyphoplasty group had greater improvements in quality of life as assessed by the validated EQ5D questionnaire from baseline to 1 month ($p < 0.01$). At 12 months, both groups showed similar quality of life scores, although conservative treatment group patients showed a constant increase of their scores from 3 months to 12 months. Both mental and physical SF-12 components improved in kyphoplasty and conservative group across the 12 months time period. Patients assigned to kyphoplasty had slightly greater improvements than controls for both physical and mental scores at 1 month and 3 months time points. The difference was statistically significant between the two groups at 3 months ($p < 0.05$). Kyphosis analysis showed a 54.55% increase in angular values for kyphoplasty treated patients at 12 months, whereas patients treated conservatively had a 6.67% decrease over their kyphosis angles at enrollment time ($p < 0.001$). No major adverse events were recorded among patients treated with kyphoplasty. Cement leak occurred in 2 (3.4%) patients, but none of them needed emergency decompression surgery or any other treatment.

Discussion

Data from this case-control study showed that kyphoplasty improved quality of life and segmental kyphosis, and reduced pain at 1 month after the procedure as compared with standard conservative treatment[17]. Differences in every score system were bigger between the two groups at 1 month after treatment and SF12 physical component showed a statistical difference at 3 months after treatment. At 12 months no statistically significant difference was observed between the two groups, most probably due to the physiological fracture healing process. At the enrollment time all patients had a substantially decreased quality of life and high back pain VAS scores (7.75 and 7.72 for kyphoplasty and conservative treatment group, respectively). Patients treated with kyphoplasty

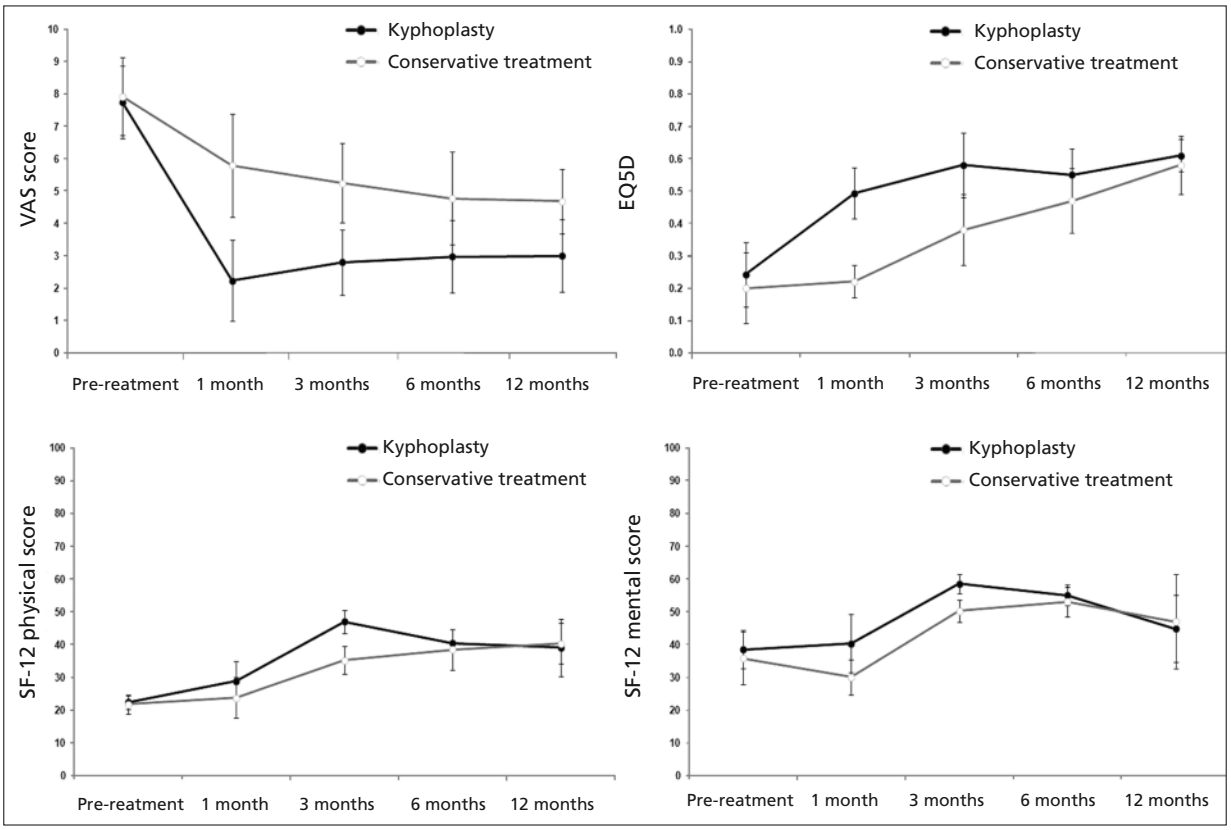

Figure 3. VAS score, EQ5D and SF-12 scores at baseline and after kyphoplasty or conservative treatment.

had a 71.2% drop in their pain scores at 1 month, whereas patients treated conservatively had only a 26.9% drop at the same time. Our findings are consistent with previous reported data and confirm the prominent pain relieving effect of kyphoplasty[18,19]. Although ANOVA analysis showed a significant decreasing trend in pain scores for both procedures at 12 months, we could not observe any significant difference at 12 months. We observed similar results for the EQ5D quality of life questionnaire and even SF-12 mental and physical components did not show any difference between treatments at 12 months. Moreover, kyphoplasty proved to restore segmental kyphosis to 54.55%. Calculated means and standard deviations are shown for both groups. Although conservative treatment showed slower improvements in pain and quality of life scores, it was largely inefficient in restoring segmental kyphosis. It is worth noting that kyphoplasty is effective in restoring segmental kyphosis only when performed no later than 30 days from the fracture time[20,21].

Conclusions

Kyphoplasty seems to be a safe and effective procedure in reducing back pain due to painful VCF[22]. The kyphosis restoring effect is also extremely interesting and can be achieved only in the first days after fracture time.

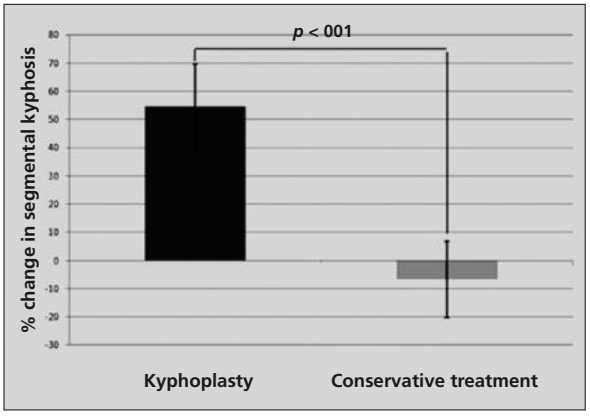

Figure 4. Percent change in segmental kyphosis at 12 months after kyphoplasty or conservative treatment.

Conflict of Interest

The Authors declare that there are no conflicts of interest.

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