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Kyphoplasty Increases Vertebral Height, Decreases Both Pain Score and Opiate Requirements While Improving Functional Status

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Abstract

Vertebral compression fractures can result from advanced osteoporosis, or less commonly from metastatic or traumatic insults to the vertebral column, and result in disabling pain and decreased functional capacity. Various vertebral augmentation options including kyphoplasty aim at preventing the sequelae of pain and immobility that can develop as the result of the vertebral fractures. The mechanism for pain relief following kyphoplasty is not entirely understood, and the restoration of a portion of the lost vertebral height is a subject of debate. We retrospectively reviewed radiographic imaging, pain relief, analgesic intake and functional outcomes in 67 consecutive patients who underwent single- or multilevel kyphoplasty with the primary goal of quantifying the restoration of lost vertebral height. We observed a mean of 45% of the lost vertebral height restored postprocedurally. Secondly, kyphoplasty was associated with significant decreases in pain scores, daily morphine consumption and improvement in patient-reported functional measures.

Keywords

vertebral compression fracture; kyphoplasty; percutaneous vertebral augmentation; vertebral height restoration; kyphosis; osteoporosis

INTRODUCTION

Vertebral compression fractures (VCFs) occur in approximately 700,000 individuals per year in the United States and in approximately 1.4 million per year in Europe; typically, elderly patients are affected, often resulting in marked functional impairment.^{1,2} Only one-third of those affected seek medical attention.³ While the presentation of VCFs varies based upon the level affected, patients often report discrete onset axial back pain after lifting or bending, at times radiating ventrally into the abdomen or into the lower extremities. Pain is generally related to mobility; therefore, these patients tend to avoid any activities, get

depressed, and lose independence. Physical examination may reveal tenderness over the spinous processes, loss of the lumbar lordosis, and a decrease in overall height.

The development of VCF often indicates advanced osteoporotic or neoplastic disease and warrants a multidisciplinary approach to correct bone loss or treat the metastatic process in addition to providing pain control. The risk of developing subsequent VCFs increases exponentially as more vertebral bodies become affected, underscoring the importance of a comprehensive treatment strategy. After acquiring a single fracture, the incidence of subsequent VCFs increases fivefold, with a 12-fold increase after two VCFs, and a 75-fold increase after three or more VCFs in patients with persistently low bone density.⁴ Perhaps as concerning as the VCFs itself are the sequelae of immobility that follow, including restrictive lung disease, gastrointestinal dysfunction, depression, and mood changes.^{5–8}

Despite the lack of a randomized control trial demonstrating the efficacy of oral analgesics, an oral opiate combined with acetaminophen is a widely prescribed first-line choice for patients with VCFs. Supplemental treatments including bisphosphonates, calcitonin, and parathyroid hormone have been shown to offer modest benefit in pain control and some functional improvement.^{9–11} For those who are intolerant to the side effects of conservative approaches, or those who have failed to achieve pain control or attain functional improvement, kyphoplasty represents a minimally invasive adjunct.

Since its introduction, kyphoplasty has gained widespread recognition as a successful modality for reducing pain, improving functional measures, and improving quality of life.^{12–26} The mechanisms underling the observed clinical success are less obvious, with uncertainty whether the clinical outcomes are attributable to correcting the local vertebral deformity or addressing the regional kyphotic deformity that results. Pradhan and colleagues radiographically demonstrated that one-, two-, or three-level kyphoplasty restores treated vertebral height, but does not correct the overall sagittal kyphosis of the spine.²⁷ The importance of the radiographic restoration in vertebral height has thus far not been correlated with clinical outcomes. We sought to quantify the restoration of the individual vertebral height and assess whether there is an association with pain relief, decreased reliance on analgesics, or improvement of the daily functional activity.

METHODS

Following institutional review board approval, demographic, historical, radiographic imaging, and outcomes data were extracted retrospectively from the electronic medical record at our tertiary care, academic referral center. Sixty-seven consecutive patients with VCF who underwent the kyphoplasty procedure using Kyphon® (Medtronic, Memphis, TN, U.S.A.) balloon kyphoplasty system were included in the analysis. The age of the vertebral fractures varied between 3 and 12 months. All patients were symptomatic at the site of the fracture, with increased pain with any activities that involved the lumbar and thoracic spine such as walking, standing, turning, or getting in and out of bed. All procedures were performed by one physician (NM), thereby eliminating variability in operator experience.

Both on the day of intervention and on the first postprocedural visit (average 4 to 5 weeks), daily analgesic use was quantified by patient report. Using an equianalgesic conversion table, opiate intake was converted to oral morphine equivalents per day.²⁸ Nonopiate analgesics were not considered for the purposes of this study. Activity level was quantified using a 5-point Likert-type scale where patients indicated postprocedural function had significantly worsened, mildly worsened, was unchanged, mildly improved or significantly improved.²⁹ Pain level was assessed using a verbal response pain (0 to 10) scale, both at baseline and at the first postoperative visit.

Kyphoplasty was performed under general anesthesia using simultaneous anterior-posterior and lateral biplanar fluoroscopic guidance. An 11-gauge working channel was passed through the pedicle in the lumbar, or extrapedicular in the thoracic levels, and into the vertebral body. A precision drill was then advanced through the cannula to create a channel that extends to the junction of the anterior and middle third of the vertebral body. The kyphoplasty balloon was then inserted into the channel and gradually inflated to create an intervertebral cavity. Under fluoroscopic guidance, semi-solid polymethylmethacrylate cement mixed with radiopaque contrast was injected under low pressure into the newly created cavity.

An investigator unaware of the study aims assessed vertebral height retrospectively. Due to the radiopaque characteristics of the injected polymethylmethacrylate mixture, blinding pre- and post-treatment images was not possible. Measurements of the vertebral body heights were quantified from archived lateral fluoroscopic images obtained during the procedure. The point of maximal vertebral body compression along the superior end plate was defined. From this point, a perpendicular dropped to the inferior endplate was measured, and this distance was defined as the minimum height. Percent height loss calculations were obtained as the difference between the height measured at the compressed area and the height of the posterior wall of the same vertebra to account for potential variations in radiographic magnification. The same measurements were obtained after the kyphoplasty and used to report the percent of height regained. Final height restored calculations were quantified using the following formula:

$$\% \text{height restored} = 1 - \left[\frac{\left(\frac{\text{minimum vertebral height preprocedure}}{\text{posterior wall height preprocedure}} \right)}{\left(\frac{\text{minimum vertebral height postprocedure}}{\text{posterior wall height postprocedure}} \right)} \right]$$

Statistical Methods

Baseline characteristics were summarized using standard univariable statistics (mean and standard deviation, median and quartiles, or proportions, as appropriate), and outcome data were summarized graphically.

Mean pain verbal response scores (VRS) were evaluated preliminarily by estimating the mean and 95% confidence interval of the difference in scores across the sample. However, this univariable result did not take into account variations in patient's baseline pain scores and comorbidities. Thus, the final evaluation of the mean VRS pain score reduction was made within a multivariable linear regression model, which adjusted for certain baseline factors (Table 1). Decrease in daily morphine equivalent dosage was analyzed in a similar fashion.

Restored vertebral body height was expressed as a percentage of increased vertebral height from baseline. This outcome was analyzed using a linear mixed effects regression model that accounts for the correlation among repeated measurements made on multiple vertebrae within a given patient. Within this multivariable model, we adjusted for the same baseline values as in our analyses of VRS pain reduction and reduction in daily opioid intake, as well as the baseline percent vertebral height loss for each observation.

R statistical software version 2.15.2 for 64-bit Unix operating system was used for the primary analysis. Wald tests for regression model coefficients, with significance level fixed at 0.05, were used for all tests.

RESULTS

One hundred eighteen vertebral bodies in 67 consecutive patients were treated with kyphoplasty for VCFs suffered from osteoporotic ($n = 61$), traumatic ($n = 3$), or metastatic ($n = 3$) etiologies. The majority (68%) were women with a mean age ($\pm$ standard deviation) of 74 years (± 10). Demographic data are summarized in Table 1. While a single VCF was found in the majority (75%) of patients, two (22%) or three contiguous levels (3%) were treated simultaneously if multiple fractures were present.

Raw data and univariable summary information on VRS pain scores before and after kyphoplasty are given in Figure 1. The figure indicates that VRS pain scores generally declined, with median [first quartile, third quartile] estimates of 7.5 [6.0, 9.0] points and 4.0 [2.0, 5.0] points before and after the procedure, respectively. After adjusting for potential confounding factors within a multivariable linear regression model, mean (95% confidence interval) VRS pain score reduction was estimated at 3.9 (3.3 to 4.5) points, which was significantly different from zero ($P < 0.001$, Wald test). Activity level improvement (Table 2) showed that 82% had some improved functionally while 18% of patients reported no change.

Percent loss of vertebral body height before and after the procedure is summarized graphically in Figure 2. Restoration of some of the vertebral body height was observed in 116 of 118 vertebrae treated. The two patients who did not show any improvement of the vertebral height were symptomatic although their fractures were 12 months old. Prior to the procedure, median [first quartile, third quartile] estimates of percent loss of vertebral body height were 40% [29%, 50%]; after the procedure, these estimates were 22% [15%, 28%]. Based on the multivariable linear mixed effects regression model, vertebral body height was significantly increased after holding the other variables constant ($P < 0.001$, Wald test); the adjusted mean (95% confidence interval) restoration of the vertebral height loss was estimated at 45% (40% to 50%).

Baseline daily morphine equivalent dose for one patient was unavailable. For the multivariable models of VRS pain score and percent loss of vertebral body height (but for the model of opioid requirements), this data element was imputed using the observed median (which was 40 mg/day). Four patients with missing postprocedure data on daily opioid dosage were removed from the analysis of opioid requirements. Dosage amounts at baseline and after the procedure among the remaining 62 patients are shown in Figure 3. Median [first quartile, third quartile] oral morphine equivalent dosage was 40 [0, 60] mg/day at baseline and 30 [0, 40] mg/day after the procedure. After adjusting for the other baseline characteristics, the estimated mean (95% confidence interval) reduction in daily opioid dosage was 7 (4 to 11) mg/day, which was statistically significant ($P < 0.001$, Wald test).

Activity level after the kyphoplasty was assessed by patient report at the first postprocedural visit (average 4 to 5 weeks). Data were unobtainable for four patients. Of the remaining patients, 11 (18%) reported no change in activity level, 38 (61%) reported moderate improvement, and 13 (21%) reported significant improvement.

DISCUSSION

Kyphoplasty restored some of the radiographic vertebral deformity in all but two of the 118 treated vertebrae, and was associated with improvement in function and decrease in both pain scores and opiate intake. Improvements were realized by the first postprocedural visit, indicating that convalescence was brief. There were no procedure-related complications in the study population, although local cement leakage resulting in neural compression, and

pulmonary polymethylmethacrylate embolism leading to morbidity and mortality, has been described in the literature.^{30,31}

Well-established standards to quantify the percentage of the vertebral height regained following kyphoplasty are lacking. Various investigators have quantified spinal deformity as percent restoration of vertebral body height previously lost and percent vertebral body height increase or degree of correction of the resultant angular deformity.^{32–34} In our cohort, measurable increases in vertebral height were observed in 98% of treated vertebral bodies, which was more frequent than 58% to 92% observed by other investigators.^{33,34}

Percent loss of vertebral height before and after treatment is illustrated graphically in Figure 2, with an observed mean increase in height of 45% attributable to the procedure. Lieberman reported a similar observation of 47% restoration of vertebral height in 49 fractures using the adjacent vertebral body as a reference measure.³² Our measures employed the ratio between the point of maximal vertebral body compression to the ipsivertebral posterior wall height rather than adjacent vertebral body height for quantification of the percent restoration calculations. This methodology accounts for the possible anatomic variability in the size of adjacent vertebral bodies and the variability of image magnification. Elucidating whether or not the use of the ipsivertebral posterior wall method caused an overestimation or underestimation of the percent height calculations would not be possible without comparative imaging obtained before development of the VCF.

Our study is retrospective in nature; thus, there is a potential that unobserved confounding variables might have affected our results. Further, in our case series, we could not exclude the possibility of placebo effects on pain, opioid intake, and activity scores. Despite the potential of randomized allocation to either kyphoplasty or a sham procedure for reducing any placebo effects in a future trial, avoiding the possibility of measurement bias in such a trial would be difficult as the radiopaque characteristics of the injected polymethylmethacrylate mixture would make treatment allocation immediately evident to the observer. In our study, vertebral body height measurements were at least performed by an investigator who at the time was blinded to the study altogether.

The mechanisms underlying pain relief following kyphoplasty remain a subject of debate, but are likely multifactorial, owing at least in part to restoration of vertebral body height, but perhaps also to reduced vertebral body compliance at microfracture sites, direct neurotoxic effects of the polymethylmethacrylate or heat-induced neurolysis which occurs during cement polymerization.³⁵ Elucidating the role of these mechanisms and characterizing any treatment-related vertebral height response relationship remain an area for further research. The current study, being retrospective in nature, could not find any correlation in statistical fashion between the vertebral height restoration and the age of the fracture, although anecdotally the only two patients who did not have any improvement in the vertebral heights after kyphoplasty were having symptomatic but relatively old fractures.

In spite of these limitations, there was a consistent association between restoring local vertebral height after kyphoplasty and significant decreases in VRS pain scores, improved functionality and decreased reliance on opiate analgesics, underscoring the continued role of this minimally invasive technique for the management of VCF.

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Figure 1.

Verbal response scale (VRS) pain scores, before and after kyphoplasty. Boxplots display the minimum, first quartile, median, third quartile, and maximum of each sample. To reduce over plotting, line widths varied in proportion to the number of patients with each pair of baseline and postkyphoplasty values; the thickest line represents $n = 5$.

Figure 2.

Raw data on percent loss of vertebral height, before and after kyphoplasty. Arrows indicate change in the vertebral height from baseline to postkyphoplasty. There were two observations for which no change was observed; these are indicated by dots on the figure. Results are displayed by vertebral level.

Figure 3.

Daily opioid requirements, before and after kyphoplasty. Results expressed in oral daily morphine equivalents (mg). Boxplots display the minimum, first quartile, median, third quartile, and maximum of each sample. To reduce over plotting, line widths varied in proportion to the number of patients with each pair of baseline and postkyphoplasty values; the thickest line represents $n = 17$.

Table 1**Baseline Characteristics of 67 Patients Undergoing Kyphoplasty**

Factor	Statistics
Age [*] (years), mean $\pm$ SD	74 $\pm$ 10
Female gender [*] , <i>N</i> (%)	45 (67)
Diagnosis	
Osteoporosis, <i>N</i> (%)	61 (91)
Trauma, <i>N</i> (%)	3 (4)
Cancer, <i>N</i> (%)	3 (4)
Number of levels [*] , <i>N</i> (%)	
1	50 (75)
2	15 (22)
3	2 (3)
Baseline VRS pain score (0 to 10) [*] , median [Q1, Q3]	8 [6, 9]
Baseline daily opioid dose ^{*†‡} , median [Q1, Q3]	40 [0, 60]

^{*} These variables were used for adjustment in our multivariable regression models; diagnosis was not used due to small cell sizes.

[†] Reported in mg oral opioid equivalent dose.

[‡] Baseline daily opioid dosage unavailable for one patient.

Table 2

Report of 62 Patients' Improvement in Activity Level Following Kyphoplasty

Significant improvement	21%
Improvement	61%
No improvement	18%