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Comparative Efficacy and Safety of Fluoroscopy-guided Caudal Epidural Steroid Injection and Transforaminal Epidural Steroid Injection for Unilateral L5-S1 Paracentral Discogenic Radicular Pain

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Learning Point of the Article:

Caudal epidural steroid injection is a simple, safe, and efficacious technique comparable to transforaminal selective nerve root block in the management of unilateral L5-S1 paracentral discogenic radicular pain with significantly less procedural time and fluoroscopy usage.

Abstract

Introduction: Epidural steroid injection (ESI) is one of the key management strategies in the management of discogenic radicular pain. This study aims to compare the efficacy and safety of fluoroscopy-guided ESI through caudal (cESI) and transforaminal (tfESI) routes for unilateral paracentral L5-S1 discogenic radicular pain.

Materials and Methods: This prospective non-randomized comparative study conducted between January 2023 and January 2024 in a tertiary care hospital included patients presenting with unilateral paracentral L5-S1 discogenic radicular pain who failed 6 weeks of conservative care. The pain and functional outcome was analyzed using numerical pain rating scale (NPRS) and Oswestry disability index, respectively, at baseline, 3-week, 6-week, and 6-month post-intervention. Procedure failure is defined as NPRS score improvement <50% or ODI improvement <40% of baseline. Other outcomes analyzed were the duration of the procedure, and fluoroscopy shots used during the procedure.

Results: We enrolled 60 patients in the study, 54 patients were available till the final follow-up with 26 patients in the cESI group and 28 patients in the tfESI group. The mean age of the cESI group (M: F 12:14) and tfESI group (M:F 10:18) was 36.1 (±4.1) years and 38.9 (±3.9) years, respectively. The pain and functional scores were significantly reduced compared to the baseline scores in both the groups ($P < 0.001$) and the reduction between the two groups was comparable at every follow-up. The tfESI group experienced significantly more failures (n = 8) at 6 months compared to the cESI group (n = 2) ($P = 0.048$). The tfESI group had significantly longer mean procedure time (18.8 min) and more fluoroscopy usage (16 shots) compared to cESI group with mean procedure time of 13 min ($P = 0.014$) and fluoroscopy usage of 10 shots ($P = 0.023$), respectively. No major adverse events were reported for either of the groups.

Conclusion: cESI is a simple, safe, and efficacious technique comparable to tfESI in the management of unilateral L5-S1 paracentral discogenic radicular pain with significantly less procedural time and fluoroscopy usage. Further, large-scale studies are needed to validate the study results.

Keywords: Radicular pain, epidural steroid injection, caudal epidural, selective nerve root block, discogenic pain.

Introduction

Low back pain (LBP) constitutes one of the major health problems with a lifetime prevalence as high as 80% and an annual prevalence of up to 45% [1]. Based on the WHO estimates, 1 in 13 people suffered from LBP amounting to 619 million, which is a 60% rise compared to 1990 and it is expected to rise to 843 million by 2050 [2]. Studies analyzing the estimates of LBP noted that >25% of patients report high-intensity pain with significant disability in their day-to-day living [3, 4]. Not only younger adults suffer from discogenic LBP, but the elderly also

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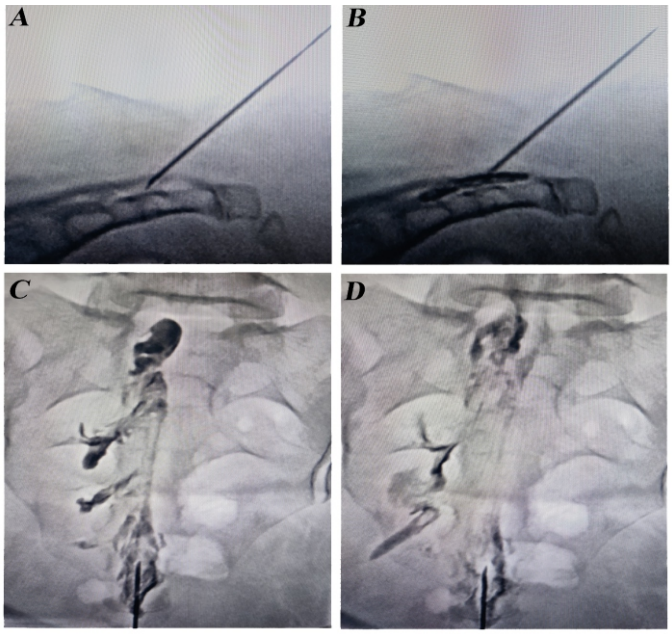

Figure 1: (A) Entry point for caudal epidural steroid injection with needle in the sacral canal; (B) confirmation of canal entry with ascending dye flow; (C) Preferential right-sided dye spread technique with bevel tilted to the ipsilateral side of pain with S1 root identification; (D) spread of dye post-injection into the sacral roots confirming drug delivery.

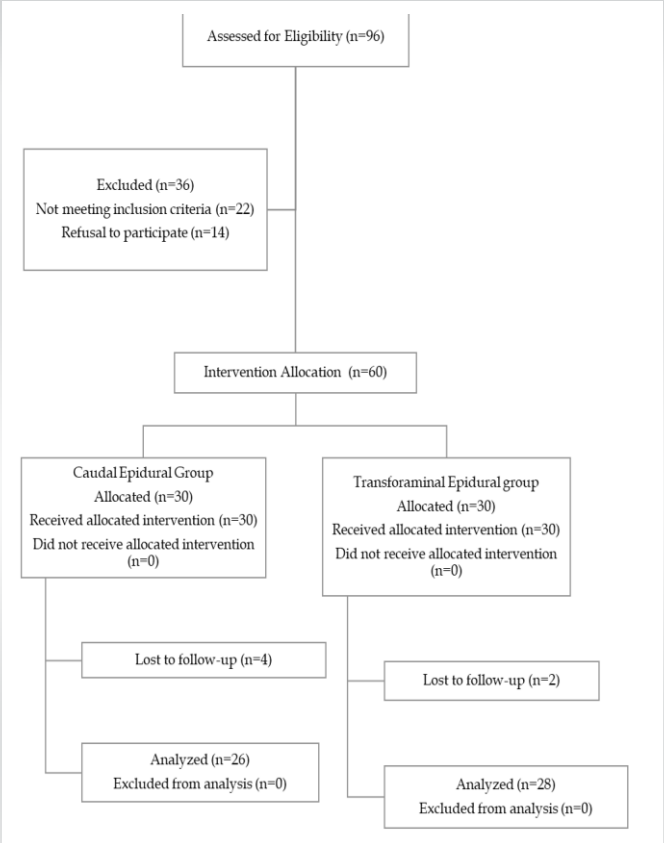

Figure 2: CONSORT flow diagram of assessment, inclusion, allocation, follow-up, and analysis of patients included in the study.

suffer from the disease due to degenerative disc disorders and it stands as an independent factor that affects the functional capacity [5-7]. Further, LBP has serious economic, societal, and health impacts that made the WHO release global guidelines on LBP management [8].

Intervertebral discs, ligaments, facet joints, muscles, fascia, and nerve roots were identified as structures capable of producing LBP [9]. Of all the mentioned structures, intervertebral disc commonly results in discogenic LBP secondary to disruption of the disc resulting in herniation and nerve root compression [10, 11]. Apart from disrupted disc, root compression can also be caused by degenerative stenosis of the foramen due to facetal hypertrophy and facetal osteoarthritis [12]. Disc disruption results in chemical radiculitis resulting in radicular LBP [11, 13].

Management of LBP with epidural injections has been one of the commonly preferred non-surgical treatment methods [14]. However, the role of injecting steroid and local anesthetic in the epidural space in managing neurogenic pain is still not well understood. The transient neural blockage achieved with the injection is considered to alter or interrupt the nociceptive input and the reflex mechanisms involved in the afferent pain fibers, along with its self-sustaining activity and patterning of the central neuronal activities [1,15,16]. The corticosteroids have been shown to decrease neuronal inflammation through inhibition of either the production or release of pro-inflammatory cytokines resulting in a reversible anesthetic effect [17, 18]. Further, the local anesthetic combined with the corticosteroid in the epidural injections was shown to provide short and long-term pain relief by direct suppression of the nociceptive discharge [19,20], inhibition of the sympathetic reflex arch [19], and its related axonal transport [21,22] along with blockade of sensitization [23] and anti-inflammatory effects [24]. The additive effects of these two components have been shown to demonstrate long-lasting effects in various nerve blocks [25, 26], especially in discogenic LBP scenarios [27].

The commonly employed routes of epidural injections include caudal, lumbar interlaminar, and transforaminal planes. While the interlaminar route is considered to deliver the drug at the site of the disc herniation, the transforaminal route is considered more specific and requires the least volume of injectate to address the root involved. The caudal epidural route although considered non-specific and requires increased usage of injectate is one of the safest and easiest procedures to address discogenic LBP. Previous studies have shown comparable efficacy of the techniques described above [1, 28, 29]. Despite the available evidence in the literature including systematic reviews, guidelines, health technology assessments, and medical review policies, there exists a disparity in the

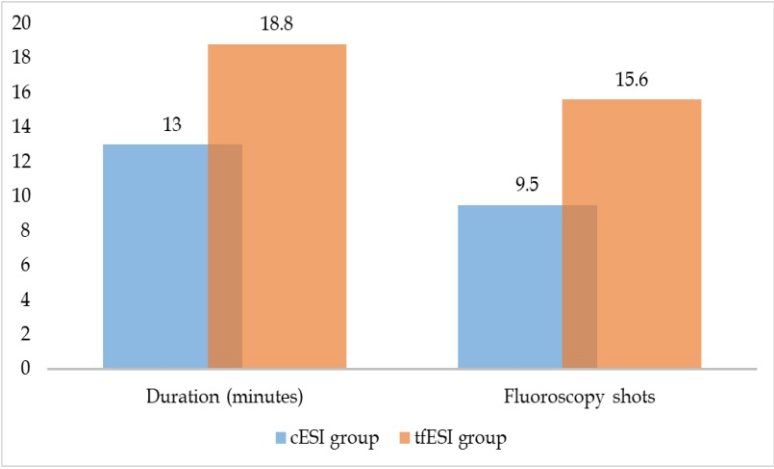

Figure 3: Comparison of procedure duration and fluoroscopy shots between the cESI group and tfESI group.

recommendations varying from indeterminate to strong based on the scenario where it is employed [30-33]. Further, the ideal route of epidural for a given scenario remains controversial requiring the need for ongoing trials in this regard [34].

The L4-L5 remains the commonly affected level due to discogenic LBP in both men and women followed by L5-S1 [35, 36]. In unilateral discogenic LBP at L4-L5, although the transforaminal route is preferred for its selectivity and low drug volume, the criticism for the caudal epidural route remains an indirect route with large volume of drug needed [37]. Further, the clinician is not sure whether the drug ascends to reach the target level to be effective. Whereas, at the L5-S1 level, both routes have their own advantages and disadvantages. Despite the advantages noted earlier for the transforaminal route, there is an anatomical disadvantage at this level due to the lumbarization, sacralization, or lumbosacral transitional vertebrae [38, 39]. Further, in the caudal epidural route despite retaining the procedural advantage, the L5-S1 level remains in close proximity to the site of injection alleviating the need for skepticism on drug ascent with the volume used. However, noted procedural complications with both routes include dural puncture, post-puncture headache, intra-venous injection, and so on [37]. Although previous studies have analyzed the efficacy of both transforaminal and caudal epidural routes in discogenic LBP,[1, 28, 29], none of them selectively analyzed the L5-S1 level for the given advantages and disadvantages with either of the epidural routes.

This study aims to selectively analyze the efficacy and safety of transforaminal epidural steroid injection (tfESI) and caudal epidural steroid injection (cESI) for unilateral L5-S1 paracentral discogenic LBP. We hypothesize that cESI would be more advantageous than tfESI in addressing L5-S1 paracentral discogenic LBP.

Characteristic	Caudal ESI group (n=26)	Transforaminal ESI group (n=28)	P-value
Age (years)	36.1 (±4.1)	38.9 (±3.9)	0.015
Women	14 (53.8%)	18 (64.2%)	0.429
Body mass index	26.5 (±3.4)	27.3 (±2.3)	0.372
Duration of pain (months)	5.5 (±3.4)	7.3 (±2.3)	0.024
Side (R:L)	12:14	16:12	0.045
L5 Sacralization	6	8	0.065
NPRS score (0–100)	84.8 (±6.9)	85.3 (±5.6)	0.992
ODI score (0–100)	82.4 (±6.8)	85.2 (±5.5)	0.288

Table 1: Characteristics of patients included in the study.

Materials and Methods

The study was conducted following approval of the protocol of conduct by the Institutional Ethical Committee (KMC/IEC/2022/6-1). This is a prospective non-randomized comparative cohort study conducted in patients with unilateral radiculopathy due to paracentral L5-S1 disc disease who have been treated with cESI or tfESI between January 2023 and January 2024.

Eligibility criteria

The study enrolled adult patients >18 years of age of both sexes presenting with unilateral radiculopathy with corresponding magnetic resonance imaging confirmed paracentral L5-S1 disc disease who failed other conservative lines of management for a duration of 6 weeks. Patients with multilevel disease, bilateral radiculopathy, prior back surgery, cauda equina syndrome, back pain due to other degenerative causes involving facet or spinal canal stenosis, back pain due to spinal fractures, and back pain of neoplastic and vascular causes were excluded along with pregnant and lactating mothers.

Patient screening

All the patients who consented to participate in the study were subjected to preliminary screening for drug/dye allergy. Patients deemed fit for the procedure were enrolled in the study and their baseline numerical pain rating scale (NPRS) [40] and Oswestry disability index (ODI) scores were recorded [41].

Treatment allocation

Patients considered for inclusion into the study were sequentially allocated to either one of the two treatment groups:

Outcome	Δ, 3 weeks	P-value	Δ, 3 months	P-value	Δ, 6 months	P-value
Caudal ESI group (n=26)						
NPRS score	−68.1 (±7.2)	<0.001	−64.5 (±10.8)	<0.001	−63.6 (±14.6)	<0.001
ODI score	−55.2 (±9.5)	<0.001	−51.3 (±13.2)	<0.001	−54.0 (±25.2)	<0.001
Transforaminal ESI group (n=28)						
NPRS score	−65.1 (±8.7)	<0.001	−58.3 (±20.9)	<0.001	−58.0 (±23.7)	<0.001
ODI score	−55.6 (±12.6)	<0.001	−49.9 (±17.2)	<0.001	−48.5 (±17.0)	<0.001

Table 2: Summary of clinical improvement noted in the patients included in the study.

cESI or tfESI following written and informed consent for participation in the study. The cESI group received an injection cocktail consisting of 2 mL of triamcinolone acetonide (40 mg/mL) with 2 mL of 2% lignocaine diluted with normal saline to make 20 mL. The tfESI group received an injection cocktail consisting of 2 mL of triamcinolone acetonide (40 mg/mL) with 2 mL of 2% lignocaine diluted with normal saline to make 5 mL.

Intervention

The intervention is done in a sterile fashion in the operating room under fluoroscopy guidance. All the intervention is done by a fellowship-trained spine specialist with a trained fluoroscopy technician. The patient lies prone on the operating table with bolsters under the chest and iliac crest.

The entry point for cESI is the sacral hiatus. The entry point is marked and 2 mL of lignocaine is infiltrated to anesthetize the injection site following sterile aseptic precautions. An 18G spinal needle is passed to enter the sacral canal at 45° angle in lateral view and its entry is confirmed with dye under fluoroscopy guidance as shown in Fig. 1a and b. Before injection of the drug cocktail, the needle is aspirated to check for intra-vascular or intra-dural entry. Based on the side of radiculopathy, the bevel of the needle is tilted to the affected side for preferential distribution of dye as shown in Fig. 1c. 4 mL of iohexol dye (350 mg/mL) is injected to confirm the epidural placement followed by injection. Confirmation of dye tracking till S1 root is ensured followed by injection of the drug cocktail as shown in Fig. 1d. The time taken for the procedure from the first-final fluoroscopy shots was recorded along with the number of fluoroscopy shots used.

The entry point for tfESI is based on the oblique view to visualize the Scotty-dog appearance of the vertebra after adjusting the cephalo-caudal tilt to align the endplate appropriately [39, 42]. The entry point is marked visualizing the sacral foramen in the neck of the scotty-dog in the oblique view and 2 mL of lignocaine is infiltrated at the injection site under sterile aseptic precautions. A 18G spinal needle is directed to reach the foramen which is confirmed to be adjacent to the sacral canal in the lateral view. Before injection of the drug cocktail, the needle is aspirated to check for intra-vascular or intra-dural entry. 4 mL of iohexol dye (350 mg/mL) is injected to confirm the epidural placement and tracking of the S1 root followed by injection. The time taken for the procedure from the first-final fluoroscopy shots was recorded along with the number of fluoroscopy shots used.

Post-operative protocol

Patients were observed for 1 h in the observation room and discharged for review at 3 weeks, 6 weeks, and 6 months with subsequent recording of their NPRS and ODI scores. Any complications observed during the study period are recorded. Procedure failure is defined as the NPRS score improvement <50% or ODI improvement <40% at any of the follow-up time points compared to the baseline.

Statistical analysis

We presented continuous variables using mean and standard

Outcome (mean±Standard deviation)	Caudal ESI group (n=26)	Transforaminal ESI group (n=28)	P-value
Baseline			
NPRS score (0–100)	84.8 (±6.9)	85.3 (±5.6)	0.992
ODI score (0–100)	82.4 (±6.8)	85.2 (±5.5)	0.288
3 weeks			
NPRS score (0–100)	16.6 (±5.0)	19.6 (±8.3)	0.161
ODI score (0–100)	28.2 (±9.1)	29.6 (±10.3)	0.541
3 months			
NPRS score (0–100)	20.3 (±9.6)	26.4 (±20.2)	0.085
ODI score (0–100)	32.1 (±11.7)	35.3 (±17.1)	0.354
6 months			
NPRS score (0–100)	21.1 (±16.5)	26.7 (±23.2)	0.314
ODI score (0–100)	29.3 (±24.9)	17.2 (±33.2)	0.207
ESI: Epidural steroid injection, NPRS: Numerical pain rating scale			

Table 3: Intergroup comparison in clinical outcome between two cohorts analyzed.

deviation and categorical variables using percentages. Improvements from the baseline were analyzed with a paired t-test, and comparisons between groups were made using one-way analysis of variance for continuous variables and Fisher-exact or Chi-square tests for categorical variables appropriately. A P-value below 0.05 was deemed statistically significant. The statistical analysis was performed with IBM SPSS Version 25 (Armonk, USA).

Results

Characteristics of patients

We enrolled 60 patients in the study, 54 patients were available till the final follow-up with 26 patients in the cESI group and 28 patients in the tfESI group as shown in Fig. 2. The mean age of the cESI group (M: F 12:14) and tfESI group (M:F 10:18) was 36.1 (±4.1) years and 38.9 (±3.9) years, respectively. The baseline characteristics of the included patients are presented in Table 1.

Clinical outcome

The mean NPRS score of the cESI group reduced from 84.8 (±6.9) to 16.6 (±5.0) at 3 weeks and 20.3 (±9.6) at 6 weeks and 21.1 (±16.5) at 6 months, respectively. Similarly, the mean ODI score of the cESI group reduced from 82.4 (±6.8) to 28.2 (±9.1) at 3 weeks and 32.1 (±11.7) at 6 weeks and 29.3 (±24.9) at 6 months, respectively. The mean NPRS score of the tfESI group reduced from 85.3 (±6.9) to 19.6 (±8.3) at 3 weeks and 26.4 (±20.2) at 6 weeks and 26.7 (±23.2) at 6 months, respectively. Similarly, the mean ODI score of the tfESI group reduced from 85.2 (±5.5) to 29.6 (±10.3) at 3 weeks and 35.3 (±17.1) at 6 weeks and 17.2 (±33.2) at 6 months, respectively. A significant decrease in pain and ODI scores were noted following the procedure at all time points compared to the baseline for both techniques as shown in Table 2. The difference in the pain and functional score reduction between the two groups was comparable at all time points as shown in Table 3.

The tfESI group experienced significantly more failures (n = 8) at 6 months compared to the cESI group (n = 2) ($P < 0.001$). Among the 8 failures noted in the tfESI group, 5 patients (63%) had L5 sacralization while none of the 2 failures noted in the cESI group had L5 sacralized.

Further, the tfESI group had a significantly longer mean procedure time of 18.8 min compared to the cESI group with a mean procedure time of 13 min ($P = 0.014$). Similarly, the tfESI group used significantly more mean fluoroscopy usage of 16 shots compared to the cESI group with mean fluoroscopy usage of 10 shots ($P = 0.023$) as shown in Fig. 3. No major adverse events were reported for either of the procedures.

Discussion

Despite the mechanical compression due to the herniated disc, chemical neuritis due to pro-inflammatory mediators triggers ectopic neuronal firing resulting in radicular pain [1, 15, 16]. Epidural injection of steroids and local analgesia is considered to reduce the inflammation and reverse the pain-induced neuronal plasticity [17,18]. The current study analyzed the efficacy and safety of ESI through caudal and transforaminal routes for unilateral paracentral L5-S1 discogenic pain. The main results are as follows:

1. Both cESI and tfESI are efficacious in significantly reducing radicular pain and disability

2. Both cESI and tfESI are comparable in their efficacy and safety

3. The tfESI group had significantly longer procedural time and fluoroscopy usage compared to the cESI group

4. The tfESI group experienced significantly more failures than the cESI group at 6-month follow-up.

Our study is in alignment with the previous studies that compared the efficacy and safety of the two routes of ESI in the management of LBP of various etiologies [29, 43-46]. Although there were controversies about the superiority of one route over the other, their efficacy is clearly established in the literature as noted in our study. Although we noted the resurgence of pain and discomfort with ongoing follow-up, the increase in NPRS and ODI noted between the follow-up time points in both the routes was not statistically significant ($P = 0.532$) or clinically relevant. There has been a recent shift in the practice preference from cESI to tfESI due to the selective nature of the latter [47]. Although Ackerman et al. [48] found tfESI to be superior to the caudal and interlaminar routes, their intervention was performed mostly at the L5 level. Similarly, most of the studies comparing cESI and tfESI lack homogenous patient groups to derive meaningful conclusions for a given scenario such as L5-S1 discogenic pain [29,43-46]. Sacralization is considered a risk factor that reduces the success rate of tfESI at the L5-S1 level [49]. Although both the groups analyzed had comparable patients with sacralization as shown in Table 1, considering the procedural difficulty, the significantly increased failures noted in the tfESI group could be accounted on this confounding factor. Further, cESI is not affected either by sacralization, lumbarization, or lumbosacral transitional vertebrae and could be considered the route of choice for L5-S1 ESI for this reason.

The reported complications of ESI with corticosteroids include suppression of the pituitary-adrenal axis, epidural lipomatosis, osteoporosis, steroid myopathy, avascular necrosis of bone, steroid psychosis, weight gain, fluid retention, hyperglycemia along with procedural complications such as infection, epidural hematoma, intra-vascular injection, and dural puncture [10,50-52]. However, at therapeutic dosage that is administered with ESI, with fluoroscopy guidance, complications due to both the drug and the procedure could be limited [33,53]. The commonly encountered complication with the L5-S1 tfESI is the location of the dorsal S1 foramen; likewise higher risk of intravascular uptake that prolongs the procedural time [54-56]. On the contrary, cESI is relatively safer with least risk of dural puncture, spinal cord injury, or risk of bleeding. Simon et al. [57] reported no adverse reactions among the 392 cESI and recommended its use safely even in patients on anti-thrombotic agents. Further, the risk of symptomatic hematoma is minimal due to the reduced vascularity in the sacral canal [58]. The radiation exposure that the surgeon receives with the lateral-based procedures such as tfESI was more compared to anteroposterior-based procedures such as cESI as noted in our study [59].

EC Ozturk et al. [60] conducted a similar study analyzing tfESI and cESI in S1 radiculopathy and found both routes to be beneficial and recommended cESI since it required shorter fluoroscopy time and radiation exposure. The major limitation of the study is short follow-up of 3 months. Our study noted increased failures in the tfESI group at 6-month follow-up. Further, we analyzed the impact of risk factors for failure such as sacralization between the two groups. The drug cocktail used in the above study was a mixture of 12 mg of dexamethasone, 1 mL of 0.5% bupivacaine, and 2 mL of saline amounting to 6 mL. Whereas, we used a high-volume cocktail consisting of 2 mL of triamcinolone acetonide (40 mg/mL) with 2 mL of 2% lignocaine diluted with normal saline to make 20 mL to ensure adequate drug spread. Further, high-volume blocks have been shown to demonstrate sustained benefits [61].

Although ESI has beneficial effects in the management of LBP due to discogenic back pain, their use is reserved for cases who failed a minimum 6–8 weeks of other conservative first-line management regimens because using ESI in acute sciatica <6–8 weeks for pain relief is not found to be cost-effective on a societal perspective [62]. However, before surgery, ESI could be considered as a cost-effective treatment method in the treatment regimen with comparable clinical benefits of surgery such as micro-discectomy without the risk of surgical complications [63].

The study has limitations to acknowledge. First, the small sample size and short-term follow-up limit the generalizability of the findings noted. We recommend larger randomized studies of longer follow-up to validate the findings noted in the given scenario. Second, we did not account for the frequency and dose of oral pain medications used during the follow-up period. However, the included patient cohort with S1 radiculopathy who represents greater possibility of successful management with cESI than oral analgesics makes the study design ideal and

valuable. Finally, we did not collect the back and leg pain scores individually, hence the failure reported during the follow-up could not delineated to either residual radiculopathy not addressed by the ESI or axial pain following resolution of radiculopathy.

Conclusion

cESI is a simple, safe, and efficacious technique comparable to tfESI in the management of unilateral L5-S1 paracentral discogenic radicular pain with significantly less procedural time and fluoroscopy usage. Further, large-scale studies are needed to validate the study results.

Clinical Message

- Both cESI and tfESI result in significant pain and functional improvement in patients with unilateral L5-S1 paracentral discogenic radicular pain
- The tfESI group experienced significantly more failures compared to the cESI group
- The tfESI group had significantly longer mean procedure time and more fluoroscopy usage compared to cESI group and fluoroscopy usage
- No major adverse events were reported for either of the groups

Declaration of patient consent: The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient has given the consent for his/ her images and other clinical information to be reported in the journal. The patient understands that his/ her names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

Conflict of interest: Nil **Source of support:** None

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