https://doi.org/ 10.33472/AFJBS.6.5.2024. 2148-2158

African Journal of Biological Sciences

A COMPARITIVE STUDY OF 0.1% ROPIVACAINE WITH FENTANYL VERSUS 0.125% BUPIVACAINE WITH FENTANYL IN EPIDURAL LABOUR ANALGESIA

[1]Dr Telugu Mahesh Kumar, [2]Dr.Raju Deshmi, [3]Dr.Thati Ajith Kumar, [4*]DrJShashidhar Reddy
[1]Associate Professor: Department of Anesthesia, Kakatiya Medical College/Govt Maternity Hospital Hanamkonda
[2]Assistant Professor: Department of Anesthesia: Kakatiya Medical College, Warangal
[3]Assistant Professor: Department of Anesthesia: Kakatiya Medical College/ M.G.M hospital, Warangal
[4*]Assistant Professor: Department of Anesthesia: Kakatiya Medical College, Warangal
***Corresponding author**
Dr J Shashidhar Reddy,
Assistant Professor,
Department of Anesthesia,
Kakatiya Medical College, Warangal

Article History
Volume 6, Issue 5, Apr 2024
Received: 29 Apr 2024
Accepted: 05 may 2024
doi: ***10.33472/AFJBS.6.5.2024. 2148-2158***

ABSTRACT:
Background and objectives: To compare the analgesic efficacy, motor blocking property and the effect on various labour outcomes of ropivacaine with bupivacaine when used in epidural labour analgesia
Methodology: Seventy ASA I&II parturients with singleton pregnancies who presented in active labour with cervical dilatation of 3-5cm were studied in a prospective, randomized control manner. Patients were randomized into Group A (ropivacaine)-35 patients and Group B (bupivacaine) - 35 patients. Epidural analgesia was performed with an 18G Tuohy needle and a 20G epidural catheter was placed in the best interlumbar space between L1 and L4. Various parameters (heart rate, blood pressure, respiratory rate, oxygen saturation, pain score) and complications if any were recorded every 15 minutes in the 1sthour, every 30 minutes in the 2ndhour and every hour later on.
Results:Pain relief as observed by verbal numerical rating scale was as low as 0.02 in both the groups till 2 hours. The mean score went upto 0.42 in Group-A(ropivacaine) and 0.52 in Group- B(bupivacaine). The fluctuations in pain were not clinically or statistically significant between the two study groups. The number of patients who required bolus were 7(20%) in both the groups. Mode of delivery differences were not statistically significant. Duration of first stage of labour was 467 minutes in both the groups. The mean duration of second stage of labour was 33 minutes in Group-A as compared to 31 minutes in Group-B. The third stage of labour was 6 minutes in both the groups. No adverse neonatal outcome(because of the drugs used) in the form of low Apgar scores or admission to NICU were noticed in both the groups. Motor block was observed in 3 patients (8.5%) in Group B(bupivacaine) only. There was no clinically observable motor blockade in Group-A(ropivacaine) and difference was not statistically significant. The incidence of complications was minimal and comparable in both groups.
Conclusion: From this study it can be concluded that ropivacaine is equipotent with bupivacaine, ropivacaine is as efficacious as bupivacaine in the concentrations used in the study.
Keywords: Ropivacaine, Bupivacaine, Epidural Analgesia, Neonatal outcome

INTRODUCTION

The ASA & ACOG have said that "Labor causes severe pain for many women. There is no othercircumstance where it is considered acceptable for an individual to experience untreated severe pain, amenable to safe intervention, while under a physician's care. In the absence of a medical contraindication, maternal request is a sufficient medical indication for pain relief during labor. Pain management should be provided whenever medically indicated."[1]

Most would agree that the ideal analgesic would be safe for the mother and newborn, would have minimal effects on the progress of labor, and would provide flexibility in changing conditions. Additionally, the ideal technique would provide long- lasting, consistent analgesia titrated to individual. Central neuraxial blocks were introduced in labour in 1950. Pioneering research in this field has lead to great development in the safe and effective practice of neuraxial techniques. Modern neuraxial labour analgesia reflects a shift in obstetrical anesthesia, thinking away from a simple focus on pain relief and towards a focus on the overall quality of analgesia.[2] Central neuraxial analgesia is the most versatile method of labour analgesia and the gold standard technique for pain control in obstetrics that is currently available. The satisfaction of birth experience is greater with neuraxial techniques.Among this epidural blockade comes close to being the ideal analgesic technique in labour.[2]

Epidural injection of a local anaesthetic combined with an opioid provides a more rapid onset of analgesia with little motor blockade. The pain relief starts sooner and also lasts longer than either drug alone. It allows both the drugs to be used in lower concentration, thereby reducing the risk of local anaesthetic systemic toxicity as well as opioid side effects. [3] Bupivacaine and Ropivacaine are widely used to provide efficient epidural analgesia in labour. The value of bupivacaine is limited by the risks of motor blockade(associated with maternal dissatisfaction and increased instrumental deliveries) and cardiac toxicity. Ropivacaine has the advantage of more sensory motor differential blockade as well as decreased risk of systemic toxicity. There have been conflicting comparisons of ropivacaine and bupivacaine for labour analgesia.Some studies have suggested that ropivacaine produces less motor block than bupivacaine while others found the drugs to be indistinguishable. Dilute solutions of epidural local anesthetics combined with opioids may be used to minimize unwanted motor block. We undertook this study to compare the efficacy of Ropivacaine and Bupivacaine in regards to pain relief, motor block, and labour characteristics.

MATERIALS & METHODS

This was a prospective randomized control trial involving 70 parturient (35 in each group) attending the Department of Obstetrics &Gynecology at Chandrakanthiah Memorial Hospital, Warangal).Institutional ethics committee and scientific committee approval was obtained. All patients admitted to the labour room were counseled regarding labour analgesia. The procedure was explained to the patient. Informed consent was obtained. Detailed history of the patient was collected. Routine investigations like blood grouping and typing, hemoglobin and platelet count were done as per our hospital labour protocol. Patients fulfilling the inclusion criteria and who gave consent were then randomly allocated to one of the study groups on the basis of computerized randomized list.

Inclusion Criteria: Normal singleton pregnancies, age of 18-35 years, ASA status- I & II, Patients in active labour with cervical dilatation – 3-5 cm.

Exclusion Criteria: Contraindications to epidural block 2. Pre-term pregnancy, multiple pregnancies and previous cesarean section.

Emergency kit with working laryngoscope, cuffed endotracheal tubes of appropriate size, airway, suction apparatus with suction catheter, Inj.Adrenaline, Inj.Atropine, Inj.Thiopentone, Inj.Succinyl choline,Boyle's Apparatus with Oxygen cylinders. Monitor for continuous monitoring for Non-invasive blood pressure, ECG, Respiratory rate, Oxygen saturation.

Methodology:

An 18G IV cannula was inserted and patient was started on an infusion Ringer lactate solution. The patient was then positioned in Lt. lateral position or sitting position based on the anaesthetist convenience and her back aligned with the edge of the bed. Under strict aseptic precautions, the skin over the lower thoracic and lumbar region was cleaned and area draped. The best interlumbar space between L_1 and L_4 was identified and infiltrated with 2% lignocaine.

The skin was pierced with 18G needle in the interlumbar space. The epidural needle was inserted with bevel facing upward and pushed till it pierced the interspinous ligament. The stylet was then removed. A 10ml LOR(Loss Of Resistance) syringe filled with either Air or saline was attached to the hub of the epidural needle. The needle was then slowly advanced with pressure exerted on the air/saline column through the plunger of the LOR syringe. The epidural space was identified with LOR to injection of air or saline. Careful aspiration was done to make sure that the duramater was not punctured. If CSF was aspirated, the needle was withdrawn and reintroduced in a different space. If no CSF was aspirated, the LOR syringe was removed. The depth of the epidural space was noted. A 20G fine epidural catheter was threaded through the needle into the epidural space. The epidural needle was removed. The catheter was positioned so that a length of 5cm of catheter remained in the epidural space. Careful aspiration of the cathter was again done to check for CSF or blood.

Once the cathter was satisfactorily sited, the puncture site was cleaned and an occlusion dressing applied over it. A bacterial filter was attached to the hub of the cathter. A small test dose of local anesthetic (3ml of 2% Lignocaine with Adrenaline) was injected via the catheter to rule out intravascular or intrathecal placement of catheter. If there were no signs of motor block (intrathecal placement) or tachycardia(intravascular placement) after 5 minutes the patient was turned supine. A bolus dose of the test drug was given followed by the infusion. The bolus and infusion protocol of each study group were as follows:

Group	Bolus	Infusion
A	6ml of 0.2% Ropivacaine	6-8ml/hr of 0.1% Ropivacaine with 2µg/ml Fentanyl
B	6ml of 0.25% Bupivacaine	6-8ml/hr of 0.125% Bupivacaine with 2µg/ml fentanyl

Breakthrough pain was managed with 6ml of either 0.2% Ropivacaine or 0.25% Bupivacaine depending on the study group they were involved.

Various maternal parameters were continuously monitored and noted every 15 minutes in the first hour, every 30 minutes in the second hour and every hourly thereafter. Continuous fetal heart monitoring was also done.
Parameters monitored as maternal heart rate, maternal Blood pressure, maternal respiratory rate & oxygen saturation an dpain relief by 11 point verbal numerical rating scale (VNRS) 5. Motor block by Bromage score (0-3)

Clinical outcome studied are pain relief, motor block, duration of labour, mode of delivery - Vaginal - Spontaneous / Assisted Cesarean section and neonatal outcome - APGAR score, NICU admission.

Sample size:

Sample size has been calculated to detect a 40% difference in the occurrence of motor block between the two groups. The optimal sample size required would be 35 in each group (70 in total) with 80% power and 5% level of significance. The incidence of significant motor block (2 or 3 on a 0–3 scale) was assumed to be 30%. (Owen 1998).[4]

Statistical analysis:

All statistical analysis were performed using SPSS(Statistical package for social sciences) version 17 for windows. The profile of the cases were compared with the treatment allocation in order to check if there was any significant imbalance. Descriptive statistics are presented as mean± 1SD. Component bar and line diagrams were drawn as and when required. Chi-square test for association was used to compare categorical variables between treatment allocations.

RESULTS

Table-1: Demographic distribution in present study

	Group-A	**Group-B**	**P-Value**
Age in years	25.37±3.85	25.23±3.623.T	0.874
weight in kgs	68±8.86	64.29±9.03	P=0.087)
Gavida in number of patients			
G1	19	26	p=0.200
G2	15	8	
G3	1	1	
Parity in number of patients			
P 0	21	27	p=0.122
P 1	14	4.4	
ASA			
I	5.7	8.6	(p=0.643
II	94.3	91.4	
Vaginal dilatation in cms	3.37±0.54	3.51±0.74	p=0.206
Level of epidural placement			
L2-L3	22.9	40	
L3-L4	68.6	51.4	p=0.287
L4-L5	8.6	8.6	

All demographic parameters are insignificant on comparision.

70 patients had their hemodynamics monitored continuously starting at baseline(befor epidural), 15min, 30min, 45min, 1, 1.5, 2, 3, 4, 5, 6, 7 hours. The minimum monitoring time was around 3 hrs in both the groups. The following table will show the number of patients monitored over the time period of their labour.

Table-2: Comparison of systolic blood pressure between the two groups during their labour.

Time	Group-A	Group-B	t value	p value
Baseline	115.6±10.5	114.8±11.2	0.308	0.759
15 mins	114.4±8.1	115.4±7.8	-0.538	0.592
30 mins	114.2±6.8	115.1±10.1	-0.442	0.660
45 mins	112.9±8.2	115.4±7.8	-1.314	0.193
1 hr	116.4±7.9	116.5±7.6	-0.092	0.927
1.5 hr	117.2±6.1	117.1±7.8	0.068	0.946
2 hr	114.4±7.8	114.5±6.8	-1.060	0.293
3 hr	114.5±5.5	115.4±10.1	-0.469	0.640
4 hr	114.7±6.3	113.8±7.7	0.538	0.592
5 hr	113.4±7.7	116.3±9.5	-1.009	0.320
6 hr	112±7.8	117.5±7.1	-1.537	0.144
7 hr	110±0.0	103.3±5.7	2.000	0.116

Systolic BP at baseline(befor epidural), 15min, 30min, 45min, 1, 1.5, 2, 3, 4, 5, 6, 7 hours are insignificant .

Table-3: Comparison of diastolic blood pressure between the two groups during their labour.

Time	Group-A	Group-B	t value	p value
Baseline	76.2±7.8	74.2±6.9	1.122	0.266
15 mins	74.7±7.9	75.4±6.1	-0.405	0.087
30 mins	74.4±7.9	74.2±6.9	-0.112	0.911
45 mins	74.6±7.7	71±12.4	1.319	0.192
1 hr	75.8±7.9	72.5±7.8	1.747	0.085
1.5 hr	77.2±6.8	74.5±6.1	1.693	0.095
2 hr	74.4±7.8	72±7.9	1.303	0.197
3 hr	77.6±6.7	75.4±6.5	1.368	0.167
4 hr	75.7±7.6	73.1±7.8	1.363	0.177
5 hr	76.5±5.9	74.2±5.1	1.290	0.205
6 hr	71.4±3.2	73.7±5.1	-1.176	0.257
7 hr	73.3±5.7	73.3±5.7	1.000	0.116

Diastolic BP at baseline(befor epidural), 15min, 30min, 45min, 1, 1.5, 2, 3, 4, 5, 6, 7 hours are insignificant .

Table-4: The following table shows the comparison of respiratory rate between the two groups during their labour

Time	Group-A	Group-B	t value	p value
Baseline	21.9±3.2	20.8±4.0	1.267	0.209
15 mins	17.4±2.4	18.1±1.7	-1.407	0.164
30 mins	17.1±1.9	17.7±1.4	-1.534	0.130
45 mins	17.7±2.3	17.7±1.4	-0.100	0.951
1 hr	16.7±2.4	17.6±1.5	-1.745	0.085
1.5 hr	17.4±5.8	17.6±1.4	-0.198	0.849
2 hr	16.8±2.2	17.5±1.3	-1.612	0.112
3 hr	16.8±2.4	17.7±1.6	-1.794	0.077
4 hr	17.4±2.1	18.1±1.5	-1.48	0.144
5 hr	17.6±2.0	17.7±2.2	-0.180	0.882
6 hr	16.6±2.0	17±2.8	-0.307	0.762
7 hr	15.3±1.1	15.3±1.2	0.000	1.000

There was no statistically significant difference in the hemodynamics of patients among both groups including heart rate, systolic blood pressure, diastolic blood pressure, respiratory rate. The oxygen saturation (SPO_2) among both groups of patients also did not vary significantly.

Table-5: Pain score (verbal numerical rating score).

Time	Group-A	Group-B	t value	p value
Baseline	7.88±0.7	7.65±0.8	1.170	0.246
15 mins	0.31±0.4	0.17±0.3	1.393	0.168
30 mins	0.02±0.1	0.08±0.2	-1.023	0.130
45 mins	0.02±0.1	0.05±0.2	-0.583	0.562
1 hr	0.02±0.1	0.08±0.2	-1.023	0.310
1.5 hr	0.11±0.5	0.05±0.2	-1.358	0.179
2 hr	0.08±0.2	0.02±0.1	1.023	0.310
3 hr	0.20±0.6	0.08±0.3	1.041	0.302
4 hr	0.28±0.8	0.09±0.3	1.235	0.221
5 hr	0.42±0.9	0.52±-.2	-0.289	0.774
6 hr	0.00±0	0.38±1.1	-1.127	0.276
7 hr	0.00±0	0.00±0	0.000	1.000

There was a noticeable decrease in the pain levels immediately after bolus. The pain levels did not go above VNRS (verbal numerical rating scale) of 3 during infusion in both the groups. Most of the increase in pain scores occurred during the second stage of labour. But the pain score variation did not have any statistical significance.

Table-6: Bolus requirement in both groups in present study

Time in minutes	Group-A	.Group-B	p value
15 mins	Nil	Nil	
30 mins	Nil	Nil	
.45 mins	Nil	Nil	
.1 hr	Nil	Nil	
.1.5 hr	1	Nil	0.314
2 hr	Nil	Nil	
3 hr	1	2	0.55
4 hr	2	Nil	0.151
5 hr	3	3	0.631
.6 hr	1	2	0.396
7 hr	Nil	Nil	

7 women in both women requiring boluses groups required boluses during their labour.The proportion of was comparable in both the groups.

Mode of delivery:

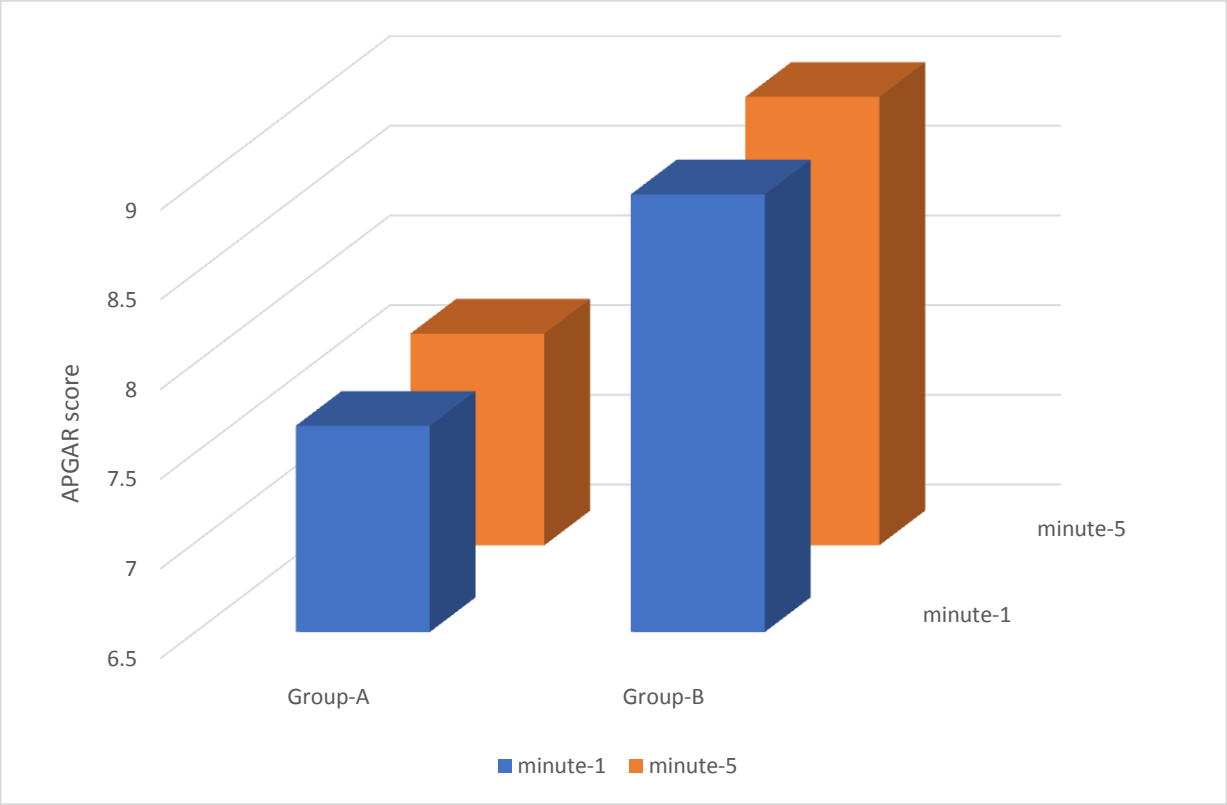
There were more spontaneous vaginal deliveries in Group-A (62.9%) compared to group-B(54.3%). Assisted vaginal deliveries were less in group- A(25.7%) compared to group-B(37.1%). Four patients in group-A(11.4%) and three patients in group-B(8.6%) had cesarean deliveries.

Table-7: Average duration of 1^{st},$2^{nd}$and 3^{rd}stage of laour in minutes. All 3 stages of labour were comparable.

.Duration(in minutes)	Group-A	.Group-B	t value	.p value
.Stage-I .	467.4±95.8	.467.6±87.8	.-0.007	.0.995
Stage-II	33.5±8.5	31.1±8.9	1.116	0.269
.Stage-III	6.8±1.7	6.1±1.2	1.769	.0.082

Table-14

Figure-1: APGAR score at 1 and 5 minute



The neonatal outcome was rated with Apgar acore at 1 & 5 minutes. The average Apgar score during 1stminute assessment was 7.65±0.59 and 7.68±0.47 in group-A and group-B respectively. At 5 minutes, the Apgar score was 8.94±0.23 and 9 in group-A & B respectively. The difference in mean values were not statistically significant at both 1 minute (p-0.460) and 5 minutes(0.221).

Five neonates(14.3%) in group-A and three neonates(8.6%) in group-B were admitted in NICU. The difference was not statistically significant (p- 0.845). The indications for admission in NICU in group-A were cord around the neck, IUGR, respiratory distress and meconium stained liquor. Corresponding indications in group-B were cord around the neck, respiratory distress and meconium stained liquor.

Motor blockade of Bromage score-1 was observed in 3 persons belonging to group-B. This was observed during the 5thhour in all 3 patients. There was no clinically observable motor blockade in Group-A. However this was not statistically significant(p-=0.071). Numbness was seen in 2 patients in group-B and compared to none in group- A. It was seen in 6thand 7thhour. The numbness rate was not statistically significant.
Pruritis: Pruritis was not seen in any patients in both the groups.

DISCUSSION

In our study we have compared bupivacaine with ropivacaine for labor epidural analgesia. Bupivacaine is a proven drug for effective labor analgesia. We decided to compare bupivacaine with ropivacaine, which is marketed as a levo- enantiomer because ropivacaine has a better sensory-motor differentiation and less cardiotoxic potential compared to bupivacaine. We decided to compare 0.1% ropivacaine with fentanyl and 0.125% bupivacaine with fentanyl to see whether ropivacaine offers the same pain relief and if it

offers any significant advantage over bupivacaine at this concentration. The parturients were comparable in regards to age, weight, gravida, parity, vaginal dilatation in both groups.

Pain is a subjective phenomenon and it is difficult to measure.. In our study we used VNRS as the pain scoring system because it was easy to use along with patients' understanding and compliance being better. In our study we found that the mean pain level was 7.8±0.7 in ropivacaine group and 7.6±0.8 in bupivacaine group. After epidural it came down to 0.31 in ropivacaine and 0.17 in bupivacaine group before epidural. The pain score went upto 0.42 in ropivcaine and 0.52 in bupivacaine group at the end of 5 hours. There was no clinically demonstrable difference in the onset of pain relief. Though our study used a less potent concentration of ropivacaine, there was no statistically significant difference in the pain relief offered.

When Halpern et al [5]did a meta-analysis comparing ropivacaine and bupivacaine he found that 19 out of 23 studies favoured ropivacaine to have minimal motor block and 5 of those studies were statistically significant. In our study, only 2 patients in bupivacaine group had demonstrable Bromage score-I motor block. There was no clinically demonstrable motor block in the ropivacaine group. This difference was not clinically significant. The incidence of motor block in our study was low in ropivacaine and also significantly lower than bupivacaine in many of the comparative studies(Fischer 2000,Meister 2000,Campbell 2000)[6,7,8]This may be because the volume of drug used in our study was low(6 ml bolus and 6-8ml/hr infusion) thereby resulting in a lesser concentration ofdrugs.

The duration of labour is determined by the intensity of uterine contraction, the dilatation of cervix and the descent of the presenting part of fetus. A meta-analysis by Halpern et al[9]concluded that epidural analgesia prolonged 1st stage of labour by 42 minutes. The results of our study correlate well with the above mentioned studies

According to ACOG guidelines, second stage of labour is said to be prolonged when the duration was more than 3 hours for primipara and more than 2 hours for multipara with regional anaesthesia. A metanalysis done by Halpern et al[5]on 2400 parturients who received either epidural analgesia or parenteral opioid analgesia found that the second stage of labour was prolonged by 14 minutes. A recent Cochrane review[10]on epidural versus non-epidural or no analgesia in labour found that women who had epidural were more likely to have a longer second stage of labour. In our study there was no difference in the duration of second stage of labour in both groups. The mean duration was 33.5 min in ropivacaine group and 31.1 min in bupivacaine group. This difference was not statistically significant. Our result coincides well with the meta-analysis done by Halpern et al [5] which took into account 23 studies comparing ropivacaine and bupivacaine for labour epidural analgesia. They found that neither bupivacaine nor ropivacaine group had any difference in the duration of second stage of labour.

Cambic and Wong [9]in their review on labour analgesia and obstetric outcomes concluded that effective second stage analgesia might be associated with an increased rate of instrumental vaginal delivery. In our study we had an instrumental delivery rate of 25.7% in ropivacaine group and 37.1% in bupivacaine group which was not statistically significant. In majority of cases, maternal failure was the cause of instrumental delivery. Our study results coincide with the study done by Finegold et al[11] , which used a similar concentration of drugs as our study. They had a instrumental vaginal delivery rate of 18% in ropivacaine group and 28% in bupivacaine. In both our studies though the instrumental delivery rates were less in ropivacaine, the differences were not statistically significant. The meta-analysis of 23 studies

comparing ropivacaine and bupivacaine in 2003 by Halpern et al[5]also did not find any difference in the mode of delivery between the two drugs.However a meta-analysis of 6 studies comparing 0.25% ropivacaine and 0.25% bupivacaine done by Writer et al[12] found that there were fewer instrumental vaginal deliveries in the ropivacaine group. This may be because of the higher concentration of bupivacaine used and difference in the motor blocking potency of ropivacaine.

In our study,we had a cesarean delivery rate of 11.4% in ropivacaine and 8.6% in bupivacaine group. The main reasons for the cesarean delivery among both groups were failure to progress, fetal distress due to cord around the neck and meconium stained liquor. Beilin et al [13]compared ropivacaine with bupivacaine and their effect on outcome of delivery. Bupivacaine group had a cesarean rate of 33% against a 30% rate in ropivacaine group. The meta-analysis by Halpern et al [5]also found no difference in cesarean delivery rates between ropivacaine and bupivacaine when used for labor epidural.

In our study the fetal heart rate during the process of labour analgesia was within normal limits. There was no incidence of post epidural fetal bradycardia. The mean APGAR score was 7.65 & 7.68 in ropivacaine and bupivacaine groups respectively. At 5 minutes it averaged to 8.94 & 9 respectively. There was no significant difference in NICU admission in both groups Beilin and Halpern in [14]did a focused review with various studies that compared bupivacaine and ropivacaine and concluded that there was no evidence that neonatal outcome is adversely affected when ropivacaine or bupivacaine is used for labor analgesia. Writer et al[12]found a difference in the neurologic and adaptive capacity score, favoring ropivacaine, at 24 hours after birth, but not at 2 hours after birth. But recent evidence suggests that the neurologic and adaptive capacity score is unreliable.The incidence of low Apgar scores at 5 minutes is approximately 2% for both drugs.In addition, the umbilical artery and vein pH are well maintained regardless of which local anesthetic is used. Also, the incidence of need for neonatal resuscitation is low and similar with both drugs.The incidence of complications were very minimal in both groups.

CONCLUSION

Obstetric analgesia strives at making childbirth, a pleasurable and painless event. As a means toward this end, we should ideally adopt the best possible technique, something that would provide excellent analgesia with minimal side effects and absolute safety to the mother and child. The observations of this study show that pain relief offered by epidural ropivacaine is as good and effective as epidural bupivacaine. Also the duration of labour, mode of delivery, neonatal outcome and complications are comparable between the two groups. From this study it can be concluded that though ropivacaine is equipotent with bupivacaine, ropivacaine is as efficacaious as bupivacaine in the concentrations used in our study.

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