Effect of Intervertebral Level on Interlaminar Epidural Steroid Injection in Lumbar Spinal Canal Stenosis: A Randomized Controlled Trial

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Abstract

**Background:** Interlaminar epidural steroid injection (ILESI) is commonly performed nonsurgical intervention in patients with lumbar spinal stenosis. There is no consensus regarding appropriate intervertebral level of ILESI that leads to maximum effectiveness. In this study, we compared the efficacy of ILESI on pain relief and functional improvement when given at the level of maximum stenosis versus at nearby less stenotic levels in patients of lumbar canal stenosis. **Materials and Methods:** In this study, 80 patients were randomly allocated to two groups: Group A received lumbar ILESI of 5mL bupivacaine (0.25%), 2 mL methylprednisolone acetate (40 mg/mL), and 1 mL normal saline at maximal stenotic intervertebral level, and Group B received the same drugs at less stenotic level, two intervertebral spaces cephalad or caudal to maximum stenosis. The effects were evaluated by Numeric Pain Rating Scale (NPRS) and Oswestry Disability Index (ODI) at 2, 6, and 12 weeks after the intervention. **Results:** Results of 30 patients in each group were assessed. Pain relief and improvement in ODI were observed in both groups after injection. Group A had significantly better pain relief at 2 and 4 weeks after injection. The ODI at 2, 6, and 12 weeks after injection was significantly lower in Group A as compared to Group B. **Conclusion:** ILESI at maximum stenotic intervertebral level leads to better pain relief and functional improvement as compared to injection given at less stenotic level in lumbar spinal canal stenosis.

Keywords: Epidural injection, lumbar spinal stenosis, low back pain, steroid

Insight: There is a paucity of literature regarding the optimal intervertebral level of ILESI that can lead to enhanced relief in symptoms and disability. Some studies suggest that ILESI can be performed at any level, preferably at L₄–₅ or L₃–₄, considering the fact that L₄–₅ is most commonly involved in DLCS. According to Milburn

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et al., it should be performed at a level of maximum stenosis. Hence, there is no consensus regarding intervertebral level of performance. It is based on personal preference and experience rather than scientific data.

In this context, this study was done to compare the effectiveness of ILESI on pain relief and functional improvement when given at a level of maximum stenosis versus at nearby less stenotic levels in patients of LCS. We hypothesized that injecting the steroid at a maximum stenotic level will maximize the effect, considering that level to be the main cause of patient’s symptoms.

Materials and Methods

This prospective, randomized, controlled, clinical study was conducted at tertiary care teaching hospital in the department of Anaesthesia. Patients over 35 years with magnetic resonance imaging (MRI) confirmed LCS suffering from chronic lower leg and back pain of at least 6 months duration and whose clinical symptoms correlate with maximal stenotic intervertebral level were included in the study. Uncooperative, psychiatric, coagulopathy, localized skin sepsis, history of previous spinal surgery, and steroid exposure in the past 6 months were excluded from the study.

The sample size was calculated using the Milburn et al. study as a reference and keeping α value of 0.05 and β value of 0.2; the sample size of 52 was calculated, i.e. 26 in each group. We include 80 patients in this study keeping into consideration the loss of follow-up. After getting approval from the ethical and scientific committee of hospital and taking detailed history, clinical examination, and informed and written consent 80 patients, of either sex who were included in the study, were randomly divided by the computer-generated random allocation technique into two groups named A and B based on the intervertebral level at which drugs were to be injected. After securing intravenous line and connecting monitors epidural injection were given under all aseptic precautions by 18-G Tuohy needle after local infiltration with 2mL of 2% lignocaine, in sitting position using interlaminar approach at the space corresponding with a maximum stenosis (confirmed by MRI) in Group A, and two intervertebral levels of cephalad or caudal corresponding to less stenotic level in Group B, using the loss of resistance technique. After confirming the correct position of needle by fluoroscopy, epidural injection of 5mL bupivacaine 0.25% (Anawin, Neon, India), 2mL methylprednisolone acetate (Depo Medrol 40 mg/mL, Pfizer, New York), and 1 mL normal saline (total 8 mL) was given. Patients were unaware of the level of injection. For blinding purposes, epidural injections were performed by one specialist, and follow-up of patients was conducted by another specialist who was blinded to the level of ILESI. To avoid confounding factors, patients were maintained on the same set of oral medicines (nonsteroidal anti-inflammatory drugs). Patients who were lost for follow-up, who had postinjection steroid exposure or underwent surgery were excluded from the study.

Of 80 patients, only 60 patients could be followed up to 12 weeks and were included in this analysis. Maximum ambulatory pain was recorded utilizing a Numeric Pain Rating Scale (NPRS), in which patients were asked to rate their pain on a scale of 0–10 (0 means no pain, and 10 means worst pain possible). Oswestry Disability Index (ODI), which is a widely used low back pain disability questionnaire was utilized to measure the functional disability. The assessment was made at preinjection and 2-, 6-, and 12-week postinjection to determine the long-term effectiveness of ILESI in reducing pain and disability.

Statistical analysis

Statistical analysis of age, weight, height, and comparison of mean NPRS and ODI between Group A and B was performed using the independent t-test. For gender Chi-square test was used. Comparison of mean NPRS and ODI within each group for follow-up was made by repeated analysis of variance.

Results

Of 80 patients that were enrolled for the study, six patients were excluded after 6 weeks, and of the remaining 74 patients, 14 patients were excluded at 12 weeks after injection due to the loss of follow-up, steroid exposure, or they underwent spine surgery. Sixty patients participated in the study until 12 weeks after injection. Mean canal narrowing was 6.3 mm (2.8–9.2mm). The most common stenotic site was L4–5 followed by L3–4.

All groups were similar demographically, and there was no significant difference with respect to age, sex, weight, height, and duration of pain [Table 1].

NPRS was comparable in both the groups before injection (P > 0.05). In both Groups A and B, mean NPRS decreased after 2 weeks and then increased after 6 weeks and furthermore after 12 weeks. Patients in both groups had significant pain relief after 2, 6, and 12 weeks as compared to baseline. There was a statistically significant difference (P < 0.05) in NPRS between both groups where Group A had significantly better pain relief as compared to Group B at 2 and 4 weeks. At 12 weeks also, the pain score was lower in Group A as compared to Group B though it was not statistically significant [Table 2].

ODI was comparable in both groups at preinjection (P > 0.05). In both groups, ODI decreased at 2 weeks and then gradually increased at 6 and 12 weeks after injection. In both the groups, there was a significant decrease in disability index at all weeks as compared to baseline. There was a statistically significant difference (P < 0.05) in mean ODI between both groups at 2, 6, and 12 weeks after the intervention. Group A had significantly lower mean ODI which implies that patients in Group A had significantly better functional improvement as compared to Group B [Table 3].

Discussion

This study aimed to analyze the effect of the intervertebral level on ILESI in lumbar spinal canal stenosis. We
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observed that irrespective of the intervertebral level, ILESI was effective in providing pain relief and functional improvement in spinal canal stenosis. This observation corresponds to other studies which proved the efficacy of ILESI in DLCS. [4,8,9]

The results suggest that Group A had statistically significant pain relief as compared to Group B at 2 and 4 weeks after injection, and though it did not reach a statistically significant level at 12 weeks. The reduction in disability score in Group A was statistically significant at 2, 6, and 12 weeks as compared to Group B during follow-up.

There was no increase in pain during injection, and postprocedure in both groups which suggest that giving ILESI at a maximum stenotic intervertebral level did not cause any pressure symptoms or discomfort. This negates the belief that pressure of the drug given at a maximum stenotic level may aggravate patient’s symptoms. In fact, injecting the drug exactly at maximal stenotic area proved to be more efficacious, as the compression of nerve fibers is maximum at that level, and it is the main source of patient’s symptoms. Delivering the drug at the level of maximum stenosis leads to increased amount of drug at the level of maximum nerve irritation, thus improving the efficacy of drug in providing symptomatic pain relief.[10]

To the best of our knowledge, similar kind of study was done only by Milburn et al., in which they conclude that ILESI at the maximal stenotic level provided greater pain relief and symptomatic improvement.[6]

The limitation of the present study was a small number of study patients and limited duration of follow-up. Hence, the preliminary results of this study should be confirmed by a large randomized clinical trial with a long-term follow-up.

**Conclusion**

From the study results, it is suggested that ILESI at maximum stenotic intervertebral level leads to better pain relief and functional improvement as compared to injection given at less stenotic level in spinal canal stenosis.

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**Conflicts of interest**

There are no conflicts of interest.

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