



## FACTORS PREDICTING THE OUTCOME AFTER PERCUTANEOUS VERTEBROPLASTY

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### ABSTRACT

This study was carried out to study the role of vertebroplasty in compression fractures of the vertebrae, the pre-operative factors that affect the functional outcome after vertebroplasty and the complications arising from the procedure. We performed Vertebroplasty under local anesthesia using the trans-pedicular approach. The pain relief and improvement in quality of life were documented. The outcomes were studied with respect to various pre-operative patient variables. Patients had excellent functional outcome as per the Roland Morris Disability Questionnaire and an excellent pain relief as per VAS scores. Cement extravasation was our only complication. There were no cases of neurologic or cardiopulmonary complications in any of the patients. A high pre-operative kyphosis angle and wedge angle are very important predictors of the functional outcome after vertebroplasty. Prior history of fragility fractures is another factor predicting a poor outcome after vertebroplasty. Cement extravasation does not co-relate with the functional outcome.

### KEYWORDS :

#### INTRODUCTION

Vertebral compression fractures occur in the elderly, osteoporotic individuals after trivial trauma<sup>1</sup>. Most of these fractures occur in elderly and if loss of vertebral height in less than 50% most of them respond well to conservative treatment and treatment of osteoporosis<sup>1</sup>. However, few fractures do continue to have pain and other symptoms and respond poorly to conservative trials<sup>1,2,3</sup>. Vertebroplasty is an attractive and simple to perform procedure in which cement is injected in the vertebral body to augment it after compression fractures and presents a viable option in these cases. There is a dearth in the literature on pre-operative factors that predict the functional outcome after vertebroplasty. This study was carried out to study the role of vertebroplasty in compression fractures of the vertebrae, the pre-operative factors that affect the functional outcome after vertebroplasty and the complications arising from the procedure.

#### MATERIALS AND METHODS

During the period between June 2007 and Dec 2009, a prospective study was conducted, where in all patients with osteoporotic wedge compression fractures of the dorso-lumbar spine were screened using the following inclusion and exclusion criteria. Only those patients that satisfied the given criteria and were willing to participate in the study were included. The protocol was reviewed and approved by an Independent Ethics Committee. Inclusion criteria: 1) Denis type 1 fracture of dorso lumbar vertebrae. 2) Age > 40 years. 3) Failed conservative trial. Exclusion criteria: 1) Neurological involvement. 2) Compression fractures secondary to bone tumours. 3) Multiple level compression fractures. Failed conservative trial<sup>1</sup>: No relief of pain even after taking bed rest for 6 weeks, and analgesics, muscle relaxants and brace support for 3 months, with gradual mobilization at 6 weeks from injury, with brace support.

#### Patient sample:

50 patients were included in this prospective case series. The age of the patients varied from 41 to 85 years with a mean of 62.26 years. There were 25 males and 25 females in our study. 25 patients had Osteoporosis, 22 were Osteopenic and 3 had a normal Bone Mineral Density. The duration of complaints or the time since fracture was  $4.12 \pm 1.29$  months range being 3 to 8 months. The amount of cement used was  $3.76 \pm 0.78$  ml per level range being 2.5 to 5 ml.

This study also focused on other factors affecting the outcome

measures namely VAS scores and RMDQS scores. The entire patient population was studied to assess how the study variables were affected by following variables of the patient: 1) Age of the patient<sup>4,5</sup> (dividing age into two groups – less than 60 years and more than 60 years). 2) Gender of the patient (males and females). 3) Level of fracture (thoracic or lumbar). 4) Previous history of fragility fractures (whether patient had any prior history of fragility fractures like fracture neck of femur, fracture lower end of radius etc). 5) Duration of complaints<sup>10</sup> (whether less or more than 4 months). 6) Patient's intake of Alcohol, Smoking<sup>7</sup>, Steroid intake<sup>7</sup> and prior treatment of Osteoporosis (for at least 6 months before the fracture). 7) The pre-operative and post-operative Kyphosis angle<sup>9</sup> (whether the angle is 10° and less or 11° and more). 8) The pre-operative and post-operative Wedge angle (whether the angle is 7° and less or 8° and more). 9) Cement Extravasation (whether present or absent).

#### Assessment:

We used the VAS scale to assess the pain relief and the Roland Morris Disability Questionnaire to assess the functional improvement over time. We selected the RMDQS because it fulfills criteria that are important for outcome measures used to evaluate the efficacy of vertebroplasty: 1) It is a back pain-specific measurement. 2) It is well validated in the literature. 3) It can be easily administered by telephone to elderly patients. 4) The RMDQS was specifically designed to assess physical disability due to lower back pain.

#### Statistical methods:

Statistical analysis was done by using SPSS software version 12. For kyphosis and wedge angle pre and post values are compared by paired t test. Non parametric test – Friedman test is used to compare the differences over the period in VAS and RMDQS over the period of follow up. Percentages in different categories are compared by chi square test (Fischer exact test wherever applicable. p value less than 0.05 (p < 0.05) was considered as statistically significant.

#### RESULTS

Patients (80%) achieved an excellent functional outcome as per the RMDQS score and an excellent pain relief as per the VAS scale, patients (11%) achieved a fair outcome, and patients (9%) had a poor outcome. The RMDQS improved from a mean of 19.47 ( $\pm 0.743$ ) pre-operatively to a mean of 4.529 ( $\pm 5.4$ ) post-operatively. This is a 76.73% change or

improvement which is statistically significant,  $p$  value  $< 0.05$ . The VAS scores improved from a mean of  $8.147 (\pm 1.709)$  pre-operatively to a mean of  $2.088 (\pm 2.065)$  post-operatively. This is a 74.37% change or improvement which is statistically significant,  $p$  value  $< 0.05$ . The Kyphosis angle improved from a mean of  $8.5^\circ (\pm 6.537^\circ)$  pre-operatively to a mean of  $7.617^\circ (\pm 6.218^\circ)$  post-operatively. This is a 10.5% change or improvement which is statistically significant,  $p$  value  $< 0.05$ . The Wedge angle improved from a mean of  $5.852^\circ (\pm 2.986)$  pre-operatively to a mean of  $4.941^\circ (\pm 2.593)$  post-operatively. This is a 13.3% change or improvement which is statistically significant,  $p$  value  $< 0.05$ .

## DISCUSSION

Vertebroplasty is a very effective procedure that affords significant improvement in the quality of life and pain relief in patients having failed a conservative trial after osteoporotic compression fractures of the dorso-lumbar vertebrae. Vertebroplasty gives significant relief in pain and improvement in the functional outcomes even in cases of severe osteoporosis with a compression fracture of the dorso-lumbar vertebrae. High pre-operative kyphosis angle of more than  $11^\circ$  and a high pre-operative wedge angle of more than  $8^\circ$  predict a poorer functional outcome and pain relief following vertebroplasty. Hence we should be careful while selecting patients for the procedure and calculate the pre-operative kyphosis and wedge angles accurately. Prior history of fragility fractures is another predictor for a poorer outcome after vertebroplasty. Variables such as Age, Gender, Level of fracture (thoracic or lumbar), Duration of the fracture, Smoking, Alcohol, Steroid intake and prior history of treatment of Osteoporosis do not affect the pain relief and functional outcome afforded by vertebroplasty. The Extravasation of cement is not a factor affecting the pain relief and functional outcome following vertebroplasty. However we must realize that concomitant treatment of osteoporosis is a must, and this must be instituted at the earliest.

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