Effectiveness of Lumbar Transforaminal Epidural Steroid Injection in Patients with Radiculopathy - A Prospective Observational Study

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KEYWORDS
Lumbar radiculopathy; Transforaminal epidural steroid injection; Pain management; Intervertebral disc prolapse; Oswestry Disability Index; Numerical Rating Scale; Patient Satisfaction Questionnaire-18.

ABSTRACT

Background: Lumbar radiculopathy is a common condition characterized by pain radiating from the lower back to the lower limb, with high prevalence rates in the Indian population.

Objectives: To evaluate the effectiveness of lumbar transforaminal epidural steroid injections in patients with radiculopathy.

Materials and Method: The present study included 31 patients with intervertebral disc prolapse and radiculopathy confirmed by MRI. Patients received lumbar transforaminal epidural steroid injection and were assessed at baseline, immediately after, and at 6, 12, and 24 weeks using Numerical Rating Scale (NRS), Oswestry Disability Index (ODI), and Patient Satisfaction Questionnaire-18 (PSQ-18). A statistically analysis was carried using the Friedman test and Post-hoc Wilcoxon signed rank test with $p<0.005$ as significant value.

Results: Numerical Rating Scale (NRS) scores decreased substantially from 6.81 to 3.45 immediately after the procedure and remained low at 6-12 weeks (3.42-3.74), with a slight increase at 24 weeks (4.23). Similarly, Oswestry Disability Index (ODI) scores improved notably from 44.19 to 29.16 immediately after the procedure and remained improved at 6-24 weeks (30.00-33.48). Patient Satisfaction Questionnaire-18 (PSQ-18), showed a brief improvement post-procedure (4.09) but returned to near baseline levels (3.97-4.01) over the long-term follow-up period. These findings were statistically significant, with p-values of 0.000 for NRS, ODI, and PSQ-18 scores over follow-ups.

Conclusion: Transforaminal epidural steroid injection is a safe and effective treatment for lumbar radiculopathy, providing short-term pain relief and functional improvement. However, long-term efficacy remains unclear, highlighting the need for further large-scale, long-term research to optimize treatment outcomes.

1. Introduction

Lumbar radiculopathy is characterized by pain originating in the lower back that radiates along a specific lumbar nerve into the lower limb. In the Indian population, point, annual, and lifetime prevalence rates are notably higher compared to global averages, affecting a substantial proportion of individuals, particularly women, rural residents, and elementary workers. This high prevalence contributes significantly to healthcare utilization and economic burden. [1]

The primary etiological factor for low back pain is changes in the intervertebral discs which can present as disc herniation, foraminal stenosis, and degenerative diseases like canal stenosis and chronic segmental instability [2]. These conditions lead to compression of nerve roots and subsequent symptoms such as pain, numbness, tingling sensations and weakness. These symptoms can severely impact quality of life, often require the use of pain-relieving medications and pose a significant burden on physical and mental health.

Mechanical issues like ligament hypertrophy, facet enlargement, and osteophyte formation can also irritate nerve roots, while inflammatory responses to exposed nucleus pulposus further contribute to nerve root pain [3].

Numerous nonsurgical treatments have been proposed, ranging from lifestyle adjustments and physical therapy to analgesics. Conservative management aims to postpone or avoid surgical intervention altogether, as many cases of radicular pain can improve spontaneously or with conservative treatment. However, cases that are

resistant to conservative measures may require surgical intervention, especially in acute situations where patients experience conditions like acute drop foot or bladder incontinence.

The efficacy of surgery in chronic radicular pain remains a topic of debate while many patients remain hesitant or medically unfit for surgery under general anaesthesia, highlighting the need for alternative management strategies.

The Epidural Steroid Injection (ESI) is a commonly utilized minimally invasive procedure known for its efficacy in alleviating lumbar radiculopathy. These injections deliver steroids or anaesthetics directly into the site where nerves are compressed [4]. Among the different approaches available, transforaminal route stands out as particularly effective.

There is paucity in studies to determine which conservative intervention is superior. Additionally, evidence supporting the effectiveness of ESI varies across studies [5]. This study examines the effectiveness of lumbar transforaminal epidural steroid injections (LTFESI) in patients experiencing radiculopathy.

2. Materials and Method

The present prospective observational study was conducted among 31 patients diagnosed with intervertebral disc prolapse, presenting with radiating pain confirmed by imaging (MRI lumbo-sacral spine with whole spine screening) at the Department of Orthopedics, Mahatma Gandhi Medical College and Research Institute, Puducherry. These patients were recruited from the out-patient department and casualty services of the Department of Orthopedics. Prior to initiating the study, institutional ethical committee clearance was obtained. Additionally, informed consent was secured from each individual participant, ensuring their awareness and agreement to participate in the study.

Inclusion criteria consisted of patients aged 18-65 years, diagnosed with lumbar disc herniation confirmed by diagnostic medical imaging (MRI), presenting with radiculopathy, and having no response to conservative treatments. Exclusion criteria comprised of lumbar disc herniation at multiple levels, cauda equina syndrome, spinal canal stenosis, spinal malignancies, spinal infections, spinal trauma, polytrauma, a history of any lumbar surgery, or bleeding diathesis.

Patients were individually analysed in the OPD or casualty setting, and their complaints were recorded. Diagnostic imaging, specifically an MRI of the lumbosacral spine with whole spine screening, was a prerequisite.

Baseline and demographic data for all patients were recorded. The study protocol were described to each patient, and informed written consent was obtained. Patients were required to pay for procedural expenses.

Patients were shifted to the operation theatre for the procedure. After confirming and marking the site, side and the level, patients were placed in prone position. An intravenous catheter was secured and monitors attached. Patients were prepped and draped to achieve strict asepsis. Local anaesthetic was given. Image intensifier was placed in antero-posterior direction, vertebra squared and level noted. Using ipsilateral oblique and lateral views, 23 G Quincke’s needle was positioned. Contrast was then injected to verify the site and rule out vascular uptake. Provocation of specific nerve root was performed using 0.9% Normal Saline to check for concordance. A combination of 80 mg Methyl Prednisolone and 5ml Bupivacaine was injected. Patients were taken to the recovery area and observed to look for efficacy of the procedure and any adverse events.

Participants were instructed to rate various scales independently before the procedure, after the procedure, and at 6, 12 and 24 weeks post-procedure. Data collected later was statistically analysed using SPSS software.

Pain intensity was assessed using the Numerical Rating Scale (NRS), which is widely used for self-reporting of pain due to its simplicity and because its 0 to 10 scale is favoured by healthcare providers.[47]

Functional ability was assessed using the Oswestry Disability Index (ODI), a self-administered questionnaire measuring "back-specific function" with a 10 item scale which covers pain intensity, personal care, lifting, walking, sitting, standing, sleeping, social life,, traveling and changing degree of pain. Each item has six response categories, with scores ranging from 0 to 5, where higher scores indicate greater impairment. These scores are then converted to a 0–100 scale. [48] Patients' ODI scores are categorized as follows -

- 0 to 20: Minimal Disability

- 21 to 40: Moderate Disability
- 41 to 60: Severe Disability
- 61 to 80: Crippled
- 81 to 100: Bed-bound or exaggerating their symptoms.

Patient satisfaction was assessed using the Patient Satisfaction Questionnaire - 18 (PSQ-18). [49]

A statistically analysis was carried using the Friedman test and Post-hoc Wilcoxon signed rank test with $p<0.005$ as significant value.

3. Results

Table 1: Patient details

Variables	Age (in years)	Frequency	Percentage
Age	21-30	4	12.90
	31-40	10	32.26
	41-50	7	22.58
	51-60	5	16.13
	>60	5	16.13
Gender	Female	11	35.48
	Male	20	64.52
Disc Involvement	L4-L5	22	70.97
	L5-S1	9	29.03
Zone of herniation	Foraminal	4	12.90
	Posterolateral	27	87.10

Baseline and demographic characteristics were analyzed as shown in table 1. The average age of the study participants was 44.68 ± 12.42 years. The majority were in the 31-40 years age range (32.26%) followed by the 41-50 years age group (22.58%). Participants aged 51-60 years and those over 60 years each comprised 16.13% of the total sample. The least populous age group was under 30 years old accounting 12.9%. 35.48% females and 64.52% were males. Anatomically, the study found that most disc herniations occurred at the L4-L5 level (70.97%), followed by the L5-S1 level (29.03%). Posterolateral herniation was predominant (87.10%, 27 cases), with foraminal herniation occurring in 12.90% (4 cases) of participants.

Table 2: Various scoring criteria through the course of the study

Scoring criteria	Time duration	Minimum	Maximum	Mean	Standard deviation
NRS score	Before procedure	6	8	6.81	0.543
	After procedure	3	4	3.45	0.506
	After 6 weeks	2	5	3.42	0.848
	After 12 weeks	2	6	3.74	0.93
	After 24 weeks	2	7	4.23	1.203
ODI score	Before procedure	34	56	44.19	6.374
	After procedure	20	40	29.16	5.628
	6 weeks	18	44	30	5.978
	12 weeks	24	44	32.45	6.06
	24 weeks	20	48	33.48	6.49
PSQ-18 average score	Before procedure	3.64	4.25	4.02	0.17
	After procedure	3.78	4.35	4.09	0.17
	6 weeks	3.64	4.43	4.01	0.22
	12 weeks	3.46	4.25	3.98	0.21
	24 weeks	3.57	4.39	3.97	0.20

Pain intensity was evaluated using the Numerical Rating Scale (NRS) throughout the study (table 2). Initially, participants reported a mean NRS score of 6.81, indicating significant pain. Following the lumbar transforaminal epidural steroid injection, pain decreased substantially, with mean scores of 3.45 (immediately after), 3.42 (6 weeks), and 3.74 (12 weeks). However, by 24 weeks, pain increased slightly, with a mean score of 4.23. The Oswestry Disability Index (ODI) scores assessed functional improvement post-procedure (table 2).

Initially, participants had a mean ODI score of 44.19, indicating significant disability. Post-intervention, functional ability improved notably, with mean ODI scores of 29.16 (immediately after), 30.00 (6 weeks), 32.45 (12 weeks), and 33.48 (24 weeks). These findings suggest substantial initial improvement, followed by a gradual decline in functional status over time. Patient satisfaction was evaluated using the Patient Satisfaction Questionnaire-18 (PSQ-18) at various time points following the lumbar transforaminal epidural steroid injection (table 2). Initially, the mean PSQ-18 score was 4.02. Post-procedure, satisfaction slightly increased to 4.09, but subsequently returned to near baseline levels at 6 weeks (4.01), 12 weeks (3.98), and 24 weeks (3.97). These findings indicate that while the intervention yielded a brief, minor improvement in patient satisfaction, overall satisfaction levels remained relatively stable and close to pre-procedure baseline over the long-term follow-up period.

The Friedman test yielded a statistically significant difference in NRS, ODI, PSQ-18 over follow-ups, $\chi^2(4) = 76.437$, $p = 0.000$; $\chi^2(4) = 92.289$, $p = 0.000$ and $\chi^2(4) = 42.683$, $p = 0.000$ respectively.

Table 3: Friedman test for NRS, ODI and PSQ-18 scores

Friedman test Statistics	NRS score	ODI scores	PSQ-18 scores
N	31	31	31
Chi-Square	76.437	92.289	42.683
Degree of freedom	4	4	4
Asymptotic significance	.000	.000	.000

Post-hoc Wilcoxon signed rank tests were conducted to further analyze specific pairwise differences in NRS scores (table 4). All comparisons - NRS after procedure versus NRS before procedure, NRS at 6 weeks versus NRS before procedure, NRS at 12 weeks versus NRS before procedure, and NRS at 24 weeks versus NRS before procedure - showed highly significant results with significance levels of 0.000, indicating consistent and statistically significant reductions in pain scores across the various time intervals after the intervention.

Table 4: Wilcoxon signed rank test for NRS scores

Test Statistics				
	NRS after - NRS before	NRS 6 weeks -NRS before	NRS 12 weeks -NRS before	NRS 24 weeks -NRS before
Z	-5.013[a]	-4.918[a]	-4.907[a]	-4.920[a]
Asymptotic significance	.000	.000	.000	.000
a. Based on positive ranks				

In each comparison using Post-hoc Wilcoxon signed rank (table 5), ODI after procedure versus ODI before procedure, ODI at 6 weeks versus ODI before procedure, ODI at 12 weeks versus ODI before procedure, and ODI at 24 weeks versus ODI before procedure - the results were statistically significant with significance levels of 0.000. This suggests statistically significant improvements in functional disability scores following the lumbar transforaminal epidural steroid injection.

Table 5: Wilcoxon signed rank test for ODI scores

Test Statistics				
	ODI after - ODI before	ODI 6 weeks -ODI before	ODI 12 weeks -ODI before	ODI 24 weeks -ODI before
Z	-4.898[a]	-4.879[a]	-4.877[a]	-4.882[a]
Asymptotic significance	.000	.000	.000	.000
a. Based on positive ranks				

The results showed a significant difference using Post-hoc Wilcoxon signed rank for PSQ - 18 (table 6) in score immediately after the procedure ($Z = -4.063$, $p = 0.000$), suggesting an initial improvement in patient satisfaction. However, at 6 weeks ($Z = -0.698$, $p = 0.485$), there was no significant change compared to baseline. At 12 weeks ($Z = -2.102$, $p = 0.036$) and 24 weeks ($Z = -2.398$, $p = 0.016$), there were statistically significant decreases in average PSQ - 18 scores compared to baseline.

Table 1: Wilcoxon signed rank test for average PSQ-18 scores

Test Statistics				
	PSQ after - PSQ before	PSQ 6 weeks -PSQ before	PSQ 12 weeks -PSQ before	PSQ 24 weeks - PSQ before
Z	-4.063[a]	-.698[b]	-2.102[b]	-2.398[b]
Asymptotic significance	.000	.485	.036	.016
a. Based on negative ranks b. Based on positive ranks				

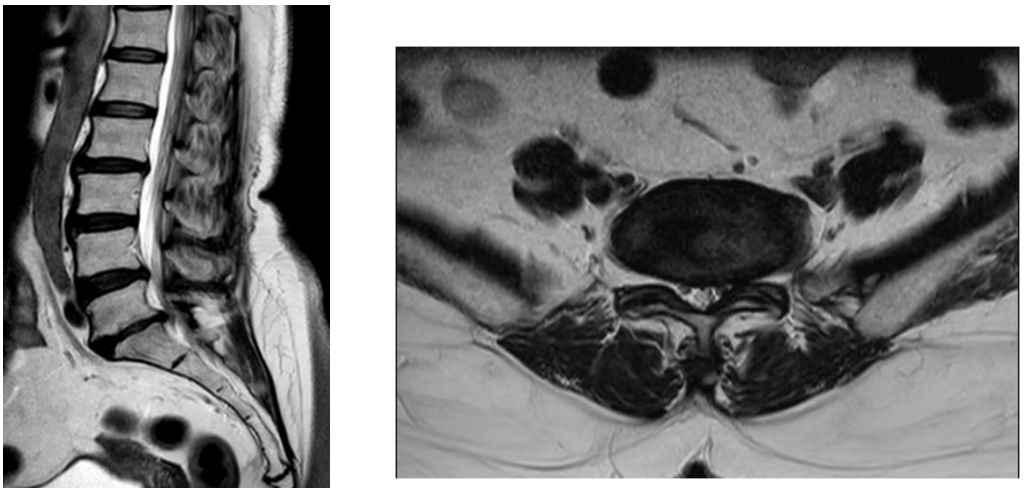

Figure 1: MRI films showing left posterolateral disc herniation at L5-S1 level

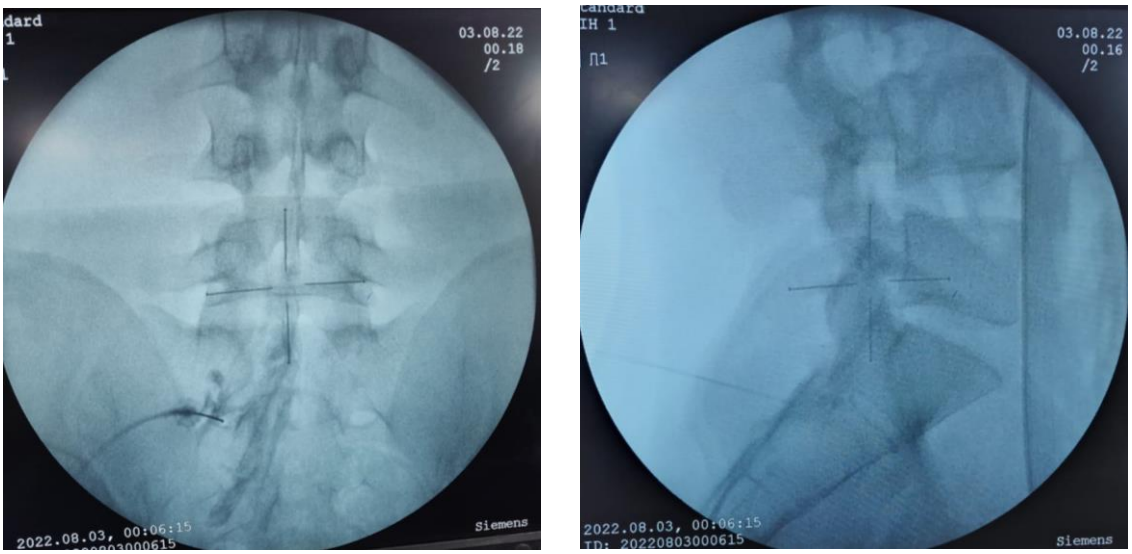

Figure 2: Injection given at left S1 nerve root

4. Discussion

The treatment landscape for lumbar radiculopathy has expanded with the introduction of various therapeutic approaches, prominently featuring surgical interventions like partial disc removal through traditional discectomy [6] or less invasive methods such as endoscopic surgery [7]. For cases marked by red flags or severe treatment-resistant pain, surgery is often recommended [8]. However, many patients are cautious due to concerns over surgical risks and anaesthesia. For uninsured patients, the cost of surgery is an issue.

In scenarios where immediate surgery may not be necessary, the search for rapid and effective alternatives becomes paramount. Epidural steroid injections play a crucial role in these situations, although they do not directly address the underlying nerve root irritation, which can impact patient prognosis.

A study by **Butterman et al** focused on patients with lumbar herniated discs who were surgical candidates. The study concluded that while epidural steroid injections are effective, they do not achieve the same level of

symptom and disability reduction as discectomy in cases of large lumbar disc herniations. Nonetheless, these injections provided substantial relief for nearly half of the patients who did not improve after six or more weeks of non-invasive treatment over a three-year period [9].

The therapeutic efficacy of local steroid infiltration is well-documented in the literature through various clinical studies, reporting success rates of pain relief as high as 88% [10]. Furthermore, epidural steroid injections can serve as a diagnostic tool; immediate relief post-procedure can confirm if the affected nerve root is the primary source of pain requiring surgical decompression. This correlation helps predict the potential relief from surgical intervention targeting that specific nerve root [11].

The Nerve root block versus surgery trial (**NERVES**), notable for comparing surgical microdiscectomy with transforaminal epidural steroid injections for treating prolapsed intervertebral discs, demonstrated that epidural steroid injections are not only cost-effective but also clinically effective [12].

As an interventional pain management procedure, epidural steroid injections necessitate collaboration among various medical specialists, including spine surgeons, radiologists, anaesthesiologists, and pain physicians [13]. Consequently, inclusion criteria and patient evaluation can vary significantly across studies. There remains a need for comprehensive studies that evaluate multiple clinical and radiological factors to better predict favourable functional outcomes.

This study investigates the effectiveness of lumbar transforaminal epidural steroid injections in patients suffering from radicular pain caused by lumbar disc herniation, demonstrating significant and clinically meaningful outcomes in the field of interventional pain management. The research highlights substantial improvements in pain relief and functional ability observed over a 6-month follow-up period, alongside an average satisfaction rating among participants.

The average age of participants in our study was 45 years, with the majority falling within the 31-40 years and 41-50 years age groups, consistent with findings reported by **Zhang et al**, where lumbar disc herniation predominantly affected individuals aged 30 to 50 years [14]. Our study included a higher proportion of male participants than females.

Our findings revealed inconsistencies when investigating the association between occupation and disc herniation, as only 45% of participants showed clear evidence of consistent spinal loading. Interestingly, other studies have suggested a higher incidence of lumbar disc herniation among individuals in high-stress occupations with frequent deadlines and lower job satisfaction [15]. Additionally, there was an increased prevalence of disc herniation among individuals engaged in heavy manual labour. However, the impact of these occupational factors on the management outcomes of lumbar disc herniation remains uncertain.

Our study found that the L4-L5 disc was the most commonly affected anatomical site, followed by the L5-S1 disc. This is consistent with previous research by **Amin et al**, which reported that around 95% of lumbar disc herniations occur at the L4-L5 or L5-S1 levels [16]. The majority of herniations in our study appeared as posterolateral, with a smaller number occurring as foraminal herniations, which aligns with findings from **Khan et al [17]**.

In our study, we observed diverse patient responses during the initial follow-up period: some initially experiencing severe pain showed gradual improvement, while others who initially found relief experienced a gradual worsening of symptoms. However, our overall findings reflect the intervention's effectiveness in delivering immediate and intermediate-term pain relief, although we noted a slight decline over the long term.

Similarly, **Kennedy et al** conducted a study investigating long-term outcomes in a homogeneous group of patients with acute lumbar radicular pain due to herniated disc following lumbar epidural steroid injection. They found that despite a high success rate at 6 months, the majority of participants experienced a recurrence of symptoms at some point in the subsequent 5 years. While few reported persistent symptoms, a small minority required additional injections, surgery, or opioid pain medications [18]. These conclusions align with the results observed in our study.

In our study, we evaluated the impact of the procedure on functional ability using the Oswestry Disability Index scores. Initially, we observed a significant improvement in disability scores, indicating a notable enhancement in patients' functional status. However, in the months following the intervention, we noted a gradual and modest decline in their functional abilities. These findings are consistent with a prior investigation by **Botwin et al**,

who conducted a prospective cohort study involving 34 patients with radiculopathy treated with epidural steroid injections. Botwin et al found that after 12 months, 64% of patients experienced improved walking tolerance, and 57% showed improved standing tolerance [19]. Our study's observation of functional improvement over time aligns with these results.

We examined the average scores from the Patient Satisfaction Questionnaire - 18 across various time points to assess patient satisfaction following the procedure. Our analysis revealed that initial satisfaction levels displayed a slight improvement immediately after the intervention. However, over the long-term follow-up periods, patient satisfaction levels tended to stabilize, returning closer to baseline levels. These findings are comparable to those reported by **Hashemi et al**, who found that mean patient satisfaction scores were 3.07 at the 2-year mark with a few cases reporting satisfaction scores equal to or greater than 4 on the Patient Satisfaction Questionnaire [20].

Transforaminal epidural steroid injection is a safe interventional approach for lumbar radiculopathy, demonstrating substantial improvements in pain relief, functional outcomes, and patient satisfaction, as indicated by the findings. This study contributes to the increasing body of evidence endorsing its efficacy as a valuable intervention. Future research should prioritize large-scale, long-term studies to optimize the benefits of epidural steroid injections across diverse patient populations.

The generalizability of the results is limited due to a small sample size and short follow-up duration. Furthermore, the absence of a control group in the study complicates the attribution of observed improvements, as other potential influencing factors cannot be adequately accounted for. Variability in pain and disability improvements among participants indicates differences in individual baseline levels, the potential impact of concurrent treatments, and the presence of confounding factors.

Future research should aim to address these limitations by incorporating larger sample sizes and including control groups to validate the findings. Longitudinal studies are recommended to assess long-term outcomes. We propose conducting further prospective, multicentre randomized trials with larger and more diverse samples to achieve robust and clinically applicable results in the field of interventional pain management.

5. Conclusion

To conclude, among the various presentations of back pain and lower extremity pain, lumbar radicular pain is quite common. Surgical treatment remains pivotal, yet alternative modalities are becoming increasingly important, with epidural steroid injections playing a crucial role in such cases. Transforaminal epidural steroid injection is a safe interventional method for treating lumbar radiculopathy, offering both diagnostic insights and therapeutic benefits. It effectively provides short-term relief in pain and functional ability post-procedure, with satisfactory patient outcomes. However, the long-term sustainability of these benefits remains uncertain and warrants future research through large-scale, extended-duration studies to optimize the efficacy of this intervention for lumbar radiculopathy.

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