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Original Research Article

A comparative study of efficacy between transforaminal epidural injection and selective nerve root block in disc prolapse of L4-L5 and L5-S1

Arindam Ghosh, Debayan Ghorai*, Dibyendu Dutta

[1]Department of Physical Medicine and Rehabilitation, Calcutta National Medical College and Hospital, Kolkata, West Bengal, India [2]Institute of Post Graduate Medical Education and Research, Kolkata, West Bengal, India
[3]Bankura Sammilani Medical College and Hospital, Bankura, West Bengal, India

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***Correspondence:**
Dr. Debayan Ghorai,
E-mail: dr.d.ghorai@gmail.com

ABSTRACT

Background: To compare efficacy between transforaminal epidural injection (TFEI) and selective nerve root block (SNRB) in prolapsed L4-L5 and L5-S1 disc.
Methods: This study was a randomized parallel group open label interventional study. Patients suffering from low back pain (LBP) with radiation due to prolapsed inter-vertebral disc (PIVD) were selected for intervention (n=78). After computer generated randomization, they were allocated into two groups (TFEI group and SNRB group) consisting 39 patients in each group. Each patient received combination of 2 ml of depot methylprednisolone acetate (40 mg/ml) and 1 ml of 0.25% preservative free bupivacaine under fluoroscopy guidance. Primary outcome measures were visual analogue scale (VAS) score of LBP and VAS score of radiation pain. Secondary outcome measure was Oswestry LBP disability questionnaire (ODQ) score.
Results: At 1-day post-intervention TFEI group showed statistically significant improvement in VAS score of LBP (p=0.000) as compared to SNRB group. At 1-month post-intervention TFEI group showed statistically significant improvement in VAS score of LBP (p=0.000) and VAS score of radiation pain (p=0.000) as compared to SNRB group. At 3-month post-intervention TFEI group again showed statistically significant improvement in VAS score of LBP (p=0.000), VAS score of radiation pain (p=0.000), and ODQ score (p=0.000) as compared to SNRB group.
Conclusions: TFEI is better than SNRB in terms of improvement in LBP, radiation pain, and functional activity up to 3-month post-intervention.

Keywords: Disc prolapse, Radiculopathy, Transforaminal epidural injection, Selective nerve root block

INTRODUCTION

Low back pain with radiation is a frequently encountered problem in a physiatry field. Majority of those cases are due to prolapsed inter-vertebral disc (PIVD). A vast majority of PIVD occur at L4-L5 and L5-S1 level causing L5 and S1 radiculopathy.[1] Irritation of a sensory root or dorsal root ganglia (DRG) of a spinal nerve caused by herniated nucleus pulposus generates impulse in distal axon which is perceived as radicular pain.[2] The external part of diseased annulus fibrosus also act as pain generator locally producing low back pain.[3] A deep seated pain starting from one side of low back and shooting down in buttock and leg as a narrow band along the territory innervated by L4, L5 and S1 nerve roots is classic feature of L4-L5 and L5-S1 PIVD. Prolonged sitting or standing and bending usually aggravate symptoms.[4]

Diagnostic imaging is generally indicated in cases with severe symptoms and who fail to respond to 6-8 weeks of conservative therapy. Jackson, et al. conducted a prospective comparative study assessing the relative accuracies of CT, myelography, CT myelography and MRI for diagnosis of PIVD. MRI was the most accurate test with 76.5% accuracy and lowest false positive rate at 13.5%.[5] Jannsen et al concluded that MRI should be the diagnostic study of choice when available.[6]

The mainstay of treatment of PIVD is conservative. Most patients generally respond well with conservative management in the form of oral medications and exercise therapy. Still there are fare numbers of patients who do not improve with conservative management, and over the past few years various interventional procedures are emerging to tackle those patients. For years, PIVD was primarily thought as a disease of surgical interest though the threshold level of surgery is increasing day by day. Now different types of intervention are getting more and more importance in managing disc diseases like TFEI, SNRB, interlaminar epidural injection and caudal epidural injection. Though different routes of intervention are used, SNRB and TFEI are emerging as an alternative to interlaminar and caudal epidural injections.

TFEI is an effective pain management tool in PIVD with radiculitis as disc prolapse causes inflammatory response.[7] SNRB can be used as a diagnostic or as a therapeutic purpose. SNRB requires more posterior needle placement so that nerve root and DRG is bathed with therapeutic agents. On the other hand, in TFEI therapeutic agents are delivered more ventrally in the epidural space.[8]

There is scarcity of literature evidence regarding comparative efficacy of above mentioned two procedures. Our study is an attempt to find out which procedure (TFEI or SNRB) is more efficacious in PIVD of L4-L5 and L5-S1 level.

METHODS

Study design

Study design for this study used was parallel group open label randomized controlled trial.

Study place

This study was conducted at the department of physical medicine and rehabilitation, IPGME and R, SSKM hospital, Kolkata.

Study period

The study was carried out for 18 months (15th February 2017 to 14th august 2018)

Before starting the study, approval was taken from institutional ethics committee. Informed written consent was taken from each patient before including them in this study. Every patient was explained about the course and prognosis of the disease, its present available management, the outcome and complications in a language that was understandable to them. All participants were given free choice to withdraw themselves from the study whenever they want.

Inclusion criteria

Inclusion criteria included patients aged 18 to 65 years suffering from mechanical LBP with radiation due to PIVD at L4-L5 and L5-S1 (diagnosed with MRI) with symptom duration of less than 1year, symptom severity of ≥6 cm VAS score for pain, and not responding to conservative management for 3 months were included in this study.

Exclusion criteria

Exclusion criteria excluded patients with uncontrolled diabetes, bleeding disorders, local infection at injection site, spondylolisthesis at lumbo-sacral region, and evidence of underlying spinal infection were not included in this study. Pregnant women, exclusive breast-feeding mothers, and patients who are allergic to local anesthetics, antibiotics or radiographic dye were also excluded. Patients suffering from concomitant painful conditions, such as lower limb joint pain or peripheral vascular diseases that might interfere with the subject's ability to determine the degree of relief of their radicular pain were also not included in our study.

Sample size for this study was calculated on the basis of VAS pain score as a primary outcome measure. It was calculated that 35 patients would be required in each group in order to detect a difference of 1 cm in VAS score at the end of 3 months following the procedure with 80% power and 5% probability of type 1 error, assuming standard deviation of 1.5 cm. Keeping a margin for 10% dropouts, the overall recruitment target was set at 39 patients/group. Since there were two groups, our overall recruitment target was 78 patients (n=78). Sample size calculation was done by using nMaster 2.0 software (department of biostatistics, Christian medical college, Vellore).

In this study patients suffering from low back pain with radiation due to PIVD at L4-L5 and L5-S1 (diagnosed by MRI of lumbo-sacral spine) were selected for intervention according to the inclusion and exclusion criteria. Detailed history was taken and clinical examination was done. Routine blood, sugar, coagulation profile and serology were checked. Every patient was injected with a combination of 2 ml depot methylprednisolone acetate (40 mg/ml) and 1 ml of 0.25% preservative free bupivacaine under strict aseptic

condition. In one group TFEI was done and in the other group SNRB was done.

Injection technique

For both the procedures patients were placed on fluoroscopic operation table on prone position with a sterile cushion underneath abdomen to rectify lumbar lordosis. After proper skin preparation with sterile gauze soaked in povidone iodine and antiseptic draping the fluoroscope was adjusted. The target area was decided based on clinical distribution of pain in specific dermatome, sensory or motor loss on a dermatome or myotome respectively, and MRI findings.

For TFEI fluoroscope was placed for AP-view to identify the desired spinal level. Then an ipsilateral 20-to-30-degree oblique view was obtained. For right sided radicular symptoms right oblique and for left sided symptoms left oblique view was taken. Squaring of the target vertebra was done by tilting the fluoroscope in cephalic or caudal direction as and when required. The 6 o'clock position of the pedicle was marked and infiltrated with 3 ml preservative free 2% lignocaine for local anesthesia. A 23G Spinocan needle was then advanced with proper alignment of fluoroscopy into the so-called "safe triangle" area which has a roof made by the pedicle, a tangential base that corresponds to the exiting nerve root and a side that is made by the lateral border of the vertebral body. The position of the needle tip was confirmed by both AP and lateral view. On the lateral view, position of the needle tip was kept just below the pedicle at the ventral aspect of the intervertebral foramen. After proper needle placement 2 ml of water-soluble non-ionic contrast material (iohexol) was injected. Care was taken to prevent any intravascular spread of contrast material by pulling the plunger of the syringe and looking for presence of blood in the needle hub. Then image was obtained in AP and lateral view with dorsal and ventral spread of the dye in the epidural space and along the nerve root indicating proper positioning of the needle tip. Then combination of 2 ml depot methylprednisolone acetate (40 mg/ml), 1 ml of 0.25% preservative free bupivacaine was injected. Again, care was taken so that there was no intravascular spread. Wash out of the contrast material was checked in lateral followed by anteroposterior view.

For SNRB at L4 level positioning of the fluoroscope was same as TFEI. The only difference was that the target point was just lateral to an imaginary line connecting the centers of two consecutive pedicles next to the lateral aspect of the superior articular process of the caudal vertebra. For L5 level SNRB the fluoroscope was tilted towards cephalic direction until the iliac crest receded caudally so that iliac crest could not create any mechanical obstruction during advancement of the needle. The target point was just lateral to an imaginary line connecting the centers of two consecutive pedicles next to the lateral aspect of the superior articular process of the caudal vertebra. Under local anesthesia a 23G Spinocan needle was introduced towards the target area and the needle tip was kept more caudal to the pedicle as compared to needle position of TFEI. The needle was then advanced until patient reported paranesthesia or tingling sensation along the distribution of targeted nerve root. Needle was then withdrawn 1-2 mm and redirected into a slightly cranial direction keeping the needle tip outside the intervertebral foramen. After proper needle placement 2 ml of water-soluble non-ionic contrast material (iohexol) was injected. AP and lateral view were taken to confirm visualization of nerve root without any epidural spread. Rest of the procedure was same as TFEI.

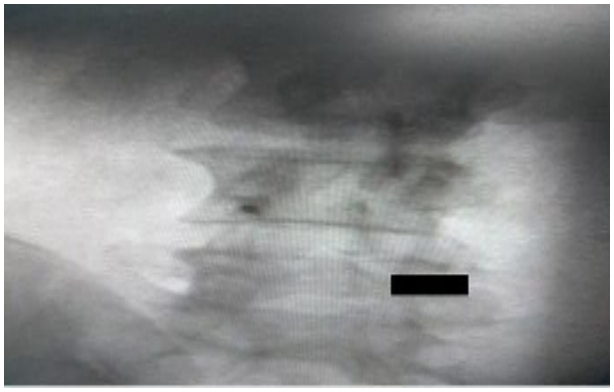

Figure 1: Needle placement in TFEI-oblique view.

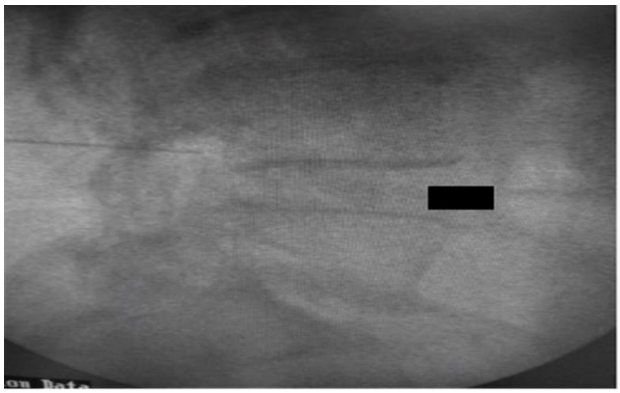

Figure 2: Needle placement in TFEI-lateral view.

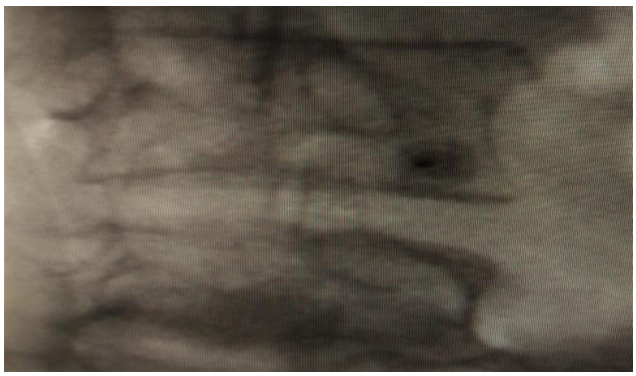

Figure 3: Needle placement in SNRB-oblique view.

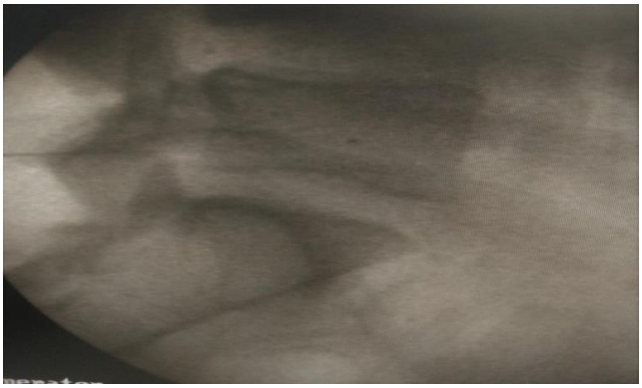

Figure 4: Needle placement in SNRB-lateral view.

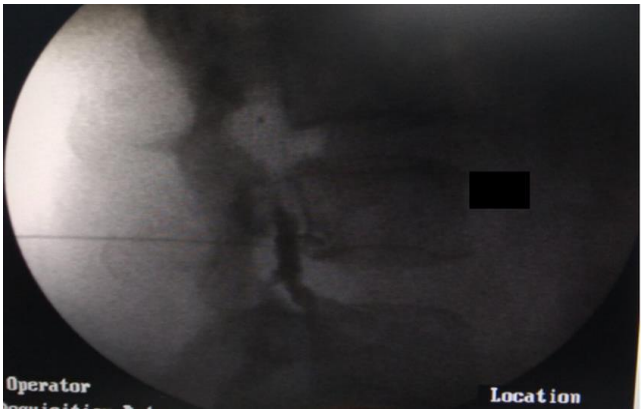

Figure 5: Spread of dye in TFEI-lateral view.

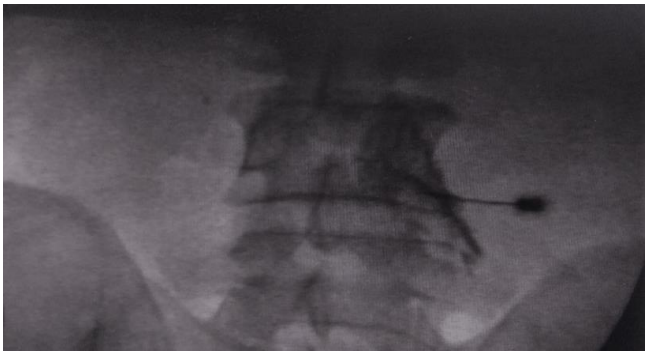

Figure 6: Spread of dye in TFEI-AP view.

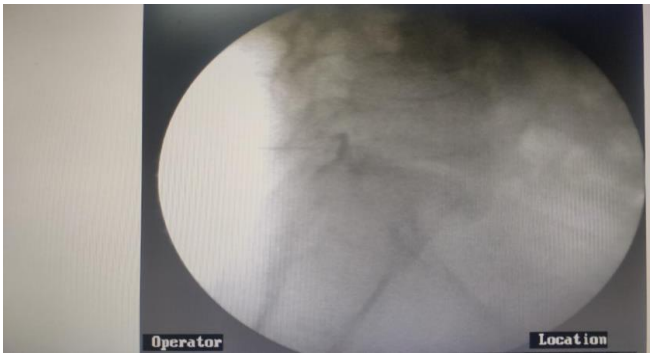

Figure 7: Spread of dye in SNRB lateral view.

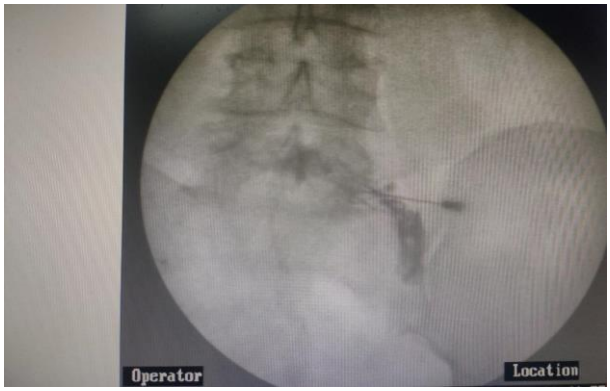

Figure 8: Spread of dye in SNRB-AP view.

Following intervention every patient received intravenous infusion of 500 ml of normal saline over 6 hours, 2 doses of intravenous ceftriaxone (1 gm) followed by a 5 days course of oral cefixime (200 mg) twice daily, aceclofenac (100 mg) twice daily, pantoprazole (40 mg) once daily and 2 weeks course of gabapentin (100 mg) thrice daily. All patients continued lifestyle modification and home-based exercise therapy.

The following parameters were studied at baseline (on the day of intervention or visit 1), 1-day post-intervention (visit 2), 1-month post-intervention (visit 3) and 3-month post-intervention (visit 4).

VAS score of LBP (0 to 10 cm scale), VAS score of radiation pain (0 to 10 cm scale) and ODQ (0 to 100 score).

Using those parameters, the results were analyzed according to the standard statistical methods to fulfill the aims and objectives of the study.

Statistical tool used for this project

We used statistica version 6 [Tulsa, Oklahoma: StatSoft Inc., 2001] and GraphPad prism version 5 [San Diego, California: GraphPad Software Inc., 2007] to analyses the data.

RESULTS

Data had been summarized by routine descriptive statistics such as mean and standard deviation for normally distributed numerical variables, median or inter-quartile range for skewed numerical variables and counts and percentages for categorical variables. Numerical variables had been compared between groups by student's independent sample t-test, when normally distributed, or by Mann-Whitney U test when skewed. Chi-square test or Fisher's exact test had been employed for inter-group comparison of categorical variables. All comparisons were two tailed and $p<0.05$ was considered statistically significant.

In this study, 8 out of 78 patients dropped out following the baseline visit (visit 1). 35 patients in each group completed all the follow up visits (visit 2, visit 3, and visit 4). Mean age of the patient population was 37.86±10.044 years in TFEI group and 37.57±10.013 years in SNRB group. In total study population, majority (64.3%) belonged to 18 to 40 years of age group. In both the groups male outnumbered female participants with a female:male ratio of 1:1.4 in total study population. Mean body weight was 51.4±6.47 kg in transforaminal epidural injection group and 52.2±6.24 kg in selective nerve root block group. Distribution of age, sex, and BMI were comparable between groups.

Comparison of parameters between groups

In this study all the injections were given by one person. Evaluation was done by two separate persons at all visits. Evaluators were blinded regarding the injection approach. Inter-reader and intra-reader reliability were done for all outcome measures.

There was statistically no significant difference between the groups regarding age, sex, and weight distribution (Table 1). At baseline (visit 1) all the outcome parameters were comparable for both the groups (Table 2). At visit-2 improvement in LBP VAS was statistically significant in TFEI group as compared to SNRB group, but improvement in radiation pain VAS and ODQ score was not significant (Table 3). At visit 3 along with improvement in LBP VAS, improvement in ODQ score also became statistically significant in TFESI group as compared to the SNRB group (Table 4). But no difference was found in improvement of radiation pain VAS between the groups at visit 3 (Table 4). At visit 4 all three outcome parameters showed statistically significant difference in improvement in TFEI group as compared to SNRB group (Table 5).

Table 1: Demographic characteristics of the patient population.

Variables	Transforaminal-epidural injection (n=35)	Selective nerve root block (n=35)	P value
Age (years) (Mean ± SD)	37.86±0.044	37.57±10.013	0.905
Sex (Male:Female)	22:13	19:16	0.624
Weight (kg) (Mean ± SD)	51.4±6.47	52.2±6.24	0.511

Table 2: Comparison of parameters between groups at visit 1.

Variables	Transforaminal-epidural injection [median (IQR)]	Selective nerve root block [median (IQR)]	P value
LBP VAS (0 to 10 cm scale)	8.1 (7.8-8.3)	8.1 (7.7-8.4)	0.937
Radiation pain VAS (0 to 10 cm scale)	8.50 (7.9-8.9)	8.40 (7.9-8.9)	0.780
ODQ score (0 to 100)	40.00 (38.00-43.00)	40.00 (38.00-43.00)	0.875

Table 3: Comparison of parameters between groups at visit 2.

Variables	Transforaminal-epidural injection [median (IQR)]	Selective nerve root block [median (IQR)]	P value
LBP VAS (0 to 10 cm scale)	3.2 (2.60-3.30)	4.0 (3.50-4.40)	0.000
Radiation pain VAS (0 to 10 cm scale)	2.50 (2.00-3.00)	2.60 (2.00-3.30)	0.250
ODQ score (0 to 100)	31.00 (30.00-33.00)	32.00 (30.00-33.00)	0.689

Table 4: Comparison of parameters between groups at visit 3.

Variables	Transforaminal-epidural injection [median (IQR)]	Selective nerve root block [median (IQR)]	P value
LBP VAS (0 to 10 cm scale)	3.50 (3.20-3.70)	4.70 (4.20-5.10)	0.000
Radiation pain VAS (0 to 10 cm scale)	3.00 (2.30-3.40)	3.00 (2.50-3.60)	0.274
ODQ score (0 to 100)	32.00 (30.00-33.00)	35.00 (33.00-37.00)	0.000

Table 5: Comparison of parameters between groups at visit 4.

Variables	Transforaminal-epidural injection [median (IQR)]	Selective nerve root block [median (IQR)]	P value
LBP VAS (0 to 10 cm scale)	5.00 (4.70-5.40)	5.80 (5.30-6.10)	0.000
Radiation pain VAS (0 to 10 cm scale)	3.60 (3.20-4.00)	4.30 (4.00-5.20)	0.000
ODQ score (0 to 100)	34.00 (32.00-36.00)	38.00 (36.00-39.00)	0.000

DISCUSSION

The effectiveness of TFEI in the management of lumbo-sacral radicular pain have been shown for many decades.[9-11] Although Selective nerve root block was used as a diagnostic procedure its therapeutic efficacy is well known.[12,13] But there is scarcity of literature comparing the effectiveness of those two procedures.

In our study we found that PIVD is more common in younger age group. In our total study population 64.29% of patients were in the age group of 18-40 years. The mean age of total study population was 37.7 years. Kuppuswamy, et al. conducted an observational study where they observed that incidence of PIVD was common in younger age group.[14] There is lack of literature support regarding sex ratio of PIVD. Although Strömqvist et al. observed statistically significant and clinically relevant sex differences where female patients had more pronounced LBP and disability.[15] In another cross-sectional open population-based study a greater number of women had disc space narrowing than men, but men had more frequent radiographic osteophytes than women.[16] But in our study population there was male preponderance that may be due to small sample size. We feel that another study with larger study population may reflect a true sex ratio in PIVD.

In our study statistically significant difference was noted for LBP VAS in all post- intervention visits with superior result in TFEI group. Statistically no significant difference between groups was observed at visit-2 and visit-3 for radiation pain VAS. It only became statistically significant at visit-4 in favor of TFEI group. While comparing ODQ score we found statistically no significant difference between groups at visit-2, but at visit-3 and visit-4 the differences were significantly better in TFEI group.

Bhatia et al showed in a meta-analysis incorporating 8 different randomized controlled trial that there was modest improvement in pain VAS score at 3 months after TFEI as compared to control.[17] In a prospective clinical study Ploumis et al showed that TFEI was superior than caudal epidural injection regarding improvement in pain VAS and function at 6 month.[18] In a systemic review Manchikanti et al concluded that fluoroscopy guided epidural injections by trained physicians offer improvement in pain and function in well-selected patients with lumbar disc herniation.[19] In a prospective randomized study Rados et al found that 21 out of the 32 patients improved 10 points or more on Oswestry scale after 6 months after a transforaminal injection.[20] Singh et al has shown in their prospective study that there was reduction of pain score by more than 50% up till 6 months in SNRB group. In that study the reduction in ODQ score in SNRB group was 52.8% at 3 months, 48.6% at 6 months and 46.7% at 1 year follow up.[21]

In our study all the three outcome parameters had best results at visit-2 in both the groups then there was gradual deterioration through visit-3 followed by visit-4. This might be due to small sample size and failure to continue post intervention life style modification and exercise therapy which was advised.

According to some literatures there are chances of adjacent root block in SNRB.[22,23] But we did not find any contrast spread to adjacent nerve roots while performing SNRB.

We took all precautionary measures keeping in mind about the adverse effects. Botwin et al mentioned that the most common and worrisome complications of transforaminal epidural steroid injections in the lumbar spine, though rare, are related to neural trauma, vascular trauma, intravascular injection, and infection.[24] In our study, two patients complained about burning sensation in needle entry point in post intervention first day which subsided without any medication. There were no other complications during or post-intervention period. It suggests that both the procedures are safe if not otherwise contraindicated.

CONCLUSION

We can conclude that TFEI is better than SNRB in terms of improvement in LBP, radiation pain, and functional activity up to 3-month post-intervention in patients with PIVD of L4-L5 and L5-S1. LBP with radiation due to PIVD of L4-L5 and L5-S1 mostly affect younger population and is more common in men than women. In future a study with longer follow up, larger sample size and a control group will provide more information in those aspects.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee by IPGME and R research oversight committee.

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