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A randomized control study to evaluate the efficacy of intrathecal hyperbaric bupivacaine 0.5% with intrathecal hyperbaric levobupivacaine 0.5% in lower abdominal and lower limb surgeries in tertiary care center

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ABSTRACT

Aims and Objectives: The purpose of this study was to compare sensory characteristics like onset of sensory blockade, maximum level of sensory block, total duration of sensory block by pin prick method, motor characteristics like onset of motor blockade by Modified Bromage scale and total duration of motor block and perioperative hemodynamic changes, following intrathecal hyperbaric Bupivacaine 0.5% and intrathecal hyperbaric Levobupivacaine 0.5% in lower abdominal and lower limb surgeries.

Material and method: A Randomized control trial was conducted at Department of Anaesthesiology, GMERS Medical College, Sola, Ahmedabad on patients undergoing lower abdominal and lower limb surgeries .

Patients were divided into two groups: Group L (n=65) received 3.5 ml of intrathecal hyperbaric Levobupivacaine (0.5%) 17.5 mg (5mg/ml) and Group B (n=65) received 3.5 ml of intrathecal hyperbaric Bupivacaine (0.5%) 17.5 mg (5mg/ml).

Results and Conclusion: Levobupivacaine has rapid onset and shorter duration of sensory as well as motor blockade, making it suitable for short duration and day care surgeries. Both the drugs are hemodynamically stable and have no significant complications. Hence, intrathecal Levobupivacaine is preferred for short duration lower abdominal and lower limb surgeries. Due to evidence of early ambulation with Levobupivacaine, it is preferable in day care surgeries.

Keywords: Levobupivacaine, intrathecal, lower abdominal and lower limb surgeries

INTRODUCTION

The development of regional anaesthesia started with the isolation of local anaesthetic, the first being cocaine (the only naturally occurring local anaesthetic). The first regional anaesthesia technique performed was spinal anaesthesia. Spinal anaesthesia is the regional anaesthesia obtained by blocking the spinal nerves in the subarachnoid space. The anaesthetic agents deposited in the subarachnoid space act on the spinal nerve roots and not on the substance of the cord[1].

Spinal anaesthesia was first performed by J. Leonard Corning in New York in 1885. The first planned spinal anaesthesia for surgery on a human was administered by August Bier on 16 August, 1898 where he injected 3 ml of 0.5% cocaine intrathecally. This was followed by successful and enthusiastic practice of spinal anaesthesia by "Rudolf Matas" in New Orleans and "Theodore Tuffier" in France[2][3].

The choice of local anaesthetic is determined by type and duration of surgery and by the intensity of the motor blockade that is required. Lignocaine was the first short acting local anaesthetic introduced in 1940. Although Lignocaine has been used for very long time, it has higher chances of neurotoxicity (seizure, agitation, unconsciousness, coma). In this prompt search for alternatives, Bupivacaine is the first long acting amide local anaesthetic discovered in 1957. Its advantage when compared to lignocaine is that its long duration of action, differential sensory as well as motor block and less

neurotoxicity due to increased lipid solubility and protein binding. However it has lower therapeutic index with respect to cardiovascular toxicity[4].

The increase in the day care surgery has generated a need for a local anaesthetic with a quick onset, shorter duration of action and less systemic toxicity following early ambulation. This has led to the development of levobupivacaine, the S-enantiomer of Bupivacaine in 1970. This L form is less cardiotoxic and has faster onset and shorter duration of action than Bupivacaine[5].

The purpose of this study was to compare sensory characteristics like onset of sensory blockade, maximum level of sensory block, total duration of sensory block by pin prick method, motor characteristics like onset of motor blockade by Modified Bromage scale and total duration of motor block and perioperative hemodynamic changes, following intrathecal hyperbaric Bupivacaine 0.5% and intrathecal hyperbaric Levobupivacaine 0.5% for lower abdominal and lower limb surgeries (Open Appendicectomy, Open Inguinal Hernioplasty, Hydrocele, Varicose veins, Foot Cellulitis, Tibia fracture, Calcaneum fracture etc.) with less than two hours duration.

MATERIAL AND METHODOLOGY

Study Area: Department of Anaesthesiology, GMERS Medical College, Sola, Ahmedabad
Study population: Patients undergoing lower abdominal and lower limb surgeries as per the inclusion criteria
Study Design: Randomized controlled trial
Study Duration: July 2022 to January 2024

INCLUSION CRITERIA

1. Patients belonging to ASA grade I or II.
2. Patients between 18-60 years of age.
3. Patients posted for elective lower abdominal and lower limb surgeries (Open Appendicectomy, Open Inguinal Hernioplasty, Hydrocele, Varicose veins, Foot Cellulitis, Tibia fracture, Calcaneum fracture etc.).
4. Duration of surgery should be <2 hours.

EXCLUSION CRITERIA

1. Patient's refusal or uncooperative patients.
2. Patients belonging to ASA grade III and IV.
3. Hypersensitivity to the drugs used in our study.
4. Patients having active skin diseases or infection over spine region.
5. Patients having coagulation disorders or on anti coagulant medications.
6. Significant neurological disease with motor or sensory deficit and congenital deformity of spine.
7. History of psychiatric illness or any other concomitant disease which may lead to unreliability in clinical assessments.
8. Patients undergoing emergency surgeries

Total sample size: 130 patients
No. of cases in group 1: 65 patients No. of cases in group 2: 65 patients Type 1 error: 0.05
Type 2 error: 0.20

130 patients, ASA grade I-II patients, age 18 to 60 years undergoing lower abdominal and lower limb surgeries under spinal anaesthesia were equally allocated into two groups after taking Institutional Ethical committee approval as per hospital rules & regulations. After taking written informed consent from every patient in their own language, intrathecal injection of local anaesthetic was administered as follows:

- Group L (n=65) received 3.5 ml of intrathecal hyperbaric Levobupivacaine (0.5%) 17.5 mg (5mg/ml)
- Group B (n=65) received 3.5 ml of intrathecal hyperbaric Bupivacaine (0.5%) 17.5 mg (5mg/ml).

Pre-anaesthetic check-up of all the Patients was done for thorough history, examination and investigations. On the day of surgery, all the patients were re-assessed in pre-operative anaesthesia room for NBM status, written informed consent and baseline vital data were recorded. After shifting the patient to the operation theatre - heart rate, ECG, NIBP, SpO2 were monitored throughout surgery, a suitable IV line was secured with 18 G intravenous cannula and inj. Ringer's Lactate 500ml was started. Patients were premedicated with injection ondansetron
0.15 mg/Kg.

Under all aseptic precautions spinal anaesthesia was performed in the lateral position using a 25-gauge spinal needle at the L3-L4 interspace. The study solution (3.5 ml) was administered. Patient was gently placed supine and tested for sensory and motor blockade immediately after 1 minute, then every 5 minutes till maximum level was achieved. This was also performed at 60 minutes, 2 hours, 4 hours and 6 hours interval to assess the total duration of sensory and motor

blockade. Pulse and NIBP were measured after induction of anaesthesia at intervals of 1 min, 5 min, 10 min, 15 min, 60 min, 2 hours, 4 hours and 6 hours.

PARAMETERS EVALUATED

1. Sensory block Characteristics:

The level of sensory block was evaluated by pinprick test using 24 G hypodermic needle. Loss of sensation to pin prick was considered as sensory block.

Onset time for the sensory block was considered when complete loss of sensation at L1 level achieved.

Time taken to achieve maximum sensory level was assessed.

Total duration of sensory block was measured until complete recovery of sensory block in post operative period.

2. Motor block Characteristics:

The onset of motor blockade was assessed using Modified Bromage scale.

1. Free movement of legs, feet, with ability to raise extended legs.
2. Inability to raise extended leg and hip flexion is decreased but full flexion of feet and knee present.
3. Inability to raise leg or flex knees, flexion of ankle and feet present.
4. Inability to raise legs, flex knees ankle or move toes.

Total duration of motor block was evaluated until complete recovery of motor block in the post operative period.

3. Hemodynamic parameters

HR, SBP, DBP, MAP, and SpO2 were recorded at 1, 5, 10, 15, 60 minutes and 2, 4 and 6 hours.

Statistical Analysis

Descriptive analysis of numerical data (mean ±SD) and categorical data (frequency and percentage) was performed. Statistical tests like student's unpaired t-test were used for continuous variables as per normality distribution of data using SPSS Statistics software and a p-value of <0.05 was considered statistically significant.

OBSERVATION

One hundred and thirty, ASA grade I-II patients, aged 18 to 60 years undergoing lower abdominal and lower limb surgeries (Open appendicectomy, open inguinal hernioplasty, hydrocele, varicose veins, foot cellulitis, tibia fracture, calcaneum fracture etc.) under spinal anaesthesia were equally divided into two groups. Group L (n=65) received 3.5 ml of intrathecal hyperbaric Levobupivacaine (0.5%) 17.5 mg (5mg/ml) and Group B (n=65) received 3.5 ml of intrathecal hyperbaric Bupivacaine (0.5%) 17.5 mg (5mg/ml). The sensory, motor and hemodynamic characteristics were compared between the two groups. Statistical test like student's unpaired t-test was used for continuous variables as per normality distribution of data and a p-value of <0.05 was considered statistically significant. The following were the observations. Both the groups, Group B and Group L are matched for age, height, weight and gender, with the difference being statistically insignificant(p>0.05)

TABLE 1: COMPARISON OF MEAN HEART RATE IN TWO GROUPS

HEART RATE	GROUP B	GROUP L	P VALUE
Before Induction	80.9 ±5.78	80 ± 4.8	0.33
1 min after induction	81.2 ± 5.74	79.9 ± 4.8	0.16
5 min	79.8 ± 6.08	80 ± 6.07	0.85
10 min	80.1 ± 5.44	79.1 ± 4.93	0.32
15 min	79.4 ± 4.71	80.2 ± 3.38	0.26
60 min	79.9 ± 3.94	80.2 ± 4.29	0.67
2 hours	81.2 ± 3.53	80.4 ± 5.41	0.31
4 hours	81 ± 4.73	82 ± 4.3	0.20
6 hours	80.15 ± 4.21	80 ± 5.7	0.86

Note - As shown in the table above, the heart rate variation between the two groups under study, at specific intervals, is statistically insignificant (p>0.05).

TABLE 2: COMPARISON OF MEAN ARTERIAL PRESSURE IN TWO GROUPS

MAP (mm hg)	GROUP B	GROUP L	P VALUE
Before induction	94.1 ± 6.66	92.9 ± 7.65	0.34
1 min after induction	93.6 ± 6.04	93.1 ± 5.15	0.61
5 min	92.6 ± 5.15	92.4 ± 4.6	0.81
10 min	86.8 ± 4.40	93.7 ± 4.71	0.00 (Significant)
15 min	82.9 ± 3.12	93.7 ± 3.9	0.00 (Significant)

60 min	85.7 ± 4.20	92 ± 5.13	0.00 (Significant)
2 hours	92.1 ± 4.48	92.2 ± 5.15	0.9
4 hours	93 ± 4.46	93.5 ± 5.17	0.55
6 hours	92.5 ± 4.5	91.4 ± 5.2	0.19

Note- As shown in the table above, the Mean arterial blood pressure variation between the two groups under study is statistically significant at intervals of 10 min, 15 min and 60 min after induction of spinal anaesthesia. In comparison to group L, in Group B fall in mean blood pressure (Not >20%) is observed at these intervals ($p<0.05$).

TABLE 3: COMPARISON OF MEAN TIME OF ONSET OF SENSORY BLOCK AT SHIN OF TIBIA, SENSORY BLOCK ACHIEVED AT T10 LEVEL AND MAXIMUM SENSORY LEVEL ACHIEVED IN TWO GROUPS

	GROUP B	GROUP L	P VALUE	INFERENCE
Onset of sensory block at shin of tibia(min)	3.63 ±0.66	1.76 ±0.30	0.00	Significant
Sensory block achieved at T10 level (min)	8.76 ±0.48	4.67 ±0.58	0.00	Significant
Maximum sensory level achieved (min)	14.84 ±1.39	9.44 ±1.02	0.00	Significant

Note :

a. As shown above, **onset of sensory block at shin of tibia** (in minutes) is Faster in group L than group B and the variation is statistically significant ($p<0.05$).
b. Time taken to achieve **sensory block at T 10 level** (in minutes) is shorter in Group L as compared to group B, and the variation is statistically significant ($p<0.05$).
c. The variation in time taken for **maximum sensory block** (in minutes) is shorter in group L than group B, and the variation is statistically significant ($p<0.05$).

TABLE 4: COMPARISON OF MEAN TIME FOR ONSET OF MOTOR BLOCK IN TWO GROUPS

MODIFIED BROMAGE SCALE	GROUP B	GROUP L	P VALUE	INFERENCE
SCALE 1	4.83 ±0.71	2.95 ±0.55	0.00	Significant
SCALE 2	7.78 ±0.89	5.77 ±0.78	0.00	Significant
SCALE 3	11.01 ±1.03	8.66 ±0.72	0.00	Significant

Note- As shown in the table, the time of onset of motor block (in minutes) as per Modified Bromage scale 1-3, is faster in Group L than in Group B, and the variation is statistically significant (p value<0.05).

TABLE 5: COMPARISON OF MEAN OF TOTAL DURATION OF SENSORY AND MOTOR BLOCK

TOTAL DURATION (MINUTES)	GROUP B	GROUP L	P VALUE	INFERENCE
Sensory Block	247.9 ± 8.36	213.5 ± 5.21	0.00	Significant
Motor Block	227.6 ± 15.6	205 ± 5.37	0.00	Significant

Note - As shown in the table, the total duration of sensory and motor block is shorter in Group L compared to Group B, and the difference being statistically significant ($p <0.05$) No significant Intra operative and post-operative complications like bradycardia, shivering, nausea, vomiting etc. were observed in either of the groups.

DISCUSSION

Spinal anaesthesia was introduced into clinical practice by Karl August Bier in 1898. It is a type of regional anaesthesia obtained by blocking spinal nerves in subarachnoid space. More than a century has passed and even today it is one of the most popular techniques for both elective and emergency surgical procedures like lower abdominal surgeries, caesarean section, orthopedic and urological surgeries just to name a few.

Spinal anaesthesia is a safe and effective alternative to general anaesthesia where the surgical site is located on lower abdomen, perineum and lower extremities. Advantages include avoidance of airway management concerns of general anaesthesia, reduced metabolic stress response to surgery, reduction in pulmonary compromise, better muscle relaxation, quick restoration of bowel movements, better post operative analgesia, the ability to monitor patients' mental status etc.
Traditionally, Bupivacaine has been the drug of choice for subarachnoid block. However, significantly long duration of action delays recovery of motor function and prolongs post anaesthesia care unit stay. In addition several studies have shown that Bupivacaine produces neurological and cardiac toxicity. The problems associated with toxicity of racemic Bupivacaine triggered the development of Levobupivacaine, the S-enantiomer of Bupivacaine which shows less cardiotoxicity and shorter duration of action.

Our study is designed to compare the efficacy of intrathecal hyperbaric solutions of Bupivacaine 0.5% and hyperbaric Levobupivacaine 0.5%. Our study design consisted of 130 patients aged between 18-60 years, ASA physical status I & II undergoing lower abdominal and lower limb surgeries under spinal anaesthesia were equally divided in two groups.

Patients with group B received Bupivacaine 17.5 mg (0.5%) and group L received Levobupivacaine 17.5 mg (0.5%) intrathecally.

The following parameters were observed:

1. Sensory blockade
a. Onset of sensory block
b. Maximum level of sensory block
c. Total duration of sensory block

2. Motor blockade
a. Onset of motor blockade by Modified Bromage Scale- I,II,III
b. Total duration of motor block

3. Hemodynamic parameters- Heart rate, Systolic blood pressure, Diastolic blood pressure and Mean arterial pressure

4. Side effects or Complications

SENSORY BLOCK

We observed that mean onset of the sensory block with Levobupivacaine (1.76 ± 0.30 min) was significantly faster than with Bupivacaine (3.63 ± 0.66 min), $p<0.05$, and the mean duration of sensory block with Levobupivacaine was significantly less (213.5 ± 5.21 min) than with Bupivacaine (247.9 ± 8.36 min), $p<0.05$. These findings correlate with the studies below.

Ajay singh et al. Reported that total duration of sensory block with 3ml 0.5% hyperbaric Levobupivacaine was significantly shorter (206 ± 18.9 min) compared to 0.5% hyperbaric Bupivacaine (224 ± 15.6 min).[6]

Andrea Casati et al. Reported that regression of anaesthesia was longer with 8 mg 0.5% hyperbaric Levobupivacaine (210 ± 63 min) compared to Bupivacaine (190 ± 51 min)[7].

Divya Sethi observed that recovery from sensory blockade was faster with 10 mg hyperbaric 0.5% Levobupivacaine (113± 39 min) and it was (122 ± 34 min) with 10 mg 0.5 % hyperbaric Bupivacaine[8].

Gulen et al. Observed that onset of sensory blockade (1.46 ± 0.37 min) as well as duration of total sensory blockade (145±11 min) was faster with 2 ml Levobupivacaine & 15 µcg fentanyl[9].

MOTOR BLOCK

In our study, we observed that onset of motor blockade in group Levobupivacaine (2.95 ±0.55 min) was faster than group Bupivacaine (4.83 ±0.71 min) and total duration of motor blockade was shorter in group Levobupivacaine (205 ± 5.37 min) compared to Bupivacaine (227.6 ± 15.6 min). These findings correlate with the studies below.

Ajay Singh et al. Observed that complete regression of motor block was faster with Levobupivacaine (185 ± 20.3 min) compared to Bupivacaine (196.4 ± 21.2 min). Early ambulation was observed with group L (L: 321± 19 min ; B: 356 ± 26.6 min)[6].

Andrea Sasati et al. Found that 84% patients receiving Lebobupivacaine had complete regression of motor blockade within 180 min compared to only 19% pateints receiving Bupivacaine[7].

Divya Sethi reported no significant difference in onset and duration of motor block between Levobupivacaine (139 ±33 min) and Bupivacaine (143 ± 30.4 min) group. **Gulen et el.** Observed that onset of motor blockade was faster with Bupivacaine (2.36± 0.61 min) than Levobupivacaine (4.1 ±0.88 min) on the contrary total duration of motor block was shorter with Levobupivacaine (99 ± 9.13 min) than Bupivacaine (132.6± 7.15 min)[8].

HEMODYNAMIC PARAMETERS

In our study, heart rate, systolic, diastolic and mean blood pressure were observed in both groups intraoperatively and postoperatively. In Some cases, a reduction in blood pressure was observed in group B but it was not significant (fall in BP not >20% of baseline) and did not require any intervention. No such hemodynamic changes observed in group L. These findings correlate with the studies below.

In their study**, M. Mantouvalou et al.** Compared the anaesthetic efficacy and safety of 15 mg 0.5% Bupivacaine, 15 mg 0.5% Ropivacaine and 15 mg 0.5% Levobupivacaine, in patients undergoing lower abdominal surgery. There was a slight reduction in mean arterial blood pressures after spinal injection in all groups, which however was significant only

in the Bupivacaine group. Intraoperative hypotension requiring treatment with I.V. ephedrine occurred more often in Bupivacaine group (42% patients) than in Levobupivacaine group (17% patients) $p<0.05$.[10]

Vanna et al. Conducted a study to compare 2.5 ml Isobaric Levobupivacaine 0.5% with 2.5 ml Hyperbaric Bupivacaine 0.5%, in patients undergoing transurethral surgeries. Study shows no significant changes in hemodynamics in either of the group[11].

Limitations

The main limitation of this study was the heterogeneity of surgical procedures. The small sample size is a limitation to generalize our observations and to look for complications associated with the drugs in use. A larger prospective double blinded study with a single surgical procedure is recommended to evaluate this further.

CONCLUSION

As per the observations and results of our study, we came to the following conclusion:

Intrathecal hyperbaric Bupivacaine and Levobupivacaine produce adequate anaesthesia for lower abdominal and lower limb surgeries (Open Appendicectomy, Open Inguinal Hernioplasty, Varicose veins, Foot Cellulitis, Tibia fracture, Calcaneum fracture etc.).

1. Levobupivacaine has rapid onset and shorter duration of sensory as well as motor blockade, making it suitable for short duration and day care surgeries.
2. Both the drugs are hemodynamically stable and have no significant complications.

Hence, intrathecal Levobupivacaine is preferred for short duration lower abdominal and lower limb surgeries. Due to evidence of early ambulation with Levobupivacaine, it is preferable in day care surgeries.

BIBLIOGRAPHY

1. Collins, Vincent J (Vincent Joseph), SPINAL ANAESTHESIA PRINCIPLES. Principle of Anaesthesiology, general and regional anaesthesia(third edition), 1993;2:p.1445
2. Hajdu SI. Discovery of the cerebrospinal fluid. Annals of Clinical & Laboratory Science. 2003;33(3):334-6
3. R D Miller, Lars I Errikson, Lec A, Fileisher Jeanine P, Wiener - Kronish, William L. Young. History of Anaesthesia. Miller's Anaesthesia(seventh edition), 2010;1:p.21
4. Mather LE, Copeland SE, Ladd LA. Acute Toxicity of Local Anaesthetics: Underlying Pharmacokinetic and Pharmacodynamic Concepts. Reg Anesth PainMed 2005;30:553-66
5. Heavner JE. Cardiac toxicity of local anaesthetics in the intact isolated heart model; a review. Reg Anesth Pain Med 2002;27:545-5
6. Singh A, Gupta A, Datta PK, Pandey M. Intrathecal levobupivacaine versus bupivacaine for inguinal hernia surgery: a randomized controlled trial. Korean J Anesthesiol. 2018;71(3):220-225
7. Casati A, Moizo E, Marchetti C, Vinciguerra F. A prospective, randomized, double-blind comparison of unilateral spinal anesthesia with hyperbaric bupivacaine, ropivacaine, or levobupivacaine for inguinal herniorrhaphy. Anesth Analg. 2004;99(5):1387-1392.
8. Sethi D. Randomised Control Trial Comparing Plain Levobupivacaine and Ropivacaine with Hyperbaric Bupivacaine in Caesarean Deliveries. Turk J Anaesthesiol Reanim. 2019;47(6):471-479
9. Guler G, Gakir G, Ugur F. A comparison of spinal anaesthesia with levobupivacaine and hyperbaric bupivacaine for caesarean section. Open Journal of Anaesthesiology, 20212;2(3).Article ID:20539,6 pages.
10. Mantouvalou M, Ralli S. Spinal anaesthesia comparison of plain ropivacaine, bupivacaine and levobupivacaine for lower abdominal surgery, Acta Anaesthesiol Belg 2008,59:65-71
11. Vanna O, Chumsang L, Thongmee S. Levobupivacaine and bupivacaine in spinal anesthesia for transurethral endoscopic surgery. J Med Assoc Thai. 2006;89(8):1133-9