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Comparative evaluation of caudal epidural, interlaminar, and transforaminal epidural steroid injection in patients with lumbar spinal canal stenosis

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ABSTRACT

Background: Lumbar spinal stenosis (LSS) is a common degenerative spinal condition which is a major cause of pain and functional disability. Epidural steroid injections with or without local anesthetics have been used for the treatment of spinal pain, particularly for radicular symptoms and spinal stenosis. **Aims and Objectives:** The primary objective was to compare the efficacy of the three routes in terms of improvement in pain, disability and patient satisfaction. Secondary objectives were to compare the requirement for repeat injections and side effects, if any. **Materials and Methods:** In this prospective, randomized study, 90 patients with medical evaluation and pain pattern consistent with a diagnosis of LSS were randomized into three groups: Group-I (n = 30) patients were administered caudal epidural steroid injection; Group-II (n = 30) interlaminar epidural steroid injection; and Group-III (n = 30) transforaminal epidural steroid injection (TFESI). The primary objective was to compare the efficacy of the three routes in terms of improvement in pain, disability, and patient satisfaction. Secondary objectives were to compare the requirement for repeat injections and side effects, if any. **Results:** There was a statistically significant improvement in pain score, Oswestry disability index (ODI) score, and Swiss spinal stenosis questionnaire (SSSQ) score in all groups at all study periods. ($P < 0.01$) The pain scores and SSSQ scores were clinically and statistically significantly lower after TFESI as compared to other groups from 1 month onward after the injection at all study interval periods ($P < 0.01$), whereas ODI scores were better from 3 months onward. **Conclusion:** All three techniques provide good pain relief and improvement in disability to the patients. TFESI is better than other two techniques in terms of improvement in pain score, treatment outcome, and functional disability.

Key words: Spinal canal stenosis; Transforaminal injection, Interlaminar; Caudal epidural injection; Oswestry disability index

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INTRODUCTION

Lumbar spinal stenosis (LSS), a common degenerative spinal condition, is a major cause of low back pain and functional disability.[1,2] The initial treatment in majority of the patients with LSS is conservative.[3] Epidural steroid injections (ESI) with or without local anesthetics are being used with increasing frequency as a less invasive, potentially safer, and cost-effective treatment. The corticosteroid delivered into the epidural space attains higher local

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concentrations over an inflamed nerve root and is more effective, with less dosage requirements compared to systemically administered steroids.[4] Local anesthetics, injected along with epidural steroids, exert analgesic effects and may provide prolonged benefits by putatively interrupting the cycle of pain.[5]

Caudal epidural steroid injection (CESI), interlaminar epidural steroid injection (ILESI), and transforaminal epidural steroid injection (TFESI) are the three routes for lumbar epidural injection. There is variable effectiveness for all three approaches in managing pain due to spinal stenosis.[4] TFESI has emerged as an alternative to ILESI and CESI. The TFESI approach is target-specific and requires the smallest volume to reach the primary site of pathology.[6,7]

Aims and objectives

There is limited literature comparing the efficacy of three routes of ESI in patients with LSS. Therefore, the present prospective study was planned with the primary objective of comparing the efficacy of CESI, ILESI, and TFESI in patients with symptomatic LSS in terms of pain and disability improvement, and patient satisfaction. Secondary objectives were to compare the requirement for repeat injections and parameters related to the block, such as side effects pertaining to the minimally invasive pain and spine interventions.

MATERIALS AND METHODS

The present prospective, randomized study was conducted in Pain Management Centre of a postgraduate institute. Approval from the institutional ethical committee was obtained. Ninety patients (ASA I-II) of either sex or age more than 40 years attending pain clinic were enrolled in the study. The inclusion criteria were: (1) history, physical examination, and pain pattern consistent with LSS of at least 3 months duration; (2) magnetic resonance imaging (MRI) findings corresponding with the patient's clinical symptoms; (3) failure to respond to 6 weeks of conservative treatment with a combination of anti-inflammatory drugs, neuromodulators, oral narcotic for severe pain and physical therapy. Patients with known contraindications for epidural injection, history of adverse reactions to local anesthetics or steroids, malignancy, infection, pregnancy, vertebral fractures, peripheral vascular disease, uncontrolled psychiatric disorders, uncontrolled medical illnesses, previous history of epidural injection in last 6 months and previous spine surgery were excluded from the study.

Informed and written consent was obtained from all the patients after explaining the procedure in detail. Assessment of pain was done by Numeric Rating Scale (NRS, 0–10) which was explained to each patient before performing the procedure. Group I (n=30) patients were administered fluoroscope-guided CESI; Group II (n=30) patients were administered fluoroscope-guided interlaminar ESI; Group III (n=30) patients were administered fluoroscope-guided TESI.

All patients were examined and detailed clinical history was taken in the pain clinic. The imaging studies (MRI) were reviewed. Strict aseptic precautions were taken. Local infiltration of lignocaine (1%, 2 mL) was done at the site of injection.

Patients were placed in prone position with a soft pillow under the lower abdomen to attenuate lumbar lordosis. In Group I, a 20-gauge spinal needle was advanced into caudal epidural space under fluoroscopic guidance. Adequate positioning was confirmed by injecting non-ionic contrast medium (1–2 mL, Omnipaque 350). After the correct placement of needle, drug solution was injected containing 8 mL 0.25% bupivacaine plus 2 mL methylprednisolone (80 mg) followed by 2 mL of normal saline as flush (Figure 1).

In Group II, an 18-gauge, 3½-inch Tuohy needle was advanced into epidural space under fluoroscopic guidance. All procedures were performed below the level of Lumbar Stenosis. After negative aspiration for cerebrospinal fluid and blood, a drug solution comprising of 4 mL 0.25% bupivacaine plus 2 mL methylprednisolone (80 mg) was injected.

In Group III, a 23-gauge, 90-mm spinal needle was placed under intermittent fluoroscopic guidance in the anterior and superior aspect of the neural foramen at the suspected symptomatic radicular level. After confirming adequate positioning of the needle, 0.5–1 mL of non-ionic contrast material (Omnipaque 350) was injected to see appropriate contrast spread along the spinal nerve into the epidural space without intravascular uptake (Figure 2). Next, a combination of 20 mg of methylprednisolone acetate (40 mg/mL) and 2 mL of 0.25% bupivacaine was injected at the level of maximum spinal stenosis.

The sample size was calculated to achieve a power of 85% to show a difference of 20% change in NRS and Oswestry disability index (ODI) with Type I error rate of 5%. A change in ODI and NRS of 20% was found to be clinically relevant in previous studies and was used for sample size calculation in the present study.

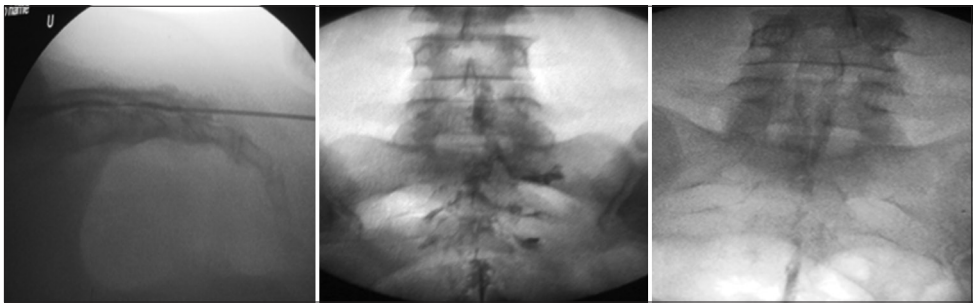

Figure 1: Fluoroscope-guided caudal epidural steroid injection

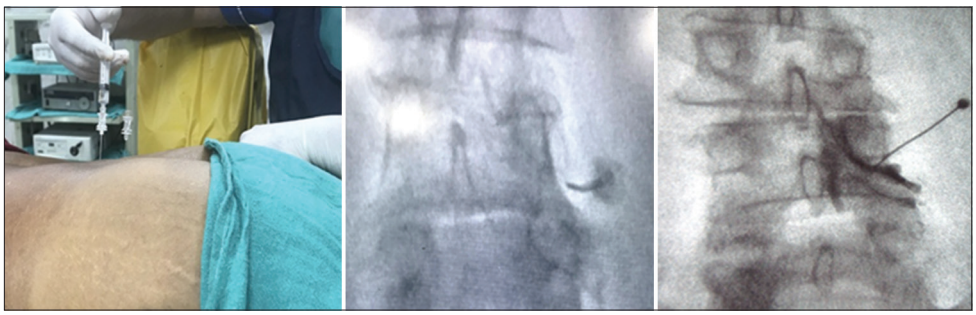

Figure 2: Fluoroscope-guided transforaminal epidural steroid injection

Patients were observed for 1 h in the recovery area. Patients were asked to reduce their activity for the rest of the day. Pain was assessed using (NRS, 0–10): Before the injection, 1 h, 2 weeks, 1 month, 2 months, 3 months, and 6 months after the injection. The ODI[8] (Oswestry Low Back Pain Disability Questionnaire) and Swiss Spinal Stenosis Questionnaire, (SSSQ)[9] a disease-specific self-report outcome questionnaire that quantifies the severity of symptoms, physical function characteristics, and patient's satisfaction after injection) were calculated before the procedure; at 2 weeks, 1 month, 2 months, 3 months, and 6 months after the procedure. Repeat injections were performed using the same technique as the initial procedure if pain relief was not significant (NRS >4). In each group, a maximum of three injections were given during the 6 months of the study period. If NRS >4 even after three injections, they were considered as ineffective. Any side effects and complications such as pain during administration of drug solution, pain at injection site, and swelling, were recorded.

Pain during administration of drug solution was assessed on a four-point scale: 1-No pain, 2-Mild pain, 3-Moderate pain, and 4-Severe pain. The need for surgery for the presenting problem was assessed and number of patients requiring surgery at the end of 6-month study period was recorded.

The Statistical Package for the Social Sciences (SPSS) version 17.0 (IBM SPSS Statistics, Inc., Chicago, Illinois, USA) was used for statistical analysis. One-way analysis of variance (Friedman's Analysis of Variance) was used to compare the difference in age, weight, and SSSQ Score among the three groups. For changes in pain score (NRS 0–10), ODI Score, and SSSQ Score, paired t-test was used at different time intervals within the three groups. Kruskal–Wallis test was used for the comparison of NRS score and ODI score among the three groups at different time intervals. The Chi-square test was used for comparison of sex distribution, pain during administration of the injectate, and number of injections among the three groups. If $P \leq 0.05$, the results were considered statistically significant.

RESULTS

The three groups were comparable in age, weight, and sex distribution (Table 1).

The variation in pain score in all three groups at different time intervals when compared to baseline was clinically and statistically significant ($P<0.001$). When pain scores were compared between the three groups, they were clinically and statistically lower in Group III as compared to Group I and II (Figure 3).

The variation in ODI score at different time intervals when compared to ODI score before injection in all the three groups was clinically and statistically significant ($P<0.001$). The change in ODI score was more in Group III as compared to Group I and II at all-time intervals (Figure 4).

Table 1: Distribution of age, sex, and weight in the three groups

Parameter	Group I (CESI) n=30	Group II (ILESI) n=30	Group III (TFESI) n=30	P-value
Age (in years) Mean±S.D.	56.13±12.71	57.56±9.83	53.03±10.68	0.279
Weight (in kg) Mean±S.D.	65.33±9.5	62.36±8.42	62.36±8.42	0.146
Male to female ratio	18:12 (64%:36%)	15:15 (50%:50%)	15:15 (50%:50%)	0.669

CESI: Caudal epidural steroid injection, ILESI: Interlaminar epidural steroid injection, TFESI: Transforaminal epidural steroid injection, SD: Standard deviation

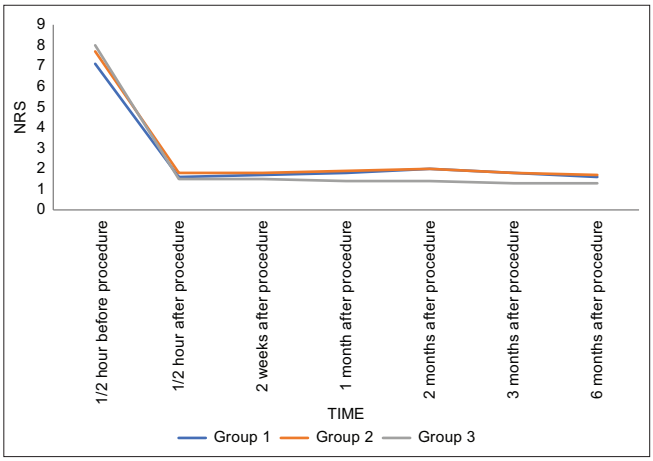

Figure 3: Pain score (numeric rating scale) at different time intervals in the three groups

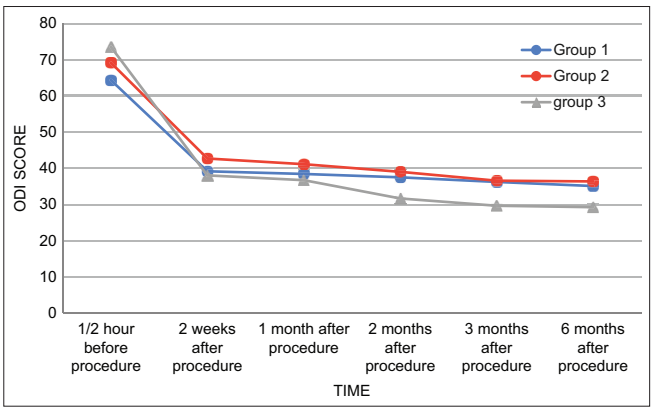

Figure 4: Oswestry disability index score at different time intervals in the three groups

The variation in SSSQ score at different time intervals when compared to SSSQ score before injection in all three groups was clinically and statistically significant (P<0.001). The change in SSSQ score was more in Group III as compared to Group I and II at all-time intervals (Figure 5).

The level of block performed in majority of the patients in Group II was L3-L4 (21 patients, 70%) and at the level of L4-L5 in nine patients (30%). In Group III, unilateral block was performed in all patients at the level of L4-L5 in 24 patients (80%) and at the level of L3-L4 in six patients (20%). In Group I, all blocks were performed through caudal route.

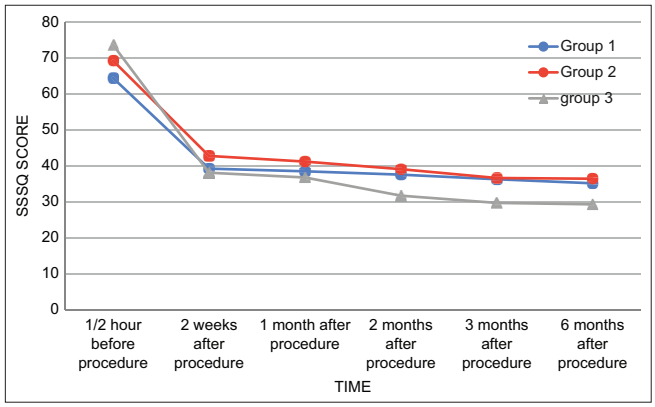

Figure 5: Swiss spinal stenosis questionnaire score at different time intervals in the three groups

In all three 3 groups, the variation in patient satisfaction scores at all-time intervals when compared to baseline was clinically and statistically significant (P<0.001). When patient satisfaction scores were compared among the three groups, they were clinically and statistically higher in Group III at all-time intervals of the 6-month study period (P≤0.001).

Number of patients requiring second injection during the study period was 7 in CESI Group, 4 in ILESI group, and 3 in TFESI group. It was comparable statistically among the three groups (P>0.05). Only one patient in CESI group required a third injection during the study period. Surgery was not required in any of the patient at the end of 6 months study period.

During injection, majority of the patients in each group had mild pain on administration of injectate (68.4% in Group I, 76.5% in Group II, and 66.7% in Group III; P>0.05). Only one patient each in Groups II and III reported severe pain on administration of the injectate. The pain was relieved within seconds of finishing the administration of the injectate.

Soreness at injection site was reported in four patients in Group I. No patient in the three group's complaints of increased pain. None of the patients developed any serious side effects related to the technique or the injectate. No patient in the three groups had any reaction to the contrast medium.

DISCUSSION

In our study, all three groups were comparable regarding baseline patient profile. The majority of patients were in the age group of 50–60 years and there was an equal distribution of males and females in all groups. Similar patient profiles have been observed in other studies.[2,7,10,11]

The mean pain score, from 1 h after the injection, in all three groups remained around two at all-time intervals throughout the study period. All patients had more than five-point improvement in the NRS score at all-time intervals when compared to before injection NRS score. There was a statistically and clinically significant improvement in pain score after injection in all three groups at all-time intervals during the 6 months study period ($P<0.001$). However, the pain scores were clinically lower in Group III at all-time intervals of the study period after TFESI as compared to ILESI and CESI groups and the difference was statistically significant from 1 month onward after the injection till the 6 months study period ($P\leq0.01$). Similar to our study, other authors have achieved significant pain relief after epidural injections in patients with LSS.[1,2,5,7,11]

The mean ODI score was <30% 2 weeks onward after the injection and <20% 3 months onward after the injection in the three groups. Meng et al., and Cooper et al., found ODI change of 10–12 to be clinically meaningful.[12,13] In our study the change in ODI was 25–37 in Group I, 28–44 in Group II, and 33–52 in Group III. There was a statistically and clinically significant improvement in ODI after injection in the three groups at all-time intervals during the study period ($P<0.001$). ODI scores were clinically lower in Group III at all-time intervals of the study period after TFESI as compared to ILESI and CESI groups. However, the difference was statistically significant at 3 and 6 months after injection ($P=0.013$ and $P=0.007$, respectively). These results were similar to results reported by other authors.[1,2,5,7,11,14]

Similarly, the decrease in SSSQ score at different time intervals in all three groups when compared to SSSQ score before injection was clinically and statistically significant ($P<0.001$). The mean SSSQ score was around 40% 2 weeks onward after the injection and around 35% 3 months onward after the injection in CESI and ILESI groups. In TFESI group, SSSQ was around 35% 2 weeks onward after the injection and around 30% 3 months onward after the injection. All the results were clinically and statistically better after TFESI as compared to ILESI and CESI ($P<0.001$). Our results are coherent with the results of other authors who have achieved significant improvement after epidural injections in patients with LSS.[1,2,5,7,11]

In our study, only one patient in CESI group required a third injection during the study period in all three groups. Our results are better than other studies.[1,2,5,7,11] The major factor leading to the failure of epidural corticosteroid injections is inadequate delivery of medication into the epidural space. We used real-time fluoroscopy during contrast injection that increased therapeutic value and avoided possible complications. No side effect due to the use of contrast was observed in our study.

Majority patients had mild pain on administration of injectate. The pain was temporary and was relieved while they were being observed in the recovery room after injection. Similarly, other authors have also shown that lumbar ESI can be performed safely on an outpatient basis and does not require sedation or special monitoring.[1,2,5]

In Group I, four patients reported soreness at injection site after the procedure. The soreness was resolved within 2–3 days with the use of cold fomentation and concurrent medications for LSS. We did not observe any serious side effect related to the technique or the injectate. None of the various types of complications, including infection, reaction to drugs, subarachnoid blockade, and weight gain were observed in any of the patients. A similar side effect profile has been observed in other studies.[1,2,5,7,11]

The overall benefit in our study appears to be greater than that seen in previous studies is likely due to several factors, including injection level with strong correlation to patient selection; clinical history, examination, and imaging; the experience and training of the injecting practitioner, and use of fluoroscopy. Lastly, since a single experienced interventional pain specialist performed all injections, this may have increased efficacy and decreased outcome variability.

Limitations of the study

The present study has a few limitations also. First, the study results may have reflected the experience of one practitioner, which may have limited the generalizability of the study findings. Second, the long-term effects should be evaluated in the future based on the results of the short-term effects. In our study, we followed patients for 6 months but trials could focus on long-term outcomes up to 1 year after the interventions. Third, this study was not conducted as a double-blind controlled study as it is very difficult to conduct a double-blind controlled study with fluoroscope-like non-traditional modalities.

CONCLUSION

All three techniques of lumbar ESI, that is, CESI, ILESI, and TFESI are safe and effective techniques for the management of patients with LSS. All three techniques provide good pain relief and improvement in disability to the patients. TFESI is better than CESI and ILESI in terms of improvement in pain score, treatment outcome, and functional disability.

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Compliance with ethical standards:
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