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Transforaminal versus Interlaminar Approaches to Epidural Steroid Injections: A Comparitive Study for Symptomatic Lumbar Intervertebral Disc Herniation.

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ABSTRACT

Background: Transforaminal epidural steroid injections (TFESI) and interlaminar epidural steroid injections (ILESI) are commonly performed procedures for the management of unilateral lumbosacral radicular pain (LSRP) due to intervertebral disc herniations. Unilateral LSRP is thought to originate from inflammation in the proximity of a damaged intervertebral disc or a narrowed neuralforamen that irritates an exiting spinal nerve root . Thus corticosteroids are commonly used to reduce inflammation in the epidural space . The purported advantage of TFESI over ILESI is attributed to enhanced deposition of medication in closest proximity to the pain generators found in the ventral epidural space and hence reaching the targeted pain generators with a smaller dose of medication. Data from multiple studies and systematic reviews of the published data support the utility of TFESI and have shown that lumbar TFESI are effective for reducing pain, improving functionality, preventing spine surgery and for treating radiculopathic pain. **Methods:** In a prospective study, 60 patients with low back pain were randomly allocated to one of the two groups of 30 patients each. In Group IL(interlaminar approach), with the patient in lateral position, under strict aseptic precautions, 18G Tuohy needle is placed by loss of resistance technique and confirmed using iohexol dye and 80 mg (2 mL) of methyprednisolone with 2 mL of normal saline is injected. In group TF(transforaminal approach), with the patient in prone position, under strict aseptic precautions, 23 G Quinke needle is placed in epidural space under C-arm guidance and confirmed by using Iohexol dye and 80 mg (2 mL) of methyprednisolone with 2 mL of normal saline is injected. Patient monitored for 15 mins after the procedure. Pain relief assessed by using Numerical Rating Scale(NRS), Verbal Rating Scale(VRS), Straight Leg Raising Test(SLRT) etc. **Results:** In Group IL, NRS decreased from 7.77±1.2 (pre-procedure) to 4.73±1.1 and 4.27±1.5 at the end of 2nd and 3rd week respectively. In Group TF, NRS decreased from 7.8±1.3 (pre-procedure) to 2.77±1.7 and 2.63±1.7 at the end of 2nd and 3rd week respectively. This difference in NRS was statistically significant both at the end of 2nd week and 3rd week with a P value of 0.001 with Group TF having better pain relief. There was no statistically significant difference among the 2 groups with respect to SLRT, improvement in walking tolerance, reduction in analgesic use and reversal of paraesthesia at the end of 3rd week. **Conclusion:** Epidural steroid injection by transforaminal route provides better subjective pain relief in the short term.

Keywords: Epidural, interlaminar, transforaminal, methyprednisolone.

INTRODUCTION

Low back ache and lumbar radiculopathy are common problems that affect most individuals at sometime during their lives. The estimated prevalence of lumbar radiculopathy has been described as 9.8 per 1,000 cases of low back pain.[1] Intervertebral disk herniation and degenerative lumbar spinal stenosis are the two most common causes of lumbar radiculopathy.[2-5] While lumbar radiculopathy secondary to disc herniation resolves spontaneously in 23% to 48% of patients, 5% to 15% of patients undergo surgery, resulting in a strain on the health care system and subsequently, the economy.[6-9] Various conservative, nonsurgical modalities for treating lumbar disc herniation or radicular pain exist, including epidural injections. Data from the Spine Patient Outcomes Research Trial (SPORT) evaluation reported the clinical and cost effectiveness of lumbar disc herniation

surgery.[10-12] Surgery is associated with failure in approximately 25% of patients in well selected cases. Due to comorbid factors, not everyone who is symptomatic is a surgical candidate; some disc protrusions and small disc herniations are not amenable to surgical interventions.[13-16] Thus, epidural injections are one of the most common nonsurgical treatments for lumbar disc herniation.[17-20] Epidural injection of corticosteroids is one of the most commonly used interventions in managing chronic low back pain. Steroids presumably exert their effects by limiting inflammatory response, inhibiting leukocyte aggregation, preventing degranulation of inflammatory mediators, stabilizing lysosomal and other membranes, and reducing the synthesis and release of proinflammatory factors.

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Epidural injections are administered by accessing the lumbar epidural space by multiple routes including interlaminar, caudal, and transforaminal. While significant differences have been described between these 3 approaches, interlaminar entry is considered to deliver the medication closely to the assumed site of pathology, even though the transforaminal approach is considered the target specific modality requiring the smallest volume to reach the primary site of pathology. Caudal epidural are considered as the safest and easiest with minimal risk of inadvertent dural puncture, and preferred modality in post-surgery syndrome, even though requiring relatively high volumes. Increasing emphasis is placed on fluoroscopically guided, target specific injections to improve treatment outcomes.

The present study was designed to compare the efficacy of Transforaminal Versus Interlaminar Approaches to Epidural Steroid Injections for Symptomatic Lumbar Intervertebral Disc Herniation

MATERIALS AND METHODS

After institutional review board approval, 60 patients of 18 to 60 years of age with be enrolled in this prospective study in patients suffering with low backache and radicular pain of lumbar disc prolapse etiology at Chelmeda Anand Rao Institute of Medical Sciences from October2015 to march 2017 . Each participant will undergo a thorough standard evaluation by a single orthopedician which included an evaluation of their clinical history, physical examination, x-rays, magnetic resonance imaging (MRI).

Inclusion Criteria

- Chief complaint of low back pain radiating to one lower extremity
- Failed analgesic and nonpharmacologic therapy trial of at least one Month
- Duration of current back and leg pain for greater than one month and less than a year
- Symptoms due to acute disc disease with prolapse
- Correlation between the clinically determined level(s) of radiculopathy and the findings on MRI.
- Inability to tolerate physical therapy or no benefited from ongoing physical therapy

Exclusion Criteria

- Previous lumbar spine surgeries or epidural steroid injections in the previous 6 months
- Multilevel degenerative spine disease, unstable spine, spondylolisthesis (> grade 1), spondylolysis
- Cauda equina syndrome, arachnoiditis, progressive neurologic deficit
- Central spinal canal stenosis (congenital or acquired) from other origins, vertebral compression fracture(s)
- Active cancer diagnosis, history of substance abuse, current psychiatric co-morbidity, pregnancy
- Myelographic contrast allergy, steroid allergy, local anesthetic allergy

Methods of Collection of Data

During the above said period 60 patients with low back pain satisfying the inclusion criteria are selected. The Patients will be randomly allocated to one of the two groups of 30 patients each. Group IL – For interlaminar approach, Group TF- For transforaminal approach Patients are explained about the procedure and informed and written consent obtained. Routine NPO protocols will be followed. Intravenous line is secured. Following monitors are connected – NIBP, SpO2, ECG. With all aseptic precautions, in group IL, needle is placed in epidural space with the patient in lateral position under fluoroscopic guidance using isohexol dye and 80 mg (2 mL) of methyprednisolone with 2 mL of normal saline is injected.

With all aseptic precautions, in group TF, needle is placed in epidural space with the patient in prone position under fluoroscopic guidance using isohexol dye and 80 mg (2 mL) of methyprednisolone with 2 mL of normal saline is injected. Patient monitored for 15 mins after the procedure and observed for immediate side effects, if any Primary outcome: pain relief at the end of 2nd and 3rd week after the epidural steroid injection using Numerical Rating Scale (NRS) and Verbal Rating Scale (VRS) Secondary outcome : Pain relief immediately after the epidural steroid injection by NRS, VRS, Straight leg raising test (SLRT) , Improvement in walking tolerance ,

Reduction in analgesic use , reversal of paraesthesia.

RESULTS

Demographics:

Table 1: Comparison of age group distribution between the two groups.

Age group(yrs)	IL group (N=30)	TF group (N=30)	P value
	n (%)	n (%)	
20-30	8 (26.7)	6 (20.0)	
30-40	9 (30.0)	14(46.7)	0.472*
40-50	7 (23.3)	5 (16.7)	
50-60	6 (20.0)	5 (16.7)	
Total	30 (100.0)	30(100.0)	
Mean age ± SD	41.4 ± 12.0	39.4 ± 10.7	0.505**

*Chi-square test, **T test

Table 2: Comparison of sex distribution between the two groups.

Sex	IL group (N=30)	TF group (N=30)	P value
	n (%)	n (%)	
Male	19 (63.3)	19 (63.3)	>0.99
Female	11 (36.7)	11 (36.7)	

The mean age of the patients in this study in Group IL was 39.4±10.7 years and in Group TF was 41.4±12.0 years. The sex distribution in the 2 groups were similar with 19 males and 11 females in each group.

Table 3: Comparison of laterality of radicular pain between the two groups.

Side	IL group (N=30)	TF group (N=30)	P value
	n (%)	n (%)	
Left	19 (63.3)	20 (66.7)	0.794
Right	11 (36.7)	10 (33.3)	

In Group IL, 19 patient suffered from left lower limb radicular pain and 11 patients had right lower limb radicular pain. In Group TF, 20 patients presented with left lower limb radicular pain and 10 patients had right lower limb radicular pain.

Table 4: Comparison of Level of approach between the two groups.

Level	IL group (N=30)	TF group (N=30)	P value
	n (%)	n (%)	
L3-L4	0 (0.0)	2 (6.7)	0.278
L4-L5	20 (66.7)	21 (70.0)	
L5-S1	10 (33.3)	7 (23.3)	

Among the sixty patients, most patients had herniation at the level of L4-L5 i.e 20 patients in Group IL and 21 patients in Group TF.

Table 5: Comparison of Numerical Rating scale for pain between the two groups.

Intervals	IL group (n=30)		TF group (n=30)		P value
	Mean	SD	Mean	SD	
NRS Before ESI	7.77	1.2	7.8	1.3	0.919
NRS15min	6.93	1.1	6.7	0.8	0.354
NRS2ndWk	4.73	1.1	2.77	1.7	0.001
NRS3rdWK	4.27	1.5	2.63	1.7	0.001

NRS 15 mins after epidural steroid injection reduced from 7.77±1.2 (pre-procedure) to 6.93±1.1 in Group IL and from 7.8±1.3(pre-procedure) to 6.7±0.8 in Group TF. The difference among the 2 groups was not significant (P value-0.354).

In Group IL, NRS decreased from 7.77±1.2 (pre-procedure) to 4.73±1.1 and 4.27±1.5 at the end of 2nd and 3rd week respectively. In Group TF, NRS decreased from 7.8±1.3 (pre- procedure) to 2.77±1.7 and 2.63±1.7 at the end of 2nd and 3rd week respectively. This difference in NRS was statistically significant both at the end of 2nd week and 3rd week with a P value of 0.001 with Group TF having better pain relief.

Table 6: Comparison of Verbal Rating Scale for pain between the two groups.

Intervals	IL group (n=30)		TF group (n=30)		P value*
	Mean	SD	Mean	SD	
VRS Before ESI	2.3	0.5	2.47	0.7	0.139
VRS15min	2.37	0.6	2.3	0.8	0.909
VRS2ndWk	1.33	0.6	1.1	0.8	0.224
VRS3rdWk	1.13	0.8	1	0.7	0.465

*Mann-Whitney test.

VRS 15 mins after epidural steroid injection reduced from 2.3±0.5(pre-procedure) to 2.37±0.6 in Group IL and from 2.47±0.7(pre-procedure) to 2.3±0.8 in Group TF. This difference was not found to be significant (P value-0.909). In Group IL, VRS improved from 2.3±0.5 (pre-procedure) to 1.1±0.8 and 1.13±0.8 at the end of 2nd and 3rd week respectively. In Group TF, it improved from 2.47±0.7 (pre-procedure) to1.33±0.6 and 1±0.7 at the end of 2nd and 3rd week respectively. This difference in VRS was not statistically significant with a P value of 0.224 and 0.465 respectively. Among the 2 groups, the difference in VRS was not statistically significant.

Table 7: Comparison of improvement in Straight leg raising test betwee the two group.

	TL group (n=30)		TF group (n=30)		P value
	Mean	SD	Mean	SD	
SLRT Before ESI	68.67	14.5	63.33	14.5	0.159
SLRT15min	70	12.5	67	11.5	0.338
SLRT2ndwk	80	8.9	79.67	8.9	0.885
SLRT3rdwk	80	8.9	80.83	8.8	0.717

In Group IL, Straight leg raising test (SLRT) pre-procedure, at fifteen minutes, at the end of 2nd and 3rd week after epidural steroid injection was 68.67±14.5, 70±12.5, 80±8.9 and 80±8.9 degrees respectively. In Group TF, it was 63.33±14.5, 67±11.5, 79.67±8.9 and 80.83±8.8 degrees. This difference was not found to be significant (P value>0.05). Among the 2 groups, the difference in the improvement in SLRT was not significant at 15 mins, end of 2nd week or 3rd week

Table 8: Comparison of improvement in walking tolerance between the two groups.

Walking	IL group (N=30)	TF group (N=30)	P value
	n (%)	n (%)	
Yes	20 (66.67)	24 (80.0)	
No	10 (33.33)	6 (20.0)	0.243

Table 9: Comparison of Reduction of analgesic use between the two groups.

Reduction in analgesic use	IL group (N=30) n (%)	TF group (N=30) n (%)	P value
No	10 (33.3)	7 (23.3)	0.39
Yes	20 (66.7)	23 (76.7)	

Table 10: Comparison of Reversal of paraesthesia between the two groups.

Reversal of paraesthesia	IL group (N=30) n (%)	TF group (N=30) n (%)	P value
Yes	10 (33.3)	11 (36.7)	
No	4 (13.3)	6 (20.0)	0.758
None	16 (53.3)	13 (43.3)	

There was no statistically significant difference among the 2 groups with respect to improvement in walking tolerance, reduction in analgesic use and reversal of paraesthesia at the end of 3rd week.

Table 11: Comparison of Complication between the two groups.

Complication	IL group (N=30)	TF group (N=30)	P value
	n (%)	n (%)	
None	29 (96.7)	30 (100.0)	0.315
Vasovagal reaction	1 (3.3)	0 (3.3)	

One patient in the IL group had a vasovagal reaction, 10 mins following the procedure which was treated with Inj.Atropine 0.6mg and i.v fluids. We did not encounter any other complication during the study.

DISCUSSION

Epidural steroid injections are simple outpatient based procedure which can be used as pain management technique, to decrease dependence on oral pain medication, increase physical performance, and facilitate rapid return to normal activities of daily living.

Watts and Silagy (1995) in a meta- analysis of efficacy of epidural corticosteroids in the treatment of sciatica, utilized 11 studies considered of good quality, including a total of 907 patients, and concluded that quantitative evidence from meta-analysis of pooled data from randomised trials illustrated that epidural administration of corticosteroids was effective in the management of lumbosacral radicular pain. Similarly, we used methylprednisolone (80 mg) made upto 4ml with saline in both the groups

Williamson A & Hoggart B (2005) compared three commonly used pain rating scales-NRS, VRS and VAS. They concluded that all three pain-rating scales are valid, reliable and appropriate for use in clinical practice, although the Visual Analogue Scale has more practical difficulties than the Verbal Rating Scale or the Numerical Rating Scale. For general purposes, the Numerical Rating Scale has good sensitivity and generates data that can be statistically analysed for audit purposes. Patients who seek a sensitive pain rating scale would probably choose this one. For simplicity patients prefer the Verbal Rating Scale, but it lacks sensitivity and the data it produces can be misunderstood. 75 So, they concluded that more importance be attached to NRS as it has good sensitivity compared to VRS which lacks sensitivity. so we used NRS for both the groups

Thomas et al (2003) conducted a randomized, controlled trial on thirty-one patients with discal radicular pain of less than 3 months duration. Patients were consecutively randomized to receive either radio-guided transforaminal or blindly performed interspinous epidural corticosteroid injections. Post-treatment outcome was evaluated clinically at 6 and 30 days, and 6 months. Outcome measures consisted of pain, functional status assessment At day 30 and 6 months, pain relief, daily activities, work, leisure activities, anxiety, and depression, were better in transforaminal group.60They concluded that transforaminal epidural steroid injection was more effective.

In our study, the primary outcome was to assess pain relief between the two groups-IL and TF at the end of 2nd and 3rd week by using numerical rating scale and verbal rating scale.In Group IL, NRS decreased from 7.77±1.2 (pre-procedure) to 4.73±1.1 and 4.27±1.5 at the end of 2nd and 3rd week respectively. In Group TF, it decreased from 7.8±1.3 (pre- procedure) to 2.77±1.7 and 2.63±1.7 at the end of 2nd and 3rd week respectively. This difference in NRS was statistically significant both at the end of 2nd week and 3rd week with a P value of 0.001 with Group TF having better pain relief. In Group IL, VRS improved from 2.3±0.5 (pre-procedure) to 1.1±0.8 and 1.13±0.8 at the end of 2nd and 3rd week respectively. In Group TF, it improved from 2.47±0.7 (pre-procedure) to1.33±0.6 and 1±0.7 at the end of 2nd and 3rd week respectively. This difference in VRS was not statistically significant with a P value of 0.224 and 0.465 respectively.

Michael K. Schaufele et al (2006) conducted a case control study -Interlaminar versus Transforaminal epidural injections for the treatment of symptomatic lumbar vertebral disc herniations. In the transforaminal group, there was a statistically

significant improvement in the NRS scores from before the injection (NRS mean 5.9) to immediately i.e 1 hour after the injection (NRS mean 2.9, $p<0.01$). In the interlaminar group, there was a statistically significant improvement in the NRS scores from before the injection (NRS mean 7.3) to immediately after the injection (NRS mean 3.1, $p<0.01$). The post-injection VRS scores showed no statistical difference between the groups at post-injection, i.e. immediately after the injection. However, at follow-up there was a statistically significant difference between the two groups in the improvement in the VRS scores ($p<0.01$) in favor of the transforaminal group and these results are comparable with the present study.

In our study, most patients showed a improvement in SLRT of about 200 in both the groups by the end of 3rd week. The improvement in SLRT was almost equal in the 2 groups and hence, the difference in the improvement of SLRT between the 2 groups was not statistically significant. There are no studies available in literature so far, comparing the 2 routes with respect to SLRT.

As far as short term benefit is considered, 80% of patients in IL group in our study had improved walking tolerance as compared to 66.67% of patients in TF group. And, 33.3% patients reported reduction in analgesic use in Group IL as compared to 23.3% in Group TF. 10 patients out of 14 in Group IL and 11 patients out of 17 in Group TF had reversal of paresthesia. The difference between the 2 groups, with respect to the above parameters were not statistically significant.

Christopher.G.Gharibo et al (2011) conducted a study to evaluate short-term benefit for IL versus TF epidural steroids for the treatment of subacute lumbar radicular pain in 42 patients with low back pain and unilateral radicular symptoms. They reported improvement in walking tolerance and reduction in opioid pill was similar among the 2 groups.

The various complications that can occur with epidural steroid injection are infection, hematoma formation, vasovagal reaction, dural puncture, anterior spinal artery syndrome, disc injury, trauma to spinal nerve or dorsal root ganglion and hypersensitivity reaction to the drug. In our study, one patient in Group IL had vasovagal reaction 10 minutes following the procedure which was managed successfully.

Vad et al reported a 84% “success” in patients with lumbosacral radiculopathy who underwent transforaminal ESI,[3] compared to 70% in our group. Although these studies looked at different outcome endpoints, the results seemed to be quite comparable to the ones reported in our study, supporting the validity of our study.

The study has obvious limitations: First, the follow-up interval for pain improvement is short. Second, the sample size is small. Third, all procedures were performed by the same orthopaedic surgeon. The results of this study therefore reflect the experience of one practitioner and may not be generalized. Fourth, the study was not randomized

CONCLUSION

Patients who received a transforaminal epidural steroid injection for the treatment of symptomatic lumbar disc herniation had significantly better short-term pain improvement and equal functional improvement when compared to ILESI. After evaluation, it can be concluded that, Epidural steroid injection by transforaminal technique provides better subjective pain relief in the short term.

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