Original Research Article

Comparison of intrathecal hyperbaric bupivacaine (0.5%) and isobaric levobupivacaine (0.5%) for elective LSCS

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Abstract

Background: Pregnancy enhances the spread of hyperbaric local anaesthetic solution in the subarachnoid space, resulting in a 25% reduction in the segmental dose requirement in term pregnant women. The effects of pregnancy on local anaesthetic potency may reflect a combined effect of mechanical factors associated with pregnancy such as dilated epidural veins decrease the volume of the epidural and subarachnoid spaces and direct effects of hormones, especially progesterone, on the susceptibility of nerves to conduction blockade by local anaesthetics per set. Aim: To compare 0.5% hyperbaric Bupivacaine 10mg and 0.5% isobaric Levobupivacaine 10mg for elective caesarean sections under spinal anaesthesia, with respect to sensory blockade, motor blockade, recovery parameters, hemodynamic changes and adverse effects. Materials and Methods: Sixty Pregnant women of between the age group of 18-35 posted for elective lower segment caesarean section were selected for the study. The patients were randomly allocated into two groups comprising of 30 patients in each group. Group L (n = 30) receives 10 mg 0.5% (2 ml) levobupivacaine, Group B (n = 30) receives 10 mg 0.5% (2 ml) bupivacaine for spinal anaesthesisa. Results: Patients who received 0.5% Isobaric Levobupivacaine 10mg intrathecally showed a better haemodynamic stability in terms of mean arterial pressure and there was no significant difference in terms of pulse rate between the two groups. Patients in bupivacaine group had a faster onset of sensory block, showed significantly longer duration of sensory analgesia and motor block. Conclusion: 0.5% Isobaric Levobupivacaine 10mg produces adequate sensory and motor blockade and stable haemodynamic parameters with minimum adverse effects than 0.5% hyperbaric bupivacaine 10mg. We concluded that isobaric levobupivacaine is a better alternative for caesarean section

Key words: Bupivacaine, Caesrean, Pregnancy, Levobupivacaine

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INTRODUCTION

Spinal anaesthesia was introduced into clinical practice by Karl August Bier in 1898. More than a century has passed and even today, it is one of the most popular techniques for both elective and emergency surgical

procedures particularly Caesarean Sections, lower abdominal surgeries, orthopaedic and urological surgeries just to name a few. Spinal anaesthesia used for providing a fast onset and effective sensory and motor blockade bupivacaine is available as a racemic mixture (dextrobupivacaine of enantiomers, levobupivacaine). Levobupivacaine is an effective long acting amide local anaesthetic produced as a pure enantiomer. The sensory block is similar to that produced by an equivalent dose of bupivacaine. However, the motor block provided is of slower onset, lesser intensity and of shorter duration. Levobupivcaine is an L enantiomer of bupivacaine. When administered for caesarean section it has been shown to have motor blockade of lesser intensity when compared to bupivacaine. It is considered more potent than ropivacaine due to its greater lipid solubility. The reduced toxic potential of both the above mentioned drugs is strongly supported by animal and volunteer studies, which report higher plasma concentrations before signs of systemic toxicity appear and also a higher success rate of cardiopulmonary resuscitation in cases of cardiac collapse. In our study we will compare the clinical effects of two drugs levobupivacaine and bupivacaine in spinal anaesthesia for elective caesarean section.

AIM OF THE STUDY

To compare the following factors in two groups (0.5% hyperbaric Bupivacaine 10mg) and (0.5% isobaric Levobupivacaine 10mg) for elective caesarean sections under spinal anaesthesia, with respect to:

- 1. **Sensory blockade**: Onset, Time to peak sensory blockade, highest level of sensory block.
- 2. **Motor blockade:** Onset, Time to maximum motor blockade, duration of motor block.
- Recovery parameters: Time to two segment regression, time to complete sensory and motor recovery.
- 4. Haemodynamic changes
- 5. Adverse effects

MATERIALS AND METHODS

After obtaining ethical committee approval from RAJAH MUTHIAH MEDICAL COLLEGE, Sixty Pregnant women of physical status (ASA) I and II between the age group of 18-35 posted for elective lower segment caesarean section at RMMCH were selected for the study. The patients were randomly allocated into two groups comprising of 30 patients in each group.

Inclusion Criteria

- ASA physical status I and II,
- Age between 18-35 years
- At Term, Elective caesarean section
- Valid informed consent
- Pregnant women with the height ranging between 150 170cms
- Pregnant women with the weight ranging between 50 90 kg.

Exclusion Criteria

- Pregnant patients having coexisting systemic disorders like neuromuscular diseases, neuronal degenerative disorder, seizure disorder, bleeding and haematological disorders, Cardiac disorders, Diabetes mellitus or gestational diabetes.
- Pregnant women with hepatic and renal disorders, severe Anaemia
- Eclampsia, placenta previa, Abruptio placenta

- Parturient in active labour, Twin' complicated pregnancy
- Spinal deformities, poliomyelitis short stature <145cm
- Weight less than 50 kgs and more than 90 kgs
- Patient refusal, Contra indications to spinal anaesthesic, Allergy to local Anaesthetic drugs.
- Fetal distress.
- Mentally retarded.

METHODS

Each patient was reassured, explained the procedure and informed consent taken. All patients were confirmed to be physically fit. Minimal fasting period was 6hrs, following application of routine monitors (NIBP, ECG, PULSE OXIMETRY), IV line secured with 18G IV cannula are given aspiration prophylaxis comprising of injection metaclopramide (10mg) and ranitidine (50mg) IV 10 min before surgery and preloaded with RL 10 - 12 ml/kg. Baseline mean arterial BP and pulse rate, Spo2 were noted. Subarachnoid block (SAB) was instituted at L3-L4 or L4-L5 intervertebral space in left, lateral position using 25-G/23-G quincke's needle.

Using a sealed envelope technique, patients were equally and randomly divided into two groups.

Group L (n = 30); 10 mg 0.5% (2 ml) levobupivacaine

Group B (n = 30); 10 mg 0.5% (2 ml) bupivacaine

Patients were turned to a left lateral supine position. Oxygen 6 L/min was administered via a facial mask. Patients were treated with titrated doses of

- Inj: Ephedrine 6mg I.V. if systolic BP <90mm/Hg or <20% baseline.
- Inj: Atropme 0.6mg I.V. if Heart Rate <50/mm After delivery of baby Inj. Oxytocin 15 IU in drip and given.

The sensory level of spinal anaesthesia was assessed by pinprick in axillary line using a 26 G needle, and was recorded at baseline prior to spinal injection, then every 2 minute for the first 15 min after injection, and every five minutes for the next 30 min, 45 min and upto 1 hr.

Blood pressure, heart rate, and the extent of motor block were recorded every 2 min for first 15 min, and 5 min for next 30 min, 45min and upto 1hr.

Once a T4-T6 level has been reached permission to perform operation given. Parameters to be evaluated **Sensory:**

- Time for onset of sensory block by pinprick
- The time taken to reach peak sensory block level
- The time to regression of two dermatomes of the sensory block Sensory score:

Sensory score:

	Response
0	normal sensation
1	analgesia (loss of pin prick sensation)
2	anaesthesia (loss of touch sensation)

Motor

Time of onset of motor block. Time to maximum motor block level. Degree of motor block (as per Bromage scale). Total duration of motor block Motor block was assessed with modified Bromage scale

Grad	Response	Degree of block
е		
0	no motor block	Nil (0%)
1	unable to straight leg raise	Partial (33%)
2	unable to flex knee against	Almost complete
	resistance	(66%)
3	unable to flex ankle	complete

The time to onset of motor block, the time to reach Bromage 3 and the time of complete disappearance were recorded.

SENSORY BLOCK ONSET TIME: Time interval between end of anaesthetic injection and appearance of cutaneous analgesia in dermatomes assessed by the pm prick test T-12, T-10, T-8, T-.6.

DURATION OF MOTOR BLOCK: Administration of anaesthetic and attainment of grade 0 in Bromage motor scale.

TIME FOR TWO SEGMENT REGRESSION: The duration of two segment regression was defined as the time taken for the sensory block to regress from the maximum level of blockade to two segment down.

DURATION OF ANALGESIA: Administration of anaesthetic agent and disappearance of cutaneous level of sensation at each dermatomal level.

POST- OP ANALGESIA DURATION: Administration of anaesthetic drug and time of analgesic requirement in post operative recovery unit. The occurrence of Adverse events including Bradycardia, Hypotension, decrease in oxygen saturation SPO2 <93 %, shivering, Nausea and vomiting were also recorded.

OBSERVATION AND RESULTS

All 60 patients in two groups completed the study without any exclusion. We did an inter group analysis and

the results were as followed. Of the 60 patients 30 belonged to Group B (Hyperbaric Bupivacaine) and other 30 categorized as Group L (Isobaric Levobupivacaine). Data were presented as range, mean, standard deviation. The probability value 'P' of less than 0.05 considered statistically significant. Table 1 shows Age, weight, height of the patient between both the groups were comparable and were not statistically significant (P>0.05). The average duration of surgery in both groups was comparable. The "P" value was 0.563, was not significant. Table 2 shows distribution of pulse rate at various intervals between two groups and p value is statistically insignificant Table 3 shows the distribution of haemodynamic variables at various interval between the two groups and p value is statistically significant Table 4 shows distribution of spo2 at various interval between two groups which is statistically insignificant The table 5shows time of onset of sensory block which was not statistically significant between two groups. In table 6 time to reach maximum sensory block in the two groups were depicted. P value is statistically significant. The time to reach maximum sensory block was faster in Group L (11.96 \pm 1.97) when compared with Group B (13.16 ± 2.57) . Table 7 shows the distribution of time to two segment regression between the two groups. In Group B the time to two segment regression was prolonged (75.13 ± 3.501) when compared with Group L (65.17± 3.29) and it is statistically significant. Table 8 shows the time of onset of motor block between groups, onset of motor block is faster in Group B(2.36 ± 0.61)when compared with Group L(4.1 ± 0.88) P value is statistically significant. In table 9 time to reach maximum motor block in the two groups were depicted. P value is statistically significant. The time to reach maximum motor block was faster in Group B (6.13 ± 0.67) when compared with Group L (11.6 \pm 2.35). In table 10 duration of motor block in the two groups were depicted. P value is statistically significant. The duration of motor block was prolonged in Group B (132.66 ± 7.15) when compared with Group L (99 \pm 9.13). Table 11 shows comparison of adverse effects between two groups. More than one adverse effect was present in one case in each Group.

 Table 1: Comparison of Age (yrs), Weight (kg), Height (cm) Distribution between the two groups

Parameter	Group	Frequency	Mean	Standard	P-Value
				Deviation	't' test
Age	В	30	25.90	9.87	0.419
	L	30	24.36	2.99	
Weight	В	30	71.00	6.41	0.779
	L	30	71.43	5.45	
Height	В	30	159.10	6.445	0.161
	L	30	160.10	6.922	

Table 2: Comparison of PR between two groups at various intervals

PULSE RATE	GROUP	FREQUENCY	MEAN	STANDARD	p VALUE
		-		DEVIATION	't' TEST
BASELINE	В	30	93.33	8.59	.512
	L	30	83.76	7.7	
2 MIN	В	30	86.4	9.82	.475
	L	30	84.73	8.04	
5 MIN	В	30	77.7	11.46	.067
	L	30	83.66	8.74	
10 MIN	В	30	84.33	9.81	.542
	L	30	80.1	5.89	
15 MIN	В	30	89.16	7.68	.088
	L	30	84.66	6.69	
30 MIN	В	30	88.43	8.81	.265
	L	30	83.03	6.68	
45 MIN	В	30	94.93	9.06	.124
	L	3 0	83.76	7.7	
1 HR	В	30	94.93	9.06	.124
	L	3 0	83.76	7.7	

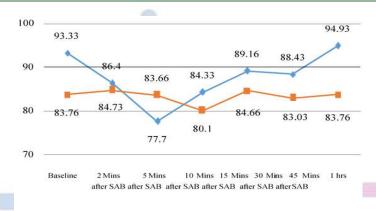


CHART 1: Comparison of Pulse Rate (min) between the two groups

--- Levobupivacaine

---- Bupivacain

Table 3: Comparison of MAP between two groups at various intervals

MAP	GROUP	FREQUENCY	MEAN	STANDARD	p VALUE
		•		DEVIATION	t' TEST
BASELINE	В	30	85.78	5.34	.356
	L	30	87.1	7.24	
2 MIN	В	30	90.06	6.09	.0258
	L	30	88.26	6.11	
5 MIN	В	30	70.56	9	.0001
	L	30	87.53	10.23	
10 MIN	В	30	68.4	6.47	.0001
	L	30	84.1	7.35	
15 MIN	В	30	69.4	5.72	.0001
	L	30	84.53	6.72	
30 MIN	В	30	71.7	6.22	
	L	30	83.46	4.5	.0001
45 MIN	В	30	74.76	4.68	
	L	30	86.66	3.53	.0001
1 HR	В	30	74.76	4.68	.0001
	L	30	86.66	3.53	

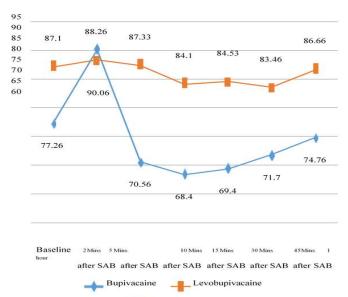


CHART 2: Comparison of Mean Arterial Pressure (mmhg) between the two groups

Table 4: Comparison of Spo2 between two groups at various intervals

PULSE RATE	GROUP	FREQUENCY	MEAN	STANDARD	p VALUE
			1	DEVIATION	't' TEST
BASELINE	В	30	99.03	1.84	.428
	L	30	99.36	1.35	
2 MIN	В	30	100	0	N/A
	L /	30	100	0	
5 MIN	В	30	100	0	N/A
	É	30	100	0	
10 MIN	В	30	99.16	0.94	.425
		30	99.4	1.27	
15 MIN	В	30	99.8	0.48	.577
	L	30	99.86	0.43	
	В	30	99.73	0.44	.177
30 MIN	L	30	99.5	0.82	
45 MIN	В	30	99.83	0.46	.074
	L	3 0	99.53	0.77	
1 HOUR	В	30	99.83	0.46	.074
	L	3 0	99.53	0.77	

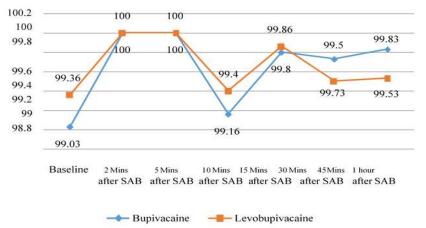


CHART 3: Comparison of SPO2 between the two groups at various intervals

Table 5: Comparison of time of onset of sensory block (min) between the two groups

	Time of onset of sensory block		
Parameter	(in minutes)		
	Group B	Group L	
Range	1-3	1-2	
Mean	1.83	2.03	
SD	0.37	1.73669	
ʻp' value	<0. 082not Significant		

Table 6: Comparison of time to reach maximum sensory level (min) between the two groups

	(in minutes)	
Parameter		
	Group B	Group L
Range	9-20	8-15
Mean	13.46	11.43
SD	1.47	1.75
'p' value	< 0.0001 Significant	

Table 7: Comparison of time to two segment regression (min) between the two groups

	Time to two segment regression		
Parameter	(in minutes)		
	Group B	Group L	
Range	70-80	60-70	
Mean	74.53	65.17	
SD	3.501	3.291	
'p' value	<0. 0001 Significant		

Table 8: Comparison of time of onset of motor block (min) between the two groups

Time of onset of motor level (in minutes)		
Group B	Group L	
2-4	2-6	
2.93	4.51	
0.52	0.87	
<0. 0001 Significant		
	2-4 2.93	

Table 9: Comparison of time to maximum motor block level between two groups

	Time to maximum motor block level		
Parameter	Group B	Group L	
Range	4-10	5-15	
Mean	6.43	11.66	
SD	1.13	2.12	
ʻp' value	< 0.0001 Significant		

Table 10: Comparison of duration of motor block level between two groups

	duration of motor block level			
Parameter	Group B	Group L		
Range	125-155	90-115		
Mean	135.03	101.06		
SD	4.81	9.42		
'p' value	<0.0001 Significant			

Table 11: Comparison of Adverse effects between two groups

Adverse effects	Group B		Group L	
	No	%	No	%
Hypotension	7	23	2	7
Bradycardia	2	7	1	3
Shivering	2	7	2	7
Vomiting	1	3	2	7
Total cases with adverse				
Effects	12*	40	7*	23

Total cases without adverse				
Effects	18*	60	23*	77
Total	30*	100	30*	100

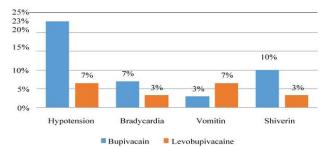


CHART 4: Comparison of Adverse effects between two groups

DISCUSSION

Spinal Anaesthesia, providing an effective surgical anaesthesia and postoperative analgesia by ensuring minimal maternal and neonatal side effects, has been reported to be more advantageous than general anaesthesia for caesarean operations. Bupivacaine is a preferred agent in obstetric anaesthesia due to its long lasting action and lower levels of placental transition; most serious side effect is cardiotoxicity, which makes pregnant women, more sensitive to this effect. Levobupivacaine is a more favorable local anaesthetic agent in terms of safety profile with similar pharmacokinetic properties to racemic bupivacaine. However, trials have reported that the cardiovascular and central nervous system-related side effects levobupivacaine are less than those of bupivacaine, though the onset and duration of action, haemodynamic changes after spinal anaesthesia are the same for levobupivacaine and bupivacaine. We conducted a randomized, double-blind, case-control study to evaluate the haemodynamic stability of intrathecal Isobaric Levobupivacaine 10mg for cesaerean which was based on study by Gulen guler et al.1 2012. He conducted a study to investigate the clinical efficacy of levobupivacaine and bupivacaine for spinal anaesthesia in caesarean section. Group L recieved 10 mg levobupivacaine with fentanyl 15 mcg and Group B received 10mg bupivacaine with fentanyl 15 mcg. They observed in group B motor block was faster and longer, bradycardia, hypotension and nausea less in group L Bremerich DH2 et al. carried out a dose finding investigation of levobupivacaine for parturients undergoing elective caesarean delivery 2007. Parturients received either 7.5, 10 or 12.5 mg intrathecal hyperbaric 0.5% levobupivacaine. They recommended 10 mg levobupivacaine for parturients undergoing elective caesarean section with spinal anaesthesia. "In our study, sensory block levels required for caesarean section were achieved in both groups, and

it was observed that the haemodynamic stability with levobupivacaine was better maintained". Goyal et al.7 conducted a study on 30 parturient for elective caesarean section. They were divided in to Group BF receiving 10 mg bupivacaine and 25 mcg fentanyl, or Group LF receiving 10 mg isobaric levobupivacaine and 25 mcg fentanyl. Haemodynamics like MAP was lower in group BF and in Group LF max sensorial block level and postoperative visual analog scale scores were higher. "Onset of motor block time, time to max motor block, time to T10 sensorial block, reversal of two dermatome, the first analgesic need were similar in both groups" They concluded that isobaric levobupivacaine is good alternative for caesarean section as it provides less motor block and maintains haemodynamics stability. In our study we observed that maximum sensory block level in bupivacaine group was higher and development of motor block was faster and lasted longer. "The results of our study are similar to Gautier et al. 17 reported during spinal anaesthesia for caesarean delivery, they compared the same doses of levobupivacaine and bupivacaine, and reported that while adequate anaesthesia was maintained in the 97% of the patients in the bupivacaine group, this rate was 80% in the levobupivacaine group, and duration of motor block and analgesia was shorter in the levobupivacaine". In a study conducted by bremerich et al. 10 involving 60 patients who were scheduled for caesarean section and were administered 0.5% levobupivacaine (10 mg) and 0.5% bupivacaine (10 mg) in combination with opioid (10 and 20 µg of fentanyl and 5 μg of sufentanil), the duration of motor block was found to be shorter with levobupivacaine compared to bupivacaine. In a study by Copperjans et al. 18 comparing 6.6 mg of bupivacaine supplemented with 3.3 µg of sufentanil, 6.6 mg of levobupivacaine and 10 mg of ropivacaine, they found a better value of systolic blood pressure in the levobupivacaine group. In our study, we used 10mg of 0.5 % Hyperbaric bupivacaine for intrathecal injection. We measured the time of onset and

duration of sensory block, haemodynamic changes, modified bromage scale, duration of motor block and adverse effects all these were measured from the time of injection of subarachnoid block. In our study, we found that both Isobaric Levobupivacaine and Hyperbaric bupivacaine produces equal efficacy of sensory blockade. Isobaric levobupivacaine produces effects with minimal adverse effect which is similar to randomized double blind study conducted by Glaser et al. 10 Mantouvalou et al. 13 performed a study to compare three local anaesthetic agents: racemic bupivacaine and its two isomers: ropivacaine and levobupivacaine, for anaesthetic efficacy and safety in patients undergoing lower abdominal surgery. They found levobupivacaine required less vasoactive drugs with equal efficacy of motor and sensory blockage. In our study hypotension is more prevalent in Hyperbaric bupivacaine than isobaric levobupivacaine. In our study we found that the time to two segment regression is earlier in Isobaric levobupivacaine than hyperbaric bupivacaine which is supported by NK Girgin et al. 11 2012. In our study we found that the potency of two drugs, duration of motor block is higher in Hyperbaric bupivacaine (Range 125-155min,) than Isobaric bupivacaine (Range 90-115min). A study carried out by Camorcia *et al.*³ in 2007 compared the relative potencies of intrathecal ropivacaine, levobupivacaine and bupivacaine for motor block. They concluded that potency for motor block when administered via intrathecal route was low for ropivacaine, intermediate for levobupivacaine and high for bupivacaine, which is in keeping with our findings. Fattorni et al. 15 conducted study on eighty patient who has been posted for major orthopedic surgery. there is no significant characteristic difference in sensory and motor block between the levobupivacaine and bupvacaine .In levobupivacaine group no incidence of severe hypotension and cardiovascular stability was maintained. Glasser et al. 10 compared that in levobupivacaine group causes less incidence of bradycardia and it reduces arterial pressure less compared to bupivacaine. In our study, we found that occurrence of bradycardia is more prevalent in Group B bupivacaine 0.5 % than Group L isobaric levobupivacaine 0.5%. This finding has been supported by Mantouvalou et al. 13 study which compared to both ropivacaine and levobupivacaine, Bupivacaine required more often the use of ephedrine and atropine.

CONCLUSION

Sixty term pregnant women of A S A I and II physical status who presented for elective caesarean section were included in this double blinded study. They were randomly and equally allotted into two groups . Patients

who received 0.5% Isobaric Levobupivacaine 10mg intrathecally showed a better haemodynamic stability in terms of mean arterial pressure and there was no significant difference in terms of pulse rate between the two groups. Patients in bupivacaine group had a faster onset of sensory block, showed significantly longer duration of sensory analgesia and motor block. 0.5% Isobaric Levobupivacaine 10mg for intrathecal injection of caesarean section produces adequate sensory and motor blockade and stable haemodynamic parameters with minimum adverse effects than 0.5% hyperbaric bupivacaine 10mg. We concluded that isobaric levobupivacaine is a better alternative for caesarean section.

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