



Quality of Life after Kyphoplasty - Clinical and Radiological Results of Vertebral Fractures due to Osteoporosis or Cancer

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Abstract

Purpose: Spinal tumors and osteoporotic fractures are a common and morbid condition. Kyphoplasty (BKP) was developed with the goal of restoring vertebral height, correction of the kyphotic angle and improving quality of life. The purpose of this retrospective study was to compare the clinical and radiological outcome of patients after Balloon Kyphoplasty (BKP) of Osteoporotic Fractures (OF) or due to cancer (VT).

Materials and Methods: Two groups of cancer and Osteoporotic Fracture patients (OF) undergoing kyphoplasty with a minimum follow up of 12 months analyzed. Clinical outcome was evaluated by Oswestry Disability Index (ODI), whereas intraoperative and radiological data such as cement volume and leakage, vertebral body restoration and realignment of the kyphosis angle served as objective parameters. Moreover, complications were documented. Statistical analysis (Spearman Correlation, Mann-Whitney-U-Test) was performed (Spearman Correlation, Mann-Whitney-U-Test).

Results: This study included 121 patients (84 × OF; 37 × VT) undergoing vertebral body augmentation. Mean operative time was 38 min, cement volume was on average 2.6 ml. Kyphosis correction was on average 6.0° in both groups and the vertebral height was restored by 3.8 mm. Statistical analysis showed no differences of the groups in terms of operative time, cement volume, rate of cement leakage, kyphosis reduction or restoration of vertebral height. There was a significant difference in the postoperative ODI between the groups with a higher grade of disability in the OF group.

Conclusion: These results demonstrate the efficacy and safety of BKP in the treatment of vertebral fractures due to osteoporosis or cancer. Postoperatively, patients with a cancer related fracture show higher quality of life measures in the ODI. We found no correlation of the restored vertebral height, the applied cement volume and the kyphosis correction to clinical outcome measures.

Keywords: Kyphoplasty; Tumor; Osteoporosis; Metastasis; Kyphosis angle; ODI

Introduction

Balloon kyphoplasty (BKP) is a minimal invasive operative technique to reduce pain in pathological vertebral body fractures due to osteoporosis or malignant diseases.

The aims of BKP are pain relief, restoration of the vertebral body height to obtain a physiological sagittal alignment and to avoid hyperkyphosis caused by a collapsed vertebra. In contrast to vertebroplasty, the development of BKP has reduced the risk of cement leakages which may cause neurological problems when the spinal canal is affected [1,2]. In addition, the technique of the inflatable balloon enabled a better vertebral body alignment and a reduction of the postoperative kyphotic angle compared to vertebroplasty [3,4]. Therefore, BKP is a standardized and well established procedure for osteoporotic fractures. However, this technique has also been applied in destroyed vertebrae due to tumor diseases for decades. In the 1980s, the first studies about the possibility of cement augmentation in metastasized vertebral bodies were published. Gallibert et al. [1] found rapid pain reduction by introducing cement into the vertebral body [1,5]. The authors described the stabilizing effects of the BKP to the collapsed and osteolytic vertebra and thus recommend it as a useful tool to prevent an imminent instability and lower the potential risk of neurologic symptoms. As a side-effect, heat development during polymerization of the PMMA cement may not only

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damage malignant cells but also reduce secretion of pain mediators. Subsequent oncological treatment with irradiation, chemotherapy or stem cell transplantation has been advocated as an adjuvant therapy after this minimal invasive surgical procedure [6,7]. Regarding pain, some data indicate that cement volume is the strongest predictor for pain relief after PKP in osteoporotic fractures [8]. However, there is a lack of evidence in the literature comparing initial disease as a predictor for pain relief after BKP in Osteoporotic Fractures (OF) or cancer (VT). This work compares the clinical and radiological outcome after BKP in cancer and osteoporotic based vertebral body fractures.

Materials and Methods

Inclusion criteria were a single or multilevel vertebral body fracture treated with BKP due to an osteoporotic fracture or a vertebral tumor with a minimum postoperative follow-up of 12 months. Exclusion criteria were previous spinal surgery or any different surgical stabilization like pedicle screw stabilization. Also traumatic fractures without osteoporosis were excluded.

In this retrospective study, patient's records, surgical protocols and reports, as well as imaging procedures were evaluated. Based on the indication for BKP the patients were divided into two groups: a) Osteoporotic Fractures (OF), b) Vertebral Tumors (VT).

The compression index of the fractured vertebral bodies was determined preoperative as well as in the postoperative X-rays in two planes. Using lateral projections the vertebral body was divided into three sections. The posterior, middle and ventral height of the fractured vertebral body and the kyphotic angle of the vertebral body were measured using digital images (Centricity Enterprises, GE Healthcare) (Figure 1).

The average vertebral height was calculated according to the formula:

$$\text{Average vertebral height} = (a+b+c)/3$$

The postoperative vertebral realignment was found with: Restored vertebral height = Average preoperative vertebral height - average postoperative vertebral height.

In addition, the vertebral kyphosis angle was measured. The degree of kyphosis and the subsequent reduction of kyphosis of the collapsed vertebra as well as the local kyphosis angle were documented on preoperative and postoperative plain standing radiographs (Figure 2).

The Segmental Lordotic Angle (SLA) was measured as the Cobb angle between lines parallel to the upper endplate of the cranial vertebra and the lower endplate of the caudal vertebra of the index level.

The intraoperative cement volume which was documented in the surgery report and a relationship of cement volume and postoperative health related quality of life was investigated. Moreover, the following parameters were analyzed: sex, patient's age at surgery and at the time of the survey, duration of the surgical procedure, hospitalization, perioperative complications and Oswestry Disability Index questionnaire.

Statistical analysis was performed using SPSS version 23.0 (IBM Corporation, Armonk, NY, USA). Due to a heterogeneous distribution of the number of cases within the groups, no normal distribution was assumed. In comparative analyzes, the non-parametric test Mann-

Table 1: Primary tumors in cancer related vertebral fracture treated with BKP.

Primary tumor	Number	Percentage (%)
Multiple myeloma	20	54.1
Lung	7	18.9
Breast	5	13.5
Liver	2	5.4
Haemangioma	1	2.7
Lymphatic	1	2.7
Bladder	1	2.7
All	37	100

Table 2: Results of the Oswestry Disability Index questionnaire which show a lower quality of life after surgery in the group of the osteoporotic fractures (21% to 40% stands for a moderate grade of disability: The patient experiences more pain and difficulty with sitting, lifting and standing. Travel and social life are more difficult and they may be disabled from work. Personal care, sexual activity and sleeping are not grossly affected and the patient can usually be managed by conservative means).

Group	Oswestry Disability Index (%)	Number
Osteoporotic	36.3	52
Cancer	21.5	18
ALL	32.5	70

Whitney U test was used and the significance level was set to $p < 0.05$.

To evaluate a correlations, the Spearman correlation coefficient r was calculated and the significance level was set to $p < 0.05$.

Results

121 patients undergoing kyphoplasty for painful vertebral body compression fractures were enrolled, 37 had a pathological fracture resulting from cancer and 84 due to osteoporosis. 217 vertebral bodies were treated with BKP, 32 patients were male and 89 female. The average patient's age at the time of surgery was 72.6 (± 10.3) years. In the OF group mean age was 75.6 years (± 8.9) and in the VT group it was 65.3 years (± 9.9).

The Osteoporotic Fracture group (OF) was formed by 84 patients, whereas the vertebral tumor group included 37 patients (VT). Primary tumor was in most of the cases a multiple myeloma with 54.1% followed by lung and breast cancer metastasis with 18.9% and 13.5%. Table 1 summarizes the results. The level with the highest fracture incidence was TH12 in 34 cases (15.7%) followed by L1 in 35 cases (16.1%).

On average, duration of hospitalization was 4.5 days (± 3.9) for all patients and there was no statistic relevant difference between the OF and VT group.

Overall, mean operative time for one vertebral body was 38 min. In the OF group it was 39.6 min and in the VT group 34.5 min, respectively.

The kyphosis reduction of the index level was measured in plain standing radiographs pre- and postoperative. Here, slightly different results could be detected: In the OF group the kyphosis angle was 22.7° (± 12.6) before surgery and changed to a Cobb angle of 16.3° (± 11.7) postoperative. This means that a correction of 6.4° (± 4.1) could be achieved with BKP intervention in this group.

In the VT group it was 26.9° (± 16.1) before and 21.2° (± 15.7) after BKP. So a change of only 5.1° (± 3.3) was found.

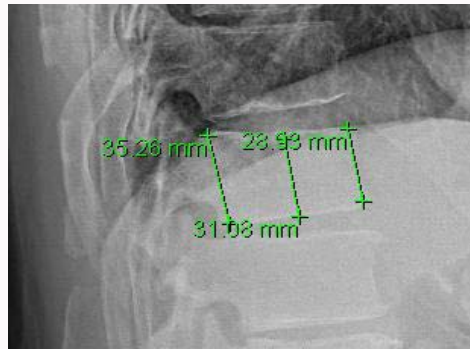


Figure 1: Lateral radiographs of the lumbar spine with measurement of vertebral height in the anterior, middle and posterior section.

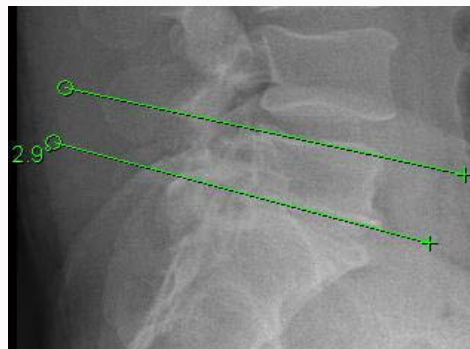


Figure 2: Lateral radiographs of lumbar spine with the vertebral kyphosis angle.

The vertebral height was measured in the middle and in the anterior and posterior part of the body. In the OF group we found preoperative a height of 20.0 mm (± 5.1), which changed to 24.0 mm (± 5.0) postoperative.

The mean vertebral height in the VT group changed from 18.0 mm (± 5.0) to 21.4 mm (± 4.9). This difference was statistically significant with $p < 0.05$.

Our goal was to include all 121 patients in a telephone survey. Unfortunately, 26 patients had already died at the time of the questionnaire, 15 from the osteoporotic group, and 9 from the cancer group. 25 patients did not answer by telephone. Finally, 70 patients (52 OF group, 18 VT group) were included in the survey and answered the ODI. The Mann-Whitney-U test revealed no influence of the kyphosis correction to the degree of disability. The Spearman correlation showed a p -value > 0.05 in the VT and in the OF group. Therefore, our hypothesis that a better kyphosis correction by BKP would result in a better quality of life of the patients was not confirmed.

The degree of disability in the Oswestry index was 36.3% in the OF group and 21.5% in the VT group (Table 2). Due to the lower health status in the OF group, we found a significant better postoperative quality of life of the tumor patients compared to patients suffering for osteoporosis.

We found no effect of the applied volume of bone cement to quality of life in our groups. Mean applied cement volume was 2.61 ml (± 1.0). In 43 cases, less than 3 ml was applied and in 27 cases more than 3 ml was filled in the vertebra body. There was no statistical difference between patients who received more or less than



Figure 3: Male patient with a multiple myeloma TH12. Preoperative MRI T2 sequence shows the vertebral tumor destruction. The conventional radiographs show the postoperative results after balloon kyphoplasty and mobilization of the patient.



Figure 4: Male patient with an osteoporotic fracture of L2 (left). STIR-MRI (middle) confirms a bone marrow edema. The right picture shows the postoperative result after balloon kyphoplasty.

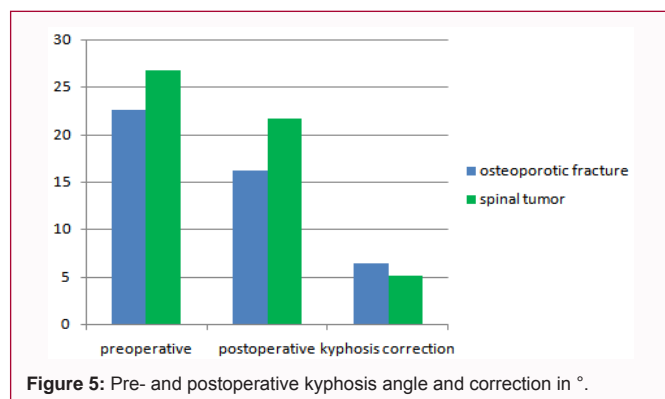
3 ml cement in the postoperative measured quality of life with the ODI.

Discussion

Although several studies about clinical results after BKP in osteoporotic fractures have been published, there is a lack in data comparing these data to cancer-induced vertebral fractures.

In our study, 121 patients (217 vertebral bodies) were enrolled. The higher incidence in women (females /males: 89/32) are corresponding to other studies and are a result of the epidemiology of osteoporosis. Ledlie et al. [3] investigated osteoporotic compression fractures and found 72% in females. Other investigators like Prokop et al. [7] included 31 patients undergoing surgery due to a metastatic vertebra and found 17 women and 14 men with an average age of 62 years [4].

Moreover, we found that the age of our probands was representative to those of other authors. At the time of surgery the average age was 72.5 years (± 10.4), 75.7 years (± 8.9) for the OF group and 65.3 years (± 9.9) in the VT group. Thus, a statistical age difference was found in both groups at time of surgery. Dudeney et al. [5] published their results of the investigation of patients treated with BKP in fractures due to spinal metastasis. They included 282 patients and found an average age of 63.5 years. No patients with osteoporotic fractures were examined [5]. Kohno et al reported postoperative complications after surgical treatment of osteoporotic spinal fractures. They found



an average age of 74.8 years which corresponds to our OF group with 75.7 years [6].

Elder patients typically experience vertebral compression fractures due to osteoporosis, while spinal bone metastasis or osteolytic lesions may affect significantly younger patients. It depends on the primary tumor and is not a result of growing age. In our study we found 54.1% patients with a multiple myeloma, 18.9% with a metastasis of a bronchial carcinoma and 13.5% with breast cancer. The mean operative time for all patients was 38 min (± 36.2) for one vertebral body. There was no statistic relevant difference between the VT group and the OF group (39.6 min vs. 34.5).

This is quite similar to the results of other studies [3-5]. Dalbayrak et al. [4] and Dudeney et al. [5] found an average operative time of 41 min and 35 min. They included 137 and 150 patients, respectively. Our results are corresponding to their documented operative time.

In our study, AP and lateral radiographs of 217 vertebral bodies were analyzed pre- and postoperatively. Predominantly, L1 and Th12 were fractured (16.1% and 15.7%). Prokop et al. [7] published a retrospective study with examination of 1069 patients and showed comparable results regarding the affected vertebra. This corresponds to data from SWISS spine™ published by Röder et al. [8]. 68.3% of their patients with an osteoporotic fracture were female and most of them occurred in the thoracolumbar junction between Th11 and L2 (71.8%). In that study, osteoporotic fractures and fractures caused by injury treated with BKP were enrolled but no tumor patients. Therefore, it is difficult to compare the clinical outcome with our findings. The authors described a higher pain relief for female patients than for male and concluded that patient's sex may influence postoperative pain levels. The authors also found that cement volume is a significant modifiable predictor for pain alleviation in BKP and they recommended cement volumes per vertebra of more than 4.5 ml to reach adequate pain relief Kaufmann et al. [9] found different results. In a retrospective analysis of 156 cases from one week to two years after surgery, they found no connection between pain reduction and the applied cement volume [9]. In addition, the group of Ioannou et al. [10] showed an improvement of pain and disability scores after BKP when low cement volumes were applied. However, the scientific impact of this hypothesis is low as only 20 patients were enrolled in their study. In our data we found no difference in postoperative outcome between patients with more or less than 3 ml cement volume.

In our opinion, pain reduction is caused by different factors and cement volume is just one of them. Another reason for pain relief might be the postoperative sagittal realignment, kyphosis correction

and restoration of vertebral body height. This is often discussed controversial in the literature. Pflugmacher et al. [11] discussed the influence of the postoperative kyphosis angle for pain reduction. Ma et al. [12] included 1081 patients and compared kyphoplasty (BKP) and vertebroplasty. In their opinion BKP is superior in restoring vertebral height and segmental kyphosis angle. However, there was no difference in postoperative pain scores and quality of life.

In our data, the VT group had a lower preoperative body height than the OF group (18.0 mm vs. 20.4 mm).

We found an average restoration of vertebral height of 3.8 mm (± 2.8 , 16.6%) for all patients. In the OF group it was 3.9 mm (16.7%), in the VT group it was 3.4 mm (16.2%). Comparable data were published by Pradhan et al. [13] who published an average vertebral body restoration of 18.2%.

Our results showed no significant difference of both groups with regard to the restoration of the vertebral height. The hypothesis that one of the two groups might benefit more cannot be confirmed.

We found a kyphosis reduction of 6.0° (± 3.89) in all patients. The correction in the OF group was 6.4° (± 4.1) and in the VT group it was 5.1° (± 3.3). The statistical analysis showed no relevant differences but higher correction values in the OF group. Schofer et al. [14] described a kyphosis reduction of 5.5° in patients with an osteoporotic fracture [14] whereas Gaitanis et al. [15] described an angle correction of 7.6°. Both investigators included osteoporotic vertebral fractures but there is still no evidence for the optimal degree of height restoration to significantly improve pain, function and quality of life.

The postoperative quality of life was measured with the ODI in our data. The VT group showed better postoperative results than the OF group. Figure 5 summarizes our investigations. Dalbayrak et al. [4] reviewed clinical data after kyphoplasty in patients with vertebral compression fractures due to spinal metastasis and multiple myeloma and tried to determine factors that may influence the outcome. For this purpose, the authors used the Visual Analog Scale (VAS) and also measured radiological heights. Other than us, they detected a correlation between quality of life and the restoration rate of the vertebral body. However, according to our results they did not see a correlation between the cement volume and the symptoms [10].

Complications of BKP like pulmonary embolism, radiculopathies, subsequent vertebral fractures or cement leakage are described in the literature from different authors [16,17].

Fourney et al. [18] recommended small cement volumes and high viscosity cement to avoid leakage complication. These data corresponds to Dudev et al. [5] who found similar results. They prospectively evaluated the safety and efficacy of BKP in the treatment of osteolytic vertebral fractures resulting from a multiple myeloma. The authors found no major complications in their study group. We also did not find major complications in our groups. Dudeney et al. [5] described a cement leakage rate of 4% and a significant improvement of SF 36 scores, physical function, vitality and social functioning with a follow up of 7.4 months.

In our data we found superior quality of life in the VT group in comparison to the OF group in the latest follow up. We saw no influence of the applied cement volume or the restoration of the vertebral height on the ODI results. There was only a difference between the average age of the two groups and this might be a relevant factor in the postoperative outcome for the patients.

Conclusion

BKP is an effective and safe treatment option in the therapy of osteoporotic fractures and an established surgical therapy of osteolytic spinal lesions or cancer related spinal pain. There is an early and late clinical improvement of pain and function but the extent of the applicated cement volume and its influence on the kyphosis correction and restoration of vertebral height still remains unclear and further investigations are needed.

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