Original Research Article

Comparative study of Bupivacaine and Ropivacaine in combination with fentanyl for Epidural anaesthesia in labour- A Randomized Controlled Trial

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Abstract

Introduction: Effective pain relief during labor is essential to reduce maternal and perinatal morbidity arising due to pain-induced maternal sympathetic activation, and to avoid unnecessary caesarean sections performed due to maternal anxiety. Despite the extensive use and relative safety of bupivacaine, newer drugs such as ropivacaine have been developed as alternative agents to decrease the risk for cardiac and central nervous system toxicity. **Objective**: To compare the effects on obstetric and neonatal outcomes between ropivacaine and bupivacaine in combination with fentanyl used in walking epidural analgesia.**Materials and Methods**: One hundred women who demanded epidural analgesia in active labor were randomly allocated into two groups; one group received 20 mL of ropivacaine 0.125% with fentanyl 50 µg and the other received 20 mL of bupivacaine 0.125% with fentanyl 50 µg. The efficacy of analgesia, adverse effects, and obstetric and neonatal outcomes of both groups were compared. SPSS was used for analysis. **Results:** There were no differences between the two study groups in the measured obstetric and neonatal outcomes. The onset time, duration of analgesia, and sensory levels were similar between the groups. Visual analog pain scale scores did not differ between the groups before analgesia or at any of the subsequent evaluation periods. **Conclusion**: Both ropivacaine and bupivacaine provide equivalent labor analgesia with high maternal satisfaction and tolerable adverse effects in the clinically used dose range.

Keywords: ropivacaine, Bupivacaine, epidural, fentanyl, labor, analgesia, obstetrics outcome.

Introduction

Labor pain is stated to be one of the most severe pains that have ever been evaluated[1,2]. 41% of women considered it as the worst experience that they had ever had. Fear of labor pain seems one of the most significant reasons for the tendency to cesarean section.[2] Moreover, pain-induced maternal sympathetic activation in labor negotiations fetal oxygenation. Therefore, effective pain relief during labor is essential to decrease maternal and perinatal morbidity and to avoid unnecessary cesarean sections performed due to maternal anxiety[3]. The ideal drugs to be used for labor analgesia should have a long duration of action with least motor blockade, limited placental transfer, and no noteworthy adverse effects on the mother and fetus[4]. Bupivacaine is the most commonly used drug for this purpose. Contempt the extensive use and relative safety of bupivacaine, newer drugs such as ropivacaine and levobupivacaine have been developed as another agents to decrease the risk for cardiac and central nervous system toxicity. The accumulation of opioids to these local anesthetics such as sufentanil or fentanyl is preferable due to their dose minimizing and adverse-effect-reducing properties[5].The rationale behind the study was to compare the effects on obstetric and neonatal outcomes between ropivacaine and bupivacaine in combination with fentanyl used in walking epidural analgesia.

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Materials and Methods

This was a prospective randomized controlled trial conducted at Great eastern medical school and hospital between Sept. 2020 to Sept. 2021. The study was approved by the Institutional Ethics Committee. Written consent for participation was obtained prior to recruitment into the study.

Inclusion criteria

Women aged 18-35 years, classified as American Society of Anesthesiologists score I and II who requested epidural analgesia in active labor with cervical dilatation 3-4 cm, and uterine contractions ≥3/10 minutes between 37-41 weeks' gestational age with a singleton pregnancy in the vertex position were enrolled in this study.

Exclusion criteria

Women with high risk pregnancies as defined by the obstetrician such as severe preeclampsia, insulin-dependent diabetes mellitus, multiple pregnancies or with any contraindications to epidural techniques such as coagulopathies, spinal deformities, local infections, and any sensitivity to the drug were excluded.

Methodology

The patients were randomized 1:1 to each treatment arm, with stratification based on parity. One hundred participants who met the above mentioned criteria were allocated into two groups. Group R received 20 mL of ropivacaine 0.125% with fentanyl 50 µg, and group B received 20 mL of bupivacaine 0.125% with fentanyl 50 µg. No sedative premedication was given to the participants. After intravenous prehydration with 500 mL 0.09% NaCl solution, a 16-gauge Touhy needle was placed in the patients at the level of L3-4 or L4-5 interspaces via a midline approach under complete aseptic

conditions. The loss of resistance technique was used to identify the epidural space. After monitoring any aspirate of blood or cerebrospinal fluid via the catheter, a 3 mL test dose of the study medication was administered. If there were no signs of an intravascular or intrathecal injection for the following 5 minutes, the remaining dose of the selected medication was administered. The catheter was inserted about 3-4 cm into the epidural space and securely fixed. After the insertion, patients were placed in the supine position with left uterine displacement. Vital parameters of the mother such as heart rate, blood pressure, respiratory rate, and maternal saturation were recorded before and every 15 minutes after the injection.

Onset of analgesia was evaluated as the time after injection until the first painless contraction occurred. The effectiveness of the epidural block was evaluated using a visual analog pain scale (VAS) (VAS: 0 to 10, with 0 being no pain and 10 being the worst imaginable pain). An additional dose of 5 mL of the analgesic solution was injected whenever the parturient had VAS ≥3 during labor. The sensory level was assessed using the pinprick method. Preservation of motor function was determined using the modified Bromage scale in both legs (0: no paralysis, full flexion of knees and feet, 1: inability to raise the extended leg and ability to move knees and feet; 2: inability to move knees but ability to move feet; 3: inability to flex ankle joints, complete motor blockade of lower limbs). Maternal adverse effects during the procedure such as nausea, vomiting, pruritus, bradycardia, trembling, and hypotension were recorded. The duration of the first and second stages of labor, and mode of delivery were recorded. Neonatal welfare was assessed using Apgar scores at 1 and 5 minutes. Maternal satisfaction about labor analgesia was determined after 24 hours on a four-point scale.

Statistical Analysis

Data were analyzed using IBM SPSS 22.0 software (SPSS Inc., IBM, Chicago, Illinois, USA), and descriptive data are expressed as mean ± standard deviations and frequencies. Student's t-test, and chi-square test we used for comparisons. A probability (p) value of <0.05 is considered statistically significant.

Results

Table 1: Demographic details, Maternal and Hemodynamic parameters

	Ropivacaine (n=50)	Bupivacaine (n=50)	p
Age (year)	23.42±3.66	22.48±3.13	0.615
Height (cm)	161.9±4.86	162.86±4.11	0.278
Weight (kg)	64.06±6.96	63.9±5.67	0.505
Parity (n) Primiparae	31	31	-
Multiparae	18	18	
ASA group (n) I	34	40	-
II	16	10	
Maternal heart rate			
Before analgesia	88.3±4.6	90.1±5.9	0.714
Fifteen minutes after injection	81.6±5.9	81.2±6.8	0.645
Thirty minutes after injection	86.1±7.4	84.5±6.2	0.812
Maternal respiratory rate Before analgesia	16.19±0.74	16.21±0.61	0.791
Fifteen minutes after injection	12.24±0.47	12.16±0.34	0.341
Thirty minutes after injection	12.06±0.37	12.22±0.41	0.410
Maternal systolic blood pressure			
Before analgesia	116.76±9.65	117.94±8.37	0.505
Fifteen minutes after injection	104.06±9.53	104.96±9.39	0.605
Thirty minutes after injection	110.50±8.22	112.20±8.64	0.396
Maternal diastolic blood pressure Before analgesia	74.40±6.03	74.28±5.80	0.909
Fifteen minutes after injection	70.24±5.98	70.18±6.07	0.920
Thirty minutes after injection	74.47±6.11	73.36±5.77	0.952
Fetal heart rate			
Before analgesia	143.02±12.59	144.68±10.37	0.454
Fifteen minutes after injection	139.22±15.68	139.62±16.19	0.940
Thirty minutes after injection	139.86±10.32	142.02±9.88	0.268

As per table 1 The enrolled 100 women were assigned to either the ropivacaine group (group R) (n=50) or the bupivacaine group (group B) (n=50). The demographic characteristics were similar between the two groups no significant difference was seen in any parameters. Maternal and fetal hemodynamic data were also comparable (p>0.05).

Table 2: Effectiveness of Analgesia with Pain Assessment through Visual-Analog Scale

	Ropivacaine (n=50)	Bupivacaine (n=50)	p
The onset time of analgesia (minute)	11.18±1.41	11.54±2.21	0.315
The duration of analgesia (minute)	123.56±19.45	130.30±19.65	0.418
Initial pain score before injection	8.30±0.67	8.12±0.62	0.141
Fifteen minutes after injection	0.42±0.92	0.20±0.80	0.219
Thirty minutes after injection	0.06±0.24	0.08±0.34	0.705
One hour after injection	0.04±0.19	0.02±0.14	0.512
Two hours after injection	0.38±0.72	0.30±0.61	0.523
Three hours after injection	4.14±1.06	3.96±0.75	0.303
Need for additional dose (%)	20	22	0.110
Maternal satisfaction of patients for labor analgesia (n)	40	39	

Excellent Good Unsatisfactory Terrible	8 2 -	8 2 1	
Data are given as mean ± standard deviations or percentages			

As per table 2 The onset time, duration of analgesia, and sensory levels were similar between the groups. VAS scores did not differ between the groups before analgesia or at any of the subsequent evaluation periods. Ten parturients in group R and 11 in group B required an additional bolus of 5 mL after 2-3 hours. Maternal satisfaction with labor analgesia was mostly defined as excellent in both groups and no significant difference was observed between the groups. The p-value was not significant.

Table 3: Obstetrics Characteristics and Neonatal Outcomes

	Ropivacaine (n=50)	Bupivacaine (n=50)	p
Gestational weeks	38.42±0.60	39.60±0.90	0.185
Initial cervical dilatation (cm)	4.36±0.49	4.47±0.57	0.071
Initial cervical effacement (%)	58.70±8.31	66.50±9.16	0.202
Duration of first stage (minute)	132.31±60.60	150.93±100.55	0.217
Duration of second stage (minute)	35.20±9.00	38.22±13.10	0.122
Duration of labor (minute)	165.52±63.20	189.16±106.37	0.199
Need for oxytocin augmentation (%)	72	80	0.388
Mode of delivery (%) Normal vaginal delivery Instrumental delivery Cesarean section	 92 0 8	 90 2 8	 0.706 0.304 0.899
Need for episiotomy (%)	56	60	0.685
The number of uterine contractions	4.46±0.86	4.48±0.88	0.919
The duration of uterine contractions (second)	68.40±19.72	66.10±19.25	0.457
Montevideo unit	208.40±56.33	197.60±57.55	0.245
Apgar score At 1 minute At 5 minute	 8.35±0.93 9.50±0.68	 8.10±1.09 9.22±0.72	 0.212 0.061
Abnormal arterial blood gases	2	4	0.557
Required mask ventilation	10	12	0.626
Incidence of respiratory distress	4	2	0.547
Required tracheal intubations	0	0	-
Required NICU admission	4	2	0.557

As per table 3 Obstetric characteristics and outcomes are shown. Four parturients in each group required cesarean section and one parturient required forceps application in group B. No significant difference was found between the groups when assessed for uterine activity. Twenty percent of patients in group B and 28% in group R required local anesthesia for closure of the episiotomy wound. There were no differences between the two study groups in the measured neonatal outcomes but it was not significant.

Discussion

Epidural analgesia has become a widely-used technique for providing pain relief in labor. Nowadays, there is an increase in the number of the epidural drugs. The most recent literature focuses on new enantiomers such as ropivacaine, which have reduced risk of cardiotoxicity compared with bupivacaine[5]. In our comparison of these two agents in the present study, no motor blockade was observed and maternal satisfaction rates were similar with tolerable adverse effects. In addition, no obstetric or neonatal adverse effects were observed. Some previous studies claimed that epidurals prolonged labor, and increased oxytocin requirements and instrumental and operative delivery rates[6,7]. In a meta-analysis, it was suggested that the type of epidural analgesia might influence spontaneous vaginal delivery rates. Analgesia combined with low-dose opioid and local anesthetic has been asserted to result in lower rates of instrumental deliveries[8]. Lv et al[5]. reported in their meta-analysis of 10 impact studies that ropivacaine was associated with less motor blockade but a higher incidence of instrumental delivery. Halpern et al[9]. showed that the rate of motor block was more frequent in the bupivacaine group but the incidence of spontaneous vaginal delivery was similar regardless of whether ropivacaine or bupivacaine were used for labor analgesia. There are conflicting results in the literature in the comparison of these two local anesthetics regarding the mode of delivery. In the current study, the vaginal spontaneous labor rate was high and there was no significant difference between the groups in regard to operative delivery. It is assumed that ropivacaine has a greater selectivity for sensory fibers than motor fibers due to its lower lipophilic capacity compared with bupivacaine. Accordingly, it is less likely to cause motor blockade and neurotoxicity[4,5]. There were no cases of motor blockade in either group in our study. This could be related to the use of very low and titrated concentrations of a local anesthetic through the addition of opioids. It may also account for our high spontaneous vaginal delivery rate. Higher concentrations of local anesthetic may be the reason of increased motor blockade and instrumental delivery rates in previous studies. Lee at al[10]. reported that bupivacaine was associated with prolongation in the first stage of labor. This may result from higher concentrations of initiated analgesia with a 0.25% solution, which triggers motor block, leading to elongation of labor. In contrast, other comparative studies using these local anesthetics in a range of 0.075-0.125% found no differences in the durations of the first or second stages of labor, similar to our results[11,12]. Our findings regarding neonatal outcomes were comparable with the literature[4,11,12]. There were no significant differences in the indicators of neonatal wellbeing between the two groups.

Conclusion

Both ropivacaine and bupivacaine can provide equivalent labor analgesia with high maternal satisfaction and tolerable adverse effects in the clinically used dose range. A combination with opioids is preferable considering their dose lowering effect. Therefore, from a clinical perspective, either drug is a reasonable choice for labor

analgesia and can be used without jeopardizing the safety of the mother and fetus.

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