

Original Research Article

Multilevel percutaneous vertebroplasty: safety, efficacy and long-term outcomes

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ABSTRACT

Background: The pain in vertebral compression fractures is severe, leading to reduced mobility and quality of life. Percutaneous vertebroplasty is a minimally invasive procedure for treating various spinal pathologies. This study evaluated the usefulness and safety of multilevel PVP (two to three vertebrae) in managing VCF.

Methods: This retrospective study evaluated 59 vertebral levels in 28 patients with VCF who had been operated on for multilevel PVP (two to three levels). There were 22 females and six males, and their ages ranged from 36 to 79 years, with a mean age of 68.95 years. We had injected two levels in 25 patients and three levels in 3 patients. The visual analogue scale was used for pain intensity measurement, and plain X-ray films, computed tomography scan and magnetic resonance imaging was used for radiological assessment. The mean follow-up period was 13.8 months (range, 11-19).

Results: Significant pain improvement was recorded in 26 patients (92.85%). More remarkable improvement in pain was noticed in the immediate postoperative period than in the subsequent follow-ups. Asymptomatic bone cement leakage anteriorly and into the disk spaces in two patients. Isolated anterior leakage has occurred in one patient. There was no encounter of pulmonary embolism.

Conclusions: Multilevel PVP for the treatment of VCF is a safe and effective procedure that can significantly reduce pain and improve patient condition without any significant morbidity. It is considered a cost-effective procedure allowing a rapid restoration of patient mobility.

Keywords: Percutaneous vertebroplasty, Vertebral metastases, Vertebral hemangioma, Osteoporosis, Polymethylmethacrylate

INTRODUCTION

Vertebral compression fractures (VCF) cause severe back pain, height loss, and spinal deformity. Significant pain can reduce physical activity and cause depression, deep vein thrombosis, pneumonia, and sores.¹ Patients may suffer impaired mobility and compromised quality of life secondary to agonizing pain.^{2,3} Pain from VCF is often abrupt and intense. Treatments include bed rest,

analgesics, back braces, other conservative treatments, and more invasive procedures, including percutaneous vertebroplasty (PVP) and open surgery.⁴ PVP is a minimally invasive procedure that injects bone cement into the vertebral body. Deramond and Galibert first performed this technique in 1987 for the treatment of vertebral hemangiomas.⁵ Since then, PVP has gained worldwide popularity and managed various spinal pathologies such as metastasis and osteoporosis.

METHODS

The present study retrospectively studied multilevel (2 to 3 levels) PVP procedural safety, efficacy, and long-term outcomes in consecutive VCF patients admitted during 60 months from January 2016 to December 2020 at Medicovert hospitals Visakhapatnam. During this period, 28 patients were treated for VCF. We injected 59 vertebrae in those 28 patients. All patients were subjected to a thorough history taking and a detailed neurologic examination. All the patients presented with a history of back pain preceding surgery. All patients had preoperative X-ray, computed tomography (CT), and magnetic resonance imaging (MRI) scans. Patients were followed side by side by internal medicine doctors, spine surgeons, medical and radiation oncologists. Physical therapy, back braces, analgesics and muscle relaxants were used to control pain. Before the operation, each patient completed visual analogue scales rating their average back pain from 0 to 100.

Inclusion criteria

Patients with painful multilevel (2 to 3 levels) vertebral compression fractures of the thoracolumbar spine of any aetiology with corresponding clinical and radiological evidence were included in the study.

Exclusion criteria

Patients with resolving pain or pain responding significantly to medical management, back pain which did not correlate to the fractured spinal level or was not related to the VCF, systemic or local infections, coagulation disorders, significant disc herniations, significant spinal stenosis with cord compression, unstable retropulsed vertebral fragments and patients with more than three vertebral compression fractures were excluded from the study.

Procedure

All PVP procedures were performed by an interventional neuroradiologist with 15 years of expertise in spine interventions. PVP using the polymethylmethacrylate (PMMA) was performed under local anaesthesia without any sedation in our patients. Patients were placed in a prone position. A sterile technique with a strict aseptic protocol was used. A unilateral transpedicular injection was used in all our patients. A transpedicular needle was introduced in the anterior third of the vertebral body (Figure 1-2). The cement mixture was injected gradually through the needle under careful fluoroscopic guidance in both anteroposterior and lateral views (Figure 3-4). Adequate consistency of bone cement was attained before injection to decrease the incidence of leakage. Suppose cement leakage was detected during injection; the procedure was halted and then restarted after 30 seconds.

After the procedure, all patients were observed for 24 hours in an intensive care unit and underwent neurological examination. The visual analogue scale (VAS) was used for pain intensity measurement, and plain X-ray films (anteroposterior and lateral views) and CT scans were used for radiological assessment in all the patients. All patients were discharged after the 3rd day of the PVP. The patients were followed up at 1, 6, 12 months postoperatively.

RESULTS

In the present study as shown in (Table 1), the ages ranged from 36 to 79, with a mean age of 68.95 years. Males were 6, and females were 22. The mean duration of symptoms was 5.89 ± 1.98 weeks. Vertebrae injected were thoracic (21), lumbar (38). Simultaneous 2 level injections were done in 25 patients, whereas 3 level injections were done in 3 patients. D12 was the most involved vertebra, whereas D7, D8 were the least involved.

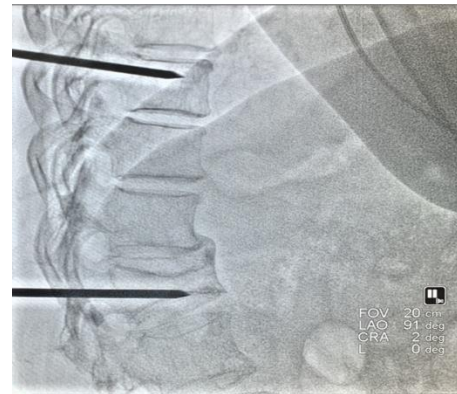


Figure 1: Lateral view of the spine showing transpedicular needle placed in the anterior one-third of the vertebral body.

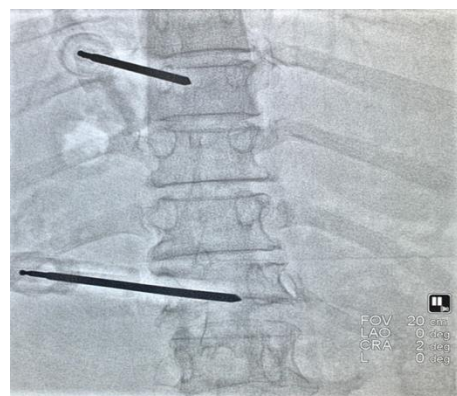


Figure 2: Anteroposterior view of showing the needle placement.

The average amount of bone cement injected into the lumbar spine is 5.6 ml and 4.3 ml in the dorsal spine. The VAS was used to appraise the intensity of back pain

before and after PVP. The preoperative mean back pain VAS value was 81.53. 24 hours after the procedure, the VAS dropped to 31.34; 27.56 after one month, 24.17 after six months and 23.12 after one year. Significant pain improvement was defined as the decrease of VAS scores by more than 50%, recorded in 26 patients (92.85%).

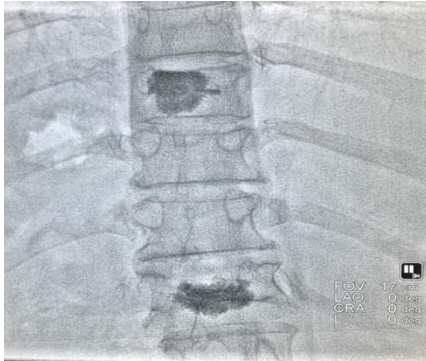


Figure 3: Anteroposterior view after injection of bone cement, no leakage of the cement was observed.

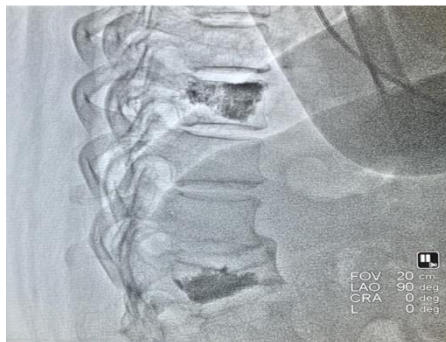


Figure 4: Lateral view after injection of bone cement, no leakage of the cement was observed.

More remarkable improvement in pain was observed in the immediate postoperative period than in the subsequent follow-ups (Figure 5).

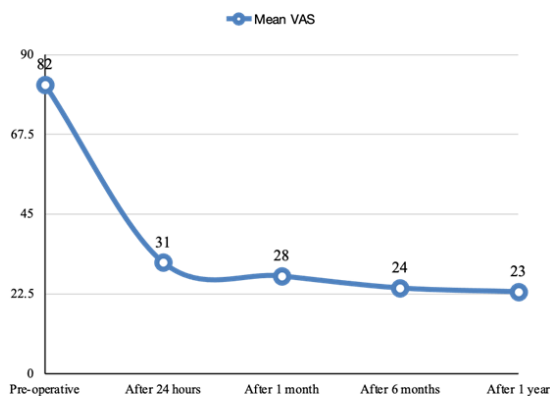


Figure 5: Mean visual analogue score (VAS) over time.

No further vertebral fractures were found in the injected vertebrae. Three out of 28 patients (10.71%) developed a new fracture and required the second vertebroplasty. Two of them had fractures adjacent to vertebroplasty levels, while the fracture was distant in the other. Asymptomatic bone cement has occurred in 3 patients (10.71%) leakage anteriorly and into the disc spaces in two patients. Isolated anterior leakage occurred in one patient. All other patients were doing fine, and no further management was required. None of the patients developed discitis, epidural or paravertebral leakage or leakage in the disc space. There was no encounter of pulmonary embolism.

DISCUSSION

In the recent guidelines of the cardiovascular and interventional radiology society, indications for PVP include painful osteoporosis VCF refractory to medical treatment for more than three weeks, painful vertebrae due to an aggressive primary bone tumour (hemangioma, giant cell tumour), painful vertebrae with extensive osteolysis due to malignant infiltration (multiple myeloma, lymphoma, metastatic cancer), painful fracture associated with osteonecrosis (Kummel's disease), reinforcement of the pedicle or vertebral body before posterior surgical stabilization procedures and chronic traumatic fracture in normal bone with nonunion of fracture fragments or internal cystic changes.⁴⁻⁶ With the increase of the ageing population worldwide, osteoporotic fractures have become very common in daily practice.⁶

Patients with osteoporotic fractures can have a single or multilevel affection (more commonly). Vertebral body hemangiomas are the most common non-painful, slow-growing, benign tumours of the spine.⁷ They represent about 2-3% of all spinal tumours, usually found in about 11% of all vertebral autopsies.⁸ Most of them remain clinically silent; in about 0.9 to 1.2% of patients, they are presented with pain symptomatology.^{7,8} 90% of vertebral column tumours are caused by metastasis from other organs. The vertebral column is the most frequent site of metastasis within the skeletal system, with 70% of diagnosed patients showing bone metastasis.⁹ Sites of metastasis break down to 60-80% in the thoracic spine, 15-30% in the lumbar spine and <10% in the cervical spine.¹⁰ The mechanism underlying this pain relief is currently not confirmed but may be related to improved strength and stiffness of the fractured vertebrae following cement injection, preventing fracture site motion affecting intraosseous or periosteal nerves.¹¹ Other researchers have postulated a possible thermal or chemical reaction affecting nerve endings in affected tissue.³ In the present study, we included patients that required two to three level injections. The maximum number of vertebral levels that can be injected at one session is still debatable. Barr et al. reported better outcomes with single-level injection than multiple levels.¹²

Other reports suggest doing no more than three injection levels in one session to reduce patient discomfort and PV-associated complications.⁶ Zoarski et al mentioned that up to five injection levels are acceptable, and treatment of eight levels or more simultaneously is not acceptable in medical practice.¹³ Mailli et al found no statistical differences when comparing PVP performed up to three vertebral levels with more than three levels per session. The study included patients with osteoporosis, metastasis, and hemangiomas. They measured the degree of pain improvement and increased mobility in the follow-up. They concluded that PV results are not dependent upon the number of levels injected per session and that PVP is an efficient and safe technique even with multilevel injection.⁵ These findings were comparable to the observations by Singh et al. and Anselmetti et al who reached the same conclusion for vertebroplasty in multiple levels.^{14,15}

In the present study, we had a refracture rate of 10.71% all in the untreated vertebrae. This was relatively consistent with reports from Kim et al., Mailli et al and Uppin et al.^{5,16,17} A higher incidence of new VCF was also reported by others and ranged from 21 to 37%.¹⁸⁻²⁰ The reason for a lower incidence of refractures in the present study may be the multilevel injection and the small sample group and short term follow-up period. It is unclear whether this is related to the natural history of the underlying disease or the treatment. Uppin et al. demonstrated that patients were at an increased risk of new-onset adjacent level fractures following PVP, and adjacent VCF occurred sooner than non-adjacent level fractures. It was hypothesized that the augmented stiffness of a vertebral body treated with cement might develop new adjacent VCF. This finding was redemonstrated by Trout et al. in 2006.^{17,21} There have been concerns that asymmetric cement distribution from a unipedicular approach may lead to suboptimal biomechanics and risk of further collapse in the nonaugmented side.²² However, several clinical and cadaveric studies have not demonstrated this concern.²³⁻²⁵ There was no significant association between pain relief or refractures and a unilateral versus a bilateral approach in the study by Kim et al.²⁶

There has been debate on the optimal amount of cement required in a PVP. Biomechanical alterations from excessively high volumes of cement injected into the vertebral body may potentially compromise adjacent vertebrae. In our study, the volume of cement did not correlate with pain relief or refracture rate, which was demonstrated in prior studies.^{23,27,28} The present study demonstrated significant pain relief (decreased VAS scores by more than 50%) in 92.85 % of the patients. This was similar to findings by, Mailli et al Grados et al and McGraw et al.^{5,29,30} Similarly, other studies of PVP for osteoporotic patients that used the VAS as an evaluation method showed similar results in pain improvement.^{13,14,31} These findings were also corroborated by Guarnieri et al, Purkayastha et al, Yang

et al, Cohen et al and Chen et al for vertebral hemangiomas.³²⁻³⁶ In the case of metastases, patients who undergo PVP for VCF have a rapid and dramatic reduction in pain within 24 hours. Gangi et al. reported significant pain relief in 60-85% in MVCF and showed a 91% reduction with analgesics.⁴ PVP may also have a limited antitumor effect. Combining PVP with other treatment approaches, such as radiosurgery, EBRT, and I-125 isotope seed implantation, achieves better pain relief in VCF due to vertebral metastases.³⁷ In our study, pain outcomes following PVP were exemplary and independent of aetiology; vertebral region treated, single level versus multilevel fracture, for an initial fracture or a refracture after an initial PVP, or the volume of cement injected into the vertebral body. Although extra vertebral cement leaks (ECL) are common after vertebroplasty, most are clinically asymptomatic. ECL can result in neurological sequelae with nerve root compression (radiculopathy) or extradural compression (myelopathy). In a large series utilizing a CT scan to detect post-vertebroplasty leakage, the frequency of extraosseous leaks ranged from 55-82%.^{38,39} The most common sites of the extraosseous leak were the intervertebral disc spaces (25%), epidural venous plexus (16%), posterior wall leaks (2.6%), neural foramina leaks (1.6%), and combinations.⁴⁰ However, the actual procedure-related morbidity was very low (<3%). 10.71% of our cases had asymptomatic leakage of bone cement into the disc space. Increased fracture risk of adjacent vertebrae had been mentioned by some authors following cement leakage into the disc space; however not fully documented.⁴¹ Proper needle position and cement viscosity, and immediate cessation of injection after any leakage reduce this event. Leakage of cement into the paravertebral veins may result in serious complications such as embolism (pulmonary or cerebral), cardiac perforation, and death. High vascular vertebral pathologies, lower cement viscosity, and high injection force help increase the intra-osseous pressure, facilitating the passage of fat and bone marrow into the venous circulation and the right heart.^{42,43} Benneker et al. performed a cadaveric study in 2008 and stated that reduction of the risk of cement embolization could be achieved by decreasing the force of injection as well as using a more viscous PMMA.⁴⁴ The literature also reports a pedicle fracture when passing the needle and posterior epidural leakage.⁵ Murphy and Deramond reported that complications associated with PV for osteoporotic fractures are less common than those in metastasis and hemangiomas.⁴⁵ Rib and transverse process fractures had also been reported to occur after PV.⁴⁶ Discitis, osteomyelitis and epidural abscess can result from infection following PV and may require surgery to remove the cement, which acts as a nidus for infection.⁴⁷

Limitations

The drawbacks with the present study are its retrospective nature, relatively fewer number of patients treated, and

vertebral bodies injected, and the lack of long-term follow up.

CONCLUSION

PVP is safe and effective treatment for management of the debilitating morbidity associated with VCF with excellent long-term outcomes.

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