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Research Article

A Randomized Comparative Study on Labor Analgesia Using Bupivacaine Vs Ropivacaine

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Abstract

Background: The pain of childbirth is arguably the most severe pain most women will endure in their lifetimes. Labor pain per se as well as the tissue damage produced by child birth is associated with direct and indirect effects on the mother and fetus. Hence control of pain should form an integral part of labor management at all levels. Of all the techniques, epidural analgesia is the most effective form and has become the "gold standard" in obstetric care. Ropivacaine, a newer local anaesthetic released in 1996, has similar pharmacokinetic and pharmacodynamic properties as Bupivacaine. It was found to be less cardiotoxic and has high sensory: motor differential blocking property.

Aim: To compare bupivacaine-fentanyl and ropivacaine-fentanyl in full term parturient for epidural labor analgesia.

Materials and Methods: After obtaining ethical committee clearance and patient consent, 60 parturient in active stage of labor were divided randomly into 2 groups of 30 each. Group B -Received 0.125% Bupivacaine with 2 µg/ml Fentanyl, Group R-Received 0.1% Ropivacaine with 2 µg/ml Fentanyl. Analgesia was maintained with intermittent bolus doses. The following parameters were monitored: level of sensory block, degree of motor blockade, pain score by VAS, mode of delivery, maternal satisfaction and total dose of local anaesthetic consumed.

Results: The group-B and group-R were similar in demographic attributes and obstetric variables. Labor analgesia in the both groups were equally effective clinically in terms of highest sensory blockade, pain scores, motor blockade, maternal satisfaction and mode of delivery. But Bupivacaine had produced statistically more motor blockade compared to Ropivacaine.

Conclusion: The combination of 0.125% bupivacaine with fentanyl 2 mcg/ml and 0.1% ropivacaine with fentanyl 2 mcg/ml are equally effective in achieving excellent labor analgesia without jeopardizing the safety of the mother and foetus.

Keywords: *Bupivacaine; Ropivacaine; Labor Analgesia; Labor Epidural*

Introduction

Pain is the single most predominant sentinel of the beginning of labor. The pain of childbirth is arguably the most severe pain most women will endure in their lifetimes. It produces significant physical and mental effects which may produce fear and anxiety during labor and may cause post-partum emotional reaction. Neuraxial epidural analgesia has been seen to completely relieve the pain of labour and is the 'gold standard' for labour analgesia [1]. The use of low concentration of local anaesthetic in combination with opioids has reduced the total dose of local anaesthetic used as well as their side effects. Ropivacaine is a relatively newer amide (s enantiomer) local anaesthetic with high pKa and low lipid solubility. Both bupivacaine and ropivacaine, drugs possess similar structure, pharmacology, mechanism of action and physiochemical properties. However, ropivacaine is believed to have lower incidence of clinical cardiac side effects than bupivacaine [2] and also has lesser motor blockade compared to bupivacaine [3]. Hence, study is undertaken to compare bupivacaine-fentanyl and ropivacaine-fentanyl in full term parturient for epidural labor analgesia.

Materials and Methods

A prospective randomized study was conducted on 60 parturient's in active stage of labor in Department of Anaesthesiology in association with Department of Obstetrics and Gynaecology at Bapuji Hospital, Approval was taken from the Institutional ethical review committee and written informed consent was taken from all the patients after explaining the study to them

60 parturient in active stage of labor with below mentioned inclusion and exclusion criteria were randomly divided into two groups of 30 each.

- Group B: Received 0.125% Bupivacaine with 2 µg/ml Fentanyl
- Group R: Received 0.1% Ropivacaine with 2 µg/ml Fentanyl.

Procedure

A detailed history, general physical examination, systemic examination, airway assessment and spine examination were done. Routine laboratory investigations like complete blood count, bleeding and clotting time, serological testing for HIV and HbsAg were done.

Parameters like demographic data, gestational age, parity were noted. The parturient was prepared as per the routine preparations done for delivery. In addition, they were asked to void the urine. The degree of cervical dilatation, condition of the membranes, adequacy of pelvis for vaginal delivery were all assessed by the attending obstetrician before institution the procedure.

Inclusion criteria

1. ASA physical status I-II.
2. Women with gestational age ≥ 36 weeks.
3. Parturient's in active stage of labor.
4. Singleton pregnancy.
5. Uncomplicated pregnancy with normal fetal heart rate.

Exclusion criteria

1. ASA physical status III or IV.
2. Preterm gestation.
3. Allergy to any study drug.
4. Contraindications or patients unwilling for labor analgesia.
5. Parturient's not in active stage of labor.
6. Pregnancy with medical complications like gestational hypertension, diabetes mellitus and other systemic disorders.

Technique

Under aseptic precautions epidural space is identified in sitting position with midline approach using 18G Tuohy's needle in L3-4 or L4-5 interspace with loss of resistance to air technique and catheter was threaded in cephalad direction. And about 3 to 4 cm of catheter was left in epidural space. The catheter was well secured with plaster. After negative aspiration for blood and CSF, a test dose of 3 ml of lignocaine 2% with 1:2,00,000 adrenaline was administered through the catheter. Intra vascular spread of the drug will be detected by a change in heart rate of more than 10 beats per minute from baseline within 20 - 40 seconds [4]. Intrathecal spread will be detected by appearance of motor blockade within five minutes. Subjects with positive test dose response will be excluded from the study.

Five minutes after administering the test drug, 10 ml of study drug of either 0.125% Bupivacaine with Fentanyl 2 µg/ml or 0.1% Ropivacaine with Fentanyl 2 µg/ml will be given in 5 ml increments over 10 minutes. Patients not experiencing analgesia at 20 minutes of initial bolus will be excluded from the study. Patients' VAS pain score was recorded every 5, 10, 20, 30, 45, 60, 90, 120, 150, 180, 210, 240, 270, 300 minutes until the delivery.

After positioning the patient in supine position, onset of analgesia and dermatomal level was assessed by the loss of temperature discrimination to alcohol swab, time of onset and degree of motor blockade was checked by Bromage scale Incremental doses of analgesia was given and maintained with intermittent bolus dose of 10 ml given in 5 ml increments in a time interval of 10 minutes, up to a maximum of 10 ml/hr. Parameters studies are Level of sensory block, degree of motor blockade, pain score by VAS, mode of delivery, maternal satisfaction and total dose of local anaesthetic consumed.

Results

Statistical Tools: The information collected regarding all the selected cases were recorded in a master chart. Data analysis was done with the help of computer using SPSS-10 software. For the numeric data like age, height, weight, heart rate, etc., mean and standard deviations were calculated. For non-numeric data frequency and percentages were calculated. In order to compare the mean values of both groups (B and R) unpaired student's T-test was used. For two attributes (comparison of proportion) like mode of delivery chi square test was applied and for comparing maternal satisfaction fisher extract applied in both the groups. The scale of age (year) variable was changed into ordinal scale i.e., categories into 18 - 21, 22 - 25 and more than 25. P value < 0.05 had been considered as significant value.

Sixty patients completed the study. Thirty patients received 0.125% Bupivacaine with Fentanyl 2 µg/ml and the remaining 30 received 0.125% Ropivacaine with Fentanyl 2 µg/ml. Demographic data such as age, height, weight between two groups were comparable.

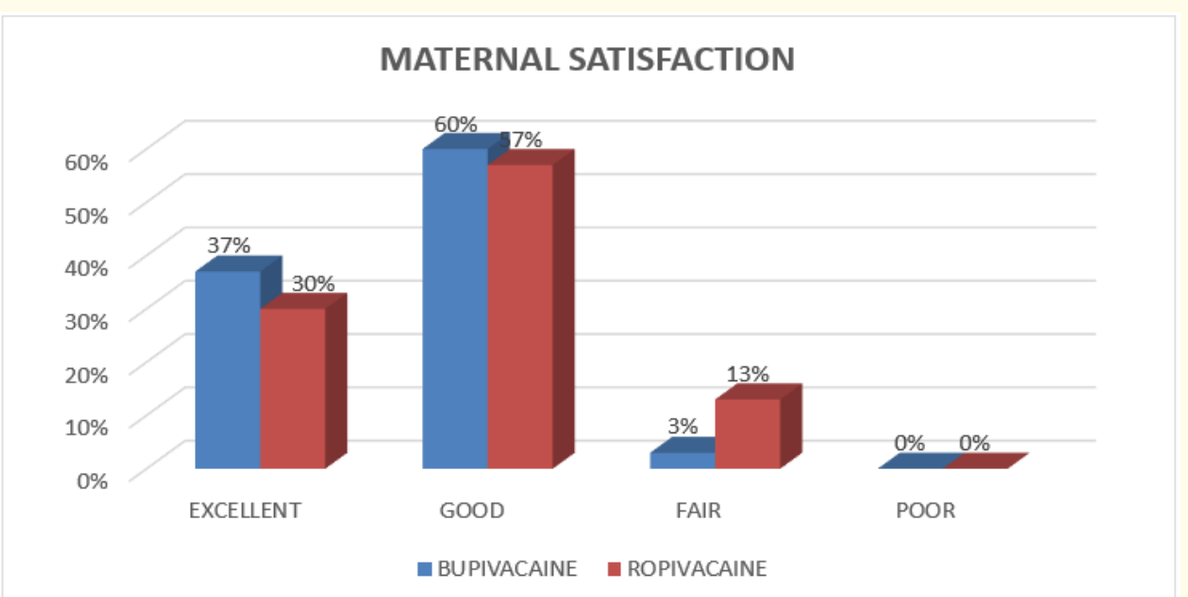
Parameters	Group B	Group R	P value
Age (year)	22.43 ± 2.34	22.7 ± 2.29	0.658
Height (centimetres)	155.1 ± 2.006	155.76 ± 1.81	0.182
Weight (kilograms)	67.7 ± 4.211	68.166 ± 3.68	0.65

Table 1: *Comparison of age and anthropometric variables of parturient's between the two groups.*

No patient achieved sensory level up to T6 either of the groups whereas up to T8 level was achieved in 25 and 26 patients and up to T10 level in 5 and 4 patients in group B and group R respectively. Pain was assessed by Visual analogue score (VAS). VAS consists of 0 - 10 scale, where 0 was no pain and 10 was the worst possible pain experienced in their life time. Scoring was done from before initiating epidural and after 5, 10, 20, 30, 45, 60 and every 30 minutes from there after until the delivery of parturient. The VAS score in each parturient varied from time to time. In our study results were expressed in mean and SD of VAS for entire duration.

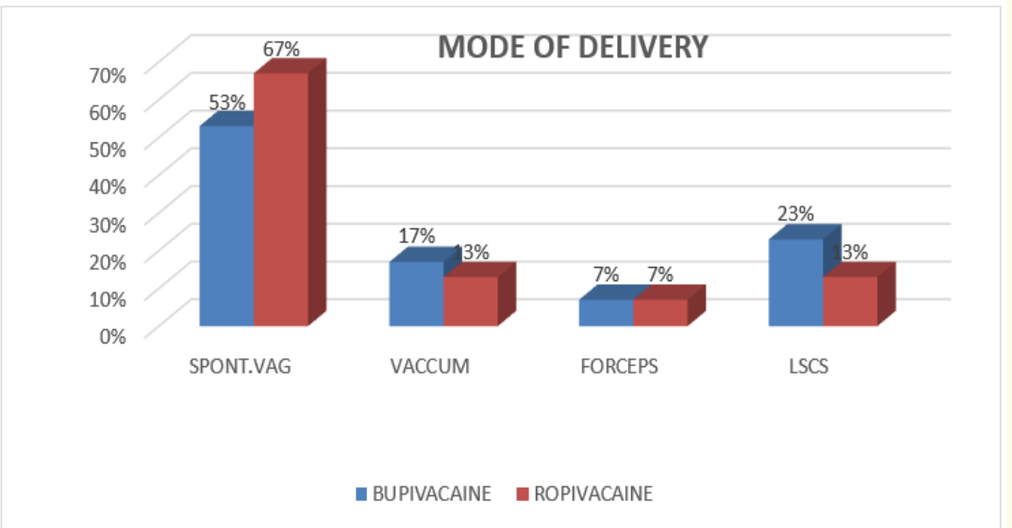
Before initiating epidural the mean score in group B was 7.9 with SD 1.35 and in group R it was 7.7 with SD 1.05. After administration of the drug the mean VAS score in group B was 1.70 with SD of 0.65 and in group R it was 1.68 with SD of 0.60 with a P-value of 0.88 which was statistically not significant.

Maternal satisfaction was assessed based on verbal numerical score as excellent, good, fair or poor. The scoring was done from 0 - 10, where 8 - 10 was taken as excellent, 5 - 7 was taken as good, 2 - 4 was taken as fair and less than 2 was taken as poor. In our study, 11 cases (37%) in bupivacaine and 9 cases (30%) in ropivacaine group rated satisfaction as excellent and 17 cases (57%) in bupivacaine and 17 cases (57%) in ropivacaine group rated as good whereas 2 cases (6%) in bupivacaine and 4 cases (13%) in ropivacaine group rated it as fair respectively and no parturient in the study rated satisfaction as poor.



Graph 1: *Showing the distribution of grading of patient satisfaction in both groups and the overall.*

In our study 16 (53%) and 20 (67%) had spontaneous vaginal delivery, 5 (17%) and 4 (13%) had vacuum assisted, 2 (7%) and 2 (7%) had forceps assisted, and 7 (23%) and 4 (13%) had caesarean delivery in group B and group R respectively. In total out of a total 60 patients, 36 patients (60%) results in spontaneous vaginal delivery, 13 patients (22%) results in instrumental delivery and 11 patients (18%) results caesarean delivery.



Graph 2: *Showing the number of patients (%) and their mode of delivery in both the groups.*

The total anaesthetic dose used in both study groups were calculated after the delivery of the baby. In group B the mean of total dose consumed was 30.33 ml (38 mg) with SD of 5.56 ml (6.8 mg) whereas it was 29.67 ml (37 mg) in ropivacaine with SD of 5.56 (6.8 mg).

Discussion

In our study, while comparing small concentrations of Ropivacaine and Bupivacaine (both combined with Fentanyl), we found equivalent excellent analgesia for labor. There was no statistically significant difference in the demographic profile, level of sensory block achieved, VAS score, maternal satisfaction, mode of delivery and total dose of local anaesthetics used among the two groups using intermittent top up technique. Though there was significant difference between motor blockade, it appears to be of no clinical relevance as it did not have any influence over mode of delivery in both the groups. Most clinical studies 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 [5,6].

The level of sensory block achieved in each parturient was variable and the dermatomal level achieved was of a non-numerical variable. Therefore, we considered the most frequent value (mode) achieved in percentage in all the 60 parturients and also separately in group-B and group-R and p-value 0.2642 which was not significant. Thus, out of 60 parturients, 51 parturients (85%) achieved a level of T8, 9 parturients (15%) achieved a level of T10 and no parturients achieved a level of T6.

Sensory level	Group B	Group R	Total	P value
T6	0 (0%)	0 (0%)	0 (0%)	0.2642
T8	25 (83%)	26 (87%)	51 (85%)	
T10	5 (17%)	4 (13%)	9 (15%)	
Total	30 (100%)	30 (100%)	60 (100%)	

Table 2: *Showing the no. of patients who achieved most frequent sensory level in both groups and all the patients over entire duration with p value (Fisher's Exact test).*

Valecha., *et al*. in 2016 [7], conducted a comparative study on 0.125% Bupivacaine versus 0.2% Ropivacaine for labor epidural analgesia, T8 level was achieved in 20 (66.7%) and 17 (56.7%) patients in respective groups (n = 30 in each group) and T10 level in 10 (33.3%) and 12 (40%) patients respectively, T6 level was achieved in no patient in bupivacaine group and in 1 patient in ropivacaine group. That was in total (n = 60) most of the patients (61.7%) patients were found to have sensory level of T8 and least (1.7%) was with T6 level which was consistent with our study.

Meister., *et al.* in 2000 [8], conducted a study on a comparison of epidural analgesia with 0.125% ropivacaine with fentanyl versus 0.125% bupivacaine with fentanyl during labor and they found that level of sensory block achieved in the bupivacaine-fentanyl group was T8 (T6-T9) and in ropivacaine -fentanyl group it was T-7 (T6-8). Similarly, in studies conducted by Polley., *et al.* [9] it was found that the most frequent sensory level achieved was T8.

The degree of motor was assessed at 20 minutes initially and every 30 minutes thereafter until the delivery using Bromage score. In our study overall mean Bromage score was calculated for entire duration in each group. In group B mean Bromage score was 0.071 with SD 0.083 and in group R it was 0.03 with SD 0.057. Their p = 0.035 which was statistically significant but as there were no difference in mode of delivery in both groups, this statistical significance was of no clinical relevance. This was probably due to use of very dilute concentration of study drugs and statistically significant difference in motor blockade in the study groups may be attributable to relative potencies of drugs. In our study among 60 parturient's all of them had Bromage score 0 and none of them had Bromage grade 1, grade 2 or grade 3 motor blockades. Hence, whatever the blockade which was achieved does not had any impact on obstetric outcome.

Group	N	Mean	SD	P value
Bupivacaine	30	0.071	0.083	0.035
Ropivacaine	30	0.03	0.057	

Table 3: *Comparison of the mean Bromage score and SD of parturient's studied in both the groups for entire duration, N = 60 (Students t test).*

Mitra., *et al.* in 2015 [1] and Badwane., *et al*. in 2016 [10] showed a significant motor blockade in bupivacaine group and concluded that that difference was neither statistically significant nor clinically meaningful. And there was no difference in mode of delivery in their study groups. Chora., *et al.* in 2014 [11], in their comparative study found that, there was no case of motor blockade in any group all the patients were able to get out of the bed during labor. All the patients were able to perform the bed side partial knee bend without difficulty. Pain was assessed by Visual analogue score (VAS). Scoring was done from before initiating epidural and after 5, 10, 20, 30, 45, 60 and every 30 minutes from there after until the delivery of parturient. The VAS score in each parturient varied from time to time. In our study results are expressed in mean and SD of VAS for entire duration. Before initiating epidural the mean score in group B was 7.9 with SD 1.35 and in group R it was 7.7 with SD 1.05. After administration of the drug the mean VAS score in group B was 1.70 with SD of 0.65 and in group R it was 1.68 with SD of 0.60 with a P-value of 0.88 which was statistically not significant.

In a similar study done by Paddalwar., *et al.* in 2013 [4], showed that the mean baseline VAS score in group R was 9.60 ± 0.968, whereas in group B, it was 9.17 ± 0.98 (P = 0.09, which was not significant). At 20 minutes, all the patients in both the groups were pain free with a VAS score of 0 - 2. Also the distribution of VAS at various intervals in both the groups was comparable and showed no statistical significance (P > 0.01).

Mitra., *et al.* in 2015 [1], found that there was significant difference in the VAS scores at 1 and 2 hours between the two groups with bupivacaine group showing significantly lower mean VAS scores, the overall mean VAS score during treatment between the two groups was statistically insignificant. Similar studies done by Lakesh., *et al*. in 2017 [12] and Guo., *et al.* in 2015 [13] also found that there were no significant difference between the mean VAS scores between bupivacaine with fentanyl and ropivacaine with fentanyl groups. In our study, the p-value was 0.6483 signifying that the difference between the two groups was not statistically significant.

Guo., *et al. [*13] in their meta-analysis on epidural analgesia with bupivacaine and fentanyl versus ropivacaine and fentanyl for pain relief in labor consisting of 3 studies involving total of 498 parturient's showed that there was no statistical difference in maternal satisfaction in two groups (p = 0.18). Bolukbasi., *et al.* [14], in their study compared maternal satisfaction on a numerical score of 1 - 4 (4-excellent, 3-good, 2-fair, 1-poor) in both first and second stage of labor. 34% and 29%, 49% and 45%, 15% and 24%, 2%and 2% rated excellent, good, fair, poor in group B and group R respectively in second stage of labor. There was no statistically significant difference between the two groups. In our study, 11 cases (37%) in bupivacaine and 9 cases (30%) in ropivacaine group rated satisfaction as excellent and 17 cases (57%) in bupivacaine and 17 cases (57%) in ropivacaine group rated as good whereas 2 cases (6%) in bupivacaine and 4 cases (13%) in ropivacaine group rated it as fair respectively and no parturient in the study rated satisfaction as poor.

Beilin Y., *et al. i*n 2007 [15] in their study found that ninety-eight women received bupivacaine, 90 ropivacaine, and 34 levobupivacaine. There was no significant difference in the operative delivery rate (bupivacaine = 46%, ropivacaine = 39%, and levobupivacaine = 32%, P = 0.35) among groups. Mitra., *et al.* in 2015 [1], in their study found that 76.7% had spontaneous vaginal delivery in both groups, 6.7% and 3% had forceps and 16.7% and 13.3% had LSCS in bupivacaine and ropivacaine group respectively. And there was nonsignificant difference in mode of delivery. In similar study done by Lakesh., *et al*. in 2017 [12] found that spontaneous vaginal delivery occurred in 92% parturient in Group R and 88% in Group B, one parturient in Group R and two parturient in Group B had forceps delivery. Two parturient in Group R and three parturient in Group B had caesarean delivery. Also in studies conducted by Bawdane., *et al.* in 2016 [10] and Halpern., *et al.* [16], showed that there was no significant difference in the incidence of spontaneous vaginal delivery and mode of delivery between two groups. In our study 16 (53%) and 20 (67%) had spontaneous vaginal delivery, 5 (17%) and 4 (13%) had vacuum assisted, 2 (7%) and 2 (7%) had forceps assisted, and 7 (23%) and 4 (13%) had caesarean delivery in group B and group R respectively. In total out of a total 60 patients, 36 patients (60%) results in spontaneous vaginal delivery, 13 patients (22%) results in instrumental delivery and 11 patients (18%) results caesarean delivery.

The wide variations in mode of delivery in various studies may be due to differences in obstetric decisions and also may be due to obstetrics indications pertaining to particular mode of delivery. But these variations were not statistically insignificant between two groups.

The total anaesthetic dose used in both study groups were calculated after the delivery of the baby. Paddalwar., *et al.* in 2013 [4] found that the mean total dose of drug required for group R was 31.83 ± 0.52 mg and for group B was 33.25 ± 7.66 mg (P = 0.444). The statistical difference between the two groups was insignificant. The mean total dose of B (P value 0.429) is not significant. Lakesh., *et al.* in 2017 [12], observed in their study that there was no significant difference in doses of local anaesthetic's used. Similarly, in another study done by Chua., *et al.* they found that the mean total dose consumed was 10.8 mg/hr and 12.5 mg/hr in group B and group R respectively. It was statistically not significant (p > 0.05). In our study, the mean total dose consumed was 30.33 ml (38 mg) in bupivacaine with SD of 5.56 ml (6.8 mg) whereas it was 29.67 ml (37 mg) in ropivacaine with SD of 5.56 (6.8 mg) which was statistically insignificant.

Conclusions

We conclude that the combination of 0.125% bupivacaine with fentanyl 2 µg/ml and 0.1% ropivacaine with fentanyl 2 µg/ml are equally effective in achieving excellent labor analgesia without jeopardising the safety of mother and foetus and hence can be recommended for labor analgesia as an alternative as ropivacaine has less cardiotoxic effect than bupivacaine.

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