How to Cite:
Akkamahadevi, P., Srinivas, H. T., Rashmi, H. S., Girish, B. K., Girish, V., & Reddy, M. C. (2022). Comparison of interlaminar and transforaminal epidural steroid injection for lumbosacral radiculopathy: A prospective randomized interventional study. *International Journal of Health Sciences*, *6*(S4), 8775–8785.
https://doi.org/10.53730/ijhs.v6nS4.10755

Comparison of interlaminar and transforaminal epidural steroid injection for lumbosacral radiculopathy: A prospective randomized interventional study

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***Abstract*---**Background: Low back pain due to Intervertebral disc herniation, intervertebral disc degeneration without disc herniation are the most common diagnosis of chronic persistent low back and lower extremity symptoms. Epidural steroid injections (ESI) are one of the most common interventional techniques for managing low back pain with or without lower extremity radiation Aims and objectives: Comparison of the effectiveness of lumbar Interlaminar and Transforaminal epidural steroid injections in managing various types of chronic low back pain. Material and methods: A total of 60 patients

Manuscript submitted: 27 April 2022, Manuscript revised: 18 June 2022, Accepted for publication: 9 July 2022

with history of lumbosacral radicular pain (≥3 months with VAS score ≥50) and magnetic resonance imaging (MRI) of the lumbar spine showing the exact disc level protrusion, who met the inclusion criteria were selected. With simple purposive sampling techniques, all patients were randomly divided into two groups. Group I Received 4 ml of 0.25% bupivacaine with 8mg dexamethasone through fluoroscopy guided interlaminar epidural route and Group T Received 2ml of 0.25% bupivacaine with 4mg dexamethasone through transforaminal route. Baseline assessment was completed just before the randomization and then follow up SLRT and VAS score recordings were taken - post 1 week, 1 month and 3 months after the procedure. Results: The baseline health related quality of life measures were also comparable between treatment groups (IL vs TESI) : The SLRT was 46.00 ± 9.14 vs 48.00 ± 10.95 respectively; P= 0.5. The pain intensity score was 3.13 ± 0.73 vs 3.00 ± 0.78, respectively; P= 0.2. Finally, the visual analogue pain scale was 6.03 ± 0.93 vs. 7.33 ± 1.03, respectively; p= 0.001. Both groups displayed comparable improvement with treatment as measured by their SLRT and VAS scores. The patient satisfaction index comparing both groups did not show statistically significant difference (1.57± 0.68 vs 1.87 ± 0.86 respectively P= 0.1. Conclusion: It can be concluded that the epidural injections is simple, safe, minimally invasive and effective mode of treatment of low-back and radicular pain. It improves the functional status and decreases the severity of pain. The study revealed comparable health benefits with both the IL and TF approach with respect to effective pain relief for managing patients with CLBP with lumbosacral radicular pain.

***Keywords*---**chronic low back pain (CLBP), transforaminal approach, interlaminar approach, epidural steroid injection (ESI).

Introduction

The high incidence of chronic low back pain (CLBP) with or without lower extremity pain impacts the lives of many patients and incurs substantial health care and other societal costs. Low back pain due to Intervertebral disc herniation, intervertebral disc degeneration without disc herniation are the most common diagnosis of chronic persistent low back and lower extremity symptoms. Epidural steroid injections (ESI) are one of the most common interventional techniques for managing low back pain with or without lower extremity radiation [1,2]. In addition to their anti-inflammatory effects steroids may inhibit pain via their ability to supress ectopic discharges from injured nerve fibres and depress conduction in normal unmyelinated C fibres[2]. Our hypothesis is that by targeting the steroid to the site of pathology near herniated disc and affected nerve roots, the Transforaminal (TF) approach using one half of the total steroid dose will be superior in improving function at 24 weeks when compared to twice the dose administered in Interlaminar (IL) approach.

Aims and Objectives

Comparison of the effectiveness of lumbar Interlaminar and Transforaminal epidural steroid injections in managing various types of chronic low back pain.

Materials and Methods

After taking ethical committee approval, the study was conducted on the patients visiting the Pain Relief Centre and Orthopaedic clinic in our hospital. Patients over the age of 18years, with a visual analogue scale (VAS) score of >5/10, diagnosed to have chronic low back pain (CLBP) and lumbosacral radicular pain for minimum 3 months , not responding to medication were included in the study. Patients with significant or unstable medical or psychiatric illness, previous surgery on lumbar spine, facet joint arthropathy, spinal canal stenosis (SCS), unstable neurological deficits or cauda equine syndrome, pregnant and lactating mothers, those with corticosteroid therapy, anticoagulant therapy and bleeding diathesis were excluded from the study. Those being treated with investigational drug within 30 days of trial and those on systemic steroids were also not included.

A total of 60 patients with history of lumbosacral radicular pain (≥3 months with VAS score ≥50) and magnetic resonance imaging (MRI) of the lumbar spine showing the exact disc level protrusion, who met the inclusion criteria were selected. With simple purposive sampling techniques, all patients were randomly divided into two groups.

Group I: Group receiving 4 ml of 0.25% bupivacaine with 8mg dexamethasone through interlaminar route (IL)
Group T: group receiving 2ml of 0.25% bupivacaine with 4mg dexamethasone through transforaminal route (TESI)
For breakthrough pain, the patients were allowed to use tramadol 50mg (one or two tablets) 6 hourly, as rescue medication.
Baseline assessment was completed just before the randomization and then follow up straight leg raising test (SLRT)and VAS score recordings were taken - post 1 week, 1 month and 3 months after the procedure.

Statistical Analysis

The data obtained was analysed using SPSS 21.0 version. All continuous data were expressed in terms of the mean and the standard deviation of the mean. T test was performed to assess the differences in mean of the two groups. Repeated measures of continuous variables, repeated measure ANOVA was done for within group. Two way repeated measure ANOVA done for between groups difference over time. The non-parametric Pearson's Chi square test was performed to investigate the relationships between grouping variables. For all tests, $p<0.05$ was considered significant.

Results

The two treatment groups included 30 patients subject to inter laminar epidural steroid injections and 30 patients subject to transforaminal epidural steroid injections. Both treatment groups (IL vs. TESI) were comparable, at baseline, in age (38.9±10.7 vs. 46.7±10.7 respectively; P-0.004), gender (females 33.3%vs33.3 males 66.7% vs 66.7% respectively; p= 0.5), side involvement (unilateral 40.0% vs 43.3% bilateral 60.0 % vs 56.7% respectively; P= 0.8) The baseline health related quality of life measures were also comparable between treatment groups (IL vs TESI) : The SLRT was 46.00 ± 9.14 vs 48.00 ± 10.95 respectively; P= 0.5. The pain intensity score was 3.13 ± 0.73 vs 3.00 ± 0.78, respectively; P= 0.2. Finally the visual analogue pain scale was 6.03 ± 0.93 vs. 7.33 ± 1.03, respectively; p= 0.001.

Both study groups displayed comparable improvement with treatment. The visual analogue scale for pain (VAS) improved from 6.03 ± 0.93 to 2.87 ± 0.90, P<0.0001 at 3 month follow up in the group treated with IL ESI. This was comparable to the improvement seen in the patients treated with transforaminal epidural steroid injections (TESI), where the baseline VAS of 7.33± 1.03 improved to 3.20± 1.27,P<0.0001.this improvement was statistically equivalent for both groups P=0.4.But during the first and second follow ups TESI showed significant improvements in the VAS scores 5.37± 0.93 vs 4.50 ± 1.17 p= 0.002 respectively at first follow up and 4.47 ± 0.94 vs 3.67 ± 1.12 P= 0.002 respectively at second follow up. Similar results were found for SLRT. Finally both groups displayed comparable improvement with treatment as measured by their SLRT and VAS scores. The patient satisfaction index comparing both groups did not show statistically significant difference (1.57± 0.68 vs 1.87 ± 0.86 respectively P= 0.1.

Table 1: Demographic characteristics of the two groups

GROUP					
		ITERLAMINAR		TRASFORAMINAL	
		NUMBER	PERCENTAGE	NUMBER	PERCENTAGE
SEX	FEMALE	10	33.3	10	33.3
	MALE	20	66.7	20	66.7
AGE	21-30	8	26.7	2	6.7
	31-40	9	30.0	7	23.3
	41-50	9	30.0	13	43.3
	>51	4	13.3	8	26.7

Table 2: Disc pathology characteristics among two groups

GROUP					
		INTERLAMINAR		TRANSFORAMINAL	
		NUMBER	PERCENTAGE	NUMBER	PERCENTAGE
LEVEL	L3-L4	2	6.7	4	13.3
	L4-L5	6	20.0	8	26.7
	L5-S1	10	33.3	3	10.0
	L3-L4,L4-L5	2	6.7	6	20.0
	L4-L5,L5-S1	8	26.7	9	30.0

	L3-L4,L4-L5,L5-S1	3	10.0	0	0
SIDE	UNILATERAL	18	60.0	17	56.7
	BILATERAL	12	40.0	13	43.3

Table 3: Pain Intensity Scores

PAIN INTENSITY SCORE	GROUP					
	INTERLAMINAR			TRANSFORAMINAL		
	MEAN	MEDIAN	SD	MEAN	MEDIAN	SD
	3.13	3.00	0.73	2.87	3.00	0.78

Figure 1: Comparison of Pain Intensity Scores in Two Methods

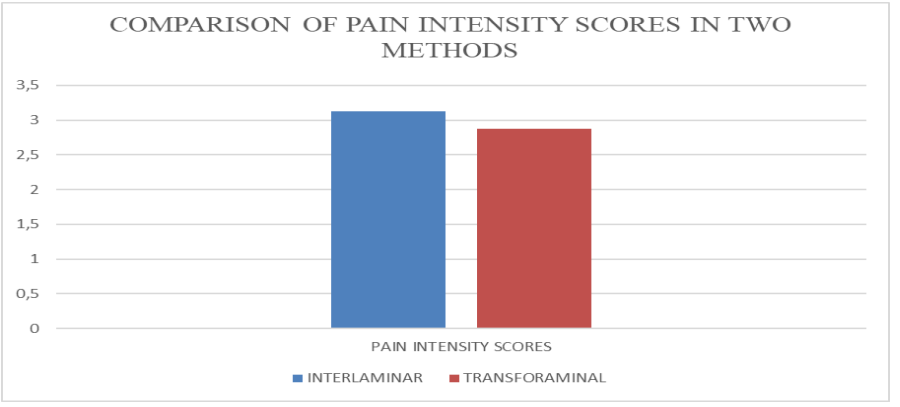
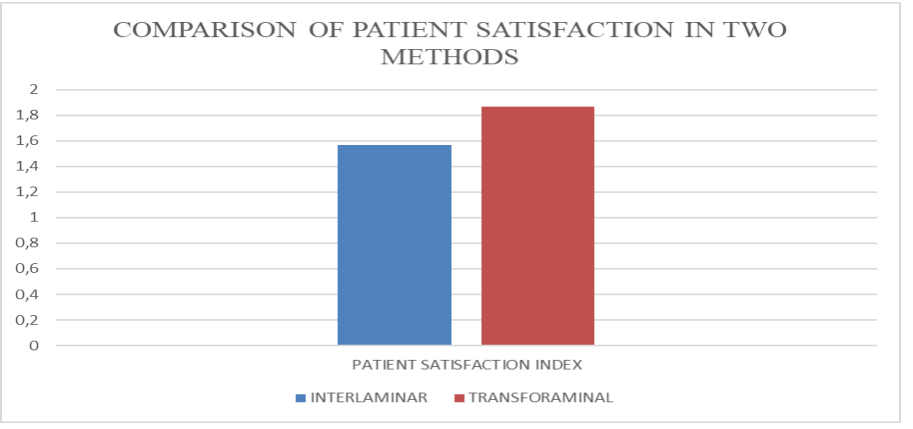


Figure 2: Comparison of Patient Satisfaction in Two Methods



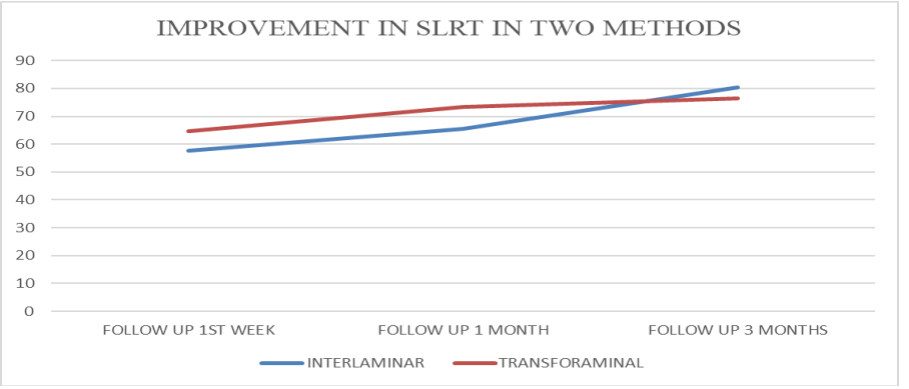


Figure 3. Improvement in SLRT in study groups I and T

Discussion

Chronic low back pain (CLBP) is a very common symptom reported in all age groups. Mechanical LBP and herniated disc (HD) syndromes are the most frequent causes in young patients while the lumbar spinal stenosis (LSS) primarily prevails in the middle-aged and older patient population. Diagnosis and management of disc herniation was first described by Mixter and Barr in 1934 [3]. All patients with lumbar disc herniation or radiculopathy do not require surgical intervention and multiple studies have shown that surgery may be avoided with epidural injections, admittedly at the variable rate of 41-56%. Epidural steroid injection is a frequently used therapeutic modality in the management of radicular pain from disc herniation and spinal stenosis, as well as axial spinal pain. The rationale for administration of ESIs is based on the assumption that inflammation of spinal nerve root causes radicular pain and the epidural corticosteroids relieves pain allowing time for healing and physiotherapy. It is believed that depositing steroids close to the nerve roots results in more efficacious control of the local inflammation. The procedures are done by assessing the epidural space either through a caudal, interlaminar or transforaminal route. The interlaminar approach is considered capable of delivering the medication closest to the assumed site of pathology, but the transforaminal approach is considered the most target specific modality, requiring the smallest volume to reach the primary site of pathology. In contrast to IL and TF, caudal epidural injections require relatively large volumes and are associated with an alleged lack of specificity to the assumed site of pathology. There is an increasing literature to support the use of transforaminal epidural injections to treat radicular symptoms for lumbar spinal stenosis and herniated nucleus pulposus.

We undertook randomized comparative study on 60 patients who were randomly divided into two groups of 30 each. First group received inter laminar epidural steroid injection and second group received transforaminal epidural steroid injection. We assessed the participants at an interval of two weeks, one month and three months, after their first injection the participants experienced more than 50% reduction in pain at approximately three months. The demographic characteristics of the present study were consistent with earlier studies (Table 1). In general population, at least 25% of the people that had serious impairment due

to LBP are over 65. In our study, 30% of the participants were 65 years and above therefore, this is representative of the population. This study sample reported results representative of the findings in the literature. The mean age was 46 in our study, almost nearer to the literature's range of 50 to 64 years old. The study sample consisted of 20 males and 10 females. This balance is consistent with the significant gender differences which were reported in the majority of epidemiological investigations of the prevalence of LBP [4].

Lee et al compared the efficacy of interlaminar and bilateral transforaminal epidural steroid injections for pain reduction in patients with axial back pain from herniated intervertebral discs (HIVD) and observed that though both the transforaminal and interlaminar epidural steroid injections provided significant pain reduction in subjects with HIVD and SCS from 2 weeks to 4 months after treatment. In subjects with SCS, the bilateral TFESI group showed a greater mean reduction in NRS score compared to the Interlaminar group [5].

Rados et al. and Ghai et al. in a randomized control trials on patients suffering from chronic low back and unilateral radicular pain, lumbar radicular pain from disc herniations compared interlaminar and transforaminal ESI and observed that pain and function assessed at 3 and 6 months following the first injection using the visual analogue scale (VAS) and the Oswestry Disability Index showed successful outcomes with 50 % improvement in VAS or greater than l0-point change in the Oswestry scale. However, there was no statistically significant difference between the two group with respect to the proportion of those with a successful pain and functional outcome [6,7].

In our study the transforaminal group had significant improvement immediately after the procedure, the pain improvement was largely maintained at follow up (table 2,3 and figure 2,3). There was a 48% improvement in SLRT immediately after the procedure. Subsequently in follow up, SLRT improved in one week by 64.67%, one month by 73.33%. and 3 months by 80% respectively. Similarly, VAS score of 7.33 was decreased to 4.50 in the first week and to 3 at the end of three months. On the other hand, the inter laminar group also had significant improvement after the injection, but improvement was not maintained at the follow up. There was a 46% improvement in SLRT immediately after the procedure. Subsequently in the follow up, SLRT improved in one week by 57.67%, one month by 65.50%. and 3 months by 80% respectively. Similarly VAS score of 6.03 was decreased to 5.37 in the first week and to 3 at the end of three months. This result indicates that the functional status of patients and pain intensity was significantly improved in all follow up visits in transforaminal group but at the end of three months there was no statistical difference found between the two groups. We agree with others that the more targeted delivery of the injectate along the inflamed spinal nerve is the most likely explanation for these better outcomes. Our study supports the findings of Riew et al. that ESIs decrease the need for discectomies for lumbar disc herniations[8]. Our surgical rate (10%) were lower than those reported in that study (29%). Our results are very similar to previous studies looking at the outcomes from interlaminar and transforaminal epidural steroid injections independently. The transforaminal approach has been the favourite approach by most interventional pain physicians for the treatment of lumbar radicular symptoms over the last several years. This is supported by two

RCTs while Karpinnen's demonstrated fewer positive results[9,10, 11, 12]. On the other hand, interlaminar ESIs have been used for many years, but current science provides only limited support for the efficacy of this treatment for lumbar radicular symptoms.

However, all currently available studies on interlaminar ESIs have significant methodological flaws, mainly due to unreliable utilization of fluoroscopic control and contrast injection and the lack of correlation of pathological findings on advanced imaging studies with the precise localization of the ESI. All of the non-fluoroscopic studies followed flawed methodology without target delivery of steroids, performing the procedures frequently between L3/4 and occasionally L4/5 in the lateral position, with poor assessment of outcomes, application and analysis. The disadvantages of this approach without fluoroscopy include dilution of the injectate, extra epidural placement of the needle, intravascular placement of the needle, preferential cranial flow of the solution, preferential posterior flow of the solution, difficult placement (with increased risks in postsurgical patients), difficult placement below L4- L5 interspace, deviation of needle to non-dependent side, dural puncture and trauma to the spinal cord. These disadvantages and potential flaws may be avoided with fluoroscopy. For accurate drug placement, ideally ESI should be performed with fluoroscopic guidance[13].

In this study we used Fluoroscopy with contrast to confirm the needle placement as a gold standard and found the outcome of the same to be more accurate and reliable to inject the drug exactly at the required pathological site. Ackerman and Ahmad, comparing efficacy of three fluoroscopically guided approaches (TF, IL, and caudal ESI) in patients with IDH, demonstrated TF ESI's superiority to IL ESI for lumbar radicular pain relief [9].

The mechanisms by which steroids exert their analgesic effects have been debated for many years. Corticosteroids inhibit the enzyme phospholipase A2, which catalytically hydrolyses the bond converting membrane phospholipids into arachidonic acid and lysophospholipids. Phospholipase A2 is itself an inflammatory mediator present in elevated concentrations in herniated and degenerative intervertebral discs, but its main role is as the rate-limiting factor involved in the production of arachidonic acid, which is the principal substrate for the cyclooxygenase and lipo-oxygenase pathways [14].

Although steroid effects are dependant largely on the total dose and not the total injected volume, the drug should reach the affected segment. Volumes of 10 mL (for L5 segment), 15 mL (for L4 segment) and upto 20 mL (for upper lumbar) is recommended through the caudal approach. This is in comparison to 1.5-2 mL through the transforaminal and 6-10 ml, through the inter-laminar technique. The theoretical disadvantage of the inter laminar and caudal approach i.e. the larger volume of medication required to reach the area of pathology, may actually benefit by lysing epidural adhesions.

Manchikanti et a1, while evaluating the effectiveness of a single injection of lumbar interlaminar local anaesthetics (LA) with or without steroids for managing chronic pain of IDH or radiculitis, reported significant pain relief in 74% patients treated with LA and 86% with LA and steroids [15]. In a study by Thomas S et al the

addition of corticosteroid to epidural local anesthetic, demonstrated that dexamethasone reduced post-operative pain and analgesic requirements [16]. In this study we used 8mg dexamethasone with 4ml of bupivacaine in inter laminar approach and 4mg dexamethasone with 2 ml of bupivacaine in transforaminal approach using fluoroscopy guidance. This supports the literature and we found that there was significant pain relief at end of 3 months follow up without any complications. There was a significant improvement in SLRT, VAS scores in both the groups(figure3). Also there was a significant improvement in the patient satisfaction index in both groups (figure 2). The results of current study indicate that the addition of dexamethasone to bupivacainc 0.25% when given epidurally and significant improvement was seen in VAS scores and SLRT scores at the end of three months without any complications.

The most common and worrisome complications of transforaminal epidural steroid injections in the lumbar spine are related to dural puncture, infection, and steroids. In a large survey of reports of adverse reactions associated with epidural steroid injections, Abram and O'Connor reported two cases of epidural abscess, and two cases of meningitis. No such reviews exist for trans foraminal epidural steroid injections [17]. None of these complications were seen in our study. Thus, this finding shows that epidural steroid injections are simple, safe, minimally invasive and early pain relief for symptomatic herniated lumbar discs.

Thus, this randomized trial provides evidence that, in contemporary interventional pain management settings epidural injections conducted under fluoroscopy guidance, patients respond to both approaches in a similar fashion. Based on the frequency of epidural injections and the duration of relief, it appears that significant improvement lasts approximately 13 or 14 weeks. Consequently, it has been shown that over a period of 12 weeks transforaminal group responded early i.e in the first and second follow up. However at the end of third follow up relief was observed in both groups. No statistical significance was observed within the groups on SLRT and VAS scores. Thus the study revealed comparable health benefits with both the IL and TF approach with respect to effective pain relief for managing patients with CLBP with lumbosacral radicular pain. Significant improvement was observed with both approaches in primary as well as secondary outcomes, pain intensity (VAS), improvement ratings in SLRT scores and patient satisfaction index.

The limitations in this study were

1. The follow up was done only for three months
2. since the patient were send back to home so we could not monitor whether the patient took any other modalities of treatment for LBP
3. The sample size is small
4. Lack of control group.

Conclusion

The study revealed comparable health benefits with both the IL and TF approach with respect to effective pain relief for managing patients with CLBP with lumbosacral radicular pain. Significant improvement was observed with both

approaches in primary as well as secondary outcomes, pain intensity (VAS), improvement ratings in SLRT scores and patient satisfaction index. However, transforaminal steroid is recommended since the dosage of steroid used is minimal and delivery of drug is more close to the effected nerve root.

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