Comparison of motor block in continuous epidural infusion *vs* intermittent epidural bolus using bupivacaine with fentanyl for labour analgesia

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Abstract

This study aimed to compare the motor blocking effect of Continuous Epidural Infusion (CEI) *vs* Intermittent Epidural Bolus (IEB) for labour analgesia using bupivacaine 0.0625% and fentanyl 4 µg/mL. Sixty primigravida patients were divided into groups of 30 that received a loading dose of 10 mL of 0.0625% bupivacaine and 4 µg/mL fentanyl in 5 mL with subsequent continuous infusion or intermittent boluses. Motor block level, blood pressure, heart rate, pain severity, maternal satisfaction, and neonatal Apgar scores were noted. All 60 participants completed the study. There were no statistical differences between the groups in Bromage score (p=0.837), Visual Analog Scale (VAS) (p=0.482). The incidence of hypotension was 15% and 0% in groups I and II, with a p-value of 0.036. APGAR scores were >7 in both groups. Analgesia was rated satisfactory by 70% and 63% of the participants in groups I and II, respectively (p<0.736). Labour analgesia was achieved with a minimal motor block in both groups. Hemodynamic parameters, pain score, Apgar scores, and maternal satisfaction were similar in both groups.

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Introduction

The use of epidural analgesia during childbirth is the gold standard as it provides adequate pain relief in both stages of labour. The use of a low concentration of local anesthetic combined with lipid-soluble opioids provides optimal analgesia without delaying the progression of labour or affecting the mode of delivery and neonatal outcomes.[1]

The mode of delivery is affected by the extent of the motor block, which in turn depends on the type, concentration, and method of administration of local anesthetic, along with the total consumption. The motor blockade affects the pelvic muscle tone, and the ability to "bear down" during the second stage of labour, which directly affects the duration of labour, and instrumental deliveries.[2]

The current standard labour epidural analgesic regimens consist of a local anesthetic in combination with an opioid delivered via Continuous Epidural Infusion (CEI) with or without Patient-Controlled Epidural Analgesia (PCEA) boluses. It has been observed that epidural bolus doses delivering the local anesthetic in comparison to continuous infusion lead to a more extensive spread of the drug in the epidural space and hence, more sensory blockade.[3,4] Therefore, administration of the drug in regularly spaced intervals can help reduce the dose of local anesthetics. However, clinical data show varied results and do not support or disprove the hypothesis regarding the wider spread of local anesthetic solution by intermittent bolus technique as the main mechanism of reduced analgesia consumption.[4-6]

In most literature, a bupivacaine dose of ≥0.1% was used, and that may have contributed to the increased incidence of motor block reported with continuous infusion. Thus, we have formulated a study to compare the efficacy of continuous epidural infusion with intermittent bolus doses for labour analgesia using a combination of low concentration of bupivacaine (0.0625%) and higher concentration of fentanyl (4 mcg/mL) to compare their effect on lower limb motor blockade as the primary outcome and the sec-

ondary outcomes were: pain score, maternal side effects, fetal Apgar score, and maternal overall satisfaction.

Materials and Methods

After approval by the medical ethics committee, this prospective randomized study was carried out on 60 para one and two hemodynamically stable patients (Figure 1). Written informed consent was taken from all patients. Inclusion criteria were ASA grade II parturients between 18-30 years of age, healthy term pregnancy who were in an active stage of labour with vertex presentation. Patients not giving consent, patients with systemic hypertension, pregnancy-induced hypertension, preeclampsia, eclampsia, diabetes mellitus, heart disease, previous Lower Segment Cesarean Section (LSCS), or an absolute indication for LSCS, allergy to study drugs, coagulopathy, infection at the site of epidural catheter insertion, evidence of spinal cord injury, and those with extremes of body weight or height were excluded.

After complete preoperative evaluation of the patients through history, examination, investigation, and obstetric consultation, all the patients were monitored for pulse rate, blood pressure, respiratory rate, and fetal heart rate. The procedure was started in the first stage of labour, with regular uterine contractions and cervical dilation of less than 4 cm. In every patient, intravenous access was achieved with an 18G peripheral cannula, and each patient was preloaded with 10 mL/kg body weight Ringer's lactate solution before induction of epidural analgesia. With proper aseptic precautions, under local anaesthesia (2% lignocaine), epidural space was identified with loss of resistance to air technique at L3-4 or L4-5 intervertebral space using an 18G Tuohy needle (Romsons Group, Delhi, India). Thereafter, a multi-hole epidural catheter was placed 4-5 cm in the epidural space. To exclude intravenous or intrathecal catheter placement, a test dose of 3 mL of 2% lignocaine with 1:200000 epinephrine (CignokenTM ADR 2%, Celon Labs, Hyderabad, India) was administered after negative aspiration for Cerebrospinal Fluid (CSF) and blood. If no toxicity reaction appeared, epidural analgesia was started. All patients were divided into two groups according to a computer-generated random number table. All the patients were given a 10 mL bolus of 0.0625% bupivacaine + 4 µg/mL fentanyl in 5 mL incremental doses while monitoring blood pressure and heart rate. Group I received a continuous epidural infusion of 0.0625% bupivacaine + 4 µg/mL fentanyl at 10 mL/hour, while Group II received 10 mL 0.0625% bupivacaine + 4 µg/mL fentanyl in bolus form every hour manually. The first dose was given one hour after the initial loading dose. Patients in both groups were given a rescue bolus dose of 5 mL of 0.0625% bupivacaine + 4 µg/mL fentanyl if they complained of breakthrough pain (VAS score >3).

After giving the drugs, we checked the level of analgesia by pinpricking using a 23G needle in the midline from the suprapubic region every five minutes till the maximum level was achieved. VAS score was used to assess the severity of pain before the block and at 15, 30, 45, and 60 min and then at 30 min intervals. VAS was measured on a 0-10 scale where no pain was considered as 0, and the worst possible pain experienced was taken as 10. Motor block was assessed bilaterally using the Breen's modified Bromage scale.[7] Motor block was assessed after the achievement of maximum sensory block and then at hourly intervals. Maternal heart rate, blood pressure, and oxygen saturation were measured non-invasively every five minutes for 15 minutes, then every 15 minutes for 45 minutes, then every 30 minutes for 180 minutes or delivery of fetus whichever was early. Bradycardia (heart rate less than 50 per minute) was treated with 0.5 mg atropine intravenous injection, which was repeated as needed. Any hypotension (Systolic Blood Pressure, SBP, <90mmHg, or Mean Arterial Pressure, MAP, <65 mmHg) was treated by intravenous infusion of normal saline and intravenous injection of ephedrine 1.5 mg, which was repeated if needed. After delivery, neonatal Apgar scores at one minute and five minutes and overall maternal satisfaction using Likert's scale were noted.

Statistics and sample size

Data were analysed using the Statistical Package for Social Sciences (SPSS) version 23 (IBM Corp., Armonk, NY). A chi-square test was used to compare categorical data. A Student's t-test was used to compare the continuous variables of the two groups. A $p<0.05$ was considered statistically significant. The sample size was calculated to be 28 in each group on the basis of variation in mean doses of two drugs to achieve similar VAS from a previous study.[8] So, in our study, we included 30 in each group with the possibility of a few dropouts. The following formula was used to calculate the sample size.

$$n=(za + zb)2\ (s12 + s22)/d2$$

where s1=3.88, the Standard Deviation (SD) of the first group dose to achieve similar VAS; s2=4.30, the SD of the second group dose to achieve similar VAS; d= the minimum mean difference considered to be clinically significant was assumed two; type I error α was taken 5% corresponding to 95% confidence level and type II error β was taken 10% for detecting results with 90% power of the study.

Results

The demographic profiles of the patients in both groups were comparable with regard to age, body weight, and height ($p>0.05$) (Table 1).

This degree of motor blockade is depicted in Table 2. The mean Bromage score was 5.63±0.19 and 5.62±0.13 in the CEI and IEB groups, respectively, which was not statistically different, with a p-value of 0.837.

Table 3 showed the duration of stages of in both group which were statistically not significant. It also showed the neonatal birth weights and Apgar scores of both groups which were also not significant. At baseline, all the hemodynamic parameters and VAS scores of the two groups were comparable. The mean cervical dila-

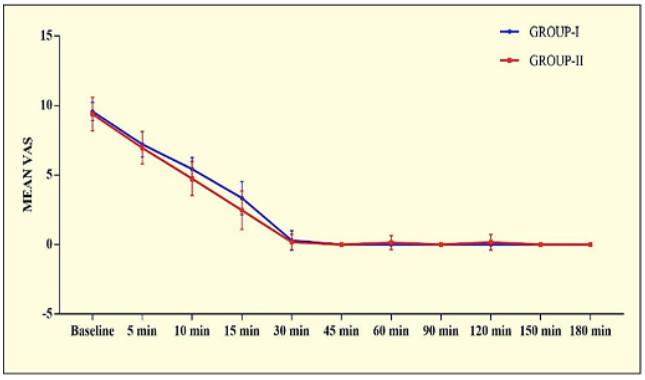

Figure 1. Graphical presentation of mean Visual Analog Scale (VAS) score in both groups.

tion at the onset of labour of patients of Group CEI and Group IEB were 2.53±0.37 cm and 3.01±0.22 cm, respectively. The mean difference was statistically insignificant (p=0.1587). Sensory level up to T-10 was achieved in all patients. After administration of the loading dose, there was a progressive decrease in VAS, and VAS remained comparable in both the groups till delivery except at 10 min (p=0.0075) and 15 min (p=0.0062) (Figure 1).

On comparing heart rates, both groups had a gradually decreasing trend from the baseline till 1 hour, after which it became relatively stable till delivery. There was no statistically significant difference between the two groups (p>0.0005). Both groups showed a gradually decreasing trend in SBP, DBP, and MAP that stabilized after 30 min of initiation of infusion and remained so till delivery. No significant inter-group difference was observed at any time interval (p>0.05) (Figures 2 and 3).

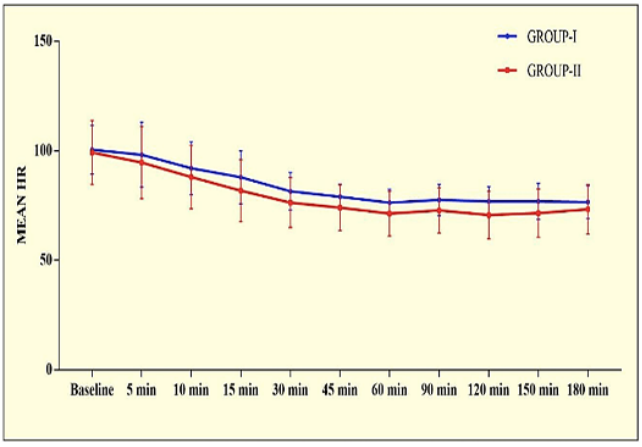

Figure 2. Graphical presentation of mean heart rate in the study population.

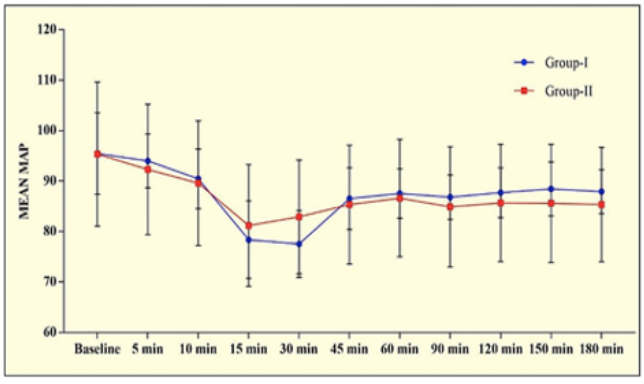

Figure 3. Graphical presentation of mean Mean Arterial Pressure (MAP) (in mm of Hg) in the study population.

Discussion

Our study compared the effect of CEI with intermittent bolus techniques in labour analgesia using bupivacaine with fentanyl as an adjuvant on the motor function of parturients. We observed in this study that there was no statistically significant difference in the incidence of motor blockade in both groups (p=0.837). There was only minimal degree of motor block in the two groups, with a mean Bromage score of 5.63±0.19 in the CEI and 5.62±0.13 in the IEB group. A transient motor block of less than 5 was detected in 2 parturients of the IEB group after administration of the initial bolus dose, but that was not significant enough to prevent ambulation during the first stage of labour nor parturients' ability to bear down in the second stage of labour. The finding of this study was similar to that of Fidkowski *et al*.,[9] who compared motor function in three groups of parturients that had epidural analgesia maintained with intermittent boluses of either 5 mL every 30 mins or 10 mL every hour of epidural solution in two groups and with 10 mL continuous infusion of the same solution (CEI) in a third group. They found no statistically significant difference in the

Table 1. Demographic characteristics of participants.

Variable	CEI (n= 30) Mean±SD	IEB (n=30) Mean±SD	t-value	p
Age (yrs)	26.25±4.19	25.10±3.82	0.907	0.370
Weight (kg)	78.45±8.96	73.0±10.77	1.73	0.090
Height (m)	1.68±0.03	1.67±0.05	0.527	0.600
BMI (kg/m^2)	27.79±2.9	26.03±3.22	1.806	0.079

CEI, continuous epidural infusion; IEB, Intermittent epidural bolus; BMI, body mass index; SD, standard deviation.

Table 2. Degree of motor block as measured by modified Bromage score.

Variable	CEI group Mean±SD	IEB group Mean±SD	t-value	p
Degree of motor block	5.63±0.19	5.62±0.13	0.208	0.837

CEI, Continuous epidural infusion; IEB, intermittent epidural bolus; SD, standard deviation.

Table 3. Tabular presentation of the duration of stages of labour, neonatal birth weight, and Apgar scores in both groups.

	Group-I (N=30)	Group-II (N=30)	t-value	p
Birth weight (kg)	2.60±0.40	2.47±0.47	1.246	0.2170#
Apgar at 1 min	6.8±0.8	6.63±1.15	0.7179	0.4753#
Apgar at 5 min	8.6±0.6	8.28±1.18	0.5363	0.5935#

#non-significant.

mean Bromage score in all three groups. However, a significant motor blockade was recorded in 11.6% and 14.7% of patients in the group that received 10 mL of local anesthetic hourly and CEI group respectively. None of the patients in the two groups of this present study had a significant motor block. The disparity in the results might be due to the higher dose of Local Anesthetic (LA) (0.125%) used in the Fidkowski *et al*.[9] study as opposed to the low dose of LA (0.0625 %) used in our study.

In another similar study, Wong *et al*.[10] also did not find any significant difference in the degree of motor blockade in the two groups of patients that had an epidural mixture administered as either IEB or CEI. Furthermore, a very low incidence of motor blockade was observed in each group, with only one patient each in the IEB (1.9%) and CEI (1.85%) groups. This similarity in trend and degree of motor block between their study and this present study could be a result of the low concentration of bupivacaine (0.0625 %) used in the two studies. Tiens *et al*.[11] also demonstrated that there is no difference in the incidence of motor blockade between two groups of patients that had an epidural mixture (containing 0.125 % bupivacaine +2 µg/mL fentanyl) administered via IEB versus CEI and no significant degree of motor blockade in any patient in both groups. The similarity in the trend of the motor block between their study and this study, despite conflicting concentrations of bupivacaine, could be attributable to the difference in volume administered. They used 5 mL/hr in CEI, 5 mL/60 minutes in PIEB, and 3 mL/30 minutes in PIEB. Tiens *et al*.,[11] Fettes *et al*.,[12] and Lim *et al*.,[13] similar to the findings of this study, found no significant difference in the incidence of motor block when an epidural mixture containing 0.1% ropivacaine (2 mg/mL) was administered via intermittent boluses or continuous infusion ($p>0.05$). However, in a study by Shidhaye *et al*.,[14] bupivacaine (0.2%) + fentanyl 0.5 µg/mL was used to maintain labour analgesia via continuous infusion of 10 mL/hr or as 6-10 mL of the same drug as intermittent boluses on patient's demand and no difference in the motor block was observed in both groups. The incidence of motor block in both groups was observed to be low, which is in keeping with the findings in this study. However, the volume of their drug was titrated to the degree of motor blockade, which could have been responsible for the low incidence of motor block despite the high concentration of bupivacaine.

Contrary to the observation in this present study, Capogna *et al*.[15] demonstrated a significant difference in motor block (37% *vs* 2.7%) in parturients in their CEI group when compared to the IEB group, reported a Bromage score of <6 while using a concentration of 0.0625% levobupivacaine +0.5 µg/mL of sufentanil. In contrast to this present study other studies demonstrated more motor blocks in their CEI group also.[16,17] The higher incidence of motor block may be attributed to the increased need for top-up boluses in the CEI groups, especially at the second stage of labour, probably due to the low concentration of opioids used to enhance the analgesic effect of the low-concentration local anesthetic. In this study, the concentration of local anesthetic used was similar to that used by Capogna *et al.,*[15] but the concentration of fentanyl was higher. The high opioid concentration in this present study may have improved the quality of pain control and reduced the need for frequent top-up boluses, consequently reducing the incidence of motor block.

In comparing VAS, we found that in both groups, the VAS was not significantly different in both groups, with the onset of analgesia achieved within 20 minutes of the loading dose. However, the mean onset was significantly faster in group I. We defined the onset of analgesia as the time from epidural drug injection to the time of recording a VAS≤ 3. VAS was comparable in both groups in our study at all times till delivery except at 10 and 15 minutes; however, this difference was not significant statistically. The rate of spontaneous vaginal deliveries, forceps, ventouse, and LSCS in the two groups was comparable, with no statistically significant difference. There was no significant difference in the duration of the first and second stages of labour, which remained normal in both groups. The Apgar scores of the neonates were similar and within the normal range in both groups. Overall, only one neonate in group I had NICU admission due to a low birth weight of 1.5 kg. On comparing hemodynamic parameters, HR, SBP, DBP, and MAP all showed a gradually decreasing trend after the loading dose that stabilized by 30 min and remained so till delivery in both groups. None of the patients had bradycardia. We preloaded the patients to avoid the incidence of hypotension, which was sufficient to avoid the incidence of transient sympathectomy-induced hypotension.

The level of satisfaction in our study was high in both groups. However, 75 % of the parturients were very satisfied in the CEI group against 65 % in the IEB group, but that was not statistically significant, and none of the parturients in the study was dissatisfied with the labour analgesia. The results in this study were similar to that reported by Sindhaye *et al*.,[14] who reported improved satisfaction in the CEI group (90% high satisfaction) compared to the IEB group, who reported 60% high satisfaction which was significant ($p<0.005$), in their study the significant difference in maternal satisfaction may be attributed to variation in the volume of epidural drug administered in the two techniques and also the time of administration of intermittent boluses which was administered on demand and may have been associated with intermittent pain surge hence the lower satisfaction in the group PIEB. Other studies by Joana *et al*.,[13] Lakshmi *et al*.,[18] and Lim *et al*.[16] comparing intermittent bolus and continuous infusion techniques of maintaining epidural labour analgesia despite using different local anesthetic agents and opioids and volumes had similar conclusions in terms of maternal satisfaction. The high level of satisfaction in our study may be a result of the effect of the high concentration of fentanyl (4 µg/mL) as against the 2 µg/mL of fentanyl used in most studies.[10,19] The high dose may have resulted in increased availability of the opioid with superior spinal and central analgesic effect despite the low concentration of local anesthetic used. Furthermore, all participants in this study were multipara, hence their previous experience of labour pain may have influenced the level of satisfaction they reported.

Conclusions

Both continuous epidural infusion and intermittent epidural boluses were effective for providing labour analgesia without any significant effect on hemodynamics. Both continuous infusion and intermittent bolus of 0.0625% bupivacaine and 4 µg/mL of fentanyl provided similar and acceptable motor blockade, adequate analgesia resulting in similar maternal satisfaction, and similar maternal and fetal cardiorespiratory stability. Both techniques have comparable and safe modes of delivery and fetal outcomes when used for epidural labour analgesia.

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