Original Research Paper

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# COMPARATIVE STUDY OF THE EFFICACY AND POSTOPERATIVE ANALGESIC EFFECTS OF HYPERBARIC ROPIVACAINE VERSUS HYPERBARIC LEVOBUPIVACAINE WITH NALBUPHINE AS AN ADJUVANT IN LOWER LIMB SURGERIES

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**ABSTRACT**

**Background and Aims:** Hyperbaric ropivacaine and hyperbaric levobupivacaine are increasingly used alternatives to bupivacaine in spinal anaesthesia due to favourable pharmacological profiles. Addition of intrathecal adjuvants such as nalbuphine may enhance block quality and prolong postoperative analgesia. This study compared the efficacy and postoperative analgesic effects of intrathecal hyperbaric ropivacaine and hyperbaric levobupivacaine when combined with nalbuphine in patients undergoing lower limb surgeries. **Material & Methods:** In this prospective, randomized, double-blind study, 58 adult patients (ASA I–II) scheduled for elective lower limb surgeries under spinal anaesthesia were allocated into two groups (n=30 each). Group R received 3 ml hyperbaric ropivacaine 0.5% with 0.1 mg nalbuphine, while Group L received 3 ml hyperbaric levobupivacaine 0.5% with 0.1 mg nalbuphine. Primary outcomes were onset and duration of sensory and motor block. Secondary outcomes included postoperative analgesia duration, hemodynamic stability, and adverse effects. **Results:** Both groups achieved adequate surgical anaesthesia. Group R demonstrated faster onset of sensory block, while Group L showed significantly longer duration of sensory and motor blockade ($p<0.05$). Postoperative analgesia was prolonged in Group L compared to Group R. Hemodynamic parameters remained stable in both groups. Incidence of adverse effects was minimal and comparable. **Conclusion:** Intrathecal hyperbaric levobupivacaine with nalbuphine provides longer duration of sensory block and postoperative analgesia compared to hyperbaric ropivacaine with nalbuphine, with stable hemodynamics and minimal side effects. It may be a better alternative for lower limb surgeries requiring prolonged postoperative pain relief.

**KEYWORDS :** Hyperbaric ropivacaine, Hyperbaric levobupivacaine, Nalbuphine, Spinal anaesthesia, Postoperative analgesia.

## INTRODUCTION

Spinal anaesthesia remains the preferred technique for lower limb orthopaedic surgeries due to its rapid onset, dense sensory and motor blockade, and avoidance of airway manipulation[1]. Traditionally, hyperbaric bupivacaine has been the most commonly used local anaesthetic agent; however, concerns about its cardiotoxicity and potential neurotoxicity have led to increasing use of safer alternatives such as ropivacaine and levobupivacaine [2,3].

Ropivacaine, the pure S-enantiomer of bupivacaine, produces differential sensory-motor block with less motor impairment and lower systemic toxicity compared to bupivacaine[4]. Levobupivacaine, the S-enantiomer of bupivacaine, is similarly associated with a more favourable safety profile while providing longer duration of analgesia[5]. Both agents have been introduced in hyperbaric formulations to improve block reliability and predictability[6].

To enhance intraoperative block quality and prolong postoperative analgesia, various intrathecal adjuvants have been investigated. Nalbuphine, a synthetic opioid with κ-agonist and μ-antagonist activity, has been shown to provide effective spinal analgesia with minimal side effects such as pruritus, nausea, and respiratory depression compared to pure μ-agonists like morphine[7]. The combination of nalbuphine with local anaesthetics may optimize surgical anaesthesia and extend postoperative pain relief[8].

Despite several studies comparing ropivacaine and levobupivacaine individually with bupivacaine, limited literature is available directly comparing hyperbaric ropivacaine and hyperbaric levobupivacaine when combined with nalbuphine as an adjuvant. Addressing this knowledge gap is clinically relevant for optimizing spinal anaesthesia drug selection in lower limb surgeries.

**Hypothesis:**

We hypothesized that intrathecal hyperbaric levobupivacaine with nalbuphine would provide longer duration of sensory blockade and postoperative analgesia compared to hyperbaric ropivacaine with nalbuphine, without increasing adverse effects.

- **Aim:** To compare the efficacy and postoperative analgesic effects of intrathecal hyperbaric ropivacaine versus hyperbaric levobupivacaine with nalbuphine in patients undergoing lower limb surgeries.
- **Primary Outcomes:** Onset and duration of sensory and motor block.
- **Secondary Outcomes:** Duration of postoperative analgesia, hemo-dynamic stability, and incidence of adverse effects.

## MATERIALS AND METHODS

The study was approved by the Institutional Ethics Committee of Pramukhswami Medical College, Karamsad (Approval No.: IEC/BU/148/Faculty/9/382/2023). Due to the retrospective nature of the study and absence of direct patient interaction, the requirement for individual informed consent was waived by the Institutional Ethics Committee.

Written informed consent was obtained from all individual participants included in the study.

**Study Design:** A randomized, double-blind, parallel-group clinical trial.

**Patient Population:** 58 adult patients, aged 18–60 years, of either sex, belonging to American Society of Anaesthesiologists (ASA) physical status I - III, scheduled for elective lower limb orthopaedic surgeries under spinal anaesthesia.

**Consent:** Written informed consent was obtained from all participants after explaining the nature of the study and anaesthetic procedure in their native language.

**Inclusion Criteria:**

- Patients undergoing spinal anaesthesia for lower limb surgery.
- 8 to 65 years old patients.
- American Society of Anaesthesiologists Physical Status grade I-III

**Exclusion Criteria:**

- Patients refusing in take part in the study
- Allergy to local anaesthetic drug & opioids
- Absolute contraindication to spinal anaesthesia Spinal deformity or infection at puncture site

**Randomization and Blinding:** Patients were randomly allocated into two equal groups (n=29 each) using a computer-generated random number table. Allocation concealment was achieved using sealed opaque envelopes. Both the patient and the anaesthesiologist assessing outcomes were blinded to group allocation. The drug solutions were prepared by an anaesthesiologist not involved in the study or data collection.

**Conduct of the Study:** All patients underwent standard preanaesthetic evaluation and routine fasting guidelines. In the operating room, baseline heart rate, non-invasive blood pressure, $SpO_2$, and ECG were recorded. Intravenous access was secured and preloading with Ringer's lactate (10 ml/kg) was done.

Under aseptic precautions, subarachnoid block was performed at the L3–L4 interspace with a Quincke spinal needle in the sitting position. Study drug solution (total volume 3 ml) was administered intrathecally over 10–15 seconds.

- Group R: 3.2 ml hyperbaric ropivacaine 0.75% + nalbuphine 1 mg (0.1 ml)
- Group L: 3.2 ml hyperbaric levobupivacaine 0.5% + nalbuphine 1 mg (0.1 ml)

Patients were positioned supine immediately after injection. Intraoperative monitoring was continued at 5-minute intervals for first 30 minutes and 15-minute intervals thereafter until the end of surgery.

**Measurements and Data Handling:**
- Sensory block: Onset time, highest dermatome achieved, duration (assessed by pinprick method).
- Motor block: Onset and duration (assessed using Modified Bromage Scale).
- Hemodynamics: Heart rate, systolic/diastolic/mean arterial pressure, $SpO_2$.
- Analgesia: Time to first request for rescue analgesia (defined as VAS ≥ 4).
- Adverse effects: Hypotension, bradycardia, nausea, vomiting, pruritus, respiratory depression.

**Sample Size Calculation:** In absence of reliable regional estimates of 0.75% hyperbaric ROPIVACAINE and 0.5 % hyperbaric LIVOBUPIVACAINE with NALBUPHINE, considering moderate effect size 0.7, study require 29 patients in each group to achieve 80% power allowing for 5 % type I error.

**Statistical Analysis:** The analyses will perform using STATA (14.2). Descriptive statistics [Frequency (%), Mean (SD)] will be used to portray the baseline profile of the study population. Independent sample t-test will be used to compare two groups of continuous variables like Incidence of hypo-tension, bradycardia and hypoxia intraoperative. Chi-square test will be used to compare the dose impact in case of categorical variables like incidence of Bradycardia, Hypotension, Respiratory depression, Pruritus, Nausea and Vomiting.

## RESULTS

A total of 58 patients were enrolled and randomized equally into two groups (n=29 each). All patients completed the study and were included in the analysis.

**Demographic and Baseline Characteristics:** Both groups were comparable with respect to demographic variables (age, sex, weight, height), ASA physical status, and duration of surgery. Baseline hemodynamic parameters were also comparable (p>0.05).

**Sensory Block Characteristics:** Comparison of Mean Sensory Onset Time The onset of sensory block at T10 dermatome was significantly faster in the Levobupivacaine group (mean 4.14 ± 1.24 min) compared to the Ropivacaine group (mean 5.10 ± 0.98 min; p < 0.01). (Table 1) The maximum dermatome level achieved was similar between groups. Comparison of Duration of Motor Block: The duration of motor block was significantly longer in the Levobupivacaine group (mean 298.28 ± 15.60 min) compared to the Ropivacaine group (mean 252.93 ± 15.90 min; p < 0.0001). (Table 2)

**Comparison of Rescue Analgesia Time:** The time to first request for rescue analgesia was significantly prolonged in the Levobupivacaine group (mean 246.90 ± 20.85 min) compared to the Ropivacaine group (mean 209.83 ± 8.91 min; p < 0.0001). (Table 3)

**Hemodynamics and Adverse Effects:** Hemodynamic parameters (heart rate, blood pressure, $SpO_2$) remained stable and comparable between groups throughout surgery (p>0.05). Incidence of side effects was minimal and similar in both groups. Two cases of hypotension occurred in each group. No episodes of bradycardia, urinary retention, nausea, vomiting, pruritus, or respiratory depression were observed.

**TABLE – 1**

| Group | Mean ± SD | 95% Confidence Interval | p-value |
|---|---|---|---|
| Group L | 4.14 ± 1.24 | 3.67 – 4.61 | 0.0018 |
| Group R | 5.10 ± 0.99 | 4.73 – 5.48 | |

**TABLE – 2**

| Group | Mean Duration (minutes) ± SD | 95% Confidence Interval | p-value |
|---|---|---|---|
| L | 298.28 ± 15.60 | 292.34 – 304.21 | <0.0001 |
| R | 252.93 ± 15.90 | 246.88 – 258.98 | |

**TABLE – 3**

| Group | Mean Time (minutes) ± SD | 95% Confidence Interval | p-value |
|---|---|---|---|
| L | 246.90 ± 20.85 | 238.97 – 254.83 | <0.0001 |
| R | 209.83 ± 8.91 | 206.44 – 213.22 | |

## DISCUSSION

The present study compared the intraoperative efficacy and postoperative analgesic effects of intrathecal hyperbaric ropivacaine and hyperbaric levobupivacaine, each combined with nalbuphine, in patients undergoing elective lower limb surgeries. The main findings were that levobupivacaine produced a significantly faster onset of sensory block, longer duration of motor block, and prolonged postoperative analgesia compared to ropivacaine, while both groups demonstrated stable hemodynamics and minimal side effects.

Our results showed that the onset of sensory block was significantly faster with levobupivacaine (4.14 ± 1.24 min) compared to ropivacaine (5.10 ± 0.98 min, p < 0.01). This observation can be attributed to the pharmacological profile of levobupivacaine, a pure S(-) enantiomer of bupivacaine, with higher lipid solubility and lower pKa allowing faster penetration into nerve fibers [9,10]. Similar findings were reported by Bajwa et al. and McNamee et al., who also observed a relatively rapid onset with levobupivacaine compared to other long-acting local anaesthetics.

The duration of motor block was significantly longer with levobupivacaine (298.28 ± 15.60 min) compared to ropivacaine (252.93 ± 15.90 min, p < 0.0001). This finding is consistent with the results of Cline et al., who demonstrated prolonged motor and sensory block with levobupivacaine relative to Ropivacaine[11]. While longer motor block may be advantageous in surgeries requiring prolonged immobilization, ropivacaine may still be preferable in ambulatory or day-care surgeries where early ambulation is desirable due to its differential block favouring sensory over motor fibers.

Postoperative analgesia, measured as time to first rescue analgesia, was significantly better in the levobupivacaine group (246.90 ± 20.85 min) compared to the ropivacaine group (209.83 ± 8.91 min, p < 0.0001). This observation is consistent with previous studies by Gupta et al. and others, who reported that levobupivacaine provides more prolonged sensory analgesia[12]. The addition of nalbuphine contributed to prolonged postoperative pain relief in both groups. Nalbuphine, a kappa-agonist and partial mu-antagonist, has been shown to enhance spinal analgesia with fewer side effects compared to morphine or fentanyl.

Hemodynamic parameters remained stable in both groups, with only two cases of hypotension observed in each, which were easily managed. No episodes of bradycardia, nausea, vomiting, urinary retention, or pruritus were reported. These findings confirm the favourable safety profile of both agents when combined with nalbuphine.

The present study adds to existing knowledge by providing direct comparative data between hyperbaric ropivacaine and hyperbaric levobupivacaine, each combined with nalbuphine. While both are effective and safe, levobupivacaine appears to offer advantages in terms of block duration and analgesic effect. Clinically, the choice may be guided by surgical requirements: levobupivacaine is more suitable when prolonged block is desirable, while ropivacaine may be preferable for procedures where early mobilization is required.

## STRENGTHS AND LIMITATIONS:

The study was prospective, randomized, and double-blind, enhancing its reliability. However, limitations include the relatively small sample size and restriction to ASA I–III patients, which may limit generalizability to high-risk populations. Long-term outcomes, such as late complications or chronic pain, were not assessed.

**Future Directions:**

Further large-scale, multicentre trials including high-risk patients and

varied surgical populations are warranted to confirm these findings. Comparative cost-effectiveness analysis of ropivacaine and levobupivacaine may also provide clinically relevant insights.

## CONCLUSIONS

Both hyperbaric ropivacaine and hyperbaric levobupivacaine, when combined with nalbuphine intrathecally, are effective and safe for spinal anaesthesia in lower limb surgeries. Levobupivacaine offers faster onset, longer block duration, and superior postoperative analgesia, whereas ropivacaine may be advantageous when early ambulation is required.

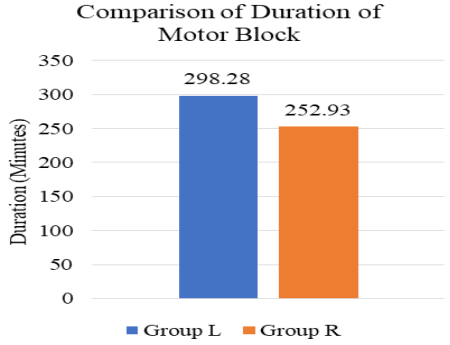


**Figure 1: Comparison of Mean Sensory Onset Time**

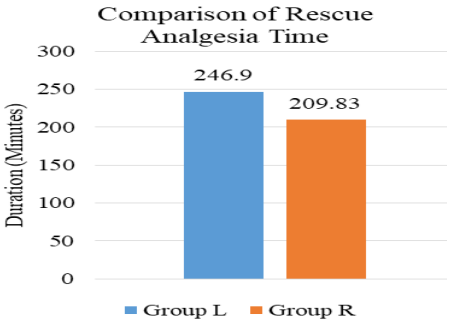


**Figure 2: Comparison of Duration of Motor Block**

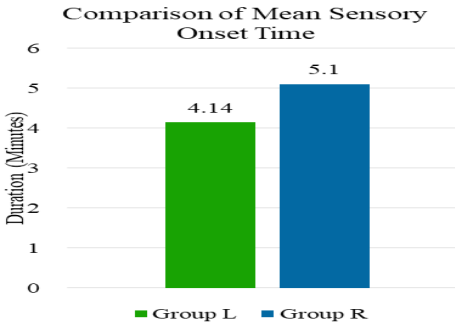


**Figure 3: Comparison of Rescue Analgesia Time**

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The authors declare no conflicts of interest related to this study.

Nil.

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