

## Percutaneous Vertebroplasty Results in Osteoporotic Vertebral Fractures

### Abstract

**Background:** Percutaneous vertebroplasty as an effective and relatively new treatment can strengthen broken vertebrae and reduce the pain of osteoporotic fractures. The Present study was conducted to assess the results of such treatment in osteoporotic vertebral fractures.

**Methods:** In the present study, all the patients with osteoporotic vertebral fractures, having undergone vertebroplasty were studied by VAS before and after vertebroplasty. Complications after vertebroplasty (infection, nerve lesion, extra vertebrae cement leakage, cement-to-lung leakage and adjacent vertebrae fracture) were documented. Statistical data were entered into SPSS statistical software version 24 and statistical analysis was performed using Chi-square and independent t-tests.

**Results:** Of the 40 evaluated cases, 10 (25%) were male and 30 (75%) females. The mean age of patients was 76.26 years. The mean of Visual Analogue Scale before vertebroplasty was 8.06, and after vertebroplasty was 1.34. The observed side effect was extra vertebrae leakage of cement, which was observed in eight cases (16%). No case of infection, nerve damage, and cement leakage into the lung or adjacent vertebral fracture was observed. Based on the analytical evaluation, there was no statistically significant difference between the mean of Visual Analogue Scale before vertebroplasty considering gender ( $P = 0.485$ ) and age ( $P = 0.134$ ). In addition, there was no significant difference between the mean of Visual Analogue Scale after vertebroplasty considering gender ( $P = 0.325$ ) and age ( $P = 0.809$ ). However, the mean of Visual Analogue Scale after vertebroplasty had a significant reduction in comparison to before vertebroplasty ( $P=0.0001$ ). The second lumbar vertebra has been the most commonly involved vertebra.

**Conclusion:** Based on observed results, percutaneous vertebroplasty can reduce the severity of pain in patients with osteoporotic vertebral fractures.

**Keywords:** Vertebroplasty, Spinal Fractures, Osteoporotic Fractures, Spine

*Received: 4 months before printing; Accepted: 2 months before printing*

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### Introduction

Osteoporotic compression fractures of vertebrae have been commonly observed in older age patients, leading to decreased quality of life, progressive vertebral deformity, sagittal imbalance and chronic pain<sup>(1)</sup>. Percutaneous vertebroplasty as a minimally invasive method, has been frequently used in osteoporotic compression fracture of vertebral body which has failed conservative treatments<sup>(2)</sup>. The method may not only provide pain reduction, but lead also to stability of fractured vertebral body through injection of small amount of bone cement into collapsed vertebral body<sup>(3, 4)</sup>. Percutaneous vertebroplasty was first reported in 1987 as a therapeutic method, for pain reduction due to different types of vertebral compression fractures<sup>(5)</sup>. Many cases with vertebral osteoporotic compression fractures have undergone percutaneous vertebroplasty due to its dramatic efficacy on pain reduction, and its usefulness has been evaluated and observed in multiple studies<sup>(6)</sup>. Anyway, the New England Journal of Medicine edition of August 2009, included studies found no significant difference between placebo and percutaneous vertebroplasty in pain reduction of vertebral osteoporotic compression fractures<sup>(7)</sup>. Acute osteoporotic compression vertebral fracture can lead to a paralysing condition of severe back pain with increased hospitalization and associated morbidity<sup>(8)</sup>. Percutaneous vertebroplasty is an

important method in management of acute osteoporotic compression vertebral fracture, however has invoked both controversy and enthusiasm<sup>(9, 10)</sup>. Different investigations have been published on the clinical usefulness of percutaneous vertebroplasty<sup>(11)</sup>. However, they often report the short-term effectiveness of vertebroplasty, and few studies have examined the long-term effects of this technique. So, several issues in percutaneous vertebroplasty remain unanswered<sup>(12, 13)</sup>. The aim of present investigation was evaluation of percutaneous vertebroplasty results in osteoporotic vertebral fractures.

## Methods

### Study Setting and Population

This study has been conducted on the referred patients to orthopaedics clinics in, Yazd city, Iran collecting the records of vertebroplasty patients who had failed their initial one-month conservative treatment during as-year period (2017 to 2020).

The Inclusion criteria were: Osteoporotic vertebral fractures, Normal posterior and middle columns, percutaneous vertebroplasty.

The Exclusion criteria were: Reduce vertebra height > 50%, Allergy to the contrast, Metastatic fracture (5 cases were excluded), Uncooperative patient, and fractures because of infection.

### Measurements

The hospitalization criteria and treatments were applied in accordance with the international and national guidelines, 2 to 3 cc of cement (Poly methyl methacrylate) has been injected for all patients. We collected data from medical records including medical history, demographic information such as gender, and age, co-morbidities (diabetes, hypertension, ischemic heart disease) in addition to pain severity. The study was performed in the research committee of the orthopaedics department of Hospital and approved by the Research Ethics Board of Yazd University of Medical Sciences. The study complied with the rules of the Helsinki Convention, and was approved with ethical code as IR.SSU.MEDICINE.REC.1399.311.

### Statistical analysis

Inferential statistics calculates statistics using data collected from the sample group and then generalizes statistics to community parameters with the help of test and estimation techniques. Statistical analysis was performed at two descriptive levels (mean, standard deviation, etc.) and inferential level (analysis of variance). Version 24 of the SPSS software was used to perform analysis of variance.

## Results

### Age and gender

Out of the 55 original cases, 5 were excluded due to being metastatic. Fractures and 10 cases did not show-up for follow-up.

The 40 evaluated cases included 10 (25%) male and 30 (75%) female. With the mean and SD of age of  $76.26 \pm 7.06$  (61-90) years (Table 1).

### Clinical data

Of our cases 10 cases did not come for follow-up for a long time, so we have 40 cases for follow-up of fracture of vertebrae that have a mean follow-up period as 2 years (8 months to 3 years). In the follow-up, radiography was taken from all patients, and no evidence of fracture was observed in the treated or adjacent vertebrae, in addition there was no evidence of loosening of cement, and cement protrusion. Also, unlike kyphoplasty, there was no change in the vertebrae height. Of evaluated cases, the observed side effects were extra vertebrae leakage of cement, which was observed in eight cases (16%), all cases have been hospitalized for 2 days. No case of infection, nerve damage, cement leakage into the lungs and fractures of adjacent vertebrae were observed, and in follow-up there was no re-fracture. In addition, neurological complication was not observed in any of the 8 patients with leaks (16.0%) (Table 2). Based on the analytical evaluation, it was observed that there was no statistically significant difference between the mean of Visual Analogue Scale before vertebroplasty considering gender ( $P = 0.485$ ) and age ( $P = 0.134$ ). In addition, there was no statistically significant difference between the mean of Visual Analogue Scale after

vertebroplasty as far as age and gender were concerned ( $P = 0.325$ ) and age ( $P = 0.809$ ) (Table 3).

#### Pain severity

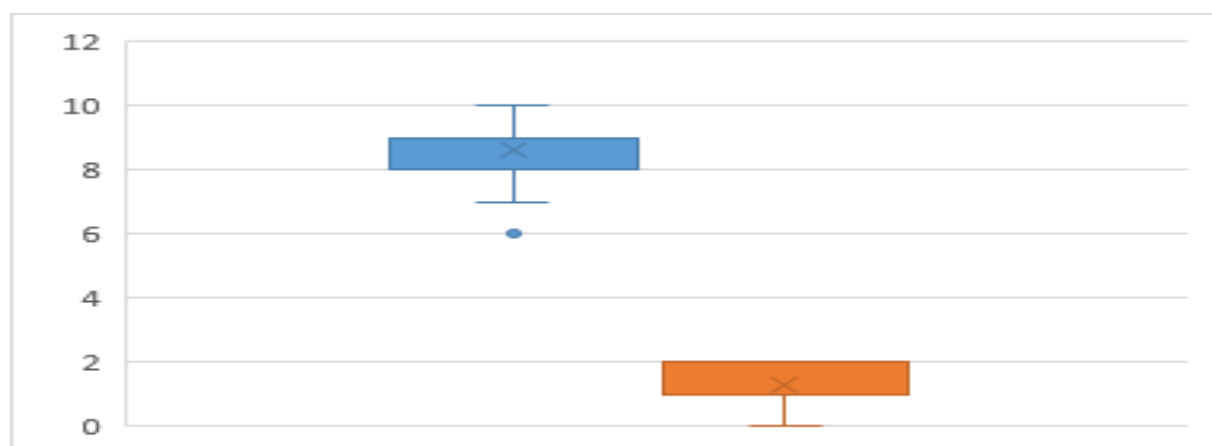
The second lumbar vertebra has been the most commonly involved vertebra. The mean and SD of Visual Analogue Scale before

vertebroplasty was  $8.06 \pm 0.81$ , and after vertebroplasty was  $1.34 \pm 0.55$ . Based on statistical evaluation the mean of Visual Analogue Scale after-vertebroplasty had a significant reduction in comparison to before-vertebroplasty ( $P=0.0001$ ) (Figure 1).

Table 1. Age and Gender in evaluated cases	
Variables	Values
<b>Age (years)</b>	
Mean	76.26
SD	7.06
Max	61
Min	90
<b>Gender</b>	
Male	10 (25%)
Female	30 (75%)

Table 3. Comparison of pain severity before and after treatment based on age, gender and co-morbidity			
Variables	Pain Severity		P Value
	Before	After	
<b>Age</b>			
61-75	$7.86 \pm 0.77$	$1.31 \pm 0.56$	0.406
76-90	$8.21 \pm 0.83$	$1.35 \pm 0.55$	
<b>Gender</b>			
Male	$7.92 \pm 0.73$	$1.21 \pm 0.57$	0.344
Female	$8.11 \pm 0.85$	$1.36 \pm 0.54$	
<b>Comorbidity</b> (diabetes, hypertension, ischemic heart disease)			0.214
Positive	$7.93 \pm 0.82$	$1.27 \pm 0.51$	
Negative	$8.29 \pm 0.77$	$1.47 \pm 0.62$	

Table 2. Clinical data in evaluated cases	
Variables	Values
<b>Cement leakage</b>	
Superior end plate	1 (2%)
Extra pedicle	4 (8%)
Anterior body	2 (4%)
Posterior body	1 (2%)
<b>Involved Vertebra</b>	
Thoracic	10 (25%)
Lumbar	30 (75%)
<b>Co-morbidity</b>	
Positive	26 (65%)
Negative	14 (35%)
<b>Involved thoracic vertebra</b>	
Inferior	12 (100.0)
<b>Involved lumbar vertebra</b>	
1	12 (30.0)
2	16 (40.0)
3	5 (12.5)
4	5 (12.5)
5	2 (5.0)



Figures 1: Comparison of pain severity before and after treatment, the mean  $\pm$  SD of Visual Analogue Scale before vertebroplasty (Blue) was  $8.06 \pm 0.81$ , and after vertebroplasty (Red) was  $1.34 \pm 0.55$ ; VAS after vertebroplasty had a significant reduction in comparison to before vertebroplasty ( $P=0.0001$ )

## Discussion

The physical support, narcotic analgesia and bed rest were the only therapeutic method for acute compression fractures of vertebra for many years. These methods had limited and low level of efficacy<sup>(8)</sup>. A novel method, named percutaneous vertebroplasty, was used for treatment of bone metastases, myeloma and aggressive angiomas, and has been increasingly used for acute osteoporotic vertebral fractures management<sup>(4, 11)</sup>.

So this method, as a minimally invasive method, has been frequently used in osteoporotic compression fractures of vertebral who have failed conservative treatments<sup>(2)</sup>. In present study we observed that, percutaneous vertebroplasty as a therapeutic method for cases with acute osteoporotic compression vertebral fracture, could reduce pain severity. We also observed cement leakage in 8 cases. However, leakage into lung and spinal canal was not observed in evaluated cases. The leakage incidence was lower than those mentioned in the literature to date<sup>(14)</sup>. Based on present study, the pain severity scores after percutaneous vertebroplasty were reduced significantly after the therapeutic method induction, and the improvement was sustained over time. Also, the reduced pain that was observed after the surgery did not decrease or increase in the follow-up of the patients. In terms of pain, vertebroplasty has been reported to reduce pain in 75 to 100% of cases with complications of less than 1%<sup>(15, 16)</sup>. In addition the presence of a bone marrow edema pattern on MRI is a good predictor of short-term pain relief with both methods, which has a clinical advantage in almost all patients<sup>(17)</sup>. However, one study observed pain reduction in 87% of patients without bone marrow edema<sup>(18)</sup>. Based on a review study by Buchbinder et al. when vertebroplasty is compared with placebo, high to moderate quality evidence from five trials indicates that vertebroplasty provides no clinically important benefit with respect to pain, disability, disease specific or overall quality of life or treatment success at one

month<sup>(19)</sup>, similar to our study. In addition, Nieuwenhuijse et al. observed that in 130 of 173 (75.1%) treated OVCFs, cement leakage was detected. Leakage incidence was found to increase approximately linear with advancing severity grade<sup>(20)</sup>, which was not confirmed in our study. The second lumbar vertebra has been the most commonly involved vertebra. The main problem with percutaneous vertebroplasty, as a method for treatment of compression vertebral fractures, is adjacent vertebrae osteoporosis causing subsequent onset of new VCFs (vertebral compression fractures), and also long-term follow-up of patients in this area. However, we observed and evaluated only six researches that documented a mean follow-up higher than 2 years after intervention for osteoporotic compression fractures<sup>(21-24)</sup>. In addition, only two of those studies reported higher than 50 cases follow-up<sup>(21, 23)</sup>. The present study followed 40 cases for a mean duration of two years. Some studies have convergence with material and methods that were used in the present research, such as telephone interviews in follow-ups for evaluation<sup>(23)</sup>, whereas questionnaires<sup>(22)</sup> have also been used.

Kallmes et al. in a 3-months follow-up have mentioned that many cases in control group (43%) crossed over to percutaneous vertebroplasty group because of continued pain, as compared to number of patients in the percutaneous vertebroplasty group who crossed over to the control group (12%), a difference with statistically difference ( $p < 0.001$ ). However, in another study by Tischer et al. mentioned that degenerative facet joint were observed in gross histological analysis, most commonly found at L4–L5 level<sup>(25)</sup>. In addition in the Framingham Heart Study, severe or moderate lumbar facet joint osteoarthritis on CT-imaging was present in 89% of those above 65 years of age<sup>(26)</sup>. This index was not evaluated in present study. In addition Manchikanti et al. mentioned that pain improvement rates after facet blocks or medial branch block in patients with back pain has been reported in the range of 29–60% in the literature<sup>(27)</sup>. In other studies by Kim et al.

and Lee et al. 70% and 69.6% of the cases had pain reduction by medial branch block, respectively<sup>(28, 29)</sup>. However, based on present study and in comparison, to other results in this area, percutaneous vertebroplasty is an effective method in reducing the pain severity and can be used for improving the patient's condition. Nevertheless, more studies are needed to confirm these results.

## Conclusion

According to the results of the present study, percutaneous vertebroplasty reduces pain severity in patients with osteoporotic fractures of adjacent vertebrae. Also, because of the very low observed side effects of this method, percutaneous vertebroplasty can be used as one of the standard methods in treatment of patients with osteoporotic vertebral fractures.

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