

## TECHNIQUE OF PERCUTANEOUS VERTEBROPLASTY IN OSTEOPOROTIC COMPRESSION FRACTURES OF SPINE-EVALUATION OF CLINICAL RESULTS AND EFFICACY

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### Abstract

**Background:** The objective of this study was to study the technique of percutaneous vertebroplasty in treatment of Osteoporotic Compression fractures of spine and evaluate the clinical results & efficacy of PVP in these patients. **Materials and Methods:** A prospective study was conducted to better define the clinical outcomes, contra-indications, technique, complications and role of adjunctive imaging in PVP. All patients in the study were evaluated at interval of 1 day, 6 weeks & 3 months using VAS score, RMDQ score & analgesic score. **Result:** A total of 20 consecutive patients were included in this study. There was a marked reduction in pain among the patients post the procedure which was found to be statistically significant. The trend in pain collaborated with the use of an analgesic as assessed by the VAS (p<0.05). There was also an improvement in disability scores by a mean of 14.3 at 3 months after the procedure. **Conclusion:** PVP is a safe and feasible treatment for patients with spinal compression fractures.

## INTRODUCTION

Vertebral compression fractures (VCFs) can be defined as the reduction in vertebral body height by 20% at anterior, posterior, or middle part of vertebra or a decrease in height by 4 mm compared to baseline.<sup>[1]</sup> As per the European Vertebral Osteoporosis study, women are more prone to VCFs than men which increases with age.<sup>[2]</sup> The lifetime risks of symptomatic VCF secondary to osteoporosis is 16% for females whereas 5% for males. The survival rate for Osteoporotic VCF after five years of diagnosis is 61%. The disease primarily affects women and older people of both sexes.<sup>[3]</sup> Apart from osteoporosis the other risk factors for VCF are alcohol consumption, tobacco use, oestrogen deficiency, early menopause, insufficient physical activity, dietary calcium and Vitamin D deficiency, trauma, neoplasm, infection.<sup>[4]</sup> Axial trauma due to fall from a height, especially in individuals with osteoporotic bone are prone to the damage, even if the fall was minor. Although these fractures rarely require hospital admission, they have the potential to cause significant disability and morbidity, often causing incapacitating back pain for

many months. The main symptom of the disease is pain associated with neurologic deficits, which tends to be quite infrequent. Over a period of time, multiple fractures lead to loss of stature which is progressive and change in posture due to continuous contraction of the paraspinal musculature. Other complications of compression fractures include constipation, bowel obstruction, progressive muscle weakness, loss of independence and kyphosis among many others.<sup>[5]</sup> Percutaneous vertebroplasty was first performed in 1984 in France by Deramond et al in a vertebral angioma to obtain analgesia and spinal stabilization.<sup>[6]</sup> Prior to the introduction of Percutaneous vertebroplasty, treatment used for VCF were conservative like bed rest, wheel chair, analgesics, uncomfortable back braces which provided restoration of mechanical stability; a painless, balanced, stable spinal column; optimal neurologic function and minimal treatment morbidity.<sup>[7]</sup> External bracing, analgesics and rest may ameliorate pain in some patients, but in others a constant administration of analgesics, often narcotics, is necessary.<sup>[8]</sup> Percutaneous vertebroplasty is a radiologically guided therapeutic procedure for the treatment of

pain caused by vertebral body compression fractures unresponsive to conservative medical therapy. This minimally invasive procedure involves the percutaneous puncture of the fractured vertebral body from a transpedicular or paravertebral approach, followed by injection of an acrylic polymer to provide bone augmentation and prevent further collapse. The internal casting of the bone alleviates pain and allows increased mobility in most patients.<sup>[9]</sup> Although vertebroplasty was first performed in 1984 by a French radiologist, it has gained a widespread acceptance in the Indian subcontinent. Though initially developed to treat painful intraosseous spinal haemangiomas, this technique was adapted to treat symptomatic osteoporotic VCFs in 1991.<sup>[10]</sup> Over the year, the procedure was adapted for vertebroplasty for treatment of traumatic fractures, malignant fractures among other indications. A prospective study was conducted to better define the clinical outcomes, contra-indications, technique, complications and role of adjunctive imaging in PVP in the Indian set-up. The objective of this study was to study the technique of vertebroplasty in treatment of osteoporotic Compression fractures of spine and evaluate the clinical results & efficacy of vertebroplasty in these patients.

## MATERIALS AND METHODS

The study was conducted in the Department of Orthopaedics at Northern Railway Central Hospital, New Delhi after obtaining ethical clearance from the Institutional Clinical Ethical Committee.

**Study Population:** A total of 20 patients with Osteoporotic compression fractures spine satisfying the under-mentioned inclusion/ exclusion criteria were included in the study. The decision to perform PVP was based on clinical and imaging evaluation

### Inclusion Criteria

1. Acute and sub-acute painful Osteoporotic Vertebral Compression Fractures
2. Severe resistant back pain with Vertebral Osteoporosis

### Exclusion Criteria

#### 1. Patient Factors

Active systemic/localized infection, cardiopulmonary compromise, bleeding disorders/ anti-coagulant therapy, improvement on medical t/t.

#### 2. Fracture Factors

High Energy Injury, Severe VB Collapse (Vertebra Plana), Neurological Compromise, Osteoblastic Metastasis, Posterior VB Wall Deficiency, Very Old Fractures, Unstable Fractures with Posterior Element Involvement especially with Facet Joint Disruption, PIVD, Facet Arthropathy, Spinal Stenosis.

### Clinical Evaluation

A detailed clinical history was taken and physical examination was performed to document the exact site & character of patient's pain and tenderness, limitation of mobility, the baseline peripheral and central neurologic examination.

### Pre-Treatment Imaging

All study sample had imaging evidence (AP and lateral spine radiographs) of a recent VB collapse corresponding to the location of pain. When indicated, cross-sectional imaging (CT/MRI) was obtained to exclude other causes of pain such as Intervertebral Disc Protrusion/ Extrusion or Spinal Stenosis and for defining the posterior cortical wall integrity of the vertebra. DEXA scan was done to document Osteoporosis in patients with resistant back pain.

### Pre-Procedural Workup

Informed consent was obtained in all cases.

### Patient Position

The patient was placed prone on soft pads with the arms extended at shoulder level on a radiolucent table.

### Procedure:

#### 1. Pedicle Targeting

The pedicle to be punctured was isolated under AP fluoroscopy. The skin, subcutaneous tissues and pedicular periosteum were anaesthetized with 7-10 cc of 0.25% Bupivacaine Hydrochloride using a 2 inch 25 G Spinal Needle and a small incision is made with a no. 11 Scalpel Blade to allow easy passage of the Vertebroplasty Needle. A simple 'Bullseye' approach to the pedicle positioned the needle tip in the mid-portion of the ipsilateral vertebral hemisphere for bi-pedicular access. When contiguous vertebral levels are to be treated, the unipedicular approach had the advantage of allowing positioning of the needles alternating between left and right pedicles, making access to the operative field less cumbersome. Before removing the needle, AP and lateral fluoroscopy were done to show the needle tip approximating the same location on the pedicle in the superior-inferior plane.

#### 2. Needle Positioning

The needle used for PVP was a 10-11 G (lumbar level) or 11-13 G (dorsal level) Trocar & Cannula System Bone Biopsy Needle 10-15 cm long with a diamond shaped or bevelled tip. The needle was advanced until the tip abutted the cortical surface in the superior to mid-point of the pedicle. Depending on the shape of the pedicle, the needle was entered at the widest point. Care was taken to position the needle tip precisely before a cortical break was made as once the track is started, repositioning is difficult. The needle was passed carefully by hand pressure (a slight back and forth twisting motion) or sometimes helped by a sterile orthopaedic hammer/ mallet, under frontal and lateral fluoroscopic control.

#### 3. Cement Preparation

The cement used in all 28 cases was the Subiton vertebroplasty cement, consisting of 5ml liquid monomer (Methyl Methacrylate 4.965 ml, N,N-dimethyl p-toluidine 0.035 ml & Hydroquinone 18-20 ppm) and 12.5 gm of powder (Polymethylmethacrylate 7.42 gm, Benzoyl Peroxide 0.08 gm & Barium Sulphate 5 gm). Working times vary depending on the OT temperature decreasing

from 12 min at 20° C to 7 min at 26° C. To liquid monomer was added the solid powder polymer and stirred slowly for not > 30 seconds in a plastic bowl until a thin cake-glaze (semi-fluid toothpaste like) consistency was achieved. The optimal period for cement injection is usually between 5-15 min.

#### 4. Cement Injection

- The PMMA was always injected very slowly under fluoroscopic control. Osteoporotic collapse <50% were injected with the syringe alone.
- Under continuous C-arm monitoring, PMMA was injected using the volumetrically controlled screw system syringe that allowed control of injection pressure and quantity of cement delivered. Lateral fluoroscopy was particularly useful to avoid extrusion of cement beyond the confines of the VB posteriorly into the epidural space.
- If injection was difficult, the delivery system was disconnected & evaluated for plug formation at the tip of the syringe or injection tubing. If there was continued difficulty, then the needle was pulled back slightly, the dead space cleared with the plunger or stylet and injection was tried again.
- If the cement crossed the midline to the medial border of opposite pedicle, the contralateral side was not punctured. Injection ceased when the cement reached the posterior ¼th or the posterior wall of the VB on the lateral projection or until resistance was met.
- If the cement reached across an end plate fracture, a small amount of material was allowed to layer onto the opposite side
- If the cement flowed into a vein, the needle was repositioned more posteriorly. If it continued to fill the vein, the material was allowed to harden for a few minutes, and a repeat injection was tried. If the material persisted in filling the vein, the injection was terminated.
- If leakage developed, patient was checked for any symptom development. With no symptoms suggesting radicular pain after waiting a short time (keeping the needle clean of PMMA) to let PMMA set up in the leakage area, PMMA was injected again.
- PMMA cements typically set within 20 minutes & achieve 90% strength within 01 hour.
- Post-Procedural Care & Discharge Advice
- Initially, most patients were admitted for a 01 day observation period following the procedure. Later on, the patients were treated routinely on an outpatient basis with a 02 hour observation period after PVP. During the 1st hour following the procedure, all patients were observed/monitored in the full supine/ prone/oblique/ lateral position for clinical stability. Before the patient was discharged home to the care of an adult, the pain level was rechecked and note was

made of any potential complication of the procedure.

- pain medications could be taken as needed and suture removed at 8 – 10 days after procedure.
- Patients were instructed to notify us of redness or discharge at the operative site, recurrent or new back pain, chest pain, shortness of breath, unexplained fever or neurologic symptoms.
- A short course of physical therapy with continued use of a brace proved useful.

#### Follow Up

Patient follow-up was done within 24 hours, 6 weeks and 3 months following the procedure. Clinical data including pre and postoperative X-ray films were reviewed for the quantity of bone cement used, cement extravasation, subsequent adjacent level fractures and neurologic & systemic complications. In addition, clinico-radiological outcomes were assessed using pain score (VAS),<sup>[11]</sup> analgesic score (0-4) for pain and use of analgesic and disability score (RMDQ),<sup>[12]</sup> for assessing reduction in disability post the procedure.

## RESULTS

The results of 20 consecutive patients who underwent percutaneous vertebroplasty for Osteoporotic compression fracture, of spine for Pain relief from January 2006 to June 2008 were Evaluated. All patients in the study were evaluated at interval of 1 day, 6 weeks & 3 months using VAS score, RMDQ score & Analgesic score.

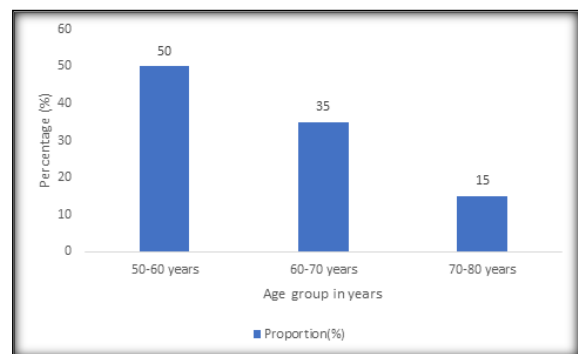


Figure 1: Age distribution of the patients

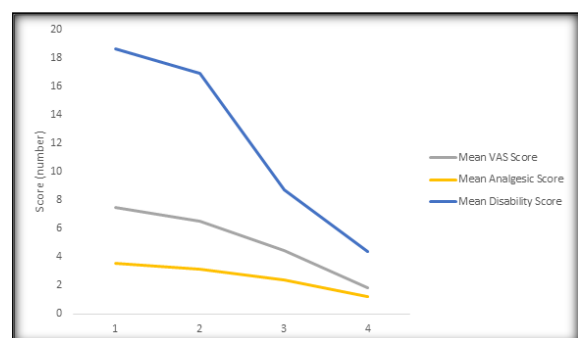


Figure 2: Trend in VAS, Analgesic score and Disability score

There were 16 females & 4 males in the age group of 50-80 years with painful compression fractures of vertebra (single/multiple level) with osteoporosis as the basic cause. All the patients were enrolled in the study after taking conservative treatment at least six weeks in the form of Bed Rest, analgesics & bracing as the initial treatment.

Of the enrolled patients, 45% reported symptoms for a period of 12 weeks, 20% reported symptoms for 6 - 12 weeks, 35% reported symptoms for 6 weeks. Conservative treatment was provided as the first line of treatment to all the patients. The regime of

conservative treatment provided has been described in the [Table 1].

As per the trend in the VAS score, there was a marked reduction in pain among the patients post the procedure which was found to be statistically significant. The trend in pain collaborated with the use of analgesic as assessed by the analgesic score, which showed a marked reduction in the use ( $p < 0.05$ ). The disability of the patient as assessed by the RMDQ also showed a marked drop in the disability and an improvement if the quality of life.

**Table 1: Regime of conservative treatment.**

Nature of Conservative Treatment	No of patient	Percentage
Bed Rest + NSAIDS	3	15%
Bracing + NSAIDS	4	20%
Bracing + Narcotic	6	30%
Bracing + Narcotics + NSAIDS	7	35%
Total	20	100%

**Table 2: Trend of Pain (VAS score), use of analgesic (Analgesic score), disability (Disability score) over a period of time.**

Time	Pre-Procedure	1 Day	6 Weeks	3 Months	Repeated measure ANOVA (p value)
Mean VAS Score	7.5	6.5	4.45	1.8	<0.05 (sign.)
Mean Analgesic Score	3.55	3.15	2.35	1.2	<0.05 (sign.)
Mean Disability Score	18.65	16.9	8.75	4.35	<0.05 (sign.)

## DISCUSSION

There are various methods for evaluation of back pain in patients who are being referred for PVP. The most commonly used parameter is pain rating. In addition to pain, patients with osteoporotic vertebral collapse also have functional disability in carrying out their activities of daily living. It is hypothesized that the pain relief is due to the destruction of nociceptive nerve endings at the vertebral site which occurs due to the heat generated by the exothermic reaction of cement polymerization.<sup>[13]</sup> The other reason for pain relief is due to the altered biomechanical axis of the spinal column for weight bearing during axial loading due to the procedure.<sup>[14]</sup> In our study, in addition to quantifying pain by means of a VAS, we also objectively assessed the disability of patients with back pain by means of the Roland-Morris Disability Questionnaire (see Appendix). This is a 24-point questionnaire which gives an overall idea of the quality of life of the patient afflicted by back pain. Analgesic use was also assessed pre- & post-PVP. Weill et al studied use of analgesics and mobility in assessing the functional status in their patients and found improvement in overall patient performance as defined by a decrease in narcotic dosage and the ability to walk, seen in 73% of patients.<sup>[15]</sup> Cyteval et al in their study of 20 cases found that pain relief assessed by VAS was complete within 24 hours in 15 patients and partial in 3. They also found that analgesic administration could be stopped in 14 of these patients.<sup>[16]</sup> Amar et al studied the use of narcotic usage, ambulation and mobility as well as the ability to sleep comfortably after the procedure. Based on their questionnaire, 74% of their

patients believed that the procedure improved their overall quality of life.<sup>[17]</sup> Our study also reported a marked reduction in pain and use of analgesic score. An approximate reduction by 65 to 80% in VAS and analgesic score was seen among the patients on follow up. PVP was also tested in cervical metastasis cases and there was a marked reduction in pain among the patients post operatively (7.9 pre-operatively to 1.7 at 3 months post procedure).<sup>[18]</sup> Trout et al also used the Roland-Morris Questionnaire in 164 patients and found that the disability scores improved by a mean of 7.0 points at 1 week and remained improved at 1 year ( $p < 0.05$ ) after vertebroplasty.<sup>[19]</sup> In our own series, we noted an improvement in disability scores by a mean of 14.3 at 3 months after the procedure ( $p < 0.05$ ). Another study conducted to test the efficacy of vertebroplasty and kyphoplasty found the reduction in disability from 16.3 to 7.3 tested by the RMDQ scale.<sup>[20]</sup>

## CONCLUSION

PVPs provided a significant reduction in the pain relief and reduction in the use of analgesics. It also improved the quality of life with a reduction in the disability. PVP is a safe and feasible treatment for patients with spinal compression fractures.

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