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Original Research Article

COMPARISON OF 0.0625% BUPIVACAINE WITH 2 mcg/ml FENTANYL AND 0.1% ROPIVACAINE WITH 2 mcg/ ml FENTANYL FOR LABOUR ANALGESIA

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In epidural labor analgesia, bupivacaine 0.625% with fentanyl 2 mcg/ml and ropivacaine 0.1% with fentanyl 2 mcg/ml offer appropriate and equivalent analgesia for labor without causing local anaesthetic toxicity.

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Abstract

Background: Ropivacaine has been gradually replacing the place of bupivacaine in labor epidural analgesia in recent years as ropivacaine provides similar analgesic effects with less motor blockade and reduced cardiovascular and central nervous system toxicity. In this study, we examine the analgesic effectiveness, motor blockade, hemodynamic stability, labor outcomes and fetal outcomes of equipotent doses of 0.0625% Bupivacaine with Fentanyl 2µg/ml and 0.1% Ropivacaine with Fentanyl 2µg/ml. **Materials and Methods:** This prospective randomized double-blinded study was conducted at Government Vellore Medical College, Vellore. Patients were randomized into two groups using a computer-generated randomization table. Group A received 0.0625% Bupivacaine with Fentanyl 2µg/ml while Group B received 0.1% Ropivacaine with Fentanyl 2µg/ml. We have measured baseline maternal blood pressure, spo2, fetal heart rate, uterine contractions, cervical dilatation, fetal head station, and visual analogue pain score. During the procedure oxygen saturation (SPO2), pulse rate (PR), non-invasive blood pressure (NIBP), foetal heart rate (FHR) and pain score are assessed using a visual analogue scale (VAS), the highest level of sensory block determined by an alcohol swab and the degree of motor blockade were monitored at specific intervals. **Results:** There was no significant difference in age, height, weight, body mass index, mode of delivery, systolic blood pressure, diastolic blood pressure, pulse rate, SpO2, FHR and VAS between groups. There was a significant difference in the duration of uterine contractions and fetal head station between groups. There was a significant difference between the groups mean onset of analgesia, the total dose used and the top-up bolus dose. In both Group A and Group B, there were no cases of hypotension or respiratory depression observed. However, pruritus was reported in one patient in each group. Additionally while there were no instances of urinary retention in either group, vomiting was reported in one patient in Group B. **Conclusion:** In epidural labor analgesia, bupivacaine 0.625% with fentanyl 2 mcg/ml and ropivacaine 0.1% with fentanyl 2 mcg/ml offer appropriate and equivalent analgesia for labor without causing local anaesthetic toxicity.

INTRODUCTION

Pain during labor is widely recognised as one of the most excruciating experiences in a woman's life and it can have detrimental effects on both the mother and fetus.[1,2] Labor pain triggers the release of stress hormones such as cortisol and epinephrine in the mother, reducing uteroplacental blood flow.[3] Additionally pain-induced hyperventilation can result in respiratory alkalosis, impacting fetal oxygen saturation (Sao2) levels. Adequate pain relief during labor offers numerous physiological and psychological benefits for both the mother and fetus.4 In many countries including ours, providing labor analgesia remains a significant challenge. Regional analgesia, particularly epidural labor

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analgesia stands out as a safe and effective option among the various methods available.[1,2,5]

Epidural labor analgesia relieves pain and enhances maternal cardiovascular and pulmonary function while maintaining fetal acid-base status.[6] One of its key advantages is that it allows the mother to remain awake, cooperative and actively participate in the labor process.[7] Moreover, compared to other pain relief methods epidural labor analgesia consistently results in the highest levels of maternal satisfaction.8 Epidural analgesia using local anaesthetic agents alone can lead to a motor block in up to 85% of patients, reducing maternal satisfaction, increasing the duration of the second stage of labor and a higher incidence of instrumental delivery. On the other hand, epidural opioids alone can provide analgesia without a motor block but may not deliver satisfactory pain relief throughout labor. Combining opioids with local anaesthetics proves effective, reducing motor block, facilitating labor progress and promoting vaginal delivery. Additionally, this combination allows for a reduction in the required local anaesthetic dose.

The addition of opioids to local anaesthetic epidural boluses has become a popular technique due to its influence on the duration of labor analgesia. When using Bupivacaine at higher concentrations for labor analgesia, there is a risk of prolonged second-stage labor and an increased incidence of assisted vaginal deliveries due to motor blockade. To address these issues, minimal local anaesthetic concentration (MLAC), minimal local anaesthetic volume (MLAV) and a low-dose regime of local anaesthetics are employed with opioids. This approach provides adequate analgesia with minimal or no motor blockade, ensures better hemodynamic stability, allows the mother to remain ambulatory (Walking Epidural) and reduces the risk of toxicity if inadvertently injected intravascularly. This approach enhances the mother and fetus's safety without negatively affecting labor progress.[8,9]

In recent years, Ropivacaine has increasingly replaced Bupivacaine in Labor Epidural Analgesia. Ropivacaine offers similar analgesic properties but with less motor blockade and reduced cardiovascular and central nervous system toxicity.[10,11] In this study, we compare equipotent doses of 0.0625% Bupivacaine with Fentanyl 2µg/ml and 0.1% Ropivacaine with Fentanyl 2µg/ml for their analgesic efficacy, motor blockade, hemodynamic stability, labor outcomes and fetal outcomes.

MATERIALS AND METHODS

This prospective randomized double-blinded study was conducted at Government Vellore Medical College Adukkamparai. Ethical approval of the study protocol was obtained from the Ethical Committee at the institution before the study was undertaken. Written informed consent was obtained from each patient in the prescribed format before performing any study-related procedures.

Inclusion Criteria

Primi gravida aged 18-40 years, adequate pelvis, no cephalopelvic disproportion, single pregnancy with vertex presentation, first stage, cervical dilatation 3-5cm, full effacement in active labour and ASA PS I & II were included.

Exclusion Criteria

Patients with contraindications to epidural blocks such as patient refusal, hypersensitivity to local anaesthetics, infection at the insertion site or coagulopathy, as well as those with preterm pregnancies, multiple pregnancies, previous caesarean sections or a history of failed epidurals were excluded.

The pre-procedural evaluation includes a thorough review of obstetric history, previous anaesthesia experiences and medical conditions, followed by a physical examination encompassing vital signs (BP, HR, SPO2, RR) and systemic examination of the respiratory system (RS), cardiovascular system (CVS), central nervous system (CNS), airway and spine, along with investigations such as haemoglobin levels, urine routine examination, blood grouping and typing and coagulation profile.

Pre-procedural preparation includes obtaining informed consent, addressing maternal anxiety through education on labor, pain management and information regarding delivery, establishing an 18G IV access, preparing drugs such as local anaesthetics, opioids, medications for hypotension, emergency intubation and resuscitation, as well as ensuring the availability of essential equipment including a PPV machine with an O2 source, airway equipment, an Ambu bag, defibrillator, multi-parameter monitor, CTG and a tilting bed.

Patients were randomized into two groups using a computer-generated randomization table. Group A received 0.0625% Bupivacaine with Fentanyl 2µg/ml, while Group B received 0.1% Ropivacaine with Fentanyl 2µg/ml. Intravenous access was secured with an 18G cannula and the parturient was preloaded with 500ml of Ringer Lactate solution. The study proceeded after measuring baseline maternal blood pressure, spo2, fetal heart rate, uterine contractions, cervical dilatation, fetal head station and visual analogue pain score.

After confirming proper placement with a negative aspiration test, a 20G epidural catheter was inserted 5 cm cranially into the epidural space, securely fastened and the patient was positioned supine with left uterine displacement; a 3ml test dose of 1.5% lignocaine with 1:2,00,000 adrenaline was administered through the catheter and the presence of intrathecal injection was determined by motor blockade within 5 minutes, while intravascular injection was indicated by increase in pulse rate of 20-30 beats per minute from baseline within 20-40 seconds.

The initial bolus dose of 10ml of a prepared local anaesthetic epidural mix (either Bupivacaine

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0.0625% or Ropivacaine 0.1% with fentanyl 2µg/kg) was administered in divided doses at a 5-minute interval, closely monitoring for any signs of intrathecal or intravascular injection. Subsequent 5ml doses were administered if the mother's vital signs remained stable for 5 minutes, with epidural top-ups given only upon the patient's complaint of pain or discomfort. During the second stage of labor, when the mother experienced perineal pain, the local anaesthetic dose was administered in a sitting posture to block the sacral segments.

The following parameters are monitored at specific intervals during the procedure: oxygen saturation (SPO2), pulse rate (PR), non-invasive blood pressure (NIBP), foetal heart rate (FHR), pain score assessed using a visual analogue scale (VAS), the highest level of sensory block determined by an alcohol swab and the degree of motor blockade assessed using the Bromage scale. SPO2, PR, and NIBP are measured at 5, 10, 15, 20, and 30 minutes, and every 30 minutes after that until delivery, while pain score, sensory block level and motor blockade are assessed 20 minutes after an initial bolus and subsequently every 30 minutes.

Before initiating ambulation in a patient who had received a walking epidural, it was essential to assess motor blockade, sensory blockade and the risk of falls sequentially. This was done by performing the straight leg raise test to evaluate leg strength, checking for postural hypotension and syncope at the bedside and assessing hypotension while standing at the bedside, evaluating leg strength during a partial knee bend and ensuring the patient could take six unassisted steps to assess their ability for ambulation safely.

After delivery catheters were removed immediately, but for operative procedures such as instrumental deliveries, cesarean sections, manual removal of the placenta and perineal tear repairs, the catheter could be extended; following removal, the blue tip was ensured to be intact and documented and then a sterile dressing was applied.

After delivery, an anaesthetist monitored all women for 24 hours, ensuring they had voided normally before discharge. Any complaints, such as severe headache, severe backache or progressive numbness and weakness in the legs occurring more than 3 hours after the removal of the epidural catheter were promptly reported to the anaesthetist.

Immediate complications of epidural analgesia included accidental dural puncture, hypotension, inadequate analgesia, a bloody tap, a high block and total spinal. In contrast, late complications could have involved epidural hematoma, nerve damage, backache, maternal fever and bladder dysfunction. The Bromage score, VAS score, mode of delivery, mother satisfaction and complications were all documented and assessed.

Statistical Analysis

Data were analysed using SPSS 11.5, and descriptive analysis for nonparametric variables was expressed in proportion and parametric variables in mean and standard deviation. The treatment difference was assessed using the t-test for independent samples for parametric variables and the Chi-square test for non-parametric variables. Statistical significance was assessed using p at 0.05 cut-off or 95% confidence interval (95% CI).

RESULTS

Physical characteristics like age, height, weight and body mass index were comparable in both groups.

There was no significant difference in age, height, weight, body mass index and mode of delivery between groups (Table 1).

There was no significant difference between groups in systolic blood pressure, diastolic blood pressure, pulse rate, SpO2, FHR and VAS. There was a significant difference in the duration of uterine contractions and fetal head station between groups (Table 2).

Patients on Group A need an earlier dose of top-up after the initial bolus than Group B. There was a significant difference between the groups mean onset of analgesia, the total dose used and the top-up bolus dose (Table 3).

Table 1: Demographic data of the groups

		Group A	Group B	Total
Age Years	<20	4	4	8
	20-30	25	25	50
	>30	1	1	2
	Mean (SD)	23.6 (3.3)	23.0 (3.2)	P value 0.5
Height Centimetres	< 150	1	3	4
	150-159	14	15	29
	>160	15	12	27
	Mean (SD)	159 (6.9)	158.3 (6.8)	P value 0.5
Weight kilograms	< 50	1	0	1
	50-59	8	5	13
	60-69	16	18	34
	70>	5	7	13
	Mean (SD)	63.49 (7.5)	64.6 (5.9)	P value 0.54
BMI Kg/m2	<18.5	0	0	0
	18.5-24.99	14	8	22
	25>	16	22	38
	Mean (SD)	25.1 (3.5)	25.8 (1.9)	P value 0.33
Mode of delivery	Vaginal delivery	27	27	

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	Assisted vaginal delivery	2	2	P value 1
	LSCS	1	1	

Table 2: Baseline parameters between groups

Baseline parameters	Mean (SD)		P value
	Group A	Group B	
SBP	117.6 (11.2)	121.5 (11.3)	0.18
DBP	75.8 (9.4)	77.3 (7.6)	0.5
PR	88.2 (6)	85.6 (6)	0.12
SPO2	98 (0)	98 (0)	0.16 not applicable
FHR	128 (6.4)	127 (4.4)	0.49
Duration of uterine contractions	49.5 (3.8)	50.8 (3.3)	0.03
Fetal head station	-2.4 (0.6)	-2.1 (0.4)	0
VAS	5.8 (0.8)	5.7 (0.9)	0.75

Table 3: Mean onset of analgesia, total dose used, and top-up bolus dose between groups

	Group A	Group B	P value
Mean onset of analgesia (minutes)	15.03 ± 1.47	19.66 ± 2.23	0
Total dose used	26.97 ± 4.97	45.67 ± 6.79	<0.0001
Top-up bolus dose	55.5 ± 5.68	59.6 ± 4.72	0.004

Table 4: Comparison of the sensory block between two groups

Time after initial bolus in minutes	Upper sensory level	Group A	Group B	P value
30	T8	22	27	0.09
	T9	8	3	
60	T10	25	25	0.5
	T11	5	5	
90	T9	26	26	1
	T10	4	4	
120	T10	8	5	0.3
	T11	22	25	
150	T8	23	27	0.2
	T9	3	2	
	T10	2	1	

Table 5: Stage of labor between groups

Mean duration in minutes	Arm		P value
	A - Bupivacaine	B - Ropivacaine	
1st stage of labor	188 ± 52.59	208.6 54.65	0.14
2nd stage of labor	20.4 ± 5.78	19.9 5.55	0.75
3rd stage of labor	5.8 1.58	6 1.72	0.64
The total duration of labor	213 56.3	234.2 57.4	0.15

Table 6: APGAR score, cervical dilatation, uterine contraction and satisfaction level between groups

		Group A Bupivacaine	Group B Ropivacaine	P value
APGAR score	Score - 7	9	21	0.78
	Score - 8	21	20	
	Mean (SD)	7.7 (0.5)	7.7 (0.5)	
Mean cervical dilatation in centimetres	0	3.6	3.9	0.09
	120	6.8	6.3	0.1
	180	8.4	8.3	0.7
Mean uterine contraction in seconds	0	49.5	50.8	0.16
	120	70.7	69.7	0.4
	180	80.4	77.2	0.01
Satisfaction level	Excellent	28	29	0.5
	Good	2	1	

No significant difference in sensory block at 30, 60, 90, 120 and 150 minutes between the groups (Table 4).No significant difference was found in VAS scores at 0, 5, 15, 20, 30, 60, 180, 240 and 300 minutes, but a significant difference at 120 minutes between groups (Figure 1). No significant difference was found between groups in the stages of labor (Table 5). No significant difference was found in systolic blood pressure at 0, 5, 10, 15, 20, 30, 60, and 120 minutes, but a significant difference at 180 minutes between groups (Figure 2). No significant difference between groups was found in diastolic blood pressure at 0, 5, 10, 15, 20, 30, 60, 120 and 180 minutes (Figure 3). No significant difference was found in pulse rate at 0, 10, 15, 20, 30, 120 and 180 minutes, but a significant difference between groups at 5 and 60 minutes (Figure 4). No significant difference was found in feat heart rate at 0, 10, 15, 20, 30, 60 and 120 minutes, but a significant difference between groups at 5 minutes (Figure 5). There was no significant difference between the groups' APGAR scores of newborns at 1 minute after delivery

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(p=0.78). All newborns in both arms had an APGAR score of 10 at 5 minutes. No significant difference in cervical dilatation at 0, 120, and 180 minutes between the groups. There was no significant difference in uterine contraction at 0 and 120, but there was a significant difference at 180 minutes between the groups. There was no significant difference in satisfaction level between the groups (p=0.5) (Table 6). In both Group A and Group B, there were no cases of hypotension or respiratory depression observed. However, pruritus was reported in one patient in each group. Additionally, while there were no instances of urinary retention in either group, vomiting was reported in one patient in Group B.

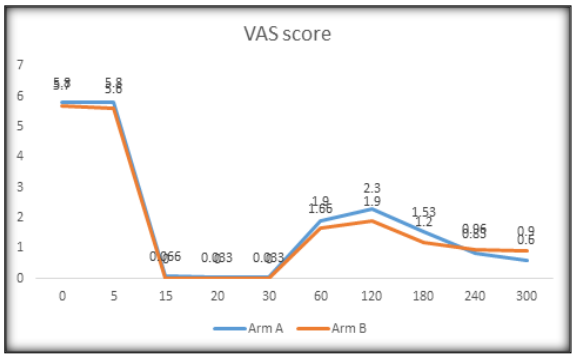

Figure 1: Visual analogue score between groups

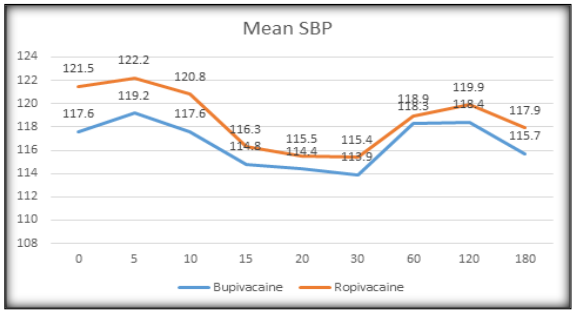

Figure 2: Mean systolic blood pressure between groups

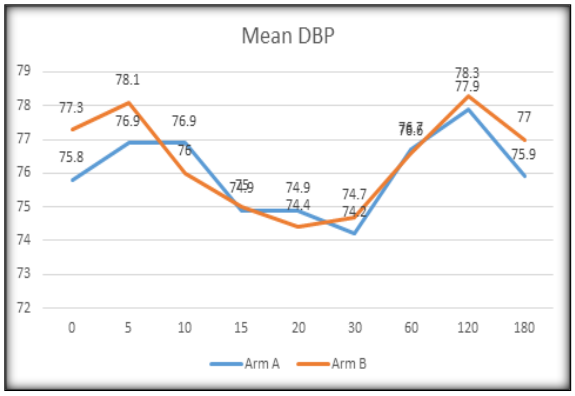

Figure 3: Mean diastolic blood pressure between groups

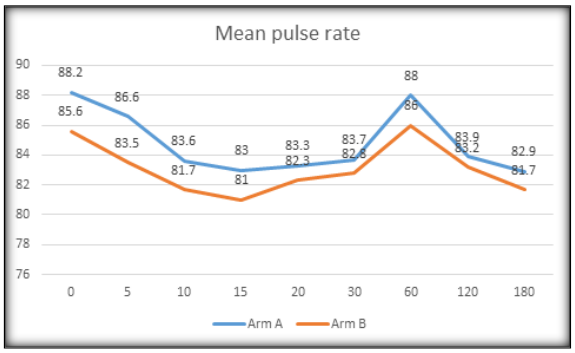

Figure 4: Mean pulse rate between groups

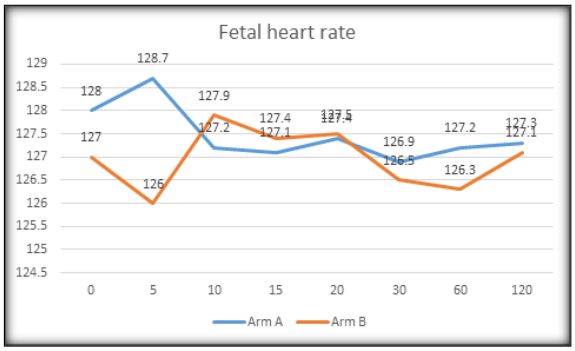

Figure 5: Mean heart rate between groups

DISCUSSION

Several methods exist to provide pain relief to the laboring parturient. Of the regional techniques, epidural analgesia is considered the gold standard among all other techniques, and it is the only technique that can provide complete and convincing pain relief, making labor a pleasurable experience. [7,8] In our study, we have used intermittent epidural bolus top-up technique using 0.0625% bupivacaine with fentanyl 2 µg /ml (group A) and 0.1%% ropivacaine with fentanyl 2 µg /ml (group B) and compared their analgesic efficacy, effects on maternal, fetal and labor outcome. Both groups were comparable in age, body mass index, and parity. There was no motor block observed in both groups. Whether epidural analgesia harms the progress and outcome of labor has been debated. One of the factors responsible for the complication was motor blockade from the epidural local anaesthetic solution. This may decrease the mobility of the patient, decrease the maternal effort and inadequate rotation of the fetal head. All these factors may lead to instrumental delivery and caesarean section. But, in our study none had motor blockade as the concentration of the local anaesthetic solution was minimal.

Contrary to the popular belief that epidural analgesia causes prolongation of the duration of labor, we found a statistically significant reduction in the duration in both groups, which our Obstetrician also observed. We attribute this to the beneficial effect of analgesia that abolishes sympathetic response and makes the uterine contraction more coordinated, apart from improving the uterine blood flow. Similar findings were observed by Khan et al.[12] No

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significant difference was observed in the mode of delivery, hemodynamics such as maternal blood pressure, pulse rate and fetal heart rate, fetal APGAR score, and complications. In both groups, no significant difference was observed in uterine contractions, cervical dilatation, and decent of the fetal head.

Chuttani et al. reported no significant difference in foetal heart rate and median APGAR scores at 1 and 5 minutes among both groups. They also noted no foetal adverse event in the groups throughout the study.[13] When comparing the onset of analgesia in the bupivacaine group (15.3 min) was earlier than the ropivacaine group (19.66), the total duration of labor in the bupivacaine group (213 min) was less than the ropivacaine group (234.2 min). The time between the top-up was also less in the bupivacaine group (55.5) than in the ropivacaine group (59.6). The total dose requirement was also less in the bupivacaine group (26 mg) than in the ropivacaine group(45mg). VAS scores at the highest level of sensory block and maternal satisfaction in both groups show the analgesic efficacy of local anaesthetics and the quality of analgesia.

According to Patil et al., the groups who received epidural infusions of either 0.25% bupivacaine with 1 ug/ml fentanyl or 0.25% ropivacaine with 1 ug/ml fentanyl had hemodynamic parameters and VAS scores that were equivalent. They also noticed that the bupivacaine group had a greater sensory block. Although the difference was not statistically significant, there were more patients in the (23.3%) bupivacaine group than in the (6.7%) ropivacaine group with a higher Bromage score.[14] Chuttani et al. observed no significant difference for the duration of all stages of labour, total duration of epidural analgesia, oxytocin consumption, the onset of analgesia, the highest level of sensory block and total local anaesthetic drug consumption among both groups.[13]

Patil et al. observed that the spacing between the motor and sensory blocks was higher with ropivacaine. Its lower lipophilicity and lower propensity to obstruct big myelinated nerve fibers may cause this.[14] Brodner et al. stated a bromage of > 0 in the bupivacaine group, while the group receiving ropivacaine had improved mobility.[15] Jorgensen et al. found that 7% and 15% of patients exhibited motor blockage in the ropivacaine and bupivacaine groups.[16] Similar conclusions were reached by Berti et al. and Paddalwar et al.[17,18]

In our study, the concentration of local anaesthetic that we used provided good maternal satisfaction, hemodynamic stability and low numbers of instrumental deliveries. However, one patient from each group had pruritis managed with one chlorpheniramine maleate dose.

CONCLUSION

We conclude that bupivacaine 0.625% with fentanyl 2 µg/ml and ropivacaine 0.1% with fentanyl 2 µg/ml in epidural labor analgesia produces adequate and equivalent analgesia for labor without producing local anaesthetic toxicity.

Limitations

The present study has some limitations due to confounding factors like maternal fever and neonatal birth weight, which can influence the mode of delivery. Another limitation was the small sample size.

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