Original Article

Double blind comparison of combination of 0.1% ropivacaine and fentanyl to combination of 0.1% bupivacaine and fentanyl for extradural analgesia in labour

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Abstract

Background and Aims: Ropivacaine is considered as a safe alternative to bupivacaine for labor analgesia. The aim was to compare epidural ropivacaine and bupivacaine in intermittent doses for obstetric analgesia.

Material and Methods: In this prospective, randomized, double-blind study, 60 women in labor were randomly allocated to receive either bupivacaine 0.1% with fentanyl 2 μg/mL (BF), or ropivacaine 0.1% with fentanyl 2 μg/mL (RF). Bromage scale, loss of cold sensation to ether swab in midclavicular line, visual analog scale were used to test for motor block, sensory block and pain, respectively. Hemodynamic parameters, onset of analgesia, dose requirement of drug to produce analgesia, duration of labor, and incidence of side effects were also recorded. Data were expressed as mean ± standard deviation and analyzed using students unpaired *t*-test, Chi-square and Mann-Whitney U-tests at $P < 0.05$.

Results: Both drugs were similar with respect to hemodynamic stability, onset of analgesia, quality of analgesia, sensory blockade, neonatal outcome, requirement of drugs, duration of labor, and incidence of side effects. Three parturient in bupivacaine (B-F) group had a motor block of Bromage 1 and were delivered using forceps. None of the parturient in ropivacaine (R-F) group had any motor block, and all had spontaneous vaginal delivery, but this difference was not statistically significant ($P = 0.081$).

Conclusions: Bupivacaine and ropivacaine provide equivalent analgesia in low (0.1%) concentration.

Key words: Bupivacaine, epidural analgesia, obstetrical analgesia, ropivacaine

Introduction

Epidural administration of local anesthetics and opioid is used for labor analgesia. Ropivacaine, a S-enantiomer of bupivacaine is claimed to produce less motor block,[1] less incidence of instrumental deliveries,[2] and better neonatal outcome[3] as compared to bupivacaine. In various studies, epidural low dose ropivacaine combined with fentanyl has been shown to produce effective labor analgesia, which is equivalent to that of low dose bupivacaine and fentanyl.[4] Ropivacaine is claimed to have an advantage of being less cardiotoxic and neurotoxic than bupivacaine.[5] Thus, ropivacaine may be more suitable for obstetric pain relief.[2]

Routine practice at our institute was using 0.1% bupivacaine and 2 μg/mL fentanyl for extradural labor analgesia. Ropivacaine is recently introduced in India, and not many studies are conducted. Previous studies have compared the pharmacological properties of both the drugs and were found to be similar.[6] Furthermore, previous studies have used similar doses. We therefore undertook this comparative, prospective, double-blind study using epidural bupivacaine 0.1% with fentanyl 2 μg/mL and epidural ropivacaine 0.1% with fentanyl 2 μg/mL with respect to onset of analgesia, quality of analgesia, incidence of motor block, sensory level achieved, requirement of local anesthetic drug, incidence of instrumental delivery, duration of labor, and incidence of side effect.

Material and Methods

Institutional review board approval was obtained, after which 60 American Society of Anesthesiologists (ASA) physical

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Status I or II parturients in active labor with a cervical dilation of more than 3 cm, having full term live fetus without any obstetric complication and requesting epidural analgesia were prospectively randomized ($n = 30$ in each group) using a computer-generated table of random numbers. The study was carried out from December 2009 to April 2012. In this double-blinded study, parturients received intermittent bolus doses of either 0.1% ropivacaine with fentanyl 2 μg/mL (RF) or 0.1% bupivacaine with fentanyl 2 μg/mL (BF).

Exclusion criteria included, body mass index more than 30, parturient's height <150 cm, age <18 years, anticipated difficult intubation, contraindication for epidural catheter placement, sensitivity to study drug, administration of intravenous (IV) analgesics within 1 h of epidural request. Parturients were explained about the study and written informed consent was obtained. They were explained and demonstrated the use of 10 cm visual analog scale (VAS), for quantification of their pain at the peak of uterine contraction.

Study solution was prepared by a qualified anesthesiologist who was not involved in patient management or data collection and handed over to the investigator. Code number was put on parturient record sheet, and decoding was done at the end of the study for statistical analysis. Intermittent epidural top-ups of study solution were administered by qualified anesthesiologist. All resuscitation equipment were kept ready. IV access was secured when parturient requested epidural analgesia and thus enrolled in the study. Parturients were rehydrated with 500 mL of Ringer Lactate solution and intermittent oral sips of clear fluid were allowed.

Epidural catheter was inserted under strict aseptic precautions, when cervical dilatation reached ≥3 cm with active labor.[7] The procedure was performed using 18 G Touhy's needle. (Epidural Minipack System 1, Portex, Smiths Medical India Pvt ltd.) A multi orifice catheter with micro bacterial filter was placed in L3-L4 or L4-L5 inter vertebral space using loss of resistance technique and advancing the catheter tip 4 cm cephalad. The parturient was placed in the supine position with left uterine displacement. A test dose of 3 mL of lignocaine (2%) with 15 ug epinephrine was administered through the epidural catheter after careful aspiration to rule out subarachnoid or IV placement of the catheter. Once negative test dose was established, then initial dose of 10 mL of study drug was administered via extradural catheter in two incremental boluses of 5 mL over 10 min. Pain was assessed at the peak of contraction using VAS.

If VAS ≥4 after 15 min of epidural bolus, further study solution was administered in aliquots of 5 mL every 5 min till VAS <4. If VAS remained ≥4 after 30 min or after 30 ml of epidural drug, rescue analgesia with 10 mL of 0.25% study drug was given in aliquots of 5 mL over 10 min. If VAS remained ≥4 in spite of rescue analgesia, then labor analgesia was considered inadequate, and other mode of analgesia or reinsertion of the epidural catheter was considered, such parturients were excluded from the study.

Initial dose of study solution required to reduce VAS ≤4 was considered as "loading dose" and time required for same was considered as "onset of analgesia."[8] Later during labor, whenever parturient had VAS ≥3, parturient were given intermittent bolus top up of 5 mL of study solution. Minimum time between top up was decided to be 5 min, with hourly limit of 30 ml. Rescue analgesia was given if VAS persisted ≥4 even after giving 30 mL of top up in an hour. Total number of top ups required, and total amount of drug required were noted. Every top up was given after confirming negative aspiration for blood and cerebrospinal fluid.

Visual analog scale score was recorded every 5 min for first 30 min, then at every 30 min till the end of labor. VAS at the end of the first stage and second stage was also noted.

Parturients were excluded from data analysis in case of a positive epidural test dose, persistent inadequate analgesia in spite of rescue analgesia, delivery within 2 h of epidural catheter placement, accidental epidural catheter removal, or inadequate data collection.

In the second stage of labor, drug was administered with parturient in semi-recumbent position and was asked to bear down with contraction. Vital parameters of mother such as blood pressure, heart rate, respiratory rate, and maternal saturation were recorded throughout the study. Blood pressure was recorded in the supine position with left lateral tilt by sphygmomanometer.[9]

Maternal sedation was assessed using modified Ramsay sedation score[10]. Motor block was assessed by Bromage scale and peak motor block achieved during study was noted. Sensory block was assessed by loss of cold sensation to ether swab in midclavicular line, every 30 min and peak sensory level achieved during the study was noted down. Analgesic effect was measured using VAS score for pain (0 = no pain and 10 = worst pain).[11]

Fetal heart rate was recorded throughout the study; neonatal welfare was assessed by Apgar score. Incidence of instrumental deliveries, total dose and hourly requirement of bupivacaine/ropivacaine and fentanyl used, was recorded. Maternal side effects like nausea, vomiting, pruritus, hypotension,

respiratory depression (respiratory <8/min) were noted and treated.

Fall in blood pressure of more than 20% of the baseline value or systolic blood pressure <90 mm/Hg was considered as hypotention and treated with fast infusion of IV fluid and vasopressor like Ephedrine if required.

Respiratory rate <8 or fall in SaO_2 <95% was considered as respiratory depression and was treated with supplemental oxygen with Venti mask, Ambu bag was also kept available as a resuscitative measure. Parturient and newborn were followed-up to 24 h for any late complications.

At study termination, parturients were asked to rate overall epidural analgesia as either excellent, good, fair, poor or absent, to know the quality of analgesia. Parturients were asked whether they were satisfied or not with labor analgesia.

Statistical analysis

The mean (standard deviation [SD]) duration of sensory block by bupivacaine and fentanyl was 140 min (50 min) reported in a previous study.[12] We considered a 20% increase in duration of sensory block by ropivacaine to be clinically superior.

With power of study 80% and Type 1 error of 5% (level of significance [α] = 0.05), the sample size required was calculated as 25 in each group and to compensate for dropouts a sample size of 30 subjects per group was chosen.

Data was expressed as mean and SD and analyzed using Student's unpaired *t*-test. VAS score, Bromage score, sedation score and Apgar score were expressed as median and interquartile range (IQR) and analyzed using Mann–Whitney U-test. For categorical data like adverse events, Chi-square test was used. In this study, $P < 0.05$ was considered to be statistically significant.

Results

Demographic variables were similar in the two groups [Table 1]. Hemodynamic parameters, oxygen saturation, sedation score, parity, onset of analgesia [Table 2], duration of labor, oxytocin use, sensory levels [Graph 1], VAS scores after epidural catheter placement, patient satisfaction, fetal heart rate, Apgar score, and requirement of loading dose [Graph 2] rescue analgesia were similar between groups.

The median VAS at the end of first stage was 2 (1-3) with the IQR of 1 in BF group and it was 2 (1-3) with IQR of 1 in RF group, which was comparable.

The median VAS at the end of second stage was 1 (0-1) with IQR of 0 in (BF) group and it was 1 (0-1) with IQR of 1 in (RF), which was comparable [Graph 3].

The mean requirement of bupivacaine was 9.90 ± 0.43 mg/h and that of ropivacaine was 10.02 ± 0.57 mg/h, mean requirement of fentanyl was 19.81 ± 0.86 μg/h in BF group and 20.04 ± 1.14 μg/h in RF group which was comparable.

Median Bromage score in BF group was 0 (0-1) with IQR of 0 and median Bromage score in RF group was 0 (0-0) with IQR of 0, as 3 (10%) parturient in bupivacaine group had motor block of Bromage grade 1 and no parturient in ropivacaine group had any motor block, but this difference was statistically insignificant [Graph 4].

Three (10%) parturient in (BF) group required forceps application for delivery, and remaining 27 (90%) had spontaneous vaginal delivery. In (RF) group, all 30 (100%) parturient had spontaneous vaginal delivery. The incidence

Table 1: Comparison of demographic data

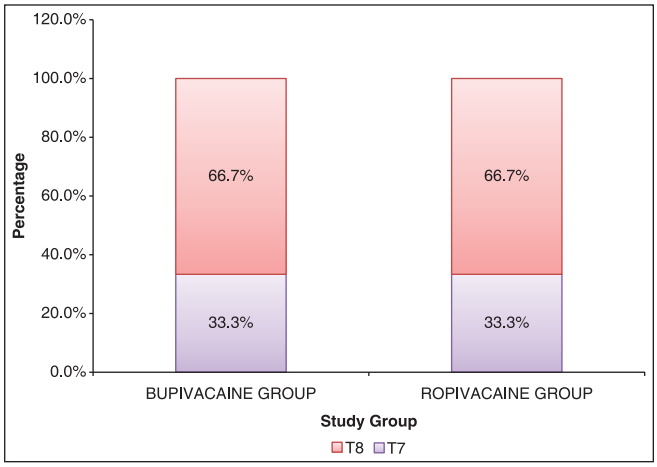
Parameter	BF (n=30)		RF (n=30)		Unpaired *t*-test	*P*
	Mean	SD	Mean	SD		
Age	23.20	1.75	22.90	1.69	0.68	0.502
Weight	57.27	1.87	57.20	1.90	0.14	0.892
Height	159.77	2.06	159.70	2.14	0.12	0.903

SD = Standard deviation, BF = Bupivacaine with fentanyl, RF = Ropivacaine with fentanyl

Table 2: Comparison of onset of analgesia in both groups

Onset of analgesia	BF	RF	*P* Student's unpaired t-test
n	30	30	0.8821
Mean±SD	16.80±2.61	16.90±2.59	

SD = Standard deviation, BF = Bupivacaine with fentanyl, RF = Ropivacaine with fentanyl



Graph 1: Comparison of sensory level in both groups

of spontaneous vaginal delivery was not significantly different in the two groups.

Mean duration of the first stage of labor was 252.83 ± 83.19 min in (BF) group and 250.33 ± 86.84 min in (RF) group ($P = 0.910$). The mean duration of second stage of labor was 31 ± 13.93 min in (BF) group and 27.73 ± 3.94 min in (RF) group ($P = 0.221$) the duration of labor in all stages was comparable between two groups [Graph 5].

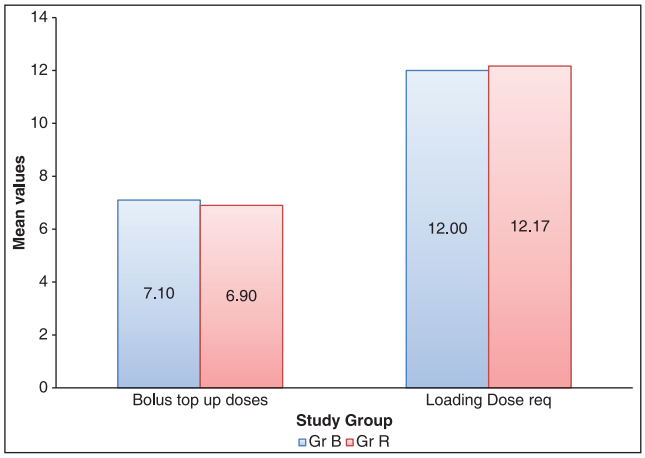
No parturient in either group had any adverse effects like nausea, vomiting, hypotension, pruritus or respiratory depression requiring treatment. Thus, the profile of side effect was comparable between two groups.

Discussion

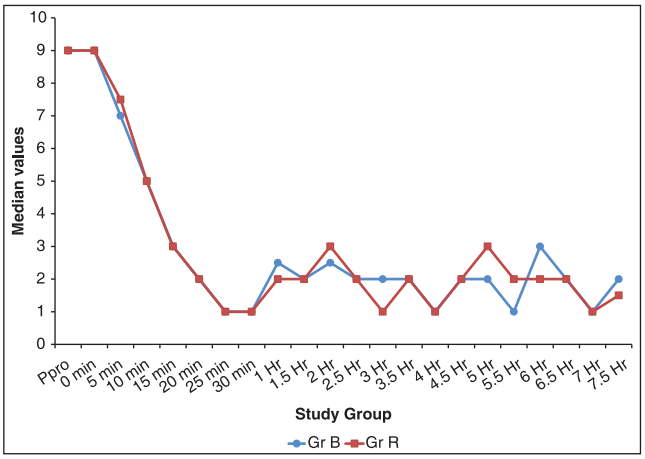
In this study, 0.1% ropivacaine with fentanyl 2 μg/mL produced analgesia equivalent to 0.1% bupivacaine with fentanyl 2 μg/ml.

Factors that have shown to correlate with great pain during labor and delivery include parity, augmentation of labor with oxytocin, younger maternal age, and increased maternal and fetal weight were analyzed. In all the parturients, process of labor was augmented using oxytocin, thus all other above mentioned factors were comparable between two groups. Therefore, the difference in the VAS score and all other parameter can be attributed to the drug used only.

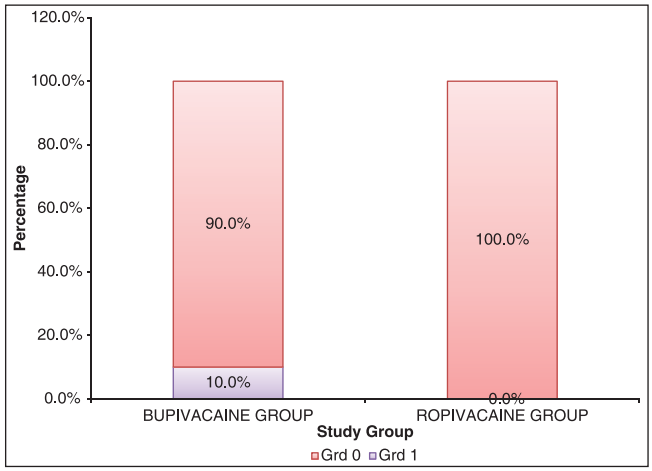
We did not find any difference regarding motor blockade in the two groups. Campbell *et al.*[13] used either 0.08% bupivacaine + fentanyl or 0.08% ropivacaine + fentanyl. Their results indicated that ropivacaine is better than bupivacaine in preserving the ability of the parturient to micturate and ambulate. Lee *et al.*,[14] analyzed epidural labor analgesia using ropivacaine or bupivacaine. Wherein analgesia was initiated with a 0.25% solution and maintained with a continuous infusion of a 0.1% solution with fentanyl 0.0002%. They found that 12.1% parturients in the bupivacaine group and 5.8% parturient in the ropivacaine group had motor block >Bromage 1. Higher motor block



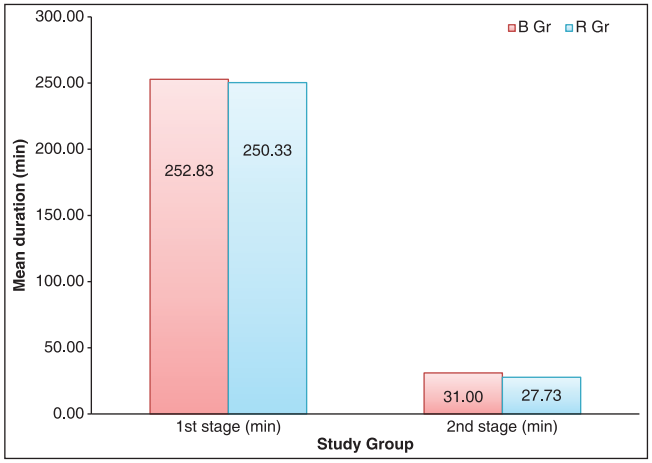
Graph 2: Profile of bolus top up and loading dose



Graph 3: Profile of median visual analog score in both groups



Graph 4: Comparison of motor block between groups



Graph 5: Comparison of duration of labor in both groups

in their study may be due to higher concentration of local anesthetic drug used initially.

Studies by Stienstra *et al.*,[3] Owen *et al.*,[4] McCrae *et al.*[6] also found that the incidence of motor block was similar in bupivacaine and ropivacaine groups.

Ropivacaine may be more selective for sensory fibers than bupivacaine, due to its lower lipid solubility and hence limited penetration of large myelinated nerve fibers, which convey motor impulse.[4]

There was no difference in the mode of delivery in the two groups in the present study. Eddleston *et al.*,[15] compared bupivacaine and ropivacaine in a concentration of 0.25% for extradural analgesia in labor. They observed ropivacaine group had a higher incidence of spontaneous vaginal delivery (70.59% vs. 52.00%), but the difference was not statistically significant. Halpern and Walsh[16] performed a meta-analysis, comparing bupivacaine and ropivacaine for labor epidural analgesia. They found that there was no significant difference in the incidence of spontaneous vaginal delivery and mode of delivery was similar between two. Less pronounced motor block in ropivacaine may have enabled more active participation and more effective bearing down resulting in increased incidence of spontaneous vaginal delivery. At the same time, less reduction in the tone of the pelvic diaphragm might have enabled normal rotation of the fetal head during the second stage.[2]

Our findings regarding requirement of local anaesthetics and fentanyl are comparable with that of Owen *et al.*[17] who administered ropivacaine 0.075% and bupivacaine 0.075% each with fentanyl 2 mcg/mL for labor epidural analgesia. Multiple other investigators Stienstra *et al.*,[3] Writer *et al.*,[2] Campbell *et al.*[13] found that total drug requirement and hourly drug requirement was similar for bupivacaine and ropivacaine in labor epidural analgesia.

Similar pain scores in bupivacaine and ropivacaine group in the first stage and second stage of labor suggests equivalent quality of analgesia. Although three studies suggest, ropivacaine is less potent than bupivacaine the two drugs appear to be equipotent at clinically used concentrations. Polley *et al.*[18] and Capogna *et al.*[19] estimated the minimum local analgesic concentrations of ropivacaine and bupivacaine using an up-down sequential allocation study design. By definition, they estimated a dose of local anesthetic that produces labor analgesia in only 50% of the patients. In contrast, McDonald *et al.*[20] compared the spinal ropivacaine with spinal bupivacaine in volunteers, not in the labor or undergoing surgery. The applicability of the findings of these three studies to clinical practice remains unknown. In our study, findings suggest that 0.1% ropivacaine and 0.1% bupivacaine are equipotent as demonstrated by mean hourly drug use, VAS scores to pain, sensory levels to ether swab, and overall patient satisfaction. Additional studies examining the relative potencies of ropivacaine and bupivacaine in the clinical setting are warranted.

There was no statistically significant difference in duration of first or second stage of labor between two groups. Owen *et al.*[17] during their comparative study using ropivacaine 0.075% and bupivacaine 0.075% each with fentanyl 2 mcg/mL for labor epidural analgesia found a similar result. In contrast to our result, Lee *et al.*,[14] in a study of epidural labor analgesia using ropivacaine or bupivacaine, initiated analgesia with a 0.25% solution and maintained with a continuous infusion of a 0.1% solution with fentanyl 0.0002%. They found that ropivacaine was associated with a shorter first stage of labor than bupivacaine, but the relative difference is probably of limited clinical importance. This may be due to higher concentration of local anesthetic used initially, which might have caused motor block, leading to prolongation of labor. Thus ropivacaine and bupivacaine in 0.1% concentration does not cause prolongation of labor, this may be attributed to lower concentration of local anesthetic drugs used in this study. In our study, no parturient in either group had any adverse effect.

Intermittent top up technique is better than continuous infusion technique. Fettes *et al.*[21] compared intermittent versus continuous administration of epidural ropivacaine with fentanyl for analgesia during labor and found that the intermittent group required fewer supplementary injections and less drug to maintain similar pain scores, compared with the continuous group. As our institute has very few PCEA pumps/infusion pumps and inability of patients to operate PCEA pumps, we chose a technique of intermittent top-ups.

Conclusion

Bupivacaine and ropivacaine provide equivalent analgesia in low (0.1%) concentration. Both the drugs are comparable in terms of onset of analgesia, quality of analgesia, incidence of motor block, sensory level achieved, requirement of local anesthetic drug, incidence of instrumental delivery, neonatal outcome, duration of labor, and profile of side effect.

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Conference Calendar January 2016

Name of conference	Dates	Venue	Name of organising Secretary with contact details
22nd Annual Conference of Indian Society of Critical Care Medicine & International Sepsis Forum CRITICARE 2016	February, 5th-9th, 2016	Agra	Dr. Ranvir Singh Tyagi, Dr. Diptimala Agarwal Telephone : 919927778889 Email Id : criticare2016@gmail.com Website :http://criticare2016.com/
19th Annual National Conference of IACTA IACTA 2016	February, 12-14th, 2016	Radisson BLU Resort Temple Bay, Mamallapuram, Chennai	Dr. Mahesh Vakamudi Organising Secretary IACTACON – 2016 A6 OR Complex, Department of Cardiac Anesthesia. Sri Ramachandra University. No 1, Ramachandra nagar, Porur, Chennai - 600116 Phone: +91 44 23860125 Mobile:+91 90426 06596
23rd International Conference of the Indian Association of Palliative Care IAPCON 2016	February, 12-14th, 2016	Pune	Dr. Priyadarshini Kulkarni Telephone: 919158286161 Email Id: info@iapcon2016pune.com Website: http://iapcon2016pune.in/index.html
2nd Ganga Anaesthesia Refresher Course GARC 2016	June 16th-19th, 2016	Ganga Hospital, Coimbatore	Dr. J. Balavenkat, Course Chairman, GARC 2016 Ganga Hospital, 313 Mettupalayam Road, Tatabad, Coimbatore - 641 043, Tamilnadu, India. Phone: 91 422 2485000(Ext 5015). Email: gangaanaesthesia@gmail.com.