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Comparison of Intermittent Epidural Bolus *vs.* Continuous Epidural Infusion in Labor Analgesia

Ruchika Choudhary, Kalpana Verma, Sakshi Kadian*, Durga Jethava and Dharam Das Jethava

Department of Anaesthesia and Critical Care, Mahatma Gandhi Medical College and Hospital, Jaipur, Rajasthan, India

***Corresponding author:** Sakshi Kadian, Department of Anaesthesia and Critical Care, Mahatma Gandhi Medical College and Hospital, Jaipur, Rajasthan, India, Tel: 8375803532; E-mail: sakshi27wow@gmail.com

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Abstract

Introduction: Intermittent epidural boluses during labor produce more uniform block and require reduced dose of local anesthetic as compared to continuous infusion but there are limited studies to assess the effect of intermittent epidural boluses on maternal motor activity, labor and neonatal outcomes.

Methods: A prospective randomized double blind comparative study was done on 100 patients (50 per group). Labor analgesia was provided by programmed intermittent epidural boluses (PIEB) with bolus of injection. Levobupivacaine 0.0625%, 20 ml+1mcg/ ml fentanyl followed by bolus 10 ml of 0.0625% levobupivacaine +1microgram/ml fentanyl every hour beginning 60 minutes after initial loading dose and continuous epidural infusion (CEI) in which bolus of 20 of 20 ml levobupivacaine 0.0625%+fentanyl 1 mcg/ml was given followed by 10 ml/hour infusion of levobupivacaine 0.0625% with fentanyl 1 mcg/ml beginning immediately after the loading dose. We compared the duration of second stage of labor, total dose of anesthetic used, mode of delivery, neonatal outcome.

Results: The total amount of levobupivaciane and fentanyl consumed (ml) was 34.33 ± 12.75 and 48.05 ± 16.83 respectively in PIEB and 39.38 ± 9.39 ($p=0.04$) and 48.05 ± 16.83 ($p<0.001$) respectively in CEI group. The PIEB group patients had shorter second stage of labor 39.32 ± 13.73 minutes in PIEB group while 45.68 ± 13.60 minutes in CEI group ($p=0.022$). The number of additional rescue boluses was 4 in PIEB and 17 in CEI ($p=0.011$).

Conclusions: PIEB is better as compared to CEI in terms of decreased dose of local anesthetic and opioid, lesser number of recue analgesic bolus requirement and shorter second stage of labor.

Keywords: Epidural; Local anesthetics; Rescue analgesia

Introduction

Motherhood is a beautiful dream but labor pain makes it a nightmare!!

The ASA & ACOG commented: "In the absence of a medical contraindication, maternal request is a sufficient medical indication for pain relief during labor. Pain management should be provided whenever medically indicated" [1].

During the antenatal period every parturient should be educated about labor and different techniques which can be helpful for her should be discussed. It should be the parturient's informed decision as to which mode of pain relief she wants. The analgesic ideal for labor analgesia should have minimal effects on the progress of labor, should be safe both for the mother and newborn and should provide flexibility in changing conditions during the progress of labor. Also, the ideal technique should provide prolonged pain relief titrated to each parturient's comfort, with no or minimal risk, no undesirable fetal or maternal adverse effects, and should cost minimal physician input.

Among various techniques, epidural anesthesia is near ideal analgesic technique in labor [2]. It provides continuous analgesia for prolonged period of time and the analgesia can be converted to anesthesia if needed, as in case of any surgical intervention. Labor analgesia has become almost synonymous with central neuraxial analgesia. Combining local anesthetic with an opioid gives the advantage of rapid onset of action along with less motor blockade. The analgesia is rapid in onset and of prolonged duration than either drug alone. Thus, the concentration of both the drugs can be decreased, thereby reducing the incidence of local anesthetic systemic toxicity and side effects of opioids [3-6].

There are various techniques for maintenance of analgesia in labor like continuous epidural infusion (CEI) or parturient controlled epidural analgesia (PCEA) and intermittent epidural boluses (IEB). There have been conflicting comparisons of both the techniques that is, programmed intermittent epidural boluses (PIEB) and continuous epidural infusion (CEI) with for analgesia in labor. Clinical studies suggest that intermittent boluses technique produces a more uniform block than a continuous infusion. Studies even show that intermittent bolus technique is associated with a reduced dose of local anesthetic and better patient satisfaction than continuous infusion. But there are limited studies available to assess the effect of intermittent epidural boluses on maternal motor activity and neonatal outcomes.

We made a hypothesis that regular bolus of low concentration of local anesthetic (0.0625% levobupivacaine) with opioid (1 mcg/ml fentanyl) by programmed intermittent epidural boluses (PIEB) technique would provide safe and better quality of labor analgesia by decreasing the total amount of drug combination.

In this study we compared the efficacy of both the techniques in regards to total local anesthetic dose and opioid requirement, number of rescue boluses required, pain relief, motor block, labor characteristics and neonatal outcome.

Patients and Methods

Study design

This double blind prospective randomized comparative study was conducted involving 100 parturients (50 per group) who attended the Dept. of Obstetrics & Gynecology, at Mahatma Gandhi Hospital, Jaipur. We obtained Institutional ethics committee and scientific committee approval. All patients who were admitted to the labor room were counseled regarding labor analgesia. Procedure explained and informed consent taken.

Routine investigations including hemoglobin and platelet count, blood grouping and typing were done as per our hospital labor protocol. Patients who gave consent and who fitted into the inclusion criteria were randomly allocated to either of the study groups on the basis of chit and box method.

Inclusion criteria:

1. Normal singleton pregnancies.
2. Age–18-35 years
3. ASA status-II
4. Patients in active labor with cervical dilatation-3-5 cm.

Exclusion criteria:

Patients unwilling for labor analgesia

Multiple or preterm gestation

Allergy to any study drug

Deranged coagulation profile

Parturients with h/o Eclampsia, pre eclampsia, seizures, hypertensive disorders.

Cervical dilatation >5 cm.

Spinal deformities and infection at injection site.

Previous cesarean section.

Methodology

IV cannulation and routine monitoring was done. The patient was postured in the sitting position. Under all aseptic precautions, between L1 and L4 interlumbar space was identified and 2% lignocaine was infiltrated (Table 1 and Figure 1).

A 18G needle and 20G fine multiorifice epidural catheter was used for all patients.

Group	Bolus	Follow up
A (PIEB)	20 ml of 0.0625% levobupivacaine+1 µg/ml fentanyl	10 ml 0.0625% levobupivacaine with 1 µg/ml fentanyl bolus every hour beginning 60 minutes after initial loading dose, given as physician controlled
B (CEI)	20 ml 0.0625% Levobupivacaine+1 µg/ml fentanyl	Infusion of 10 ml/hour of 0.0625% Levoupivacaine with 1 µg/ml fentanyl beginning immediately after the loading dose.

Table 1: Study drugs protocol.

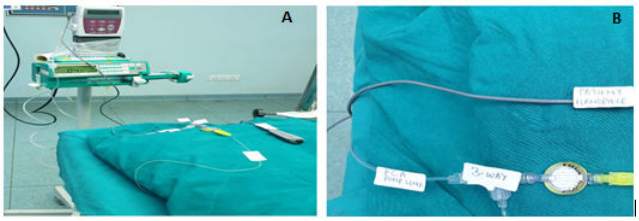

Figure 1: The images show the connection of basal infusion pump with PCEA pump *via* 3 way connector.

Patient controlled epidural analgesia (PCEA) was given with the help of a second infusion pump using 5 ml of 0.125% Levobupivacaine +1 µg/ml fentanyl, to treat any breakthrough pain. This pump was connected to the first pump *via* a 3 way connector, which was opened whenever the patient complained of pain.

The following maternal parameters were monitored continuously and noted every 15 minutes in the first hour, every 30 minutes in second hour and thereafter hourly. Continuous monitoring of fetal heart rate was also done.

Parameters monitored:

1. Maternal Heart rate
2. Maternal Blood pressure
3. Maternal respiratory rate & oxygen saturation.
4. Pain relief by 10 point verbal numerical rating scale (VNRS)
5. Motor block by Bromage score (0-3)

Clinical outcome studied:

Pain relief

Duration of labor

Mode of delivery-Vaginal-Spontaneous/Assisted, Cesarean section

Neonatal outcome-APGAR score

Motor block

Results

A total of 100 patients were analysed in the study, with 50 patients in each group. Significantly higher mean of Levobupivacaine consumed (mg) was observed in group B 39.38 ± 9.39 as compared to group A 34.33 ± 12.75 (p=0.04 S) (Table 2 and Figure 2). No significant

difference was observed among the groups according to complication. Although these were observed in very few cases.

Levobupivacaine consumed (mg)		
Group	Mean ± SD	p value LS
Group A (n=50)	34.33 ± 12.75	
Group B (n=50)	39.38 ± 9.39	0.04 S
Total (n=100)	36.85 ± 11.46	-

Table 2: Distribution of cases according to amount of Levobupivacaine consumed (in mg) among the groups.

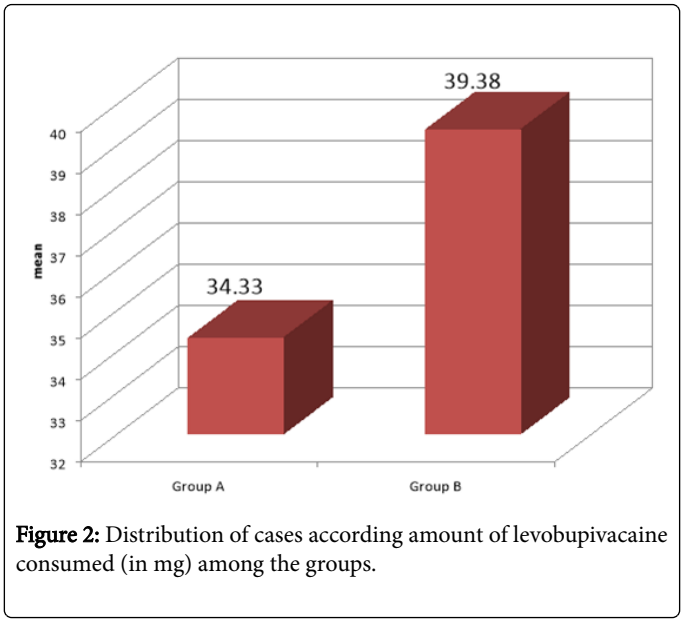

Figure 2: Distribution of cases according amount of levobupivacaine consumed (in mg) among the groups.

The total amount of levobupivaciane and fentanyl consumed (ml) was 34.33 ± 12.75 and 48.05 ± 16.83 respectively in PIEB and 39.38 ± 9.39 (p=0.04) and 48.05 ± 16.83 (p<0.001) respectively in CEI group (Table 3 and Figure 3).

Fentanyl consumed (in mcg)		
Group	Mean ± SD	p value LS
Group A (n=50)	48.05 ± 16.83	
Group B (n=50)	56.81 ± 7.232	<0.001 S
Total (n=100)	52.43 ± 13.62	

Table 3: Distribution of cases according amount of Fentanyl consumed (in mcg) among the groups.

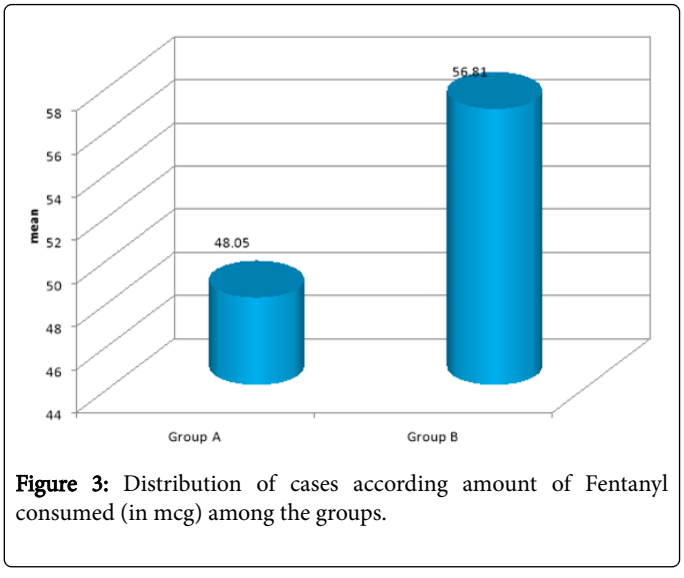

Figure 3: Distribution of cases according amount of Fentanyl consumed (in mcg) among the groups.

% Chi-square=12.957 with 4 degrees of freedom; p=0.011 S (Table 4 and Figure 4).

	Group A		Group B		Grand Total
Bolus	No	%	No	%	
0	46	92	33	66	79
1 (5 ml)	4	8	7	14	11
2 (10 ml)	0	0	7	14	7
3 (15 ml)	0	0	2	4	2
4 (20 ml)	0	0	1	2	1
	50	100	50	100	100

Table 4: Rescue Bolus at baseline among the groups.

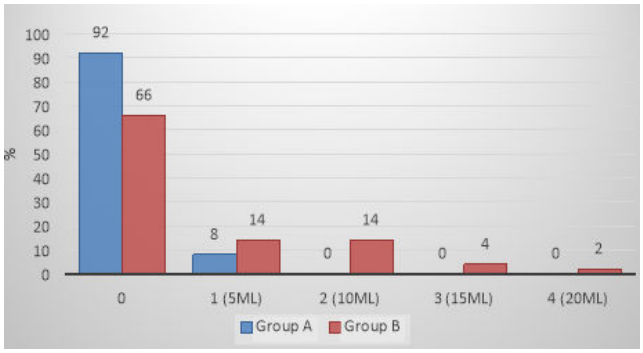

Figure 4: Rescue Bolus at baseline among the groups.

%Chi-square=0.000 with 1 degree of freedom; p=1.000 NS (Table 5 and Figure 5).

	Group A		Group B		Total
	No.	%	No.	%	
Vaginal assisted	7	14	6	12	13
Vaginal spontaneous	43	86	44	88	87
Total	50	100	50	100	100

Table 5: Distribution of the cases according to mode of delivery.

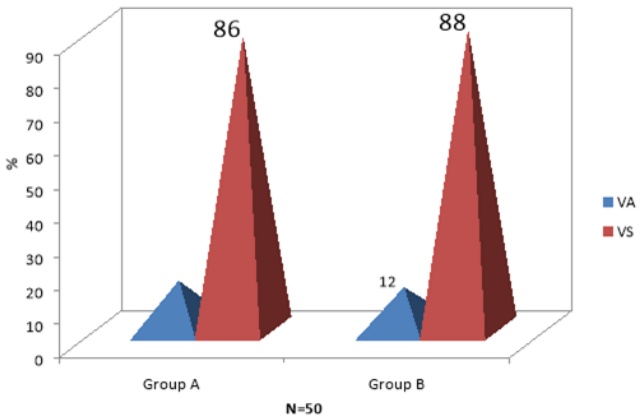

Figure 5: Distribution of cases according to mode of delivery.

APGAR of groups at different time intervals (Table 6 and Figure 6).

	Group A(n=50)	Group B (n=50)	p value LS
APGAR at 1 min	7.70 ± 0.463	7.60 ± 4.95	0.29 NS
APGAR at 5 min	8.88 ± 0.385	8.90 ± 0.364	0.79 NS

Table 6: Distribution of cases according to APGAR at 1 minute and 5 minutes among the groups.

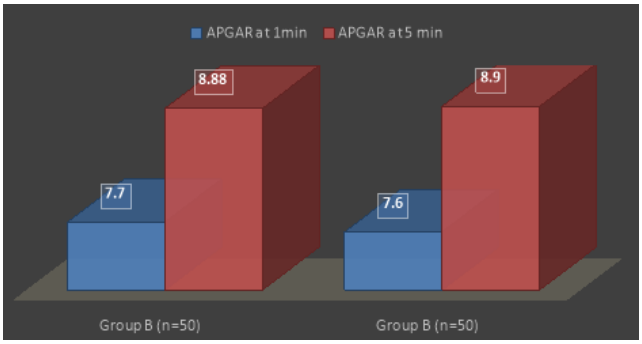

Figure 6: APGAR at 1 minute and 5 minutes among the groups.

Duration of labor among the groups (Table 7 and Figure 7).

	Group A	Group B	
	Mean ± Sd	Mean ± Sd	**p Value LS**
Stage 1 (N=50)	193.78 ± 90.08	221.02 ± 43.401	0.057 NS
Stage 2 (N=50)	39.32 ± 13.73	45.68 ± 13.60	0.022 S
Stage 3 (N=50)	6.88 ± 2.067	6.62 ± 1.915	0.516 NS

Table 7: Distribution of cases according to duration of labor (in minutes) among the groups.

VNRS at different time interval among the groups (Table 8 and Figure 8).

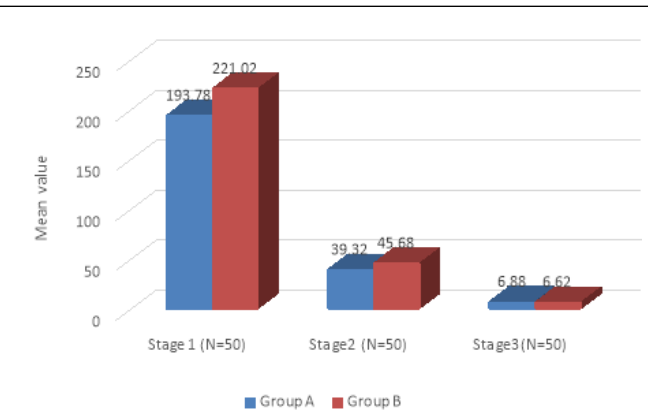

Figure 7: Duration of labor among the groups.

VNRS		0 minute	15 minutes	45 minutes	1 hour	2 hours	3 hours	4 hours	5 hours	6 hours
	N	**50**	**50**	**50**	**50**	**47**	**37**	**24**	**9**	**3**
	Mean	8.62	4.98	1.48	1.66	1.45	1.97	1.46	1.11	1.33
Group A	SD	0.49	1.097	0.677	0.772	0.904	0.957	0.658	0.333	0.577
	N	50	50	50	50	50	49	35	14	2
	Mean	8.54	5.2	1.5	1.9	2.16	2.53	2.31	1.43	1
Group B	SD	0.503	0.756	0.58	0.953	1.33	1.356	1.409	0.514	0
p Value LS		0.423 NS	0.24 NS	0.87 NS	0.17 NS	0.003 S	0.036 S	0.008 S	0.116 NS	0.495 NS

Table 8: Distribution of cases according to VNRS at different time interval among the groups.

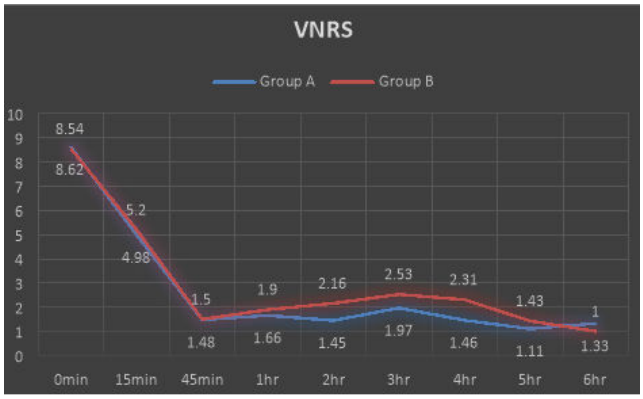

Figure 8: VNRS at different time interval among the groups.

Complications occurred during the labor among the groups (Table 9).

	Group A		Group B	
	No	%	No	%
Absent	41	82	37	74
Present	9	18	13	26
Hypotension	1	11.11	2	15.38
Nausea and vomiting	2	22.22	4	30.77
Pruritus	3	33.33	2	15.38
Urinary retention	3	33.33	5	38.46
Motor block	0	0	0	0

Table 9: Distribution of the cases according to complication among the groups.

Complications [6-9]:

Motor block: not seen in any parturient of either group.

Numbness: was not seen in any patients in both the groups.

Hypotension: seen in one patient in group A and 2 patients in group B which could be attributed to dehydration and increased venous capacitance because of sympathetic blockade, which was managed with co-loading with fluids.

Pruritis: Was seen in 3 patients of group A and 2 patients in group B.

Nausea and vomiting: Incidence was 2 patients in group A and 4 patients in group B (p=0.67 NS).

Urinary retention: 3 patients in group A and 5 patients in group B with no statistical significance (p=0.72).

NICU Admission: No NICU Admission was done.

Discussion

Hemodynamics

All parturients were found to be hemodynamically stable throughout the course of labor and delivery in regard to blood pressure and heart rate. The parturients in the study were found to be comparable in regards to systolic BP, diastolic BP, mean BP, heart rate, SpO_2, temperature and respiratory rate in both the groups at baseline and during the complete process of epidural analgesia.

Pain relief

In our study we found no significant difference according to VNRS up to 1st hour, but it became statistically significant in 2nd, 3rd, 4th hour (Table 7). In group B, more no. of parturient required boluses as compared to Group A. The finding is in consistence with many studies [7-12] with a significant difference in maternal satisfaction in terms of VAS score. Research showed a similar score comparable with our study with initial not significant VAS followed by lower VAS in IEB at later stage [12]. On the contrary, other studies [9,11,13] showed no difference in terms of pain scores.

Motor blockade

The degree of motor block after epidural analgesia depends on the drug used and the cumulative dose of local anesthetic used. In our study we did not observe any motor blockade which can be attributed to very low concentration of levobupivacaine (0.0625%) and fentanyl (1 mcg/ml) [14].

Duration of labor

Various factors determining the duration of labor are intensity of uterine contraction, cervical dilatation and the descent of the presenting part of fetus. Studies like Cochrane review compared the epidural and non-epidural methods of labor analgesia but did not find any significant difference in the length of 1st stage of labor. In present study the duration of first stage of labor was 193.78 ± 90.08 minutes in intermittent group and 221.02 ± 43.401 minutes in continuous infusion group. It was not statistically significant (p=0.057). The result here is in consistence with a number of studies [7-11,15-17] with no difference in first stage of labor but statistically significant shorter 2nd stage of labor. In our study the duration of second stage of labor was 39.32 ± 13.73 minutes in PIEB group while 45.68 ± 13.60 minutes in CEI group, which was statistically significant (p=0.022). According to ACOG guidelines, second stage of labor is considered prolonged if the duration is greater than 3 hours for primipara and greater than 2 hours for multipara with regional anesthesia. [17] did meta-analysis on 2400 parturients who received either epidural analgesia or parenteral opioid analgesia and they observed that the second stage of labor was prolonged by duration of 14 minutes. Another Cochrane [18] review on epidural versus non-epidural or no analgesia in labor found that parturients with epidural analgesia had prolonged second stage. The duration of third stage was not significant (p=0.516).

Analgesic effect

Amount of drug (levobupivacaine and fentanyl) consumed:

The total amount of levobupivaciane consumed was 34.33 ± 12.75 in PIEB and 39.38 ± 9.39 in CEI group which was statistically significant with p=0.04. The total amount of fentanyl consumed was 48.05 ± 16.83 in PIEB and 56.81 ± 7.23 in CEI group which was statistically significant with p<0.001. This significant result was similar to many studies showing lower dose of drug consumption in PIEB group [7-11,15-17]. Our most significant finding of higher cumulative drug dose requirement in CEI group compared to PIEB group can be attributed to a uniform spread of drug in PIEB compared to CEI. This result may also be attributed to the dispersion of solution in the epidural space [19-22]. [20] stated that analgesic effect is attributed to the movement of LA from extraneural space in nerve *via* diffusion gradient. Usually when we inject a large volume dug with high injectate pressure then the solutions spread evenly. This type of longitudinal and uniform spread of local anesthetic leads to more extensive blockade with intermittent route as compared to limited and localized block with continuous infusion technique. Another probability is a greater spread of infusate from a multiorificed catheter in intermittent technique, proved experimentally. However with continuous infusion, there was practically no flow through the distal hole while in intermittent bolus, the infusate would flow out from all the holes. Hogan and Lim et al. conducted studies and stated that cryomicrotome sectioning showed uniform spread of liquid in the epidural space through the intervertebral foraminae and along the nerve sheaths when large volumes of injection and a high injection pressure was used. This theory may support low incidence of rescue boluses in IEB group in our study.

Bolus requirements

In our study we have found that the number of additional rescue boluses required by parturients at different time interval was 4 in Group A and 17 in Group B which was proportionally very high as compared to Group A with p=0.011. This was in consistence with the study done by [11-13,20] where they found the frequency of boluses were decreased in PIEB Group.

Mode of delivery

Anim-Somuah et al. [19] in their meta-analysis found that women with epidural were twice as likely to have an instrumental vaginal delivery as compared to control groups. Cambic and Wong in their review on labor analgesia and obstetric outcomes concluded that effective second stage analgesia might be associated with an increased rate of instrumental vaginal delivery. In our study the incidence of instrumental delivery was same in both groups i.e. p=1.0. This was in consistence with many other studies [7-11,15-17]. In our study none of the cases underwent cesarean section.

Fetal and neonatal outcome

The recent Cochrane review [18] compared epidural analgesia and other forms of analgesia that included inhalational and intravenous (mainly opioids) agents and observed that there were fewer incidences of fetal acidosis and less naloxone administration to the babies who were born to mothers who received epidural analgesia for labor. In this study during the complete process of labor analgesia, the fetal heart rate was within the normal limits. There was no incidence of any post epidural fetal bradycardia. No significant difference in fetal heart rate (FHR) and APGAR scores was observed between the both groups.

Drawbacks

- To assess the neurobehavioral outcome of the baby, we used Apgar score.
- To know the effect of drugs on the acid base status of the newborn, we did not measure the umbilical cord pH.

Conclusion

Aim of obstetric analgesia is to make childbirth a pleasurable and painless event. To ensure this, we should ideally adopt the best possible technique, which would provide excellent analgesia and ensures minimal side effects and absolute safety to both the mother and child.

The observations of this study show that pain relief offered by epidural levobupivacaine and fentanyl by intermittent boluses infusion is better than the continuous epidural infusion with a reduction in amount of total levobupivacaine and fentanyl consumed, number of patients who required additional PCEA boluses, mean number of PCEA boluses required per patient (lower in the PIEB group) and shorter second stage of labor. No significant difference was observed in pain scores and duration of labor analgesia. The mode of delivery, neonatal outcome and complications were comparable among the two groups. No incidence of motor blockade was observed in either group.

Hence, concluding that intermittent bolus method is preferable over continuous infusion in terms of lesser total drug consumption and incidence of breakthrough pain. There by representing PIEB as more efficacious mode of epidural drug delivery.

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