Original Research Paper

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COMPARATIVE STUDY OF INTRATHECAL BUPIVACAINE AND LEVOBUPIVACAINE WITH FENTANYL FOR CESAREAN SECTION

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KEYWORDS :

INTRODUCTION:

Spinal anesthesia was first administered by J.Leonard Corning's in Newyork in 1885.The first planned spinal anaesthesia for surgery in man was administered by August Bier on 16 August 1898, in Kiel, where he injected 3ml of 0.5% cocaine into intrathecal space. More than a century has passed and even now, it is one of the most popular technique for both elective and emergency surgical procedures such as caesarean sections, lower abdominal procedures, orthopedic and urological surgeries. Spinal anaesthesia is widely used, providing a fast onset and effective sensory and motor blockade. Bupivacaine is available as a racemic mixture of its enantiomers, levobivacaine and dextrobupivacaine. In recent years, its pure S-enatiomers. Levobupivacaine, ropivacaine, have been introduced into clinical practice because of their lower toxic effects for cardiovascular and central nervous system and hemodynamic effects, in this study intrathecal levobupivacaine and bupivacaine with fentanyl as additive has been evaluated in elective cesarean section.

Aim Of The Study

To compare the effects of intrathecal administration of 8.75 mg of 0.5% Hyperbaric Bupivacaine and 12.5 mcg of fentanyl with 8.75 mg of 0.5 % Hyperbaric Levobupivacaine and 12.5 mcg of fentanyl in cesarean section with respect to the following:1.Efficacy of sensory blockade,2.Efficacy of motor blockade,3.Duration of analgesia,4.Hemodynamic parameters,5.Neonatal outcome in both the groups.

MATERIALS AND METHODS

After obtaining approval from Institutional Ethical Committee, the study was conducted in 60 ASA I and ASA II parturients, who underwent elective caesarean section. This study was prospective, randomised, double blinded study. The study was conducted in Viswabharathi medical college, Kurnool. All the patients were explained about the procedure and written informed consent were obtained. It was observed in various studies that 0.5% Hyperbaric Levobupivacaine with fentanyl given intrathecally in elective caesarean section had less intense motor blockade and better hemodynamic stability with less hypotension, bradycardia, nausea and vomiting than with the 0.5 %hyperbaric Bupivacaine with fentanyl. 60 parturients were randomly allotted with the help of sealed envelope technique into 2 groups, Group B and Group L, with 30 parturients in each group. Group B received 0.5% hyperbaric Bupivacaine 8.75 mg with fentanyl, 12.5 mcg making a total volume of 2mL. Group L received 0.5 % Hyperbaric Levobupivacaine 8.75 mg with fentanyl 12.5 mcg making a total volume of 2 ml.

The inclusion criteria 1.parturient of age >20years, 2.height between 150 to 170 cm,3.weight between 50-80 kgs 4.gestational age >37 weeks. **The Exclusion Criteria** 1. Parturient who had contraindication to spinal anaesthesia ,2. allergic to local anaesthetics , 3. emergency LSCS,4. objection to spinal anaesthesia,5. patient with moderate anaemia (Hb < 10gm %), 6. patient with spine deformities.

Pre-operative evaluation was done in all these patients with detailed case history , general examination, systemic examination, assessment of airway and evaluation of the investigations . Day before surgery the parturients were asked to fast for 8 hours. Every patient included in the study were pre-medicated with Inj Ranitidine 50 mg im and Inj, Metaclopramide 10 mg im 1 hour before surgery. In the operating room peripheral Intravenous line was established with 18G and preloaded with infusion of 10ml /kg of Ringer lactate 10 minutes before the procedure. Standard intra operative monitoring consisted of ECG, NIBP, Pulse oximetry (SPO2). At the end of preloading, basal parameters were recorded. Patient in sitting position, skin over the back was prepared with antiseptic solution and draped with sterile towel. Subarachnoid block was performed by using 25G Quinckes needle in the L3-L4 interspace. Correct needle placement was identified by free flow of cerebrospinal fluid and 2 mL of study drug was injected over 10 seconds. Then the patient was turned supine position immediately and the level of sensory blockade achieved was evaluated by bilateral loss of pinprick sensation (20-gauge hypodermic needle). The test was performed every 2 min for first 10 minutes to access maximum sensory blockade and every 10 minutes there after till it regressed to L1.

We checked bilaterally L1,T12,T10,T8,T6,T4,T2 dermatomes by needle protrusion of 2mm through a guard.

Motor Blockade Was Evaluated Using Bromage Score:

0 = no motor blockade 1 = hip blockade (inability to raise extended leg; able to flex knees and feet) 2 = hip and knee blockade (inability to raise extended leg and flex knee; able to move feet) 3 = hip, knee and ankle blockade. The onset of sensory blockade was defined as time interval between intrathecal administration of drug and maximum pinprick score. The onset of motor blockade was defined as time interval between intrathecal administration of drug and a Bromage score of 3 Two segment regression time was defined as time interval between maximum sensory blockade and two segment regression of sensory blockade.

Evaluation Of Duration Of Motor Blockad:

After the intrathecal drug injection the Bromage score was recorded for every minute till achieving a score of BROMAGE 3. Thereafter for every 15 minutes until it recovered to BROMAGE 0. The duration of sensory block was defined as the time interval between intrathecal administration of drug to regression to L 1 sensory blockade level. The duration of motor block was defined as the time interval between intrathecal administration of drug to the point in which the Bromage score was back to zero Time to achieve the maximum sensory blockade, duration of analgesia (request for rescue analgesia), time to attain bromage 0 and APGAR score at 1 minute and 5 minutes were recorded. Intra operative hemodynamic parameters were recorded every 5 minutes for first 30 minutes and then every 10 minutes thereafter till the end of surgery.

Rescue Measures

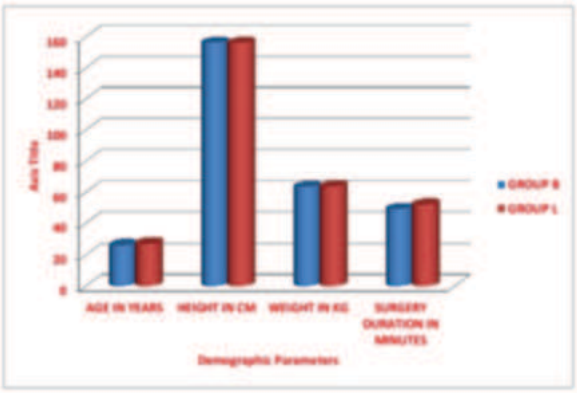
Whenever hypotension occurred (Any fall in MAP >20 % from base line value) Inj Ephidrine 6mg IV bolus was given as rescue dose and repeated if necessary. And in case of bradycardia (fall in heart rate of < 50/min) was treated with inj Atropine 0.6 mg iv bolus. Shivering, was treated with inj tramadol 0.5 mg/kg. Nausea and vomiting was treated with Inj Ondansetron 0.1 mg/kg.

Statistical Analysis:

Socio demographic details, patient profiles and variables used in this study were calculated by descriptive analysis. Categorical data of each group was compared by using Chi-square test Mean value of 2 groups

were compared using student t testData was expressed as mean +/-SD, median (range) or number of parturients (n). p value of < 0.05 was considered statistically significant.

OBSERVATION AND RESULTS

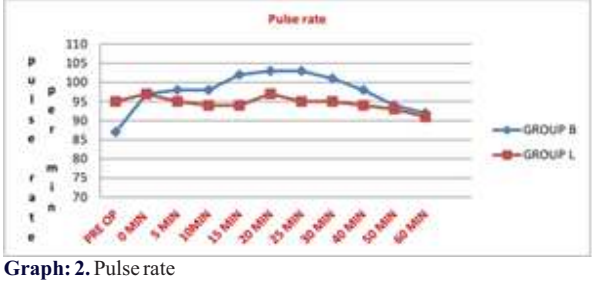


Graph :1 Demographic parameters

Table: 1. Demographic Parameters.

	n	Mean	Standard deviation	p value
AGE				
B Group	30	26.50	4.167	0.567 Not Significant
L Group	30	27.03	2.748	
HEIGHT				
B Group	30	156.73	4.631	0.957 Not significant
L Group	30	156.80	4.930	
WEIGHT				
B Group	30	63.20	7.112	0.781 Not significant
L Group	30	63.67	5.791	
DURATION OF SURGERY				
B Group	30	49.90	5.989	0.065 Not significant
L GROUP	30	52.30	6.717	

From table 1: the following parameters such as age, height, weight and duration of surgery was insignificant.

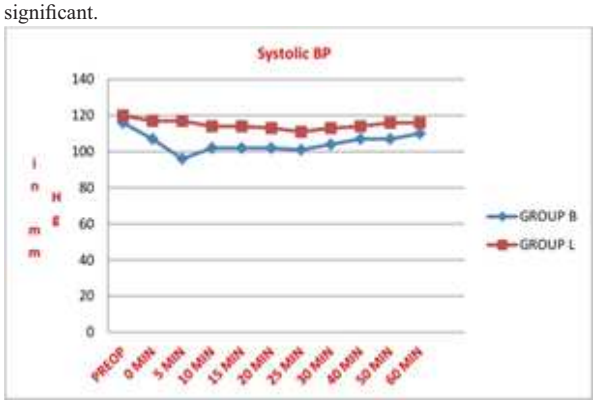


Graph: 2. Pulse rate

Table: 2. Pulse Rate

Pulse Rate	Pre Op	0 min	5 min	10 min	15 min	20 min	25 min	30 min	40 min	50 min	60 min
Group B	86	95	99	98	102	103	100	98	98	94	91
Group L	94	97	95	92	94	96	97	96	95	90	90
P Value	0.000	0.764	0.142	0.108	0.001	0.002	0.000	0.004	0.005	0.007	0.274

Table: 2 showed, significant change in the pulse rate in group B from 15 minutes to 40 minutes when compared to group L. p value is significant.

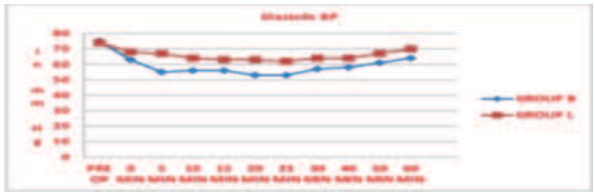


Graph:3- SystolicBP

Table :3 Systolic BP

Systolic Bp	Pre Op	0 min	5 min	10 min	15 min	20 min	25 min	30 min	40 min	50 min	60 min
Group B	116	107	96	102	102	102	101	104	107	107	110
Group L	120	116	116	114	114	112	111	113	114	116	114
P Value	0.037	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000

Table 3 showed that the systolic BP was significant from 0 minutes to 60 minutes

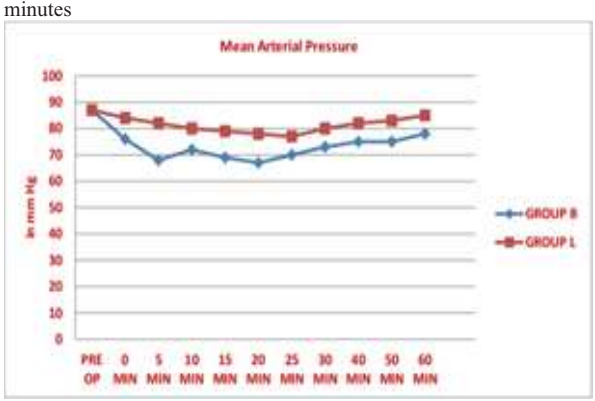


Graph :4. Diastolic BP

Table: 4. Diastolic BP

Diastolic Bp	Pre Op	0 min	5 min	10 min	15 min	20 min	25 min	30 min	40 min	50 min	60 min
Group B	75	63	55	56	57	54	54	57	59	61	65
Group L	74	68	68	65	64	65	62	64	65	68	72
P Value	0.590	0.540	0.000	0.001	0.002	0.000	0.000	0.001	0.001	0.002	0.001

From the table 4: the p value of diastolic BP showed significant difference in between group B and group L from 5 minutes to 60 minutes

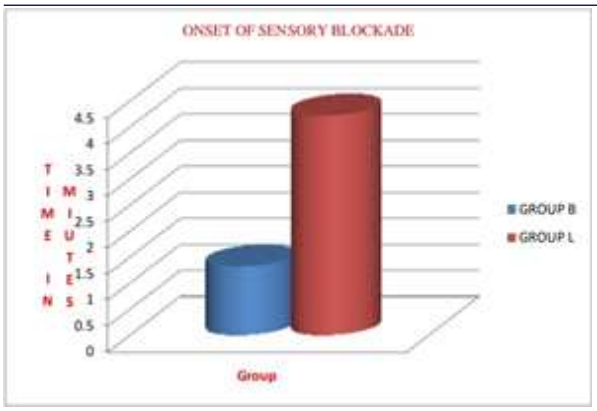


Graph: 5. Mean arterial pressure

Table :5. Mean Arterial Pressure

MAP Bp	Pre Op	0 min	5 min	10 min	15 min	20 min	25 min	30 min	40 min	50 min	60 min
Group B	87	76	68	70	70	68	71	74	76	76	78
Group L	87	84	80	82	79	78	77	80	82	84	86
P Value	0.915	0.030	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000

From above table the p value of MAP was significant from 0 minutes to 60 minutes.

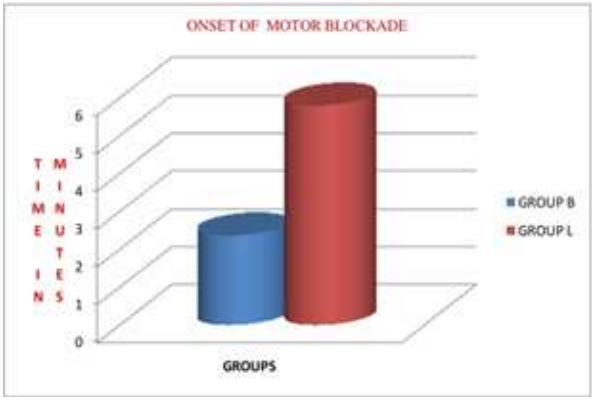


Graph: 6 Onset of sensory blockade

Table :6 Onset Of Sensory Blockade

Group	N	Mean	Standard Deviation	P value
Group B	30	1.32	0.107	0.000 Significant
Group L	30	4.22	0.168	

Table 6 showed that onset of sensory blockade was 1.32 minutes (+ 0.107) in group B and 4.22 minutes (+ 0.168) in group L. p value is significant.

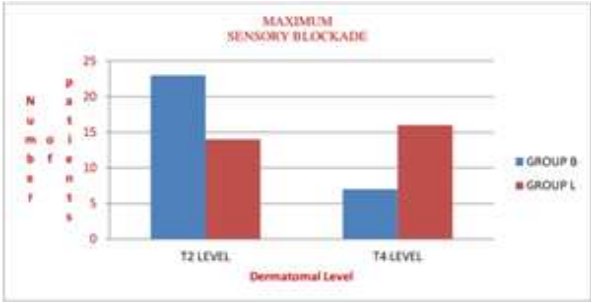


Graph : 7 Onset of Motor blockade

Table: 7 Onset Of Motor Blockade

Group	N	Mean	Standard Deviation	P value
Group B	30	2.36	0.282	0.001 Significant
Group L	30	5.85	0.364	

Table showed that the p value was significant.



Graph: 8 Maximum sensory blockade level

Table: 8 Maximum Sensory Blockade Level

Maximum Sensory Blockade	Group B		Group L		Total		P value
	f	%	f	%	f	%	
T 2	23	76.7	14	46.7	37	61.7	0.017 Significant
T 4	7	23.7	60	53.7	23	38.3	

Since the p value is <0.05 .it is significant

DISCUSSION

Spinal anaesthesia is the most preferred technique in LSCS, because of easy and rapid induction, effective sensory and motor blockade and has no significant effect on the fetus. Addition of opioids fasten the onset of sensory blockade and thereby it prolonged the duration of anaesthesia without any adverse out come in foetus. For cesarean section, adequate sensory and motor blockade and better hemodynamic stability with minimum adverse effect is necessary. Hypotesion and bradycardia are the most common and unavoidable complications of sub arachanoid block and are even more serious in caesarean section because of aorta-caval compression by the gravid uterus.

This study is a prospective, randomized controlled study, conducted to observe the efficacy of sensory blockade, efficacy of motor blockade, duration of analgesia, hemodynamic parameters, neonatal outcome in both the B and L group.

In this study, evaluated the hemodynamic stability of intrathecal administration of 0.5 % Hyperbaric Levobupivacaine 8.75 mg and 12.5 mcg of fentanyl in Group L, which was based on Prabha P et al., we observed the effective sensory blockade and less motor blockade and stable hemodynamics in caesarian section.

Further, in this study we evaluated the hemodynamic stability of intrathecal administration of 8.75 mg of 0.5 % hyperbaric Bupivacaine and fentanyl 12.5 mcg in Group B.

The following parameters are observed 1. Time of onset and duration of sensory block, 2. Onset of motor blockade, 3. Duration of motor blockade 4. Hemodynamic changes, 5. Adverse effects.

All these were observed from the time of injection of the study drugs into the subarachnoid space. Prabha P et al observed that the fall in Mean Arterial Pressure noted in group B was statistically significant, and also noted about 30 % fall in systolic BP in 10 patients.

In this study intraoperatively we noted that in group B, there was a fall in MAP of > 20 % of the basal value. Where as in group L there was no such fall in MAP noted.

In this study we noted that in group B the intra operative heart rate was increased 20 % more from basal heart rate, whereas in group L, stable heart rate was documented intra-operatively. This Shows that intrathecal 0.5 % Hyperbaric levobupivacaine with fentanyl had better hemodynamic stability than 0.5% hyperbaric Bupivacaine with fentanyl in LSCS. Erdil et al. noted in spinal anaesthesia, that low dose Levobupivacaine plus fentanyl had better hemodynamic stability when compared with low dose Bupivacaine with fentanyl. Gulen Guler et al. concluded that time since motor block is shorter, and adverse effects like hypotension , bradycardia and nausea were less in Levobupivacaine (10 mg) with fentanyl (15 mcg) group than that of the Bupivacaine(10 mg) with fentanyl (15 mcg) group in LSCS.

Prabha P et al., observed that, the mean time taken for induction to skin incision was prolonged in group L, and it showed slower onset of action. Maximum sensory blockade level was variable in group B and in group L, it was T4 in all cases. Motor blockade was significantly shorter in group L, as noted by time taken to regress to Bromage 0. The time duration needed for rescue analgesia was more in group L when compared to group B.

All neonates had a APGAR score of more than 7 at 5 minutes. It concluded that both the local anaesthetic and opioids had no adverse effect on neonate. In this study, found that the time taken from intrathecal injection to skin incision in group B were 3 min 34 seconds and in group L it was 5 min 32 seconds and p value is <0.05. This shows that group L had late onset of sensory blockade when compared to group B. The duration of sensory blockade was 175 min in group B and 203 min in group L, and p value was < 0.05. This shows that group L had longer duration of anaesthesia.

And in this study, noted that the time to request for rescue analgesia was 184 min in group B and 208 min in group L . The p value was < 0.05, which is significant.

Turkmen A et al. Observed that time to achieve maximum sensory and motor blockade was shorter in Intrathecal administration of Bupivacaine (7.5 mg) with fentanyl (15mcg) group and longer duration of anaesthesia and shorter duration of motor blockade was achieved in levobupivacaine (7.5 mg) with fentanyl (15 mcg) group.

Idowu et al. found that the addition of 25 mcg of fentanyl to 2.5 ml of 0.5 % hyperbaric Bupivacaine increased the duration of analgesia.

Goel et al., in a study observed that intrathecal fentanyl added to low dose local anaesthetic, produced a synergic effect without increasing sympathetic blockade or delaying discharge from hospital.

In this study, noted that the mean APGAR score in 5 minutes were about 9 in both group B and L and it showed that study drug had no adverse effect in neonate.

Lirk et al., found in his study that intrathecal bupivacaine, ropivacaine, and levobupivacaine used for LSCS had no adverse effect as evaluated by APGAR and the pH of arteries in umbilical cord. Bremerich DH et al., studied variable doses of Levobupivacaine (7.5 mg/ 10 mg / 12.5 mg) without any additives. They recommended 10 mg of Levobupivacaine for parturients who underwent elective caesarean section with spinal anaesthesia.. They also observed that Levobupivacaine showed significantly shorter and less dense motor blockade when compared to Bupivacaine in subaracnoid block in elective caesarean section. In this study we noted that, both the drugs 0.5 % Hyperbaric Bupivacaine and 0.5 % Hyperbaric Levobupivacaine with fentanyl 12.5 mcg achieved satisfactory sensory and motor blockade. The time to attain maximum sensory blockade and to the regression of sensory level to below L1 was longer in group L than group B. We also noted that the duration and density of motor blockade was shorter in group L making early ambulation possible.

The incidence of adverse effects such as hypotension, nausea,vomiting were lesser in group L compared to group B.

Complications:
No respiratory depression occurred in any of these patients

Fetal Outcome:
Low dose opiods do not have adverse effects on fetus and neonates.

SUMMARY

We conducted a double blinded randomized control study in 60 parturients belonging to ASA I and II posted for elective caesarean section at Viswabharathi medical college, Kurnool. They were randomly allotted into two groups namely , group L and group B. Parturients in Group B received 0.5 % Hyperbaric Bupivacaine 8.75 mg and fentanyl 12.5 mcg , making a total volume of 2 mL and it was given intrathecally.

Parturients in Group L received 0.5% Hyperbaric Levobupivacaine 8.75 mg and Fentanyl 12.5 mcg, making a total volume of 2 mL and it was given intrathecally.

In this study, observed the efficacy of sensory blockade, efficacy of motor blockade, hemodynamic parameters, APGAR score for neonatal out come and time to request for rescue analgesia.

The collected data was analysed using chi square test and p value of < 0.05 was considered significant.

Group L showed a better hemodynamic stability in terms of pulse rate ,mean arterial pressure (MAP), decreased incidence of adverse effect such as hypotension , nausea and vomiting, prolonged sensory blockade , lesser duration of motor blockade.

Group B showed a significant fall in MAP, and had significant adverse effects, longer duration of motor blockade.

CONCLUSION

From this study we conclude that 8.75 mg of 0.5 % Hyperbaric Levobupiacaine with 12.5 mcg fentanyl when given intrathecally in elective caesarean section had prolonged sensory blockade ,with earlier regression of motor blockade, stable heamodyamic parameters and decreased incidence of adverse effects such as hypotension , nausea and vomiting than 8.75 mg of 0.5 % Hyperbaric Bupivacaine with 12.5 mcg fentanyl. APGAR score at 5 minutes was more than 7 in both the groups and it showed that study drugs had no adverse effect in neonates.

So we conclude that 0.5 % Hyperbaric Levobupivacaine with fentanyl is a better alternative to 0.5 % Hyperbaric Bupivacaine with fenanyl in elective caesarean section.

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