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Original Research Article

A clinical study of comparison of effect with 0.15% ropivacaine and fentanyl 2mcg/ml versus 0.125% bupivacaine and fentanyl 2mcg/ml epidurally for labour analgesia

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ABSTRACT

Background: Adequate pain control is vital during labor as it can have negative impacts on maternal and fetal physiology. Epidural Bupivacaine with opioid has been in use for many years. Ropivacaine is almost similar to bupivacaine in terms of onset, duration, and quality of sensory blockade, but it is less toxic and produces less motor blockade.
Methods: Authors did a prospective randomized controlled study on 50 prim gravidas of ASA I category with singleton pregnancy in full-term labor, undergoing normal vaginal delivery, admitted to the antenatal ward requesting labor analgesia. They were randomly divided into two groups of 25 each receiving 8 ml Epidural bolus of either 0.125% Bupivacaine with 2ug/ml Fentanyl or 0.15% Ropivacaine with 2ug/ml Fentanyl by the epidural catheter.
Results: Analgesia in Ropivacaine group lasted 7.84 minutes longer than Bupivacaine group ($p<0.001$). Only 28% in the Ropivacaine group needed 3 analgesia top-ups or more compared to 76% in Bupivacaine group. No one out of 25 subjects in Ropivacaine group developed motor block, whereas 21 subjects (84%) in Bupivacaine group developed partial motor (grade 2) block. There was no significant difference in maternal or neonatal outcome between the groups.
Conclusions: Subjects in Ropivacaine group on comparison with Bupivacaine group experienced excellent labor analgesia, with greater duration of action, and reduced fentanyl, a local anesthetic requirement with similar VAS scores, maternal and neonatal outcomes besides the major advantage of reduced incidence of motor block.

Keywords: Bupivacaine, Epidural analgesia, Fentanyl, Labour analgesia, Ropivacaine

INTRODUCTION

One of the major challenges encountered by females during their lives is Labor pain. Neuraxial analgesia is the mainstay analgesic, frequently administered to women in labor.[1-3] Analgesic adequacy is vital during labor as painful labor can have negative impacts on maternal and fetal physiology.[4] Neuraxial analgesia involves injection or infusion of analgesics into the spinal cord by using a catheter, either intrathecally usually or epidurally to block transmission of pain signals to the brain. Epidural administration of amide local anesthetics in combination with opioids has been widely used for pain relief in labor because of the dose minimizing and side effects reducing benefits.[5-7] For many years, bupivacaine has been used for labor analgesia because of its longer action with minimal fetal and neonatal effects.[8] But because of its cardiotoxic nature and lipophilic nature enabling penetration of large myelinated motor fibers, resulting in the motor blockade, there are growing concerns and there

is a search for an alternative. Ropivacaine was then introduced into obstetric anesthetic practice as it caused less motor block compared with Bupivacaine, but the clinical benefits with regard to obstetric outcome need to be evaluated. Ropivacaine is virtually identical to bupivacaine in terms of onset, quality, and duration of sensory block, but seems to produce less motor block.[9] Ropivacaine is a long-acting amide local anesthetic agent producing labor analgesia through reversible inhibition of sodium ion influx in nerve fibres.[9,10] With reducing the cost of ropivacaine in the recent decades, further evidence is needed to support its role for regular use in labor analgesia.[9] so authors carried out our study with the objective of comparing epidural Bupivacaine and Ropivacaine in labor analgesia with fentanyl with regards to efficacy in relieving pain, effects on fetal and maternal outcomes and safety.

To compare epidural Bupivacaine and Ropivacaine in labor analgesia with regard to Efficacy of pain relief. Effect on fetal and maternal outcomes. Patient comfort and the ease of ambulation during labor. and Safety.

METHODS

Authors did a prospective randomized controlled study after getting approval from the ethics committee of Rajah Muthiah Medical College and Hospital. Fifty parturients who were admitted to the antenatal ward and who requested pain relief during labor were selected for the study. The procedure was explained to them in detail and written consent was obtained from them. Authors included only primigravida with singleton pregnancy, in full-term and established labor for normal vaginal delivery with cervical dilatation of 3-5 cms, belonging to ASA I category,

Authors excluded subjects with PIH, DM, bleeding disorder or other systemic disorders and subjects who have already received any opioid drugs or systemic analgesics. Subjects refusing regional anesthesia techniques or with known allergy to local anesthetic or other drugs or having any contraindication for central neuraxial techniques were also excluded.

The subjects were randomly divided into two groups of twenty-five each. The subjects received drugs for analgesia by a 18G epidural catheter inserted and kept inside the epidural space, taped firmly to the back.

Subjects in Group I (Bupivacaine) received epidural drugs (0.125% Bupivacaine with 2ug/ml Fentanyl) as 8ml bolus with 5ml top-ups. Subjects in Group II (Ropivacaine): Received epidural drugs (0.15% Ropivacaine with 2ug/ml Fentanyl) as 8ml bolus with 5 ml top-ups. In both the groups, at the start of the second stage of labor, a top-up of 5ml bolus was used. The top-ups were given only when the patient requested additional pain relief.

Before the procedure, the visual analog scale was shown to them and interpretation of the scale explained in detail. The patients were shifted to the operation theatre for insertion of the epidural catheter in an aseptic manner. Anesthesia machine was checked and all emergency airway equipment like laryngoscopes, blades of different sizes, endotracheal tubes, LMAs, oropharyngeal airways were kept ready. An emergency drug tray containing all the emergency drugs was also kept ready. IV access was secured with a 18G venflon. All patients included in the study were preloaded with 1000ml of Lactated Ringer's Solution. Patient's vital parameters like heart rate, blood pressure. SP02. respiratory rate and fetal heart rate were continuously monitored during the procedure. The baseline values were recorded, the drugs to be administered epidurally were prepared and stored in a sterile container. After the procedure, Epidural top-ups were not given till patients complained of pain or discomfort. With the catheter in place, patients were shifted to the labor ward where they were closely monitored until delivery.

Study procedure

The needles used for both groups were of Vygon make (18G Tuohy epidural and 18 G epidural catheter) and the epidural injection was performed as per the standard procedure using *'loss of resistance to air'* technique. No test dose was given, rather the bolus dose itself was given in two divided doses with 5 mins interval checking for motor block after the first dose.

The following parameters were observed:

1. HR, BP, $SP0_2$, FHR, Resp. the rate at 0, 5, 15, 30, 60 MMS and fifteen minutes thereafter.
2. Time of onset of analgesia.
3. Level of sensor}' blockade with loss of sensation to pinprick.
4. Motor block with Modified Bromage scale
5. Visual analog pain scale (VAS).
6. Hourly cervical dilatation.
7. Mode of delivery, duration of labor.
8. Birth weight of baby and APGAR score at 1 and 5 mins.
9. Patient comfort, satisfaction (4 - excellent, 3 - good, 2 - fair, 1- poor).
10. Side effects - Hypotension, nausea and vomiting, pruritis, respiratory depression, urinary retention.

The patients were informed to ask for additional pain relief even when they felt mild discomfort/pain. 5ml top-ups were given. During the onset of the second stage, a 5ml top-up was given in sitting position and further top-ups if needed were given in 5 ml boluses.

The routine obstetric practice was allowed to continue. In this institution obstetricians give Inj. Oxytocin infusion for most of the patients to accelerate labor. The artificial rupture was done if indicated. During the entire labor, the

mothers were positioned supine with left side tilt. If the patients were willing they were allowed to ambulate after Assessing their motor power. The following tests were done sequentially to assess their motor power.

- Straight leg raising
- Sit at edge of cot Unsupported
- Stand for a minute without support
- Performed a deep knee bend test
- Take three unassisted steps.

The study was approved by the Institutional human ethics committee. Informed written consent was obtained from all the participants. The confidentiality of the personal information was maintained throughout the study. Data were analyzed using IBM SPSS version 21. All the quantitative variables were checked for a normal distribution within each group, using visual inspection of histograms and normality Q-Q plots. Shapiro-Wilk test P values and Skewness and Kurtosis Z-values were also analyzed for this purpose. Normally distributed quantitative variables were compared between the two groups using independent sample t-test. Non normally distributed quantitative variables were tested between the two groups using Mann-Whitney U test. Categorical variables were compared between two groups using chi square test/Fisher's exact test. The time changing variables were compared between two groups using mixed methods ANOVA. A p value <0.05 was considered as statistically significant.

RESULTS

The mean age of group I (bupivacaine) was 22.17±2.99 and group II (ropivacaine) was 22.64±2.31, the association between two groups was statistically not significant (P value 0.539). The mean weight of group I (bupivacaine) was 62±5.4 and group II (ropivacaine) was 63+5.97, the association between two groups was statistically not significant (P value 0.537). The mean height of group I (bupivacaine) was 156.30±4.73 and group II (ropivacaine) was 155.36±5.47, the association between two groups was statistically significant (P value 0.047). Among the group, I (bupivacaine), 23 (92%) women had labor natural delivery and 2 (8%) had outlet forceps delivery. Among the group II (ropivacaine), 24 (96%) women had labor natural delivery and 1 (4%) had outlet forceps delivery.

The mean duration of first stage of labour in group I (bupivacaine) was 160±12.5 and group II (ropivacaine) was 164.4±12.35, the association between two groups was statistically not significant (P value 0.216). The mean duration of second stage of labour in group I (bupivacaine) was 53.16±7.40 and group II (ropivacaine) was 55.8±6.71, the association between two groups was statistically not significant (P value 0.192). The mean duration of third stage of labour in group I (bupivacaine) was 15.4±4.10 and group II (ropivacaine) was 14.72±3.80, the association between two groups was statistically not significant (P value 0.667) (Table 1).

Table 1: Comparison of Baseline Parameters between two study groups.

Parameter	Group I (Bupivacaine)	Group II (Ropivacaine)	P Value
Age	22.17±2.99	22.64±2.31	0.539
Weight	62±5.4	63+5.97	0.537
Height	156.30±4.73	155.36±5.47	0.047
Mode of delivery			
Labour natural	23 (92%)	24 (96%)	*
Outlet forceps	2 (8%)	1 (4%)	
Duration of Labour in minutes			
First Stage	160±12.5	164.4±12.35	0.216
Second Stage	53.16±7.40	55.8±6.71	0.192
Third Stage	15.4±4.10	14.72±3.80	0.667

*No P value can be computed as expected frequency is <5 in more than 20 % of the cells

Table 2: Comparison of duration of analgesia and additional analgesic requirement between the two study groups.

Parameter	Group I (Bupivacine)	Group II (Ropivacaine)	P Value
Duration of Analgesia	51.8±7.32	59.64±7.57	<0.001
No. of top ups			
1	0 (0%)	2 (8%)	*
2	6 (24%)	16 (64%)	
3	15 (56%)	7 (28%)	
4	5 (20%)	0 (0%)	
Total dose of drugs used			
Fentanyl (ug)	42±7.07	32.6±6.88	<0.001
Local Anesthetic (mg)	40.4±6.25	34.4±5.22	<0.001

*No P value can be computed as some of the cells contain observed frequency <1.

The mean duration of analgesia of group I (bupivacaine) was 51.8±7.32 and group II (ropivacaine) was 59.64±7.57, the association between two groups was statistically significant (P value <0.001). Among the group I (bupivacaine), 6 (24%) were number 2 top ups, 15 (56%) were number 3 top ups and 5 (20%) were a number of 4 top ups. Among the group II (ropivacaine), 2 (8%) was number 1 top ups, 16 (64%) were number 2 top ups, and 7 (28%) was number 3 top ups. The mean fentanyl (ug) of group I (bupivacaine) was 42±7.07 and group II (ropivacaine) was 32.6±6.88, the association between two groups was statistically significant (P value

<0.001). The mean local anesthetic of group I (bupivacaine) was 40.4±6.25 and group II (ropivacaine) was 34.4±5.22, the association between two groups was statistically significant (P value <0.001) (Table 2).

Among the group, I (bupivacaine), 3 (12%) were Bromage scaled 0, 21 (84%) were Bromage scaled 1 and 1 (4%) were Bromage scaled 2. Among the group II (ropivacaine), all of the 25 (100%) were Bromage scaled 0. Among the group I (bupivacaine), 17 (68%) had sensory level T8, 3 (12%) had sensory level T9 and 5 (20%) had sensory level T10. Among the group II (ropivacaine), 3 (12%) had sensory level T6, 15 (60%) had sensory level T8, 4 (14%) had sensory level T9 and 3 (12%) had sensory level T10 (Table 3).

Table 3: Comparison of the degree of the mortal block and maximum level of the sensory block between two groups.

Parameter	Group I (Bupivacine)	Group II (Ropivacaine)
Bromage Scale (maximum block)		
0	3 (12%)	25 (100%)
1	21 (84%)	0 (0%)
2	1 (4%)	0 (0%)
3	0 (0%)	0 (%)
Sensory level		
T6	0 (0%)	3 (12%)
T7	0 (0%)	0 (0%)
T8	17 (68%)	15 (60%)
T9	3 (12%)	4 (14%)
T10	5 (20%)	3 (12%)

*No P value can be computed as some of the cells contain observed frequency <1.

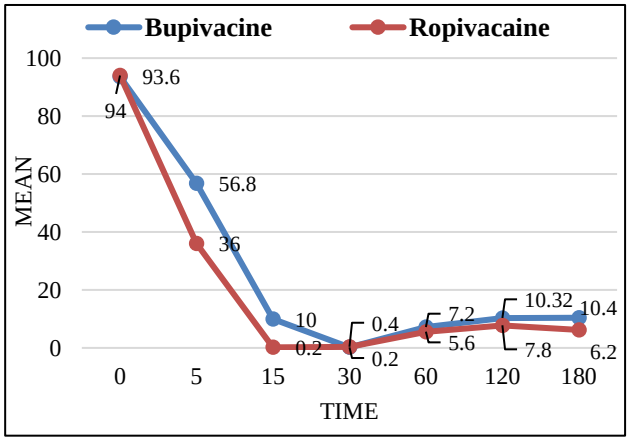

Figure 1: Comparison of VAS scores between study groups at different follow up intervals.

The mean VAS score was comparable between both the study groups throughout the follow up period. It has declined sharply till 15 minutes after the administration of the drug, in which ropivacaine has showed comparatively sharper decline. After 15 minutes even though the mean VAS was slightly lesser in ropivacine group, throughout the post operative period, the difference was very minimal between two groups (Figure 1).

The pulse rate was within normal physiological range in both the study groups and was slightly lower in ropivacaine group throughout the assessment period. (Figure 2).

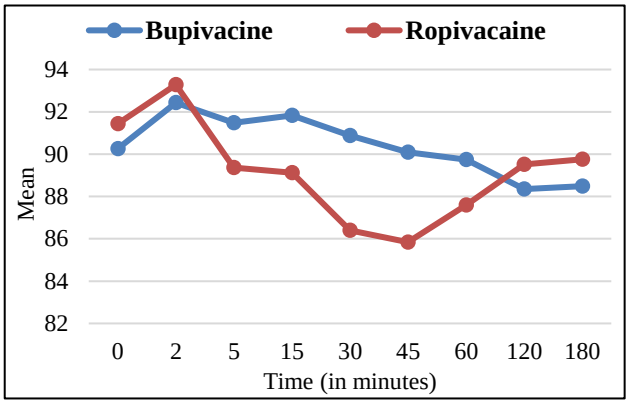

Figure 2: Comparison of pulse rate between study groups at different follow up intervals.

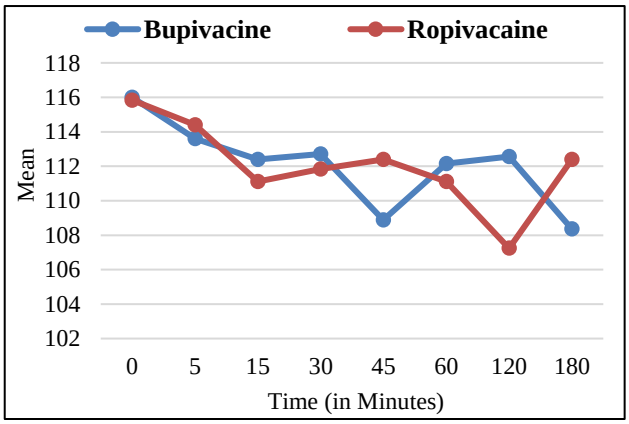

Figure 3: Comparison of systolic BP between study groups at different follow up intervals.

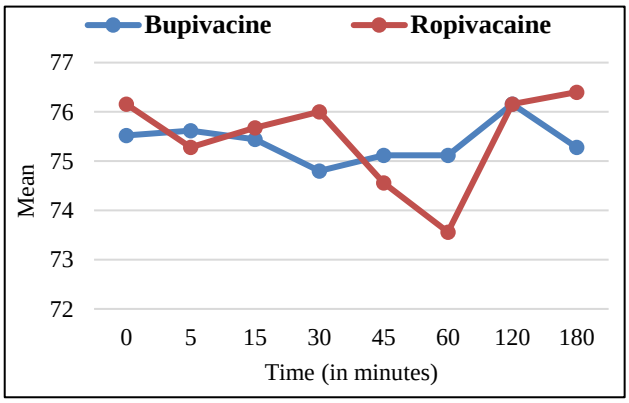

Figure 4: Comparison of diastolic BP between study groups at different follow up intervals.

No significant differences were found between the two groups in terms of other haemodynamic parameters like systolic BP and diastolic BP (Figure 3 and 4). The Fetal heart rate was also comparable between the two study groups, with no statistically significant difference (Figure 5).

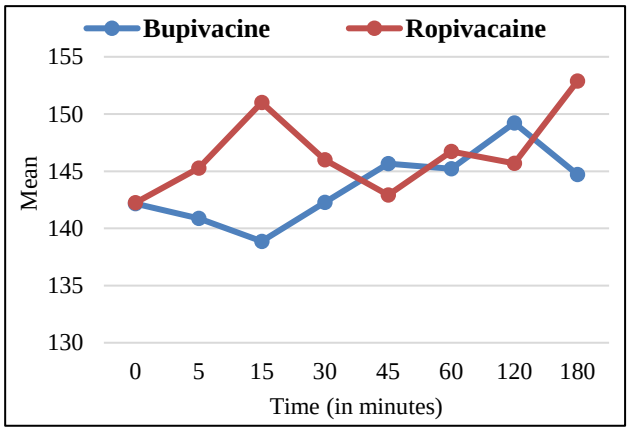

Figure 5: Comparison of FHR between study groups at different follow up intervals.

DISCUSSION

Painful labor results in major maternal physiological changes affecting maternal and fetal wellbeing. There is a surge in maternal catecholamines because of labor pain resulting in increased maternal oxygen consumption, leading to decreased placental perfusion and reduced fetal oxygen delivery.[4] Also, severe labor pain may lead to postpartum depression and posttraumatic stress.[11] So neuraxial analgesia was then introduced into labor and commonly used. But earlier observational studies suggested they increased adverse effects on labor outcome. But later, several randomized controlled trials and meta-analyses on comparing the outcome effects of neuraxial analgesia to non-neuraxial analgesia suggested that their administration does not increase the risk of side effects or Cesarean section.[3,12,13] Epidural administration of amide local anesthetics in combination with opioids has been widely used. In this study, authors assessed the analgesia, local anesthetic use, motor block, patient satisfaction and side effects of Bupivacaine Vs Ropivacaine for labor analgesia when administered along with fentanyl.

In this study, the baseline parameters were comparable between the study groups as shown in Table 1. The study groups were comparable with respect to age, weight, mode of delivery, stage of labor. Hence the variation in pain intensity at various stages of labour may not affect our study results. The mean age of subjects studied by Asik I et al, 5, Meister GC et al, Halpern SH et al, were 5 to 6 years higher than our study population.[14-16] Subjects in their study were also taller and heavier on an average than our subjects.

Neha A et al, in their study on Indian population reported a similar mean age (23.43 years in Bupivacaine Vs 23.6 years in Ropivacaine group) to our study (22.17 in Bupivacaine Vs 22.64 in Ropivacaine group).[17] But they weighed 10kgs lesser than our study population. Paddalwar S et al, also did their study on similar age group in India.[18]

Different concentrations of Ropivacaine and Bupivacaine were used by several authors. Authors used Bupivacaine 0.125% and Ropivacaine 0.15% which was similarly used by Paddalwar S.[18] Neha A et al, Halpern SH et al, studied Bupivacaine 0.1% and Ropivacaine 0.1 %. Asik I et al, used 0.2% Bupivacaine and Ropivacaine.[5,16,17]

In this study, authors found the higher duration of analgesia ($p<0.001$), reduced fentanyl and local anesthetic use ($p<0.001$), the reduced motor blockade in Ropivacaine group compared to Bupivacaine group. Analgesia in Ropivacaine group lasted for 7.84 minutes longer than Bupivacaine group, which was statistically significant ($p<0.001$) as shown in Table 2. Similar to our study, Dresner M et al, also observed that Pain relief, VAS score, the need for top up, satisfaction scores were consistently better in the ropivacaine group.[6] Authors also observed VAS scores to be slightly better in the Ropivacaine group in initial 30 minutes, but the distribution of VAS score at various intervals in both the groups was comparable and showed no statistical significance. Paddalwar S et al, in their study also observed that Ropivacaine showed no difference in the mean VAS scores and the quality of analgesia, as compared to Bupivacaine.[18]

Most studies and reviews have found epidural Ropivacaine and Bupivacaine, with or without opioids, to be similar when compared at equal concentrations ranging from 0.125 to 0.25% for maintenance of labor analgesia and this may not be consistent with different concentrations and their analgesic potency must also be considered.[5,15,16,19-21]

In this study, Bupivacaine group needed a higher number of top-ups compared to Ropivacaine group. Only 28% in the Ropivacaine group needed 3 top ups or more compared to 76% in Bupivacaine group. None of the subjects in Ropivacaine group required 4 top ups compared to 5(20%) in Bupivacaine group. In this study, the mean Fentanyl and Local anesthetic requirement were also higher in Ropivacaine group compared to Bupivacaine group ($p<0.001$) as shown in Table 2. Neha A et al, in their study on Indian population in, observed that both drugs provided excellent patient satisfaction with no major side effects and rapid, equivalent pain relief during labor.[17] They achieved statistical significance only for the higher number of top-ups required in Bupivacaine group compared to Ropivacaine.

Similar to our study, Dresner M et al, also observed that Patients receiving ropivacaine received fewer routine top-

ups (median 1.0 vs. 2.0, P=0.001) and fewer escape top-ups (9.8% vs. 21.8%, P=0.02).[6]

In this study, No one out of 25 subjects in Ropivacaine group developed motor block, whereas 21 subjects (84%) in Bupivacaine group developed partial motor (grade 2) block, which means the ability to weakly flex the knees (Bromage Scale). One other subject developed almost complete motor (grade 3) block. The level of sensory block was almost similar between the groups. Similarly, Asik I et al, also observed that motor block was observed in 10 patients in the Bupivacaine group whereas only two patients had a motor block in the Ropivacaine group (P <0.05).[5] Similar to our study, Guo S et al, in their meta-analysis also found that Analgesia with ropivacaine in combination with fentanyl is associated with lower incidence of motor blocks in comparison with bupivacaine and fentanyl at a similar ratio (0.1%: 0.0002%).[19] Meister GC et al, also observed similar results to our study. In contrast, Halpern SH et al, observed that there was no significant difference between the two drugs in the mode of delivery, maternal satisfaction, or neonatal outcomes.[15,16] Whether or not there is a difference in the motor block at clinically relevant doses is unresolved. Dresner M et al, also observed that there were no significant differences in patients' assessment of motor block between the groups.[6] Halpern SH et al, in their systematic review also observed that Low concentrations of bupivacaine or ropivacaine provide excellent analgesia without a significant motor block. Similarly, Paddalwar S et al, in their study also observed that No patient in group R developed motor block, whereas five patients in group B developed grade 2 (mild) motor block.[13,18]

In this study Maternal pulse rate, Blood pressure, and Fetal heart rate were comparable between the groups. There was no occurrence of Hypotension, Maternal, and fetal bradycardia. Similar to our study, Guo S et al, Meister GC et al, Halpern SH et al, also found no statistically significant differences between both the groups in terms of maternal and fetal outcome.[15,16,19]

Ropivacaine is a long-acting amide local anesthetic agent with effects similar to bupivacaine. Being less lipophilic than bupivacaine, it is less likely to penetrate large myelinated motor fibers, thus causing relatively reduced motor blockade and is superior to bupivacaine for epidural labor analgesia and is better or identical than bupivacaine in terms of onset, quality, and duration of sensory block, maternal or neonatal outcome. The lesser toxicity and reduced cardiovascular toxicity compared with bupivacaine may be a distinct feature of ropivacaine.

Limitations of the study include authors could not study the effects of bupivacaine and ropivacaine at different concentrations because of practical feasibility and cost involved.

CONCLUSION

Authors conclude that 0.15% Ropivacaine with 2ug/ml Fentanyl on comparison with 0.125% Bupivacaine with 2ug/ml Fentanyl produced excellent labor analgesia, with greater duration of action, and reduced fentanyl, a local aesthetic requirement with similar VAS scores, maternal and neonatal outcomes besides the major advantage of reduced incidence of motor block.

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Ethical approval: The study was approved by the Institutional Human Ethics Committee

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