ORIGINAL RESEARCH PAPER

Anaesthesiology

# INTRATHECAL HYPERBARIC LEVOBUPIVACAINE AND HYPERBARIC ROPIVACAINE IN SPINAL ANAESTHESIA FOR ELECTIVE LOWER EXTREMITY ORTHOPAEDIC SURGERIES: A COMPARATIVE OBSERVATIONAL STUDY OF ANAESTHETIC AND HAEMODYNAMIC SPECTRUM.

**KEY WORDS:** HYPERBARIC, ROPIVACAINE, LEVOBUPIVACAINE, SPINAL ANAESTHESIA

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**ABSTRACT**

**Background:** Neuraxial anaesthesia is a preferred and most commonly used procedure in hip joint and lower extremity orthopaedic surgeries using hyperbaric bupivacaine. Spinal anaesthesia with hyperbaric bupivacaine provides intense analgesia but its adverse effects have been reported. The newer local anaesthetics like levobupivacaine and ropivacaine came into practice to cutdown adverse effects and utilize the desired effects. Both hyperbaric levobupivacaine and ropivacaine provide satisfactory levels of anaesthesia. This study aims to observe the effectiveness of subarachnoid hyperbaric levobupivacaine and hyperbaric ropivacaine in spinal anaesthesia in elective lower extremity orthopaedic surgeries. **Materials And Methods:** A total of 100 patients were selected and were randomly divided into two groups: one under hyperbaric levobupivacaine (n=50) and another under hyperbaric ropivacaine (n=50). Duration of analgesia, onset, duration of sensory block, duration of motor block, intraoperative hemodynamic stability and adverse effects were evaluated between the groups. Independent t test and chi square test were used for statistical analysis. **Results:** The onset time of sensory loss to pinprick was significantly higher in hyperbaric ropivacaine group (7.6±1.3 min) as compared to hyperbaric levobupivacaine group (3.2±1.1 min). The onset of motor block was significantly slower in hyperbaric ropivacaine(R) group (14.9±1.6 min) as compared to hyperbaric levobupivacaine(L) group (10.1±1.3 min). The time duration of motor block was shorter in R group (122.4±9.2 min) compared to L group (161.3±12.6 min). The time duration of analgesia was slightly shorter in R group (169.8±19.8 min) than in L group (171.3±13.6 min). The hemodynamic parameters were comparable in both the groups. **Conclusion:** The patient satisfaction as well as quality of anaesthesia was excellent in both R and L group. Despite delayed onset, hyperbaric ropivacaine can be used as an alternative to hyperbaric levobupivacaine for subarachnoid block especially in patients requiring early mobilisation and less requirement of muscle relaxation.

## INTRODUCTION

After the introduction of spinal anaesthesia by Karl August Bier, in 1898, it became popular in the surgical field. Attainment of spinal anaesthesia is by administering local anaesthetic drugs in the subarachnoid space and thereby blocking nerves. This is a preferred method for lower extremity orthopaedic surgical procedure.[1] Spinal anaesthesia with lignocaine was widely used for surgical procedures because of its fast onset and short duration profile; but it was also associated with a considerable incidence of transient neurological symptoms. Small doses of long-acting drugs were suggested as possible alternatives to lignocaine for spinal anaesthesia. Single shot spinal anaesthesia with hyperbaric bupivacaine provides intense analgesia but its adverse effects have been reported in many studied. Hence, the newer local anaesthetics like levobupivacaine and ropivacaine came into clinical practice.[2-4]

Bupivacaine and ropivacaine are amide local anaesthetics characterised as pipecoloxylidides. They are chiral compounds having S or R enantiomers. Levobupivacaine is a pure S enantiomer. On a per-milligram basis, it is less cardio toxic in comparison to bupivacaine, as it has lower potency at the sodium channel. Studies have suggested that it has equivalent clinical efficacy to bupivacaine.[5-7] Ropivacaine is almost similar in chemical structure to bupivacaine except in hydrocarbon group, but it is 30-40% less potent than bupivacaine and provided shorter spinal block than levobupivacaine. Intrathecal ropivacaine is safe, has shorter duration of action and lesser incidence of transient neurological symptoms, less cardiotoxic and better haemodynamic stability compared to other available amino ester drugs.[8-10]

On this context, the present study was devised and performed to compare the desired effect of intrathecal hyperbaric levobupivacaine and hyperbaric ropivacaine in spinal anaesthesia in elective lower extremity orthopaedic surgical procedures.

## MATERIALS AND METHODS

After getting institutional ethics committee approval and informed written consent from all the patients the study was initiated and maintained. The study was a comparative prospective observational study. A total of 100 patients were selected and were randomly divided into two groups with 50 patients in each group: one under hyperbaric levobupivacaine (Group L, n=50) and another under hyperbaric ropivacaine (Group R, n=50). Patients were included in our study when following criteria were fulfilled 1. ASA physical status I and II,2. Age 18 to 60 years,3. BMI 18-25 kg/metre square and were excluded on the following conditions 1. Patient refusal, 2. ASA physical status 3 and 4,3. History of any systemic diseases,4. Known hypersensitivity to drugs,5. Pregnant and lactating mothers,6. Spinal deformities,7. Coagulation disorder.

## METHODOLOGY

After obtaining institutional ethics committee clearance the study was conducted in those patients who have given informed written consent to participate in this study. Preoperative assessment and all relevant and recommended preoperative investigations were done prior to surgery according to institutional protocol. All patients were kept fasting according to standard fasting protocol and premedicated with tab Etizolam (0.25mg), tab Famotidine (40mg) night prior to surgery as per standard protocol followed in our hospital. In the operating room standard monitors were attached, ECG limb lead II, non-invasive blood pressure, pulse oximeter was applied via multipara monitor. A wide bore intravenous (IV) cannula was inserted and secured beforehand.

Premedication as injection ondansetron 2-4 mg was given IV and co loading done with ringer lactate at 15 ml/kg during the spinal anaesthesia and surgery. Those patients receiving hyperbaric levobupivacaine were put in Group L and those receiving hyperbaric ropivacaine were in Group R keeping

50 in each group: Group L- 3ml hyperbaric levobupivacaine (0.5%) and Group R- 3ml hyperbaric ropivacaine (0.75%).

After starting coloading, spinal anaesthesia was performed. Patients were explained about the procedure at the beginning. They were kept in sitting positions during the procedure. Antiseptic dressing and draping were done with povidone iodine (7.5%) and chlorhexidine. Identification of level was done using trans crestal line as a guide which pass through L3-L4 intervertebral space. A 26G Quincke's spinal needle was inserted in midline in the interspinous space at L3-L4 level. Needle inserted from skin to subarachnoid space and correct needle placement was identified by free flow of CSF. The desired and allotted local anaesthetic solution among levobupivacaine and ropivacaine heavy was injected intrathecally over 10-15 seconds. After giving the drugs patients were placed in supine position immediately. Adequate intravenous (IV) fluid was given with crystalloids balance the compensatory volume expansion. Intraoperative hypotension (defined as decrease in Mean Arterial Pressure ≥ 20% from baseline value) was managed by IV vasopressors (inj. mephentermine IV in incremental doses). Duration of analgesia, onset, duration of sensory and motor block, intraoperative hemodynamic changes and side effects were evaluated and compared between the groups.

Sensory block was assessed by blunt sterile pin prick. The following parameters were observed and were noted, onset time after giving anaesthesia, total duration of sensory block (time period from onset of block to the time of two segment regression from T10). Motor block was evaluated by using Bromage scale. Time of onset (when Bromage scale 3 ie. patient is unable to move the hip, knee and ankle joint is achieved), Duration of motor blockade were noted (time period from onset to Bromage scale 0 ie. patient is able to move the hip, knee and ankle joint).

## STATISTICAL ANALYSIS

The collected data was processed and tabulated in Microsoft excel and analysed with Statistical Package for the Social Sciences (SPSS Inc., Chicago, IL, USA) version 24. The continuous variables were presented with mean and standard deviation. The categorical variables were presented with frequency and percentage. Independent t test and chi square test were used for the comparisons. The critical p value was 0.05.

## RESULTS

The demographic profile of the patients was comparable in the two groups with no significant difference in age, sex distribution, ASA grade distribution, height and weight (p>0.05) (Table 1).

**Table 1: Demographic profile**

| Demographic parameters | Group L | Group R | P value | Significance |
|---|---|---|---|---|
| Age (years) | 42.7±4.2 | 45.3±4.8 | 0.827 | NS |
| Male: Female ratio | 27:23 | 21:29 | 0.229 | NS |
| ASA -PSI:II ratio | 19:31 | 24:26 | 0.312 | NS |
| Height (cm) | 164.2±6.7 | 161.7±6.1 | 0.503 | NS |
| Weight (kg) | 58.5±3.9 | 59.1±3.2 | 0.911 | NS |

NS-Not significant

The onset of sensory block was significantly slower in hyperbaric ropivacaine group (7.6±1.3 min) as compared to hyperbaric levobupivacaine group (3.2±1.1 min) (p<0.05). The onset of motor block was significantly slower in hyperbaric ropivacaine group (14.9±1.6 min) as compared to hyperbaric levobupivacaine group (10.1±1.3 min) (p<0.05). The duration of motor block was significantly shorter in hyperbaric ropivacaine group (122.4±9.2 min) compared to hyperbaric levobupivacaine group (161.3±12.6 min). The duration of adequate analgesia was slightly shorter in hyperbaric ropivacaine group (169.8±19.8 min) than in hyperbaric levobupivacaine group (171.3±13.6 min) (Table 2, Figure 1, 2). The hemodynamic parameters (heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure and arterial oxygen saturation) were comparable in both the groups.

**Table 2: Anaesthetic characteristics**

| Anaesthetic characteristics | Group L | Group R | P value | Significance |
|---|---|---|---|---|
| Onset time of sensory block (min) | 3.2±1.1 | 7.6±1.3 | 0.031 | S |
| Onset time of motor block (min) | 10.1±1.3 | 14.9±1.6 | 0.018 | S |
| Total duration of motor block (min) | 161.3± 12.6 | 122.4±9. | 0.005 | NS |
| Duration of adequate analgesia (min) | 171.3± 13.6 | 169.8± 19.8 | 0.062 | NS |

S- Significant; NS-Not significant

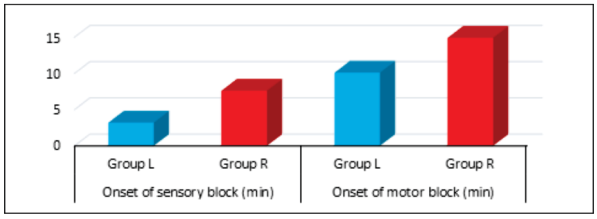


**Figure 1. Comparisons of onsets of sensory and motor block**

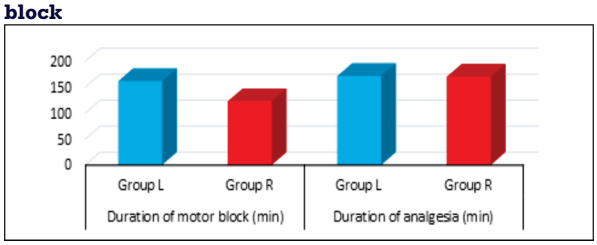


**Figure 2. Comparisons of durations of motor block and analgesia**

## DISCUSSION

Early mobilization and lower limb movement after operation reduces the incidence of deep vein thrombosis and increasing psychological wellbeing. Prolonged undesirable motor blockade with local anaesthetic drugs may limit early desirable limb movement and discharge. So, the search for a local anaesthetic agent which is safe, efficacious and less toxic with early ambulation is being carried out throughout the world.

This study was devised to compare the pharmacological effect of intrathecal hyperbaric levobupivacaine and hyperbaric ropivacaine in spinal anaesthesia in elective lower extremity orthopaedic surgeries. There were no significant differences in demographic parameters such as age, sex, ASA PS GRADES, height and weight between the levobupivacaine and ropivacaine groups. Similar profiles were described in studies by Yadav et al (2020)[11], and George et al (2022)[12] where the groups carried insignificant differences in their demographic parameters.

This observational study showed that, the time onset of sensory block was significantly slower in ropivacaine group as compared to levobupivacaine group. This result goes in accordance with the results of Yadav et al (2020)[11] where the onset of sensory block was significantly slower in ropivacaine group (7.05±2.96 min) as compared to levobupivacaine group (3.90±1.37 min). The onset of motor block in this present study was also significantly slower in ropivacaine

group as compared to levobupivacaine group. Yadav et al (2020)[11] showed that, onset of motor block was significantly slower in ropivacaine group (0.912±0.184 log min) as compared to levobupivacaine group (0.721±0.147 log min).
The present study showed that, the duration of motor block was significantly shorter in ropivacaine group compared to levobupivacaine group. Gautier et al (2003)[12] reported shorter duration of motor block in ropivacaine group (116±19 min) than levobupivacaine group (121±25 min). Luck et al (2008)[13] reported shorter duration of motor block in ropivacaine group (90 min) than levobupivacaine group (180 min). Mantouvalou et al (2008)[14] reported shorter duration of motor block in ropivacaine group (269±20 min) than levobupivacaine group (273±80 min).

The duration of analgesia in the present study was slightly shorter in ropivacaine group than in levobupivacaine group. Yadav et al (2020)[11] also reported slightly shorter duration of analgesia in ropivacaine group (264.25±41.11 min) than levobupivacaine group (279.25±40.40 min). Khan et al (2016)[15] reported slightly shorter duration of analgesia in ropivacaine group (187.67±23.92 min) than levobupivacaine group (190.27±18.61 min).

The present study showed that there were no significant differences in heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure and arterial oxygen saturation between two groups. Yadav et al (2020)[11] also reported similar results and they mentioned that, within the groups, statistically significant but clinically insignificant fall in systolic blood pressure, diastolic blood pressure and heart rate were present when compared with baseline till 10 min of intrathecal injection.

## CONCLUSION

The quality of anaesthesia and patient satisfaction was excellent in both groups. In spite of delayed onset, hyperbaric ropivacaine can be used as an alternative and/ side by side to hyperbaric levobupivacaine for spinal anaesthesia especially in patients requiring early mobilisation. Hyperbaric ropivacaine can be specifically used for patients who is at higher risk of cardiac toxicity, and surgeries of less requirement of muscle relaxation without much alteration on time of onset or duration of motor and sensory blocks.

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