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A Comparative Study of 0.1% Bupivacaine V/S 0.18% Ropivacaine in Labour Analgesia

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Abstract
This study was done to compare the effects of 0.1% Bupivacaine v/s 0.18% Ropivacaine with by lumbar epidural technique in producing labour analgesia. Hundred primigravida parturients in the age group of 18-26 years belonging to ASA grade 1 and 2, all being primigravidae were randomly selected and divided into 2 groups of 50 each. Group 1 parturients were given 0.1% Bupivacaine, Group -2 parturient were given 0.18% Ropivacaine by lumbar epidural technique. Haemodynamic monitoring of the mother and fetus were done during the procedure. Onset of analgesia 8.18±1.6&10.68±6.95, duration of analgesia 100.68±9.19 & 122.19±14.24, quality of analgesia1.42±1.9&1.34±1.5 and duration of labor 302.9±42.68 & 290.18±47.49 in Bupivacaine and ropivaine groups respectively. Duration of analgesia and total no of doses required were significant. Incidence of instrumental deliveries, incidence of side effects and neonatal outcome were recorded, compared and analyzed statistically. The duration of analgesia with the 1st dose was significantly more in the group-2 also the requirement of top up doses was also less in group -2 and the quality of analgesia is equal in both group-1&group-2. There was no significant increase in the requirement of instrumentation, surgical intervention in both the groups. Neonatal outcome was good and almost equal in both the groups without any respiratory depression.

Keywords: *Labour, Epidural analgesia, Bupivacaine, Ropivacaine, VAS score.*

Introduction

Variety of regional analgesia techniques are available to offer flexibility while relieving pain during labour including intrathecal opioids, epidural local anaesthetics alone epidural local anaesthetics and epidural opiates, caudal technique using local anaesthetics and opioids.

Of all these techniques epidural analgesia using local anaesthetics has gained popularity as a safe and effective technique of pain relief largely replacing other modalities. It is the only pharmacological technique capable of producing complete pain relief with local anaesthetics controlling somatic pain effectively. But it is not without complications, so greater skill, experience and complete facilities for resuscitation make the technique a success.

The primary indication for epidural analgesia is labour pain. It is the only effective technique to

relieve severe labour pain. It offers trial of labour in high risk parturients, previous caesarian section, anticipated difficult intubation and obesity.

Epidural analgesia has been shown to significantly, improve intervillous blood flow in pre-eclampic parturients. Using Doppler techniques showed that in pre-eclamptics parturients epidural blockage decreases significantly the uterine vascular resistance. Maternal indications of epidural analgesia are pre-elcampsia, pulmonary, renal and some cardiac problems. The fetal indications are prematurity and small for date babies, due to their excellent analgesia, increase the maternal oxygen saturation, and allow a more controlled delivery because of relaxed pelvic floor muscles and decreased urge to push.

Epidural analgesia is a popular and effective method for pain relief during labour[1]. Epidural analgesia is attractive to the parturient because she can remain awake, watch delivery, and able to interact almost immediately with her newborn[2].

Bupivacaine, a highly lipophilic long acting local anaesthetic has been the most commonly used anaesthetic agent in its class to date. Unfortunately, like all amide type anaesthetics, Bupivacaine has been associated with high rate of cardiac and local toxicity. An important aspect of this toxicity is that it involves stereospecificity, with the S(-) enantiomer showing significantly less cardiodepressant effects than the R(+) enantiomer.[3] Based on investigations of the etiological mechanism of local anaesthetic induced cardiotoxicity[4], the search for less toxic alternatives to Bupivacaine was concentrated, an amide linked agents comprised of a single enantiomer. As the result of these efforts, the long acting local anaesthetic Ropivacaine was found, which has been recently introduced in India[5]. Ropivacaine is a long acting regional anaesthetic that is structurally related to Bupivacaine. Thus Ropivacaine represents the monohydrate of the hydrochloride salt of 1-propyl-2-6-pipecoloxylidide[6].

Material and Methods

The present clinical study on 'Obstetric analgesia by epidural route' has been carried out at Government Chanda Kanthaiah Memorial Maternity Hospital, Kakatiya Medical College Warangal. The study was undertaken to compare the effectiveness of Bupivacaine v/s Ropivacaine in relieving pain during labor. A total number of 100 parturients studied were divided into two groups randomly. All of them were between age groups of 18-26 years and their deliveries were expected to be normal vaginal deliveries. Group -1 and Group-2 are study groups.

Group-1: Total number of parturients- 50: This Group received Bupivacaine. The initial bolus dose was 0.1% Bupivacaine 10ml and top up doses were 0.1% Bupivacaine [10ml].

Group-2: Total number of parturients -50: This Group received Ropivacaine. The initial bolus dose was 0.18% Ropivacaine 10ml and top up doses were with 0.18% Ropivacaine [10ml].

Parturients were thoroughly assessed such that the parturients having associated diseases like PIH, heart disease and diabetes mellitus were excluded from the study. Hematological parameters including hemoglobin level, clotting time, bleeding time and Biochemical parameters like blood sugar, blood urea, serum creatinine were noted and were within the normal limits. Neonatal evaluation was done in all the cases with APGAR score at 1 min and 5min intervals.

This study has been approved by the hospital ethical committee.

Inclusion criteria

1) Healthy Gravida I patients at term (ASA I / ll)
2) Maternal request for epidural analgesia
3) Well informed literate subjects.
4) Age group 18- 30years
5) Women in active labour with cervical dilatation in primi of *3-5*cms
6) Vertex presentation

Exclusion criteria

1) Patients unwilling for the procedure.
2) Parturients- multigravida.
3) Parturients with multiple pregnancies.

4) Severe anaemia.
5) Cephalo-pelvic disproportion.
6) Breech presentation.
7) Previous LSCS.
8) History of antepartum haemorrhage
9) History of allergy to local anaesthetic
10) History of bleeding disorders
11) Diabetes mellitus
12) History of psychiatric or neurologic disease
13) Pregnancy induced hypertension
14) History of CVS/RS disorder

Procedure

All the parturients were explained the procedure of the technique and written consent was obtained. The patients were thoroughly evaluated and examined. Pulse rate, blood pressure, fetal heart rate were recorded before providing epidural analgesia. An intravenous line was secured with 18G IV cannula and all the parturients were preloaded with 500ml of Ringer lactate. Mid line approach was used in all cases. Either L2-3 or L3-4 interspinous space was selected according to the convenience. After local infiltration with 1% lignocaine, 18G epidural needle was placed exactly in midline perpendicular to the skin with the bevel facing upwards. With the bevel of the needle directed cephalad, the catheter was threaded through the needle while the needle was held steadily. A slight resistance was felt as the catheter enters the epidural space. A further 3-4cm length of catheter was introduced. The needle was withdrawn over the catheter by maintaining pressure on the catheter during withdrawal.

The position of catheter in epidural space was confirmed once again with aspiration test. 3cc of 1.5% lignocaine with epinephrine [15mcg] was administered and observed for the development of any subjective symptoms including sensory and motor blockade in the lower limbs, dizziness, light headedness, palpitations and objective signs of rise in pulse rate and blood pressure to rule out either inadvertent intrathecal or intravascular injection of local anaesthetic.

Group-1:

This group of parturients received Bupivacaine 0.1% during the procedure until the delivery of fetus. The loading dose consisted of 10ml of Bupivacaine0.1%. The top up doses were 10ml of 0.1% Bupivacaine administered whenever the parturients complained of pain. When parturients enters into second stage a further 12-15ml was injected with parturients in sitting position or semi-sitting position.

Group-2:

This group of parturients received Ropivacaine. The loading dose consisted of 10ml of Ropivacaine 0.18%. The top up doses included Ropivacaine 0.1% alone in 10ml solution whenever the parturients complained of pain. When parturients enter into second stage, then an additional dose of 12-15ml was injected with parturients in sitting position or semi-sitting position. The stages and progress of labor was monitored with the help of an obstetrician.

Timing of induction of epidural analgesia**:** Epidural analgesia for child birth is administered in two stages and depending upon the demand of the parturient.

Assessment of Stage –1: Segmental sensory block T10 - L1 is required in relation to stretching of uterine tissues and simultaneously dilatation of cervix and stretching of lower segment.

Assessment of Stage – 2: Segmental sensory T10-S4 is required in relation to stretching of pelvic structures and perineum added to pain of uterine contractions.

Maternal blood pressure, pulse rate, fetal heart rate were monitored every 1-2min for first 10min and then every 5-10min for subsequent 30min and later every half an hour. Time of onset of analgesia, level of sensory blockade and motor blockade, if any was noted. visual analogue pain scale [vaps] assessed pain at different time intervals. The sedation was assessed by Wilson grading and the motor blockade was assessed by Bromage scale. All the newborns in both the groups were assessed for the effect of the drug by determining the APGAR scores immediately after delivery at 1min and 5min.

Statistical analysis

In our study data was expressed as mean + or - standard deviation where appropriate, statistical analysis for parametric data which included age, height, weight, cervical dilatation, onset of analgesia, duration of analgesia, number of top up doses. Probability values < 0.005 were considered as statistically significant.

Results

The study was undertaken to compare the effectiveness of Bupivacaine v/s Ropivacaine in relieving pain during labor. A total number of 100 parturients studied were divided into two groups randomly. All of them were between age groups of 18-26 years and their deliveries were expected to be normal vaginal deliveries. Group -1 and Group-2 are study groups. All parturients were weighing between 55-65kgs

Table 1. Demographic data

Parameter	Group-1 Bupivacaine	Group-2 Ropivacaine
Primigravida	50 (100%)	50 (100%)
Age (years)	23.38 ± 2.47	22.48 ± 2.20
Height (cms)	160.07 ± 4.95	160.18± 4.82
Weight (kgs)	60.48 ± 2.48	60.02 ± 2.02
Cervicaldilatation (cms)	3.06 ± 0.37	3.08 ± 0.39
Oxytocics used	35 (70%)	36 (72%)

Initiation of epidural analgesia

The epidural analgesia was initiated to parturients with cervical dilatation as depicted below:

Table 2: cervical dilatation

	3cm	4cm	5cm
Group-1 Bupivacaine	43 [86%]	5 [10%]	2 [4%]
Group-2 Ropivacaine	42 [84%]	6 [12%]	2 [4%]

The mean values in group 1 was 3.18±0.23 and group II was 3.2±0.23

Epidural analgesia

The onset of analgesia was taken as the time from injection of the drug and the time at which parturient appreciated pain relief (in minutes).The duration of analgesia with the first (loading) dose was taken as a time for complete pain relief to the time when the parturients first complained of pain (in minutes). The duration of labour was calculated from the initiation of epidural analgesia to the time of delivery of fetus in minutes.

Table 3: Epidural analgesia

Parameter	Group 1 Bupivacaine	Group 2 Ropivacaine
On set of analgesia (min)	8.18±1.6	10.68±6.95
Duration of analgesia (min)	100.68±9.19	122.19±14.24
Total no of doses	4.58±0.82	2.82±0.71
Duration of Labour (min)	302.9±42.68	290.18±47.49
Quality of analgesia (VAPS)	1.42±1.9	1.34±1.5

Comparison of APGAR Scores

The neonatal outcome was assessed by APGAR scoring system at 1min and 5min. The comparison statistical data is tabulated as follows:

Table 4: APGAR Scores

APGAR	1 Minute		5 Minutes	
Group	Group-1	Group-2	Group-1	Group-2
Mean	7.36±1.10	7.6±0.9	9.36±1.10	9.6±.98

Unpaired student *t* test results found to be same for both 1min and 5min. this difference is considered to be not statistically significant.

Comparison of mode of delivery

Mode of delivery was recorded as normal spontaneous vaginal deliveries, vaginal deliveries, vaginal deliveries with instrumental intervention and caesarean section are tabulated as follows:

Table 5: Mode of delivery

	Spontaneous Vaginal Deliveries	Instrumental Deliveries	Caesarean Deliveries
Group-1	40 (80%)	8 (16%)	2 (4%)
Group-2	43 (86%)	5 (10%)	2 (4%)

Discussion

Labor pain is a subjective experience with sensory and emotional components. Epidural analgesia using low concentration of local anesthetic and newer opioids, gained wide popularity as safe and effective technique of pain relief during labor. The present clinical study is undertaken to compare Bupivacaine v/s Ropivacaine in relieving the pain and its effect on neonatal outcome.

Bupivacaine provides effective analgesia for laboring parturients; however, adverse effects of potential cardiovascular toxicity and motor nerve blocked impose limitations on usefulness. Unintentional intravenous injection of Bupivacaine

has been reported to result in maternal cardiac arrest and death[7,8,9,10].

Ropivacaine is an amino acid local anaesthetic structurally related to Bupivacaine, but it differs in that ropivacaine is stereoisomer, whereas Bupivacaine is a racemic mixture[11]. Ropi vacaine has similar potency and duration to that of Bupivacaine, but has less cardiotoxicity[12]. In human volunteers, ropivacaine has shown to be less toxic than Bupivacaine when injected intravenously[13]. The use of low dose epidurals may actually reduce the cesarean delivery rate by allowing patients to mobilize during labour and push more effectively during delivery[14].

Fernadez et al[4] Studied two groups of 30 patients to compare analgesic efficacy and extent of motor block for Ropivacaine versus Bupivacaine, when given continuous epidural infusion through an epidural catheterduring labour. It was concluded that both groups were equally effective for controlling pain accompanying labour & Ropivacaines reduced motor block effect at the doses administered might offer an advantage in some situations. Writer et al[5] performed a meta-analysis of six prospective studies that compared Bupivacaine 0.25% to ropivacaine 0.25% and they found fewer instrumental assisted vaginal deliveries in the ropivacaine group. Polley at al[6] found that ropivacaine was significantly less potent than Bupivacaine for epidural analgesia in first stage of labour.

A total number of 100 parturients, all primigravidae belonging to ASA1-2 were selected and randomly divided into 2 groups of 50 each. The parameters observed and statistically analyzed were onset of analgesia, duration of analgesia with loading dose, total number of doses required during the labor, APGAR scores at 1min, 5 min and expression of parturients regarding pain relief. Other parameters like pulse rate, blood pressure, respiratory rate, temperature, SpO2, fetal heart rate, level of sensory block and level of motor block and side effects, if any, are noted. The pain relief was assessed using Visual analogue pain scale (AVPS) consisting of 0-10cm with no pain and worst pain at both ends.

Onset of analgesia is equal in both groups,Group-1who received 0.1% Bupivacaine and Group-2 who received 0.18%ropivacaine; when it was statistically analyzed by students 't' test, not significant. With regard to onset of analgesia, both the groups 1&2 are comparable to other authors [4,5,6].

Duration of analgesia with 1st dose is the advantage with Ropivacaine group, since the mean duration of analgesia with 1st dose in group -2 is more than that seen in the group -1 which is statistically significant. The longer duration in group -2 could be due to Ropivacaine has a greater selectivity for sensory fibers. The duration of analgesia is comparable to authors [11,12,13].

The requirement of top up doses is also significantly less in the group -2 when compared to that in the group-1, which is significant. Decreased number of top up doses of ropivacaine in the group -2 is comparable to other studies[5,6,14]. The total time duration from injection of drug to delivery was in Group -1(272.8 ±42.92], Group-2 [261.2 ± 47.49] in our study. When it was analyzed statistically the p value is >0.5 which is not statistically significant [15].

Quality of analgesia is equal in both groups as assessed by visual analogue scale which is statistically not significant. All this observations correlate well with previous studies[4,5,10,15]

When the mode of delivery in both the groups was compared, the requirement of instrumental intervention and caesarian section were almost similar in both the groups[5,15,16]. The indications for caesarian section in the parturients studied were cord around the neck, cord prolapse, fetal distress.

The neonatal outcome was assessed with APGAR scoring at 1min and 5min. In most of them the APGAR scores at 1min were between 7and 8 in both groups except in one neonate in Group -2 who had fetal distress due to cord around the neck during delivery. But the APGAR scores at 5 min were between 9 and 10 indicating lack of clinically relevant respiratory depression and depressed neurobehavior scores in neonates.

All the results clearly indicate that both Bupivacaine and ropivacaine equally effective in producing excellent analgesia during the period of labour.

Number of top ups required is decrased in ropivacaine group when compared to Bupivacaine group, but quality of analgesia is equal in both groups.

This is very advantageous in promoting obstetric analgesia as there was no significant incidence of neonatal asphyxia as revealed by APGAR scoring.

Conclusion

From this study it may be concluded that using 0.1% Bupivacaine v/s 0.18% Ropivacaine during epidural analgesia for labour provides equal excellent pain relief, prolonged duration of action with simultaneously decreasing the top-ups required with 0.18% Ropivacaine, thereby reducing the total local anaesthetic requirement compared to 0.1% Bupivacaine.

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