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A COMPARATIVE STUDY OF HYPERBARIC BUPIVACAINE AND LEVOBUPIVACAINE IN LOWER LIMB SURGERIES UNDER SPINAL ANAESTHESIA

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ABSTRACT

Background: Hyperbaric racemic bupivacaine is commonly used for spinal anaesthesia however racemic bupivacaine has some drawbacks. It has a high propensity to cause hypotension and bradycardia following intrathecal injection, and catastrophic cardiac toxicity due to the high affinity to cardiac myocytes. Levobupivacaine has a lower affinity for cardiac sodium channels. thus, reducing the risk of cardio toxicity. **Aim:** To compare Intraoperative quality, duration & complications of anaesthesia in patients undergoing lower limb surgeries with hyperbaric racemic bupivacaine and levobupivacaine administered intrathecally. **Methodology**: Prospective Cross-sectional Time Bound Study with duration of 18 months done on 70 patients undergoing elective lower limb surgeries of American Society of Anesthesiologists (ASA) physical status I and II of age group 18– 60 years. These patients were randomized into two groups of 35 patients each. one group received racemic mixture of bupivacaine while other received levobupivacaine. **Results**: In the present study results showed that mean duration of effective analgesia was more in Bupivacaine induced group was 239.5 (±19.5) minutes compared to levobupivacaine group 230.9(±16.6) minutes. The difference between mean onset of action bupivacaine with levobupivacaine was found to be significant The mean onset of sensory block initiation for bupivacaine was 6.31 minutes and for levobupivacaine was 6.11 minutes Time onset of Motor block initiation was lower in levobupivacaine 8.31(±0.9) minutes compared to bupivacaine 8.82(±1.1) minutes Highest level of sensory loss achieved was T3 in the 2 study subjects receiving bupivacaine whereas 15 study subjects achieved T4 level. Whereas in Levobupivacaine group highest level achieved was T4 in 11 study subjects Most common complication in both the groups was hypotension followed by nausea. Levobupivacaine showed comparable outcome to that of bupivacaine given its similar efficacy and fewer cardiovascular and CNS side effects. **Conclusion**: According to present study, levobupivacaine is found to be an alternative to bupivacaine for spinal anaesthesia in lower limb surgeries because it is a well-tolerated anaesthesia that offers similar effectiveness and less cardiotoxicity

ISSN: 0975-3583,0976-2833 VOL15, ISSUE 11, 2024

INTRODUCTION

Spinal anaesthesia has been a popular anaesthesia technique for lower abdominal orthopaedics, obstetrics, gynaecological and urological surgeries.[1]

Spinal block Results in a combination of sympathetic blockade, sensory blockade, or motor blockade depending on the dose, concentration, or volume of local anesthetic administered. It requires a small mass (i.e., volume) of drug that is almost devoid of systemic pharmacologic effects to produce rapid (>5 minutes), profound, reproducible sensory analgesia.[2]

When considering neuraxial anesthesia, the nature and duration of surgery, patient comorbidities, the ease of spinal insertion (i.e., positioning, and spinal pathology), and the relative benefits and risks to the individual are important. Spinal anesthesia may be useful when patients wish to remain conscious or when comorbidities such as severe respiratory disease or a difficult airway increase the risks of using general anesthesia

Hyperbaric racemic bupivacaine is commonly used for spinal anaesthesia due to its long duration of action and combined motor and sensory blockade. However, the use of hyperbaric racemic bupivacaine in spinal anaesthesia has some drawbacks. It has a high propensity to cause hypotension and bradycardia following intrathecal injection, and there is potential for catastrophic cardiac toxicity due to the high affinity of bupivacaine to cardiac myocytes. Racemic bupivacaine is an equimolar mixture of dextro and levobupivacaine.[3,4]

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. Plain levobupivacaine has been shown to be isobaric with respect to cerebrospinal fluid and thus leads to more predictable drug spread, decreasing the incidence of hypotension and bradycardia. Levobupivacaine also results in earlier motor recovery compared with racemic bupivacaine. These advantages make levobupivacaine an attractive alternative to racemic bupivacaine for spinal anesthesia.[4,5,6]

This study was designed to compare hyperbaric levobupivacaine with hyperbaric racemic bupivacaine with respect to intraoperative quality of an anaesthesia, patient satisfaction and recovery profile in patients undergoing elective lower limb surgeries.

AIM AND OBJECTIVES

Aim:

To compare Intraoperative quality, duration & complications of anaesthesia in patients undergoing lower limb surgeries with hyperbaric racemic bupivacaine administered intrathecally as compared to levobupivacaine administered intrathecally

OBJECTIVES:

1. To study and compare the quality of anaesthesia of hyperbaric racemic bupivacaine and levobupivacaine
2. To study and compare the onset & Duration of anaesthesia of hyperbaric racemic bupivacaine and levobupivacaine
3. To study and compare onset and duration of sensory blockade and motor blockade of hyperbaric racemic bupivacaine and levobupivacaine
4. To study and compare haemodynamic parameters of hyperbaric racemic bupivacaine and levobupivacaine
5. To study the complications / Side effects. (If any.) of hyperbaric racemic bupivacaine and levobupivacaine

ISSN: 0975-3583,0976-2833 VOL15, ISSUE 11, 2024

MATERIALS AND METHODS

STUDY GROUP:

Study was conducted on patients admitted in Tertiary Health Care Hospital, since this was a Prospective Cross-sectional Time Bound Study from July 2022 to Dec 2023, all patients undergoing elective lower limb surgeries in our institute fulfilling the inclusion criteria were included in our study group **Inclusion Criteria**: 1. Patients willingly participating in the study. 2. Patients belonging to ASA physical status class I and II. 3. Patients with age between 18 - 60 years of either gender. 4. Patients undergoing elective arthroscopic knee surgeries. **Exclusion criteria**: 1. Patients age below 18, pregnant females or above 60 years. 2. Contraindications of spinal anaesthesia, such as patient's refusal, coagulopathy, cardiorespiratory problems, neurological disease, allergic to used drugs. 3. Morbid obesity. 4. Complicated surgeries. 5. Patients with ASA grade III & above. 6. Emergency surgeries. Randomization was carried out by double blinding technique using coin toss method. Pre anesthetic checkup was be done 1 day prior to surgery as well as before surgery. Patients were examined thoroughly for any uncontrolled systemic diseases/disorder and laboratory investigations conducted as per existing protocols. Informed consent taken for participation in study. All patients were kept nil per oral overnight

Technique:

Informed consent obtained, with proper documentation of the discussion of risks. Resuscitation equipment should be kept available whenever a spinal anesthetic procedure was performed. The patients had adequate intravenous access and be monitored with pulse oximetry, non-invasive arterial blood pressure, and electrocardiogram. Patients were preloaded with 500ml RL. Spinal anesthesia given after taking all aseptic measures with Quincke's 23G needle via midline approach in L3-L4 intervertebral space after confirming free flow of cerebrospinal fluid with the injection of study drug

The Data recorded are changes in pulse rate, Blood pressure, peripheral SpO2. Time to achieve T12-T10 dermatomal level sensory block to be assess by negative pin prick method. Time for onset of complete motor block and the duration assess by modified Bromage scale. Time for two segment regression from T10 to T12 level and for assessment of pain visual analogue scale (VAS) will be used.

STATISTICS

The data was collected in Microsoft Excel Sheet and subjected to appropriate Descriptive statistics and inferential statistics.

Mean and standard deviation (mean±SD) were used to reflect quantitative variables, whereas frequency and percentage were used to reflect qualitative variables (including age, weight, height, body mass index (BMI), and ASA physical status).

The time of onset, spread to the maximum level, two-segment regression, and duration of either motor or sensory blockade analysed using a one-way analysis of variance (ANOVA) test. The surgical time and hemodynamic variables such as heart rate, mean arterial pressure, systolic blood pressure, and diastolic blood pressure were analysed using a two-way ANOVA test.

Intergroup comparison was done using Tukey's post hoc test.

The incidence of adverse effects was analysed using a chi-squared test. The analysis was considered significant when the P value was less than 0.

RESULTS

ISSN: 0975-3583,0976-2833 VOL15, ISSUE 11, 2024

In the present study we included 70 study subjects selected. In each treatment modality there were 35 study subjects

1. **Distribution of the study subjects**
   35 study subjects were randomly allotted to each arm. Age and sex wise distribution of the study subjects in each treatment arm showed homogeneity. (p>0.05)

Table 1: Distribution of the study subjects

Study Variables		**Bupivacaine**	**Levobupivacaine**	**Chi-square (p-value)**
Age in years	<20 Years	3	3	4.6(0.32)
	21-30	10	16	
	31-40	19	11	
	41-50	3	4	
	51-60	0	1	
	Mean age	32.5(±6.8)	30.4(±7.9)	0.22
Gender	**Male**	27	30	0.81(0.35)
	Female	8	5	

2. **Effective Analgesia**
   In the present study mean duration of effective analgesia was more in Bupivacaine induced group compared to levobupivacaine group. The difference between mean duration bupivacaine with levobupivacaine was found to be significant.

Table 2: Mean duration of effective analgesia

Study Variables	**Bupivacaine**	**Levobupivacaine**	**T -test (p-value)**
Effective analgesia (in Minutes)	239.5 (±19.5)	230.9(±16.6)	0.05

3. **Characteristics of Blocks**
   In the present study we observed that mean duration for both sensory and motor block was lower in levobupivacaine induced study subjects compared to bupivacaine induced one. And time duration for motor block between the two agents was found to be significant (p<0.05)

Table 3: Characteristics of Blocks

Study Variables	**Bupivacaine**	**Levobupivacaine**	**T -test (p-value)**
Time for motor Block (in Min)	8.82(±1.1)	8.31(±0.9)	0.04
Time for sensory Block (in Min)	6.31	6.11	0.4

4. **Highest level achieved**

ISSN: 0975-3583,0976-2833 VOL15, ISSUE 11, 2024

In our study Highest level of sensory loss achieved was T3 in the 2 study subjects receiving bupivacaine whereas 15 study subjects achieved T4 level. Whereas in Levobupivacaine group highest level achieved was T4 in 11 study subjects.

Table 4: Highest level achieved in the Study Subjects

Highest Level of Sensory block	Bupivacaine	Levobupivacaine	Total
T3	2 (100)	0(0)	2(2.8)
T4	15 (57.7)	11(42.3)	26(37.1)
T5	4 (33.3)	8(66.7)	12(17.1)
T6	10 (47.6)	11(52.4)	21(30)
T8	4 (44.4)	5(55.6)	9(12.8)
Total	35 (50)	35(50)	70

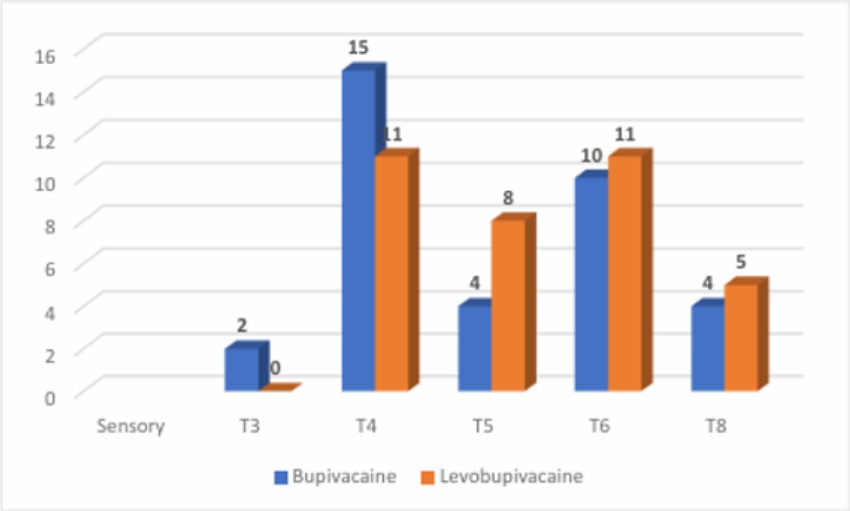

Figure 1: Highest level achieved

5. **Quality of Anaesthesia**

Excellent score was observed in 20% (7/35) study subjects receiving levobupivacaine and 17.1% (6/35) in bupivacaine receiving study subjects. Whereas satisfactory score was present in 80% (28/35) of study subjects receiving levobupivacaine and 82.9% (29/35). The difference between the two was not significant.

Table 5: Quality of anaesthesia

Study Variables		Bupivacaine	Levobupivacaine	T -test (p-value)
Score	**Excellent**	06	07	0.09(0.75)
	Satisfactory	29	28	

6. **Complications**:

Most common complication in both the groups was hypotension followed by nausea. Hypotension was seen in 7 study subjects of bupivacaine induced group whereas only 4 study subjects had hypotension in levobupivacaine group. Similarly, nausea was seen

ISSN: 0975-3583,0976-2833 VOL15, ISSUE 11, 2024

in the 4 study subjects of bupivacaine group and 2 study subjects of levobupivacaine group. Whereas we observed higher incidence of vomiting in levobupivacaine group (3/35) present in 3 study subjects whereas only one study subject reported vomiting in bupivacaine group.

Table 6: Complications

Complications	Bupivacaine	Levobupivacaine	Total	T -test (p-value)
Bradycardia	2(66.6)	1(33.3)	3(4.3)	4.3(0.497)
Hypotension	7(63.6)	4(36.3	11(15.7)	
Nausea	4(66.7)	2(33.3)	6(8.6)	
Vomiting	1(25)	3(75)	4(5.7)	
Total	**35(50)**	**35(50)**	**70**	

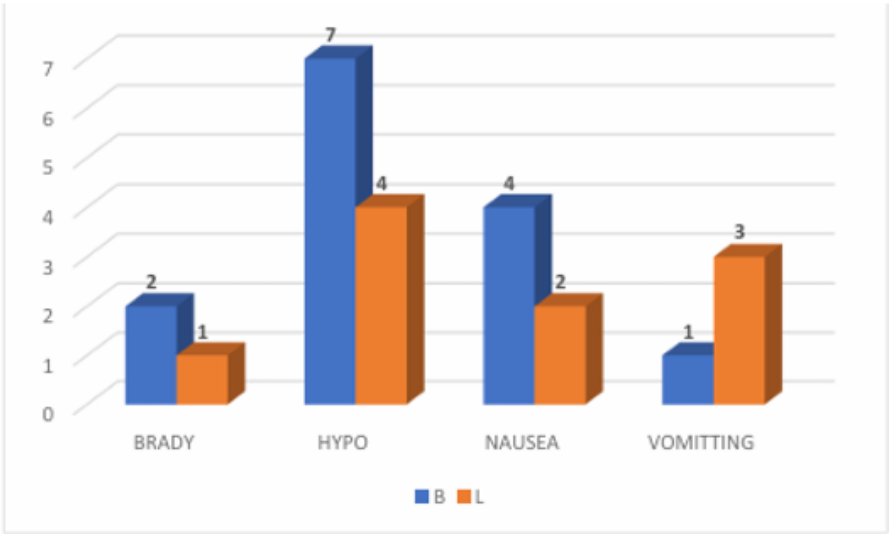

Figure 2: Complications in the study subjects

ISSN: 0975-3583,0976-2833 VOL15, ISSUE 11, 2024

DISCUSSION

In the present study we allocated 35 patients to each treatment arm. Patients undergoing lower limb surgeries under spinal anesthesia with hyperbaric racemic bupivacaine were compared to spinal anesthesia with levobupivacaine.

Mean age observed was 31.4±7.4 years whereas the range was 16-56 years. Most of the study subjects were in the age group 31-40 years 30(42.8%) followed by 21-30 years 26(37.1%). Whereas only one study subject was above 50 years of age. This was similar to the Guirro *et al.* while studying the effect of spinal anesthesia with bupivacaine and fentanyl associated with femoral nerve block in postoperative analgesia in the reconstruction of the anterior cruciate ligament.[7]

In the present study mean duration of effective analgesia was more in Bupivacaine induced group was 239.5 (±19.5) minutes compared to levobupivacaine group 230.9(±16.6) minutes. The difference between mean duration bupivacaine with levobupivacaine was found to be significant. Similarly, Singh *et al.* observed higher mean duration of effective analgesia in bupivacaine Whereas, Erbay *et al.* reported a longer duration of analgesia with levobupivacaine.[8,9]

In the present study we observed that mean duration of sensory block initiation for bupivacaine was 6.31 minutes and for levobupivacaine was 6.11 minutes. Yadav *et al.* also observed that time to reach maximum sensory block level was earliest in group Levobupivacaine as compared to groups Bupivacaine and Ropivacaine. This seems to be linked with the isobaricity of levobupivacaine.

Time duration of Motor block initiation was lower in levobupivacaine 8.31(±0.9) minutes compared to bupivacaine 8.82(±1.1) minutes. Singh *et al.* also observed the duration of motor block being shorter with levobupivacaine than with bupivacaine. The faster offset of motor block may cause quicker motor recovery.

In our study Highest level of sensory loss achieved was T3 in the 2 study subjects receiving bupivacaine whereas 15 study subjects achieved T4 level. Whereas in Levobupivacaine group highest level achieved was T4 in 11 study subjects. This was also consistent with Del-Rio Vellosillo *et al.* findings. They also noted higher level of sensory blockade in bupivacaine group.[9] Whereas, Singh *et al.* did not observe any significant difference in achieving higher sensory level.[8]

Most common complication in both the groups was hypotension followed by nausea. Hypotension was seen in 7 study subjects of bupivacaine induced group whereas only 4 study subjects had hypotension in levobupivacaine group. Singh *et al.* and Erdil *et al.*so noticed higher incidence of hypotension in bupivacaine group compared to levobupivacaine. Bupivacaine is more potent local anesthetic which causes greater sympathetic blockade, resulting in a greater incidence of hypotension.[8,11]

Most of the clinical studies that compared levobupivacaine and bupivacaine have discovered few differences between them and report that both have comparable effects. Glaser *et al.* in their randomized, double-blind prospective study compared isobaric solutions (3.5 mL of 0.5% levobupivacaine; 3.5 mL of 0.5% bupivacaine) in 80 patients undergoing elective hip replacements. In their study they did not find clinical differences and concluded that both drugs were equipotent and offered similar durations, onset times, and degrees of motor and sensory blockades.

Levobupivacaine showed comparable outcome to that of bupivacaine given its similar efficacy and fewer cardiovascular and CNS side effects. Its pharmacokinetic properties are similar to

ISSN: 0975-3583,0976-2833 VOL15, ISSUE 11, 2024

those of racemic bupivacaine. its faster protein binding rate suggests a lower degree of toxicity.[13,14]

SUMMARY

This study was designed to compare hyperbaric levobupivacaine with hyperbaric racemic bupivacaine with respect to intraoperative quality of an anaesthesia, patient satisfaction and recovery profile in patients undergoing elective lower limb surgeries.

Objective of study was to check Quality of anaesthesia., Onset & Duration of anaesthesia, Onset and duration of sensory blockade and motor blockade, Haemodynamic parameters & Complications if any

Patients undergoing elective knee arthroscopic surgeries in our institute fulfilling the inclusion and exclusion criteria, were included in our study group. Randomization was carried out by double blinding technique using coin toss method.

In the present study 35 patients were allocated to each treatment arm. Patients undergoing lower limb surgeries under spinal anesthesia with hyperbaric racemic bupivacaine were compared to spinal anesthesia with levobupivacaine

Requirement of new local anaesthetic molecules which would provide better cardiovascular stability, optimum surgical anaesthesia and rapid recovery after anaesthesia is need of hour

In the present study results showed that mean duration of effective analgesia was more in Bupivacaine induced group was 239.5 (±19.5) minutes compared to levobupivacaine group 230.9(±16.6) minutes. The difference between mean duration bupivacaine with levobupivacaine was found to be significant

The mean duration of sensory block initiation for bupivacaine was 6.31 minutes and for levobupivacaine was 6.11 minutes

Time duration of Motor block initiation was lower in levobupivacaine 8.31(±0.9) minutes compared to bupivacaine 8.82(±1.1) minutes

Highest level of sensory loss achieved was T3 in the 2 study subjects receiving bupivacaine whereas 15 study subjects achieved T4 level. Whereas in Levobupivacaine group highest level achieved was T4 in 11 study subjects

Most common complication in both the groups was hypotension followed by nausea.

Levobupivacaine showed comparable outcome to that of bupivacaine given its similar efficacy and fewer cardiovascular and CNS side effects

CONCLUSION

In the present study we noticed that faster induction of sensory and motor block in levobupivacaine group. Effective analgesia time was more for bupivacaine group. But levobupivacaine had lesser incidences of hypotension and bradycardia compared to bupivacaine.

According to present study, levobupivacaine is found to be an alternative to bupivacaine for spinal anaesthesia in lower limb surgeries because it is a well-tolerated anaesthesia that offers similar effectiveness and less cardiotoxicity

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