

## RESEARCH ARTICLE

# Percutaneous Vertebroplasty in Iranian Patients with Osteoporotic Vertebral Fractures

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## Abstract

**Background:** Osteoporotic compression vertebral fractures are common clinical problems. In those with refractory fractures, percutaneous cement augmentation has been suggested. The aim of this study was to evaluate the functional outcome of percutaneous vertebroplasty in Iranian patients with refractory osteoporotic fractures.

**Methods:** We retrospectively studied 37 osteoporotic fractures in 28 patients (6 men and 22 women), who had been treated with vertebroplasty from August 2009 to June 2012. The mean follow-up period was  $12.1 \pm 3.6$  (range: 6-42 months). The patients' states were assessed by the visual analogue scale and short form-36 questionnaire. Student t test was used to analyze the pre- and postoperative data.

**Results:** The mean age of the patients was  $71.6 \pm 6.1$  (range: 50 to 91 years) and the most common fractured vertebrae were L1 and T12. There were five patients with two levels of vertebral fractures and two with three levels. Vertebroplasty could improve the scores for pain and quality of life from preoperative  $7.6 \pm 1.4$  and  $44.8 \pm 7.6$  to  $1.8 \pm 0.4$  and  $74.1 \pm 5.3$  at four weeks after surgery. At the last follow-up visit, this improvement continued with no significant decline. The most common complication was cement leakage (32.4% per vertebra), wherein all of the patients were clinically asymptomatic. Adjacent vertebral fracture occurred in six cases.

**Conclusion:** By understanding the risks, we propose vertebroplasty in Iranian patients with refractory osteoporotic vertebral fracture. If correctly performed, this procedure can significantly improve the pain and quality of life in these elderly osteoporotic patients.

**Keywords:** Vertebroplasty, Osteoporosis, Compression fracture

## Introduction

Osteoporotic compression fractures (OCFs) are common clinical problems and its incidence is rising as the mean age of the population does as well. In spite of numerous late debilitating adverse effects of these fractures, most of them gradually become asymptomatic and may only cause a short stature and stooping posture; however, this problem may remain symptomatic in 23-33% of involved patients (1). In symptomatic patients, usually analgesic drugs associated with some modifications in activity of daily living and sometimes elastic braces suffice to be effective (2-5).

There are some cases that are refractory to this conservative treatment and this group comprises a challenging crowd. These osteoporotic patients are usually contraindicative to usual surgical instrumentation (due to a high incidence of loosening and implant failure). The presence of a variety of comorbidities in these elderly patients also

prevent them from being operated on with routine prolonged spinal surgeries. Percutaneous cement augmentation first reported by Galibert in 1987 has revolutionized the treatment plan in these patients (6). Although percutaneous cement augmentation currently has widespread application throughout the world, this modality of treatment, due to its relative high cost, high radiation exposure to the surgeons, and probably its less familiarity among Iranian spinal surgeons, it is not commonly used in this country hence, the aim of this study was to evaluate the functional outcome of percutaneous vertebroplasty (PVP) in Iranian patients with refractory OCFs (7-9).

## Materials and Methods

After obtaining our local institutional review board approval (code number 89532), we retrospectively studied our patients with OCFs treated by PVP from August 2009 to June 2012. Inclusion criteria comprised aggressive conse-

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rative treatment more than six weeks (analgesics, calcitonin, and bracing), local posterior midline pain and tenderness, age more than 50 years with a T-score  $-2.5$  or lower, conformity of local pain with the location of the involved vertebra, magnetic resonance imaging (MRI) or Technetium bone scan showing some signs of recent fracture (increased isotope uptake on isotope scan or increased signal intensity on T2 weighted or decreased signal intensity on T1 weighted MRI scanning), and signing the informed consent forms (10-12). Those cases with neurologic deficit, spinal canal compromise more than 30%, 13 an uncorrectable bleeding disorder, spinal infection, inability to be placed on the prone position for more than two hours, fracture due to an underlying tumor, and those patients with a follow-up period less than six months were excluded from the study (13).

We pre- and postoperatively assessed the patients with two types of questionnaire. The severity of pain was evaluated with a 0 to 10 scaling system, the visual analogue scale (VAS) (14). Functional states of the cases were also evaluated by the Short Form-36 (SF-36), which included eight subscale categories (15-17).

All the patients were operated on by the same surgical team and surgical technique. We routinely used polymethylmethacrylate (PMMA) cement with the Stryker Precision Cement Delivery System and recorded all significant intra or postoperative complications.

### Surgical Technique

If the procedure was limited to one or two vertebrae, we tried to do it under local anesthesia. The patient was positioned prone on two transverse rods (below the chest and pelvis). This position helps to restore the fractured vertebra height. Under biplanar fluoroscopic control, we introduced the trocar number 11 into the fractured vertebra's pedicle and injected PMMA into the anterior third of the vertebrae. With the arrival of the cement into the dorsal third of the vertebral body, cement injection was stopped. If cement injection had a suitable emission, then the bi-

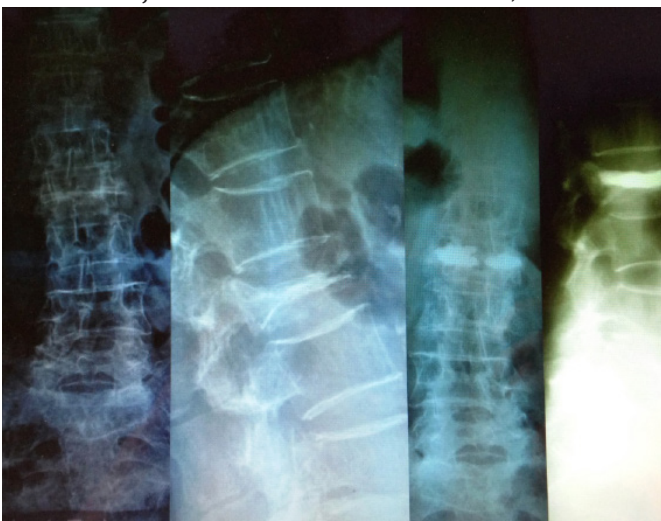


Figure 1. An 80 year old female presented with refractory L2 OCF. During the PVP, the unilateral approach was unsatisfactory and so a bipedicular approach to obtain uniform cement augmentation was tried.

**Table 1. Effects of PVP on eight domains of SF-36 in our patients.**

Domain	Mean Score (SD <sup>o</sup> )
<b>Physical Functioning (PF):</b>	
- Preop	33.4(7.8)
- 4w <sup>a</sup> postop	72.9(11.5)
- Last postop	74(12.6)
<b>Role - Physical (RP):</b>	
- Preop	20.2(16.6)
- 4w postop	74(14.2)
- Last postop	74.8(9.7)
<b>Bodily Pain (BP):</b>	
- Preop	31.7(11.2)
- 4w postop	72.8(11.8)
- Last postop	75.8(11.3)
<b>General Health (GH):</b>	
- Preop	58.5(8.0)
- 4w postop	74.6(4.8)
- Last postop	73.2(6.9)
<b>Vitality (VT):</b>	
- Preop	52.6(12.3)
- 4w postop	67.2(10.9)
- Last postop	68.1(9.8)
<b>Social Functioning (SF):</b>	
- Preop	57.4(14)
- 4w postop	74.8(12.2)
- Last postop	75.3(14.5)
<b>Role - Emotional (RE):</b>	
- Preop	50.4(28.9)
- 4w postop	68.3(24.8)
- Last postop	71.2(20.9)
<b>Mental Health (MH):</b>	
- Preop	62.5(10.9)
- 4w postop	74(11.2)
- Last postop	71(10.5)
<b>Total Score SF-36:</b>	
- Preop	44.8(7.6)
- 4w postop	74.1(5.3)
- Last postop	75.02(7.2)
*SD: Standard Deviation	
*W: week	

pedicular approach was not tried (Figure 1).

### Statistics

We used the Statistical Package for the Social Sciences (SPSS) program, version 11.5 and considered p-value less than 0.05 as statistically significant. Student t test was used to analyze the pre- and postoperative data.

## Results

Initially, we considered 31 patients to participate in the study, but three cases failed to fulfill the criteria and were excluded. Eventually, we treated and followed-up on 37 OCFs in 28 cases, with a female/male ratio 3.67, mean age  $71.6 \pm 6.1$  (range: 50 to 91 years), and mean follow-up period  $12.1 \pm 3.6$  (range: 6 to 42 months). The mean T score (bone mineral density) for the lumbar vertebrae was  $-2.9$ . Prevalence of fractured vertebrae is depicted in Figure 2. There were five patients with two levels of OCFs and two with three levels of OCFs.

The mean preoperative VAS was  $7.6 \pm 1.4$ . PVP could improve this score to  $1.8 \pm 0.4$  at four weeks after surgery. At the last follow-up visit, this improvement in pain continued ( $1.9 \pm 0.9$ ) with no significant difference with the four weeks postoperative state ( $p=0.81$ ).

Similarly, PVP showed improvement in all eight domains of the SF-36 questionnaire and this improvement in quality of life also continued throughout this follow-up period (Table 1).

The recorded complications encountered with PVP in our patients are shown in Table 2. Although leakage of the cement was relatively common (32.4% per vertebra), none of them were associated with significant clinical consequences. As the table shows, subsequent vertebral fracture occurred in six patients (only one of them needed to be re-operated with PVP due to this adjacent fracture). This adjacent segment fracture in 66.7% of the patients occurred next to the previously augmented vertebra. The mean patient satisfaction score among our patients was  $1.8 \pm 0.8$  (range: 1 to 4).

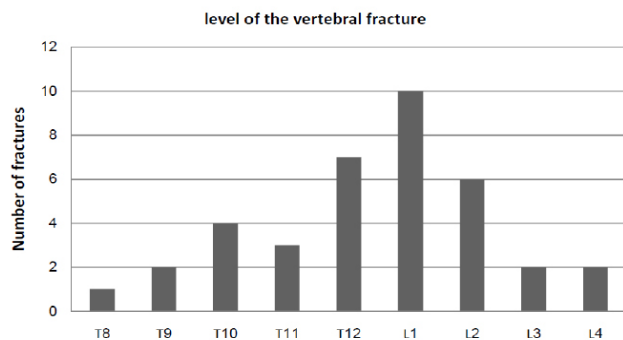


Figure 2. Prevalence of the fractures among our patients.

## Discussion

Our results confirmed that in those patients with refractory OCF, PVP with a relatively quick, reliable and safe effect could significantly reduce their pain and improve their quality of life. Fortunately, this effect persisted throughout the follow-up as well.

Grados and their co-authors in 2000 reported the first long-term study on the functional outcome of PVP in 25 patients with OCF and their mean follow-up period was 48 months (18). Based on VAS, the mean preoperative scale of 8.0 significantly decreased to 3.7 one month after surgery and these results were stable throughout the follow-up (3.4 at the last visit). They reported no significant complications, but a slight rise in adjacent segment fracture

Table 2. complications of cement augmentation procedures in 37 OCFs (28 cases).

Type of complication	Incidence per vertebra (%)
<b>Intra-operative:</b>	
- Rib fracture	2 (5.4)
- Cement leakage inside the needle tract	4 (10.8)
- Cement leakage into disc space	6 (16.2)
- Cement leakage into paravertebral space	1 (2.7)
- Cement leakage into vertebral canal	1 (2.7)
- Combined leak (any combination of above)	0
<b>Post-operative:</b>	
- Non-adjacent vertebral fracture	2 (5.4)
- Superior adjacent vertebral fracture	1 (2.7)
- Inferior adjacent vertebral fracture	3 (8.1)

was encountered. The authors finally recommended PVP as a safe and successful procedure with acceptable short and long term results in the treatment of patients with refractory OCFs. In our study, the long-term effect of this procedure was also confirmed (mean preoperative VAS of 7.6 changed to 1.8 and 1.9, at one month and last visit, respectively). Subsequent vertebral fracture occurred in six patients (21.4%), wherein in four of those cases (66.7%) this fracture occurred adjacent to the previously augmented vertebra.

The prevalence of subsequent vertebral fracture after PVP in OCF patients varied (range: 12-52%), but most of the authors believe that these subsequent fractures are usually located adjacent to the previously augmented vertebra (18-21). Li et al. in a retrospective study, reviewed and analyzed the risk factors for subsequent fractures after single level PVP (22). They treated 166 cases and followed them up for 15.3 months and reported a re-fracture rate of 38%. In their study, most fractures at follow-up also occurred at the bordering level within the first three months and the volume of injected cement and the amount of vertebral height restoration both positively correlated with the subsequent adjacent vertebral fracture. In the study we conducted, although a gentle hyperextension maneuver was tried in the prone position, the amount of vertebral height restoration and the volume of the injected cement were not assessed. In comparison with Li et al.'s study, our re-fracture rate was somewhat lower (21.4%), but most of them (66.7%) similarly occurred adjacent to the previously augmented segment.

There are many papers regarding various complications occasionally associated with this minimally invasive procedure. Clinically significant complication rate is 1.3% and the leading complication is leakage of the bone cement Lotfinia and Sayyahrnelli in 2010 reported that their complications occurred with PVP in 28 cases (23-25). In this clinical study, the prevalence of disc space leakage, epidural and foraminal leakage, and venous epidural leak were 23.3%, 20%, and 6.7%, respectively. They reported no death or delayed complications and the mean VAS improved from  $7.65 \pm 0.87$  to  $2.13 \pm 0.11$ . In comparison, we

found a cement leak rate of 32.4% per vertebra wherein, similarly, none of them was associated with significant clinical consequents. The most common type of leakage in our patients included leakage into disc space with an incidence of 16.2% per augmented vertebra. Our mean VAS similarly changed from a preoperative score of  $7.6 \pm 1.4$  to  $1.9 \pm 0.9$  at the last follow-up visit.

Since our study was a retrospective design on a relatively limited number of patients there were some limitations. Consequently some important information may have been missed, and therefore a prospective randomised control trial study on a relatively large number of cases is certainly suggested. We must confess that even though the issue of PVP is not a new one, a comprehensive study on Iranian patients with refractory OCF treated with PVP is relatively new and can be helpful for surgeons responsible to treat these patients. In conclusion, by understanding the risks, we propose PVP in refractory OCF. This procedure should only be carried out by experienced well educated surgeons in a well equipped place for probable immediate neurologic decompression. If correctly performed, it can significantly reduce pain and improve

the quality of life of these osteoporotic patients.

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