

VERTEBROPLASTY VERSUS CONSERVATIVE TREATMENT IN ACUTE VERTEBRAL COMPRESSION FRACTURES: A PROSPECTIVE STUDY

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Received : 30/07/2024
Received in revised form : 20/09/2024
Accepted : 04/10/2024

Keywords:
Vertebroplasty, Conservative Treatment, Acute, Vertebral Compression Fractures.

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DOI: 10.47009/jamp.2024.6.5.72

Source of Support: Nil,
Conflict of Interest: None declared

Int J Acad Med Pharm
2024; 6 (5); 387-391



Abstract

Background: Spinal column vertebral compression fractures, or VCFs, are produced by an axial, compressive, and occasionally flexional strain that causes the bone to biomechanically fail and fracture. The study to compare the functional outcomes of Vertebroplasty and conservative therapy in acute osteoporotic vertebral compression fractures. **Materials and Methods:** This is a prospective study, carried out in the Department of Orthopaedics in B.L.D.E. (DEEMED TO BE UNIVERSITY) Shri B.M.Patil Medical College, Hospital and Research Centre, Vijayapura with the diagnosis of osteoporotic vertebral compression fracture and age 50years and older. The study period between 1 August 2022 - 31 January 2024. **Result:** The level of fracture was categorized into two regions, T10-T12 and L1-L5 .13(32.5%) of the patients overall suffered fractures in the T1-T12 area, but the majority27(67.5%) had fractures in the L1-L5 region. The majority of the participants, 38(95%) out of 40, had a single fracture. Only 2 participants (5%), had more than one fracture. The long-term efficacy of conservative therapy vs vertebroplasty was assessed by contrasting Visual Analogue Score (VAS) ratings at one, three, and six months following the intervention. At one month, the average VAS score for individuals undergoing vertebroplasty was 3, but the average score for those receiving conservative care was higher, at 5. At the three-month follow-up, patients who had vertebroplasty reported a VAS score of 0, which represents total symptom relief, continuing the pattern. The conservative management group, on the other hand, had an average VAS score of 4. The advantages of vertebroplasty persisted at the six-month point, as patients continued to have a VAS score of 0. Conversely, the average score for those managed conservatively was 3. **Conclusion:** Vertebroplasty is a safe and efficient treatment for individuals with acute osteoporotic spinal compression fractures. It improves functional results, reduces reliance on painkillers, and provides quick and long-lasting pain relief.

INTRODUCTION

By definition, VCFs endanger the spine's anterior column, putting the anterior longitudinal ligament (ALL) and the front half of the vertebral body (VB) at risk. The outcome is the characteristic wedge-shaped deformity.^[1-3]

Each year, between one to 1.5 million VCFs occur in the United States alone. Based on the age- and sex-adjusted incidence, it is projected that 25% of women 50 years and older have at least one VCF.^[4] Furthermore, it is suspected that between 40 and 50

percent of adults over the age of 80 have had a VCF, either acutely or incidentally, during a clinical workup for another condition.^[5] According to recent research, 60% to 75% of VCFs occur in the thoracolumbar junction, or the area between T12 and L2, with another 30% occurring in the L2 to L5 range.

In younger patients, vehicular accidents account for around 50% of spine fractures, while falls account for another 25%.

According to demographic surveys, the annual incidence of VCFs is 10.7 per 1000 women and 5.7 per 1000 males.

Osteoporosis is the leading cause of VCFs, making them the most prevalent kind of fragility fracture. Nonetheless, compression fractures have a bimodal distribution, with younger individuals incurring these injuries as a result of high energy processes (falling from a height, car accident, etc.).^[6-8]

Because of the anatomical and ligamentous abnormalities noted during the transition from the thoracic to the lumbar level, this area is prone to instability and is commonly the source of injury. As part of the first examination of spine fractures, the neurologic function of the arms, legs, bladder, and intestines is examined after the fracture is stable. Patience and organization are required for a complete exam. It should be emphasized that many high-energy compression fractures are associated with injuries to the limbs, brain, and abdomen, all of which require evaluation.

Individuals with suspected back injuries undergo anterior-posterior (AP) and lateral radiographs of the afflicted region as part of the assessment procedure. Until the spine team provides the all-clear or bracing is provided, they should be acquired in the trauma setting while supine and with spinal precautions. One advantage of wearing a brace is that standing radiographs can eventually be used to guide therapy, as sitting down can artificially minimize a displaced fracture.^[9-11]

The decision to have surgery can sometimes be contentious. For four to twelve weeks, conservative treatment is accomplished by the use of orthosis/bracing techniques. When the patient no longer feels pain at the fracture site and there is radiographic evidence of healing, the bracing may be removed.

Lower lumbar VCFs may necessitate a lumbosacral corset for adequate immobilization, whereas midthoracic and upper lumbar VCFs can be treated with a thoracolumbosacral orthosis. Bracing is not always safe and might be difficult for people with pulmonary impairment, obesity, or a barrel-chested appearance. It is vital to consider these things. Some individuals may not tolerate bracing or analgesic medications effectively. If bracing is inadequate or poorly tolerated, the clinician may use percutaneous techniques to stabilize the fracture. Surgery options are mostly determined by the type of the fracture and the level of brain injury. Compression fractures seldom need instrumented stabilization. For these people, cement augmentation—via vertebroplasty or kyphoplasty—is a common surgical option.

Vertebroplasty, a minimally invasive procedure in which cement is injected into the vertebral body via the pedicle, was initially developed for spinal hemangiomas. During the procedure, supine position with extension is employed to enhance spinal alignment; however, alignment restoration is not the goal of the vertebroplasty itself. During kyphoplasty surgery, the wedge-shaped vertebra is

first reduced by inflating a balloon to improve the residual local kyphotic alignment. Once the vertebral height has been restored, cement is injected.

Cement augmentation should be considered for persons who have not responded to a conservative treatment attempt or who are hospitalized as a consequence of pain and limited function due to a VCF.^[4]

The purpose is to compare the functional outcomes of Vertebroplasty and conservative therapy in acute osteoporotic vertebral compression fractures.

MATERIALS AND METHODS

This is a prospective study, carried out in the Department of Orthopaedics in B.L.D.E. (DEEMED TO BE UNIVERSITY) Shri B.M.Patil Medical College, Hospital and Research Centre, Vijayapura with the diagnosis of osteoporotic vertebral compression fracture and age 50 years and older. The patients will be informed about the study in all respects and informed written consent would be obtained. The study period between 1 August 2022 - 31 January 2024

Patients aged 40 or older with vertebral compression fractures on spine radiography. Patients were randomly assigned to percutaneous vertebroplasty or conservative therapy using computer-generated randomization codes with a block size of six. The scoring system for pain was obtained by using visual analogue scale/Graphic rating scale. The primary outcome was pain reduction at one, three, and six months.

Sample size calculation

The sample size calculation is done by using G*Power ver. 3.1.9.4 software, the VAS at 12 months for conservative therapy (Mean=3.92, SD=1.96) and vertebroplasty (Mean=2.21, SD=0.83) need a total sample size of 40 (for each group, 20 assuming equal group sizes). To attain a power of 93% for detecting a difference means (t tests - Means: Difference between two independent means (two groups)) at a 5% threshold of significance.

Follow-up assessment

The patients in the study were evaluated for pain using a Visual Analog Scale on the day of presentation as well as following therapy at one month, three months, and six months.

Statistical analysis

A Microsoft Excel document is created using the collected data. Conducted with the Statistical Package for the Social Sciences (SPSS) Version 20. Graphs, counts and percentages, mean, and standard deviation are used to display the findings. An independent sample t-test will be employed to examine the differences between the two groups in continuously distributed normally distributed data. For variables that are not normally distributed, the Mann-Whitney U test is employed. Because of The Fisher's exact test or the Chi-square test are used to

compare categorical variables between the two groups. If $P < 0.05$, then the statistical data is considered significant. Two tails were used for every statistical analysis.

RESULTS

This prospective study involves 40 participants. Comprehending the participant demographics is essential for analyzing the findings and deriving significant inferences from the information. In this study the baseline characteristics of study participants, which include age, gender, level of fracture and the total number of fracture are obtained. The sample consists of three age groups: 40-50 years, 50-60 years, and over 60 years. Each of the first two groups, 40-50 years and 50-60 years, includes 13 participants (13.5%), each. The group over 60 years consists of 14 (35%) participants of the total sample. The sex distribution of participants shows about 24 (60%) male and 16 (40%) of female. The level of fracture was categorized into two regions, T10-T12 and L1-L5. 13 (32.5%) of the

patients overall suffered fractures in the T1-T12 area, but the majority 27 (67.5%) had fractures in the L1-L5 region.

The majority of the participants, 38 (95%) out of 40, had a single fracture. Only 2 participants (5%), had more than one fracture.

The long-term efficacy of conservative therapy vs vertebroplasty was assessed by contrasting Visual Analogue Score (VAS) ratings at one, three, and six months following the intervention. At one month, the average VAS score for individuals undergoing vertebroplasty was 3, but the average score for those receiving conservative care was higher, at 5. At the three-month follow-up, patients who had vertebroplasty reported a VAS score of 0, which represents total symptom relief, continuing the pattern. The conservative management group, on the other hand, had an average VAS score of 4. The advantages of vertebroplasty persisted at the six-month point, as patients continued to have a VAS score of 0. Conversely, the average score for those managed conservatively was 3.

Table 1: Distribution of baseline characteristic of study participants (N=60)

Sno	Variable	Frequency	P value
1	Age 40-50 50-60 >60	13(32.5) 13(32.5) 14(35)	<0.05
2	Gender Male Female	24(60) 16(40)	<0.05
3	Level of fracture T10-T12 L1-L5	13(32.5) 27(67.5)	<0.05
4	Number of fracture 1 More than 1	38(95) 2(5)	<0.05

Table 2: VAS Scores Comparison Between Vertebroplasty and Conservative Management

Management	VAS SCORES		
	1 MONTH	3 MONTH	6 MONTH
Vertebroplasty 20 each	3	0	0
Conservative management 20 each	5	4	3

The higher efficacy of vertebroplasty in addressing pain and functional limitations resulting from spinal compression fractures is evident from these data, which show improvement over time. Since vertebroplasty consistently results in lower VAS ratings over a six-month period, it is clearly a very successful therapy that improves quality of life and expedites recovery when compared to conservative care.

DISCUSSION

Our research shows that, in comparison to conservative treatment, vertebroplasty resulted in quicker and more substantial pain relief for individuals with acute osteoporotic spinal compression fractures. After undergoing a vertebroplasty, patients reported significant pain

relief and required a lower dosage of painkillers than those who got conservative treatment or no medication at all. Over the course of the follow-up period, the discomfort was significantly reduced. When compared to vertebroplasty, conservative treatment produced delayed and less effective pain relief. Also, throughout the first month, there was a tendency for the requirement for pain treatment to increase.

The conservative treatment group's first month-long decline in VAS score can be linked to two factors: the psychological effects of regular, attentive care and the deliberate selection of the most effective pain treatments.

When compared to conservative care, the Kaplan-Meier survival curve showed that considerable pain relief was achieved earlier after vertebroplasty.

The way that painkillers were administered to patients in both groups was individualised, with daily modifications made to the kind and dose of medicine. This method implies that the improved pain relief after vertebroplasty, in contrast to conservative therapy, is due more to the procedure than to differences in medication.

However, several of the control group patients developed chronic back pain, possibly as a result of the fracture not healing. The goal of identifying these people may be the subject of more research. Regarding vertebroplasty, no noteworthy issues were noted. This result is in line with the results of other studies.^[12,13]

Although all of the patients had no symptoms, CT scans usually showed little cement leakage. New fractures after vertebroplasty and conservative treatment occurred at a rate that was equivalent over the follow-up period. The results of additional studies are in line with this discovery.^[14,15]

Our research compares vertebroplasty with conservative treatment in patients with acute osteoporotic vertebral compression fractures. It is a prospective study with a mid-term follow-up. According to the results of a thorough review of available research, vertebroplasty effectively reduced pain.

Nevertheless, the included retrospective follow-up studies lacked control groups for comparative analysis. Our results were in line with previously reported improvements in VAS ratings. A subset of patients with subacute spinal compression fractures were randomly randomized to undergo vertebroplasty as part of the VERTOS investigation. During the short-term monitoring period, these patients had improved mobility and immediate pain relief.^[16]

The experiment ended early because a large number of people switched between treatment groups, although the results were similar to our own. According to our research, only 10% of those assigned to conservative treatment changed to vertebroplasty.

In patients with osteoporotic vertebral compression fractures, two randomized studies reported the therapeutic benefits of vertebroplasty compared with a sham procedure.^[17,18]

Similar increases in pain and pain-related disability were seen in both groups. Two key differences separated our study from the sham-controlled trials. While subacute fractures up to a year old were included in the trials with a control group, our initial focus was on acute fractures. Moreover, an MRI's bone oedema was not always a criterion for inclusion, which is contrary to our findings. These differences might account for the somewhat higher average VAS score seen in the sham control trials compared to our findings and the 2008 meta-analysis's findings.¹³

Apparently, therapy started within a year of the onset of symptoms is less effective in relieving pain

than vertebroplasty done 1-2 weeks after the onset of symptoms.

As a result, the clinician was unsure of the best course of action because the sham-controlled trials lacked a control group that got no kind of intervention. By contrasting vertebroplasty with the conservative course of care, our study provided doctors with instantly useful guidance on the best course of action for their patients.

In a sample of 300 patients with acute spinal compression fractures, the study,^[15] compared kyphoplasty with non-surgical care. Using an inflated bone tamp to create a hollow within the vertebral body so that cement may be injected, kyphoplasty is not the same as vertebroplasty. Percutaneous vertebroplasty and this surgery are thought to be directly competitive.

The FREE trial's design was quite similar to ours, with the exception that kyphoplasty was used rather than vertebroplasty. In our investigation, kyphoplasty shown a similar beneficial effect on pain relief to vertebroplasty, leading to an immediate and long-lasting improvement. Moreover, the degree of pain alleviation was comparable among those who were treated conservatively. One advantage of vertebroplasty is that, unlike kyphoplasty, which requires general anesthesia and hospitalization, it may be done as an outpatient procedure with local anesthetic.^[19] Furthermore, kyphoplasty may incur up to 20 times the amount of procedure costs compared to vertebroplasty.^[20]

Our study was limited by its design, as we were unable to employ a double-blind treatment strategy. It is possible that patients' knowledge of the therapy assignment affected their responses to questionnaires or radiologists' judgments. In contrast to conservative therapy, the vertebroplasty planning process resulted in an average 9-day delay before treatment started. We suggest that it was unlikely that this slight variation in the natural course of events would have an impact on the outcomes at the one-, three-, and six-month points.

Overall, vertebroplasty has been shown to be safe and beneficial in a certain population of patients with acute osteoporotic vertebral fractures and persistent pain. Over six months has passed after the procedure when there is immediate pain relief.

CONCLUSION

In conclusion, vertebroplasty is a safe and efficient treatment for individuals with acute osteoporotic spinal compression fractures. It improves functional results, reduces reliance on painkillers, and provides quick and long-lasting pain relief. These results strengthen the usefulness of vertebroplasty as a treatment option for acute spinal compression fracture patients, improving their quality of life and patient care.

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