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Original Research Article

OPTIMIZING LABOUR ANALGESIA: A RANDOMIZED CLINICAL STUDY COMPARING ONSET, DURATION, AND SAFETY OF EPIDURAL AND COMBINED SPINAL–EPIDURAL APPROACHES

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ABSTRACT

Background: Labour analgesia remains an essential component of obstetric anaesthesia practice, aimed at providing effective pain relief while ensuring maternal safety and favourable neonatal outcomes. Among the various modalities, epidural analgesia has long been considered the gold standard. However, combined spinal–epidural (CSE) anaesthesia has gained attention due to its rapid onset, dense block, and potential for reduced local anaesthetic requirements. Comparative evaluation of these techniques is crucial to optimize patient care and guide practice in diverse obstetric populations [1].

Materials and Methods: This prospective comparative study was conducted at the Department of Anaesthesia from January 2024 to December 2024. A total of 120 parturients (ASA II–III, term, singleton pregnancies) requesting labour analgesia were enrolled and randomized into two groups: Epidural group (n=60) and CSE group (n=60). Standardized protocols were followed for block administration. Maternal demographics, onset of analgesia, duration of effective analgesia, need for top-ups, hemodynamic changes, mode of delivery, maternal satisfaction, and neonatal outcomes (Apgar scores) were recorded. Data were analyzed using SPSS v26.0, with t-tests, chi-square tests, and $p<0.05$ considered statistically significant.

Results: CSE demonstrated a significantly faster onset of analgesia (mean 5.2 ± 1.4 min vs 14.8 ± 2.9 min, $p<0.001$) and higher maternal satisfaction scores (mean 8.9 ± 0.8 vs 8.1 ± 1.1, $p=0.002$) compared to epidural analgesia. Duration of effective analgesia and frequency of top-ups were significantly lower in the CSE group. Hemodynamic stability and neonatal Apgar scores were comparable between groups.

Conclusion: CSE provides faster and more effective labour analgesia with high maternal satisfaction while maintaining safety comparable to epidural anesthesia. It may be considered a preferable option in clinical practice where rapid and reliable analgesia is desired.

Keywords: Labour analgesia, epidural anaesthesia, combined spinal–epidural, obstetric anaesthesia, maternal satisfaction, neonatal outcome.

INTRODUCTION

Labour is often regarded as one of the most painful experiences in a woman's life, and the provision of safe and effective analgesia during childbirth is a cornerstone of modern obstetric anaesthesia. The objective of labour analgesia is not only to reduce maternal pain but also to promote maternal comfort, facilitate cooperation during delivery, and ensure favourable obstetric and neonatal outcomes.[1] Over the decades, multiple techniques have been developed to achieve these goals, ranging from systemic opioids and inhalational agents to regional anaesthesia. Among these, neuraxial techniques, specifically epidural and combined spinal–epidural

(CSE) analgesia, have emerged as the most effective and widely accepted modalities.[2]

Epidural analgesia has long been considered the gold standard for labour pain management, owing to its ability to provide continuous analgesia, titratable dosing, and hemodynamic stability.[3] However, it is associated with certain limitations such as delayed onset of analgesia, occasional patchy blocks, and the need for higher volumes of local anesthetics.[4] In contrast, the CSE technique, which combines the rapid onset of spinal anaesthesia with the flexibility of epidural dosing, was introduced to address some of these shortcomings.[5] By administering a small intrathecal dose followed by epidural catheter placement, CSE provides fast, dense analgesia while allowing extension of duration as labour progresses.[6]

The choice between epidural and CSE techniques has significant clinical implications. Several maternal factors such as body mass index, stage of labour, and obstetric risk profile influence the effectiveness and safety of these methods.[7] In addition, neonatal well-being is an essential consideration, as maternal hemodynamic fluctuations or drug exposure may impact neonatal outcomes.[8] While studies have demonstrated the efficacy of both techniques, conflicting evidence exists regarding their comparative advantages. Some reports highlight faster onset and superior maternal satisfaction with CSE, whereas others suggest minimal difference in maternal and neonatal outcomes when compared with conventional epidural analgesia.[9]

Despite extensive research, a consensus has not been established regarding the superiority of one technique over the other. Variability in patient populations, anaesthetic regimens, drug concentrations, and outcome measures across studies contribute to this lack of uniformity.[10] Furthermore, in low-resource or high-volume obstetric centres, practical considerations such as technical ease, availability of drugs, and staff expertise also play a critical role in determining the choice of technique.[11]

The present study was therefore designed to conduct a prospective comparison between epidural and CSE techniques for labour analgesia.

MATERIALS AND METHODS

This prospective, randomized comparative study was conducted in the Department of Anaesthesia between January 2024 and December 2024, following approval from the Institutional Ethics Committee (IEC/ANES/2023/114). Written informed consent was obtained from all participants prior to enrolment, and the study adhered to the principles of the Declaration of Helsinki.

Study Population: A total of 120 healthy parturients were recruited for the study. Participants were selected based on the following inclusion criteria: term singleton pregnancy, age between 18 and 35 years, American Society of Anesthesiologists (ASA) physical status II or III, cervical dilatation between 3–5 cm at the time of analgesia request, and willingness to provide informed consent. Exclusion criteria included contraindications to neuraxial anaesthesia (e.g., coagulopathy, spinal deformities, local infection at puncture site), known hypersensitivity to study drugs, multiple gestations, pre-eclampsia, chronic hypertension, and refusal to participate.

Randomization and Group Allocation: Participants were randomly assigned into two groups (n=60 each) using a computer-generated randomization sequence. Group E received labour analgesia via epidural technique, while Group CSE received combined spinal–epidural analgesia. Allocation concealment was maintained using sealed opaque envelopes.

Anaesthetic Technique: Baseline maternal vitals (heart rate, blood pressure, and oxygen saturation) and fetal heart rate were recorded. Intravenous access was established, and preloading with 500 mL of Ringer's lactate was performed.

- Group E (Epidural group): An 18G Tuohy needle was inserted at the L3–L4 interspace using the loss-of-resistance technique. A test dose of 3 mL lignocaine with adrenaline (1:200,000) was given to exclude intrathecal or intravascular placement. Analgesia was initiated with 10 mL of 0.125% bupivacaine combined with 2 µg/mL fentanyl, followed by intermittent top-ups of 8–10 mL as required.
- Group CSE (Combined spinal–epidural group): A 27G spinal needle was advanced through the Tuohy needle at the L3–L4 interspace. A 2.5 mg intrathecal dose of bupivacaine with 25 µg fentanyl was administered. An epidural catheter was then inserted, secured, and activated when analgesia from the spinal component waned.

Data Collection and Outcome Measures

The following parameters were assessed:

1. Demographic data: Age, weight, height, and parity.
2. Primary outcomes: Onset time of analgesia (time from drug administration to VAS ≤3), duration of effective analgesia, and need for additional top-ups.
3. Secondary outcomes: Maternal hemodynamic stability, mode of delivery (normal vaginal, instrumental, or caesarean section), maternal satisfaction (10-point Likert scale), and neonatal outcomes (Apgar scores at 1 and 5 minutes).
4. Adverse events: Hypotension, pruritus, nausea, vomiting, or post-dural puncture headache.

Statistical Analysis: Data were analyzed using SPSS version 26.0 (IBM Corp., Armonk, NY). Continuous variables were expressed as mean ± standard deviation (SD) and compared using independent Student's t-test. Categorical variables were presented as frequencies and percentages and analyzed using chi-square or Fisher's exact test as appropriate. A p-value <0.05 was considered statistically significant. Confidence intervals (95%) were reported for key outcome measures.

RESULTS

Table 1: Demographic Characteristics

Parameter	Epidural Group (n=60)	CSE Group (n=60)	p-value
Age (years)	26.4 ± 3.8	26.1 ± 4.1	0.68
Weight (kg)	64.8 ± 6.2	65.3 ± 6.7	0.57
Height (cm)	158.2 ± 5.9	157.5 ± 6.1	0.49
Parity (Primigravida/Multigravida)	35 / 25	33 / 27	0.72

Table 2: Primary Outcomes

Parameter	Epidural Group (n=60)	CSE Group (n=60)	p-value
Onset of analgesia (min)	14.8 ± 2.9	5.2 ± 1.4	<0.001
Duration of effective analgesia (min)	88.5 ± 12.4	121.7 ± 15.6	<0.001
Top-ups required (mean number)	3.2 ± 0.9	1.9 ± 0.7	<0.001

Table 3: Secondary Outcomes

Parameter	Epidural Group (n=60)	CSE Group (n=60)	p-value
Maternal satisfaction score (0–10)	8.1 ± 1.1	8.9 ± 0.8	0.002
Mode of delivery (NVD/Instrumental/CS)	43 / 8 / 9	45 / 7 / 8	0.88
Neonatal Apgar at 1 min	7.9 ± 0.5	8.0 ± 0.6	0.34
Neonatal Apgar at 5 min	9.2 ± 0.4	9.3 ± 0.4	0.29

Table 4: Maternal Hemodynamics and Adverse Events

Parameter	Epidural Group (n=60)	CSE Group (n=60)	p-value
Hypotension (%)	6 (10.0%)	8 (13.3%)	0.56
Pruritus (%)	2 (3.3%)	7 (11.7%)	0.08
Nausea/Vomiting (%)	3 (5.0%)	4 (6.7%)	0.70
Post-dural puncture headache (%)	0 (0%)	1 (1.7%)	0.32

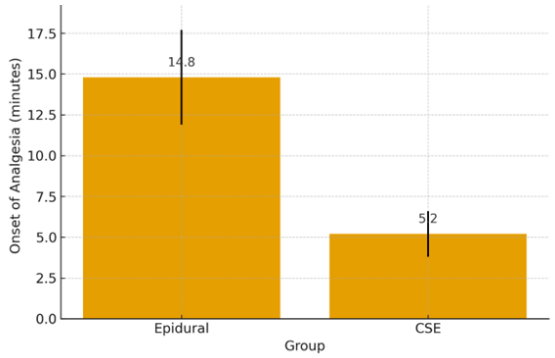

Figure 1: Comparison of Onset of Analgesia between Groups

The demographic profile was comparable between groups, with no statistically significant differences in age, weight, height, or parity distribution, confirming baseline homogeneity.

Primary outcomes demonstrated marked differences between the two groups. The onset of analgesia was significantly faster in the CSE group (5.2 ± 1.4 min) compared to the epidural group (14.8 ± 2.9 min, p<0.001). Duration of effective analgesia was also longer in the CSE group (121.7 ± 15.6 min vs 88.5 ± 12.4 min, p<0.001), reducing the need for additional top-ups (1.9 ± 0.7 vs 3.2 ± 0.9, p<0.001).

Secondary outcomes revealed higher maternal satisfaction with CSE (8.9 ± 0.8) compared to epidural analgesia (8.1 ± 1.1, p=0.002). However, the mode of delivery remained similar across both groups, with no significant differences in rates of normal vaginal delivery, instrumental delivery, or caesarean section. Neonatal Apgar scores at both 1 and 5 minutes were comparable between groups, indicating that neither technique adversely affected neonatal well-being.

Adverse events were low and not statistically different between groups. Hypotension occurred in 10.0% of the epidural group and 13.3% of the CSE group (p=0.56). Pruritus was slightly more frequent with CSE (11.7%) compared to epidural (3.3%), though the difference was not statistically significant (p=0.08). Nausea, vomiting, and post-dural puncture headache were rare and evenly distributed.

Overall, CSE provided a faster onset and longer duration of analgesia with fewer top-ups and greater maternal satisfaction, while maintaining comparable maternal and neonatal safety profiles relative to epidural analgesia.

DISCUSSION

Labour analgesia is a critical component of obstetric anaesthesia, with the primary aim of ensuring effective maternal pain relief without compromising safety. This study compared epidural with combined spinal–epidural (CSE) analgesia to evaluate onset, duration, maternal satisfaction, hemodynamics, and neonatal outcomes.

In our study, CSE produced a faster onset of analgesia (5.2 ± 1.4 min) compared with epidural (14.8 ± 2.9 min, p<0.001). Simmons et al,[12] reported a similar advantage, demonstrating that women receiving CSE achieved adequate pain relief within 4.7 ± 1.2 minutes, while those with epidural required 12–15 minutes. Collis et al,[13] also observed a significantly shorter onset with CSE (median 5 min) compared to epidural (median 15 min), reinforcing the rapid action of intrathecal drugs.

The mean duration of effective analgesia in our study was longer with CSE (121.7 ± 15.6 min) than epidural (88.5 ± 12.4 min, p<0.001). Norris et al,[14] similarly found that intrathecal fentanyl with bupivacaine in CSE prolonged analgesia to 120–130 minutes, compared to 80–90 minutes with epidural regimens.

Maternal satisfaction was significantly higher in our CSE group (8.9 ± 0.8) compared to epidural (8.1 ± 1.1, p=0.002). Pan et al,[15] reported comparable results, noting higher satisfaction scores (mean 9/10) with CSE versus 8/10 with epidural, attributing this to more rapid and dense block quality.

Regarding obstetric outcomes, our study found no significant difference in mode of delivery between the groups. Lee et al,[16] also showed similar caesarean section rates (12.5% in epidural vs 11.8% in CSE) and instrumental delivery rates across techniques, indicating that analgesic choice does not adversely affect delivery mode.

Neonatal well-being was unaffected in our study, with comparable Apgar scores at 1 and 5 minutes. Thakur et al,[17] documented Apgar scores >7 in over 95% of neonates with both epidural and CSE, while Abrao et al,[18] similarly reported no statistically significant difference in neonatal outcomes.

Adverse events were low in both groups in our study, though pruritus was slightly higher with CSE (11.7% vs 3.3%). Jouppila et al,[19] also found that intrathecal fentanyl in CSE was associated with increased pruritus (10–15%) compared with epidural (3–5%), without affecting hemodynamic stability or neonatal safety.

Taken together, our results are consistent with published evidence that CSE provides faster onset, prolonged analgesia, and higher maternal satisfaction, without altering obstetric or neonatal outcomes. Although CSE may be preferred in settings requiring rapid and reliable analgesia, epidural remains valuable for its established safety and ease of titration.

Study limitations include the single-center design, modest sample size, and exclusion of high-risk obstetric groups. Future multicentric trials, including high-risk pregnancies, long-term maternal outcomes, and cost-effectiveness analyses, are warranted to strengthen practice recommendations.

CONCLUSION

This prospective comparative study demonstrated that combined spinal–epidural (CSE) analgesia offers clear advantages over conventional epidural analgesia in labour. CSE was associated with a significantly faster onset of pain relief, longer duration of effective analgesia, fewer top-up requirements, and higher maternal satisfaction scores. Importantly, both techniques were comparable in terms of maternal haemodynamic stability, obstetric outcomes, and neonatal well-being, as reflected by similar Apgar scores. Adverse events were minimal and did not differ significantly, although pruritus occurred more frequently in the CSE group, consistent with the intrathecal opioid component.

Overall, these findings support the use of CSE as a safe and effective alternative to epidural, particularly in settings where rapid and reliable analgesia is desirable. Nevertheless, epidural analgesia remains a valuable option, especially in situations requiring prolonged titration. Adoption of either technique should be individualised based on patient characteristics, clinical setting, and provider expertise.

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