

The effect of epidural injection of triamcinolone and bupivacaine on pain and functional disability in patients with lumbar spinal stenosis, A quasi-experimental study

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Background: Lumbar spinal canal stenosis is an important contributor to pain and functional disability. This study aimed to investigate the effect of epidural injection of triamcinolone combined with bupivacaine on pain intensity and functional disability in patients with lumbar spinal stenosis.

Materials and Methods: In this quasi-experimental study, 100 patients with symptoms of lumbar spinal stenosis were randomly selected and enrolled. The interlaminar epidural injection consisted of 8 cc of a bupivacaine solution, with the addition of 2 cc (80 mg) of triamcinolone, resulting in a total injectate volume of 10 cc administered into the epidural space. Variables were assessed before injection and one month thereafter. The primary outcome was pain intensity, while secondary outcomes included functional disability stratified by sex and age. A p -value of < 0.05 was considered statistically significant.

Results: The mean pain intensity and functional disability one month after injection in all patients were decreased and were statistically significant ($p < 0.001$). The mean pain intensity decreased in men and women after injection inter groups ($p < 0.001$) but didn't reach a significant level between groups (mean difference = 1.43 ± 0.52 , $p = 0.59$). The mean functional disability decreased in men and women after injection in per group ($p < 0.001$) but mean difference between them didn't reach a significant level (mean difference = 2.11 ± 1.50 , $p = 0.95$). Although the mean reduction in pain intensity and functional disability was more in younger people, there was no significant difference between the different ages and sexes.

Conclusion: Epidural injection of a triamcinolone and bupivacaine solution appears to be a safe and effective intervention for reducing pain intensity and functional disability in patients with lumbar spinal canal stenosis.

Keywords: Epidural injection, triamcinolone, bupivacaine, pain, disability, spinal stenosis

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Introduction

Lumbar spinal canal stenosis (LSCS) is defined as the narrowing of the spinal canal space secondary to

disc herniation, disc extrusion and protrusion, and disc bulging associated with osteophytes and degenerative



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changes in the facet joints, which causes compression and entrapment of nerve roots and vessels in the area. This stenosis occurs most frequently in the lower lumbar vertebrae (1).

LSCS is an important factor in causing functional disability in people and is one of the most important reasons for lumbar spine surgery in people over the age of 60. LSCS manifests itself with symptoms such as pain in the gluteal region and lower extremities, with or without neurogenic claudication, sensory impairment, and gait disturbance, and in more advanced stages, drop foot, and urinary incontinency. Symptoms in these patients may be related to neurovascular mechanisms such as impaired arterial blood flow in the cauda equina, venous congestion, increased epidural pressure, nerve root irritation by local inflammation, or direct pressure in the central canal (2).

Gait impairment may lead to increased unilateral or bilateral lower extremity pain and functional disability. Pain and mobility limitations in these patients significantly reduce quality of life and functional disability. These limitations have negative physical, psychological, and financial impacts on the patient and on the health care system (3).

Common treatments for these patients include NSAIDs, lifestyle changes, physiotherapy, and epidural steroid injections, and ultimately surgery (4,5).

Surgical treatment is the most common intervention for relieving nerve root entrapment in these patients (2). If conservative treatments are not effective for these patients, the most common intervention for pain control in these patients is epidural injection. Epidural injection reduces pain and improves function by reducing inflammation and removing inflammatory pressure on the nerve roots (6).

Given the desire to use minimally invasive treatments in health care, epidural steroid injection is used as a minimally invasive, safer, and cheaper treatment method (5). Of course, epidural injections are also associated with some complications. These complications include intravascular injection, CSF leak, headache, and arachnoiditis. These complications are preventable and can be controlled with careful monitoring (5, 6).

Several studies have been conducted on the effect of steroid injections along with other analgesics in reducing symptoms and their impact on pain, quality of life, and functional disability in patients with LSCS, but the results of the studies have been different and contradictory, and have not reported similar results. As the results of some studies show that epidural steroid injections, along with other drugs, have reduced pain, reduced functional disability, and improved quality of life in these patients (6-9).

However, some studies have also reported that the effect of epidural injection on pain and functional disability is low or ineffective (10, 11).

Given the different and contradictory results of studies conducted on the effects of epidural injections on pain and functional disability, as well as the few studies that have been published on the effects of triamcinolone and bupivacaine injections in patients with spinal stenosis, this study aimed to investigate the effect of epidural injections of triamcinolone and bupivacaine on pain and functional disability in patients with lumbar spinal stenosis. Changes in pain intensity were the primary outcome, and changes in functional disability and age and gender were secondary outcomes.

Materials and methods

With a quasi-experimental study from between available samples aged 20 to 80 years with symptoms of lumbar spinal stenosis were randomly selected and entered the study. With a confidence level of 95%, power of 80%, and a sigma assumption of 25% to reduce the questionnaire score by 7%, 100 patients were selected. The study was done in Beheshti Research Hospital in Babol university of medical science in Iran. Inclusion criteria included a definitive diagnosis of spinal stenosis through MRI findings, including hypertrophy of the fascia, hypertrophy of the ligamentum flavum, reduction in spinal cord diameter at the same level or below to less than 9 to 10 millimeter, and partial to complete blockage of cerebrospinal fluid in myelogram, and age over 20 years. Exclusion criteria included patients with perforated disc, diabetes, wound or infection of the injection site, defect in the cauda

equina, and coagulation disorders, previous surgeries, and traumatic injuries to the lumbar vertebrae (12).

The study procedures were fully explained to the patients, and patients entered the study by filling out an informed consent form. For gathering of information face-to-face interview, file reviews and physical exams were done. The visual analogue scale (VAS) was used to measure pain intensity (13), and the Persian version of modified Oswestry questionnaire, which had high validity (Cronbach's α coefficient was 0.69) and reliability (ICC=0.43-0.8), was used to assess functional disability. This questionnaire has 10 sections, each of which has a maximum of 5 points, and the maximum score is 50. After calculating the points obtained for the patient, it is divided by 50 and multiplied by 100 to determine the percentage of functional disability of each patient. This questionnaire values functional disability between zero and one hundred (14).

After measuring the pain intensity and completing the functional disability questionnaire, patients were epidural injected with bupivacaine solution and triamcinolone. Then, the pain intensity and functional disability level of the patients were measured one month after the injection by filling out the functional disability questionnaire. To examine the effect of epidural injection on the functional disability of the patients, the difference in the score obtained before and after injection was calculated and multiplied a number by 100 percent. If this difference was between 0 and 20% (slight disability), between 21 and 40% (moderate disability), between 41 and 60% (severe disability), between 61 and 80% (paralysis), and between 80 and 100% (absolute and paralyzed patients) was considered (15).

Ethical approval

The study was approved by the Ethics Committee of Babol University of Medical Sciences with the ethics code MUBABOL.REC.1399.300.

Epidural injection technique

The interlaminar injection steps were performed in the operating room. The patient was placed on the operating room bed in a sitting position. The patient was under cardiac monitoring and blood pressure control. First, the area was anesthetized with 2cc of a

2% lidocaine solution, and then the interlaminar injection was performed with an epidural set. A neurosurgeon and anesthesiologist conducted all procedures using fluoroscopic guidance. The injected drug solution consisted of 8 cc of a 2500 mg solution of bupivacaine and the addition of two cc (80 mg) of triamcinolone to the solution, which in total of 10 cc of this mixture was injected slowly and gradually into the epidural space.

Data Analysis

Mean and standard deviation were used to analyse demographic data. A paired *t*-test was employed to compare the results of the intervention before and after the injection. Student's *t*-test and one-way analysis of variance (ANOVA) were used to analyse the results. A *p*-value of less than 0.05 was considered statistically significant. Statistical analysis and plotting were performed using SPSS version 25 software.

Results

In this cross-sectional study, 100 patients who met the inclusion criteria completed all stages of the study. The mean age of the patients was 49.53 ± 10.59 years. Of the participants, 39 (39%) were male and 61 (61%) were female. As shown in **Table 1**, the mean pain intensity in all patients before injection was 73.80 ± 19.00 mm, which decreased to 44.8 ± 25.6 mm after injection.

The results demonstrated a significant reduction in mean pain intensity following injection ($p < 0.001$). The mean functional disability in all patients before injection was $44.34 \pm 13.29\%$ (severe disability), which decreased to $25.5 \pm 12.07\%$ (moderate disability) after injection. The paired *t*-test showed that the mean functional disability significantly decreased after injection ($p < 0.001$).

Table 1. Mean pain intensity and functional disability before and after injection in all patients

		before	after	P*
Pain intensity (mm)		73.80±	44.80±2	<0.001
		19.00	5.60	
Functional disability (%)		44.34±	25.50±1	<0.001
		13.29	2.07	

*Paired t-test

In examining the effects of epidural injection of triamcinolone and bupivacaine on mean pain intensity and functional disability in men and women, **Table 2** shows that mean pain intensity decreased significantly after injection in both male and female patients compared with baseline ($p < 0.001$). Although the mean reduction in pain intensity was greater in women than

in men, this difference did not reach statistical significance ($p = 0.59$). Mean functional disability also decreased significantly after epidural injection in both women and men ($p < 0.001$). The results further indicated that the difference in the mean reduction in functional disability between the two groups was not statistically significant ($p = 0.95$).

Table 2. Mean pain intensity and functional disability before and after injection in males and females

Variables	(M±SD) female	(M±SD) male	P*
Functional disability (before-%)	45.02±13.94	43.28±12.30	0.52
Functional disability(after-%)	25.44±11.83	25.59±12.60	0.95
p**	<0.001	<0.001	
Pain intensity (before- mm)	72.13±21.68	76.44±13.66	0.44
Pain intensity (after- mm)	42.95±24.99	47.69±26.60	0.59
p**	<0.001	<0.001	

Independent t-test* Paired t-test **

To investigate the effect of epidural injection on pain intensity and functional disability across different age groups, patients were divided into three groups: younger than 40 years, 41–60 years, and older than 61 years. The highest mean pain intensity and functional disability were observed in patients older than 61 years. The results showed that, after injection, the mean pain intensity within each age group decreased compared

with before injection, and this reduction reached a statistically significant level ($p < 0.001$). According to **Table 3**, although one-way analysis of variance (ANOVA) demonstrated no statistically significant difference between the mean functional disability across the different age groups ($p = 0.11$), the greatest reduction in mean functional disability was observed in patients younger than 40 years.

Table 3. Mean pain intensity and functional disability before and after injection in different age groups

	>61y	41-61 y	<40y	P*
Pain intensity (before-mm)	84.00±13.52	70.00±17.27	78.95±24.47	0.12
Pain intensity (after-mm)	54.67±25.59	40.00±21.34	43.83±34.60	0.11
p**	<0.001	<0.001	<0.001	
Functional disability (before-%)	49.20±14.69	43.30±11.33	44.11±17.77	0.3
Functional disability (after-%)	31.47±18.21	23.9±8.07	26.11±16.44	0.1
p**	<0.001	<0.001	<0.001	

*One way ANOVA **Paired t- test

The results showed that the greatest mean difference in pain intensity, as well as the greatest mean reduction in functional disability before and after injection, occurred in both men and women younger than 40 years of age (**Table 4**), which may be attributable to the younger age of the patients. In the male group, although the mean differences in pain

intensity and functional disability before and after injection reached a statistically significant level within each age group ($p < 0.001$), one-way analysis of variance demonstrated that these mean differences did not differ significantly across the age groups ($p = 0.31$).

In the female group, the greatest mean difference in pain intensity before and after injection was observed

in patients younger than 40 years, and the greatest reduction in mean functional disability was also seen in this age group.

One-way ANOVA showed that the differences in mean pain intensity ($p = 0.22$) and in the reduction of

functional disability across different age groups in both women and men did not reach statistical significance ($p = 0.27$).

Overall, the findings suggest that younger patients may be more responsive to epidural injections.

Table 4. Mean difference in functional disability and pain intensity before and after injection in two groups of women and men of different ages

	>60y	40-60y	<40y	P*
Functional disability (male-%)	25.50±8.85	26.58±8.04	30.73±19.76	0.31
Functional disability (female-%)	21.36±12.8	24.19±8.17	24.75±7.59	0.27
P**	<0.02	0.24	<0.01	
Pain intensity (male-mm)	26.25±24.26	26.11±12.34	10.23±31.12	0.16
Pain intensity (female-mm)	22.12±8.26	23.37±11.15	27.16±9.25	0.22
P**	<0.02	<0.03	<0.01	

*One way ANOVA **Paired t- test

Discussion

The results of the present study showed that epidural injection of a combination of triamcinolone and bupivacaine is effective in reducing pain intensity and functional disability in patients with lumbar spinal canal stenosis. The effects of epidural injection were not significantly different between men and women, although the pain reduction rate was greater in women than in men. The results showed that the mean difference in functional disability before and after injection were greater in women, but there was no significant difference between the two sexes. Our study showed that although reduction in functional disability was greater in younger groups (<40y), there was no significant difference among all age groups.

The results of a meta-analysis study conducted by Liu et al. showed that epidural steroid injections have very effective short and long-term effects in reducing pain in patients with lumbar spinal stenosis (10). The results of the meta-analysis conducted regarding the effectiveness of steroid drugs in epidural injections are consistent with the present study, which used steroid drugs.

Studies conducted on the type of steroid drugs for epidural injection to affect patients' pain show that researchers used a variety of drugs for injection. A study by Hashemi et al. of the combination of Dexmedetomidine, Triamcinolone, and Bupivacaine

compared to Triamcinolone and Bupivacaine on the severity of patients' pain showed that the addition of Dexmedetomidine had more lasting effects than the other group (16). The study of Cohen et al. showed that although epidural steroid injections may have better effects than Gabapentin on the severity of pain and the level of motor disability of patients, the difference in the effects of the injections in the two groups was small but not significant (17).

A study by Manchikanti et al comparing the effects of three types of drugs for epidural injections, including steroid plus Saline, local anesthetic alone, and steroid plus local anesthetic in patients with LSCS, showed that corticosteroid injection plus Bupivacaine or sodium chloride solution was almost ineffective, but Lidocaine injection alone or Lidocaine in combination with Corticosteroids was very effective. (7) The results of a systematic review study by Laxinaiaha et al. showed that epidural injection with or without local anesthetics in patients with spinal stenosis reduces short and long-term pain in the lower extremities (18). The results of our study are consistent with previous studies showing that the combination of triamcinolone and bupivacaine alone can control pain intensity and reduce functional disability in patients with LSCS.

Conflicting results have been reported regarding the effect of steroid injections on patients' functional disability. The results of a meta-analysis study

conducted by Qureshi *et al.* showed that although epidural steroid injections reduce and control pain, they do not affect patients' functional disability (19). On the other hand, the results of another meta-analysis study by Meng *et al.* showed that epidural steroid injections in patients with lumbar canal spinal stenosis reduce pain intensity and increase the functional level of patients (20). Although the results of our study showed that epidural triamcinolone injection with bupivacaine can reduce pain intensity and functional disability in these patients, given the conflicting results of the studies, further studies are recommended.

The study by Sandra L *et al.* showed that gender plays an important role in the effectiveness of steroid injections in these patients due to the different perception of pain in women compared to men (21). The study by Klonoff *et al.* and Wise *et al.* showed that women are more sensitive to pain perception than men, and this factor reduces their recovery rate (22, 23). However, in our study, the results of the effect of epidural injection in two groups of women and men showed that after the injection, the level of functional disability and pain intensity decreased in both groups, but there was no statistically significant difference between them. This indicates that the gender of the patients did not affect the effectiveness of the patients from injected steroids, which requires further studies.

The results of the present study demonstrated that epidural injection reduced pain intensity and improved functional ability across different age groups (< 40 years, 40–60 years, and > 61 years). Although the magnitude of improvement was greater in younger patients, no statistically significant differences were observed between the age groups. These findings suggest that the therapeutic effects of epidural injections are not substantially influenced by patient age; however, younger patients may experience more favourable outcomes, possibly due to greater physical capacity and fewer comorbid conditions.

The results of a study by Takahashi *et al.* indicated that elderly patients experience less improvement than younger individuals, which was attributed to underlying diseases and additional physical limitations (24). The findings of the present study are consistent with those of Takahashi *et al.*

regarding the more pronounced effects of epidural injections in younger patients. Furthermore, Stafford *et al.* reported that the injection of steroids and local anaesthetics reduces pain intensity by inhibiting prostaglandin synthesis, stabilising cell membranes, suppressing immune responses, increasing nerve blood flow, facilitating the clearance of inflammatory mediators from the site of injury, and blocking neurotransmission of C-type fibres (25).

Accordingly, the reduction in pain observed in the present study suggests that the improvement in pain intensity and functional disability in patients with lumbar spinal canal stenosis, particularly in younger individuals, may be explained by one or more of these mechanisms. Nevertheless, further studies are required to clarify these effects.

Conclusion

The results of our study showed that triamcinolone injection with bupivacaine can be used as a safe and effective treatment to reduce pain intensity and functional disability in patients with lumbar spinal canal stenosis, regardless of age and gender. However, due to the inconsistencies regarding the effect of age and gender on the results of epidural injection, further studies should be conducted.

Declaration

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Conflict of Interest Statement

There is no conflict of interest

Author Contributions

Concept and design: H A, Y J, SH

Analysis and interpretation: DV, YJ, HA

Data collection: DV

Writing the article: YJ, HA

Critical revision of the article: HA, SH, YJ

Final approval of the article: HA, YJ

Statistical analysis: DV, HA

Obtained funding: HA, DV

Overall responsibility: YJ, HA.

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