Comparative evaluation of midline versus parasagittal interlaminar epidural steroid injection for management of symptomatic lumbar intervertebral disc herniation

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ABSTRACT

Background and Aims: Epidural steroid injections (ESIs) with or without local anaesthetics have been used for the past several years for the treatment of back pain, especially for radicular symptoms. The aim of this prospective study was to compare the efficacy of midline with parasagittal approach for interlaminar ESI in the management of symptomatic lumbar intervertebral disc herniation. Methods: Sixty patients (aged 20–60 years) with pain pattern consistent with lumbar radiculopathy caused by lumbar intervertebral disc herniation and who did not respond to conservative treatment were included in the study. They were randomly divided in two groups of 30 each: group I (MILESI, n = 30) consisting of midline interlaminar ESI, and group II (PSILESI, n = 30) consisting of parasagittal interlaminar ESI. They were administered a combination of 80 mg of methylprednisolone acetate (40 mg/ml) and 6 ml of 0.25% bupivacaine (total volume of 8 ml). Pain, patient satisfaction, and the Oswestry Disability Index (ODI) were assessed at different time intervals before and after the procedure for up to six months. Results: The improvement in pain score after ESI was statistically significant in both the groups at all intervals of time, with no significant difference between the two groups. The mean pain score was <3 from two weeks onwards after the injection. The pain score decreased by more than five points and it was around two points at the end of the six-month study period. Around 50% of patients in both groups had excellent satisfaction. Conclusion: Both techniques were effective in providing good analgesia. Pain relief and improvement in disability were clinically better with the parasagittal interlaminar approach.

Key words: Disc herniation, epidural injection, radiculopathy, steroid

INTRODUCTION

Epidural steroid injections (ESIs) with or without local anaesthetics have been used for the past several years for the treatment of back pain, especially for radicular symptoms. Epidurally administered corticosteroids inhibit the synthesis of prostaglandins, have anti-inflammatory effects, and inhibit ectopic discharges that arise from sensory nerves that are injured. The purpose of injection of an epidural steroid is to deliver the drug close to the affected nerve roots that are the source of the symptoms. The three routes of lumbar ESIs are caudal, interlaminar, and transforaminal. [1–5] With interlaminar entry of the lumbar epidural space, the epidural needle can be erroneously placed by missing the targeted interspace by one or two levels. Moreover, preferential cranial flow of the

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solution in the epidural space probably necessitates the positioning of the needle a level below the site of the suspected pathology. This can be difficult in patients with L₅ or S₁ nerve root involvement. There is a potential for deviation of the needle toward the non-dependent side. The interlaminar epidural injection may produce spinal cord trauma, especially in the upper lumbar region. There is an inherent risk of dural puncture, and as a result post-lumbar puncture headache and total spinal block is a probability. Interlaminar epidural injection can be performed through a parasagittal or midline approach. In parasagittal interlaminar approach, the most lateral aspect of the epidural space is used to administer the drug. It has been suggested that parasagittal approach is clinically more effective than midline interlaminar ESI, as greater anterior epidural spread of the drug is achieved.

We conducted this prospective study with the aim of comparing the efficacy of the midline with the parasagittal approach for interlaminar ESI in the management of symptomatic lumbar intervertebral disc herniation in terms of producing pain relief.

**METHODS**

This prospective, randomised study was conducted at the pain management centre of the department of Anaesthesiology of a postgraduate teaching institute from March 2018 to May 2019 after obtaining institutional ethics committee approval (No. IEC/Th/18/Anst dated Jan, 2018). The study was conducted in accordance with the principles of the Declaration of Helsinki. Sixty patients of either gender and in the age group of 20–60 years attending the pain clinic and fulfilling the following three criteria were included in the study: (i) history, physical examination, and pain pattern consistent with lumbar radiculopathy, that is, low back or unilateral/bilateral leg pain of radicular nature caused by a lumbar intervertebral disc herniation; (ii) magnetic resonance imaging (MRI) showing disc herniation at single/multiple levels with compression of nerve roots and this corresponding with the patient's clinical symptoms; (iii) a combination of anti-inflammatory drugs, centrally acting muscle relaxants, neuromodulators, oral narcotic for severe pain, and physical therapy not producing an effective response after six weeks. Patients with known contraindications for epidural interventions, history of adverse reactions to local anaesthetics and steroids, previous ESI, previous lumbar spine surgery, unstable neurological deficits and cauda equina syndrome, those with uncontrolled diabetes mellitus, and pregnant women were excluded from the study.

In the pain centre, a detailed clinical history was elicited, the patients were examined, and a detailed review of the imaging studies including the MRI was done. The procedure of interlaminar ESI was explained in detail to the patients and informed written consent was obtained from them. Numeric rating scale (NRS) (0–10) for assessment of pain was explained to each patient before performing the procedure. The patients were randomly divided in two groups of 30 each with the help of a computer-generated randomisation number table. Group I (MILESI, n = 30) patients were administered midline interlaminar ESI, and group II (PSILESI, n = 30) patients were administered parasagittal interlaminar ESI.

The patients were placed in the prone position with a pillow under the pelvis to attenuate lumbar lordosis. The procedure was performed under aseptic precautions. lignocaine 1% was infiltrated subcutaneously. An 18-gauge, 3½-inch Tuohy needle was advanced into the epidural space under fluoroscopic guidance using the loss-of-resistance to air technique, in the midline in the midline interlaminar injection (group I) and parasagittally in the parasagittal interlaminar injection (group II). After negative aspiration for cerebrospinal fluid and blood, a combination of 80 mg of methylprednisolone acetate (40 mg/ml) and 6 ml of 0.25% bupivacaine (total volume of 8 ml) was injected.

A sample size of 30 per group was calculated to achieve a power of 85% to show a difference of 20% change in Oswestry Disability Index (ODI) and in NRS with type I error rate of 5%. A 20% change in ODI and NRS was found to be clinically relevant in previous studies and was also used for sample size calculation in the present study.

Pain relief, patient satisfaction, and disability improvement were the primary outcomes of the study. The need for epidural steroid injection to be repeated, the side effects and complications related to the procedure, and the need for surgery were the secondary outcomes.

Pain was assessed using the NRS (0–10). They were asked to sit, stand, and walk before rating their pain. NRS was measured and recorded at various time intervals: one hour before the procedure, one hour
after the procedure, and two weeks, one month, two months, three months, and six months after the procedure.

Patient satisfaction was assessed two weeks, one month, two months, three months, and six months after the procedure on a four-point scale: “excellent” to denote when the pain was completely gone or reduced by 75% or more; “good” when the pain reduced by 50%–74%; “fair” when the pain reduced by 25%–49%; “poor” when the pain reduction was less than 25% or there was an increase in pain.

The ODI—also known as Oswestry Low Back Pain Disability Questionnaire—was calculated one hour before the procedure, and two weeks, one month, two months, three months, and six months after the procedure.

Patient follow-up was done for six months after the first injection to find out the need for further ESIs. In case of inadequate pain relief (NRS >4), repeat ESIs were given with the same approach that had been followed in the initial sitting. Also, not more than three injections of epidural steroids were administered in any patient. Side effects and complications like dural puncture, infection, rash, itching, weight gain, etc., if any, were recorded. Pain during administration of drug solution was assessed on a four-point scale: 1 for no pain, 2 for mild pain, 3 for moderate pain, and 4 for severe pain. The need for surgery for the presenting problem was assessed and the number of patients requiring surgery at the end of the six-month study period was recorded.

The Statistical Package for the Social Sciences (SPSS) version 17.0 [International Business Machines SPSS Statistics Inc. Chicago, Illinois, USA] was used for statistical analysis. Friedman’s one-way analysis of variance (ANOVA) was used to compare the difference in age and weight amongst the two groups. Paired t-test was used to compare change in pain score (NRS 0–10) and change in the ODI score within the two groups at different time intervals. Kruskal–Wallis test was used to compare the NRS score and ODI score at different time intervals amongst the two groups. The Chi-square test was used to compare gender distribution, patient satisfaction, number of injections, and pain during administration of the injectate amongst the two groups. The results were considered to be statistically significant if P value was ≤0.05.

### RESULTS

The two groups were comparable in terms of age, weight, and gender distribution [Table 1].

The variation in pain score in both the groups at different time intervals when compared to baseline was clinically and statistically significant (P < 0.001). When pain scores were compared amongst the two groups, they were clinically and statistically comparable in the two groups at baseline. In group I, mean pain score (NRS score) before injection was 7.67 ± 1.04 which decreased to 3.63 ± 1.21 one hour after injection. Pain score was 2.30 ± 0.72, 2.41 ± 0.84, 2.41 ± 1.12, 2.44 ± 1.31, and 2.15 ± 1.03 at two weeks, one month, two months, three months and six months after injection, respectively. In group II, mean pain score (NRS score) before injection was 7.89 ± 0.57 which decreased to 3.07 ± 1.33 one hour after injection. Pain score was 2.29 ± 0.81, 2.39 ± 1.20, 2.21 ± 1.17, 2.00 ± 1.02, and 2.00 ± 1.02 at two weeks, one month, two months, three months, and six months after injection, respectively [Figure 1]. After the epidural injection, the pain scores were clinically lower in group II at all time intervals of the study period after PSILESI compared to the MILESI group.

During the comparison of patient satisfaction between the two groups, it was observed that there was a statistically significant better patient satisfaction in group II compared to group I at one month. However, at the end of the six-month study period, patient satisfaction was statistically comparable in both the groups.

There was a clinically and statistically significant variation in ODI score at different intervals of time when compared to ODI score before injection in both the groups (P < 0.001). When ODI scores were compared amongst the two groups, they were clinically and statistically comparable in both the groups at baseline. In group I, mean ODI score before

### Table 1: Distribution of age, gender, and weight in the two groups

| Parameter               | Group I (MILESI) | Group II (PSILESI) | P   |
|-------------------------|------------------|-------------------|-----|
| Age (in years)          | 53.11±11.20      | 53.57±13.68       | 0.5 |
| Weight (in kg)          | 63.22±13.28      | 58.93±7.40        | 0.069 |
| Male-to-female ratio    | 11:16 (40.7%; 59.3%) | 6:22 (21.4%; 78.6%) | 0.279 |

SD: Standard deviation
injection was 58.32 ± 13.91 which decreased to 26.84 ± 12.35 two weeks after injection. ODI score was 26.64 ± 11.98, 21.67 ± 13.82, 21.32 ± 14.93, and 17.24 ± 12.28 at one month, two months, three months, and six months after injection, respectively. In group II, the mean ODI score before injection was 59.66 ± 14.03 which decreased to 23.63 ± 13.26 two weeks after injection. ODI score was 24.34 ± 15.34, 18.83 ± 14.83, 15.93 ± 14.83, and 15.93 ± 14.83 at one month, two months, three months, and six months after injection, respectively [Figure 2]. After the epidural injection, the ODI scores were clinically lower in group II at all time intervals of the study period in the PSILESI group compared to the MILESI group. However, the difference was statistically comparable.

The number of patients requiring second injection during the six-month study period was five in the MILESI group and one in the PSILESI group. It was comparable amongst the two groups statistically (P > 0.05). No patient required surgery at the end of the six-month study period. However, a six-month follow-up is not sufficient to determine the number of patients requiring surgery for lumbar disc herniation.

During injection, a majority of the patients had mild pain on administration of injectate (29 out of 35 in group I and 25 out of 31 in group II; P > 0.05). Three patients in group I, five patients in group II had no pain on injection (P > 0.05). One patient each in group I and group II reported moderate pain on administration of the injectate. Four patients in group I reported soreness at injection site after the injection. No patient in the two groups reported increased pain. The soreness was resolved within two to three days with the use of cold fomentation. No serious side effects related to the technique or the injectate were observed.

**DISCUSSION**

A majority of the patients in our study were in the age group of 40–60 years and 66% of them were females. The female preponderance could be attributed to the social milieu of our region. The incidence of road traffic accidents and falls is common in the age group of 40–60 years. The rest of the patients had degenerative disc disease, which is more common in the elderly age group.

Patient satisfaction was similar to pain score trend over the study period in our study population. Around 50% of patients in both the groups had excellent satisfaction and around 40% had good satisfaction after epidural injection in both the groups at different time intervals of the study period, except at one hour. One hour after epidural injection, patient satisfaction was clinically and statistically better in group II.

In the present study, we had planned to repeat the injection by the same technique as the initial procedure, if required. The number of patients requiring second injection during the six-month study period was five in the MILESI group and one in the PSILESI group. We used a drug solution comprising of 6 ml of 0.25% bupivacaine plus 2 ml of methylprednisolone (80 mg) in both groups. Nevertheless, a similar volume of drug solution has been used in other studies.\[10–14\]

The corticosteroid delivered into the epidural space attains higher local concentrations over an inflamed nerve root and is more effective than a steroid administered either orally or by intramuscular injection. It also has been postulated that local anaesthetics provide the relief by multiple mechanisms, which include suppression of nociceptive discharge,
the blockade of sympathetic reflex arc, the blockade of axonal transport, the blockade of sensitisation, and anti-inflammatory effects.[1-4,5]

The midline ILESI technique delivers the injection fluid into the posterior epidural compartment with the needle placed directly between adjacent spinous processes or between adjacent laminae. The midline ILESI technique has the advantage of delivering injectate to the bilateral epidural space and covering multi-level pathologies. This is especially useful in patients with bilateral radicular pain.[10,11,15] In parasagittal interlaminar epidural injection, the most lateral aspect of the epidural space is used to administer the drug to achieve greater anterior epidural spread of the drug.

The use of fluoroscopy involves exposure to radiation and administration of contrast medium. However, exposure to radiation can be minimised by following standard operational principles. In the present study, we used non-ionic contrast medium (0.5–2 ml, Omnipaque 350). No side effects due to the use of contrast were observed. A majority of the patients had mild pain on administration of injectate. The pain was temporary and was relieved within seconds of finishing the administration of the injectate. No procedural complications were observed in our study in any of the patients in the two groups. On similar lines, other authors have shown that lumbar ESI can be administered safely on an outpatient basis and does not require sedation or special monitoring.[8,11,14]

This study has a few limitations. Firstly, all the interventions were performed by the senior pain physician and the study results may have reflected the experience of one practitioner only, which may limit the generalisability of the study findings. Second, long-term effects should be evaluated in the future based on the results of the short-term effects of this study. We followed patients for six months, but trials could focus on long-term outcomes up to one year after the interventions. Third, the study was not conducted as a double-blinded, controlled study. It is difficult to conduct a double-blinded, controlled study with non-traditional modalities such as fluoroscopy.

**CONCLUSION**

Both the techniques of fluoroscopic guided lumbar ESI, that is, midline interlaminar and parasagittal interlaminar ESI are safe and effective techniques for the management of patients with lumbar intervertebral disc herniation. Both the techniques provide good pain relief and improvement in disability to the patients. Pain relief and improvement in disability are clinically better with parasagittal interlaminar ESI compared to midline interlaminar ESI.

**Declaration of patient consent**

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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**Conflicts of interest**

There are no conflicts of interest.

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