

Journal homepage: http://www.journalijar.com Journal DOI: 10.21474/IJAR01

INTERNATIONAL JOURNAL OF ADVANCED RESEARCH

RESEARCH ARTICLE

COMPARATIVE STUDY OF CONTINUOUS EPIDURAL INFUSION OF BUPIVACAINE 0.125% AND ROPIVACAINE 0.2% WITH FENTANYL AS ADJUVANT FOR LABOUR ANALGESIA.

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Manuscript Info

Manuscript History:

Received: 12 April 2016 Final Accepted: 19 May 2016 Published Online: June 2016.

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Kev words:

Labour analgesia, Ropivacaine, Bupivacaine, Epidural infusion.

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Abstract

Background:- Epidural analgesia is the most popular method which can provide excellent pain relief yet, allows the mother to be awake and cooperative during labour. In comparision to bupivacaine, Ropivacaine is less lipid soluble, less cardiotoxic, with less motor block and better haemodynamic stability.

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Objective:- To study and compare the continuous epidural infusion of Ropivacaine with Fentanyl versus Bupivacaine with Fentanyl for labour analgesia.

Methodology:- 100 healthy primigravid women, aged 18 to 35 yrs, > than 37 weeks gestation, with spontaneous onset of labour were selected. An epidural catheter was inserted at L2-L3 or L3- L4 level. It was activated after 4cm cervical dilatation with test dose of 3ml 1% lignocaine with 1:200,000 epinepherine. The parturients were randomized into two groups. In Bupivacaine group 8 ml 0.125% Bupivacaine Fentanyl 25 ug followed by continuous infusion of 0.125% Bupivacaine and injection Fentanyl 2 ug/ml at the rate of 6ml/hr was given. In Ropivacaine group 8 ml 0.2% Ropivacaine + Inj Fentanyl 25 ug followed by continuous infusion of 0.2% Ropivacaine with injection Fentanyl 2ug/ml at the rate of 6ml/hr was given. Monitoring was done hrly until they reached 10 cm dilatation and the following data were recorded: maternal blood pressure and heart rate, fetal heart rate, VAS score, motor block, sensory level, mode of delivery, Apgar score, and maternal satisfaction.

Results:- In our study, motor block was observed in 13(26%) patients in the Bupivacaine group whereas only five (10%) patients had motor block in Ropivacaine group (P < 0.05) and Eight patients in Bupivacaine group and two patients in Ropivacaine group delivered by assisted vaginal deliveries (P < 0.05). There were no significant differences between the two groups in patient characteristics, maternal haemodynamic variables and patient satisfaction.

Conclusion:- Ropivacaine 0.2% combined with fentanyl 2 mcg mL (-1) provided effective analgesia with significantly less motor block and less need

for an instrumental delivery than a Bupivacaine/fentanyl combination during labour and delivery.

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Introduction:-

Epidural analgesia is one of the most popular and safe methods of labour analgesia. Good analgesia with minimal motor block are important components of ideal labour analgesia. Continuous infusion of low concentration of local anesthetic with opioids is commonly used to maintain epidural labour analgesia. Low concentration of Bupivacaine with fentanyl is commonly used for the same.

Ropivacaine was introduced in market with the claim that it produces less motor blockade.^[1] Ability to block the pain fibers with relative sparing of the motor fibers makes Ropivacaine a suitable agent for labour epidural analgesia as greater mobility during labour analgesia is associated with greater maternal satisfaction.^[2] Hence we decided to compare combination of low concentration of Ropivacaine and fentanyl with low concentration of Bupivacaine and fentanyl.

Materials and Methods:-

One hundred ASA physical status I or II nulliparous women with term, with spontaneous onset of labour, singleton pregnancy with the vertex as the presenting part were enrolled in this randomized double-blind study. The following were exclusion criteria for the study: severe medical or obstetrical conditions, drug or alcohol abuse, neurological disease, administration of parenteral analgesics < one hour before the block, allergy to study drug and patient refusal. Following written informed consent, parturients in active labour (cervical dilatation 4 cm) were randomized using a computer generated list to either Bupivacaine or Ropivacaine group. An independent anesthesiologist was responsible for preparing the study drug. Neither the patient nor the investigator knew what drug was being used in a given patient. After checking written informed consent and NPO status, monitors (NIBP, cardioscope, pulsoximeter) were attached. Patients were preloaded with 500 ml Ringers Lactate solution. With the patient in the sitting position, the epidural space was identified at the L2-3 or L3-4 interspace and epidural catheter was inserted. Patient was made supine and then 3 ml test dose of lidocaine 1% with 1:200,000 epinepherine was administered through the catheter. Bupivacaine 0.125% and ropivacaine 0.2% were chosen for initiation of epidural analgesia. In the Bupivacaine group, 8 ml bolus of Bupivacaine 0.125% with 2 mcg/ml fentanyl was injected. If the patient was still uncomfortable after 10 min, an additional 4 ml of the same solution was given and further boluses of 2 ml each were given every 10 minutes if patient was uncomfortable. In the Ropivacaine group, the protocol was similar except that 0.2% Ropivacaine was used for the induction of the block in place of 0.125 % Bupivacaine.

The patients were asked to rate their pain intensity on a VAS (0-100 mm) during two consecutive contractions 5 – 10 min before the test dose was given. After the patient reported at least a 70% reduction in her visual analog scale (VAS) score for pain, she was connected to a local anesthetic infusion containing fentanyl at 2 µg/ml at a fixed rate of 6 ml/hr in both groups. The patients in the bupivacaine group received bupivacaine 0.125% with 2 mcg/ml fentanyl and those in the Ropivacaine group ropivacaine 0.2% with 2 mcg/ml fentanyl. If the pain relief was inadequate at any time throughout labour (VAS score > 40), the investigator gave an additional 5 ml bolus of the study drug. The onset time for analgesia was noted. The sensory level was assessed by using pinprick method. The intensity of motor block was graded using a Bromage (Br) score 1-4: Br 1 indicated a complete motor block with the patient unable to flex both hips and knees, Br 2 indicated flexion only at the ankle, Br 3 indicated flexion only at the knee and ankle, Br 4 indicated flexion at the hips, ankles and knees. Bromage scores for each lower extremity were assessed separately. Only those patients with bilateral Br 4 scores were considered to have no demonstrable motor block. Bradycardia was defined as heart rate <60/min and was treated with Inj Atropine 0.6 mg IV. Hypotension was defined as fall in BP 30 mm Hg from baseline or systolic BP <100 mm Hg and was treated with 6 mg ephedrine boluses IV. The patients were assessed every hour until they reached 10 cm dilatation and the following data were recorded: fetal heart rate (FHR), maternal blood pressure and heart rate (HR), VAS pain scores, motor block and sensory level. In addition, total amount of drug used as initial bolus, number of patients requiring rescue doses, mode of delivery, neonatal Apgar score at one minute and five minutes and patient satisfaction were recorded. The study was terminated if the block failed or if the patient refused participation. Data are presented as mean \pm SD.

Results:-

One hundred nulliparous women were enrolled in the study. 50 were in the Bupivacaine group and the remaining 50 in the Ropivacaine group. No differences existed between the two groups in maternal height, weight, and age, systolic blood pressure (SBP) and HR and FHR (Table I).

Table I:- Demography.

	Bupivacaine	Ropivacaine	P value*
Age (yrs)	22 ± 3.7	23 ± 2.8	0.0162
Weight (Kg)	63 ± 6.7	64 ± 5.4	0.0330
Height (cm)	155± 4.8	156 ± 4.4	0.3881

*Using t-test for independent samples

The data are mean \pm 1 SD. No differences existed between the groups in any of the parameters.

Table II:- Adverse effects.

	Bupivacaine ($n = 50$)	Ropivacaine ($n = 50$)	P value*
Number of Episodes of Hypotension	7(14%)	4(8%)	0.5227
Number of Episodes of Bradycardia	2(4%)	1(2%)	0.9999
Demonstrable Motor blockade	13(26%)	5(10%)	0.0373(significant)

^{*}Using Z-test for proportions

Table III:- Local Anaesthetic Requirment and duration of labour.

	Bupivacaine(n = 50)	Ropivacaine (n= 50)	p- value
Initial bolus volume	14.08	13.84	0.9891*
(ml)			
No of pts who required	7(14%)	8(16%)	0.9999**
rescue doses			
Onset of analgesia (min)	9.5 ±3.2	10.7 ±2.1	0.0293 (Used t-test)
			(significant)
At 10 cm dilatation(min)	288±161.5	286.5± 135.3	0.9245*
Stage II duration (min)	128.3±74.3	104.2±72.7	0.0231*

^{*} Using t-test for independent samples, **Using Z - test for proportions

Table IV:- Local anesthetic usage and duration of labour.

	Bupivacaine $(n = 50)$	Ropivacaine(n= 50)	P value*
Initial bolus volume (ml)	14.08	13.84	0.9891
No of pts who required rescue doses	7(14%)	8(16%)	0.9999

*Using Z-test for proportions

Table V:- Mode of delivery.

	Bupivacaine(n = 50)	Ropivacaine(n = 50)	P value*
Normal vaginal delivery	33(66%)	38(76%)	0.2705
Assisted vaginal delivery	8(16%)	2(4%)	0.0455
Caesarean delivery	9(18%)	10(20%)	0.9999

^{*}Using Z-test for proportions

Table VI:- Assessment of maternal satisfaction by patient.

Grade	Bupivacaine $(n = 50)$	Ropivacaine $(n = 50)$	P value*
Excellent	28	25	0.8978
good	5	7	
satisfactory	5	6	
unsatisfactory	2	2	

^{*}Using Pearson's Chi – square test

Discussion:-

Childbirth is arguably one of the most painful experiences a woman can undergo. Degree of pain experienced and the quality of pain relief affect patients' satisfaction with the birthing process and may have long-term emotional and psychological effects. The quality of labor neuraxial analgesia has surpassed parenteral opioids, nitrous oxide, and non-pharmacologic measures, with limited effect on the mode of delivery and maternal and neonatal outcomes. Epidural analgesia is one of the most popular and safe methods of labour analgesia. Low concentration of Bupivacaine with fentanyl is commonly used for the same. Ability to block the pain fibers with relative sparing of the motor fibers makes Ropivacaine a suitable agent for labour epidural analgesia as greater mobility during labour analgesia is associated with greater maternal satisfaction. Hence we decided to compare combination of low concentration of Ropivacaine and fentanyl with low concentration of Bupivacaine and fentanyl. We chose to use 0.125% Bupivacaine and 0.2% Ropivacaine as it offers good analgesia. [3,4]

We included only nulliparous women to assess the sensory and motor effects of local anesthetics and to study analgesia as they have strong labor pain for prolonged duration as compared to multipara women. This helped us to assess effects over prolonged period of time. [5]

In comparison of Bupivacaine with Ropivacaine, the median VAS scores did not differ between the groups before initiation of labour analgesia, soon after onset of action or at any of the subsequent evaluation periods. The results suggest that epidural Bupivacaine 0.125% and Ropivacaine 0.2% combined with fentanyl (2mcg/ml) produced equivalent analgesia for pain relief during labour and delivery. Owen et al. also concluded that 0.125% concentrations of bupivacaine and Ropivacaine were clinically indistinguishable when used for labour analgesia. [6]

But in this study, the local anesthetics were administered by the patient controlled analgesia mode and no opioids were added to the local anesthetic solution.

Pirbudak et al also found that epidural infusion of Bupivacaine 0.05% or Ropivacaine 0.05% together with fentanyl provided good and safe analgesia during labour. Helen et al also found that median VAS scores were not different between Bupivacaine and Ropivacaine group at any of the evaluation period. All these studies showed that Ropivacaine, despite its lower potency, provided similar degree of analgesia as Bupivacaine at comparable concentration. In our study, onset time did not differ between the two groups. Helen Finegold et al also found similar results. Initial bolus volume and number of patients who required rescue doses for break-through pain during labour were similar in both the groups.

Helen Finegold et al also found similar results. Eight patients in Bupivacaine group and two patients in Ropivacaine group delivered by assisted vaginal deliveries (P < 0.05). There were less instrumental deliveries in Ropivacaine fentanyl combination group than Bupivacaine-fentanyl combination. Asik et al also found similar results. In the study by Eddleston et al. parturients given Ropivacaine 0.25% had more spontaneous vaginal deliveries than those given Bupivacaine 0.25%.

But, Helen Finegold et al found no difference in the Ropivacaine and Bupivacaine group with regards to mode of delivery. No baby from either group had an Apgar score of <7 at one minute or <9 at five minutes.

Helen Finegold et al also found no difference in the Ropivacaine and Bupivacaine group in relation to fetal outcome.

In our study, motor block was observed in 13(26%) patients in the Bupivacaine group whereas only five(10%) patients had motor block in Ropivacaine group (P < 0.05). Asik et al in their study, concluded that Ropivacaine 0.2% combined with fentanyl 2 mcg/ml causes less motor block than Bupivacaine-fentanyl combination at the same concentration. Helen et al found that 80% patients in Ropivacaine group had no demonstrable motor block after the first hour compared with 55% of patients given Bupivacaine. Merson et al also found that Ropivacaine produced significantly less motor block than Bupivacaine in the 0.25% and the 0.125% loading doses. However, Eddleston et al. demonstrated no differences in sensory or motor effects between Ropivacaine 0.25% and Bupivacaine 0.25% in parturients receiving labour analgesia. However, in this study, intermittent injection rather than infusions were used for analgesia and the Bupivacaine group needed more top-up injections than did the Ropivacaine group. Maternal haemodynamic variables were not different between the two groups at any assessment period. There were no significant differences in patients' satisfaction between the two groups.

Conclusion:-

We conclude that Ropivacaine 0.2% combined with fentanyl 2 mcg mL(-1) provided effective analgesia with significantly less motor block and less need for an instrumental delivery than a Bupivacaine/fentanyl combination during labour and delivery.

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