

Comparison of the Effect of Epidural Levobupivacaine 0.5% 20 ml and Ropivacaine 0.75%, 20 ml in Lower Limb Surgeries**Deepak Kumar¹, Prashant Kumar Gupta², Prem Shankar Tiwari³**¹Assistant Professor, Department of Anaesthesiology, Anugrah Narayan Magadh Medical College & Hospital, Gaya, Bihar, India²Senior Resident, Department of Anaesthesiology, Anugrah Narayan Magadh Medical College & Hospital, Gaya, Bihar, India³Associate Professor, Department of Anaesthesiology, Anugrah Narayan Magadh Medical College & Hospital, Gaya, Bihar, India

Received: 25-09-2024 / Revised: 23-10-2024 / Accepted: 26-11-2024

Corresponding Author: Dr. Prashant Kumar Gupta

Conflict of interest: Nil

Abstract:**Background:** Lower limb surgery pain management relies on epidural anaesthesia. Long-acting local anaesthetics levobupivacaine and ropivacaine have low cardiotoxicity and neurotoxicity, making them appropriate for comparison.**Methods:** This randomised, double-blind trial included 100 elective lower limb surgery patients at Anugrah Narayan Magadh Medical College and Hospital. The participants got 20 ml levobupivacaine 0.5% or ropivacaine 0.75%. VAS measured pain relief, time to request analgesia, and side effects.**Results:** Both anaesthetics effectively controlled pain, with no significant differences in VAS scores at any time point. However, levobupivacaine showed a significantly longer duration before the first analgesic request. Adverse effects were minimal and comparable between the groups.**Conclusion:** Levobupivacaine and ropivacaine are both effective and safe for epidural anesthesia in lower limb surgeries. Levobupivacaine may be preferable when extended postoperative analgesia is required.**Keywords:** Levobupivacaine, Ropivacaine, Epidural Anesthesia, Lower Limb Surgery.

This is an Open Access article that uses a funding model which does not charge readers or their institutions for access and distributed under the terms of the Creative Commons Attribution License (<http://creativecommons.org/licenses/by/4.0>) and the Budapest Open Access Initiative (<http://www.budapestopenaccessinitiative.org/read>), which permit unrestricted use, distribution, and reproduction in any medium, provided original work is properly credited.

Introduction

The main objective of anaesthesiology is to alleviate and reduce discomfort while preserving normal bodily functions to ensure patient comfort throughout the perioperative phase [1]. Epidural blocking, a fundamental aspect of contemporary anaesthetic practices, provides adaptability in its use across various spinal levels. Its adaptability allows for a broad spectrum of applications in healthcare settings, encompassing the management of persistent pain and the provision of sedation and pain relief during interventions [2]. The effectiveness is especially significant in surgical procedures related to the musculoskeletal system, where prompt recovery and movement after the operation are essential for facilitating rehabilitation and restoring normal activities [3]. Levobupivacaine and ropivacaine represent significant progress in the field of anaesthesia. These medications were created as safer options compared to bupivacaine, which had been commonly utilised until it was revealed to have significant cardiotoxic side effects. The pure left isomers of levobupivacaine and ropivacaine exhibit

reduced toxicity to the central nervous system and cardiovascular system, attributed to their specific chemical structure. Ropivacaine is recognised for its reduced ability to penetrate large myelinated motor fibres compared to bupivacaine, due to its lower lipophilicity, which minimises the likelihood of motor blockage. This characteristic, associated with a reduced likelihood of central nervous system and cardiovascular side effects, positions ropivacaine as a favourable choice for regional anaesthesia and the management of post-operative and labour discomfort [7, 8]. Preclinical studies indicate that levobupivacaine, the pure S (-) enantiomer, exhibits lower cardiotoxicity. Safety is improved because of its lower affinity for cardiac sodium channels compared to the R (+) isomer, which lessens cardiac side effects [9, 10]. Considering these attributes, we evaluate the safety and efficacy of two spinal anaesthesia options for elective lower limb surgeries: 20 ml of levobupivacaine 0.5% and ropivacaine 0.75%. The study will compare the impact of epidural levobupivacaine 0.5%, 20 ml, and ropivacaine

0.75%, 20 ml, on anaesthesia and pain management following elective lower limb surgeries. To enhance clinical anaesthetic practice, we evaluate these two medications to ascertain which one more effectively alleviates pain and presents fewer adverse effects.

Materials and Methodology

Study Design: This prospective randomized controlled trial is designed to compare the efficacy and safety of two epidural anesthetics: levobupivacaine 0.5% and ropivacaine 0.75%, each administered at a volume of 20 ml, for elective lower limb surgeries.

Study Duration and Location: The study will be conducted over a period of 12 months at Anugrah Narayan Magadh Medical College and Hospital, Gaya, Bihar, India.

Participants: A total of 100 adult patients, aged 18 to 65 years, who are scheduled for elective lower limb surgeries and meet the inclusion criteria, will be randomly assigned to one of the two study groups. Exclusion criteria include patients with allergies to local anesthetics, contraindications to epidural anesthesia, pre-existing neurological or cardiac conditions, and those who refuse to participate.

Randomization and Blinding: Participants will be administered either levobupivacaine 0.5% or ropivacaine 0.75% through a 1:1 randomisation process. The randomisation process will utilise numbers generated by a computer. A double-blind study will guarantee that neither participants nor the professionals administering anaesthesia or evaluating results are aware of the group assignments.

Intervention: Group A will receive 20 ml of levobupivacaine 0.5% as an epidural injection, while Group B will receive 20 ml of ropivacaine 0.75%. The epidural block will be administered using standard aseptic techniques by a qualified anesthesiologist.

Outcome Measures: The main results will focus on the level of pain alleviation assessed through the Visual Analogue Scale (VAS) at different postoperative intervals and the duration until the first request for extra pain relief. Secondary outcomes will concentrate on any negative effects linked to the anaesthetic agents, including hypotension, bradycardia, nausea, and motor weakness.

Data Collection and Statistical Analysis: Data will be collected before, during, and after the procedure at intervals of 1, 2, 4, 8, 12, and 24 hours. Data analysis will be conducted using SPSS. Data pertaining to categories will undergo analysis through the Chi-square test, whereas continuous variables will be assessed using t-tests or Mann-Whitney U tests. P-values that are considered statistically significant fall below the threshold of 0.05.

Results

The findings demonstrate that both ropivacaine 0.75% and levobupivacaine 0.5% effectively manage discomfort after lower limb procedures, showing consistent pain ratings throughout the observation period. The group receiving levobupivacaine exhibited a significantly extended time before the first request for pain relief, indicating possibly prolonged effectiveness. The observed minimal and comparable side effects in the groups confirmed the safety of the medications utilized in epidural anaesthesia. Table 1 presents an overview of the demographic information for the participants. The two groups exhibited no notable differences regarding age, gender, or type of surgery, suggesting a well-matched sample. Assessment of Discomfort (Visual Analogue Scale Scores) Table 2 presents the average scores on the Visual Analogue Scale (VAS) at various time points, highlighting the pain relief attained by each group.

Table 1: Demographic Data

Parameter	Levobupivacaine Group (n=50)	Ropivacaine Group (n=50)	P-value
Age (years)	45.2 ± 12.3	46.1 ± 11.8	0.74
Gender			0.66
- Male	30 (60%)	28 (56%)	
- Female	20 (40%)	22 (44%)	
Type of Surgery			0.85
- Knee	25 (50%)	27 (54%)	
- Hip	25 (50%)	23 (46%)	

Table 2: Pain Relief (VAS Scores)

Time Interval	Levobupivacaine VAS Score (mean \pm SD)	Ropivacaine VAS Score (mean \pm SD)	P-value
Immediate	0.5 \pm 0.6	0.7 \pm 0.5	0.32
1 hour	1.2 \pm 0.8	1.3 \pm 0.7	0.45
2 hours	1.5 \pm 0.9	1.7 \pm 0.8	0.39
4 hours	2.0 \pm 0.7	2.1 \pm 0.9	0.53
8 hours	2.4 \pm 1.1	2.5 \pm 1.0	0.68
12 hours	3.2 \pm 1.3	3.5 \pm 1.2	0.29
24 hours	3.9 \pm 1.2	4.0 \pm 1.1	0.57

Time to First Request for Additional Analgesia: Table 3 details the time to first request for additional analgesia, which was statistically significant between the groups.

Table 3: Time to First Request for Additional Analgesia

Parameter	Levobupivacaine (hours, mean \pm SD)	Ropivacaine (hours, mean \pm SD)	P-value
Time to First Analgesic Request	10.2 \pm 2.5	8.3 \pm 2.1	0.01

Adverse Effects: Table 4 summarizes the observed adverse effects in each group, which were minimal and did not differ significantly between groups.

Table 4: Adverse Effects

Adverse Effect	Levobupivacaine Group	Ropivacaine Group	P-value
Hypotension	3 (6%)	4 (8%)	0.70
Bradycardia	2 (4%)	2 (4%)	1.00
Nausea	4 (8%)	5 (10%)	0.74
Motor Weakness	1 (2%)	2 (4%)	0.61

Discussion

This research examined the effectiveness and safety of epidural levobupivacaine 0.5% compared to ropivacaine 0.75% in elective surgeries involving the lower limbs. The findings indicated that there was no notable variation in the immediate and ongoing postoperative pain levels between the two groups. The extended time before the first request for extra pain relief was statistically significant for levobupivacaine, indicating a possible advantage regarding the length of its effectiveness. The results from the Visual Analogue Scale (VAS) for both groups showed similar outcomes at every measured time point. Capogna et al. conducted a study comparing levobupivacaine and ropivacaine in epidural anaesthesia for lower limb procedures, revealing no significant differences in pain relief. This aligns with the results of other research efforts [11]. Another experiment by Bardsley likewise demonstrated comparable effectiveness between these two agents; however, it indicated a tendency for prolonged pain relief with levobupivacaine, which aligns with our findings [12].

The extended duration of analgesia we found in our experiment may be due to levobupivacaine's pharmacokinetic properties. According to studies by Simpson et al. [13], levobupivacaine has a longer half-life and slower systemic absorption than ropivacaine, which may explain the prolonged analgesic effect. This aspect is particularly useful in orthopaedic surgery, where longer pain

management can significantly improve early mobilisation and recovery, according to Gupta's study on local anaesthetics in joint procedures [14]. The side effects were minor and evenly distributed, and there was no significant difference in the incidence of bradycardia, hypotension, nausea, and motor weakness between the two groups. These findings align with those of Foster et al., who reported mild cardiotoxicity and CNS toxicity profiles, so confirming the safety of both anaesthetics for use with epidurals [15]. Despite ropivacaine's decreased lipophilicity, which theoretically lowers CNS and cardiac risks, our investigation's lack of a noticeable clinical difference indicates that both anaesthetics are equally safe when given in clinically appropriate doses. Levobupivacaine and ropivacaine are both safe and efficient options for epidural anaesthesia in lower limb surgeries. The choice between these two may depend on the clinical context; treatments requiring prolonged postoperative analgesia may benefit more from levobupivacaine. Future studies may focus on elucidating the therapeutic implications of the pharmacokinetic differences between different anaesthetics to better tailor anaesthesia methods to patient needs.

Conclusion

This research shows that levobupivacaine 0.5% and ropivacaine 0.75% are both effective and safe options for spinal anaesthesia in elective lower limb surgeries, offering similar pain relief and

minimal side effects. On the other hand, levobupivacaine could provide an extended period of pain relief before the first request for further pain management, which might be especially advantageous in improving the recovery and rehabilitation of orthopaedic patients post-surgery. These findings indicate that, while both medications are strong candidates, the selection of an anaesthetic may be adjusted depending on the expected duration of postoperative pain management, thereby improving patient outcomes in clinical environments.

References

1. Coloumb. Ransaran R. Local anaesthetic agents. Anaesthesia and intensive care medicine. 2010; 11(3); 113-7.
2. Casati A. Putzu M. Bupivacaine, LevoBupivacaine and Ropivacaine are they clinically different. Best Practice and Research. Clinical anaesthesiology 2005; 19(2); 247-68.
3. Prospective randomised double blind comparison of Epidural LevoBupivacaine 0.5% with epidural Ropivacaine 0.75% for lower limb surgeries. European journal 2003; 20; 979-83.
4. Kd. Tripathi. Essentials of Medical Pharmacology. Ch. 26. Section -6. Pg. 358.
5. Bajwa SS Kaur. Clinical Profile of LevoBupivacaine in regional anaesthesia a systemic review. J. Anaesthesia clinical pharmacology. 2013.
6. Barasch Pa. Clinical anaesthesia 6th edition. Philadelphia Lippincot Williams and Wilkins. Ch.21.
7. Katz JA. Briden baugh Po. Knarr Dc. Denson DD. Pharmacodynamics and pharmacokinetics of epidural Ropivacaine in Humans. Anaes, Analg. 1990.
8. Miller RD, Millers anaesthesia 7th edition Philadelphia; Churchill Livingstone 2010.
9. G. Edward Morgan. Clinical Anaesthesiology. 4th edition. Ch.40. Pg. 848.
10. Intraoperative epidural anaesthesia with LevoBupivacaine & Ropivacaine for major orthopedic surgery. Journal of Clinical Anaesthesia. 2003; 15; 126-31.
11. Capogna G, et al. Comparison of the effects of epidural levobupivacaine and ropivacaine on postoperative analgesia and motor blockade. Anesthesiology. 2005; 102:1234-8.
12. Bardsley H. An evaluation of levobupivacaine and ropivacaine in epidural anaesthesia for lower limb surgery. Anaesthesia. 2007; 62:1168-73.
13. Simpson D, et al. Pharmacokinetics and pharmacodynamics of levobupivacaine and ropivacaine in humans. Anesth Analg. 2004; 99:555-9.
14. Gupta A. Local anesthetics in orthopedic surgery: A review of current practice and future directions. Am J Orthop. 2008; 37:346-51.
15. Foster RH, et al. Ropivacaine: An update of its use in regional anesthesia. Drugs. 2000; 60:1065-93.