Section: Anaesthesia

Original Research Article

A RANDOMISED CONTROL TRIAL COMPARING CONTINUOUS EPIDURAL INFUSION VERSUS INTERMITTENT EPIDURAL BOLUSES OF 0.2% ROPIVACAINE AND FENTANYL FOR EPIDURAL LABOUR ANALGESIA

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ABSTRACT

Background: Regular intermittent epidural bolus technique although is recognised technique of producing good analgesia, availability of infusion pumps administrating continuous infusion has been came into routine. Hence both techniques need to be evaluated for efficacy in producing analgesia.

Materials and Methods: This was double blind randomized trial which enrolled 52 primigravidae and had lumbar catheter insertion for labour analgesia and received ropivacaine and fentanyl combination till T10 sensory block was achieved. After initial bolus of 10 ml, parturients were given as intermittent boluses or continuous infusion. Parturients were assessed for analgesia, sensory and motor block, total amount of local anaesthetic solution required, rescue doses, maternal satisfaction and neonatal wellbeing.

Results: Two groups had no differences in patient characteristics, maternal and neonatal outcome and sensory-motor block. However, total amount of local anaesthetic required and rescue doses required were higher in continuous infusion group. Duration of analgesia was better in intermittent boluses group.

Conclusion: As parturients in intermittent boluses group required less volume of drug and lesser rescue boluses to achieve similar analgesia compared to continuous infusion technique, intermittent bolus technique remains more effective technique for labour analgesia.

INTRODUCTION

Neuraxial anaesthesia particularly epidural anaesthesia remains popular technique for pain relief in parturient undergoing labour. Epidural administration of drug involves two techniques which includes intermittent boluses administration or continuous infusion with intermittent boluses for breakthrough pain.[1,2] Historically, regular administration of epidural boluses is well recognised and simple technique with more efficacy than continuous epidural administration. Despite knowing this fact, continuous technique became widely used technique as it provides consistent analgesia, better patient satisfaction and decreases workload of anaesthesiologists. However, it is also associated with some disadvantages like increase consumption of local anaesthetics which may cause motor block reducing bearing down efforts of parturient during second stage of labour. Reduced muscle tone also increases chances of shoulder dystocia and instrumental delivery.[3,4]

There are many studies conducted in the other countries; however, these kinds of studies are less in Indian scenario. Hence, we aimed to compare continuous epidural infusion versus intermittent epidural boluses of 0.2% ropivacaine and fentanyl for epidural labour analgesia. Our primary objectives were to compare efficacy of two techniques by comparing VAS scores at various intervals, incidence of breakthrough pain and requirement of ropivacaine. Our secondary objectives were to assess level of sensory block,

motor block, degree of maternal satisfaction, mode of delivery and neonatal outcome.

MATERIALS AND METHODS

It was a prospective, randomised double blind study enrolling 52 primiparous, parturients with singleton pregnancy of 36-42 weeks with vertex presentation with active labour with cervical dilatation of 3 -4 cm in 18-30 years of age group.

Study was conducted in tertiary care institute after obtaining institutional ethics committee approval during period of June 2022 to December 2024. This study was conducted in accordance with Good Clinical Practice and in a manner to conform to the Helsinki Declaration of 1975, as revised in 2013 concerning human rights. Well-being and safety of patients were maintained during study.

Patients were randomly allocated in two groups of 25 each using block randomisation and computer-generated sequence. Patients refusing to give consent, allergic to local anaesthetic, local site infection, bleeding diathesis, ASA 3 or more (pregnancy induced hypertension, preeclampsia, eclampsia, heart disease) bad obstetric history, foetal and placental abnormality, previous lower segment section (lscs) or any absolute indication for lscs, having cephalopelvic disproportion were excluded.

Patients were evaluated preoperatively including detailed airway examination and investigated according to institutional protocol. Study protocol was explained to patient and written informed consent was obtained. Patient was explained about VAS scale preoperatively. NPO status and consent was checked. Sips of water and clear liquids were allowed, an iv line was secured and RL was started. Patients were attached with standard monitors including ECG, SPO2, NIBP, ETCO2, temperature probe and baseline parameters were recorded.

With proper aseptic precautions, under local anaesthesia (2% lignocaine), epidural space was identified with loss of resistance to air technique at L3-4 orL4-5 intervertebral space using 17G Tuohy needle and multi-hole 19 G epidural catheter was placed 4-5cm in the epidural space. Occlusive dressing was applied. The patient was turned supine with a pillow under her right buttock to provide left uterine displacement. A test dose of 3 ml of 2% lignocaine with 1:200000 epinephrine was administered after negative aspiration for cerebrospinal fluid and blood. If no adverse reaction appeared for 5-10 minutes, labour epidural analgesia was initiated. All the patients were given a initial epidural bolus dose of 10 ml of 0.2% ropivacaine +1µg/ml fentanyl while monitoring blood pressure and heart rate. Hemodynamic parameters were assessed every 5 minutes for 15 minutes and then at 15-minute intervals.

Level of analgesia was assessed by pinprick using a 23G needle in a mid- clavicular line, every five minutes till the maximum level is achieved. Motor block was assessed bilaterally using the modified Bromage scale at hourly intervals. The onset of analgesia was defined at time taken for parturients to achieve T10 sensory block. The time of maximum analgesia was defined as the time from epidural drug injection to the time of recording a VAS ≤ 3 during active uterine contraction. After 30 minutes of initial bolus epidural dose, parturient was shifted to the labour ward under supervision where multipara monitor including heart rate, non-invasive blood pressure and oxygen saturation were attached. These parameters were assessed at regular intervals of 15 minutes. FHS were also monitored in 15-minute intervals using foetal doppler.

At 1 hour, patients received interventions according to their group allocation based on computerized randomization. Epidural catheter ports of parturients who were randomised to group CEI were connected to syringe infusion pump (Fresenius Kabi Infusia SP7) containing 50 ml of 0.2% ropivacaine+ 1 mcg/ml fentanyl (50 mcg fentanyl). Continuous epidural infusion at the rate of 10ml/hour was started at 1 hour mark. (n= 25) Parturients who were randomised to Group IEB received intermittent epidural bolus dose of 5 ml 0.2% Ropivacaine with 1 mcg/ml fentanyl every hour manually/ when patient complains of breakthrough pain (VAS>3). (n= 25)

First bolus dose of 5 ml 0.2% ropivacaine+1 mcg/ml fentanyl was given one hour after the initial loading dose in intermittent epidural bolus group irrespective of VAS. Maternal heart rate, non-invasive blood pressure, and oxygen saturation was measured every five minutes for 15 minutes, then every 15 minutes till delivery of foetus. Patients were assessed at every 15 minutes for VAS score. Patients in both groups were given a rescue bolus dose of 5ml of 0.2% Ropivacaine and 1 mcg/ml fentanyl if they complain of breakthrough pain (VAS score >3). At the time of crowning, an additional 5ml bolus dose was given in both groups. Motor block was assessed after the achievement of maximum sensory block and then at hourly intervals. The total dose of local anaesthetic required, and the number of boluses needed for breakthrough pain (VAS>3) in both the groups were noted. Duration of the second stage of labour, mode of delivery in the form of normal vaginal delivery or instrumental delivery or LSCS was noted. Further, complications including nausea, vomiting, pruritus, hypotension, bradycardia, difficulty in breathing were noted. Neonatal APGAR score at one minute and five minutes as well as maternal satisfaction at 24 hours were noted. Hypotension (≥20% decrease in systolic blood pressure) was treated with i.v. boluses of mephenteramine 6 mg and bradycardia (HR <60/min) was treated with Inj. atropine 0.6 mg i.v.

RESULTS

We enrolled 60 patients in study out of which 50 continued study and 10 withdrawn due to study protocol violation and inadequate analgesia. In all,50 patients, were grouped into two categories to receive said intervention. There was no statistically significant difference amongst two groups with regard to demographic data (Table 1), obstetric characteristics and foetal outcome. [Table 6]

Table 1: Comparison of Demographic parameters in Two Groups

Parameter	Group CEI (Mean±SD)	Group IEB (Mean±SD)	P value
Age (years)	26.80 ± 3.34	25.19 ± 2.99	0.9187
Height(cm)	159.5 ± 3.54	159.5 ± 1.820	0.81
Weight (kg)	67.88 ± 4.32	67.59 ± 4.72	0.27
Gestational age (weeks)	39.30 ± 1.40	39.00 ± 1.20	0.40
Cervical dilatation (in cms)	2.7± 1.2	2.7 ±1.0	0.85
Duration of epidural (minutes)	270.2 + 62.19	262.3 + 51.19	0.53
Site of insertion of epidural catheter **L_3-L_4(%)** **L_4-L_5 (%)**	 14(56%) 11(44%)	 15(60%) 10(40%)	0.719
Time to achieve T10 sensory level in minutes	13.88±1.64	13.28 ±1.81	0.0959

(p- value <0.05 is considered significant)

Sensory spread (analgesia to pinprick) and motor block (Bromage score Table 2) were similar in the two groups. None of the patients in either group developed unilateral block defined as difference of at least two levels on the Bromage. Hemodynamic changes were also small having no statistically significant difference in two groups.

Table 2: Comparison of sensory and motor block between parturients of Group-CEI and Group-IEB

Parameter	Group CEI (Mean±SD)	Group IEB (Mean±SD)	P value
Sensory Block **T_8**(%) **T_{10}**(%)	 4(16%) 21(84%)	 6(24%) 19(76%)	 0.8
Motor block (Modified Bromage scale) **0(%)** **1(%)**	 23(92%) 2(8%)	 25(100%) 0(%)	 0.5

(p- value <0.05 is considered significant)

After an initial bolus of 10 ml ropivacaine, pain relief was achieved in all patients (VAS 0-1) and sensory level of T10 was achieved. Although good pain relief was maintained in both groups, CEI group required a greater number of rescue boluses to maintain same degree of analgesia. (Table 3). Seven patients in group CEI required one bolus while 15 required two boluses. In contrast, IEB group required one bolus in 19 patients and only two patients required two boluses. This difference was statistically significant. Further, total amount of ropivacaine consumed was also higher in CEI group and was most significant finding of the study (Table 4).

Table 3: Comparison of no. of rescue doses required between parturients of Group-CEI and Group-IEB

No. Of rescue doses	Group CEI (Mean±SD)	Group IEB (Mean±SD)	P value
0	3(12%)	4(16%)	0.05
1	7(28%)	19(76%)	
2	15(60%)	2(8%)	

(p- value <0.05 is considered significant)

Table 4: Total ropivacaine dose consumed between parturients of group CEI and group IEB

Parameter	Group CEI (Mean±SD)	Group IEB (Mean±SD)	P value
Ropivacaine dose consumed(ml)	60.20 + 21.10	40.45 + 14.62	0.005

(p- value <0.05 is considered significant)

Table 5: Maternal satisfaction and foetal outcome

Parameter	Group CEI (Mean±SD)	Group IEB (Mean±SD)	P value
Apgar scores 1minute 5 minute	 8.6 ± 1.2 9.4 ± 0.3	 8.7 ± 1.3 9.5 ± 0.4	 1.00 1.00
Maternal satisfaction Excellent Good Average	 15(60%) 9(36%) 1(4%)	 20(80%) 5(20%) 0(0%)	 0.3

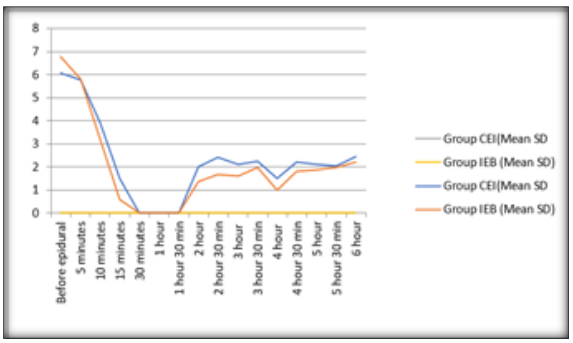
(p- value <0.05 is considered significant)

Maternal satisfaction during labour analgesia period was almost similar in two groups without any statistically significant difference.[Table 5] Further, mode of delivery as seen from table 6 had no significant difference in two groups. APGAR score was also comparable at 1 and 5 minutes. [Table 5]

Table 6: Mode of delivery in parturients of two groups

Parameter	Group CEI (Mean±SD)	Group IEB (Mean±SD)	P value
Caesarean	10(40%)	9(36%)	0.334
Vaginal	14(56%)	16(64%)	
Instrumental	1(4%)	0(0%)	

(p- value <0.05 is considered significant)



Graph 1: VAS Score at different time intervals in both groups

DISCUSSION

Our study demonstrated efficacy of regular intermittent epidural bolus injection technique (IEB) over continuous epidural infusion (CEI) technique. Intermittent epidural bolus technique needed less rescue doses and needed reduced epidural dose of drug with equivalent analgesia as that of continuous epidural infusion (CEI) technique using ropivacaine and fentanyl. This was also associated with good hemodynamic stability without increase in obstetric complications.

It's been observed that continuous epidural infusion (CEI) technique is common practice in most set ups despite knowing the fact that it is associated with early regression of sensory block needing rescue medications regularly and associated increase incidence of motor block.[5,6]

Hence, we decided to undertake this study particularly in our set up where high patient workload along with low doctor: patient ratio makes it difficult to provide labour analgesia. And those receiving labour analgesia, it is usually provided with CEI technique due to ease of providing it reducing workload of anestheiologist.[7]

Further, it has been suggested that bolus injection of local anaesthetics given with high pressure as done in IEB through multiorifice catheter leads to more uniform spread of drug throughout epidural space and sensory block produced is wider 8. As opposed to IEB technique, in CEI technique, solution exists at most proximal end of catheter which limits spread of drug.[9]

This was further supported by cadaveric dissection. Cryomicrotome sectioning found that large volume of liquid when injected with high pressure in epidural space, had uniform distribution of drug in space, along nerve sheaths and in the intervertebral foraminae.[10]

In our study, we preferred using ropivacaine as it has less cardiotoxic potential compared to bupivacaine and is less lipophilic which restricts its penetrability to larger myelinated fibres reducing possibility of motor blockade. Further, addition of fentanyl which has local anaesthetic sparing action in dose dependent manner reduces EC50 of ropivacaine.[11,12]

Most significant finding of our study was total dose of ropivacaine consumption which was less in group IEB compared to group CEI (40.45±14.62 ml vs 60.20±21.12 ml) and this difference was statistically significant. This is attributable to more uniform spread of large volume of drug when given with pressure in IEB technique compared to localised spread as occurs in CEI technique.[13]

We did not find any difference in spread of sensory blockade. Similarly, we didn't find statistically significant differences in two groups with respect to development of overall motor block. However, this difference might be expected. It is important parameter to evaluate as motor blockade may change mode of delivery. Pelvic floor becomes lax due to lumbosacral region blockade delaying foetal head rotation needing assistance in delivery. Further, pelvic sensation loss results in obtundation of Fergusson reflex which decreases maternal oxytocin secretion leading to reduced strength of contractions and bearing down effect during second stage of labour. In our study, mode of delivery in both groups was although similar, second stage of labour was significantly less in group IEB than in group CEI and difference was statistically significant.

One more important finding which needs to be mentioned is requirement of rescue doses which were relatively higher in CEI group and this was statistically significant. This may be a reason that we did not find any difference in degree of analgesia in both groups. Further, this was also reason for better maternal satisfaction in both groups. Although IEB group showed better maternal satisfaction score compared to CEI group, this difference was not significant statistically.

Metanalysis published in 2013 by George et al. analysed trials comparing programmed intermittent epidural boluses with continuous epidural infusion with or without patient-controlled epidural analgesia for labour analgesia. It was found that epidural

boluses were associated with better efficacy including reduced amount of local anaesthetic consumption, decreased duration of second stage of labour and better maternal satisfaction while mode of delivery, duration of labour and rescue doses were not much different.[14]

Fettes et al. in their study also found that IEB required lesser amount of total local anaesthetic and less rescue medication for same degree of analgesia and reduced motor blockade, further duration of analgesia was also longer as shown by lesser number of rescue doses required in IEB group. Both groups had stable hemodynamics. They reported that IEB technique to be better in providing labour analgesia. Our findings were consistent with the findings of this study.[15]

In our study we assessed APGAR score at 1 and 5 minutes to assess effects of opioids and local anaesthetics on foetus and both groups had comparable scores. Parturients in both groups were hemodynamically stable without need of any vasopressors or any other active intervention. This could be because of adequate hydration at beginning of epidural. We did not report incidence of any significant adverse effect in any group.

To conclude, our study showed intermittent bolus group required significantly less total amount of local anaesthetic solution, required less rescue doses, had shorter second stage of labour and better maternal satisfaction compared to continuous infusion group for same degree of pain relief, sensory and motor block. Further, less rescue doses indicate that duration of analgesia was better in intermittent bolus group. It can be stated that intermittent bolus technique causes more uniform spread of drug giving better sensory block than continuous infusion technique and hence should be able to reduce workload of anaesthesiologist.

However, large sample size is needed to study with inclusion of multigravidas into study population which may vary with their pain threshold.

CONCLUSION

As parturients in intermittent boluses group required less volume of drug and lesser rescue boluses to achieve similar analgesia compared to continuous infusion technique, intermittent bolus technique remains more effective technique for labour analgesia.

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