



Original Article

# Percutaneous vertebroplasty for symptomatic osteoporotic compression fractures: A single-center prospective study

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## ABSTRACT

**Background:** Osteoporotic vertebral compression fractures (OVCFs) increasingly occur with advancing age, and are associated with significant morbidity, mortality, and cost. We assessed the clinical efficacy, radiological, and functional outcomes for patients undergoing percutaneous vertebroplasty (PVP) due to OVCFs, with a special focus on the frequency of new vertebral compression fractures (VCFs).

**Methods:** This study, carried from 2018 to 2020, included 22 females and 4 males. They averaged 60.15 years of age (range, 50–70) were followed an average of 14.5 months (range 12–36 months), and had 30 VCFs between the T7–L2 levels. Multiple variables were studied, including: anterior vertebral height (AVH) and kyphotic angle (KA), new VCFs, and functional outcomes.

**Results:** The postoperative Visual Analog Scale and Oswestry Disability Index were significantly reduced at 12 months after PVP. Improvements for AVH and KA were also statistically significant; 23 patients (88.46%) had a dramatic decrease in pain on post-operative day 1, while 3 patients (11.53%) had no decrease in pain after PVP on post-operative day 1–1 postoperative month. No major complications were observed except high incidence of cement leakage at 8 levels (26.67%) in 6 patients. Additionally, new VCFs occurred in 10 vertebrae in 8 patients (30.76%), involving 6 adjacent (60%), and 4 nonadjacent vertebrae (40%).

**Conclusion:** PVP is an effective procedure in the management of painful OVCFs refractory to medical treatment. These PVP procedures yield immediate vertebral stabilization, relieve pain, and restore function with minimal associated morbidity.

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

## INTRODUCTION

Approximately 3–16% of women and 1–8% of men aged >50 years are reported to have sustained a clinically symptomatic vertebral compression fracture (VCF).<sup>[7]</sup> Percutaneous vertebroplasty (PVP) are widely performed, and provide immediate reduction of pain, disability, analgesia, and stability.<sup>[1,2]</sup> However, further work is needed to define the benefits of PVP compared to the standard non-surgical treatment. Here we studied the clinical efficacy, radiological and functional outcome of PVP utilized to treat Osteoporotic vertebral compression fractures (OVCFs), to largely determine the frequency of new post-procedural VCFs.

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## MATERIALS AND METHODS

### Clinical variables

With Institutional Review Board approval, (2018–2020) we retrospectively reviewed the charts of 22 females and 4 males with OVCS. Patients averaged 60.15 years of age, the mean follow-up period was 14.5 months, and exhibited 30 VCFs (T7–L2) [Table 1]. Multiple medical comorbidities were also recorded, including smoking, alcohol use and diabetes [Table 2]. All patients had moderate ( $n = 8$ ) to severe ( $n = 18$ ) back pain.

### Radiological work up

All patients underwent radiological assessment (plain X-rays, computed tomography [CT], and Magnetic resonance imaging [MRI] scans) plus laboratory investigations [Figures 1a-d]. Plain X-rays were used to evaluate the degree of height loss, type of fracture, grade of fracture and progression of deformity. MRI scans differentiated between acute, subacute and healed OVCFs and allowed for assessment of the spinal canal, retro-pulsed fragments, and degree of spinal cord compression. CT scans evaluated the integrity of the posterior wall of the vertebral body or suspected pedicle and or posterior element fractures.

### Outcome evaluation

Postoperatively, patients were evaluated utilizing Visual Analog Scale (VAS), Oswestry Disability Index (ODI) score, and radiological parameters (anterior vertebral height [AVH], kyphotic angle [KA]; plain standing X-rays on 1 day and 1, 4, 6, 12 months, and yearly thereafter) [Figures 1 e-h, 2 a-c].

**Table 1:** Inclusion and exclusion criteria.

Inclusion criteria	
1.	Back pain caused by single or double level osteoporotic VCF (moderate or severe type) involving dorso-lumbar region (T7–L2)
2.	Any sex, and age >50 years
3.	X-ray, MRI, CT scan and BMD (T score <-2.5 suggestive of osteoporotic VCFs)
Exclusion criteria	
1.	Back pain attributed to myelopathy or radiculopathy resulting from stenosis of the vertebral canal or narrowing of the intervertebral foramen
2.	Burst fracture
3.	Any other bone disease except osteoporosis that could affect the mechanical integrity of vertebrae in Dorso-lumbar region of spine
4.	Infection
5.	Elderly patient with uncontrolled medical co-morbid condition

### PVP procedure

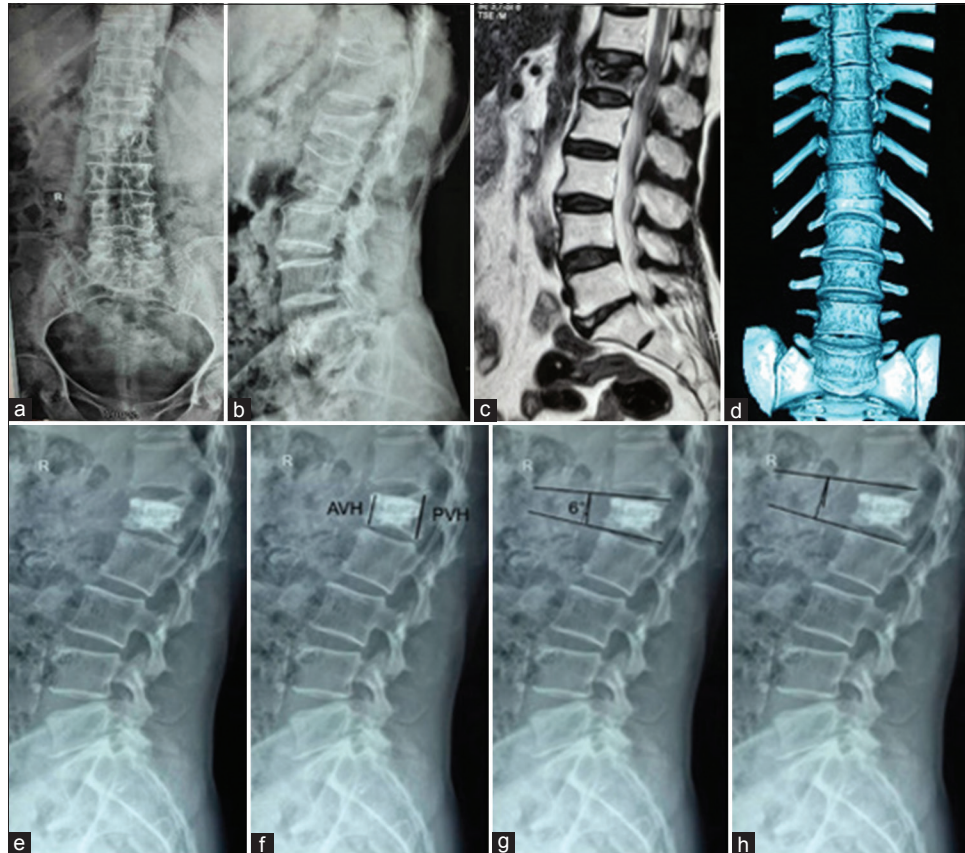
Routine PVP were performed under general anesthesia or local anesthesia using a C-arm. Bilateral cannulations were favored due to increase the likelihood of adequate/safer cement injections. The routine procedures were then performed.

### Statistical analysis

The quantitative data were analyzed statistically using Statistical Package for the Social Science, version 25, Armonk, NY, INM Corp. Statistical significance was set at  $P < 0.05$  and

**Table 2:** Demographic profile of the patients with PVP ( $n=26$ ).

Characteristics	n (%)
Age (years)	
52–60	16 (61.5)
61–72	10 (38.5)
Sex	
Male	4 (15.4)
Female	22 (84.6)
Occupation	
Business	4 (15.4)
Housewife	22 (84.6)
Associated risk factors	
Smoking	8 (30.7)
Alcohol	2 (7.7)
Diabetes	8 (30.7)
Steroid use	3 (11.5)
Chronic renal failure	6 (23.0)
Low body mass index	4 (15.4)
Hypothyroidism	4 (15.4)
Time from fracture to PVP	
2 weeks–6 weeks	8 (30.8)
7 weeks–12 weeks	16 (61.5)
>12 week	2 (07.7)
Cause of trauma	
A level fall	22 (84.6)
Lifting heavy objects	4 (15.4)
No. of level of fracture	
Single level	22=22 (73.33)
Double level	4=8 (26.67)
Location of fracture (n=30)	
T7	2 (6.67)
T8	2 (6.67)
T11	2 (6.67)
T12	13 (43.33)
L1	8 (26.67)
L2	3 (10.00)
Types of fracture	
Wedge	20
Concave	6
Grade of fracture	
Moderate fracture (25–40% height loss)	22 (84.6)
Severe fracture (>40% height loss)	4 (15.4)



**Figure 1:** 72-year-old lady underwent percutaneous vertebroplasty following osteoporotic vertebral compression fracture (VCF) at L1 level on July 28, 2018 after 8 weeks of onset of symptoms. (a and b) plain X-ray lumbosacral spine shows compression fracture L1, (c-d) T2 weighted sagittal view magnetic resonance imaging and computed tomography scan showing VCF and (e-h) shows subsequent follow up at 1, 3, 6 and at 12 months, and measurement of anterior vertebral height (increased 70% at 12 month) and kyphotic angle decrease from 15 to 6 degree.

confidence interval set at 95% level. Continuous variable was expressed as mean with standard deviation and categorical variables as frequency with percentage. Numerical data were assessed by paired *t*-test.

## RESULTS

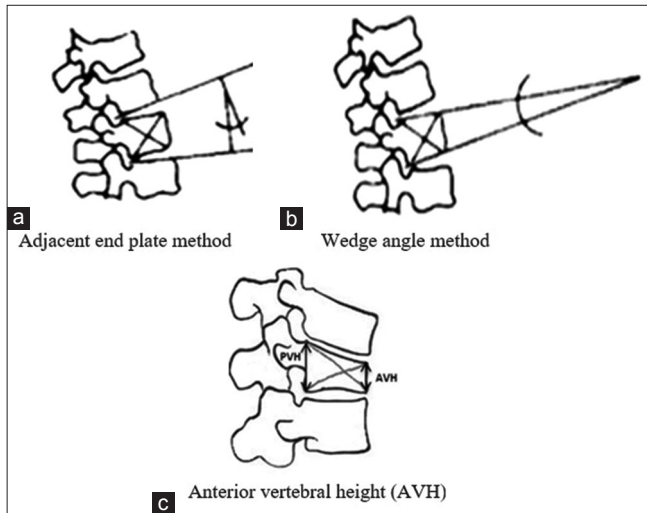
The mean post-operative VASs and ODI scores were significantly reduced at 12 months after PVP [Table 3]. Twenty-three out of 26 patients (88.46%) had dramatic decrease in pain on post-operative day 1, while 3 patients (11.53%) had no decrease in pain after PVP during their early follow up (post-operative day 1 and 1 month). The preoperative mean VAS score of these 3 patients was 8.3 and it was reduced to 7.6 at post-operative day 1, 6.8 in the post-operative 1<sup>st</sup> month, 4.1 in the post-operative 6<sup>th</sup> month, and 2.3 in the last follow up (at 12 month). There was no significant difference between the preoperative VAS scores and the post-operative VAS scores of these 3 patients at day 1 and in the 1<sup>st</sup> month, while the VAS scores at 6 and 12 months was significantly decreased ( $P < 0.05$ ). The

mean post-operative AVH and KA were also significantly improved at last follow up [Table 3]. The mean volume of cement injected was 5.28 mL (range, 3.5–6.5 mL) per level. Cement leakage was seen at 8 levels (26.67%), of which intradiscal leakages was found in 5 levels (16.67%), anteriorly in 2 levels and another one through the path of trocar and cannula but clinically no significant complications were encountered. New VCFs occurred in 10 vertebrae in 8 patients (30.76%), affecting 6 adjacent (60%) and 4 nonadjacent vertebrae (40%). In addition, subsequent new fractures occurred in 5 (19.23%) patients within 3 months and 3 (11.5%) patients, within 12 months after initial treatment and subsequent vertebroplasty were performed in 4 cases. Two cases were performed at <6 month and two cases at 6–12 months. One case developed progressive symptomatic kyphotic deformity at D12 vertebrae level following VP. Instrumented stabilization was performed with cannulated pedicular screws with cement injection and rod, one level above and one level below the affected vertebrae at 7 months later. Rest was treated conservatively.

**Table 3:** Pre- and post-operative clinical and radiographic data (n=26).

Pre-operative	Post-operative						P-value
	Day 1	Month 1	Month 3	Month 6	Month 12		
Mean VAS score	7.77±0.44	3.07±0.18	2.73±0.3	2.15±0.32	2.04±0.14	1.2±0.20	<0.001
Mean ODI score	65.08±0.49	-	17.77±0.60	17.69±0.48	17.54±0.52	15.20±0.48	<0.00
AVH (%)	53.08±2.53	-	72.38±0.65	72.31±0.63	71.38±1.26	70.2±1.26	<0.001
Kyphotic angle (°)	15.40±0.67	-	6.67±0.37	6.66±0.35	6.39±0.49	6.68±0.32	<0.001

VAS: Visual analogue scale, ODI: Oswestry disability index, AVH: Anterior vertebral height



**Figure 2:** Measurement technique for assessing fracture kyphosis (a and b) and anterior vertebral height (c). Segmental kyphosis (a) was assessed by measuring the angle between the inferior end plate of the upper vertebra and superior end plate of the lower vertebra and vertebral kyphosis (b) by measuring the angle between the two end plates of the fractured vertebra

## DISCUSSION

The efficacy of PVP in decreasing pain has been reported to be 60–90%.<sup>[4]</sup> Marked or complete pain relief was demonstrated in 90% of patients with OVCFs.<sup>[8]</sup> A meta-analysis also reported a success rate of 87%.<sup>[5]</sup> In this Quasi-experimental study, 88.46% patients had dramatic decrease in pain on post-operative day 1, while 11.53% patients had no decrease in pain after PVP during their early follow up period (post-operative day 1 and 1 month), but VAS scores at 6 and 12 months follow up was found to be significantly decreased ( $P < 0.05$ ).

The amount of cement used during the PVP procedure is critical for its success. Recently it has been mentioned that 16% of the vertebral corpus volume should be augmented in order to balance the distribution of stress over the vertebra.<sup>[12]</sup> The average amount of cement applied in our patients was 5.28 mL (range, 3.5–6.5 mL) per level which was sufficient and consistent with the literature. In this study mean KA and

AVH was significantly improved after 12 months which is similar to other study.<sup>[6]</sup>

A major problem that occurs after PVP is a new fracture in adjacent vertebra. A meta-analysis demonstrated that incidence of new fractures after PVP was 8–52%<sup>[15]</sup> and 41–67% of subsequent fractures occurred over adjacent levels to the augmented vertebra.<sup>[14]</sup> Several risk factors are associated for subsequent fractures after PVP, including the involvement of multiple fractures, intradiscal cement leakage, the presence of an intravertebral cleft or solid pattern cement filling,<sup>[13]</sup> a low body mass index, steroid medication, the severity of the wedge angle, and well-achieved vertebral height or kyphosis correction, smoking, and collagen disease.<sup>[9]</sup> In our study, new VCFs occurred in 10 vertebrae in 8 patients (30.76%), which is similar to the study of Tanigawa *et al.*<sup>[13]</sup> [Table 4]. Kamano *et al.*<sup>[9]</sup> mentioned an incidence of 18.1% of subsequent fractures in within 3 months and 24.1% occurred within 12 months.

Vertebroplasty has a complication rate of 1–3%. The most frequently reported complications are cement extravasation. There were no major complications in the present study despite a relatively high incidence of cement leakage at 8 levels (26.67%). New VCFs occurred 10 vertebrae in 8 patients (30.76%), and one patient exhibited progressive kyphotic deformity (3.84%). In Lee *et al.*<sup>[11]</sup> they found the following; 75% of patients with asymptomatic, 1.48% with symptomatic leakage, 18% along with new fractures (adjacent level 51.6% and remote level 48.2%). Layton *et al.*<sup>[10]</sup> found 25% cement leakage, mostly into the disc space (12%); only 1.8% patients were symptomatic and 1 case developed pulmonary cement embolism [Table 4]. The frequency of new VCF varied, ranging from 8% to 52% and most of them occurred at adjacent level.<sup>[14]</sup>

PVP is a procedure that improve stability and pain relief, and but have been associated with new fractures of adjacent vertebra versus conservative pain management.<sup>[1]</sup> Currently, the AAOS clinical practice guidelines strongly recommended that vertebroplasty not be used for the treatment of symptomatic OVCFs.<sup>[3]</sup> Despite the evidence against the use of vertebroplasty, most reports including our study point out its beneficial effect on pain relief and overall disability while still being reasonably safe.



**Table 4:** Complications following vertebroplasty in previous study.

Study	Cement leak	New VCF (%)
Layton <i>et al.</i> <sup>[10]</sup> (2006)	25% (asymptomatic) 1.8% (symptomatic)	23
Lee <i>et al.</i> <sup>[11]</sup> (2009)	75% (asymptomatic) 1.48% (symptomatic)	18
Tanigawa <i>et al.</i> <sup>[13]</sup> (2011)	42.6%	33.5
Current study	26.67% (all asymptomatic)	30.76

VCF: Vertebral compression fracture

## CONCLUSION

PVP is a safe and effective procedure in the management of painful OVCFs refractory to medical treatment. This procedure can be performed rapidly and is alternative to open surgeries in patients with comorbidities.

### Declaration of patient consent

Patient's consent not required as patients identity is not disclosed or compromised.

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Nil.

### Conflicts of interest

There are no conflicts of interest.

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