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Randomized controlled trial of percutaneous vertebroplasty versus optimal medical management for the relief of pain and disability in acute osteoporotic vertebral compression fractures

Clinical article

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Object. Osteoporotic vertebral compression fractures (VCFs) are a major cause of increased morbidity in older patients. This randomized controlled trial compared the efficacy of percutaneous vertebroplasty (PV) versus optimal medical therapy (OMT) in controlling pain and improving the quality of life (QOL) in patients with VCFs. Efficacy was measured as the incidence of new vertebral fractures after PV, restoration of vertebral body height (VBH), and correction of deformity.

Methods. Of 105 patients with acute osteoporotic VCFs, 82 were eligible for participation: 40 patients underwent PV and 42 received OMT. Primary outcomes were control of pain and improvement in QOL before treatment, and these were measured at 1 week and at 2, 6, 12, 24, and 36 months after the beginning of the treatment. Radiological evaluation to measure VBH and sagittal index was performed before and after treatment in both groups and after 36 months of follow-up.

Results. The authors found a statistically significant improvement in pain in the PV group compared with the OMT group at 1 week (difference −3.1, 95% CI −3.72 to −2.28; $p < 0.001$). The QOL improved significantly in the PV group (difference −14, 95% CI −15 to −12.82; $p < 0.028$). One week after PV, the average VBH restoration was 8 mm and the correction of deformity was 8°. The incidence of new fractures in the OMT group (13.3%) was higher than in the PV group (2.2%; $p < 0.01$).

Conclusions. The PV group had statistically significant improvements in visual analog scale and QOL scores maintained over 24 months, improved VBH maintained over 36 months, and fewer adjacent-level fractures compared with the OMT group. *(DOI: 10.3171/2010.12.SPINE10286)*

Key Words • **osteoporosis** • **vertebroplasty** • **vertebral compression fracture** • **spine** • **pain**

Osteoporosis is a skeletal disorder characterized by low bone mass, which decreases bone strength, causing the bones to become fragile and increases the risk of fracture. Most osteoporotic fractures are VCFs.[30] Increased morbidity and mortality rates in patients with VCFs is associated with progressive spinal deformity, pulmonary dysfunction, severe back pain, deep vein thrombosis, muscle atrophy, pressure sores, sleep disorders, and depression. These fractures occur in 20% of people over the age of 70 years and in 16% of postmenopausal women.[4] One-third of all osteoporotic VCFs become chronically painful.[26] Osteoporotic VCFs occur more often as the population becomes older.[12]

Traditional treatment for VCF includes bed rest, oral or parenteral analgesics, muscle relaxants, external back bracing, and physical therapy. Traditional treatments use narcotic agents and a variety of expensive spinal orthoses.[30] Although some patients respond to medical therapy for acute osteoporotic VCF, its effectiveness may be limited because of its high cost and the fact that the patients need to take medications for a long time.[4,12,19,30]

Percutaneous vertebroplasty is a minimally invasive

Abbreviations used in this paper: LBP = low-back pain; OMT = optimal medical therapy; PV = percutaneous vertebroplasty; QOL = quality of life; RCT = randomized controlled trial; SI = sagittal index; VAS = visual analog scale; VB = vertebral body; VBH = VB height; VCF = vertebral compression fracture.

technique in which acrylic cement is injected through a needle into the vertebra to stabilize the fracture.[9] The first PV was performed by Deramond in 1984, and Galibert et al.[10] used it to treat hemangioma in the cervical spine in 1987. Indications for PV now include osteoporotic VCF.[5,6,15]

Although PV might provide immediate pain relief and improved function in patients with VCF,[18,19,30] few clinical trials of this procedure have been done, and reports published to date involved limited numbers of patients and lacked long-term follow-up results.[2,25] Additionally, 2 recent studies published in the *New England Journal of Medicine* reported negative findings.[1,16] We designed an RCT to assess the short- and long-term effect of PV on pain relief and QOL in comparison with OMT in patients with osteoporotic VCFs. Specifically, we determined the influence of PV on the incidence of new fractures over 2 years and evaluated the ability of PV to restore VBH and correct spinal deformity.

Methods

Study Design

We performed a single-blind RCT, in which 82 patients of a total of 105 were eligible to participate and were enrolled between September 2004 and January 2006. A 3-year follow-up period was planned from January 2006 to January 2009. Patients had painful osteoporotic VCFs refractory to analgesic therapy for at least 4 weeks and less than 1 year. Analgesic therapy was prescribed by referring physicians before the patients entered the trial. A general practitioner not only assessed 105 patients for eligibility but also evaluated baseline characteristics of eligible patients before randomization. All patients gave their informed consent in writing. Eligible participants were assigned randomly by opening a sealed envelope. The envelopes were prepared beforehand and sorted randomly using random allocation software (computerized random number generators). Patients in the study group underwent PV performed by a neurosurgeon, and those in the control group received OMT administered by another physician. Neither the neurosurgeon nor the physician knew about the other group and had no role in allocation. All patients were followed by 2 independent raters who were unaware of the study. A third rater, who was likewise unaware of the study, verified the results. The raters were not involved in the care of the patients. The medical research ethics committee of Shiraz University of Medical Sciences approved the study, and it was registered online at www.irct.ir (IRCT138804252193N1).

Patients and Evaluation

During a 15-month period from September 2004 to January 2006, 105 patients were selected for participation, and 82 were randomized according to the Consolidated Standards for Reporting of Trials flow diagram shown in Fig. 1. We excluded 23 patients in accordance with the exclusion criteria. Of the 82 remaining patients, 40 were assigned to undergo PV and 42 to receive OMT. Any patient in the OMT group was permitted to undergo PV after 1 month (crossover).

Inclusion Criteria

The inclusion criteria were as follows: 1) VCF with 10%–70% loss of VBH on x-ray of the spine; 2) severe back pain related to VCF that was refractory to analgesic medication for at least 4 weeks and no longer than 1 year; 3) focal tenderness on physical examination related to the level of vertebral fracture; 4) bone attenuation (T-score less than –2.5) on bone densitometry; 5) vacuum phenomenon or bone marrow edema of the vertebral fracture on MR imaging; and 6) unresponsiveness to the medical therapy before entering the trial.

Exclusion Criteria

The exclusion criteria were as follows: 1) uncorrected coagulopathy; 2) local or systemic infection; 3) secondary osteoporosis; 4) inability to give informed consent; 5) impaired cardiopulmonary function; 6) dementia; 7) posterior wall defect of the VB on CT studies; 8) painless VCF; 9) spinal cancer; 10) traumatic fracture; and 11) neurological complications.

Patients were evaluated before randomization based on a complete history, physical examination, and neuroimaging evaluation (x-ray, CT, and MR imaging). Radiographs (anteroposterior and lateral views) of the thoracic and lumbar spine were taken, preferably in a standing position if the patient was able or in a sitting position if not. Height of the fractured vertebra was estimated by calculating the average VBH (height of the posterior wall + height of the anterior wall/2) from x-ray studies and sagittal reconstruction view CT images. The shape and grade of VCF was scored using a visual grading scale of vertebral deformities according to Genant et al.[11] The shape of the VCF was classified on the basis of reduction in anterior height (wedged), middle height (concave), and posterior height (crush). The grade of VCF as a percentage of height reduction was recorded as mild (15%–25%), moderate (26%–40%), or severe (> 40%).

We used the SI to measure deformity angle. Angulation was measured by first drawing a line parallel to the most caudal uninjured inferior vertebral endplate. A line perpendicular to this line was drawn, and then a line was drawn marking the most cranial uninjured inferior vertebral endplate, along with its perpendicular. The angle in degrees of kyphotic angulation (the SI) was calculated from the 2 perpendicular lines.[7,8,23] Transverse and sagittal CT scans were obtained in all patients to evaluate the integrity of the posterior wall and the height of the fractured VB, respectively.

All patients underwent MR imaging in a sequence consisting of T1- and T2-weighted images to record bone marrow edema as an index of an acute or unhealed fracture.

Percutaneous Vertebroplasty Technique

The procedure was performed in the operating room after induction of conscious sedation (a combination of intravenous fentanyl and midazolam) in 10 patients (25%) and general anesthesia in 30 patients (75%). The patients were placed prone, and single-plane C-arm equipment was used. Venography is not performed routinely at our

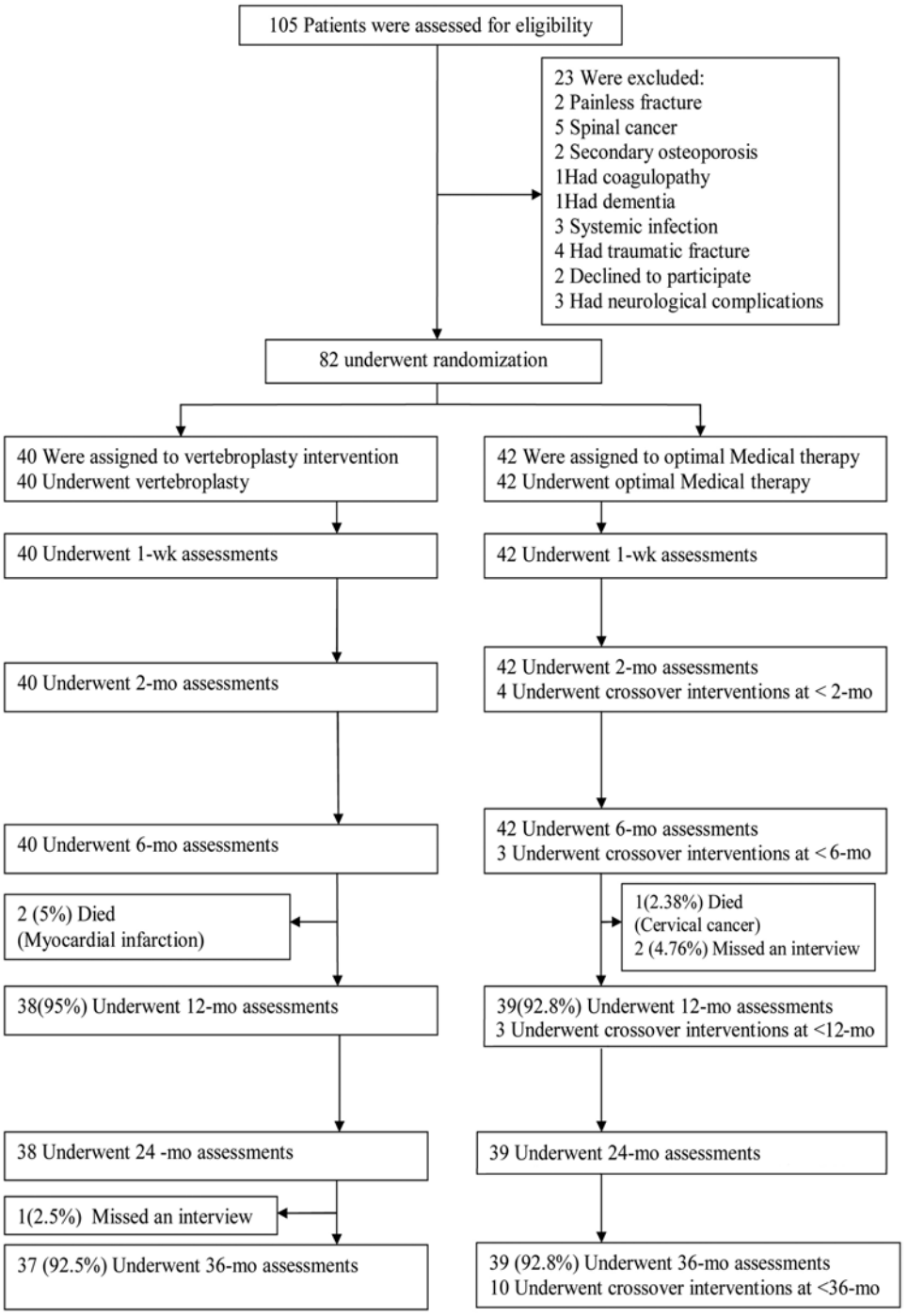

Fig. 1. Flow chart showing enrollment, assigned intervention, follow-up, and outcomes in patients who underwent PV or OMT for osteoporotic VCFs.

institution. Using sterile techniques, an 11-gauge needle was inserted into the VB via a unilateral parapedicular approach in 35 patients (87.5%) and via a bilateral transpedicular approach in 5 patients (12.5%). A bilateral transpedicular approach was used only if there was inadequate instillation of cement with the unilateral approach under fluoroscopy. A polymethylmethacrylate mixture was injected into the VB. Following the procedure, the patient remained supine in bed. Patients who had received conscious anesthesia rated pain on a VAS after 6 hours, and those who had received general anesthesia rated pain on a VAS 1 day after the procedure. During cement injection, fluoroscopic monitoring with a C-arm unit was used in both planes.

Optimal Medical Therapy

All patients had been treated unsuccessfully with acetaminophen or NSAIDs before they were referred to us

by physicians at different centers. For all patients in the OMT group we prescribed 250 mg acetaminophen with codeine twice daily, 400 mg ibuprofen twice a day, 1000 mg calcium daily, 400 IU vitamin D daily, 70 mg alendronate orally once weekly, and 200 IU calcitonin daily. It is worthwhile to add that doses of analgesics were a baseline suggestion, and the physician could increase them to achieve an optimum dose.[33] However, change in lifestyle and physical treatment was also suggested to patients in both groups.

Outcome Measures

All 82 patients completed a questionnaire regarding pain and LBP-related disability. Evaluation measures were performed before randomization and at different follow-up periods for up to 3 years. The primary outcomes were pain and functional QOL. According to methods detailed by Ploeg et al.,[25] the average pain was evaluated during a 24-hour period by using the Huskisson VAS, with scores ranging from 1 (no pain) to 10 (excruciating pain).

Quality of life or functional daily activity was evaluated using a questionnaire based on the Oswestry LBP disability scale.[7] This scale is a functional measurement of QOL that comprises 6 items in 10 dimensions: pain intensity, personal care, lifting, walking, sitting, standing, sleeping, social life, traveling, and change in the degree of pain.

Follow-up data were collected by raters at 1 week and at 2, 6, 12, 24, and 36 months, with the VAS pain score and the Oswestry LBP scale used to measure QOL in both groups. Radiographic studies were also taken at 2 and 6 months and at 1, 2, and 3 years to measure VBH and SI in both groups.

Statistical Analysis

The data were analyzed according to the intention-to-treat principle. Differences in baseline characteristics between the groups were analyzed with the Student t-test for continuous variables and the chi-square test for categorical variables. The Student t-test and the post hoc Mann-Whitney U-test for nonparametric data were used after Bonferroni adjustment to compare the differences in scores (with 95% CIs) after different follow-up intervals. The paired t-test and Wilcoxon signed-rank test were used to compare differences in the VAS and Oswestry LBP scale scores, respectively, with 95% CIs, before and after PV in crossover patients. All analyses were done with SPSS version 14 software (SPSS, Inc.).

Results

During a 15-month period starting in September 2004, 105 patients were selected for enrollment and 82 of them were randomized (Fig. 1). Baseline characteristics in the 2 groups were similar (Table 1).

All patients had back pain and severe limitations in daily activities. The mean VAS and QOL scores are shown in Table 2. The mean VAS score of 8.4 ± 1.69 in 97% of patients in the PV group decreased to 3.3 ± 1.5 at 1 week (difference –5.1, 95% CI –6.72 to –3.22; $p < 0.011$), but the reduction in the OMT group was smaller, from 7.22 ± 1.72 to 6.4 ± 2.1 at 1 week (difference –0.8, 95% CI –1.21 to 0.81; $p < 0.15$). There was a significant improvement in pain relief and functional QOL in the PV group immediately after the procedure, with maximum improvement 6 months after the procedure. No significant improvement was seen in the control group ($p < 0.21$). The VAS and QOL scores at different times are shown in Table 2. All patients could walk 1 day after PV, but only 1 patient (2%) in the OMT group was able to walk at this time ($p < 0.011$).

The mean amount of cement injected per level in patients with a 1-level fracture was 3.5 ml (median 3.1 ml, range 1–5.5 ml). Twenty patients (50%) had multiple VCFs: 16 (40%) had 2-level fractures, 2 (5%) had 3-level fractures, and 2 (5%) had 4-level fractures. In patients with multiple VCFs, the mean total amount of polymethylmethacrylate injected was 5 ml (median 4 ml, range 1–9 ml). Cement extravasation in the epidural, discal, and paravertebral space occurred in 1 (1%), 5 (5%), and 8 (8%), respectively, of a total of 100 PV levels. No infection or cement emboli occurred.

The most common vertebral fracture level was L-1 (Fig. 2) in both groups. Multiple fractures were seen in 16 patients (40%) in the PV group and in 14 patients (33%) in the OMT group ($p < 0.02$). In the PV group, MR imaging demonstrated swelling of the VB (bone marrow edema) as a sign of acute fracture in 28 (64%) of 44 cases, and vacuum cleft suggesting an unhealed fracture was seen in 16 (36%) of 44 cases. Radiographic images were obtained to evaluate the restoration of VBH and the correction of sagittal deformity at different follow-up periods (Table 3). One week after treatment, significant differences compared with pretreatment values were seen for mean VBH ($p < 0.002$) and SI ($p < 0.011$) in the PV group. However, these changes were not significant in the control group ($p = 0.22$ and $p < 0.80$, respectively). New symptomatic adjacent fractures developed in 1 patient (2.6%) in the PV group and in 6 patients (15.4%) in the OMT group ($p < 0.01$) after 2 years of follow-up.

Persistent pain (VAS Score 6) and a low QOL (Oswestry LBP Score 45) were found in 10 patients (25.6%) in the OMT group 1 year after the initiation of treatment. These patients requested treatment with PV (Fig. 1). The mean VAS score in these patients compared with the remainder of the patients in the OMT group differed significantly (95% CI 1.22 to 3.88; Table 4).

Postoperative Complications

In 1 patient, epidural cement leakage caused severe right lower-extremity pain and weakness. Immediate decompression through a bilateral laminectomy and evacuation of bone cement was done. Fortunately, the patient could walk unassisted with no radicular pain after 2 months. There were no instances of venous emboli or infection.

Discussion

One week and 2, 6, 12, and 24 months after initiating treatment, pain relief and QOL were significantly better in patients treated by PV than in patients given OMT. Percutaneous vertebroplasty restored VBH and prevented

TABLE 1: Baseline characteristics of 82 patients treated for osteoporotic VCFs*

Characteristic	PV Group	OMT Group	p Value
no. of patients	40	42	
mean age in yrs (range)	72 (59–90)	74 (55–87)	0.7
no. females (%)	30 (75)	30 (71)	
duration of LBP in wks (range)	27 (4–50)	30 (6–54)	0.11
total no. of preexisting VCFs	56	50	<0.11
mean (range)	3.3 (1–8)	3.1 (1–8)	
total no. of treated VCFs	100	90	0.71
mean (range)	2.5 (1–4)	2 (1–3)	
distribution of treated VCFs	T4–L5	T5–L5	
grade of treated VCFs (%)			
mild	24 (60)	29 (69)	<0.39
moderate	12 (30)	12 (29)	<0.11
severe	4 (10)	1 (2)	<0.44
mean height of fractured vertebra (cm)	2.8 ± 1.5	2.5 ± 1.0	0.7
mean SI (°)	20.0 ± 5.5	20.0 ± 3.2	<0.64
shape of treated VCFs (%)			
wedge	90 (90)	70 (78)	
biconcave	10 (10)	20 (22)	
no. (%) w/ T-score for BMD			
lumbar	34 (85)	40 (95)	0.7
initial mean VAS score for pain†	8.4 ± 1.6	7.2 ± 1.7	0.39
mean Oswestry LBP scale score	51.2 ± 2.2	47.1 ± 2.8	0.30
initial pain medication			
no. w/ acetaminophen w/ codeine (%)	30 (75)	30 (71)	0.31
no. w/ NSAIDs (%)	20 (50)	32 (76)	0.41

* Plus-or-minus values are the mean ± SD throughout. Abbreviation: BMD = bone mineral density.

† The overall pain score was measured and recorded as the initial VAS score for pain.

spinal deformity compared with OMT. There were more new vertebral fractures in the OMT group than in the PV group.

We found a statistically significant difference in the primary and secondary outcome measures between the 2 groups in favor of PV. These results are similar to 2 recent RCTs reported by Voormolen et al.[34] and Rousing et al.[27] However, 2 RCTs published by Buchbinder et al.[1] and Kallmes et al.[16] suggested that the relief of pain from VCF and improvements in daily function were similar in patients who underwent PV and those treated with a sham procedure. The interpretation of these studies has been open to some speculation. Our patients had severe focal back pain related to acute fracture, but the trials reported by Kallmes et al. and Buchbinder et al. involved patients with general back pain. Furthermore, the questions they asked were back pain related, but not fracture specific. Therefore, 30% of potentially eligible participants declined to participate in the study of Buchbinder et al. This may indicate that VCF was not the primary reason for referral, but rather that chronic back pain, which can have different causes, was one of the inclusion criteria. Consequently, selection bias may have affected the results in both trials.

Interestingly, Buchbinder et al.[1] reported a high rate of painful complications such as osteomyelitis, puncture site pain, and burning or pain in the thigh or leg in the PV group, and rib fractures in the sham group. The prolonged duration of pain from these complications may have biased the effect of pain treatment in both groups. None of the participants in our trial had infection, rib fracture, or radicular pain. Kallmes et al.[16] reported that 63% of the patients in the placebo group and 51% of those in the PV group correctly guessed their own treatment 14 days after the initiation of treatment. This may raise questions about whether inadequate concealment of study group assignments affected the outcomes.

In our study, patients who crossed over to PV had significant pain relief, a finding also reported by Voormolen et al.[34] Kallmes et al.[16] reported that 27 patients (43%) in the placebo group crossed over to the PV group ($p < 0.001$); these authors noted that more patients in the placebo group may have had an unsatisfactory outcome in terms of pain than in the PV group, but the investigators were unable to detect this difference with their measure of pain intensity. They suggested that PV may have been more effective than the control intervention for a subgroup of patients but noted the need for further research to explore this possibility. No crossover was permitted in the study by Buchbinder et al.[1] The possible role of the

TABLE 2: Primary outcome according to group in 82 patients treated for VCFs*

Outcome Measure	PV Group	OMT Group	Mean Difference, Treatment Effect (95% CI)	p Value
VAS for pain				
baseline	8.4 ± 1.6	7.2 ± 1.7		
1 wk	3.3 ± 1.5	6.4 ± 2.1	−3.1 (−3.72 to −2.28)	<0.001
2 mos	3.2 ± 2.2	6.1 ± 2.1	−2.9 (−4.9 to −0.82)	<0.011
6 mos	2.2 ± 2.1	4.1 ± 1.5	−1.9 (−3.25 to −0.55)	<0.021
12 mos	2.2 ± 2.1	4.1 ± 1.8	−1.9 (−2.9 to 0.9)	<0.11
24 mos	2.8 ± 2.0	3.7 ± 2.0	−0.5 (−1.39 to 0.5)	<0.37
36 mos	1.8 ± 1.7	3.7 ± 2.5	−1.5 (−9.85 to 6.85)	<0.81
Oswestry LBP score for QOL				
baseline	52.2 ± 2.4	50.4 ± 2.8		
1 wk	30.1 ± 3.0	44.0 ± 2.5	−14.0 (−15.0 to −12.82)	<0.028
2 mos	15.0 ± 2.2	30.0 ± 3.1	−15.0 (−16.76 to −13.24)	<0.019
6 mos	10.0 ± 2.0	21.0 ± 2.5	−11.0 (−12.17 to −7.83)	<0.011
12 mos	8.0 ± 3.2	20.0 ± 1.7	−12.0 (−13.5 to −11.5)	<0.021
24 mos	8.0 ± 2.2	20.0 ± 2.0	−12.0 (−13.32 to −10.68)	<0.041
36 mos	8.0 ± 1.7	22.0 ± 1.2	−14.0 (−14.91 to −13.09)	<0.01

* In the PV group there were 40 patients at baseline, 1 week, and 2 and 6 months; 38 at 12 and 24 months; and 37 at 36 months. In the OMT group there were 42 patients at baseline, 1 week, and 2 and 6 months; and 39 at 12, 24, and 36 months. See Fig. 1 for details.

placebo effect remained unclear, because these effects on pain reduction were larger than in previous studies in which both pharmacological and psychological interventions were used.[14,31]

Despite the quality of these trials,[1,16] they were weakened by serious limitations such as unclear patient selection criteria, high rates of pain-related complications, short follow-up periods, the high crossover rate in one of the trials, the unblinded nature of one of the trials, lack of permission for crossover in one of the trials, and use of opioid medications in more than half of the participants in both groups after the procedure. These limitations, in light of our positive findings, lead us to question the conclusion that PV was no more effective than the sham intervention or periosteal block.

At 1 week and at 2, 6, and 12 months after initiating treatment, pain relief was significantly better in patients treated with PV compared with those treated with OMT. Moreover, we found that PV had beneficial effects compared with OMT in patients with acute painful osteoporotic VCFs. Two and 3 years after the initiation of treatment, the differences were not significant. This result showed that PV was most effective in patients with acute, painful VCF.

Improvements in QOL were significantly greater in the PV group throughout the follow-up period. Earlier reports also found treatment with PV to be rapidly effective.[18,19,25] In addition, early mobilization was seen only in the PV group,[18] which also showed a significant improvement in daily activities, whereas patients in the OMT

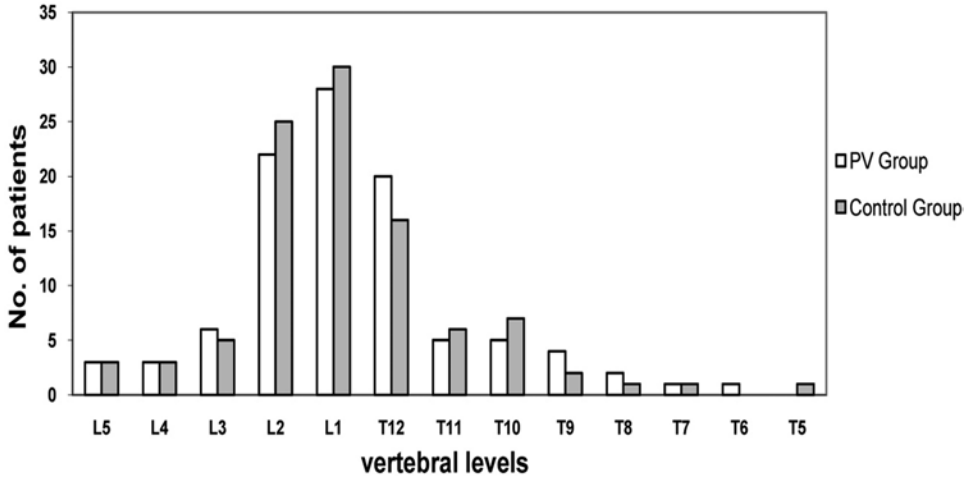

Fig. 2. Bar graph showing distribution of the vertebral fracture levels.

TABLE 3: Radiological outcome according to group in 82 patients treated for VCFs*

Measure	PV Group	OMT Group	Mean Difference, Treatment Effect (95% CI)	p Value
VBH (cm)				
baseline	2.8 ± 1.5	2.5 ± 1.3		
1 wk	3.2 ± 1.1	2.0 ± 1.0	1.2 (1.73–0.67)	<0.011
6 mos	3.2 ± 1.1	1.9 ± 1.4	1.3 (2.05–0.55)	<0.027
12 mos	3.2 ± 1.5	2.0 ± 1.2	1.2 (2.03–0.37)	<0.001
24 mos	3.0 ± 1.5	2.1 ± 1.2	0.9 (1.75–0.05)	<0.04
36 mos	3.0 ± 1.2	2.0 ± 1.0	2.0 (1.5–0.44)	<0.01
SI (°)				
baseline	20.0 ± 5.5	21.0 ± 4.2		
1 wk	10.0 ± 2.5	22.0 ± 2.2	−12.0 (−12.96 to −11.04)	<0.027
6 mos	10.1 ± 2.6	23.0 ± 2.1	−13.0 (−13.73 to −11.37)	<0.031
12 mos	10.0 ± 1.0	23.0 ± 2.0	−13.0 (−13.47 to −12.53)	<0.001
24 mos	9.0 ± 1.0	23.0 ± 2.3	−14.0 (−14.53 to −13.57)	<0.001
36 mos	8.9 ± 1.0	23.0 ± 2.0	−14.0 (−14.96 to −13.04)	<0.011

* In the PV group there were 40 patients at baseline, 1 week, and 6 months; 38 at 12 and 24 months; and 37 at 36 months. In the OMT group there were 42 patients at baseline, 1 week, and 6 months; and 39 at 12, 24, and 36 months. See Fig. 1 for details.

group had lower functional scores on the Oswestry LBP scale. We suggest that the acrylic cement made the spine more stable and led to pain relief and an improvement in daily activities.

Although the success of the PV technique has been reported in case series or personal experiences, RCTs are needed in evidence-based medicine as a standard tool for scientific research.[2,25] Our trial was designed to provide robust evidence of the effectiveness of PV versus OMT for acute osteoporotic VCFs. The present study is, to our knowledge, the first RCT in patients with painful osteoporotic VCF in which VBH and SI were evaluated after short- and long-term follow-up. Although the ability of PV to maintain VH restoration and correct sagittal deformity is questionable, the average VH restoration in our patients who underwent PV was 8 mm, and correction of the spinal deformity after PV was 8°. Similar results were reported by McKiernan et al.[21] (100% of the original VBH maintained), and Hiwatashi et al.[13] reported short-term and long-term increases in VBH. Our results were maintained during 36 months. Conservative treatment including rest in a supine position and the use of bracing will not prevent kyphotic curvature from increasing, and as Kayanja and colleagues[17] noted, "kyphosis begets kyphosis." Increasing kyphotic deformity during OMT was confirmed by our trial, and the difference between the groups in terms of kyphotic deformity after follow-up was statistically significant ($p < 0.01$). Although the primary indication for PV in VCFs is to control pain, the good results of PV in restoring VBH were comparable to the results obtainable with kyphoplasty. Recovery of VBH was also reported by Mathis.[20] Not only prone position[32] during PV but also high pressure within the VB produced by the injected cement can expand it and correct kyphotic deformity to some extent.

The incidence of paraspinal, intradiscal, and venous cement leakage after PV was reported as 40%–75% in earlier studies,[19,28] but only 14% of the vertebral levels treated in our patients had this complication. This figure is similar to the incidence in earlier reports.[19] The low rate of cement extravasation in our study may be explained by the use of a unilateral (parapedicular or unipedicular) approach in most cases and the vacuum phenomenon in some cases. Epidural leakage occurred in 1 patient (1%) for reasons that we were unable to determine. Epidural leakage may occur through posterior wall defects, the basivertebral foramina, or the anterior internal venous plexus.[28] The rates of this complication were reported as 1%–5% in different studies.

We found a lower percentage of new fractures than in other recent studies.[29,33] This may be explained by the use of the unilateral approach and the existence of the vacuum phenomenon in some patients, which both require a low volume of cement injection. Interestingly, we detect-

TABLE 4: Mean scores in 10 patients receiving OMT who requested crossover to PV 1 year after the study started

Outcome Measure at 1 Yr	OMT Group	After Crossover to PV	Mean Difference, OMT vs PV (95% CI)
no. of patients	39	10	
VAS for pain	4.1 ± 1.8	1.8 ± 2.0	2.3 (1.22–3.88)
Oswestry LBP score for QOL	20.0 ± 1.7	18.0 ± 2.0	2.0 (3.34–0.66)
VBH (cm)	2.0 ± 1.2	3.2 ± 1.4	−1.2 (−2.12 to −0.28)
SI (°)	23.0 ± 2.0	10.0 ± 0.8	13.0 (14.37–11.73)

ed more new bone fractures in the OMT group than in the PV group. According to a National Osteoporosis Foundation prevalence report,[22] the risk of additional fractures after the first osteoporotic VCF was 5-fold higher in the medical treatment group. Mathis[20] and Old and Calvert[24] showed that the weakened anterior portion of the fractured vertebra creates a kyphotic deformity, especially in the thoracolumbar region. The upright posture causes a constant compressive load on the anterior part of the VB, which can in turn lead to further compression fractures. These biomechanical and pathomorphological changes in the spinal column can thus cause a new VCF in patients given medical treatment only. We did not perform prophylactic vertebroplasty in the vertebral segment between the 2 collapsed vertebrae, although this strategy was used by Masala et al.[19] to prevent a new fracture. Chiang et al.[3] showed that prophylactic augmentation may be helpful to prevent adjacent vertebral failure.

Study Limitations

The Oswestry LBP scale was developed for English-speaking patients, and no Persian translation was available when we designed this study. Our Persian translation of this instrument may have retained some cultural or linguistic biases. Nevertheless, this problem is common to many studies that are conducted in nonnative English–speaking settings.

Conclusions

Compared with patients who received OMT, patients who received PV had statistically significant improvements in pain relief and QOL that were maintained for 2 years, sustained improvements in VBH and corrections in spine deformity after 3 years, and had fewer adjacent-level fractures.

Disclosure

The authors report no conflict of interest concerning the materials or methods used in this study or the findings specified in this paper. The vice-chancellor for research affairs of Shiraz University of Medical Sciences and Apadana Tajhizgostar Co. provided grant support, but they had no role in the design of the trial, the collection or analysis of data, preparation of the manuscript, or the decision to submit it for publication.

Author contributions to the study and manuscript preparation include the following. Conception and design: Farrokhi. Acquisition of data: Farrokhi, Maghami. Analysis and interpretation of data: Farrokhi, Maghami. Drafting the article: all authors. Critically revising the article: Farrokhi, Alibai. Reviewed final version of the manuscript and approved it for submission: all authors. Statistical analysis: Farrokhi, Maghami. Administrative/technical/material support: Farrokhi, Alibai. Study supervision: Farrokhi, Alibai.

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