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Comparison Of Efficacy Of Hyperbaric Ropivacaine 0.75% With Hyperbaric Levobupivacaine 0.5% In Subjects Undergoing Lower Limb Orthopaedic Surgeries Under Spinal Anaesthesia - A Randomised Control Study

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Abstract

Background: *Spinal anaesthesia, also known as a subarachnoid block (SAB), is a specialized technique for achieving regional anaesthesia by administering anaesthetic agents into the cerebrospinal fluid for pain management and muscle relaxation of below-umbilical surgical procedures. While hyperbaric bupivacaine is commonly used, levobupivacaine and ropivacaine are being preferred due to their lower cardio-neuro toxicity as compared to bupivacaine.*

Objective: *This study was conducted to compare the efficacy of hyperbaric Ropivacaine 0.75% and hyperbaric Levobupivacaine 0.5% under spinal anaesthesia for elective orthopaedic lower limb procedures.*

Method: *A randomized study was conducted between two groups of thirty ASA 1 & 2 patients each, aged 18 to 55 years, who underwent lower limb orthopaedic procedures at Adichunchanagiri hospital. Group A received 3cc of intrathecal hyperbaric Ropivacaine 0.75% and Group B received 3cc of intrathecal hyperbaric Levobupivacaine 0.5%. The time of onset and duration of sensory and motor blockade were compared along with intraoperative hemodynamic parameters.*

Results: *The mean time for the onset of sensory and motor blockade was significantly faster in Group B compared to Group A patients ($p<.005$). The mean time for regression of sensory blockade by two segments from peak sensory level in Group B was higher than in Group A ($p<0.05$). The mean duration of motor blockade and analgesia in Group B was interpreted to be higher than in Group A ($p<0.05$). The observations like mean heart rate, systolic blood pressure, and diastolic blood pressure showed statistically significant differences between Group A and Group B.*

Conclusion: *It has been shown that 3cc of intrathecally administered 0.75% hyperbaric ropivacaine and 0.5% hyperbaric levobupivacaine provide clinically acceptable anaesthesia for elective lower limb orthopaedic procedures. Compared to hyperbaric levobupivacaine, hyperbaric ropivacaine shows stable hemodynamic. Group B has an earlier onset of sensory and motor blockade, a longer duration of sensory blockade, motor blockade than Group A, and both have sufficient postoperative analgesia at an equipotent dose.*

Key words: *0.5% hyperbaric levobupivacaine, 0.75% hyperbaric ropivacaine, cardiovascular stable, lower limb orthopaedic surgeries, spinal anaesthesia.*

INTRODUCTION:

Spinal anaesthesia has a rich history dating back to the late 19th century. J. Leonard Corning performed the first spinal anaesthesia in 1885 by unintentionally injecting cocaine into the subarachnoid space. August Bier then performed the first planned spinal anaesthetic on a human on August 16, 1898, using
0.5% cocaine. Ropivacaine, an amide local anaesthetic chemically analogous to bupivacaine, is a notable advancement in the field, introduced as a safer alternative due to its lower cardiotoxicity on a milligram basis [1,2]. Spinal ropivacaine demonstrates reduced potency [3,4,5], potentially facilitating more dependable spinal anaesthesia with a shorter recovery duration [6]. This prospective profile, along with a reduced motor block intensity, may render ropivacaine particularly appropriate for outpatient use [7].

Levobupivacaine is a highly potent, long-acting local anaesthetic with a rather gradual onset of action [8,9]. Studies show that levobupivacaine possesses comparable potency but a reduced risk of cardiovascular and central nervous system toxicity relative to bupivacaine [8,9,10]. The quality of anaesthesia, features of sensory and motor

block, and hemodynamics in patients undergoing lower abdominal procedures following hyperbaric or isobaric levobupivacaine are of significant interest [11,12].

2. Aim and Objectives of the Study

The primary aim was to evaluate the efficacy of Hyperbaric Ropivacaine Hydrochloride 0.75% and Hyperbaric Levobupivacaine hydrochloride 0.5% in subjects undergoing lower limb orthopaedic surgeries under spinal anaesthesia.

The specific objectives were to determine:

1. Onset of sensory blockade (T10).
2. Onset of motor blockade.
3. Time to attain maximum sensory level (T6).
4. Time for two-segment regression of sensory level.
5. Duration of sensory blockade and motor blockade.
6. Hemodynamic changes (e.g., heart rate, blood pressure).
7. Side effects, if any.

3. METHODOLOGY

Study Design and Duration: This was a randomized, double-blind study conducted over 18 months from June 2023 to November 2024.

Source of Data and Sample Size: A total of **60 patients** (30 per group) were included.

Inclusion criteria: Patients of both sexes, aged 18-55 years, with ASA physical status I and II, undergoing lower limb orthopaedic surgeries of less than 3 hours under spinal anaesthesia, and who provided written informed consent.

Exclusion criteria: Subjects unwilling to consent, with known hypersensitivity to the drugs, local pathology at the block site, contraindications for spinal anaesthesia, receiving certain medications (MAO inhibitors, Phenothiazines, Tricyclic antidepressants, anticongulants), pregnant or lactating females, and those with ASA physical status III & IV.

Groups:

Group A: Received 0.75% Hyperbaric Ropivacaine.

Group B: Received 0.5% Hyperbaric Levobupivacaine.

Data Collection and Procedures:

Patients were randomly allocated to groups using a slips-in-a-box technique. Baseline vitals (HR, NIBP, SPO2) were recorded. Spinal anaesthesia was performed with a 25-gauge Quincke spinal needle at the L3-L4 interspace. The following parameters were measured by a blinded observer:

Onset and Duration of Sensory Block: Assessed by the pinprick method, noting the time to reach T10 and the duration of the block.

Onset and Duration of Motor Block: Assessed using the Bromage Scale.

Hemodynamics: HR, NIBP, and MAP were monitored at regular intervals.

Adverse Effects: Nausea, vomiting, hypotension, and bradycardia were noted.

Statistical Analysis: Data was analyzed using MS Excel and SPSS. An independent t-test was used for quantitative variables and a Chi-square test for qualitative variables. A p-value < 0.05 was considered statistically significant.

4. RESULTS

1. Demographic and Physical Status Distribution

The study found no statistically significant differences in age, gender, or ASA physical status between the two groups. This is a crucial finding, as it ensures that the groups were comparable at the start of the study, and any observed differences in efficacy can be attributed to the anaesthetic drugs themselves.

2. Onset and Duration of Sensory and Motor Blockade

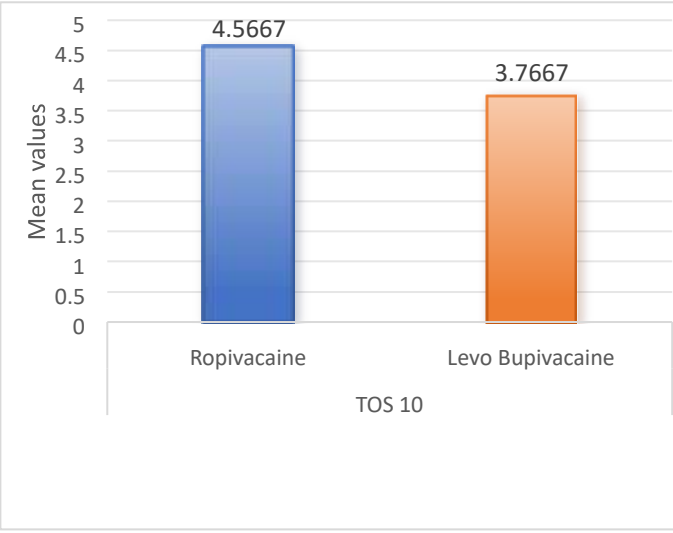
The study revealed statistically significant differences in the onset and duration of the anaesthetic effects between the two groups.

- **Time of Onset of Sensory Block:** The onset of the sensory block at level T10 was significantly faster in the Levobupivacaine group (Group B) with a mean time of **3.766 minutes** compared to the Ropivacaine group (Group A) with a mean time of **4.566 minutes** ($p<0.001$). This data is presented in **Table 1** and **Graph No. 1**

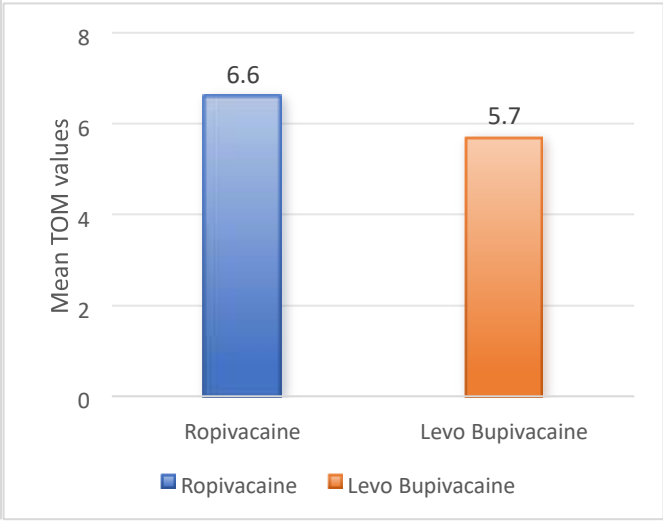
- **Time of Onset of Motor Block:** The onset of motor block was also significantly faster in Group B, with a mean time of **5.7 minutes** compared to **6.6 minutes** in Group A (p<0.001). **Table 1** and **Graph No. 2** detail this finding.
- **Time to Attain Maximum Sensory Level:** Group B achieved its peak sensory level (T6) significantly faster than Group A, with a mean time of **9.96 minutes** versus **11.1 minutes** respectively (p=0.00).
- **Time for Two-Segment Regression of Sensory Level:** Interestingly, Group A showed a faster regression of the sensory block by two segments with a mean time of **101 minutes** compared to **107.1667 minutes** for Group B (p=0.001).
- **Duration of Sensory Blockade:** The Levobupivacaine group (Group B) had a significantly longer duration of sensory blockade, with a mean of **230.1667 minutes** compared to **214.5 minutes** for the Ropivacaine group (Group A), as shown in **Table 1** and **Graph No. 3** (p=0.000).
- **Duration of Motor Blockade:** The motor block also lasted significantly longer in Group B, with a mean duration of **181.83 minutes** compared to **170.33 minutes** in Group A (p=0.000), as shown in **Table 1** and **Graph No. 4**.

Table 1: Comparison of parameters between two groups

Parameter	Group A (Ropivacaine) Mean ± SD (minutes)	Group B (Levobupivacaine) Mean ± SD (minutes)	p-Value
Onset of Sensory Block (T10)	4.5667 ± 0.50401	3.7667 ± 0.43018	<0.001
Onset of Motor Block	6.6 ± 0.93218	5.7 ± 0.46609	<0.001
Time to Max Sensory Level (T6)	11.1 ± 0.92289	9.9667 ± 0.66868	0.000
Two-Segment Sensory Regression	101 ± 6.74665	107.1667 ± 6.90868	0.001
Duration of Sensory Blockade	214.5 ± 10.69563	230.1667 ± 17.97907	0.000
Duration of Motor Blockade	170.33 ± 8.89918	181.83 ± 13.16234	0.000



GRAPH NO. 1: ONSET OF SENSORY BLOCKADE BLOCK



GRAPH NO. 2: ONSET OF MOTOR

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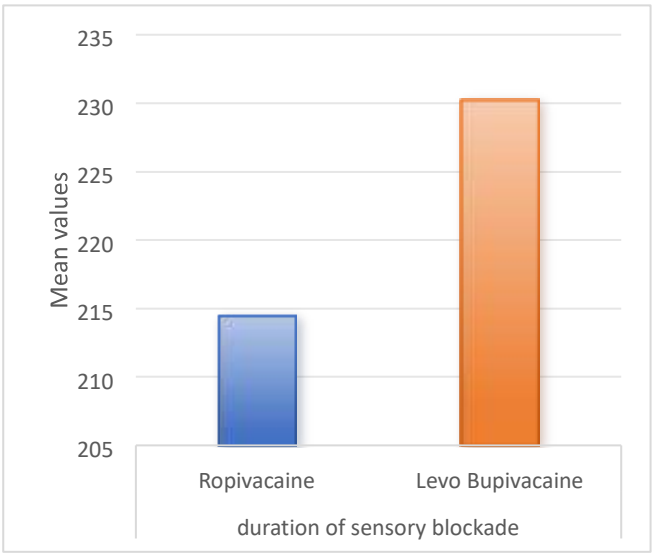
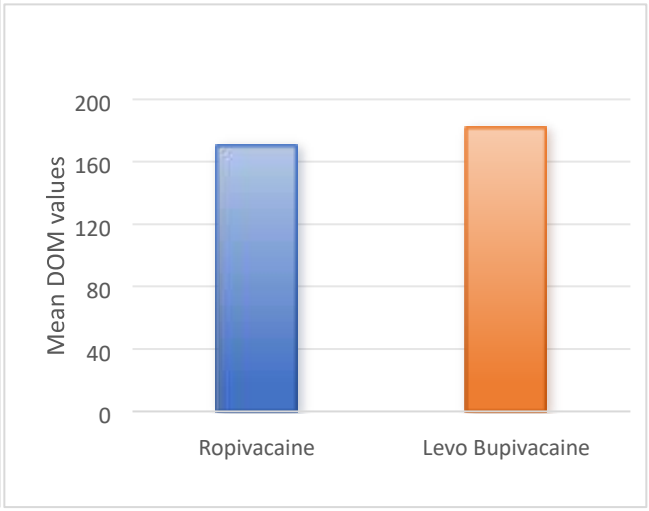


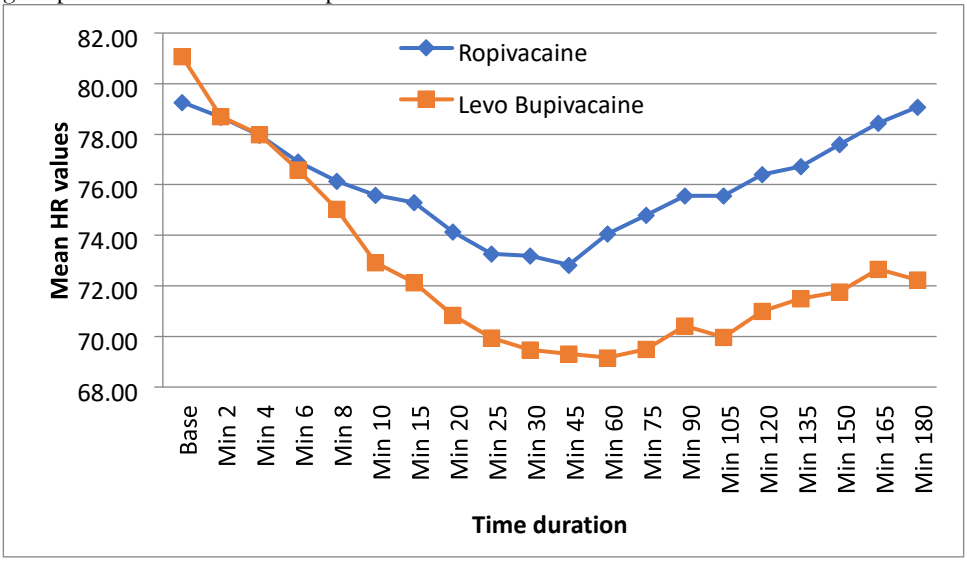


GRAPH NO. 3: DURATION OF SENSORY BLOCKADE GRAPH NO. 4: DURATION OF MOTOR BLOCK

3. Comparison of Vital Parameters

The vital parameters showed significant differences between the two groups, particularly concerning hemodynamic stability.

Heart Rate (HR): The heart rate showed statistically significant differences between the groups, especially after 60 minutes, where the Ropivacaine group maintained a higher mean HR compared to the Levobupivacaine group. This is visible in Graph **No. 5**.



GRAPH NO. 5: HEART RATE

Blood Pressure (BP): For Systolic Blood Pressure (SBP), the two groups were similar initially, but a statistically significant difference ($p<0.001$) emerged after the 8-minute mark, with Group A maintaining a more stable mean SBP as demonstrated in Graph **No. 6**. Similarly, for Diastolic Blood Pressure (DBP), statistically significant differences were noted starting at the 6-minute mark ($p<0.046$), with Group A's mean DBP remaining more stable. This is shown in **Table 16** and **Graph No. 7**. The Mean Arterial Pressure (MAP) also showed a similar pattern; while the values for both groups remained within the normotensive range, the Ropivacaine group's MAP was consistently higher and the difference between the groups became statistically significant after the 4-minute mark ($p<0.022$). This data is available in **Graph No. 8**. This overall data suggests that while both drugs are effective, ropivacaine provides a more stable hemodynamic profile.

Respiratory Rate (RR) and SpO2: There were no statistically significant differences in respiratory rate or oxygen saturation (SpO2) between the two groups at any point during the study ($p > 0.05$). This indicates that both anaesthetics maintained stable respiratory function and oxygen levels.

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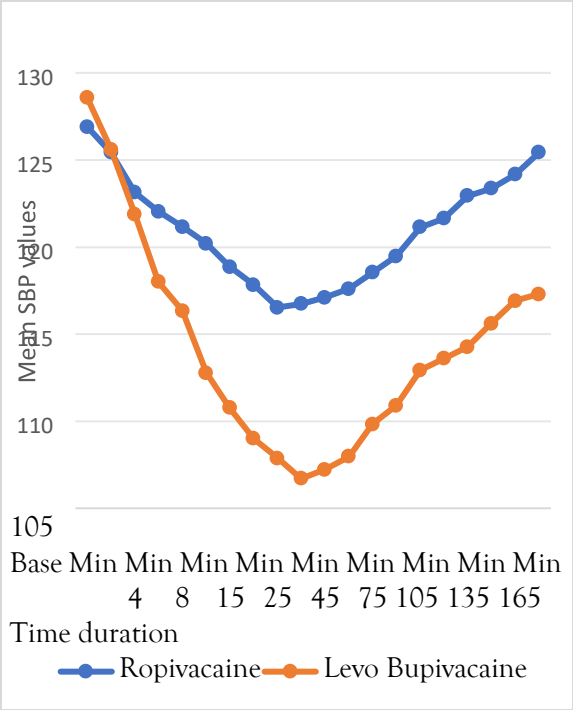
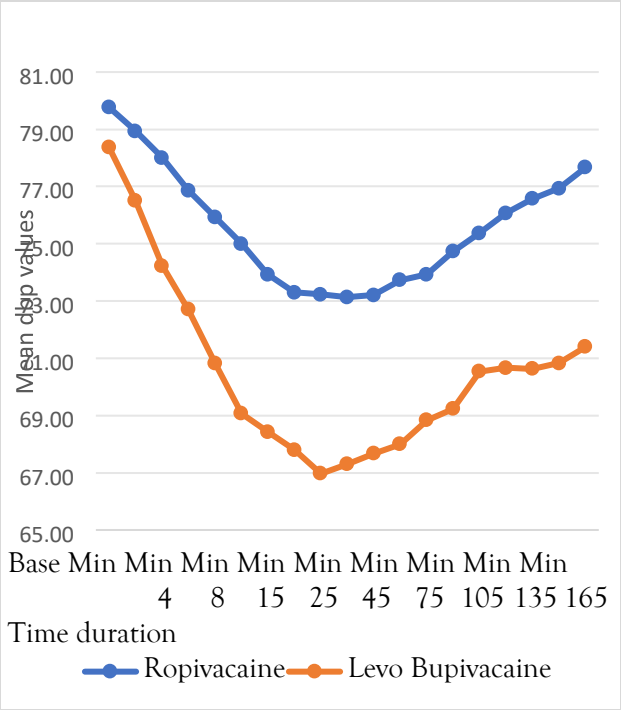
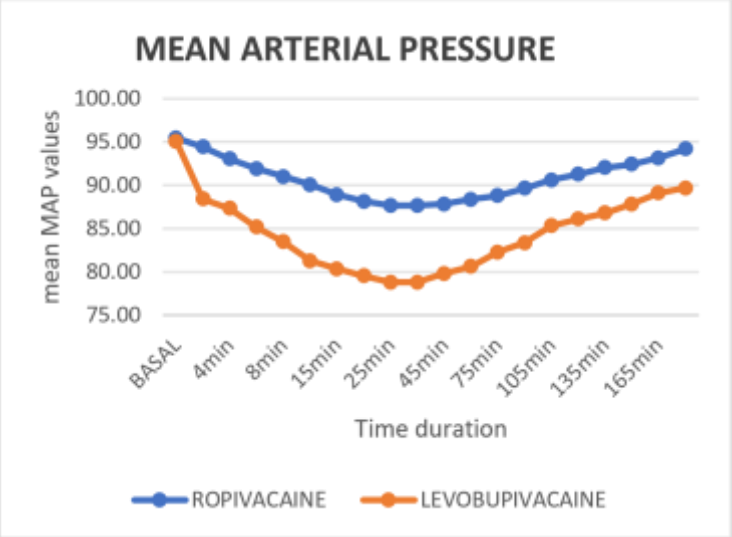


GRAPH NO. 6: SYSTOLIC BLOOD PRESSURE



GRAPH NO. 7 DIASTOLIC BLOODPRESSURE



GRAPH NO. 8: MEAN ARTERIAL PRESSURE

5. DISCUSSION

Spinal anaesthesia is a preferred technique for infraumbilical surgeries due to its ability to provide adequate pain management and muscle relaxation while avoiding the adverse effects associated with general anaesthesia. This study aimed to compare the efficacy and safety of intrathecal hyperbaric 0.75% ropivacaine and 0.5% levobupivacaine, which are considered equipotent and cardio-stable alternatives to bupivacaine.

Demographic and Baseline Characteristics

Our findings confirmed that there were no statistically significant differences between the two study groups concerning age, gender, and ASA physical status. This ensures that the groups were comparable at the start, and the observed effects can be directly attributed to the anaesthetic agents. These results are consistent with a previous study by Haque et al. [13]. ***Onset and Duration of Blockade***

Consistent with previous research by Haque et al. [13], Priyanka Samar et al. [14], and Alpha M Patel et al. [15], our findings indicate that hyperbaric levobupivacaine demonstrated a significantly faster onset of sensory block (T10) compared to ropivacaine (mean 3.766 minutes vs. 4.566 minutes, $p<0.001$). Similarly, levobupivacaine also showed a more rapid onset of motor blockade (mean 5.7 minutes vs. 6.6 minutes, $p<0.001$), aligning with observations from studies such as Mantouvalou et al. [11], who noted levobupivacaine's motor block onset was

comparable to bupivacaine and faster than ropivacaine. The quicker onset characteristic of levobupivacaine could translate to reduced preparation time in the operating room, potentially enhancing surgical workflow efficiency.

Regarding the time to attain maximum sensory level, Group B (levobupivacaine) achieved this significantly faster than Group A (ropivacaine) (mean 9.96 minutes vs. 11.1 minutes, p=0.000). This result is in line with the findings of Yadav et al. [16]. However, some studies, like that by Manazir et al. [17], reported contrasting results, while Priyanka Singh et al. [18] found no significant difference, highlighting the variability in literature.

In terms of block duration, the two-segment regression of sensory level was found to be faster in the ropivacaine group (mean 101 minutes) compared to the levobupivacaine group (mean 107.1667 minutes), with a statistically significant difference (p=0.001). This aligns with studies by Priyanka Singh et al. [18], J.F. Luck et al. [19], Alpa M. Patel et al. [15], and Yadav et al. [16]. Furthermore, the total duration of sensory blockade was significantly longer in the levobupivacaine group (mean 230.1667 minutes) compared to the ropivacaine group (mean 214.5 minutes, p=0.000). Similarly, the total duration of motor blockade was also significantly longer with levobupivacaine (mean 181.83 minutes) compared to ropivacaine (mean 170.33 minutes, p=0.000). The longer duration of sensory and motor blockade with levobupivacaine observed in our study is in agreement with findings from Manazir et al. [17], Haque et al. [13], and Kanta Bhati et al. [20]. This prolonged analgesia provided by levobupivacaine could potentially delay the need for postoperative analgesics, contributing to enhanced patient comfort. While a longer duration of motor block might delay ambulation, ropivacaine's shorter motor blockade is advantageous for early mobilization and thus reduces the risk of venous thromboembolism. ***Hemodynamic Parameters***

Hemodynamic stability is a critical consideration in spinal anesthesia. Our study found statistically significant differences in heart rate, systolic blood pressure, diastolic blood pressure, and mean arterial pressure between the two groups over most time intervals, with ropivacaine generally showing more sustained hemodynamic levels. Specifically, ropivacaine demonstrated greater hemodynamic stability compared to levobupivacaine, leading to a numerically lesser incidence of bradycardia and hypotension in the ropivacaine group. This finding is supported by research from Manazir et al. [17], Priyanka Oraon et al. [21], and Srinivas et al. [22], who also reported less hypotension with intrathecal ropivacaine. Mantouvalou et al. [11] further highlighted that both agents are hemodynamically more stable than bupivacaine. While some studies, such as those by Priyanka Samar et al. [14] and Alpa M. Patel et al. [15], contradict these findings by suggesting levobupivacaine is more stable, our data support ropivacaine's superior hemodynamic profile in this cohort. Both drugs, however, maintained mean arterial pressure values within the normotensive range. No statistically significant differences were observed in respiratory rate or oxygen saturation between the groups throughout the intraoperative period. Furthermore, other intraoperative parameters and adverse effects were comparable between the two groups.

A limitation of our study is the relatively small sample size, which may limit the generalizability of these findings to a broader population. Additionally, restricting the study to elective lower limb orthopedic surgeries of shorter duration might introduce a potential bias concerning the total duration of sensory blockade. Future larger-scale studies encompassing a wider range of surgical procedures and patient populations would be beneficial to further validate these observations.

6. CONCLUSION

Overall, both ropivacaine and levobupivacaine are effective alternatives to bupivacaine for spinal anaesthesia. Levobupivacaine provides a faster onset and a longer duration of sensory and motor blockade, which can delay the need for postoperative analgesia. Conversely, ropivacaine offers superior hemodynamic stability, which is a significant clinical advantage, particularly in older patients or those with comorbidities.The ability of ropivacaine to facilitate earlier ambulation and its favorable hemodynamic profile makes it a strong contender, particularly in patients with potentially unstable hemodynamics. The choice between these two agents may therefore be individualized based on specific patient characteristics, surgical requirements, and the desired balance between rapid onset/prolonged analgesia and hemodynamic stability.

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