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PROSPECTIVE COMPARISON STUDY OF HYPERBARIC 0.5% LEVOBUPIVACAINE VERSUS 0.5% HYPERBARIC BUPIVACAINE FOR SPINAL ANESTHESIA IN ELECTIVE INFRAUMBILICAL SURGERIES.

Anaesthesiology

Dr. Jeyasureyan R. M Post Graduate, Sri Lakshmi Narayana Medical College, Osudu, Puducherry,605502, India.

Dr. Ranjitha Nethaji Assistant Professor, Sri Lakshmi Narayana Medical College, Osudu, Puducherry,605502, India.

Dr. Vishwanath Hiremath Professor, Sri Lakshmi Narayana Medical College, Osudu, Puducherry,605502, India.

ABSTRACT

Background: Spinal anesthesia (SA) is the preferred technique for infraumbilical surgeries due to its effectiveness and safety profile. While racemic bupivacaine is commonly used due to its long duration of action, it carries risks such as myocardial depression and potential cardiac arrest. Levobupivacaine, an S-enantiomer of bupivacaine, has a better safety profile. This study aimed to compare the efficacy, duration of analgesia, and safety of hyperbaric levobupivacaine versus bupivacaine for elective infraumbilical surgeries. **Methods:** A prospective, randomized, double-blind study was conducted following WHO Good Clinical Practice (GCP) guidelines. Sixty adult patients aged 18-60 years, scheduled for lower limb surgeries, were enrolled and randomly assigned to two groups. Group L received 3 ml of 0.5% hyperbaric levobupivacaine, and Group B received 3 ml of 0.5% hyperbaric bupivacaine. The onset and duration of sensory and motor blockade, the level achieved, regression, hemodynamic parameters, and side effects were recorded and analyzed. **Results:** Group L exhibited a longer onset of sensory (4.07 ± 0.83 minutes) and motor blockade (4.83 ± 0.74 minutes) compared to Group B (2.93 ± 0.45 minutes for sensory and 3.83 ± 0.59 minutes for motor, $p < 0.05$). The duration of sensory (184 ± 12.42 minutes) and motor blockade (212 ± 10.48 minutes) was shorter in Group L compared to Group B (203 ± 7.56 minutes for sensory and 232 ± 10.95 minutes for motor, $p < 0.05$). The time to two-segment regression was faster in Group L (159 ± 24.47 minutes) versus Group B (180 ± 21.02 minutes, $p < 0.001$). The incidence of complications was similar between the groups. **Conclusion:** Levobupivacaine provided shorter duration of sensory and motor blockade, allowing for earlier mobilization, which may be advantageous in ambulatory and day-care surgeries. Both drugs demonstrated comparable safety profiles, making levobupivacaine a viable alternative to bupivacaine for infraumbilical surgeries.

KEYWORDS

Bupivacaine, Levobupivacaine, Hyperbaric, Spinal anesthesia.

INTRODUCTION

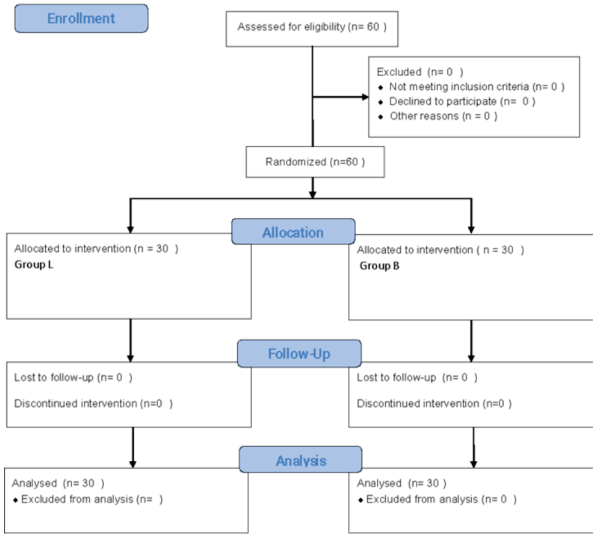
Spinal anesthesia (SA) is a central neuraxial blockade technique widely used in infraumbilical surgeries. It provides effective surgical anesthesia by inducing adequate sensory and motor blockade, making it preferable to general anesthesia due to its rapid onset, reduced need for multiple drugs, and preservation of consciousness. Hyperbaric bupivacaine is the most commonly used local anesthetic for spinal anesthesia in infraumbilical surgeries. However, despite its advantages—such as a prolonged duration of action and cost-effectiveness—bupivacaine poses a risk of severe cardiac complications, including bradycardia and cardiac arrest, especially with accidental intravascular injection. These risks, albeit rare, have prompted the search for safer alternatives. Levobupivacaine, the S-enantiomer of racemic bupivacaine, has emerged as a promising alternative due to its lower cardiovascular toxicity and quicker motor recovery. Although isobaric levobupivacaine has been associated with inadequate blockade and higher failure rates, hyperbaric levobupivacaine was developed to address these limitations. Given the limited studies on hyperbaric levobupivacaine, this study aims to compare its efficacy and safety against hyperbaric bupivacaine in elective infraumbilical surgeries.

MATERIALS AND METHODS

Study Design and Participants

We conducted this prospective, randomized, double-blinded interventional study in the Department of Anesthesiology at Sri Lakshmi Narayana Institute of Medical Sciences, Puducherry from August 2022 to January 2023 after Institutional Ethics Committee (IEC) approval. The CONSORT flow diagram was used for patient enrollment and allocation .

Sixty patients aged 18-60 years, undergoing elective lower limb surgeries, were enrolled and randomized into two groups of 30 each using a computer-generated table. Group L received 3 ml of 0.5% hyperbaric levobupivacaine, while Group B received 3 ml of 0.5% hyperbaric bupivacaine. The spinal anesthesia procedure was standardized for all patients. Primary outcomes is to measure the duration of analgesia. Secondary outcomes measured included the onset of sensory and motor blockade, maximum sensory and motor levels achieved, time to two-segment regression, duration of analgesia, and incidence of side effects. Hemodynamic parameters, including heart rate and blood pressure, were also monitored and compared between the groups. The sample size was calculated based on probable availability of cases in OT posted for elective infra umbilical surgeries during the study period. Considering the results of parameters from the earlier published study at 95% confidence interval and 90% power of the study, the required minimum sample size came to be 60 patients having at least 30 patients in each group.



Study Protocol

Patients undergoing elective infra umbilical surgeries were enrolled and divided into 2 groups of 30 each. A pre-anaesthetic evaluation was performed at least 24 hrs before the surgery. The patient was kept nil per oral for solids 8hrs, for light meal 6hrs, juices with pulp for 4hrs and clear liquids 2hrs and T. pantoprazole 40mg was given the night before surgery. On the day of surgery, patient reviewed in the preoperative room and an intravenous line was placed in the non dominant hand with an 18G intravenous cannula and Patient was preloaded using 20

ml of crystalloid RL/kg body weight and was shifted to OT. All ASA standard monitors attached and the following baseline parameters were recorded; pulse rate, blood pressure (systolic, diastolic and MAP), electrocardiography and pulse oximetry. Under all aseptic precautions, the subarachnoid blocks was performed using 25G Quincke spinal needle with patient in the sitting position at L3-L4 intervertebral space. Surgery will be done under spinal anaesthesia using 3ml of 0.5% hyperbaric Levobupivacaine in group L and using 3ml of 0.5% hyperbaric bupivacaine in group B. The patient was made supine immediately after giving spinal anaesthesia. After the block, vitals were monitored every min for 5 mins until 30 mins and thereafter every 30 min till the end of the surgery.

Level of sensory blockade was assessed by cold swab every min for 10 mins and thereafter every 5 mins for next 10 mins. The onset of sensory blockade is defined as the time taken for the blockade to reach T10 level and peak sensory level of blockade was noted. After completion of the surgery, the sensory block was tested at 15 min intervals to assess two segment regression from peak level and time taken to reach T10 noted. Motor blockade was assessed by Bromage scale (Scale 0 = No motor blockade , 1 = Hip blockade, 2 = Hip and knee blockade, 3 = Hip, knee and foot blockade). The onset of motor blockade is defined as the time taken to reach the level of bromage scale 2. The highest level of motor blockade noted. Motor blockade was assessed every 15 mins from the end of the surgery till it becomes zero. Total duration of motor blockade was taken from the onset of blockade (bromage scale 1/2/3) to completely recover from blockade (Bromage scale 0).

Statistical Analysis

The statistical analysis was performed with version 24.0 of the Statistical Package for the Social Sciences (SPSS, Inc., Chicago, Illinois, USA). The mean and standard deviation were used to characterize the study variables. When comparing quantitative variables, the two-tailed independent sample t-test was employed, when comparing qualitative variables, the Chi-squared test was utilized. The P value of <0.05 was considered significant.

RESULTS

The demographic parameters and baseline characteristics, including age, gender, height, weight, BMI, and duration of surgery, were comparable between the two groups. All patients in both groups had an ASA status of I or II. The onset time of the sensory block was delayed in Group L, with a mean of 4.067 ± 0.828 minutes, compared to Group B, which had a mean onset time of 2.933 ± 0.450 minutes. Similarly, the onset time of the motor block was delayed in Group L, with a mean of 4.83 ± 0.74 minutes, compared to 3.83 ± 0.59 minutes in Group B, and the difference was statistically significant. The highest level of sensory blockade attained was statistically insignificant (p > 0.05). The duration of two-segment regression was faster in Group L, with a mean of 159 ± 24.47 minutes, compared to 180 ± 21.02 minutes in Group B (p < 0.001). The duration of sensory blockade was shorter in Group L, with a mean of 184 ± 12.415 minutes, compared to 203.500 ± 7.560 minutes in Group B, and this difference was statistically significant. Additionally, the duration of motor blockade was shorter in Group L, with a mean of 212.5 ± 10.48 minutes, compared to 232 ± 10.95 minutes in Group B, showing statistical significance. Analgesic requirements were earlier in Group L, with a mean of 91 ± 26.70 minutes, compared to 101.5 ± 23.75 minutes in Group B, which was also statistically significant. Parameters such as hypotension, bradycardia, and respiratory depression were comparable between the groups, with no statistically significant differences (p > 0.05). Similarly, heart rate, systolic blood pressure, and diastolic blood pressure did not show significant differences between the groups (p > 0.05). Complications, including incidences of hypotension, bradycardia, shivering, and respiratory depression, were observed to be comparable between the two groups and were not statistically significant.

Table 1 : Characteristics of Motor and Sensory Block

	Group L (n=30)	Group B (n=30)	p value
Onset of sensory blockade	4.06 ± 0.82	2.9 ± 0.44	<0.001
Onset of motor blockade	4.83 ± 0.74	3.76 ± 0.56	
Duration of two segment regression	159 ± 24.47	180.5 ± 21.02	
Duration of sensory blockade	184 ± 12.4	203.5 ± 7.56	
Duration of motor blockade	212.5 ± 10.48	232 ± 10.95	
Total duration of analgesia	91 ± 26.7	101.5 ± 23.75	

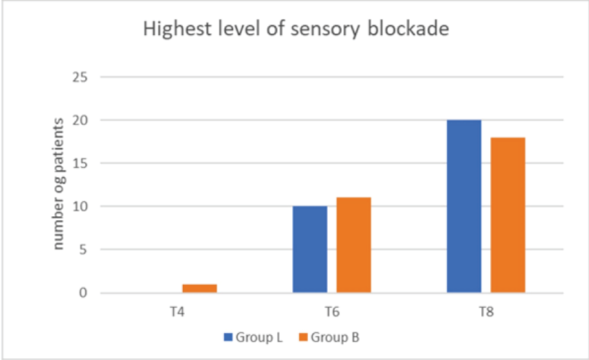


Figure 1 : Level of Maximum Sensory Blockade

DISCUSSION

Spinal anaesthesia is more advantageous than general anaesthesia in rapidity of providing adequate surgical anaesthesia with added advantages of avoiding multiple drugs which have been used in the general anaesthesia. Levobupivacaine, a pure S enantiomer of racemic bupivacaine has better safety profile, with similar pharmacokinetic properties to racemic bupivacaine. As there are only fewer studies about hyperbaric levobupivacaine, we conducted the study on hyperbaric levobupivacaine.

In our study, onset of sensory blockade was delayed in group L, with a mean of (4.067 ± 0.828) and Group B with a mean of (2.933±0.450). The difference between the two groups was found to be statistically significant which was in accordance with the study by Girish et al[1] who conducted a comparative study using 0.5% hyperbaric levobupivacaine with 0.5% hyperbaric bupivacaine and found that the onset time for sensory block varied from 1.5 to 4 min bupivacaine group when compared with a mean of 2.51 mins and 2- 5 mins in levobupivacaine group with a mean of 2.68 mins.

The onset time of motor block was delayed in group L, with a mean of (4.83 ±0.74) and Group B with a mean of (3.83±0.59). The difference between the two groups was statistically significant which was found to be in similar results with Kiranpreet Kaur et al[2] who did a comparative study of intrathecal bupivacaine and levobupivacaine for patients undergoing caesarean section and observed that the onset time of motor block was delayed with levobupivacaine (4.19 ±1.74 than with bupivacaine (3.05 ±1.11).

The duration of two segment regression was faster in group L, with a mean of (159 ±24.47) and Group B with a mean of (180 ± 21.02). The difference between the two groups was statistically significant and is comparable to studies conducted by Petchara Sundarathiti et al[3] compared the effects of intrathecal hyperbaric bupivacaine 10mg with intrathecal bupivacaine 11mg and levobupivacaine 11mg, all with 10mcg of fentanyl, for cesarean section. Time for two segment regression was early in levobupivacaine group (46.00±13.54mins) and longer in bupivacaine group (50.00±13.65mins). In our study the two segment regression of levobupivacaine was earlier than bupivacaine with a mean of 159 ±24.47 in group L as compared to mean of 180.5 ±21.02 and this was statistically significant (p < 0.001).

In our study the highest level of sensory blockade attained in group L is T6 whereas in group B it is T4. Similar results were found in Mahendra kumar et al[4], he observed that the peak sensory level achieved in both the groups was T6, it was comparable between both the groups.

In our study the duration of sensory blockade shorter in group L, with a mean of (184 ±12.415) when compared to Group B with a mean of (203.500±7.560). The difference between the two groups was statistically significant (p < 0.001). which is in corroboration with the study conducted by Ajay S et al[5]. He compared intrathecal levobupivacaine against intrathecal bupivacaine for inguinal hernia surgery. Duration of sensory blockade was longer with Bupivacaine (224.1±15.6) than with levobupivacaine (206.2 ± 18.9)

The duration of motor blockade was shorter in group L, with a mean of

(212.5±10.48) and Group B with a mean of (232±10.95). The difference between the two groups was statistically significant ($p < 0.001$) even Sayan gangopadhay et al[6] conducted a study comparing intrathecal hyperbaric levobupivacaine with hyperbaric ropivacaine in patients posted for elective orthopedic lower extremity surgeries and observed that the duration of motor blockade with levobupivacaine was longer with mean of 161.3 ±12.6 and it was statistically significant ($p < 0.05$)

The faster onset of motor blockade with bupivacaine may be attributed to its higher lipid solubility and faster onset of action compared to levobupivacaine. On the other hand, the shorter duration of motor blockade with levobupivacaine may be due to its shorter elimination half life and lower degree of protein binding, leading to more rapid clearance from the central nervous system.

The slower onset but shorter duration of motor blockade with levobupivacaine may offer advantages in terms of earlier sensory recovery, earlier motor recovery and reduced postoperative sensory and motor impairment. This may contribute to enhanced patient satisfaction, faster postoperative mobilization and shorter hospital stays. In our study the analgesic requirement was early in group L, with a mean of (91±26.70) and Group B with a mean of (101.5±23.75). Similarly Ayesha Goyal et al[7] conducted a study comparing isobaric levobupivacaine with fentanyl and hyperbaric bupivacaine with fentanyl in elective cesarean sections and they observed that first analgesic requirement was early in isobaric levobupivacaine with fentanyl group (159.59±12.8mins) and hyperbaric bupivacaine group had late first analgesic requirement (174.71±13.49mins).

CONCLUSION

This study compared the anaesthetic efficacy and safety of 0.5% hyperbaric levobupivacaine and 0.5% hyperbaric bupivacaine for spinal anaesthesia in elective infraumbilical surgeries. Regarding the level of sensory and motor blockade, the racemic bupivacaine group exhibited rapid onset and longer duration than levobupivacaine group. The hemodynamic differences were observed between the groups and was statistically not significant. Racemic bupivacaine provides adequate sensory blockade and profound motor blockade for moderate to extended duration surgeries. However, levobupivacaine can be an alternative to racemic bupivacaine for day care surgeries which require early mobilization with hemodynamic stability.

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