VOLUME - 14, ISSUE - 06, JUNE - 2025 • PRINT ISSN No. 2277 - 8160 • DOI : 10.36106/gjra

Original Research Paper

Anaesthesiology

A RANDOMISED CONTROLLED STUDY COMPARING HYPERBARIC LEVOBUPIVACAINE 0.5% WITH HYPERBARIC BUPIVACAINE 0.5% FOR IT'S EFFICACY IN SPINAL ANAESTHESIA FOR LOWER ABDOMINAL AND LOWER LIMB SURGERIES.

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ABSTRACT **Introduction-** Spinal anaesthesia is a widely used technique for lower abdominal and lower limb surgeries. The choice of local anaesthetic agent can significantly impact the quality of anaesthesia and patient outcomes. **Materials And Methods-** This randomized controlled study included 60 ASA I & II patients undergoing lower abdominal or lower limb surgeries. Patients were randomly allocated into two groups: Group B (n=30) received 3.2 ml hyperbaric bupivacaine 0.5% and Group LB (n=30) received 3.2ml hyperbaric levobupivacaine 0.5%. The onset and duration of sensory and motor blockade, haemodynamic parameters and side effects were assessed and compared between the two groups. **Result-** The bupivacaine group demonstrated faster onset of motor blockade and longer duration of both sensory and motor blockade. The levobupivacaine group showed better haemodynamic stability. The incidence of side effects was low in both groups, with no statistically significant difference. **Conclusion-** Both hyperbaric levobupivacaine 0.5% and hyperbaric bupivacaine 0.5% provided effective spinal anaesthesia for lower abdominal and lower limb surgeries

KEYWORDS : Spinal anaesthesia; Hyperbaric levobupivacaine; Hyperbaric bupivacaine; Motor and sensory blockade; Haemodynamic stability

INTRODUCTION

Spinal anaesthesia is a widely used technique for lower abdominal and lower limb surgeries due to its rapid onset, reliable effectiveness, and minimal systemic effects. The choice of local anaesthetic agent plays a crucial role in determining the quality and duration of the nerve block, as well as the incidence of side effects.

Bupivacaine, a long-acting amide local anaesthetic, has been the gold standard for spinal anaesthesia for decades. However, concerns about its potential for cardiovascular and central nervous system toxicity have led to the development of newer agents. Levobupivacaine, the S (-) enantiomer of bupivacaine, has emerged as a promising alternative due to its reduced toxicity profile while maintaining almost similar anaesthetic properties.

Hyperbaric formulations of local anaesthetics allow for more predictable spread of the anaesthetic within the subarachnoid space. While numerous studies have compared plain bupivacaine and levobupivacaine, there is limited research directly comparing their hyperbaric formulations. Hyperbaric levobupivacaine has become available recently. Hence, this study was conducted to compare the effects of hyperbaric formulations of levobupivacaine 0.5% and bupivacaine 0.5% in lower abdominal and lower limb surgeries.

MATERIALS AND METHODS

After obtaining approval from the Institutional Ethics Committee, a prospective randomized controlled study was conducted in 60 patients, aged 18 - 65 years, belonging to ASA I & II category, undergoing lower abdominal and lower limb surgeries under spinal anaesthesia. Exclusion criteria were patient refusal, patients with known allergy to local anaesthetics, raised intracranial pressure, bleeding disorders/current use of anticoagulant medications, fixed cardiac output states or any diagnosed neuromuscular conditions. Patients with active infections at the injection site and spinal deformities that may complicate the procedure, as well as pregnant or lactating women were also excluded from the study.

After taking a valid written consent, patients were randomly allocated to two groups (30 patients each) using a computer-generated randomization sequence. The allocation was concealed using sealed opaque envelopes.

- **Group B:** Received spinal anaesthesia with 3.2 ml of hyperbaric bupivacaine 0.5%
- **Group LB:** Received spinal anaesthesia with 3.2 ml of hyperbaric levobupivacaine 0.5%

All patients underwent a thorough pre-anaesthetic evaluation including clinical assessment and routine investigations. On the day of surgery, patients were taken to the operating room, where standard ASA monitoring was established. Intravenous access was secured and Ringer's lactate infusion was started. Under aseptic precautions, lumbar puncture was performed in the sitting position at L3-L4 interspace using a 25G Quincke spinal needle. After confirming free flow of cerebrospinal fluid, the study drug was injected intrathecally over 15 seconds. Patients were immediately placed in the supine position after the injection.

Haemodynamic Parameters - heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), and mean arterial pressure (MAP) were recorded at 2minute intervals for the first 20 minutes, and then at 10 minute intervals until 60 minutes, followed by 30minute interval until complete regression of the block.

Sensory block was assessed bilaterally using the pinprick method with a short-bevelled 27-gauge needle in the midclavicular line. Motor block was evaluated using the Modified Bromage scale (I- Free movement of legs and feet, II- Just able to flex knees with free movement of feet, III – Unable to flex knees, but with free movement of feet, IV – Unable to move legs and feet). The parameters recorded were (i) onset of sensory block (taken as the time from the deposition of drug

to the evidence of analgesia to pinprick at T12 level), (ii) total duration of sensory block (taken as the time from the onset of sensory block to the sensory regression to L1), (iii) the maximum level of sensory block achieved, (iv) time to reach the maximum sensory block, (v) onset of motor block (time taken from the deposition of drug to achieve modified Bromage score of II), (vi) time for complete motor blockade (time taken from the deposition of drug to achieve modified Bromage score of IV), (vii) total duration of motor blockade(time taken from the onset of motor blockade to complete recovery of motor movements of legs and feet).

Incidence of side effects (hypotension, bradycardia, nausea, vomiting, shivering) were noted. Hypotension (defined as a decrease in SBP > 20% from baseline or < 90 mmHg) was treated with intravenous fluid bolus and/or ephedrine 6 mg IV boluses. Bradycardia (heart rate < 50 beats/min) was treated with atropine 0.6 mg IV.

Data was entered in excel sheet and analysed using the Statistical Package for the Social Sciences 20 (SPSS Inc. Chicago). Results were presented in tabular and graphical forms. Mean, median, standard deviation and ranges were calculated for quantitative data. Qualitative data were expressed in terms of frequency and percentages. Student t test (Two Tailed) was used to test the significance of mean between the 2 groups and P value <0.05 was considered significant.

RESULTS

The two groups were demographically comparable in terms of age, ASA classification and duration of surgery.

Table 1: Comparison Of Groups According To Age, ASA Classification, Duration Of Surgery.

Mean + SD		Group LB	Group B	p-value
Age(years)		45.4 ± 9.1	45 ± 9.5	0.84
ASA Classification	I	20 (66.7%)	20 (66.7%)	1.0
	II	10 (33.3%)	10 (33.3%)	
Duration of surgery(mins)		118.2 ± 19.5	119.2 ± 22.4	0.84

Table 2: Comparison Of Groups According To Motor Blockade

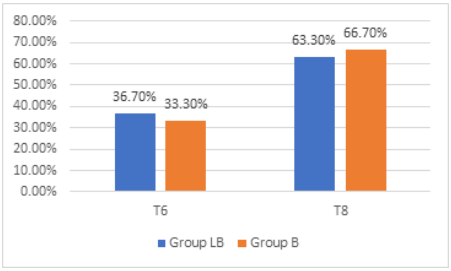
Motor blockade (mean ± SD)	Group LB	Group B	p-value
Onset of motor blockade(mins)	5.2 ± 0.51	3.45 ± 0.45	<0.001
Time taken for complete motor blockade(mins)	12.7 ± 0.7	10.7 ± 0.7	<0.001
Total duration of motor blockade(mins)	180.03 ± 3.2	189.1 ± 2.9	<0.001

Group LB showed significantly slower onset of motor blockade and a longer time for complete blockade as compared to group B. Group LB had shorter total duration of motor blockade. All these differences were statistically significant **(p<0.001).**

Table 3: Comparison Of Groups According To Sensory Blockade

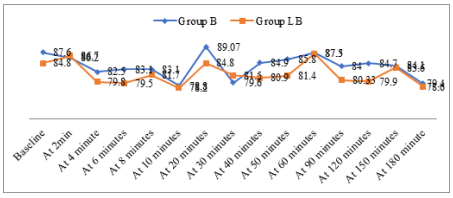
Sensory blockade (mean ± SD)	Group LB	Group B	p-value
Onset of sensory blockade(mins)	6.1 ± 1.1	5.6 ± 0.9	0.06
Time taken for highest sensory level(mins)	15.6 ± 0.57	13.6 ± 0.608	<0.001
Total duration of sensory blockade(mins)	195.07 ± 2.6	206.1 ± 19.3	0.003

While the onset of sensory blockade was not significantly different, Group LB took longer to reach the highest sensory level and had a shorter total duration of sensory blockade compared to Group B.



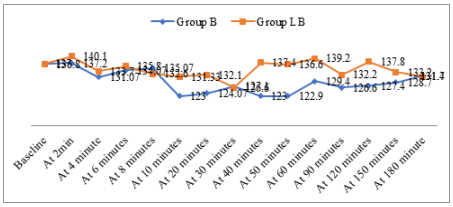
Graph 1: Comparison of groups according to highest sensory level achieved

Majority of patients in both groups reached T8 level (63.3% in Group LB, 66.7% in Group B), with the rest reaching T6 level. The p-value of 0.78 suggests that both drugs were capable of providing similar levels of sensory blockade.



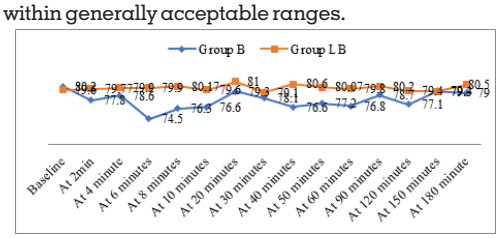
Graph 2: Comparison of Heart Rate among groups

At baseline, and for the first 30 minutes, there were no statistically significant differences in HR between the two groups (all p-values > 0.05). At 40 and 50 minutes, statistically significant differences emerged with Group B showed higher heart rates compared to Group LB. The differences became non-significant again from 60 to 90 minutes, suggesting that the effects of both drugs on HR became more similar as time progressed. Another significant difference appeared at 120 minutes: Group B showed a higher HR (84.7 ± 7.1) vs Group LB (79.9 ± 9.1); **p - 0.03.** In the final hour of observation, there were no significant differences between the groups, suggesting that the effects of both drugs on HR had largely equalized by this time.



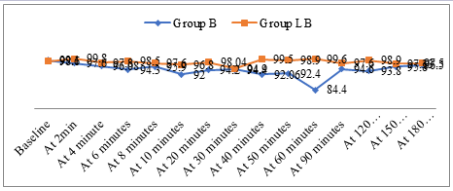
Graph 3: Comparison of Systolic BP among groups

Initially, there were no significant differences in SBP, but from 10 minutes onwards, levobupivacaine caused less hypotension compared to bupivacaine. It is important to note that while statistically significant, the differences may not always be clinically significant, and both drugs maintained SBP within generally acceptable ranges.



Graph 4: Comparison of Diastolic BP among groups

The DBP comparison showed fewer significant differences compared to SBP. Significant differences were observed at 6, 8 and 40 minutes, with Group levobupivacaine showing less hypotension. However, the differences in DBP were smaller than those seen in SBP, suggesting that the drugs' effects on DBP are less pronounced.

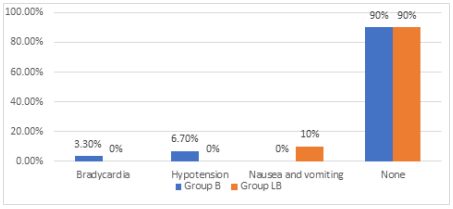


Graph 5: Comparison of MAP among groups

The MAP comparison shows a pattern similar to SBP and DBP, with Group LB generally maintaining higher MAP values. Significant differences were observed at several time points, particularly at 6, 10, 20, 40, 50, 60 and 120 minutes ($p<0.001$ for many of these). This consistent pattern across SBP, DBP, and MAP strongly suggests that levobupivacaine has a more favourable profile in terms of maintaining blood pressure.

Comparison Of Respiratory Rate And SpO2 Among Groups

Both groups maintained similar and stable respiratory rates and SpO2 throughout the procedure.



Graph 6: Comparison of side effects among groups

In Group B, one patient had bradycardia and 2 patients experienced hypotension. In Group LB, 3 patients experienced nausea and vomiting. Importantly, 90% of patients in both groups experienced no side effects.

DISCUSSION

Spinal anaesthesia or subarachnoid block is a widely used technique for lower abdominal and lower limb surgeries due to its reliability, simplicity, and cost-effectiveness. The choice of local anaesthetic agent plays a crucial role in determining the quality and duration of anaesthesia, as well as the occurrence of side effects.

In our study, the onset of sensory blockade was slightly faster in the bupivacaine group (5.6 ± 0.9 min) compared to the levobupivacaine group (6.1 ± 1.1 min), although this difference was not statistically significant ($p = 0.06$). This finding is consistent with the results reported by ***Guler et al***, who found no significant difference in the onset of sensory block between levobupivacaine and bupivacaine groups.

We observed a significant difference in the time taken to achieve the highest sensory level, with the bupivacaine group reaching it faster (13.6 ± 0.608 min) compared to the levobupivacaine group (15.6 ± 0.57 min, $p < 0.001$). This contrasts with the findings of ***Fattorini et al,*** who reported no significant difference in the time to reach maximum sensory block height between levobupivacaine and bupivacaine groups.

The total duration of sensory blockade was significantly longer in the bupivacaine group (206.1 ± 19.3 min) compared to the levobupivacaine group (195.07 ± 2.6 min, p - 0.003). This aligns with the results of ***Glaser et al***, who found a longer duration of sensory block with bupivacaine compared to levobupivacaine in Caesarean sections.

The bupivacaine group demonstrated faster onset of motor blockade (3.45 ± 0.45 min vs. 5.2 ± 0.51 min, $p < 0.001$), quicker time to complete blockade (10.7 ± 0.7 min vs. 12.7 ± 0.7 min, $p < 0.001$), and longer total duration (189.1 ± 2.9 min vs. 180.03 ± 3.2 min, $p < 0.001$) compared to the levobupivacaine group. These findings are partially supported by ***Sathitkarnmanee et al,*** who reported faster onset of motor block with bupivacaine, but no significant difference in the duration of motor block.

With regard to haemodynamic parameters, the bupivacaine group showed lower SBP at multiple time points. MAP was also significantly lower in the bupivacaine group at several time points. These findings suggest that levobupivacaine may offer better haemodynamic stability compared to bupivacaine. This observation is consistent with the results reported by ***Vanna et al***, who found that levobupivacaine provided better cardiovascular stability than bupivacaine in elderly patients undergoing lower limb surgery.

The incidence of side effects was generally low in both groups. However, we observed some differences in the type of side effects experienced. The bupivacaine group had one case of bradycardia (3.3%) and two cases of hypotension (6.7%), while the levobupivacaine group had three cases of nausea and vomiting (10%). These findings suggest a slightly different side effect profile between the two drugs, with bupivacaine potentially having a greater impact on cardiovascular parameters. This observation aligns with the findings of ***Erdil et al***, who reported a higher incidence of hypotension with bupivacaine compared to levobupivacaine in patients undergoing urological surgery. However, the overall low incidence of side effects in our study suggests that both drugs can be considered safe for use in spinal anaesthesia when administered at the doses used in our protocol.

CONCLUSION

The results of our study show that bupivacaine exhibited a faster onset of both motor and sensory blockade, as well as a longer duration of action. However, the bupivacaine group also showed a higher incidence of hypotension and bradycardia, suggesting a greater impact on cardiovascular parameters. In contrast, levobupivacaine demonstrated better haemodynamic stability throughout the procedure. Though its onset was slightly slower and duration shorter compared to bupivacaine, it provided adequate anaesthesia for the surgeries performed.

These findings suggest that the choice between hyperbaric levobupivacaine and hyperbaric bupivacaine for spinal anaesthesia may depend on the specific requirements of the surgery and the patient's cardiovascular status. For procedures requiring rapid onset and prolonged duration of anaesthesia, bupivacaine may be preferred. However, for patients with cardiovascular concerns or in cases where haemodynamic stability is crucial, levobupivacaine might be the better choice. The slightly different side effect profiles observed also warrant consideration in patient selection.

Further research exploring different doses, baricity, and applications in various patient populations and surgical procedures would provide additional insights to guide clinical practice.

REFERENCES

1. Girish, B. K., Srinivas, H. T., Reddy, S. M., & Archana, K. N. (2018). A comparative study of hyperbaric 0.5% levobupivacaine with bupivacaine 0.5% for spinal anaesthesia in elective surgeries. Indian Journal of Anesthesia and Analgesia, 5(12), 2013–2020. https://doi.org/ 10.21088/ ijaa. 2349.8471.51218.8
2. Hocking G, Wildsmith JA. Intrathecal drug spread. *Br J Anaesth*. 2004;93(4): 568-578. doi:10.1093/bja/aeh204
3. Fettes PD, Hocking G, Peterson MK, Luck JF, Wildsmith JA. Comparison of plain and hyperbaric solutions of ropivacaine for spinal anaesthesia. *Br J Anaesth*. 2005;94(1):107-111. doi:10.1093/bja/aei008
4. Bardsley H, Gristwood R, Baker H, Watson N, Nimmo W. A comparison of the cardiovascular effects of levobupivacaine and rac-bupivacaine following intravenous administration to healthy volunteers. *Br J Clin Pharmacol*. 1998; 46(3):245-249. doi:10.1046/j.1365-2125.1998.00775.x
5. Foster RH, Markham A. Levobupivacaine: a review of its pharmacology and

use as a local anaesthetic. *Drugs*. 2000;59(3):551-579. doi:10.2165/00003495-200059030-00013
6. Sanansilp V, Trivate T, Chompubai P, Visalyaputra S, Suksopee P, Permpolprasert L, von Bormann B. Clinical characteristics of spinal levobupivacaine: hyperbaric compared with isobaric solution. Scientific World Journal. 2012;2012:169076. doi: 10.1100/2012/169076. Epub 2012 Apr 24. PMID: 22619612; PMCID: PMC3349113.
7. Piacherski V, Muzyka L. Comparison of the efficacy of 0.5% isobaric bupivacaine, 0.5% levobupivacaine, and 0.5% hyperbaric bupivacaine for spinal anaesthesia in lower limb surgeries. Sci Rep. 2023 Feb 15;13(1):2736. doi: 10.1038/s41598-023-29711-9. PMID: 36792639; PMCID: PMC9932064.
8. Sury MRJ, Palmer JHMG, Cook TM, Pandit JJ, Mahajan RP. The state of UK anaesthesia: a survey of National Health Service activity in 2013. *British Journal of Anaesthesia* 2014; **113**: 575-84.
9. Calatayud J, Gonzalez A. History of the development and evolution of local anaesthesia since the coca leaf. Anaesthesiology 2003; 98: 1503-8.
10. Brown DL, Fink BR. The history of regional anaesthesia. In: Cousins MJ, Carr DB, Horlocker TT, Bridenbaugh PO, eds. Cousins and Bridenbaugh's neural blockade in clinical anaesthesia and pain medicine. Philadelphia: Lippincott Williams & Wilkins; 2009: 9-18.
11. Neustein SM. The use of lidocaine for spinal anaesthesia. Anaesthesia and Analgesia 2008; 106: 1586-7.
12. Dripps RD, Vandam LD. Long-term follow-up of patients who received 10,098 spinal anaesthetics: failure to discover major neurological sequelae. Journal of the American Medical Association 1954; 156: 1486-91.
13. New York School of Regional Anaesthesia. The history of spinal anaesthesia, 2020. Available from: https://www.nysora.com/techniques/neuraxial-and-perineuraxial-techniques/spinal-anaesthesia/ (accessed 10/3/2021).
14. Warren, D.T. & Liu, S.S. (2008). Neuraxial Anaesthesia. In D.E. Longnecker et al (eds) Anaesthesiology. New York: McGraw-Hill Medical.
15. Carpenter RL, Caplan RA, Brown DL, Stephenson C, Wu R. Incidence and risk factors for side effects of spinal anaesthesia. Anaesthesiology. 1992 Jun;76(6):906-16.
16. Wong GK, Pehora C, Crawford MW. L-carnitine reduces susceptibility to bupivacaine-induced cardiotoxicity: an experimental study in rats. Can J Anaesth. 2017 Mar;64(3):270-279.
17. Sethi D. Randomised Control Trial Comparing Plain Levobupivacaine and Ropivacaine with Hyperbaric Bupivacaine in Caesarean Deliveries. Turk J Anaesthesiol Reanim. 2019 Dec;47(6):471-479.
18. Gurpreet Singh, Niraj Mansukhlal Rathod, Kirti Patel. Comparison of Equipotent Doses of Hyperbaric Ropivacaine and Hyperbaric Levobupivacaine in Spinal Anaesthesia for Patients Undergoing Lower Abdominal and Lower Limb Surgeries. Indian J Anesth Analg. 2019;6(1):249-54.
19. Guler G, Cakir G, Ulgey A, et al. A Comparison of Spinal Anaesthesia with Levobupivacaine and Hyperbaric Bupivacaine for CaesareanSections: A Randomized Trial. Open J Anesthesiol. 2012;2(3):84-89.
20. Fattorini F, Ricci Z, Rocco A, et al. Levobupivacaine versus racemic bupivacaine for spinal anaesthesia in orthopaedic major surgery. Minerva Anestesiol. 2006;72(7-8):637-644
21. Glaser C, Marhofer P, Zimpfer G, et al. Levobupivacaine versus racemic bupivacaine for spinal anaesthesia. Anesth Analg. 2002;94(1):194-198.
22. Sathitkarnmanee T, Thongrong C, Tribuddharat S, et al. A comparison of spinal isobaric levobupivacaine and racemic bupivacaine for lower abdominal and lower extremity surgery. J Med Assoc Thai. 2011;94(6):716-720.
23. Vanna O, Chumsang L, Thongmee S. Levobupivacaine and bupivacaine in spinal anaesthesia for transurethral endoscopic surgery. J Med Assoc Thai. 2006;89(8):1133-1139.
24. Erdil F, Bulut S, Demirbilek S, et al. The effects of intrathecal levobupivacaine and bupivacaine in the elderly. Anaesthesia. 2009;64(9):942-946.