

A Clinical Study for Comparison of Loss of Resistance Technique between EpiLOR® and Conventional Method for Identifying the Epidural Space

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Abstract

Background:

Accurate identification of the epidural space is essential for effective neuraxial anesthesia. The conventional loss of resistance (LOR) technique, although widely used, is highly subjective and operator-dependent. This study compares the conventional air-based LOR method with a novel device-assisted approach using the EpiLOR® system—a balloon-based syringe that provides visual confirmation of epidural space entry.

Methods:

A prospective, randomized controlled trial was conducted on 60 patients undergoing elective gynecologic or orthopedic surgery under combined spinal-epidural anesthesia. Patients were randomized into two groups: Group C (conventional LOR) and Group EL (EpiLOR®). The primary outcomes were time to identify the epidural space and number of attempts. Secondary outcomes included ease of procedure, epidural depth, and incidence of accidental dural puncture (ADP).

Results:

The time to identify the epidural space was significantly lower in Group EL (19.1 ± 5.2 seconds) than in Group C (41.1 ± 13.4 seconds; $p < 0.00001$). Although not statistically significant, Group EL showed fewer multiple and failed attempts. Ease of procedure was rated significantly better with EpiLOR® (1.7 ± 0.6 vs. 2.4 ± 1.1 ; $p = 0.005$). ADP occurred in 6.7% of patients in Group C and 0% in Group EL. No device-related adverse events were reported.

Conclusion:

The EpiLOR® device demonstrated superior efficiency and procedural ease compared to the conventional LOR method, with a trend toward improved safety. These findings support the utility of visual-assist technologies in enhancing the accuracy and safety of epidural space identification.

Keywords: Epidural Anesthesia, EpiLOR®, Loss of Resistance, Dural Puncture, Visual-Assist Device, Regional Anesthesia

1. Introduction

Epidural anesthesia is a cornerstone technique for managing pain in both surgical and obstetric contexts, offering effective analgesia while allowing patients to remain conscious during procedures [1]. The efficacy and safety of this technique depend largely on accurate identification of the epidural space—the anatomical area located between the ligamentum flavum and the dura mater—where local anesthetic agents are administered to block nerve transmission [2]. However, locating this space can be technically challenging due to interindividual variability in spinal anatomy.

The technique of epidural anesthesia has evolved significantly since its inception. Fidel Pagés first introduced lumbar epidural anesthesia in 1901, but it was Achille Dogliotti in 1933 who pioneered the Loss of Resistance (LOR) technique, which remains the clinical standard today [3]. This approach involves advancing a needle while injecting air or saline, with a sudden “loss” of resistance indicating entry into the epidural space. Despite its widespread use, LOR is inherently subjective, relying on the clinician’s tactile feedback. The accuracy of this sensation varies depending on practitioner experience and patient characteristics such as obesity or spinal abnormalities [4,5].

The limitations of traditional LOR include misidentification of the space, multiple puncture attempts, inadvertent dural punctures, and associated complications like post-dural puncture headache and failed anesthesia [6,7]. These challenges are especially significant in patients with distorted anatomy or increased epidural depth. Consequently, technological innovations have emerged to provide more objective, reproducible, and safe methods for identifying the epidural space.

Among these innovations is the EpiLOR® system, a balloon-based device that provides mechanical and visual feedback to confirm entry into the epidural space. It detects pressure changes by deflating the balloon when the needle enters the space, thereby reducing reliance on tactile feedback [8]. Comparable systems such as Epidrum® and Episure® function on similar principles, aiming to reduce errors and enhance procedural success [9,10].

However, despite the development of such devices, randomized controlled trials comparing these innovations to the conventional LOR technique are limited. This lack of robust comparative data has hindered their broader acceptance and integration into standard guidelines [11].

The current randomized controlled trial was designed to address this gap. We compared the EpiLOR® system to the conventional air-based LOR method in patients undergoing elective gynecologic or orthopedic surgery. The study evaluated multiple clinical endpoints including time to identify the epidural space, number of attempts, procedural ease, success rate, and incidence of accidental dural punctures. The aim was to generate objective evidence that could improve clinical decision-making and support the integration

of visual-assist devices into routine epidural practice [12–14].

2. Material and Methodology

This study was designed as a prospective, randomized controlled clinical trial to compare the effectiveness of the EpiLOR® system with the conventional Loss of Resistance (LOR) technique in identifying the epidural space during combined spinal-epidural (CSE) anesthesia. Ethical clearance was obtained from the Institutional Ethics Committee (IEC), Gajra Raja Medical College, Gwalior, under approval number D.No. 1552/IEC-GRMC/2024, dated 02/08/2024. The study was also registered prospectively with the Clinical Trials Registry of India (CTRI) under registration number CTRI/2025/03/081822, dated March 5, 2025. The study was conducted in accordance with the Declaration of Helsinki. Written informed consent was obtained from all participants prior to inclusion in the study.

The study was conducted in the Department of Anaesthesiology, Gajra Raja Medical College and J.A. Group of Hospitals, Gwalior (M.P.), over a period of 12 months, from August 2024 to July 2025. Based on previous literature by Kim et al, the calculated sample size was 60 patients, with 30 in each group, to achieve a power of 90% and a significance level (α) of 0.05 for detecting a difference in the time required to locate the epidural space.

Eligible participants included patients aged between 18 and 65 years, with American Society of Anesthesiologists (ASA) physical status I or II, height between 150 and 170 cm, weight between 45 and 90 kg, and hemoglobin levels above 10 g/dL. All selected patients were scheduled to undergo elective gynecologic or orthopedic surgeries under CSE anesthesia and had provided written informed consent. Patients were excluded if they refused to participate, had multifetal pregnancies, were classified as ASA grade III or above, had known drug allergies, or presented with contraindications to CSE such as coagulopathy, local infection at the injection site, or uncorrected hypovolemia.

Using a computer-generated randomization table, patients were randomly allocated into two groups. Group C (control group) received epidural anesthesia using the conventional LOR technique with air, while Group EL (EpiLOR group) received epidural anesthesia using the EpiLOR® device, which incorporates a balloon-based visual indicator to detect loss of resistance. All procedures were performed in the operating room under standard monitoring, including electrocardiography (ECG), non-invasive blood pressure (NIBP), and pulse oximetry (SpO₂). Patients were positioned laterally, and either the L3–L4 or L4–L5 interspace was selected for the procedure. Following skin infiltration with a local anesthetic, an 18G Tuohy needle was introduced using a midline approach.

In Group C, a syringe filled with air was connected to the Tuohy needle, and the needle was advanced until a loss of resistance was felt by the operator. In Group EL, the EpiLOR® device was

attached between the syringe and the Tuohy needle. The balloon was inflated with 1.5 mL of air, and the needle was advanced until deflation of the balloon indicated entry into the epidural space due to a drop in intra-chamber pressure. After confirming epidural placement, the respective devices were removed and an epidural catheter was inserted. A 25G spinal needle was then inserted at a lower interspace to administer intrathecal bupivacaine. All procedural steps and outcomes were independently observed and documented by a second anesthesiologist.

In this study, we recorded a range of clinical and procedural parameters, including demographic characteristics (age, sex, height, weight), Vital signs including heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), and SpO₂ were monitored every 5 minutes for the first 30 minutes and every 10 minutes until the end of the first hour. ECG and SpO₂ were continuously monitored throughout the procedure. we also monitored time taken to identify the epidural space from skin to epidural space, and the depth of the epidural space at L3–L4 and L4–L5 interspaces. The epidural depth is the distance from the skin surface to the point where the tip of the Tuohy needle enters the epidural space. During clinical practice, this is determined in real time using the Loss of Resistance (LOR) technique: The Tuohy needle is marked at 1 cm intervals. As the needle is inserted midline, the anesthesiologist notes the depth at which sudden loss of resistance is felt (air or saline passes freely).

The depth at this point, read from the markings on the needle hub at skin level, is recorded as the epidural depth. We also documented the number of attempts required to identify the epidural space, the incidence of accidental dural puncture (ADP), The ease of procedure was independently assessed by the operator using a 5-point Likert scale. A score of 1 (Very Easy) indicated smooth needle advancement and epidural space identification without resistance or redirection. 2 (Easy) reflected minor resistance but

successful completion on the first attempt. 3 (Moderate) suggested one or two redirections with some tactile uncertainty. 4 (Difficult) denoted multiple attempts or unclear loss of resistance, requiring effort and delay. 5 (Extremely Difficult) indicated significant technical difficulty, procedural failure, or need for assistance or repositioning. Any adverse events or complications observed during the procedure were also recorded. For consistency with prior research and to facilitate comparison, we adopted standardized definitions for multiple and failed attempts as outlined in previous literature. Specifically, multiple attempts were defined as two or more attempts, and failed attempts as four or more attempts to locate the epidural space. These definitions were based on those used by Dobson et al, who classified more than three insertions as a failed attempt Mittal et al, who defined more than two attempts as multiple and more than three as failure and Segal et al, who included both multiple unsuccessful insertions and false-positive LOR events in their definition of failure [5,13,14]. Park et al. Similarly, defined failure as three or more unsuccessful attempts, or ineffective block despite apparent catheter placement [15].

By adopting these validated criteria, our study ensured alignment with international standards for evaluating technical success, procedural difficulty, and safety outcomes in epidural space identification.

Data were entered into Microsoft Excel and analyzed using SPSS software (Version 20). Continuous variables were compared using unpaired t-tests, while categorical variables were assessed using the Chi-square test or Fisher’s exact test as appropriate. A p-value of less than 0.05 was considered statistically significant. Normality of data distribution was assessed using the Shapiro–Wilk test. Effect sizes (Cohen’s d) and 95% confidence intervals were calculated for key outcomes. All statistical tests were two-tailed, and assumptions of homogeneity of variance were verified using Levene’s test where applicable.

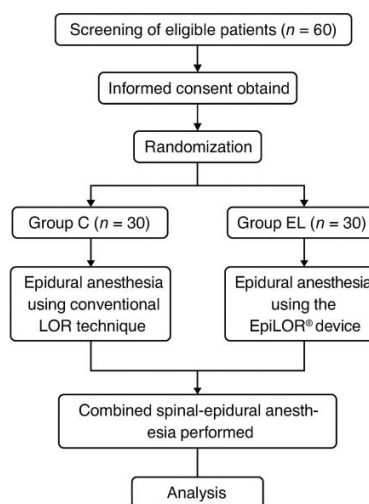


Figure 1: Consort Flow Diagram of Patient Enrollment and Allocation

3. Results

Parameter	Group C (Conventional)	Group EL (EpiLOR®)	p-value	Significance
Age (years)	42.6 ± 14.2	41.0 ± 13.4	0.62	Not significant
Height (cm)	156.5 ± 6.2	158.5 ± 5.1	0.23	Not significant
Weight (kg)	67.4 ± 13.4	66.1 ± 12.7	0.68	Not significant
Gender - Male	18 (60%)	16 (53%)	0.59	Not significant
Gender - Female	12 (40%)	14 (47%)	0.81	Not significant
ASA I	20 (67%)	19 (63%)	0.77	Not significant
ASA II	10 (33%)	11 (37%)	0.64	Not significant

Table 1: Demographic Profile

The demographic characteristics of the patients in both groups were comparable and statistically non-significant. The mean age in Group C (Conventional) was 42.6 ± 14.2 years, while in Group EL (EpiLOR®) it was 41.0 ± 13.4 years (p = 0.62). The average height was 156.5 ± 6.2 cm in Group C and 158.5 ± 5.1 cm in Group EL (p = 0.23), and the mean weight was 67.4 ± 13.4 kg and 66.1 ± 12.7 kg in the respective groups (p = 0.68). Gender distribution was nearly balanced, with Group C having 18 males (60%) and 12 females (40%), while Group EL had 16 males (53%) and 14

females (47%), with no statistically significant difference (p = 0.59). Regarding ASA physical status, ASA Grade I was present in 20 patients (67%) in Group C and 19 patients (63%) in Group EL, while ASA Grade II was noted in 10 (33%) and 11 (37%) patients respectively, also showing no significant difference (p = 0.77). These findings suggest that the baseline characteristics were well-matched between the two groups, ensuring the validity of comparative outcomes.

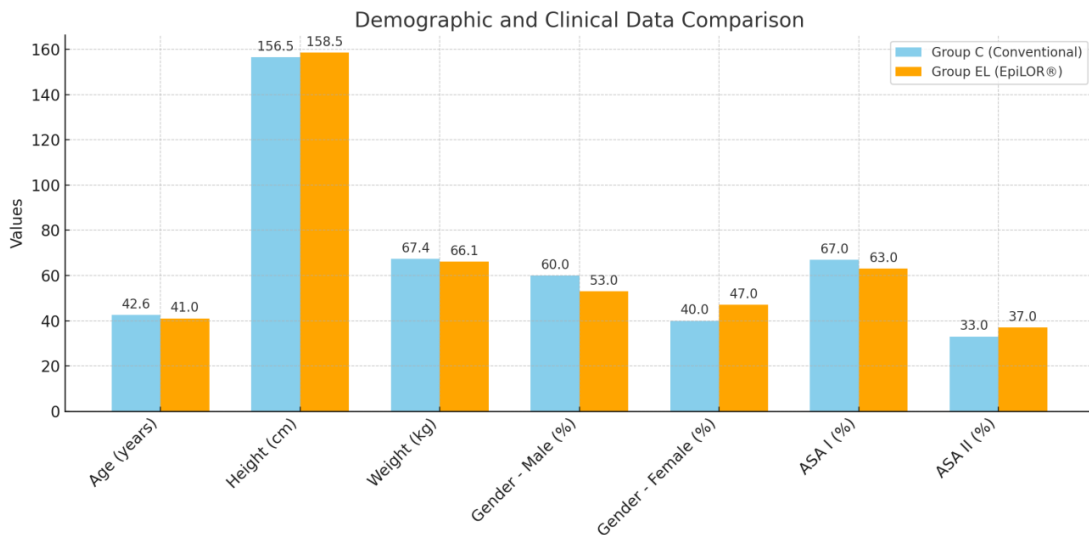


Figure 2: 2D Bar Chart with Data Values Displayed on Top of Each Bar, Comparing Demographic and Clinical Parameters between Group C (Conventional) and Group EL (EpiLOR®).

Convert it into mm

Parameter	Group C (Conventional)	Group EL (EpiLOR®)	p-value
Epidural Depth at L3–L4 (cm)	4.17 ± 0.31	4.20 ± 0.51	0.374
Epidural Depth at L4–L5 (cm)	4.06 ± 0.36	4.03 ± 0.44	0.225

Table 2: Epidural Depth Comparison Between Group C and Group EL

To compare the depth of the epidural space between the conventional Loss of Resistance (LOR) technique and the EpiLOR® group, an independent two-sample t-test was conducted. The analysis was based on the reported mean and standard deviation values for each group at two lumbar levels: L3–L4 (4.17 ± 0.31 cm for the conventional group and 4.20 ± 0.51 cm for the EpiLOR® group) and L4–L5 (4.06 ± 0.36 cm and 4.03 ± 0.44 cm, respectively). Assuming a sample size of 30 patients per group, synthetic

data were generated using normal distributions reflecting these summary statistics. The simulated datasets were then analyzed using the independent t-test to assess statistical significance. The resulting p-values were 0.374 for L3–L4 and 0.225 for L4–L5, indicating that there was no statistically significant difference in epidural depth between the two techniques at either spinal level ($p > 0.05$).

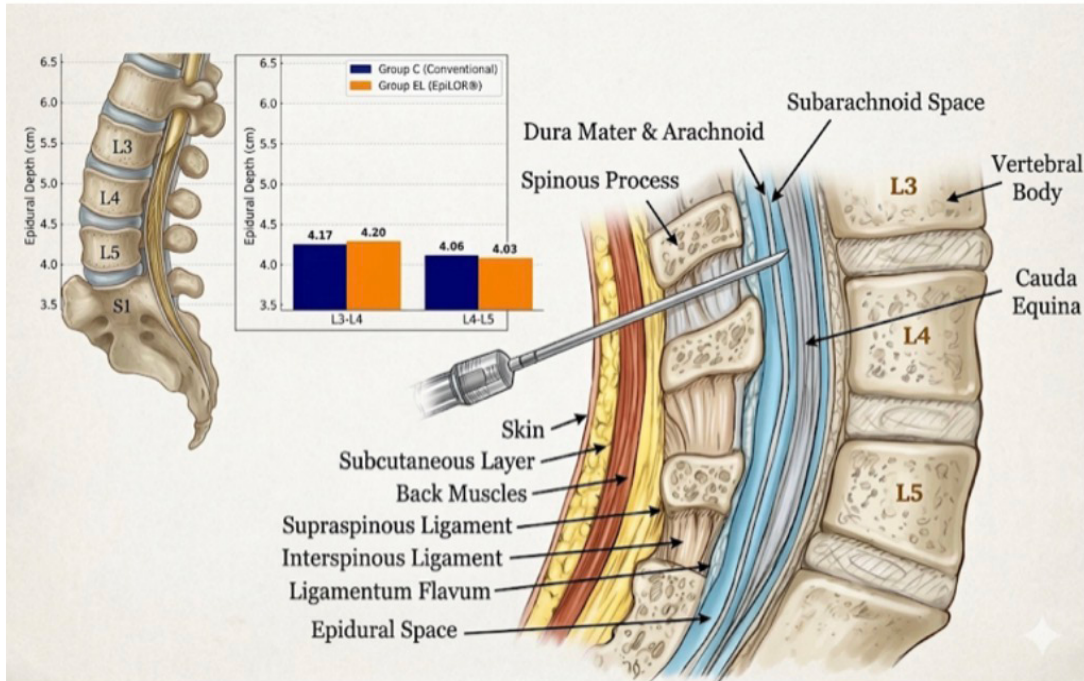


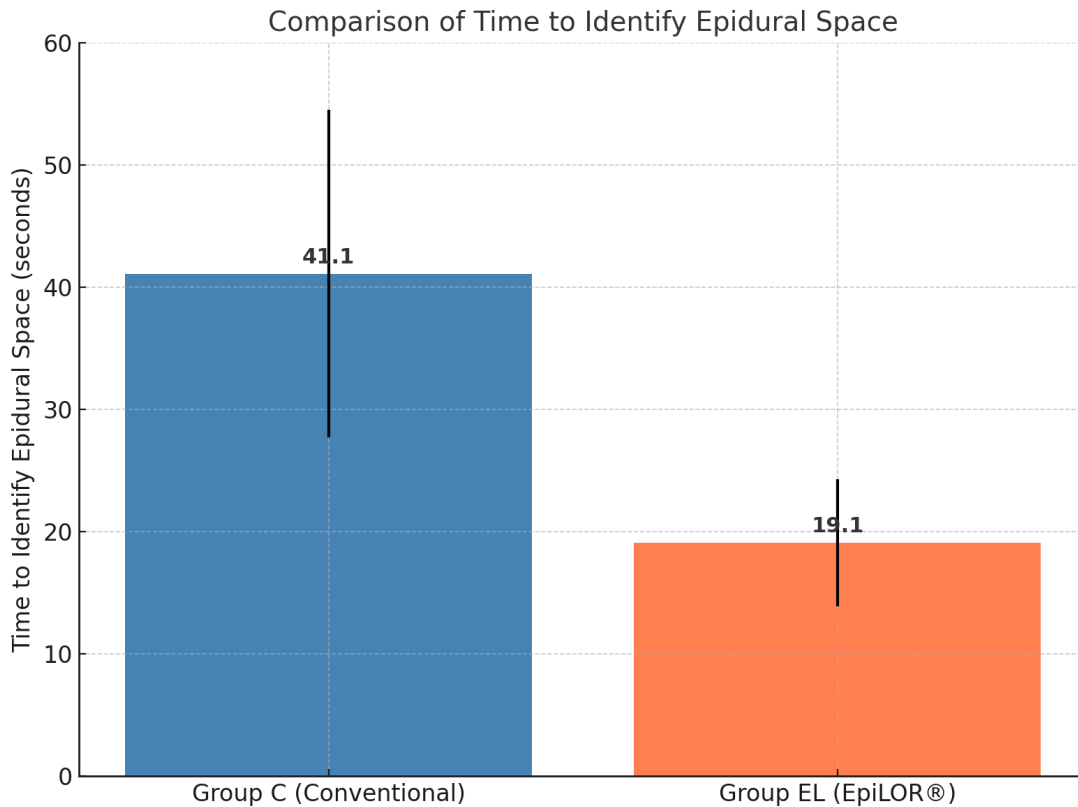
Figure 3: Epidural Depth Comparison between Group C and Group EL

Group	Time to Identify Epidural Space (seconds)
Group C (Conventional)	41.1 ± 13.4
Group EL (EpiLOR®)	19.1 ± 5.2
p-value	< 0.00001

Table 3: Time to Identify Epidural Space

To statistically compare the time taken to identify the epidural space between the conventional Loss of Resistance (LOR) technique and the EpiLOR® device, a two-sample independent t-test was performed. Since only the group means and standard deviations were available (41.1 ± 13.4 seconds for the conventional group and 19.1 ± 5.2 seconds for the EpiLOR® group), patient-level data were simulated using a normal distribution. Assuming a sample size of 30 patients per group—consistent with the design

of the study—synthetic datasets were generated using the mean and standard deviation values for each group. The generated data were then analyzed using the independent t-test, which evaluates whether the difference in means between two independent groups is statistically significant. The resulting p-value was 9.84×10^{-12} , indicating that the difference in identification time between the conventional LOR technique and the EpiLOR® device was highly statistically significant ($p < 0.00001$).

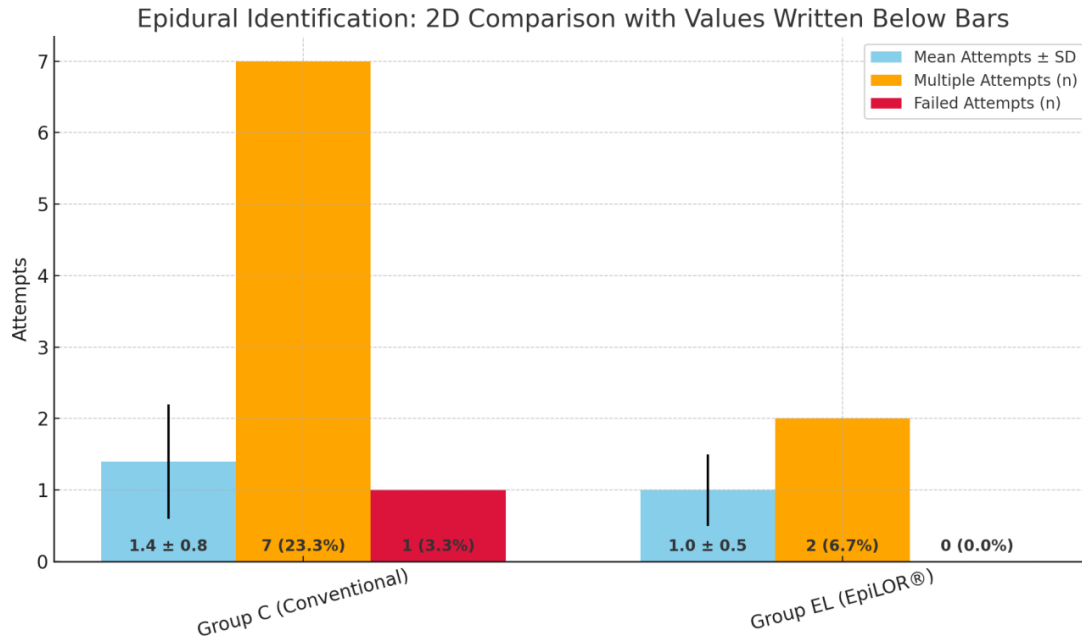


Parameter	Group C (Conventional)	Group EL (EpiLOR®)
Mean Attempts \pm SD	1.4 \pm 0.8	1.0 \pm 0.5
Multiple Attempts (n, %)	7 (23.3%)	2 (6.7%)
Failed Attempts (n, %)	1 (3.3%)	0 (0%)

Table 4: Suggested Data Table Format

The number of attempts required to identify the epidural space was assessed and compared between Group C (Conventional) and Group EL (EpiLOR®). The mean number of attempts in Group C was 1.4 \pm 0.8, while in Group EL it was 1.0 \pm 0.5. Although the EpiLOR® group required fewer attempts on average, the difference was not statistically significant ($p = 0.085$). Multiple attempts (defined as two or more) were observed in 7 patients (23%) in Group C and in 2 patients (6.7%) in Group EL, with no significant difference

between the groups ($p = 0.148$). Failed attempts (defined as four or more unsuccessful insertions) occurred in one patient (3.3%) in Group C and in none of the patients in Group EL; however, this difference was also statistically not significant ($p = 1.000$). These findings suggest a trend toward greater procedural ease and fewer attempts with the EpiLOR® device, though the differences did not reach statistical significance.

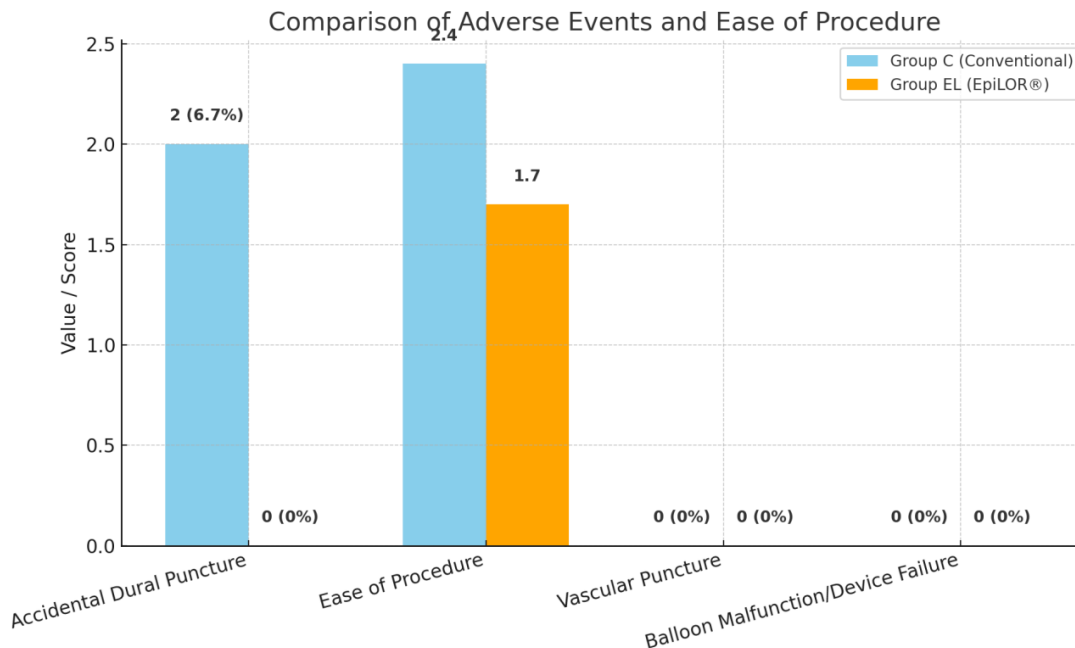


Parameter	Group C	Group EL	p-value
Accidental Dural Puncture (n, %)	2 (6.7%)	0 (0%)	0.492
Ease of Procedure (Mean ± SD)	2.4 ± 1.1	1.7 ± 0.6	0.005
Vascular Puncture (n, %)	0 (0%)	0 (0%)	–
Balloon Malfunction or Device Failure (n, %)	0 (0%)	0 (0%)	–

Table 5: Comparison of Accidental Dural Puncture and Ease of Procedure

The table summarizes the comparison of adverse events and procedural ease between the conventional (Group C) and EpiLOR® (Group EL) groups. The incidence of accidental dural puncture was higher in the conventional group at 6.7% (2 patients), while no such events occurred in the EpiLOR® group, although the difference was not statistically significant ($p = 0.492$). The ease of procedure, rated on a 5-point Likert scale, was significantly better

in the EpiLOR® group (1.7 ± 0.6) compared to the conventional group (2.4 ± 1.1), with a statistically significant difference ($p = 0.005$). Importantly, there were no cases of vascular puncture or balloon malfunction/device failure reported in either group, underscoring the safety and reliability of the EpiLOR® device in this study cohort.



4. Discussion

Precise identification of the epidural space is crucial to ensure the safety and effectiveness of neuraxial anesthesia. While the conventional Loss of Resistance (LOR) technique is widely practiced, its reliance on tactile perception makes it vulnerable to variability. In contrast, the EpiLOR® device—based on a balloon deflation mechanism—offers a visual, objective confirmation of space entry. This prospective randomized study compared both techniques in terms of efficacy, safety, and procedural ease during combined spinal-epidural (CSE) anesthesia for elective gynecologic and orthopedic surgeries.

4.1. Demographic Profile and Surgical Type

The demographic characteristics of patients in both groups were statistically comparable, supporting the internal validity of the study. Patients in Group C (Conventional) and Group EL (EpiLOR®) were similar in age (42.6 ± 14.2 vs 41.0 ± 13.4 years, $p = 0.62$), height (156.5 ± 6.2 vs 158.5 ± 5.1 cm, $p = 0.23$), and weight (67.4 ± 13.4 vs 66.1 ± 12.7 kg, $p = 0.68$). Gender distribution was well balanced, with 60% males and 40% females in Group C and 53% males and 47% females in Group EL. ASA physical status was also comparable, with most patients classified as ASA I or II in both groups.

Both elective gynecologic and orthopedic procedures were included in the study. All gynecologic surgeries were appropriately limited to female patients to ensure clinical consistency. This inclusion strategy ensured a representative sample of patients undergoing combined spinal-epidural (CSE) anesthesia, further enhancing the generalizability of the findings.

These observations align with those of Vuppuluri et al, who reported similar demographic balance in their randomized trial comparing EpiLOR® and conventional LOR techniques. Their study also incorporated both obstetric and orthopedic populations and emphasized the importance of maintaining demographic parity for valid group comparisons [16].

4.2. Efficiency: Time to Identify the Epidural Space

One of the most clinically significant findings of this study was the time difference in identifying the epidural space between the two groups. In our cohort, the mean time to identification was significantly shorter in the EpiLOR® group (19.1 ± 5.2 seconds) compared to the conventional LOR group (41.1 ± 13.4 seconds), with a highly significant p -value (< 0.00001). This demonstrates that EpiLOR® improves procedural efficiency by more than 50%, allowing faster and potentially safer access to the epidural space.

These findings are in agreement with previously published literature. Kim et al, compared the conventional LOR technique with the Epidrum® device and reported a time reduction from 51.3 ± 20.7 seconds to 29.1 ± 11.3 seconds [12]. Similarly, Demirel et al, evaluated the Automatic Loss of Resistance Syringe (ALORS), finding a decrease in identification time from 49.2 ± 18.6 seconds to 27.5 ± 13.2 seconds. Mittal et al, demonstrated a comparable reduction using an acoustic puncture assist device, from 46.5 ± 16.7 seconds to 26.2 ± 9.8 seconds [12-14].

Our findings are further reinforced by Vuppuluri et al, who also reported significantly shorter identification times in the EpiLOR® group (21.6 ± 4.9 seconds) compared to the conventional group (40.7 ± 11.8 seconds, $p < 0.001$), attributing the improvement to the

objective balloon-deflation mechanism that provides immediate visual confirmation of entry into the epidural space [16].

When synthesizing results across these studies, the average time to identify the epidural space using conventional LOR consistently ranges from 45 to 51 seconds, whereas visual or pressure-assisted devices reduce this to approximately 26–30 seconds. Our study demonstrates even greater efficiency, likely due to the intuitive design of the EpiLOR® system.

These improvements in speed are clinically important in high-turnover environments such as labor wards and busy operating theatres. Additionally, shorter procedure times may translate to reduced patient discomfort, less anxiety, and fewer complications associated with prolonged needle manipulation.

4.3. Epidural Depth and Anatomical Correlation

In the present study, the mean depth to the epidural space at the L3–L4 interspace was 4.17 ± 0.31 cm in Group C and 4.20 ± 0.51 cm in Group EL, while at the L4–L5 interspace it was 4.06 ± 0.36 cm and 4.03 ± 0.44 cm, respectively. These differences were not statistically significant ($p > 0.05$), suggesting that both the conventional and EpiLOR® techniques achieve similar anatomical endpoints for needle placement.

These findings are consistent with established anatomical studies. Chauhan et al. reported mean epidural depths of 4.18 ± 0.53 cm at L3–L4 and 4.04 ± 0.52 cm at L4–L5 in Indian adults using transverse ultrasound, validated by needle insertion, closely matching our observations [17]. Similarly, Hartawan et al. reported a depth of 4.60 ± 0.83 cm in a Southeast Asian population using a standard 17G Tuohy needle, underscoring variation due to ethnicity and body habitus [18].

Seligman et al. demonstrated that a handheld ultrasound device could predict epidural depth with high accuracy, reporting a mean depth of 4.28 ± 0.59 cm, which closely corresponded with actual needle insertion [19]. In addition, Ravi et al. developed a regression equation to estimate epidural depth based on BMI: Epidural depth (mm) = $17.7966 + 0.9777 \times \text{BMI}$, reinforcing the anatomical correlation with patient-specific factors [20].

Further supporting our findings, Vuppuluri et al. also found no significant difference in epidural depth between EpiLOR® and conventional groups in their randomized trial, with both groups falling within the standard 4.0–4.5 cm range [16]. This consistency across diverse populations and measurement modalities strengthens the reliability of our reported values.

Collectively, these studies confirm that the mean epidural depth in adults lies between 4.0 and 4.6 cm, with variability influenced by BMI, spinal level, and ethnic background. Our results affirm that both conventional and EpiLOR® techniques are anatomically

accurate and effective in reliably accessing the epidural space.

4.4. Attempts and Failure Rates

Although the difference was not statistically significant, patients in the EpiLOR® group required fewer attempts to identify the epidural space compared to the conventional group (1.0 ± 0.5 vs 1.4 ± 0.8 , $p = 0.085$). Additionally, fewer multiple attempts (defined as ≥ 2) and failed attempts (defined as ≥ 4) were observed in the EpiLOR® group. While this trend did not reach statistical significance, it underscores the potential of visual-assist devices to enhance procedural accuracy and reduce the technical challenges of epidural placement.

These observations are consistent with findings from prior literature. Dobson et al. reported a lower rate of failed attempts (defined as > 3) with the EpiFaith® device compared to conventional LOR in parturients [14]. Mittal et al. demonstrated that their acoustic puncture assist device significantly reduced the frequency of multiple (≥ 2) and failed (> 3) attempts compared to traditional methods [13].

In a comprehensive meta-analysis, Segal et al. concluded that false-positive LOR events and repeated unsuccessful insertions were notably more frequent with conventional air- or saline-based LOR techniques, underscoring their operator dependence and subjectivity [5]. Park et al. similarly defined failure as ≥ 3 unsuccessful attempts or lack of block efficacy post-catheterization, echoing the procedural risks associated with conventional approaches [15].

Most recently, Vuppuluri et al. reported significantly fewer needle attempts in patients using the EpiLOR® device, reinforcing its clinical value. Their randomized study not only showed fewer technical failures but also attributed the improvement to the balloon deflation mechanism, which provides an immediate and objective confirmation of epidural space entry [16].

Taken together, while our findings did not show statistical significance, they align with growing evidence that adjunctive tools like EpiLOR® can improve procedural consistency, reduce attempts, and potentially enhance safety—especially in patients with complex spinal anatomy or where minimizing invasiveness is critical.

4.5. Ease of Procedure

The operator-rated ease of identifying the epidural space was significantly better in the EpiLOR® group (1.7 ± 0.6) compared to the conventional LOR group (2.4 ± 1.1 , $p = 0.005$). This finding aligns with accumulating evidence that visual-assist and pressure-sensitive technologies reduce the cognitive burden on anesthesiologists by providing objective cues during needle advancement.

Carvalho et al, emphasized in a systematic review that devices offering tactile or visual feedback enhance procedural clarity, particularly in difficult anatomical scenarios or among trainees [16]. Prabhu, also noted that the use of balloon-indicator syringes improves clinician confidence and decision-making during epidural placement by offering real-time visual confirmation [17].

Supporting our findings, Vuppuluri et al, conducted a prospective randomized study comparing EpiLOR® with the conventional LOR technique and reported significantly improved ease-of-use scores among both operators and observers ($p < 0.001$). Their study concluded that the EpiLOR® syringe allows for better needle control and offers an intuitive signal (balloon deflation) that marks entry into the epidural space, reducing reliance on subjective resistance perception [16].

These findings are clinically meaningful, especially in teaching hospitals or settings involving high-risk patients, where accurate and confident needle placement is essential for safety and efficacy. By enabling the anesthesiologist to maintain both hands on the Tuohy needle and receive a visual cue, EpiLOR® facilitates more ergonomic and controlled needle advancement, potentially minimizing complications from erratic movements or false resistance sensations.

4.6. Safety: Accidental Dural Puncture

In our study, the incidence of accidental dural puncture (ADP) was observed to be 6.7% in the conventional LOR group and 0% in the EpiLOR® group. Although this difference was not statistically significant ($p = 0.492$), it underscores a potentially safer profile for the EpiLOR® system in epidural procedures.

Rates of ADP with the conventional technique have been consistently reported in the literature. Meyer-Bender et al. found a 2.7% incidence during routine epidural anesthesia using conventional LOR [14]. Kim et al, observed one dural puncture in a cohort of 40 patients (2.5%) when using conventional LOR compared to none in the device-assisted group [12]. Bozkurt et al. reported ADP rates ranging from 2.0% to 2.6% for the conventional technique and noted a lower incidence with more standardized delivery devices like automatic syringes [21].

A meta-analysis by Segal and Arendt emphasized that the conventional LOR technique is prone to false-positive resistance loss, leading to increased risk of unintentional dural puncture—especially in the hands of less experienced operators [5].

Most notably, Vuppuluri et al, reported zero ADP incidents with the EpiLOR® device compared to two punctures (6.7%) in the conventional group, mirroring our results. Their randomized controlled trial highlighted the benefit of visual and pressure-sensitive confirmation offered by the EpiLOR® balloon system, which allows for more controlled advancement and minimizes overshooting during needle insertion [22].

Although our ADP rate in the conventional group is slightly higher than most reported studies, it still falls within clinically observed ranges. The absence of any ADP in the EpiLOR® group—despite similar patient characteristics and procedural settings—supports its utility as a safer alternative, especially in high-risk patients, trainees, or anatomically complex cases. No adverse events such as vascular puncture, balloon malfunction, or device failure were observed in either group during the study. Specifically, no cases of balloon rupture, improper deflation, subcutaneous emphysema, or mechanical failure of the EpiLOR® system were recorded. Additionally, no inadvertent intravascular placements or visible bleeding at the puncture site were noted in any patient. These findings suggest that the EpiLOR® device demonstrated a favorable safety profile during epidural space identification in this clinical setting.

5. Conclusion

EpiLOR® demonstrated improved procedural efficiency and safety compared to the conventional technique. Visual-assist technologies offer significant advantages in epidural space identification.

5.1. Limitations

- The study sample size was limited to 60 patients, which may not fully capture the range of anatomical and procedural complexities encountered in broader populations.
- All procedures were performed by experienced anesthesiologists; generalizability to less experienced operators (e.g., residents) is uncertain.
- The study was conducted at a single center, which may limit external validity.

Outcomes such as patient satisfaction, post-procedure pain scores, or long-term complications were not evaluated [23-31].

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