Journal of Southeast Asian Orthopaedics
ISSN 2821-9848 (Print)
ISSN 2821-9864 (Online)
https://doi.org/10.56929/jseaortho-2026-0285 https://jseaortho.org

Landmark Loss-of-Resistance Versus Fluoroscopy-Guided Caudal Epidural Steroid Injection for Sciatica: A Prospective Comparative Study

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Purpose: To compare clinical outcomes, procedure time, and adverse events between landmark loss-of-resistance (LOR) and fluoroscopy-guided (FL) caudal epidural steroid injection (CESI) for sciatica due to magnetic resonance imaging (MRI)-confirmed lumbar disc protrusion or extrusion.

Methods: In a prospective, randomized, 1:1-allocation trial, patients received LOR or FL CESI using an identical injectate. Pain (Visual Analog Scale [VAS]), disability (Oswestry Disability Index [ODI]), and patient satisfaction (Patient Satisfaction Score [PSS]) were assessed at baseline and at 1, 3, 6, and 12 months. Procedure time and adverse events were recorded. The primary between-group inference at 12 months used baseline-adjusted analysis of covariance (ANCOVA), reported as adjusted mean differences (AMD; LOR−FL) with 95% confidence intervals (CIs).

Results: Seventy patients were randomized equally (LOR n = 35; FL n = 35). Both groups showed improvement in VAS, ODI, and PSS over 12 months. At 12 months, adjusted between-group differences were small and not statistically significant: VAS 0.41 (95% CI -0.54 to 1.36), ODI 1.96 (95% CI -2.96 to 6.87), and PSS 0.37 (95% CI -0.45 to 1.20). Procedure time was significantly shorter with LOR (6.37 ± 1.99 vs 14.09 ± 2.20 minutes; $p < 0.001$). Adverse events were rare, with no dural puncture or bleeding in either group.

Conclusions: In this single-center randomized study, LOR and FL CESI showed comparable 12-month outcomes for pain, disability, and satisfaction. LOR required much less procedure time and may be a practical alternative when fluoroscopy is unavailable or resources are limited.

Keywords: caudal epidural steroid injection, fluoroscopy, loss-of-resistance, sciatica, lumbar disc herniation

Lumbar disc herniation (LDH) is a major cause of sciatica and functional limitation in adults. When symptoms persist despite conservative treatment, caudal epidural steroid injection (CESI) is commonly used because it is minimally invasive, repeatable, and adaptable across diverse clinical settings [1-5].

Fluoroscopy-guided (FL) CESI is widely used because real-time imaging can verify needle position and contrast spread, potentially improving technical accuracy and reducing malposition. However, fluoroscopy requires imaging facilities, trained personnel, radiation safety measures, additional time, and increased cost. These requirements may limit access in resource-constrained settings and busy outpatient practices [6,7].

Article history:
Received: September 28, 2025 Revised: May 12, 2026
Accepted: May 22, 2026
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Landmark loss-of-resistance (LOR) CESI relies on anatomic palpation of the sacral hiatus and tactile confirmation of entry into the epidural space[8,9]. This technique is portable, relatively inexpensive, and feasible in routine procedure rooms without imaging infrastructure. Nonetheless, concerns remain regarding technical variability, accuracy, and the potential for suboptimal injectate delivery when compared with image-guided approaches [10,11].

Existing evidence suggests that both image-guided and landmark-guided CESI can improve pain and function in patients with lumbosacral radiculopathy, but the literature remains heterogeneous in study design, sample size, and outcome definitions. In addition, longer-term comparative outcomes and procedure-level measures, such as total procedure time and adverse events, are reported inconsistently [12,13].

Ultrasound-guided CESI is an important alternative imaging technique and continues to gain clinical interest [14]. However, fluoroscopy remains a widely used reference standard because it allows direct confirmation of needle position and contrast spread. Accordingly, the present study was designed to compare the pragmatic landmark-guided LOR technique with fluoroscopy-guided CESI, which is commonly used in current practice as an imaging-confirmed reference.

The purpose of this prospective randomized study was to compare clinical outcomes, procedure time, and adverse events between LOR and FL CESI in adults with sciatica secondary to MRI-confirmed lumbar disc herniation. We hypothesized that both techniques would yield comparable patient-reported outcomes at 12 months, with LOR requiring less procedure time.

METHODS

Study Design and Participants

We conducted a prospective randomized comparative trial of landmark loss-of-resistance (LOR) versus fluoroscopy-guided (FL) caudal epidural steroid injection (CESI) in adults with sciatica secondary to lumbar disc herniation. Seventy patients were enrolled between December 2023 and September 2024. Institutional review board approval was obtained, and written informed consent was provided by all participants. Inclusion criteria were age 20 years or older, MRI-confirmed LDH (protrusion or extrusion) at L3-4, L4-5, or L5-S1, symptom duration of at least 8 weeks despite conservative therapy, baseline VAS pain score of at least 6/10, concordant positive straight-leg raise or femoral stretch test, and ability to complete follow-up outcomes. Exclusion criteria included bulging or sequestrated LDH, predominant spinal stenosis, prior spinal surgery, progressive neurologic deficit, spondylolisthesis, infection, coagulopathy or non-interruptible anticoagulation, pregnancy, uncontrolled diabetes or hypertension, known allergy to injectable components, or CESI within the preceding 3 months.

Sample Size and Randomization

Sample size was estimated for the primary outcome, VAS at 12 months, using standard methods for continuous outcomes. We assumed a clinically important between-group difference of 1.5 VAS points and a common standard deviation of 2.0 points. With a two-sided alpha of 0.05, 90% power, and 1:1 allocation, the required sample size was 32 participants per group. To allow for up to 10% loss to follow-up, the planned enrollment was 35 participants per group. After baseline assessment, participants were randomized 1:1 to the LOR or FL group using a computer-generated sequence with concealed allocation. Proceduralists could not be blinded because of the nature of the interventions.

Interventions

All procedures were performed by an attending team experienced in caudal epidural steroid injection (CESI). Patients were positioned prone with a small abdominal bolster. After sterile skin preparation, local anesthesia was administered at the sacral hiatus using 5 mL of 2% xylocaine without epinephrine. The procedure was then performed according to group allocation.

In the landmark loss-of-resistance (LOR) group, the sacral cornua and sacral hiatus were identified by palpation. An 18-gauge Tuohy needle

(Perican, B. Braun; 1.3 × 80 mm) was inserted at an angle of approximately 15°. Entry into the caudal epidural space was confirmed using the loss-of-resistance technique with approximately 4 mL of air. No imaging guidance was used. After negative aspiration for blood or cerebrospinal fluid, triamcinolone 80 mg/2 mL was mixed with 18 mL of normal saline (total volume, 20 mL) and injected slowly.

In the fluoroscopy-guided (FL) group, a 22-gauge needle (UNISIS; 0.72 × 90 mm) was advanced under fluoroscopic guidance (Philips Health System BV Pulsera C-arm) using lateral and anteroposterior views. Needle placement was confirmed with 1 mL of nonionic contrast medium (Ultravist 300), which demonstrated epidural spread, thereby excluding intravascular or subarachnoid injection. After negative aspiration, the same standardized injectate (total volume, 20 mL; triamcinolone 80 mg plus normal saline) was administered.

The injectate composition and total volume were identical in both groups, as per the prespecified protocol. All patients were observed for at least 30 minutes after the procedure.

The procedural steps for the landmark LOR and fluoroscopy-guided techniques are illustrated in Figures 1 and 2, respectively.

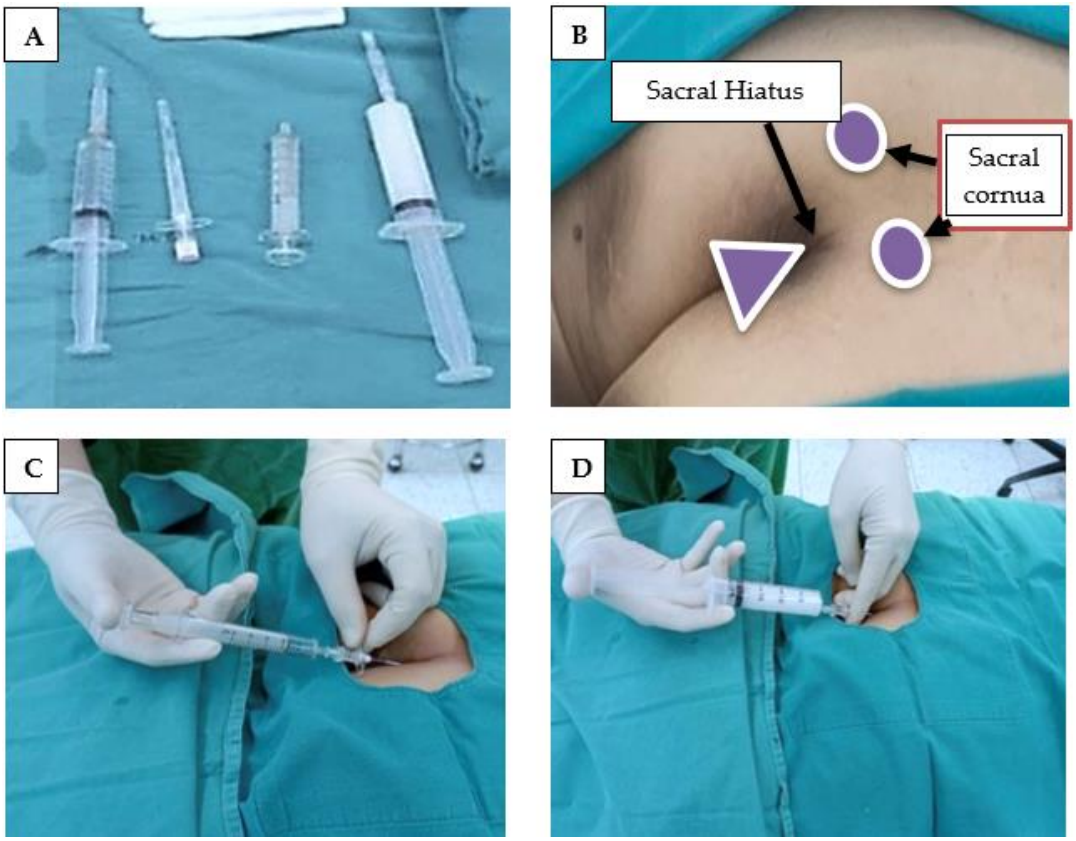

Fig. 1 Landmark loss-of-resistance (LOR) technique for caudal epidural steroid injection. (A) Standard equipment set and injectate prepared for the procedure, including the spinal needle, syringes, and triamcinolone 80 mg/2 mL mixed with 18 mL of normal saline solution. (B) Patient positioned prone after sterile draping, with the sacral hiatus and sacral cornua identified as the key surface landmarks for needle entry. (C) After needle placement through the sacral hiatus, entry into the caudal epidural space through the sacrococcygeal ligament was confirmed using the loss-of-resistance technique with gentle injection of approximately 4 mL of air. (D) After confirmation of epidural entry, the steroid-saline mixture was injected slowly through the needle.

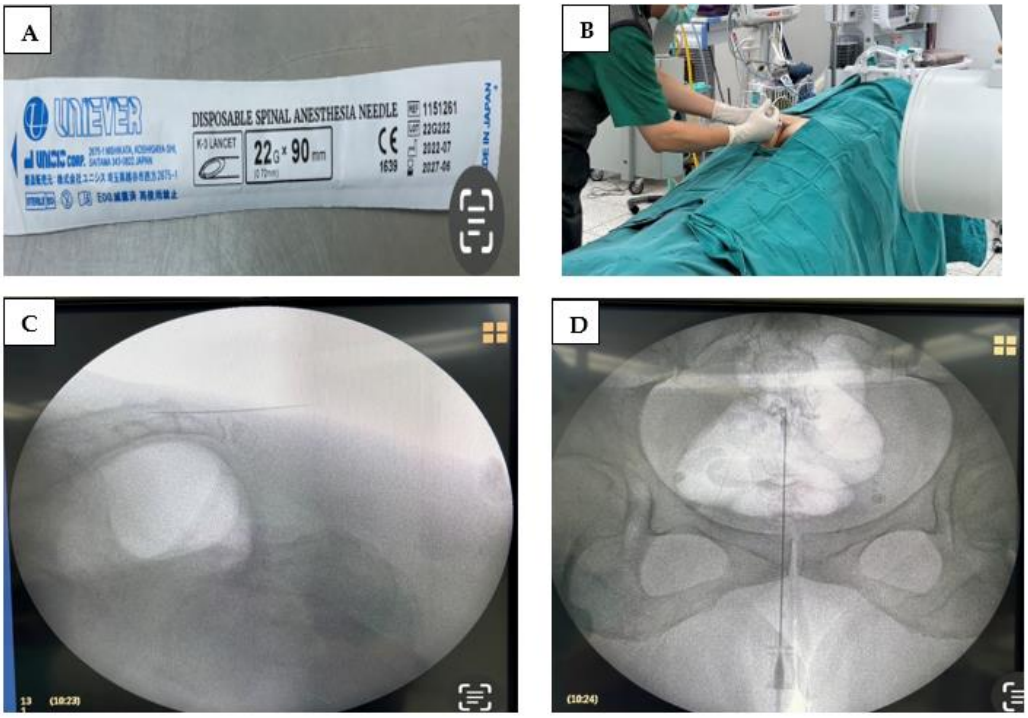

Fig. 2 Fluoroscopy-guided (FL) technique for caudal epidural steroid injection. (A) Spinal needle used for the fluoroscopy-guided procedure. (B) Patient positioned prone under fluoroscopic guidance during caudal epidural steroid injection. (C) Lateral fluoroscopic view demonstrating needle entry into the caudal epidural space through the sacral hiatus. (D) Anteroposterior fluoroscopic view demonstrating midline needle placement through the sacral hiatus with contrast distribution consistent with caudal epidural placement.

Outcomes

Primary clinical outcomes were pain (Visual Analog Scale [VAS], 0-10), disability (Oswestry Disability Index [ODI], 0-100), and patient satisfaction (Patient Satisfaction Score [PSS], 0-10). Outcomes were assessed at baseline and at 1, 3, 6, and 12 months. Procedure time was defined a priori as the interval from first needle-to-skin contact to needle withdrawal and was measured by an independent nurse using a standardized stopwatch protocol. Adverse events were monitored during recovery and at each follow-up visit. Concomitant analgesics and physical therapy were recorded during follow-up but were not protocolized, because the trial was designed to compare guidance techniques under routine clinical care rather than isolate the injection as the sole treatment determinant. All patients received a single study intervention.

Statistical Analysis

Continuous variables are presented as mean ± standard deviation (SD), and categorical variables are presented as numbers (percentages). Baseline and per-timepoint between-group comparisons of observed values were assessed using Welch's t-test for continuous variables and Fisher's exact test for categorical variables, as appropriate. Because outcomes were measured repeatedly over time, repeated outcome measurements for VAS, ODI, and PSS collected at baseline and 1, 3, 6, and 12 months were additionally examined using linear mixed-effects models with fixed effects for treatment group, time, and the group × time interaction, and a patient-level random intercept to account for within-patient correlation over time. Model-based estimated marginal means (EMMs) with 95% confidence intervals are presented in Table 3. The primary

between-group inference at 12 months was based on baseline-adjusted analysis of covariance (ANCOVA), with treatment group as the main factor and the corresponding baseline score as a covariate; results are reported as adjusted mean differences (AMD; LOR−FL) with 95% confidence intervals. All tests were two-sided, and $p < 0.05$ was considered statistically significant. Analyses were conducted using Stata 18.0.

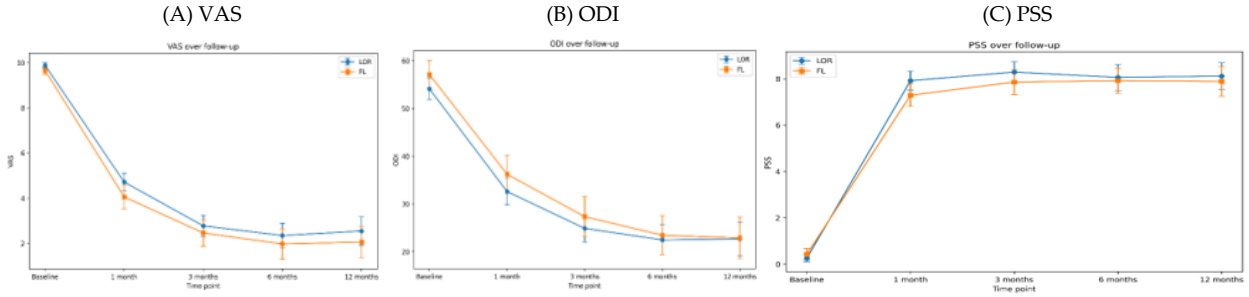

Fig. 3 Longitudinal changes in clinical outcomes over follow-up. (A) Visual Analog Scale (VAS). (B) Oswestry Disability Index (ODI). (C) Patient Satisfaction Score (PSS). Error bars indicate 95% confidence intervals.

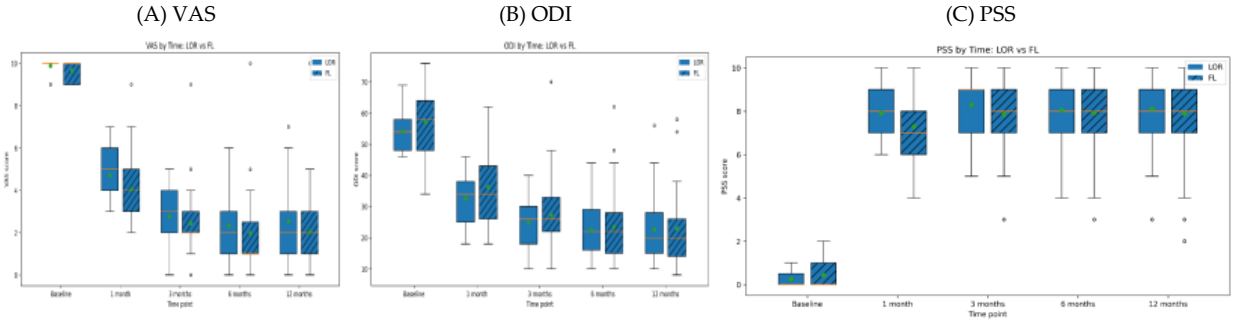

Fig. 4 Distribution of clinical outcomes at each follow-up time point. (A) Visual Analog Scale (VAS). (B) Oswestry Disability Index (ODI). (C) Patient Satisfaction Score (PSS). Boxes represent the interquartile range, and the horizontal line within each box represents the median, blue dots indicate the mean, and whiskers represent the minimum and maximum values excluding outliers.

RESULTS

Seventy adults with sciatica due to lumbar disc herniation were randomized to LOR (n = 35) or FL (n = 35) CESI. Baseline characteristics were broadly comparable between groups (Table 1), although baseline VAS was modestly higher in the LOR group and baseline ODI was slightly higher in the FL group.

Both groups improved substantially over time in pain, disability, and patient satisfaction. In the observed summaries (Table 2), mean VAS decreased from 9.89 to 2.54 in the LOR group and from 9.66 to 2.06 in the FL group; mean ODI decreased from 54.09 to 22.63 and from 57.09 to 22.86, respectively; and mean PSS increased from 0.26 to 8.11 and from 0.43 to 7.89, respectively. Model-based estimated marginal means from the linear mixed-effects models were consistent with these observed patterns across follow-up (Table 3).

At 12 months, the baseline-adjusted between-group differences remained small and not statistically significant: VAS AMD 0.41 (95% CI -0.54 to 1.36), ODI AMD 1.96 (95% CI -2.96 to 6.87), and PSS AMD 0.37 (95% CI -0.45 to 1.20). Although the LOR group showed numerically higher raw VAS values at several follow-up time points, the adjusted analyses did not demonstrate a material between-group difference at 12 months.

Procedure time was significantly shorter in the LOR group than in the FL group (6.37 ± 1.99 vs 14.09 ± 2.20 minutes; p < 0.001). Adverse events were infrequent and self-limited in both groups (LOR: 11.4% [4/35] vs FL: 0% [0/35]; p = 0.114). No dural puncture, bleeding, infection, or severe neurologic complication was recorded.

Table 1 Baseline characteristics, procedure time, and adverse events.

Characteristic	LOR (n=35)	FL (n=35)	p-value
Age (years)	48.06 ± 11.63	45.34 ± 11.46	0.329
Male, n (%)	14 (40.00%)	13 (37.14%)	1.000
BMI (kg/m2)	27.44 ± 2.77	26.70 ± 3.18	0.301
VAS baseline	9.89 ± 0.32	9.66 ± 0.48	0.023
ODI baseline	54.09 ± 6.60	57.09 ± 8.74	0.110
PSS baseline	0.26 ± 0.44	0.43 ± 0.70	0.225
LDH protrusion, n (%)	18 (51.43%)	19 (54.29%)	1.000
LDH extrusion, n (%)	17 (48.57%)	16 (45.71%)	1.000
Target level L3-4, n (%)	8 (22.86%)	4 (11.43%)	0.342
Target level L4-5, n (%)	23 (65.71%)	20 (57.14%)	0.624
Target level L5-S1, n (%)	4 (11.43%)	11 (31.43%)	0.078
Symptom duration (weeks)	12.74 ± 3.18	13.37 ± 5.11	0.539
Procedure time (minutes)	6.37 ± 1.99	14.09 ± 2.20	<0.001
Adverse events, n/N (%)	4/35 (11.40%)	0 (0.00%)	0.114

Abbreviations: Values are mean ± SD or number (percent). p-values are from Welch's t-test for continuous variables and Fisher's exact test for categorical variables, as appropriate. LOR = landmark loss-of-resistance; FL = fluoroscopy-guided; VAS = Visual Analog Scale; ODI = Oswestry Disability Index; PSS = Patient Satisfaction Score.

Table 2 Observed means ± SD by group and time.

Outcome (time)	LOR (n=35)	FL (n=35)	p-value
VAS - baseline	9.89 ± 0.32	9.66 ± 0.48	0.023
VAS - 1 month	4.71 ± 1.10	4.06 ± 1.53	0.044
VAS - 3 months	2.77 ± 1.35	2.46 ± 1.72	0.399
VAS - 6 months	2.34 ± 1.57	1.97 ± 1.96	0.385
VAS - 12 months	2.54 ± 1.82	2.06 ± 2.00	0.292
ODI - baseline	54.09 ± 6.60	57.09 ± 8.74	0.110
ODI - 1 month	32.57 ± 8.10	36.20 ± 11.42	0.130
ODI - 3 months	24.86 ± 8.39	27.31 ± 12.12	0.328
ODI - 6 months	22.46 ± 9.23	23.43 ± 11.85	0.703
ODI - 12 months	22.63 ± 10.24	22.86 ± 12.65	0.934
PSS - baseline	0.26 ± 0.44	0.43 ± 0.70	0.225
PSS - 1 month	7.91 ± 1.20	7.29 ± 1.41	0.048
PSS - 3 months	8.29 ± 1.30	7.86 ± 1.57	0.218
PSS - 6 months	8.06 ± 1.41	7.91 ± 1.40	0.667
PSS - 12 months	8.11 ± 1.40	7.89 ± 1.27	0.487

Abbreviations: Values are mean ± SD; p-values compare groups at each time point (Welch's t-test). For changes over time and relative between-group differences, see Table 3.

Table 3 Model-based EMM (95% CI) by group and time with AMD@12m (95% CI).

Outcome	Time	LOR EMM (95% CI)	FL EMM (95% CI)	AMD@12m (95% CI)
VAS	baseline	9.89 (9.39-10.38)	9.66 (9.16-10.15)	
VAS	1 month	4.71 (4.22-5.21)	4.06 (3.56-4.55)	
VAS	3 months	2.77 (2.28-3.27)	2.46 (1.96-2.95)	
VAS	6 months	2.34 (1.85-2.84)	1.97 (1.48-2.47)	
VAS	12 months	2.54 (2.05-3.04)	2.06 (1.56-2.55)	0.41 (-0.54 to 1.36)
ODI	baseline	54.09 (50.73-57.44)	57.09 (53.73-60.44)	
ODI	1 month	32.57 (29.22-35.92)	36.20 (32.85-39.55)	
ODI	3 months	24.86 (21.51-28.21)	27.31 (23.96-30.67)	
ODI	6 months	22.46 (19.11-25.81)	23.43 (20.08-26.78)	
ODI	12 months	22.63 (19.28-25.98)	22.86 (19.51-26.21)	1.96 (-2.96 to 6.87)
PSS	baseline	0.26 (-0.21 to 0.72)	0.43 (-0.04 to 0.89)	
PSS	1 month	7.91 (7.45-8.38)	7.29 (6.82-7.75)	
PSS	3 months	8.29 (7.82-8.75)	7.86 (7.39-8.32)	
PSS	6 months	8.06 (7.59-8.52)	7.91 (7.45-8.38)	
PSS	12 months	8.11 (7.65-8.58)	7.89 (7.42-8.35)	0.37 (-0.45 to 1.20)

Abbreviations: Values are model-based estimated marginal means (EMMs) with 95% confidence intervals, derived from linear mixed-effects models that include fixed effects for treatment group, time, and group × time interaction, with a patient-level random intercept. The rightmost column presents the adjusted mean difference at 12 months (AMD@12m; LOR−FL) from baseline-adjusted ANCOVA. Observed means ± SD and per-timepoint between-group comparisons are shown in Table 2.

DISCUSSION

In this prospective randomized comparison of caudal epidural steroid injection (CESI) guidance techniques for sciatica due to MRI-confirmed lumbar disc herniation, both landmark loss-of-resistance (LOR) and fluoroscopy-guided (FL) approaches resulted in substantial improvements in pain, disability, and patient satisfaction over 12 months. The principal finding was that adjusted between-group differences at 12 months were small for all three outcomes, and no material between-group differences were detected in the medium-term clinical results.

The modestly higher baseline VAS score in the LOR group deserves comment. Because of this baseline imbalance, the primary inferential comparison was based on baseline-adjusted analysis of covariance rather than on raw follow-up means alone. This approach was prespecified because it more appropriately accounts for baseline differences than simple unadjusted comparisons or percentage change calculations. After adjustment, the between-group difference in VAS at 12 months remained small and not statistically significant, supporting the interpretation that the persistent numerical difference in raw VAS values did not translate into a meaningful difference in adjusted outcome.

The longitudinal analyses were consistent with this interpretation. Model-based estimated marginal means from linear mixed-effects models followed the same overall pattern as the observed summaries: both groups improved early after injection and maintained benefit through 12 months, with no clinically meaningful separation between techniques. Taken together, the adjusted 12-month analysis and the longitudinal modeling support the conclusion that the two approaches yielded comparable patient-reported outcomes within the precision of this study.

From a practical perspective, the most important difference between techniques was procedure time. LOR required substantially less time than FL-guided CESI. This finding may be

relevant to clinical throughput, patient access, and service delivery, particularly in settings where fluoroscopy is unavailable or only intermittently available, or is resource-intensive. In such environments, a simpler, shorter technique may help expand treatment capacity without materially compromising medium-term clinical outcomes.

These findings should be interpreted within the clinical context of CESI [21-24]. The goal of epidural steroid injection is to reduce inflammation and nociceptive sensitization around the affected nerve root, thereby improving pain and function. Fluoroscopy provides visual confirmation of needle position and contrast spread, whereas the landmark-guided LOR technique offers greater simplicity, portability, and lower resource requirements [11,16,17]. Our data suggest that when performed by an experienced team using a standardized injectate protocol, both techniques can be associated with clinically relevant improvement over time.

Importantly, the present study compared two guidance techniques rather than the isolated efficacy of a single injection as a stand-alone treatment. Therefore, the observed improvement should not be interpreted as attributable solely to the injection procedure. Clinical change likely reflects a combination of factors, including the injection, concurrent conservative management, and the natural history of lumbar radiculopathy. We therefore interpret these findings as a comparison of procedural strategies in real-world care rather than as proof that a single CESI definitively controls lumbar disc herniation.

The rationale for choosing fluoroscopy rather than ultrasound as the imaging comparator should also be considered. Ultrasound-guided CESI is clinically relevant and continues to gain interest because it avoids radiation exposure and may improve accessibility in some settings [22,26,27]. However, fluoroscopy remains a widely used reference technique because it allows direct confirmation of needle position and contrast spread. For this reason, fluoroscopy-guided CESI was selected as the imaging-confirmed comparator in the present study. Future studies should directly compare landmark-guided, ultrasound-guided, and fluoroscopy-guided CESI using harmonized outcome measures and predefined co-intervention protocols.

This study has several strengths. It used a prospective randomized design, MRI-confirmed lumbar disc pathology, a standardized injectate, repeated follow-up through 12 months, and inclusion of both procedural and patient-reported outcomes. These features strengthen the internal consistency of the comparison and increase its practical relevance to routine clinical care. In addition, including procedure time and adverse events provides information directly relevant to workflow and real-world decision-making, not just symptom improvement.

Limitations

This study has several limitations. First, it was a single-center trial with a modest sample size and was not designed as a formal non-inferiority or equivalence trial. Therefore, the absence of a statistically significant difference should not be interpreted as proof of equivalence. Second, concomitant medications and physical therapy were recorded but not standardized, which introduces the possibility of residual confounding. Third, the study compared real-world procedural strategies and therefore cannot fully separate treatment effects attributable to the injection itself from those related to concurrent care or natural recovery. Fourth, ultrasound-guided CESI was not evaluated in the present protocol. Finally, the procedures were performed by an experienced team, and the results may not be fully generalizable to settings with different levels of operator experience.

Overall, the findings suggest that LOR may provide a practical alternative to fluoroscopy-guided CESI in appropriately selected patients and settings, while producing comparable medium-term patient-reported outcomes within the limits of this study design.

CONCLUSIONS

In this prospective randomized comparative study, landmark loss-of-resistance and fluoroscopy-guided caudal epidural steroid injec-

tion produced comparable 12-month outcomes for pain, disability, and patient satisfaction in patients with sciatica due to MRI-confirmed lumbar disc herniation. Although fluoroscopy provides imaging confirmation of needle position and contrast spread, the landmark-guided technique required substantially less procedure time, and adverse events were infrequent in both groups. Within the limitations of this study, LOR may serve as a practical alternative in settings where fluoroscopy is unavailable or resources are constrained.

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