RESEARCH PAPER

EFFICACY OF INTERLAMINAR EPIDURAL INJECTION OF ROPIVAICAINE WITH OR WITHOUT STEROID FOR LOW BACK PAIN DUE TO LUMBAR CANAL STENOSIS: A PROSPECTIVE, RANDOMIZED, DOUBLE BLIND STUDY

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ABSTRACT

Background: Lumbar canal stenosis (LCS) is a common cause of chronic low back pain and disability. Interlaminar epidural injections of local anaesthetics are widely used for symptomatic management; however, the added benefit of corticosteroids remains controversial.

Objective: To compare the efficacy and safety of interlaminar epidural injection using Ropivacaine with and without corticosteroid in patients with lumbar canal stenosis.

Methods: This prospective, randomized, double-blind study was conducted on 90 patients diagnosed with lumbar canal stenosis. Participants were randomly allocated into two groups (n=45 each): Group T received ropivacaine (0.2%) with triamcinolone (40 mg), and Group N received ropivacaine (0.2%) with normal saline. Pain intensity (VAS), functional status (Revised Oswestry Disability Index), and walking distance were assessed at baseline, immediately after the procedure, and at 1 day, 15 days, 1 month, 3 months, and 6 months. Secondary outcomes included percentage reduction in VAS, requirement of repeat injections, need for surgery, and incidence of adverse events.

Results: Both groups demonstrated significant improvement in pain and functional outcomes. The non-steroid group showed better short-term pain relief at 1 month ($p=0.034$), while the steroid group demonstrated significantly better pain relief at 3 and 6 months ($p<0.001$ and $p=0.047$). ODI scores were significantly lower in the non-steroid group at 3 and 6 months ($p=0.031$ and $p<0.001$). Walking distance improved significantly in both groups but was consistently greater in the steroid group from day 15 onwards ($p<0.001$). A higher proportion of patients in the steroid group achieved ≥50% and ≥75% pain reduction at 3 months. Repeat injections and surgical interventions were more frequent in the non-steroid group. Both groups had minimal and comparable adverse events.

Conclusion: Interlaminar epidural injections of ropivacaine with or without corticosteroids are effective in managing pain due to lumbar canal stenosis. While ropivacaine alone provides comparable short-term relief and functional improvement, the addition of corticosteroids offers superior long-term pain control and functional mobility with a favorable safety profile.

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KEYWORDS: Lumbar canal stenosis; Epidural injection; Corticosteroids; Ropivacaine; Pain management; Oswestry Disability Index; Randomized controlled trial

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INTRODUCTION

Low back pain (LBP) is a major global health concern and a leading cause of disability, particularly among individuals in the productive age group. Epidemiological studies suggest that nearly 80% of adults experience at least one significant episode of LBP during their lifetime, highlighting its widespread and recurrent nature. The burden of LBP extends beyond physical discomfort, contributing significantly to reduced quality of life, increased healthcare utilization, work absenteeism, and substantial socioeconomic loss [1]. Among the various etiologies of LBP, lumbar canal stenosis (LCS) is one of the most common and debilitating conditions, especially in the elderly population.

Lumbar canal stenosis is characterized by a narrowing of the spinal canal, leading to compression of neural elements including the cauda equina and nerve roots. This narrowing is usually the result of degenerative changes such as intervertebral disc bulging, hypertrophy of facet joints, thickening of the ligamentum flavum, and osteophyte formation. These structural alterations are often age-related but may also be influenced by genetic predisposition, mechanical stress, and lifestyle factors [2]. Clinically, LCS presents with symptoms such as chronic low back pain, radiculopathy, paresthesia, lower limb weakness, and neurogenic claudication, which typically worsens with standing or walking and improves with spinal flexion [2].

The management of lumbar canal stenosis follows a stepwise approach, beginning with conservative modalities such as pharmacotherapy, physiotherapy, and lifestyle modifications. Pharmacological treatment typically includes non-steroidal anti-inflammatory drugs (NSAIDs), muscle relaxants, and neuroleptic agents. However, a considerable proportion of patients fail to achieve adequate symptom relief with conservative measures alone. In such cases, interventional pain management techniques, particularly epidural injections, are commonly employed as an intermediate therapeutic option before considering surgical intervention [3].

Epidural steroid injections (ESIs) have been widely used for decades due to their potent anti-inflammatory effects, which help reduce nerve root irritation and alleviate pain. Corticosteroids such as triamcinolone act by inhibiting inflammatory mediators and decreasing edema around neural structures, thereby improving symptoms of pain and functional disability. Evidence from systematic reviews and meta-analyses suggests that ESIs can provide modest but clinically meaningful short- and long-term improvements in pain, functional status, and walking capacity in patients with lumbar canal stenosis [4]. However, despite their widespread use, concerns have been raised regarding the potential adverse effects associated with corticosteroids, particularly with repeated administration. These include adrenal suppression, hyperglycemia, increased susceptibility to infections, osteoporosis, myopathy, and other systemic complications, which are especially relevant in elderly patients with multiple comorbidities [5,6].

In view of these concerns, there has been growing interest in exploring alternative epidural injection strategies that avoid the use of corticosteroids. Interlaminar epidural injection (ILEI) using local anesthetics alone has emerged as a potential option. Local anesthetics exert their effect by blocking sodium channels and interrupting nociceptive signal transmission. While their analgesic action is typically immediate but short-lived, emerging evidence suggests that repeated administration may modulate central sensitization and disrupt chronic pain pathways, potentially leading to sustained clinical benefit [7].

Several studies have reported promising outcomes with epidural injections using local anesthetics alone, demonstrating comparable improvements in pain relief and functional outcomes when compared to steroid-containing regimens. However, the existing literature is limited by methodological heterogeneity, small sample sizes, lack of standardized protocols, and insufficient follow-up durations. Furthermore, many studies lack rigorous randomized and double-blind designs, thereby limiting the strength and generalizability of their conclusions [7].

Given these gaps in evidence, there is a need for well-designed randomized controlled trials to directly compare the efficacy and safety of interlaminar epidural injections of ropivaicaine with and without corticosteroids in patients with lumbar canal stenosis. Such evidence is crucial for guiding clinical decision-making and optimizing patient outcomes while minimizing potential risks.

Therefore, the present study was undertaken as a prospective, randomized, double-blind trial to evaluate and compare the therapeutic efficacy, functional outcomes, and safety profile of interlaminar epidural

injections of ropivaicaine administered with and without corticosteroids in patients suffering from low back pain due to lumbar canal stenosis.

MATERIALS AND METHODS

Study Design and Setting: This study was designed as a prospective, randomized, double-blind clinical trial conducted at the Department of Anaesthesiology and Pain Medicine, Geetanjali Medical College and Hospital (GMCH), Udaipur, Rajasthan, India, over a period of one year from July 2024 to June 2025. Ethical clearance was obtained from the Institutional Human Research Ethics Committee (HREC No.: GU/HREC/EC/2023/2212), and the trial was registered with the Clinical Trials Registry of India (CTRI/2024/06/069051). Written informed consent was obtained from all participants prior to enrolment.

Study Population: Patients presenting to the pain clinic with chronic low back pain secondary to lumbar canal stenosis were screened for eligibility.

Inclusion Criteria

- Patients aged 18–70 years of either sex
- Chronic low back pain attributed to lumbar canal stenosis confirmed by MRI
- Willingness to participate and provide informed consent

Exclusion Criteria

- Contraindications to epidural procedures (infection, coagulopathy, anticoagulant therapy)
- Known hypersensitivity to study drugs or contrast agents
- History of prior lumbar spine surgery
- Low back pain due to prolapsed intervertebral disc (PIVD)
- Uncontrolled hypertension or uncontrolled type 2 diabetes mellitus

Sample Size Calculation: The sample size was calculated using Epi Info™ 7 software, assuming a confidence level of 95% ($\alpha = 0.05$) and power of 80% ($\beta = 0.20$). Based on a standard deviation of 2.4 and an expected mean difference of 1.5 in Visual Analogue Scale (VAS) scores at 1 month, the calculated sample size was 40 patients per group. Considering a 10% attrition rate, a total of 90 patients were enrolled, with 45 patients in each group.

Randomization and Blinding: Participants were randomly allocated into two groups using a computer-generated randomization sequence:

- **Group T (Steroid group):** Ropivacaine (0.2%) 5 mL + Triamcinolone 40 mg (1 mL)
- **Group N (Non-steroid group):** Ropivacaine (0.2%) 5 mL + Normal saline (0.9%) 1 mL

Double blinding was ensured by having the study drugs prepared by an independent anaesthesiologist not involved in patient management or outcome assessment. Both the patients and the investigators conducting follow-up assessments were blinded to group allocation.

Pre-procedural Assessment: All patients underwent a detailed pre-anaesthetic evaluation. Baseline demographic data and clinical characteristics were recorded. Pain intensity was assessed using the Visual Analogue Scale (VAS), functional disability using the Revised Oswestry Disability Index (ODI), and functional capacity by measuring walking distance (in meters). Patients were educated regarding these assessment tools prior to the procedure.

Intervention Procedure: All procedures were performed in the operating room under strict aseptic precautions. Baseline vital parameters including heart rate, blood pressure, respiratory rate, and oxygen saturation were recorded. A wide-bore intravenous cannula was secured, and intravenous fluids were initiated. Patients were positioned prone with lumbar flexion. After skin preparation and draping, local infiltration with 1% lignocaine was administered. The interlaminar epidural space was identified using an 18G Tuohy needle via the loss-of-resistance technique under fluoroscopic guidance. Correct needle placement was confirmed by injection of 1 mL of non-ionic contrast (Iohexol and omnipaque) demonstrating appropriate epidural spread and ruleout vascular or subarachnoid entry. Following confirmation, the study drug was injected according to group allocation.

Post-procedural Monitoring: Patients were observed in the post-anaesthesia care unit for four hours. Vital parameters were continuously monitored, and any immediate complications such as hypotension, bradycardia, nausea, vomiting, or allergic reactions were recorded and managed accordingly.

Follow-up and Outcome Measures: Patients were followed up through outpatient visits and telephonic communication. Assessments were conducted at baseline, immediately post-procedure, 24 hours, day 15, and at 1, 3, and 6 months.

Primary Outcomes

- Pain intensity measured using VAS at 1, 3, and 6 months
- Improvement of Functional status assessed using revised ODI (Oswestry Disability Index) and walking distance at 1,3 and 6 months

Secondary Outcomes

- Proportion of patients achieving ≥50% reduction in VAS score
- Requirement of repeat epidural injections
- Incidence of adverse events (e.g., post-dural puncture headache, hypotension, bradycardia, vasovagal episodes, intrathecal or

intravascular injection, allergic reactions, Nausea, vomitting)

Data Collection: Data collected included demographic variables (age, sex, height, weight), clinical parameters (duration of pain, baseline VAS, ODI, walking distance), procedural details, and follow-up outcomes.

Statistical Analysis: Data were entered into Microsoft Excel and analyzed using IBM SPSS Statistics version 21. Continuous variables were expressed as mean ± standard deviation, while categorical variables were presented as frequencies and percentages. Intergroup comparisons of continuous variables were performed using the Student's t-test, and categorical variables were analyzed using the Chi-square test. A p-value <0.05 was considered statistically significant, and p <0.001 was considered highly significant.

RESULTS

A total of 90 patients were randomized into two groups: Group T (Steroid, n=45) and Group N (Non-steroid, n=45). All participants completed the study and were included in the final analysis.Both groups were comparable in demographic, clinical, and radiological parameters (p>0.05) (Table 1).

Table 1: Baseline Demographic, Clinical, and Radiological Characteristics

Variable	Group T (n=45)	Group N (n=45)	p-value
Age (years)	62.62 ± 11.40	63.30 ± 10.50	0.861
Gender (Male:Female)	25:20	29:16	0.371
Weight (kg)	73.06 ± 12.80	73.75 ± 14.17	0.964
Height (cm)	166.70 ± 9.92	166.95 ± 11.23	0.732
Duration of pain (months)	6.66 ± 3.44	6.73 ± 3.53	0.924
VAS score (baseline)	8.26 ± 1.14	8.59 ± 0.66	0.096
ODI score (baseline)	34.71 ± 3.71	34.61 ± 3.91	0.901
Walking distance (m, baseline)	131.00 ± 39.97	116.09 ± 37.75	0.072
Level of stenosis			0.150
L3–L4	20 (44.44%)	13 (28.89%)	
L4–L5	8 (17.78%)	15 (33.33%)	
L5–S1	17 (37.78%)	17 (37.78%)	
Grade of stenosis			0.670
Mild	17 (37.78%)	21 (46.67%)	
Moderate	12 (26.67%)	11 (24.44%)	
Severe	16 (35.56%)	13 (28.89%)	

Significant pain reduction was observed in both groups. The non-steroid group showed better relief at 1 month (p=0.034), whereas the steroid group demonstrated superior outcomes at 3 and 6 months (p<0.001 and p=0.047). Percentage reduction in VAS was comparable throughout (Table 2).

Table 2: Comparison of VAS Scores and Percentage Reduction Over Time

Time Point	Group T (Mean ± SD)	Group N (Mean ± SD)	p-value	% Reduction T	% Reduction N	p-value
Baseline	8.26 ± 1.14	8.59 ± 0.66	0.096	—	—	—
Immediate	1.40 ± 0.49	1.20 ± 0.49	0.056	82.65 ± 6.68	83.49 ± 6.25	0.539
Day 1	1.30 ± 0.50	1.55 ± 0.50	0.636	82.32 ± 6.82	82.93 ± 6.34	0.661
Day 15	1.70 ± 0.70	1.81 ± 0.63	0.138	79.38 ± 9.11	79.95 ± 7.43	0.745
1 Month	2.50 ± 0.70	2.20 ± 0.62	**0.034***	69.60 ± 9.83	70.77 ± 7.45	0.540
3 Months	3.00 ± 0.80	3.80 ± 0.76	**<0.001***	63.16 ± 11.36	60.78 ± 8.81	0.286
6 Months	3.64 ± 0.72	3.98 ± 0.88	**0.047***	55.14 ± 10.43	54.10 ± 9.90	0.640

Both groups improved significantly. ODI scores were lower in the non-steroid group at 3 and 6 months (p=0.031, p<0.001), while walking distance was consistently higher in the steroid group from day 15 onwards (p<0.001) (Table 3).

Table 3: Comparison of Functional Outcomes (ODI and Walking Distance)

Time Point	ODI (Group T)	ODI (Group N)	p-value	Walking Distance T (m)	Walking Distance N (m)	p-value
Baseline	34.71 ± 3.71	34.61 ± 3.91	0.901	324.15 ± 19.14	322.71 ± 11.81	0.660
Immediate	36.33 ± 3.79	35.90 ± 3.97	0.011	—	—	—
Day 1	36.33 ± 3.79	35.90 ± 3.97	0.326	330.60 ± 19.52	329.16 ± 12.04	0.670
Day 15	29.00 ± 3.00	29.90 ± 3.19	0.477	518.60 ± 30.61	493.74 ± 18.06	<0.001
1 Month	23.70 ± 3.67	24.95 ± 3.37	0.092	551.06 ± 32.53	523.47 ± 19.48	<0.001
3 Months	20.00 ± 2.70	18.85 ± 2.27	0.031	551.27 ± 32.51	516.33 ± 18.89	<0.001
6 Months	22.00 ± 3.00	17.23 ± 3.58	<0.001	502.44 ± 29.66	484.06 ± 17.71	<0.001

A greater proportion of patients in the steroid group achieved ≥50% and ≥75% pain relief at 3 months (p=0.05, p=0.001). Differences at 6 months were not statistically significant (Table 4).

Table 4: Clinical Efficacy (≥50% and ≥75% Pain Reduction) and Need for Interventions

Outcome	Group T	Group N	p-value
≥50% VAS reduction (3 months)	40 (88.9%)	29 (64.4%)	0.05
≥50% VAS reduction (6 months)	33 (73.3%)	26 (57.8%)	0.16
≥75% VAS reduction (3 months)	9 (20.0%)	2 (4.4%)	0.001
≥75% VAS reduction (6 months)	0	0	NA
Repeat injections (6 months)	2 (4.4%)	5 (11.1%)	—
Surgical intervention (6 months)	1 (2.2%)	3 (6.7%)	—

Repeat injections and surgical interventions were more frequent in the non-steroid group. Both groups had minimal and comparable complications (Tables 4 & 5).

Table 5: Comparison of Post-Procedural Complications

Complication	Group T (n=45)	Group N (n=45)
PDPH	0	0
Hypotension	1 (2.22%)	2 (4.44%)
Bradycardia	1 (2.22%)	2 (4.44%)
Nausea/Vomiting	1 (2.22%)	3 (6.67%)
Vasovagal reaction	1 (2.22%)	1 (2.22%)
Intrathecal injection	0	0
Intravascular injection	0	0
Allergic reactions	0	0

Both interventions were effective. The non-steroid group showed better short-term relief, while the steroid group provided superior long-term outcomes.

DISCUSSION

Lumbar canal stenosis (LCS) is a common cause of chronic low back pain and radiculopathy, resulting from degenerative changes such as ligamentum flavum hypertrophy, facet joint enlargement, and disc bulging, leading to neural compression. Importantly, symptom severity does not always correlate with the degree of anatomical narrowing, reflecting the complex pathophysiology of the disease [8-9].

Management of LCS typically begins with conservative therapy; however, patients who fail to respond often require interventional procedures or surgery. Epidural injections have emerged as an effective minimally invasive alternative, particularly in elderly patients with comorbidities, as they avoid

surgical risks while providing symptomatic relief [10-12]. Nevertheless, the role of corticosteroids in epidural injections remains controversial, with ongoing debate regarding their long-term efficacy and safety [13].

In the present prospective, randomized, double-blind study, both groups were comparable in baseline demographic and clinical parameters, consistent with previous studies [6,14-16]. The distribution of stenosis level and severity was also similar between groups, minimizing confounding and ensuring internal validity. The relatively shorter duration of symptoms observed in our study compared to others [14,16] may reflect earlier clinical presentation or differences in treatment-seeking behavior.

Pain relief, assessed using VAS, showed significant improvement in both groups immediately after the procedure, highlighting the effectiveness of interlaminar epidural injections irrespective of steroid use. Early pain relief (up to 1 month) was comparable between groups, suggesting that local anaesthetic plays a primary role in immediate analgesia. However, beyond 1 month, the steroid group demonstrated significantly better sustained pain relief, particularly at 3 and 6 months. This delayed but prolonged effect can be attributed to the anti-inflammatory properties of corticosteroids, which reduce neural edema and cytokine-mediated irritation.

These findings are consistent with studies by Manchikanti et al. [14] and Do KH et al. [17], which reported superior long-term pain control with steroid-based epidural injections. Similarly, Benyamin et al. [15] highlighted the intermediate-term benefits of steroids in lumbar stenosis. In contrast, Friedly et al. [6] observed only transient benefits, suggesting that patient selection and disease severity may influence outcomes. The higher proportion of patients achieving ≥50% and ≥75% pain relief in the steroid group in our study further reinforces the clinical relevance of steroid use in achieving meaningful analgesia.

Functional outcomes, assessed by ODI, showed improvement in both groups; however, the non-steroid group demonstrated significantly better scores at 3 and 6 months. This finding is intriguing and suggests that functional recovery may not be solely dependent on pain reduction. Similar observations have been reported in previous studies [6,18], where functional improvements did not consistently correlate with steroid use. Possible explanations include neural adaptation, rehabilitation effects, and modulation of central sensitization by local anaesthetics.

In contrast, walking distance—a key indicator of functional mobility—improved significantly in both groups but was consistently higher in the steroid group from day 15 onwards. These findings suggest that while subjective disability (ODI) may improve independently, objective functional capacity benefits more from the addition of steroids. Comparable improvements in walking capacity have been reported in studies by Kim et al. [18] and Do KH et al. [17], particularly in patients with moderate stenosis. However, Friedly et al. [6] reported minimal functional gains, highlighting variability across populations.

The requirement for repeat injections was low in both groups but slightly higher in the non-steroid group, suggesting a shorter duration of effect. This is in line with findings by Manchikanti et al. [14,19], who reported repeated injections over long-term follow-up to maintain symptom control. Similarly, the need for surgical intervention was lower in the steroid group, indicating that epidural injections may delay or reduce the need for surgery, as supported by previous literature [12,16].

Both interventions demonstrated a favorable safety profile, with only minor and transient adverse events reported. No major complications such as dural puncture or neurological injury were observed. These findings are consistent with prior studies [15-17,20], which report low complication rates with fluoroscopy-guided epidural injections. Although some studies have reported higher systemic side effects with steroids [6], such effects were not observed in our cohort, likely due to careful patient selection and dosing.

Overall, the findings of this study suggest that while both steroid and non-steroid interlaminar epidural injections are effective in the short term, the addition of corticosteroids provides superior long-term pain relief and functional mobility. However, local anaesthetic (ropivacaine) alone remains a viable alternative, particularly in patients where steroid use is contraindicated.

CONCLUSION

This prospective, randomized, double-blind study demonstrates that interlaminar epidural injection using ropivacaine, with or without corticosteroid, is effective in reducing pain and improving functional outcomes in patients with lumbar canal stenosis. Both treatment groups showed significant improvement in VAS scores, revised ODI, and walking distance over the study period. The non-steroid group provided comparable short-term pain relief and demonstrated better improvement in disability scores at later follow-ups. However, the addition of corticosteroid resulted in superior and sustained pain relief at 3 and 6 months, along with greater improvement in walking capacity and reduced need for repeat interventions and surgical management. Both techniques were safe, with minimal and comparable adverse events. These findings suggest that while Ropivacaine alone is a viable alternative, particularly in patients with contraindications to steroids, the addition of corticosteroid offers significant long-term clinical benefits in the management of lumbar canal stenosis.

DECLARATIONS

Ethical Approval and Consent to Participate: The study was approved by the Institutional Human Research Ethics Committee (GU/HREC/EC/2023/2212). Written informed consent was obtained from all participants.

Trial Registration: Registered with Clinical Trials Registry of India (CTRI/2024/06/069051).

Consent for Publication: Not applicable.

Availability of Data and Materials: Data available from the corresponding author on reasonable request.

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Conflict of Interest: The authors declare no conflict of interest.

Authors ' Contributions: All authors contributed to study design, data collection, analysis, and manuscript preparation. All authors approved the final manuscript.

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