Journal of Clinical Neuroscience 21 (2014) 473–477

Contents lists available at ScienceDirect

Journal of Clinical Neuroscience

journal homepage: www.elsevier.com/locate/jocn

Clinical Study

Percutaneous vertebroplasty compared with conservative treatment in patients with chronic painful osteoporotic spinal fractures

Dong Chen *, Zhi-Quan An, Sa Song, Jian-Fei Tang, Hui Qin

Department of Orthopaedics, The Sixth Affiliated People's Hospital, Shanghai Jiao Tong University, No. 600, Yi Shan Road, Shanghai 200233, China

ARTICLE INFO

Article history:
Received 28 October 2012
Accepted 26 May 2013

Keywords:
Conservative treatment
Osteoporosis
Pain
Percutaneous vertebroplasty
Vertebral compression fracture

ABSTRACT

The efficacy of percutaneous vertebroplasty (PVP) for patients with chronic painful osteoporotic compression fractures remains unknown. The purpose of this study was to compare the efficacy of PVP and conservative treatment (CT) for pain relief and functional outcome in patients with chronic compression fractures and persistent pain. Ninety-six patients with chronic compression fractures confirmed by MRI and persistent severe pain for 3 months or longer were prospectively randomly assigned to undergo PVP (n = 46, Group A) or CT (n = 50, Group B). The primary outcome was pain relief and functional outcome at 1 week, 1 month, 3 months, 6 months and 1 year. A total of 89 patients (46 in Group A and 43 in Group B) completed the 1 year follow-up assessment. Pain relief and functional outcomes were significantly better in Group A than in Group B, as determined by visual analogue scale scores, Oswestry Disability Index scores, and Roland Morris Disability scores at 1 week, 1 month, 3 months, 6 months and 1 year (all $p < 0.001$). The final clinical follow-up assessment indicated complete pain relief in 39 Group A patients and 15 Group B patients ($p < 0.001$). PVP for patients with chronic compression fractures and persistent severe pain was associated with better pain relief and improved functional outcomes at 1 year compared to CT.

1. Introduction

Vertebral compression fractures (VCF) are the most common complication of osteoporosis [1,2], occurring in 20% of those over the age of 70 years [3]. These fractures represent an important cause of disability and morbidity in the elderly, and they have a negative effect on quality of life, physical function, mental health and survival [4]. Before the introduction of percutaneous vertebroplasty (PVP), conservative treatment (CT) and surgery were the two most commonly used management strategies for vertebral fractures. Conservative measures, including rest, analgesics, anti-inflammatory drugs or the use of external braces may be useful for the relief of pain, but contribute little to vertebral stability, especially in the case of chronic osteoporotic vertebral fractures. Furthermore, chronic medication can produce undesirable side effects, while excessive rest can exacerbate bone demineralization, increasing the risk of bone fractures. Surgery is often reserved for fractures associated with vertebral instability or neurological compromise, but poor bone quality and functional performance of patients with osteoporosis reduces the likelihood of a successful outcome [5].

Since its introduction in 1987, PVP has become a widely accepted treatment for patients with painful VCF [6–11]. The procedure not only results in substantial pain relief, but also provides the possibility of stabilizing vertebral fractures by injecting a small quantity of bone cement into the collapsed vertebral body [6,7]. A recent systematic literature review demonstrated the effectiveness of PVP in 87% of patients, in terms of pain relief as well as in short- and long-term physical function [8]. However, to our knowledge there have been few reports in the literature of the use of PVP for the management of patients with chronic painful osteoporotic compression fractures. Therefore, the purpose of this study was to compare the efficacy of PVP with that of CT in terms of pain and functional outcome in patients with chronic compression fractures and persistent severe pain.

2. Materials and methods

2.1. Study design and patients

This was a single center study of the treatment of chronic compression fractures and persistent severe pain. Patients were recruited from our departments and prospectively allocated to PVP or CT. The Institutional Review Board approved the study protocol and patients provided informed consent before participation.

Between January 2007 and December 2012, 96 consecutive patients with chronic osteoporotic compression spinal fractures on MRI (low signal on T1-weighted and high signal on T2-weighted

* Corresponding author. Tel./fax: +86 021 6485 4193.
E-mail address: cd76cx77cc@sina.com.cn (D. Chen).

0967-5868/$ - see front matter © 2013 Elsevier Ltd. All rights reserved.
http://dx.doi.org/10.1016/j.jocn.2013.05.017

scans) and persistent back pain for at least 3 months were enrolled. Patients were randomly allocated to receive either PVP or CT initially, and PVP was also performed after CT if the patient did not improve during the follow-up period. Initially, the study population consisted of 46 patients in the PVP group (Group A) and 50 patients in the CT group (Group B). Of these, four patients in Group B refused CT and decided to have PVP at the 3 month follow-up, and seven patients (four in Group A and three in Group B) were lost to follow-up. Therefore, a total of 46 and 43 patients were included in Group A and Group B, respectively, at the 12 month follow-up. The demographic and clinical characteristics of the 89 patients with chronic painful osteoporotic compression spinal fractures are summarized in Table 1. The patients included 27 men and 62 women, with a mean (± standard deviation) age of 65.53 ± 9.11 years (range, 51–83 years).

2.2. MRI protocol

MRI was performed using a 1.5 or 3 Tesla MRI scanner (GE Medical Systems, Milwaukee, WI, USA). The following MRI sequences were employed: sagittal T1-weighted (repetition time [TR]/echo time [TE], 400/13 ms), T2-weighted spin echo (TR/TE, 3500/120 ms) and short T1 inversion recovery (TR/TE, 2500/70 ms) and transverse T2-weighted turbo-spin echo (TR/TE, 2500/120 ms) at the level of the affected VCF.

2.3. Interventions

All procedures were performed under local anesthesia and were undertaken on a single plane angiography system under fluoroscopic guidance.

The patient was placed in a prone position on the operating table. After local anesthesia, a small incision was made with a scalpel blade. Thereafter, a bone puncture needle (13 G, Cook Medical, Bloomington, IN, USA) was placed transpedicularly in the fractured vertebra. After removal of the inner needle, commercially available polymethyl methacrylate (PMMA) (Osteo-Firm, Cook Medical) was carefully injected into the fractured vertebra under continuous fluoroscopic monitoring via lateral and anteroposterior (AP) projections in order to ensure adequate lesion filling and to avoid PMMA leakage or migration into the venous system with pulmonary embolism. Injection was ceased when substantial resistance was met or when the cement reached the cortical edge of the fractured vertebral body; injection was also stopped if cement leaked into extraosseous structures or veins. In general, a total of 3–5 mL of PMMA was injected into the fractured vertebral body. Post-procedural fluoroscopic evaluation was obtained to show optimal filling of the lesion with no evidence of PMMA extravasation. PVP was also performed with one or more procedures on other fractures seen on MRI at adjacent levels above and below the chronic osteoporotic compression fractures to prevent new fractures [12]. After the procedure, a computed tomography scan of the treated vertebral bodies was done with 2 mm slices to identify the distribution of cement in the lesion, cement leakage outside the vertebral body, or other local complications.

Patients in the CT group were hospitalized and offered brace treatment, analgesia, general mobilizing physiotherapy, and osteoporotic medication treatment, including vitamin D (Rocaltrol, Roche, Basel, Switzerland) and diphosphonate (Fosamax, Merck, Whitehouse Station, NJ, USA).

2.4. Clinical outcome evaluation

Patients were clinically examined by one of the authors, who gathered the initial and follow-up data at baseline and 1 day, 1 week, and 1, 3, 6 and 12 months thereafter.

The primary outcome was pain relief as measured and assessed by a 0–10 cm visual analogue scale (VAS) [13], in which 0 = no pain and 10 = the worst pain imaginable. The second outcome was the capacity for walking, standing and sleeping, as measured by the Oswestry Disability Index (ODI) [14]. The ODI comprises a 10 item questionnaire on pain, personal care, lifting, walking, sitting, standing, sleeping, sex life, social life, and traveling, with patients scoring each item on a scale from 0 (best possible state) to 5 (worst possible state). The tertiary outcomes were quality of life, as measured with the physical function items in the Roland Morris Disability (RMD) questionnaire [15]. Standard questionnaires, including additional questions about pain treatment, hospital stay, outpatient visits and medical aids were completed with the help of a nurse practitioner.

In addition, imaging follow-up consisted of AP and lateral spinal radiograph examinations at 1 month, 6 months, and 1 year after the procedure (Fig. 1). All patients underwent computed tomography scans 3 days after PVP to study cement distribution or extravasations. MRI was performed 3 months and 1 year after the procedure in all patients (Fig. 1).

2.5. Statistical analysis

Descriptive data are given as the mean ± standard deviation. Student's *t*-test was used to compare VAS score, global ODI score, RMD score and the score for each ODI item between the two groups. Significant pain relief over time was determined using the Kaplan–Meier method and the log rank test was used to evaluate between group differences. The Statistical Package for the Social Sciences version 13.0 (SPSS, Chicago, IL, USA) was used for the analyses.

3. Results

3.1. Primary procedural results

The technical and initial clinical outcomes of the two groups are shown in Table 2. PVP was technically successful in all patients without complications. Forty-six patients underwent PVP on 69 vertebrae that took place 3 to 5 days after referral to our

Table 1
Baseline clinical characteristics of all patients with chronic painful osteoporotic spinal fractures

	Percutaneous vertebroplasty (n = 46)	Conservative treatment (n = 43)	*p* value
Age, years	64.63 ± 9.10	66.49 ± 9.11	0.339
Male/Female (n)	14/32	13/30	0.983
Duration of back pain (months)	7.07 ± 3.00	6.81 ± 2.51	0.670
Number of VCF at baseline	2.28 ± 1.00	2.00 ± 0. 09	0.150
Use of osteoporosis drugs n (%)	12 (26%)	18 (42%)	0.116
Bone density T score	−3.02 ± 0.80	−3.00 ± 0.44	0.875

Data are presented as mean ± standard deviation unless otherwise stated.
VCF = vertebral compression fracture.