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PROSPECTIVE STUDY OF PERCUTANEOUS VERTEBROPLASTY FOR CHRONIC PAINFUL OSTEOPOROTIC VERTEBRAL COMPRESSION FRACTURE

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ABSTRACT

Background: Percutaneous vertebroplasty (PVP) for patients with chronic painful osteoporotic compression fractures has not been extensively studied.

Objective: To prospectively evaluate the efficacy of PVP for patients with chronic painful osteoporotic vertebral compression fractures (VCFs).

Methods: Sixty-two consecutive patients with chronic painful osteoporotic VCFs for ≥3 months underwent PVP. All procedures were performed under local anesthesia. The outcomes were pain relief at one week, one month, three months, six months and one year.

Results: The PVP procedures were technically successful and well tolerated in all patients. Sixty-two patients underwent PVP on 92 vertebrae in 73 procedures three to five days after referral, and no 30-day mortality was observed.

Conclusion: PVP is effective in patients with chronic painful osteoporotic VCFs. Pain relief after PVP was immediate, was sustained for one year and may be an important factor for reducing persistent pain.

KEYWORDS : Osteoporosis, Pain, Percutaneous vertebroplasty, Vertebral compression fracture

INTRODUCTION

Percutaneous vertebroplasty (PVP), which involves percutaneous injection of bone cement into the fractured vertebral body, is a widely accepted treatment for patients with painful vertebral compression fractures (VCFs). The procedure results in substantial pain relief for most patients. A recent systematic literature review demonstrated the effectiveness of PVP in 87% of patients in terms of pain relief as well as a short- and long-term improvement of physical function.

PVP not only results in substantial pain relief but also provides the possibility to stabilize vertebral fractures by injecting a small quantity of bone cement into the collapsed vertebral body. However, PVP for patients with failure of conservative treatment, especially for chronic painful VCFs, has been less well studied. Therefore, the purpose of the present study was to evaluate the efficacy of PVP for patients with chronic painful VCFs, focusing on pain relief, functional outcomes and stability of vertebral fractures.

MATERIAL AND METHODS

Study subjects

This present study conducted at Orthopaedics Unit of Usha Hospital, Muzaffarpur, Bihar, patients with history of chronic painful VCFs ≥3 months or more prospectively underwent PVP treatment.

The inclusion criteria for the present prospective study were as follows: patients ≥50 years of age with definite history of VCF with back pain for at least three months (Figure 1); level of fracture between T5 and L5; visual analogue scale (VAS) score of ≥5; focal tenderness at fracture level as assessed by an internist on physical examination; decreased bone density (T scores ≤−1); and clinical and imaging follow-up taken ≥12 months after the initial treatment. Exclusion criteria were: severe cardiopulmonary comorbidity (n=0); untreatable coagulopathy (n=0); systemic or local spine infection (n=0); suspected underlying malignant disease (n=0); radicular syndrome (n=2); spinal cord compression syndrome (n=3); and contraindication for magnetic resonance imaging (MRI) (n=5).

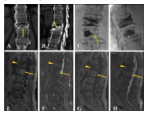

Figure 1

A 74-year-old male patient with persistent back pain and a visual analogue scale score of 7 for >10 months. Coronary (A) and sagittal (B) computed tomography reconstruction demonstrates a border of osteosclerosis at the fracture site (arrow). Anteroposterior (C) and lateral (D) plain films show bone cement injected into the L1 and L2 vertebral bodies with slight vein leakage (arrow) at the L2 level. Magnetic resonance imaging reveals low signal (arrowhead) on T1WI images (E) and high signal (arrowhead) on T2WI (F) at the L1 level before percutaneous vertebroplasty. Note also a hemangioma (arrow) at the L2 level. Magnetic resonance imaging displays low signal (arrowhead) on T1WI (G) and slightly high signal (arrowhead) on T2WI (H) images at the L1 level one year after percutaneous vertebroplasty with stability of the vertebral body without obvious focal kyphosis

A total of 77 patients with chronic painful VCFs were enrolled in the present study. Of these, 15 patients did not meet the inclusion criteria and were excluded from the study, with follow-up of <12 months in eight patients and follow-up loss in seven patients (four in the sixth month and three in 12th month). The remaining 62 patients were enrolled. There were 22 men and 40 women with a mean age of 65.45±8.68 years (range 51 to 83 years); demographic and clinical characteristics of these patients are summarized in Table 1.

Table – 1

Demographic and clinical characteristics of patients with chronic osteoporotic vertebral fractures (n=62)

Characteristic	
Age, years, mean ± SD	65.45±8.68
Male/female, n/n	22/40
Duration of back pain, months, mean ± SD (range)	7.0±2.78 (3–13)
Number of VCFs at baseline, mean ± SD (range)	2.13±0.89 (1–4)
Number and grading of VCFs	
Mild (15% to 25%)	11 (17)
Moderate (>25% to 40%)	42 (68)
Severe (>40%)	9 (15)
Wedge	49 (79)
Biconcave	13 (21)
Crush	0 (0)
Initial pain treatment	

None	0 (0)
Nonopiate drugs	13 (21)
Weak opiate derivatives	32 (52)
Strong opiate derivatives	17 (27)
Use of osteoporosis drugs	47 (76)
Bone density T score	−2.90±0.70

MRI protocol

MRI was performed using a 1.5 or 3 Tesla MRI scanner. The following MRI sequences were employed: sagittal T1 (TR/TE, 400 ms/13 ms), T2 Spin Echo (TR/TE, 3500 ms/120 ms), STIR (TR/TE, 2500 ms/70 ms) and transverse T2 TSE (TR/TE, 2500 ms/120 ms) at the level of the affected VCF. The grade of VCF was classified, as a percentage of height reduction, as mild (15% to 25%), moderate (>25% to 40%) and severe (>40%) according to the grading system of Genant et al.

Interventions

PVP was performed by two of the orthopedic surgeons (HYT and LMW) who specialize in spine surgery, and was performed on a single-plane angiography system under fluoroscopic guidance. Blood pressure, heart rate, oxygen saturation and other vital signs were monitored using an electrocardiogram monitor during the procedure.

The patient was placed in a prone position on an operating table. After local anesthesia, a small dermatotomy incision was made with a scalpel blade. Thereafter, a bone puncture needle was placed transpedicularly in the fractured vertebral. After removal of the inner needle, commercially available polymethyl methacrylate (PMMA) was carefully injected into the fractured vertebral under continuous fluoroscopic monitoring via lateral and anteroposterior projections to ensure adequate lesion filling, and to avoid PMMA leakage or migration into the venous system toward the lungs. 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. Postprocedural fluoroscopic evaluation was obtained to show optimal filling of the lesion with no evidence of PMMA extravasation. After the procedure, a computed tomography (CT) scan of the treated vertebral bodies was performed with 2 mm slices three to five days after PVP to identify the distribution of cement in the lesion, cement leakage outside the vertebral body or other possible local complications.

Clinical outcome evaluation

The patients were clinically examined by one of the authors, who gathered the initial and follow-up data before and at one day, one week and one, three, six and 12 months after the procedure. Imaging follow-up consisted of anteroposterior and lateral spinal x-ray examinations at one month, six months and one year after the procedure. MRI was performed in the same manner as before the procedures, at three month and one year after the procedure in all patients (Figure 1).

Data regarding the technical success, pain relief, Oswestry Disability Index (ODI), quality of life, physical function and complications were evaluated during the one year follow-up. Technical success was defined as successfully performed PVP without major complications.

The pain relief was measured using a VAS score ranging from 0 (no pain) to 10 (worst pain ever). The functional status of patients for walking, standing and sleeping was measured using the ODI. The ODI comprises a 10-item questionnaire on pain, personal care, lifting, walking, sitting, standing, sleeping, sex life, social life and travelling, with patients scoring each item on a scale from 0 (best possible state) to 5 (worst possible state). The quality of life was measured with the Quality of Life Questionnaire of the European Foundation for Osteoporosis (QUALEFFO), and the physical function was measured with the Roland-Morris Disability (RMD) questionnaire. Standard questionnaires including additional questions about pain treatment, hospital stay, outpatient visits and medical aids were completed with the help of a nurse practitioner.

Any complications following PVP, such as wound infections, nerve injuries, cement leakage and pulmonary embolism, were recorded.

Statistical analysis

Descriptive data are presented as means ± SDs. Comparisons of preand postprocedure VAS and ODI scores were analyzed using nonparametric tests for paired samples, and the correlation was evaluated using the Wilcoxon signed-rank test. Significant pain relief over time was determined using the Kaplan-Meier method and the log-rank test was used to evaluate between-group differences. SPSS version 13.0 was used for the analyses; P≤0.05 was considered to be statistically significant.

RESULTS

Primary procedural results

The chronic osteoporotic VCFs before PVP and treated vertebrae post-PVP is summarized in Table 2. The PVP procedures were technically successful and well tolerated in all patients. Sixty-two patients underwent PVP on 92 vertebrae in 73 procedures that occurred three to five days after referral to the authors' department, with a technique successful rate of 100%. All procedures were performed by the same two surgeons together. Forty-five patients had injections in single vertebra and 17 had injections in multiple vertebra (nine patients in two vertebrae, three patients in three and five patients in four). Fifty-one patients completed the procedures in a single session, whereas 11 patients required two sessions. Vertebroplasty was performed using a single pedicle technique in 25 patients and dual pedicle technique in the remaining 37 patients. The mean (± SD) volume of injected cement per vertebral body was 3.6±1.3 mL (range 1 mL to 6 mL). CT scanning showed cement leakage in 53 (58%) of the 92 treated vertebral bodies. Most leakages were discal or into segmental veins; none were into the spinal canal. Fluoroscopy showed cement migration into the venous system toward the lungs in two patients (6.5%); however, these patients remained asymptomatic without complications during follow-up. The mean postoperative hospitalization time for the procedure was 5.7 days (range three to eight days), and the 30-day mortality rate was zero.

Table – 2

Summary of the chronic osteoporotic vertebral compression fractures (VCFs) before percutaneous vertebroplasty (PVP) and treated vertebrae post-PVP

Vertebrae	Chronic osteoporotic VCFs (n=62)	Treated vertebrae* (n=92)
T3		1
T4		2
T5	1	2
T6	1	3
T7	2	3
T8	3	5
T9	4	4
T10	5	7
T11	6	8
T12	9	13
L1	10	12
L2	7	10
L3	6	10
L4	5	7
L5	3	5

Follow-up results

One-year follow-up were completed for all patients, and baseline and follow-up VAS, ODI, QUALEFFO and RMD scores are presented in Table 3. Compared with baseline scores, improvement in VAS, ODI, QUALEFFO and RMD scores were significantly greater after PVP at one week (P<0.001), one month (P<0.001), three months (P<0.001), six months (P<0.001) and one year (P<0.001).

Table – 3 Baseline and follow-up variables of percutaneous vertebroplasty

Evaluation	Preprocedure	One week	One month	Three months	Six months	One year
VAS score	6.58±0.81	3.39±0.56	2.84±0.52	2.77±0.62	2.74±0.77	2.77±0.72
ODI score	58.77±2.36	30.32±2.94	20.74±3.11	16.42±1.50	15.55±1.09	14.84±1.42
QUALEFFO score	57.45±3.03	46.65±3.09	44.87±2.75	40.93±3.29	39.93±2.57	40.0±1.91
RMD score	18.16±2.0	14.10±1.94	12.35±1.45	10.84±1.70	10.03±1.35	9.10±1.54
Pain treatment, n	62	26	13	8	8	9

After PVP, the number of patients using drugs for pain treatment was

significantly reduced compared with baseline at one week (P<0.001), one month (P<0.001), three months (P<0.001), six months (P<0.001) and one year (P<0.001). In addition, five new fractures were reported by x-ray and/or MRI in five of 62 patients treated with PVP during follow-ups.

CONCLUSION

Although further clinical trials and expanded follow-up studies are needed, our study proved that PVP is effective in patients with chronic painful VCFs and failure of conservative treatment. Pain relief after PVP is immediate, sustained for one year, and may be an important factor for reducing persistent pain.

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