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Clinical Study

The efficacy of interlaminar epidural steroid administration in multilevel intervertebral disc disease with chronic low back pain: a randomized, blinded, prospective study

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Abstract

BACKGROUND CONTEXT: Epidural steroid injection is commonly used in patients with chronic low back pain. Applying a mixture of a local anesthetic (LA) and steroid using the interlaminar (IL), transforaminal, and caudal techniques is a preferred approach.
PURPOSE: The present study aims to investigate the efficacy of interlaminar epidural steroid administration in patients with multilevel lumbar disc pathology (LDP) and to assess the possible correlation of the procedure's success with age and body mass index (BMI).
STUDY DESIGN: A randomized controlled trial was performed.
PATIENT SAMPLE: We administered interlaminar epidural steroid to a total of 98 patients with multilevel LDP.
OUTCOME MEASURES: The visual analog scale (VAS) and Oswestry Disability Index (ODI) scoring were performed on the study population at pretreatment (PRT), posttreatment, and 1, 3, 6, and 12 PRT months. A possible correlation of BMI and age with the procedure success was evaluated.
METHODS: The LA group (Group L, n=50) received 10 mL 0.25% bupivacaine, whereas the steroid+LA group (Group S, n=48) received 10 mL 0.25% bupivacaine+40 mg methylprednisolone at L4–L5 intervertebral space in prone position under the guidance of C-arm fluoroscopy.
RESULTS: There was no statistical difference in the PRT VAS and ODI scores between the groups ($p<.05$), whereas the VAS and ODI scores at 1, 3, 6, and 12 posttreatment months were higher in Group L, compared with Group S ($p<.05$). Age and BMI were not found to be related with the success of the procedure.
CONCLUSIONS: Our study results showed that the VAS and ODI scores were lower in patients with multilevel LDP receiving steroid, following the administration of IL epidural injection. However, further studies are required to establish a robust conclusion on the dispersion of IL epidural injections in the epidural area and the dose of steroid.

Keywords: Epidural steroid injection; Interlaminar; Local anesthetic; Low back pain; Multiple level radiculopathy; Steroid

Introduction

Low back pain is a symptom observed in approximately 80% of individuals in the overall population and is experienced at least once throughout their lives. Although there are many causes of low back pain, lumbar disc herniation (LDH) is one of the most common causes in clinical practice [1]. Besides mechanical pressure, inflammatory process has also been shown to be one of the leading factors in the low back pain etiology, as pain is not likely to occur without the development of inflammation in the nerve roots [2]. In this case, corticosteroids (CSs) are used to reduce inflammation [1].

Patients with LDH may benefit from conservative treatments, such as bed rest, medical therapy, physical therapy, and exercise; however, 5%–8% of low back pain has been reported to become chronic [3,4]. Because of the conflicting outcomes in cases other than those with definite indications

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EVIDENCE & METHODS

Context
The authors conducted a prospective randomized study evaluating the utility of interlaminar epidural steroid in patients with multilevel disc pathology. The control group received only a local anesthetic.

Contribution
The study included 98 patients, with 50 in the control group and 48 in the experimental cohort. The authors report superior improvement in VAS and ODI scores for patients randomized to the interlaminar epidural steroid intervention.

Implications
Although this study was a randomized trial, the heterogeneity of the cohort as well as the socio-cultural context in which the study was conducted could preclude generalization of study findings. Readers should pay special attention to the inclusion criteria and consider whether patients in whom they wish to apply evidence from this work are sufficiently comparable to the individuals under study.

for surgery (ie, neurologic deficit such as foot drop, fecal and urinary incontinence), alternative treatment methods have been introduced [5]. As one of the minimally invasive procedures, epidural steroid (ES) injections can be administered under the guidance of fluoroscopy to diagnose and treat LDH-related low back pain [6]. An epidural practice administered through the interlaminar (IL), transforaminal, and caudal routes, the IL method was first administered in 1925 to the lumbar epidural area by injecting high volumes of saline and procaine [1]. The results of the studies on interlaminar epidural steroid (ILES) practice, which is commonly used today, are still controversial. Several studies have reported that it is an effective treatment method [6–9]. On the other hand, there are data suggesting that ILES is not a successful treatment option and that ventral epidural drug dispersion affects the chance of success [10–13].

In this study, we aimed to investigate the efficacy of ILES administration in patients with multilevel lumbar disc pathology.

Methods

After the approval of local Ethics Committee was obtained, this prospective, randomized single-blind study included a total of 120 patients who met the inclusion criteria. A written informed consent was obtained from each patient. The study was conducted in accordance with the principles of the Declaration of Helsinki.

Inclusion criteria

The inclusion criteria were as follows: (1) low back pain for more than 6 months; (2) pain unresponsive to conservative treatment methods (physical therapy, medical therapy, etc.); (3) the presence of magnetic resonance imaging findings (disc bulge and protrusion) for the definite diagnosis of lumbar disc pathology; (4) the presence of nerve root pressure symptoms; and (5) visual analogue scale (VAS) score >5.

Exclusion criteria

The exclusion criteria were (1) moderate and severe spinal stenosis; (2) spondylolisthesis; (3) previous spinal infection; (4) neuropathic pain; (5) previous lumbar or spinal surgery; (6) previous minimal invasive procedure (ES, intradiscal therapy, etc.).

The patients admitted to the clinic underwent physical examination and detailed neurologic examination. Laboratory tests were performed. The patients were then divided into two groups by simple randomization, as the local anesthetic (LA) group (Group L, n=60) and the steroid+LA group (Group S, n=60).

Complete blood count and laboratory parameters of hemostasis were evaluated upon the admission of the patients to the pain clinic and pretreatment (PRT) VAS and Oswestry Disability Index (ODI) scores were recorded. The patients underwent an intervention in the operating room. The patients were discharged from the hospital after 1-day hospitalization. The patients were contacted by telephone on Day 15 and at 1, 3, 6, and 12 months and were invited to the hospital for re-examination and completion of forms. The posttreatment (PST) day 15, PST month 1 (PST1m), PST month 3 (PST3m), PST month 6 (PST6m), and PST month 12 (PST12m) follow-ups of all patients were recorded using the VAS and ODI scoring systems. A second epidural procedure was applied to the patients who did not exhibit a 50% reduction in the VAS scores on Day 15.

In addition, there were patients who were excluded from the study for several reasons by the time of 1-year follow-up results. In Group S, 10 patients had another systemic disorder and 2 patients missed appointments for family reasons. In Group L, seven patients had another systemic disorder, one patient missed the appointment for family reasons, and two patients moved to another city. As a result, Group L included a total of 50 patients and Group S included a total of 48 patients (Figure).

A possible correlation of the body mass index (BMI) (kg/m^2) and age with the success of the procedure was also evaluated, based on the PRT and PST12m values.

All procedures were performed under the guidance of the C-arm fluoroscopy in the operating room. L4–L5 intervertebral space was identified in prone position. Following local anesthesia with 5 cc 2% lidocaine, posterior epidural area was accessed using the loss-of-resistance technique in the midline with an 18-gauge, 3.5-in. Tuohy needle (B. Braun, Ankara, Turkey). After negative cerebrospinal fluid and blood aspiration results, 2 mL iohexol (30 mg/mL, Omnipaque 300,