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# Symptomatic relief of pain following percutaneous vertebroplasty compared to conservative management in patients with osteoporotic vertebral compression fractures. A prospective cohort study from a low-middle-income country

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**Keywords**
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## ABSTRACT

**Objectives:** To determine the efficacy of percutaneous vertebroplasty in pain management over conservative management in patients with osteoporotic vertebral compression fractures.

**Materials and Methods:** A prospective cohort study was conducted from 13th December 2018 to 12th December 2019 at PIMS/SZABMU, Islamabad, Pakistan. A total of 76 patients (Aged: 35-75 years) of both genders having osteoporotic vertebral compression fractures involving a maximum of two vertebrae were enrolled. Patients were divided equally into two groups. One group was managed surgically through vertebroplasty (Group A) and the other group was managed conservatively (Group B). All the patients were asked about the intensity of pain, assessed by Visual Analogue Scale (VAS) score at the presentation and after 24 hours, 3rd and 6th week of given treatment and compared using independent sample t-test in both groups. Complications were also assessed and compared in both groups.

**Results:** In group A, dorsal vertebrae were involved in 23.7%, lumbar vertebrae in 68.4% and dorsal/lumbar vertebrae in 7.9% of cases. In group B, dorsal vertebrae were involved in 21.1%, lumbar vertebrae in 60.5% and dorsal/lumbar vertebrae in 18.4% of cases. At baseline, mean VAS was 8.01 ± 0.99 in group A and it was 8.35 ± 0.75 in group B. At 24 hours after the intervention, mean VAS was 4.37 ± 0.79 in group A and it was 7.29 ± 1.21 in group B. At 3 weeks after the intervention, mean VAS was 4.03 ± 0.85 in group A and it was 6.37 ± 0.91 in group B and at 6 weeks after the intervention, mean VAS was 3.87 ± 1.09 in group A and it was 5.37 ± 0.97 in group B. The overall complication rate was 10.5% at 24 hours in group A and it was 5.3% in group B. At 3 weeks, the complication rate was 5.3% in group A and it was 28.9% in



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group B. At 6 weeks, the complication rate was 21.1% in group A and it was 55.3% in group B patients.

**Conclusion:** Mean VAS score was found to be significantly lower in patients who underwent vertebroplasty as compared to those managed conservatively. Overall complication rate was similar in both groups at 24 hours; however, it was significantly lower at 3rd and 6th weeks in patients who underwent vertebroplasty as compared to those managed conservatively.

## Introduction

Osteoporosis is one of the most common diseases of elderly and post-menopausal women characterised by fragile bone with increased susceptibility to fracture. The fracture may be at multiple skeletal sites, most commonly involving the spine, hip and wrist.[1] Osteoporotic vertebral compression fractures (OVCF) are the most common type of osteoporotic fracture accounting about 1.4 million worldwide every year.[2,3] Studies have shown that among individuals above 50 years of age about one fourth will sustain at least one vertebral fracture over lifetime.[4] They are considered to be low energy fractures which are more frequently seen in post-menopausal women and its prevalence increases with age in both genders.[5]

Osteoporotic vertebral compression fractures result in serious health concerns such as pain, disability and often mortality[6] and so the quality of life is markedly decreased in patients with OVCF. Conservative management such as rest, immobilisation, analgesics, bisphosphonates have been widely used but remain ineffective.[7] Furthermore, if a patient is of old age, bed rest and decreased activity leads to associated pneumonia, decubitus ulcer, venous thromboembolism and even death.[8] So, considering all these disadvantages, Percutaneous Vertebroplasty (PVP) is considered to be another alternative. It is minimally invasive procedure, which involves injection of cement (polymethylmethacrylate, PMMA) into the OVCF resulting in immediate pain relief.[3] Vertebroplasty was initially used in the treatment of hemangioma about 25 years ago and with time it is being used in osteoporotic fractures starting from late 1990's.

According to published data, there is considerable relief of pain following PVP compared to conservative treatment for OVCF.[4] Given the scenario of high rate of morbidity associated with non-operative management, PVP seems to be the best alternative for not only the pain management but also for return of functional independence, decreased rate of readmission, and fewer admission to skilled nursing or long term care facilities.

## Materials and Methods

**Study design:** Prospective cohort study.

**Setting:** Department of Neurosurgery, Pakistan Institute of Medical Sciences (PIMS)/Shaheed Zulfiqar Ali Bhutto Medical University (SZABMU), Islamabad**,** Pakistan.

**Duration of Study:** One year (13th December, 2018 to 12th December, 2019).

**Sample Size:** Calculated by WHO sample size calculator with the following parameters:

- Sample size (n)=76 i.e, 38 in each group
- Level of significance = 5%
- Power of test=80%
- Test value of population (Mean value of VAS score after 24hrs in PVP group) p1: 4.7
- Anticipated population (Mean value of VAS score after 24hrs in conservative treatment group) p2: 7.1

**Sampling Technique:** Non-probability based consecutive sampling.

### Sample Selection

#### Inclusion Criteria

1. Patients of both genders (Age: 35-75 years) having osteoporotic vertebral compression fracture.
2. Osteoporotic vertebral compression fracture involving maximum of two vertebrae.
3. VAS score at presentation ≥4.

#### Exclusion Criteria

1. Patients who did not give consent.
2. Patients having osteoporotic vertebral fractures involving more than two vertebrae.
3. Patients who had untreatable coagulopathy.
4. Patients who had spinal cord compression syndrome.
5. Patients having any pre-existing infection at the surgical site.

### Data Collection Procedure

This study was conducted after taking approval from the hospital's ethical review committee. Patients admitted to Neurosurgery ward who had osteoporotic vertebral compression fracture as

evidenced by thorough clinical examination, X-rays and Computed Tomography (CT), Magnetic Resonance Imaging (MRI), dual-energy x-ray absorptiometry (DEXA) scan, serum calcium and Vitamin D3 levels were included in the study. Informed written consent was taken from each patient. Initial data about age, sex, contact number and date of admission were recorded on predesigned proforma. Patients were divided into two groups. One group was managed conservatively and the other was operated via vertebroplasty. Vertebroplasty involves the percutaneous injection of bone cement under image guidance into a fractured vertebra whereas conservative management includes pain control and activity modification. Oral analgesics are first-line therapy for the relief of acute pain. Options include acetaminophen, ibuprofen, naproxen, mild opioids combined with acetaminophen, or mixed mechanism drugs (e.g, tramadol, tapentadol), centrally acting analgesics whose mode of action is based both on mu-opioid receptor binding and monoamine (serotonin and norepinephrine) reuptake blockade. Both the groups were asked about the severity of pain which was assessed by VAS score at the presentation and after 24 hours, 3$^{rd}$ week and 6$^{th}$ week of given treatment. Any complication associated with the drugs such as dizziness, headache, gastric upset was noted. Also the complications associated with vertebroplasty such as cement leakage, adjacent fracture, infection were noted in the subsequent follow up.

### Data Analysis Procedure

Collected data was analysed with SPSS version 26. Mean and standard deviation were calculated for numerical variables like, age and pain score. Frequency and percentages were presented for categorical variables like, gender and complications in both groups. Independent sample t-test was used to compare pain between both groups. Chi-square test was applied to compare complication rate between both groups. P-value <0.05 was considered significant.

## Results

### Demography of the selected population

A total of seventy six (n=76) patients (Age: 35-75 years) of both genders having osteoporotic vertebral compression fracture involving a maximum of two vertebrae were enrolled into this study. All the enrolled patients had moderate degree of pain (VAS≥4). Patients were divided equally (n=38 in each group) into two groups. One group was managed surgically through vertebroplasty procedure (Group A) and the other group was managed conservatively (Group B). Gender distribution was similar in both groups. There were 39.5% (n=15/38) males and 60.5% (n=23/38) females in group A and 36.8% (n=14/38) males and 63.2% (n=24/38) females in group B (Table. 1). Age distribution was also similar in both groups. Mean age of Group A patients was 62.3 years ± 13.4 SD while it was 65.8 years ± 15.1 SD in group B patients (Table. 2).

### Baseline patient characteristics in both groups

In group A patients, dorsal vertebrae were involved in 23.7% (n=9/38), lumbar vertebrae in 68.4% (n=26/38) and both dorsal/lumbar vertebrae in 7.9% (n=3/38) of cases. In group B patients, dorsal vertebrae were involved in 21.1% (n=8/38), lumbar vertebrae in 60.5% (n=23/68) and both dorsal/lumbar vertebrae in 18.4% (n=7/38) of cases (Table. 3). Analysis of comorbid conditions at baseline revealed that comorbids were present in 63.2% (n=24/48) of cases in group A and 63.2% (n=24/48) of cases in group B patients (Table. 4). At baseline, mean VAS was 8.01 ± 0.99 in group A and it was 8.35 ± 0.75 in group B patients (Table. 5).

### Mean VAS Score at different time intervals:

Mean VAS score was estimated at different time intervals. At 24 hours after the intervention, mean VAS was 4.37 ± 0.79 in group A and it was 7.29 ± 1.21 in group B (p=0.001, Table. 5), at 3 weeks after the intervention, mean VAS was 4.03 ± 0.85 in group A and it was 6.37 ± 0.91 in group B (P=0. 001, Table. 4) and at 6 weeks after the intervention, mean VAS was 3.87 ± 1.09 in group A and it was 5.37 ± 0.97 in group B (P=0. 001, Table. 5). Mean VAS was found to be significantly lower at all time intervals in patients who underwent vertebroplasty procedure (group A) as compared to those managed conservatively (group B).

### Complication rate in both groups:

Overall complication rate was 10.5% (n=4/38) (cement leakage) at 24 hours in group A patients and it was 5.3% (n=2/38) (2 DVT) in group B patients (P=0.395, Table. 6). At 3 weeks, complication rate was 5.3% (n=2/38) in group A patients (DVT, sleep disorder [mainly insomnia]) and it was 28.9%

(n=11/38) in group B patients (5 pressure sores, 3 pneumonia, 2 depression, 1 DVT) (P=0.006, Table. 6). At 6 weeks, complication rate was 21.1% (n=8/38) in group A patients (3 UTI, 2 pneumonia, 2 sleep disorder [mainly insomnia], 1 DVT) and it was 55.3% (n=17/38) in group B (6 pneumonia, 5 pressure sores, 4 constipation, 2 depression) patients (P=0.002, Table. 6). Overall complication rate was similar (P>0.05) in both groups at 24 hours, however, it was significantly lower (P<0.05) at 3 and 6 weeks in patients who underwent vertebroplasty procedure (group A) as compared to those managed conservatively (group B).

**Table 1.** Gender distribution in both the study groups.

| Gender | Groups | | Total | P-value |
|---|---|---|---|---|
| | Vertebro-plasty | Conser-vative | | |
| Male | 15 (39.5%) | 14 (36.8%) | 29 (38.2%) | 0.813329 |
| Female | 23 (60.5%) | 24 (63.2%) | 47 (63.2%) | |
| Total | 38 (100%) | 38 (100%) | 76 (100%) | |

**Table 2.** Age distribution in both the study groups

| Groups | n | Mean Age ± SD (years) |
|---|---|---|
| Vertebroplasty | 38 | 62.3 ± 13.4 |
| Conservative | 38 | 65.8 ± 15.1 |

**Table 3.** Vertebrae involved in both the study groups

| Diagnosis | Groups | | Total | P-value |
|---|---|---|---|---|
| | Vertebro-plasty | Conser-vative | | |
| Dorsal | 9 (23.7%) | 8 (21.1%) | 17 (22.4%) | 0.398022 |
| Lumbar | 26 (68.4%) | 23 (60.5%) | 49 (64.5%) | |
| Dorsal + Lumbar | 3 (7.9%) | 7 (18.4%) | 10 (13.2%) | |
| Total | 38 (100%) | 38 (100%) | 76 (100%) | |

**Table 4.** Baseline Comorbidities in both the study groups

| Comorbidities | Groups | | Total |
|---|---|---|---|
| | Vertebro-plasty | Conser-vative | |
| None | 14 (36.8%) | 14 (36.8%) | 28 (36.8%) |
| Hypertension | 12 (31.6%) | 16 (42.1%) | 28 (36.8%) |
| Diabetes | 4 (10.5%) | 0 (0%) | 4 (5.3%) |
| *HTN + DM | 8 (21.1%) | 5 (13.2%) | 13 (17.9%) |
| *HTN + DM + IHD | 0 (0%) | 3 (7.9%) | 3 (7.9%) |
| Total | 38 (100%) | 38 (100%) | 76 (100%) |

*DM: Diabetes Mellitus, HTN: Hypertension, IHD: Ischemic Heart Disease

**Table 5.** Mean VAS at different time intervals in both groups

| VAS | Groups | Mean VAS ± SD | P-value t-test |
|---|---|---|---|
| Baseline | Vertebroplasty | 8.01 ± 0.99 | 0.101 |
| | Conservative | 8.35 ± 0.75 | |
| 24 Hours | Vertebroplasty | 4.37 ± 0.79 | 0.001 |
| | Conservative | 7.29 ± 1.21 | |
| 3 Weeks | Vertebroplasty | 4.03 ± 0.85 | 0.001 |
| | Conservative | 6.37 ± 0.91 | |
| 6 Weeks | Vertebroplasty | 3.87 ± 1.09 | 0.001 |
| | Conservative | 5.37 ± 0.97 | |

**Table 6.** Complications at 24 hours in both the study groups

| Compli-cations | | Groups | | Total | P-Value Chi-square |
|---|---|---|---|---|---|
| | | Vertebro-plasty | Conser-vative | | |
| 24 Hours | Present | 4 (10.5%) | 2 (5.3%) | 6 (7.9%) | 0.395 |
| | Absent | 34 (89.5%) | 36 (94.7%) | 70 (92.1%) | |
| 3 Weeks | Present | 2 (5.3) | 11 (28.9%) | 13 (17.1%) | 0.006 |

| | | | | | |
|---|---|---|---|---|---|
| | Absent | 36 (94.7%) | 27 (71.1%) | 63 (82.9%) | |
| 6 Weeks | Present | 8 (21.1%) | 21 (55.3%) | 29 (38.2%) | 0.002 |
| | Absent | 30 (78.9%) | 17 (44.7%) | 47 (61.8%) | |

## Discussion:

Given the scenario of high rate of morbidity associated with non-operative management, PVP has been reported as the best alternative to conservative management for the management of OVCF for not only pain management but also for return of functional independence, decreased rate of readmission and fewer admission to skilled nursing or long term care facilities. In the current study, we determined the efficacy of PVP in pain management over conservative management in patients with OVCF. The baseline characteristics of patients in both the groups were comparable. Our study showed that patients who underwent PVP had greater pain relief in terms of VAS score at 24 hours, 3 and 6 weeks compared to conservative management. Per-operative fluoroscopic imaging of Vertebroplasty of one of our cases is shown in Fig. 1 A&B.

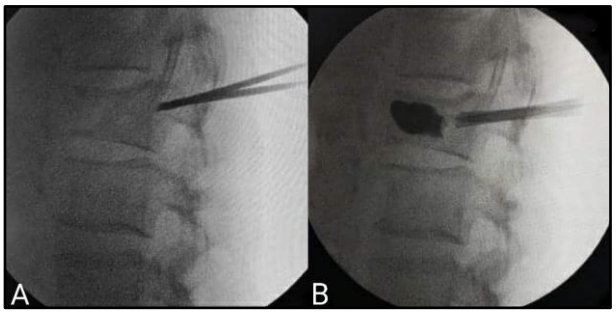


**Figure 1. A&B**: Per-operative fluoroscopic imaging of Vertebroplasty at L1 vertebral level.

Our study results are similar with other reports in the literature. Mattie R et al.[9] in their meta-analysis compared PVP with conservative treatment for the management of osteoporotic compression fractures in terms of pain relief. They had included eleven (n=11) trials comprising 1048 subjects. Patients treated with PVP (n=531) showed significantly lower intensity of pain when compared with patients treated conservatively at 1 to 2 weeks, 2 to 3 months, and 12 months. They concluded that the pain relieving effect of PVP exceeded the effect of conservative management in patients with osteoporotic compression fractures up to one year after the treatment. Our study showed similar results upto 6 weeks of follow up. We did not follow our patients up to one year. In fact several other reports showed similar results in studies by Liu et al.[10], Xie et al.[11], Luo W et al.[12], Lou S et al.[13], Zuo et al.[14], Zuo RS[15] and Chen LX[16]. In the pooled analysis by Zuo XH et al.[14], they evaluated the efficacy and safety in percutaneous vertebroplasty for osteoporotic vertebral compression fractures in comparison with conservative treatment, kyphoplasty and nerve block. They included eighteen (n=18) trials comprising 1994 patients. They concluded that both vertebroplasty and kyphoplasty had better performance than conservative management in terms of short and long-term pain relief.

However, randomised controlled trials by Kallmes et al.[17] and Buchbinder et al.[18] showed that vertebroplasty offered no benefit over sham procedure/simulated procedure over varying time intervals in terms of pain relief, physical function and quality of life. However, the sham/simulated procedure offered in these studies are difficult to achieve in surgical practice and ethically unacceptable. Furthermore, Samuel Butler[19] stated that these two studies had samples of fewer than 300 patients in both the vertebroplasty and control groups, and that many patients were unwilling to accept randomisation, particularly those in severe pain. As a result of the small sample size and selection bias, these studies were deemed untrustworthy. Further, if we observe the statistical trend in the above studies, PVP shows higher rate of clinical improvement of pain compared to conservative or sham treatment.

In Cochrane review of twenty-one trials, Buchbinder R et al.[20,21] compared benefits and side effects of vertebroplasty for treatment of osteoporotic vertebral fractures with placebo (sham), conservative care or some other intervention. There were five trials that compared vertebroplasty with placebo (n=541 subjects), eight trials comparing vertebroplasty with conservative care (n=1136 subjects), seven trials comparing it with kyphoplasty (n=968 patients) and one trial was included that compared vertebroplasty with facet joint glucocorticoid injection (n=217 patients).

Authors found no remarkable benefit in terms of pain relief when compared with a sham procedure and conservative care. The heterogeneity of included data could not be ignored and warrants a large-scale single randomised controlled trial.

Zhang L et al.[22] in another meta-analysis summarised current best evidence on the efficacy of PVP and conservative treatment (CT) for pain management and functional results among OVCFs patients. Their analysis revealed that PVP had benefits on pain relief at 1 week and 1 month, but not at 3 months along with improved quality of life, without increasing the incidence of vertebral fracture compared with the CT group. Wang D et al.[23] recently designed a clinical trial comparing the efficiency and safety of vertebroplasty versus conservative treatment for acute OVCFs. The primary outcome was pain relief at 1 month and 1 year, measured with the VAS score. The preliminary results showed vertebroplasty provides a rapid decrease of pain and an early return to daily life activities compared with the control group. However, detailed results are yet awaited. The mechanism of pain relief that occurs within minutes to hours after vertebroplasty remains unknown. Following the injection of the cement, pain pathways in the surrounding tissue appear to be altered in response to mechanical, chemical, vascular, and thermal stimuli.[24]

In summary, results of the present study and bulk of evidence cited in the literature suggest that percutaneous vertebroplasty has been consistently showing better results in terms of pain relief associated with osteoporotic vertebral compression fractures when compared with conservative treatment. Present study has some limitations. Firstly, the sampling technique can result in some bias and the sample size was relatively smaller, yet sufficient enough for interpretation. Nonetheless, it is not wise to extend our results to the general population; a larger sample size is needed for that purpose. Secondly, we did not use a placebo (sham) procedure. Thirdly, we did not follow our patients beyond 6 weeks and hence, were not able to evaluate long-term efficacy and risk of subsequent fractures associated with the procedure. We suggest future studies addressing these limitations taking larger sample size and taking into account the placebo effect, longer durations of follow up and comparison with other treatment modalities for pain relief like, nerve block and kyphoplasty.

## Conclusion

Mean VAS score was found to be significantly lower ($P<0.05$) in patients who underwent vertebroplasty procedure as compared to those managed conservatively. Overall complication rate was similar ($P>0.05$) in both groups at 24 hours, however, it was significantly lower ($P<0.05$) at 3rd and 6th weeks in patients who underwent vertebroplasty procedure as compared to those managed conservatively.

## List of abbreviations

VAS: Visual Analogue Scale
OVCF: Osteoporotic vertebral compression fractures
PVP: Percutaneous Vertebroplasty
PMMA: Polymethylmethacrylate
CT: Computed Tomography
MRI: Magnetic Resonance Imaging
DEXA: Dual-energy x-ray absorptiometry
DVT: Deep Vein Thrombosis

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