

Original Research Article

COMPARISON OF INTERMITTENT BOLUS DOSES WITH CONTINUOUS INFUSION OF ROPIVACAINE AND FENTANYL FOR EPIDURAL LABOUR ANALGESIA: A PROSPECTIVE RANDOMISED STUDY IN SHYAM SHAH MEDICAL COLLEGE REWA

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ABSTRACT:

INTRODUCTION: In India, labour analgesia is not routinely practiced, there is a need to educate the Indian population about benefits of labour analgesia. Pain relief in labour is complex and often challenging. There are many methods of pain relief during labour but Epidural analgesia is the most effective method of providing pain relief. This study was done to find a superior method of epidural analgesia by comparing intermittent bolus doses with continuous infusion of Ropivacaine (0.2%) and Fentanyl.

OBJECTIVES:

Primary objective – To compare the incidence of breakthrough pain (VAS \geq 3) in both the groups.

Secondary objective- To compare total consumption of drug, duration of labour, number of caesarean sections in between these two groups.

MATERIALS AND METHOD: We studied 70 patients who were scheduled for normal vaginal delivery and 35 patients each were divided into two groups.

Group A: Patients in this group received continuous epidural infusion of 0.2% Ropivacaine with Fentanyl at the rate of 10ml/hour

Group B: Patients in this group received 10ml 0.2% Ropivacaine with Fentanyl in bolus form manually. First dose 1 hour after initial bolus dose.

Patients in both groups were given bolus dose of 5ml 0.2% Ropivacaine (in titrated form) as rescue when patient complained of breakthrough pain (with VAS score \geq 3).

Data was compared with respect to hemodynamic parameters, number of episodes of breakthrough pain, total consumption of drug, duration of labour, number of caesarean section in between these two groups.

RESULT: We found that in between these two groups maintaining epidural analgesia intermittent epidural bolus resulted in significantly reduced incidences breakthrough pain, total dosage requirement and lower caesarean delivery rates.

CONCLUSION: We concluded that intermittent bolus doses are better than continuous epidural analgesia.

KEY WORDS: Labour pain, Normal vaginal delivery, Epidural analgesia

1. INTRODUCTION:

Labour pain induce a maternal stress response that is detrimental to both the fetus and the mother. Evidence suggests that stress due to labour pain causes problems such as maternal hypertension, meconium staining and fetal distress. Thus, maternal pain management benefits not only the parturient, but also her newborn.[1] There are various treatment modalities available for management of labour pain i.e., nonpharmacologic methods which includes psychoprophylaxis (Lamaze method), hydrotherapy, acupuncture, and hypnosis (hypnobirthing), transcutaneous electrical nerve stimulation (TENS) etc. Scientific assessment of these methods has yielded inconsistent results. These techniques tend to work early in the first stage of labour when the pain is least intense and may decrease pharmacologic use at that time[2]. Pharmacologic treatment options include parenteral opioids, regional analgesia (epidural, spinal, combined spinal-epidural, paracervical, caudal, and pudendal nerve blocks), and inhalational analgesia[3]. Epidural analgesia is thought to be the most effective method of providing pain relief in labour. According to Silva, Marcos, and Stephen H Halpern (2010), in first and second stages of labour epidural block gives significantly more analgesia than parenteral opioids evaluated by visual analogue scale[4]. Epidural analgesia involves placing a very fine catheter into the epidural space for administration of local anaesthetics.[5]. This method of pain relief has made it possible for women to walk and move around more easily, while retaining mild sensation of uterine contraction and urgency of bearing down, thereby facilitating pushing the baby out in the second stage of labour. Thus, epidural analgesia is also known as walking analgesia.[6,7]. Possible explanations have been proposed to support the advantages of intermittent bolus compared with intermittent infusion administration of epidural solutions. Cadaveric dissections with cryomictotome sectioning have shown a more uniform spread of liquid in the epidural space, when using large volumes of injection pressures. This suggests that epidural solutions spread more evenly when injected as a bolus than as a continuous infusion[8,9].

In this study we have compared the efficacy of continuous epidural infusion with intermittent bolus doses for labour analgesia. The use of low concentration of local anaesthetic combined with lipid soluble opioids provides optimum analgesia without delaying the progression of labour and affecting neonatal outcomes. In intermittent bolus technique, the bolus is given at a regular time interval. If a parturient has an epidural bolus injection (top-up) of an analgesic solution analgesia will take effect and then wane, leaving with intervals of discomfort as the analgesia wears off. It requires a constant presence of clinician capable of providing analgesia. Continuous infusion provides a smoother analgesic experience for the mother and it requires clinician presence only for boluses for breakthrough pain.

2. MATERIALS AND METHODOLOGY

The present study “COMPARISON OF INTERMITTENT BOLUS DOSES WITH CONTINUOUS INFUSION OF ROPIVACAINE AND FENTANYL FOR EPIDURAL LABOUR ANALGESIA: A PROSPECTIVE RANDOMISED STUDY IN SHYAM SHAH MEDICAL COLLEGE REWA” was conducted in the Department of Anaesthesiology, Shyam Shah Medical College & associated Sanjay Gandhi Memorial and Gandhi Memorial Hospitals, Rewa (M.P.) from March 2023 to February 2024 (12 Months) after approval by institutional ethics committee and obtaining written informed consent. . Pre-anaesthetic examination of the patients was done. Each patient was subjected to complete general physical and systemic examination and detailed history was taken. Basic demographic characteristics such as age, height, sex and weight were noted. The patient was explained about the procedure and shifted to the operation theatre. In every patient, an intravenous access was achieved and each patient was preloaded with 10ml/kg body weight Ringer's Lactate solution before induction of epidural analgesia. Under all aseptic precautions, 18 G epidural catheter was placed in L3-4 or L4-5 space using the loss of resistance technique and the catheter was threaded cephalad 5 cm into the epidural space. After negative aspiration of blood and CSF, 3ml test dose of 2% lignocaine with 1:200000 epinephrine was administered and observer for 5 min to exclude intravenous and subarachnoid placement, if no toxicity appeared, epidural analgesia was started. The study design was prospective and randomized with a sample size of 70 patients who are randomly divided into two groups: GROUP A (n=35) who received continuous epidural infusion of 0.2% ropivacaine with fentanyl at 10ml/hr and GROUP B (n=35) who received 10ml 0.2% ropivacaine with fentanyl in bolus form manually every hour. Patients in both groups were given bolus dose of 5ml 0.2% Ropivacaine (in titrated form) as rescue when patient complained of breakthrough pain (with VAS score ≥ 3). When crowning of fetal head was seen, 5ml bolus dose was given in both the groups. At the end of delivery, the epidural catheter was removed.

Both the groups were monitored for haemodynamic parameters (Maternal blood pressure, heart rate, oxygen saturation) every 5 minutes. Block level was checked by pin prick method. The severity of pain was assessed by visual analogue scale from 0 to 10 (0=no pain and 10=worst pain experienced) before the block and at 15,30,45,60 minutes and then at 30 minutes intervals. Motor block was assessed bilaterally after attainment of maximum sensory block and then at hourly interval using Modified Bromage scale. Number of episodes of break through pain experienced by the patients were recorded in each group, here break through pain is pain in which VAS ≥ 3 where rescue bolus is given. Total dose of local anaesthetic drug requirement in ml and number of bolus doses required in each group was noted. Duration of first stage and second stage of labour was noted to see if there is any delay in progression of labour. Mode of delivery was noted to see the number of normal vaginal delivery, instrumental delivery using forceps and ventouse and number of lower segment caesarean section. The statistical analysis was done using SPSS (Statistical Package for Social Science) Version 21.0 statistical analysis software. The values were represented in number (%) and mean \pm SD.

3. RESULTS

The mean age of patients of Group A and Group B were 26.22 ± 2.84 and 27.24 ± 2.88 , respectively, on comparison which was statistically insignificant ($p=0.078$). Similarly, mean heights of Group A and Group B were 1.62 ± 0.03 and 1.61 ± 0.03 respectively, for which the mean difference was statistically insignificant ($p=0.879$). Mean weights of Group A and Group B were 81.56 ± 3.33 and 81.76 ± 3.20 respectively, for which the mean difference was

statistically insignificant ($p=0.76$). Mean BMI of Group A and Group B were 31.23 ± 0.71 and 31.35 ± 0.78 respectively, for which the mean difference was statistically insignificant ($p=0.4$). Mean heart rate of Group A and Group B were gradually decreasing for initial 30 minutes of follow ups when compared to baseline and then reaching a stable state. Mean differences at different at different time interval in between these two groups were comparable and statistically insignificant (p -value more than 0.05). Mean SBP of Group A and Group B were gradually decreasing for initial 30 minutes of follow ups when compared to baseline and then reaching a stable state. Mean differences at different at different time interval in between these two groups were comparable and statistically insignificant (p -value more than 0.05). The mean DBP of Group A and Group B were gradually decreasing for initial 30 minutes of follow ups when compared to baseline and then reaching a stable state. Mean differences at different at different time interval in between these two groups were comparable and statistically insignificant (p -value more than 0.05). The level of block in both the groups was comparable with majority of patients experienced sensory block upto T10 level, however, the mean difference was between the groups was statistically insignificant ($p=0.45$).

TABLE-1: Tabular presentation of mean duration of labour in the study population.

Duration of labour	Group		P value
	Group A	Group B	
	N=35	N=35	
1 st Stage	240.57±31.92	234.59±29.68	t=0.8117 p=0.4198
2 nd Stage	39.68±9.32	36.75±7.46	t=1.452 p=0.1511

Student t-test

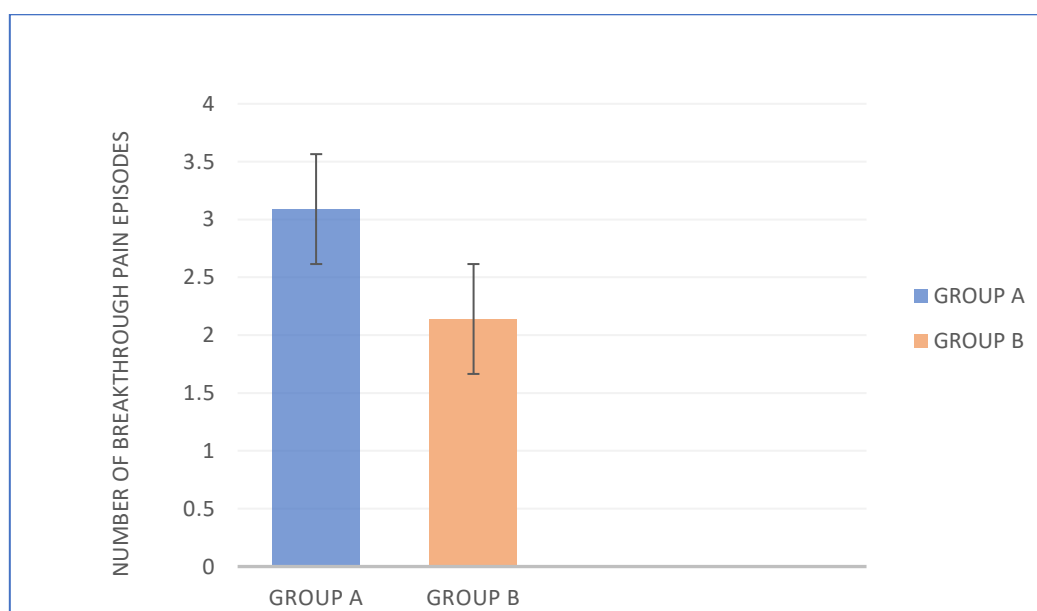
TABLE-1 represents the mean duration of 1st stage and 2nd stage of labour in patients of Group A and Group B, the mean difference was statistically insignificant ($p=0.4198$ for 1st stage and $p=0.1511$ for 2nd stage).

TABLE-2: Tabular presentation of number of break through pain episodes (VAS \geq 3) in both the groups.

Group				P value
Group A (N=35)		Group B (N=35)		
MEAN	SD	MEAN	SD	
3.09	0.43	2.14	0.37	t=9.908 p<0.0001

Student t-test

TABLE-2 depicts the comparison of Group-A and Group-B in terms of number of breakthrough pain episodes. The difference was statistically significant (p<0.0001).

**Figure-1: Graphical presentation of mean episodes of break through pain (VAS \geq 3) in both the groups.****TABLE-3: Tabular presentation of the mean of the number of boluses and total dose received by the patients in both the groups.**

	Group				P-value
	Group A (N=35)		Group B (N=35)		
	MEAN	SD	MEAN	SD	
BOLUS	5.83	1.07	3.42	0.45	t=12.28 p<0.0001
Total dose required (ml)	58.97	3.88	49.53	3.65	t=10.48 p<0.0001

Student t-test

TABLE-3 depicts that the mean number of boluses received by patients in group-A and group-B were 5.83 ± 1.07 and 3.42 ± 0.45 , respectively. The mean difference was statistically significant ($p < 0.0001$). Similarly, total dose requirement of patients in group-A and group-B were $58.97 \pm 3.88\text{ml}$ and $49.53 \pm 3.65\text{ml}$, respectively. The mean difference was statistically significant ($p < 0.0001$).

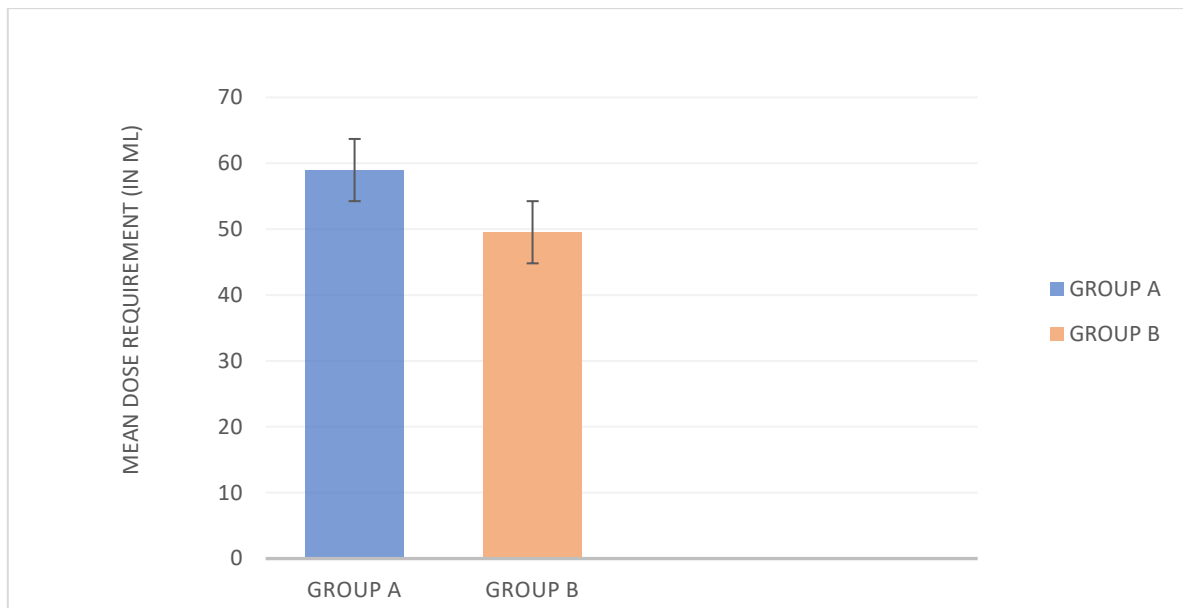


Figure-2: Graphical presentation of mean total dose required (in ml) in both the groups.

TABLE-4: Tabular presentation of the mode of delivery in the study population.

	Group				P-value
Mode of delivery	Group A (N=35)		Group B (N=35)		
NVD	26	74%	30	85.71%	X=4.095 P=0.2514
FORCEPS	3	8.57%	4	11.43%	
VENTOUSE	1	2.86%	0	0.00%	
LSCS	5	14.29%	1	2.86%	

Chi square test

TABLE-4 depicts the comparison of Group-A and Group-B in terms mode of delivery of patients. Majority of patients in group-A had normal vaginal deliveries (NVD)[N=26] followed by lower segment caesarean sections (LSCS)[N=5], similarly majority of patients in

group-B had normal vaginal deliveries (NVD)[N=30] followed by forceps[N=4]. The mean difference was statistically insignificant ($p=0.2514$).

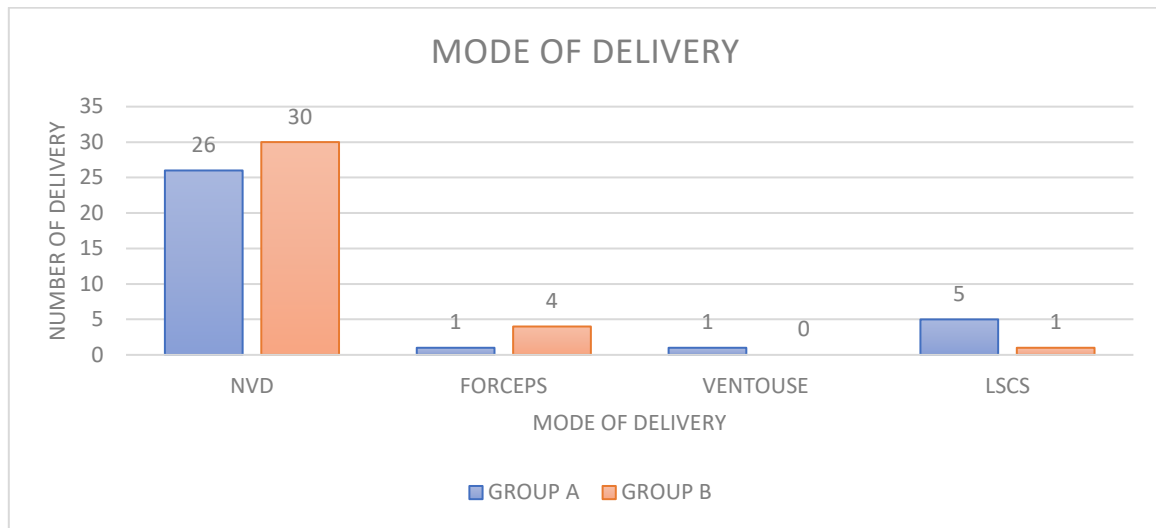


Figure-3: Graphical presentation of the mode of delivery in the study population.

4. DISCUSSION

In the present study demographic parameters like mean age, gender, mean height, mean weight and mean BMI were comparable, with a p-value of more than 0.05 which was statistically insignificant. Hemodynamic parameters mean HR, mean SBP, mean DBP, mean SPO2 levels were comparable, with a p-value of more than 0.05 which was statistically insignificant.

In our study patients in group-A received continuous epidural infusion of 0.2% ropivacaine with fentanyl at 10 ml/hour and the patients in group-B received bolus doses of ropivacaine with fentanyl every hour manually. The patients were also given rescue bolus dose of 5 ml of 0.2% ropivacaine and fentanyl whenever they complained of pain.

Bullingham et al. (2018) [10] in cohort study compared continuous epidural infusion (CEI) with programmed intermittent epidural bolus (PIEB) and found that group receiving PIEB had significantly shorter duration of second stage of labour, in our study we also found that in intermittent group the duration of labour was shorter than that in the continuous group, but the differences were statistically insignificant. George et al. (2013) [11] also did a similar study where they concluded that duration of labour was shorter for continuous epidural infusion group when compared with programmed intermittent epidural bolus group. In our study when mean duration of 1st stage and 2nd stage of labour in patients of Group A and Group B was compared, the mean difference was statistically insignificant ($p=0.4198$ for 1st stage and $p=0.1511$ for 2nd stage).

Delgado et al [12] performed a retrospective study comparing continuous epidural infusion with programmed intermittent epidural bolus using 0.0625% bupivacaine with fentanyl 2mcg/ml and found that group receiving intermittent boluses required lesser number of topups when compared to group receiving continuous epidural infusion. In our study we also found that mean number of boluses received by patients in group-A and group-B were 5.83 ± 1.07 and 3.42 ± 0.45 , respectively. The mean difference was statistically significant ($p < 0.0001$). Similarly, total dose requirement of patients in group-A and group-B were

58.97±3.88ml and 49.53±3.65ml, respectively. The mean difference was statistically significant ($p<0.0001$).

Mckenzie et al [13] in 2016 conducted a retrospective study to compare the analgesic efficacy of PIEB with CEI for maintenance of labour analgesia and found that bolus doses and the time it takes for anaesthesia to begin was significantly reduced for PIEB, however in their study there were no differences in the time to first rescue bolus, rate of instrumental delivery or the patients overall pain level.

Nunes et al [14] compared continuous epidural infusion with intermittent epidural boluses and found that intermittent epidural boluses were associated with reduced caesarean delivery rates. Our study showed a similar result that is a lesser number of LSCS in the group receiving intermittent boluses but the difference was statistically insignificant ($p=0.2514$).

There have been limited studies comparing continuous epidural infusion with intermittent bolus doses for labour analgesia in Indian scenario. We found significantly improved outcomes with intermittent epidural bouses compared to continuous epidural infusion when incidences of breakthrough pain, number of topups(boluses), total anaesthesia dose, number of LSCS and instrumental deliveries were compared. Intermittent boluses provide better maternal and foetal outcomes.

LIMITATIONS OF THE STUDY

The present study's limitations are single-centric design and small sample size.

5. CONCLUSION:

Epidural analgesia is very effective in relieving the pain and the discomfort that patient experiences during the process of active labour. From our study it can be concluded that intermittent epidural boluses yielded significantly improved outcomes when compared to continuous epidural infusion in many aspects like incidence of breakthrough pain were lower, reduced number of top-ups (boluses) required, lesser number of LSCS and instrumental delivery and reduced total drug dose required.

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