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COMPARISON OF HYPERBARIC BUPIVACAINE VERSUS HYPERBARIC LEVOBUPIVACAINE IN SUBARACHNOID BLOCK FOR INFRAUMBILICAL SURGERY: A RANDOMIZED CONTROLLED TRIAL

Anaesthesiology

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ABSTRACT

Background: Subarachnoid block has mainly been achieved using hyperbaric bupivacaine. But hyperbaric levobupivacaine has also proved to be effective with shorter motor block duration in infraumbilical surgeries. **Aim and Objectives:** This study was undertaken for comparison of motor block duration after injecting the drugs intrathecally. Secondary objectives included comparison of onset of sensory block, onset of motor block, peak level, time to 2 segment regression, duration of effective analgesia and adverse effects of drug or procedure. **Materials and Methods:** 60 patients were undertaken for this randomized controlled study, undergoing infraumbilical surgeries with subarachnoid block. After the block was administered to Group B (3ml of 0.5% hyperbaric bupivacaine) and Group L (3ml of 0.5% hyperbaric levobupivacaine) intrathecally, they were compared for motor and sensory block characteristics. **Results:** Duration of motor block was significantly more in bupivacaine group (193.87 ± 41.47 minutes) versus levobupivacaine group (132.37 ± 24.72 minutes) **Conclusion:** Hyperbaric levobupivacaine provides adequate level of sensory blockade with shorter duration of motor blockade when compared to equivalent dose of hyperbaric bupivacaine. This can allow early ambulation and faster hospital discharge. In addition, levobupivacaine was shown to be hemodynamically stable compared to bupivacaine and can be considered in cardiac patients.

KEYWORDS

Spinal anesthesia, hyperbaric bupivacaine, hyperbaric levobupivacaine, infraumbilical surgery

INTRODUCTION

In human surgery, spinal anesthesia was administered for the first time by August Bier on August 16, 1898, in Kiel, using 3ml of 0.5% cocaine.[1] This anesthetic modality is popular even today and is used commonly for surgeries of lower half of the body.

It is beneficial as the patient is awake, spontaneously breathing, minimal postoperative nausea and vomiting, immediate post operative pain relief, thus allowing earlier ambulation and faster recovery.[2]

Effect is attained by using local anaesthetics which bind to specific locations in voltage gated sodium ion channels impeding nerve impulse conduction via inhibition of sodium ions flowing through neurons thereby decreasing excitability of nerve cells and cardiac cells.[3]

Hyperbaric racemic bupivacaine is an amide having long duration of action. It is an equimolar amalgam of its enantiomers, 'dextrobupivacaine' and 'levobupivacaine'. Commercially it is available either as a hyperbaric solution or as a plain solution.[4] However, hyperbaric bupivacaine has its limitations with increased predisposition to produce hypotension and bradycardia as it has high affinity for cardiac sodium channels, leading to cardiac toxicity, which can become catastrophic.[5]

"S (-) enantiomer of bupivacaine" is levobupivacaine. Racemic bupivacaine has been replaced with levobupivacaine as a spinal anaesthetic alternative and is associated with less cardiotoxicity and neurotoxicity owing to greater plasma protein binding affinity rather than for cardiac myocytes.[6] Levobupivacaine when compared with racemic bupivacaine showed earlier motor recovery.[7] Compared to its isobaric counterpart, use of hyperbaric levobupivacaine accelerates onset of motor and sensory blockade.[8]

0.5% concentrations of isobaric levobupivacaine and hyperbaric bupivacaine have been compared by various studies. Very few studies were found comparing hyperbaric bupivacaine and hyperbaric levobupivacaine where levobupivacaine was made heavy by manual addition of dextrose. Levobupivacaine had better hemodynamic profile, a long sensory blockade, good postoperative pain relief, and shorter motor blockade duration than bupivacaine[9].

Hence this study was done for comparing the block characteristics of 0.5% concentration of hyperbaric solutions of bupivacaine and levobupivacaine (commercially available solution) in subarachnoid block for infraumbilical surgeries, which may aid in selecting adequate patient population for surgery.

We hypothesized that levobupivacaine will produce early motor blockade recovery than bupivacaine which can be due to faster clearance of unbound drug.

MATERIALS AND METHODS

This prospective, double blinded randomized controlled study was conducted after approval by Institutional Ethics Committee; registration with Clinical Trial Registry India (CTRI No. : CTRI/2023/02/049812); and obtaining informed consent. Patients included were of either sex, between 18-65 years of age, ASA physical status I and II, BMI ≥ 20 to ≤ 35 kgm^2, surgical duration of 2- 2.5 hours in infraumbilical surgeries. Patients with local site infection, coagulopathy and platelet disorders, contraindication or allergy to study drugs, pain in any other area than the surgery site, sensory or motor problem in the lower limb, failed to understand the VAS scoring system, pregnant and lactating women, current history of psychiatric illness, communication difficulties were eliminated from the study. 60 patients were randomly allocated to two equal groups. To get a significant decrease of 10% between two groups with an alpha of 0.05 and a power of 90%, 25 patients in each group was needed. To allow a 20% dropout, we recruited 30 patients per group. Patients were randomly allocated using computer generated random number table and coded opaque sealed envelopes were used for blinding, into one of the following groups:

Group B (n=30): Patients were given 3ml of 0.5% hyperbaric bupivacaine intrathecally

Group L (n=30): Patients were given 3ml of 0.5% hyperbaric levobupivacaine intrathecally

Patients were evaluated for fitness for surgery a day prior. Patients were explained about procedure, kept nil per oral from midnight; and pre-medicated with Alprazolam 0.25 mg and Ranitidine 150 mg orally a night before surgery.

In the operation theatre, monitoring of heart rate, systolic blood pressure, diastolic blood pressure, mean arterial blood pressure,

continuous electrocardiogram, respiratory rate, and arterial oxygen saturation (Spo2) was done. Baseline values were recorded. Intravenous access was secured and Ringer's solution infusion was started.

Then, patient was instructed to maintain sitting position and the spine was palpated to identify L3-4 and L4-5 interspaces. After ensuring aseptic precautions, local anesthetic loaded in a 2 ml syringe was injected, producing a subcutaneous wheal. Then 26 gauge spinal needle was used to perform lumbar puncture. After free flow of CSF occured, intrathecal 0.5% Hyperbaric Bupivacaine/ Levobupivacaine 15 mg was injected according to group allocation. After administration of drug, patient was placed in supine position. Both patient and anaesthesiologist were blinded in both groups and all the recordings were by an anaesthesiologist blinded to the group allocation.

Assessment of sensory block was done using sterile pin prick method. After this, motor block assessment was done using Modified Bromage scale. We assessed sensory and motor blockade by a minute for first 10 minutes, intraoperatively every 10 mins, and every 15 minutes postoperatively. Time to onset of sensory and motor blockade were noted. Highest dermatomal level of sensory blockade and recovery time of both sensory and motor block were recorded. Anesthesic regression from maximal level to two dermatomes below defined the time to recovery of sensory blockade. Modified Bromage scale helped in determining motor block.

Time taken for first request for analgesia postoperatively (VAS ≥3) was noted as total duration of spinal analgesia.

After spinal anesthesia, record of haemodynamic parameters like Heart rate, Blood pressure, Respiratory Rate and Arterial oxygen saturation (Spo2) was done every 5 minutes till 15 minutes, then every 15 minutes till complete reversal of spinal effect. Treatment of hypotension (addressed by 20% decrease in MAP below baseline or SBP < 90 mmHg) was accomplished with incremental doses of Mephentermine 3 mg iv and Ringer's lactate solution as appropriate. Treatment of bradycardia (HR < 50 bpm) was done with Atropine 0.3 mg iv. Assessment of nausea/ vomiting was done with a four point scale. Any episode of shivering and dizziness was also noted.

The block parameters were defined as:
1. Onset of Sensory block: Time interval from spinal injection to time taken to achieve T8 blockade (T_{T8})
2. Onset of Motor block: Time interval from spinal injection to Bromage scale 3 (T_{Brom3})
3. Duration of Sensory block: Time interval from spinal injection time to regression of sensory block by two dermatomes from peak level (T_{reg2})
4. Duration of Motor block: Time interval from onset of motor block to attainment of complete movements (Bromage 0) in both lower limbs (T_{MB})
5. Duration of analgesia: Time interval from onset of sensory block to requirement of first rescue analgesia (T_{anal})

Primary outcome was comparison of duration of motor block after injecting the drugs intrathecally. Secondary outcome was comparison of onset of sensory and motor block, peak level, time to 2 segment regression, duration of effective analgesia and any side effects of drug or procedure.

Statistical Analysis

All measurable data were checked for normality using the Kolmogorov–Smirnov/Shapiro-Wilk test within each group. Normally distributed data was compared using Student's t-tests, and presented as descriptive statistics like Mean and SD; whereas for skewed (non-normally distributed) or ordinal data, distributions was compared using Mann-Whitney test. Categorical/classified data/side effects data was analyzed using the Chi-Square test or Fisher's Exact test, whichever was applicable. Hemodynamic parameters were compared using Repeated Measures ANOVA. All tests were two-sided. At the end of study, data collected was analysed using statistical software package SPSS 20.0.

RESULTS

Results of analysed data were expressed in terms of mean, median and standard deviation. P < 0.05 was taken as level of significance.

Demographic characteristics were comparable statistically for both groups with respect to Age, Gender, ASA status, Weight, Duration of surgery (Table 1).

Table 1: Demographic Characteristics

Demographic Characteristics	Group B (n = 30)	Group L (n = 30)	p value
Age (years)	43.00 ± 14.47	39.10 ± 12.75	0.420
Male /Female	27 (90%)/ 3 (10%)	26 (87%)/ 4 (13%)	0.430
ASA (I)/ (II)	25 (84%)/5 (16%)	26 (87%)/ 4 (13%)	0.478
Weight (kg)	70.13 ± 11.07	67.33 ± 13.08	0.400

Data is represented in Mean ± SD, where p <0.05 is statistically significant.

ASA: American Society of Anaesthesiologists

There was a statistically significant difference between the groups indicating shorter motor block duration in Group L (132.37 ± 24.72 mins) compared to Group B (193.87 ± 41.47 mins). Time to two segment regression was statistically significant with Group B (79.46 ± 14.37 mins) having faster regression in comparison to Group L (100.60 ± 21.44 mins). The time to first analgesic requirement was statistically significant with Group L (248.60 ± 49.87 mins) requiring earlier rescue analgesia compared to Group B (317.10 ± 93.27 mins) (Table 2). No significant difference were noted in terms of time to onset of sensory block, time to onset of motor block and peak block height. In both groups, T6 was achieved as the majority in peak block height (Figure 1).

Both groups were comparable in terms of heart rate, blood pressure, respiratory rate, SpO2 values. Significant difference was noted in systolic and diastolic blood pressure, mean arterial pressure, Respiratory rate, SpO2 (Figure 2).

In terms of side effects, there was no statistical difference (e.g. Hypotension, Bradycardia, Nausea/Vomiting, Shivering) at any time interval (Table 3).

Table 2: Characteristics Of Sensory And Motor Block In Group B And Group L

Time (min)	Group B (n=30)	Group L (n=30)	P value
Time to Onset of Sensory block (TT8)	5.46 ± 1.30	5.43 ± 1.59	0.982
Onset of Motor block (TBrom3)	3.60 ± 1.10	4.03 ± 1.56	0.330
Time to two segment regression (Treg2)	100.60 ± 21.44	79.46 ± 14.37	0.000
Duration of Motor block (TMB)	193.87 ± 41.47	132.37 ± 24.72	0.000
Duration of analgesia (Tanal)	317.10 ± 93.27	248.60 ± 49.87	0.005

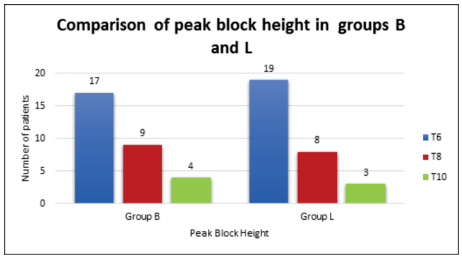

Figure 1: Highest Level Of Sensory Block Achieved In Group B And Group L. Values Are Number Of Patients.

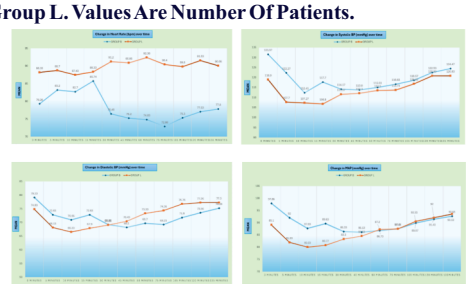

Figure 2: Hemodynamic Changes In Group B And L

Table 3: Comparison Of Side Effects In Group B And L

Side effects	Group B (n = 30)	Group L (n = 30)	Fisher's Exact test
			p value
Hypotension	8 (26.6%)	5 (16.6%)	0.532
Bradycardia	0 (0.0%)	0 (0.0%)	1.000
Nausea/ Vomiting	4 (13.3%)	2 (6.6%)	0.671
Shivering	3 (10.0%)	1 (3.3%)	0.612

Discussion

We observed that 0.5% hyperbaric levobupivacaine 15 mg can provide adequate subarachnoid blockade in comparison with similar dose of bupivacaine. The study was done to compare block characteristics as well as incidence of associated side effects.

A randomized double blinded volunteer study determined that 1:1 is the respective clinical efficacy of levobupivacaine to bupivacaine in spinal anaesthesia. Equivalent doses of the drugs provide a comparable profile for motor and sensory block and time till patient gets discharged. It inferred that hyperbaric levobupivacaine can be considered in place of racemic bupivacaine but does not offer any special advantages.[10]

In a double blinded prospective randomized study, racemic bupivacaine and isobaric levobupivacaine were found to be equally potent for subarachnoid block, in motor as well as sensory block characteristics like time of onset, duration of blockade in elective hip replacement in eighty study subjects.[11]

A study in hundred patients undergoing surgery for inguinal hernia contrasted concentrations of 0.5% of plain levobupivacaine and hyperbaric bupivacaine. The authors noted that levobupivacaine had a shorter span of anesthesia, motor blockade and time taken to walk unassisted as opposed to bupivacaine.[12]

A study noticed that shorter period of analgesia with late onset and shorter action of motor blockade were noted with hyperbaric levobupivacaine in comparison to hyperbaric bupivacaine in patients undergoing surgery for transurethral injury under spinal anaesthesia.[13]

A study found that isobaric levobupivacaine provided longer sensory blockade with late first requirement of analgesic than isobaric bupivacaine.[14] A prospective randomized double blinded study observed late onset with shorter motor blockade in isobaric levobupivacaine than hyperbaric bupivacaine group in patients undergoing elective caesarean section.[15]

A study in seventy patients undergoing endoscopic transurethral surgery compared intrathecal injection of 2.5ml each of 0.5% concentration of isobaric levobupivacaine or hyperbaric bupivacaine and inferred that onset of effective anesthesia for starting surgery, sensory blockade duration, time taken for drug to regress two segments below and upto T12 regression were comparable.[16] Another study found earlier regression in motor block in isobaric levobupivacaine compared with hyperbaric bupivacaine in patients undergoing caesarean section.[17]

Various studies have been conducted comparing different drug concentrations of bupivacaine and levobupivacaine with conflicting results.[7,9,10,11,12,13,14,15] Studies have also been done with intrathecal local anaesthetics in addition to opioids as adjuvants. A randomized double blinded study by Thakore et al was done comparing hyperbaric levobupivacaine and bupivacaine with fentanyl in patients undergoing medical termination of pregnancy and sterilization, where plain levobupivacaine was made heavy by the manual addition of 5% dextrose.[9] The authors compared the specific gravity of the newly prepared hyperbaric levobupivacaine and commercially available hyperbaric bupivacaine with the CSF of pregnant women. This was done to confirm that the drugs were hyperbaric when matched with CSF. In the present study, comparison between 0.5 % hyperbaric bupivacaine and commercially available 0.5% hyperbaric levobupivacaine was done in infraumbilical surgeries. It bypassed the arduous process of making a drug hyperbaric, allowed the comparison of these hyperbaric drugs at concentrations of 0.5%, without using intrathecal opioids as adjuncts. Limited studies are available hence, this study was undertaken.

Demographic parameters like age and weight were comparable in both groups. Patients'mean age were 43.00 and 39.10 years in Group B and L respectively . Mean weight of patients in group B was 70.13 kgs while in group L, it was 67.33 kgs. Both groups had a predominantly male gender distribution with Group B accounting for 27 males (90%) and group L composing of 26 males (87%). The variables were compared and was found comparable.

We observed that bupivacaine had longer motor block duration in comparison to levobupivacaine. Mean recovery time of motor blockade in bupivacaine group was 193.87 minutes while in levobupivacaine group, it was 132.37 minutes. A study by Camorcia et al contrasted the motor block potencies of intrathecal bupivacaine, levobupivacaine and ropivacaine and reported shorter duration of motor block with levobupivacaine.[18] Another study by Liao et al in unilateral spinal blockade reported a shorter motor block duration in hypobaric levobupivacaine group in comparison to hypobaric bupivacaine.[19] Shorter motor block duration of levobupivacaine may be due to faster clearance of unbound drug. This property of levobupivacaine can aid in an earlier discharge of the patients from the post anaesthetic care unit and early ambulation.

In a study by Lee et al in urological surgery, spinal anaesthesia comparing racemic bupivacaine to levobupivacaine observed no difference in characteristics of motor blockade.[20] Similar finding was noted by Alley et al in volunteers on comparison of intrathecal hyperbaric levobupivacaine to racemic bupivacaine.[10]

Onset of sensory block in our study was comparable between both groups. Another randomized controlled trial by Singh et al in inguinal hernia patients, onset of sensory blockade was comparable between intrathecal 0.5% concentrations of hyperbaric bupivacaine and isobaric bupivacaine.[12] Parallel findings were reported by Sahin et al and Glaser et al.[7,19]

Erdil et al observed in patients who underwent transurethral prostate surgery that intrathecal 0.5% plain bupivacaine had an earlier onset of sensory blockade compared to levobupivacaine.[21] Our study revealed that levobupivacaine had a slightly longer motor blockade onset in contrast to bupivacaine. Thakore et al, Hakan et al, Duggal et al showed a delayed onset of motor blockade with levobupivacaine in contrast to bupivacaine in their studies.[9,13,15]

Peak block height in our study was seen ranging from T6 to T10 in both groups, with maximum participants having peak block height of T6 level. The findings were similar to those of Thakore et al.[9] In a prospective randomized control trial for patients undergoing inguinal herniorrhaphy under unilateral spinal anaesthesia by Casati et al, peak block height of hyperbaric bupivacaine, levobupivacaine and ropivacaine were comparable.[22]

Regarding time to two-segment regression, a significant difference was observed with levobupivacaine having shorter regression time compared to bupivacaine. This may be attributed to levobupivacaine's shorter half life and faster clearance and thereby causing it's concentration to rapidly decline at the site of action. Decreased binding capacity of levobupivacaine to the sodium channels also causes faster dissociation from these channels and thereby a shorter duration of action. In a randomized control study by Goyal et al in infraumbilical surgeries, the time for the anaesthetic to regress two dermatomal levels was observed to be equivalent in isobaric levobupivacaine and bupivacaine but increased in the case of hyperbaric bupivacaine.[23] However, two segment regression was higher with levobupivacaine as observed by Glaser et al which was perhaps due to the higher drug volume (3.5ml of 0.5% levobupivacaine).[11]

In parallel to other clinical studies, levobupivacaine was shown to be equally effective in providing subarachnoid block in comparison with bupivacaine. Şahin et al observed intrathecal administration of 3 ml each of 0.5% concentration of isobaric levobupivacaine to isobaric bupivacaine in patients undergoing surgery of lumbar disc and found both drugs to be equally effective.[7] Glaser et al observed in patients undergoing elective hip replacement surgery comparing intrathecal 0.5% isobaric (3.5 ml each of) bupivacaine to levobupivacaine and found satisfactory analgesia in both groups.[11]

A significant observation was noted with bupivacaine providing a longer time to first analgesic requirement compared to levobupivacaine. Mean time of effective analgesia in bupivacaine group was 317.10 minutes contrasted to levobupivacaine group which lasted 248.60 minutes. This comparable finding was noted by Glaser et al, Goyal et al in their research study.[19,23] This may be attributed to the

longer regression time of bupivacaine. Sahin et al, Vanna et al reported longer sensory blockade with levobupivacaine in comparison to bupivacaine, which was in contrast to our findings.[7,16] The cause for these inconsistent results can be related to the dose and baricity of the local anesthetics, type of surgery and associated pain, addition of opioids as adjuvant.

Though there was significant variation statistically in haemodynamic parameters like blood pressure (non invasive), heart rate, arterial oxygen saturation, respiratory rate, clinically significant changes were not notable in both the groups. Erdil et al, Goyal et al observed better hemodynamic stability including reduced side effects with levobupivacaine group which was comparable to what we observed.[21,23]

In relation to side effects, the bupivacaine group had a greater incidence of hypotension with 8 patients compared to levobupivacaine where 5 patients had hypotension. Similarly, the bupivacaine group experienced more nausea/vomiting and shivering compared to levobupivacaine. This may be due to the more potent sympathetic blockade effect of bupivacaine. Both groups did not report any incidence of bradycardia. This may be attributed to the fact that T6 was the height of highest sensory block achieved in both groups. Carpenter et al observed that peak height of block during spinal anaesthesia was the major factor contributing to hypotension and bradycardia.[24] Therefore, adequate block height for surgeries may be considered to prevent hypotension.

It was observed though that incidence of side effects was not significant statistically.

The study's limitations include a comparatively small sized sample, different surgeries and a single centric study. In the event that research is conducted on other ethnic groups, variable results may be attributable to discrepancy in body mass, dosage and effect of drugs and addition of adjuncts. Future trails can be implemented in larger populations to validate the findings.

CONCLUSION

We concluded that 15 mg of 0.5% hyperbaric levobupivacaine provides adequate level of sensory blockade with shorter motor block duration when compared to equivalent dose of hyperbaric bupivacaine. In addition, levobupivacaine was shown to be hemodynamically stable compared to bupivacaine. Hence, this study supplements to other available sources of evidence that hyperbaric levobupivacaine may be considered as an alternative to hyperbaric bupivacaine for intrathecal administration owing to its satisfactory levels of sensory blockade, better hemodynamic profile and shorter duration of motor blockade. This can allow early ambulation of the patients and faster hospital discharge. Though the shorter duration of motor blockade appear to be a disadvantage for surgeries of longer duration, maybe selecting patients appropriately can overcome this drawback.

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