

Safety and efficacy of vertebroplasty in the treatment of osteoporotic vertebral compression fractures: a prospective multicenter international randomized controlled study

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Summary

Background. Vertebral compression fractures (VCFs) treated non-operatively can diminish function and quality of life, and lead to chronic health effects. The short-term safety and effectiveness of vertebroplasty for symptomatic VCFs are well-documented, but long-term follow-up is needed.

Purpose. The aim of this paper was to analyse a multicenter international experience of 200 compression fractures treated with percutaneous vertebroplasty (VP) and compare the results of this procedure with the result of 200 patients treated conservatively. To estimate cost-effectiveness of VP compared to conservative care in terms of: pain reduction, quality of life, complications, secondary fractures and mortality.

Materials and methods. 400 patients have been enrolled in a prospective randomized controlled study with painful VCFs with bone edema on MR imaging, local back pain for 6 weeks or less, osteoporosis and aged 55 years or older; after obtaining informed consent patients are included and randomized for VP or conservative care. Before treatment and at follow-up with regular intervals during 1-year period were administered to patients standard questionnaires addressing: clinical symptoms, pain medication, Visual Analogue Scale (VAS) score for pain, Oswestry Disability Index (ODI) score to evaluate functional activity.

Results. 200 patients treated with PV compared with 200 patients treated conservatively had significantly better VAS and used less analgesics 1 day after treatment. Twenty-four hours after VP, there was a reduction in pain scores and an improvement in physical functions, whereas remain unchanged in the patients treated conservatively.

Conclusions. Pain relief and improvement of mobility and function after PV is immediate and significantly better in the short term compared with non-surgical care treatment.

KEY WORDS: osteoporotic vertebral compression fractures (VCFs); percutaneous vertebroplasty (PV); conservative care; multicenter prospective randomized study.

Introduction

Percutaneous vertebroplasty (VP) consists of injection polymethylmetacrylate (PMMA) bone cement in a vertebral compression fracture (VCF). VP stabilizes the fractured vertebral body and provides for the immediate reduction or improvement of the pain caused (1). Initially the VCF symptomatic patients with cancer primary or secondary vertebral osteolytic were treated with VP. Today, the main target population is subjected to VP is represented by patients with pain, VCF osteoporotic therapy-resistant or non-responsive to analgesics, rest or other therapies conservative (1). The VP was used in the United States and Europe since 1990 and has been shown that it was able to quickly and efficiently reduce the pain compared to conventional therapies (2-4). Thanks to its efficacy in reduce pain, his instructions quickly extended the treatment of painful fractures caused by metastases or multiple myeloma and osteoporosis. The risks of such a procedure include the leakage of PMMA into the venous system resulting in pulmonary embolism or into the epidural space causing neurological problems because of low viscosity of the concrete and of the high filling pressure as described by other Authors (5, 6).

An acute osteoporotic vertebral fracture may be a disabling disorder that causes severe back pain with associated morbidity and prolonged hospitalization (7-9). VP has represented an important step forward in the management of this syndrome (10, 11) but has aroused enthusiasm on the one hand and controversy (12-16) on the other hand, in part because the technique has not been compared with other forms of therapy. In this study, we compared the clinical results of 200 patients osteoporotic subjected to VP with 200 patients who were managed with conservative care.

Materials and methods

Participants in this multicenter international prospective randomized controlled study were 400 women in post-menopausal affected from one thoracic or lumbar symptomatic VCF caused by primary or secondary osteoporosis. Patients were randomized in two groups of 200 units each: conservative care consisting of pain medication, osteoporosis medication, physiotherapy or bracing (group I); VP with osteoporosis medication and analgesics if necessary (group II). Each of the four hospitals involved in the present study treated 100 patients including 50 with VP and the remaining 50 with conservative care. The age of patients was between 56 and 82 years. The inclusion criteria were acute pain from severe spinal fracture, VCF height of the visible loss of vertebral body in radiography and standard, evidence of osteoporosis to bone den-

sitometry, bone marrow edema of the affected by VCF visible on MRI of the spine and the presence of evidence of an acute fracture imaging RM; while the exclusion criteria were from a pathological fracture due to myeloma / metastasis, retropulsion mass of bone fragments in the spinal canal, unstable cardiopulmonary conditions, coagulopathy incurable, systemic infection in progress, or local infection spine (osteomyelitis, spondylodiscitis), radicular syndrome or spinal cord compression.

The purpose of this paper is to estimate cost-effectiveness of VP compared to conservative care in terms of: pain reduction, quality of life, complications, secondary fractures and mortality.

Surgical procedure

VP was performed using transpedicular approach under local anesthesia with mepivacaine 2% and naropin 10%. A mean volume of 4 ml of PMMA (Osteo-Firm® COOK Medical, Bloomington, Indiana, USA) was injected into each fractured vertebral body with supervision of fluoroscopy. All the patients were subjected to analgesia after surgery, according to individual needs. According to increasing analgesic power, the patients were treated with acetaminophen, non-steroidal drugs (NSAIDs), or derivatives of morphine.

Results evaluation

The complications and the VAS score were evaluated at presentation, at 24 and 48 hours, 1 month later, 3 months, and 6 months after surgical or conservative care. These times were calculated from the day of VP in the group I underwent surgery or enlistment in the day study in the group II treated conservatively. Duration of the hospital stay was recorded for all patients. The scale of the VAS pain assessment using a visual analog scale from 0 (no pain) to 5 (maximum pain). The patient records the level of pain associated with each of the five activities: walking, sitting and rising from a chair, bathing, dressing, and at rest. The score is recorded immediately upon waking, before the administration of the morning dose of analgesic. The total score is the sum of all five scores (on a scale of 0 to 25). Oswestry Disability Index (ODI), a validated measure of the state of widely used in spinal surgery health, it was choice for evaluating the functional improvement before procedure and 6 months later.

Statistical analysis

The groups were compared using the chi-square test, paired or unpaired with the Student's t test or the test Mann-Whitney (17, 18). The results were analyzed in different times and were compared by analysis of variance, with post hoc Tukey test. The variables were corrected for baseline values by subtracting the measure follow-up from baseline, and expressing the difference as a percentage of the baseline value.

Results

The patients included in the study were followed for six months. VP was performed in 200 patients including 95 lumbar and 105 thoracic vertebrae. We treated only one level in every woman. In 15 patients submitted to procedure was not possible to complete the surgery since in 7 cases for technical reasons related to poor quality images in fluoroscopy where has not been possible to find the pedicles of the fractured vertebra; however in other 8 cases women have failed to maintain the prone position for the execution of the VP. Minor complications were observed in 2 patients after VP, these include fracture of a transverse process and the bleeding of psoas muscles in 1 patient. Three patients treated with VP developed pain in his recurring back within six weeks related

to new vertebral fractures above treated vertebra (19, 20). The clinical features of patients underwent VP had characteristics similar to those treated conservatively. A woman treated with VP and 3 patients treated conservatively died after 6 months from their fractures.

Outcomes assessed 24 hours after surgery in group I using VAS pain score and ODI score showed a mean value of 2.3 points in VAS scores, whereas preoperative mean value was 4.8 ($p \leq 0,023$), and 31.7% in the ODI whereas preoperative mean score was 53.6% ($p \leq 0,012$); 120 (65%) treated with VP were able to stop any analgesia after 48 hours ($p \leq 0,0001$). These results were unchanged at the last follow-up visit. Patients treated conservatively had no immediate benefit on pain and disability. The clinical results 6 weeks and 3 to 6 months were similar in both groups.

Discussion

VP is designed for the treatment of aggressive hemangiomas, bone metastases and myeloma. It has also been used increasingly for the management of acute osteoporotic vertebral fractures. In this randomized study with a follow-up of six months, we compared the clinical results of 200 patients with severe osteoporotic vertebral compression fractures that they have been subjected to VP with those of 200 patients treated with the only conservative care. Several longitudinal studies have assessed the benefits of VP with validated results. In our study, the prompt reduction in scores of pain and improvement of physical function was observed 24 hours after VP than patients treated conservatively. Many more patients treated with VP were able to discontinue taking analgesics within 48 hours, and the duration of hospitalization was shorter in the patients who have undergone the procedure. Both groups, however, had improvements in clinical outcomes similar to 6 weeks, and 3 to 6 months after the conservative treatment. Conservative is not directed towards the cause of the problem: VCF. On the contrary, the aim of the VP is to relieve immediately the pain and improve the disability through the stabilization of VCF with the cement (21, 22). The first VP was performed for the treatment of an aggressive cervical vertebral body hemangioma and carried out by Galibert and Deramond in 1987 (3) whereas the first case of VP in an osteoporotic VCF was published in 1989 by Lapras and Dusquenel (23). In a recent review of the literature on clinical trials in patients with osteoporotic VCF treated with VP, we discovered that these studies have indicated that VP is a treatment minimally invasive safe for the treatment of painful osteoporotic VCF, with an immediate and excellent result clinical long-term. However, most of these studies we were conducted retrospectively and almost all had one or more methodological flaws. Most of the studies included a small group of patients. The benefits of VP depend on patient selection, the skills of the operators, and the rates of complications. However, there are no criteria defined for the selection of ideal patients, or when run VP. Faciszewski et al. suggested that the characteristics of a VCF, including morphometry, chronicity, the reparative activities, dynamic stability, the destruction of trabeculae intervertebral, and the violation of the rear wall, are essential for patient selection (24). Contraindications to the VP include disorders coagulation, osteomyelitis, vertebra plana, and presence of serious retropulsion of fracture fragments. We chose to perform the procedure already 1-2 weeks after the break, because many patients were unable to cope with the pain. Immediate VP can also prevent further loss in height of the affected vertebra, although this hypothesis has not been proven. The effects of VP on the risk of future adjacent vertebral fracture are unknown (9, 17). The adjacent vertebrae may be at increased risk, especially if you have a cement extravasation (25-27). There also seems

proper to make a comparison between VP and kyphoplasty (KP). Both procedures are valid in the “management” of the syndromes spinal analgesic. According to our experience and our results, we believe that, in view of the differences technical and economic of the two methods, the use to VP in osteoporotic vertebral collapse, angiomatosis aggressive and neoplastic, is more suitable for rapid execution and less invasive. KP, however, is preferable in recent vertebral fractures type Magerl A1 and A3, for the characteristic of “restoration” of the static spinal and for a better distribution of the cement in the fractured vertebral body. The direct comparison between VP and KP is not possible because of the lack of prospective studies randomized comparing the two procedures. Both improve the functional status of patients in most of the studies, although it is difficult to put together with available data because of different scales measurement used (28). With the rise in popularity of both techniques, especially in the last decade, an increasing number of publications has reported in a manner detailed potential secondary complications to extravasation of cement, by the compression of neural elements to venous embolism. The overall rates of complications for both procedures are low (28). Systematic reviews have found significantly higher rates of cement leakage after VP (40%) vs CP (8%), with a 3% to symptomatic leakage after VP. When you make by an experienced operator in properly selected patients, both VP and KP are efficacy and safe treatments for recent VCFs. (28).

Conclusion

Our findings suggest that the pain and disability caused by acute osteoporotic VCFs appear to be treated with more efficacy through the VP than with the conservative therapy alone. Are needed long-term clinical studies carefully designed and well executed for verify that VP is superior to conservative therapy for the acute management of osteoporotic VCFs in women after menopause. Pain relief and improve mobility, functionality physics after VP are quick and significantly better in the near compared to non-surgical treatment.

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