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Comparative study of Intrathecal Hyperbaric Levobupivacaine 0.5 percent and Hyperbaric Ropivacaine 0.75 percent with Buprenorphine in patients undergoing lower abdominal and lower limb procedures under subarachnoid block. A prospective randomised double blind study

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KEYWORDS

Hyperbaric Levobupivacaine 0.5 percent, Hyperbaric Ropivacaine

ABSTRACT:

Spinal anesthesia is a frequently used regional anesthetic treatment that has various advantages, including convenience of administration, cost-effectiveness, quick onset, and dependable sensory and motor blockage. Because it can deliver sufficient anaesthesia and muscle relaxation in a regulated and predictable way, it is particularly favoured for lower abdomen and lower limb procedures.[1].

INTRODUCTION

Spinal anesthesia is a frequently used regional anesthetic treatment that has various advantages, including convenience of administration, cost-effectiveness, quick onset, and dependable sensory and motor blockage. Because it can deliver sufficient anaesthesia and muscle relaxation in a regulated and predictable way, it is particularly favoured for lower abdomen and lower limb procedures.[1].

Bupivacaine, a long-acting amide local anaesthetic, has long been preferred in spinal anaesthesia due to its great potency[2] and extended analgesia[3]. However, its use has been linked to serious adverse effects that are both neurotoxic and cardiotoxic[4,5], especially when an overdose or accidental intravascular delivery occurs. Newer, safer alternatives with similar anaesthetic efficacy but better safety profiles have been developed and clinically adopted as a result of this.

Levobupivacaine and Ropivacaine have become well-known among them. Compared to its dextro isomer, levobupivacaine, the pure S(-) enantiomer of bupivacaine, has a higher capacity to bind plasma proteins and a reduced affinity for cardiac sodium channels. Its decreased risk for cardiotoxicity and neurotoxicity is a result of these characteristics[6]. In comparison to racemic Bupivacaine, Ropivacaine, a long-acting amino amide and a pure S(-) enantiomer, has reduced cardiovascular and central nervous system toxicity as well as lesser lipid solubility[7,8].

Adjuvants like opioids are frequently co-administered intrathecally with local anaesthetics to increase analgesic efficacy and extend spinal anaesthesia duration. Buprenorphine is a strong partial μ-opioid receptor agonist with κ-antagonistic effects. It

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is a semi-synthetic derivative of the opium alkaloid thebaine. In comparison to full agonists, it offers efficient analgesia at low receptor occupancy and is linked to a decreased incidence of respiratory depression.[9]. Its potency is greater than that of morphine, making it a valuable adjuvant in regional anesthesia.

This study aims to compare the clinical efficacy and safety of intrathecal hyperbaric Levobupivacaine (0.5%) and hyperbaric Ropivacaine (0.75%), each combined with Buprenorphine (60 mcg), in patients undergoing lower abdominal and lower limb surgeries under subarachnoid block.

MATERIAL AND METHODS

This was a prospective, randomized, double-blind interventional study conducted at Chettinad Hospital and Research Institute, Kelambakkam, Chennai, after obtaining Institutional Ethical Committee approval and registration with the Clinical Trial Registry of India (CTRI/2024/12/078362). The aim of the study was to compare the clinical efficacy of intrathecal hyperbaric Levobupivacaine (0.5%) and hyperbaric Ropivacaine (0.75%), each combined with Buprenorphine (60 mcg), in patients undergoing lower abdominal and lower limb surgeries under subarachnoid block. The primary objectives were to compare the onset time and duration of sensory and motor blockade, and to evaluate and compare the hemodynamic parameters, including heart rate and blood pressure, between the two study groups. The secondary objectives included comparing the two-segment sensory regression time and assessing the incidence of adverse effects such as hypotension, bradycardia, nausea, and vomiting associated with each intrathecal drug combination. A total of 70 patients scheduled for elective or emergency lower abdominal and lower limb surgeries under spinal anesthesia were enrolled. The sample size was calculated using the formula $n= 2(Z_{\alpha/2} + Z_{\beta})^2 X \sigma^2/ (\mu1- \mu2)^2$ for comparing two independent means based on a previous study by Oraon et al., which reported a total duration of analgesia of 137.67±16.95 minutes for Levobupivacaine and 126.67±15.55 minutes for Ropivacaine. With a significance level of 0.05 and power of 80%, the required sample size was 35 patients per group. Patients were randomized into two equal groups using computer-generated random allocation: Group A (n=35) received 3.5 ml of intrathecal hyperbaric Levobupivacaine 0.5% + 0.2 ml (60 mcg) Buprenorphine and Group B (n=35) received 3.5 ml of intrathecal hyperbaric Ropivacaine 0.75% + 0.2 ml (60 mcg) Buprenorphine. The study drug was prepared by an independent anesthesiologist not involved in patient management or data collection to maintain blinding. Inclusion Criteria were ASA Grade I–III patients aged 18–60 years of both sexes scheduled for infraumbilical surgeries under spinal anesthesia. Exclusion criteria were Patient refusal, drug allergy, spinal deformities or previous surgery, coagulopathy, skin infection at puncture site, neurological disorders, major systemic illnesses, BMI >35, height <140 cm, or anticipated major blood loss. All patients received premedication with Tab. Alprazolam 0.5 mg and Tab. Ranitidine 150 mg the night before and on the morning of surgery. After establishing IV access and standard monitors (ECG, NIBP, SpO_2), 18G IV cannula was secured and RL was started. Under all aseptic precautions L3-L4 inter-space will be infiltrated with 2ml of 2% Inj. Lignocaine followed by which spinal anesthesia was administered at the L3–L4 interspace in a sitting position using a 26G Quincke needle. Following confirmation of free cerebrospinal fluid flow, 3.7 ml of the study drug was injected intrathecally under aseptic precautions. Patients were positioned supine post-injection. The onset of sensory and motor blockade was assessed at baseline and at 3-minute intervals up to 15 minutes following intrathecal injection. Vital parameters, including heart rate, non-invasive blood pressure, respiratory rate, and SpO_2, were continuously monitored every 3 minutes for the first 15 minutes and subsequently at 5-minute intervals up to 30 minutes. The level of sensory blockade and motor function, evaluated using the Modified Bromage score, were recorded at 30-minute intervals for up to 5 hours. Rescue analgesia with IV Paracetamol 15 mg/kg was administered when VAS ≥3. Side effects were managed with IV Ondansetron 4 mg for nausea/vomiting, Atropine 0.6 mg for bradycardia, and fluids/Ephedrine 6 mg IV for hypotension.

Outcome Measures were-

Onset of Sensory Block: Defined as loss of cold sensation at T10

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Onset of Motor Block: Defined as Modified Bromage score of 2
Duration of Sensory Block: Time to two-segment regression
Duration of Motor Block: Time to Modified Bromage score of 0
Duration of Analgesia: Time from intrathecal injection to first analgesic requirement (VAS ≥3)

RESULTS:

A total of 70 patients who met the inclusion criteria were enrolled and randomly allocated into two equal groups: Hyperbaric Levobupivacaine (HLB) group and Hyperbaric Ropivacaine (HRB) group, with 35 patients in each group. The demographic characteristics, clinical profiles, sensory and motor block characteristics, intraoperative hemodynamic parameters, side effects, and postoperative analgesic requirements were systematically assessed and compared between the groups. The following section presents the statistical findings of the study.

Table 1: Baseline Demographic and Clinical Characteristics of Patients in the Hyperbaric Levobupivacaine and Hyperbaric Ropivacaine Groups

S.No	Patient characteristics		Total Frequency (%) / Mean±SD	Hyperbaric Levobupivacaine Group Frequency (%) / Mean±SD	Hyperbaric Ropivacaine Group Frequency (%) / Mean±SD	p-value
1	Age in years		41.83±12.58	45.17±11.39	38.49±12.97	0.025*
2	Sex	Male	59(84.3%)	29(82.9%)	30(85.7%)	0.743
		Female	11(15.7%)	6(17.1%)	5(14.3%)	
3	Height in centimeters		164.03±8.32	163.71±7.76	164.34±8.94	0.754
4	Weight in kilograms		67.02±11.36	65.89±10.04	68.16±12.59	0.407
5	BMI		24.90±3.78	24.54±3.04	25.27+4.41	0.423
6	ASA Grade	I	18(25.7%)	11(31.4%)	7(20%)	0.084
		II	46(65.7%)	19(54.3%)	27(77.1%)	
		III	6(8.6%)	5(14.3%)	1(2.9%)	

*Statistically significant

The study included a total of 70 patients, with comparable baseline characteristics between the two groups receiving hyperbaric Levobupivacaine and hyperbaric Ropivacaine with Buprenorphine. The mean age was significantly higher in the Levobupivacaine group (45.17±11.39 years) compared to the Ropivacaine group (38.49±12.97 years; p=0.025). The majority of participants were male (84.3%), with a similar gender distribution in both groups (p=0.743). The mean height (164.03±8.32 cm), weight (67.02±11.36 kg), and BMI (24.90±3.78) did not differ significantly between the groups (p>0.05). Most patients belonged to ASA Grade II (65.7%), followed by Grade I (25.7%) and Grade III (8.6%), with no statistically significant difference in ASA classification between the groups (p=0.084).

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Table2: Comparison of Sensory and Motor Block Characteristics, and Rescue Analgesia Requirements Between Hyperbaric Levobupivacaine and Hyperbaric Ropivacaine Groups

S.No	Variables		Total Frequency (%) / Mean±SD	Hyperbaric Levobupivacaine Group Frequency (%) / Mean±SD	Hyperbaric Ropivacaine Group Frequency (%) / Mean±SD	p-value
1	Onset of sensory block in minutes		2.70±1.07	2.71±1.07	2.69±1.08	0.912
2	Duration of sensory block in minutes		225.43±41.10	241.71±38.46	209.14±37.45	0.001*
3	Highest sensory block level	T4	16(22.9%)	7(20%)	9(25.7%)	0.846
		T6	48(68.6%)	25(71.4%)	23(65.7%)	
		T8	6(8.6%)	3(8.6%)	3(8.6%)	
4	Time to highest sensory block in minutes		9.51±3.01	9.97±2.95	9.06±3.05	0.206
5	Onset of motor block in minutes		2.40±0.82	2.49±0.85	2.31±0.80	0.388
6	Duration of motor block in minutes		265±27.28	276.29±21.16	253.71±28.29	0.000*
7	Rescue analgesia given	Yes	16(22.9%)	6(17.1%)	10(28.6%)	0.255
		No	54(77.1%)	29(82.9%)	25((71.4%)	
8	Time to rescue analgesia in minutes		271.88±20.40	275±12.25	270±24.50	0.651

*Statistically significant

The comparison of sensory and motor block characteristics between the two groups revealed that the onset of sensory block was comparable between hyperbaric levobupivacaine and hyperbaric ropivacaine groups (2.71 ± 1.07 vs. 2.69 ± 1.08 minutes; p = 0.912). However, the duration of sensory block was significantly longer in the levobupivacaine group (241.71 ± 38.46 minutes) compared to the ropivacaine group (209.14 ± 37.45 minutes; p = 0.001). The highest sensory block level achieved was predominantly at T6 in both groups, with no statistically significant difference (p = 0.846). The time to reach the highest sensory level was comparable between the groups (p = 0.206). Similarly, the onset of motor block did not differ significantly between the groups (p = 0.388). The duration of motor block was significantly longer in the levobupivacaine group (276.29 ± 21.16 minutes) compared to the ropivacaine group (253.71 ± 28.29 minutes; p < 0.001). Although more patients in the ropivacaine group required rescue analgesia (28.6%) than in the levobupivacaine group (17.1%), the difference was not statistically significant (p = 0.255). Among those who required it, the mean time to rescue analgesia was similar between the groups (p = 0.651).

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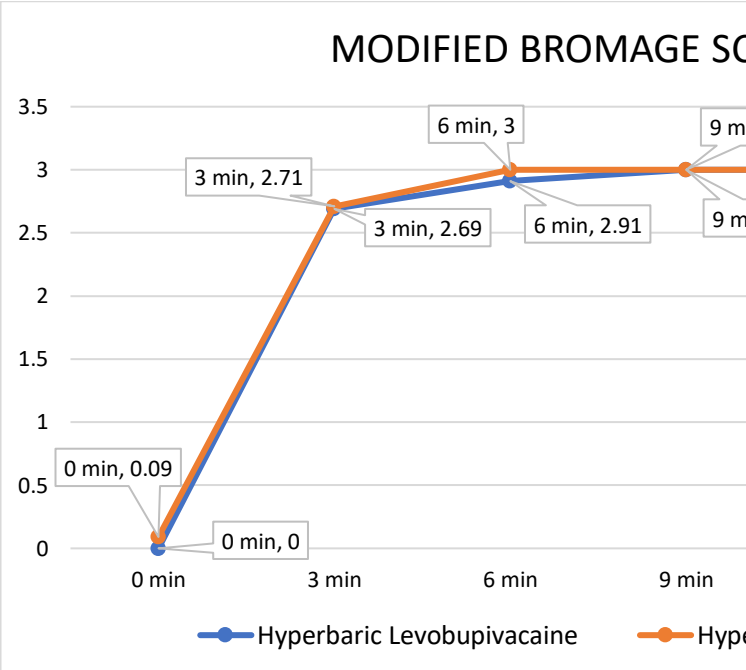
Table 3: Comparison of Hemodynamic Changes and Side Effects Between Hyperbaric Levobupivacaine and Hyperbaric Ropivacaine Groups

S.No	Hemodynamic parameters and Side effects		Hyperbaric Levobupivacaine Group Frequency (%) / Mean±SD	Hyperbaric Ropivacaine Group Frequency (%) / Mean±SD	p-value
1	Bradycardia	Yes	0(0%)	1(2.9%)	1.000*
		No	35(100%)	34(97.1%)	
2	Hypotension	Yes	2(5.7%)	2(5.7%)	1.000*
		No	33(94.3%)	33(94.3%)	
3	Shivering	Yes	1(2.9%)	0(0%)	1.000*
		No	34(97.1%)	35(100%)	
4	Nausea	Yes	0(0%)	0(0%)	-
		No	35(100%)	35(100%)	
5	Vomiting	Yes	0(0%)	0(0%)	-
		No	35(100%)	35(100%)	

*Fisher's Exact Test (2-sided) p-value

The comparison of hemodynamic parameters and side effects between the Hyperbaric Levobupivacaine and Hyperbaric Ropivacaine groups revealed no statistically significant differences. Bradycardia was observed in one patient (2.9%) in the Ropivacaine group and none in the Levobupivacaine group (p = 1.000). Hypotension occurred equally in both groups, with two patients (5.7%) affected in each group (p = 1.000). Shivering was noted in one patient (2.9%) in the Levobupivacaine group and none in the Ropivacaine group (p = 1.000). No cases of nausea or vomiting were reported in either group, and hence statistical analysis was not applicable for these variables. All p-values for the adverse events were derived using Fisher's Exact Test due to small cell counts.



DISCUSSION:

This prospective, randomized double-blind study was conducted to compare the clinical efficacy of intrathecal hyperbaric levobupivacaine (0.5%) and hyperbaric ropivacaine (0.75%) with buprenorphine as an adjuvant in patients undergoing lower abdominal and lower limb surgeries under subarachnoid block. The comparison was based on the onset and duration of sensory and motor blockade, intraoperative

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hemodynamic stability, incidence of side effects, and the need for postoperative rescue analgesia. The findings of this study provide insight into the relative effectiveness and safety profiles of these two local anesthetic agents in the context of spinal anesthesia for infraumbilical procedures. These results are discussed in relation to existing literature to highlight their clinical implications and relevance.

The mean age was slightly higher in the Levobupivacaine group compared to the Ropivacaine group. Otherwise, all the other patient characteristics like sex, height, weight, BMI, ASA grade did not vary significantly between the groups. This homogeneity in patients' baseline characteristics helped minimize potential confounding factors, thereby ensuring that the intraoperative and postoperative outcomes were not influenced by them.

The onset of sensory block was comparable in both levobupivacaine and ropivacaine group (2.71 ± 1.07 vs. 2.69 ± 1.08 minutes; p = 0.912). this finding is similar to finding reported by Kallio et al.,[10] who did a similar comparison study in 90 patients, which reported that median onset of sensory block was similar in both groups. In contrast to our findings, a similar comparison study done by Malinowski et al.,[11] among patients undergoing transurethral resection of bladder or prostrate reported a longer onset time of 13 ± 8 minutes for the ropivacaine group and 11 ± 7 minutes for the bupivacaine group. This difference could be due to variations in patient population, drug baricity, and the volume of local anesthetic used. Greene NM[12], who studied on the Distribution of local anesthetic solutions within the subarachnoid space reported that the major factor which plays a role in the spread of intrathecal anesthesia is the dose of local anesthetic injected.

The highest sensory block level achieved was predominantly at T6 dermatome in both groups, with no statistically significant difference. A similar study done by Vampugalla PS et al.[13] reported similar findings where highest sensory block level was same in both groups, although in their study the highest level attained was T4. On the other hand, Bhat et al.[14] reported variability in the sensory level achieved, with the ropivacaine group reaching up to T8 and the bupivacaine group up to T6. The similar distribution of sensory levels in both groups in our study suggests a comparable spread and efficacy of both drugs when administered under standardized conditions. The time to reach the highest sensory level was comparable between the groups without any statistical significance (p = 0.206).

The duration of sensory block was significantly longer in the levobupivacaine group (241.71 ± 38.46 minutes) compared to the ropivacaine group (209.14 ± 37.45 minutes; p = 0.001). Similar findings were ported by Vampugalla PS et al.[13] and Chung CJ et al.,[15] where ropivacaine group consistently demonstrated a shorter duration of sensory blockade. This implies that levobupivacaine may be more suitable for procedures requiring longer durations of anesthesia, whereas ropivacaine might be preferred in ambulatory or shorter-duration surgeries where quicker recovery is desired.

In our study, we observed that time to the onset of motor block did not differ significantly between the groups (p = 0.388). This is in line with the findings of previous study done by Vampugalla PS et al.[13], Malinowski et al.,[11] and Kallio et al.,[10] who reported that there were no significant result. Another study focusing on intrathecal administration for infraumbilical surgeries found that both 0.5% isobaric bupivacaine and levobupivacaine had similar onset times for motor blockade, although specific times were not detailed[16].

The duration of motor block was significantly longer in the levobupivacaine compared to the ropivacaine group (p < 0.001). In support to our findings, similar studies done by Kallio et al.,[10] Vampugalla PS et al.,[13] Chung CJ et al.,[15] McNamee et al.,[17] and Mantaouvalou et al.,[18] also reported consistent findings where duration of motor block was significantly shorter in the ropivacaine group compared to the bupivacaine group. The difference in motor block duration can be attributed to the lower lipid solubility and reduced affinity of ropivacaine for motor fibers, which results in preferential sensory block and faster motor recovery as reported by Kuthiala and Chaudhary[19]. These characteristic makes ropivacaine a preferred agent in procedures where early ambulation or rapid post-operative motor recovery is desired. On the other hand, the prolonged motor block associated with levobupivacaine may be advantageous in surgeries requiring prolonged muscle relaxation or pain control. Additionally, levobupivacaine, being a pure S-

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enantiomer of bupivacaine, retains potency with a better safety profile in terms of cardiotoxicity and neurotoxicity, making it a viable option in high-risk patients.

We also observed that a higher proportion of patients in the ropivacaine group (28.6%) required rescue analgesia compared to the levobupivacaine group (17.1%), although this difference was not statistically significant. Among those who required it, the mean time to rescue analgesia was comparable between the groups ($p = 0.651$). This finding is consistent with the results of a study by Gautier P et al., which compared these two agents in patients undergoing Caesarean section and found no statistically significant difference in the time to first rescue analgesia. The slightly higher need for rescue analgesia in the ropivacaine group may be due to its relatively shorter sensory block duration, as reported in our study. While ropivacaine is well-known for providing effective sensory blockade with comparatively reduced motor blockade, its shorter duration may necessitate earlier supplemental analgesia.

Bradycardia was observed in one patient in the ropivacaine group, while no cases were reported in the levobupivacaine group. Hypotension occurred with equal frequency in both groups, affecting two patients in each. Shivering was reported in one patient in the levobupivacaine group and none in the ropivacaine group. These findings suggest that both drugs are associated with a favorable hemodynamic profile when used in appropriate dosages with intrathecal buprenorphine. The low incidence of bradycardia and hypotension in both groups aligns with previous studies that have demonstrated the relatively stable cardiovascular profile of both levobupivacaine and ropivacaine compared to racemic bupivacaine[6–8]. There was only one patient who had shivering, a common perioperative issue. This may be because buprenorphine, an opioid adjuvant, has been shown to have some anti-shivering effects when administered intrathecally[20].

One of the main strengths of this study is its prospective, randomized, double-blind design, which reduced selection and observer bias, thereby improving the internal validity of the data. Standardised dosage, methodology, and adjunct (buprenorphine) were used in both groups to guarantee comparability and minimise confounding. Furthermore, a thorough review of the intraoperative and postoperative parameters, as well as the sensory and motor block features, offered a full assessment of the two local anaesthetic agents' safety and effectiveness profiles. The study does have several drawbacks, though. The sample size could not have been sufficiently powered to detect minor differences in uncommon complications or less frequent adverse effects, even though it was sufficient for primary outcome comparisons. Additionally, the study was only carried out at one location, which would restrict how broadly the results can be applied to different clinical contexts or demographics. Last but not least, patient-reported satisfaction metrics and long-term outcomes were excluded, despite the fact that they may offer important information about postoperative recovery and overall patient experience.

CONCLUSION:

This study contributes valuable insights into the comparative efficacy and safety of two commonly used intrathecal anesthetic agents in lower abdominal and lower limb surgeries. This study demonstrates that both intrathecal hyperbaric levobupivacaine and hyperbaric ropivacaine, when combined with buprenorphine, are effective and safe for lower abdominal and lower limb procedures. However, levobupivacaine provided a significantly longer duration of both sensory and motor blockade compared to ropivacaine. The onset times for sensory and motor block, as well as the level of sensory block achieved, were comparable between the two groups. Although more patients in the ropivacaine group required rescue analgesia, this difference was not statistically significant These findings may aid clinicians in selecting appropriate anesthetic regimens tailored to the duration and nature of surgical procedures, ultimately enhancing patient care and outcomes.

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