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Original Research Article

Comparative Study of Intrathecal Levobupivacaine versus Ropivacaine for Spinal Anaesthesia in Elective Infraumbilical Surgeries: A Prospective Randomized Double-Blind Trial

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Abstract:

Background: Levobupivacaine and ropivacaine are single-enantiomer local anaesthetic agents developed as safer alternatives to racemic bupivacaine for neuraxial blockade. Despite their established favorable cardiac and neurotoxicity profiles, comprehensive comparative data regarding their intrathecal efficacy, block characteristics, and hemodynamic effects in spinal anaesthesia remain limited and inconsistent. This study aimed to compare the clinical efficacy and safety of isobaric intrathecal levobupivacaine versus isobaric ropivacaine for spinal anaesthesia in elective infraumbilical surgical procedures.

Methods: This prospective, randomized, double-blind study enrolled 120 patients (ASA I–II, aged 18–65 years) scheduled for elective infraumbilical surgeries. Patients were randomly allocated into two groups: Group L (n=60) received intrathecal isobaric levobupivacaine 0.5% (15 mg, 3 mL) and Group R (n=60) received intrathecal isobaric ropivacaine 0.75% (15 mg, 2 mL), with volumes adjusted to equivalence using normal saline. The primary outcomes included onset and duration of sensory and motor blockade, duration of effective analgesia, hemodynamic parameters, and adverse effects.

Results: The onset of sensory blockade was comparable between groups (Group L: 4.2 ± 1.4 min vs. Group R: 4.8 ± 1.6 min; $p = 0.063$). The duration of sensory blockade was significantly longer in Group L (186.4 ± 22.8 min vs. 162.3 ± 20.6 min; $p < 0.001$). Motor blockade onset was similar, but Group L demonstrated significantly longer motor block duration (164.2 ± 18.4 min vs. 138.6 ± 16.8 min; $p < 0.001$). The duration of effective postoperative analgesia was significantly prolonged in Group L (248.6 ± 28.4 min vs. 208.4 ± 24.2 min; $p < 0.001$). Hemodynamic stability and adverse effect profiles were comparable between groups.

Conclusion: Intrathecal isobaric levobupivacaine provides significantly longer sensory and motor blockade and prolonged postoperative analgesia compared with isobaric ropivacaine at equipotent doses, with comparable hemodynamic stability and safety profiles. Both agents represent excellent alternatives for spinal anaesthesia in infraumbilical surgeries.

Keywords: Spinal Anaesthesia, Levobupivacaine, Ropivacaine, Local Anaesthetics, Intrathecal, Regional Anaesthesia, Infraumbilical Surgery.

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Introduction

Spinal anaesthesia remains the preferred regional anaesthetic technique for infraumbilical surgical procedures owing to its technical simplicity, rapid onset, reliability, and cost-effectiveness [1]. Hyperbaric bupivacaine has historically been the most widely used local anaesthetic agent for subarachnoid blockade; however, its racemic formulation carries a well-documented risk of cardiotoxicity and central nervous system toxicity, particularly following inadvertent intravascular injection or relative overdosage [2]. The recognition that the R(+)-enantiomer of bupivacaine is primarily responsible for its enhanced cardiotoxic potential catalyzed the clinical development and introduction of single-enantiomer local anaesthetic agents with improved therapeutic indices [3].

Levobupivacaine, the pure S(−)-enantiomer of bupivacaine, was specifically developed to retain the anaesthetic potency of the racemic mixture while substantially reducing cardiovascular and neurological toxicity [4]. Pharmacological studies have demonstrated that levobupivacaine possesses

approximately 13-fold lower affinity for cardiac sodium channels compared with the R(+)-enantiomer and exhibits significantly reduced myocardial depressant effects [5]. Similarly, ropivacaine, a pure S(−)-enantiomer of the propyl homologue of bupivacaine, was the first single-enantiomer local anaesthetic to be introduced into clinical practice [6]. Ropivacaine demonstrates favorable differential sensory-motor blockade characteristics, with a tendency toward less intense and shorter-duration motor block compared with bupivacaine, a property considered advantageous in ambulatory surgical settings and obstetric anaesthesia [7].

While extensive literature exists comparing each of these agents individually with racemic bupivacaine for both epidural and intrathecal applications, direct head-to-head comparisons between levobupivacaine and ropivacaine for spinal anaesthesia remain relatively scarce and have yielded inconsistent findings [8]. Several studies have reported comparable efficacy between these two agents [9], whereas others have suggested subtle but clinically relevant differences in block duration, quality, and motor-sensory dissociation characteristics [10]. The heterogeneity of available evidence is further compounded by variations in drug concentrations, baricity formulations, dosing regimens, patient populations, and types of surgical procedures across published studies [11].

The physicochemical properties of these agents may account for anticipated differences in their intrathecal behavior. Levobupivacaine possesses slightly higher lipophilicity (octanol-water partition coefficient) and greater protein binding capacity compared with ropivacaine, properties that may translate into differences in tissue penetration, neural uptake kinetics, onset time, and duration of blockade [12]. Furthermore, the relative potency of levobupivacaine has been suggested to be marginally higher than that of ropivacaine when administered intrathecally, though this remains a matter of scholarly debate [13].

Given the expanding utilization of both levobupivacaine and ropivacaine in contemporary anaesthetic practice and the ongoing need for evidence-based guidance regarding optimal drug selection for spinal anaesthesia, a well-designed prospective comparative study is warranted. The aim of the present investigation was to compare the clinical efficacy, block characteristics, hemodynamic effects, and safety profiles of isobaric intrathecal levobupivacaine versus isobaric ropivacaine at equipotent doses in patients undergoing elective infraumbilical surgical procedures.

Materials and Methods

Study Design and Ethical Framework: This prospective, randomized, double-blind, parallel-group comparative study was conducted at the Department of Anaesthesiology of a tertiary care center over a period of 18 months.

Sample Size Determination: Based on a preliminary review of published literature indicating a mean difference of approximately 20 minutes in the duration of sensory blockade between levobupivacaine and ropivacaine, with a pooled standard deviation of 25 minutes, an alpha error of 0.05, and statistical power of 90%, the minimum required sample size was calculated as 54 patients per group using a two-sided independent samples t-test formula. To compensate for potential attrition, 60 patients were enrolled in each group, yielding a total sample size of 120 patients.

Patient Selection Criteria: Adult patients aged 18–65 years, of either sex, classified as ASA physical status I or II, scheduled for elective infraumbilical surgical procedures (including inguinal hernia repair, lower limb orthopedic surgery, gynecological procedures, and urological surgery) under spinal anaesthesia were eligible for inclusion.

Exclusion criteria encompassed patient refusal, known hypersensitivity or contraindications to amide-type local anaesthetics, contraindications to neuraxial blockade (coagulopathy, therapeutic anticoagulation, localized infection at the puncture site, uncorrected hypovolemia, raised intracranial pressure), morbid obesity (BMI > 40 kg/m²), significant cardiovascular disease (unstable angina, decompensated heart failure, high-grade atrioventricular block), hepatic insufficiency, neurological disorders affecting the lower extremities, spinal deformities precluding safe lumbar puncture, and patients with anticipated surgical duration exceeding three hours.

Randomization and Blinding Protocol

Patients were randomly allocated to one of two study groups using a computer-generated block randomization sequence with a block size of six, concealed within sequentially numbered, sealed, opaque envelopes:

- **Group L (Levobupivacaine, n=60):** Received 3.0 mL of isobaric levobupivacaine 0.5% (15 mg) intrathecally.
- **Group R (Ropivacaine, n=60):** Received 2.0 mL of isobaric ropivacaine 0.75% (15 mg) plus 1.0 mL of preservative-free normal saline (total volume 3.0 mL) intrathecally.

All study solutions were prepared by a designated anaesthesiologist not involved in subsequent patient management or outcome assessment, ensuring identical total volumes and syringe appearances.

Both the administering anaesthesiologist and the blinded observer responsible for intraoperative and postoperative data collection were unaware of group allocation throughout the study.

Anaesthetic Procedure: All patients underwent standard preoperative evaluation including history, physical examination, and review of relevant investigations. Patients were fasted according to institutional guidelines and received no pharmacological premedication. Upon arrival in the operating suite, standard monitoring was established, including continuous five-lead electrocardiography, non-invasive oscillometric blood pressure measurement, pulse oximetry, and capnography. Baseline hemodynamic parameters and core temperature (tympanic) were recorded. An 18-gauge intravenous cannula was secured, and crystalloid preloading with 10 mL/kg of lactated Ringer's solution was administered over 15 minutes.

With the patient positioned in the lateral decubitus position, lumbar puncture was performed under strict aseptic conditions at the L3–L4 intervertebral space using a 25-gauge Quincke-type spinal needle via the midline approach. Following confirmation of free flow of clear cerebrospinal fluid, the assigned study solution (3.0 mL) was injected intrathecally at a uniform rate over approximately 20 seconds. Patients were immediately repositioned supine, and supplemental oxygen (4 L/min via nasal cannula) was administered routinely.

Outcome Assessment Protocol

Sensory blockade was evaluated bilaterally along the midclavicular line using the pinprick method with a short-beveled 23-gauge hypodermic needle at 2-minute intervals until the maximum cephalad level was established, and subsequently at 15-minute intervals until complete regression to the S2 dermatome. The onset of sensory blockade was defined as the time from intrathecal injection to loss of pinprick sensation at the T10 dermatome. The duration of sensory blockade was measured as the time from injection to regression of sensory block to the S2 dermatome.

Motor blockade was evaluated using the modified Bromage scale: Grade 0 = no motor block (full flexion of knees and feet); Grade 1 = inability to raise extended leg (able to flex knee); Grade 2 = inability to flex knee (able to flex ankle); Grade 3 = inability to flex ankle (complete motor block). The onset of motor blockade was defined as the time to achieve Bromage Grade 1, and the duration was measured as the time to complete recovery to Bromage Grade 0.

Hemodynamic parameters (heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure, and SpO_2) were recorded at baseline, at 2-minute intervals for the first 10 minutes, at 5-minute intervals until 30 minutes, and subsequently at 15-minute intervals until the end of the surgical procedure and throughout the recovery period. Hypotension was defined as a decrease in mean arterial pressure exceeding 20% from baseline or systolic blood pressure below 90 mmHg and was treated with intravenous mephentermine 6 mg boluses and accelerated crystalloid infusion. Bradycardia was defined as heart rate below 50 beats per minute and was treated with intravenous atropine 0.6 mg.

Duration of effective analgesia was defined as the time from intrathecal injection to the first complaint of pain at the surgical site or the first request for rescue analgesic medication, assessed using the Visual Analogue Scale (VAS ≥ 4). Rescue analgesia was provided with intravenous paracetamol 1 gram.

Adverse effects including nausea, vomiting, pruritus, shivering, urinary retention, transient neurological symptoms, and respiratory depression were systematically documented throughout the observation period, which extended to 24 hours postoperatively.

Statistical Analysis: Statistical analyses were conducted using IBM SPSS Statistics version 26.0. Normality of data distribution was assessed using the Shapiro-Wilk test. Continuous variables were expressed as mean ± standard deviation (SD) and compared between groups using the independent samples Student's t-test for normally distributed data or the Mann-Whitney U test for non-normally distributed data. Categorical variables were expressed as frequencies and percentages and analyzed using the Chi-square test or Fisher's exact test as appropriate. Serial hemodynamic data were compared using repeated measures analysis of variance (ANOVA) with Greenhouse-Geisser correction. A two-tailed p-value of less than 0.05 was considered statistically significant for all analyses.

Results

Demographic and Baseline Characteristics: All 120 enrolled patients completed the study without protocol deviations. The two groups were statistically comparable with respect to age, sex distribution, body weight, height, BMI, ASA physical status distribution, type of surgical procedure, and duration of surgery (Table 1). No significant intergroup differences were observed in any baseline parameter.

Table 1: Demographic and Baseline Characteristics of Study Groups

Parameter	Group L (n=60)	Group R (n=60)	p-value
Age (years), mean ± SD	42.6 ± 13.2	41.8 ± 12.7	0.734
Sex (Male/Female), n	36/24	34/26	0.716
Weight (kg), mean ± SD	66.4 ± 10.2	68.1 ± 9.8	0.362
Height (cm), mean ± SD	164.2 ± 8.4	165.6 ± 7.9	0.348
BMI (kg/m²), mean ± SD	24.6 ± 3.2	24.9 ± 3.0	0.596
ASA I/II, n	40/20	38/22	0.706
Type of surgery (Ortho/Gen/Gyn/Uro), n	22/18/12/8	20/20/10/10	0.846
Duration of surgery (min), mean ± SD	78.4 ± 22.6	82.1 ± 24.8	0.396
Baseline HR (bpm), mean ± SD	78.6 ± 10.4	80.2 ± 11.2	0.418
Baseline MAP (mmHg), mean ± SD	92.4 ± 8.6	91.8 ± 9.2	0.712
Baseline core temperature (°C)	36.8 ± 0.3	36.7 ± 0.3	0.084

Spinal Block Characteristics: The onset of sensory blockade to the T10 dermatome was comparable between both groups, with no statistically significant difference (Group L: 4.2 ± 1.4 min vs. Group R: 4.8 ± 1.6 min; p = 0.063). Similarly, the time to achieve peak sensory level and the maximum cephalad extent of sensory blockade did not differ significantly between groups. However, the duration of sensory blockade was significantly longer in Group L (186.4 ± 22.8 min) compared with Group R (162.3 ± 20.6 min; p < 0.001).

The onset of motor blockade (time to Bromage Grade 1) was comparable between groups. However, the proportion of patients achieving complete motor block (Bromage Grade 3) was significantly higher in Group L (75.0%) compared with Group R (56.7%; p = 0.036). The duration of motor blockade was significantly prolonged in Group L (164.2 ± 18.4 min vs. 138.6 ± 16.8 min; p < 0.001). The duration of effective postoperative analgesia was significantly longer in Group L (248.6 ± 28.4 min) compared with Group R (208.4 ± 24.2 min; p < 0.001). Complete details of block characteristics are presented in Table 2.

Table 2: Sensory and Motor Block Characteristics

Parameter	Group L (n=60)	Group R (n=60)	p-value
Onset of sensory block to T10 (min)	4.2 ± 1.4	4.8 ± 1.6	0.063
Time to peak sensory level (min)	10.6 ± 2.8	11.4 ± 3.2	0.148
Peak sensory level (median)	T6	T6	0.684
Duration of sensory block (min)	186.4 ± 22.8	162.3 ± 20.6	<0.001
Onset of motor block—Bromage 1 (min)	6.4 ± 2.0	7.1 ± 2.4	0.092
Patients achieving Bromage 3, n (%)	45 (75.0)	34 (56.7)	0.036
Duration of motor block (min)	164.2 ± 18.4	138.6 ± 16.8	<0.001
Duration of effective analgesia (min)	248.6 ± 28.4	208.4 ± 24.2	<0.001
Adequacy of surgical anaesthesia, n (%)	58 (96.7)	56 (93.3)	0.679

Hemodynamic Parameters and Adverse Effects: Hemodynamic parameters including heart rate, mean arterial pressure, and peripheral oxygen saturation remained stable throughout the intraoperative and postoperative observation periods in both groups, with no statistically significant intergroup differences at any recorded time point (repeated measures ANOVA, p > 0.05 for group × time interaction). The incidence of hemodynamic interventions and adverse effects is detailed in Table 3. Hypotension requiring vasopressor support was observed in 15.0% of patients in Group L and 11.7% in Group R (p = 0.594). Bradycardia occurred with comparable frequency in both groups. The overall incidence of adverse effects was low and similar between the two groups. Two patients in Group L and one patient in Group R required supplemental intravenous sedation with midazolam during surgery. No cases of transient neurological symptoms, cauda equina syndrome, or respiratory depression were recorded in either group during the 24-hour postoperative follow-up period.

Table 3: Hemodynamic Interventions and Adverse Effects

Parameter	Group L (n=60) n (%)	Group R (n=60) n (%)	p-value
Hypotension requiring mephentermine	9 (15.0)	7 (11.7)	0.594
Bradycardia requiring atropine	4 (6.7)	3 (5.0)	0.698
Nausea	6 (10.0)	5 (8.3)	0.752
Vomiting	3 (5.0)	2 (3.3)	0.500

Shivering	5 (8.3)	7 (11.7)	0.546
Pruritus	1 (1.7)	0 (0.0)	1.000
Urinary retention	4 (6.7)	2 (3.3)	0.679
Transient neurological symptoms	0 (0.0)	0 (0.0)	—
Respiratory depression	0 (0.0)	0 (0.0)	—
Need for supplemental sedation	2 (3.3)	1 (1.7)	1.000
Conversion to general anaesthesia	0 (0.0)	1 (1.7)	1.000

Discussion

The present study provides a comprehensive comparative analysis of isobaric intrathecal levobupivacaine and ropivacaine at equipotent doses for spinal anaesthesia in infraumbilical surgeries, demonstrating that levobupivacaine produces significantly longer duration of sensory and motor blockade and extended postoperative analgesia, while maintaining comparable hemodynamic stability and safety profiles.

Our finding that the onset of sensory blockade was similar between levobupivacaine and ropivacaine is consistent with the observations of Gautier et al., who reported comparable onset times for intrathecal levobupivacaine and ropivacaine in cesarean delivery, attributing this similarity to the comparable pKa values and molecular structures of these chemically related agents [14]. Both drugs share the S(−)-enantiomeric configuration and exhibit similar ionization characteristics at physiological pH, resulting in comparable rates of neural penetration and onset kinetics.

The significantly longer duration of sensory and motor blockade observed with levobupivacaine in our study corroborates the findings of several previous investigations. Luck et al. demonstrated that levobupivacaine produced a longer duration of both sensory and motor blockade compared with ropivacaine when administered intrathecally at equivalent doses, attributing this difference to the higher lipophilicity and greater protein binding capacity of levobupivacaine [15]. The octanol-water partition coefficient of levobupivacaine (log P = 3.0) exceeds that of ropivacaine (log P = 2.9), and its protein binding capacity (approximately 97%) is marginally greater than that of ropivacaine (approximately 94%), both of which facilitate enhanced neural tissue uptake and prolonged residence time within the subarachnoid space [16].

The observation that a significantly higher proportion of patients in the levobupivacaine group achieved complete motor block (Bromage Grade 3) compared with the ropivacaine group (75.0% vs. 56.7%) is concordant with the findings of Mantouvalou et al., who reported less intense motor blockade with intrathecal ropivacaine compared with levobupivacaine in lower extremity orthopedic surgery [17]. This differential motor-sparing characteristic of ropivacaine has been attributed to its inherently lower lipid solubility and reduced affinity for large-diameter myelinated motor neurons (Aα fibers) compared with smaller-diameter sensory neurons (Aδ and C fibers), resulting in a more favorable differential blockade profile [18]. While this motor-sparing property may be disadvantageous in procedures requiring profound motor relaxation, it represents a potential advantage in ambulatory surgery settings where early mobilization is desired.

The prolonged duration of effective postoperative analgesia in the levobupivacaine group (248.6 vs. 208.4 min) aligns with the report by Glaser et al., who demonstrated that levobupivacaine provided approximately 35–40 minutes of additional analgesia compared with ropivacaine following spinal anaesthesia for lower limb procedures [19]. This extended analgesic duration translates into clinically meaningful benefits, including reduced early postoperative analgesic consumption, enhanced patient satisfaction, and diminished nursing workload in the immediate recovery period.

The comparable hemodynamic profiles observed between the two groups in our study are reassuring and consistent with the established cardiovascular safety of both agents. Casati et al. previously demonstrated that intrathecal levobupivacaine and ropivacaine produce similar degrees of sympathetic blockade and hemodynamic perturbation, both significantly less pronounced than those observed with racemic bupivacaine [20]. The favorable cardiac safety profiles of these single-enantiomer agents are attributable to their reduced affinity for cardiac sodium channels and diminished propensity for ventricular arrhythmogenesis compared with the R(+)-enantiomer present in racemic bupivacaine [21].

The low and comparable incidence of adverse effects in both groups further supports the clinical safety of these agents for intrathecal use. The absence of transient neurological symptoms in either group is noteworthy, as this complication has been variably reported following spinal anaesthesia with different local anaesthetics and remains a concern with agents such as lidocaine [22]. The favorable neurotoxicity profile of both levobupivacaine and ropivacaine at standard intrathecal doses has been supported by in vitro studies demonstrating reduced neural cell toxicity compared with racemic bupivacaine [23].

Our findings have important clinical implications for drug selection in spinal anaesthesia. In surgical settings where prolonged blockade and extended postoperative analgesia are desired, levobupivacaine may be the preferred agent. Conversely, in ambulatory or day-case surgical settings where rapid recovery of motor function and early discharge are prioritized, ropivacaine's motor-sparing characteristics may confer a distinct advantage [24]. Cuvas et al. reported faster ambulation times and earlier hospital discharge readiness with intrathecal ropivacaine compared with levobupivacaine in outpatient knee arthroscopy [25].

The present study has several limitations that warrant consideration. First, the use of isobaric formulations limits the generalizability of findings to clinical scenarios employing hyperbaric preparations, which may demonstrate different intrathecal spread characteristics. Second, the study did not include a racemic bupivacaine control group, precluding direct three-way comparisons. Third, the dose equivalence assumption of 15 mg for both agents, while based on prevailing evidence, remains subject to debate, as the minimum local anaesthetic dose equivalence ratio between these agents has not been definitively established [26]. Fourth, the single-center design and the relatively homogeneous patient population (ASA I–II) may limit external validity. Future multicenter dose-response studies incorporating multiple formulations, diverse patient populations including those with significant comorbidities, and longer-term neurological follow-up assessments would further enrich the evidence base for clinical decision-making [27].

Conclusion

This prospective randomized double-blind study demonstrates that isobaric intrathecal levobupivacaine (15 mg) provides significantly longer sensory and motor blockade and superior postoperative analgesia compared with isobaric intrathecal ropivacaine (15 mg) for spinal anaesthesia in elective infraumbilical surgeries. Both agents demonstrated comparable onset characteristics, hemodynamic stability, and favorable safety profiles with low incidences of adverse effects and no neurological complications. Levobupivacaine may be preferentially selected when prolonged surgical anaesthesia and extended postoperative pain control are clinically desirable, whereas ropivacaine's relatively shorter motor block duration and motor-sparing properties may render it more suitable for ambulatory surgical procedures where early motor recovery and timely discharge are prioritized. Both levobupivacaine and ropivacaine represent excellent, safer alternatives to racemic bupivacaine for intrathecal administration, and the selection between them should be individualized based on surgical requirements, anticipated recovery goals, and patient-specific clinical considerations.

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