

PERCUTANEOUS VERTEBROPLASTY VERSUS CONSERVATIVE TREATMENT AND REHABILITATION IN WOMEN WITH VERTEBRAL FRACTURES DUE TO OSTEOPOROSIS: A PROSPECTIVE COMPARATIVE STUDY

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Background: Percutaneous vertebroplasty is commonly used in the management of osteoporosis-related vertebral fractures, although there is controversy on its superiority over conservative treatment. Here we compare pain and function in women with vertebral osteoporotic fractures who underwent percutaneous vertebroplasty versus conservative treatment with a protocolized rehabilitation program. **Methods:** A longitudinal and comparative prospective study was conducted. Women ≥ 60 years of age with a diagnosis of osteoporosis who had at least one vertebral thoracic or lumbar compression fracture were included and divided into two groups, conservative treatment or vertebroplasty. The Visual Analogue Scale (VAS) and Oswestry Disability Index (ODI) were used to assess pain and function, respectively, as the outcome measures. **Results:** We included 31 patients, 13 (42%) treated with percutaneous vertebroplasty and 18 (58%) with conservative treatment. Baseline clinical characteristics, bone densitometry and fracture data were similar in both groups. At baseline, VAS was 73.1 ± 28.36 in the vertebroplasty group and 68.6 ± 36.1 mm in the conservative treatment group ($p = 0.632$); at three months it was 33.11 ± 10.1 vs. 42 ± 22.21 mm ($p = 0.111$); and at 12 months, 32.3 ± 11.21 vs. 36.1 ± 12.36 mm ($p = 0.821$). The ODI at baseline was 83% in the vertebroplasty group vs. 85% for conservative management ($p = 0.34$); at three months, 36 vs. 39% ($p = 0.36$); and at 12 months, 29.38 vs. 28.33% ($p = 0.66$). **Conclusions:** Treatment with percutaneous vertebroplasty had no advantages over conservative treatment for pain and function in this group of women ≥ 60 years of age with osteoporosis. (REV INVES CLIN. 2015;67:98-103) Corresponding author: María del Pilar Diez García, pdiez2002@yahoo.com.mx

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BACKGROUND

Vertebral body fractures associated with osteoporosis occur when compressive forces exceed the load capacity of osteoporotic vertebrae; this can be spontaneous or as a consequence of light trauma during daily activities¹. Each year in the USA 1.5 million fractures secondary to osteoporosis occur, with 700,000 of them being vertebral fractures². The lifetime risk of presenting a vertebral compression fracture is 16% for women (25% for post-menopausal women) and 5% for men³.

For Mexicans, according to the LAVOS study (Latin-American Vertebral Osteoporosis Study), the prevalence of osteoporosis in persons > 50 years of age is 9% in men and 17% in women. Data also show a prevalence of vertebral fractures similar to Caucasian and Asian Americans, but higher than African Americans^{4,5}.

There are different treatment options for fractures, including the use of calcitonin, spinal orthoses, relative rest, or exercise and physical rehabilitation. Over the past decade, minimally invasive procedures have been developed, with the main objective of alleviating pain and preventing vertebral collapse. One of these procedures is percutaneous vertebroplasty, which consists of injecting acrylic cement into the spongy portion of a partially collapsed vertebra⁶. This procedure has been widely used, although recent debate has emerged as to whether it should be recommended; because of complications, the procedure may not have more clinical benefits when compared with conservative management.

The objective of this study was to evaluate the pain and function in women with vertebral fractures caused by osteoporosis and treated with percutaneous vertebroplasty, compared with a group receiving conservative treatment under a rehabilitation program protocol.

METHODS

Study design and participants

A comparative, prospective, longitudinal study was conducted at the osteoporosis clinic of the National

Rehabilitation Institute (Instituto Nacional de Rehabilitación) in Mexico City. The study was approved by the Institutional Review Board. Women ≥ 60 years of age who presented with pain of acute or sub-acute onset underwent a series of studies to verify the diagnosis of a vertebral compression fracture. Studies consisted of a simple radiographic study with AP projection, a lateral of the dorso-lumbar spine (where height loss and vertebral wedging were assessed), and a sequence of magnetic resonance imaging (MRI).

The MRIs were interpreted by an expert radiologist who diagnosed vertebral fractures as those with vertebral collapse, an identifiable fracture line, or a geographical pattern with low signal in pondered T1 images or with a high intensity signal in T2. The STIR sequence, a technique designed to suppress signal from fat allowing for increased signal intensity, was used to distinguish between acute and sub-acute fractures.

All patients fulfilled the criteria for osteoporosis in accordance with the World Health Organization (WHO) classification guidelines. This was defined as a T-score of -2.5 SD in at least one segment of the lumbar spine in a DEXA test.

Once an acute or sub-acute vertebral compression fracture was diagnosed, patients were prescribed nonsteroidal anti-inflammatories, with tramadol for rescue analgesia, for 10 days (although patients could continue in case of pain), as well as intranasal calcitonin 200 IU daily during four weeks. A thoracolumbar brace with semi-rigid bars was indicated for six weeks, as well as relative rest and initiation of the rehabilitation program.

Rehabilitation program

The program consisted of 20 sessions of physical therapy, conducted Monday through Friday at the osteoporosis clinic. The program was standardized, with each hour-long session including the following:

1. Superficial thermotherapy for 15 minutes.
2. Analgesic electrotherapy with interferential currents at 100 Hz in crossed tetra polar mode at the dorsal or lumbar spine for 15 minutes.

3. Therapeutic ultrasound at the fracture region at a dose of 1 watt/cm² pulsed at 50%.
4. Stretching exercises of the postural lumbar fascia, according to patient tolerance.
5. Isometric contraction exercises to strengthen the dorso-lumbar extensor musculature (spine, abdomen, and gluteus extensors). Isotonic exercises for the scapular and pelvic muscles, according to patient tolerance.

In addition, patients were instructed to apply superficial heat and to perform the prescribed exercises at home; patients were provided with a written description of this program. At the end of a 20-session cycle, a new clinical evaluation was performed where physicians determined if the patient needed additional treatment sessions. Independently, patients continued with their exercises at home during the entire study period. Patients who did not attend at least 80% of their rehabilitation sessions were excluded.

Outcome measures

Data on pain, assessed by means of the Visual Analogue Scale (VAS), and function, assessed using the Oswestry Disability Index (ODI), were collected at baseline (Time 0), and at three, six, and 12 months. Patients in the conservative treatment group were evaluated after six weeks only regarding pain. All patients who remained with a pain intensity of > 50 mm in the VAS continued in the study; those presenting a decrease in pain intensity were excluded.

Percutaneous vertebroplasty

The patients with persistent pain (> 50 mm) were evaluated to see whether they fulfilled the criteria to undergo percutaneous vertebroplasty; those who did, continued, whereas those who did not were excluded. The criteria were: vertebral collapse of 15-50% of the height of the vertebral body, without affections of the posterior segments, and without signs of neurological compromise.

Patients who continued in the study (with persistent pain and who met the criteria for vertebroplasty) were informed on the procedure and the possible risks and benefits. Patients who accepted the procedure

signed an Informed Consent, were sent to the Spinal Surgery Unit and continued rehabilitation; those who refused the procedure continued with their conservative treatment plan. Thus, two groups were formed with the patients who consented to the study, one of vertebroplasty plus conservative treatment and one receiving conservative treatment.

Percutaneous vertebroplasty was performed by a group of attending physicians of the spinal surgery service. Methyl methacrylate material was used on the affected thoracic and lumbar segments. No complications were reported during the procedures and all were considered satisfactory.

In addition to the ODI and the VAS, other variables considered were age, number of fractured vertebrae, location of fractured vertebrae, presence of complications, and reintegration into daily home and/or work activities.

STATISTICAL ANALYSIS

Data were first analyzed using descriptive statistics. A chi-square test was used to contrast qualitative variables, and a Mann-Whitney *U* test was used for quantitative variables. Kruskal-Wallis test was used for repeated comparisons. All analyses were made on SPSS V. 20.0 (Chicago, IL).

RESULTS

A total of 42 women with acute or sub-acute vertebral fractures were screened for the study. Eleven were excluded due to failure to adhere to the initial treatment because they experienced an improvement in pain measurements, or because they did not fulfill the criteria for vertebroplasty. In all, 31 patients were included in the study and divided in two treatment groups. The mean age in the vertebroplasty group was 73 ± 8.42 years, and 72 ± 7.75 years in the group receiving conservative treatment ($p = 0.56$). The degree of vertebral compression was 40% in the vertebroplasty group and 43% in the conservative treatment group ($p = 0.32$). Patients who underwent vertebroplasty had similar characteristics to those with conservative treatment (Table 1). The median time between fracture and initiation of physical therapy was

Table 1. Characteristics of patients undergoing vertebroplasty compared with those on conservative treatment at baseline and 12-month follow-up

Characteristics	Treatment		p
	Vertebroplasty (n = 13)	Conservative (n = 18)	
	Frequency (%) or mean \pm SD		
Age	73 \pm 8.42	72 \pm 7.75	0.56
New vertebral fracture*	1 (7.69%)	0	0.232
Radicular compression*	1 (7.69%)	0	0.232
DLA reincorporation*	92.31%	83.33%	0.462
Work reintegration*	76.92%	83.33%	0.656
Antiresorptive therapy	9 (69.23%)	14 (77.78%)	0.865
Lumbar T-score	-3.52 \pm 0.75	-3.06 \pm 0.62	0.085
Hip T-score	-2.84 \pm 0.65	-2.56 \pm 0.64	0.198

DLA: daily life activities.

*At 12 months of follow-up.

Table 2. Pain assessment during follow-up using the Visual Analogue Scale (in mm)

Treatment group	Baseline	3 months	p*	6 months	p*	12 months	p*	Dif†
Vertebroplasty	73.1 \pm 28.36	33.11 \pm 10.1	0.01	31.22 \pm 11.1	0.84	32.3 \pm 11.21	0.86	40.8
Rehabilitation	68.6 \pm 36.1	42.0 \pm 22.21	0.03	33.45 \pm 12.11	0.1	36.1 \pm 12.36	0.23	32.5
p†	0.632	0.111		0.34		0.821		

*Intra-groups comparison (before-after)

†Comparison between groups

‡Baseline and 12-month differences.

60 days (30-86 days) in the vertebroplasty group and 74 days (42-90) in the control group ($p = 0.22$). The median time to vertebroplasty after referral for evaluation was 26 days (19-36).

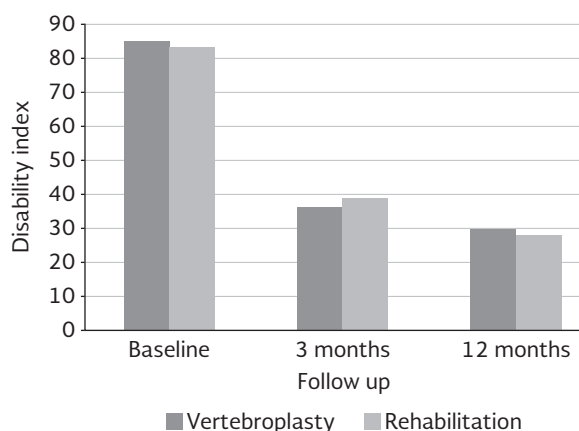
Percutaneous vertebroplasty was performed in 13 patients (42%) on 23 vertebrae, including 15 thoracic (T4 = 2, T5 = 1, T8 = 1, T9 = 2, T10 = 1, T11 = 4, T12 = 4) and eight lumbar (L1 = 3, L2 = 3, L3 = 2). The procedure was performed in one level in six patients, two levels in four patients, and three levels in three patients.

The conservative treatment group included 18 patients (58%) for a total of 34 vertebrae with compression fractures. Of these fractures, 22 were thoracic (T6 = 1, T7 = 1, T8 = 2, T9 = 2, T10 = 4, T11 = 2, T12 = 10) and 12 were lumbar (L1 = 9, L3 = 1, L4 = 1, L5 = 1). Treatment was performed in one level in six patients, two levels in eight patients, and three levels in four patients, without differences between groups ($p = 0.22$).

At the 12-month evaluation, no differences were found between groups regarding reintegration to daily domestic and work activities.

Results of the VAS evaluation are presented in table 2. At 12 months, 85% of the patients who underwent percutaneous vertebroplasty had a VAS of ≤ 40 mm, compared to 83% of those on conservative treatment ($p = 0.162$). There were differences between groups in the before/after evaluation at three months ($p < 0.05$), but not at the six- and 12-month assessments. Regarding the ODI, which classifies disability in percentages, the average at initiation of treatment was 83% disability for the vertebroplasty group and 85% for the conservative treatment group ($p = 0.34$); at three months it was 36% for vertebroplasty and 39% for conservative treatment ($p = 0.36$); and at 12 months it was 29.38 and 28.33%, respectively ($p = 0.66$) (Fig. 1). There was significant improvement in the intra-group evaluation at three months in both groups, which remained at month 12 ($p < 0.001$).

Figure 1. Comparative Oswestry Disability Index results at baseline, three, and 12 months



DISCUSSION

The use of percutaneous vertebroplasty has expanded for the management of osteoporosis-related vertebral fractures. In spite of its initial widespread acceptance and propagation, there has been controversy in recent studies regarding the advantages compared to conservative treatment or placebo⁷⁻¹⁰.

In this study, a significant reduction of pain was observed in both groups at three months. Afterwards, the pain remained without significant changes at months 6 and 12, without differences between groups. This demonstrates a positive effect of both methods on pain, especially at the beginning of therapy.

With respect to the ODI, a significant improvement was observed in all the intra-group evaluations, without differences between them. In other words, in spite of the lack of pain modification, patients improved their functionality over time. These results differ from other studies where they found differences in function immediately and at the first month post-intervention in favor of the vertebroplasty group¹¹.

It should be mentioned that the patients included in the study were those who continued with pain after the initial treatment period of six weeks, since the vertebroplasty was performed after this period

of rehabilitation. For this reason, patients who received only invasive treatment from the beginning were not eligible for evaluation, and this may be the subgroup of patients that benefitted the most from the procedure.

In the vertebroplasty group, one case of a new compression fracture and one of radiculopathy occurred in the last follow-up period. No such cases were found in the conservative treatment group; these complications are similar to what has been reported by other studies^{12,13}. Recent evidence demonstrates that vertebroplasty affects spinal biomechanics, increasing compression in adjacent segments and, therefore, increasing the incidence of new vertebral fractures¹⁴.

In 2011, a meta-analysis was published on the use of vertebroplasty and kyphoplasty, comparing them with placebo and standard treatment, and concluding that there was no advantage to using these procedures over conservative treatment¹⁵. However, in 2012, a systematic review comparing the effects of vertebroplasty, kyphoplasty, and conservative treatments found that the first two interventions showed advantages in regard to pain reduction and functionality when compared to the conservative treatment¹⁶. In the same year, a meta-analysis concluded that vertebroplasty significantly improved pain measurements and quality of life when compared to conservative treatment¹⁷. However, criticisms about this article were published in 2013, pointing out certain deficiencies¹⁸. It is clear that there is still controversy on the usefulness of this procedure¹⁹.

This study has shown that a conservative, standardized rehabilitation treatment program has the same therapeutic efficacy as vertebroplasty. This is different from other published articles that precisely detail established rehabilitation programs and call for protocolized programs.

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