



PERCUTANEOUS VERTEBROPLASTY IN THE TREATMENT OF OSTEOPOROTIC VERTEBRAL COMPRESSION FRACTURES

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ABSTRACT

BACKGROUND:

Percutaneous vertebroplasty is a radiologically guided and a very widely used therapeutic procedure that consists of injecting Polymethylmethacrylate (PMMA) into a vertebral lesion to treat acute and subacute painful osteoporotic vertebral fractures and to relieve pain and strengthening of vertebra that is previously weakened (Chen et al, 2003; Buchbinder et al, 2015). For the treatment of aggressive angiomas, bone metastases, and multiple myeloma eliciting rapid and marked pain relief, vertebroplasty has been known to be a promising novel technique. It is a safe and a very useful procedure for treating painful and persistent osteoporotic fractures of a vertebra (Chen et al, 2003).

OBJECTIVES:

To access the safety and efficacy of percutaneous vertebroplasty in the treatment of osteoporotic vertebral fractures and to report the results of its use.

PATIENT SELECTION AND METHODS:

One hundred and fifty-six (156) patients were included in this study with two hundred sixty-three (263) compression fractures and suffering from disabling back pain refractory to analgesic therapy and were treated in this study. The age range of the subjects was from 42 to 94 years (mean age: 72.8), and one to twelve months was the medical treatment period range.

The technique involved percutaneous puncture of the involved vertebra via a transpedicular approach followed by the injection of polymethylmethacrylate (PMMA) into the compressed vertebra. To quantify the degree of pain, patients were asked to use the Huskisson's visual analogue scale and the assessment of the clinical symptoms and surgical results was carried out.

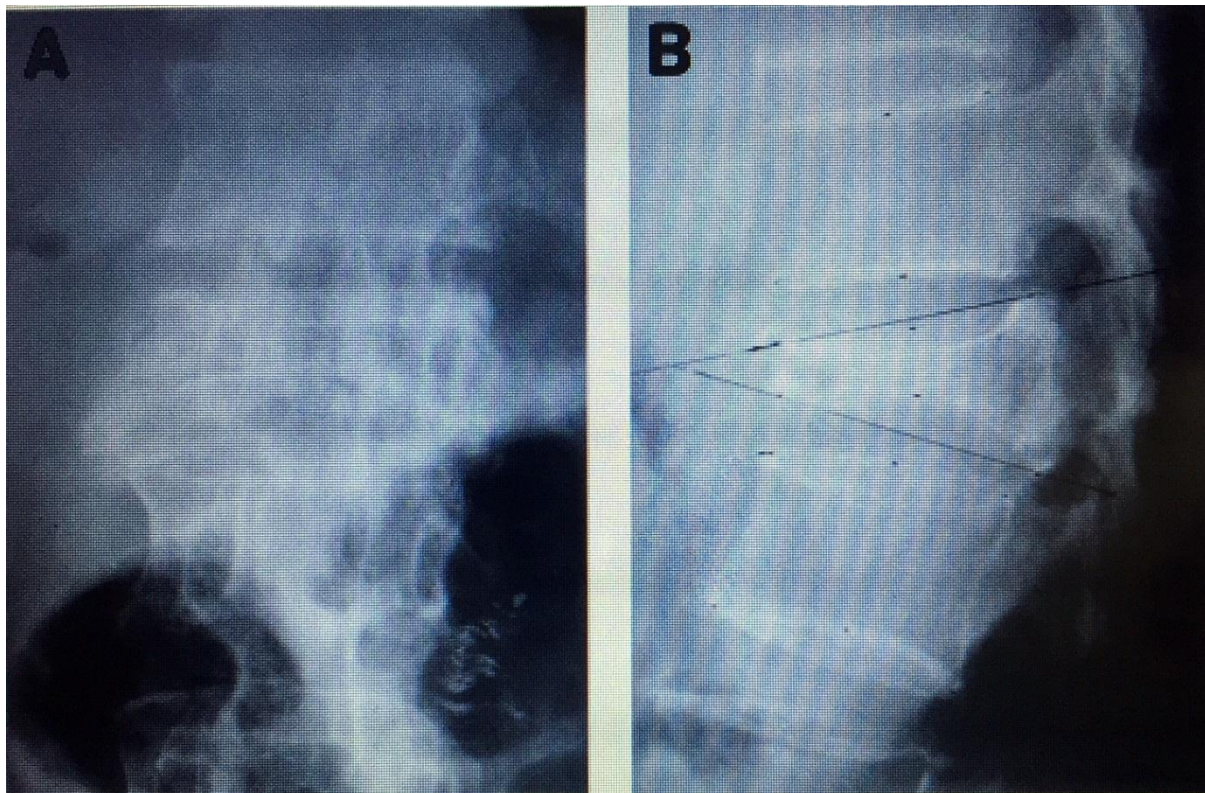
RESULT AND CONCLUSION:

Technically, the procedure was successful for all patients, and no complications arose relating to either surgical procedure or the anaesthesia. At the first postoperative day, pain decreased from 83 ± 15 mm at baseline to 38 ± 22 mm, and 34 ± 19 at three month. $P < 0.05$ showed the statistical significance of the reduction in pain. After the treatment, all the patients were capable in lifting their quality of life and return to their previous activities.

KEY WORDS: Osteoporosis, Vertebroplasty, Percutaneous vertebroplasty, Polymethylmethacrylate, Vertebral compression fracture

INTRODUCTION

Osteoporotic vertebral compression fractures are minimal trauma fractures of the vertebral (spine) bones that can cause disability and severe pain (Buchbinder et al, 2015). Vertebral fractures frequently produce often excruciating and persistent pain that may significantly impair the quality of life of the patients and may greatly influence patient's morbidity. For these patients, analgesics, external bracing and bed rest may be all that could have been prescribed in the past. However, for an effective pain control, an extended period of bed rest and a constant need of narcotics may be necessary. But further osteoporotic vertebral compression fractures can be possibly induced by such activities (Consensus Development Conference, 1993; Melton, 1997).



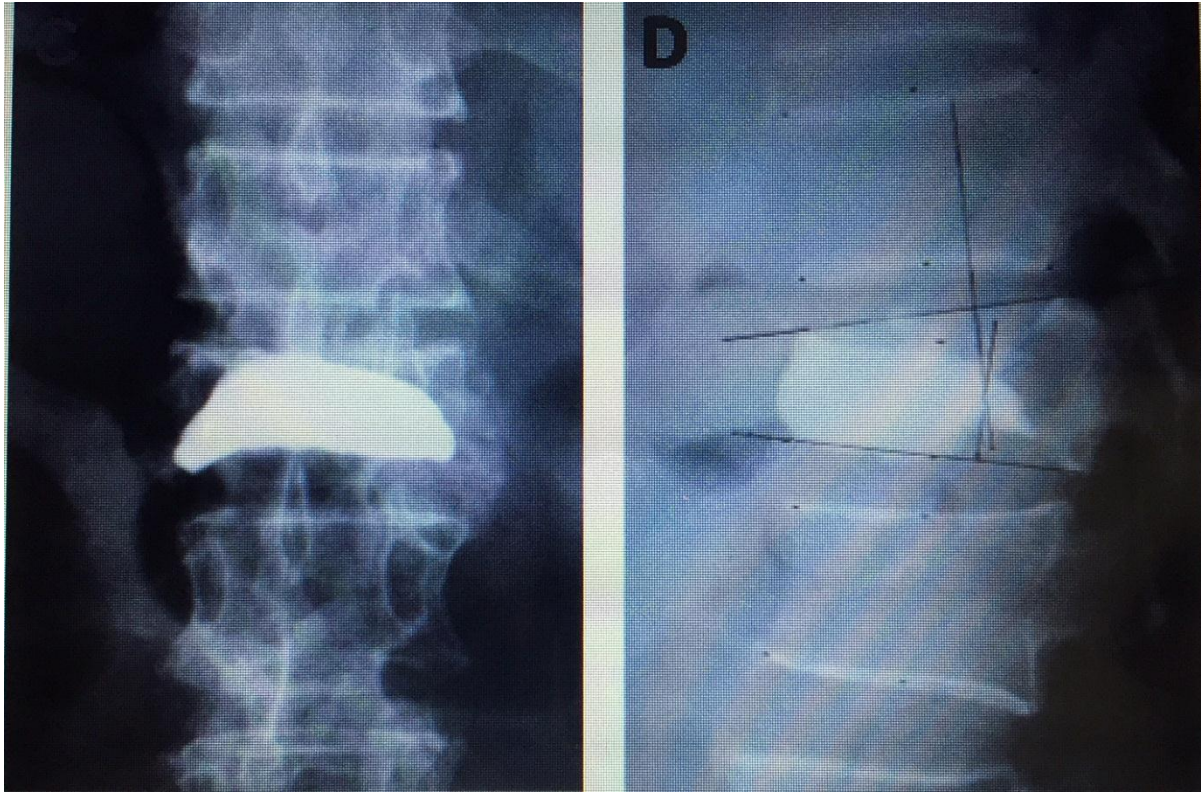


Figure. This is an example of an L1 osteoporotic compression fracture with the preoperative anteroposterior (A), lateral (B) views, and the postoperative anteroposterior (C), lateral (D) views.

Percutaneous vertebroplasty is a radiologically guided therapeutic technique pioneered by Deramond et al in the year 1985 for the treatment of aggressive or symptomatic vertebral angiomas (Deramond et al, 1987). Polymethylmethacrylate (PMMA) vertebroplasty is a relatively new procedure of injecting PMMA into the vertebral body of a damaged vertebra for relief of pain and previously weakened vertebra strengthening (Cortet et al., 1997; Debusche-Depriester and Deramond, 1991; Gangi et al., 1994; Jensen et al., 1997; Mathis, 1998). For the treatment of bone metastases, aggressive angiomas, and multiple myeloma eliciting marked and rapid pain relief, vertebroplasty has been shown to be a very promising novel technique (Cortet et al., 1997; Debusche-Depriester and Deramond, 1991; Gangi et al., 1994; Jensen et al., 1997; Mathis, 1998). For treating persistent, painful osteoporotic fractures of a vertebra, it is a safe and a very useful procedure (Cortet et al., 1999). For the treatment of osteoporotic fractures, a figure of 90-100% pain relief has been previously reported by percutaneous vertebroplasty (Gangi et al., 1994; Cotton et al., 1998; Deramond et al., 1989).

PATIENTS SELECTION AND METHODS

Patient selection was limited to those with intense, focal, and deep pain associated with plain-film evidence of a progressive or a new vertebral compression fracture. Often, the experience of pain radiated along the ribs to the abdomen or the chest. To determine each patient's general condition and the subject's ability to tolerate lying in a prone position for one to two hours, physical examinations were conducted. In

order to evaluate possible radicular symptoms, neurological examination was performed. All the patients were subjected to a set of dynamic, anteroposterior, and lateral radiographs and evidence of recently occurring, or progressive vertebral-body compression fractures were revealed. The relative dimension of fractures and respective level of pain appeared to correspond well with each other. To manage patients with such injuries, typically analgesics for controlling pain and bed resting were initially used. Some of the patients afterwards became stable and with bracing some could ambulate. If increased kyphotic deformities were indicated on the follow-up radiographs and pain persisted, vertebroplasty was considered to be a viable surgical option on a delayed basis. In such situations, in order to access the relative degree of posterior vertebral wall continuity and for the exclusion of the potential for pain's other causes, magnetic resonance images or/and spinal computer tomographic scans were typically obtained. Percutaneous vertebroplasty procedure was performed in the operating rooms of the hospital under strict sterile conditions with monitoring. Blood pressure, heart rate, oxygen saturation and other vital signs were monitored using an electrocardiogram monitor during the procedure (Elnoamany, 2015). The patient was placed in a prone position on an operating table. Vertebroplasty was performed with the patient under conscious sedation or general anesthesia. All vertebroplasty procedures were performed under the guidance of C-arm fluoroscopy, and an 11- or 13-gauge needle was used to traverse the right, left, or both pedicles. The needle was introduced under continuous fluoroscopic guidance into the anterior one third of the vertebral body closest to the midline as possible, without compromising the medial wall of the pedicle or the anterior cortex of the vertebral body. Once the needle was inserted into the vertebral body, the contrast agent Isovist-300 was injected in anticipation of leakage (Elnoamany, 2015). The needle was then cleared with saline. The cement, consisting of 40 g of methylmethacrylate powder and 20 mL of monomer liquid were mixed together. Cement was injected into the vertebral body until the injected cement reached the posterior one fourth of the vertebral body, or if epidural, venous, or trans-endplate extra-vasation of cement was observed. Patients were kept supine for 2 hours after the procedure (Elnoamany, 2015).

Assessment of the surgical results and the clinical symptoms was carried out by asking the patients to quantify their degree of pain on the Huskisson's visual analogue (VAS: 0 mm for no pain; 100 mm for the worst possible pain), before vertebroplasty, on the third day after vertebroplasty, and three months after vertebroplasty. Using a ruler, the score was determined by measuring the distance (mm) on the 10 cm line between the 'no pain' anchor and the patient's mark, providing a range of scores from 0-100. A higher score indicates greater pain intensity (Elnoamany, 2015). Based on the distribution of pain VAS score in post-surgical patients who described their postoperative pain intensity as none, mild, moderate, or severe, the following cut points on the pain VAS have been recommended: NO pain (0-4mm), mild pain (5-44mm), moderate pain (45-74mm), and severe pain (75-100 mm). The group data of VAS values were then compared with Wilcoxon signed rank non-parametric test (Buchbinder et al, 2015).

RESULTS

One hundred and fifty-six patients (with 263 compression fractures) suffering from disabling back pain refractory to analgesic therapy were analysed and treated in this study. In the study, 42-94 years was the age range of the subjects (mean: 72.8) and 1-12 months was the range of medical treatment period. Fractures associated with age-related osteopenia (Table 1) was exhibited by all 156 patients, and all of them experienced severe pain that limited their mobility and substantially altered their quality of life.

For all the patients, the surgical procedures used were technically successful. Effective transpedicular puncture of the vertebral body and the injection of PMMA resulted in no complications relating to the overall surgical procedure or anaesthesia. The number and level of vertebrae that are fractured is shown in Table 2. The mean time of cementing-material injection was 12 minutes.

| Factor | Cases | |
|------------------------|-------|------|
| | No. | % |
| Sex | | |
| Male | 37 | 23.7 |
| Female | 119 | 76.3 |
| | | |
| Age (Years) | | |
| 41-50 | 6 | 4 |
| 51-60 | 7 | 4 |
| 61-70 | 35 | 23 |
| 71-80 | 63 | 40 |
| 81-90 | 39 | 25 |
| >91 | 6 | 4 |
| | | |
| Offending level | | |
| Single level | 55 | 35 |
| Double level | 95 | 61 |
| Triple level | 6 | 4 |

Table 1: Clinical summary of 156 patients treated with percutaneous vertebroplasty

| Level | Number | % |
|-------|--------|------|
| T5 | 2 | 0.7 |
| T6 | 4 | 1.5 |
| T7 | 3 | 1.1 |
| T8 | 5 | 1.9 |
| T9 | 5 | 1.9 |
| T10 | 8 | 3.0 |
| T11 | 24 | 9.1 |
| T12 | 55 | 20.9 |
| L1 | 71 | 27.0 |
| L2 | 34 | 12.9 |
| L3 | 19 | 7.2 |
| L4 | 23 | 8.7 |
| L5 | 10 | 3.8 |

Table 2: Level of treated compression fracture

Postoperative radiographs revealed evidence of PMMA leakage for 46 vertebrae (17.5%) through the endplate fracture site into either the paravertebral space or the disc space, without any evidence of clinical symptoms. Pain decreased from 83 ± 15 mm at baseline to 38 ± 22 mm on the first postoperative day, and 34 ± 19 on three months after the procedure. The reduction in pain were statistically significant ($P < 0.05$). The degree of pain at the first postoperative day and after three months of follow-up had no statistical difference. All patients were able to return to their quality of life and pre-injury activities.

DISCUSSION

Osteoporosis is a major health problem in elderly population worldwide, and fractures are the major causes (Denis, 1983) in producing severe musculoskeletal pain (Dorr, 1982). As because many of the osteoporotic spine fractures are asymptomatic and diagnostic criteria made for them are not standardized, the true incidence of osteoporotic spine fractures is very difficult. It is however clear that the osteoporotic spine fracture incidence is sex and age-dependent (Ferguson & Allen, 1984). Osteoporosis represents a normal process of aging, a consequence of senescence, and its pathophysiology is still unclear (Gertzbein, 1992; Gertzbein, 1994). Depending on identifiable causes, such as chronic corticosteroid therapy or immobilization, osteoporosis can be broadly classified as primary or secondary. The most commonly encountered form of osteoporosis is primary involution osteoporosis, which includes both and senile osteoporosis and postmenopausal osteoporosis (Chen et al., 2003).

Acute, excruciating back pains are commonly presented by osteoporotic compression fractures. Osteoporotic compression fractures are precipitated by minor stress such as bending forward and are not

usually a result of an obvious trauma (Chen et al., 2003). Kyphotic deformity and height loss following osteoporotic compression fractures may produce muscle spasm, stress on ligaments, spasms of muscles, or/and nerve root irritation, which, in turn, produce chronic back pain. Osteoporotic fractures followed by severe neurological deficits are unusual but may be developed in a delayed fashion. Fractures, which are frequently multiple, occur most commonly at the thoracolumbar junction, followed in order of frequency by the middle thoracic and the lower lumbar and middle thoracic vertebrae (Cortet, 1994; Weill et al., 1996).

PMMA vertebroplasty is a relatively new procedure. The range of the reported treatment complications was found to be in between 0 and 5.4%, most of which being relatively minor, with multidisciplinary approaches to patient management and selection being essential (Bascoulergue et al., 1988). The patients with chronic pain refractory to medical therapy and bracing and the patients with severe, disabling pain as elicited by the more acute fractures were the two classes of patients considered to be appropriate for treatment through vertebroplasty (Cotton et al., 1998, Deramond et al., 1991). The treatment of ambulatory patients with acute fractures however remains controversial. Contraindications to vertebroplasty are, very severe cardiopulmonary disease cases and uncorrectable coagulopathy (Chen et al., 2003).

There are different hypotheses with respect to the pathophysiology of pain relief following vertebroplasty, including the reduction of mechanical stress, the stabilization of micro-fractures, and the destruction of neural endings by the cement's chemical, mechanical, thermal and cytotoxic activity as well as by its anti-inflammation action (Cortet et al., 1999; Chiras et al., 1997). For the patients in this study, the symptoms improved via the enhancement of vertebral strength, the stabilization of the fractured vertebral fragments, and a reduction in mechanical stress to the damaged vertebra. Therefore, especially for the elderly, for the treatment of osteoporotic compression fractures, percutaneous vertebroplasty is an alternative procedure. When performed by experienced neuroradiologist or surgeons, percutaneous vertebroplasty can eliminate the need for major spinal surgery and, through prompt pain relief, the effective rehabilitation of a compression fracture patient and early mobilization remains a clear possibility for the elderly polymorbid patients (Chen et al., 2003).

Percutaneous vertebroplasty, however, is not an absolutely safe procedure. From the leakage of acrylic cement into the venous system or through a gap of the fractured vertebra into spinal canal, percutaneous vertebroplasty inherits considerable amount of danger. A life-threatening complication of vertebroplasty is cement leakage into the inferior vena cava or into the azygous vein with migration into the lungs (Cotton et al., 1996; Chiras et al., 1997). Leading to the progressive accumulation of acrylic material within the spinal canal, cement spillage typically occurs through the basivertebral plexus into the anterior internal venous plexus. Consequent damage to neural structures by either thermal or compressive effects arising during the polymerization of the methyl methacrylate and bone cement leakage are well known sources of complications (Cotton et al., 1996; Chiras et al., 1997). Although the pathophysiology of neural damage by a direct compressive effect of bone cement is probably the major source of neurological

complication, the neurological function compromisation by chemical and thermal effects is still a controversial topic (Jensen et al., 1997; Wang et al., 1979; Wang et al., 1984). Disc and paravertebral spillage are asymptomatic and often arise in severely compressed vertebrae cases. Subsequent damage of the neural tissue and intradural filling of bone cement may be led by malposition of the tip of the needle. Another serious problem is the infection of treated vertebrae, and aseptic operative procedure can eliminate this problem. Usually, by assuming the appropriate needle position, and steady injection of cementing material, as well as the extensive and continuous monitoring of the surgical procedure with the fluoroscope, the posterior extrusion of bone cement into the spinal canal can be eliminated. The procedure of percutaneous vertebroplasty in this study appeared to be tolerated by all the patients with no clinically-relevant side effects. Although for 46 patients (17.5%), leakage of the cement outside the vertebral body was observed. The frequency ranged from 26% to 73% which was less than those reported elsewhere (Cortet et al., 1997; Gangi et al., 1994; Jensen et al., 1997; Mathis, 1998; Cortet et al., 1999). The experience with the process of vertebroplasty therefore indicated that the initial slow and steady introduction of acrylic cement and frequent fluoroscopic check might reduce the risk of leakage, probably by obliterating the major connection to the basivertebral venous plexus. In conclusion, the study reveals that vertebroplasty provides the potential to actually achieve a good outcome for patients with a vertebral compression fracture due to osteoporosis, the condition causing persistent and severe pain. Percutaneous vertebroplasty is capable of eliminating the risk and need for major spinal surgery. Effective rehabilitation, prompt pain relief, and early mobilization of a vertebral compression fracture therefore remains a clear possibility for polymorbid elderly patients. To establish consensus for vertebroplasty indications, further studies, particularly controlled studies incorporating the long-term follow-up, are greatly required.

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