Student's Journal of Health Research Africa
e-ISSN: 2709-9997, p-ISSN: 3006-1059
Vol. 5 No. 3 (2024): March2024 Issue
https://doi.org/10.51168/sjhrafrica.v5i3.1147
Original Article

A RANDOMIZED INVESTIGATION INTO THE USE OF ISOBARIC LEVOBUPIVACAINE AND ROPIVACAINE FOR SPINAL ANAESTHESIA DURING ELECTIVE LOWER LIMB ORTHOPAEDIC PROCEDURES, DHANBAD, INDIA.

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ABSTRACT.

Background:
Objectives: The investigation aimed to contrast the anesthetic activity of isobaric ropivacaine and levobupivacaine in lower limb orthopedic surgeries, examining their respective onset, duration of loss of motor and sensory functioning, as well as overall safety profile.

Methods:
A randomized, double-blind investigation spanning over a year was conducted at Shahid Nirmal Mahato Medical College in Dhanbad, Jharkhand, India to contrast the effectiveness of ropivacaine and levobupivacaine in orthopedic surgeries of lower extremities among 120 ASA Class I and II adult patients. Employing a shuffled sealed envelope method, participants were categorized into two cohorts (Group R and Group L), and various parameters, such as sensory blockade, motor blockade, and changes in the hemodynamic profile, in addition to safety, were assessed.

Results:
The investigation, involving 120 patients, categorized into Group R (Ropivacaine) and Group L (Levobupivacaine) revealed no statistically significant variations in the average time taken for surgery (81.23 min vs. 73.48 min). A similar observation was noted with the average time of commencement of sensory analgesic effect after 10 minutes (6.89 min vs. 9.24 min). The analysis of the loss of sensory and motor functioning, particularly in context with the average duration needed for the maximum level of blocking sensory functioning (12.45 min vs. 16.39 min) was comparable in both cohorts. Furthermore, both groups exhibited stable hemodynamics, and neither reported common complications.

Conclusion:
The study demonstrates comparable efficacy and safety profiles between isobaric ropivacaine and levobupivacaine in lower limb orthopedic surgeries, highlighting their interchangeability for anesthesia management in such procedures.

Recommendation:
The study recommends further research exploring specific patient populations or surgical contexts to refine anesthetic choices for enhanced clinical outcomes.

Keywords: *Levobupivacaine, Ropivacaine, Spinal Anaesthesia, Lower Limb Orthopaedic Surgery*
Submitted:2024-03-26 Accepted:2024-03-28

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INTRODUCTION.

Regional anesthesia, particularly spinal anesthetics, is frequently employed in surgical procedures of the lower extremities and lower abdomen. The primary choice of drug for spinal anesthesia was bupivacaine 0.5% heavy; however, owing to its adverse impact on the neurological system and heart, alternatives like ropivacaine and levobupivacaine began to gain widespread use [1-3].

In comparison to bupivacaine, ropivacaine is a local anesthetic with lower lipophilicity and a longer duration of action, which results in diminished motor blockage [1, 2]. Levobupivacaine, an S(-) enantiomer of bupivacaine, is another promising anesthetic as it exhibits reduced cardiotoxicity and central nervous system adverse effects [3]. This enantiomer is also well-tolerated in the diverse regional anesthetic methods and shows infrequent and reversible instances of toxicity [4].

Despite the benefits of these alternative counterparts, bupivacaine continues to be widely utilized in clinical settings [4]. Patient-oriented investigations reveal no major variations in the commencement, period, as well as sensory blockade caused by these agents; nevertheless, the total recovery of sensory function is enhanced by levobupivacaine [5-7]. Evidence also shows that recovery

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of motor functions is faster when ropivacaine and levobupivacaine are used in contrast to bupivacaine [8]. There is minimal research on isobaric 0.5% levobupivacaine and isobaric 0.75% ropivacaine as spinal anesthetics in surgical procedures, particularly abdominal, orthopedic, and obstetric surgeries within the Asian demographic [9-15]. Furthermore, the existing literature predominantly concentrates on labour and epidural analgesia, besides blockage of the peripheral nerve functioning [15-18].

Acknowledging the existing gap, the present investigation aims to assess and contrast the effectiveness of isobaric levels of 0.75% ropivacaine and 0.5% levobupivacaine concerning the level, commencement, period of motor and sensory blockade, hemodynamic alterations, and safety.

MATERIALS AND METHODS.

Study design.

The study employed a randomized, double-blind design. The use of this design assisted in contrasting the effectiveness of two different local anesthetics, levobupivacaine, and ropivacaine, in individuals scheduled for orthopedic surgical procedures of the lower extremities. Various parameters relevant to the loss of motor and sensory functioning, changes in the hemodynamic profile besides safety were noted in this study.

Study setting.

The present investigation was carried out at Shahid Nirmal Mahato Medical College in Dhanbad, Jharkhand, India for a period from 2022-2023.

Study population.

This randomized investigation included 120 adult patients.

Inclusion and exclusion criteria.

Patients belonging to the ASA Class I and II, aged between 18 to 60 years, and were admitted to SNNMCH for undergoing lower extremity orthopedic surgery were included in the study. Pregnant women, emergency surgery cases, participants with a BMI > 28 kg/m², and individuals < 150 cm or > 180 cm in height, were excluded from this study. In addition, the exclusion criteria also filtered out those with a known allergic reaction to levobupivacaine or ropivacaine to avoid any mishaps.

Study size.

The investigation was carried out on 120 patients who were not allergic to the study drugs and opted for elective orthopedic surgery of the lower extremities.

Procedure.

Before the study, a pre-anesthetic checkup was performed on all the participants. All the procedures were carried out by the same anaesthesiologist for consistency, ensuring a double-blind approach to both participants and observers throughout the study.

Patient Randomization.

The study involved 120 patients who were randomized using the shuffled sealed envelope method, to result in 2 cohorts: Group L (Levobupivacaine) and Group R (Ropivacaine), with 60 participants per cohort.

Preoperative Procedures.

Following a pre-anesthetic checkup, patients were administered Alprazolam and adhered to fasting protocols. An 18-gauge cannula was used to gain intravenous access, and 30 minutes before the spinal anesthesia, the participants were preloaded with Ringer lactate solution (10 ml).

Anesthesia Administration and Monitoring.

Lumbar puncture at L3-L4 subarachnoid space was performed with a 27G Quincke spinal needle, to administer either 3ml of the local anesthetic (0.5% Levobupivacaine or 0.75% Ropivacaine) in the respective groups. The same anaesthesiologist conducted subarachnoid blocks and served as the observer, to achieve double-blinding. All patients were continuously monitored to collect data such as heart rate, ECG, pulse oximetry, and NIBP.

Sensory and Motor Blockade Assessment.

Blockage of sensory functioning was evaluated by the pinprick method, while the Modified Bromage scale was employed to identify the grade of motor blockade. As per this scale, normal motor functioning was denoted by grade 0 while total loss of motor functioning was denoted by grade 4. Parameters recorded included the commencement of loss of motor and sensory functioning, two-segment sensory regression time, maximum grade of motor function loss, the total period of analgesia, and the period of loss of motor function.

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Postoperative Monitoring.

Post-surgery, the hemodynamic parameters, adverse effects (vomiting, nausea, hypersensitivity reactions, pruritus), and complete recovery of motor and sensory functioning of all participants were rigorously monitored.

Bias.

Selection bias arose in this investigation as a result of the exclusion criteria, potentially limiting the generalizability of findings. Additionally, performance bias may also have arisen as the same anaesthesiologist performed both subarachnoid blocks and observed the study, introducing a potential source of bias.

Ethical consideration.

All the ethical protocols were strictly followed in this study after getting approval from the Institutional Review Board. The participants were informed about the procedure and proper written consent was acquired before commencing the investigation.

Statistical Analysis.

Data analysis was done using SPSS v. 22 with the help of descriptive statistics. Student's t-test was employed to assess quantitative variables with statistical significance set at $p < 0.05$.

RESULTS/OUTCOMES.

Participants.

The study encompassed 120 patients, evenly distributed into 2 groups with 60 participants per group. The gender distribution among the two groups is mentioned in table 1. The average duration of surgery (81.23 min in Group L, 73.48 min in Group R) did not alter drastically in both cohorts. Furthermore, no statistically significant variation was seen concerning the average time of onset of sensory analgesia at 10 minutes between both cohorts (6.89 min vs 9.24 min). Analysis of the parameters related to the loss of motor and sensory functioning showcased the superiority of levobupivacaine in establishing the maximum level of sensory blockade in contrast to ropivacaine (12.45 min vs 16.39 min). Additionally, no significant differences in the commencement of Grade I motor block, and the total period of loss of motor functioning ($p > 0.05$) were noted. These results imply comparable outcomes in various parameters between the Levobupivacaine and Ropivacaine groups in the context of lower limb surgeries (Table 2).

Table 1: Gender distribution of the study population.

Gender	Group L (n = 60)	Group R (n = 60)
Male	28	34
Female	32	26

Table 2: Comparative Analysis of Patient Characteristics and Anaesthesia Parameters in Group L (Levobupivacaine) and Group R (Ropivacaine).

Characteristics	Group L (n = 60)	Group R (n = 60)	p-value
Average height (cm)	157.37	156.35	0.534
Average weight (kg)	57.69	55.23	0.185
The average duration of surgery (min)	81.23	73.48	>0.05
Average time of commencement of sensory analgesia at 10 min	6.89	9.24	0.368
Average time to reach the maximum level of sensory blockage (min)	12.45	16.39	0.579
Average time for two-segment sensory recovery (min)	102.31	73.17	<0.05
Average total period of complete loss of sensory functioning (min)	252.14	211.62	>0.05
Average time of commencement of grade I motor block (min)	1.92	2.96	>0.05
Average time of commencement of max. motor block (min)	9.15	13.07	>0.05
Average number of patients with grade 4 motor blockage (%)	82.5%	52.9%	>0.05
Average total period of motor blockage (min)	262.84	148.29	>0.05

Hemodynamic variables, such as heart rate and blood pressure, showed no significant fluctuations at multiple time intervals in the groups. Additionally, neither group reported signs of headache, shivering, vomiting, nausea, nor oxygen desaturation. These findings emphasize the overall safety and absence of common complications

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associated with Levobupivacaine and Ropivacaine administration in lower limb surgeries (Table 3).

Table 3: Adverse effects recorded in the patients.

Parameters	Group L (n = 60)	Group R (n = 60)
Hypotension	2	-
Bradycardia	4	-
Shivering	-	-
Nausea	-	-
Vomiting	-	-
Headache	-	-

DISCUSSION.

The study compared the effects of levobupivacaine and ropivacaine in lower limb surgeries among 120 patients, evenly distributed into two groups. Analysis of various parameters related to anesthesia administration and patient characteristics revealed comparable outcomes between the two groups.

There were no significant differences in the average duration of surgery or the average time of onset of sensory analgesia at 10 minutes between the levobupivacaine and ropivacaine groups. However, levobupivacaine demonstrated superiority in establishing the maximum level of sensory blockade compared to ropivacaine, with statistically significant differences observed in the average time to reach maximum sensory blockage and the average time for two-segment sensory recovery.

Despite these differences, no significant variations were noted in the commencement of Grade I motor block or the total period of loss of motor functioning between the two groups. Additionally, hemodynamic variables remained stable, and neither group reported common adverse effects such as headache, shivering, vomiting, nausea, or oxygen desaturation.

Overall, the study suggests that levobupivacaine and ropivacaine exhibit comparable efficacy and safety profiles in lower limb surgeries, with no significant differences in anesthesia parameters or adverse effects. These findings imply that both anesthetics can be considered suitable options for anesthesia management in this context, providing clinicians with flexibility in choosing between the two based on patient-specific factors or preferences.

With these considerations, studies by Glaser et al and other studies recommended 17.5 mg of isobaric levobupivacaine, or 17.5 to 25 mg of ropivacaine in hip replacement surgery [5, 19, 20]. Despite these variations, the findings of Sell et al reveal that the Minimum Local Analgesic Dose (MLAD) of both drugs for hip replacement surgery is similar [7]. With this as the basis, the present study was carried out using 15 mg (3 ml of 0.5%) of each drug for orthopedic surgical procedures of the lower extremity.

The current investigation reveals a rapid onset of loss of sensory functioning with levobupivacaine (6.89 min) in contrast to ropivacaine (9.24 min), which is concordant with the results of other studies [21-23]. Furthermore, the present investigation emphasizes the slower onset time for achieving maximum sensory block with levobupivacaine (12.45 min) in contrast to ropivacaine (16.39 min) aligning with the findings from prior studies [9, 22, 24, 25]. Notably, Glaser et al reported a contradictory finding whereby the maximum level of sensory loss was attained faster (8-10min) when a higher dose (3.5 ml) of levobupivacaine was used [5].

In contrast to the present investigation and previously reported ones, Wahedi et al. observed a prolonged time (24 min) for achieving maximum sensory block with 0.5% ropivacaine [12]. This discrepancy may stem from their use of cold sensation loss assessment, which is less sensitive to the activity of local anesthesia on non-myelinated C fibers [12].

Levobupivacaine exhibited prolonged two-segment sensory recovery time and duration of analgesic effect unlike its counterpart, ropivacaine, aligning with that observed by Mantouvalou et al. and Sanansilp et al. [9, 22]. However, discrepancies were noted in the study conducted by Glaser et al., who reported a higher two-segment regression with a higher dose of levobupivacaine [5]. The period of analgesic effect elicited by levobupivacaine was identified to be in line with the outcomes from the study carried out by Glaser et al and Vellosillo et al, but owing to the isobaric nature of the drug, these results contrasted those of other studies [5, 24-26]. In contrast, Van Kleef et al and Fattorini et al reported longer durations with ropivacaine differing from the present observations, probably due to their consideration of the time required for total sensory recovery [10, 25].

Levobupivacaine exhibited a rapid onset of loss of motor functioning (1.92 mins) in contrast to ropivacaine (2.96 mins), consistent with Mantouvalou et al.'s findings [9]. Levobupivacaine resulted in a more intense and earlier attainment of Bromage grade 4 motor blockade, aligning with the results of previous findings [9, 24]. In contrast, Van Kleef et al showcased a delayed maximum motor blockade with 0.5% ropivacaine (21 mins), possibly due to the differences in patient height [25]. A longer duration of loss of motor functioning was noted with Levobupivacaine unlike ropivacaine in the present study, concordant with the results of Mantouvalou et al and Fattorini et al [9, 10].

Both the study cohorts in the present investigation maintained a stable hemodynamic profile, possibly as a result of preloading with Ringer's lactate solution and the use of a lower limb tourniquet in all the participants, consistent with previous results [9, 23]. This study, focusing on isobaric ropivacaine and levobupivacaine in orthopedic surgeries of the lower extremities, contributes novel insights into their comparative effects and highlights the importance of proper choice of drug for optimized anesthesia management in diverse surgical scenarios.

GENERALIZABILITY.

The generalizability of the present investigation is restrained by its specific focus on lower limb orthopedic surgeries and the unique context of using only isobaric levobupivacaine and ropivacaine. While the findings provide valuable insights for this particular scenario, caution is warranted when extrapolating them to broader anesthesia practices.

CONCLUSION.

The study on the comparative analysis of the anesthetic activity of isobaric ropivacaine and levobupivacaine in orthopedic surgical procedures of the lower extremities revealed distinct variations in the commencement, duration, and intensity of loss of motor and sensory functioning. Levobupivacaine demonstrated a rapid onset of sensory block, stronger motor blockade, and prolonged duration of analgesic effect, in contrast to ropivacaine. These findings offer valuable insights into the potential benefits of these local anesthetics over bupivacaine.

LIMITATIONS.

The present study is limited by its focus on a specific patient population undergoing lower limb orthopedic surgeries. Additionally, the short-term nature of the observations might not capture long-term effects or complications.

RECOMMENDATIONS.

The study recommends further research encompassing a broader patient population and diverse surgical procedures to enhance the applicability of findings emphasizing the need for personalized approaches based on the specific surgical and patient characteristics.

ACKNOWLEDGMENT.

The authors acknowledge and thank all the patients for their active participation and cooperation throughout the study.

LIST OF ABBREVIATIONS.

ASA - American Society of Anaesthesiologists
BMI – Body Mass Index
MLAD -Minimum Local Analgesic Dose

SOURCE OF FUNDING.

The study had no funding

CONFLICT OF INTEREST.

The authors declare no competing interests.

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https://doi.org/10.51168/sjhrafrica.v5i3.1147
Original Article

Publisher details.

SJC PUBLISHERS COMPANY LIMITED

Category: Non-Government & Non-profit Organisation
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