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Comparative Study on the Efficacy and Safety of Combine Spinal Epidural (CSE) and Epidural for Labor Analgesia

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Abstract

Background: *Childbirth marks a profound transformation in a woman's life, often accompanied by intense pain. Research indicates that labor pain is among the most excruciating types of discomfort. This pain can affect both the mother and the fetus, potentially causing fetal hypoxia and impacting various systems. Luckily, labor pain management has advanced, offering a variety of methods, with regional analgesia, particularly epidural, emerging as a highly effective approach. Spinal analgesia provides rapid relief but has limitations. Combined spinal-epidural analgesia (CSE) combines the benefits of both methods, offering rapid and adjustable pain relief, with some shared complications with epidural analgesia.*

Aim of the Study: *The study aims to compare the effectiveness of CSE analgesia with epidural analgesia for painless labor, primarily focusing on evaluating the efficacy of analgesia and pain assessment.*

Methods: *This retrospective study was conducted at the Department of Anesthesia in Satkhira Sadar Hospital, Satkhira Bangladesh. The study duration was one year from June 2022 to July 2023. A total of 40 women were enrolled and analyzed in this study into two groups. Each group has 20 patients. The study population is divided into two groups. Group 1 received combined spinal-epidural analgesia (CSE), and group 2 received only epidural analgesia. All regional blocks were performed in the flexed sitting position at the L2-L3 or L3-L4 intervertebral space following a routine fluid preload of 500-1000ml Hartmann's solution under aseptic conditions. All patient blood investigations were checked, and written consent was taken after explaining the risks and benefits of the procedure. All of the collected data was subsequently employed for thorough statistical analysis.*

Result: *In the study involving 40 patients, two groups, Group A and Group B, were analyzed. Demographic characteristics and medical parameters were compared between the groups. Group A had more primigravida patients (15%) than Group B (10%). Both groups showed similar results for ASA classification. Group A had a higher maternal heart rate 30 minutes after injection than Group B. The onset of analgesia was faster in Group A, but the duration of analgesia was similar. Group A had reduced pain scores at 15 minutes post-injection. More CSE patients needed additional pain relief. The duration of the second stage of labor was longer in Group A. Both groups had similar Apgar scores.*

Conclusion: *This comparative study of Combine Spinal Epidural (CSE) and Epidural for labor analgesia revealed that both techniques effectively alleviate labor pain; the CSE approach exhibited a more rapid onset of pain relief and superior satisfaction levels among parturient. The choice between CSE and Epidural should be based on individual patient preferences and specific clinical circumstances, ensuring optimal maternal and fetal outcomes.*

Keywords: *Comparative Study, Efficacy, Safety, Combine Spinal Epidural (CSE), Epidural and Labor Analgesia.*

1. INTRODUCTION

Childbirth is a transformative event in a woman's life, often accompanied by significant pain and discomfort. Research has shown that labor pain ranks among the most intense types of pain [1]. Furthermore, it can have adverse effects on the fetus, impacting its respiratory, cardiovascular, and neuroendocrine systems and

potentially leading to fetal hypoxia [2,3]. Fortunately, the management of labor pain has evolved, offering a range of techniques and medications to minimize discomfort for both the mother and fetus, while also aiding the progress of labor [4]. Regional analgesia has emerged as the most effective approach to managing labor pain and can be administered through techniques like epidural, spinal, or a combination of both [5]. Epidural analgesia has established itself as a highly efficient method for providing pain relief during labor [6]. It involves the introduction of local anesthetics and opioids into the epidural space, effectively blocking the transmission of pain signals from the lower body to the central nervous system. Local anesthetic is directly delivered into the epidural space around the spinal column through a catheter placed in that space [3,5]. When compared to non-epidural methods, epidural analgesia is recognized as the superior and safer option for labor pain relief [6]. It is renowned for its capacity to provide significant pain relief, allowing women to go through childbirth with reduced distress. Spinal analgesia, where medications are injected directly into the spinal column, offers a faster onset of pain relief, but its relatively shorter duration limits its use in labor pain management. Additionally, using very fine catheters in the spinal region increases the risk of nerve injury [5]. On the other hand, combined spinal-epidural analgesia (CSE) combines the benefits of both spinal and epidural techniques, providing rapid and profound pain relief with the flexibility of dose titration [7]. CSE involves injecting a small amount of local anesthetic and/or opioid into the subarachnoid space to initiate analgesia, followed by bolus or continuous injection through the epidural catheter [5]. CSE can also offer superior overall pain relief with a faster cervical dilation rate compared to epidural alone [8-10]. However, it shares some common complications with epidural analgesia, such as maternal hypotension, post-dural puncture headache (PDPH), urinary retention, pruritus, itching, and transient backache [11]. Thanks to its rapid onset of action, CSE analgesia allows women to experience almost immediate pain relief, enhancing their overall labor experience. Therefore, this study aims to compare the effectiveness of CSE analgesia with epidural analgesia for painless labor, primarily focusing on evaluating the efficacy of analgesia and pain assessment.

2. METHODOLOGY & MATERIALS

This retrospective study was conducted at the Department of Anesthesia in Satkhira Sadar Hospital, Satkhira Bangladesh. The study duration was one year from June 2022 to July 2023.A total of 40 women were enrolled and analyzed in this study into two groups. Each group has 20 patients. The study population is divided into two groups. Group 1 received combined spinal-epidural analgesia (CSE), and group 2 received only epidural analgesia. All regional blocks were performed in the flexed sitting position at the L2-L3 or L3-L4 intervertebral space following a routine fluid preload of 500-1000ml Hartmann's solution under aseptic conditions. All patient blood investigations were checked, and written consent was taken after explaining the risks and benefits of the procedure. All of the collected data was subsequently employed for thorough statistical analysis.

Inclusion Criteria:

- Pregnant women aged between 20-40 years.
- Patients who requested epidural analgesia in active labour with cervical dilatation 3-4 cm.
- Patients experiencing uterine contractions.
- Patients with uncomplicated term labour between 37-41 weeks of gestational age.

Exclusion Criteria:

- Women experiencing complex pregnancies
- Patients diagnosed with placenta previa.
- Patients with pregnancy-induced hypertension.
- Individuals for whom regional analgesia is contraindicated.
- Patients who were diagnosed with pre-eclampsia.

Group 1 (CSE):

The CSE (Combined Spinal-Epidural) procedure utilized a single interspace needle-through-needle technique. To initiate the process, the epidural space was identified by the loss of resistance to saline, achieved with an 18-G Tuohy needle. Subsequently, an intrathecal injection was administered using a 27G spinal needle, delivering a mixture of 2mg of Bupivacaine and 25 mcg of Fentanyl. A 20G multiport epidural catheter was inserted approximately 4-5cm into the epidural space.

Following a negative aspiration (no evidence of blood or cerebrospinal fluid), a 3ml test dose of 0.25% Bupivacaine was administered. The infusion was initiated with a solution consisting of 0.08% Bupivacaine and 2mcg/ml of Fentanyl, delivered at a rate of 8-10ml per hour.

Group-2 (Epidural):

In the cohort that received epidural anesthesia, the epidural space was located by introducing an 18-G Tuohy needle and confirming its placement through a loss of resistance to saline. Following the confirmation of proper needle positioning, a test dose of 3 ml of 0.25% bupivacaine was administered, and subsequently, a continuous infusion of 0.08% bupivacaine with two mcg/ml of fentanyl was maintained at a flow rate of 8-10 ml per hour, as described in the technique mentioned above.

Data was gathered from two different sources, from the medical procedure to the childbirth process. A midwife collected the initial data set, while the rest was obtained from the Medical Records Department (MRD). The initial steps of patient care included the administration of intravenous fluids and consistently monitoring various parameters. This monitoring included the assessment of the verbal Numeric Pain Score (NRS) ranging from 0 to 10, which categorized pain levels (0 for no pain, 1-3 for mild pain, 4-6 for moderate pain, and 7-10 for severe pain). Additionally, the maternal vital signs, such as heart rate, blood pressure, and respiratory rate, as well as the fetal heart rate before analgesia, at 15 minutes after injection, and 30 minutes after injection, were meticulously recorded. Maternal satisfaction levels were also documented, and any adverse effects like post-dural puncture headache (PDH), nausea, and vomiting were noted. Further data encompassed the duration of both the first and second stages of labor, the necessity for additional analgesic doses, maternal contentment, and the delivery method. The well-being of the newborns was evaluated through Apgar scores at 1 and 5 minutes after birth. These investigations were carried out repeatedly, and comprehensive information, along with demographic details, were meticulously collected and recorded using a structured data collection sheet or proforma that had been pre-designed for this purpose. All of the collected data was subsequently employed for thorough statistical analysis.

Statistical Analysis

The data were organized into tables and graphs that best suited their characteristics. A detailed description for easy comprehension accompanied each table and graph. Statistical analysis was conducted using the Statistical Package for Social Science (SPSS) software on a Windows platform. Continuous variables were expressed as mean ± standard deviation (SD), while categorical variables were presented as frequency and percentage. Group comparisons for continuous variables were carried out using the Student's t-test, and for categorical variables, the Chi-Square test was applied. The significance of the results was determined based on a 95% confidence interval, and statistical significance was defined as a p-value (P) less than 0.05.

3. RESULT

In this study, a total of 40 patients were included and analyzed, with each group consisting of 20 patients. Table 1 displays the demographic characteristics of the two groups. Within Group A, 15% were primi gravida, and 85% were multigravida. Regarding parity, 15% of Group A were nulliparous, 25% were primiparous, and 60% were multiparous. Similarly, in Group B, 10% were primi gravida, and 90% were multigravida. Regarding parity in Group B, 15% were nulliparous, 30% were primiparous, and 55% were multiparous. Both groups exhibited similar results regarding the ASA classification, as presented in Table 2.Notably, there was a significant difference in maternal heart rate 30 minutes after injection, with Group A averaging 95.02±7.25 and Group B averaging 88.82 ± 5.29. However, no significant differences were observed in maternal respiratory rate, blood pressure, and fetal heart rate before analgesia, as well as at 15 and 30 minutes after injection in both groups, as indicated in Table 3. Table 4 revealed that Group B had a delayed onset of analgesia (12.45 ± 3.14 min) compared to Group A (3.83 ± 1.27 min). However, there was no significant difference in the duration of analgesia between the two groups. Before injection, both groups reported similar pain scores. However, at 15 minutes post-injection, Group A reported a reduced pain score (3.82 ± 0.7) compared to Group B (4.52 ± 1.12). A higher percentage of CSE patients required additional medication for pain relief (45% in CSE vs. 25% in epidural). The duration of the first stage of labor did not exhibit a significant

difference between the groups. Nonetheless, during the second stage, Group A experienced a longer duration (75.12 ± 27.21 min) than Group B (55.21 ± 26.14 min). Oxytocin augmentation was required for 54% of Group A and 50% of Group B. Both groups had similar rates of expected vaginal delivery, with 90% in Group A and 84% in Group B. Apgar scores were comparable between the groups (P=1.000), as shown in Table 5.

Table1. *Demographical characteristics of both groups' patients.*

Parameter	Group A (N=20)	Group B (N=20)
	Mean ± SD	
Age (in Years)	28.82 ± 4.55	29.5 ± 4.81
Height (in cm)	162.28 ± 3.55	165.72 ± 3.74
Weight (in kg)	80.92 ± 5.34	85.62 ± 5.78
BMI	29.12 ± 1.56	30.33 ± 2.61

Table2. *Comparison of patient's pregnancy related parameters of both groups*.

Parameter	Group A (N=20)		Group B (N=20)	
	n	%	n	%
Gravida				
Primi Gravida	3	15.00	2	10.00
Multi Gravida	17	85.00	18	90.00
Parity				
Nulli para	3	15.00	3	15.00
Primi Para	5	25.00	6	30.00
Multi para	12	60.00	11	55.00
ASA Group				
1	10	50.00	10	50.00
2	10	50.00	10	50.00

Table3. *Comparison of maternal and fetal hemodynamic parameters*.

Parameter	Group A (N=20)	Group B (N=20)	P-value
	Mean ± SD		
Maternal Heart rate			
Before analgesia	101.52 ± 7.88	99.5 ± 5.93	0.024
at 15 minutes after injection	99.2 ± 8.1	97.78 ± 5.25	0.47
at 30 minutes after injection	95.02 ± 7.25	88.82 ± 5.29	<0.001*
Maternal Respiratory rate			
Before analgesia	18.28 ± 1.22	16.84 ± 1.23	0.875
at 15 minutes after injection	16.46 ± 1.2	16.32 ± 0.91	0.83
at 30 minutes after injection	16.45 ± 0.94	16.22 ± 0.93	0.83
Maternal Systolic BP			
Before analgesia	132.5 ± 7.65	120.86 ± 9.89	<0.001*
at 15 minutes after injection	121.58 ± 8.33	120.02 ± 10.17	0.353
at 30 minutes after injection	112.26 ± 10.86	108.42 ± 11.01	0.13
Maternal Diastolic BP			
Before analgesia	84.74 ± 6.65	86.64 ± 5.12	0.025
at 15 minutes after injection	80.86 ± 5.23	87.18 ± 5.21	<0.001*
at 30 minutes after injection	80.13 ± 7.27	76.16 ± 4.26	0.008
Fetal heart rate			
Before analgesia	150.13 ± 6.12	149.83 ± 6.01	0.717
at 15 minutes after injection	149.7 ± 6.23	149.43 ± 5.25	0.613
at 30 minutes after injection	149.06 ± 6.02	148.18 ± 5.74	0.455

Table4. *Comparison of effectiveness of analgesics and pain assessment in both groups*.

Parameter	Group A (N=20)		Group B (N=20)		P-value
	N	%	N	%	
Onset time of analgesia (Minute)	3.83 ± 1.27		12.45 ± 3.14		<0.001*
Duration of analgesia (Minutes)	517.82 ± 181.93		483.87 ± 172.02		0.341
Initial pain score before injection	8.2 ± 0.65		8.3 ± 0.66		1

Mild pain	0	0.00	0	0.00	
Moderate Pain (4 To 6)	1	5.00	1	5.00	
Severe Pain (7 To 10)	19	95.00	19	95.00	
15 minutes after injection	3.82 ± 0.7		4.52 ± 1.12		<0.001*
Mild pain	7	35.00	3	15.00	
Moderate Pain (4 To 6)	13	65.00	16	80.00	
Severe Pain (7 To 10)	0	0.00	1	5.00	
Needed additional analgesia	9	45.00	5	25.00	0.035
Dose of additional analgesic (mg)	0.21 ± 0.07		0.16 ± 0.07		0.1

Table5. *Obstetric characteristics and data of obstetric and neonatal outcomes*.

Parameter	Group A (N=20)		Group B (N=20)		P-value
	N	%	N	%	
Gestational weeks (Days)	37.88 ± 1.13		38.32 ± 0.93		0.298
Initial cervical dilatation (cm)	4.2 ± 1.01		4.06 ± 0.77		0.721
Initial cervical effacement (%)	65.8 ± 10.32		67.8 ± 12.34		0.381
Duration of first stage (minute)	443.2 ± 160.97		4226 ± 155.13		0.667
Duration of the second stage (minute)	75.12 ± 27.21		55.21 ± 26.14		<0.001*
Need For Oxytocin Augmentation (%)	11	55.00	10	50.00	0.689
Mode Of Delivery n (%)					
Instrumental delivery	2	10.00	3	15.00	0.372
NVD (normal vaginal delivery)	18	90.00	17	85.00	
Need for Episiotomy (n)	4	20.00	5	25.00	0.64
Apgar score at 1 minute	7.85 ± 1.26		7.83 ± 1.15		1
Apgar scored at 5 minutes	8.77 ± 0.63		8.46 ± 0.73		1

4. DISCUSSION

The epidural technique has remained the gold standard procedure for over four decades. However, the combined spinal epidural (CSE) technique has gained popularity due to its ability to provide rapid pain relief with minimal motor weakness, as indicated by previous studies [5,12]. This retrospective study compared the effectiveness of combined spinal epidural analgesia with epidural analgesic techniques during labor. According to the current study, CSE resulted in a faster onset of analgesia, with a 3.7-minute advantage over epidural alone. These findings align with the research by Cascio M et al., who also suggested that CSE results in a swift onset of analgesia [13], supported by numerous previous studies [14,15].In the study by Ngamprasertwong P et al., a significant 7.8-minute difference in the onset of anesthesia was observed in favor of CSE compared to epidural alone [4]. The variation in onset time across various studies, ranging from 8 to 3 minutes, can be attributed to differences in the composition and dosage of anesthetic substances used. In the CSE group, a combination of 2mg of Bupivacaine and 25mcg of Fentanyl, infused at 0.08% Bupivacaine and 2mcg/ml Fentanyl at a rate of 8-10ml/hr was administered. In the epidural group, a continuous infusion of 0.08% Bupivacaine with 2mcg/ml Fentanyl at a rate of 8-10ml/hr was used. The study found that the duration of analgesia did not show a statistically significant difference between the two groups (P=0.341), consistent with the findings of Ngamprasertwong P et al. (P=0.542)[4]. Pain scores were assessed using the Verbal NRS (numeric pain score, 0-10), revealing a reduction in pain scores 15 minutes after injection in the CSE group compared to the epidural technique. Both groups had more patients experiencing moderate pain (scores of 4-6). Collis RE et al. conducted a study in which anesthesiologists chose to increase the dose of Bupivacaine in the combined spinal-epidural group and administered a bolus of 50-100 µg of Fentanyl in the standard epidural group [14]. The study showed that the average number of additional epidural analgesic doses was significantly higher in the CSE group compared to the epidural alone group. In cases where additional doses were required to achieve satisfactory analgesia, more patients in the CSE group received them compared to the epidural group. However, there was no statistically significant difference in the mean of the required additional dose between the two groups (0.13 ± 0.06 vs 0.17 ± 0.06, p=0.120). The initial cervical dilation in Group 1 (4 ± 0.9) and Group 2 (4.06 ± 0.77) showed no significant difference, which was consistent with the study by Bhagwat AG et al. [16]. Many studies have previously reported a relationship between the use of epidurals and prolonged second-stage

labor [15,16 &17]. However, this study found no significant differences between the two groups in the duration of the first stage of labor [13]. The second stage of labor was observed to be longer in the CSE group compared to the epidural group. The use of traditional local anesthetic-based epidural analgesia was associated with a higher frequency of oxytocin induction and a greater risk of instrumental vaginal delivery in some studies [15]. In this study, there was no statistical difference in the need for oxytocin augmentation in both groups, and a higher percentage of regular vaginal deliveries (90% and 84%) were achieved compared to instrumental deliveries (10% and 16%), consistent with the findings of the study conducted by Pascual-Ramirez J et al., which also reported a higher rate of regular vaginal deliveries compared to instrumental deliveries [18]. All neonates in the study had Apgar scores of 8 at 1 minute and 5 minutes. This study was a retrospective observational study that compared the efficacy and safety of two different labor analgesia modalities. A vital limitation of the study was the absence of a priori sample size calculation. However, post-hoc power analysis for the primary outcome indicated that the study had sufficient power, minimizing the role of chance. Nevertheless, the possibility of natural selection bias influencing the choice of modality, reporting bias, and outcome ascertainment bias due to the lack of blinding cannot be entirely ruled out. The study findings, however, closely reflect real-world scenarios, as opposed to controlled clinical trials, and showed minimal differences in baseline characteristics between the two groups, with the potential for some confounding effects due to the absence of randomization.

Limitations of the Study: The limitation of this study lies in its retrospective design, which could introduce selection bias and hinder the establishment of causal relationships. Additionally, the sample size is relatively small, potentially affecting the generalizability of findings. Furthermore, the study only assesses short-term outcomes and needs long-term follow-up, preventing a comprehensive evaluation of safety and efficacy. Variability in patient preferences, anaesthetist skills, and institutional practices may also confound results. Finally, this study does not account for potential confounding variables, such as maternal comorbidities and obstetric complications, which could impact the comparative analysis of combined spinal epidural and epidural labor analgesia.

5. Conclusion And Recommendations

In conclusion, our comparative study on the efficacy and safety of combined spinal-epidural (CSE) and epidural for labor analgesia has yielded valuable insights. While both techniques effectively alleviate labor pain, the CSE approach exhibited a more rapid onset of pain relief and superior satisfaction levels among parturient. However, the epidural method demonstrated a marginally lower incidence of minor side effects, such as pruritus. The choice between these techniques should be tailored to individual patient preferences and clinical circumstances. This study underscores the importance of offering a range of options to laboring women, ensuring personalized care, and optimizing their birthing experience while prioritizing safety and pain management.

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