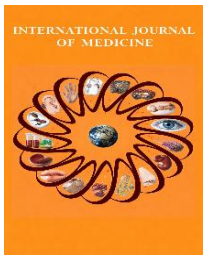

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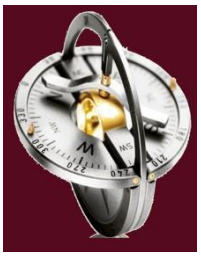

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Original Research

Comparative Clinical Evaluation of Heavy Ropivacaine vs Levobupivacaine in Lower Limb Orthopaedic Procedures

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Abstract

Background Bupivacaine, an amide-type local anesthetic, has traditionally been the agent of choice due to its long duration of action and ability to provide dense sensory and motor blockade. However, its racemic mixture is associated with notable cardiotoxicity and central nervous system toxicity, especially in inadvertent intravascular injections or overdoses. In response to these concerns, newer enantiomerically pure agents such as Ropivacaine and Levo-Bupivacaine were developed. Ropivacaine is a long-acting amide local anesthetic and the pure S(-)-enantiomer of Bupivacaine, formulated to reduce the cardiotoxic and neurotoxic risks associated with its racemic predecessor. Its pharmacodynamic properties include a strong sensory blockade with relatively less intense motor block, making it ideal for procedures where early ambulation is desired. ***Materials & Methods*** This prospective, randomized, double-blinded, comparative clinical study was conducted in the Department of Anesthesiology at Shadan Institute of Medical Sciences, Teaching Hospital, and Research Center, Hyderabad, Telangana over a period of 1 year. To evaluate and compare the efficacy of intrathecal 0.75% hyperbaric Ropivacaine and 0.5% hyperbaric Levo-Bupivacaine in patients undergoing elective orthopedic lower limb surgeries under spinal anesthesia. Standard anesthetic equipment, monitoring devices (ECG, pulse oximeter, NIBP monitor), spinal needles (23G Quincke), and resuscitative drugs (Atropine, Mephentermine, Oxygen) were used throughout the study. ***Results*** In the present study, the mean age in Group R was 1.87 ± 0.89 and in Group L was 2.57 ± 1.07, suggesting a relatively younger patient profile in the Ropivacaine group. The gender distribution, also appearing as coded data, showed a mean of 1.27 ± 0.45 in Group R and 1.33 ± 0.47 in Group L, indicating a nearly equal male-to-female ratio across both groups. The mean VAS score in Group R (Ropivacaine) was 5.63 ± 1.90, while in Group L (Levo-Bupivacaine) it was 5.77 ± 1.52. In Group R (Ropivacaine), the mean duration of analgesia was 280.0 ± 22.2 minutes, whereas in Group L (Levo-Bupivacaine), it was 340.0 ± 29.24 minutes. In Group R (Ropivacaine), the mean motor block duration was 217.3 ± 22.61 minutes, while in Group L (Levo-Bupivacaine), it was 254.0 ± 21.51 minutes. ***Conclusion*** Levo-bupivacaine was associated with a faster onset of sensory block, prolonged duration of analgesia, and a more sustained motor block, making it a suitable choice for longer surgical procedures and enhanced postoperative pain control. Conversely, ropivacaine provided adequate surgical anesthesia with a shorter duration of motor block and quicker two-segment regression, supporting its use in ambulatory settings and in procedures where early postoperative mobilization is desired.

Keywords: *Bupivacaine, Ropivacaine, Levo-Bupivacaine, surgical anesthesia.*

Introduction

INTRODUCTION

Regional anesthesia, particularly spinal anesthesia, has become the technique of choice for a wide range of orthopedic lower limb surgeries due to its favorable safety profile, effective intraoperative analgesia, and improved postoperative outcomes. Spinal anesthesia offers several advantages over general anesthesia, including reduced intraoperative blood loss, minimal airway manipulation, decreased risk of postoperative respiratory complications, and early postoperative mobilization, which is crucial in orthopedic rehabilitation. 1 The technique allows for a rapid onset of action, predictable block height, and excellent muscle relaxation, facilitating various procedures such as open reduction and internal fixation, total knee arthroplasty, and tibial or femoral nailing.2 Moreover, spinal anesthesia significantly reduces the need for systemic opioids, thereby lowering the incidence of opioid-related adverse effects such as nausea, vomiting, and respiratory depression.3

The selection of local anesthetic agents for spinal anesthesia has undergone significant evolution, primarily driven by the need to improve the safety and efficacy of neuraxial blockade. Bupivacaine, an amide-type local anesthetic, has traditionally been the agent of choice due to its long duration of action and ability to provide dense sensory and motor blockade. However, its racemic mixture is associated with notable cardiotoxicity and central nervous system toxicity, especially in inadvertent intravascular injections or overdoses.4 In response to these concerns, newer enantiomerically pure agents such as Ropivacaine and Levo-Bupivacaine were developed. These agents offer a more favorable pharmacological and safety profile with reduced affinity for cardiac sodium channels, thus lowering the risk of arrhythmias and seizures.5 The introduction of hyperbaric preparations has further enhanced the predictability and efficacy of spinal anesthesia by controlling drug spread within the cerebrospinal fluid based on Baricity.6

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Ropivacaine is a long-acting amide local anesthetic and the pure S(-)-enantiomer of Bupivacaine, formulated to reduce the cardiotoxic and neurotoxic risks associated with its racemic predecessor. Its pharmacodynamic properties include a strong sensory blockade wi th relatively less intense motor block, making it ideal for procedures where early ambulation is desired.7 Ropivacaine has a lower lipid solubility compared to Bupivacaine, contributing to its reduced penetration into myelinated motor fibers and preferential action on sensory nerves.8 The hyperbaric formulation of 0.75% Ropivacaine, achieved by adding dextrose, offers improved control over the level and duration of anesthesia during spinal administration. It has shown good hemodynamic stability, rapid clearance, and reduced systemic toxicity, thereby making it a suitable agent for day-care orthopedic surgeries and patients with cardiovascular risk factors.9 Clinical studies have demonstrated that Ropivacaine provides effective anesthesia with fewer complications such as hypotension and bradycardia when compared to traditional agents.10
Levo-Bupivacaine is the S(-)-enantiomer of Bupivacaine and was developed to retain the desirable anesthetic properties of Bupivacaine while minimizing the risk of cardiotoxicity and neurotoxicity. It exhibits high protein binding and a lower affinity for myocardial and CNS sodium channels, leading to a more favorable safety profile.11 Levo-Bupivacaine produces dense sensory blockade with an intermediate degree of motor blockade, which is often considered adequate for orthopedic surgeries without significantly delaying postoperative mobilization. The 0.5% hyperbaric formulation ensures a reliable cephalad spread of the anesthetic agent when administered intrathecally, thereby enhancing its predictability and efficacy during surgery.12 Studies have shown that Levo-Bupivacaine offers longer-lasting sensory and motor block compared to Ropivacaine, making it a preferred choice in prolonged lower limb procedures where sustained intraoperative and postoperative analgesia is desired.13 Additionally, it maintains stable intraoperative hemodynamics and exhibits minimal adverse effects, supporting its role as a safe and effective alternative to racemic Bupivacaine.14

Materials and Methods

This prospective, randomized, double-blinded, comparative clinical study was conducted in the Department of Anesthesiology at Shadan Institute of Medical Sciences, Teaching Hospital, and Research Center, Hyderabad, Telangana over a period of 1 year. To evaluate and compare the efficacy of intrathecal 0.75% hyperbaric Ropivacaine and 0.5% hyperbaric Levo-Bupivacaine in patients undergoing elective orthopedic lower limb surgeries under spinal anesthesia.

Inclusion Criteria

i. Patients aged 18 to 65 years.
ii. ASA physical status I or II.
iii. Scheduled for elective orthopedic lower limb surgery.
iv. Willing to provide informed written consent.

Exclusion Criteria

i. Known hypersensitivity to amide local anesthetics.
ii. Coagulation disorders or anticoagulant therapy.
iii. Local infection at the site of injection.
iv. History of chronic back pain or spinal deformities.
v. Neurological or psychiatric illness.
vi. Cardiovascular, renal, or hepatic dysfunction.

Materials

Standard anesthetic equipment, monitoring devices (ECG, pulse oximeter, NIBP monitor), spinal needles (23G Quincke), and resuscitative drugs (Atropine, Mephentermine, Oxygen) were used throughout the study.

Methodology

Preoperative evaluation included history taking, physical examination, and standard pre-anesthetic investigations. All patients were premedicated with intravenous ondansetron 4 mg and ranitidine 50 mg. Spinal anesthesia was administered in the sitting position at the L3-L4 or L4-L5 interspace using a 23G spinal needle via a midline approach. After confirming the free flow of cerebrospin al fluid, the study drug was injected intrathecally over 10–15 seconds.
Hemodynamic parameters (heart rate, systolic and diastolic blood pressure, SpO_2) and sensory and motor block characteristics were assessed at regular intervals intraoperatively and postoperatively. Sensory block was assessed using a pinprick method, and motor block was evaluated using the Bromage scale.

Study Tool

A structured proforma was used to collect data regarding demographic details, block characteristics, hemodynamic parameters , duration of analgesia, and any adverse effects.

Group Allocation

Patients were randomized into two groups using the chit-and-box method:
1. Group R (n=30): Received 3.5 mL of 0.75% hyperbaric Ropivacaine + 0.1 mL saline (total 3.6 mL).
2. Group L (n=30): Received 3.5 mL of 0.5% hyperbaric Levo-Bupivacaine + 0.1 mL saline (total 3.6 mL).

Parameters to be assessed

i. Total duration of analgesia
ii. Visual analogue scales (VAS) at first analgesia.
iii. Total duration of motor blockade
iv. Time to start regression of analgesia by 2 segments.

Demographic data

The data was collected in a case record form (CRF) designed for the study. Patient name, age, gender, address, contact details, height, weight, post-operative records.
a. Total duration of analgesia
b. Visual analogue scales (VAS) at first analgesia.
c. Total duration of motor blockade
d. Time to start regression of analgesia by 2 segments.
Duration of surgery and Hemodynamic parameters were collected.

Statistical Analysis

Data was analyzed using SPSS software (version 20.0). Descriptive statistics (mean, standard deviation, percentages) were used for demographic and clinical characteristics. Comparative statistics were applied: Student's t-test for continuous variables. p values $<0.05^*$ were considered statistically significant.

RESULTS

Table 1: Demographic and clinical characteristics of the study groups

Variables	Group R (Ropivacaine) (n=30)	Group L (Levo-Bupivacaine) (n=30)
	Mean±SD	Mean±SD
Age (18 - 65 years)	1.87±0.89	2.57±1.07
Gender (M/F)	1.27±0.45	1.33±0.47
Height (cms)	164.17±9.97	159.10±9.63
Weight (kgs)	69.37±10.20	62.83±9.80
Duration of surgery (Mins)	11.79±19.51	11.90±18.74

In the present study, the mean age in Group R was 1.87 ± 0.89 and in Group L was 2.57 ± 1.07, suggesting a relatively younger patient profile in the Ropivacaine group. The gender distribution, also appearing as coded data, showed a mean of 1.27 ± 0.45 in Group R and 1.33 ± 0.47 in Group L, indicating a nearly equal male-to-female ratio across both groups. The average duration of surgery was comparable between the groups, with Group R reporting a mean duration of 11.79 ± 19.51 minutes, while Group L had a mean of 11.90 ± 18.74 minutes.

Table 2: Duration of surgery

Duration of surgery	Group R (Ropivacaine) (n=30)		Group L (Levo-Bupivacaine) (n=30)	
	Frequency (n)	Percentage (%)	Frequency (n)	Percentage (%)
45mins	06	20%	07	23.3%
1 hour	11	36.7%	12	40%
1.5 hours	13	43.3%	11	36.7%
TOTAL	30	100%	30	100%

The duration of surgery was comparable between the study groups. In Group R (Ropivacaine), 43.3% of patients underwent procedures lasting 1.5 hours, followed by 36.7% with surgeries lasting 1 hour, and 20% with a duration of 45 minutes. Similarly, in Group L (Levo-Bupivacaine), 40% of procedures lasted 1 hour, 36.7% lasted 1.5 hours, and 23.3% were completed within 45 minutes.

Table 3: Comparison of Haemodynamic parameters

Haemodynamic parameters	Group R (Ropivacaine) (n=30)		Group L (Levo-Bupivacaine) (n=30)		p value
	Initial	Final	Initial	Final	
Heart Rate (HR)	79.53±6.15	90.33±4.73	75.67±6.26	78.27±6.90	0.001*
Mean arterial pressure (MAP)	81.60±5.43	85.07±5.38	83.57±5.96	83.90±5.81	0.001*
SpO2	99.37±0.66	99.67±0.47	99.43±0.62	99.60±0.49	0.001*

In terms of heart rate (HR), Group R (Ropivacaine) showed a statistically significant increase from a mean baseline of 79.53 ± 6.15 bpm to 90.33 ± 4.73 bpm by the end of the procedure. In contrast, Group L (Levo-Bupivacaine) exhibited a more modest rise from 75.67 ± 6.26 bpm to 78.27 ± 6.90 bpm. Regarding mean arterial pressure (MAP), Group R demonstrated a rise from 81.60 ± 5.43 mmHg to 85.07 ± 5.38 mmHg, whereas Group L showed a relatively stable MAP, with initial and final values of 83.57 ± 5.96 mmHg and 83.90 ± 5.81 mmHg, respectively.

Table 4: Comparison of sensory levels

Study period	Sensory level	Group R (Ropivacaine) (n=30)		Group L (Levo-Bupivacaine) (n=30)	
		Frequency (n)	Percentage (%)	Frequency (n)	Percentage (%)
05 mins	L1	14	46.7%	18	60%
	L2	16	53.3%	12	40%
10 mins	L1	08	26.7%	15	50%
	L2	07	23.3%	05	16.7%
	T12	15	50%	10	33.3%
20 mins	T10	17	56.7%	23	76.6%
	T11	13	43.3%	07	23.3%
30 mins	T10	23	76.7%	23	76.6%
	T11	07	23.3%	07	23.3%
60 mins	T8	14	46.7%	04	13.3%
	T10	16	53.3%	26	86.7%

In table 4, at 5 minutes, the predominant level achieved in Group L (Levo-Bupivacaine) was L1 (60%), whereas Group R (Ropivacaine) showed a slightly more even distribution between L1 (46.7%) and L2 (53.3%), suggesting a marginally slower initial sensory spread with ropivacaine. By 60 minutes, the block in Group L remained primarily at T10 (86.7%), while Group R showed higher cephalad spread, with 46.7 % of patients at T8 and 53.3% at T10. This suggests that Ropivacaine may exhibit a slightly more extensive cephalad spread over time.

Table 5: Comparison of time to 1st pain medication

	Group R (Ropivacaine) (n=30)	Group L (Levo-Bupivacaine) (n=30)
Time to 1st pain medication	4.08±0.60	7.05±0.82

In the present study, patients in Group R (Ropivacaine) required their first analgesic dose at a mean duration of 4.08 ± 0.60 hours

postoperatively, whereas those in Group L (Levo-Bupivacaine) experienced a significantly longer pain-free interval, with the first analgesic requested at 7.05 ± 0.82 hours.

Table 6: Comparison of VAS score

	Group R (Ropivacaine) (n=30)	Group L (Levo-Bupivacaine) (n=30)
VAS Score	5.63±1.90	5.77±1.52

The mean VAS score in Group R (Ropivacaine) was 5.63 ± 1.90, while in Group L (Levo-Bupivacaine) it was 5.77 ± 1.52. The scores in both groups indicate moderate pain levels postoperatively, with no clinically significant difference observed between the two grou ps.

Table 7: Comparison of total duration of analgesia

	Group R (Ropivacaine) (n=30)	Group L (Levo-Bupivacaine) (n=30)
Total duration of analgesia	280.0±22.2	340.0±29.24

In Group R (Ropivacaine), the mean duration of analgesia was 280.0 ± 22.2 minutes, whereas in Group L (Levo-Bupivacaine), it was 340.0 ± 29.24 minutes.

Table 8: Comparison of total duration of Motor blockade

	Group R (Ropivacaine) (n=30)	Group L (Levo-Bupivacaine) (n=30)
Total duration of Motor blockade	217.3±22.61	254.0±21.51

In Group R (Ropivacaine), the mean motor block duration was 217.3 ± 22.61 minutes, while in Group L (Levo-Bupivacaine), it was 254.0 ± 21.51 minutes.

Table 9: Comparison of post-operative complications

Post-operative complications	Group R (Ropivacaine) (n=30)	Group L (Levo-Bupivacaine) (n=30)
Nausea/Vomiting	Nil	Nil
Sedation	Nil	Nil
Urinary retention	Nil	Nil

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DISCUSSION

In this study during the initial period of 5 to 10 minutes following administration, it was observed that Levo-bupivacaine exhibited a significantly more rapid and uniformly consistent ascent of the sensory block, achieving the T10 level in a remarkable 76 .6% of patients by the 20-minute mark, in stark contrast to the 56.7% achievement rate within the ropivacaine cohort. This finding indicates a more expedited and reliable intrathecal distribution mechanism associated with Levo-bupivacaine, thereby rendering it particularly advantageous in clinical scenarios where the prompt establishment of surgical anesthesia is of paramount importance.

By the 60-minute interval, it was noted that both pharmacological agents were able to achieve comparable block heights at the T10 level; however, it is noteworthy that ropivacaine exhibited a slightly more cephalad spread in a subset of patients, reaching up to the T8 level, which implies a slower yet persistent upward migration of the anesthetic agent within the neural structures.
In a comparative analysis of the total duration of motor blockade, it was observed that the group administered ropivacaine experienced a significantly shorter duration, quantified at an average of 217.3 minutes with a standard deviation of 22.6 minutes, as opposed to the Levo-bupivacaine group, which exhibited an average duration of 254.0 minutes with a standard deviation of 21.5 minutes; this disparity is statistically significant and underscores the pharmacological differences between these two local anesthetics. This particular finding lends credence to the extensively documented pharmacodynamic property of ropivacaine, which is known to facilitate a differential block characterized by a more pronounced and sustained sensory blockade in contrast to the relatively shorter duration of motor block, a phenomenon that is particularly beneficial in clinical scenarios where rapid postoperative mobilization is deemed essential, such as in protocols designed for enhanced recovery following surgical interventions (ERAS).15,16

The interval leading to the necessity for the initial analgesic intervention was observed to be significantly extended within the cohort administered Levo-bupivacaine, recorded at an impressive mean duration of 7.05 ± 0.82 hours, in stark contrast to the considerably shorter duration experienced by those in the ropivacaine group, which was noted to be merely 4.08 ± 0.60 hours. In a similar vein, the overall duration of analgesia experienced by participants receiving Levo-bupivacaine was markedly prolonged, quantified at 340 ± 29.24 minutes, as opposed to the 280 ± 22.2 minutes noted in the ropivacaine cohort. This notable extension of analgesic efficacy aligns seamlessly with the pharmacokinetic characteristics inherent to Levo-bupivacaine, which is distinguished by its considerable protein-binding capability and comparatively diminished systemic clearance rate, thus facilitating a more sustained sensory blockade that enhances patient c omfort post-surgery.17,18

The findings regarding the two-segment regression time served to further substantiate and elucidate the notable disparities observed in the duration of sensory block, which is a critical factor in the field of anesthesiology. Specifically, the local anesthetic agent Ropivacaine exhibited a significantly more rapid regression time, quantified at 116.6 ± 7.58 minutes, when juxtaposed with its counterpart, Levo-bupivacaine, which demonstrated a comparatively prolonged regression time of 124.6 ± 8.19 minutes; this noteworthy difference suggests a potential for an earlier resolution of the sensory block induced by Ropivacaine.

Interestingly, it is worth noting that while the administration of Levo-bupivacaine resulted in an extended duration of analgesia, the Visual Analog Scale (VAS) pain scores recorded at the time of assessment revealed a remarkable similarity between the two groups, specifically reflecting values of 5.63 ± 1.90 in Group R and 5.77 ± 1.52 in Group L, which collectively indicate that once the analgesic effect of the medication dissipated, the patients from both groups subsequently experienced comparable levels of pain intensity..

Conclusion

Levo-bupivacaine was associated with a faster onset of sensory block, prolonged duration of analgesia, and a more sustained motor block,

making it a suitable choice for longer surgical procedures and enhanced postoperative pain control. Conversely, ropivacaine provided adequate surgical anesthesia with a shorter duration of motor block and quicker two-segment regression, supporting its use in ambulatory settings and in procedures where early postoperative mobilization is desired. Hemodynamic parameters remained stable in both groups, although ropivacaine demonstrated slightly greater cardiovascular stability with less sympathetic blockade. No significant adverse effects were reported with either agent, reinforcing their favorable safety profiles when used intrathecally.

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