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"COMPARATIVE STUDY OF FUNCTIONAL EFFICACY OF TRANSFORAMINAL VS INTERLAMINAR EPIDURAL STEROID INJECTION FOR LUMBAR DISC DISEASE"

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Aims and objective: To compare efficacy of pain relief function of therapeutic transforaminal vs interlaminar epidural steroid injections and to assess improvement in functional outcome in lumbar disc disease patients after treatment.

Methodology: Patients with back pain documented with lumbar disc disease treated initially with rest, analgesics and physiotherapy for 6 weeks, will be analyzed clinically and radiologically. All the patients selected for the study be examined according to protocol, clinical and radiological investigations. Patients will be subjected into two groups by simple random sampling containing 30 members each. Group A will be given transforaminal epidural steroid injection and Group B will be given epidural steroid injection by Interlaminar route. Post epidural steroid injection patients were followed up for 6months and post injection disability and pain was assessed using Roland morris low back pain disability questionnaire, visual numerical score, finger floor distance, patient satisfaction score.

Results: Pre procedure Roland Morris Disability mean score was compared with post epidural steroid injection. Reduction of 5 score or more after procedure considered significant. In a group receiving transforaminal epidural steroid, among 30 patients 24 patients had relief at end of 1month, 16 patients had relief at end of 6 months, and in other group receiving epidural steroid through interlaminar technique in that 12 patients had significant relief at 1 month, 8 patients had significant relief at the end of 6 months. On comparison of both the groups Roland morris disability mean score was statistically significance at 1month, 3 months and 6 months in TFESI group compared to ILESI group ($p<0.05$). On comparison of pre and post procedure Finger floor distance of both the groups it was significant in TFESI group compared to ILESI group at 1 month and 3 months ($p<0.05$) and was not significant at 6 months. Comparison by Patient satisfaction group was significant at 3 months in TFESI group compared to ILESI group ($p<0.05$) and was not significant at 1month and 6 months. On comparison by Visual numerical score both the groups did not show any statistical significance. Post procedure the complications, such as dural puncture, excessive bleeding or infection were not reported in both groups. But headache was reported in 2 patients in ILESI.

Conclusion: Patients with radicular pain from disc herniation or lumbar canal stenosis obtain significant relief from a TFESI. Transforaminal epidural steroid therapy has better outcome with respect to Roland Morris disability assessment, Visual Numeric Scale, Finger Floor Distance. Patient Satisfaction and Pain Relief - majority of the patients have a significant improvement which lasts for 6 months.

KEYWORDS: ILESI, TFESI, Disc herniation

BACKGROUND

Lower back pain with or without lower limb pain is the most common problem among acute and chronic pain disorders, and has significant implications.[1---3] Chronic lower back pain is a multifactorial disorder with many possible etiologies.[4,5] The lifetime prevalence of spinal pain is reportedly 65 - 80% in the neck and lower back.[6] Kuslich et al.[7] identified intervertebral discs, facet joints, ligaments, fascia, muscles, and nerve root dura as the tissues capable of transmitting pain in the lower back.

Disc-related pain is caused by disk degeneration, disc herniation, or biochemical effects including inflammation. Degeneration of the human intervertebral disc is a major clinical problem and the leading cause of pain and disability, resulting in significant health care-related costs. The degenerative process in intervertebral discs is associated with a series of biochemical and morphological changes that combine to alter the biomechanical properties of the motion segment. Disk degeneration with or without disc herniation can lead to lower back pain.[8]

Several systematic reviews and meta-analyses have concluded that epidural steroid injections are efficacious when used to relieve pain in patients with lumbosacral radicular pain.[9-11]

Patients receiving such treatment are allowed adequate analgesia to conduct physical therapy, aqua therapy, and other forms of rehabilitation. To date, most studies on lumbar epidural steroid injections involved classical, interlaminar (IL) approach.[12]

The use of this technique results in deposition of medication in the posterior epidural space. Conversely, disc/nerve root pathology occurs in the anterior epidural space. Only a handful of clinical trials have looked at the transforaminal (TF) approach to lumbar epidural steroid injections[13-17], and there are currently no prospective studies comparing the classical IL approach with the TF approach when used for unilateral radicular pain.[12]

Still, the IL approach could be safer but less effective than the TF approach.[17,18] Similarly to IL epidural steroid injection studies, there has been no real attempt at identifying the best candidates to receive TF epidural steroid injections. The purpose of this randomized, prospective study is to compare the efficacy of two different routes for administering epidural steroid injections using the IL vs TF in patients with unilateral radicular pain. The TF approach to epidural injections results in deposition of the steroids in the anterior epidural space in close proximity to the site of pathology and may require lesser steroid dose.[12,19]

Therefore, our hypothesis is that by targeting the steroid to the site of pathology near the herniated intervertebral disc and affected nerve root, the TF approach using one-half of the total steroid dose will be superior in improving function at 24 weeks when compared with twice the dose administered in an IL approach.

AIMS AND OBJECTIVE

To compare efficacy of pain relief function of therapeutic transforaminal vs interlaminar epidural steroid injections and to assess improvement in functional outcome in lumbar disc disease patients after treatment in Rajarajeswari Medical College and Hospital, Bengaluru, Karnataka, India.

STUDY DURATION

October 2019 to August 2021 in Rajarajeswari Medical College and Hospital, Bengaluru, Karnataka, India.

MATERIAL AND METHODS

A Prospective study. Patients with back pain documented with lumbar disc disease treated initially with rest, analgesics and physiotherapy for at least 6 weeks, admitted to Rajarajeswari Medical College and Hospital, Bangalore Satisfying the inclusion criteria are taken for this study from Oct 2019 to August 2021.

The Sample Size is **30** in each group. About 30 cases in each group during the study period, by using simple randomized sample technique. Patients with back pain documented with lumbar disc disease treated initially conservatively for at least 6 weeks, after taking consent, will be analyzed clinically and radiologically. All the patients selected for the study be examined according to protocol, clinical and radiological investigations. Patients will be subjected into two groups by simple random sampling.

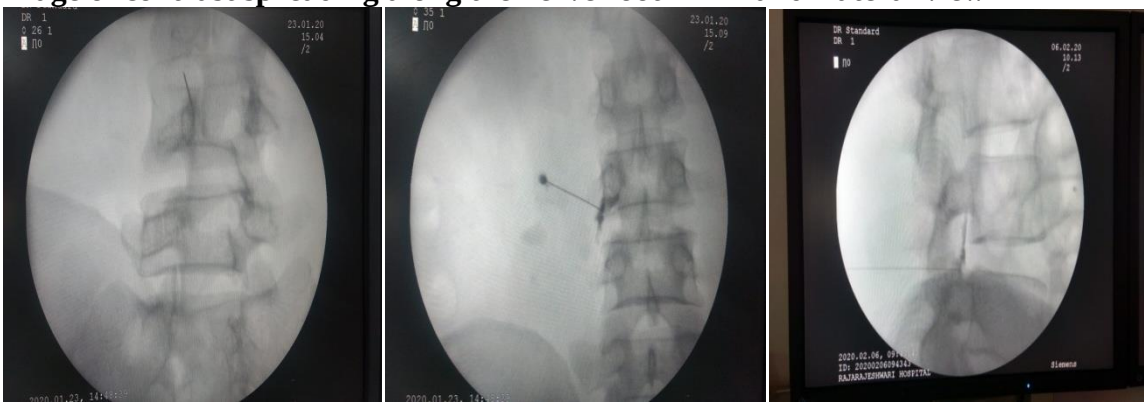
Group A will be given epidural steroid injection by Interlaminar route and Group B will be given transforaminal epidural steroid injection.

Group A patients ESI were given using the 17 guage hypodermic needle, 3 ½ inch tuohy epidural needle. Advanced it within the soft tissue track vertically until contact made with the laminavunder fluoroscopic image guidance. 10-mL syringe containing 1 mL of 1% preservative-free lidocaine and 2 mL of 40 mg/mL triamicinolone. Inject the corticosteroid preparation slowly into the epidural space. In group B patients ESI was given by a 22-gauge, 4 ¾ inch spinal needle is then inserted and advanced within the anesthetized soft tissue track under fluoroscopy guidance until contact is made near the junction of the superior articular process and lower edge of the superior transverse process. The spinal needle is retracted 2 to 3 mm, redirected towards the base of the appropriate pedicle and advanced it slowly to the 6-o'clockposition of the pedicle under fluoroscopy. Adjusted the C-arm to a lateral projection to confirm the position, and then returned the C-arm to the anteroposterior view. Confirmed placement in safe triangle. Safe triangle roof is formed by pedicle, exiting nerve root forms tangential base and vertebral body forms lateral border. After documenting adequate flow of contrast to target site and no blood or cerebrospinal fluid was aspirated, 2ml of triamicinolone (each ml containing 40 mg) with 1ml of preservative free lignocaine were given. Injections were never given more than 2 levels to avoid systemic side effects of steroid.

Post epidural steroid injection patients were followed up for 6months. Followed by that the outcome was measured using patient satisfaction scale, Roland morris low back pain disability questionnaire (RMDQ), measurement of finger-to floor distance, visual numeric pain scale

Image showing the Injection of Transforaminal Epidural Steroid

C-arm image showing site of needle placement in the c-arm, and image showing C-arm image of contrast spreading along the nerve root in AP and Lateral view



INCLUSION CRITERIA

1. Patients with duration of back pain and radiculopathy for more than 6 weeks with radiological evidence (MRI & X- RAY) of lumbar disc disease.
2. MRI scan showing an herniated inter-vertebral disc with less than 50% inter- vertebral canal narrowing with manifestations of backache and radiculopathy. Herniated intervertebral disc at various interspaces (L3–L4, L4–L5, L5–S1) and with differing axial presentations (*e.g.*, far lateral, paracentral, and central protrusion) were examined.
3. Age group between 18 to 65 years.

EXCLUSION CRITERIA

1. Patients with more than 2 level lumbar disc disease.
2. Patients with progressive neurological deficits.
3. Patients who underwent prior lumbar surgery.
4. Patients with a large herniation with severe central or foraminal stenosis on MRI.
5. Coagulation disorder.
6. Patients with a history of anaphylaxis to local anaesthetics or corticosteroid.

Patients who met inclusion criteria were obtained informed consent after explaining all risks, benefits, objectives and outcomes of the study. They were all explained about nature of study.

STATISTICAL ANALYSIS

Data was entered into Microsoft excel data sheet and was analysed using SPSS 22 version software. Categorical data was represented in the form of frequencies and proportions, continuous data was represented as mean and standard deviation.

Independent t test used to determine significant difference between the two groups, dependent t test used to determine significant difference between pre and post treatment.

Graphical representation of data: MS Excel and MS world was used to obtain various types of graphs.

p value (probability that result in true) of <0.05 was considered as statistically significant after assuming all the rules of statistical tests.

Statistical software: MS Excel, SPSS version 22 (IBM SPSS Statistics, Somers NY, USA) was used to analyze data.

RESULTS

Sixty patients fulfilled the inclusion criteria, these patients were divided into 2 groups containing 30 people each. Twenty one were male and nine were female in TFESI group, eighteen were male and twelve were female in TFESI group. Their ages ranged from 25 years to 65 years, and the mean age was 47 years in TFESI group and 43.33 in ILESI group.

In the TFESI group pre procedure Roland Morris Disability mean score was 16.77 and it got reduced to 10.97 by end of one month, was 11.77 by 3rd month, and by the end of the study period, the mean Roland- Morris score in TFESI was 12.50.The Pre procedure Finger floor distance mean score was 63.67 and it got reduced to 32.77 by end of one month, was 34.97 by 3rd month, and by the end of the study period, the mean finger floor distance in TFESI was 37.87.The Pre procedure Patient satisfaction score mean score was 0.2 and it got increased to 2.9 by end of one month, was 2.83 by 3rd month, and by the end of the study period, the mean patient satisfaction score in TFESI was 2.6

The Pre procedure visual numerical mean score was 8.4 and it got reduced to 3.43 after TFESI on 0^{th} day and was 3.6 by end of one month, was 3.8 by 3rd month, and by the end of the study period, the mean visual numerical score in TFESI was 4.07. Fifty percent mean reduction was noticed in transforaminal group till end of six months. Results were significant in transforaminal group.

In the ILESI group pre procedure Roland Morris Disability mean score was 17 and it got reduced to 13.07 by end of one month, was 13.2 by 3rd month, and by the end of the study period, the mean Roland- Morris score in TFESI was 13.83. The Pre procedure Finger floor distance mean score was 62.33 and it got reduced to 42.5 by end of one month, was 43.67 by 3rd month, and by the end of the study period, the mean finger floor distance in TFESI was 44.87. The Pre procedure Patient satisfaction score mean score was 0.03 and it got increased to 2.43 by end of one month, was 2.07 by 3rd month, and by the end of the study period, the mean patient satisfaction score in TFESI was 2.17. The Pre procedure visual numerical mean score was 8.5 and it got reduced to 4.3 after TFESI on 0^{th} day and was 4.47 by end of one month, was 4.67 by 3rd month, and by the end of the study period, the mean visual numerical score in TFESI was 5.

Among 30 people in each group 10 patients in TFESI and 16 patients in the ILESI group received repeated or second dose of epidural steroid injection.

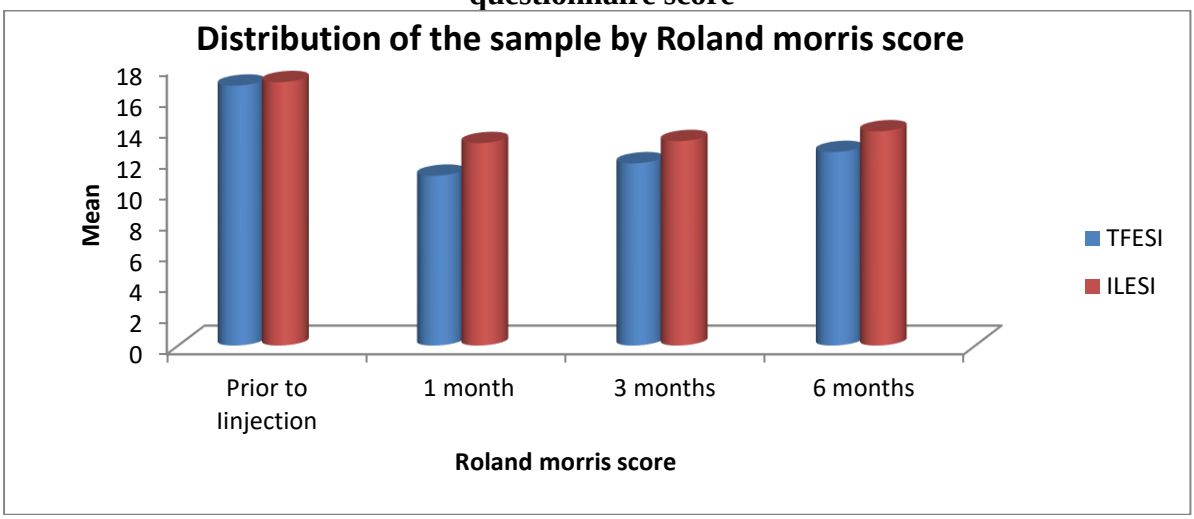
Patients in both the groups were assessed using Roland morris score at prior to injection, at 1month, at 3 months and 6 months post epidural steroid injection. Roland morris score was lower in TFESI group compared to ILESI group at 1 month 3 months and 6 months post epidural steroid injection and was statistically significant. Reduction of 5 score or more after procedure considered significant.

In TFESI group 24 patients 1^{st} month and 19 patients at 3 months and 16 patients at 6months showed significant in roland morris disability score. In ILESI group 12 patients 1^{st} month and 10 patients at 3 months and 8 patients at 6months showed significant in roland morris disability score.

Table showing comparison of both groups by Roland morris Low back pain Disability questionnaire score

Duration	Group		P Value
	TFESI	ILESI	
Pre	16.77±1.96	17.00±1.37	0.595
1 Month	10.97±2.49	13.07±1.74	0.0001
3 Months	11.77±2.52	13.20±2.33	0.026
6 Months	12.50±2.53	13.83±1.97	0.026

Figure showing comparison of both groups by Roland morris Low back pain Disability questionnaire score

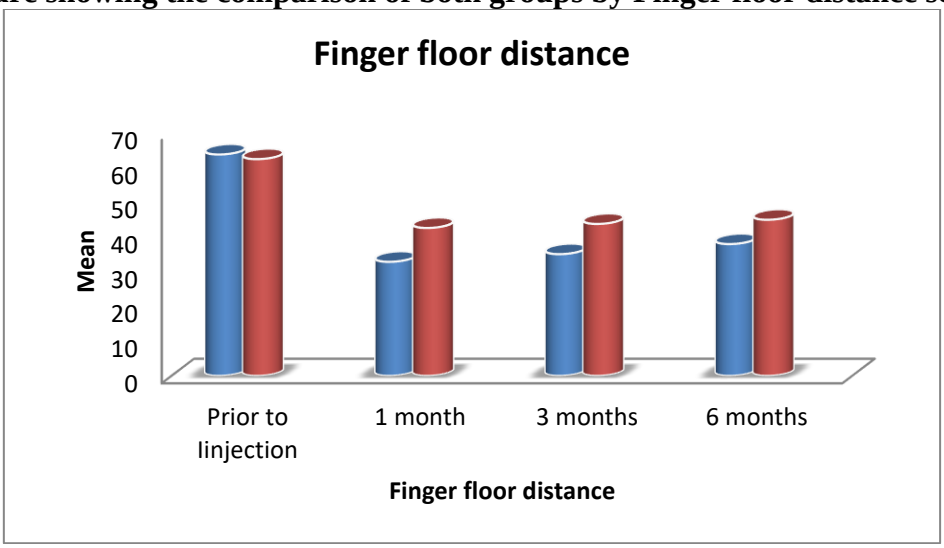


Patients in both the groups were assessed using Finger floor distance at prior to injection, at 1month, at 3 months and 6 months post epidural steroid injection. Finger floor distance was lower in TFESI group compared to ILESI group at 1 month 3 months post epidural steroid injection and was statistically significant. At 6 months of follow up score was lower and was statistically not significant.

Table showing the comparison of both groups by Finger floor distance score

Duration	Group		P Value
	TFESI	ILESI	
Pre	63.67±9.39	62.33±5.05	0.496
1 Month	32.77±14.31	42.50±12.76	0.007
3 Months	34.97±14.13	43.67±12.94	0.016
6 Months	37.87±15.30	44.87±13.12	0.062

Figure showing the comparison of both groups by Finger floor distance score



Patients in both the groups were assessed using patient satisfaction score at prior to injection, at 1month, at 3 months and 6 months post epidural steroid injection. Finger floor distance was lower in TFESI group compared to ILESI group at 1 month 3 months post epidural steroid injection and was statistically significant. At 6 months of follow up score was lower but was statistically not significant.

Table showing the comparison of both groups by Patient satisfaction score

Duration	Group		P Value
	TFESI	ILESI	
Pre	0.20±0.41	0.03±0.18	0.045
1 Month	2.90±1.21	2.43±1.07	0.120
3 Months	2.83±1.02	2.07±1.23	0.011
6 Months	2.60±0.93	2.17±1.78	0.243

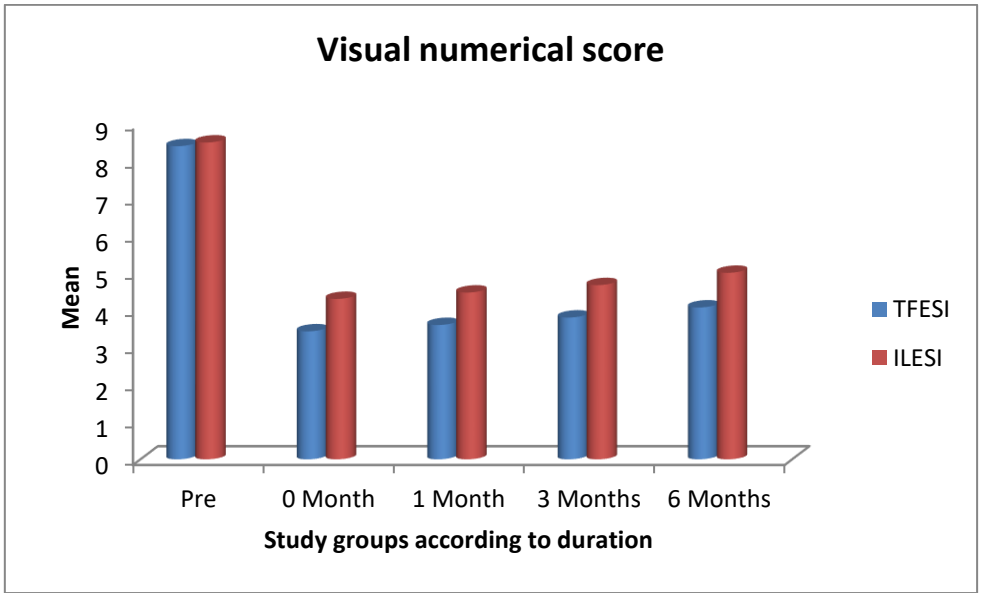
Figure showing the comparison of both groups by Patient Satisfaction score

In TFESI, the Visual Numeric Pain pre procedure mean was 8.40 and after procedure it got reduced to 3.43 immediately, 3.60 by end of one month, was 3.8 by 3rd month, by 6th month 4.07.
In ILESI, the Visual Numeric Pain pre procedure mean was 8.50 and after procedure it got reduced to 4.30 immediately, to 4.47 by end of one month, was 4.67 by 3rd month. By 6th month 5.00.

Table showing comparison of both the groups with visual numerical score

Duration	Group		P Value
	TFESI	ILESI	
Pre	8.40±0.72	8.50±0.82	0.618
0 Month	3.43±2.09	4.30±2.29	0.132
1 Month	3.60±2.09	4.47±2.37	0.139
3 Months	3.80±1.99	4.67±2.59	0.152
6 Months	4.07±2.12	5.00±2.60	0.133

Chart showing comparison of both the groups with visual numerical score



Roland morris score was assessed prior to ESI and at 1month, 3 months and 6 months in TFESI and ILESI groups. The chart shows the mean and standard deviation of both the groups and the results at 1 month, 3 months and 6 months were compared with the prior value and result was significant at 1 month, 3 months and 6 months in both the groups.

Table showing the comparison of Roland Morris Low back pain disability questionnaire by Group

Group	Duration	Mean	Standard Deviation	P Value
TFESI	Pre	16.77	1.96	0.0001
	1 Month	10.97	2.49	
	Pre	16.77	1.96	0.0001

	3 Months	11.77	2.52	
	Pre	16.77	1.96	0.0001
	6 Months	12.50	2.53	
ILESI	Pre	17.00	1.37	0.0001
	1 Month	13.07	1.74	
	Pre	17.00	1.37	0.0001
	3 Months	13.20	2.33	
	Pre	17.00	1.37	0.0001
	6 Months	13.83	1.97	

Finger floor distance was assessed prior to ESI and at 1month, 3 months and 6 months in TFESI and ILESI groups. The reduction in the distance was noted as improvement chart shows the mean and standard deviation of both the groups and the results at 1, 3 and 6 months were compared with the prior value and result was significant at 1 month, 3 months and 6 months in both the groups.

Table showing the comparison Finger Floor distance by Group

Group	Duration	Mean	Standard Deviation	P Value
TFESI	Pre	63.67	9.39	0.0001
	1 Month	32.77	14.31	
	Pre	63.67	9.39	0.0001
	3 Months	34.97	14.13	
	Pre	63.67	9.39	0.0001
	6 Months	37.87	15.30	
ILESI	Pre	62.33	5.05	0.0001
	1 Month	42.50	12.76	
	Pre	62.33	5.05	0.0001
	3 Months	43.67	12.94	
	Pre	62.33	5.05	0.0001
	6 Months	44.87	13.12	

Patient satisfaction score was assessed prior to ESI and at 1, 3 and 6 months in TFESI and ILESI groups. The chart shows the mean and standard deviation of both the groups and the results at 1, 3 and 6 months were compared with the prior value and result was significant at 1, 3 and 6 months in both the groups.

Table showing the comparison Patient Satisfaction score by Group

Group	Duration	Mean	S D	P Value
TFESI	Pre	0.20	0.41	0.0001
	1 Month	2.90	1.21	
	Pre	0.20	0.41	0.0001
	3 Months	2.83	1.02	
	Pre	0.20	0.41	0.0001
	6 Months	2.60	0.93	
	Pre	0.03	0.18	0.0001
	1 Month	2.43	1.07	

ILESI	Pre	0.03	0.18	0.0001
	3 Months	2.07	1.23	
	Pre	0.03	0.18	0.0001
	6 Months	2.17	1.78	

Visual numerical score was assessed prior to ESI and at 1month, 3 months and 6 months in TFESI and ILESI groups and reduction in score was considered as the improvement. The chart shows the mean and standard deviation of both the groups and the results at 1 month, 3 months and 6 months were compared with the prior value and result was significant at 1 month, 3 months and 6 months in both the groups.

Comparison Visual numerical score by Group

Group		Mean	Standard Deviation	P Value
TFESI	Pre	8.40	0.72	0.0001
	0 Month	3.43	2.09	
	Pre	8.40	0.72	0.0001
	1 Month	3.60	2.09	
	Pre	8.40	0.72	0.0001
	3 Months	3.80	1.99	
	Pre	8.40	0.72	0.0001
	6 Months	4.07	2.12	
ILESI	Pre	8.50	0.82	0.0001
	0 Month	4.30	2.29	
	Pre	8.50	0.82	0.0001
	1 Month	4.47	2.37	
	Pre	8.50	0.82	0.0001
	3 Months	4.67	2.59	
	Pre	8.50	0.82	0.0001
	6 Months	5.00	2.60	

Post procedure the complications, such as dural puncture, excessive bleeding or infection were not reported in both groups. But headache was reported in 2 patients in ILESI.

DISSCUSION

As per **North American Spine Society (NASS)** 2013 opinion – "TFESI is recommended to provide relief of radicular pain. TFESI has been found to be effective in providing pain relief for at least one month in more than fifty percent of patients, with half of these patients continuing to benefit from treatment for a year or more." In our study also 24 patients (80 percent) had significant immediate relief. This effect persisted in 18 patients (80 percent) till the follow up period of 6 months.

Gahribo et al [20] study in 2011 showed pain improvement of 73.4% in TFESI group and 44.3% in ILESI group. But he followed patients only for 3 weeks. This result similar to our study which had similar results of significant pain relief as 80% in TFESI and 53.3% in ILESI initially (visual numeric scale group 1-3 mild pain)

As per North American Spine Society - "Karpinnen et al [21] study provides therapeutic evidence that: (1) LTFESI at four weeks after treatment achieves significantly greater improvements in pain and disability in patients with contained herniations, but not in patients

with extrusions; and (2) for providing at least 75% relief of radicular pain." In our study also patients had significant improvement of 80 % reduction in disability by one month. But Kolsi et al [12] study did not find any difference in pain relief in both groups. Both groups had similar pain relief of 62.8% and 63.5%. His duration of study also 28 days. His study group had only 17 patients in group I and 13 patients in group II.
Ackerman and Ahmad [22] had 72% pain improvement by the end of 24 weeks in transforaminal group and 35.2% in interlaminar group. Out of 30 patients in transforaminal group 9 patients had complete pain relief. In our study also we found by 24 weeks, 3 patients in TFESI and 4 patients in ILESI with Visual Numeric Scale of one and two (Visual Numeric Scale 1-2 mild pain). Ackerman didn't use any numeric scale to assess pain. He divided patients into complete relief, partial relief and no relief.

Functional improvement
Rado et al [23] study reported functional improvement as 28.3 in TFESI and 25.0 in ILESI group by the end of 24 weeks. In our study by the end of 6 months 53.3%% in TFESI and 26.6% in ILESI group had significant disability improvement of five scales as per **Roland Morris low back pain Disability Questionarre.**

Ng et al [24] conducted a prospective RCT. Of the 86 consecutively assigned patients included in the study, 43 were randomly assigned to receive LTFESI (bupivacaine + corticosteroid) and 43 received injections of bupivacaine alone. Outcomes were assessed at three months using the VAS and ODI along with patient satisfaction and change in walking distance. Intent to treat analysis did not demonstrate a statistically significant difference in Oswestry scores between the two treatment groups. In critique, this was a small study which was insufficiently powered to be an equivalence study.

CONCLUSION
Epidural steroid injections are safe without any major adverse effects. Patients with radicular pain from disc herniation or lumbar canal stenosis obtain significant relief from a preganglionic LTFESI irrespective of age, gender, level of injection, symptom duration and pain intensity. Transforaminal epidural steroid therapy has better outcome with respect to Roland Morris disability assessment, Visual Numeric Scale, Finger Floor Distance assessment, Patient Satisfaction Score. Transforaminal steroid injection is superior to ILESI as it gives target specific administration. Interlaminar steroid administration is also useful if it is done under fluoroscopic guidance. But mostly it is given blindly and hence the chances of the needle misplacement are there, so lesser success rate. Non responders rate is high in ILESI group. Transforaminal group disablity improves significantly. Maximum improvement occurs with in one month. Further improvement rate diminishes. In majority of the patients response lasts more than 6 months. Patient Satisfaction and Pain Relief - majority of the patients have a significant improvement which lasts more than 6 months. Lumbar transforaminal epidural steroid injections (LTFESI) are cost effective. Transforaminal epidural steroid treatment better medication for pain relief, patient satisfaction, disability improvement and functional improvement.

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