

Retrospective Analysis of Correlative Factors Affecting Kyphosis Angle Reduction of Osteoporotic Vertebral Compression Fractures with Kyphoplasty

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ABSTRACT

AIM: The aim of this retrospective study was to evaluate the correlative factors that affect vertebral kyphotic angle reduction with kyphoplasty.

METHODS: This retrospective study was carried out from the Affiliated Hospital of Jiangsu University, Jiangsu, China. One hundred and thirty patients with single-level osteoporotic vertebral compression fracture, undertook kyphoplasty between April 2013 and March 2016 in our institution, were examined and followed to a maximum of one year. An established seven hypothetic independent factors such as; patient variables (Age, Sex), fracture variables (Level, Age and Pre-operative kyphotic angle), and surgical variables (total cement volume, amount of cement leaked) cum kyphotic angle reduction as a dependent variable. Univariate and multivariate linear regression statistic were used to correlate the association between these variables and kyphotic angle reduction. Data processing and analysis were carried out in SPSS 16.0. Results were deemed significant at the 0.05 level ($p < 0.05$).

RESULTS: Statistical significance occurred in the kyphotic angle immediate postoperative and the final follow-up compared with the

preoperative values. Univariate analyses indicated a correlation of kyphotic angle reductions with cement volume used, cement volume leaked and pre-operative kyphotic angle. A final multiple linear regression model indicated a correlation between kyphotic angle reductions with cement volume used and pre-operative kyphotic angle. The conclusive multilinear regression model with all predicted independent variables amounted to a formula that account for 12% of variability in kyphotic angle reduction; pre-operative kyphotic angle ($b = 0.195$, $p = 0.022$) and cement volume ($b = -0.194$, $p = 0.024$).

CONCLUSION: The preoperative kyphotic angle and cement volume used are the major predictors of kyphotic angle reduction postoperative.

Key words: Kyphoplasty; Osteoporotic vertebral compression fractures (OVCFs); Kyphosis; Polymethylmethacrylate

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INTRODUCTION

Osteoporotic vertebral compression fractures (OVCFs) are a product of complication of osteoporosis and place the afflicted patient into a state of intractable agony of pain, functional disability and jeopardy of survival. The incidence of OVCFs is rising astronomically over the years, dominantly among the elderly with high predilection for women notably postmenopausal women. The economic burden on national health care and family care for many of these OVCFs patients enduring hard pain and sometimes functionally disable can no longer be underestimated.

Vertebroplasty is a most widely applied clinical technique for relieving pain caused by OVCFs, but it neither restore the vertebral body height nor correct kyphotic deformity. Kyphoplasty, which was derived from vertebroplasty, aid in normalizing the kyphotic angle

and reduces kyphosis thus resulting in an esthetic improvement, improved posture and mitigate the risk of fracture of the adjacent vertebral due to any abnormal load bearing and pain. The cost effectiveness of these procedures has been topical, some literature reported that the procedures appear to be cost effective. Perhaps, if you factor in time frame, treatment effect, less days in bed and mortality especially in the long-term, our conclusion is, cost effectiveness is uncertain. That notwithstanding, a lot of studies including Civelek *et al*^[1], Atalay *et al*^[2], Saxena BP *et al*^[3] suggests that kyphoplasty is an effective and safe procedure for patients with OVCFs.

However, few studies have been focused on the correlative factors affecting kyphotic angle reduction with kyphoplasty. Attaining an optimal kyphotic angle reduction postoperative is central to the overall effectiveness of the procedure. The objective of our study was to evaluate the correlative factors that affect vertebral kyphotic angle reduction with kyphoplasty.

MATERIALS AND METHODS

Ethics

All procedures performed in this study involving human participants were in accordance with the ethics committee of the Affiliated Hospital of Jiangsu University. All authors abided by the ethical standards. Inform consent both written and oral was obtained from all patients included in this study.

Patients

The research evaluated one hundred and thirty patients with single-level OVCFs who took the procedure at the Affiliated Hospital of Jiangsu University, Zhenjiang in the period between April 2013 and March 2015. Patients were included in the study if they met the following criteria: Osteoporotic based on their BMD score, spine radiographs showing vertebral compression fractures (Genant's grade 1 or better), fracture at T7 or lower and establishing that the fracture is the possible pain trigger by comparing the physical findings with the fractured vertebral on T2 weighted fat suspension magnetic resonance imaging.

Patients were excluded from the study if they had a traumatic fracture in the absence of osteoporosis, any pathologic compression fracture, multiple vertebral fractures, osteoporotic fractures with associated neurologic deficits and spinal cord compression. The fracture age was determined by the time between the point of inception of symptoms and the date of surgery.

Kyphoplasty technique

All the patients who underwent the procedure were first laid in a prone position on a surgical table with the spine extended by chest and pelvic bolsters. The patient's skin was incised, then an eleven-gauge needle was percutaneously inserted into the posterior section of the vertebral body through a bilateral transpedicular approach. In the operating channel of the vertebral body, a (kyphon) inflatable bone tamp was percutaneously advanced bilaterally into the collapsed vertebral body. The bone tamps were then inflated with manometric control thus elevating the depressed endplates creating a central cavity, and compacting the remaining trabeculae to the peripheral, the degree to which the height of the vertebral body and the angulation of the depressed endplates are corrected to, vary from case to case. The maximum volume of the balloon and the pressure required for inflation determined the inflation of the balloon, and therefore, the degree of height restoration, once height is improved,

the balloon catheters are subsequently deflated and withdrawn, the cavity is then filled under low pressure with viscous preparation of polymethylmethacrylate cement. This was done under a strict visual control to attain sufficient filling and avoid possible extravasation of cement. To determine the occurrence of cement leakage outside of the vertebral body, intraoperative fluoroscopy and postoperative radiographs were employed.

Radiographic analysis

Kyphosis was determined by estimating the kyphotic angle between the base plate of one normal vertebrae below the fractured vertebrae and the cover plate of one normal vertebrae above the fractured vertebrae in a fashion where the fractured vertebrae is sandwich between two normal vertebrae. Kyphotic angle reduction was computed by the difference between postoperative kyphotic angle and preoperative kyphotic angle.

In quantifying the fracture severity, the following grading according to Genant *et al*^[4] was employed; Grade 1 < 25% collapse; Grade 2, 25-40% collapse; Grade 3, 40-67% collapse; Grade 4 > 60% collapse.

Statistical analysis

SPSS version 16 software (SPSS, Inc, Chicago, Illinois) was the software engaged in the analysis. The radiographic and clinical data differences pre and post-operative were analyzed using a paired *t*-test.

Seven independent variables were included; patient variables (Age, Sex); fracture variables (fracture level, fracture age, and preoperative kyphotic angle) and surgical variables (total volume of cement injected and cement leakage). The dependent variable was the kyphotic angle reduction. Univariate analyses were carried out to assess the correlation between independent variables and the dependent variable. Pearson product-moment correlation coefficient (*r*) and spearman rho correlation coefficient were used to determine correlation between continuous variables and non-parametric variables respectively. A multivariate linear regression analyses involving all predicted independent variables (*p* values less than 0.05) in the univariate analyses were conducted to identify the factors associated with kyphotic angle reduction as dependent variable. A backward stepwise method was used to test all predictor variables.

RESULTS

A total of one hundred and thirty subjects were enrolled, comprising of one hundred and eight women and twenty two men with an average age of 68.34 ± 6.87 years. The mean of the fracture age was 35.20 ± 36.1 days and kyphotic angle reduction was 3.97 ± 1.63°. A little amount of polymethylmethacrylate leaked in twenty three subjects without associated clinical symptoms, pulmonary embolism, or infection, as indicated in Table 1.

Mean ± SD postoperative kyphotic angle was 11.9 ± 3.1° elaborating quite a significant improvement compared to preoperative kyphotic angle 15.9 ± 2.9° as indicated in Table 2.

Likewise in Figure 1. Lateral radiograph of 73 years old man with L2 vertebral compression fracture treated after 5 days debilitating pain, kyphotic angle improved from 22° (a) preoperative to 16° (b) postoperative. Lateral radiograph of 82 years old man with L1 vertebral compression fracture treated after 3 days debilitating pain, kyphotic angle improved from 16° (c) preoperative to 9° (d) postoperative. All patients had improved kyphotic angle reduction postoperative compared to preoperative values.

Univariate analysis reflected that kyphotic angle reduction was

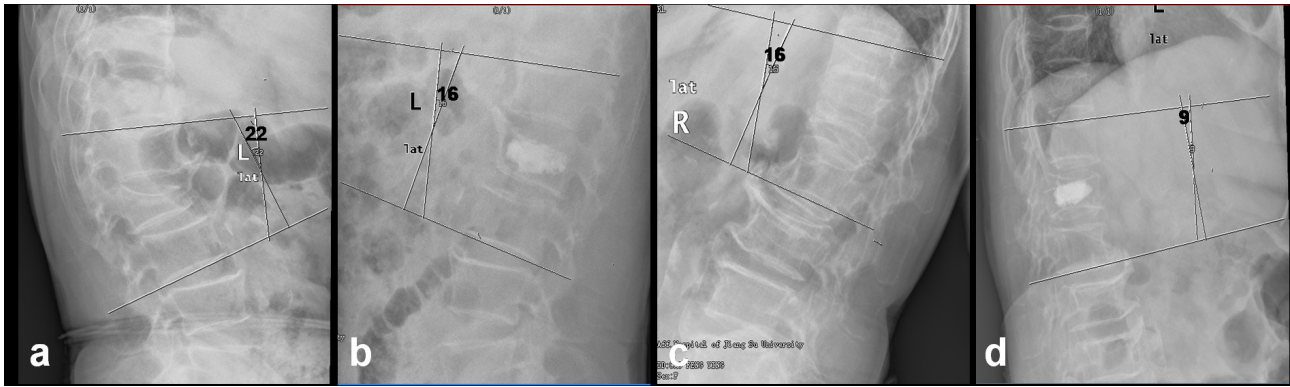


Table 1 Total subjects variables (*n* = 130).

Variable	Value
Age (yrs)	68.34 ± 6.87
Sex (F:M)	108: 22
Fracture age	
< 6wk	74 (56.90%)
6-12wk	22 (16.90%)
> 12wk	34 (26.20%)
Fracture severity grade, No. (%)	
1. (20-25)	39 (30%)
2. (25-40)	45 (34.6%)
3. (40-65)	38 (29.20%)
4. (> 45)	8 (6.20%)
Fracture location, No	
T7-T10	10
T11-L2	107
L3-L5	13
Total injected cement volume(mL)	4.52 ± 0.09
Cement leakage, No. (%)	23 (17.70%)
Kyphotic angle reduction(°)	3.97 ± 1.63

Table 2 Kyphotic angle at different observed times.

Data	Preoperative	Postoperative	Follow up
Kyphotic angle(°)	15.9 ± 2.9	11.9 ± 3.1*	11.7 ± 2.2*

**p* <0.05 compared with preoperative value.

correlated with preoperative kyphotic angle (*r* = 0.228; *p* = 0.009) cement volume (*r* = -0.231, *p* = 0.008) and cement leaked (*r* = -0.206, *p* = 0.019) depicted in Table 3. No correlation coefficient between independent variables (age, sex, fracture level, fracture age, preoperative kyphotic angle, cement volume or cement leakage) was greater than 0.8, therefore, multicollinearity was not evident. Using enter method, the final multiple linear regression model, which included only correlated predictive variables in the univariate analyses. Preoperative kyphotic angle and cement volume were significant culminating in a formula that accounted for 12% of the variability in kyphotic angle reduction; preoperative kyphotic angle (*b* = 0.195; *p* = 0.022) and cement volume (*b* = -0.194, *p* = 0.024) presented in Table 4.

DISCUSSION

The discourse on the optimal efficacy of kyphoplasty procedure is well debated and documented. From the current study, the immediate postoperative outcomes are significant. The Mean ± SD kyphotic angle, literally represent a significant improvement postoperative in comparison with preoperative values, this is attributable to the procedure, with the elevation of the endplates and augmentation of the height result in stabilizing the fracture fragments thereby reducing or eliminating pain and promoting healing as well as

Table 3 Predictors of kyphotic angle reduction univariate analysis.

Variable	Variable correlation Coefficient (<i>r</i>)	<i>p</i>
Patients Variables		
Age	0.005	0.954
Sex	-0.148	0.093
Fracture variables		
Level	-0.166	0.059
Age	0.036	0.686
Preoperative kyphotic angle	0.228*	0.009*
Surgical variable		
Cement volume	-0.231*	0.008*
Cement leakage	-0.206*	0.019*

*Indicates statistical significant finding.

Table 4 Predictors of kyphotic angle reduction multivariate analysis.

Predictor	Partial regression coefficient	Standard coefficientβ	<i>p</i>	<i>R</i> ²
Preoperative				
kyphotic angle	0.107	0.195	0.022	0.120
Cement volume	-0.340	-0.194	0.024	

correcting the kyphosis deformity. Kyphosis reduction is a cardinal goal of vertebral augmentation, achieving an optimal kyphotic angle reduction postoperative is paramount to improving preoperative kyphosis deformity. Many studies^[5-6] reported optimal kyphotic angle reduction as well as visual analogue scale and Oswestry disability index scores postoperatively.

In the present research, two independent variable preoperative kyphotic angle and cement volume were significant factors that impacted on kyphotic angle reduction, it therefore implies that kyphotic deformity correction was improved in association with the degree of preoperative kyphosis and the amount of injected cement volume. The bonecement is a vital component of the new vertebral body construct to provide strength, stiffness and maintained augmented height of the vertebral body. A reasonable volume of cement is required depending on the fracture severity grade on case to case basis, usually, the balloon volume is predictive of the cement volume as such we obtained better kyphosis angle reduction with sufficient bone cement volume. Preoperative kyphotic angle association with kyphotic angle reduction could be as a result of the prevertebral muscles and ligaments condition in the fractured vertebral. The more compress the vertebral as it is the case in the fractured vertebral, the more relax are the muscles and ligaments thereby posing less biomechanical resistance during the procedure as such we obtained improved kyphotic angle correction in subjects whose preoperative kyphotic angle were greater. Belermann *et al*^[7] also reported there was a potential for kyphotic angle reduction correlated to the preoperative kyphotic angle, this is consistent with our findings. Kyphotic deformity restrict respiratory function causing

declines in pulmonary function and directly related to the degree of kyphosis and the number of vertebral fractures, kyphoplasty improve the respiratory function^[8-10].

The follow-up study of patients showed no significant difference between the postoperative values and the follow-up values. The author's however observed that in a subset of patients, there was a significant decreased kyphotic angle, but no significant change in the kyphotic deformity. Secondly a subset had adjacent vertebrae fracture. Fracture of adjacent vertebrae and the risk are well recorded in many literatures^[11-15]. The fracture of the subsequent adjacent vertebral is premised on the weak osteoporotic vertebrae and the physics of load-bearing distribution been altered creating abnormal stress points on the adjacent vertebral. However, the issue of incidence of recurrent fracture after kyphoplasty is a controversial one. It is difficult to say if recurrent fracture is due to surgical intervention or the natural history of disease process, osteoporosis^[16]. Mudano AJ *et al*^[17] reported that, risk of subsequent fracture was significantly greater among treated patients, especially within 90 days of the procedure, on the contrary, Villarrage ML *et al*^[18] suggested a subsequent fracture was due to the underlying etiology rather than surgical intervention. There is still the augment that kyphoplasty alone do not influence the incidence of subsequent vertebral compression fractures Civelek E, Cansever T, Yilmaz C, *et al*^[1].

Liu *et al*^[19] reported on long-term follow-up to verify the clinical outcomes of kyphoplasty and vertebroplasty in which they observed 100 cases of vertebral compression fractures, with a follow-up period of 5 years they noted that kyphotic angle correction among others was not evidently altered contrary to what we observed in some patients in our follow-up study.

The limitations of the study were diverse, for instance, in some patients with lower back pain, the exact time that a fracture occurred could not be established with ease. Nonetheless, we can also conclude that prognosis of kyphotic angle reduction with kyphoplasty can be predicted with preoperative kyphotic angle and volume of cement injected.

CONFLICT OF INTEREST

Balaara Augustine (Author): Declares no conflict of interest, he has received no research grant, speaker honorarium, nor owns any stock and not a member of any committee. Xu Xiao Fang (Author): Declares no conflict of interest, he has received no research grant, speaker honorarium, nor owns any stock and not a member of any committee. Huang Young-Hui (Author): Declares no conflict of interest, he has received no research grant, speaker honorarium, nor owns any stock and not a member of any committee. Abdul Raheem (Author): Declares no conflict of interest, he has received no research grant, speaker honorarium, nor owns any stock and not a member of any committee.

Ethical standards

Ethical approval of human subjects: All procedures performed in this study involving human participants were in accordance with the ethics committee of the affiliated hospital of Jiangsu University. All authors abided by the ethical standards.

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