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Original Research Article

Intrathecal Isobaric Levobupivacaine 0.5% As An Alternative For Hyperbaric Bupivacaine 0.5% For Spinal Anesthesia In Elective Lower Segment Caesarian Section - A Randomised Double Blind Study

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ABSTRACT

Background: Isobaric levobupivacaine is being used as an alternative for hyperbaric bupivacaine in many surgical procedures. The pure enantiomer levobupivacaine has less central nervous system and cardiovascular toxicity. The study was undertaken to compare the effects of intrathecally administered 0.5% Hyperbaric Bupivacaine and Isobaric Levobupivacaine 0.5% on sensory and motor block characteristics, and also quality of intraoperative and postoperative analgesia in cesarean section.
Materials and methods: 40 parturients were included in the study according to the inclusion criteria. They were randomly divided into two groups receiving either Levobupivacaine 0.5% 2ml or Hyperbaric Bupivacaine 0.5% 2ml for spinal anaesthesia. Characteristics of sensory and motor block were assessed with pinprick and Bromage scale, respectively. Side effects such as hypotension, bradycardia, nausea, and vomiting were recorded.
Results: Cases receiving Levobupivacaine has shorter duration of sensory and motor block ($p>0.05$).The maximum height attained was lower in levobupivacaine group ($p<0.05$) which was beneficial in preventing rapid fluctuations in the cardiovascular parameters. Statistically significant hypotension was observed in the Hyperbaric Bupivacaine group ($p<0.05$).No significant adverse cardiovascular effects were observed in both the study groups.
Conclusion: Isobaric levobupivacaine 0.5% can be an alternative for hyperbaric bupivacaine 0.5% for elective Lower segment Caesarean sections. The qualities of motor and sensory blockade were comparable. Lower duration of block in the levobupivacaine group can be beneficial for early ambulation in these sorts of cases. Incidence of hypotension was significantly lower in Levobupivacaine group.

Keywords: Levobupivacaine, spinal anesthesia, Caesarean section, isobaric.

INTRODUCTION

Spinal anaesthesia is safe, reliable and inexpensive technique with the advantage of providing surgical anaesthesia and prolonged post operative pain relief by using various adjuvant drugs along with local anesthetic agents. It blunts operative pain and autonomic, somatic and endocrine responses Spinal anaesthesia is therefore commonly employed for caesarean delivery and is safer method than general anaesthesia.

Spinal anaesthesia being simple to perform, economical, with rapid onset of anaesthesia and complete muscle relaxation is the preferred one for caesarean section. Hyperbaric bupivacaine (0.5%), an amide type of local anaesthetic is commonly employed in intrathecal injections for caesarean sections. Large doses of intrathecal bupivacaine were associated with

severe hypotension and delayed recovery of motor block. [1]

Levobupivacaine is a pure S (-) enantiomer of bupivacaine which offers advantages of lower cardiotoxicity and neurotoxicity and shorter motor block duration which can be a good alternative for hyperbaric bupivacaine. [2]

In this study we aim to compare the intrathecal effects of commonly used agent bupivacaine with levobupivacaine which is a pure enantiomer of racemic bupivacaine in caesarean sections. Dose used was 10mg (0.5%) of the agents.

Aims and objectives

1. To study and compare the effects of intrathecally administered 0.5% Hyperbaric Bupivacaine and Isobaric Levobupivacaine 0.5% on sensory and motor block characteristics, and also quality of intraoperative and postoperative analgesia in cesarean section.
2. To study haemodynamic changes in all the groups.
3. To study the side effects if any.

Inclusion criteria

- Patients belonging to ASA class I and II with singleton pregnancy with term gestation posted for cesarean section, who have no contraindication for spinal anaesthesia.

Exclusion criteria

- Patients with co-morbid conditions like diabetes mellitus, asthma, hypertension, cardiac disease, hematological disease etc.
- Patients belonging to ASA class > III.
- Patients with PIH, eclampsia, multiple pregnancy placenta previa.
- Allergy to local anesthetics

Design of the study the data was collected in a pretested proforma meeting the objectives of this study. After obtaining approval from the Institutional Ethical Committee and informed written consent from the patients, 40 ASA class I and II pregnant women were selected. They were randomly being divided into two groups of 20 patients each.

Preoperative assessment was done for each patient in detail. Baseline readings of pulse rate, blood pressure and arterial oxygen saturation were recorded. Resuscitation equipments for the newborn were also kept ready. On reaching the operation theatre, Intravenous (IV) line will be obtained with 18 gauge IV cannula and preloaded with Ringer lactate 10ml/kg over 15 min.

Monitoring was initiated with multiparameter monitor having pulse-oximeter, ECG and NIBP. Base line recording of heart rate, blood pressure and saturation was noted down. All patients received IV premedication with Injection Ranitidine 50 mg + Inj. Metoclopramide 10 mg. Before the commencement of anaesthesia, patients were instructed on the method of sensory and motor assessments.

Sensory level blockade was measured by pin prick at the mid clavicular line on both sides with a blunt 27G needle, every minute until the block reached T6 dermatome. Thereafter, the level was checked every 2 minutes, until the maximal sensory block achieved. The loss of sensation to pinprick at T10 dermatome was taken as the onset of sensory block.

Motor block in the lower limb was graded according to modified Bromage scale, until the return of normal motor functions. 0 - no motor blockade, able to lift leg at the hip.1 - able to flex the knee and ankle but not able to lift the leg at the hip 2 - able to move the foot only 3 - unable to move even the foot (complete blockade).

With patient in right lateral position, midline lumbar puncture was performed at L2-L3 or L3-L4 interspace with 25G Quincke's spinal needle. After confirming free and continuous flow of Cerebrospinal Fluid (CSF), the test drug was injected intrathecally, over 30 seconds. The anaesthesiologist who performed the procedure was blinded to the study drug. Group B received 10 mg of 0.5% hyperbaric Bupivacaine. Group LB -received 10 mg of 0.5% Levobupivacaine.

Immediately after spinal injection, patients were placed supine with 10 cm wedge placed under the right hip. Heart rate, blood pressure, sensory and motor block were recorded every 1-min for the first 15 min, and then every 5 min till the end of surgery. Sensory and motor assessment was performed immediately.

Surgical incision was made when sensory level is at or above T6 dermatome, and motor blockade is adequate. Thereafter, the block was assessed until complete recovery of motor function and sensation at the L1 dermatome.

Side effects such as hypotension, bradycardia, nausea, and vomiting were recorded. Hypotension was defined as a >20% decrease in mean arterial pressure from its baseline value. It was treated with 3-6 mg boluses of mephentermine till return to within 20% of baseline pressure. Bradycardia was defined as a pulse rate of <50 beats/min and was treated with 0.6 mg intravenous atropine

Statistical analysis

The sample size was calculated to be 20 for each group based on the duration of analgesia (mean and standard deviation) in both groups from previous studies. This was obtained after accepting an Alfa error of 5% (95% confidence interval) and beta error of 20%.

SPSS statistical software package (version 17 Illinois, Chicago, USA) was employed for statistical analysis. Independent sample T-Test was employed for comparing variables with normal distribution. Pearson's Chi-square test was used to compare qualitative variables. $P < 0.05$ was considered to be statistically significant and $P < 0.001$ as highly significant. Data were presented as mean or median where appropriate.

RESULTS

A total of 40 parturients were studied in two groups, receiving either bupivacaine (B) or Levobupivacaine (LB).The group were comparable in demographic characters.

Table 1: Patient characteristics of both the study groups

	grp	N	Mean (years)	Std. Deviation	p Value
AGE	B	20	26.55	4.371	0.189 (Not significant)
	LB	20	25.40	3.378	
WT	B	20	53.25	4.667	0.477 (Not significant)
	LB	20	60.35	4.368	
HEIGHT	B	20	161.15	6.385	0.78 (Not significant)
	LB	20	163.90	6.577	

None of the patients required conversion to general anesthesia. No supplement analgesia was needed in the cases. Surgeons were able to complete the procedure with adequate level of analgesia in both the study groups. Adequate levels of sensory and motor block were achieved in both the groups.

No statistically significant difference was noted in the study groups with respect to the onset of block or the duration of sensory or motor block. P value was >0.05

Block characteristics

The patients in Bupivacaine group showed faster onset of sensory loss at T10 dermatome. The time of regression to L1 dermatome was also prolonged in the bupivacaine group. The results were statistically non significant (P>0.05)

Table 2: Onset of block and duration of sensory block

ONSET T10 (seconds)	B	20	139.20	24.109	5.391	p value 0.224 (Not significant)
	LB	20	158.50	29.784	6.660	
TIME TO L1 (seconds)	B	20	168.75	13.365	2.988	0.821 (Not significant)
	LB	20	134.50	13.563	3.033	

Duration of motor block

Levobupivacaine group showed shorter duration of block in comparison to Bupivacaine group. The results were statistically not significant (p>0.05).

Table 3: Duration of motor block in minutes

Duration In Minutes	B	20	184.50	15.035	3.36	P value 0.219 (Not significant)
	LB	20	153.00	11.743	2.626	

Maximum Block Height

The maximum block height obtained in the levobupivacaine group was lower than that obtained in the bupivacaine group (P<0.05). The maximum height obtained in both the groups was up to T4.No cases had block levels more than T4 in any of the study groups.

Table 4: Maximum block height achieved in both the groups

Group	MAX HT				P value
	T4	T5	T6	T7	0.026 (significant)
B	6	7	7	0	
	30.0%	35.0%	35.0%	.0%	
LB	4	1	14	1	
	20.0%	5.0%	70.0%	5.0%	

Majority of cases in the Levobupivacaine group showed maximum height at the T6 level (70%). This showed statistical significance P<0.05.

Higher levels of block were obtained in the Bupivacaine group in comparison to the Levobupivacaine group in the present study.

No incidences of bradycardia were noted in the study groups.

Hypotension was observed in 14 of the 20 cases which received bupivacaine for spinal anesthesia. Hypotension in bupivacaine group was statistically significant (p value less than 0.05) only one case out of 20 in the Levobupivacaine group had hypotension.

Table 5: Incidence of Hypotension in the study groups

Group		HYPOTENSION		P value
		NO	YES	0.037 (significant)
B	Count	14	6	
	% within grp	70.0%	30.0%	
LB	Count	19	1	
	% within grp		5.0%	

Vomiting

Table 6: Incidence of vomiting in the study groups

Group		VOMITING		P value
		NO	YES	0.29 (Not significant)
B	Count	17	3	
	% within grp	85.0%	15.0%	
LB	Count	19	1	
	% within grp	95.0%	5.0%	

Only 3 out of 20 cases in bupivacaine group and 1 out of 20 cases in Levobupivacaine group had vomiting. The results were statistically not significant.

DISCUSSION

The lack of data comparing the effects of intrathecal isobaric Levobupivacaine and Hyperbaric bupivacaine in elective LSCS procedures for spinal anesthesia made us to undertake this study.

In the present study we compared the block characteristics and side effects of the commonly used drug Hyperbaric Bupivacaine 0.5% with the newer pure enantiomer Levobupivacaine which is isobaric 0.5%.

The results of the present study indicate that Levobupivacaine can be used for spinal anesthesia in caesarian section with less incidence of hypotension and with adequate levels of motor and sensory blockade. The duration of block achieved was satisfactory for elective lower segment caesarean section.

None of our cases in the Levobupivacaine group needed supplement analgesia or conversion to general anaesthesia. The intraoperative hemodynamics was stable with no significant hypotension or bradycardia in the Levobupivacaine group. Bupivacaine group showed statistically significant hypotension.

Only very few studies have been done for comparing the block characteristics of Levobupivacaine and Bupivacaine for spinal anesthesia in caesarean section. Many studies done in parturients have utilised opioids as adjuvants for spinal anaesthesia. Other studies utilised Levobupivacaine as an epidural analgesic agent.

We decided the dose of Levobupivacaine as 10 mg as per the study done by Bremerich DH et al. [3,4] In the

study authors concluded that Levobupivacaine 7.5 mg did not provide satisfactory intraoperative analgesia in all parturients. They recommended 10 mg Levobupivacaine for parturients undergoing elective caesarean section with spinal anaesthesia. So we decided upon the dosage as 10 mg of Levobupivacaine.

We compared solutions with two baricity; Levobupivacaine which is isobaric with hyperbaric bupivacaine. Although hyperbaric solutions are being extensively used for spinal anaesthesia, high spinals have been reported frequently.

Isobaric solutions may prove less sensitive to position issues. This is very useful in a short procedure such as cesarean section where the hyperbaric local anesthetic that has not fixed could migrate after early mobilization and cause hypotension or bradycardia.

Gori et al [5] had done studies on the influence on positioning on plain levobupivacaine for spinal anaesthesia in caesarian section. Their study did not find any influence of gravity on the spread of levobupivacaine. All cases in our study group also had similar results. The spread and level of block were also predictable.

In our study the onset of motor block was slower in comparison to the bupivacaine group. The maximum block height attained was also lower in the Levobupivacaine group. The study showed similar result to that made by Duggal R et al [6] where they could obtain a statistically significant difference in the onset of motor block, duration of the block and the maximum height obtained.

Our study though similar could not yield similar result. It may be due to the difference in the sample size we selected.

Bremerich DH et al [3] noted that Levobupuvacaine showed significantly shorter and less pronounced motor blockade when compared to Bupivacaine. Our study also showed similar results to the study, altough we could not get any statistical significance.

The patients in Bupivacaine group showed faster onset of sensory loss at T10 dermatome. The time of regression to L1 dermatome was also prolonged in the bupivacaine group. The results were statistically non significant (P>0.05).

Gulen Guler et al [7] used 10 mg isobaric levobupivacaine with 15 mcg of fentanyl and proposed the combination an alternative for bupivacaine and 15mcg of fentanyl. They found out that the dose provided sufficient sensory block level, shorter motor block, and lesser side effects.

The present study also agrees with their finding although we could not find any statistical significance (p value>0.05).Our study did not use any opioid adjuvants and this may attribute to the lesser duration of motor and sensory block we observed in the present study.

Erkilic et al [8] used low dose 7.5 mg of intrathecal levobupivacaine with fentanyl for caesarean sections and compared with 7.5 mg isobaric bupivacaine .Their observation about the duration of motor block and sensory block was similar to the present study. We infer that the dosage we used (10 mg of isobaric levobupivacaine) produce similar duration of motor block as with 7.5 mg Levobupivacaine and Fentanyl. The results we obtained were statistically not significant p>0.05.

Higher levels of block were obtained in the Bupivacaine group in comparison to the Levobupivacaine group in the present study. Higher blocks can cause significant hypotension and other adverse cardio respiratory problems. [1] The greater mean spread of hyperbaric solutions may be associated with an increased incidence of cardio respiratory side effects. In our study the hyperbaric bupivacaine group had hypotension which was statistical significant (p value<0.05). Similar results were obtained in the studies of Gautier P [9] and Sarvela et al. [10]

The present study did not record any adverse cardiorespiratory incidence in any study subjects of the hyperbaric bupivacaine group.

The present study couldnot find any statistical significance in the time of onset of block, maximum height of block achieved, duration of the motor block and sensory block. Simialr results were obtained in the study Narayanappa AB et al. [11] the lesser duration of motor block can be of benefit in early ambulation of elective lower segment caesarian section cases.

There were no cases of bradycardia recorded in both the study groups. The incidence of side effects like nausea and vomiting were also statistically insignificant in the present study.

CONCLUSION

In the present study we conclude that isobaric levobupivacaine 0.5% can be used as an effective alternative for hyperbaric 0.5% bupivacaine for elective caesarean section. The qualities of sensory and motor block were comparable. The intraoperative hemodynamics were stable the duration of motor block was less which may help in early ambulation. No significant adverse effects were noted. Thus isobaric levobupivacaine 0.5% can be good alternative for hyperbaric bupivacaine 0.5% for elective caesarean sections.

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