IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)
e-ISSN: 2279-0853, p-ISSN: 2279-0861.Volume 23, Issue 11 Ser. 8 (November. 2024), PP 48-53
www.iosrjournals.org

A Comparative Study Between Intrathecal Hyperbaric Bupivacaine And Hyperbaric Levobupivacaine For Lower Abdominal Surgeries In A Teaching Hospital Of Bihar

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Abstract:
Background*: Spinal anesthesia is an inexpensive and preferable technique. It has been a popular anesthesia technique for short, lower abdominal and inguinal hernia surgeries. Hyperbaric racemic bupivacaine is commonly used for spinal anesthesia due to its long duration of action and combined motor and sensory blockade. It also has a high propensity to cause hypotension and bradycardia. Levobupivacaine has a lower affinity for cardiac*
sodium channels and greater plasma protein binding affinity compared with the dextro isomer; thus, reducing the risk of cardio-toxicity. This study was designed to compare hyperbaric levobupivacaine with hyperbaric racemic bupivacaine with respect to intraoperative quality of anesthesia and the postoperative recovery profile in patients undergoing lower abdominal surgeries.
Materials and Methods*: In this prospective randomized controlled study, 80 patients of ASA physical status I and II belonging to age group of 18-60years undergoing elective lower abdominal surgery under sub-arachnoid block were randomly allocated into 2 groups of 40 patients each, Group HB (3ml of hyperbaric bupivacaine) and Group HL (3ml hyperbaric levobupivacaine). Monitoring included non-invasive blood pressure monitoring, Electrocardiogram and pulse oximeter. Heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP) and mean arterial pressure (MAP). The onset and duration of sensory and motor blockade, 2 segment regression, duration of postoperative analgesia, side-effects and hemodynamic parameters were compared between the groups.*
Results*: The mean duration of sensory block was higher in HB group as compared to HL group. The total duration of analgesia was 207 minutes in HB group which was higher than 192 minutes in HL group. Similarly, two point regression time was lower in HL group being 130 minutes as compared to HB group with 133 minutes. All the differences were statistically significant (p<0.05).*
Conclusion *Hyperbaric bupivacaine 0.5% is still an effective choice over hyperbaric levobupivacaine 0.5% for spinal anesthesia in elective surgery, but hyperbaric levobupivacaine is also a better choice for shorter procedures and ambulatory spinal anesthesia.*
Key Word*: Intrathecal; Bupivacaine; Levobupivacaine; hyperbaric; Postoperative analgesia.*

Date of Submission: 29-11-2024 Date of Acceptance: 09-12-2024

I. Introduction

Subarachnoid block is popular and commonly used worldwide. The advantage of an awake patient, minimal drug cost and rapid patient turnover has made this the method of choice for many surgical procedures. Subarachnoid block technique enables good cardiovascular stability and makes early discharge to home possible [1].

There is an increased requirement for lower abdominal, lower limb and perineal surgeries. Better understanding of the physiological aspects of subarachnoid block, availability of long acting local anaesthetic agents and understanding of pharmacokinetics and pharmacodynamics of these agents; have greatly contributed to the reincarnation of subarachnoid block during the last two and a half decades. It reduces surgical stress and attenuates increase in plasma catecholamines and other hormones. Regional anaesthesia gives intra and postoperative pain relief with full preservation of mental status and normal reflexes. In recent years levobupivacaine, the pure S (-) - enantiomer of bupivacaine, emerged as a safer alternative for regional anaesthesia than its racemic parent [2]. It demonstrated less affinity and strength of depressant effects onto myocardial and central nervous vital centres in pharmacodynamics studies, and a superior pharmacokinetic profile.

The purpose of this study is to compare the onset, duration of sensory block and motor block, postoperative analgesia and haemodynamic changes occurring with 0.5% hyperbaric bupivacaine and 0.5% hyperbaric levobupivacaine when given intrathecally.

II. Material And Methods

This prospective randomized controlled study was carried out on patients of Department of general anesthesia at Katihar Medical College, Katihar, Bihar for 1.5 year after the approval from ethical committee. A total 80 adult subjects (both male and females) of aged ≥ 18, years were enrolled for in this study.

Study Design: Prospective randomized controlled study

Study Location: This was a tertiary care teaching hospital-based study done in Department of general anesthesia at Katihar Medical College, Katihar, Bihar.

Study Duration: 18 Months, August 2022- February 2023.

Sample size: 80 patients.

Sample size calculation: The sample size was estimated on the basis of a single proportion design. on a study by Hussien A and Halim M (12) in which the mean blood pressure 5 min after the intrathecal administration of heavy levobupivacaine and heavy bupivacaine were 92.25 +_ 2.04 and 90.00+_4.41 respectively. With alpha value of 5% and beta value of 20% (80%). The sample size was found to be 37 in each group. We planned to include 80 , Group HB (3ml of hyperbaric bupivacaine) and Group HL (3ml hyperbaric levobupivacaine).

Subjects & selection method: The study population was drawn from patients who presented to of general anesthesia at Katihar Medical College, Katihar, Bihar between from August 2022- February 2023. Patients were divided into two groups (each group had 40 patients).

Group A (n=40) received 3 ml of hyperbaric bupivacaine intrathecally at L1-L2 interspace with 25 G QuinKe needle in sitting position.

Group B (n=40) received 3 ml of hyperbaric bupivacaine intrathecally at L1-L2 interspace with 25 G Quinke needle in sitting position.

Inclusion criteria:
1. ASA grade I and II
2. Age group of 16 to 60 years undergoing elective lower abdominal surgery under spinal anesthesia.

Exclusion criteria:
1. Patient refusal
2. Local Infection at injection site
3. Coagulopathy
4. Allergic to local anesthetic drugs
5. H/O seizures and neurological deficit

Procedure methodology

After written informed consent was obtained, a well-designed questionnaire was used to collect the data of the recruited patients. The questionnaire included socio-demographic characteristics such as age, gender, height, weight, pulse rate. Blood pressures (systolic, diastolic and mean) recordings.

Apart from general physical and systemic examination, routine investigations, blood urea, serum creatinine, serum electrolytes, ECG and X- Ray chest was performed in all patients.

Upon arrival in the operating room, IV-line access was established and lactate Ringer's infusion was started. After administration of 500 ml of intravenous fluid spinal anaesthesia was given using 25 gauze Quinke needle at L2-L3 interspace. Onset time of sensory and motor block duration of sensory and motor block two segment regression time.

Monitoring included non-invasive blood pressure monitoring, Electrocardiogram and pulse oximeter. Heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP) and mean arterial pressure (MAP) was recorded every minute for first three minutes, thereafter every 5 minutes till the completion of surgery. After completion of the surgery patient were shifted to post-anaesthesia care unit and vitals were recorded every 15 min till the end of surgery.

1. Assessment of sensory blockade: sensory blockade was assessed by pin prick and time noted for the block to reach different dermatomal level.

• Onset of sensory block
• Level of sensory blockade • Maximum height reached • Duration of analgesia.
2. Assessment of onset of motor blockade.
3. Degree of motor blockade by modified Bromate scale.
4. Quality of intraoperative anaesthesia.
5. Assessment of total duration of motor blockade and total duration of sensory blockade.
6. Duration of analgesia (time between block and first analgesic dose).
7. Postoperative complications if any. Patients were also monitored for any side effects like nausea, vomiting, sedation, respiratory depression and pruritus

Statistical analysis

Data was analyzed using SPSS version 20 (SPSS Inc., Chicago, IL). Independent *t*-test was used to ascertain the significance of differences between mean values of two continuous variables and confirmed by nonparametric Mann-Whitney test. Chi-square and Fisher exact tests were performed to test for differences in proportions of categorical variables between two or more groups. The level $P < 0.05$ was considered as the cutoff value or significance.

III. Result

The demographic profile of the patients comparing age, sex, weight, height and also type of surgeries show no statistically significant difference and were comparable in both groups of our study. All base line vital parameters were similar in both groups. The mean age was between 45 to 49 years and mean BMI was around 26. Similarly, the mean weight was 68-69 kg for both the groups and mean height was 162 cm. Male to female ratio was 1:1.

The mean time for the onset of sensory block in group HB was observed to be 2.55 mins compared to 2.67 mins in group HL, with a p value of 0.18 which was found to be statistically insignificant.

The mean time for the onset of motor block in group HB was observed to be 3.48 mins compared to 4.17 mins in group HL, with a p value of 0.003 which was found to be statistically significant (Table 1).

Mean two segment regression time in group HB was 133.04 mins compared to group HL was 131 mins and was statistically significant (p value =0.00). Mean and SD of total duration of sensory blockade in Group HB were 206.1 and 2.4 mins whereas in group L were 193.3 and 0.8 respectively. Total duration of motor blockade in Group HB was 188.5±1.86 mins whereas in group HL was 181±1.08 mins. (Figure 1). The mean duration of analgesia in group HB was 207.50 mins and in group HL was 192.7 mins, with p value < 0.00 which is statistically significant (Table 2).

Mean pulse rate changes and blood pressure changes were comparable in both groups and is found to be statistically insignificant. Intra-operative complication between two groups was comparable and is found to be statistically insignificant (Figure 2,3).

The frequency of hypotension was seen in 20% of HB group and 12%of HL group, frequency of PONV was seen in 12% of HB group and 7.5 %of HL, frequency of bradycardia was seen in 10% of HB group and 7.5% of HL group and frequency of shivering was seen in 20% of HB group and 17.5% of HL group. The difference was not statistically significant.

Table no 1 Descriptive statistics on onset of sensory and motor blocks in both the groups

Mean duration of onset of block (min)	GROUP	N	Mean	Std. Deviation	Sig. (2-tailed)
Onset of sensory block	HB	40	2.55	0.27	.183
	HL	40	2.67	0.46	
Onset of motor block	HB	40	3.48	0.29	.000
	HL	40	4.17	0.56	

Table no 2 Descriptive statistics on duration of sensory and motor blocks, total analgesia duration in both the groups

Mean duration of analgesia (min)	GROUP	N	Mean	Std. Deviation	Sig. (2-tailed)
Two point regression time	HB	40	133.04	1.98	.000
	HL	40	130.86	1.69	
Duration of sensory block	HB	40	206.15	2.43	.000
	HL	40	193.32	0.85	
Duration of motor block	HB	40	188.25	1.86	.000
	HL	40	181.70	1.08	
Total duration of analgesia	HB	40	207.06	3.47	.000
	HL	40	192.25	2.05	

Figure no 1 Bar diagram comparing duration of sensory and motor blocks in both the groups

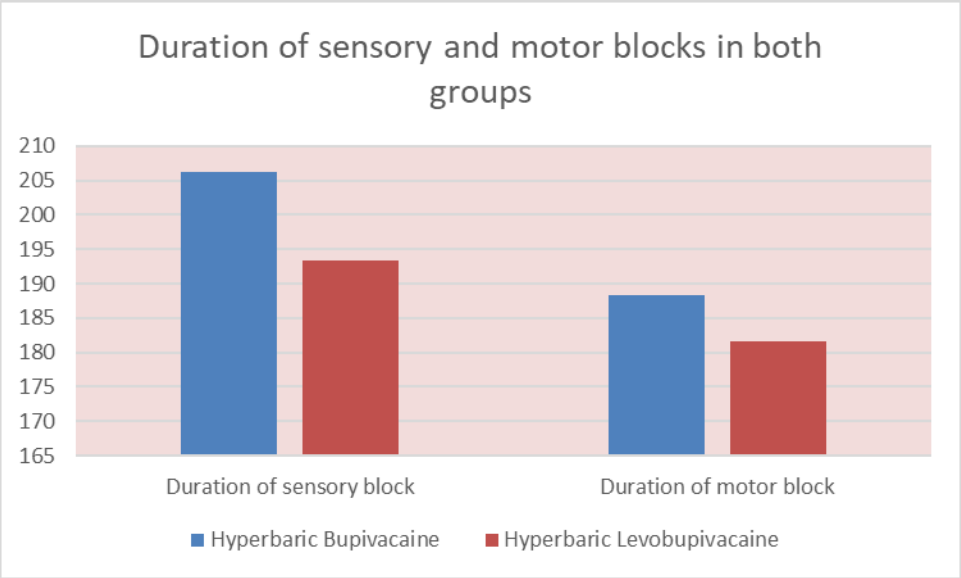


Figure no 2 Line diagram showing trend of Mean Arterial Blood Pressure (MAP) in both groups

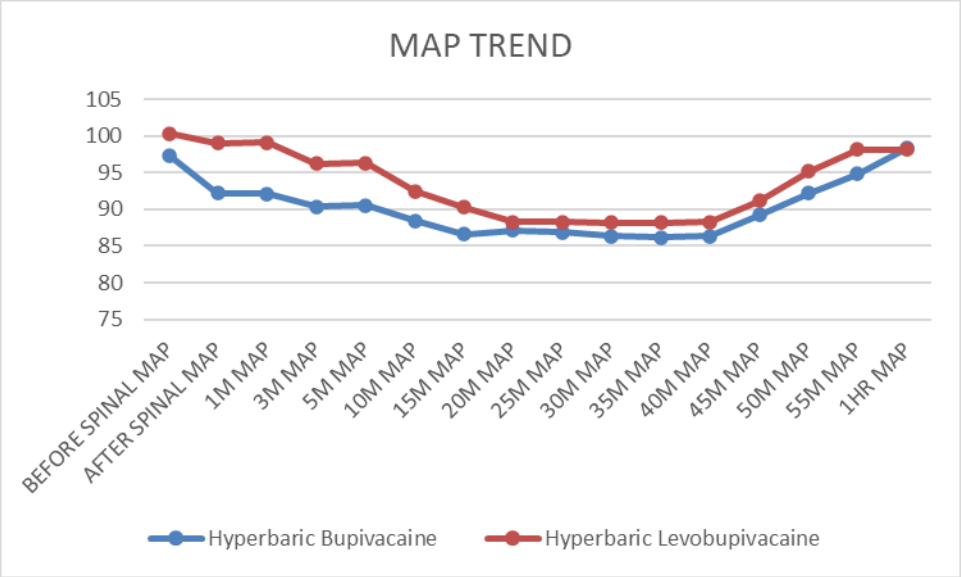
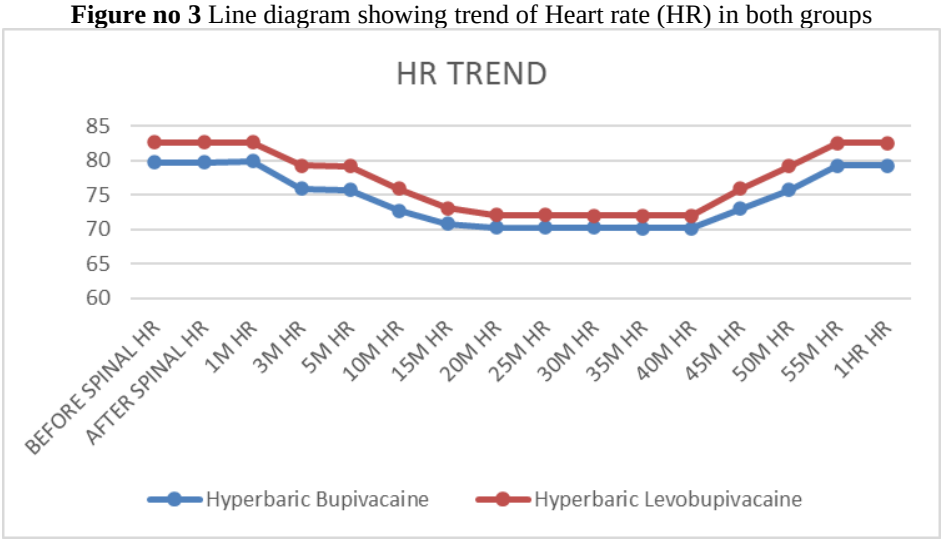


Figure no 3 Line diagram showing trend of Heart rate (HR) in both groups



IV. Discussion

Regional anaesthesia has several advantages over general anaesthesia in terms of reduced bleeding due to hypotension, better intraoperative and postoperative analgesia, awake patient, less requirements of parenteral opioids, decreased incidence of nausea and vomiting, reduction in venous thromboembolism, myocardial infarction, respiratory complications and renal failure

Subarachnoid block is the current wide spread popular anaesthetic technique available today. Subarachnoid block has the definitive advantage that profound nerve block can be produced in a large part of the body by the relatively simple injection of a small amount of local anaesthetic. An ideal anaesthetic agent used in subarachnoid block should have rapid onset of action, intense analgesia, adequate motor blockade, long duration of action, adequate postoperative analgesia and minimal cardiovascular change. Bupivacaine introduced by Ekenstam in 1957 seems to fulfil most of the requirements of an ideal local anaesthetic agent. It is a widely used local anaesthetic that has a prolonged action. Bupivacaine may be more cardiotoxic than other local anaesthetics and has been associated with deaths when accidentally injected intravenously.

Levobupivacaine is the pure S (¯)-enantiomer of racemic bupivacaine, developed as an alternative anaesthetic agent to bupivacaine. Levobupivacaine has similar blocking properties and greater margin of safety due to reduced toxic potential.

We started our study with a null hypothesis that hyperbaric levobupivacaine is comparable with hyperbaric bupivacaine in all its characteristics and concluded with the acceptance of null hypothesis

We started the study with 80 patients in the age group between 18-80 years, posted for various elective surgeries under spinal anaesthesia belonging to ASA physical status I and II were selected. There were no statistically significant differences in terms of demographic properties or ASA grading, the mean age, weight, height and gender of patients were comparable in both the groups.

The first characteristic studied was the duration of onset of sensory block. The onset of sensory block was taken as the time in minutes from the deposition of drug to the evidence of analgesia to pinprick at T12 level. In the present study, patients who received bupivacaine had a mean onset of sensory block faster than those who received levobupivacaine, but this was statistically insignificant. The mean time for the onset of sensory block in group HB was observed to be 2.55 mins compared to 2.67 mins in group HL, with a p value of 0.18 which was found to be statistically insignificant which was comparable to studies conducted by Gulen Guler et al. [3] and J.F. Luck et al. [4].

The mean time for the onset of motor block in group HB was observed to be 3.48 mins compared to 4.17 mins in group HL, with a p value of 0.003 which was found to be statistically significant.

Mean two segment regression time in group HB was 133.04 mins compared to group HL was 131 mins and was statistically significant (p value =0.00). Mean and SD of total duration of sensory blockade in Group HB were 206.1 and 2.4 mins whereas in group L were 193.3 and 0.8 respectively. Total duration of motor blockade in Group HB was 188.5±1.86 mins whereas in group HL was 181±1.08 mins. The mean duration of analgesia in group HB was 207.50 mins and in group HL was 192.7 mins, with p value < 0.00 which is statistically significant.

Maximum level of sensory block achieved is comparable in both groups in our study. In majority of the cases the maximum level of sensory block reached was T6 – 13.33% in Group HB and 10% in Group HL. In F. Fattorni et al. [5] study and Glaser et al. [6] study there was no difference between bupivacaine and levobupivacaine group in the highest level of sensory block achieved in the two groups (T8, T8) or in the time to reach peak level.

Mean two segment regression time in group HB was 133.04 mins compared to group HL was 131 mins and was statistically significant (p value =0.00) which is comparable to study conducted by Christian Glaser et al. [6]. The mean time for the onset of motor block in group HB was observed to be 3.48 mins compared to 4.17 mins in group HL, with a p value of 0.003 which was found to be statistically significant which is comparable to the study conducted by J.F. Luck et al. [4].

Degree of motor blockade in bupivacaine group that is number of patients with scale 3 blockade was 96.7% when compared to levobupivacaine group that is number of patients with scale 3 blockade was 63.4% and was found to be statistically significant with p value 0.01. Degree of motor blockade is superior with levobupivacaine when compared to levobupivacaine.

In bupivacaine group the mean value for total duration of motor blockade was 188.50 ±12.39 mins and in levobupivacaine group 182±12.3mins. For motor blockade P value 0.046 and was statistically significant. This observation is comparable to study conducted by J.F. Luck et al. [4]. In bupivacaine group the mean value for total duration of sensory blockade was 207.5±16.06 mins compared to levobupivacaine group 192.7±16.5mins which is comparable to study conducted by Christian Glaser et al. [6].

Post-operative complications were comparable in both groups and postoperatively incidence of vomiting, shivering, post dural puncture headache and hypotension were observed and all these incidences were similar in both the groups and statistically not significant. Similar Findings was seen in other studies also [8,9,10].

Patients were mobilized late in bupivacaine group than in the levobupivacaine group and it was found to be statistically significant (p value 0.03). The same results were found in the study conducted by J.F. Luck et al. [4]. In our study patients micturated late in levobupivacaine group than in bupivacaine group but it was statistically insignificant (p value 0.9). The same results were found in study conducted by Elizabeth A. Alley et al. [11].

V. Conclusion

The neurological and cardiovascular adverse reactions associated to the accidental intravenous administration are well known, as well as the possible hemodynamic impact of their intrathecal injection.

Since, its introduction into clinical practice, levobupivacaine has been appreciated because of the lower degree of toxicity when compared in particular with the racemic bupivacaine. Investigations have emphasized the association of levobupivacaine to a higher convulsive threshold and to a lower influence on cardiac or stroke indexes and ejection fraction.

Although levobupivacaine has very similar pharmacokinetic properties to those of racemic bupivacaine, several studies support the notion that its faster protein binding rate reflects a decreased degree of toxicity. The decreased cardiovascular and central nervous system toxicity make levobupivacaine an interesting alternative to racemic bupivacaine.

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