Original Research Article

A randomized, prospective, comparative study to evaluate the sensory blockade properties of 3ml of 0.5% isobaric levobupivacaine and 3ml of 0.5% isobaric ropivacaine for spinal anaesthesia in patients undergoing elective lower limb orthopaedic surgeries

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Abstract

Background: Regional anaesthesia is the preferred technique for most of the lower abdomen and lower limb surgeries. Bupivacaine has increased incidence of fatal cardiac toxicity after accidental intravascular injection, because of narrow Cardiovascular Collapse/Central Nervous System toxicity (CC/CNS) ratio. Ropivacaine and Levobupivacaine, both being S-enantiomers of Bupivacaine have similar duration of sensory and motor blockade as racemic Bupivacaine but having safe cardio vascular profile. As Levobupivacaine and Ropivacaine have been recently introduced in India, not many studies have been done in India comparing the use of isobaric Levobupivacaine 0.5% and isobaric Ropivacaine 0.5% for spinal anaesthesia. Hence the present study was undertaken to compare sensory blockade properties of these two drugs for intrathecal anaesthesia. **Materials and Methods:** A prospective, randomized, comparative study was undertaken to evaluate the sensory blockade properties of intrathecal 0.5% isobaric Levobupivacaine and 0.5% isobaric Ropivacaine in patients undergoing elective lower limb orthopaedic surgery. **Results:** The onset of sensory block at T10 was faster in Levobupivacaine group compared to Ropivacaine group (6.23± 1.906 mins vs 8.33±2.496 mins, p=0.001). Time to attain maximum sensory blockade was also quicker in the Levobupivacaine group than in Levobupivacaine group(11.93±1.507 min vs 14.60±2.860 min, p=0.003). The duration of sensory blockade in Levobupivacaine group was 250.33±22.203 mins, whereas the duration of sensory block in Ropivacaine was 240.00±10.828 mins. The duration of sensory block was statistically significant between the two groups (p=0.027). **Conclusion:** From the present study we can conclude that 0.5% isobaric Levobupivacaine (15 mg) produced faster onset, prolonged and higher level of sensory blockade compared to 0.5% isobaric Ropivacaine (15 mg) in adult patients undergoing elective lower limb surgeries. Hence Ropivacaine can be a better drug for day care surgeries and Levobupivacaine for prolonged surgeries.

Key Words: Levobupivacaine, Ropivacaine, Sensory block, intrathecal anaesthesia.

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INTRODUCTION

Regional anaesthesia is the preferred technique for most of the lower abdomen and lower limb surgeries. It allows the patient to remain awake, minimizes or completely avoids the problems associated with airway management, it is simple to perform, the onset of anaesthesia is more rapid allowing the surgical incision to be made sooner, avoids poly-pharmacy, and also provides post operative analgesia.[1] For decades Lidocaine had been the local anaesthetic of choice for spinal anaesthesia. Its

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advantages are rapid onset of action and good motor block manifested as good muscle relaxation. Its use however is limited by its short duration of action and its implication in transient neurologic symptoms and cauda equina syndrome following intrathecal injection.[2,3] Bupivacaine is three to four times more potent than Lidocaine[4] and has longer duration of action. Its disadvantages are slow onset of action and decreased motor block. In addition, Bupivacaine has increased incidence of fatal cardiac toxicity after accidental intravascular injection, because of narrow Cardiovascular Collapse/Central Nervous System toxicity (CC/CNS) ratio[5]. Ropivacaine and Levobupivacaine, both being S-enantiomers of Bupivacaine have similar duration of sensory and motor blockade as racemic Bupivacaine but having safe cardio vascular profile.[6] Ropivacaine is shown to be effective for subcutaneous infiltration, epidural, intrathecal and peripheral nerve block, obstetrics and postoperative analgesia.[5] Levobupivacaine (S-1-butyl-2-piperidylformo-2', 6'-xylidide hydrochloride) is the pure S (-) enantiomer of racemic Bupivacaine. Because of its significantly decreased cardiovascular and central nervous system toxicity and its relative potency ratio with racemic Bupivacaine being 0.98:1, Levobupivacaine also seems to be an attractive alternative to Bupivacaine.[6] As Levobupivacaine and Ropivacaine have been recently introduced in India, not many studies have been done in India comparing the use of isobaric Levobupivacaine 0.5% and isobaric Ropivacaine 0.5% for spinal anaesthesia. Hence the present study was undertaken to compare sensory blockade properties of these two drugs for intrathecal anaesthesia.

MATERIALS AND METHODS

A prospective, randomized, comparative study was undertaken from December 2014 to June 2015 to evaluate the sensory blockade properties of intrathecal 0.5% isobaric Levobupivacaine and 0.5% isobaric Ropivacaine in patients undergoing elective lower limb orthopaedic surgery at BGS Global Hospitals, Bengaluru. Sixty patients of ASA class I and II of age group 18 to 65 years posted for elective lower limb surgeries were divided into two groups- group A (n=30) received Levobupivacaine 0.5% and group B (n=30) Ropivacaine 0.5%, using computer generated random number chart. Onset, duration of sensory blocks, time for maximum sensory block were recorded in a proforma. Data were tabulated and analyzed using SPSS 16.0 software. Descriptive statistics such as mean and standard deviation (SD) were used for continuous variables, median and range for non-normally distributed variables and categorical variables were summarized using percentages. Chi-Square Test, Fisher's exact test was used. The study was conducted after scientific and institutional ethical committee approval and after taking informed written consent from all patients.

Inclusion Criteria: Adult subjects of either gender, aged between 18-65years, belonging to ASA Class I and II scheduled for elective lower limb orthopaedic surgeries of duration less than 180 minutes were included in the study.

Exclusion Criteria: Pregnancy, ASA class III and IV, subjects posted for Emergency surgeries, subjects with body mass index more than 29.9kg/$m^{2,}$ subjects shorter than 150 cm and longer than 180 cm were excluded.

Group A: patients received 3ml (15mg) of 0.5% isobaric levobupivacaine.

Group B: patients received 3ml (15mg) of 0. 5% isobaric Ropivacaine.

Preoperative assessment was done for each patient. All patients were premedicated on the night before surgery with Tab. Pantoprazole 40 mg and Tab. Alprazolam 0.5mg. Intravenous line was obtained with 18 gauge cannula. Monitoring was done using multiparameter monitor having pulse oximetry (spo2), ECG and NIBP. Patients were placed in sitting position. Under aseptic precautions lumbar puncture was performed at the level of L3-L4 through a midline approach using 26 G Quincke's spinal needle and study drug was injected after confirmation of needle tip in the subarachnoid space by free flow of CSF. Patients were made to lie down in the supine posture immediately, with the table kept flat horizontally and supplementary oxygen was given. Sensory blockade was tested using pinprick method with a blunt 26G hypodermic needle at 1 min interval for the first 15 mins after the spinal injection and subsequently at 3 mins interval during next 15 mins, then at 5 mins intervals for next 30 mins and then at every 15 mins interval till the end of surgery and thereafter at 30 mins intervals until complete recovery.

RESULTS AND OBSERVATIONS

The mean age in Levobupivacaine 0.5% (group A) is 39.33±15.858 and in Ropivacaine 0.5% (group B) is 35.40±14.357. Group A had 21 male and 9 female patients, group B had 24 male and 6 female patients. Group A mean height was 160.93 ± 5.010 cms, Group B mean height was 161.57 ± 4.446 cms. The mean body weight in group A is 61.63±5.774 kgs and in group B is 61.43±6.579 kgs. The mean body mass index in group A is 23.80±1.659 kg/m^2 and in group B is 23.53±2.130 kg/m^2. The number of patients undergoing various types of lower limb orthopaedic procedures among the groups were Arthroscopic ACL reconstruction group A 7(23.3%) and group B 10(33.3%), Intramedulary nailing group A 14(46.7%)and group B 14(46.7%), Implant removal group A 6(20%)and group B 3(10%), Total hip

replacement group A 1(3.3%) and group B 2(6.7%), Total knee replacement group A 2(6.7%) and group B 1(3.3%). ASA Class I group A had 19(63.3%) and group B had 25(83.3%) patients, ASA Class II group A had 11(36.7%) and group B had 5(16.7%) patients.

Table 1: Duration of surgery (min), Time of onset of Sensory block at T10 (mins), Time taken to attain Maximum Sensory Level (mins), Duration of Sensory Block (mins).

	Study group	Mean	SD	P value
Duration of surgery(min)	A	83.50	12.942	0.920
	B	83.17	12.763	
Time of onset of sensory block at T10 (mins)	A	6.23	1.906	0.001
	B	8.33	2.496	
Time taken to attain maximum level of sensory block(min)	A	11.93	1.507	0.0001
	B	14.60	2.860	
Duration of sensory block(min)	A	250.33	22.203	0.027
	B	240.00	10.828	

The mean duration of surgery in levobupivacaine 0.5% group is 83.50±12.942 mins and in Ropivacaine 0.5% group is 83.17±12.763 mins. There is no statistically significant difference in both the groups in relation to the duration of surgery(p value=0.920). The mean time of onset of sensory blockade at T10 in Levobupivacaine 0.5% group is 6.23±1.906 mins and in Ropivacaine 0.5% group is 8.33±2.496 mins. There is a statistically significant faster onset of sensory block in Levobupivacaine group compared to Ropivacaine group (p=0.001). The mean time taken to attain maximum level of sensory blockade in Levobupivacaine 0.5% group is 11.93±1.507 mins and in Ropivacaine 0.5% group is 14.60±2.860 mins. There is a statistically significant faster onset of sensory block in Levobupivacaine group compared to Ropivacaine group (p=0.0001). The mean duration of sensory blockade in Levobupivacaine 0.5% group is 250.33±22.203 mins and in Ropivacaine 0.5% group is 240.00±10.828 mins. There is a statistically significant duration of sensory block in Levobupivacaine group compared to Ropivacaine group (p=0.027).

Table 2: Maximum level of sensory blockade attained

		Study group A	Study group B	Total number of patients (%)	P value
		Number of patients (%)	Number of patients (%)		
Maximum level of sensory block	T4	14(46.6%)	1(3.3%)	15(25%)	0.001
	T5	5(16.7%)	2(6.7%)	7(11.7%)	
	T6	4(13.3%)	9(30%)	13(21.7%)	
	T7	0(0%)	1(3.3%)	1(1.7%)	
	T8	2(6.7%)	10(33.3%)	12(20%)	
	T9	3(10%)	2(6.7%)	5(8.3%)	
	T10	2(6.7%)	5(16.7%)	7(11.6%)	
Total		**30(100%)**	**30(100%)**	**60(100%)**	

In the Levobupivacaine group 23 patients had maximum sensory block of T6 and above and in the Ropivacaine group 12 patients had maximum sensory block of T6 and above. This is statistically significant (p=0.001). Only 1 patient had T4 as maximum sensory blockade in Ropivacaine group compared to 14 patients in the Levobupivacaine group, which is statistically highly significant (p=0.0001).

Adverse effects: There was no incidence of nausea, vomiting, headache, shivering, SpO_2<93%, hypotension, bradycardia in any patient in both the study groups.

DISCUSSION

A study entitled "A randomized, prospective, comparative study to evaluate the sensory blockade properties of 3ml of 0.5% isobaric levobupivacaine and 3ml of 0.5% isobaric ropivacaine for spinal anaesthesia in patients undergoing elective lower limb orthopaedic surgeries" was undertaken in BGS Global Hospital, Bengaluru from December 2014 to June 2015. It has been found that isobaric local anaesthetics are ideal for surgeries below T10 level block and high volumes are required for surgeries above T10[7]. Hence in our study all the patients selected were for lower limb orthopaedic surgeries requiring a blockade below T10. With respect to age and gender distribution, height and weight of the patients and the nature of surgical procedure were similar in both the groups and there was no statistically significant difference among the groups.

Sensory blockade Onset of sensory blockade: In our study onset of sensory block is defined as time taken from the completion of the injection of the study drug till the

patient does not feel the pin prick at T10 level. Sensory block in the present study was tested using loss of sensation to pin prick as used by Van Kleef *et al*[8]. The choice of this method, instead of others (such as loss of sensation to ice, pain perception, tetanic twitch or chemical irritation with capsaicin), was based on Hocking's study which proved the reliability and easy application of the pin prick method[9]. In the Levobupivacaine group the onset of sensory block was at 6.23±1.906 min whereas in the Ropivacaine group the onset of sensory blockade took 8.33±2.496 min. This difference in the onset time for the two drugs is statistically significant (p=0.001). The values obtained for Levobupivacaine in our study correlate well with that of Sanansilp V *et al*[10] (6.6±4.7 min) and those of Sen H *et al*[11] 7(3-19) min. In these studies the criteria for onset of sensory blockade is loss of pin prick sensation at T10 dermatomal level, similar to our study. However, the minor differences in the mass of drug used (13.5 mg by Sen H *et al*[11] and 12.6 mg by Sanansilp V *et al*[10] from the dose of drug in the present study (15 mg) did not lead to significant difference. The onset time for Levobupivacaine in our study is slightly different from that of Casati *et al*[12] (10±5 min) and that of Mantouvalou *et al*[13] (11±6 min). This difference may be due to the lower dose (8 mg) of Levobupivacaine used by Casati *et al*[12] and the higher dermatomal level (T8) taken for reference by Mantouvalou *et al*[13] Glaser C *et a1*[14] using 3.5 ml of 0.5% Levobupivacaine in their study, reported the onset time as 11±6 min. However they did not define the exact dermatomal level for onset. The values of onset time for sensory in the Ropivacaine group in our study correlates with those obtained by Casati *et al*[12] (10±6 min), and those of Kallio H *et al*[15] (10 min). Though Mantouvalou *et al*[13] used doses similar to our study, they reported its onset time as (12±7 min). This difference may be due to higher dermatomal level (T8) taken by the authors as reference level.

Maximum sensory level: In our study the maximum level of sensory blockade was T4 (n=14) in Levobupivacaine group and T4 (n=1) in Ropivacaine group. Median sensory level of block was T5 in Levobupivacaine group and T8 Ropivacaine group. This is statistically significant (p=0.001). All patients in both the groups had adequate surgical anaesthesia. Guler G *et al*[16] obtained maximum sensory levels of T4 with Levobupivacaine (10 mg) and Fentanyl (15 mcg), similar to our results. However the maximum level of analgesia obtained with Levobupivacaine was T8 with Casati *et al*[12] and Sanansilp V *et al*[10] and T6 with M Del-Rio-Vellosillo *et al*[17] These differences may be due to the smaller dose of Levobupivacaine used by Casati *et al*[12] (8 mg),Sanansilp V *et al*[10] (12.6 mg) and M Del-Rio-Vellosillo *et al*[17] (12.5 mg). In studies conducted by Fettes *et al*[18] and Mantouvalou M *et al*[13] the median level of sensory block with 0.5% Ropivacaine was T8/T9 which is comparable with our results of Ropivacaine 0.5% group (T8). In the studies conducted by Malinovsky *et al*[19] and Kallio *et al*[15] the maximum level of sensory block when 15 mg was the intrathecal dose, was T8 which again compares with our results for Ropivacaine 3 ml (15 mg). Van Kleef *et al*[8] in their study with 0.5% Ropivacaine reported the maximum sensory blockade of T11. The maximum level of sensory block attained in the above study is much lower than the results in our study. This is probably due to the patients selected were taller than the patients in our study. The mean height of the patients selected was 177 cms by Van Kleef *et al*[8] study while the average height of patients in our study in Ropivacaine group is 161.57 cms.

Time for maximum sensory level: Time for maximum sensory level is defined as the time from the completion of the injection of the study drug to the maximum sensory blockade attained. In our study the mean time for achieving maximum sensory level is 11.93±1.507 mins in Levobupivacaine group vs. 14.60±2.860 min in Ropivacaine group. There is a statistically highly significant difference between the groups in the time taken for achieving maximum sensory level (p=0.0001). The values for time to maximum sensory blockade using Levobupivacaine in our study are consistent with those obtained by Guler G *et al*[20] (11.96±1.97 min) and those by Sanansilp V *et al*[21] (13.8±6.8 min). However Glaser C *et al*[14] had obtained the time taken for maximum level of sensory blockade as (8-10 min), this variation may be attributed to the higher mass of drug used (3.5 ml of 0.5% Levobupivacaine) and their specification of maximum sensory level as T8. Mantouvalou M *et al*[13] reported 11±6 min as the time taken to reach maximum sensory level and this variation may be due to their definition of maximum sensory level as T8. Regarding 0.5% Ropivacaine, our results (14.60±2.860 mins) are also comparable with the studies conducted by van Kleef *et al*[8] (15 mins) and Mantouvalou M *et al*[13] (12±7 mins). However, our values for Ropivacaine 0.5% do not correspond with the study conducted by Wahedi *et al*[22] where the time for maximum sensory block with 0.5% Ropivacaine was 24 mins. This is probably because in our study the sensory level was assessed using pin prick method and in Wahedi *et al*[22] study it was using loss of sensation to cold.

Duration of sensory blockade: Duration of sensory blockade is defined as the time taken from completion of the injection of the study drug till the sensory regression to S2. In our study the duration of sensory block was 250.33±22.203 mins in Levobupivacaine group compared

to 240.00±10.828 mins in Ropivacaine group which was statistically significant (p=0.027). The duration of sensory blockade for Levobupivacaine obtained in our study is similar to those of Del-Rio-Vellosillo M *et al*[17] (247 mins) and Glaser C *et al*[14] (228±77 min). However there is a wide variation in the duration of sensory blockade by Levobupivacaine in studies by various investigators. While Fattorini F *et al*[23] reported sensory blockade up to 391±96 mins, Sen H *et al*[11] reported a shorter analgesic duration of 100 (34-180) min. This wide variation in duration of sensory blockade reported with Levobupivacaine may be due to its isobaric nature as suggested by Sanansilp V *et al*[10]. In the study conducted by Mantouvalou *et al*[13] the duration of sensory blockade was 220±30 mins which compares with our study. The duration of sensory blockade for Ropivacaine obtained in our study compares with the study conducted by Van Kleef *et al*[8] (268 mins), Fettes *et al*[18] (270 mins) and Kallio *et al*[15] (210 mins).

Adverse effects: No adverse effects attributable to the intrathecal drugs were noticed in any patient in both the groups. This is similar to the studies of Mantouvalou *et al*[13] and Casati A *et al*[12]

CONCLUSION

From the present study we can conclude that 0.5% isobaric Levobupivacaine (15 mg) produced faster onset, prolonged and higher level of sensory blockade compared to 0.5% isobaric Ropivacaine (15 mg) in adult patients undergoing elective lower limb surgeries. Hence Ropivacaine can be a better drug for day care surgeries and Levobupivacaine for prolonged surgeries.

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