

# Effectiveness of Epidural Methylprednisolone Injection in Management of Lumbar Prolapsed Intervertebral Disc: A Comparison of Caudal, Transforaminal and Interlaminar Routes

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## Learning Point of the Article:

- Epidural steroid injections are effective in reducing pain and disability in lumbar disc herniation.
- The transforaminal route gives the best results by directly targeting the affected nerve root.
- Route selection should be based on patient factors and safety considerations, with fluoroscopy improving accuracy.

## Abstract

**Introduction:** Lumbar prolapsed intervertebral disc (PIVD) is a prevalent cause of radicular pain and functional impairment. Epidural steroid injections are an established non-surgical treatment option. This study compares the efficacy of caudal, transforaminal, and interlaminar routes for methylprednisolone delivery.

**Objectives:** To evaluate and compare the analgesic and functional outcomes of different ESI routes in managing lumbar PIVD.

**Materials and Methods:** In this prospective, randomized study, 75 patients aged 25–75 years with magnetic resonance imaging -confirmed single-level PIVD and refractory symptoms were allocated to one of three intervention groups: Caudal, transforaminal, or interlaminar ESI (n = 25 each). All patients received methylprednisolone acetate injections under fluoroscopic guidance. Pain and function were assessed using the Visual Analog Scale (VAS) and Oswestry Disability Index (ODI) at baseline, 1, 2, and 4 weeks, and at 3 months post-intervention.

**Results:** All groups showed significant reductions in VAS and ODI scores over time ( $P < 0.001$ ). At 3 months, the transforaminal group had the greatest improvement (VAS:  $0.72 \pm 1.1$ ; ODI:  $2.92 \pm 4.61$ ), followed by caudal and interlaminar routes. Analysis of variance and post hoc analysis confirmed the superiority of the transforaminal approach ( $P < 0.001$ ).

**Conclusion:** Transforaminal ESI with methylprednisolone provides superior pain relief and functional recovery compared to caudal and interlaminar routes. Route selection should consider anatomical precision and patient-specific factors.

**Keywords:** Lumbar disc prolapse, epidural steroid injection, methylprednisolone, caudal, transforaminal, interlaminar, radiculopathy, Visual Analog Scale, Oswestry Disability Index, fluoroscopy.

## Introduction

Low back pain (LBP) remains a leading cause of disability worldwide and is particularly prevalent in India due to sedentary lifestyles and limited access to early interventions [1]. Lumbar disc herniation is a common etiology of LBP, where the nucleus

pulposus protrudes through the annulus fibrosus, compressing spinal nerve roots and resulting in radiculopathy, pain, and neurological deficits [2, 3].

Non-surgical interventions, including non-steroidal anti-inflammatory drugs, physiotherapy, and muscle relaxants, are

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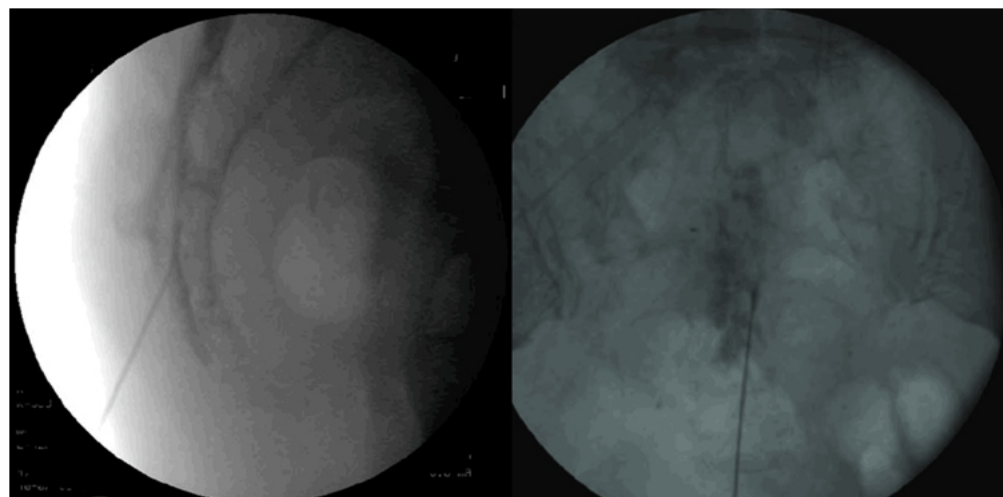
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**Figure 1:** Needle positioning of caudal injection in anteroposterior view and lateral view.

often used but can be inadequate for persistent cases [4, 5, 6]. Epidural steroid injections (ESIs) offer targeted anti-inflammatory action to reduce pain and disability. Methylprednisolone is commonly used due to its efficacy and safety profile [7, 8, 9].

The route of administration – caudal, transforaminal, or interlaminar – plays a crucial role in clinical outcomes. Caudal ESI is technically simple with fewer risks but provides diffuse medication spread [10, 11]. Transforaminal injections target the affected nerve root directly, leading to faster relief but with a higher risk profile [12, 13]. Interlaminar ESI allows posterior epidural access near the affected disc level, balancing safety and efficacy [14].

This study compares these three approaches in patients with single-level lumbar prolapsed intervertebral disc (PIVD) who failed conservative therapy, with outcomes assessed using the

Visual Analog Scale (VAS) and Oswestry Disability Index (ODI).

### Materials and Methods

This prospective, randomized clinical study was conducted in the Department of Orthopaedics at SGT Medical College and Hospital, Budhera, Gurgaon. Institutional Ethical Committee approval was obtained (IEC/FMHS/MD/MS/2023–31), and informed consent was secured from all participants.

### Study design and participants

A total of 75 patients, aged 25–75 years, diagnosed with magnetic resonance imaging (MRI)-confirmed single-level lumbar PIVD, and refractory to at least 6 weeks of conservative treatment, were enrolled. Using IBM Statistical Package for the Social Sciences (SPSS) v23, participants were randomized equally into three intervention groups of 25 each.

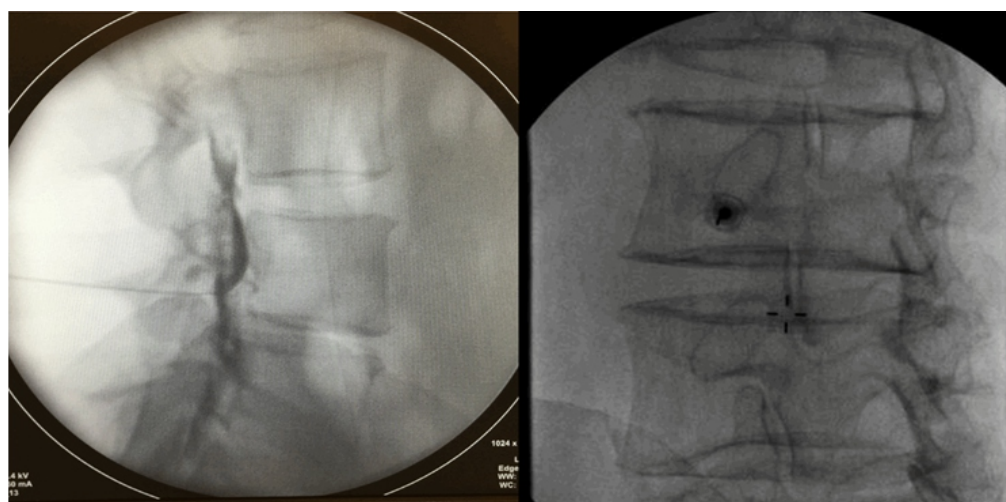
### Inclusion criteria

- Patients aged 18–75 years old
- Diagnosis of single disc herniation (protrusion and extrusion) through MRI
- Failure of at least 6 weeks of conservative treatment

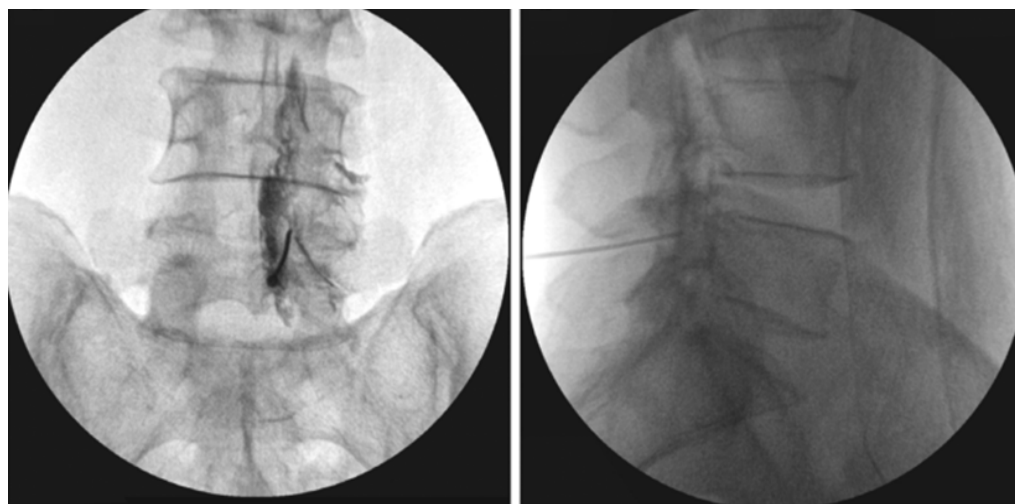
- Previously diagnosed as PIVD
- No past history of lumbar surgery.

### Exclusion criteria

- Migrated or sequestered herniation on imaging
- Diagnosis of multiple-level disc herniation through MRI
- Motor deficit
- Cauda Equina Syndrome
- Segmental instability
- Spinal canal stenosis
- Medical problems that



**Figure 2:** Needle positioning of transforaminal injection in anteroposterior view and lateral view.



lignocaine was administered for local anesthesia at the puncture site. Using an 18G lumbar puncture needle with a stylet, the needle was inserted at an angle of approximately 30° into the sacral hiatus. The needle was carefully advanced into the sacral canal under continuous fluoroscopic guidance, ensuring its tip was correctly positioned without penetrating the dura mater. Once the position was confirmed with anteroposterior (AP) and lateral fluoroscopic views, a test

**Figure 3:** Needle positioning of interlaminar injection in anteroposterior view and lateral view.

contraindicate the procedure

- History of allergic reaction to local anesthetics or corticosteroids
- Psychogenic disorders, tumors, malformation deformities, post-traumatic root compression, or infectious etiologies.

The injection procedure was tailored based on the route of administration: Caudal, interlaminar, or transforaminal. Each technique was performed under sterile conditions with fluoroscopic guidance to ensure accurate needle placement and delivery of the medication.

### Caudal epidural injection

For the caudal route, patients were positioned prone on the procedure table with a pillow placed under their abdomen to reduce lumbar lordosis. The sacral cornua were identified through palpation, and the skin overlying the sacral hiatus was cleaned thoroughly with povidone-iodine and alcohol-based solutions. Sterile draping was applied. A 1 mL injection of 2%

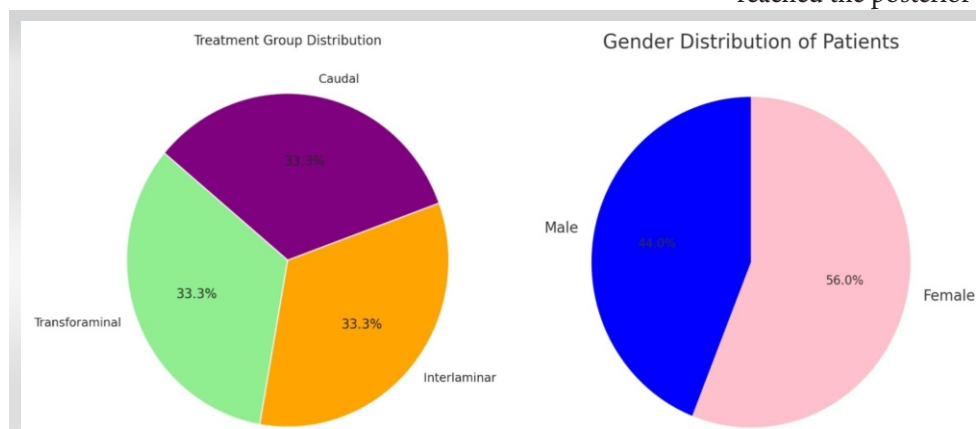
injection of contrast dye (1–2 mL) was administered to confirm epidural spread and rule out intravascular or intrathecal placement. The therapeutic injection comprised a mixture of 6 mL of normal saline, 2 mL of 2% xylocaine, and 80 mg (2 mL) of methylprednisolone acetate (Fig. 1).

### Transforaminal epidural injection

For the transforaminal route, patients were positioned prone on a radiolucent table, and the area was cleaned with povidone-iodine and alcohol, followed by sterile draping. The affected nerve root level was identified using fluoroscopy. Under oblique fluoroscopic guidance, the needle insertion site was marked at the eye of the “Scotty dog,” corresponding to the target neural foramen. After administering 1 mL of 2% lignocaine for local anesthesia, a 22G spinal needle was inserted at a 30–45° angle toward the foramen. The needle was advanced under continuous fluoroscopic guidance, with adjustments made using both oblique and lateral views. Once the needle tip reached the posterior aspect of the foramen, a test injection of

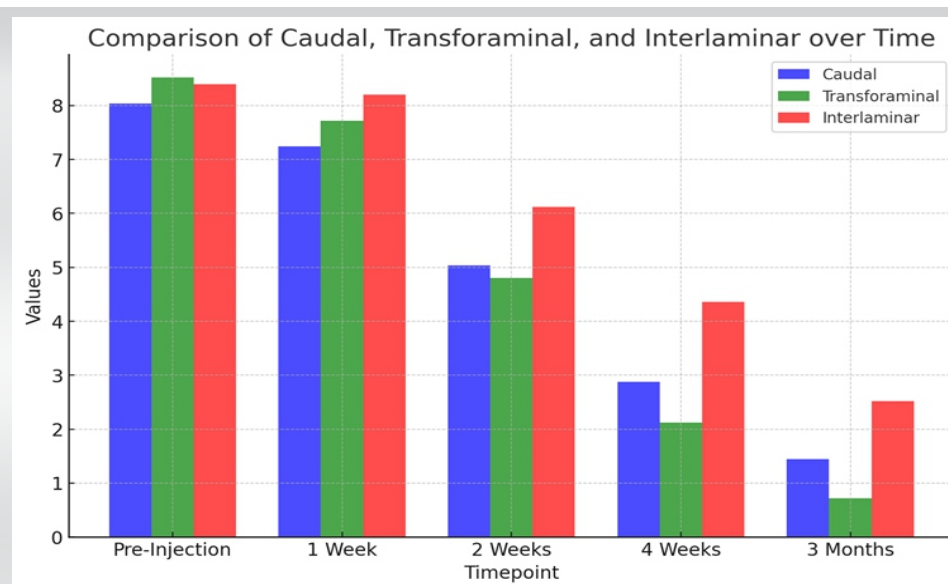
0.5–1 mL of contrast dye was administered to confirm proper epidural spread and avoid intravascular placement. The therapeutic injection consisted of 1 mL of 2% xylocaine and 1 mL (40 mg) of methylprednisolone acetate (Fig. 2).

The rationale for using 40 mg of methylprednisolone acetate instead of 80 mg, as administered in caudal or interlaminar epidural injections, is based on the precision and localized



**Figure 4:** Demographic summary.





**Figure 5:** Graphic representation of Visual Analog Scale score over time.

nature of the transforaminal technique. Since transforaminal injections target the nerve root directly within the neural foramen, a lower dose is sufficient to achieve therapeutic effects at the site of inflammation while minimizing systemic exposure. In addition, the lower dose reduces the risk of complications, such as chemical irritation or vascular compromise, which are more significant in this route due to its proximity to segmental arteries. This dose adjustment is further supported by evidence demonstrating that 40 mg is effective for localized radicular pain without added benefit from higher doses in the transforaminal approach.

### Interlaminar epidural injection

For the interlaminar route, patients were positioned prone on the procedure table with a pillow under the abdomen. The spinous processes of the lumbar vertebrae were palpated, and the specific interlaminar space for the injection was identified. After the area was cleaned and draped, 2% lignocaine (1 mL) was injected locally for anesthesia. Using an 18G or 20G spinal needle, the needle was inserted into the midline of the selected interlaminar space at a slight upward angle. The needle was advanced through the skin, subcutaneous tissue, supraspinous ligament, interspinous ligament, and ligamentum flavum until a loss of resistance was felt, indicating entry into the epidural space. Fluoroscopic guidance in AP and lateral views confirmed correct needle placement. A test dose of contrast dye was injected to ensure epidural placement and rule out intravascular or subarachnoid injection. The injection contained 4 mL of 2% xylocaine and 2 mL (80 mg) of methylprednisolone acetate (Fig.3).

### Post-procedure assessment and monitoring

Following each procedure, patients were monitored in the day care ward for at least 4–6 h post-procedure. Vital signs were checked regularly, and patients were observed for any immediate complications, such as nausea, dizziness, vasovagal reactions, and headache. Post-procedure follow-up was scheduled at 1, 2, and 4 weeks, as well as 3 months, to assess the efficacy of the intervention using validated tools, such as the ODI, and VAS.

### Statistical analysis

Data were compiled in Microsoft Excel and analyzed using SPSS v23.

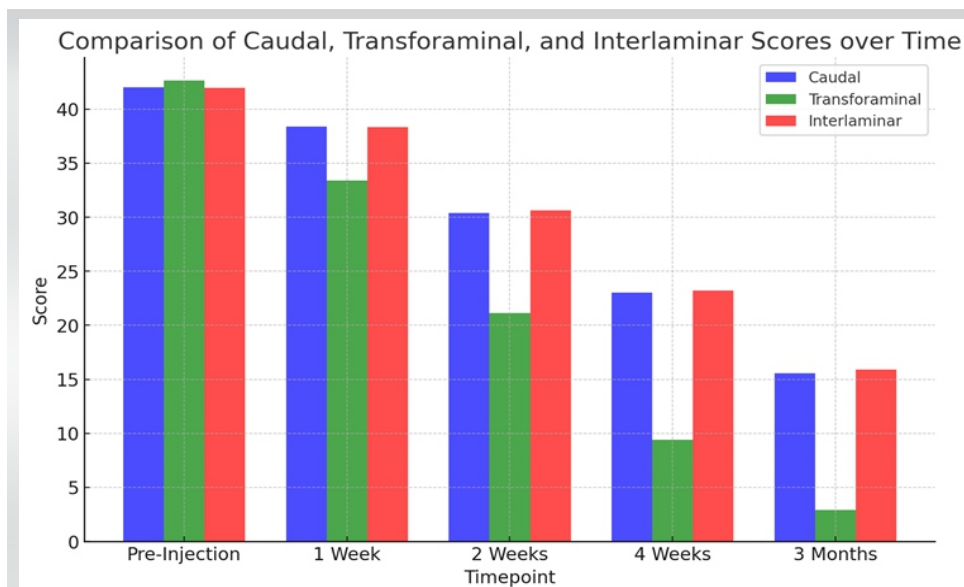
- Analysis of variance (ANOVA) was used to compare group means
- Tukey's HSD post hoc test identified intergroup significance
- $P < 0.05$  was considered statistically significant.

### Results

This prospective randomized study included 75 patients diagnosed with single-level lumbar disc herniation who did not respond to conservative treatment for at least 6 weeks. The patients were randomized into three groups of 25 individuals each, receiving a single 80 mg dose of methylprednisolone acetate through one of the three common epidural routes – caudal, transforaminal, or interlaminar. The groups were compared with respect to pain relief and functional recovery, as assessed by the VAS and ODI at baseline and during follow-up at 1 week, 2 weeks, 4 weeks, and 3 months.

The demographic distribution across the three groups was comparable. Of the 75 patients, 42 were females (56%) and 33 were males (44%). Gender distribution was relatively balanced across groups, with 15 females and 10 males in the caudal group, 16 females and 9 males in the transforaminal group, and 11 females and 14 males in the interlaminar group. Chi-square analysis showed no statistically significant difference in gender distribution among the groups ( $P = 0.321$ ). Similarly, age distribution was statistically equivalent. The overall mean age was  $49.3 \pm 14.4$  years, with age ranges spanning from 25 to 75 years. The mean ages of the caudal, transforaminal, and interlaminar groups were 47.7, 47.1, and 53.1 years, respectively. ANOVA yielded no statistically significant difference in age between the groups ( $P = 0.312$ ), thus





**Figure 6:** Graphic representation of Oswestry Disability Index score over time.

(Table 2 and Fig. 6).

- The pre-injection scores were  $42 \pm 5.276$ ,  $42.64 \pm 5.114$ , and  $41.96 \pm 4.886$
- At 1 week, the scores were  $38.36 \pm 9.278$ ,  $33.4 \pm 8.822$ , and  $38.32 \pm 9.873$
- At 2 weeks, the scores were  $30.4 \pm 9.937$ ,  $21.12 \pm 9.563$ , and  $30.64 \pm 10.02$
- At 4 weeks, the values were  $23.04 \pm 9.347$ ,  $9.4 \pm 8.884$ , and  $23.24 \pm 10.101$
- At 3 months, the scores were  $15.56 \pm 9.496$ ,  $2.92 \pm 4.609$ , and  $15.88 \pm 10.199$ .

At the 3-month follow-up, pain relief peaked across all groups. Mean VAS scores were  $1.44 \pm 1.58$  for the caudal group,  $0.72 \pm 1.10$  for the transforaminal group, and  $2.52 \pm 1.89$  for the interlaminar group. ANOVA

confirming demographic comparability (Fig. 4).

### Visual analog scale (VAS) scores

The mean pre-injection visual analog scale (VAS) scores for all three injection routes indicate severe pain levels: Caudal ( $8.04 \pm 1.136$ ), Transforaminal ( $8.52 \pm 1.194$ ), and Interlaminar ( $8.4 \pm 1.155$ ). These values suggest that all patients had significant baseline pain before intervention.

Table 1 presents the visual analog scale (VAS) pain scores at different time points for three injection techniques: Caudal, Transforaminal, and Interlaminar (Table 1 and Fig. 5).

- Pre-injection VAS scores were  $8.04 \pm 1.136$ ,  $8.52 \pm 1.194$ , and  $8.4 \pm 1.155$
- In 1 week, the scores were  $7.24 \pm 1.899$ ,  $7.72 \pm 1.595$ , and  $8.2 \pm 1.607$
- For 2 weeks, the scores were  $5.04 \pm 2.263$ ,  $4.8 \pm 1.803$ , and  $6.12 \pm 1.787$
- In 4 weeks, the VAS scores were  $2.88 \pm 2.166$ ,  $2.12 \pm 1.9$ , and  $4.36 \pm 1.777$
- For 3 months, the scores were  $1.44 \pm 1.583$ ,  $0.72 \pm 1.1$ , and  $2.52 \pm 1.896$ .

### ODI scores

The mean ODI scores before injection were comparable across all three groups, with Caudal ( $42 \pm 5.276$ ), Transforaminal ( $42.64 \pm 5.114$ ), and Interlaminar ( $41.96 \pm 4.886$ ), indicating a similar baseline level of disability due to pain.

Table 2 presents the scores at different time points for three injection techniques: Caudal, Transforaminal, and Interlaminar

analysis yielded an F value of 8.42 with  $P < 0.001$ , confirming a statistically significant difference among groups. Post hoc Tukey's test showed that the transforaminal route was significantly more effective than the interlaminar route ( $P < 0.001$ ). The difference between transforaminal and caudal routes, though numerically favoring the transforaminal route, was not statistically significant ( $P = 0.239$ ). However, the interlaminar group had significantly worse outcomes than the caudal group ( $P = 0.044$ ).

Final ODI scores at 3 months reflected consistent patterns of improvement. The caudal group achieved a mean ODI of  $15.56 \pm 9.50$ , while the transforaminal group demonstrated near-complete functional recovery with an ODI of  $2.92 \pm 4.61$ . The interlaminar group remained behind, with a final mean ODI of  $15.88 \pm 10.19$ . ANOVA analysis showed significant differences ( $F = 19.02$ ,  $P < 0.001$ ). Post hoc comparisons revealed that the transforaminal group differed significantly from both the caudal ( $P < 0.001$ ) and interlaminar groups ( $P < 0.001$ ), while the difference between caudal and interlaminar routes was not statistically significant ( $P = 0.990$ ) (Tables 3 and 4).

### Discussion

The present study investigated the comparative efficacy of epidural methylprednisolone injection through three commonly used routes – caudal, transforaminal, and interlaminar – in patients with lumbar PIVD. Our findings demonstrate that the transforaminal route yields superior pain relief and functional improvement, as measured by VAS and ODI scores at 3 months post-injection. While all three techniques were effective in reducing symptoms, the

**Table 1: VAS score reduction over time for different epidural injection approaches**

Timepoint	Caudal	Transforaminal	Interlaminar
Pre-injection	8.04±1.136	8.52±1.194	8.4±1.155
1 week	7.24±1.899	7.72±1.595	8.2±1.607
2 weeks	5.04 ±2.263	4.8±1.803	6.12±1.787
4 week	2.88±2.166	2.12±1.9	4.36±1.777
3 months	1.44±1.583	0.72±1.1	2.52±1.896
Pre-injection - 1 week	0.089	0.057	0.632
Pre-injection - 2 weeks	<0.001	<0.001	<0.001
Pre-injection - 4 weeks	<0.001	<0.001	<0.001
Pre-injection- 3 months	<0.001	<0.001	<0.001
VAS: Visual Analog Scale			

transforaminal group consistently outperformed the others, showing statistically significant improvements. These outcomes align with a growing body of literature supporting the transforaminal approach for its targeted drug delivery and clinical efficacy [12, 15, 16].

Lumbar disc herniation frequently compresses adjacent nerve roots, leading to an inflammatory cascade that sensitizes nerve fibers and results in radiculopathy. Methylprednisolone, as a potent glucocorticoid, reduces inflammation by suppressing pro-inflammatory cytokines and immune cell activity [6, 7]. The choice of injection route influences both drug concentration at the site of inflammation and risk of complications.

The transforaminal route delivers corticosteroids directly to the anterior epidural space near the affected nerve root. This route enables maximum drug concentration at the site of pathology with minimal systemic exposure [9, 12, 13]. In our study, patients receiving transforaminal injections showed the most rapid and sustained pain reduction. The VAS score dropped

from  $8.52 \pm 1.19$  pre-injection to  $0.72 \pm 1.1$  at 3 months. Similarly, ODI improved markedly to  $2.92 \pm 4.61$ .

These results are in agreement with those of Vad et al. [15], who demonstrated that transforaminal injections provide better outcomes compared to caudal and interlaminar routes. Karppinen et al. [16] also reported improved function and reduced surgical requirement following transforaminal ESI. Furthermore, Riew et al. [13] found that transforaminal ESI reduced the need for surgical intervention by up to 40% in patients with radiculopathy.

The advantages of this route, however, come with procedural challenges. Precise needle placement is critical, as intravascular injection, nerve root injury, or inadvertent dural puncture are potential complications [17]. In our study, no major complications were observed, likely due to the use of fluoroscopic guidance and adherence to strict procedural protocols.

Caudal ESI involves injection through the sacral hiatus, resulting in more diffuse drug distribution. While this route is considered the safest, particularly in patients with altered anatomy or prior spinal surgeries, it is less efficient in achieving high local drug concentrations at the affected nerve root [10, 11]. In our study, the caudal group showed significant improvement in VAS and ODI scores, but to a lesser degree than the transforaminal group (VAS:  $1.44 \pm 1.58$ ; ODI:  $15.56 \pm 9.49$  at 3 months).

These findings are consistent with the literature. Buenaventura et al. [9] reported pooled success rates of 64% for caudal injections compared to 78% for transforaminal. Cousins et al. [18] emphasized its ease of administration and low complication rate, but acknowledged that caudal ESI may require repeated injections for optimal results.

The interlaminar route permits access to the posterior epidural space at or near the level of the herniated disc. It provides a balance between safety and targeted delivery [14]. In our study, the interlaminar group had better outcomes than caudal but was significantly less effective than transforaminal ESI in both VAS and ODI scores at 3 months (VAS:  $2.52 \pm 1.89$ ; ODI:  $15.88 \pm 10.19$ ).

This trend mirrors the findings of Manchikanti et al. [17] and Kennedy and Plataras [19], who reported moderate efficacy of interlaminar ESI, particularly in non-foraminal pathology. Nelson and King [14] suggested that interlaminar ESI is less effective in cases of far lateral or foraminal disc herniation due to limited anterior epidural spread.

**Table 2: Functional improvement following epidural injections**

Timepoint	Caudal	Transforaminal	Interlaminar
Pre-injection score	42±5.276	42.64±5.114	41.96±4.886
1 week	38.36±9.278	33.4±8.822	38.32±9.873
2 weeks	30.4±9.937	21.12±9.563	30.64±10.02
4 weeks	23.04±9.347	9.4±8.884	23.24±10.101
3 months	15.56±9.496	2.92±4.609	15.88±10.199
Pre-injection - 1 week	0.142	<0.001	0.077
Pre-injection score - 2 weeks	<0.001	<0.001	<0.001
Pre-injection score - 4 weeks	<0.001	<0.001	<0.001
Pre-injection score - 3 months	<0.001	<0.001	<0.001

**Table 3: ANOVA for comparison of combined VAS and ODI scores at 3 months**

Variable	Source of variation	Sum of squares	df	Mean square	F	P-value
VAS score at 3 months	Between groups	41.04	2	20.52	8.421	<0.001
	Within groups	175.44	72	2.437		
	Total	216.48	74			
ODI score at 3 months	Between groups	2731.947	2	1365.973	19.021	<0.001
	Within groups	5170.64	72	71.814		
	Total	7902.587	74			
VAS: Visual Analog Scale, ANOVA: Analysis of variance, ODI: Oswestry Disability Index						

systemic exposure and reduces adverse effects.

In India, surgical treatment for lumbar disc herniation is often inaccessible to a large proportion of the population. Thus, safe and effective interventional pain management techniques are crucial. Indian studies, such as Rajkumari et al. [23], Pandey et al. [24], and Patel et al. [25], have confirmed the efficacy of ESI in local populations. In our study, the results echo global trends and reinforce the role of transforaminal ESI in routine practice.

Analyzing pain relief over time, our study noted that significant improvement occurred after the 2nd week across all groups, with maximum benefit achieved by 3 months. This is supported by Helm et al. [20], who reported sustained pain relief with transforaminal ESI up to 1 year in discogenic pain. Early pain relief (within 1 week) was modest across groups, possibly due to the time required for corticosteroids to suppress local inflammatory mediators.

In this study, the transforaminal group received 40 mg methylprednisolone versus 80 mg in the other groups. This dose reduction is justified due to the precision of drug placement in transforaminal ESI. Studies by Botwin et al. [21] and Lee et al. [22] support the effectiveness of lower steroid doses when delivered with anatomical accuracy. This minimizes

Our study has several strengths, including a robust design with well-defined methodology, standardized assessment tools for evaluating pain relief and functional improvement, and a diverse patient population, enhancing the generalizability of our findings. It also provides valuable comparative data on different epidural injection techniques, supporting evidence-based clinical decision-making. However, the relatively small sample size may limit the broader applicability of the results, and the short, 3-month follow-up restricts assessment of long-term outcomes and recurrence rates. In addition, factors, such as quality of life, psychological impact, and long-term recurrence were not evaluated, highlighting areas for further research to provide a more comprehensive understanding of the overall effectiveness

**Table 4: Interpretation of injection route effectiveness**

Dependent variable	(I) Route of injection	(J) route of injection	Mean difference (I-J)	Standard error	Significance	95% confidence interval
VAS score at 3 months	Transforaminal	Interlaminar	-1.800*	0.442	<0.001	-2.86 to -0.74
	Transforaminal	Caudal	0.72	0.442	0.239	-0.34 to 1.78
	Interlaminar	Caudal	1.080*	0.442	0.044	0.02 to 2.14
ODI score at 3 months	Transforaminal	Interlaminar	-12.960*	2.397	<0.001	-18.70 to -7.22
	Transforaminal	Caudal	-12.640*	2.397	<0.001	-18.38 to -6.90
	Interlaminar	Caudal	0.32	2.397	0.99	-5.42 to 6.06
<b>VAS: Visual Analog Scale, ODI: Oswestry Disability Index</b>						



of epidural injection techniques.

### Conclusion

The present study evaluated 75 patients with lumbar disc herniation treated with ESIs through three different approaches: Caudal, interlaminar, and transforaminal. Patients were evenly divided among the three groups, each receiving a standard combination of methylprednisolone and 2% lignocaine. While 80 mg of methylprednisolone was administered for caudal and interlaminar routes, a reduced 40 mg dose was used in the transforaminal group due to its highly targeted drug delivery, minimizing systemic side effects.

At the 3-month follow-up, the transforaminal approach demonstrated the most significant improvement in pain (VAS reduction from 7.8 to 2.63, 66.3%) and disability (ODI reduction from 42.64 to 16.4, 61.5%) compared to caudal (VAS 51.9%, ODI 48.4%) and interlaminar (VAS 46.3%, ODI 43.7%) routes. This superior outcome is likely due to precise corticosteroid deposition at the inflamed nerve root, enhancing therapeutic efficacy and reducing complications.

Importantly, no major adverse effects were reported in any group throughout the follow-up period. The transforaminal route, with its focused drug delivery, minimized the risk of complications typically associated with more diffuse epidural techniques, reinforcing it as a safe and effective non-surgical treatment option for patients with lumbar disc herniation.

### Clinical Message

Epidural steroid injections (ESIs) are an effective treatment for lumbar prolapsed intervertebral disc (PIVD) with significant pain and disability reduction. Among the three common routes—caudal, transforaminal, and interlaminar—the transforaminal route provides superior pain relief and functional recovery. This technique is the most targeted, delivering corticosteroids directly to the affected nerve root, making it the most effective in achieving rapid and sustained symptom improvement. It is critical, however, to select the injection route based on the patient's anatomy and specific clinical conditions, as well as to use fluoroscopy for precise needle placement to minimize risks.

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

**Conflict of interest:** Nil **Source of support:** None

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