

ADDING EPIDURAL INJECTION TO VERTEBROPLASTY IMPROVES FUNCTION IN PATIENTS WITH VERTEBRAL COMPRESSION FRACTURE

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ABSTRACT

Objective: Pain may not resolve, and even new painful conditions may arise in a certain proportion of patients after vertebroplasty/kyphoplasty procedure performed for vertebral compression fractures. This study assessed the efficacy of targeting multiple pain generators, i.e., simultaneous use of vertebroplasty and epidural injections, in patients with vertebral compression fractures.

Materials and Methods: A total of 58 patients who underwent percutaneous vertebroplasty (PVP) at the lumbar level because of osteoporotic compression fracture of the lumbar vertebra were included in this retrospective study. The patients received PVP alone or PVP plus epidural injection. The two groups were compared in terms of pain severity using visual analog scale (VAS) as well as Oswestry disability index (ODI) scores during the 3-month follow-up period. Additionally, requirements for narcotic analgesics and additional interventions were compared.

Results: The two groups did not differ regarding the change in VAS scores over time ($p=0.201$). They differed regarding ODI scores, where the vertebroplasty plus epidural group had significantly lower ODI scores at 1 week (22.4 ± 3.6 vs. 17.2 ± 2.8), 1 month (21.1 ± 3.8 vs. 15.7 ± 2.4) and 3 months (22.9 ± 5.5 vs. 15.0 ± 2.7) ($p<0.001$ for all). Additionally, more patients in the vertebroplasty alone group required additional intervention (28.6% vs. 3.3% , $p=0.011$) and more were still requiring narcotics at three months (32.1% vs. 6.7% , $p=0.013$).

Conclusion: Interlaminar epidural injections combined with PVP appear superior to PVP alone in improving lumbar function and in reducing the need for additional narcotics and interventions after such procedures. Further studies are warranted to confirm these observations.

Keywords: Vertebroplasty, epidural injection, visual analogue scale (VAS), Oswestry disability index (ODI), vertebral compression fracture, narcotic need

INTRODUCTION

Vertebral compression fracture (VCF) is the most common type of fracture associated with osteoporosis and represents a major global health problem⁽¹⁾. Studies have reported prevalence rates between 18% and 28% among women aged 50 years or older⁽²⁾, while data from Europe have indicated a prevalence of 12% in males between 50 and 79 years of age⁽³⁾.

Bed rest, back brace, multimodal physical therapy and analgesics are the mainstay of treatment in patients diagnosed with symptomatic VCFs. Medical strategies targeting treatment and prevention of osteoporosis are also essential components of multidisciplinary management. Despite some controversy regarding the use of minimal invasive interventions such as vertebroplasty/kyphoplasty in selected patients, these methods are commonly used both to achieve stabilization of the spine and to alleviate pain⁽⁴⁾. Percutaneous vertebroplasty/kyphoplasty (PVP) is an interventional technique suitable for patients with severe pain unresponsive to conservative management

and is based on the injection of materials such as polymethyl methacrylate (PMMA) into the body of the compressed vertebra under radiological imaging guidance.

It has been well established that pain may not resolve, and even new painful conditions may occur in a certain proportion of patients undergoing vertebroplasty due to severe pain. Persistent or new back pain following vertebroplasty have been reported to occur in 5% to 22% of patients following vertebroplasty⁽⁵⁻¹⁰⁾. Pain associated with VCF or pain occurring after vertebroplasty may arise from pain eliciting factors other than the compression fracture of the body of the vertebra, and may also be associated with underlying or newly developing conditions resulting in chronic pain⁽⁹⁻¹¹⁾.

The importance of the central and peripheral nervous systems in the treatment of spine-related acute or chronic pain is well known. Clinical and experimental studies have clearly established the very critical role of dorsal root ganglions and other components of the epidural space in the generation, transmission, and modulation of pain^(9,10,12,13). Despite relatively

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limited evidence, epidural injections for blocking dorsal root ganglions have been effectively utilized not only for the treatment of VCF pain, but also for new or residual pain after vertebroplasty^(9,12,14).

Although epidural injections have been shown to be effective for the control of acute or chronic low back pain of spinal origin and for the recovery of functional capacity in affected patients, until now no studies have described simultaneous use of epidural injections and vertebroplasty for residual or newly emerging pain after the intervention. The multimodal mechanisms involved in VCF pain may be more amenable to a therapeutic strategy that targets multiple pain generators all at once.

This study was undertaken to assess the ability of the simultaneous use of vertebroplasty and epidural injections to prevent or alleviate pain that persist or occur after vertebroplasty and to assess functional pain-related outcomes, using visual analogue scale (VAS) and Oswestry disability index (ODI).

MATERIALS AND METHODS

Patients

A total of 58 patients undergoing PVP at lumbar levels (L1 to L5) due to osteoporotic compression fracture of the lumbar vertebra between 2015 and 2019 were included in this retrospective study. Indications for PVP were acute or subacute severe axial low back pain unresponsive to medical treatment and confirmed diagnosis of vertebral body compression fracture(s), as documented by radiological imaging. Failure of medical treatment was defined as minimal or no reduction of pain despite bed rest for 1 to 3 weeks and analgesics. Prior to the procedure, computed tomography or magnetic resonance images were assessed in each patient. Patients with a vertebral height loss exceeding 75% or those having significant stenosis (>25%) at the level of the fracture with radiculopathy findings and American Society of Anesthesiologists 3 or higher scores were excluded. Also excluded were patients with abnormal neurological examination findings, patients that underwent vertebroplasty outside of lumbar levels, and those requiring bilateral intervention after failure on one side during the procedure. Patients who had undergone vertebroplasty alone and those who had received additional epidural injections were included and compared in terms of VAS and ODI changes during the 3 months following the procedure.

Interventions

Percutaneous vertebroplasty only

The procedure was performed under conscious sedation with continuous monitoring of blood pressure, electrocardiography, and oxygen saturation. Patients were placed in face-down position on the surgical table. The skin covering the site of

intervention was cleansed with antiseptics and the pertinent vertebrae were identified fluoroscopically. Local anesthesia with spinal needle was administered to the skin and subcutaneous tissues, including the periosteum of the bone at the site of planned entry. In all patients, a unilateral intervention was performed after radiological determination of the safer side for transpedicular approach. A 10 or 2 o'clock position for the right/left peduncles, respectively, was used for entry to vertebra. Under anterior-posterior (AP)/lateral fluoroscopic guidance and via transpedicular approach, a 11-13 gauge (G) vertebroplasty cannula was advanced up to anterior third of the vertebral body to reach a safe location near the midline. For each vertebral body to be treated, a total of 2-3 mL of PMMA was injected. After AP/lateral fluoroscopic control, the procedure was terminated, and skin was closed with dressings.

Percutaneous vertebroplasty plus epidural injection

In patients undergoing PVP plus epidural injection, after completion of the vertebroplasty as described above, interlaminar epidural injection one level below the vertebral fracture was administered using the loss of resistance method under fluoroscopic guidance. A 16 G Tuohy epidural needle was placed into the epidural space, and a 16 G silicon catheter (B/Braun, Germany) was advanced 4 cm upwards into the epidural space through this needle. A radio-contrast solution consisting of 5 cc of iohexol (Omnipaque, Opakim, Turkey) + 5 cc of physiological saline was prepared and injected into the catheter to check accurate dispersal within the epidural space, followed by the administration of methylprednisolone (Depomedrol, Pfizer, Turkey) 40 mg + lidocaine (Aritmal, Osel, Turkey) 80 mg diluted with physiological saline to a total of 10 cc. The catheter and Tuohy needle was removed, and skin dressings were applied.

In both groups, patients were kept under medical observation for 6 to 8 hours and were discharged after wearing supportive corsets. A multi-modal physical therapy program including osteoporosis treatment and prevention was scheduled, starting 3 days after discharge.

Assessments

In all patients, pain severity was assessed before, and one week, one month, and three months after vertebroplasty using a VAS with a score range of 1 to 10. Also, ODI scoring tool was used to assess the low back function before the procedure as well as one week, one month, and three months after⁽¹⁵⁾. At the end of 3 months, patients who required narcotic analgesics were determined in both groups.

After the 3-month follow-up was completed, patients with a VAS score of >5 despite medical treatment and multimodal physical therapy underwent interventional injections following clinical and radiological examinations.

Ethical approval for the study was obtained from the Demiroğlu Bilim University Clinical Research Ethics Committee (date no: 23/06/2020, approval no: 44140529/9270).

Statistical Analysis

SPSS (Statistical Package for Social Sciences) version 21 software was used for data analysis. Hypothesis tests and graphical methods were used to test normality. Between-group comparisons of continuous variables were done using student t-test for independent samples or Mann-Whitney U test, depending on data distribution. Pearson chi-square test or Fisher's Exact test was used for the between-group comparison of categorical variables, where appropriate. Two-way ANOVA test for repeated measurements was used to examine the significance of changes and differences between groups in ODI and VAS scores over time. Between-subject comparisons were done using student t-test or Mann-Whitney U test, where appropriate. Two-sided p values <0.05 were considered indication of statistical significance.

RESULTS

Table 1 shows the comparison of the patient characteristics of the two study groups. Groups did not differ regarding demographical characteristics, multiple versus single procedure level, previous history of low back pain before the development of VCF, additional magnetic resonance imaging findings, baseline VAS or ODI scores, and osteoporotic medications following the procedure (p>0.05 for all). Table 2 shows the distribution of vertebroplasty levels. Residual post-procedure pain was of axial nature in all patients, but five patients (8.6%) had radicular pain in addition to axial pain.

Changes in VAS Scores Over Time

Figure 1 shows changes in VAS scores over a 3-month period. A significant change in VAS scores was evident over time

(p<0.001). However, the two groups did not differ regarding the change in VAS scores (p=0.201).

Changes in ODI Scores Over Time

Figure 2 shows changes in ODI scores over a 3-month period. A significant change in ODI scores was evident over time (p<0.001) and the two groups differed regarding the change in ODI scores (p<0.001). At baseline, the two groups had similar ODI scores (p>0.05, Table 1). However, vertebroplasty plus epidural group had significantly lower ODI scores compared to the vertebroplasty alone group at 1 week (22.4±3.6 vs. 17.2±2.8), 1 month (21.1±3.8 vs. 15.7±2.4) and 3 months (22.9±5.5 vs. 15.0±2.7) (p<0.001 for all comparisons).

Comparison of Patients with and without Previous History of Back Pain

At baseline, patients with previous history of back pain had higher VAS (8.6±0.8 vs. 7.9±1.2, p=0.032) and ODI scores (38.3±3.2 vs. 35.7±4.5, p=0.030), when compared to the patients without such history. In addition, the two groups differed regarding the course of VAS (p=0.010) and ODI scores (p=0.038) over time. Regarding VAS scores, the two groups differed at baseline (p=0.032), 1 month (p=0.005), and 3 months (p=0.011), with worse scores in patients with previous history of pain; nevertheless, both groups exhibited improvements during the study period. On the other hand, the two groups differed only at baseline regarding ODI scores. Figures 3 and 4 show the VAS and ODI changes in the two groups.

Other Outcome Measures

During a 3-month period, more patients in the vertebroplasty alone group required additional intervention (epidural, sacroiliac, facet or trigger point injection, or a combination) when

Table 1. Patient characteristics

Characteristic	All patients (n=58)	Vertebroplasty alone (n=28)	Vertebroplasty plus epidural (n=30)	p
Age, y	60.6±6.6	60.1±6.6	61.0±6.7	0.611
Female gender, n (%)	34 (58.6%)	16 (57.1%)	18 (60.0%)	0.825
Body mass index, kg/m ²	25.9±2.9	26.0±3.1	25.8±2.7	0.805
Multiple level, n (%)	11 (19.0%)	6 (21.4%)	5 (16.7%)	0.644
Previous history of low back pain*	19 (32.8%)	9 (32.1%)	10 (33.3%)	1.000
Additional MRI findings [†]				
Degenerative changes	53 (91.4%)	26 (92.9%)	27 (90.0%)	0.533
Spinal stenosis	5 (8.6%)	3 (10.7%)	2 (6.7%)	0.467
Spondylolisthesis	4 (6.9%)	2 (7.1%)	2 (6.7%)	0.667
Baseline VAS score	8.1±1.1	8.4±0.9	7.9±1.2	0.136
Baseline ODI score	36.5±4.3	36.8±4.1	36.3±4.4	0.668
Osteoporotic medications following procedure				
Vitamin D plus calcium	51 (87.9%)	25 (89.3%)	26 (86.7%)	0.540
Anabolic agent (parathyroid hormone)	24 (41.4%)	12 (42.9%)	12 (40.0%)	0.825
Antiresorptive agent (denosumab)	15 (25.9%)	7 (25.0%)	8 (26.7%)	0.885

*History of back pain before the development of vertebral compression fracture. [†]MRI findings other than vertebral fracture. Unless otherwise stated, data presented as mean ± standard deviation. VAS: Visual analogue scale, ODI: Oswestry disability index, MRI: Magnetic resonance imaging

compared to the vertebroplasty plus epidural group (28.6% vs. 3.3%, $p=0.011$). In addition, more patients in the vertebroplasty alone group were still requiring narcotic prescription after 3 months (32.1% vs. 6.7%, $p=0.013$).

DISCUSSION

The results of this study show that combined use of PVP and epidural injections in patients with VCFs was associated with significant improvements in low back functions, as documented by the changes in ODI scores, in addition to reducing the need for narcotic analgesics as well as the need for additional interventions for new or residual pain after vertebroplasty. To the best of our knowledge, the efficacy of the combined use of PVP and epidural injection in terms of pain control has not been tested in patients with symptomatic osteoporotic VCF. Persistent or new occurrence of pain after PVP is not uncommon⁽⁵⁻¹⁰⁾. Two approaches regarding the origin of the pain due to symptomatic VCF should be considered collectively.

One of these relates to the fact that the aging spine harbors multiple possible pain generators, and the other relates to the concept of chronic pain, which is an important consideration in current therapeutic strategies⁽⁹⁻¹¹⁾.

While most systematic reviews and placebo/sham controlled studies do not suggest a clinically significant benefit for vertebroplasty, studies comparing vertebroplasty (PVP) with conservative treatments generally indicate superiority of vertebroplasty for reduction in pain and disability⁽¹⁶⁻¹⁸⁾. A conclusion that can be drawn from this controversy is that the body of the vertebra with the compression fracture may not always represent the sole source of pain, and that more successful results can be obtained with multi-modal therapeutic strategies targeting other pain generators as well. The leading hypotheses regarding the mechanisms of pain reduction by vertebroplasty include decreased micro-mobility in the fracture, neurolysis effect within the vertebral body resulting from the heat generated by the cement material (PMMA), and restoration of the impaired biomechanics^(19,20).

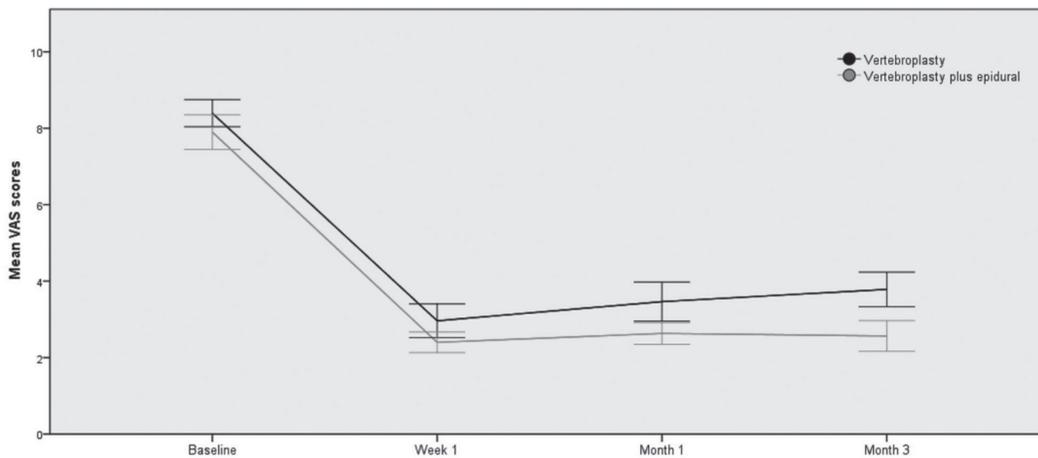


Figure 1. Changes in mean visual analogue scale (VAS) scores over time in vertebroplasty alone versus vertebroplasty plus epidural group. Error bars indicate 95% confidence intervals

Table 2. Distribution of vertebroplasty levels

Characteristic	All patients (n=58)	Vertebroplasty alone (n=28)	Vertebroplasty plus epidural (n=30)
Single level			
L1	13 (22.4%)	6 (21.4%)	7 (23.3%)
L2	12 (20.7%)	5 (17.9%)	7 (23.3%)
L3	12 (20.7%)	6 (21.4%)	6 (20.0%)
L4	8 (13.8%)	5 (17.9%)	3 (10.0%)
L5	2 (3.4%)	0 (0.0%)	2 (6.7%)
Multiple level			
L1 + L2	5 (8.6%)	3 (10.7%)	2 (6.7%)
L2 + L3	1 (1.7%)	0 (0.0%)	1 (3.3%)
L3 + L4	4 (6.9%)	2 (7.1%)	2 (6.7%)
L4 + L5	1 (1.7%)	1 (3.6%)	0 (0.0%)

Data presented as n (%)

In a study by Kamalian et al.⁽¹⁰⁾, where 23% of the patients experienced low back pain after PVP, it was concluded that the pain was generally not related with a failed procedure, and

it was rather associated with the sacroiliac or facet joints, as shown by the therapeutic test injections. Other documented causes of pain persisting after PVP include costal fractures,

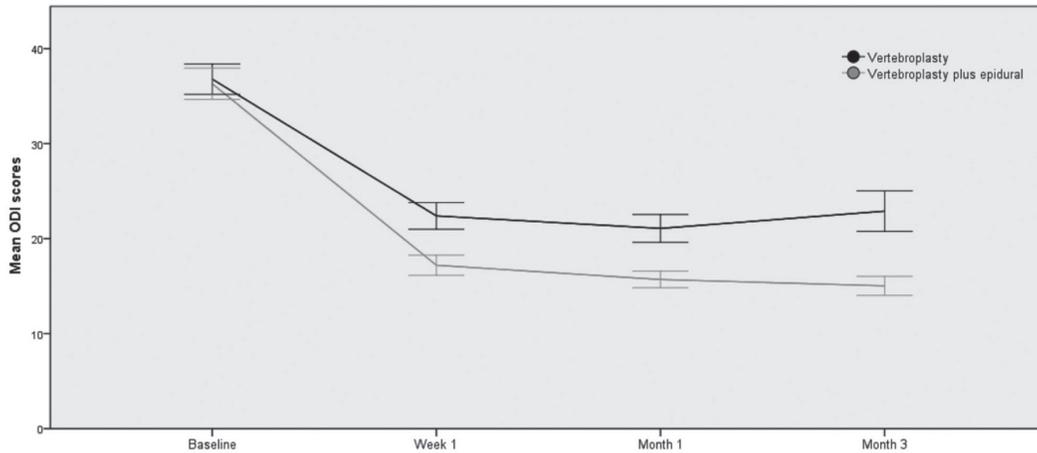


Figure 2. Changes in Oswestry disability index (ODI) scores over time in vertebroplasty alone versus vertebroplasty plus epidural group. Error bars indicate 95% confidence intervals

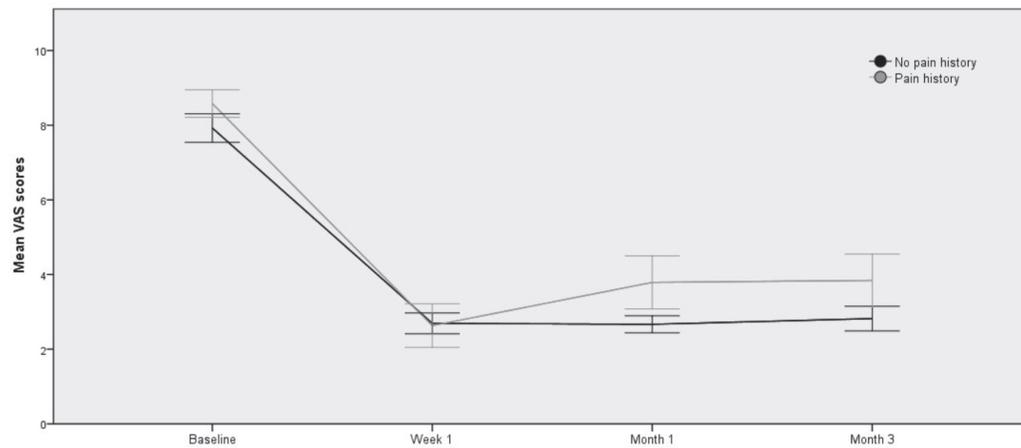


Figure 3. Changes in mean visual analogue scale (VAS) over time in patients with and without previous history of low back pain. Error bars indicate 95% confidence intervals

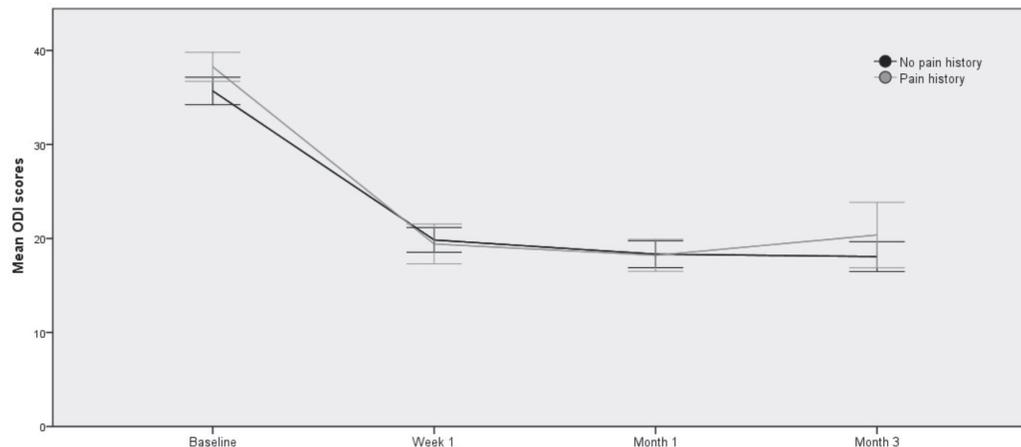


Figure 4. Changes in Oswestry disability index (ODI) scores over time in patients with and without previous history of low back pain. Error bars indicate 95% confidence intervals

compression of spinal cord and radicular nerves by cement leakage, spondylitis, non-healing bone-cement interface, and newly occurring VCFs, as well as thoracolumbar fascia injury during PVP, as suggested by some studies^(21,22).

In another study involving 144 patients who underwent PVP, Georgy⁽⁹⁾ reported improvement of residual pain in 26 of the 34 patients with epidural injection, while the remaining subjects received interventional pain treatment such as intercostal block, and sacroiliac, facet joint, and trigger point injections. It has also been reported that epidural injection targeting dorsal root ganglia may also provide an effective monotherapy for pain associated with VCFs^(12,14). Other published systematic reviews also suggested that pain due to VCFs may be associated with the posterior elements, and that successful results can be obtained using facet joint injections and medial branch radiofrequency ablation⁽¹⁹⁾.

Multimodal therapeutic strategies have a well-established role in pain management. In the current study, patients receiving epidural injections together with PVP had significant improvement in ODI scores, while no significant differences could be observed in terms of the improvement in VAS. We believe that supplemental use of narcotics for pain management might have contributed to this result. Likewise, smaller proportion of patients undergoing PVP plus epidural injection was on narcotic prescription at the end of follow-up. This latter observation may be particularly valuable since it may avoid side effects of narcotics. Furthermore, the number of patients requiring additional procedures due to uncontrolled pain with medical treatment was lower in subjects who received PVP and epidural injections together.

Osteoporosis and degenerative changes comprise two fundamental and independent processes in spinal aging. Pain and immobilization due to symptomatic osteoporotic compression fractures may lead to impaired stability of the spine, potentially initiating a downward vicious cycle with further pain, immobility, and vertebral fractures⁽²³⁾. In addition to age-related degeneration and structural pathologies, many other factors including occupational⁽²⁴⁾, lifestyle-related^(25,26) and psychological factors may contribute to the development of chronic low back pain. Pain lasting more than three or six months is considered chronic. Since pain leads to further immobility and confinement, it is critically important to restore the spinal functions and to control the pain as soon as possible, in order to reduce morbidity and mortality.

It has been reported that chronic low back pain develops in nearly one fourth of all patients with VCFs, regardless of treatment with conservative measures or PVP⁽¹¹⁾. Generally, the disc degeneration in the aging spine is considered the origin of low back pain. Primary pain is thought to occur due to sensitization of the nociceptive nerve fibers within the disc by cytokines and neuropeptides released as a result of degeneration⁽²⁷⁾. However, other sources of nociception within a spinal unit, i.e. muscles, ligaments, and facets, should not be

disregarded. Interconnected nociception arising from different tissues complicates the process of accurately identifying the actual source of pain. In addition, it should be borne in mind that pain is not only due to nociception, and hypersensitivity mechanisms involving both the process of pain transmission at the peripheral level and also at the central nervous system play a role in the development of chronic low back pain⁽²⁸⁾. In some recent reviews, the level of evidence reported for the efficacy of epidural injections was rated between I and III when this treatment modality was used in a number of clinical conditions including acute or chronic pain of spinal origin, particularly disc herniation, axial or discogenic pain, central spinal stenosis, and failed back surgery syndrome⁽²⁹⁾.

We believe that the results of our study hold some promise for the treatment of new or residual pain after PVP as well as for prevention of chronicity of such pain. Treatment of osteoporotic vertebral fractures, which generally occur in the elderly population, is rather challenging due to common occurrence of secondary comorbid conditions. We recommend concomitant use of epidural injections with PVP to achieve more rapid and effective symptomatic relief, as these injections represent a practical, cost-effective, and safe therapeutic modality, even in high-risk patients.

Study Limitations

Due to the retrospective nature of this study, it could not be designed as randomized. Even if indicating insignificance differences for demographics, clinical and radiological findings in the treatment groups potentiate the study, designing a prospective study with more number of patients would be more convenient.

CONCLUSION

Interlaminar epidural injections combined with PVP appear to be superior to PVP alone in improving lumbar functions and in reducing the need for additional narcotics and interventions after such procedures. Further studies with larger sample size are warranted to confirm these observations.

Ethics

Ethics Committee Approval: Ethical approval for the study was obtained from the Demiroğlu Bilim University Clinical Research Ethics Committee (date no: 23.06.2020, approval no: 44140529/9270).

Informed Consent: Retrospective study.

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Authorship Contributions

Surgical and Medical Practices: S.Ç., M.O.A., O.Ö., Concept: S.Ç., M.O.A., O.Ö., Design: S.Ç., M.O.A., Data Collection or Processing: S.Ç., M.O.A., Analysis or Interpretation: S.Ç., M.O.A., O.Ö., Literature Search: S.Ç., M.O.A., O.Ö., Writing: S.Ç., M.O.A., O.Ö.

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