Original Article

Comparison of ultrasound and fluoroscopy-guided caudal epidural block in low back pain with radiculopathy: A randomized controlled study

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Abstract

Background and Aims: Low back pain (LBP) with radiculopathy is a significant global health concern, often leading to reduced quality of life and work absenteeism. Steroid injection using the caudal epidural route offers a non-surgical approach to the management of chronic LBP with radiculopathy. Although fluoroscopy-guided injections are the standard, ultrasound-assisted injection is emerging as an alternative. The aim of this study was to assess and compare the feasibility and effectiveness of caudal epidural blocks assisted by ultrasound versus fluoroscopy in managing LBP with radiculopathy.

Material and Methods: A prospective randomized controlled trial was conducted with 30 patients aged 20–80 years suffering from chronic LBP and bilateral radiculopathy. Patients were assigned to ultrasound-assisted (group I) or fluoroscopy-guided (group II) caudal epidural injections. The primary outcome measure was needle placement time. Secondary outcomes included pain assessment, disability evaluation, patient satisfaction, and adverse effects. Statistical analyses were performed using *t*-tests, ANOVA, and Chi-square tests.

Results: The fluoroscopy-guided group exhibited statistically significantly shorter needle placement time (137.13 s) compared to the ultrasound-assisted group (185.60 s) ($P < 0.001$). Both groups demonstrated significant improvements in pain scores and disability indexes from their respective baselines. Patient satisfaction and adverse effects were comparable between the groups.

Conclusion: Although fluoroscopy remains the gold standard for caudal epidural injections, ultrasound-assisted procedures demonstrated comparable pain relief, disability improvement, patient satisfaction, and adverse effects. Ultrasound guidance shows promise as technology and expertise advance, offering a potential alternative for managing LBP with radiculopathy.

Keywords: Anesthesia, caudal, epidural, fluoroscopy, injection, lower back pain, pain management, radiculopathies

Introduction

Low back pain (LBP) constitutes a widespread issue of global health significance, carrying substantial implications for both individuals and society as a whole.[1] Statistics indicate that approximately 60%–80% of adults will encounter episodes of LBP at some point in their lifetimes, resulting in diminished quality of life and increased instances of work absenteeism.[2] Whereas acute LBP is typically managed with NSAIDs, muscle relaxants, and advice for physical activity, chronic LBP persists beyond 3 months and often involves pathological or anatomical instability. Epidural steroid injections (ESIs) have been employed since 1952 as a non-surgical approach to alleviate LBP, particularly when

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accompanied by radiating symptoms to the lower extremities. ESI efficacy varies, necessitating single or multiple injections, and the treatment is targeted at pain resulting from spinal nerve root irritation and inflammation, such as radicular pain with dermatomal radiation.[3-5]

Differing from interlaminar and transforaminal epidural approaches, caudal epidural injections are characterized by their relatively lower precision, necessitating larger quantities for effective administration into the targeted region. Despite this, they are recognized for their safety and simplicity, minimizing the risk of inadvertent dural puncture and related complications.[6,7] Caudal epidural injections offer potential relief from chronic LBP that does not respond to conservative medical management. Although applicable for non-malignant lumbar discomfort, these injections are especially recommended for individuals devoid of facet joint pain or those experiencing a combination of facet and discogenic joint discomfort.[8] The caudal approach has gained traction, especially when repeated injections are necessary, although its success rate varies in adults compared to children.[9,10] Caudal epidural injections can be performed using fluoroscopy or ultrasonography (USG). Fluoroscopy-guided injections are recognized as the gold standard for pain procedures due to their detailed visualization, though they entail radiation exposure and contrast use with potential side effects.[9,11,12] In contrast, USG has emerged as a precise tool for sacral hiatus identification and needle guidance.[13]

Despite its potential advantages, studies investigating the utility of USG-assisted caudal epidural blocks for LBP remain limited. This paucity of research underscores the need for comprehensive investigations to establish its viability in routine clinical practice. Thus, the present study was designed to rigorously compare the efficacy and potential adverse effects of USG-assisted versus fluoroscopy-guided caudal epidural blocks in managing LBP accompanied by radiculopathy. By systematically evaluating these two techniques, we aim to contribute valuable insights to the existing body of knowledge and inform evidence-based clinical decision-making.

Material and Methods

This randomized controlled study was prospective and was undertaken by the Anesthesia and Intensive Care Department in collaboration with the Orthopedics Department. The study received ethical approval from the institutional ethics committee (Approval No.: GMC/IEC/2019/205R/03, dated December 16, 2019), and it was registered with the Clinical Trial Registry of India (CTRI/2020/02/023830, dated March 09, 2020). Written informed consent was secured from a total of 30 patients, aged between 20 and 80 years, who were attending the Pain Clinic. These patients had chronic LBP persisting for more than 3 months, accompanied by bilateral radiculopathy. They had not responded to conservative treatment and were classified under American Society of Anesthesiology physical status I or II. In addition, these patients had disc protrusion and bulge at various lumbar levels, along with impingement of exiting and traversing nerve roots, as confirmed by magnetic resonance imaging (MRI).

Patients meeting specific exclusion criteria were not included in the study. These criteria encompassed individuals who declined to participate despite informed consent; those with systemic or local infections at the injection site; bleeding diathesis; significant allergic reactions or hypersensitivity to contrast, anesthetic, or corticosteroids; local malignancies; uncontrolled diabetes mellitus; severe cardiovascular, respiratory, renal, or hepatic conditions; pregnancy; severe motor weakness; rapidly progressing neurological deficits; or cauda equina syndrome.

The primary outcome measure was the time required for accurate needle placement (in seconds). Secondary outcome measures included pain assessment by using the Numeric Rating Scale (NRS), evaluation of lumbosacral nerve root irritation by using the straight leg raise test (SLRT), determination of disability extent by utilizing the Oswestry Disability Index (ODI), assessment of patient satisfaction, and monitoring of adverse effects.

Prior to the caudal ESI procedure, patients underwent routine blood investigations, including complete blood count, coagulation parameters (prothrombin time, prothrombin time index, activated partial thromboplastin time, and international normalized ratio), serum electrolytes, urea, creatinine, viral markers for HBsAg, HCV and HIV screening, random blood sugar analysis, and chest X-ray. Furthermore, an electrocardiogram (ECG) and MRI of the lumbosacral spine were conducted. In the dedicated pain operating room, intravenous access was established through a 20-G cannula. Continuous monitoring of blood pressure, pulse rate, oxygen saturation, and ECG was maintained. Preparations for resuscitation were readily available, and patients were positioned in the prone posture with pelvic support using a pillow. Allocation of patients to the two study groups was achieved via a computer-generated random number table and coded sealed opaque envelopes. Pre-procedural pain assessment was conducted using the NRS and ODI. NRS involves the patient assigning a specific number on a 0–10 scale to indicate pain severity, where 0 signifies no pain and 10 indicates the utmost pain. This method is simpler and more understandable for patients compared to the visual analog scale (VAS). ODI, on the contrary, is a validated

tool for assessing functional impairment due to chronic pain, frequently employed for evaluating disability stemming from chronic LBP.

On the day of the intervention, patients were advised to continue their chronic pain medication, following standard fasting guidelines. In group I (ultrasound group), ultrasound assistance was utilized for needle placement. The sacral hiatus, sacral cornu, apex of the sacral hiatus, and sacrococcygeal ligament were identified using a linear array transducer (Edge II Sonosite™, USA, portable ultrasound using a linear array probe 6–13 Hz). After local infiltration with 2 mL of preservative-free 2% lignocaine, the epidural needle was guided through the sacrococcygeal ligament into the epidural space under ultrasound assistance by using an in-plane technique. Vascular structures were avoided during this process. In group II (fluoroscopy group), the sacral hiatus was identified and local anesthesia was administered. An 18-G epidural needle was introduced guided by lateral and anteroposterior fluoroscopic images. Injection of iohexol solution confirmed proper needle placement. Both groups received a caudal epidural injection consisting of a solution containing 2 mL (80 mg) of triamcinolone and 8 mL of 0.25% bupivacaine. The time taken from introducing the needle to its correct placement was recorded for both groups. Following injection, patients were observed for 4 h, after which they were discharged with instructions to return to the pain clinic for follow-up at 2 weeks and subsequently on a monthly basis for 3 months. Pain scores (NRS) and ODI values were recorded during these follow-up visits.

Disability due to LBP was assessed using the Oswestry Disability Questionnaire, which employs a 10-parameter scoring system on a scale of 0–5. Baseline ODI scores were determined during pre-procedural evaluation, and these scores were subsequently reassessed at 2 weeks and at the end of the 1st, 2nd, and 3rd months. Patients were also contacted via phone at regular intervals (2nd week, 1st month, 2nd month, and 3rd month post injection) to obtain pain scores (NRS) and ODI values. Finally, patient satisfaction was assessed by administering a 0–100 VAS to the patients at the 2nd week, 1st month, 2nd month, and 3rd month post procedure.

Statistical power analysis indicated that a sample size of 25 patients per group was necessary to detect a difference of 10% effect size in needle placement time between the two groups (as per Hazra *et al*.[10]) with 80% power and a type I error of 0.05. Accounting for potential dropouts, a total of 60 patients were initially planned for recruitment, but due to the constraints posed by the COVID-19 pandemic, a total of 30 patients were ultimately included in the study.

Collected data were inputted into an Excel spreadsheet and analyzed using IBM SPSS Statistics version 20. Continuous data were presented as mean ± standard deviation and analyzed through independent samples *t*-test. Within-group analysis utilized ANOVA. Longitudinal data comparison between groups employed 2-way mixed ANOVA with post-hoc Scheffe's test. Categorical data, reported as patient numbers (n), underwent Chi-square analysis. A significance level of $P < 0.05$ indicated statistical significance.

Results

The demographic characteristics, pre-procedure investigations, and monitored vital signs demonstrated comparability between both study groups, as detailed in Table 1. The CONSORT diagram, illustrating the study's progression, is presented in Figure 1. The time required for precise needle placement exhibited a notable discrepancy between the ultrasound-assisted group (185.6000 ± 15.25404 s) and the fluoroscopy-guided group (137.1333 ± 16.13721 s) ($P < 0.001$), as depicted in Figure 2. Analysis of the SLRT outcomes revealed consistent findings before and after the procedure in both study groups.

In terms of pain scores, a statistically significant difference was not observed between the two groups (F value = 1.313; $P = 0.253$). However, within each group, notable variations emerged across different observation time points (F value = 435.045; $P < 0.001$). In the USG group (group 1), pain scores experienced a significant reduction from baseline. Similarly, in the C-arm group (group 2), pain scores were consistently lower compared to baseline throughout all observation periods. Assessment of the ODI scores revealed no significant overall contrast between the two groups. Similar to pain scores, significant differences were noted within each group across various observation time points (F value = 363.761; $P < 0.001$). In the USG group (group 1), ODI scores demonstrated a noteworthy decrease from baseline, whereas in the C-arm group (group 2), ODI scores exhibited a consistent reduction compared to baseline throughout all observation intervals.

Patient satisfaction levels exhibited remarkable parity between the ultrasound-assisted and fluoroscopy-guided

Table 1: Comparison of patient characteristics between two groups

Characteristics	Group 1	Group 2	*P*
Age (years)	50.13±13.76	43.80±14.81	0.235
BMI (kg/m^2)	27.21±2.12	27.59±1.99	0.617
Duration of symptoms (months)	7.73±2.31	8.47±2.67	0.428

The data are represented as mean±standard deviation. n=number of patients

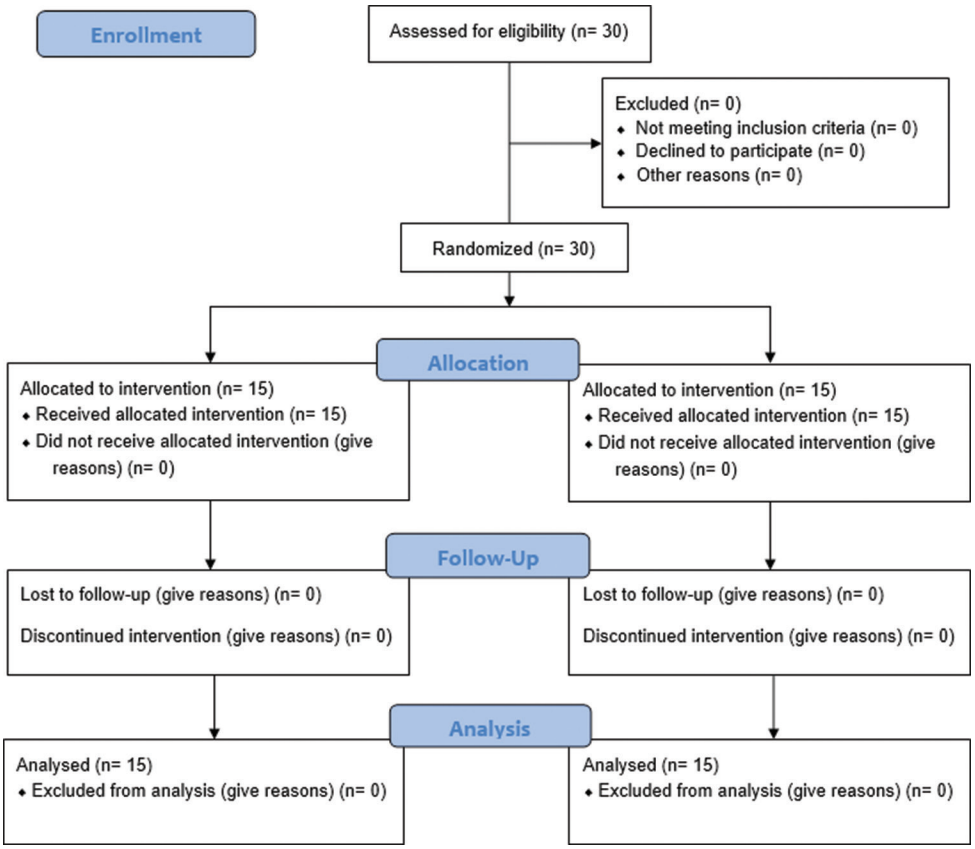

Figure 1: CONSORT flow diagram

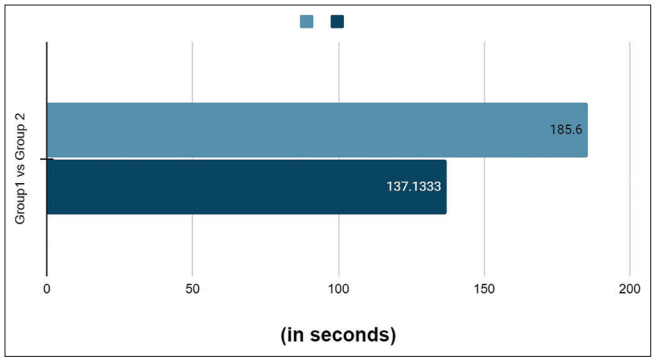

Figure 2: Time to correct placement of needle

groups. Notably, the occurrence of adverse effects did not exhibit clinically significant differences between the two study groups.

Discussion

The current study has provided valuable insights into the efficacy and comparability of USG and fluoroscopy-guided caudal ESIs in the management of chronic LBP with bilateral radiculopathy. The discussion below elaborates on the key findings and their implications, contextualizing them within the existing body of literature.

The primary outcome measure, the time required for accurate needle placement, demonstrated a statistically significant advantage in favor of the fluoroscopy-guided group. This finding is consistent with studies such as Chen *et al*.,[13] which highlighted the precision of ultrasound in locating the sacral hiatus and guiding needle placement. However, it is noteworthy that the study also indicated successful needle placement under ultrasound assistance, implying the technique's potential with growing expertise and refined equipment. Furthermore, though the difference was statistically significant, the clinical significance and meaningfulness of the difference of a few seconds of correct needle placement remains debatable. It may be considered that although the clinical meaningfulness of the difference in time for correct needle placement between the two methods remains inconclusive, the USG-based method has the distinct advantage of avoiding the hazards associated with fluoroscopic radiation exposure.

The investigation's secondary outcome measures encompassed pain assessment through the NRS, SLRT outcomes, and the ODI scores. Although there was no statistically significant disparity between the two groups in terms of pain reduction, SLRT outcomes, and ODI scores, both groups exhibited substantial and comparable improvements over time. This finding is congruent with the studies by Hazra *et al*. and

Senkal *et al*., which showed comparable reductions in VAS scores and ODI scores with both USG and fluoroscopy-guided interventions.[10,14] In addition, the research by Elashmawy *et al*.[15] revealed improvements in SLRT outcomes, VAS, and ODI scores for both techniques. Comparisons of nerve root irritation, patient satisfaction, and adverse effects showed no discernible differences between the two groups. This concurs with other investigations, including the study by Hazra *et al*.,[10] which reported comparable outcomes in terms of patient satisfaction and adverse effects. Several prior studies have examined the effectiveness of caudal epidural injections for managing chronic LBP and radiculopathy. For instance, Barre *et al*. and Bhattarai *et al*.[16,17] demonstrated the safety and effectiveness of fluoroscopy-guided caudal ESI for lumbar spinal stenosis and LBP. These findings are in line with the current study's observation of pain reduction and disability improvement.

Studies such as Lee *et al*.'s[18] research on axial LBP patients with central disc protrusions emphasized the benefits of caudal ESIs for enhancing pain and function. Similarly, Conn *et al*.'s[19] systematic review concluded that caudal epidural injections provide relief for various forms of chronic LBP. The current study's alignment with the aforementioned research further supports the value of caudal epidural injections in pain management and functional improvement. Notably, the research by Sayegh *et al*., and Kanthimathy *et al*. emphasizes the positive impact of caudal ESIs on pain relief and quality of life.[20-22] This aligns with the present study's focus on pain reduction and functional enhancement through both USG and fluoroscopy-guided interventions.

Although the study design and methodology contribute to its credibility, there are limitations that warrant consideration. The reduced sample size due to the pandemic's impact on patient recruitment may have influenced the power to detect minor differences in secondary outcomes. The relative inexperience of the investigator with ultrasound guidance also introduces a potential variable in the results. Future studies with larger sample sizes and experienced operators could potentially yield further insights.

The study underscores the overall comparable efficacy of ultrasound-assisted and fluoroscopy-guided caudal ESIs in managing chronic LBP with bilateral radiculopathy. While the primary outcome showed a time advantage for fluoroscopy guidance, both techniques demonstrated significant and comparable improvements in pain reduction and functional enhancement. The study's findings contribute to the growing body of evidence supporting the utility of caudal epidural injections as a viable treatment option for chronic LBP and radiculopathy.

Conclusions

The fluoroscopy-guided procedure remains the established gold standard in terms of precision and procedural efficiency. Both the fluoroscopy-guided and ultrasound-assisted procedures exhibit comparability across essential clinical parameters of significant importance. These encompass pain management, nerve irritation, disability alleviation, patient satisfaction, and the occurrence of adverse effects. The congruence observed in these vital clinical aspects implies promising potential for the future adoption and refinement of the ultrasound-guided procedure. With advancements in technology and growing expertise, the utilization of ultrasound-assisted procedures holds promise for enhanced effectiveness and broader applicability in the clinical realm.

Data availability

The data that support the findings of this study are available from the corresponding author, Dr. Sukanya Mitra, upon reasonable request.

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Conflicts of interest

There are no conflicts of interest.

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