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A Comparative Study of 0.1% Ropivacaine with Fentanyl and 0.1% Bupivacaine with Fentanyl for Epidural Labor Analgesia

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Abstract

Objective: A randomized, double blind study to compare the analgesic efficacy, maternal and neonatal outcome of ropivacaine 0.1% and bupivacaine 0.1% both with fentanyl for labor epidural analgesia. *Methods:* Sixty term parturient of ASA Grade I & II with singleton pregnancy in vertex presentation and adequate cervical dilatation requesting painless labor were divided into two groups of 30 each. Group BF parturient received bupivacaine 0.1% with fentanyl 20 μg and Group RF parturient received ropivacaine 0.1% with fentanyl 20 μg as intermittent bolus doses epidurally. After written informed consent, epidural catheter was placed in L3-4/4-5 space followed by study drug administration and top up doses intermittently. Maternal hemodynamics, Visual Analogue Score (VAS), Foetal heart rate, sensory analgesia, motor block, neonatal APGAR score at 1 and 5 min and labor characteristics were recorded. *Results:* The groups were comparable in demographic and obstetric characteristics. Two patients in Group BF developed motor block of Grade 1 while none of the patient in Group RF had motor block. VAS score and quality of analgesia was comparable in both the groups. Onset of sensory block was longer in Group RF. No significant difference was found in both groups with regards to hemodynamics. *Conclusion:* We conclude that ropivacaine 0.1% with fentanyl produced excellent analgesia comparable to bupivacaine 0.1% with fentanyl and can be used safely for labor epidural analgesia.

Keywords: Epidural; Labor analgesia; Ropivacaine; Bupivacaine.

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Introduction

Epidural labor analgesia is the widely used labor analgesic technique and become a 'Gold Standard' in obstetrics.[1] Because of excellent sensory block provided during labor and delivery, bupivacaine is the most commonly used local anesthetic agent for epidural labor analgesia. But bupivacaine is prone to cause motor blockade development, cardiovascular and central nervous system toxicity. However, risk of these side effects reported to be reduced by using smaller concentrations of bupivacaine.[2]

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Ropivacaine is another amide local anesthetic agent and its chemical structure is related to bupivacaine. In various studies ropivacaine has been found to produce less motor blockade, thereby reduces the incidence of instrumental deliveries[3,4] with more vaginal deliveries. Furthermore, ropivacaine has been found to produce less incidence of cardiovascular and central nervous system toxicity as compared to bupivacaine.[5–9] Because of these advantages, ropivacaine is gaining popularity in epidural labor analgesia. Although epidurally administered local anesthetic agent alone provides good analgesia during labor, the addition of fentanyl further improves the quality of analgesia.[1]

Looking to the above facts, we had compared the analgesic efficacy, maternal and neonatal outcome of equal concentrations of ropivacaine and bupivacaine both with fentanyl for epidural labor analgesia with intermittent top up doses.

Materials and Methods

After approval of institutional ethical committee and written informed consent, the present study was conducted on 60 term parturient of ASA Grade I & II with singleton pregnancies in vertex presentation and cervical dilatation 3–6 cm, requesting painless labor. All parturient in this study were subjected to detailed preblock evaluation. Parturient who were morbidly obese, having bleeding disorders, history of allergy to local anaesthetics, hypovolemia, thrombocytopenia, local sepsis, antepartum hemorrhage, severe eclampsia and cephalopelvic disproportion and cervical dilatation > 6 cm were excluded from the study. After confirming the active first stage of labor and cervical dilatation 3–6 cms, parturient were randomly divided by sealed envelope method into two groups of thirty parturient each. In Group BF, parturient received 0.1% bupivacaine 10 ml with fentanyl 20 μg and in Group RF parturient received 0.1% ropivacaine 10 ml with fentanyl 20 μg. An independent anesthesiologist prepared the study drugs in coded syringes. Neither the parturient nor the anesthesiologist, who was recording the parameters, knew what drug was being used in given patient.

An intravenous line with 18 G cannula was established and at least 500 ml of Ringer's lactate solution was given. Standard monitoring were applied using multiparameter monitor for heart rate, Noninvasive arterial Blood Pressure (NIBP), pulse oximetry (SpO_2) and ECG. Parturient were placed in the left lateral position and under strict aseptic precautions, midlumbar epidural space L3-L4/ L4-L5 was identified by using a loss of resistance to saline technique with a 16 G Touhy needle. A 20 G single orifice epidural catheter was inserted and the parturient were turned to supine position. To exclude intravascular or intrathecal placement, a test dose of 2 ml of 2% lignocaine with adrenaline was used. First dose of 10 ml study drug bolus was injected according to group allocated. Following 10 minutes parturient were asked to lift legs straight, without flexing knees. When parturient were able to lift legs easily without bending knees, they were asked to take a trial walk. All parturient were given the following instructions:

1. Pass urine every hour
2. Do not walk barefooted

The onset time for analgesia was recorded. Pain intensity was noted using 0–10 cm Visual Analog Scale (VAS), where 0 = no pain and 10 = worst pain. A VAS score of < 3 was considered to be satisfactory. Both sensory and motor blockade were assessed by alteration in temperature sensation to ice and modified Bromage score, shown in Table 1 respectively. Measurements were continued until return of normal sensation and motor function (Bromage score 0). If analgesia was inadequate (VAS > 3), top up dose was repeated up to maximum of 10 ml at a time. Before giving each top up, aspiration was done. In the second stage of labor, top up was given in the sitting position. The study was ended at the time of vaginal delivery, assisted or not, or when the decision was made to perform a cesarean delivery.

Table 1: Modified Bromage score

Grade	
0	Normal movement in hip, knee and foot, No motor block
1	Weakness in hip muscles, Inability to raise extended leg
2	Weakness in knee muscles, Inability to flex knee
3	Motor block of hip, knee, Inability to flex ankle joint

Parturient were assessed every 5 min for half an hour and thereafter, every 30 min for maternal heart rate, NIBP, SpO_2, VAS score and degree of motor block. Subsequent top up doses were given after assessing pain relief (when VAS reached > 3). Following every top up dose, parturient were monitored carefully for 10 minutes to detect any weakness or inadequate analgesia. In addition sensory and motor block levels, duration of first and

second stage of labor, mode of delivery (normal, forceps assisted or cesarean), total amount of rescue doses, foetal heart rate, neonatal APGAR score at 1 and 5 min, complications and side effects were studied. Hypotension was defined as systolic blood pressure < 90 mm Hg and was treated by positioning the patient on her left side and if necessary, administering inj ephedrine. After delivery epidural catheter was removed. Parturient were interviewed a day after delivery for satisfaction level and quality of analgesia on four point scale (Excellent, Good, Fair and Poor). Statistical analysis of data was done using Student's '*t*' test and Chi-square test. A p - value ≤ 0.05 was considered as statistically significant.

Results

Demographic and obstetric characteristics were comparable in both the groups (Table 2). Onset of analgesia was significantly longer in group RF as compared to Group BF (p < 0.05), (Table 1). The VAS Score was comparable in both the groups for each time interval at which it was assessed (Fig. 1). None of the parturient in Group RF developed motor block while two parturient in Group BF developed motor block (Grade 1) and the difference was statistically insignificant, (Table 3).

Table 2: Demographic and obstetric characteristics

Variables	Group BF	Group RF
Age (yr)	23 ± 3.15	24.26 ± 3.62
Weight (kg)	67.73 ± 3.87	69.76 ± 4.53
Height (cm)	158.96 ± 2.72	158.20 ± 2.36
Duration of labor (min)		
First stage	226 ± 42.18	242 ± 43.39
Second stage	45 ± 14.57	47 ± 14.51
Onset of analgesia (min)	17.93 ± 1.55	23.53 ± 1.67*
Level of sensory block	T8 (T7-T9)	T8 (T7-T9)
Mode of delivery, no (%)		
Vaginal delivery	28 (93.33)	29 (96.66)
Forceps delivery	1 (3.33)	1 (3.33)
Cesarian delivery	1 (3.33)	0
Total dose of		
Study drug (mg)	21.17 ± 2.15	24.67 ± 2.6
Fentanyl (μg)	42.33 ± 4.3	49.33 ± 5.21
APGAR Score at		
1 min	8.06 ± 0.69	8.33 ± 1.06
5 min	10 ± 0	9.83 ± 0.74
Patient satisfaction, no (%)		
Excellent	24 (80)	25 (83.33)
Good	5 (16.66)	5 (16.66)
Fair	1 (3.33)	0
Poor	0	0

Values are expressed as mean ± SD, no (Percentage) and median (range) *p < 0.05 Group RF *vs* BF

Table 3: Motor block

Bromage score Grade	Group BF no (%)	Group RF no (%)
0	28 (96.66)	30 (100)
1	2 (6.66)	0
2	0	0
3	0	0

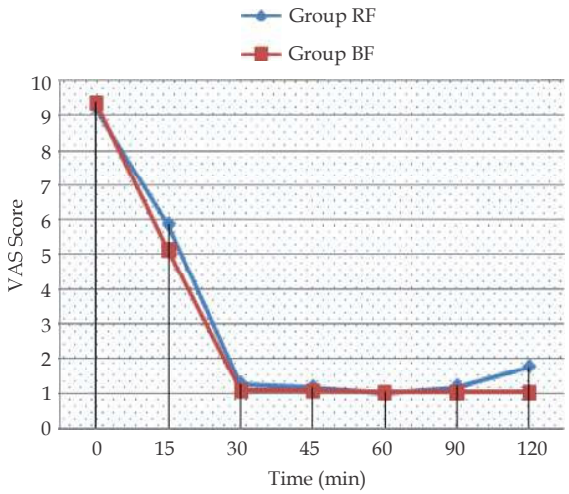

Fig. 1: VAS Scores.

The duration of Stage I and II of labor was comparable in both the groups (Table 1). One parturient in Group RF had forceps delivery. None of the parturient in Group RF required cesarean section. While in Group BF, one delivery was assisted by outlet forceps and one parturient required cesarean section due to prolong second stage of labor, (Table 1).

There was no significant difference between two groups with regard to total dose of study drug administered during first and second stage of labor, (Table 1). Maternal heart rate and arterial blood pressure were comparable in both the groups. No difference was found in neonatal APGAR score at 1 and 5 minutes after delivery in both the groups, (Table 1). None of the parturient in either group had hypotension or bradycardia. Two parturient in each group developed vomiting. One parturient in Group RF had pruritis. However, incidence of side effects in both the groups showed no statistical difference. One day after delivery, all parturient in both groups satisfied and judged the analgesia to be fair to excellent. None of the parturient judged the analgesia to be poor.

Discussion

We had compared 0.1% bupivacaine and 0.1% ropivacaine, both with fentanyl 20 micrograms for

epidural labor analgesia with intermittent topup doses. In our study, we used fentanyl with local anesthetic agent to improve the analgesic efficacy of local anesthetic agent without increasing the motor block, as opiods are reported to reduce the effective concentration of local anesthetic agent in a dose dependent manner.[1]

Ropivacaine is a local anesthetic agent with high differential sensory: motor block ratio and reported to cause less motor blockade compared with similar concentration of bupivacaine. However, in our study motor blockade produced by ropivacaine was comparable to bupivacaine. Paddalwar S et al.[1] compared the efficacy of ropivacaine 0.125% and bupivacaine 0.125%, both with fentanyl in epidural labor analgesia and did not find any significant difference in motor block between two groups. In the present study, we did not find any difference in the sensory levels, motor block, VAS score, analgesic potency, duration of labor, mode of delivery and side effects among both groups. Equal concentration of bupivacaine and ropivacaine for epidural labor analgesia has been compared in various studies. Some studies compared 0.25% bupivacaine and 0.25% ropivacaine and did not observe any significant difference either in quality of analgesia or in motor block.[4,10–13] While comparing 0.125% bupivacaine and 0.125% ropivacaine for epidural labor analgesia, Owen et al.[14] failed to observe any significant clinical difference between two drugs. Similar results were also reported by Gautier P et al.[15] In another study, Meister et al.[16] used 0.125% bupivacaine and 0.125% ropivacaine with fentanyl 2 mcg/kg for epidural labor analgesia and they found that both drugs were equipotent. Their results are consistent with our observations although mode of drug delivery was different. Comparable VAS scores, observed in both groups in our study, suggests that there was no difference in the potency of study drug solution, which was also noted in other studies.[13,17–18]

Epidurally administered local anesthetics may cause motor block that may lead to increased rate of instrumental delivery or cesarean section as motor block developed after epidural block may decrease maternal motility, reduces maternal efforts during second stage of labor and may also cause inadequate rotation of presenting foetal part due to the relaxation of pelvic floor muscles.[19–20] Local anesthetic induced motor block can be reduced by decreasing the concentration of agent and also by adding the opiods like fentanyl as demonstrated in Comparative Obstetric Mobile Epidural Trial.[3] This trial shows a lesser incidence of forceps delivery with bupivacaine 0.1% plus fentanyl 0.0002%. In our study also, the incidence of forceps delivery was much less as we used local anesthetic agent in reduced concentration. Although there was no statistically significant difference in degree of motor block, there were a higher number of women who had spontaneous delivery in ropivacaine group.

As shown in Table 2, total drug requirement for labor epidural analgesia (bupivacaine or ropivacaine plus fentanyl) was comparable in both groups. Similar results were reported by Writer et al.[4] and Campbell et al.[18] Traditionally, neonatal condition has been assessed with the APGAR scoring system. The mean APGAR score of neonates was within normal range and comparable in both groups. The results of our study are in accordance with Chopra et al.[21], who also found normal neonatal APGAR score in bupivacaine and ropivacaine groups.

Conclusion

We conclude that 0.1% ropivacaine with fentanyl produced excellent labor analgesia without detriment to foetus, comparable to 0.1% bupivacaine with fentanyl. However, ropivacaine may offer some advantage over bupivacaine with regard to less tendency to cause cardiovascular and CNS toxicity and can be used safely in parturient requesting painless labor.

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