

## Efficiency of Balloon Kyphoplasty in the Treatment of Osteoporotic Vertebral Compression Fractures

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**Eighty-seven osteoporotic vertebral fractures of 82 patients were treated with balloon kyphoplasty. Preoperative, postoperative and follow-up outcomes of functional impairment, pain scores and vertebral height restorations of the patients were recorded and evaluated statistically.**

Seventy-two of the patients were female (87.8%) and 10 (12.2%) were male. Mean age of all patients were 66.4 years. Preoperative mean Anterior Vertebral Body Height of  $48.20 \pm 13.94$  % and Middle Vertebral Body Height of  $59.40 \pm 14.26$  % were recorded as  $79.91 \pm 9.50$  % and  $86.90 \pm 8.38$  % respectively postoperatively and noted to be  $73.26 \pm 8.59$  % and  $84.65 \pm 8.19$  % at last controls respectively. The mean Oswestry Disability Index and Visual Analog Pain Scale also improved significantly. Local Kyphosis of all the patients were also evaluated and a significant improvement was noted postoperatively.

The long term results of this study suggest that balloon kyphoplasty is an effective and safe treatment option in osteoporotic vertebral fractures and should be considered for functional improvement, pain relief and height restoration.

### INTRODUCTION

Vertebral compression fractures are a serious debilitating complication of osteoporosis. The exact rate of vertebral compression fractures due to osteoporosis is not reported in western countries but in United States, over 700.000 compression fractures are reported per year [1-2]. Progressive bone mineral loss especially in elderly people causes decreased strength to axial forces on the vertebral column and may result osteoporotic compression fractures often after a minimal or no trauma [3]. This process leads to changes in spinal biomechanics and usually kyphotic deformity [4]. Pain and spinal deformity causes decreased quality of life, significant decline in lung capacity, changes of mood, depression and increased medical costs [5-15].

Conservative treatment of osteoporotic vertebral compression fractures consists of bed rest, narcotic analgesics and bracing [16]. However prolonged conservative treatment can also alter the patients' clinical status negatively leading further demineralization and may predispose further osteoporotic fractures [17-18]. On the other hand open surgical intervention is also less desirable because of associated co-morbidities [19-20].

Vertebroplasty and kyphoplasty are two minimally invasive treatment options in patients with symptomatic osteoporotic vertebral fractures [21-22]. Vertebroplasty was first introduced in 1987 by Galibert et al involving injection of less viscous cement in to the fractured vertebra [23]. Kyphoplasty was introduced in 1998 involving the inflation of balloon introducing percutaneously to restore vertebral height followed by injection of more viscous cement under low pressure. A high success in clinical outcome as well as restoration of vertebral body height have been reported with kyphoplasty [24-27].

### MATERIALS AND METHODS

Eighty-seven osteoporotic vertebral fractures of 82 patients were treated with balloon kyphoplasty. Pre-operatively all the patients were evaluated with a detailed history, and physical examination. Next antero-posterior and lateral plain radiograms of the fractured site, Bone Mineral Densitometry (BMD) and Magnetic Resonance Imaging (MRI) of the patients were taken. All the patients were evaluated with Oswestry Disability Index (ODI) and Visual Analog Scale (VAS) to access pain status preoperatively, postoperatively and at the last controls. Balloon kyphoplasty procedure was performed to patients in acute, edema phase or incompletely healed fractures not exceeding 2 months.

In radiological evaluation anterior vertebral body height (AVBH), mid-vertebral body height (MVBH), and posterior vertebral body height of the fractured vertebra (PVBH) were measured preoperatively, postoperatively and at the follow up. Radiograms were taken from 120 cm to eliminate magnification in all patients. Dimensions of the index vertebra, AVBH, MVBH and PVBH were expressed as percentage of the analogous dimension of the referent vertebra: (fractured vertebral height/mean adjacent referent vertebrae height) x 100. Local kyphosis (LK) angle is determined as the angle between the line parallel to superior endplate of one cephalad vertebra and the line parallel to inferior endplate of one caudal vertebra of the fractured vertebra.

MRI of the patients were examined and time of the trauma and edema phase in STIR phase were taken in care to consideration to plan kyphoplasty procedure. Time exceeding 3 months from the initial trauma or pain without trauma at the fracture sign or absence of edema in the fracture site were regarded as exclusion criteria for kyphoplasty procedure.

After clinical and laboratory examinations all kyphoplasty procedures were performed under general anesthesia in the operating room with the patient placed prone. All the procedures were performed with the same surgeon under biplanar fluoroscopic imaging. A Jamshidi needle was introduced percutaneously either transpedicular or extrapedicular bipedicular route depending on the fracture level and guidewires were placed meticulously under biplanar fluoroscopic control. Verifying the correct positions of the guidewires working canulas were placed through the guide wires and after reamerisation correct size of inflatable bone tamps (IBT) were placed and were inflated. The IBT's were then withdrawn and polymethyl metacrylate (PMMA) bone cement was filled to the vertebral cavity created with the ITB's with the use of filler devices. After settling the bone cement the working canula were removed. An antibiotic prophylaxis of 1 gram Cephazolin Sodium were administered preoperatively to the patients. All The patients were mobilized at the 1st postoperative day and discharged from the hospital. No braces or external support were applied to any patients. All the patients received an osteoporosis treatment at the follow-up and BMD's were screened routinely. All the patients were followed up for postoperative 2nd, 4th weeks, 3rd, 6th, 12th months and yearly till the last controls. Mean follow-up period was 49 months (71-24 months). All the procedures were performed under general anesthesia.

**Statistical Analysis:** Patients were evaluated clinically with Oswesrty Disability Index (ODI) and Visual Analogue Score (VAS) and preoperative, postoperative and follow-up (control) values of local kyphosis angle (LK), and anterior, middle and posterior vertebral body heights (AVBH), (MVBH), (PVBH) of the affected segments were measured and recorded. All the data were entered, checked for missing values and analyzed using SPSS version 11.0 (SPSS Inc., Chicago, IL, USA) and SAS version 7.0 (SAS Institute, Cary, NC, USA) statistical programs. Dimensions of the index vertebra, AVBH, MVBH and PVBH were expressed as percentage of the analogous dimension of the referent vertebra: (fractured vertebral height/mean adjacent referent vertebrae height) x 100. Descriptive statistics, such as the mean and standard deviation, were used to describe the main variables. The Kolmogorov–Smirnov test was conducted to assess the distribution of the variables in order to use a parametric or non-parametric test. AVBH, MVBH, PVBH and LK variables were normally distributed, whereas ODI and VAS variables were not normally distributed. Therefore, possible differences in AVBH, MVBH, PVBH and LK variables between the preop, postop and control groups were evaluated using repeated measure analysis of variance and nonparametric Friedman analysis of variance was employed for ODI and VAS variables. Pairwise comparisons between preop, postop and control groups were performed using a two-tailed paired Student's *t* test for AVBH, MVBH, PVBH and LK variables and Wilcoxon Signed Rank test for ODI and VAS variables. A two-sided probability value of <0.05 was considered to be statistically significant.

## RESULTS

From 2009 to 2014, 87 osteoporotic vertebral fractures of 82 patients were treated with balloon kyphoplasty. Seventy-two of the patients were female (87.8%) and 10 (12.2%) were male. At the time of admission the mean age of all patients were 66.4 years (Range 38-89 years). Regarding the fracture level, most of the fractured vertebra were at the thoraco-lumbar junction (62%) by L1=30 and T12=24 levels ranging from T7 to L5.

Preoperative mean AVBH of 48.20±13.94 % and MVBH of 59.40±14.26 % were recorded as 79.91±9.50 % and 86.90±8.38 % respectively postoperatively and noted to be 73.26±8.59 % and 84.65±8.19 % at the follow-up (last control) respectively. There were statistically significant differences between preoperative, postoperative and follow-up scores of AVBH and MVBH (p=0.000). However the mean values of PVBH were found to be almost the same over time. Compared to preoperative heights, mean AVBH and MVBH were significantly higher ( $p < 0.001$ ) than both postoperative control heights (**Figure 1**). However only a slight difference was observed between postoperative and control heights of AVBH (p=0.020). LK improved significantly from 16.98 ±3.20 before surgery to 4.92 ± 1.84 after surgery (Table I) (p=0.000). It remained almost the same between postoperative and control levels (p=0.090).

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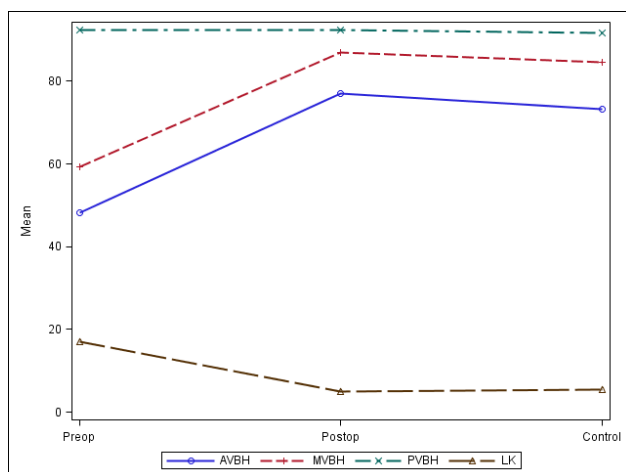


Figure 1. Mean values of standard 6-point vertebral body height measurements (AVBH, MVBH and PVBH) and local kyphosis angle (LK).

VAS were recorded by the patients with self assessment as 1-10 grading scale with 1 point no pain and 10 as worst intractable pain. The preoperative pain level showed a mean VAS score of 7.97, mean VAS was 2.21 at the postoperative pain level, and 1.98 at the control level (**Table I**). **Figure 2** shows a sharp decrease in mean pain scores. Overall differences in mean VAS scores were found to be statistically significant ( $p=0.000$ ). It was also found that all the pair-wise comparisons showed significant differences.

**Table I.** Comparison of preoperative postoperative and control values of AVBH, MVBH, PVBH, LK, ODI and VAS

	AVBH*	MVBH*	PVBH*	LK**	ODI*	VAS
<b>Preop</b>	48.203±13.944	59.402±14.259	92.365±7.844	16.98±3.202	64.69±9.434	7.97±1.410
<b>Postop</b>	79.913 ± 9.501	86.902 ± 8.381	92.365±7.844	4.92 ± 1.844	22.55±7.292	2.21±0.878
<b>Last Control</b>	73.257 ± 8.586	84.652 ± 8.188	91.552±7.874	5.52 ± 1.629	21.52±6.054	1.98±0.664
<b>F</b>	177.85	178.66	0.31	736.02	138.07	149.84
<b>P</b>	0.000	0.000	0.733	0.000	0.000	0.000
<b>Pre-post (t/p)</b>	-17.324/0.000	-17.022/0.000	0.000/1.000	34.074/0.000	8.106/0.000	8.152/0.000
<b>Pre-control (t/p)</b>	-15.118/0.000	-15.629/0.000	0.683/0.495	32.275/0.000	8.106/0.000	8.161/0.000
<b>Post-control(t/p)</b>	2.206/0.028	1.393/0.165	0.683/0.495	-1.701/0.090	2.333/0.020	2.410/0.016

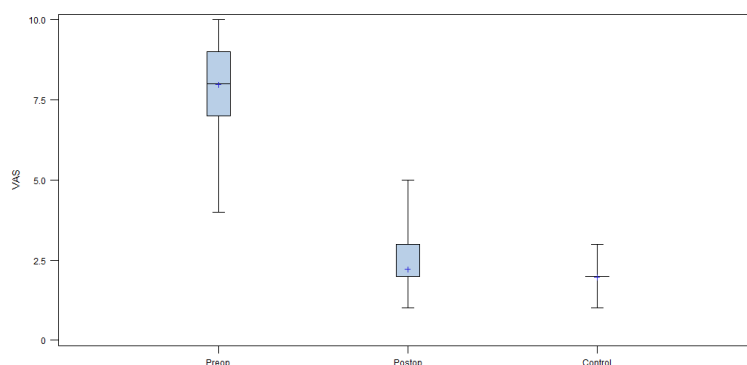
\*Values are in percents, \*\*Values are in degrees

Values are given as mean ± SD; comparisons by means of paired t test.

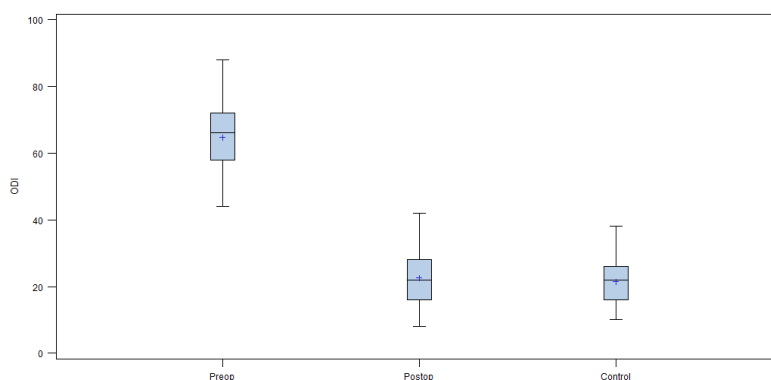
AVBH= anterior vertebral body height; MVBH=middle vertebral body height; PVBH=posterior vertebral body height; LK=local kyphosis angle; ODI= Oswesrty Disability Index; VAS= Visual Analogue Score

The Oswestry disability index (ODI), assessing the functional parameters relevant to individual patients, is expressed as a percentage score. It ranges from minimum disability (0-20%) to being bedbound (81-100%). It can be easily seen from Table I that preoperatively, the mean ODI was 64.69 and decreased, being 22.55 at the postoperative level and 21.52 at the control level (**Figure 3**), and differences were statistically significant ( $p=0.000$ ).

There were no significant cement extravasations into the canal, neural foramina and no paravertebral cement leaks occurred in our series. Only in one patient minimal symptomatic intradiscal cement leak occurred and was followed-up non-operatively. Any cement embolization and neurologic deficit did not occur postoperatively. 5 patients admitted with adjacent osteoporotic vertebral fractures one at the postoperative 4<sup>th</sup> month and four at the 2<sup>nd</sup> year and were treated with balloon kyphoplasty. No postoperative infections were noted.



**Figure 2.** Mean VAS pain scores in which 1 indicates no pain, and 10 indicates severe pain.



**Figure 3.** ODI trend in our patients

## DISCUSSION

The mainstay of management of symptomatic vertebral fractures are relief of pain, restoring vertebral height and sagittal profile, improving general health status of the patient and providing early mobilization. Balloon kyphoplasty is a minimally invasive, safe and efficient treatment of such cases. The aim of our study is to evaluate our results and discuss with the relevant literature.

Ledlie et al reported VAS scores of 117 patients and main pain scores to be decreased from 8.9 to 2.8 postoperatively and 1.5 at the follow-up period [28]. Hulme et al reported a systematic review of 69 clinical studies and VAS score of 4 studies with a sum of 183 cases and ODI score of two studies with a sum of 77 patients showed preoperative score of 7.15 improved to 3.5 and 60 to 32 postoperatively respectively [29]. Our study reports clinical and radiographic outcomes of 87 osteoporotic vertebral fractures of 82 patients treated with balloon kyphoplasty. In our series pain scores of the patients were evaluated with VAS and function with ODI scores and statistically significant improvements were noted in both parameters. The mean VAS score of 7.97 decreased to 2.21 postoperatively and to 1.98 at the follow-up period. Similarly the mean preoperative ODI score of 64.69 improved to 22.55 postoperatively and to 21.52 at the follow-up.

Several methods were defined to evaluate fractured vertebral heights [30-31]. In our study we used same landmarks and calculated dimensions of the index vertebra, AVBH, MVBH and PVBH were expressed as percentage of the analogous dimension of the referent vertebra: (fractured vertebral height/mean adjacent referent vertebrae height) x 100. There were statistically significant differences between preoperative, postoperative and follow-up scores of AVBH and MVBH which were 48.20±13.94 % and 59.40±14.26 % preoperatively were recorded as 79.91±9.50 % and 86.90±8.38 % postoperatively respectively and noted to be 73.26±8.59 % and 84.65±8.19 % at the follow-up (control) respectively. Mc Kiernan et al and Voggenreiter [30, 31] postulated dynamic fracture mobility proposing spontaneous reduction of fractured vertebra during placing the patient in to prone position and recommended a consensus reporting method to be proposed. However up to

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date there is not a standardized method in evaluating efficiency of balloon kyphoplasty regarding spontaneous correction of the deformity in prone positioning. We considered referent height restoration in evaluating our data and our results are comparable and parallel to the literature.

LK of our patients also improved significantly from  $16.98 \pm 3.20$  before surgery to  $4.92 \pm 1.84$  after surgery ( $p=0.000$ ). It remained almost the same between postoperative and control levels. Balloon kyphoplasty in restoring LK is noted to be effective and can improve the sagittal profile and general condition of the patient [32-35].

Complications during or after balloon kyphoplasty procedures were reported as infection, pedicle or transverse process fractures, cement extravasation, pulmonary embolism, cardiac arrest, neurologic deficit due to foraminal or neural canal cement leak [1, 25, 36]. In our series complication rate was 7.3% including one patient with asymptomatic intradiscal cement leak and 5 patients with adjacent osteoporotic vertebral fractures treated with balloon kyphoplasty. Adjacent segment fractures may be a result of a more rigid segmental construct leading higher junctional stress to the adjacent treated level.

There are several limitations of our study. First in considering height restoration, dynamic fracture mobility was not recorded in the patients treated with balloon kyphoplasty. This might affect postoperative correction rates to be higher and could result in misinterpreting the results, however we think our study is comparable to the literature in this manner but further prospective studies must be considered. Second a wide time in follow-up period was present in our study as this could affect the final clinical condition of the patients. Third radiographic measurements were done by two separate authors and this might affect inter-observer reliability.

In conclusion the results of this study suggest that balloon kyphoplasty is an effective and safe treatment option in osteoporotic vertebral fractures and should be considered for functional improvement, pain relief and height restoration.

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