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A Comparative Study Comparing Anaesthetic Efficacy Of Intrathecal Isobaric Levobupivacaine (0.5%) With Intrathecal Isobaric Ropivacaine (0.75%) For Lower Abdominal And Lower Limb Orthopedic Surgeries.

Dev Kumar Harkawat[1]*, Nidhi[2], and SP Sharma[3].

[1]Associate Professor, Department Of Anesthesiology, Jaipur National University Institute for Medical Sciences and Research Centre, Jaipur, Rajasthan, India.
[2]PG Resident, Department Of Anesthesiology, Jaipur National University Institute for Medical Sciences and Research Centre, Jaipur, Rajasthan, India.
[3]Professor Head of Department, Department Of Anesthesiology, Jaipur National University Institute for Medical Sciences and Research Centre, Jaipur, Rajasthan, India.

ABSTRACT

Bupivacaine available as a racemic mixture of its enantiomers dextro and levo bupivacaine has been the gold standard for intrathecal use in spinal anaesthesia. Levo bupivacaine and Ropivacaine are the two recently introduced alternatives to Bupivacaine in clinical practice. The aim of our study is to evaluate the effect of intrathecal administration of isobaric Levobupivacaine and isobaric Ropivacaine in patients undergoing lower abdominal and lower limb orthopaedic surgeries. This study was conducted in our department. The patients were randomly assigned to two groups of 30 patients each. Group A received intrathecal 3 ml (0.75%) isobaric Ropivacaine (22.5mg), Group B received intrathecal 3 ml (0.5%) isobaric Levo Bupivacaine (15 mg). The observations were discussed in terms of vital parameters; onset, duration and recovery from sensory and motor blockade and side effects. It was found that isobaric Ropivacaine 0.75% intrathecally provides shorter duration of motor and sensory block compared to Levo bupivacaine 0.5%. Also, there were less episodes of hypotension which indicate that 0.75% isobaric Ropivacaine provides more hemodynamic stability than Levo Bupivacaine 0.5% intrathecally.

Keywords: Levobupivacaine, Ropivacaine, Lower Limb Orthopaedic Surgeries, Subarachnoid Block.

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Corresponding author

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INTRODUCTION

Discoveries in the field of medicine are self-perpetuating. One discovery leads to the other and the quest is ceaseless. Three decades ago, few patients who were given bupivacaine developed life threatening arrhythmias, which were refractory to treatment. On recognizing this life-threatening cardiotoxicity of bupivacaine, the search for newer, safer local anaesthetic drugs began [1]. An important aspect of this cardiotoxicity is that it is related to the stereospecificity of bupivacaine with the 'S' isomer having very less cardiotoxic potential compared to the 'R' form [2]. Moreover, it has been observed that the chance of success of cardiopulmonary resuscitation was high when cardiovascular collapse was induced with these drugs compared to bupivacaine. Ropivacaine also showed the advantage of lesser motor blockade making it preferable when early mobilization is suggested. This helps to hasten the postoperative recovery [3]. Since its introduction into market in 1996, Ropivacaine has been put to extensive use in epidural, intrathecal and peripheral nerve blocks [4]. Levobupivacaine, the pure S(-) enantiomer of bupivacaine, due to its safety and superior pharmacokinetic properties is an emerging alternative to bupivacaine [5]. The regression of motor block occurs earlier than bupivacaine which makes it favourable for ambulatory surgery [5]. Ropivacaine and levobupivacaine are the recent local anaesthetic drugs that have significantly lower cardiotoxicity compared to bupivacaine [1]. The aim of our study was to compare the anaesthetic efficacy of intrathecal isobaric 0.5% levobupivacaine with intrathecal isobaric 0.75% ropivacaine for lower abdominal and lower limb orthopaedic surgeries.

MATERIAL AND METHODS

After the approval of Institutional ethical committee and after obtaining informed consent from all the patients, sixty patients of ASA I and II of age 18 to 60 years of either sex were included in our study. These patients were randomly assigned to 2 Groups, 30 each. Group A and B who received intrathecal 3 ml 0.75% isobaric Ropivacaine (22.5mg) and 3 ml 0.5% Levo Bupivacaine (15 mg) respectively. Patients who refuse for consent, Infection at site of injection, coagulopathy or any other bleeding disorder, severe hypovolemia, severe hypotension, increased intracranial tension, severe stenotic valvular heart disease or ventricular outflow obstruction were excluded from our study. All patients underwent pre-anaesthetic check-up where detailed history was taken, they were physically examined and relevant routine and special investigations were carried out. Informed and written consent for anaesthetic procedure was taken from patient for surgery. They were kept nil orally for at least 6 hours prior to starting the procedure. Heart Rate, Blood Pressure, Respiratory Rate, Oxygen Saturation and Electrocardiogram were noted. An intravenous cannula was inserted and connected to Ringer lactate / Normal Saline at 10 ml/kg. Under all aseptic precautions, subarachnoid block was given with patient placed in the lateral decubitus with affected limb uppermost by midline approach between third and fourth lumber space via 25 Gauge Quincke's spinal needle. On confirmation of free flow of Cerebrospinal fluid, the calculated drug was injected slowly. After injection patient was immediately turned supine. No tilt was given. All patients received oxygen at 4 L/min by oxygen mask. Continuous monitoring of B.P, HR, RR, SpO2 and ECG was done during intraoperative period at regular intervals. Onset of sensory blockade and motor blockade was noted in all the patients. Determination of onset of sensory block was done by pin prick technique; while assessment of motor blockade was done using Modified Bromage Scale

Grade 0 No motor block, able to lift the leg at the hip
Grade I Inability to flex the hip, able to move knees and feet
Grade II Inability to move hip and knee, able to move feet
Grade III Complete motor block of limb, unable to move even the feet

Postoperative Observation: H.R, B.P., R/R, SpO2 and ECG was observed till the requirement of 1st rescue analgesic dose. Duration of sensory and motor blockade was observed postoperatively and duration of 1st rescue analgesia was noted in all the patients. Patients were observed for side effects like hypotension, bradycardia, nausea/vomiting, shivering

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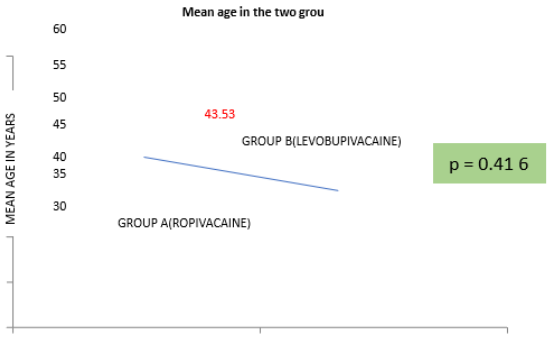
RESULTS

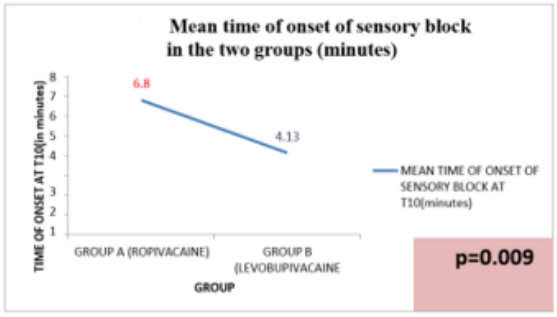
Distribution of age in the two groups

Group	N	Mean age (in years)	Standard Deviation	Standard Error Mean	
Group A (Ropivacaine)	30	43.53	12.555	2.292	p=0.416
Group B (Levobupivacaine)	30	40.83	12.978	2.369	



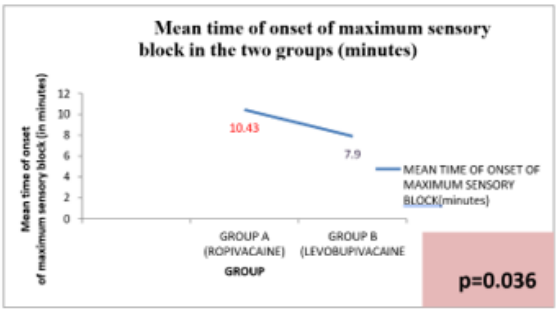
Time of onset of sensory block at T10

Group	N	Mean (minutes)	Standard Deviation	Standard Error Mean	
Group A (Ropivacaine)	30	6.8	4.715	0.861	p=0.009
Group B (Levobupivacaine)	30	4.13	2.636	0.481	



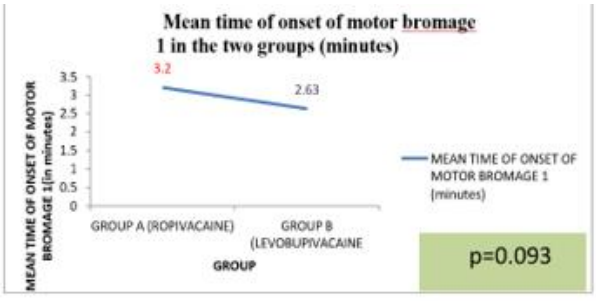
Time of onset of maximum sensory block

Group	Mean (minutes)	Standard Deviation	Standard Error Mean	
Group A (Ropivacaine)	10.43	4.854	0.886	p=0.036
Group B (Levobupivacaine)	7.9	4.245	0.775	



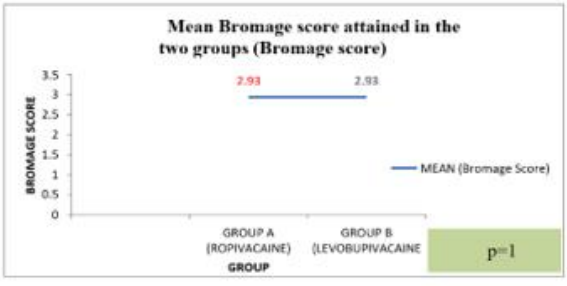
Time of onset of motor (Bromage 1) block

Group	Mean (minutes)	Standard deviation	Standard error mean	
Group A (Ropivacaine)	3.2	1.54	0.281	p=0.093
Group B (Levobupivacaine	2.63	0.964	0.176	



Maximum motor Bromage score attained

Group	N	Mean (Bromage Score)	Standard deviation	Standard error mean	
Group A (Ropivacaine)	30	2.93	0.365	0.067	p=1
Group B (Levobupivacaine	30	2.93	0.254	0.046	



Time of Onset of Maximum motor Bromage Score

8.83

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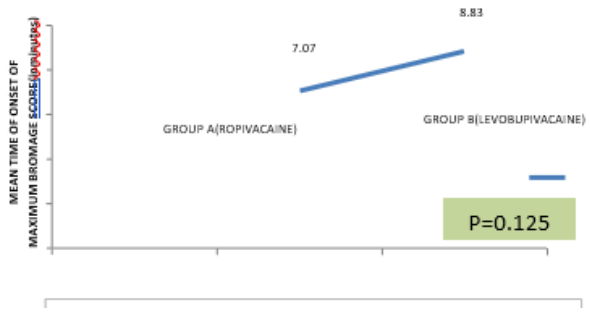
Time of Onset of Maximum motor Bromage Score

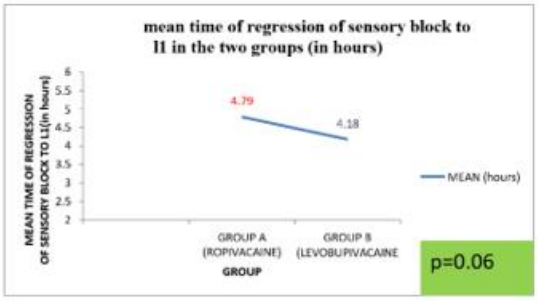
Group	N	Mean (minutes)	Standard deviation	Standard error mean	
Group A (Ropivacaine)	30	7.07	4.258	0.777	p=0.125
Group B (Levobupivacaine	30	8.83	4.526	0.826	



Time to regression of sensory block Upto L1

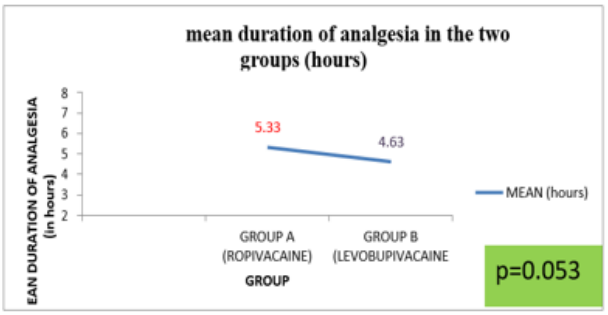
Time to regression of sensory block Upto L1

Group	N	Mean (hours)	Standard deviation	Standard error mean	
Group A (Ropivacaine)	30	4.79	1.33	0.243	p=0.06
Group B (Levobupivacaine)	29	4.18	1.084	0.201	



Duration of Analgesia

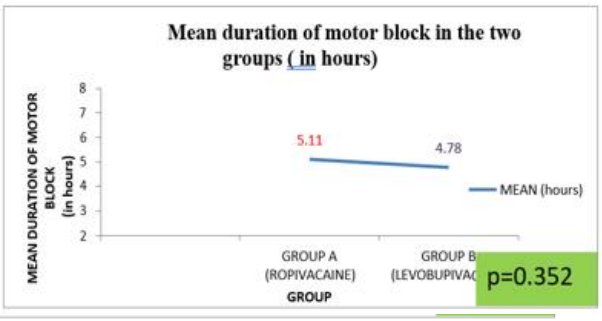
Group	N	Mean (hours)	Standard deviation	Standard error mean	
Group A (Ropivacaine)	30	5.33	1.501	0.274	p=0.053
Group B (Levobupivacaine	29	4.63	1.202	0.223	



Duration of Motor Block

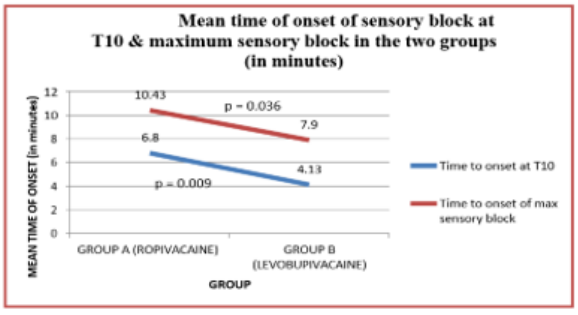
Duration of Motor Block

Group	N	Mean (hours)	Standard deviation	Standard error mean	
Group A (Ropivacaine)	30	5.11	1.429	0.261	p=0.352
Group B (Levobupivacaine	30	4.78	1.347	0.246	



Side effects in the two groups

Side effects	Group A (Ropivacaine)	Group B (Levobupivacaine)
No Side Effects	21(70%)	23(77%)
Shivering	3(10%)	3(10%)
Hypotension	4(13%)	3(10%)
Nausea	1(3%)	1(3%)
Bradycardia	2(7%)	0



No significant difference in Pulse Rate and Blood Pressure was noted between the two groups in the intraoperative and postoperative period.

Statistical Analysis

In this study, the data were either quantitative data or qualitative data. For quantitative data descriptive statistics was presented by Mean, Standard Deviation and Range. For qualitative data, frequency count (N) and percentage were displayed in a tabular manner. For statistical analysis IBM SPSS (version 21) software was used. To analyze the data appropriate statistical tests were applied. For the comparison of the two groups, Independent Samples t-Test was used. Other data are displayed by various tables and charts by using Microsoft excel. Observations were duly recorded, tabulated and then statistically analyzed. P value < 0.05 was considered clinically significant.

DISCUSSION

The efficacy of spinal anesthesia is assessed in terms of onset, level, intensity and duration of sensory as well as motor blockade produced. In our study, we compared the time of onset, level attained anddduration of sensory as well as motor blockade. We also noted the occurrence of adverse effects such as hypotension, bradycardia and nausea, vomiting and shivering. A total of 60 patients fulfilling the inclusion criteria were chosen in our study and none of the participants were completely excluded from the study. Of the 30 patients in levobupivacaine group, one patient did not attain the sensory level as mandated by the onset time as defined in our study. That patient was excluded while analyzing variables such as duration of analgesia and time for regression of sensory block to L1.

The demographic characteristics such as age, height, weight and sex were comparable in the two groups. Camorcia et al [10] reported a potency ratio of 0.83 for ropivacaine/ levobupivacaine. According to Sia et al [11], levobupivacaine was 1.31 times more potent than ropivacaine. Coppejans et al. [12] proposed that ropivacaine requires atleast a 50% larger dose compared to levobupivacaine. Parpaglioni et al [8].

suggested a potency ratio of 1.34 between intrathecal levobupivacaine and ropivacaine. However decided the dose of ropivacaine based on the study by D'Souza et al [7] presuming a ropivacaine dose 1.5 times as that of levobupivacaine.

The two drugs had different times of onset of the sensory block. The time of onset of loss of sensation to pin prick at T10 was much shorter 4.13 ± 2.636 minutes in group B (levobupivacaine) compared to group A (ropivacaine) in which time of onset at T10 was 6.8 ± 4.7515 minutes. The p value was 0.009 and the difference was statistically significant.

The mean time of onset of motor block with a Bromage score of 1 (inability to flex the hip) was comparable in the two groups with no statistical difference 3.2 ± 1.54 minutes for ropivacaine group and 2.63 ± 0.964 minutes for levobupivacaine group (p=0.094).

In the study by D'Souza et al [7] who compared the block characteristics of 3ml of intrathecal hyperbaric 0.5% bupivacaine, isobaric 0.75% ropivacaine and isobaric 0.5% levobupivacaine, there was no significant dissimilarity noted between ropivacaine and levobupivacaine in terms of sensory block but times of onset of motor block of bromage 1 and bromage 3 were shorter in levobupivacaine group with median 2.5 and 5.5minutes vs 5 and 5.25 minutes in group ropivacaine. Similarly, there was a statistically significant difference in the median duration of sensory block but no difference in the median duration of motor Bromage 3. In contrary to this study, we observed a significant difference in the onset of sensory block but not on the onset of the motor block.

The two groups also showed a dissimilarity in the time of onset of maximum level of the sensory block which was 7.9 ± 4.245 minutes in group B (levobupivacaine) and 10.43 ± 4.854 minutes in group A (ropivacaine). The p value was 0.036 and the difference was statistically significant.

The mean time of onset of maximum motor block, i.e, a Bromagescore 3 in both the groups, was similar with 7.07 ± 4.258 minutes in ropivacaine group and 8.83 ± 4.526 minutes in group levobupivacaine. (p=0.125) There was no remarkable difference in the time to regression of sensory

block to L1 level in both the groups. The mean time to regression to L1 was 4.79 ± 1.33 hours in group ropivacaine and 4.18 ± 1.084 hours in group levobupivacaine (p value=0.059).

The mean duration of analgesia was 5.33 ± 1.501 hours in group ropivacaine which was slightly longer than for group levobupivacaine in which the mean duration of analgesia was 4.63 ± 1.202 hours but this difference was not statistically significant (p=0.052).

The duration of motor block was also longer in the ropivacaine group. The mean duration of motor block was 5.11 ± 1.429 hours compared to 4.78 ± 1.347 hours in the levobupivacaine group though this difference was also not statistically significant (p=0.353).

The hemodynamic parameters such as pulse rate and blood pressure were comparable in the two groups. The incidence of side effects such as nausea, vomiting, shivering, hypotension and bradycardia were comparable. Casati and colleagues [9] compared hyperbaric solutions of the three drugs for unilateral spinal anesthesia. They also found no significant dissimilarity in the onset time of sensory block in the two groups. The time for complete regression of sensory block was faster in ropivacaine group compared to levobupivacaine group (166 ± 42 vs 210 ± 63 minutes, p=0.03). But no such difference in duration of analgesia or time to regression of sensory block to L1 was observed in our study. In fact, the duration of analgesia was longer with ropivacaine than levobupivacaine.In our study though no statistically, significant difference could be proved.But in the study by Casati et al., the authors had used hyperbaric solutions and the intrathecal spread of the hyperbaric drugs cannot be compared with the isobaric solutions used in ours.

All the patients in our study were monitored with pulse oximetry and NIBP in the postoperative period and there was no hypotension / hypertension and decrease in oxygen saturation in both the groups. The VAS scores were also assessed and when the patient had a VAS score of 4 or more it was taken as the end point of analgesia and rescue analgesic inj. Paracetamol 1g iv given. The time from onset of sensory block at T10 to this point was taken as the duration of analgesia.

CONCLUSION

Thus, we conclude that both intrathecal isobaric 0.75% ropivacaine and 0.5% levobupivacaine possess similar block characteristics except difference in their time to onset and attainment of maximum level for sensory block which was significantly shorter with levobupivacaine compared to ropivacaine. Duration of analgesia and motor blockade were comparable. Further, both the drugs produce similar hemodynamic effectswith very less adverse effects.

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