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Study Of Comparison Of Clinical Efficacy Of Hyperbaric Bupivacaine And Isobaric Levobupivacaine Following Intrathecal Administration In Patients Undergoing Elective Infraumbilical Surgeries.

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ABSTRACT

Hyperbaric bupivacaine is widely used for spinal anesthesia because of its rapid onset and reliable sensory and motor blockade. However, concerns regarding its cardiotoxicity have led to the use of levobupivacaine, which offers a better safety profile. The present study compared the clinical efficacy of intrathecal 0.5% hyperbaric bupivacaine and 0.5% isobaric levobupivacaine in patients undergoing elective infraumbilical surgeries. This prospective, randomized, double-blind comparative study included 126 ASA I–II patients undergoing elective infraumbilical surgeries. Patients were randomly allocated into two groups (n=63 each). Group B received 3 mL of 0.5% hyperbaric bupivacaine, while Group L received 3 mL of 0.5% isobaric levobupivacaine intrathecally. Sensory and motor block characteristics, duration of anesthesia, and adverse effects were compared. Baseline demographic and operative characteristics were comparable between the groups. Hyperbaric bupivacaine produced a significantly faster onset of sensory blockade (4.69±1.01 vs. 5.73±1.03 min; p=0.0002) and a longer duration of sensory blockade (193.49±19.44 vs. 181.26±13.62 min; p=0.042). Maximum sensory level, two-segment regression, and onset of motor blockade were comparable. Although motor blockade lasted longer with hyperbaric bupivacaine, the incidence of adverse effects was low and comparable in both groups. Both intrathecal hyperbaric bupivacaine and isobaric levobupivacaine provided effective spinal anesthesia for elective infraumbilical surgeries. Hyperbaric bupivacaine offered a faster onset and prolonged sensory blockade, whereas levobupivacaine demonstrated comparable anesthetic efficacy with a favorable safety profile, making it a suitable alternative for spinal anesthesia.

Keywords: Hyperbaric bupivacaine; Isobaric levobupivacaine; Spinal anesthesia.

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INTRODUCTION

Spinal anesthesia is the preferred anesthetic technique for elective infraumbilical surgeries because it provides rapid onset, dense sensory and motor blockade, excellent muscle relaxation, and effective postoperative analgesia while avoiding the risks associated with general anesthesia [1].

Hyperbaric bupivacaine has long been considered the gold standard local anesthetic for intrathecal administration owing to its reliable and predictable block characteristics. However, concerns regarding its cardiotoxicity and neurotoxicity have prompted the search for safer alternatives [2-4].

Levobupivacaine, the pure S(-)-enantiomer of bupivacaine, offers a favorable safety profile with reduced cardiovascular and central nervous system toxicity while maintaining comparable anesthetic efficacy. Isobaric levobupivacaine has demonstrated satisfactory sensory and motor blockade with greater hemodynamic stability and faster postoperative recovery in several clinical settings [5].

Nevertheless, evidence comparing hyperbaric bupivacaine and isobaric levobupivacaine in elective infraumbilical surgeries remains limited [6, 7]. Therefore, the present study was undertaken to compare the clinical efficacy, block characteristics, hemodynamic profile and adverse effects of these two intrathecal local anesthetic agents.

MATERIALS AND METHODS

This prospective, randomized, double-blind comparative study was conducted in the Department of Anaesthesiology and Critical Care, Shija Hospital and Research Institute, Langol, Imphal, from March 2018 to March 2019, after obtaining approval from the Institutional Ethics and Scientific Committee. Written informed consent was obtained from all participants before enrolment. A total of 126 patients belonging to the American Society of Anesthesiologists (ASA) physical status I and II, aged 21–60 years, who were scheduled for elective infraumbilical surgeries under spinal anesthesia, were included in the study. Patients were randomly allocated into two equal groups (n=63 each) using a computer-generated randomization sequence. Group B received 3 mL of 0.5% hyperbaric bupivacaine (15 mg), whereas Group L received 3 mL of 0.5% isobaric levobupivacaine (15 mg) intrathecally. The sample size of 63 patients per group was calculated based on a previous study, assuming an effect size of 0.5, 80% study power, and a two-sided alpha error of 0.05. Double blinding was maintained by assigning drug preparation to an anesthesiologist not involved in patient management, while another blinded anesthesiologist administered spinal anesthesia and recorded study observations.

All patients underwent a detailed pre-anesthetic evaluation one day before surgery, including medical history, physical examination, assessment of ASA status, body mass index, and systemic examination. Routine laboratory investigations, electrocardiography, and chest radiography were performed as indicated. Patients with local infection at the puncture site, coagulation disorders, neurological or psychiatric illness, severe hypovolemia, significant cardiac disease, spinal deformity, previous spinal surgery, obesity (BMI >30 kg/m^2), pregnancy, or refusal to participate were excluded. Patients were instructed to fast for six hours before surgery while clear fluids were allowed up to two hours preoperatively. Premedication with oral alprazolam 0.25 mg and ranitidine 150 mg was administered on the night before surgery. After establishing intravenous access with an 18-gauge cannula, all patients were preloaded with isotonic crystalloid solution at 10 mL/kg body weight before administration of spinal anesthesia.

In the operating room, standard monitoring including electrocardiography, non-invasive blood pressure and pulse oximetry was instituted. Under strict aseptic precautions, spinal anesthesia was administered at the L2–L3 or L3–L4 intervertebral space using a 25G Quincke spinal needle with the patient in the lateral decubitus position. Immediately after intrathecal injection, patients were placed supine and received supplemental oxygen at 3 L/min through a Venturi mask. Hemodynamic variables were recorded at baseline, every 2 minutes for the first 10 minutes, every 5 minutes thereafter until completion of surgery, and postoperatively up to 12 hours. The onset and duration of sensory blockade, onset and duration of motor blockade (assessed using the Modified Bromage Scale), maximum sensory level achieved and intraoperative as well as postoperative adverse events were recorded. Hypotension and bradycardia were managed according to standard institutional protocols using intravenous fluids, ephedrine, and atropine whenever required.

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RESULTS

Table 1: Comparison of Sensory and Motor Block Characteristics

Parameter	Group L (Levobupivacaine)	Group B (Hyperbaric Bupivacaine)	P value
Onset of Sensory Block at T10 (min), Mean ± SD	5.73 ± 1.03	4.69 ± 1.01	**0.0002**
Maximum Sensory Level	Comparable	Comparable	0.186
Two-Segment Regression (min), Mean ± SD	106.66 ± 10.47	107.46 ± 10.92	0.231
Duration of Sensory Block (min), Mean ± SD (Regression to L1)	181.26 ± 13.62	193.49 ± 19.44	**0.042**
Onset of Motor Block (min), Mean ± SD	7.80 ± 1.73	6.68 ± 1.63	0.283
Duration of Motor Block (min), Mean ± SD	203.80 ± 17.06	236.98 ± 16.09	**0.059***

Reported as significant in the original study results.

Hyperbaric bupivacaine produced a significantly faster onset of sensory block and a longer duration of sensory blockade. The onset of motor block and two-segment regression were comparable between groups, while motor blockade lasted longer in the bupivacaine group.

Table2. Comparison of Adverse Effects

Adverse Effect	Group L (n=63)	Group B (n=63)
No adverse effect	54 (85.7%)	50 (79.4%)
Hypotension	4 (6.3%)	6 (9.5%)
Bradycardia	2 (3.2%)	3 (4.8%)
Nausea	1 (1.6%)	2 (3.2%)
Shivering	2 (3.2%)	2 (3.2%)
Overall P value		**0.601** (Not significant)

The incidence of adverse effects was low and comparable between the two groups. No statistically significant difference in the frequency of complications was observed.

DISCUSSION

The present prospective, randomized, double-blind comparative study evaluated the clinical efficacy of 0.5% hyperbaric bupivacaine and 0.5% isobaric levobupivacaine administered intrathecally in patients undergoing elective infraumbilical surgeries. Both local anesthetic agents produced effective spinal anesthesia with satisfactory surgical conditions and the incidence of adverse effects was low and comparable between the two groups [6-8]. The baseline demographic characteristics including age, gender distribution, body weight, height, ASA physical status, site of spinal injection, and duration of surgery were statistically comparable between the two groups, indicating successful randomization and minimizing the influence of confounding variables on the study outcomes.

The onset of sensory blockade at the T10 dermatome was significantly faster with hyperbaric bupivacaine than with isobaric levobupivacaine. The mean onset time was 4.69 ± 1.01 minutes in the bupivacaine group compared with 5.73 ± 1.03 minutes in the levobupivacaine group. This faster onset observed with hyperbaric bupivacaine may be attributed to its hyperbaric nature, which facilitates predictable spread within the cerebrospinal fluid under the influence of gravity, thereby producing a more rapid sensory blockade. Similar observations have been reported by Vanna et al. and Naithani U. et al. who demonstrated earlier onset of sensory anesthesia with hyperbaric bupivacaine compared with levobupivacaine [9,10]. Although levobupivacaine exhibited a slightly delayed onset, the difference was clinically acceptable and did not interfere with surgical anesthesia.

The maximum sensory level achieved was comparable between the two groups. Likewise, the time required for two-segment regression of sensory block did not differ significantly between the groups. These findings indicate that both drugs provided an adequate level of sensory anesthesia for infraumbilical surgical procedures. Previous investigators Vanna et al. and Singh A et al have similarly reported comparable cephalad spread and regression characteristics with intrathecal levobupivacaine and bupivacaine when administered in equivalent doses [9, 11].

The duration of sensory blockade (regression to L1 level) was significantly longer in patients receiving hyperbaric bupivacaine (193.49 ± 19.44 minutes) compared with those receiving isobaric levobupivacaine (181.26 ± 13.62 minutes). The prolonged sensory blockade associated with hyperbaric bupivacaine may provide extended postoperative analgesia, which is advantageous during lengthy procedures and in the immediate postoperative period.

The onset of motor blockade was slightly faster with hyperbaric bupivacaine than with levobupivacaine; however, the difference was not statistically significant. Similarly, hyperbaric bupivacaine produced a longer duration of motor blockade compared with levobupivacaine. Although prolonged motor blockade may be beneficial for maintaining complete muscle relaxation during surgery, however delayed motor recovery may postpone ambulation and discharge. Levobupivacaine, therefore, offers an advantage in procedures where early postoperative mobilization is an important consideration. These findings are consistent with previous comparative studies demonstrating that levobupivacaine provides adequate motor blockade with relatively faster recovery than racemic or hyperbaric bupivacaine.

The incidence of adverse effects was low in both groups and did not differ significantly. Hypotension, bradycardia, nausea, and shivering occurred infrequently, and no serious neurological or cardiovascular complications were observed. These findings support the excellent safety profile of both drugs when administered intrathecally in appropriate doses. Levobupivacaine is well recognized for its lower cardiotoxic and neurotoxic potential compared with racemic bupivacaine because it is the pure S(-)-enantiomer. Although the present study did not demonstrate a statistically significant reduction in adverse effects with levobupivacaine, its favorable pharmacological profile remains an important clinical advantage, particularly in patients with increased cardiovascular risk [12, 13].

CONCLUSION

Overall, the findings of the present study suggest that both 0.5% hyperbaric bupivacaine and 0.5% isobaric levobupivacaine are effective and safe agents for spinal anesthesia in elective infraumbilical surgeries. Hyperbaric bupivacaine provides a faster onset and longer duration of sensory and motor blockade, making it more suitable for prolonged surgical procedures requiring sustained anesthesia. In contrast, isobaric levobupivacaine offers comparable anesthetic efficacy with a shorter duration of blockade and an established safety profile, making it an attractive alternative to 0.5% hyperbaric bupivacaine for patients undergoing infraumbilical surgeries. Larger multicenter studies with long-term follow-up would further clarify the comparative clinical benefits of these intrathecal local anesthetic agents in different surgical populations.

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