ORIGINAL RESEARCH PAPER
Volume - 14 | Issue - 11 | November - 2025 | PRINT ISSN No. 2277 - 8179 | DOI : 10.36106/ijsr
INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

A COMPARATIVE STUDY OF 0.5% HYPERBARIC BUPIVACAINE AND 0.5% HYPERBARIC LEVOBUPIVACAINE FOR INFRAUMBILICAL SURGERIES

Anaesthesiology

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ABSTRACT

Introduction: Levobupivacaine, the S-enantiomer of bupivacaine, is a newer local anaesthetic known for similar efficacy with better cardiovascular safety. This study compares 0.5% hyperbaric levobupivacaine and 0.5% hyperbaric bupivacaine for spinal anaesthesia in infraumbilical surgeries, focusing on sensory and motor block characteristics and adverse effects. **Materials And Methods:** A prospective, randomized controlled study was conducted on 70 ASA I–II patients aged 18–60 years undergoing infraumbilical surgery. Patients were randomized into two groups (n=35 each). Group L received 3 ml of 0.5% hyperbaric levobupivacaine, and Group B received 3 ml of 0.5% hyperbaric bupivacaine intrathecally. Sensory block (via pinprick test) and motor block (using the Modified Bromage Scale) were assessed alongside intraoperative hemodynamic parameters. **Results:** Group B demonstrated a significantly faster onset of sensory block (164.91 ± 29.62 sec) and motor block (180.71 ± 28.93 sec) compared to Group L (332.86 ± 44.36 sec and 318 ± 43.37 sec respectively; $p < 0.001$). However, Group L showed significantly prolonged duration of anaesthesia (199.06 ± 14.85 min), sensory block (212.43 ± 11.27 min), motor block (217.83 ± 10.46 min), and effective analgesia (206.43 ± 11.67 min) compared to Group B ($p < 0.01$). Both groups maintained stable hemodynamics, though marginally higher HR and MAP were noted in the levobupivacaine group. **Conclusion:** While bupivacaine ensures quicker onset, levobupivacaine provides a longer duration of anaesthesia and analgesia with comparable safety. Hence, levobupivacaine is a promising alternative for prolonged infraumbilical surgeries under spinal anaesthesia.

KEYWORDS

Levobupivacaine, Bupivacaine, Spinal Anaesthesia, Sensory Block, Motor Block, Infraumbilical Surgery

INTRODUCTION:

Spinal anaesthesia is one of the most commonly employed regional anaesthesia techniques worldwide for infraumbilical surgical procedures. It offers several advantages over general anaesthesia, including the avoidance of airway manipulation, reduced polypharmacy, and superior postoperative analgesia. In recent years, hyperbaric local anaesthetic solutions have largely replaced plain solutions in spinal anaesthesia, owing to their more predictable cephalad spread, prolonged duration of effective sensory and motor blockade, and faster regression of sensory block and recovery from motor block.[1]

Among the available agents, hyperbaric racemic bupivacaine—a mixture of the D- and L-isomers—has been widely used due to its efficacy and availability. However, the D-isomer (dextrobupivacaine) possesses a lower affinity for plasma proteins and has been associated with a higher risk of cardiotoxicity.[2] This has driven the search for a safer alternative with similar anaesthetic properties but a better safety profile.

Levobupivacaine, the pure S(-)-enantiomer of bupivacaine, was introduced as a safer alternative. It exhibits similar clinical efficacy in spinal anaesthesia but with a superior pharmacokinetic and pharmacodynamic profile.[3] Studies have demonstrated that levobupivacaine has a lower affinity for cardiac sodium channes than the R-isomer, resulting in fewer cardiac side effects. Additionally, animal studies have reported reduced neurotoxicity with levobupivacaine use.[4] As a result, it is gaining increasing clinical relevance, particularly in patients where cardiovascular stability is a concern.

This study was undertaken to compare 0.5% hyperbaric levobupivacaine and 0.5% hyperbaric bupivacaine in spinal anaesthesia for infraumbilical surgeries. The primary objective was to compare their sensory and motor block characteristics. Secondary objectives included assessing the onset and duration of sensory block using the pinprick test, evaluating the onset and duration of motor block using the modified Bromage scale, and comparing the incidence of adverse effects between the two agents.

MATERIALS AND METHODS

This was a prospective, randomized controlled study conducted over 18 months after obtaining approval from the Institutional Ethics Committee. A total of 70 patients aged 18 to 60 years, belonging to the American Society of Anesthesiologists (ASA) physical status I or II and scheduled for infraumbilical surgeries under spinal anaesthesia, were enrolled after informed consent. Patients with ASA grades III or IV, spinal deformities, contraindications to spinal anaesthesia, drug allergies, or refusal to participate were excluded.

Participants were randomly allocated into two groups (n=35 each) using a computer-generated randomization table and opaque envelope technique. Group L received 3 ml of 0.5% hyperbaric levobupivacaine intrathecally, while Group B received 3 ml of 0.5% hyperbaric bupivacaine. Standard monitors were attached in the operating room, and baseline vitals were recorded. After preloading with 10 ml/kg of Ringer's lactate, spinal anaesthesia was administered at the L2–L3 or L3–L4 interspace using a 25G Quincke spinal needle with the patient in the sitting position. Sensory block was assessed using the pinprick method, and motor block was evaluated using the modified Bromage scale. Hemodynamic parameters were recorded every 5 minutes for the first 30 minutes and every 10 minutes thereafter until the end of surgery.

Patients were observed for five hours postoperatively. The onset and duration of sensory and motor block, duration of anaesthesia and analgesia, and any adverse effects such as hypotension, bradycardia, nausea, or vomiting were recorded. Data were entered in Microsoft Excel and analyzed using SPSS version 26. Continuous variables were compared using the unpaired t-test, and categorical variables were analyzed using the Chi-square test. A p-value <0.05 was considered statistically significant.

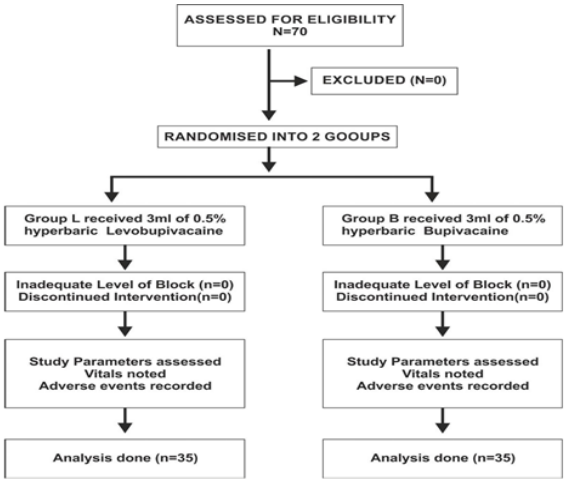

Figure 1: consort flow chart

RESULTS

A total of 70 patients scheduled for infraumbilical surgeries under spinal anaesthesia were enrolled in this comparative study, with 35 patients each in the 0.5% hyperbaric Levobupivacaine group and the 0.5% hyperbaric Bupivacaine group. Both groups were comparable in terms of baseline demographic and clinical characteristics.

Demographic And Clinical Characteristics

The mean age of participants in the Levobupivacaine group was 38.34 ± 11.04 years, while in the Bupivacaine group, it was 42.86 ± 13.00 years, with no statistically significant difference ($p > 0.05$). Age distribution was fairly uniform across the groups, with a predominance of individuals in the 41–50 and 20–30 age categories in the Levobupivacaine group, and a higher proportion in the 51–60 years category in the Bupivacaine group. (Table No:1)

Both groups exhibited a male predominance, with 82.86% males in the Levobupivacaine group and 80% males in the Bupivacaine group. ASA physical status distribution was also comparable: ASA Grade I was seen in 45.7% and 57.14% of the Levobupivacaine and Bupivacaine groups respectively, while the remaining participants were ASA Grade II (Table No:1).

BMI classification revealed most patients in both groups were either normal or pre-obese, with no significant differences. The Levobupivacaine group had 3 underweight, 17 normal, and 15 pre-obese patients, whereas the Bupivacaine group had 1 underweight, 20 normal, 12 pre-obese, and 2 obese patients. (Table No:1)

Table No:1 Demographic And Clinical Characteristics Of Study Population (N=35 each)

Variables	Levobupivacaine Group (%)	Bupivacaine Group (%)
Age Group		
20-30	31.43	22.86
31-40	22.86	20
41-50	34.29	22.86
51-60	11.43	34.29
Gender		
Male	82.8	80
Female	17.2	20
ASA Grade		
Grade 1	45.7	57.14
Grade 2	54.2	42.86
BMI Category		
Underweight	8.6	2.8
Normal	48.6	57.1
Pre-obesity	42.8	34.3
Obese	0	5.7

Sensory And Motor Block Characteristics

The onset of sensory block was significantly faster in the Bupivacaine group (164.91 ± 29.62 seconds) compared to the Levobupivacaine group (332.86 ± 44.36 seconds), with a p-value of 0.001. Similarly, the onset of motor block was significantly quicker in the Bupivacaine group (180.71 ± 28.93 seconds) versus the Levobupivacaine group (318 ± 43.37 seconds, $p = 0.002$). (Table No:2)

In contrast, the duration of anaesthesia was significantly longer in the Levobupivacaine group (199.06 ± 14.85 minutes) compared to the Bupivacaine group (186.86 ± 9.71 minutes, $p = 0.002$). A similar trend was noted in the duration of effective analgesia, which was 206.43 ± 11.67 minutes for Levobupivacaine and 192.71 ± 7.61 minutes for Bupivacaine ($p = 0.001$). (Table No:2)

The total duration of sensory block was significantly longer in the Levobupivacaine group (212.43 ± 11.27 minutes) compared to the Bupivacaine group (190.06 ± 7.30 minutes, $p = 0.002$). The total duration of motor block also favored Levobupivacaine (217.83 ± 10.46 minutes vs. 195 ± 4.54 minutes in the Bupivacaine group, $p = 0.001$). (Table No:2)

Table No:2 Comparison of Sensory and Motor Block Characteristics Between 0.5% Levobupivacaine and 0.5% Bupivacaine

Parameter	Groups	Mean	Std. Deviation	t Value	p Value
Time of Onset Sensory Block (s)	0.5% Levobupivacaine	332.86	44.363	18.26	0.001
	0.5% Bupivacaine	164.91	29.615		
Motor Block Onset Time (s)	0.5% Levobupivacaine	318	43.373	15.58	0.002
	0.5% Bupivacaine	180.71	28.931		
Duration of Anaesthesia (min)	0.5% Levobupivacaine	199.06	14.848	4.07	0.002
	0.5% Bupivacaine	186.86	9.708		
Duration of Effective Analgesia	0.5% Levobupivacaine	206.43	11.668	5.8	0.001
	0.5% Bupivacaine	192.71	7.606		
Total Sensory Block Duration (min)	0.5% Levobupivacaine	212.43	11.27	9.8	0.002
	0.5% Bupivacaine	190.06	7.304		
Total Motor Block Duration (min)	0.5% Levobupivacaine	217.83	10.459	11.85	0.001
	0.5% Bupivacaine	195	4.537		

Intraoperative Hemodynamic Parameters

Intraoperative hemodynamic monitoring showed no statistically significant differences between the two groups at baseline (0 minutes). At most time intervals, both drugs maintained stable hemodynamic parameters. However, heart rate was significantly higher in the Levobupivacaine group at 30, 60, 90, and 120 minutes. At 120 minutes, SBP (120.71 ± 8.40 vs. 114.77 ± 10.75 mmHg, $p = 0.012$) and MAP (87.74 ± 5.25 vs. 84.34 ± 6.55 mmHg, $p = 0.019$) were also significantly higher in the Levobupivacaine group. (Table No:3)

At other intervals, including 5, 10, 15, 180, and 240 minutes, no significant differences in SBP, DBP, or MAP were observed, suggesting that both drugs were hemodynamically stable, with only transient variations noted, particularly in heart rate. At 180 and 240 minutes, all hemodynamic parameters (HR, SBP, DBP, MAP) were comparable between the two groups ($p > 0.05$).(Table No:3)

Table No:3 Comparison of Intraoperative Hemodynamic Parameters Between 0.5% Levobupivacaine (L) and 0.5% Bupivacaine (B) Groups at Various Time Intervals

Time	Parameter	Group	Mean	Std. Deviation	p value
0 min	HR	L	83.63	10.611	0.561
		B	82.14	10.642	0.561
	SBP	L	133.4	10.974	0.698
		B	132.46	9.217	0.698
	DBP	L	80.11	7.062	0.6
		B	79.26	6.541	0.6
	MAP	L	97.63	6.791	0.668
		B	96.94	6.521	0.668
30 min	HR	L	76.34	10.781	0.04
		B	71.46	9.102	0.04
	SBP	L	114.49	12.219	0.295
		B	111.49	11.574	0.295
	DBP	L	68.97	6.415	0.096
		B	66.26	7.039	0.096
	MAP	L	82.71	8.743	0.313
		B	80.71	7.695	0.313
60 min	HR	L	75.46	9.814	0.023
		B	70.29	8.747	0.023
	SBP	L	115.34	11.088	0.463
		B	113.29	12.162	0.463
	DBP	L	68.77	6.431	0.958
		B	68.86	6.194	0.958
	MAP	L	84.29	7.637	0.694
		B	83.57	7.477	0.694
120 min	HR	L	77.63	9.188	0.005
		B	71.57	8.318	0.005
	SBP	L	120.71	8.404	0.012
		B	114.77	10.754	0.012
	DBP	L	71.43	4.572	0.23
		B	69.89	5.984	0.23
	MAP	L	87.74	5.254	0.019
		B	84.34	6.548	0.019
240 min	HR	L	76.06	9.049	0.906
		B	76.31	9.106	0.906
	SBP	L	122.03	8.129	0.771

		B	122.6	8.24	0.771
	DBP	L	73.17	4.932	0.129
		B	71.29	5.317	0.129
	MAP	L	89.26	5.58	0.469
		B	88.31	5.246	0.469

DISCUSSION

This randomized controlled trial compared the intrathecal administration of 0.5% hyperbaric levobupivacaine and 0.5% hyperbaric bupivacaine in patients undergoing infraumbilical surgeries. The groups receiving 0.5% Levobupivacaine and 0.5% Bupivacaine had similar baseline demographics. Their mean ages were 38.34±11.04 years and 42.86±13.00 years, with no significant difference ($p>0.05$). This aligns with Ajay Singh et al[5], who also found comparable mean ages in both groups. Both groups had comparable demographics, with more younger participants in the Levobupivacaine group and slightly more older participants in the Bupivacaine group. ASA status and BMI were similarly distributed, reducing confounding factors. This baseline balance enhances the validity of comparing the drugs' pharmacological effects. This pattern was also noted in similar trials, including the study by Bajwa et al.[6] and Vanna et al.[7]

Our results demonstrated a significantly faster onset of both sensory and motor blockade in the bupivacaine group compared to the levobupivacaine group. This could be attributed to the racemic nature and higher lipid solubility of bupivacaine, enhancing its ability to penetrate neural tissues rapidly. These findings are in line with the studies conducted by Glaser et al.[8], Gulec D et al[9] and Duggal et al[10], although some contrasting observations have been reported by Isha Yadav et al.[11] and Mudiganti et al[12], likely due to methodological differences. Interestingly, our study found a longer duration of both sensory and motor blocks with levobupivacaine, differing from studies like Singh A et al.[5], but partially supported by Gulec D et al[9], indicating that baricity and patient factors may influence block duration.

In terms of intraoperative hemodynamics, both agents were largely stable, but levobupivacaine showed modestly higher heart rate and arterial pressures between 30 to 120 minutes. These differences, while statistically significant, were clinically minor and resolved spontaneously, indicating transient sympathetic stimulation or lesser autonomic blockade. Our findings align with prior reports by Glaser et al[8], Guler et al[13], and Singh A et al.[5], who emphasized the favorable cardiovascular safety profile of levobupivacaine. Moreover, the lower incidence of hypotension and bradycardia in the levobupivacaine group, though not statistically significant, corresponds with the findings of Huang et al.[14], supporting the notion of its reduced cardiotoxicity.

This study's strengths include the use of standardized tools like the pinprick test and Modified Bromage Scale, the inclusion of side effect profiles, and a direct comparison of two commonly used anesthetics, enhancing clinical relevance and objectivity. However, its single-center design, limited follow-up duration, and potential inter-observer variability in sensory testing may affect the generalizability and consistency of the findings.

Overall, both 0.5% hyperbaric bupivacaine and levobupivacaine proved effective for infraumbilical surgeries. While bupivacaine offered faster onset, levobupivacaine provided prolonged duration of anaesthesia and analgesia with a more favourable hemodynamic profile. These results suggest that the choice of agent can be individualized based on clinical context, patient comorbidities, and procedural requirements.

Limitation:

It includes a small sample size (70 patients) and restriction to ASA I-II patients, limiting applicability to high-risk population

CONCLUSION

Both Levobupivacaine and Bupivacaine are effective and safe for spinal anaesthesia in infraumbilical surgeries. Bupivacaine is advantageous for shorter procedures requiring rapid onset. Levobupivacaine is more suitable for longer surgeries or when prolonged postoperative analgesia is desirable. Additionally, Levobupivacaine's lower cardiotoxicity profile makes it a potentially safer choice for patients with cardiovascular comorbidities.

Financial support and sponsorship: Nil

Conflicts of interest: None

ACKNOWLEDGEMENTS:

would like to express my heartfelt gratitude to all who contributed to the completion of this article. My deepest thanks to

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