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A Prospective Comparative Study of Combined Spinal Epidural with (0.1%) Ropivacaine versus (0.1%) Levobupivacaine with Fentanyl for Labour Analgesia

V.S.S.N. Murthy[1], S.V. Ravi Kanth[2], Anand Acharya[3]

[1,2]Associate Professor, Department of Anaesthesia [3]Professor and Head, Department of Pharmacology, Konaseema Institute of Medical Science, Amalapuram, Andhra Pradesh 533201, India.

Abstract

Background: Various studies have been conducted regarding efficacy of Bupivacaine, Levobupivacaine and Ropivacaine; all these drugs provide adequate analgesia without significant effect on duration of Labour and neonatal outcome. But Levobupivacaine and ropivacaine has been encouraged in low dose that is 0.1%, because of more safety and less motor block. *Material and Method:* Parturients with singleton pregnancy, cephalic presentation and active labour were selected for this study as per exclusion and inclusion criteria, they were randomized by computer generated randomization table into two groups. Each group consists of 30 patients – group I and group II. Group I parturients received 3mg of isobaric Levobupivacaine with 25ug fentanyl intrathecally followed by epidural top ups of 14ml 0.125% isobaric Levobupivacaine and 30ug fentanyl making total volume of 15ml. Group II parturients in this group received 4mg isobaric ropivacaine with 25ug fentanyl intrathecally followed by epidural top-ups of 14ml 0.2% isobaric ropivacaine and 30ug fentanyl making total volume of 15ml. *Result:* Similar both group were statistically comparable to each other with respect to height, weight, ASA scare and cervical dilatation. Regarding block characteristics, the maximal dermatomal level of sensory block achieved in group I was T5 and in group II it was T6 with P value 0.04. Seven parturient in group I and five parturient in group II has developed grade 1 motor blockade. The mean time of onset of analgesia was 4.52 min in group I and 5.95 min in group II with P value 0.00001. The duration of analgesia was longer in group I then group II (107.06±13.06 versus 91.43±9.38) with P value 0.00001. The number of epidural top up requirement was less in group I then group II (1.287±0.192 versus 1.71±0.267) with P value 0.00053. *Discussion and Conclusion*: Onset of analgesia was early in group I then group II.The duration of analgesia was longer in group I then group II, The number of epidural top-up requirement was more in group II. To conclude both drugs found to be effective in respect to onset and duration of analgesia but Levobupivacaine was better than ropivacaine.

Keywords: Ropivacaine; Levobupivacaine; Labour Analgesia.

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Introduction

Labor pain is very intense which involves both psychological and physiological factors. This pain is subjective and having interpersonal variability. The pattern of pain differs from pregnancy to pregnancy [1]. Ether was introduced by James, Y. Simpson in obstetrics analgesia in year 1847, since than the search for perfect agent and perfect method for labour analgesia started [2].

At present concept of labour analgesia is changed and gained popularity. Pain during labour is a result of complex interactions. The progress of

Corresponding Author: S.V. Ravikanth, Associate Professor, Department of Anaesthesia, Konaseema Institute of Medical Science, Amalapuram, Andhra Pradesh 533201, India.
E-mail: anand_kims@yahoo.co.in

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labour is divided in to three stages. In stage I pain is caused by mechanical dilatation of cervix and contraction of uterine muscle. It is mediated by T10 to L1 spinal segments. In stage II pain is due to stretching of the vagina, and perineum. The pain is carried out through T12, to L1 and S2 to S4 spinal segments [1,3].

Labor is only severe pain which is accepted by the patients, but it effects fetomaternal well-being as well. Because of stress of pain various chemical mediators are released like, nor adrenaline, adrenaline, corticotrophins, which has deleterious effect on mother and foetus.Maternal effect ranges from prolongation of labour to compensatory metabolic acidosis. Labour pain promote acidosis in foetus as well [3,4]. The ultimate aim of labour analgesia is to eliminate these responses without affecting maternal safety, progress of labor and fetal well-being.Various pharmacological and non-pharmacological methods are available for pain relief but neuraxial analgesia is considered to be gold standard.

In 1943 Hingson and Edward et al. published an article in JAMA on continuous caudal anaesthesia and they emphasized that they have produced analgesia by continuous bathing the nerve trunk of sacral and lumber plexus with in the peridural space [5]. But combined spinal and epidural analgesia has become more popular now, because of its rapid onset, short duration, increased rate of cervical dilation and good maternal satisfaction. This is proved by the work of R.E. collis et al. They found that low dose combined spinal epidural technique is associated with faster onset, less motor block and greater self control [6].

Bupivacaine is used extensively for combined spinal epidural block but its cardio toxicity, neurotoxicity and high incidence of motor blocks leads to increase interest in newer drugs like Levobupivacaine and ropivacaine.

Various studies have been conducted regarding efficacy of Bupivacaine, Levobupivacaine and Ropivacaine; all these drugs provide adequate analgesia without significant effect on duration of Labour and neonatal outcome. But Levobupivacaine and ropivacaine has been encouraged in low dose that is 0.1%, because of more safety and less motor block [7,8].

The present study has been designed to compare the quality of analgesia with Levobupivacaine versus ropivacaine in combination with fentanyl, in combined spinal epidural analgesia. Primary objective of this labour study is to study the quality of analgesia and the secondary objective is to compare onset, degree and duration of block, maternal and fetal outcome, and side effects,

Maternal and Method

Present study is a randomised double blind trail conducted in the dept.of anaesthesia Konaseema institute of medical science Amalapuram Andhra Pradesh from November 2016 to April 2018.

Study Population

Sixty parturientswith singleton pregnancy, cephalic presentation and active labour were selected for this study as per exclusion and inclusion criteria, they were randomized by computer generated randomization table into two groups. Each group consists of 30 patients – group I and group II.

Group I parturients received 3mg of isobaric Levobupivacaine with 25ug fentanyl intrathecally followed by epidural top ups of 14ml 0.125% isobaric Levobupivacaine and 30ug fentanyl making total volume of 15ml.

Group II parturients in this group received 4mg isobaric ropivacaine with 25ug fentanyl intrathecally followed by epidural top-ups of 14ml 0.2% isobaric ropivacaine and 30ug fentanyl making total volume of15ml.

Inclusion Criteria

-Term gestation, cephalic presentation, Inactive first stage of labour,

-Planned booked case,

-Cervical dilatation>3cm and <5cm

- ASI I and II

- AGE 20 to 35yrs

-Height>150cm

Exclusion Criteria

-Placenta previa,

-Inertia uteri

-CPD

-Diabetes, Asthma, Epilepsy, thyroid disorder

-Spinal abnormality.

Preparation of the parturients

In addition to routine preparation for delivery they were prepared for epidural block also. A detailed general examination was performed and base line HR, BP and respiratory rate was recorded. A detailed pelvic examination, onset of active labour and cervical

dilatation was assessed by attending obstetrician. I.V line was Started with ½ to 1 litre of RL. Equipment for resuscitation of mother and baby was kept ready.

The drug preparation was done by senior resident, as per group allocation and for which investigator is blinded. The parturients were placed in left lateral decubitus position, local infiltration with 1cc of 2% lignocaine in the L3-4/ L4-L5. 18- Gauge Touchy needle was placed in slowly in to the epidural space using the loss of resistance to air technique. Intrathecal injection was given by 25- gauge quincke needle and then epidural catheter was inserted 3-5cm into the epidural space.

Epidural bolus dose was given when the parturient reported two consecutive painful contraction or VAS> 3. The onset of analgesia was taken as time taken for achieving visual analogue scale lessthen 3. The level of sensory block was assessed by loss of sensation to pinprick using 22-guage hypodermic blunt needle. Highest degree of sensory block was noted. The assessment of motor block was done by modified Bromage scale.

0 No motor blockage

1 Unable to lift leg straight

2 Not able to flex knees

3 Not able to flex ankles

Onset and duration of motor block were also reported. Duration of analgesia was taken as time interval form the onset of analgesia till the return of painful contraction or till regression of sensory level to below T12.

Base line maternal pulse rate and blood pressure recorded and again these parameters are recorded after block at every 5 minutes interval in first 20min, then at 30 min, and every 15min thereafter. Fetal heart rate was monitored by cardiotocograph. Hypotension was defined when fall in SBP was 20% to 30% from the base line, bradycardia was defined when pulse rate was, less than 60beats/min and treated appropriately. Progress of labour was observed closely after instituting block. If there is requirement of instrumental delivery the epidural dose was repeated every 15min before procedure in both groups. If there is evidence of fetal distress or failure of progress of labour, caesarean section was performed by the block with 0.5% Levobupivacaine in group I and 0.5% Ropivacaine in group II.

Side effects and complications were recorded. APGAR score at 1 and 5thmin was used to access neonatal well being .patient satisfaction score was recorded as 1= excellent, 2= good and 3= poor.

Ethics

Before start of this study approval was taken from institutional ethics committee. A written informed consent was taken from all the parturients before enrolment in study.

Statistical Analysis

Data was analysed by using SPSS 16.0 the parametric data was analysed by unpaired T-test and nonparametric data was analysed by chi square test. P value <0.05 was considered statistically significant.

Result

As per Table 1 mean age of parturient in group I was 25.66yrs in comparison to 26.733 yrs in group IIwith p- value 0.24 and they are comparable to each other statistically. Similar both group were statistically comparable to each other with respect to height, weight, ASA scare and cervical dilatation.

Regarding block characteristics, the maximal dermatomal level of sensory block achieved in group I was T5 and in group II it was T6 with P value 0.04. Seven parturient in group I and five parturient in group II has developed grade 1 motor blockade. The mean time of onset of analgesia was 4.52 min in group I and 5.95 min in group II with p value 0.00001. The duration of analgesia was longer in group I then group II (107.06+13.06 versus 91.43+9.38) with P value 0.00001. The number of epidural top up requirement was less in group I then group II (1.287+0.192 versus 1.71+0.267) with p value 0.00053. Labour characteristic of both the group were statistically comparable to each other as per Table 2,3.

Table 1: Base line characteristics of the study participants

Parameters	Group-I (mean)	Group –II (mean)	P value
Age (yrs)	25.666±5.77	26.733±6.13	0.249095
Height(m)	154.833±3.688	155.77±3.67	0.169231
Weight(kg)	66.03±8.59	64.84±6.37	0.272802
Baseline VAS	9.46±47	9.66±0.48	0.6804
Cervical (cm) dilatation.	3.88±0.65	3.71±0.59	0.2073

As per Table 4 ,28 parturients in group I and 29 parturients in group II have normal vaginal delivery. One parturient in group I have forceps delivery. One parturient in each group required LSCS. Apgar score were similar or in both group with P value >0.05.

As per Table 5 the basal vital parameters were statistically comparable to each other in both groups, with p value >0.05.

Regarding side effect and patient satisfaction, 23 parturients in group I and 24 parturients in group II have pruritus, 2 parturients in group I and 1 parturient in group II has developed hypotension, 2 parturients in each group has developed urinary retention.

Eighteen patient in group I explained her experience excellent, 12 patients told good, but in

Table 2: Block characteristics

Parameters	Group - I (mean)	Group –II (mean)	P value
Maximum dermatomal sensory level achieved	T_5	T_6	0.04
Motor block (Bromage>0)	7/30	5/30	0.518
Onset of analgesia	4.52±.396	5.95±0.92	0.00001
Duration of analgesia	107.06±13.06	91.43±9.38	0.00001
Number of epidural top ups.	1.287±0.192	1.71±0.267	0.00053

Table 3: Labour characteristics

Variables	Group - I (mean)	Group –II (mean)	P value
Duration of first stage (min)	578.33±50.59	589.9±56.13	0.2065
Duration of second stage (min)	87.33±6.201	85.61±6.50	0.151410
Duration of third stage (min)	6.94±4.201	6.31±2.50	0.0911
Total duration of labour (min)	694.759±64.7	700.655± 64.7	0.3542

Table 4: Fetomaternal outcome

Parameter	Group - I (mean)	Group –II (mean)	P value
Normal vaginal delivery	28	29	-
forceps	1	0	-
LSCS	1	1	-
Apgar 1 min(mean)	7.32±0.24	7.48±0.142	0.2462
Apgar 5 min(mean)	8.84±0.32	8.94±0.42	0.4142

Table 5: Basal vital parameters

Variables	Group - I (mean)	Group –II (mean)	P value
SBP (mm of Hg)	123.92±7.89	126.42±10.05	0.37578
DBP (mm of HG)	78.07±7.19	77.93±4.2	0.689
RR (per min)	24.14±4.27	23.67±3.32	0.17890
HR (per min)	97.54±5.99	98.642±6.02	0.134216
Spo2	98.94±0.243	9901.±0.143	0.9463
FHR (beats min)	128.46±6.72	129.732±4.32	0.4321

Table 6: Complication, side effects patient satisfaction

Parameters	Group - I (mean)	Group –II (mean)	P value
Pruritus	23(76.67)	24(80%)	Chi square state= 2.090 p=0.754001
Hypotension	2/30	1/30	Chi square state=0.3500 p=0.553617
Urinary retentions	2/30	2/30	Chi square state= 0 p=1
Patient			
Excellent	18	14	Chi square statistic 0.971 p value
Good	12	14	0.615375
Poor	0	2	

group II 14 patient told excellent, 14 patient told good but two patient told poor, which was not significant statistically.

Discussion

Neuraxial labour analgesia is gold standard technique for providing labour analgesia. Various effective local anaesthetic agents are used for this and it is becoming more popular.

Levobupivacaine and Ropivacaine are used in low concentration, and have replaced bupivacaine slowly because of its cardio and neurotoxicity. Studies havebeen conducted to examine the role of Levobupivacaine and ropivacaine in labour analgesia. As per the study of casati et al Levobupivacaine is more potent then ropivacaine in nerve block, low concentration of these drugs are effective in pain relief [9]. Similar study was conducted by M.C. Atienzar et al in labour analgesia. He observed thatthese drugs produces adequate epidural analgesia and sensory and motor block are greater with bupivacaine then Levobupivacaine. Greater sensory and motor separation will be advantage when motor block is undesirable [10].

Both the groups were statically comparable to each other in with respect to base line characteristics.

In present study the highest dermatomal sensory level achieved was T5 in group I and T6 in group II which is supported by the work of J.P. Attri et al. [11] but the study of T.N. Chethanananda et al. the maximum dermatomal sensory level achieved was T 6 in both group [12]. The onset of motor block was 7 out of 30 in Levobupivacaine group and 5 out of 30 in ropivacaine which was measured by Bromage scale, this difference was not significant. Low dose of these drugs are having greater motor and sensory separation, this finding is supported by camorica et al. [13]. Onset of analgesia was early in group I then group II. As per priyankachuttani et al duration was early in Levobupivacaine group which support our study but the study of N.L purdie does not corroborate with our finding [14,15]. The duration of analgesia was longer in group I then group II, which is supported by work J.P Attri et al. [11] and Kim et al. [16]. The number of epidural top-up requirement was more in group II which corroborates with the study of N.L. purdie et al. [15]. The basal vital parameters and duration of labour was statically comparable to each other in both groups.

Mode of delivery was not different in both group, cause of one LSCS and one forcep delivery in group I was mainly obstetric in region which is supported by the work of Priyankachuttani et al. [14].

Apgar scare was more than 7 in both group at 1 min and more than 8 at 5 min in both group which corroborates withthe work of N.L. purdie et al. [15]. Parturients satisfaction and risk factor as statistically comparative each other in both group, Levobupivacaine group satisfaction was better than ropivacaine, which is supported by the work of P. Chuttani et al., Purdi et al. and Lee B B et al. [14,15,17].

Regarding difference in the side effect both groups has not reached statisticallysignificant level.Both group of patients developed hypotension having p=0.553617. Complications like pruritus and urinary retention was also not significant (p=0.754 and p=1). This finding is supported by the work of Joginder Pal Atri et al. [11].

Conclusion

From present study we would like to conclude that both drugs found to be effective in respect to onset and duration of analgesia but Levobupivacaine has early onset of analgesia and better sensory and motor separation so it is was better thanropivacaine. Duration of labour was not prolonged and no babies required resuscitation. Complication and side effect of both group are same.

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