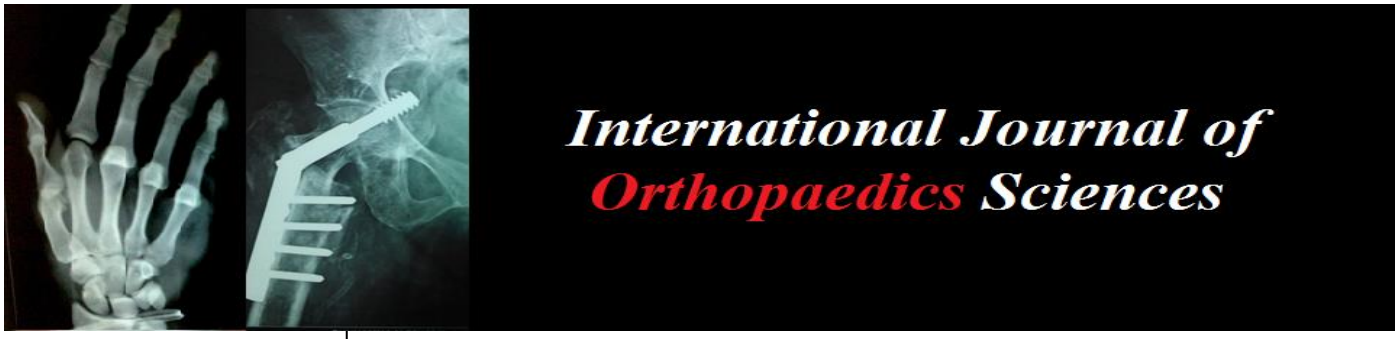

E-ISSN: 2395-1958
P-ISSN: 2706-6630
IJOS 2023; 9(2): 265-273

https://www.orthopaper.com
Received: 04-02-2023
Accepted: 07-03-2023

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Role of triamcinolone acetate in treatment of symptomatic intervertebral disc herniations via interlaminar vs transforaminal approach

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DOI: https://doi.org/10.22271/ortho.2023.v9.i2d.3377

Abstract
Introduction: Lowback pain is one of the most common chronic pain disorders, with 2-3% incidence of lumbar disk herniations among population. Epidural corticosteroid injections have been used since 1952 for treatment of lumbar radiculopathy with or without discogenic back pain in patient with failed medical and conservative management. Local Steroids such as triamcinolone acetate acts by limiting inflammatory response. Several approaches are available; interlaminar, transforaminal and caudal. This study was conducted to compare the efficacy of triamcinolone acetate injection by interlaminar vs transforaminal approach.
AIM: To compare the efficacy of triamcinolone acetate in terms of pain relief between interlaminar approach and transforaminal approach.
Methodology: In this study 60 patients with low back pain are randomly allocated to one of the two groups of 30 patients each. In both group 40mg of triamcinolone acetate solution is used. In IL approach, drug is injected blindly in the epidural space, while in TF approach drug is injected under fluoroscopic guidance using dye. Outcome consists of measuring pain relief at 2nd and 4th week after injection using Numerical Scale and Verbal Rating Scale. Data was collected after 15mins, at 2nd week and at 4th week after the injection. RESULTS**:** The pain relief in NRS and VAS at 2nd week was more in patient who received triamcinolone acetate via transforaminal approach.
Conclusion: Transforaminal is superior to interlaminar, as it gives target specific administration of triamcinolone acetate and is more effective than ILESI comparing the NRS and VAS score in terms of pain relief.

Keywords: IVDP, Disc prolapse, Interlaminar, Transforaminal, Epidural steroid infiltration.

Introduction
Lumbar disk herniation consists of displacement of the nucleus pulposus contained in the intervertebral disk through the annular fibrous ring. This displacement may lead to compression and irritation of the lumbar nerve roots and dural sac, which are characterized clinically by the pain known as sciatica [1]. The etiology of sciatica is multifactorial. It can be caused by mechanical compression of the intervertebral disk and by the release of inflammatory and nociceptive mediators coming from the nucleus pulposus [2, 3, 4, 5, 6, 7, 8]. It has been estimated that 2-3% of the population has lumbar disk hernias, with prevalence of 4.8% among men and 2.5% among women over the age of 35 years. Furthermore, it is the commonest diagnosis among degenerative alterations of the lumbar spine and the main cause of surgery in elderly age group [1]. The initial treatment for disk hernia in most cases is conservative. Surgery is a uncommon form of treatment that should only be used when all other conservative measures have failed, or if a patient has a growing neurological disability, or they have cauda equina syndrome [1, 9]. Epidural steroid injections (ESI) with SI joint infiltrations are used in the treatment of backpain and radicular pain [16-19]. Among the minimally invasive methods for treating lumbar disc hernia, epidural steroid injection is a suitable choice. This makes it possible to reduce the inflammatory response, improve the state of pain, reduce the consumption of analgesics, maintain work activities and eliminate the need for surgery, among most individuals [8, 11-13].

In an effort to delay or even avoid surgery for individuals who are unresponsive to proper conservative treatment, epidural steroid injections may be recommended. While administering epidural steroid injections, both Dexamethasone and Triamcinolone acetate have been considered, but transforaminal injections have been proved to be effective for short term relief of lumbar radiculopathy [35]. This can be done using interlaminar and transforaminal approach, or caudally (via the sacral hiatus) [1, 14, 15]. We propose to conduct this study to compare the efficacy of triamcinolone acetate injection by interlaminar and transforaminal approach.

Materials and Methods

The present study was conducted in AJ Institute of Medical Sciences, Mangalore during August 2019 to September 2021. The patients visiting orthopaedics department will be included in the study.

Method of collection of data

Inclusion criteria

- Patients of either sex, aged between 18-60 years.
- Low back pain with unilateral/bilateral lumbar radicular pain of duration greater than three months.
- Patients with MRI suggestive of intervertebral disc bulge or protrusions.

Exclusion criteria

- Patient refusal for the procedure.
- Patients with multilevel disc bulge/protrusion.
- Patients with disc extrusion and sequestration as per MRI findings.
- Patients with significant coagulopathies and use of anticoagulants.
- Patient with history of allergy to contrast media, steroids and local anaesthetic agents.
- Previous lumbar spine surgeries or epidural steroid injections.
- Multi-level degenerative spine disease, unstable spine, vertebral compression fractures, spondylolisthesis, cauda equina syndrome and arachnoiditis.
- Patient diagnosed to have active cancer, history of substance abuse, current psychiatric co-morbidity, pregnancy, diabetes mellitus and congestive cardiac failure.
- Critically ill patients.
- Acute febrile illnesses.
- Chronic liver disease.
- Pregnant women.

Sample size

The sample size has been estimated using the G Power software v. 3.1.9.2. Considering the effect size to be measured at 77%, power of the study at 80% and the margin of the error at 5%, the total sample size needed is 40. Therefore total 40 units taken will be divided in to 20 in each group. Since the non-response rate is high during the pandemic, considering chance of drop out in between the study duration an additional of 12 had considered in each group among them 30 in each group were present till the end of the study. Therefore sample size in each group was 30. Out of 60 patients, 40 patients had L4-L5 disc herniations and 20 patients had L5-S1 disc herniations. The Patients were randomly allocated to one of the two groups of 30 patients each.

1. Group 1 – For Interlaminar approach.
2. Group 2 – For Transforaminal approach.

Sample and sampling technique

- **Study design:** Computer generated randomisation.
- **Set-up:** The AJ Institute of Medical Sciences, kuntikana, Mangalore.
- **Age group:** patients visiting AJIMS whose age is more than 18 years and less than 60 years.
- **Sampling technique:** purposive sampling.

Methodology

- Patients are explained about the procedure and informed and written consent obtained.
- Routine NPO protocols will be followed, i.e., for 3 hours.
- Intravenous line is secured with 20G cannula.
- Following monitors are connected – NIBP, SpO2, ECG.
- With all aseptic precautions, in group IL, 18G spinal needle is placed in L3-L4 epidural space in interlaminar region with the patient in lateral or sitting position, a mixture of 1ml of triamcinolone acetate with 3ml of 0.5% levoanawin is injected by an experienced anesthetist.
- With all aseptic precautions, in group TF, spinal needle is placed in foraminal space with the patient in prone position under fluoroscopic guidance using iohexol dye, mixture of 0.5% of 3ml levoAnawin with 1ml of triamcinolone is injected by an orthopaedic spine surgeon at transforaminal region.
- Patient monitored for 15 mins after the procedure in the operation room and for 1 hour in post operative ward, for any immediate adverse effects.

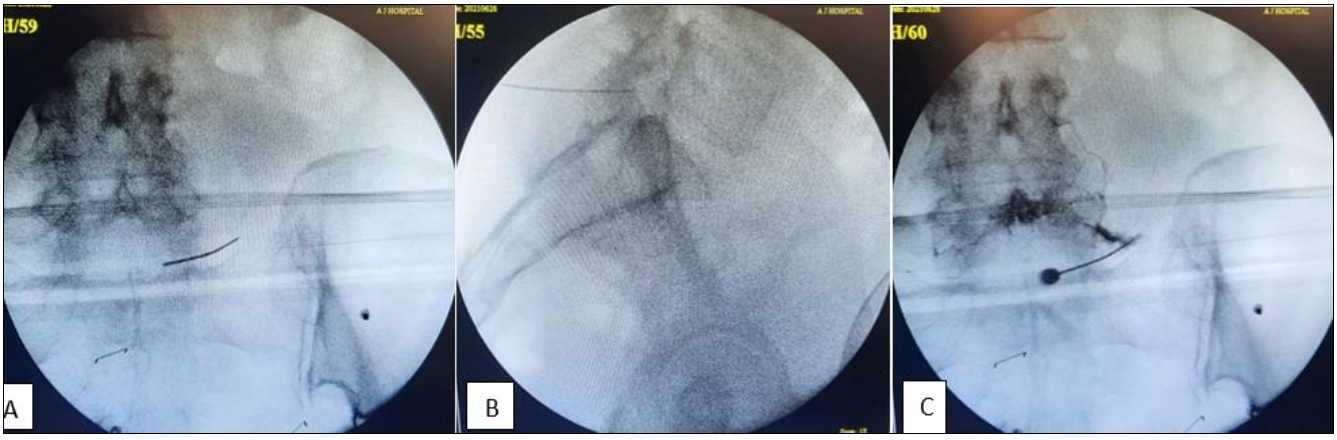

Fig 1: A: Anteroposterior image on image intensifier confirming spinal needle location in right 1.5 foraminal region. Fig B: lateral image on image intensifier confirming needle at 1.5 transforaminal region. Fig C: image intensifier showing right exiting L5 nerve root after dye injection.

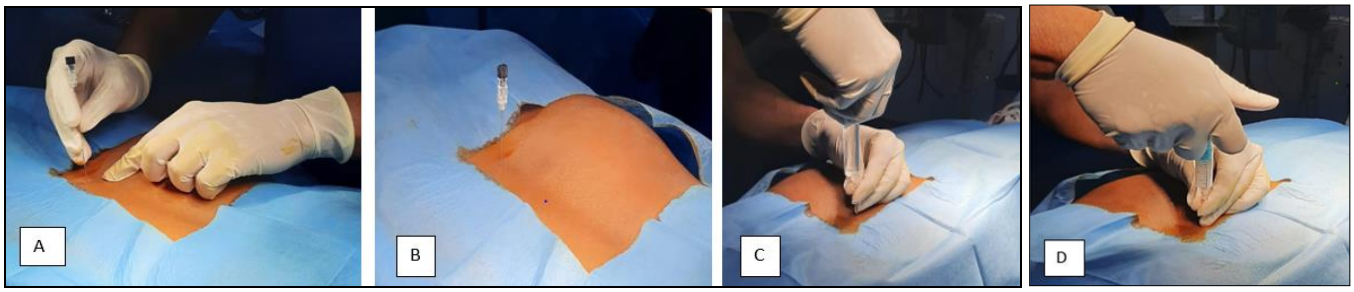

Fig 2: A: Inserting 22G spinal needle to right 15 transforaminal space. Fig B: spinal needle positioned in right LS transforaminal space. Fig C: confirming the placement of spinal needle by injecting normal saline. Fig D: Injecting steroid injection through transforaminal approach.

Outcome measures consists

Primary outcome: Pain relief at the end of 2nd and 4th week after the triamcinolone acetate injection using Numerical Rating Scale (NRS) and Visual analogue Scale (VAS). NRS being objective tool and VAS being subjective tool.

Secondary outcome

- Assessment of pain relief immediately after the triamcinolone acetate injection by using NRS, VAS.
- Reduction in analgesic requirement data was collected after 15mins, at the end of 2nd week and at the end of 4th week after the triamcinolone acetate injection.

Results

Data analysis and interpretation: Statistical analysis of the data was done by using the software SPSS23.0. Descriptive statistics were calculated and summarised. Which includes frequency, percentage, Mean, standard deviation. Inferential statistics had been carried out in the present study. Pre post comparison was done by paired t test and between groups comparison was done by unpaired t test. Chi-square test was used to find association. Level of significance was set at 0.05%.

In Interlaminar approach group average age is 33.833±8.522 years and in transforaminal group average age is 34.843±8.179 years. There was no significant difference between ages of the groups. In Interlaminar group majority 24(80%) are male and 6(20%) are females. In transforaminal group majority 23(76.7%) are male and 7(23.3%) are female. There was no significant association between sex and the group.

Table 1: Showing cross tabulation of symptoms and group

	Interlaminar Approach	Transforaminal Approach	Total
Pain, Tingling, Weakness	21 70.0%	17 56.7%	38 63.3%
Pain	5 16.7%	6 20.0%	11 18.3%
Pain, Tingling	4 13.3%	3 10.0%	7 11.7%
Pain and Weakness	0 0.0%	4 13.3%	4 6.7%
Total	30 100%	30 100%	60 100%

In interlaminar group, majority of 21(70%) had all the three symptoms (pain, weakness, tingling sensation), 5(16.7%) had only pain and 4(13.3%) had pain and tingling sensation. In transforaminal group, majority of 17(56.7%) had all the three symptoms (pain, weakness, tingling sensation), 6(20%) had only pain and 3(10%) had both pain, tingling sensation and 4(13.3%) had pain and weakness.

Association between symptoms and group showed chi square value = 4.655 with $p>0.05$, which indicated there was no significant association between symptoms and the group.

Table 2: Showing mean and standard deviation of NRS in Interlaminar approach group.

	N	Minimum	Maximum	Mean	Std. deviation
At presentation	30	7.00	9.00	7.866	0.681
Week 2	30	3.00	7.00	4.966	1.188
Week 3	30	2.00	6.00	4.033	1.129

In Interlaminar group NRS of pain in interlaminar approach group was significantly reduced at 2nd and 4th week post procedure.

Table 3: Showing pre post comparison in NRS – Interlaminar approach

	Mean difference	T Value	Result
At presentation – week 2	2.900	15.438	$p<0.05$
Week2 – week4	0.933	20.149	$p<0.05$
Baseline – week4	3.833	21.304	$p<0.05$

Patients who underwent procedure through interlaminar approach their initial presentation to second week average reduction in NRS is 2.9 with $p<0.05$. This indicates there is significant reduction in pain at second week after procedure. Second week to fourth week average reduction in NRS score is 0.933 with $p<0.05$ and from the base line to fourth week average reduction in pain is 3.833 with $p<0.05$.

Table 4: Showing mean and standard deviation of VAS in Interlaminar approach group

	N	Minimum	Maximum	Mean	Std. Deviation
Base line	30	3.00	5.00	4.100	0.844
Week2	30	2.00	5.00	3.366	0.850
Week4	30	.00	4.00	1.933	0.284

Base line VAS score was 4.1±0.844 which reduced to 3.366±0.850 in the second week and in the fourth week it

further reduced to 1.933±0.284 in interlaminar approach.

Table 5: Showing pre post comparison in VAS – Interlaminar approach

	Mean difference	T Value	Result
Base line - week2	0.733	5.117	$p<0.05$
Week2 – week4	1.433	6.277	$p<0.05$
Base line – week4	2.166	7.740	$p<0.05$

In Interlaminar approach study shows from at second week post procedure, average reduction in VAS was 0.733 with p<0.05. This indicates there is significant reduction in pain at second week. Second week to fourth week average reduction in VAS score is 1.433 with $p<0.05$. From baseline to fourth week average reduction in pain is 2.166 with $p<0.05$.

Table 6: Showing mean and standard deviation of NRS Transforaminal group

	N	Minimum	Maximum	Mean	Std. Deviation
Base line	30	7.00	9.00	7.733	0.691
Week2	30	3.00	6.00	4.566	0.727
Week4	30	.00	5.00	2.900	1.37

Table 7: Showing pre post comparison in NRS – Transforaminal approach

	Mean Difference	T Value	Result
Base line – week2	3.166	32.684	$p<0.05$
Week2 – week4	1.666	6.312	$p<0.05$
Base line – week4	4.833	5.362	$p<0.05$

In Transforaminal group base line average numeric pain score is 7.733±0.691 which reduced to 4.566±0.727 in the second week and in the fourth week it further reduced to 2.9±1.37.

Table 8: Showing mean and standard deviation of VAS in Transforaminal group

	n	Minimum	Maximum	Mean	Std. Deviation
Base line	30	3.00	5.00	3.966	0.808
Week 2	30	1.00	4.00	2.50	0.776
Week4	30	.00	3.00	.866	0.819

Post procedure through Transforaminal at second week average reduction in NRS are 3.166 with p<0.05. This indicates there is significant reduction in pain at second week. Second week to fourth week average reduction in NRS score is 1.666 with $p<0.05$. From base line to fourth week average reduction in pain is 4.833 with $p<0.05$. The above tables shows there is significant reduction in pain from base line to fourth week.

Base line average VAS score is 3.966±0.808 which reduced to 2.5±0.776 in the second week and in the fourth week it further reduced to 0.866±0.819 in Transforaminal group.

Table 9: Showing pre post comparison in VAS in Transforaminal group

	Mean difference	T Value	Result
Base line – week 2	1.466	7.712	$p<0.05$
Week2 – week4	1.633	8.147	$p<0.05$
Base line – week4	3.1	13.676	$p<0.05$

Post procedure Study in Transforaminal group shows at second week average reduction in VAS are 1.466 with p<0.05. This indicates there is significant reduction in pain at second week. Second week to fourth week average reduction in VAS score is 1.633 with p<0.05. From base line to fourth week average reduction in pain is 3.1 with p<0.05. The above tables shows there is significant reduction in VAS score from base line to fourth week.

Table 10: showing comparison between interlaminar approach group and Transforaminal group in NRS

	Group	Average improvement	T Value	Result
Baseline to 2nd week	Interlaminar Transforaminal	2.7667 3.4000	2.863	$p<0.05$
2nd week to 4th week	Interlaminar Transforaminal	1.0000 1.6667	2.660	$p<0.05$
Base line to 4th week	Interlaminar Transforaminal	3.7667 5.0667	4.059	$p<0.05$

Post procedure comparison between interlaminar and Transforaminal groups in NRS was done. It shows improvement in pain at 2nd week in interlaminar group is 2.7667 and in Transforaminal group it is 3.4. 2nd week to 4th week improvement in interlaminar group is 1.0 and that of Transforaminal group is 1.6667. Improvement from base line to 4th week in interlaminar group is 3.766 and in Transforaminal group it is 5.066 with P Values < 0.05 in all the cases.

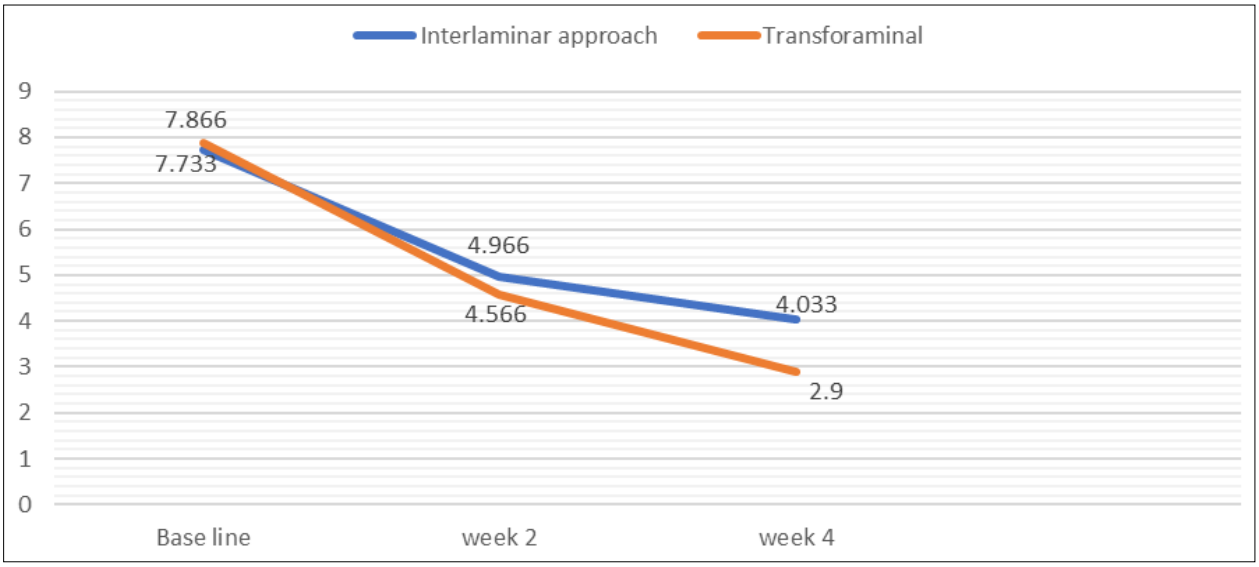

Fig 3: Comparision of NRS between groups

Table 11: Showing comparison between Interlaminar approach group and Transforaminal group in VAS

	Group	Average improvement	T Value	Result
Baseline to week 2	Interlaminar Transforaminal	0.7333 1.4667	3.080	$p<0.05$
Week2 to week4	Interlaminar Transforaminal	1.4333 1.6333	2.994	$p<0.05$
Base line to week 4	Interlaminar Transforaminal	2.1667 3.1	2.591	$p<0.05$

Comparison between interlaminar approach and Transforaminal in VAS post procedure shows, improvement in pain at 2nd week in interlaminar group is 0.733 and in Transforaminal group it is 1.466. 2nd week to 4th week improvement in interlaminar group is 1.433 and that of Transforaminal group is 1.633. Improvement from base line to 4th week in interlaminar group is 2.166 and in Transforaminal group it is 3.1 with P Values < 0.05 in all the cases.

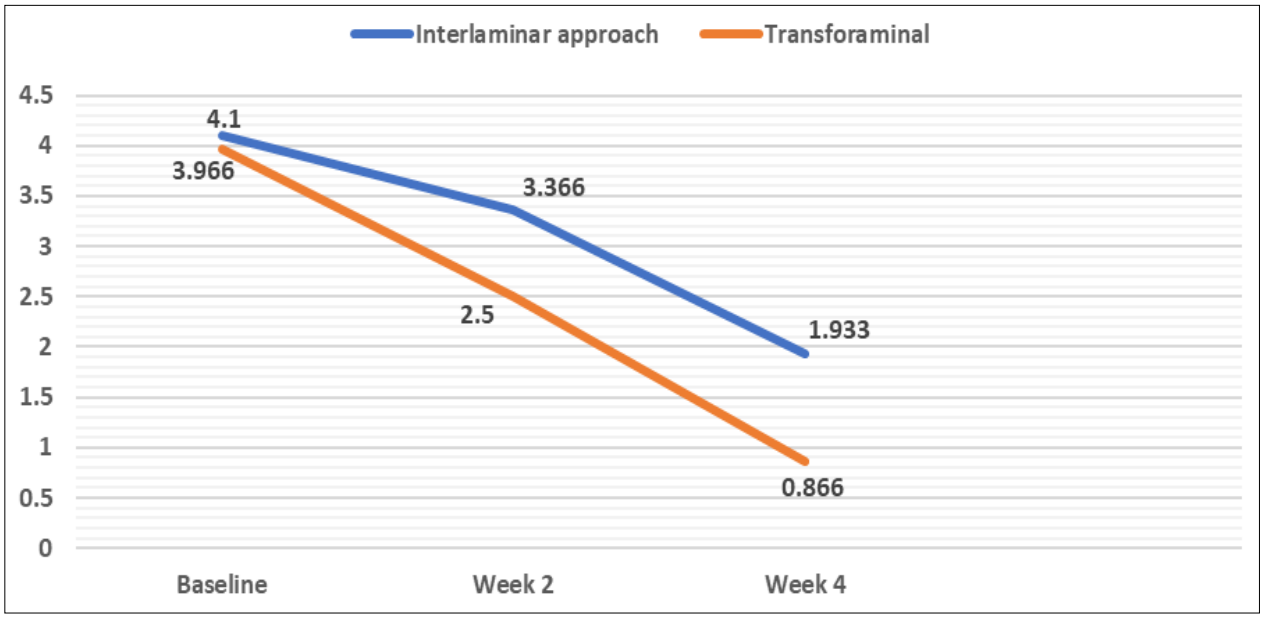

Fig 4: Comparision of VAS between groups

Discussion

Lower back pain with or without lower limb pain is the most common problem among acute and chronic pain disorders, and has significant implications [20-22]. Chronic lower back pain is a multifactorial disorder with many possible etiologies [23, 24]. The lifetime prevalence of back pain is reportedly 65%-80% in the lower back [25]. Kuslich *et al*. [26] identified intervertebral discs, facet joints, ligaments, fascia and muscles as the tissues capable of transmitting pain in the lower back.

Park CH *et al*, [35] conducted a study to prove the efficacy of particulate and non-particulate steroids in lumbar radiculopathy, he utilized Dexamethasone and Triamcinolone acetate for his study. A month after the treatment, mean pain scores were significantly reduced in group who received

triamcinolone acetate via transforaminal approach than the group who received dexamethasone (p=0.000). Reduction of pain score was 71% for triamcinolone group when compared to, dexamethasone group which was 40%. He concluded that transforaminal injection of triamcinolone acetate is better for short term relief of lumbar radicular pain.

This study shows 68% had very good relief of pain immediately in TFESI group and it was 46% for ILESI group. At the end of study period, significant relief persisted in 54% in Transforaminal group and 34% in interlaminar group. It shows pain relief of triamcinolone acetate starts very early and lasts longer than disability improvement.

Assessment of pain with Numeric rating scale among 30 cases of ILESI group showed on an average 35.5% pain relief is found at first week, from first week to second week pain relief percentage was 48.1%. A comparison from base line to second week showed there was 48.1% relief in pain in ILESI group. Assessment in TFESI group had showed the pain relief of 44% at first week, 65.4% pain relief from first week to second week and 65.4% pain relief is observed from base line to second week in TFESI group.

Table 12: Pain scores at 1st and 2nd follow-up in different studies.

Sl. No	Study	Group	Sample size	Base line(mean)	I follow up (mean)	II follow up (mean)
1	Present study	ILESI group	30	7.866	4.966	4.033
		TFESI group	30	4.1	3.366	1.933
2	Schaufele *et al.* [27]	ILESI group	20	7.3	3.1	5.9
		TFESI group	20	5.9	2.9	3.2
3	Smith *et al*. [28]	ILESI group	19	7.57	2.05	4.57
		TFESI group	19	6.73	1.94	4.68
4	Serbülent Gökhan Beyaz	ILESI group	173	7.8	3.9	3.5
		TFESI group	126	7.6	3.5	3.2

It shows effect of triamcinolone acetate deteriorates over a time period in majority of patients has given pain relief in both ILESI and TFESI group. In the present study 6.7% of patients from TFESI group got 100% pain relief and 0% of ILESI group had 100% pain relief. In ILESI group, age in years ranged from 20 years to 65 years. The average pain relief seen in patients of below 35 age was 57.15% and the average pain relief seen in patients of above 35 age was 57.92%.

The study group consisted 13 female and 47 male. Average pain relief found in 13 female patients were 53.7% and in male average pain relief found was 57.59%. Comparison of NRS of pain relief between male and female had shown T Value=0.706 with p=0.583 which did not show any significant difference between male and female pain relief in NRS.

In Transforaminal group, age in years ranged from 20 years to 56 years. The mean% of pain relief seen in patients of below 35years was 67.1% and that of above 35years mean relief % was 63.21%. The study group consisted 7 female and 23 male. Average pain relief found in 7 female patients were 56.46% and in male average pain relief found was 68.14%. Comparison of NRS pain relief between male and female had shown T Value=1.633 with p=0.114 which did not show any significant difference between male and female pain relief in NRS. Assessment of 30 cases through VAS in ILESI group, on an average 16.9% pain relief is at first week, from first week to second week pain relief percentage was 50.9%. A comparison from base line to second week showed there was 50.9% relief in pain in ILESI group. TFESI group had showed the pain relief of 35.1% at first week, 66.7% pain relief from first week to second week and 76.7% pain relief is observed from base line to second week in TFESI group.

Table 13: Pain relief of > 50% in different studies.

SL. No	Study	Group	Pain relief > 50%
1	Present study	ILESI group	50.9%
		TFESI group	76.7%
2	Ivan rados	ILESI group	53%
		TFESI group	63%
3	Babitha Ghai	ILESI group	78%
		TFESI group	76%

Table 14: comparision of NRS in different studies.

NRS summary of transformational vs Interlinear			
Author	TFESI Group (N)	ILESI Group (N)	Pain improvement Transformational vs Interlinear
Present study	30	30	65.4% vs 48.1%
Gharibo *et al* [29]	20	20	73.5% vs 44.3%
Rados *et al* [30]	32	32	45.6% vs 43.5%
Kolsi *et al* [31]	17	13	62.8% vs 63.5%
Smith *et al* [28]	19	19	30.5% vs39.5%
Scaufele *et al.* [27]	20	20	45.8% vs 19.2%

The study shows 57.9% showed average improvement ≥ 50% in ILESI group of age below 35 years. 42.1% showed average improvement < 50% in ILESI group of age below 35 years. 45.5% showed average improvement of ≥ 50% in ILESI group of age above or equal to 35 years. 54.5% showed average improvement of < 50% in ILESI group of age above or equal to 35 years. In female, 33.3% showed average improvement of ≥ 50% and 66.7% showed average improvement < 50% in TFESI group of age below 35 years. 92.3% showed average improvement of ≥ 50% in TFESI

group of age above or equal to 35 years. 7.7% showed average improvement of < 50% in TFESI group of age above or equal to 35 years. In female, 100% showed average improvement of ≥50%. In male, 91.3% showed average improvement ≥ 50% and 8.7% showed average improvement < 50%.

According above table pain improvement in TFESI group is more than ILESI group. As per North American Spine Society (NASS) opinion

1. No more than two injections be used to attempt to achieve a beneficial response in the first instance.
2. It seems reasonable to use up to three injections in a six month period to reinstate and maintain benefit once it has been achieved.

Gharibo *et al*. [29] study showed pain improvement of 73.4% in TFESI group and 44.3% in ILESI group. But he followed patients only for 3 weeks. But Kolsi *et al*. [31] 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.

Lee *et al*. [32] described a retrospective comparative study assessing the effectiveness of interlaminar, caudal and Transforaminal techniques with small and large volume of injectate in the treatment of lumbosacral HIVD or spinal stenosis. Of the patients included in the study, 54 received caudal injections, 64 received ILESI and 115 received TFESI. Outcomes were assessed at two weeks, one month and two months using the VAS (Visual Analog pain Scale), Patient Satisfaction Index (PSI) and Roland Five Point Pain Scale. A higher ratio of successful results was found for translaminar and TFESI techniques than caudal technique in VAS in the HIVD group and in VAS and PSI in the stenosis group.

This study and other studies provide evidence that: In both ILESI and TFESI group there is significant relief in pain both in NRS and VAS, from base line to second week. But patients who underwent steroid injections via TFESI had better therapeutic effects than patients who underwent steroid injections via interlaminar approach.

Conclusion

This study concluded that, 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 the pain irrespective of age, gender, symptom duration and pain intensity. Transforaminal steroid injection is superior to interlaminar steroid injections as it gives target specific administration. Interlaminar steroid probably administered blindly and hence the chances of the needle misplacement and hence lesser success rate.

Variables in this study were: Interlaminar steroid injections were performed by a single experienced anesthetist, whereas TFESI was performed by an orthopaedic spine surgeon.

In this study - Base line to second week pain relief is significantly better in TFESI group (65.4%) than ILESI (48.1%) in NRS. Base line to second week pain relief is significantly high in TFESI (76.66%) than ILESI (50.88%) in VAS. Present study showed there was no significant association between symptoms and the groups. Results obtained in this study are backed by following studies,

1. In 2006, Schaufele *et al*. [27] conducted a study on 20 patients comparing the two approaches of epidural steroid injections, and concluded the Transforaminal was more effective. However, significant limitations existed in their study; the population number was very small (n = 20), and the age of patients were wide range.
2. In 2007, Ackerman *et al*. [33] conducted a study on 90 patients comparing the Transforaminal, interlaminar approaches, and concluded that the Transforaminal was the most effective.
3. These results are supported by two randomized controlled studies [33, 34]. Thus, numerous studies on TFESI and ILESI have been published, which indicate positive or negative results with over 6 months of efficacy. Recently, TFESI provided more efficient results, but ILESI studies were conducted as randomized controlled studies using a blind technique for single level injections. Hopwood and Abram [36] described 33 factors associated with the success rate of lumbar epidural steroid injections, and suggested that all factors should be considered when treating chronic lumbar pain patients with epidural steroids. The procedure's performer's expertise, however, continues to be a crucial aspect that affects the success/satisfaction rate.

Acknowledgment

It is indeed a great pleasure to recall the people who have helped me in completion of this article. Naming all the people who have helped me in achieving this goal would be impossible, yet I attempt to thank a few, who have helped in diverse ways.

It gives me immense pleasure to express my deep sense of gratitude to our HOD, Dr. Sudeep Shetty, MBBS, M.S. Ortho, Professor and HOD, Department of Orthopaedics, A J. Institute of Medical Sciences and Research Centre, Mangalore for their valuable suggestions, guidance and encouragement during the preparation of this article.

I am extremely grateful to Dr. Ashok Hegde, MBBS, M.S. Gen. Surgery, Professor and Dean of AJ. Institute of Medical Sciences and Research Centre, Mangalore for his valuable help and kind support.

I thank the Lord, Almighty for giving me the strength to perform all my duties. At the onset of this study, I thank all my patients who formed the backbone of this study without whom this would not have been possible. I heartily acknowledge my sincere thanks to all my Lecturers in the Department of Orthopaedics and to the Department of Radiology for the kind help as well as for providing necessary materials required for this study.

Conflict of Interest

Not available

Financial Support

Not available

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How to Cite This Article
Kumar DV, Shetty M, Bhandary B, Manjunath S. Role of triamcinolone acetate in treatment of symptomatic intervertebral disc herniations via interlaminar vs transforaminal approach. International Journal of Orthopaedics Sciences. 2023;9(2):265-273.