



THE ROLE OF TRANSFORAMINAL STEROIDAL INJECTIONS IN CASES OF LUMBAR PROLAPSE OF INTERVERTEBRAL DISCS.

Orthopaedics

Dr. Nishant Jaiswal	3 rd Year Junior Resident, Department of Orthopaedics, KEM Hospital, Mumbai, Maharashtra, India.
Dr. S. S. Bava	Professor, Department of Orthopaedics, KEM Hospital, Mumbai, Maharashtra, India.
Dr. Vasav Somani	3 rd Year Junior Resident, Department of Orthopaedics, KEM Hospital, Mumbai, Maharashtra, India.
Dr. Bharath Bharadwaj	3 rd Year Junior Resident, Department of Orthopaedics, KEM Hospital, Mumbai, Maharashtra, India.

ABSTRACT

Purpose: This study was conducted in order to evaluate the outcomes of Transforaminal epidural steroid injections (TFESI) in patients presenting with radicular pain due to lumbar Prolapse of Intervertebral disc (LPID) and to determine those characteristics that will give a favourable outcome. **Method and Material:** A sample size of 52 patients with complaint of low back ache and radiculopathy due to LPID confirmed on MRI scan was given TFESI in operation theatre under fluoroscopic guidance in a span of 1 year from January 2021-2022. Pre and post procedural pain NRS scores were noted. **Result:** The mean and standard deviation of pre-procedure and immediate post-procedure NRS score were found to be 8.21 ± 0.97 and 3.10 ± 1.34 respectively. The P value is <0.001 implying pain relief immediately after the procedure is highly significant. The mean and standard deviation of the 1-month post procedure NRS was found to be 3.23 ± 1.23 . The success rate of this study considering successful treatment as more than 50% reduction in the NRS Score at 1 months when compared to pre-treatment NRS Score came out to be 78.8%. (41 of 52 patients). **Conclusion:** The study has come to assess that a single dose of transforaminal epidural steroid injection in selected group of patients can significantly improve the pain relief within a short-term period and thus further improve patient care and management for at least a period of 1 month independent of age and sex. Pain relief can help further rehabilitation of the patient with physiotherapy.

KEYWORDS

Transforaminal block, Radiculopathy, Steroid injections, Lumbar PID.

INTRODUCTION

Low back pain and radiculopathy are very common conditions. In fact, most individuals experience neck and/or low back pain at least once in their life, and with increasing age, a greater number of patients with such symptoms are seen by family physicians and in outpatient clinics

The most common sign and symptoms of lumbar disc herniation is weakness in motor distribution of one or more lumbosacral nerve roots radiating pain and sensory abnormalities. Patient complaining of increased leg pain with coughing, sneezing, straining, focal paresis or limited trunk flexion are also indicative symptoms. This manoeuvre is associated with increased disc pressure by nearly 40%, thus increased pain during sitting is frequently reported by patients.

Radiculopathy may be defined as pain and/or neurologic deficit in a specific nerve root distribution, including motor loss, sensory changes, and sometimes depression of reflexes. This study was conducted in order to determine the efficacy of transforaminal epidural steroid injections as a method for symptomatic relief for patients and help in better rehabilitation.

Anatomy

Consist of three major components: the inner or nucleus pulposus (NP), the outer or annulus fibrosus (AF), and the cartilaginous endplates that anchor the discs to adjacent vertebrae. [1]

The NP is a gel-like structure that sits at the center of the intervertebral disc and accounts for much of the strength and flexibility of the spine. It is made of 66% to 86% water, with the remainder consisting primarily of type II collagen (it may also contain type VI, IX, and XI) and proteoglycans.

The AF is a ring-shaped disc of fibrous connective tissue that surrounds the NP. This structure is highly organized, consisting of 15 to 25 stacked sheets, or "lamellae," of predominantly collagen, with interspersed proteoglycans, glycoproteins, elastic fibers, and the connective tissue cells that secrete these ECM products. Each lamella contains collagen uniformly oriented in a plane that differs in orientation to the adjacent lamella by about 60 degrees. The outer annulus contains mostly type I collagen, while the inner has predominantly type II. The inner annulus also contains more proteoglycans than the inner. The ratio of type I to type II changes gradually: as the distance from the NP increases, the amount of type II

collagen decreases, while the amount of type I increases. [2]

In the lumbar regions, the traversing nerve root is more commonly affected than the exiting nerve root in cases of central or paracentral protrusions of disc material. The nerve components become extrathecal when the dura mater surrounding the nerve root merges with the epineurium. (Fig. 1)

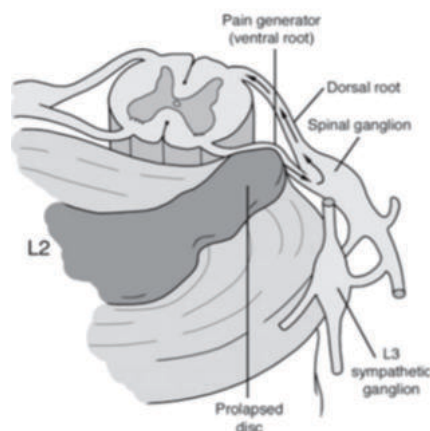


Figure 1: Assessment Of Patients

Pathophysiology

- Mechanism of discogenic pain

In 1979, Brodsky and Binder [3] characterized the mechanism for the provocation of pain with discography. Their findings included following:

- (1) Stretching of the fibers of an abnormal annulus
- (2) Bulging of the annulus putting pressure on nerves posteriorly
- (3) Extravasation of extradural irritating substances such as lactic acid, glycosaminoglycans and acidic media.
- (4) Hyperflexion of posterior joints on disc injection
- (5) The presence of vascular granulation tissue and pain caused by scar distension. [4]

Endplate deflection may provoke pain generators in the end plate was

speculated as another mechanism.

- Biochemical changes occurring in intervertebral discs are

 1. Loss of Proteoglycan
 2. Loss of Collagen
 3. Increase in Fibronectin
 4. Enzymatic Activity

Among the tests that are used to evaluate prolapsed intervertebral disc in lumbar spine- the straight leg raising test is most commonly used by clinicians.

METHODS AND MATERIALS

Study Design

An interventional, prospective study of 1 year of patients who presented in the year 2021-2022. A total number of adult patients between 20-49 years posted for elective lumbar TFESI receiving transforaminal block 52 patients were enrolled.

Sample Size

The sample size was calculated using online sample size calculator available at <http://www.sample-size.net/sample-size-study-paired-t-test/> to assess the sample size for comparing two paired means.

The above calculator uses the following formula and following assumptions were taken,

$$\text{Sample size} = S(\Delta)^2 (Z\alpha + Z\beta)^2 / E^2$$

Where, $S(\Delta)$ = Standard Deviation of the change in the outcome = 0.5,

$Z\alpha = 1.960$, critical value at alpha error of 0.05

$Z\beta = 0.842$, critical value at power of 80% ($\beta = 0.2$)

E = Effect size = 0.2

The output obtained was $49.06 = 49$ (rounded off) + expected dropouts
Thus, we will have to enroll at least 52 patients with LPID.

Inclusion Criteria

Inclusion criteria of patients of suspected lumbar nerve root pain by history taking, clinical examination and protrusion of the intervertebral disc over the relevant nerve root identified by lumbar magnetic resonance imaging.

- (1) Age: 20-49 years old
- (2) Presentation with > 3 months history of symptomatic lumbar pain with radiculopathy of at least 4 on numeric rating scale, despite of oral medications [NRS: 0 = No Pain, 10 = Worst pain]
- (3) MRI findings of a LPID Pathology matching with LPID Symptom.
- (4) Chief and primary complain of leg pain that is not resolved by minimum 6 weeks staged treatment consisting of NSAIDs, Bed rest, Physiotherapy.
- (5) Radicular pain from below L1 due to lumbar PID.

Exclusion Criteria

- (1) Associated ligamentum flavum hypertrophy, spondylolisthesis, end plate modic changes, myelopathy, or infection on the spine, spinal deformity, facet joint arthritis, tumours.
- (2) Previous history of surgery of spine, such as Laminectomy or lumbar fusion.
- (3) Involvement of multiple segments and Bilateral presentation
- (4) Coagulation disorder.
- (5) Peripheral neuropathy.
- (6) Negative consent by the patient for the procedure.
- (7) History of allergy to local anaesthetic and contrast material being used.
- (8) neurologic motor and sensory deficit.
- (9) Spinal cysts and tumour
- (10) Fracture spine patient.
- (11) Patients with Cauda equina syndrome.

Method For Block

All the 52 Patients were placed in the prone position with bolsters under the abdomen to reduce lumbar lordosis. The parts scrubbed and draped. The fluoroscopic projection was directed on the Kambin's triangle (5) defined as a right-angled triangle over the dorsolateral disc. (Fig. 2) At that location, a 90 mm 23 Gauge spinal needle was inserted into the skin toward the lateral lower part of the superior articular process and the process was touched. The needle was then advanced up to 1 mm until loss of bony resistance is felt. This is the base of Kambin's triangle. On anteroposterior view, the needle tip was seen just lateral to the line passing through medial border line of the superior and inferior pedicle. (Fig.3,4) After the final location of the needle was secured, 1

cc of non-ionic contrast Iomeprol solution agent was administered to observe diffusion location and scope of the contrast agent, and then 2 cc of the prepared agent (0.5% Bupivacaine 1 ml + 1 ml of tramcinolone acetate 40mg/ml) was administered.

The efficacy of transforaminal steroid injection is done on the basis of questionnaire considering the scoring system. (Fig. 5)



Figure 2: Landmark For Needle Entry Site.

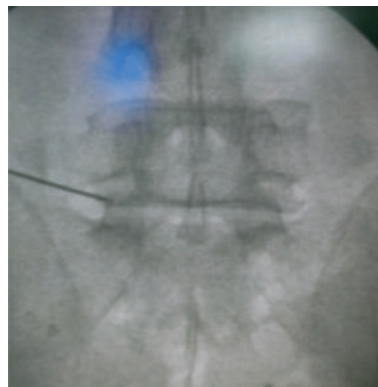


Figure 3: Needle Tip Position On Anteroposterior Fluoroscopy Shoot



Figure 4: Needle Tip Position In Lateral Fluoroscopy Shoot.

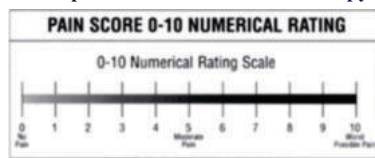


Figure 5: Numerical Rating Scale

RESULTS

Data was entered into Microsoft Excel (Windows 7; Version 2007) and analyses were done using the Statistical Package for Social Sciences (SPSS) for Windows software (version 22.0; SPSS Inc, Chicago). Descriptive statistics such as mean and standard deviation (SD) for continuous variables, frequencies and percentages were calculated for

categorical Variables were determined. Comparison of mean of quantitative Variables were analyzed using unpaired t test and ANOVA (Analysis of Variance) respectively for variables having 2 and more than 2 categories respectively. Bar charts and Pie charts were used for visual representation of the analyzed data. Level of significance was set at 0.05.

From a sample size of total 52 patients, 67.3% patients belonged to age group of between 41 years to below 49 years, 21.2% between age 31 to 40 years and 11.5% between age 21 to 30 years. 51.93% were male(n=27) and 48.07% were female(n=25) patients. 26 patients had left lower limb radiculopathy and rest 26 had right sided lower limb radiculopathy.

The level of disc prolapse was determined by MRI finding and clinical correlation. 25 patients had L5-S1, 21 patients had L4-L5, 5 patients had L3-L4 disc herniation. Only 1 patient presented as L2-L3 disc prolapse. Patient with L5-S1 disc made 48.1% of the study sample. 40.4% patient had L4-L5 disc prolapse and 9.6% patient had L3-L4 disc prolapse. (Table 1)(Fig. 6)

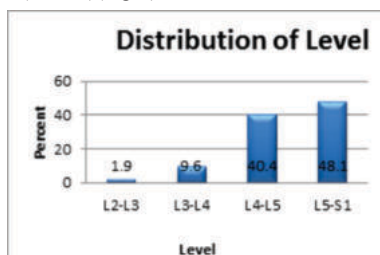


Figure 6: Distribution Of Level.

Table 1: Distribution Of Study Subjects According To The Level (n=52)

NRS	Mean (SD)	Mean Difference	P Value
Pre-Procedure	8.21 (0.97)	-	-
Post-Procedure	3.10 (1.34)	5.11	<0.001*
At 1 Month	3.23 (1.23)	4.98	<0.001*

Paired t Test, P Value * Significant

Table 2: Distribution Of Study Subjects According To The NRS Score (n=52)

Level	No.	Percent
L2-L3	1	1.9
L3-L4	5	9.6
L4-L5	21	40.4
L5-S1	25	48.1

88.5% presented as low back pain with radiculopathy with 46 patients of the total sample size. 9.6% patients(5/52) had only radiculopathy. Only 1 patient presented with low back pain (1.9%).

The Numeric rating scale of the patients were analyzed. The mean NRS score pre-procedure was found 8.21 with standard deviation 0.97. The mean NRS score post-procedure was 3.10 with standard deviation 1.34. The mean NRS 1 month post procedure was 3.23 with standard deviation of 1.23. The P value on comparing the two NRS score was found to be <0.0001 (highly significant). (Table 2)(Fig. 7)

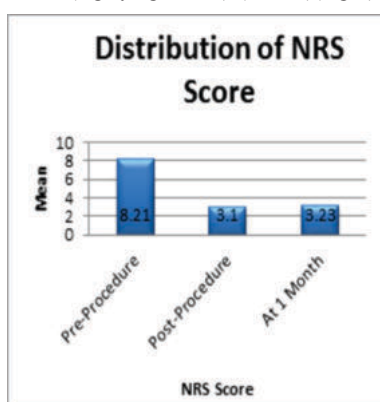


Figure 7: Distribution of NRS Score

DISCUSSION

The study conducted to assess the various factors and success rate of transforaminal epidural steroid injections has given an insight on to the reliance of this method for pain relief. The success rate of this study is 78.8%.

The mean and standard deviation of pre-procedure and immediate post-procedure NRS score were found to be 8.21 ± 0.97 and 3.10 ± 1.34 respectively. The P value is <0.001 implying pain relief immediately after the procedure is highly significant. The mean and standard deviation of the 1-month post procedure NRS was found to be 3.23 ± 1.23 with a P value of <0.001 showing the pain relief after 1 month of procedure being highly significant.

The most common level of involvement of the disc prolapse is L5-S1 followed by L4-L5. Two patients presented with the complaint of L3-L4 involvement. Only one patient presented with complaints where L2-L3 disc was involved.

In a prospective Study by VB Vad et al, [6] Randomized by choice of patient, patients received either a transforaminal epidural steroid injection or a saline trigger-point injection. Treatment outcome was assessed using a patient satisfaction scale with choice options of 0 (poor), 1 (fair), 2 (good), 3 (very good), and 4 (excellent) and a Roland-Morris low back pain questionnaire. A successful outcome required a patient satisfaction score of 2 (good) or 3 (very good), improvement on the Roland-Morris score of 5 or more, and pain reduction greater than 50% at least 1 year after treatment.

In a systematic review by Ricardo M. Buenaventura et al, [7] the primary outcome measure was pain relief (short-term relief = up to 6 months and long-term > 6 months). Secondary outcome measures were improvement in functional status, return to work, reduction in opioid intake and psychological status. The indicated evidence is Level II-1 for short-term relief and Level II-2 for long-term relief in managing chronic low back and lower extremity pain. The indicated evidence for transforaminal lumbar epidural steroid injections is Level II-1 for short-term relief and Level II-2 for long-term improvement in the management of low back pain and lumbar nerve root.

In a comprehensive review study by Benoy benny et al [8], to review and critically evaluate literature focusing on the efficacy of lumbosacral transforaminal steroid injections. Results were stated as: In all there were 10 randomized trials, 8 prospective studies and 4 retrospective studies found. Among the 10 randomized control studies only 8 satisfied inclusion criteria. There was a total of 9 prospective trials showing a positive short term as well as long-term outcome and that used both fluoroscopic injections as well as CT guided injections. All 8 of the randomized control studies included show a positive outcome in both the short term and long-term results. This systemic review included retrospective, prospective and randomized clinical trials showed that there was strong evidence for transforaminal injections in the treatment of lumbosacral radicular pain for both short term and long-term relief.

In an outcome study by Gregory Lutz et al [9], to determine the therapeutic value and long-term effects of fluoroscopic transforaminal epidural steroid injections in patients with refractory radicular leg pain. Sixty-nine patients met our inclusion criteria and were followed for an average period of 80 weeks with range of 28 to 144 weeks of which 75.4% of patients had a successful long-term outcome, reporting at least a >50% reduction between pre injection and post injection pain scores, as well as an ability to return to or near their previous levels of functioning after only 1.8 injections per patient with range of 1 to 4 injections. Of all the patients, 78.3% were satisfied with their final outcomes. Fluoroscopic transforaminal epidural steroids were an effective nonsurgical treatment option for patients with lumbar herniated nucleus pulposus and radiculopathy in whom more conservative treatments are not effective and should be considered before surgical intervention.

A retrospective analysis of the efficacy of epidural steroid injections by Rosen CD1, Kahan Ovitz N, Bernstein R, Viola K, [10] forty patients were studied retrospectively to evaluate the effect of epidural steroid injections on low back pain and sciatica characteristic of a herniated lumbar disc or spinal stenosis. From this study, it appears that approximately 50% of patients with radicular symptoms may receive temporary relief with steroid injection. However, long-term relief occurs in less than 25% of patients.

Research published by S. Natarajan et al [11] in 2017 showed the outcome of fluoroscopically guided transforaminal epidural steroid injection in patients suffering from lumbar disc herniation. It was a prospective study with a patient recruitment size of 43. The study concluded that Transforaminal steroid injection (TFESI) provides significant short-term pain relief in patients suffering from a single level lumbar herniated disc and is a viable and effective short-term analgesic tool to address pain and retard an early surgical intervention with negligible complications. Patient who underwent physiotherapy post procedure showed longer lasting effects.

CONCLUSION

The study has come to assess that a single dose of transforaminal epidural steroid injection in selected group of patients can significantly improve the pain relief within a short-term period and thus further improve patient care and management for at least a period of 1 month independent of age and sex. Pain relief can help further rehabilitation of the patient with physiotherapy. The fluoroscopic guidance helps in precise anatomic location and local delivery of steroid drug, thus increasing local drug concentration and help diminish their systemic side effects.

Although there are certain limitations to the study

(1) We were unable to assess the long-term outcome Post TEFSI

The Functional Status of the patients was not assessed.

The success rate of this study considering successful treatment as more than 50% reduction in the NRS Score at 1 months when compared to pre-treatment NRS Score came out to be 78.8%. (41 out of 52 patients).

REFERENCES

- Huang, Y. C., Hu, Y., Li, Z., & Luk, K. D. (2018). Biomaterials for intervertebral disc regeneration: Current status and looming challenges. *Journal of tissue engineering and regenerative medicine*, 12(11), 2188-2202.
- van Uden, S., Silva-Correia, J., Oliveira, J. M., & Reis, R. L. (2017). Current strategies for treatment of intervertebral disc degeneration: substitution and regeneration possibilities. *Biomaterials research*, 21(1), 1-19.
- Brodsky, A. E., & Binder, W. F. (1979). Lumbar discography: Its value in diagnosis and treatment of lumbar disc lesions. *Spine*, 4(2), 110-120.
- Heggeness, M. H., & Doherty, B. J. (1993). Discography causes end plate deflection. *Spine*, 18(8), 1050-1053.
- Park, J. W., Nam, H. S., Cho, S. K., Jung, H. J., Lee, B. J., & Park, Y. (2011). Kambin's triangle approach of lumbar transforaminal epidural injection with spinal stenosis. *Annals of rehabilitation medicine*, 35(6), 833-843.
- Vad, V. B., Bhat, A. L., Lutz, G. E., & Cammisia, F. (2002). Transforaminal epidural steroid injections in lumbosacral radiculopathy: a prospective randomized study.
- Buenaventura, R. M., Datta, S., Abdi, S., & Smith, H. S. (2009). Systematic review of therapeutic lumbar transforaminal epidural steroid injections. *Pain Physician*, 12(1), 233-51.
- Benny, B., & Azari, P. (2011). The efficacy of lumbosacral transforaminal epidural steroid injections: a comprehensive literature review. *Journal of back and musculoskeletal rehabilitation*, 24(2), 67-76.
- Lutz, G. E., Vad, V. B., & Wisneski, R. J. (1998). Fluoroscopic transforaminal lumbar epidural steroids: an outcome study. *Archives of physical medicine and rehabilitation*, 79(11), 1362-1366.
- Rosen CD, Kahan Ovitz N, Bernstein RA, Viola KA 1988 Mar. A retrospective analysis of the efficacy of epidural steroid injections. *Clinical orthopaedics and related research*. 1(228):270-2.
- Natarajan, S., Krishnamurthy, A. V., Kalanithi, R., & Ilavarasan, M. D. (2017). Study on the functional outcome of fluoroscopically guided transforaminal epidural steroid injections in patients suffering from lumbar disc herniation. *Int J Res Orthop*, 3(3), 607-613.