Agri 2025;37(3):142–148
doi: 10.14744/agri.2024.57983

ORIGINAL ARTICLE

Transforaminal epidural steroid injection versus high-volume lumbar erector spinae block in patients with low backache and radicular pain – a randomized clinical trial

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SUMMARY

Objectives: Transforaminal lumbar epidural steroid injection (TFESI) has been used to treat lumbar radiculopathies. Erector spinae plane block (ESPB) has been employed to provide postoperative analgesia following spine and back surgeries. We aimed to compare TFESI with high-volume lumbar ESPB in patients with low backache and radicular pain.

Methods: This was a prospective, randomized, single-centre interventional study. After obtaining institutional ethical committee clearance and written informed consent, 60 patients aged 18 to 50 years with unilateral low backache were randomly allocated into two groups of 30 each—Group T and Group E. Group E received ultrasound-guided lumbar ESPB with 30 mL of 0.25% bupivacaine and 20 mg triamcinolone, whereas Group T received fluoroscopy-guided TFESI with 2 mL of 0.25% bupivacaine and 20 mg triamcinolone. The primary outcome was pain relief as assessed by the numeric rating scale (NRS) at 3 months. Secondary outcomes included NRS at 1 hour and 1 month, the Modified Oswestry Disability Index (MODI), the number of patients requiring rescue analgesia, and procedure-related complications.

Results: The mean post-procedure NRS scores at 1 hour, 1 month, and 3 months were significantly lower in Group T compared to Group E (p=0.001, 0.013, and 0.007, respectively). MODI scores were significantly lower in both groups after treatment (p<0.001). In Group T, 6.9% of patients experienced a vasovagal attack and 3.4% had flushing, both of which resolved spontaneously. In contrast, no complications were observed in Group E.

Conclusion: ESPB is effective for providing analgesia in patients with chronic low back pain and radiculopathy; however, TFESI showed superior pain relief as reflected in more favourable NRS scores. Nevertheless, TFESI requires greater precision and expertise and carries a higher risk of serious complications. ESPB may be a safer alternative when TFESI is difficult to perform or contraindicated.

Keywords: Erector spinae block; low back pain; radicular pain; transforaminal epidural steroid injection.

Introduction

Chronic low back pain (LBP) is one of the most disabling chronic pain conditions, causing excessive burden on health services and severely affecting the quality of life. In 2020, LBP affected 619 million people and the number is expected to rise to 843 million by 2050 globally.[1] The radicular pain seen in these patients is mostly the result of lumbar disc herniation resulting from degenerative disc diseases. Medical management alone is often not sufficient, and surgical treatment poses the risk of grievous complications. This has led to the development of image-guided interventions like transforaminal epidural steroid injection (TFESI), which has established its role in providing adequate pain relief in such patients.

Submitted: 20.09.2024 **Received:** 21.10.2024 **Accepted:** 05.11.2024 **Available online:** 24.06.2025

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In the era of ultrasonography, various interfascial plane blocks have evolved, among which erector spinae plane block (ESPB) has paved its way in chronic pain management, besides acute pain conditions.[2] ESP block was first described by Forero et al.[3] in 2016 in the management of chronic thoracic neuropathic pain in two patients. Since then, it has been employed as an analgesic technique in various acute and chronic pain conditions with variable success rates.

Erector spinae block in the management of LBP has been used in a few case series and rarely in comparative studies. The mechanism of action of the ESP block is a matter of debate, but blockade of dorsal rami branches innervating the spine and paravertebral tissues has been demonstrated in many studies and is responsible for its analgesic effects following spine and back surgeries.[4–7]

Owing to the large number of studies, multiple systematic reviews and meta-analyses have already been published demonstrating the efficacy of TFESI in chronic LBP patients.[8,9] However, we did not come across any study comparing TFESI with lumbar ESP block in LBP patients. The purpose of this study was to compare TFESI with high-volume lumbar ESP block in patients with chronic LBP associated with radiculopathy. We hypothesized that high-volume lumbar ESP block should be non-inferior to TFESI in the management of LBP with radiculopathy.

Materials and Methods

The study was conducted after Institutional Ethical Committee approval (IEC Letter No. Dean/2021/EC/2505 dated 15.02.2021) and written&informed consents from patients. The clinical trial registration number is Clinical Trial Registry India (CTRI)/2022/07/043660, and the study was conducted in accordance with the Declaration of Helsinki. In this prospective, randomized controlled trial, 60 American Society of Anaesthesiologists grades I and II patients, between the age group of 18 to 50 years of either sex, with unilateral low backache (single level) and radicular pain persisting despite medical treatment were randomly allocated to either of the two groups: fluoroscopy-guided TFESI and ultrasound-guided high-volume ESP block. The exclusion criteria were: patient's age<18 years and>50 years, patient refusal, coagulation disorders, allergy to local anaesthetics and study drugs used in this study, infection at the injection area, previous history of spinal surgery, patients with co-morbidities, spinal injury or deformities, more than 2 levels of disc hernia, and degenerated and sequestered disc.

Sample size calculation was based on a previous study where two forms of epidural steroid injections were compared, where the true mean difference in providing pain relief between the two approaches was thought to be zero with equal group allocation.[10] In that study, the pain relief at the end of 3 months was assumed to be to the tune of 75%, with the largest clinically acceptable effect to be able to declare equivalence being 15% (90% CI of effective pain relief would lie between 60–90%). Power analysis was done by independent t-test, while the primary target was pain relief at 3 months. Keeping type I error of 0.05 and power of 90%, we obtained a sample size of 27 patients to be recruited in each arm. In order to avoid loss due to dropouts, we assessed 70 patients for eligibility.

Patients were assigned to one of the trial groups using a computer-generated random number table. The patient study code number and group allocation were typed on separate pages, folded, and concealed in sequentially numbered sealed envelopes. Patients were nil by mouth for 8 hours for fatty solid meals. In the operation theatre, an 18-gauge intravenous (IV) cannula was secured, and monitors were applied, including electrocardiogram, pulse oximeter, and non-invasive blood pressure. All blocks were carried out or supervised by consultant anaesthesiologists with experience in pain and regional anaesthesia, who were familiar with both techniques. Fluoroscopy-guided and ultrasound-guided (USG) blocks were performed under full aseptic conditions according to the randomization. The site and level of injection were based on magnetic resonance imaging studies of patients' lumbar regions and the characteristics of radicular pain.

Group E: High-Volume ESP Block

Patients were placed in the prone position, and the vertebrae were counted cephalad to caudad from the most prominent spinous process of C7 until reaching the lumbar spinous process. The low-fre-

quency curvilinear probe was first placed in the midline, then gradually shifted laterally while identifying the spinous process, lamina, and transverse process (TP). The ESP muscle was recognized lying immediately superficial to the hyperechoic TP. A 22G 80 mm echogenic needle (Stimuplex A, B Braun, Melsungen, Germany) was introduced in-plane from cranial to caudal direction until the tip touched the TP just deep to the erector spinae muscle. Correct needle tip position was confirmed by injecting 1 mL of normal saline and visualizing spread under the erector spinae muscle with the help of the USG probe. The block was completed with 30 mL of 0.25% bupivacaine along with 20 mg of triamcinolone injection in the ESP plane.

Group T: TFESI

In Group TFESI, patients were placed in the prone position on the operating table. Under strict aseptic conditions and fluoroscopy guidance, a 22G Quincke's spinal needle was inserted into the target neuroforamen. The target nerve root and its epidural space were confirmed by injecting water-soluble nonionic contrast, ensuring only epidural flow of contrast with no intravascular, intradural, or subcutaneous infiltration. TFESI was performed by injecting 2 mL bupivacaine of 0.25%+triamcinolone 20 mg at the corresponding level.

The operator performing the blocks was aware of the group allocation. However, the patients, investigators involved in data collection, and data analysts were unaware of the patients' group allocation and did not have access to the randomization until after data analysis was complete. Therefore, this study had a double-blind design.

Pain relief was assessed using the Numeric Rating Scale (NRS) (range 0–10, 0 being no pain and 10 being the worst imaginable pain) at 1 hour, and after 1 and 3 months of intervention. The primary target was pain relief at 3 months. Secondary outcomes were NRS at 1 hour and 1 month, Modified Oswestry Disability Index (MODI) at 1 hour, 1 month, and 3 months, patients requiring rescue analgesia, and complications. Tablet tapentadol 50 mg, paracetamol 650 mg, aceclofenac 100 mg, and pregabalin 25 mg were given as analgesics until 1 month after the intervention. The number of patients requiring rescue analgesics

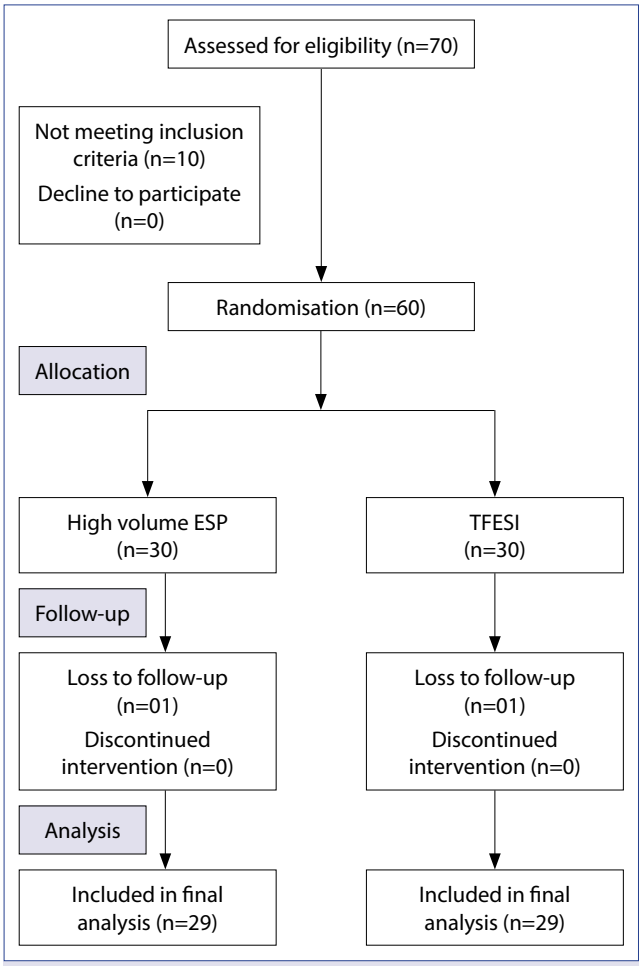

Figure 1. Study CONSORT.

(a combination of paracetamol 650 mg and tapentadol 50 mg) after the 1-month period was noted. MODI is a 10-point disability score used to measure the level of disability and monitor changes over time in LBP patients. This self-reporting questionnaire includes 10 questions on pain intensity, personal care, lifting, walking, sitting, standing, sleeping, social life, traveling, and employment/homemaking. Each point is scored from 0–5 (from minimum to maximum level of disability).

Statistical Methods

Descriptive analysis was carried out by mean and standard deviation for quantitative variables, and frequency and proportion for categorical variables. Two-way repeated ANOVA was used for inter- and intra-group comparisons of NRS and MODI with post hoc comparison using the SNK test. Chi-square test or 2-sample independent Student t-test was used to analyze demographic data. P value<0.05 was considered statistically significant. IBM SPSS version 26 was used for statistical analysis.

Table 1. Comparison of demographic characteristics

	TFESI (n=30)	ESP (n=30)	p
Age (years)*	37.7±10.5	35.2±8.9	0.32
Male: Female**	15:15 (50:50)	14:16 (46.7: 53.3)	0.80
BMI (kg/m^2)*	24.2±2.6	24.8±3.2	0.43
Duration of LBP (months)*	6.8±2.2	7.2±1.8	0.44

TFESI: Transforaminal lumbar epidural steroid injection; ESP: Erector spinae plane; BMI: Body Mass Index; LBP: Low back pain; *: Values in mean±standard deviation; **: Values in numbers (%).

Table 2. Comparison of mean NRS between study groups

	TFESI (n=29)	ESP (n=29)	p
Pre NRS	6.1±0.9	6.0±0.8	0.66
Post NRS 1 Hr	1.73±0.9	2.7±1.1	0.001
Post NRS 1 month	2.62±1.2	3.52±1.4	0.01
Post NRS 3 month	3.45±1.4	4.59±1.6	0.007

TFESI: Transforaminal lumbar epidural steroid injection; ESP: Erector spinae plane; NRS: Numeric Rating Scale.

Table 3. Descriptive of mean pre and post intervention NRS Score intragroup

Group	NRS	Mean±SD	p	95% CI	
				Lower	Upper
TFESI	Pre intervention	6.1±0.9			
	Post intervention 1 hour	1.7±0.9	<0.001	4.1	4.7
	Post intervention 1 month	2.6±1.2	<0.001	3.1	3.9
	Post intervention 3 months	3.5±1.4	<0.001	2.3	3.1
ESP	Pre intervention	6.0±0.8			
	Post intervention 1 hour	2.7±1.1	<0.001	2.9	3.7
	Post intervention 1 month	3.5±1.4	<0.001	1.9	2.9
	Post intervention 3 months	4.6±1.6	<0.001	0.8	1.9

TFESI: Transforaminal lumbar epidural steroid injection; ESP: Erector spinae plane; values in mean±standard deviation; NRS: Numeric Rating Scale; CI: Confidence interval.

Results

In this study, a total of 70 patients were assessed for eligibility, out of which 10 were excluded for not meeting the inclusion criteria, as shown in the study CONSORT (Fig. 1). Sixty patients were randomized into two groups, T and E, with 30 patients each. The demographic details of both groups were comparable (Table 1) (p>0.05). One patient in each group was lost to follow-up at 1 and 3 months, and the final analysis included a total of 58 patients.

Mean NRS in both groups was comparable before interventions. Post-intervention NRS in Group T was significantly lower than Group E at 1 hr, 1 month, and 3-month assessments, i.e. 1.73±0.9, 2.62±1.2, 3.45±1.4 vs 2.7±1.1, 3.52±1.4, 4.59±1.6, respectively (Table 2) (p<0.05). Intragroup comparisons also showed significant differences in NRS from pre- to post-intervention periods in both groups (p<0.001) (Table 3).

The number of patients requiring rescue analgesics was significantly higher in Group E compared to Group T (p<0.05) (Table 4).

There was a significant reduction in MODI score post-intervention in both groups compared to their pre-intervention values. However, the reduction was significantly greater in Group T compared to Group E at all time points (p<0.05) (Table 5).

There was no sensory or motor loss demonstrated in any of the groups. There were no major complications in either group. Two patients (6.9%) in Group T developed vasovagal symptoms, and one (3.4%) developed facial flushing, which resolved in a few minutes without any intervention. In Group E, no complications were observed.

Table 4. Comparison of number of patients taking rescue analgesics in 1 month post intervention

Rescue analgesic	TFESI	ESP	Total
No	10 (34.5)	3 (10.3)	13 (22.4)
Yes	19 (65.5)	26 (89.7)	45 (77.6)
Total	29 (100)	29 (100)	58 (100)

Chi square – 4.858, p value- 0.028 (Significant). TFESI: Transforaminal lumbar epidural steroid injection; ESP: Erector spinae plane.

Discussion

In this study, the effectiveness of TFESI and lumbar ESP high-volume block was compared in providing adequate pain relief in LBP patients, and it was found that pain relief occurred in both groups, but it was better in the TFESI group. The fluoroscopy-guided TFESI technique is a very common procedure in LBP patients, and its effectiveness is well established.[8,9] The ESP block, on the other hand, is a novel interfascial plane block that has gained widespread usage in multiple clinical conditions. It has been used in the management of LBP, but mostly as a part of multimodal postoperative analgesic regimens following spine and back surgeries, with favorable results.[11,12] Ma et al.[13] conducted a systematic review and meta-analysis of 12 articles of RCTs that compared preoperative ESPB with no block for postoperative analgesia in spine surgery involving 828 patients, and concluded that ESPB had a significant effect on reducing postoperative pain scores at rest and during movement at different time intervals, except during movement at 48 h. ESPB significantly decreased opioid consumption in the 24 h after surgery.

On the other hand, Avis et al.[14] compared bilateral ultrasound-guided ESP block with saline versus ropivacaine (3.75 mg/mL) in patients undergoing lumbar spine surgery. They concluded that ESPB neither resulted in a significant reduction in opioid consumption nor provided any long-term pain relief.

Anshus and Oswald used ESPB in 6 patients presenting to the emergency department with atraumatic acute LBP. They inferred that ESPBs can result in decreased pain, decreased length of stay, decreased opiate requirements, and decreased admissions for refractory pain.[15]

Table 5. Comparison of pre and post intervention MODI

	TFESI (n=29)	ESP (n=29)	p
Pre MODI	41.2±11.3	40.1±8.1	0.69
Post MODI 1 hr	23.2±8.8	30.6±12.8	0. 01
Post MODI 1 month	20.1±9.7	28.4±9.2	0.001
Post MODI 3 month	24.5±10.3	35.9±12.7	0.0004

TFESI: Transforaminal lumbar epidural steroid injection; ESP: Erector spinae plane; MODI: Modified Oswestry Disability Index; values in mean±standard deviation.

Soni et al.[16] evaluated the analgesic potency of ESPB in 2 patients with chronic severe LBP not responding to conservative and invasive treatments. Both patients demonstrated significant improvement in symptoms along with improved quality of life after the block, which persisted during the 3-month follow-up. Similar results were also obtained by Hong et al.[17] in a series of 3 cases.

Recently, in one observational study, Durmus et al.[18] studied the effect of ESPB in 96 chronic LBP patients with radiculopathy due to disc herniation and found significantly reduced mean visual analog scale (VAS) and ODI scores compared to pre-procedural values, similar to our findings. However, they did not find any significant difference in analgesic consumption after ESPB application ($p>0.05$). In our study too, the requirement of rescue analgesics was significantly higher in the ESP group compared to the TFESI group.

We could find only one prospective randomized trial comparing LBP relief and spread level after upper and lower lumbar ESP block.[19] The authors concluded that both the L2 and L4 ESPB groups demonstrated a significant reduction in LBP and improvement in disability. The L2 ESPB group demonstrated a significantly increased spread level compared to the L4 ESPB group. To our knowledge, our study is the first prospective randomized trial comparing ESPB with TFESI in the management of LBP with radiculopathy.

Several cadaveric dye studies have been conducted to elucidate the mechanism of ESP block, especially for thoracic ESP block.[20,21] Harbell et al.[22] demonstrated extensive dye staining of the deep back muscles and dorsal ramus in a cadaveric study, providing evidence for the mechanism of motor and sensory

blockade achievable with lumbar ESP block, though the craniocaudal and lateral spread was not as extensive as seen in thoracic ESP. It's also argued that cadaveric studies may not truly reflect the pattern in normal patients because of decreased tissue tension due to loss of vitality.[23]

TFESI has been extensively used in LBP management, but it is not without complications. Major complications include epidural hematoma, abscess, dural puncture, and even paraplegia. The incidence of minor complications is reported to be 2.4–9.6% and includes headache, vasovagal symptoms, facial flushing, increased back or leg pain, and transient nerve root irritation.[24] In our study too, patients receiving TFESI developed only minor complications, with 6.9% developing vasovagal symptoms and 3.4% developing facial flushing, all of which resolved spontaneously without any major sequelae. Erector spinae block, on the other hand, has very few complications reported to date. Pneumothorax, the most serious one, has been reported with thoracic ESPB. In lumbar ESPB, rare complications like priapism and accidental motor block have been documented in case reports.[23] In our study, no such complications were observed in any of the ESPB group patients.

Celik et al.[25] used a high-volume mixture (40 mL) in left lumbar ESPB in a patient with LBP and studied the spread of contrast, which involved the paravertebral space from L1–S4, lumbar plexus, epidural space, left lumbar neural foramina, and facet joints, associated with>70% decrease in the symptoms. It is inferred that high-volume lumbar ESPB in these patients is effective due to causing lumbar plexus block. However, one has to be cautious, as seizures following such high volumes have also been reported.[26] In our study, no complications were observed in the ESPB group.

This study has multiple limitations. First, the two procedures were completely different in terms of techniques and drug doses, which could lead to observer bias. However, the operator was not involved in data collection, analysis, or interpretation, which were done by another co-investigator blinded to group allocation. Second, the observations were limited to only 3 time points, i.e. 1 hr, 1 month, and 3 months; no observations were made in between, which could have led to the loss of important data or findings. A weekly assessment of parameters would have been more appropriate. Third, we used MODI for the assessment of disability, which includes only elements of physical disability. The impact upon psychosocial aspects of quality of life was not taken into consideration. Lastly, the frequency of rescue analgesic intake and overall consumption were not compared, which could have provided important insight into the effectiveness of the two procedures.

Conclusions

Both TFESI and ESP are effective in managing low backache with radiculopathy. However, TFESI provided better control of pain post-intervention and at follow-up, as assessed by lower NRS scores in these patients compared to those receiving ESP block. Nonetheless, more complications were observed in the TFESI group compared to ESP. Therefore, ESP block can be considered in LBP patients where TFESI is either contraindicated or not feasible.

Ethics Committee Approval: The Banaras Hindu University Institute of Medical Sciences Ethics Committee granted approval for this study (date: 15.02.2021, number: Dean/2021/EC/2505).

Informed Consent: Written informed consents were obtained from patients who participated in this study.

Conflict-of-interest issues regarding the authorship or article: None declared.

Financial Disclosure: This study has no funding or sponsor.

Use of AI for Writing Assistance: Not declared.

Authorship Contributions: Concept – AKP; Design – DR, SP; Supervision – AKP, NV; Resources – DR, AR; Materials – RAS; Data collection and/or processing – RAS, AV; Analysis and/or interpretation – AR, NV; Literature search – DR; Writing – RAS, DR; Critical review – AKP, SP, AV.

Peer-rewiew: Externally peer-reviewed.

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