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Original Article

Anaesthesia Section

Effectiveness of 0.125% Bupivacaine versus 0.125% Ropivacaine in Epidural Labour Analgesia- A Randomised Clinical Study

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ABSTRACT

Introduction: Epidurally administered local anaesthetics provide most effective analgesia during labour process. Among the available local anaesthetics, bupivacaine and ropivacaine are the most commonly used drugs in concentrations ranging from 0.0625% to 0.125% and 0.08% to 0.125%, respectively. Both these drugs are weak bases, highly protein-bound, highly lipid soluble, and have a pKa of 8.1, low unionised fraction, thus, having a slightly longer time for onset of action but with a longer duration of action and have less transfer across the placenta. Hence, they are ideal drugs for use in labour analgesia.

Aim: To compare the effectiveness of programmed intermittent bolus of 0.125% bupivacaine vs 0.125% ropivacaine in low volumes in full term primigravidas for epidural labour analgesia.

Materials and Methods: This randomised clinical study was conducetd at PES Institute of Medical Sciences and Research, Kuppam, Andhra Pradesh, India, between June 2020 and December 2021 among 80 full-term primi parturients requiring normal vaginal delivery. They were randomly divided into two groups of 40 each. Group B received 10 mL of 0.125% bupivacaine and group R received 10 mL of 0.125% ropivacaine as initial bolus dose. Repeat doses of 5 mL was given every 60 minutes or when the patient had Visual Analogue Score (VAS) score >4 with a maximum dose of 10 mL/hr with a 20 minute interval between two doses. Parameters assessed were onset, duration, level and quality of analgesia, motor blockade, number of epidural top ups, total volume of drug consumed, mode of delivery, duration of labour, APGAR score, haemodynamics, patient satisfaction and complications. Data was entered in Microsoft Excel 2010 version and analysed using Statistical Package for Social Sciences (SPSS) version 20.0.

Results: Both drugs were equally effective in terms of analgesia, maternal and foetal outcomes. Bupivacaine had a faster onset of action (7.075±0.916 min) compared to ropivacaine (8.225±0.891 min) (p-value=0.001). Ropivacaine had a shorter duration of action (43.1±2.30 min vs 47.9±4.16 min in group B) (p-value=0.0001), requiring more top-up doses (5.2±0.46 vs 4.77±0.61 in group B) (p-value=0.0007), and more total volume of drug (38.5±3.08 mL vs 35.5±4 mL in group B) (p-value=0.002). It also caused lesser motor blockade (Bromage score of 1 in 1 parturient vs 8 parturients in group B) (p-value=0.0129) and better overall maternal satisfaction score (excellent) in 30 parturients vs 25 parturients in group B. APGAR scores at 1 minute and 5 minutes were comparable between the two groups. Mean heart rates, mean blood pressures were also comparable between the two groups. There were no significant adverse effects in either groups.

Conclusion: By providing minimal motor blockade and adequate analgesia 0.125% ropivacaine allows parturients to go through the labour process with excellent maternal satisfaction and minimal adverse effects compared to 0.125% bupivacaine.

Keywords: Maternal satisfaction, Motor blockade, Programmed intermittent epidural labour analgesia

INTRODUCTION

Labour is an extremely painful process and is the main contributor to anxiety and stress. A painful uterine contraction increases sympathetic nervous system activation resulting in increased plasma catecholamines in mother affecting endocrine, respiratory, cardiovascular systems and uteroplacental circulation and thereby, affecting both mother and foetus [1-3].

The primary care provider's responsibility is to titrate analgesic requirements based on circumstances like pain tolerability, anticipated duration of labour, and foetal condition. Epidural blockade is an effective method of providing analgesia during labour [4]. With the emerging concept of minimal strength local anaesthetic dose and volumes, all present-day labour epidurals are given minimal strength local anaesthetic doses of 0.125% to 0.0625% also known as walking epidurals [5,6]. These low dose regimes limits motor blockade and do not affect the progress of labour and have minimal side-effects to mother and foetus [7]. Bupivacaine in various strength is the most widely used local anaesthetic for epidural labour analgesia but is associated with motor blockade, decreased maternal bearing down efforts in the second stage of labour and increased instrumental deliveries. Ropivacaine is a homologue of bupivacaine, which causes less motor blockade and less cardiotoxicity and hence, a local anaesthetic of choice in labour analgesia [8].

Programmed intermittent bolus injections into the epidural space has been found to be more effective method for labour analgesia compared to other techniques, as there is significantly short second stage of labour, slightly lesser total anesthetic used, and higher maternal satisfaction [9,10].

Hence, the present study was undertaken to study the effectiveness of bupivacaine and ropivacaine in low concentrations of 0.125% with low volumes of 5 mL top-up doses when used as programmed intermittent bolus injections for epidural labour analgesia without any adjuvants. The primary outcomes measured were onset of analgesia, duration of analgesia, VAS scores, degree of motor block and maternal satisfaction. The secondary outcomes measured were total volume of local anaesthetic used, number of top-ups used, haemodynamic variables, APGAR score at 1st and 5th minute and side-effects.

MATERIALS AND METHODS

The randomised clinical study was undertaken at PES Institute of Medical Sciences and Research, Kuppam, Andhra Pradesh, India. between June 2020 and December 2021. The Institutional Human Ethical Committee had approved the study (PESIMSR/IHEC/31/2019).

Sample size calculation: A sample size of 37 parturients per group was calculated using the formula:

$$'N'=2\{Z_{1-\alpha/2}+Z_{1-\beta/2}\}^2\times\sigma^2/\delta^2$$

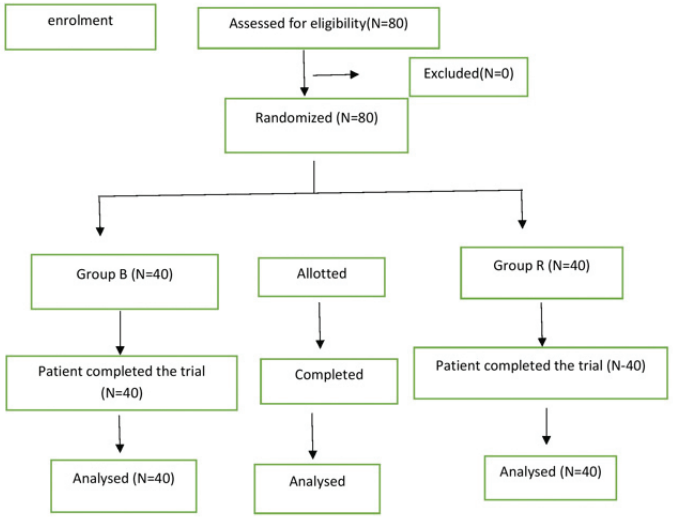
($Z_{1-\alpha/2}$=1.96,$Z_{1-\beta/2}$=0.84,α=0.05, β=0.80, σ=3.46, δ=2.23) and was rounded of to 40 parturients in each group [11].

Inclusion criteria: All primigravida parturients of ASA physical status I and II with singleton uncomplicated pregnancy with vertex presentation in labour, with a cervical dilatation of 3-4 cm were included in the study.

Exclusion criteria: All patients with allergy to study drugs, unwilling parturients, deranged coagulation profile and infection, at the site of epidural catheter insertion were excluded from the study.

The Consolidated Standards of Reporting Trials (CONSORT) flowchart is as shown in [Table/Fig-1]. All the parturients who were enrolled received a successful epidural analgesia, there were no dropouts from the study. The parturients were randomly allotted to either group B or group R, using blinded opaque envelopes sorted by computer-generated random allocation.

- Group B: Patients were given 10 mL of 0.125% Bupivacaine as bolus.
- Group R: Patients were given 10 mL of 0.125% Ropivacaine as bolus.



[Table/Fig-1]: CONSORT flow diagram.

Study Procedure

A detailed preanaesthetic evaluation was done including demographic data, parity, gestational age and the condition of the membrane. After explaining the procedure and obtaining informed written consent, 18 G intravenous cannula was secured and preloaded with 300 mL of ringer's lactate, standard monitors applied and baseline values were recorded. Epidural space was identified with 18 G Tuohy's needle in L3-4 or L4-5 interspace with loss of resistance to air technique and a 18 G epidural catheter threaded and fixed with approximately 3 cms of the catheter inside the epidural space. An epidural test-dose of 2 mL 2% lignocaine with 1:2,00,000 adrenaline administered to rule out intravascular or intrathecal injection. After confirming the position of the epidural catheter, parturients in group B were given 10 mL of 0.125% bupivacaine as bolus and those in group R were given 10 mL of 0.125% ropivacaine as bolus. Analgesia was maintained by intermittent bolus injections of 5 mL every 60 minutes. Parturients, who experienced inadequate analgesia {Visual Analogue Score (VAS) >4} during the labour process were supplemented with an additional 5 l of study drug up to a maximum of 10 mL/h until the delivery of the baby. Supplementation was given only after 20 minutes of the previous dose. The anaesthesiologist performing the procedure and recording the study parameters were blinded to the study. All the essential drugs and equipment were kept ready near the patients throughout the labour period.

The onset and duration of analgesia, motor block using Bromage scale, pain scores using VAS score on a scale of 0-10, total volume of drug used, intrapartum haemodynamics, mode of delivery, Appearance, Pulse, Grimace, Activity and Respiration (APGAR) score at 1 and 5 minutes, maternal satisfaction on a 4-point scale as excellent, good, fair, or poor on a verbal numerical score from 0 to 10 were noted [12]:

Score 8-10 was taken as excellent,

Score 5-7 as good,

Score 2-4 as fair,

Score <2 as poor

Side-effects, if any, were monitored continuously after administering the study drug.

All the above parameters were recorded at 0, 5, 15, 30 min and every 30 min, and after each top-up every five minute for 15 min, untill delivery.

STATISTICAL ANALYSIS

Data was entered in Microsoft Excel 2010 version and analysed using Statistical Package for Social Sciences (SPSS) version 20.0. For descriptive analysis, the categorical variables were analysed by calculating frequency and percentages, continuous variables were analysed by calculating mean and standard deviation. For inferential analysis, the numerical data were analysed with t-test, mean values of both the groups, were compared with unpaired Student's t-test. Chi-square test analysed categorical data and two attributes like mode of delivery, maternal satisfaction score. A p-value <0.05 was considered as statistically significant.

RESULTS

There was no statistical difference in demographic data, gestational age and cervical dilatation between the two groups at the time of enrollment [Table/Fig-2].

Parameters	Group B (Mean±SD)	Group R (Mean±SD)	p-value
Age (year)	21.2±3.62	22.1±2.74	0.2143#
Weight (kg)	63.52±5.12	63.12±5.27	0.365#
Height (cm)	158.4±4.68	158.5±4.03	0.54#
Gestational age (weeks)	38.42±0.84	38.35±0.62	0.326#
Cervical dilatation n (%)			
3 cm	16 (40%)	20 (50%)	0.808$
4 cm	24 (60%)	20 (50%)	-

[Table/Fig-2]: Demographic profile of study groups.
*p-value <0.05 was significant, #t test, $Chi-square test

There was a faster onset of analgesia in group B. Mean duration of analgesia after each dose, was significantly longer in group B compared to group R, so number of top-up doses required and total volume of study drug used was significantly lesser in group B. Maximum Bromage score achieved was 1 in both groups but more number of parturients in group B were 8 (20%) achieved this score compared to 1 (2.5%) parturient in group R. Mean duration of second stage of labour significantly prolonged in group B. One patient in group B had hypotension compared to none in group R, two patients in group B had nausea compared to one patient in group R both the incidences were statistically insignificant. There was no statistically significant difference in level of block, APGAR score, mode of delivery, haemodynamic parameters and complications [Table/Fig-3] between two groups. Though more number of parturients in group R had better maternal satisfaction score, this was statistically not significant [Table/Fig-3].

There was no significant difference in the VAS scores for the entire duration of labour between the two groups [Table/Fig-4].

Parameters	Group B (n=40) (Mean±SD)	Group R (n=40) (Mean±SD)	p-value
Onset of analgesia (min)	7.075±0.916	8.225±0.891	0.001#
Level of block			
T6	1 (2.5%)	1 (2.5%)	0.730$
T8	22 (55%)	18(45%)	
T10	17 (42.5%)	20 (50%)	
Duration of analgesia (min)	47.9±4.16	43.1±2.30	0.0001#
Bromage scale >1; n (%)	8 (20%)	1 (2.5%)	0.0129$
Duration of labour (min)			
1st stage	160.0±9.4	163.0±10.2	0.192#
2nd stage	54.2±6.16	49.9±6.83	0.01#
3rd stage	14.8±4.06	16.2±3.9	0.134#
Total	229.0±14.47	229.1±13.5	1.00#
Total number of top-ups	4.77±0.61	5.2±0.46	0.0007#
Total volume of local anaesthetic used (mL)	35.5±4.0	38.5±3.08	0.002#
Mode of delivery n (%)			
Spontaneous vaginal	34 (85%)	35 (87.5%)	
Instrumental vaginal	3 (7.5%)	2 (5.0%)	0.898$
Caesarean section	3 (7.5%)	3 (7.5%)	
Haemodynamics			
Heart rate (min)	88±4.3	90.2±3.6	0.99#
Blood pressure (mmHg)			
Mean arterial	84.4±1.9	85.2±1.6	0.72#
Systolic	112.2±2.24	112.4±2.6	0.1#
Diastolic	71.63±1.5	72.2±1.6	0.104#
APGAR score			
1 min	7.65±0.62	7.55±0.74	0.514#
5 min	8.9±0.266	8.9±0.266	1.00#
Patients satisfaction score n (%)			
Excellent	25 (62%)	30 (75%)	
Good	15 (38%)	10 (25%)	1.45$
Fair	0	0	
Poor	0	0	
Complications n (%)			
Hypotension	1 (2%)	0	1.38$
Nausea/Vomiting	2 (5%)	1 (2%)	

[Table/Fig-3]: Comparison of analgesia, local anaesthetic doses, mode of delivery, haemodynamics, APGAR score, maternal satisfaction score and complications between the two groups.
*p-value <0.05 was considered as significant. #t test, $Chi-square test

VAS score	Group B (Mean±SD)	Group R (Mean±SD)	p-value (Student's t-test)
At 0 min	8.4±0.74	8.6±0.76	0.14
At 5 min	4.7±0.70	4.45±0.71	0.06
At 15 min	0.42±0.67	0.4±0.77	0.87
At 30 min	0.25±0.49	0.75±0.26	0.052
At 60 min	0.46±0.59	0.67±0.79	0.2
At 90 min	0.6±0.81	0.4±0.59	0.21
At 120 min	0.77±0.7	0.52±0.59	0.10
At 150 min	0.75±0.66	0.62±0.625	0.385
At 180 min	0.70±0.6	0.725±0.59	0.57
At 210 min	1.075±0.61	1.075±0.69	1
At 240 min	1.25±0.46	1.75±0.50	0.11

[Table/Fig-4]: Mean Visual Analogue Scale (VAS) scores.
*p-value <0.05 was considered as significant

DISCUSSION

Labour pain is the most severe form of pain that is experienced and it varies at different stages of labour. Pain during the first stage is due to dilatation, stretching, tearing of the lower uterine segment and cervix, mediated through the visceral fibers to T10-L1 segments, hence the pain is vague [13]. In the second stage of labour, pain intensity increases as the foetus passes through the birth canal dilating, stretching and tearing the tissues along the birth canal and is mediated through the somatic nerves to the lumbosacral segments, hence, the intensity is more [13].

Adequate analgesia can be produced by blocking these nerve segments through the epidural route. Bupivacaine and ropivacaine are the most commonly used drugs to provide labour analgesia in concentration ranging from 0.08%-0.2%. Bupivacaine is an amide which is composed of a racemic mixture of R and S isomers in equal proportions. It acts by binding to sodium channels in its inactivated state, block the movement of sodium ions across the nerve membrane, thus, prevents repolarisation of nerve membrane and nerve conduction. Bupivacaine is highly protein bound, lipophilic drug with pKa of 8.1, at physiologic pH exists in ionised form with a foetal-maternal concentration of 0.2-0.4 [14,15]. It provides differential blockade of nerve fibers based on the drug concentration, size of nerve fiber and rate of nerve depolarisation. The smaller myelinated nerve fibres are more sensitive than larger and non myelinated fibres, hence, it produce analgesia by blocking the A γ and A δ fibres even at low concentration. Ropivacaine is an homologue of bupivacaine has similar properties, but as it is formulated as a single levorotatory isomer, it is less cardiotoxic, with lesser motor blocking property than bupivacaine at equal concentrations with foetal maternal concentration ratio of 0.2 [14,15].

The present study compared effectiveness of bupivacaine vs ropivacaine in low concentration (0.125%) as intermittent bolus doses in low volume (5 mL) and found that though ropivacaine had a slower onset and shorter duration of analgesia, it was associated with less number of patients having motor block, hence, shorter second stage of labour compared to bupivacaine and hence, it had a better maternal satisfaction score.

The slower time for onset of analgesia with ropivacaine was due to lower lipid solubility, which results in longer time taken for the drug to enter and block nerve transmission. These results correlated with study by Finegold H et al., who compared 0.25% bupivacaine followed by 0.125% bupivacaine with fentanyl 2 mcg/mL and 0.2% ropivacaine followed by 0.1% ropivacaine with fentanyl 2 mcg/mL and found the onset of analgesia in bupivacaine was faster compared to ropivacaine [16]. Shenvi SS and Jaiswal AV, compared 15 mL of 0.1% bupivacaine vs 0.1% ropivacaine with 2 mcg/mL fentanyl and found a faster onset time for bupivacaine group [11].

In the present study, the sensory level in most of the parturients was T8 in both groups. Kumar GS et al., did a randomised comparison of bupivacaine 0.125% vs ropivacaine 0.125% with fentanyl 2 mcg/mL. They observed that the upper sensory level was T10 in all the groups [17]. The results of the present study were comparable to others where the sensory blockade achieved was T8 in most of the parturients [5,18,19]. These results suggest that, both the study drugs in low concentrations produced adequate sensory blockade irrespective of the additives used.

The mean VAS scores before the study drug injection and at different time intervals, after study drug injection between groups was comparable and statistically insignificant. Similar findings were reported by Kulkarni K and Patil R, who compared bupivacaine 0.125%, ropivacaine 0.125% with the addition of

fentanyl 2 mcg/mL and observed no difference in VAS score between both the groups [20]. Similar results were also reported by few others [11,17,19,21]. The time to achieve a VAS score of 2 in the two groups in the study by Kulkarni K and Patil R, was 10 minutes and a score of 1 was achieved at 15 minutes in both the groups [20]. In the present study, a VAS score of 4 was achieved at five minutes and a score of 0.42 was achieved by 15 minutes in both the groups. These results suggest that, both study drugs produce satisfactory analgesia, when used without any adjuvants.

The mean duration of analgesia was significantly longer in bupivacaine group and hence, required lesser top-up doses. But analgesia remained excellent in both groups. There were episodes of breakthrough pain at 180 min and 210 min in ropivacaine group, but VAS scores were <4. This is probably because of ultralow concentrations of the local anaesthetic solutions used at regular intervals. A few contributory factors include increased intensity of pain towards the second stage of labour, misinterpretation of discomfort due to head on perineum as pain. This findings had no clinical significance because VAS score were within 4, and maternal satisfaction remained good. Duration of analgesia and VAS scores were comparable to study done by Kumar GS et al., and Kulkarni K and Patil R [17,20].

Motor blockade mainly depends on the potency, concentration, and volume of the local anaesthetic solution used. Among 80 parturients, 8 (20%) in bupivacaine group and 1 (2.5%) in ropivacaine group had a Bromage score of 1. Remaining all the parturients in both groups had Bromage score of zero. This higher Bromage score in group B probably had effect on prolonging the duration of second stage of labour. These results were comparable to the study conducted by Fernández-Guisasola J et al., wherein the second stage of labour duration was 57±47 min in group B (0.0625% bupivacaine) and 47±38 min in group R (0.1% ropivacaine) [19]. The present study results also matched with study by Kumar GS et al., who found a significant less motor blockage with ropivacaine with fentanyl [17].

The higher Bromage score did not affect the mode of delivery, as equal number of parturients in both groups had normal vaginal delivery. Though more number of parturients in ropivacaine group had an excellent maternal satisfaction scores, there was no statistically significant difference in overall quality of analgesia between the two groups. This correlated with the study by Steinstra R et al., [22]. The overall duration of labour was comparable between the two groups which correlates with studies by Kumar GS et al., and Wang L et al., who compared both, ropivacaine and bupivacaine in equal concentrations [17,23]. The results of the present study showed that irrespective of the additives used both drugs were effective with respect to the onset of analgesia, duration of analgesia, VAS scores, and the degree and incidence of motor block.

Total volume of drug used was 38.5 mL and 35.5 mL of ropivacaine and bupivacaine, respectively, which was statistically significantly but relatively less than in study by Meister GC et al., [21]. Relatively better APGAR scores at one minute and five minute were observed in group R compared to group B but was not statistically significant. This correlated with study by Gaiser RR et al., wherein APGAR >7 was 100% in Group R vs 97% in Group B at five minute [24]. Trends of mean of heart rate, systolic, diastolic and mean arterial pressure for the entire duration of labour, recorded in two groups did not show any clinical or statistical difference. These haemodynamic parameters correlated with study by Wang L et al., [23].

The most common side-effect in both the groups was nausea and/or vomiting, with an incidence of 5% in group B and 21% in group R, and it was treated with injection ondensetron 5 mg intravenous.

Limitation(s)

The study was conducted in ASA I and II primigravidas with uncomplicated pregnancies. Moreover, results can not be generalised to multigravida, parturients with co-existing diseases and parturients with complicated pregnancies like breech presentation, twin pregnancy, preterm delivery.

CONCLUSION(S)

To conclude, both bupivacaine and ropivacaine in concentrations of 0.125% in low volumes given as intermittent bolus doses epidurally without any adjuvants produced satisfactory labour analgesia, without compromising maternal safety or foetal outcome. Ropivacaine produced lesser incidences of motor blockade compared to bupivacaine and hence, better maternal satisfaction, but had a shorter duration of action requiring more number of top-up doses and greater total volume of drug used, but this had no effect on the outcome of labour or foetal well-being.

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