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Comparing Clinical Outcomes Following Percutaneous Vertebroplasty with Conservative Therapy for Acute Osteoporotic Vertebral Compression Fractures

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Abstract

Objective. To compare the efficacy of percutaneous vertebroplasty (PV) with conservative therapy for patients with acute vertebral compression fractures.

Design. Prospective, nonrandomized, comparison study.

Background. The efficacy of PV has not been well established because there have been few comparative studies with conservatively treated control groups.

Patients and Methods. Fifty-five consecutive patients (8 men and 47 women, age 47–94) with osteoporosis and symptomatic acute vertebral compression fractures were enrolled. Thirty-two patients received PV, whereas 23 received conservative therapy.

Outcome Measures. Changes in pain intensity, physical functioning, and pain medication requirement were evaluated.

Results. Both PV and conservative therapy provided pain reduction ($P < 0.001$), improvements in physical functioning ($P < 0.001$), and decreased medication ($P < 0.001$). Reductions in visual analogue pain scores were more significant in the vertebroplasty group at 1 ($P < 0.001$) and 4 weeks ($P < 0.001$) but not at 12 months. Improvements in physical functioning were significant at 1 ($P < 0.001$) and 4 weeks ($P < 0.001$). Medication requirements were lower in the vertebroplasty group at all three time points.

Conclusions. Pain relief, physical functioning improvement, and medication requirement after vertebroplasty are immediately and significantly better when compared with conservative therapy.

Key Words. Compression Fracture; Vertebroplasty; Osteoporosis

Introduction

Acute osteoporotic vertebral compression fracture is a crippling disorder, frequently resulting in severe and prolonged back pain, lengthy hospitalization, physical decline, and a potential risk of increased mortality [1,2]. With graying population trends worldwide, a marked rise in the incidence of osteoporotic vertebral compression fractures has been noted [3]. Bed rest, opioid analgesia, and external bracing were once the only therapies available, and they had limited success [4]. Percutaneous vertebroplasty (PV) is an alternative for acute osteoporotic vertebral compression fractures refractory to conventional medical therapy [5–9]. However, the efficacy of PV is not well established because few studies have compared PV with conservative treatement [10,11]. One concern is that the PV could increase the incidence of new vertebral compression fractures in adjacent vertebrae [6,8,9,12]. Moreover, the procedure is neither simple nor risk free; serious complications have been reported [13–16].

We performed a nonrandomized, prospective study of 32 patients with acute osteoporotic vertebral compression fractures treated by PV and 23 patients who declined PV, and were managed conservatively. The purpose of this study was to compare pain reduction, physical functioning improvement, pain medication requirement, and complications between PV and conservative treatment.

Methods

Patients and Eligibility

This prospective study was approved by the institution review board. From April 2007 to February 2008, all patients with symptomatic acute osteoporotic vertebral compression fractures were approached to participate in this study. Patients underwent physical examinations, bone densitometry, and various combinations of imaging study (plain films, computed tomography, and magnetic resonance imaging [MRI]) to exclude other causes of pain eligible for surgery. Inclusion criteria were acute pain (lasting less than 6 weeks), low signal intensity on T1-weighted and high signal intensity on T2-weighted MRI images of the fractured vertebrae, vertebral compression fractures with more than 20% loss of height, age over 50, focal tenderness at the fractured level, and decreased bone density T-score –1 [17]. Exclusion criteria were pathological fracture due to malignancy/myeloma, osteomyelitis, major retropulsion of bony segments into the spinal canal, and coagulopathy.

Study Protocol

After informed consent, the patients were divided into two groups (PV and conservative treatment) according to consent or refusal to have PV. Thirty-two patients were offered PV. Twenty-three patients who declined PV because of the possibility of PV complications were managed conservatively. Patients who declined PV were evaluated longitudinally and served as controls. Follow-up imaging was performed as needed. All patients were offered external bracing and similar analgesia (paracetamol, nonsteroidal anti-inflammatory drugs [NSAIDs], and opiate derivatives). All patients received antiosteoporotic medications such as oral alendronate (70 mg weekly) or teriparatide subcutaneous injection. The intention of the study was to evaluate pain reduction, physical functioning improvement, pain medication requirement, and complications of both groups for the short term (1–4 weeks) and for the long term (12 months). Patients who received conservative treatment but who still had severe pain could receive PV if they wanted to cross over. Any patient could leave the study without explanation of their motivation at any moment.

Intervention

PV was performed under strict sterile conditions in an operating room. All patients received conscious intravenous sedation prior to the procedure in order to keep them comfortable. Local anesthesia with 2% lidocaine was administered through the skin to the periosteum of the targeted pedicle. Each patient was placed in the prone position, and the skin overlying the target area was prepared and draped. The procedure was performed using a unipedicle method [7]. Targeted pedicles were localized under the guidance of biplanar fluoroscopy. After a small incision, an 11-gauge bone biopsy needle (Stryker Instruments, Kalamazoo, MI) was advanced until its tip abutted the pedicle. Under said guidance, the needle was pushed through the cortex, traversed the pedicle, and was directed into the anterior third of the vertebral body. Bone cement was prepared from methylmethacrylate polymer (15 g powder, 10 mL solvent) and sterile barium (5 g powder to increase radio-opacity). Cement was injected forcibly into the vertebral body with a 1-mL syringe under continuous fluoroscopic imaging guidance. After the procedure, radiographs of the treated vertebral bodies were taken to identify cement leakage or other local complications.

Outcome Assessment

Pain intensity, physical functioning, and pain medication were assessed on presentation, at 1 week, at 4 weeks, and at 12 months after enrollment. PV was usually performed on the next day after enrollment. All patients were independently assessed by a nurse who was blinded to the treatment undertaken. Patients were followed up in the outpatient department after discharge. Patients were encouraged to have radiography or MRI for recurrent back pain.

Changes in pain intensity were recorded using a visual analogue scale (VAS) ranging from 0 to 10 (0: “no pain” and 10: “the most severe pain ever experienced”) [18]. Physical functioning was evaluated using a Revised Oswestry Disability Index (ODI) [19]. The ODI questionnaire was completed by the patients, and scores (0–100) were reported prior to and after treatment.

Pain medication, prior to and after treatment, was assessed using a scale ranging from 0 to 4 (0 = no medication; 1 = use of paracetamol; 2 = use of NSAIDs; 3 = use of opiate derivates; 4 = routinely scheduled opiates derivates).

Complications related to PV and recurrent vertebral compression fractures were recorded during follow-up. Recurrent vertebral compression fractures were defined as a decrease of body height of more than 20% and bone edema change on MRI.

Statistical Analysis

Descriptive statistics were used to characterize the patients. Pre- and posttreatment ranges, means, and standard deviations were calculated. Friedman repeated measures variance test was performed to compare the differences within groups across time. Differences between groups were evaluated using $\chi 2$, Fisher’s exact test, or Mann–Whitney *U*-test, as appropriate. Comparisons were performed with Bonferroni correction. We used two-tailed tests of significance ($P < 0.05$). Data were analyzed using SPSS vs. 12.0 (SPSS Inc., Chicago, IL).

Results

Baseline Characteristics

The 55 patients (8 men, 47 women) in this study were followed at least for 12 months. Their mean age was

Table 1 Demographics of the both study groups

Characteristics	Treatment: Percutaneous Vertebroplasty (N = 32)	Treatment: Conservative Therapy (N = 23)	*P*
Age	72.9 ± 12.4	72.7 ± 9.1	0.84
Gender			0.98
Male (%)	5 (16)	3 (13)	
Female (%)	27 (84)	20 (87)	
Body Mean Index	22.7 ± 3.7	21.4 ± 2.86	0.33
Lumbar spine T score	–2.7 ± 0.9	–2.6 ± 0.7	0.60
Femoral neck T score	–2.4 ± 0.9	–2.4 ± 0.7	0.99
Vertebral compression	36 ± 8%	42 ± 13%	0.08
Previous vertebral fractures	2.9 ± 2.2	1.8 ± 1.4	0.07
Re-fractures (%) after treatment	8 (25)	1 (4)	0.06

72.8 ± 11.1 (range: 47–94). Thirty-two patients received PV (5 men, 27 women) for 42 acute osteoporotic vertebral compression fractures. PV was performed at one level in 22 patients and at two levels in 10 patients. PV was performed on 19 thoracic (T6 = 2; T7 = 2; T9 = 2; T10 = 2; T11 = 4; T12 = 7) and 23 lumbar vertebrae (L1 = 10; L2 = 2; L3 = 9; L4 = 1; L5 = 1). All PV procedures were performed via a unipedicular technique because there was sufficient filling across the midline to obviate the need for contralateral injection. The mean injection volume of bone cement was 4.3 ± 1.2 mL (range: 1.5–7). The 23 patients (3 men, 20 women) who underwent conservative therapy had 10 thoracic (T7 = 2; T10 = 1; T11 = 3; T12 = 4) and 17 lumbar fractures (L1 = 7; L2 = 2; L3 = 4; L4 = 2; L5 = 2).

Patients who underwent PV had similar characteristics to those who declined the procedure (Table 1). There were no significance differences in age, gender, Body Mass Index, T scores of the femoral neck and lumbar spine, vertebral compression, or preexisting fractures. Three (13%) of the 23 patients in the conservative therapy group requested PV after 6 weeks because of poor response to conservative therapy (Figure 1).

Clinical Outcomes

Table 2 and Figures 2–4 present outcome data for the patients in both groups. After 1 week, changes in VAS scores ($P < 0.001$), revised ODI scores ($P < 0.001$), and

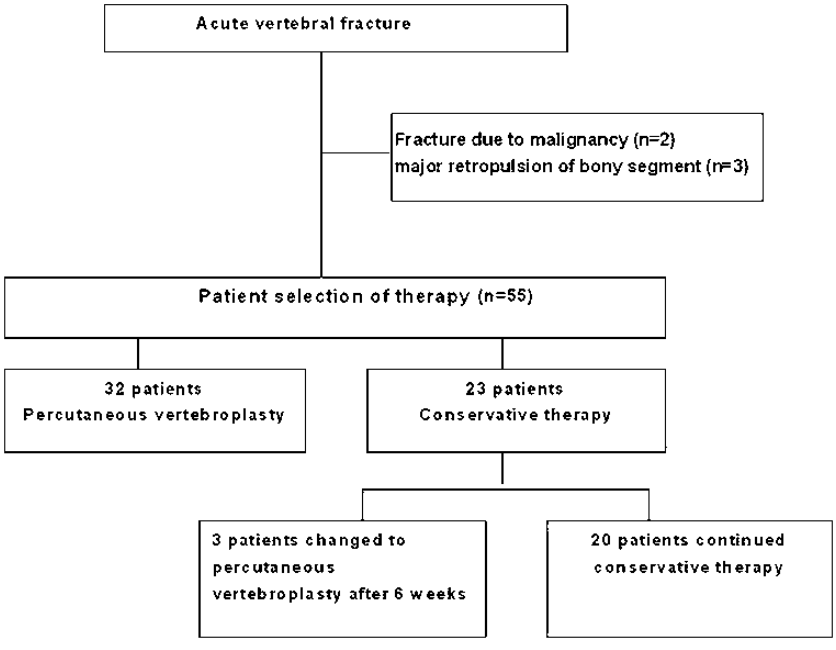

Figure 1 Flow diagram demonstrating study recruitment and treatment selection.

Table 2 Outcomes comparison between both study groups

	Percutaneous Vertebroplasty (N = 32)	Conservative Treatment (N = 23)	*P*
Pain scores			
Baseline	7.5 ± 0.9	7.1 ± 1.1	0.159
1 week	3.3 ± 1.3	5.9 ± 1.4	0.001
Scores change	–4.1 ± 0.9	–1.3 ± 0.9	0.001
4 weeks	2.9 ± 2.0	4.7 ± 2.0	0.002
Scores change	–4.6 ± 1.8	–2.5 ± 1.6	0.001
12 months	2.3 ± 1.4	3.2 ± 1.9	0.687
Scores change	–4.8 ± 1.6	–4.0 ± 1.7	0.094
ODI score			
Baseline	66.8 ± 18.0	61.3 ± 18.0	0.278
1 week	42.8 ± 18.6	54.4 ± 18.9	0.047
Scores change	–24.0 ± 8.4	–6.9 ± 5.7	0.001
4 weeks	37.4 ± 18.6	46.4 ± 22.3	0.118
Scores change	–29.4 ± 11.5	–15.1 ± 9.5	0.001
12 months	34.4 ± 21.1	36.1 ± 17.6	0.851
Scores change	–31.9 ± 12.7	–26.9 ± 11.6	0.071
Pain medication			
Baseline	2.6 ± 0.6	2.5 ± 0.7	0.469
1 week	1.8 ± 0.5	2.3 ± 0.7	0.01
Scores change	–0.8 ± 0.6	–0.2 ± 0.4	0.001
4 weeks	1.3 ± 0.8	2.0 ± 0.9	0.004
Scores change	–1.3 ± 0.8	–0.5 ± 0.6	0.001
12 months	0.9 ± 0.9	1.5 ± 1.1	0.045
Scores change	–1.7 ± 0.9	–1.0 ± 1.0	0.017

ODI = Revised Oswestry Disability Index.

medication scores ($P < 0.001$) were significantly greater in the vertebroplasty group than the conservative group. These changes remained significantly greater at 4 weeks. Twelve months later, there were no differences in changes of VAS and ODI scores between the groups. Only changes of pain medication scores were significant in the PV group after 12 months ($P = 0.017$). Thus, whereas PV could provide better immediate effects (1–4 weeks) for

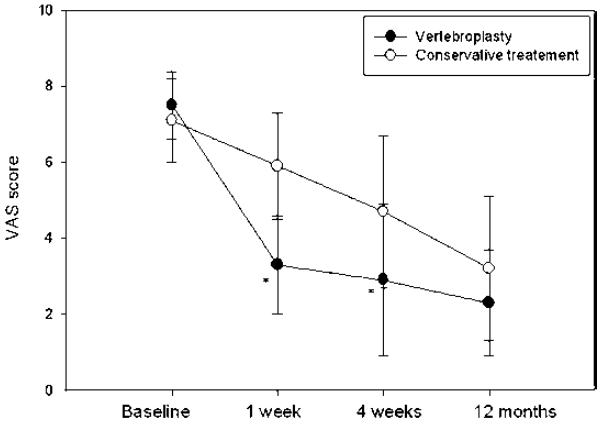

Figure 2 Longitudinal changes in mean (±SD) visual analog scale (VAS) scores. Patients treated by percutaneous vertebroplasty are compared with patients treated conservatively. Asterisk indicates $P < 0.01$ for between-group comparisons.

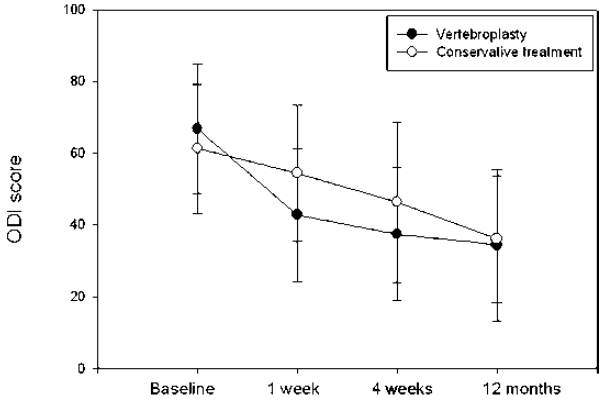

Figure 3 Longitudinal changes in mean (±SD) Revised Oswestry Disability Index (ODI) scores. Patients treated by percutaneous vertebroplasty are compared with patients treated conservatively. Asterisk indicates $P < 0.01$ for between-group comparisons.

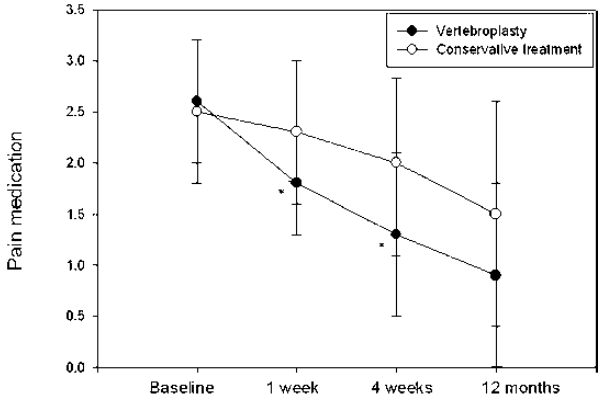

Figure 4 Longitudinal changes in pain medication scores. Patients treated by percutaneous vertebroplasty are compared with patients treated conservatively. Asterisk indicates $P < 0.01$ for between-group comparisons.

pain reduction and physical functioning, the effects were not significantly different after 12 months.

Friedman analysis indicated that for both groups, there were significant differences ($P < 0.001$) in VAS, ODI, and medication scores across four phases. Both PV and conservative therapy provide pain reduction, improvements of physical functioning, and decreases in medication.

Complications and Recurrent Fractures

There were no major complications, except for one procedure (2.3%) in which polymethylmethacrylate (PMMA) migrated toward the lungs, which was visible on fluoroscopy. The procedure was ceased when the migration occurred. The patient had no clinical symptoms of PMMA emboli.

Symptomatic re-fractures were noted in nine patients. Eight PV patients (25%) had re-fractures within 12 months (Table 3) and underwent subsequent PV. Only 1 patient (4%) in the conservative group had symptomatic re-fracture and was treated medically. This amounted to a nonsignificant trend ($P = 0.06$) toward a higher re-fracture rate in the PV group. Half (4/8) of new vertebral compression fractures were adjacent to a level initially treated with PV and occurred sooner than nonadjacent fractures.

Discussion

Although several studies have reported that PV is effective [5–10], none used a control group. Only three previous studies compared PV with conservative treatment [10,11,20]. In a nonrandomized study, Diamond et al. [11] found prompt pain reduction and improvement in physical functioning at 24 hours after PV, as compared with patients in a conservative group. However, the benefits of PV were not evident at 6 weeks or at 6 months. Both groups, after 6 weeks, had similar improvements in pain reduction and physical functioning [11]. Subsequently, Diamond et al. [10] conducted another study and found better pain relief and physical functioning in the PV group both at 24 hours and at 6 weeks after treatment. A randomized study demonstrated immediate improvements (at 2 weeks) in pain score, physical functioning, and medication requirements in the PV group, but long-term follow-up data were not available [20].

The present study demonstrates that at 1 and 4 weeks after treatment initiation, changes in pain are significantly greater after PV. At 12 months, the differences were not significant because conservative therapy could gradually provide pain relief for most patients. Improvements of ODI scores were significantly greater in the PV group at 1 and 4 weeks, and patients in the PV group also used less medication. PV provides prompt pain relief, rapid improvements in physical functioning, and a decline in medication-related complications [21].

Recently, two randomized controlled trials found no attributable effect of PV for osteoporotic spinal compression fractures [22,23], but these studies enrolled patients who had been symptomatic for up to 1 year. Our study evalu-

Table 3 Re-fractures after percutaneous vertebroplasty in 8 patients

Patient No	Age/ Gender	Vertebroplasty Levels	Re-fracture Level	T Score of Spine	BMI	Osteoporosis Treatment	Time to Re-fracture
1	80/F	L2	T12	–2.0	18	Alendronate	6 months
2	92/F	L3, L4	L1	–3.5	19	Alendronate	7 months
3	64/F	L3	T11, T12	–3.2	27	Teriparatide	<1 month
4	73/F	L1	L2, L3	–1.7	24	Teriparatide	4 months
5	59/F	T9	T4, T7	–2.7	27	Alendronate	1.5 months
6	94/F	L1	T12	–2.2	18	Teriparatide	12 months
7	80/F	T9	T8	–3.3	23	Alendronate	<1 month
8	80/F	T12	T11	–3.6	22	Teriparatide	<1 month

BMI = body mass index.

ated the efficacy of PV within 6 weeks of fracture. Others have found it to be more effective for fractures within 8 weeks [24] or 3 months [25]. It may be that delayed treatment is less effective. Further research could focus on this possibility.

Overall complication rates associated with PV for treatment of osteoporotic compression fractures are reported to be very low [26]. However, the procedure is not free of risk [13–16]. Serious complications, such as pulmonary PMMA embolism caused by cement leakage during its injection, have been reported [13,15,27]. To avoid this, adequate cement preparation, and slow and steady delivery of cement, should be considered [7]. Pulmonary PMMA emboli caused by cement leakage can be asymptomatic or life-threatening [13,15,27]. Their prevalence has been reported to be 0–4.8% [27]. In the current study, the prevalence was 2.3%. Proper use of fluoroscopy and slow delivery of PMMA in repeated small quantities makes large pulmonary PMMA emboli rare [27]. We perform PV by using a 1-mL syringe instead of a 3- or 5-mL syringe for slow and steady delivery of PMMA cement after having encountered a serious complication of pulmonary PMMA emboli [13].

There is controversy as to whether PV predisposes to new vertebral compression fractures. The incidence of new fractures after PV can be as high as 48% within 1 year [8]. Some authors believe the incidence of new fractures to be higher than natural history, with a 21% incidence in the first 60 days alone [28]. However, Diamond et al. found no difference in the incidence of new fracture between PV and conservative groups [10,11]. In the present study, the incidence of new symptomatic fractures in the PV group was 25% in 12 months, higher than the conservative treatment group (4%). Although the present study showed a higher incidence, there was no statistical significance. A larger sample is needed. A study with 38 cases in the VP group and 53 cases in the conservative treatment group would have a power of 0.80 to exclude a difference.

For patients treated by conservative therapy, significant back pain further hindered mobility and physical functioning. This may have a protective effect against new vertebral compression fractures. Whether PV does or does not increase future fractures is unclear. Perhaps the most important risk factor for future fracture is the underlying osteoporosis itself. In our study, 62.5% of new fractures occurred in patients who had a T score less than –2.5. Patients with severe osteoporosis need more intensive clinical and radiological follow-up.

Half (4/8) of the new fractures were adjacent to a level initially treated with PV. Three of the adjacent fractures occurred within 4 months. The incidence of adjacent fractures was higher than nonadjacent fractures. This is consistent with another study [29] that showed a relative risk of 4.62 for fracture of adjacent vs nonadjacent vertebrae. Adjacent fractures also occurred sooner [29]. This suggests a local unfavorable biomechanical situation in some patients who suffer adjacent-level fractures and underlying disease process (usually osteoporosis) in the remote fracture group [9]. This study has some limitations. A nonrandomized study with patients recruited according to consent or refusal to have PV could have some self-selection bias. However, the nonsignificance of statistical results in pretreatment variables (Table 1) and three baseline scores (Table 2) argue against this concern. Although patients were encouraged to have imaging for recurrent back pain, some asymptomatic new re-fractures might not have been detected because imaging was not undertaken. The sample size was too small to investigate the role of PV in re-fractures. Randomized, prospective, controlled trials with larger sample sizes could clarify these issues.

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