

# A randomized, prospective, comparative study to evaluate the motor 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

Prasanna Kumara V R<sup>1</sup>, Suresh S B<sup>2\*</sup>

<sup>1</sup>Assistant Professor, <sup>2</sup>Associate Professor, Department of Anaesthesiology, Shridevi Institute of Medical Sciences and Research Hospital, NH-4, Bypass Road, Tumkur- 572106.

Email: [hrbs2006@yahoo.co.in](mailto:hrbs2006@yahoo.co.in)

## Abstract

**Background:** Levobupivacaine is S (-) enantiomer of bupivacaine. It is somewhat less cardiotoxic than the racemic bupivacaine. It seems to be an attractive alternative to Bupivacaine. Ropivacaine is a long acting regional anaesthetic that is structurally related to Bupivacaine. It is less lipophilic than Bupivacaine and is less likely to penetrate large myelinated motor fibers. 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 evaluate the motor 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. **Materials and Methods:** Group A (n=30) received Levobupivacaine 0.5% and group B (n=30) Ropivacaine 0.5%. Onset, duration of motor blocks, time for maximum motor block, quality of motor block were recorded. **Results:** Onset of motor blockade (Levobupivacaine group 4.43±0.858 minutes vs 6.70±1.535 minutes in Ropivacaine) and the time for maximum motor block (Levobupivacaine group 9.63±1.129 minutes vs 13.20±1.827 minutes in Ropivacaine) between the two groups were statistically significant p values being (p=0.0001) and (p=0.0001) respectively. Twenty patients in Levobupivacaine group had complete motor blockade compared to eighteen patients in Ropivacaine group, which was statistically not significant. The duration of motor blockade in Levobupivacaine group was 222.00±14.716 minutes, whereas the duration of motor block in Ropivacaine was 138.33±12.617 minutes. The duration of motor block were statistically significant between the two groups (p=0.0001 for motor block). **Conclusion:** 0.5% isobaric Levobupivacaine (15 mg) produced faster onset and prolonged motor blockade compared to 0.5% isobaric Ropivacaine (15 mg) in adult patients undergoing elective lower limb surgeries, without significant haemodynamic changes. Hence Ropivacaine can be a better drug for day care surgeries and Levobupivacaine for prolonged surgeries.

**Key Words:** Levobupivacaine, Ropivacaine, Motor block, intrathecal anaesthesia.

## \*Address for Correspondence:

Dr. Suresh S B, Associate Professor, Department of Anaesthesiology, Shridevi Institute of Medical Sciences and Research Hospital, NH-4, Bypass road, Tumkur- 572106, INDIA.

Email: [hrbs2006@yahoo.co.in](mailto:hrbs2006@yahoo.co.in)

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## INTRODUCTION

Levobupivacaine is S (-) enantiomer of bupivacaine. It is somewhat less cardiotoxic than the racemic bupivacaine. It is also less potent, and tends to have longer duration of action. Levorotatory isomers were shown to have a safer pharmacological profile with less cardiac and neurotoxic adverse effects. The decreased toxicity of Levobupivacaine is attributed to its faster protein binding rate. Levobupivacaine (S-1-butyl-2-piperidylformo-2', 6'-

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xylidine 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.<sup>1</sup> Ropivacaine is a long acting regional anaesthetic that is structurally related to Bupivacaine. Unlike Bupivacaine which is racemic mixture, Ropivacaine is a pure S (-) enantiomer developed for the purpose of reducing the potential cardiovascular toxicity and improving the relative sensory and motor block profiles.<sup>2</sup> Like other local anaesthetics, Ropivacaine elicits nerve block via reversible inhibition of sodium ion influx in nerve fibers. This action is potentiated by dose dependent inhibition of potassium channels.<sup>3</sup> Ropivacaine is less lipophilic than Bupivacaine and is less likely to penetrate large myelinated motor fibers. Therefore it has selective action on the pain transmitting A $\delta$  and C nerves rather than A $\beta$  fibers, which are involved in motor function.<sup>1</sup> Ropivacaine is shown to be effective for subcutaneous infiltration, epidural, intrathecal and peripheral nerve block, obstetrics and postoperative analgesia.<sup>4</sup> 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 evaluate the motor 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.

## AIM AND OBJECTIVES

To evaluate motor blockade properties of 3ml of 0.5% isobaric Levobupivacaine and 3ml of 0.5% isobaric Ropivacaine for spinal anaesthesia in subjects undergoing elective lower limb orthopaedic surgeries. To find out a better drug for day care surgeries and better drug for prolonged surgeries. To assess the onset, duration, quality and time taken for the maximum motor blockade.

## MATERIALS AND METHODS

A prospective, randomized, comparative study was undertaken from December 2014 to June 2015 to evaluate the motor 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 motor blocks, time for maximum motor block, quality of motor 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.

**Sample Size:** A difference of 60 min in the duration of motor block (modified Bromage score >1) was taken as clinically significant. Sample size calculation showed that to detect a 60 min difference in motor block between the two groups at a power of 80% and confidence interval of 95% a sample size of 26 was required. And as well as to compensate for the dropout from the study and also to make sure that, the sampling size was not inadequate a total number of 60 patients were selected and divided randomly into two groups of 30 patients each by computer generated random number chart.

**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:** Subjects belonging to the following classes pregnancy, ASA class III and IV, subjects posted for Emergency surgeries, subjects with body mass index more than 29.9kg/m<sup>2</sup>, subjects shorter than 150 cm and longer than 180 cm. The study was conducted after scientific and institutional ethical committee approval and after taking informed written consent from all patients.

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

**Group B:** patients received 3ml (15mg) of 0.5% isobaric Ropivacaine.

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. Quality of motor blockade was assessed by modified Bromage scale.

## RESULTS AND OBSERVATIONS

The mean age in Levobupivacaine 0.5% (group A) is  $39.33 \pm 15.858$  and in Ropivacaine 0.5% (group B) is  $35.40 \pm 14.357$ . Group A had 21 male and 9 female patients, group B had 24 male and 6 female patients. Group A mean height was  $160.93 \pm 5.010$  cms, Group B mean height was  $161.57 \pm 4.446$  cms. The mean body weight in group A is  $61.63 \pm 5.774$  kgs and in group B is

$61.43 \pm 6.579$  kgs. The mean body mass index in group A is  $23.80 \pm 1.659$  kg/m<sup>2</sup> and in group B is  $23.53 \pm 2.130$  kg/m<sup>2</sup>. 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%), Intramedullary 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:** Onset of Motor Block (minutes), Time taken to attain maximum motor block (minutes), Duration of motor block (minutes),

	Study group	Mean	SD	P value
Onset of motor block(min)	A	4.43	0.858	0.0001
	B	6.70	1.535	
Time to attain maximum motor block(min)	A	9.63	1.129	0.0001
	B	13.20	1.827	
Duration of motor block(min)	A	222.00	14.716	0.0001
	B	138.33	12.617	

Time taken for the onset of motor blockade is  $4.43 \pm 0.858$  minutes in Levobupivacaine 0.5% group and  $6.70 \pm 1.535$  minutes in Ropivacaine 0.5% group. There is statistically highly significant difference between the groups ( $p=0.0001$ ). The mean duration of motor blockade is  $222.00 \pm 14.716$  minutes in Levobupivacaine 0.5% group and  $138.33 \pm 12.617$  minutes in Ropivacaine 0.5% group. There is statistically highly significant difference between the groups ( $p=0.0001$ ). Recovery from maximum motor block was faster in Ropivacaine 0.5% group compared to Levobupivacaine 0.5%.

**Table 2:** Grade of motor blockade

	Study group		Total		P value
	A Number of patients (%)	B Number of patients (%)	number of patients (%)		
Bromage 3	10(33.3%)	12(40%)	22(36.7%)		
4	20(66.7%)	18(60%)	38(63.3%)	0.789	
<b>Total</b>	<b>30(100%)</b>	<b>30(100%)</b>	<b>60(100%)</b>		

Complete motor block (Bromage 4) was attained in 20 patients [out of 30 patients] in Levobupivacaine group and in 18 patients [out of 30 patients] in Ropivacaine group which was statistically not significant ( $p=0.789$ ).

**Adverse effects:** There was no incidence of nausea, vomiting, headache, shivering, SpO<sub>2</sub><93%, hypotension, bradycardia in any patient in both the study groups.

## DISCUSSION

A study entitled “A prospective, randomized, comparative clinical study of effect of 0.5% isobaric Levobupivacaine and 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 to evaluate the motor blockade properties. It has been found that isobaric local anaesthetics are ideal for surgeries below T10 level of block and high volumes are required for surgeries above T10. Hence in our study all the patients selected were for lower limb orthopaedic surgeries requiring a blockade below T10.<sup>5</sup> 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.

**Motor blockade Onset of motor blockade:** Onset of motor blockade is defined as the time taken from the completion of injection of the study drug till patient develops Bromage-score 1. The mean time taken for the onset of motor blockade is  $4.43 \pm 0.858$  minutes in Levobupivacaine 0.5% group and  $6.70 \pm 1.535$  minutes in Ropivacaine 0.5% group. There is statistically highly significant difference between the groups ( $p=0.0001$ ). Onset of motor blockade with Levobupivacaine is consistent with the results obtained by Guler G *et al.*<sup>6</sup> ( $4.1 \pm 0.88$ ) and Vanna O *et al.*<sup>7</sup> ( $3.9 \pm 1.7$ ). Onset of motor block with Ropivacaine 0.5% is consistent with results obtained by Mehta A *et al.*<sup>8</sup> ( $6.46 \pm 1.14$ ). Various investigators using Bromage 1 or 2 as onset of motor blockade have found similar faster onset with Levobupivacaine.

**Degree of motor blockade:** In our study it was found that, there was no statistically significant difference between two groups with regard to degree of motor blockade ( $p=0.789$ ). In Levobupivacaine 0.5% group, 20 patients attained Bromage 4 and 10 patients attained Bromage 3 where as in Ropivacaine 0.5% group 18 patients attained Bromage 4 and 12 patients attained Bromage 3.

**Time for maximum motor blockade:** Time taken for maximum motor blockade is defined as the time from the completion of the injection of the study drug to the maximum motor blockade attained. The mean time for maximum motor blockade is  $9.63 \pm 1.129$  minutes in Levobupivacaine group and  $13.20 \pm 1.827$  minutes in Ropivacaine group which was statistically significant ( $p=0.0001$ ), which compared with the study of Mantouvalou *et al.*<sup>9</sup> Values for Levobupivacaine similar to our study were also reported by Guler G *et al.*<sup>6</sup> ( $11.36 \pm 2.35$ ) using 10 mg Levobupivacaine and 15 mcg Fentanyl. The time for maximum motor blockade with

isobaric Levobupivacaine was  $13.6 \pm 7.3$  min as observed by Sanansilp V *et al.*<sup>10</sup> which is slightly longer than the duration observed in our study. This may be due to lower mass of drug. In the study conducted by van Kleef *et al.*<sup>11</sup> time for maximum motor block blockade was 21 minutes for Ropivacaine 0.5% which was longer than our study. This is probably due to the mean height of the patients selected was 177 cms in 0.5% group in Van Kleef *et al.*<sup>11</sup> study and average height in our study is 161.57 cms.

**Duration of motor blockade:** Duration of motor blockade is the time taken from the time of injection of study drug till the patient attains complete motor recovery, Bromage score 0. The duration of motor blockade in Levobupivacaine group is  $222.00 \pm 14.716$  minutes compared to  $138.33 \pm 12.617$  minutes in Ropivacaine group. The duration of motor blockade with Levobupivacaine is more prolonged than with Ropivacaine which is statistically highly significant ( $p=0.0001$ ). Mantouvalou *et al.*<sup>9</sup> studied the duration of motor block by regression from Bromage scale 3 to 2, 2 to 1 and from 1 to 0. They concluded that complete regression of motor block to 0 took 351 minutes in the Levobupivacaine group and 249 minutes in the Ropivacaine group and that motor block regression was significantly faster in the Ropivacaine group. In our study also the motor block regression was significantly faster with Ropivacaine group. Fattorini F *et al.*<sup>12</sup> using 15 mg isobaric Levobupivacaine reported duration of motor blockade as  $256 \pm 86$  min, this is in comparison with the results of our study. Similar motor blockade duration ( $280 \pm 84$  min) was reported by Glaser C *et al.*<sup>13</sup> Our findings correlate with this study. In the study conducted by Kallio *et al.*<sup>14</sup> duration of motor block using Ropivacaine 0.5% was 150 minutes which is in consistent with our study. In studies conducted by van Kleef *et al.*<sup>11</sup> and Wahedi *et al.*<sup>15</sup> duration of motor block using 0.5% Ropivacaine was 178 (65-290) minutes and 160 minutes respectively which is comparable to our study.

**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.*<sup>35</sup>

## CONCLUSION

From the present study we can conclude that 0.5% isobaric Levobupivacaine (15 mg) produced faster onset and prolonged motor blockade compared to 0.5% isobaric Ropivacaine (15 mg) in adult patients undergoing elective lower limb surgeries, without significant haemodynamic changes. Hence Ropivacaine can be a better drug for day care surgeries and Levobupivacaine for prolonged surgeries.

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