e-ISSN: 0976-822X, p-ISSN:2961-6042

Available online on http://www.ijcpr.com/

International Journal of Current Pharmaceutical Review and Research 2026; 18(6); 1330-1336

Original Research Article

A Comparative Study of Equipotent Doses of Intrathecal Hyperbaric Ropivacaine and Hyperbaric Levobupivacaine

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Received: 01-03-2026 / Revised: 15-04-2026 / Accepted: 21-05-2026

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Conflict of interest: Nil

Abstract

Background: Spinal anaesthesia is widely used for lower abdominal and lower limb surgeries due to its efficacy, simplicity, and hemodynamic stability. Hyperbaric formulations of levobupivacaine and ropivacaine offer potential advantages in block characteristics and postoperative analgesia.

Objective: To compare the clinical efficacy and safety of intrathecal hyperbaric 0.5% levobupivacaine versus 0.75% ropivacaine in patients undergoing elective infraumbilical and lower limb surgeries.

Methods: This prospective, randomized, double-blind study enrolled 60 ASA I–II patients, aged 20–60 years, divided equally into two groups. Group A received 3 ml of hyperbaric 0.75% ropivacaine, and Group B received 3 ml of hyperbaric 0.5% levobupivacaine. Outcomes assessed included onset and duration of sensory and motor blockade, quality of motor block (Modified Bromage Scale), duration of postoperative analgesia, intraoperative hemodynamic changes, and adverse effects. Data were analyzed using SPSS v25, with $p < 0.05$ considered significant.

Results: Group B demonstrated a faster onset of sensory block at T10 (1.80 ± 0.93 min vs 3.40 ± 0.98 min, p = 0.01) and motor block (4.20 ± 1.86 min vs 6.80 ± 2.36 min, p = 0.02) compared to Group A. Sensory and motor block durations were significantly longer in Group B (113.40 ± 13.03 min vs 81.00 ± 11.06 min, p = 0.01; 171.40 ± 17.61 min vs 126.00 ± 20.94 min, p = 0.05). Postoperative analgesia was prolonged in Group B (262.00 ± 48.73 min vs 176.00 ± 31.90 min, p = 0.03), with fewer patients requiring rescue analgesia (16.7% vs 40%, p = 0.04). Hemodynamic stability and incidence of adverse effects were comparable between groups.

Conclusion: Hyperbaric 0.5% levobupivacaine provides faster onset, longer sensory and motor blockade, and prolonged postoperative analgesia compared to 0.75% ropivacaine, with comparable safety. Levobupivacaine is preferable for surgeries requiring extended spinal anaesthesia and analgesia. But Ropivacaine's lower cardiotoxicity makes it a safer alternative in patients with cardiac risk factors.

Keywords: Spinal anaesthesia, hyperbaric levobupivacaine, hyperbaric ropivacaine, Sensory blockade, Motor blockade, Postoperative analgesia.

DOI: 10.25258/ijcpr.18.6.215

Introduction

Regional anaesthesia, particularly spinal anaesthesia (also known as subarachnoid block or SAB), plays a pivotal role in modern anaesthetic practice due to its effectiveness, simplicity, and cost-efficiency [1]. SAB involves the administration of a local anaesthetic into the subarachnoid space via a fine-gauge needle, resulting in reversible blockade of sensory, motor, and autonomic nerve fibers. Since its first clinical use by Karl August Bier in 1898, spinal anaesthesia has become the technique of choice for a wide spectrum of lower abdominal, pelvic, and lower limb surgeries because of its rapid onset, profound nerve blockade, minimal systemic toxicity, and reduced requirement for general anaesthesia-related resources [2].Bupivacaine, an amide-based long-acting local anaesthetic, has traditionally been the most frequently used agent for SAB since its introduction in 1956. It is a racemic mixture of S(–) and R(+) enantiomers [3]. The R-isomer, however, has been implicated in dose-dependent cardiotoxicity and neurotoxicity due to its higher

affinity for myocardial voltage-gated sodium channels, raising concerns regarding its safety, particularly with high doses or inadvertent intravascular injection [3]. These limitations necessitated the development and increasing adoption of safer, enantiomerically pure alternatives—namely levobupivacaine and ropivacaine [3,4].Levobupivacaine is the pure S(–) enantiomer of bupivacaine and was specifically developed to overcome the cardiovascular and central nervous system adverse effects associated with the racemic mixture [5]. It provides equivalent sensory and motor blockade to bupivacaine but with significantly reduced cardiotoxicity and neurotoxicity [5].

Its favorable pharmacokinetics and pharmacodynamics have led to widespread use in various regional anaesthetic techniques, including spinal, epidural, and peripheral nerve blocks. Clinical studies have demonstrated promising results with levobupivacaine in terms of block quality, duration of analgesia, and hemodynamic stability [5,6].Ropivacaine, a monoisomeric S(–) enantiomer belonging to the pipecoloxylidide group of local anaesthetics, is structurally similar to bupivacaine but features a propyl substitution at the piperidine nitrogen instead of a butyl group [7]. This chemical modification reduces lipid solubility, resulting in diminished penetration into large myelinated motor fibers. Consequently, ropivacaine produces less intense motor block while maintaining effective sensory blockade, a property advantageous for procedures requiring early ambulation or differential blockade [8]. Its safety advantage over bupivacaine has been well documented, with lower incidences of systemic toxicity, cardiovascular depression, and central nervous system complications.

However, ropivacaine is approximately 30–40% less potent than bupivacaine, necessitating equipotent dose comparisons with bupivacaine or levobupivacaine to achieve similar anaesthetic outcomes [9].Hyperbaric solutions, achieved by adding glucose to local anaesthetics, offer enhanced control over anaesthetic spread in cerebrospinal fluid, following a gravity-dependent distribution that allows predictable cephalad spread and consistent block levels [10]. While hyperbaric bupivacaine is extensively studied and widely used, hyperbaric formulations of ropivacaine and levobupivacaine are now clinically available. These hyperbaric formulations may provide improved block reliability and safety in spinal anaesthesia, particularly in high-risk or ambulatory patients [11]. Although individual studies have investigated hyperbaric levobupivacaine and ropivacaine separately, direct comparative data on equipotent doses for spinal anaesthesia remain scarce. Evidence suggests both agents provide satisfactory sensory and motor blockade, but differences in onset, duration, recovery profiles, and hemodynamic effects are not fully elucidated, and adverse effect incidences such as hypotension, bradycardia, and nausea may vary by agent and patient characteristics [12,13].

Given the clinical need to balance effective spinal anaesthesia with patient safety and faster postoperative recovery, particularly in short-stay procedures, a direct comparison of hyperbaric levobupivacaine and ropivacaine is essential. This study was undertaken to evaluate and compare the clinical efficacy and safety of equipotent doses of intrathecal hyperbaric ropivacaine and hyperbaric levobupivacaine in patients undergoing lower abdominal and lower limb surgeries.

Materials and Methods

This prospective, randomized, double-blind interventional study was conducted in the Department of Anaesthesiology at Basaveshwara Teaching and General Hospital, attached to Mahadevappa Rampure Medical College, Kalaburagi. The study period extended from 1st May 2023 to 31st October 2024. The study protocol adhered to the principles of the Declaration of Helsinki and was approved by the Institutional Ethical Committee.A total of 60 adult patients, aged 20–60 years and classified as American Society of Anaesthesiologists (ASA) physical status I or II, scheduled for elective lower abdominal or lower limb surgeries under spinal anaesthesia, were enrolled in the study after obtaining written informed consent.

Inclusion Criteria

- Age between 20–60 years
- ASA physical status I and II
- Scheduled for elective infraumbilical surgeries under spinal anaesthesia

Exclusion Criteria

- Known or suspected allergy to study drugs
- Contraindications to spinal anaesthesia
- Local infection at the injection site or spinal deformities
- Pregnant or lactating women

Randomization and Blinding

Patients were randomly allocated into two groups using a computer-generated random number table. Allocation concealment was achieved with sealed opaque envelopes.

- **Group A:** received 3 ml of 0.75% hyperbaric ropivacaine
- **Group B:** received 3 ml of 0.5% hyperbaric levobupivacaine

The study drugs were prepared by an independent anaesthesiologist not involved in data collection. Both the patient and the observer recording outcomes were blinded to group allocation.

Preoperative Assessment and Preparation: A detailed pre-anaesthetic evaluation was performed a day prior to surgery, including medical history and examination of cardiovascular, respiratory, and neurological systems. Patients were kept nil per oral for 6 hours for solids and 2 hours for clear fluids. Baseline vitals including pulse rate, non-invasive blood pressure, ECG, and oxygen saturation were recorded. An 18G peripheral intravenous line was secured, and patients were preloaded with intravenous fluids prior to spinal anaesthesia.

Anaesthetic Technique: Under strict aseptic precautions, spinal anaesthesia was administered in the left lateral decubitus position at the L3–L4 interspace using a 25G Quincke spinal needle. After confirming free flow of cerebrospinal fluid, the study drug was injected intrathecally according to group allocation. Patients were immediately positioned supine, and oxygen at 2–5 L/min was administered via a Venturi mask.

Monitoring: Hemodynamic parameters—including heart rate, blood pressure, oxygen saturation, and ECG—were continuously monitored. Measurements were recorded every 2 minutes for the first 10 minutes and every 5 minutes thereafter until the end of the procedure.

Outcome Measures

Sensory Block Assessment

- Onset time: Time from intrathecal injection to loss of pinprick sensation at T10 level
- Maximum block level time: Time to highest dermatomal sensory block
- Duration of sensory block: Time from maximum block to two-segment regression

Motor Block Assessment

- Onset of motor block: Time to achieve Bromage grade 3
- Duration of motor block: Time from Bromage 3 to recovery to Bromage 0
- Quality of motor block: Assessed using the Modified Bromage Scale:
    - 0 = Full motor function
    - 1 = Unable to raise extended leg, able to move knee and feet
    - 2 = Unable to raise extended leg and knee, able to move feet
    - 3 = Complete motor block

Duration of Analgesia: Time from intrathecal injection to first request for rescue analgesia.

Adverse Events: Patients were monitored for hypotension (SBP <90 mmHg or DBP <60 mmHg; treated with mephentermine 6 mg IV), bradycardia (HR <60 bpm; treated with atropine 0.6 mg IV), nausea, vomiting, pruritus, shivering, and respiratory discomfort. All adverse events were documented and managed appropriately.

Statistical Analysis: Data were analyzed using IBM SPSS version 25. Continuous variables were expressed as mean ± standard deviation and compared using the unpaired Student's t-test. Categorical variables were expressed as frequencies and percentages and analyzed using the chi-square test or Fisher's exact test as appropriate. A p-value <0.05 was considered statistically significant.

Results

The age distribution among the study population showed that in Group A, the majority of patients (73.3%) were in the 35–50 years age group, while only 3.3% were in the 20–34 years category.

In Group B, 53.3% were aged 35–50 years, and 23.3% were in the 20–34 years group. Both groups had an equal proportion of patients over 50 years (23.3%). The mean age in Group A was slightly lower (34.63 ± 16.08 years) compared to Group B (37.80 ± 14.14 years). The difference in age distribution between the groups was not statistically significant ($p = 0.18$). Male patients predominated in both groups, with 86.7% in Group A and 80% in Group B, whereas females accounted for 13.3% and 20%, respectively ($p = 0.37$). These demographic characteristics are summarized in Table 1 and Figure 1.

Group B exhibited a faster onset of sensory and motor block compared to Group A. The mean time to achieve sensory block at the T10 level was 1.80 ± 0.93 minutes in Group B versus 3.40 ± 0.98 minutes in Group A, which was statistically significant ($p = 0.01$). The time to reach maximum sensory block at T6 was shorter in Group B (3.40 ± 1.10 minutes) than Group A (5.60 ± 1.25 minutes), although this difference did not reach statistical significance ($p = 0.07$). The onset of motor block was also significantly faster in Group B (4.20 ± 1.86 minutes) compared to Group A (6.80 ± 2.36 minutes, $p = 0.02$). Additionally, the duration of sensory block was longer in Group B (113.40 ± 13.03 minutes) versus Group A (81.00 ± 11.06 minutes, $p = 0.01$), and the duration of motor block was extended in Group B (171.40 ± 17.61 minutes) compared to Group A (126.00 ± 20.94 minutes, $p = 0.05$). These findings are presented in Table 2 and illustrated in Figure 2.

The mean duration of analgesia was significantly longer in Group B (262.00 ± 48.73 minutes) compared to Group A (176.00 ± 31.90 minutes, p =

0.03). Furthermore, the requirement for rescue analgesia within the first 6 hours was significantly higher in Group A (40.0%) than in Group B (16.7%, p = 0.04), indicating more prolonged and effective postoperative analgesia in Group B. These outcomes are summarized in Table 3. The incidence of intraoperative hypotension and bradycardia was comparable between the groups. Hypotension occurred in 20.0% of Group A and 26.7% of Group B (p = 0.54), while bradycardia was noted in 13.3% and 16.7% of patients, respectively (p = 0.72). Adverse effects such as nausea, vomiting, shivering, pruritus, and respiratory issues were infrequent and similarly distributed between the two groups, with no statistically significant differences (all p > 0.05). These data are summarized in Table 4.

Table 1: Demographic Characteristics of Study Population

Parameter	Group A (n=30)	Group B (n=30)	p-value	Statistical Test
Age 20–34 years	1 (3.3%)	7 (23.3%)	0.18	Independent t-test
Age 35–50 years	22 (73.3%)	16 (53.3%)		
Age >50 years	7 (23.3%)	7 (23.3%)		
Mean ± SD (years)	34.63 ± 16.08	37.80 ± 14.14		
Male	26 (86.7%)	24 (80%)	0.37	Independent t-test
Female	4 (13.3%)	6 (20%)		

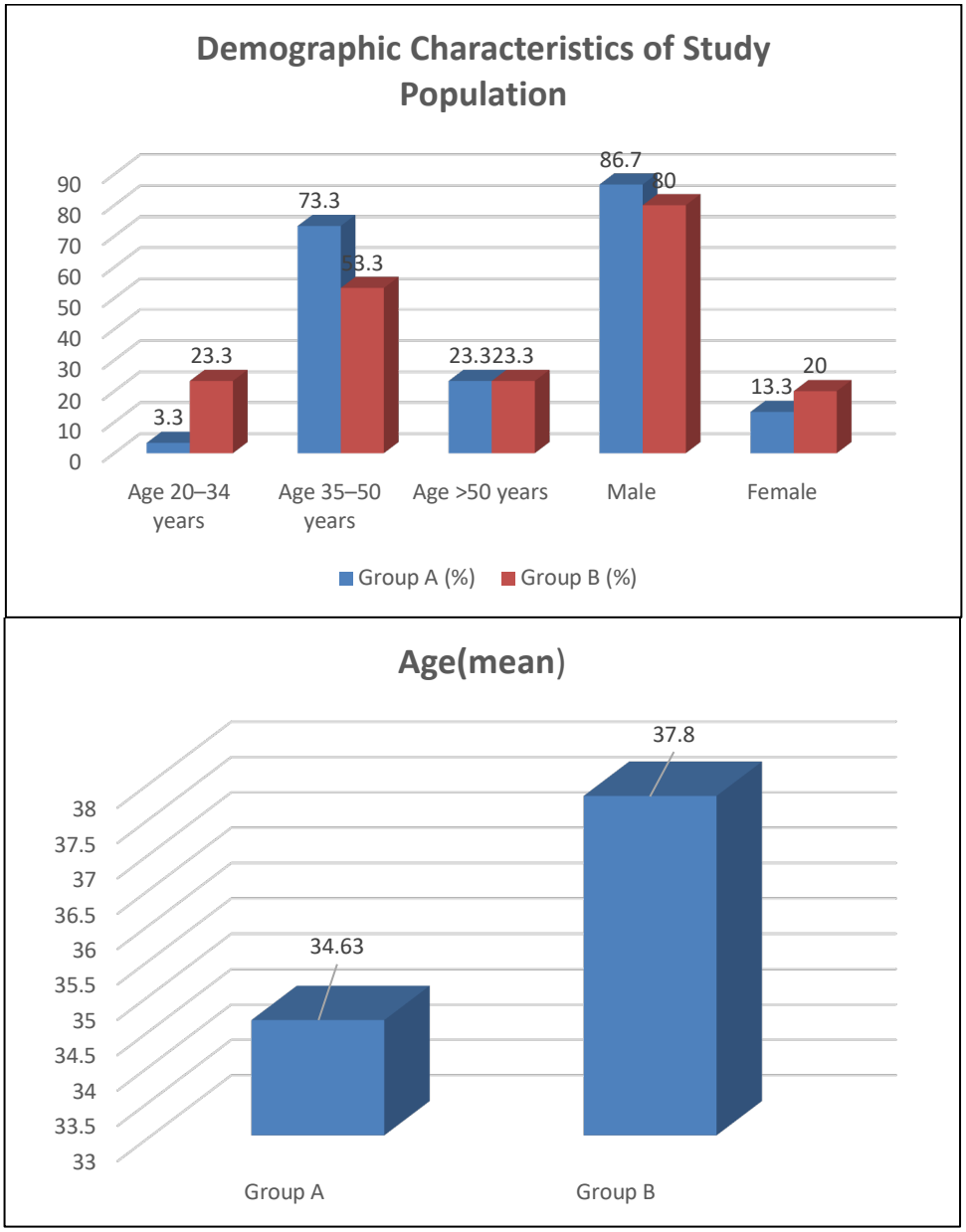

Figure 1: Demographic Characteristics of Study Population

Table 2: Comparison of Onset and Duration of Sensory and Motor Block

Parameter	Group A Mean ± SD	Group B Mean ± SD	p-value	Statistical Test
Onset of Sensory Block (T10, min)	3.40 ± 0.98	1.80 ± 0.93	0.01	Independent t-test
Onset of Max Sensory Block (T6, min)	5.60 ± 1.25	3.40 ± 1.10	0.07	Independent t-test
Onset of Motor Block (min)	6.80 ± 2.36	4.20 ± 1.86	0.02	Independent t-test
Duration of Sensory Block (min)	81.00 ± 11.06	113.40 ± 13.03	0.01	Independent t-test
Duration of Motor Block (min)	126.00 ± 20.94	171.40 ± 17.61	0.05	Independent t-test

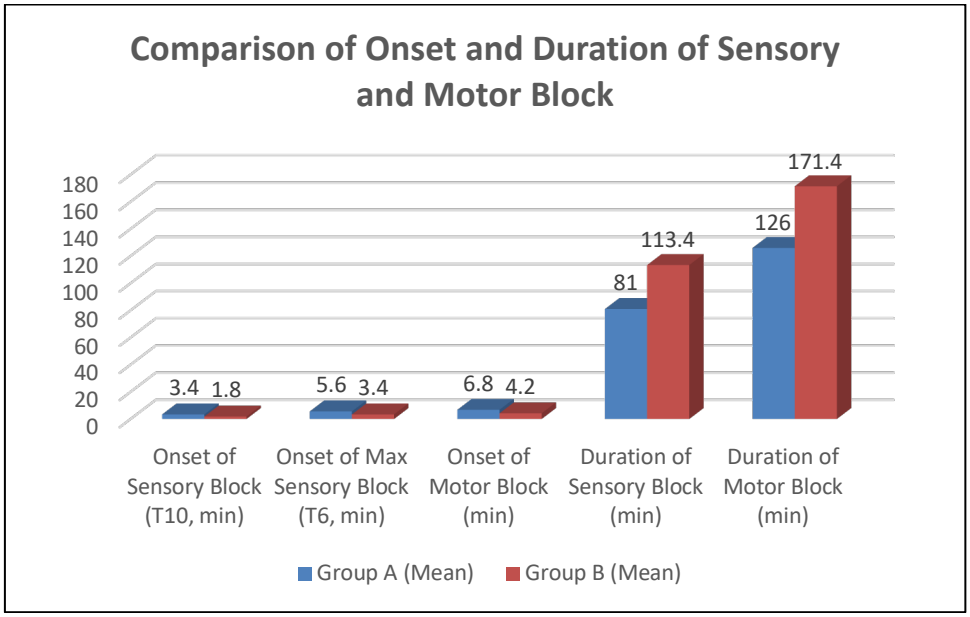

Figure 2: Comparison of Onset and Duration of Sensory and Motor Block

Table 3: Duration of Analgesia and Rescue Analgesia Requirement

Parameter	Group A (n=30)	Group B (n=30)	p-value	Statistical Test
Duration of Analgesia (min)	176.00 ± 31.90	262.00 ± 48.73	0.03	Independent t-test
Rescue Analgesia within 6 h – Yes	12 (40.0%)	5 (16.7%)	0.04	Chi-square test
Rescue Analgesia within 6 h – No	18 (60.0%)	25 (83.3%)		

Table 4: Intraoperative Hemodynamic Changes and Adverse Effects

Parameter	Group A (n=30)	Group B (n=30)	p-value	Statistical Test
Hypotension	6 (20.0%)	8 (26.7%)	0.54	Chi-square test
Bradycardia	4 (13.3%)	5 (16.7%)	0.72	Chi-square test
Nausea	3 (10.0%)	4 (13.3%)	0.69	Chi-square test
Vomiting	2 (6.7%)	3 (10.0%)	0.64	Chi-square test
Shivering	4 (13.3%)	5 (16.7%)	0.73	Chi-square test
Pruritus	1 (3.3%)	2 (6.7%)	0.55	Chi-square test
Respiratory Issues	0 (0.0%)	1 (3.3%)	0.31	Chi-square test

Discussion

This prospective, randomized, double-blind study compared the clinical efficacy and safety of intrathecal hyperbaric ropivacaine (0.75%) and hyperbaric levobupivacaine (0.5%) in 60 ASA I–II patients undergoing elective lower abdominal and lower limb surgeries. Group A received 3 ml of 0.75% hyperbaric ropivacaine, and Group B received 3 ml of 0.5% hyperbaric levobupivacaine. Key outcomes included onset and duration of sensory and motor block, quality of motor block, duration of postoperative analgesia, intraoperative hemodynamic changes, and adverse effects. Demographically, Group A had a majority of patients aged 35–50 years (73.33%) compared to 53.33% in Group B, while Group B included younger patients (20–34 years, 23.33%). Both groups had 23.33% of patients over 50 years.

Mean ages were comparable (Group A 34.63 ± 16.08 years vs Group B 37.80 ± 14.14 years, p = 0.18), in line with Sharma et al. [14], Hazarika et al. [15], and Manjula and Shaine [16]. Male predominance was noted (86.66% in Group A vs 80% in Group B, p = 0.37), reflecting previous

demographic trends in spinal anaesthesia studies. Surgical procedures were distributed evenly in Group A across Appendicectomy, Inguinal Hernioplasty, Haemorrhoidectomy, Jaboulay's Procedure, and Lateral Colorectal Tear Repair (20% each), while Group B predominantly underwent Appendicectomy (40%) with others at 20% each ($p = 0.32$).

Comparable distributions were reported by Sharma et al. [14], Kalbande et al. [17], and Kumar and Preetha [18], whereas Hazarika et al. [15] and Manjula and Shaine [16] focused on orthopaedic surgeries, highlighting procedural variations rather than anesthetic efficacy.

Sensory block onset at T10 was significantly faster in Group B (1.80 ± 0.93 min) versus Group A (3.40 ± 0.98 min, $p = 0.01$). Maximum sensory block at T6 was faster with levobupivacaine (3.40 ± 1.10 min) compared to ropivacaine (5.60 ± 1.25 min), though not statistically significant ($p = 0.07$), consistent with Dinesh et al. [19], Vinod et al. [20], and Neelam et al. [21]. Motor block onset was also faster with levobupivacaine (4.20 ± 1.86 min vs 6.80 ± 2.36 min, $p = 0.02$), mirroring prior studies [19,21]. Maximum sensory levels were usually T6, with a higher cephalad spread to T4 in Group B (16.7% vs 6.7%, $p = 0.08$). Modified Bromage Scale assessment indicated Grade 3 motor block in 73.3% of Group B vs 56.6% in Group A ($p = 0.21$), reflecting slightly denser blockade with levobupivacaine.

Duration of sensory block was significantly prolonged with levobupivacaine (113.40 ± 13.03 min vs 81.00 ± 11.06 min, $p = 0.01$), as was motor block duration (171.40 ± 17.61 vs 126.00 ± 20.94 min, $p = 0.05$). Postoperative analgesia was longer in Group B (262.00 ± 48.73 min vs 176.00 ± 31.90 min, $p = 0.03$), with fewer patients requiring rescue analgesia (16.7% vs 40%, $p = 0.04$), consistent with Sharma et al. [14], Hazarika et al. [15], and Manjula and Shaine [16].

Intraoperative hemodynamic changes, including hypotension (20.0% vs 26.7%, $p = 0.54$) and bradycardia (13.3% vs 16.7%, $p = 0.72$), were comparable between groups. Adverse effects such as nausea, vomiting, shivering, pruritus, and respiratory complications were rare and not statistically different (all $p > 0.05$), confirming the safety and tolerability of both agents.

Conclusion

In this study, hyperbaric 0.5% levobupivacaine demonstrated a faster onset and longer duration of both sensory and motor blockade compared to hyperbaric 0.75% ropivacaine in patients undergoing lower abdominal and lower limb surgeries. Levobupivacaine also provided significantly prolonged postoperative analgesia, with fewer patients requiring rescue analgesia within the first six hours. Both agents were hemodynamically stable and well tolerated, with a low incidence of adverse effects. These findings suggest that levobupivacaine is preferable for procedures requiring extended anaesthesia and postoperative pain control, whereas Ropivacaine's lower cardiotoxicity makes it a safer alternative in patients with cardiac risk factors. Overall, both drugs are effective and safe options for spinal anaesthesia in infraumbilical surgeries

Limitations

The present study was limited by a relatively small sample size of 60 patients, which may affect the generalizability of the findings. Only elective infraumbilical and lower limb surgeries were included, so results may not apply to other surgical types or high-risk populations. The study did not assess long-term postoperative outcomes or patient satisfaction. Additionally, inter-individual variability in drug response could have influenced sensory and motor block characteristics. Future multicentric studies with larger samples are needed to validate these findings across diverse populations.

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