

A prospective randomised double blind clinical study comparing ropivacaine and fentanyl with bupivacaine and fentanyl for labour epidural analgesia

Apoorva Gupta¹, Manasa Dhananjaya^{2,*}, Nagaraja PS³, Naveen G Singh⁴, Nanjappa SN⁵

^{1,2,4,5}Assistant Professor, ³Associate Professor, Dept. of Anaesthesiology, ¹Vydehi Institute of Medical Sciences and Research Center, Bengaluru, Karnataka, ²⁻⁵Sri Jayadeva Institute of Cardiovascular Sciences and Research, Bengaluru, Karnataka, India

*Corresponding Author: Manasa Dhananjaya

Email: docnag10@gmail.com

Received: 12th December, 2018

Accepted: 2nd January, 2019

Abstract

Introduction: The ideal labour analgesia technique should dramatically reduce the pain of labour, while allowing the parturient to actively participate in the birthing experience. In addition, it should have minimal effect on the fetus and the progress of labour. A randomised prospective comparative clinical study using epidural Inj ropivacaine hydrochloride (0.125%) with Inj fentanyl citrate 2µg/ml was compared with Inj Bupivacaine hydrochloride (0.125%) with Inj fentanyl citrate 2µg/ml for onset and quality of analgesia, incidence of motor block, progress, duration and outcome of labour, incidence of instrumental deliveries and neonatal outcome.

Materials and Methods: A total of 65 Full term labouring parturients of ASA I and II grade with cephalic singleton pregnancy from 36 to 42 weeks of gestation having cervical dilatation of 4-5 cm were enrolled in this study. Group R (Ropivacaine): received epidural Inj ropivacaine hydrochloride (0.125%) with inj fentanyl citrate 2µg/ml as a continuous infusion at 6 ml/h after a bolus dose of 15ml of the above drug combination. Group B (Bupivacaine): received epidural Inj bupivacaine hydrochloride (0.125%) with inj fentanyl citrate 2 µg/ml as a continuous infusion at 6 ml/h after a bolus dose of 15ml of the above drug combination. Hemodynamic parameters, onset of analgesia, modified bromage scale for motor blockade, pain scores were documented and compared between the two groups.

Results: The mean time for onset of analgesia after the bolus dose via the epidural catheter was also similar in both the groups. It was 16.03 m in ropivacaine group and 15.33 m in bupivacaine group. Verbal pain score and Visual analogue scale were also comparable between the two groups. Motor block was mild (0 to 1) in most of the parturients and did not differ with ropivacaine or bupivacaine treatment. Neonatal outcome was similar in both the groups in our study. All the infants had Apgar score more than 7 at 5 minutes after delivery.

Conclusion: We found the combination of ropivacaine (0.125%) with fentanyl (2 µg/ml) when compared to bupivacaine (0.125%) with fentanyl (2 µg/ml) as a good alternative drug for labour analgesia with minimal side effects.

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

Introduction

The pain of labour in an untrained primipara is said to be comparable to amputation of a digit. Preserving the active participation of the parturient in the birthing experience along with effective reduction in pain of labour with minimal effects on progress of labour and fetal outcome should be the ideal characteristic of labour analgesia.

Reviewing the literature suggested that regional analgesia has minimum to no alterations in progress and outcome of labour.¹ With epidural analgesia there is neither a need for labour augmentation with oxytocics, nor the rates of vaginal delivery differs. Maternal satisfaction was significantly increased in parturients administered epidural analgesia.¹

Injection (Inj) Bupivacaine hydrochloride has been frequently used in epidural analgesia for many years. Inj fentanyl citrate or Inj sufentanyl have been used as adjuvants to inj. Bupivacaine to hasten the onset and increase the duration of analgesia. The risk of placental transfer of bupivacaine is minimal as the drug is highly protein bound. Although lidocaine and 2-chloroprocaine have shorter latencies than bupivacaine, their duration of analgesia is significantly shorter, thus limiting their usefulness for routine labour analgesia. Additionally,

lidocaine is less protein bound than bupivacaine, and therefore has a higher umbilical vein to maternal vein ratio.²

Inj ropivacaine hydrochloride is a single levorotatory enantiomer, which is a homologue of Inj bupivacaine hydrochloride. It has similar duration of action as bupivacaine³ however, it is reported to be 40% less potent⁴ with reduced cardiotoxicity. The previous studies using low concentrations of ropivacaine and bupivacaine for labour analgesia reported that both drugs were equipotent with respect to sensory blockade for labour analgesia.^{5,6} Ropivacaine was also associated with less motor blockade when compared to bupivacaine.^{5,7}

However, the available literature is not very clear about the comparative advantages of using the ropivacaine in labour analgesia. Especially so when the low dose technique is adopted along with opioid adjuvant like fentanyl. By the virtue of its direct action on opioid receptors,⁸ opioids exhibit a synergistic effect.

Hence a prospective clinical study comparing epidural Inj ropivacaine hydrochloride (0.125%) and Inj fentanyl citrate 2µg/ml with Inj Bupivacaine hydrochloride (0.125%) and Inj fentanyl citrate 2µg/ml was conducted. The onset of analgesia, quality of analgesia, motor blockade incidence, duration of labour, progress and outcome of labour and neonatal outcome were compared.

Materials and Methods

Following institutional ethical committee approval and informed written consent from the parturient, a prospective randomised double blinded comparative clinical study was conducted on 65 full term labouring parturients of ASA I and II grade requesting for labour epidural analgesia.

Parturients with cephalic singleton pregnancy having cervical dilatation of 4-5 cm were enrolled in this study. Exclusion criteria included history of pre-eclampsia, diabetes, sepsis, preterm labour, bleeding disorders, scoliosis or any spine deformity, morbid obesity, allergy to local anaesthetic or receiving opioid analgesics in the previous 6h. Failure to locate the epidural space or failure to thread the catheter or accidental CSF tap were also excluded from the study.

Parturients were assigned randomly to one of the two groups using closed envelope method.

Group R (Ropivacaine): Received epidural Inj ropivacaine hydrochloride (0.125%) with inj fentanyl citrate 2µg/ml as a continuous infusion at 6 ml/hr following 15ml bolus of the above drug combination.

Group B (Bupivacaine): Received epidural Inj Bupivacaine hydrochloride (0.125%) with inj fentanyl citrate 2 µg/ml as a continuous infusion at 6 ml/hr following 15ml bolus of the above drug combination.

Labour Analgesia Technique

After confirmation of written informed valid consent from the parturient, pre-anaesthetic examination was done. Parturients who were in active labour were shifted to the labour room. Baseline vital parameters like heart rate, non-invasive blood pressure (systolic, diastolic, mean arterial pressure), pulse oximeter reading, temperature, respiratory rate, fetal heart rate were checked and documented as baseline in the labour epidural proforma. Parturient was preloaded with ringer lactate via an 18 gauge intravenous cannula placed on the nondominant hand.

Parturients were properly positioned in the left lateral side achieving maximum spine flexion. Under strict aseptic precautions, L3-4 or L4-5 inter vertebral space was identified. Inj. lignocaine 2% was given for local skin infiltration at the intervertebral space. Identification of epidural space was done with 18 gauge Touhy needle using loss of resistance to air technique. 20 gauge epidural catheter was threaded and secured at the skin leaving 5cms inside. A test of intravascular or intrathecal presence of catheter was tested with 2ml of 2% lignocaine with adrenaline (1:200000). It was given after negative aspiration of cerebrospinal fluid (CSF) or blood through the epidural catheter. The presence of an intravascular injection was seen as a 20% increase in heart rate without the presence of uterine contraction or parturient having symptoms of dizziness, metallic taste or tinnitus in 2-3 mins post-test dose injection. Intrathecal spread was ruled out by the absence of inability to move the lower limbs and more than 20% drop in baseline blood pressure immediately post-test dose. Catheter was secured on the parturient's back and sterile dressing was applied. Patient was then placed supine

with a 15-degree left lateral tilt using a Crawford wedge under the right hip. 15 ml of the combination solution was given via the epidural catheter five mins after test dose if accidental subarachnoid injection was ruled out.

The loading dose of 15 ml was deposited in aliquots of 5ml over 10min. Analgesia was considered adequate if the parturient felt no pain at the height of contraction. Parturient was requested to rate her pain 5 min after the first dose and every 2 min thereafter for 15min on the visual analogue scale. If there was no pain relief in 15 min, then the catheter was withdrawn by 1 cm. An incremental dose of 5ml of the study solution was deposited through the catheter. If still after all the above interventions the patient complained of no pain relief, then patient was excluded from the study group.

After the initial dose, analgesia was maintained using a continuous infusion of 0.125% Inj. ropivacaine hydrochloride and 2 µg/ml inj. fentanyl citrate (ropivacaine group) or 0.125% inj. bupivacaine hydrochloride and 2µg/ml inj. fentanyl citrate (bupivacaine group). Infusions were started at a basal rate of 6ml/hr. For the breakthrough pain, further boluses of 5ml of the study group solution was deposited in the epidural space every 10min not exceeding 15 ml/h.

Data Recording

Parturient's non-invasive blood pressure (systolic, diastolic, mean arterial pressure), heart rate, respiratory rate, visual analogue scale(VAS), verbal pain scale(VPS), bromage score, straight leg raise test, rhomberg's sign, fetal heart rate(FHR) were recorded at the time of deposition of the loading dose and then at 5min, 10min, 15min, 30min, 45min, 60min, 90min, 2h, 3h, every hour till the extraction of baby and placenta.

VAS: The level of analgesia was assessed by pressing a pin head every 5 min till the desired level was achieved. Duration for achieving adequate analgesia was documented. Analgesic efficacy was assessed using 100-mm visual analogue scale, with 20 mm or less within 30 min defined as effective. The parturient was asked to grade the labour pain on a scale of 10 using verbal pain score, with less than 3 within 3 min as effective.

Motor Block Assessment: Assessment of motor power was done by modified bromage score, straight leg raise test and Rhomberg's sign.

Motor blockade was measured with modified Bromage score as detailed below:

Grade 0 - moving legs and feet, raising legs extended – No block.

Grade 1 – not able to raise leg in extension, decreased knee flexion, full flexion of ankle and feet present – Partial block 33%.

Grade 2 – not able to flex knees or raise legs, flexion of ankle and feet present – Partial block, 66%.

Grade 3- not able to raise leg, flex knee or ankle or move toes – complete paralysis.

Progress of labour and delivery was conducted according to the standard obstetric protocol.

Method of delivering the baby whether normal/instrumental/caesarean was noted. Injection to delivery time was documented. It was taken as the time from initiation of first epidural dose till delivery of baby.

Continuous fetal heart rate monitoring was done using a cardiocotograph. Decelerations were recorded. APGAR scoring was done for neonatal assessment at 1 min and thereafter 5 min.

The degree of hypotension was graded as mild (20 – 25%), moderate (25 – 30%) and severe (more than 30%) according to the fall in mean arterial pressure from the baseline value. Documentation of hypotension and interventions required during the study was done. Mild to moderate hypotension was treated with intravenous fluids initially. Intravenous ephedrine was used in increments of 6 mg only if blood pressure continued to be low in spite of the fluids. All these events and any other adverse events were charted at regular intervals.

On the day, after delivery parturient was requested to grade the quality of analgesia during labour. Scoring was done on a scale of 0 to 3 (excellent, satisfactory, incomplete, failure). In case of caesarean section then the scoring was done as NPE (not possible to evaluate).

Any side effects seen during the study were also recorded.

Statistical Analysis

Based on an earlier study by Meister et al⁹, it was determined that for the study to have a power of 0.09 and a

median effective size the number of parturients to be recruited for the study should be 28. For the study to have a power of 90% with a Type I error of 0.05, the study needed to have at least 28 patients. Adjusting for drop-outs 65 patients were enrolled. Data was shown as mean ± SD. Chi-square test was used for analysis of categorical data. Unpaired t test was used for analysis of continuous variables. p value < 0.05 was considered statistically significant.

Results

65 parturients belonging to ASA I and II undergoing labour analgesia were enrolled in the study. Thirty parturients were administered ropivacaine (0.125%) with fentanyl (2 µg/ml). The other thirty parturients were administered Bupivacaine (0.125%) with fentanyl (2 µg/ml). Five parturients were excluded because of inadequate analgesia requiring catheter manipulation (3 in ropivacaine group, 2 in bupivacaine group).

Demographic (age, height, and weight) (Table 1) and hemodynamic variables (Fig. 1a and 1b) in both groups were comparable. The mean pulse rate in ropivacaine group was 97.89±3.09 and 98.71±3.17 in bupivacaine group (p=0.314). Whereas the mean arterial pressure in ropivacaine group was 90.78±6.86mmHg when compared to 87.98±4.90mmHg in bupivacaine group (p=0.074).

Table 1: Showing distribution age, height (Ht), weight (Wt) between two groups

Demographic variable	Group	N	Mean	Std. Deviation	P value
Age (yrs)	Ropivacaine	30	27.56	3.20	0.733
	Bupivacaine	30	27.23	4.25	
Ht (cms)	Ropivacaine	30	159.46	5.09	0.559
	Bupivacaine	30	158.7	5.03	
Wt (kgs)	Ropivacaine	30	78.06	4.40	0.419
	Bupivacaine	30	78.96	4.17	

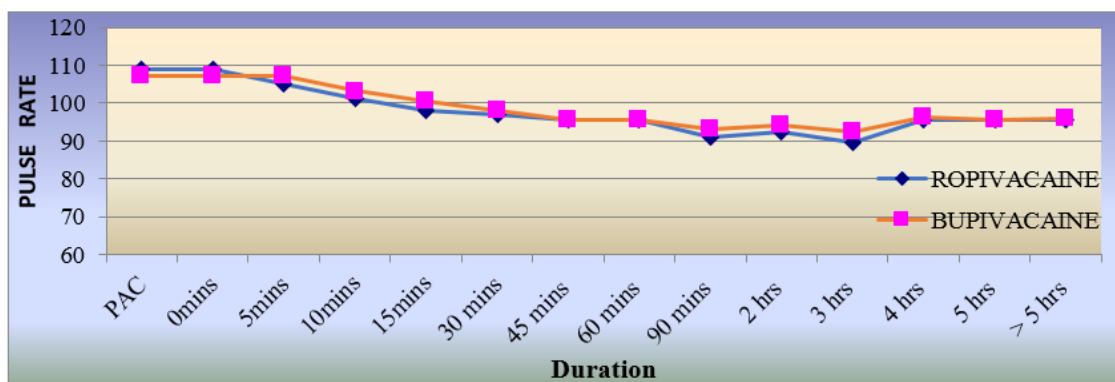


Fig. 1a: Pulse rate trend between the groups

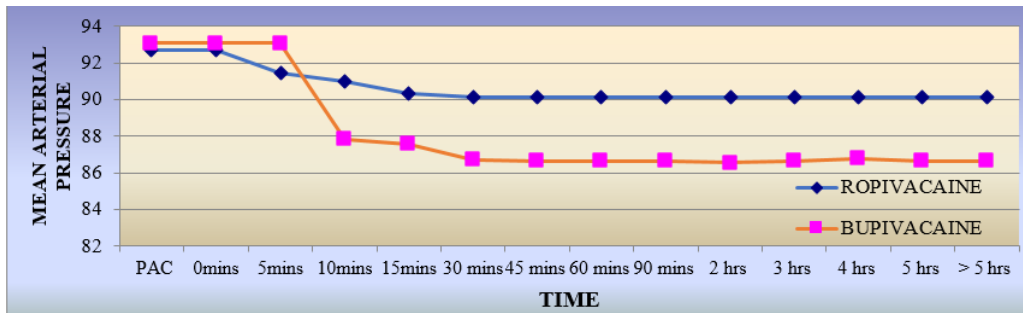


Fig. 1b: Mean arterial pressure trend between the groups

Both the groups showed a similar mean time for establishment of analgesia following the epidural bolus. (Table 2). Ropivacaine group took 16.03 ± 2.59 min whereas

bupivacaine group took 15.56 ± 3.61 min for the onset of analgesia. $p=0.567$, hence statistically insignificant.

Table 2: Onset of analgesia in the groups

Onset of analgesia(mins)	Groups (no. of Patients)		P value
	Ropivacaine	Bupivacaine	
5 – 10	0	2	0.567
11 – 15	22	18	
16 – 20	8	10	

Verbal pain score (0 to 10) was compared between the groups (Fig. 2). Ropivacaine group scored 8 ± 0.74 before epidural placement whereas Bupivacaine group scored $7.8 \pm$

0.84 ($p=0.335$). This score gradually decreased to 3.66 ± 0.66 in ropivacaine and 3.9 ± 0.75 in bupivacaine group by 30 min ($P= 0.209$).

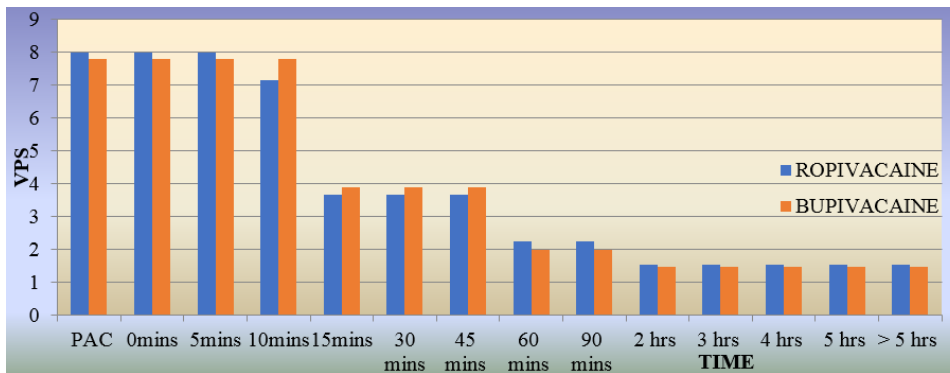


Fig. 2: Verbal pain score between the two groups

Visual Analogue Scale (0 to 100) in both groups were comparable (Fig. 3). The score before epidural placement was 72 ± 6.643 in ropivacaine group and 70 ± 6.432 in

bupivacaine group ($p=0.241$). This score gradually decreased to 15.34 ± 4.138 in ropivacaine and 16.67 ± 3.555 in bupivacaine group by 30 m ($P= 0.186$).

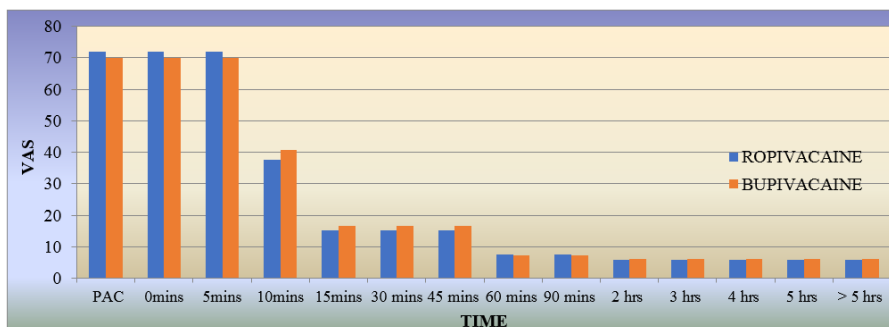


Fig. 3: Visual analogue scale between the two groups

The upper segmental level of sensory block for ropivacaine group had ranged from dermatome T6 to T8 with 80% parturients in the T6 dermatomal level whereas in bupivacaine level of sensory block had a range from

dermatome T4 to T8 with 56.6% parturients having it at the T6 dermatomal level (Table 3). It explains that bupivacaine causes a higher sensory block compared to ropivacaine. ($p = 0.009$).

Table 3: Sensory block achieved after epidural injection of drug

		Ropivacaine	Bupivacaine	P value
Level of sensory block	T4	0	8(26.6%)	0.009
	T6	24(80%)	17(56.6%)	
	T8	6(20%)	5(16.6%)	
Total parturients		30	30	

The duration of labour analgesia required in multigravida varied from 4 to 5.5h while in primigravida varied from 5h to 6.5h (Table 4) which was comparable between the two groups.

Table 4: Duration of labour in primigravida and multigravida in both groups

	No: of labour hours	Ropivacaine	Bupivacaine	P value
Multigravida	4	5(33.3%)	5(27.77%)	0.78
	4.5	2(13.33%)	2(11.11%)	
	5	5(33.33%)	9(50%)	
	5.5	3(20%)	2(11.11%)	
	Total parturients	15(100%)	18(100%)	
Primigravida	5	8(53.33%)	2(16.66%)	0.16
	5.5	1(6.66%)	4(33.33%)	
	6	5(33.33%)	5(41.66%)	
	6.5	1(6.66%)	1(8.33%)	
	Total parturients	15(100%)	12(100%)	

Motor block was mild (0 to 1) in most of the parturients and did not differ with ropivacaine or bupivacaine treatment ($p = 0.371$).

In the present study, ropivacaine group had 17 parturients and bupivacaine group had 12 parturients who delivered spontaneously. 8 parturients in ropivacaine group and 12 parturients in bupivacaine group had assisted

deliveries. However, parturients who underwent cesarean section were 5 in ropivacaine group and 6 in bupivacaine group for the obstetric indication. i.e, cephalopelvic disproportion with nonprogressive labour or fetal distress (Table 5). The values were statistically insignificant but the number of instrumental and cesarean deliveries were comparatively more in bupivacaine group.

Table 5: Mode of deliveries

Mode of delivery	Group (no. of parturients)		P value
	Ropivacaine	Bupivacaine	
Spontaneous delivery (SpnD)	17(56.7%)	12(40%)	0.292
Instrumental(vacuum/forceps)	8(26.7%)	12(40%)	
LSCS	5(16.7%)	6(20%)	
	30	30	

Both the groups had similar neonatal outcome with APGAR scoring more than 7 post-delivery at 5 min.

Parturient satisfaction was excellent in 22(73.3%) and good in 8(26.6%) in ropivacaine group whereas in bupivacaine group parturient satisfaction was excellent in 20(66.67%) and good in 10 (33.33%) with a p value of 0.573 which is statistically not significant.

Both the groups had similar incidence of adverse effects like nausea, vomiting, pruritis, hypotension, transient fetal bradycardia and urinary retention. Urinary retention was seen in 4 parturients in both groups. Fetal bradycardia was seen in 2 parturients in bupivacaine group and 1 parturient

in ropivacaine group, which was reverted after giving fluid bolus along with left lateral tilt.

Discussion

Though labour analgesia had been evolving at a fast pace in the 20th century, the dawn of the 21st century has set the standards in obstetric care by providing a safe and pain free labour throughout the world.

Of all the methods that have been in vogue from time to time, the labour epidural analgesia has stood the test of time and is widely regarded as the "gold standard" against which all other means are benchmarked.

Epidural analgesia has become the commonest choice of labouring women and has been associated with greater satisfaction and outcome this is largely because of the observations that there is no significant depression in maternal or fetal vitals, good to excellent analgesia and minimal interference with labour process.

Lyons et al¹⁰ found the minimum local analgesic volume (MLAV) and minimum local analgesic dose (MLAD) of epidural bupivacaine 0.125% and 0.25% as an initial bolus. 13.6 ml was found as the MLAV of bupivacaine 0.125% whereas 9.2 ml was found for bupivacaine 0.25%.¹¹ Hence, it was seen that by reduction in the concentration of bupivacaine, labor analgesia was achieved without altering the analgesic efficacy. It provided a safer margin and allowed fine-tuning during labour analgesia.

In our study sixty five parturients (multigravida and primigravida) were enrolled and sixty completed the study. Five parturients were excluded because of inadequate analgesia requiring catheter manipulation (3 in ropivacaine group, 2 in bupivacaine group). Hemodynamics were comparable between the groups in our study. The variation in hemodynamic parameters between the two groups was statistically insignificant.

In our study the mean total volume of ropivacaine (45.5±4.10 mg) with fentanyl (91±8.20µg) required for labour analgesia was similar to bupivacaine (45.7±4.14mg) with fentanyl (91.4±8.29µg). Lee et al⁶ used ropivacaine (0.125%) 85mg and bupivacaine(0.125%) 95mg with fentanyl 2µg/ml for continuous labour analgesia. In their study, infusions were started at 8 ml/h and adjusted as required within a range of 4 to 12 ml/h. Additional top ups of 5–10 mL boluses of ropivacaine 0.25% or bupivacaine 0.25% were given from the allocated randomized syringes for breakthrough pain. Hence the increased total dose of drug was administered throughout labour. However, Meister et al⁹ compared ropivacaine 0.125% (113±43.3 mg) with fentanyl (180.8±69.2µg) versus bupivacaine 0.125% (102.5±82.4mg) with fentanyl (164.0±82.4µg) for labouring patients using PCEA with background continuous infusion. Patients who requested additional analgesia during labour, received a 10ml bolus of study solution through the PCEA device in 5-mL increments. Hence the significant difference in total doses between the above study when compared to the present study. The mean total dose of ropivacaine was 123.64mg and bupivacaine was 98.46mg in the study conducted by Owen et al.¹² They used a background infusion with PCEA boluses when required. Whereas our study had no intermittent boluses and no PCEA facility provided to the parturient so the total dose was less but we were able to achieve adequate labour analgesia in our parturients.

The mean time to achieve adequate analgesia after the initial bolus epidural dose was similar in the study groups. Ropivacaine group took 16.03 min whereas Bupivacaine group took 15.33 min. McCrae et al¹³ also showed that the median onset time for pain relief after the bolus dose was

18min (range 7-27m) in the ropivacaine group as compared to 12min (3-24m) it took for the bupivacaine group.

Stienstra et al¹⁴ had their mean onset of analgesia within ten mins in each group after an epidural bolus of 10 ml of each drug, as he used 0.25% of bupivacaine and ropivacaine.

Visual analogue scale in the study groups were comparable. Before epidural placement ropivacaine group had a score of 72mm whereas it was 70mm in bupivacaine group. After 30 mins of epidural placement VAS score recorded in ropivacaine was 15.34mm and 16.67mm in bupivacaine group. This was seen because the epidural bolus was given in aliquots of 5ml every 5m till 15ml was administered (P = 0.186). Evron et al¹⁵ evaluated the influence of PCEA using low doses of bupivacaine versus ropivacaine on labour pain and concluded that the median average VAS score during treatment was 9.61 ± 5.90 mm in ropivacaine group and 10.6 ± 8.16mm in bupivacaine group. The total dose required for ropivacaine was 41% higher for the primiparous women and 34% higher for the multiparous women (P < 0.0001) hence showed similar values like our study. Stienstra et al¹⁴ showed the median VAS scores before instillation of epidural analgesia in ropivacaine group was 90mm whereas 88.5mm in bupivacaine group. The median average VAS score in our study for ropivacaine group was 12mm and 5mm for bupivacaine group.

Chua et al¹⁶ showed VAS in ropivacaine group of 83 and in bupivacaine group 80 before insertion of epidural catheter which was identical to our study. The VAS reduced to 15 in ropivacaine and 10 in bupivacaine group by 2 hrs. It further decreased to 10 in ropivacaine and 8 in bupivacaine group by 4hrs. In our study for ropivacaine group VAS reduced to 5.97 and for bupivacaine group reduced to 6.1 by 2hrs.

Verbal pain scores were also comparable between the study groups. It decreased from 8 to 3.66 by 15 min in ropivacaine group after epidural catheter placement. However, in bupivacaine group it decreased from 7.8 to 3.9 by 15 min after epidural catheter placement. Owen et al¹² showed a decrease in VPS from 8.6+0.3 to 2.0+0.3 in ropivacaine group after epidural analgesia and similarly in bupivacaine group from 8.7+0.3 to 2.2+0.4 after epidural analgesia.

In this study, the level of sensory block ranged for ropivacaine group from dermatome T6 to T8 with 80% parturients in the T6 dermatomal level whereas in bupivacaine group level of sensory block had a range from dermatome T4 to T8 with 56.6% parturients having it at the T6 dermatomal level. Lee et al⁶ had their parturients upper level of sensory block around T9 in both ropivacaine and bupivacaine groups. Similarly, Meister et al⁹ had the level of sensory block at T7 for ropivacaine group and T8 for bupivacaine group. Chua et al¹⁶ had the highest thoracic dermatomal block of T7 in ropivacaine and T8 in bupivacaine group.

Meister et al⁹ reported duration for labour analgesia as 6.6 hr and 6 hr in ropivacaine group and bupivacaine group respectively. Lee et al⁶ reported duration of labour for

ropivacaine group as 8hrs 40mins and for bupivacaine group as 10hrs 45mins. Chua et al¹⁶ documented 6.4 hrs in ropivacaine and 6.2 hrs in bupivacaine group as the duration of labour analgesia which is identical to the present study.

In this study, degree of motor block did not have significant difference between the groups. Motor block was mild (0 to 1) in most of the parturients and did not differ with ropivacaine or bupivacaine treatment. Similar results were confirmed by Lee et al⁶ and Owen et al.¹² Girard et al¹⁷ also did not find any difference in the incidence of motor block between parturients receiving either ropivacaine or bupivacaine. Chua et al¹⁶ and Bawdane et al¹⁸ also

confirmed in their study that the incidence of motor block in both the study groups was statistically insignificant.

According to the obstetricians, the maintenance of the maternal expulsive power was similar in both groups. In this study parturients who delivered spontaneously in ropivacaine group were 17 and in bupivacaine group were 12. Assisted deliveries in ropivacaine group was performed for 8 parturients while in bupivacaine group was performed for 12 parturients. Caesarean section was done in ropivacaine group for 5 parturients and in bupivacaine group for 6 parturients with an obstetric indication.

References	Groups	Number of patients	Spontaneous vaginal delivery	Instrumental vaginal delivery	Caesarean section
Yaakov Beilin ¹⁹	Ropivacaine	930	538 (58%)	233 (26%)	138 (15%)
	Bupivacaine	917	499 (54%)	242 (27%)	151 (17%)
Girard et al ¹⁷	Ropivacaine	27	13 (48%)	11 (41%)	3 (11%)
	Bupivacaine	33	11 (33%)	15 (45%)	7 (21%)
Lee et al ⁶	Ropivacaine	173	66 (38.2%)	46 (26.6%)	61 (35.2%)
	Bupivacaine	173	72 (41.6%)	41 (23.7%)	60 (34.7%)
Chua et al ¹⁶	Ropivacaine	16	9 (56.2%)	3(18.7%)	4(25%)
	Bupivacaine	16	8 (50%)	3(18.7%)	5(31.25%)
Meister et al ⁹	Ropivacaine	25	80%	16%	4%
	Bupivacaine	25	80%	16%	4%
Owen et al ¹²	Ropivacaine	26	54%	31%	15%
	Bupivacaine	25	72%	12%	16%
Present study	Ropivacaine	30	17 (56.7%)	8 (26.7%)	5 (16.7%)
	Bupivacaine	30	12 (40%)	12 (40%)	6 (20%)

The meta-analysis of random trials showed that the rate of assisted vaginal deliveries was doubled.²⁰ A recent randomized trial documented an increase in forceps deliveries from 3 percent in the opioid group to 12 percent in the epidural-analgesia group.²¹ However, the reason for this increase with epidural analgesia remains unclear. One hypothesis is that the motor blockade may prevent the mother from pushing and thereby necessitate the use of instruments. It is also possible that the presence of an epidural block may sometimes decrease the threshold of obstetrician for conducting assisted deliveries.²²

Both the study groups had similar neonatal outcome. All the infants had Apgar score more than 7 at 5 minutes after delivery. Yaakov Beilin,¹⁹ Girard et al,¹⁷ Owen et al¹² and Paddalwar S et al²³ all showed similar results.

We found that patient satisfaction in ropivacaine group was excellent in 22(73.3%) and good in 8(26.67%) while in bupivacaine group 20(66.67%) parturients had excellent and 10(33.33%) parturients had good patient satisfaction.

Similar results were shown by Owen et al¹² where 69% parturients in ropivacaine group had excellent analgesia and 27% had good analgesia whereas in bupivacaine group 76% had excellent and 24% had good analgesia. Yaakov Beilin¹⁹ stated that 77% of parturients had excellent analgesia in ropivacaine group and 76% in bupivacaine group.

Limitation of the study would be requirement of a larger sample size.

Conclusion

We found 0.125% ropivacaine and 0.125% bupivacaine to be clinically identical. They did not show differences regarding onset of analgesia, VAS and VPS, amount of local anesthetic used, level of sensory block, motor blockade, duration of labour, method of delivery, side effects or satisfaction of patient between the local anesthetics using continuous infusion for labour analgesia, both being highly effective. We found the combination of ropivacaine (0.125%) and fentanyl (2 µg/ml) when compared to bupivacaine (0.125%) and fentanyl (2 µg/ml) as a good alternative drug for labour analgesia with minimal side effects.

Conflict of Interest: None.

References

1. Wong C.A, Scavone B.M, Peaceman A.M, Robert J. McCarthy, John T. Sullivan, Nathaniel T. Diaz et al. The risk of cesarean delivery with neuraxial analgesia given early versus late in labor. *N Engl J Med* 2005;352(7):655–665.
2. Kennedy R.L, Bell J.U, Miller R.P, Doshi D, de Sousa H, Kennedy MJ et al. Uptake and distribution of lidocaine in fetal lambs. *Anesthesiol* 1990;72(3):483–489.
3. Katz J.A, Bridenbaugh PO, Knarr DC, Helton SH, Denson DD. Pharmacodynamics and pharmacokinetics of epidural ropivacaine in humans. *Anesth Analg* 1990;70(1):16–21.

4. Polley L.S, Columb MO, Naughton NN, Wagner DS, van de Ven CJ. Relative analgesic potencies of ropivacaine and bupivacaine for epidural analgesia in labor: implications for therapeutic indexes. *Anesthesiol* 1999;90(4): 944-950.
5. Beilin Y, Guinn NR, Bernstein HH, Zahn J, Hossain S, Bodian CA. Local anesthetics and mode of delivery: bupivacaine versus ropivacaine versus levobupivacaine. *Anesth Analg* 2007;105(3):756-763.
6. Lee BB, Ngan Kee WD, Ng FF, Lau TK, Wong EL. Epidural infusions of ropivacaine and bupivacaine for labor analgesia: a randomized, double-blind study of obstetric outcome. *Anesth Analg* 2004;98(4):1145-1152.
7. Lacassie HJ, Habib AS, Lacassie HP, Columb MO. Motor blocking minimum local anesthetic concentrations of bupivacaine, levobupivacaine, and ropivacaine in labor. *Reg Anesth Pain Med* 2007;32(4):323-329.
8. Wong A Cynthia. Advances in labor analgesia. *Int J Women's Health* 2009;1:139-154.
9. Meister Greg C, D'Angelo R, Owen M, Nelson KE, Gaver R. A Comparison of Epidural Analgesia with 0.125% Ropivacaine with Fentanyl Versus 0.125% Bupivacaine with Fentanyl during Labor. *Anesth Analg* 2000;90:6327.
10. Lyons G.R, Kocarev M.G, Wilson R.C, Columb M.O. A comparison of minimum local anesthetic volumes and doses of epidural bupivacaine (0.125% w/v and 0.25% w/v) for analgesia in labor. *Anesth Analg* 2007;104:412-415.
11. Iijima Tetsuya, Ishiyama Tadahiko, Kashimoto S, Yamaguchi, Toshiaki, Andoh et al. A Comparison of Three Different Concentrations of Ropivacaine with Fentanyl for Patient-Controlled Epidural Analgesia. *Anesth Analg* 2007;105:507-511.
12. Owen Medge D., Angelo Robert D, Gerancher JC, Thompson JM, Foss ML, Babb JD et al. 0.125% Ropivacaine is similar to 0.125% Bupivacaine for labor analgesia using patient-controlled epidural infusion. *Anesth Analg* 1998;86:527-531.
13. McCrae A. F., Jozwiak H., McClure J. H. Comparison of ropivacaine and bupivacaine in extradural analgesia for the relief of pain in labour. *Br J Anaesth* 1995;74:261-265.
14. Stienstra Rudolf, Jonker Tim A, Bourdrez P, Kuijpers JC, van Kleef JW, Lundberg U. Ropivacaine 0.25% versus Bupivacaine 0.25% for continuous Epidural Analgesia in labour: A double blind comparison. *Anesth Analg* 1995;80:285-289.
15. Evron Shmuel, Glezerman Marek. Patient-controlled epidural analgesia for labor pain: effect on labor, delivery and neonatal outcome of 0.125% bupivacaine vs 0.2% ropivacaine. *Int J Obstet Anesth* 2004;13:5-10.
16. Chua N. P, Sia A.T, Ocampo C. E. Parturient-controlled epidural analgesia during labour: bupivacaine vs. ropivacaine. *Anaesth* 2001;56:1169-1173.
17. Girard T, Kern C, Hosli I, Heck A, Schneider MC. Ropivacaine versus Bupivacaine 0.125% with Fentanyl 1µg/ml for Epidural Labour Analgesia: Is Daily Practice More Important Than Pharmaceutical Choice? *Acta Anaesth. Belg* 2006;57:45-49.
18. Bawdane KD, Magar JS, Tendolkar BA. Double blind comparison of combination of 0.1% ropivacaine and fentanyl to combination of 0.1% bupivacaine and fentanyl for extradural analgesia in labour. *J Anaesthesiol Clin Pharmacol* 2016;32:38-43.
19. Beilin Yaakov, Halpern Stephen: Ropivacaine Versus Bupivacaine for Epidural Labor Analgesia. *Anesth Analg* 2010;111:482-487.
20. Halpern SH, Leighton BL, Ohlsson A, Barrett JF, Rice A. Effect of epidural vs parenteral opioid analgesia on the progress of labor: a meta-analysis. *JAMA* 1998;280:2105-2110.
21. Sharma SK, Alexander JM, Messick G, Bloom SL, McIntire DD, Wiley J et al. Cesarean delivery: a randomized trial of epidural analgesia versus intravenous meperidine analgesia during labor in nulliparous women. *Anesthesiol* 2002;96:546-551.
22. Bofill JA, Vincent RD, Ross EL, Martin RW, Norman PF, Werhan CF et al. Nulliparous active labor, epidural analgesia, and cesarean delivery for dystocia. *Am J Obstet Gynecol* 1997;177:1465-1470.
23. Paddalwar S, Nagrale M, Chandak A, Shrivastava D, Papalkar J. A randomized, double-blind, controlled study comparing Bupivacaine 0.125% and Ropivacaine 0.125%, both with Fentanyl 2 µg/ml, for labor epidural analgesia. *Indian J Pain* 2013;27:147-153.

How to cite this article: Gupta A, Dhananjaya M, Nagaraja PS, Singh NG, Nanjappa SN. A prospective randomised double blind clinical study comparing ropivacaine and fentanyl with bupivacaine and fentanyl for labour epidural analgesia. *Indian J Clin Anaesth* 2019;6(1):81-88.