Comparison of motor and haemodynamic profiles of epidural 0.5% Levobupivacaine with 0.75% Ropivacaine in patients undergoing elective below umbilical surgery

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ABSTRACT

Introduction: Our study focuses on comparing the motor and haemodynamic effects of levobupivacaine 0.5% and ropivacaine 0.75% when administered as epidural anaesthesia for surgeries below the umbilicus. This comparison is particularly important given that the racemic mixture of bupivacaine, which includes the dextro (D-(+)) and levo (L-(-)) isomers in equal proportion, is associated with significant cardiovascular and central nervous system complications, particularly due to the R-(+)-isomer. In contrast, the levorotatory isomers like our study drug levobupivacaine and ropivacaine are noted for their more reliable and stable pharmacological profiles.

Materials And Methods: Fifty-six patients with the American Society of Anaesthesiologists (ASA) classification 1 and 2 classifications were randomly assigned to one of two study groups.(17 ml of 0.5% levobupivacaine was given epidurally in Group L, while Group R received 17 ml of 0.75% ropivacaine).The prospective randomised double blinded study was carried out at Saveetha Medical College Hospital, S.I.M.A.T.S., from 2022 to 2024.

Results: The duration, onset, and regression of motor block were comparable in both groups. The motor block grade as per MBS in the two groups showed significant differences. (p<0.001) Group R achieved maximum motor blockage in 40.18 minutes, whereas group L achieved it in 17.86 minutes (p=0.043). In group R, the average duration of motor block was 146.25±48.58 minutes, while in group L it was 160.71±46.64 minutes (p>0.05). Heart rate (HR), mean arterial pressure (MAP), and oxygen saturation (SpO2) exhibited no significant differences between the two groups at various time intervals.

Discussion: Both levobupivacaine 0.5% and ropivacaine 0.75% effectively provide epidural anaesthesia for surgeries below the umbilicus. Levobupivacaine achieved maximum motor block more quickly than ropivacaine, but overall motor block duration was similar. Haemodynamic parameters were stable with no significant differences between the two groups.

KEYWORDS:
Epidural Anaesthesia, Levobupivacaine, Ropivacaine, Motor Profile, and Hemodynamic Profile. Isomers in Local anaesthesia drugs, Cardiotoxicity and Neurotoxicity in Local anaesthesia use

INTRODUCTION

Local anaesthetics work by blocking sodium channels on neural membranes, causing the interruption of neural conduction. The continuous pursuit of more advanced and secure anaesthetic drugs is vital to anaesthetics.[1] Isomerism is a crucial topic in this study since it refers to the phenomenon where compounds with the same chemical compositions exhibit distinct structures, leading to diverse behaviours. The local anaesthetic we use is usually a racemic mixture of dextro bupivacaine (D-(+) isomer) and levobupivacaine (L-(-) isomer), which is an equal amount of each thing.[2-4] Accidental intravascular injection has been associated with significant complications in the CVS and the CNS. The reactions are associated with the R-(+)-isomer of bupivacaine. Conversely, the levorotatory isomers demonstrate a pharmacological profile that is more reliable and stable. The equivalent dose of 0.5% levobupivacaine is 0.75% ropivacaine due to the decreased lipophilicity of ropivacaine.[1] The lipid solubility of levobupivacaine is 30, while the lipid solubility of ropivacaine is 2.8. The "up-down sequential allocation" technique was utilised to determine the minimum local anaesthetic concentration (MLAC) for pain management during childbirth. The findings indicate that bupivacaine has approximately 40% more potency compared to ropivacaine.[5,6] Our study looks at the differences and similarities in motor and hemodynamic effects between levobupivacaine 0.5% and 0.75% ropivacaine when given as epidural anaesthesia to people having surgery below the umbilicus.

MATERIALS AND METHODS

Ethical Approval and Consent

After obtaining approval from the Institutional IRB and IEC (clearance number: 009/06/2023/IEC/SMCH) and obtaining written consent from participants, 56 patients, who were scheduled for below-umbilical surgery with epidural anaesthesia, were included in our study. The prospective randomised double blinded study was carried out at Saveetha Medical College Hospital, S.I.M.A.T.S from 2022 to 2024.

Study Population

The study included patients aged between 15 and 65 years who were classified as the American Society of Anaesthesiologists (ASA) classification grades 1 and 2, with no history of allergic responses to amide local anaesthetics and no absolute or relative contraindications to regional

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anaesthesia. Exclusion criteria were patients younger than 15 years or older than 65 years, those with confirmed hypersensitivity reactions to amide local anaesthetics, individuals with a medical history and treatment of psychiatric disorders, patients classified as ASA grades 3, 4, or 5, and those with relative or absolute contraindications for regional anaesthesia.

Randomisation and Blinding
The participants were allocated into R and L groups, by computer-generated random numbers. The trial was done using a double-blind methodology which ensured that both the patients and the anaesthetic providers were unaware of the group assignments. Group R received a 17 ml dose of ropivacaine solution at a concentration of 0.75%, while Group L received a 17 ml dose of levobupivacaine solution at a concentration of 0.5%.

Preoperative Preparation
Prior to the procedure, each patient received a visit, and their consent was gained after being fully informed. The sequential development of events in the theatre was clarified. After confirming adequate fasting, patients were infused IV with 500 ml of Ringer Lactate solution. Upon entering the operating room, the patient's non-invasive blood pressure, their electrocardiogram (ECG), and their oxygen saturation using pulseoximetry were monitored. The aforementioned haemodynamic parameters were documented before the insertion of the epidural, at the commencement of the study, at 5-minute intervals until the 30-minute mark, and subsequently every 30 minutes thereafter. Group R was administered 17 millilitres of ropivacaine solution at a concentration of 0.75%, while Group L was administered 17 millilitres of levobupivacaine solution at a concentration of 0.5%.

Epidural Placement Procedure
The patients were positioned on their left lateral posture, and the L3-L4 interspinous area was located. 3 ml of 2% lignocaine was injected into the skin and subcutaneous tissue. The extradural space was located with an 18G Tuohy needle by employing the technique of loss of resistance to air. After verifying negative aspiration for blood or cerebrospinal fluid (CSF), 3 ml of 2% lidocaine with 1:200,000 adrenaline (test dose) was administered via extradural catheter. After ruling out the possibility of subarachnoid or intravascular injection, the double-blinded study drug was administered two minutes after the test dose.

In Group R, a total of 17 ml of 0.75% ropivacaine was given over a period of 5 minutes. After each dose of 6 ml, there was a 1-minute break, and after the second dose, there was another 1-minute break before providing the last dose of 5 ml and Group L was administered a total of 17 ml of 0.5% levobupivacaine over a period of 5 minutes, consistent with the prior statement.

Assessment of Motor and Sensory Blocks
The starting point for subsequent evaluations was the time of completion of the administration of the research drug. A 20-gauge catheter was placed 5 centimetres into the epidural space, and then the needle was removed. The patient was thereafter placed in a supine posture, lying on their back. Continuous monitoring was conducted on the patients' pulse rate (PR), blood pressure (BP), and oxygen saturation (SpO2). The administration of oxygen to all patients was done using a Hudson face mask at a flow rate of 4 L/min. The surgical operation commenced 30 minutes following the injection of the epidural drug. If the mean arterial pressure (MAP) decreased by more than 20%, it was addressed by administering a 6 mg dose of Ephedrine. If the heart rate (HR) fell below 50 beats per minute, it was administered a dosage of 0.6 mg of Atropine.

The sensory analgesia level was evaluated by doing a pin prick with the blunt end of a 25G needle. The commencement of surgical block was the block needed to attain the T10 dermatome level sensory block. If patients had inadequate sensory block after 30 minutes, an extra 7 ml of the experimental medication was administered. Following surgery, patients who desired pain medication were given an epidural administration of 100 mg of Tramadol mixed with 10 ml of distilled water, and the time of administration was documented.

The motor block onset was defined as the time taken to attain a Modified Bromage Score of 2, while the duration of the motor block refers to the time interval during which the score remained ≥2. The Modified Bromage Scale is as follows: Zero indicates a lack of paralysis with full flexion of hips, knees, and ankles; One indicates the ability to flex at the knee but an inability to raise the extended leg; Two indicates the ability to flex the ankle but an inability to flex the knee; and Three indicates total immobilisation of the lower extremity.
All patients received a sedative dose of 0.05 mg/kg of Midazolam throughout the surgery, and they were allowed to breathe spontaneously during the procedure. Patients who encountered dural puncture were supplemented with general anaesthesia and excluded from the study.

Statistical analysis
The most recent version of SPSS was used. The descriptive statistics were computed by the mean, standard deviation, range, and proportion. The inferential statistics used were the unpaired t-tests, and chi-square tests to determine significance. The p-value represents the probability, at a significance level of 0.05, for the given degree of freedom. ($p<0.05$ is considered statistically significant whereas $p<0.01$ are deemed highly significant).

RESULTS

The study compared the motor and hemodynamic effects of levobupivacaine 0.5% and ropivacaine 0.75% administered as epidural anaesthesia for surgeries below the umbilicus. The findings revealed that the duration, onset, and regression of motor block were comparable between the two groups. However, significant differences were observed in the motor block grade as per the Modified Bromage Scale (MBS) ($p<0.01$). Group R (ropivacaine) achieved maximum motor blockage in 40.18 minutes, whereas Group L (levobupivacaine) reached it in 17.86 minutes ($p=0.043$) (Tables I and II). The average duration of motor block was 146.25±48.58 minutes for Group R and 160.71±46.64

MOTOR PROFILE:

Table I: Motor block from 0 to 180 minutes

Time	R	L	p value
5	0.68±0.94	0.89±0.49	0
10	1.18±1.02	1.32±0.54	0.01
15	1.57±0.92	1.71±0.89	1
20	2.00±0.66	2.00±0.90	0.06
25	2.25±0.70	2.11±0.87	0.08
30	2.36±0.73	2.18±0.86	0.27
60	2.50±0.79	2.25±0.84	0.47
90	2.46±0.69	2.14±0.89	0.04
120	2.36±0.67	1.82±0.72	0.91
150	1.82±1.09	1.50±0.63	0.02
180	1.29±1.3	1.18±0.67	0

The Table I shows the motor block as per MBS from 0 to 180 minutes between Group R and L.

Table II: Motor Block Variables

Motor Block Variables	R	L	p value
MO	24.64	16.43	0.5
MR	170.54	177.14	0.84
TTMBS≥2	146.25	160.71	0.53
Maximum MBS	2.86	2.21	0
Time taken for maximum MBS	40.18	17.86	0.004

Table II shows the time for motor onset (as defined by Modified Bromage Scale ≥2 (MO), time for motor reversal <2 (MR), time to reach MBS ≥2 (TTMBS2), maximum MBS reached, and time taken to reach maximum MBS between Group R and L.

HAEMODYNAMIC PROFILE:

Table III: Heart rate from 0 to 180 minutes

Time	R	L	p value
Pre procedure	86.68±19.22	83.54±17.31	0.39
0	88.54±19.11	84.61±17.05	0.33
5	88.64±24.43	83.93±17.68	0.19
10	85.54±16.69	81.18±19.39	0.26
15	79.25±16.73	79.43±18.77	0.45
20	77.79±14.04	106.21±154.71	0.93
25	78.75±15.63	78.21±16.66	0.84
30	77.04±14.77	79.46±16.34	0.59
60	74.11±14.05	79.11±15.28	0.62
90	70.29±13.47	77.43±15.43	0.27
120	72.75±14.06	78.11±16.25	0.31
150	74.36±14.02	78.50±14.18	0.85
180	76.64±15.37	78.32±13.19	0.6

Table: III display heart rate between 0 to 180 minutes between Group R and L.

Table IV: Mean Arterial Pressure (MAP) from 0 TO 180 minutes

Time	R	L	p value
Pre procedure	98.40±15.71	93.97±10.62	0.05
0	98.80±15.65	89.16±10.28	0.01
5	87.090±14.70	86.68±10.62	0.05
10	83.68±15.68	83.64±10.83	0.08
15	81.47±17.18	82.52±12.56	0.24
20	79.40±10.71	81.81±12.76	0.53
25	81.27±15.46	82.48±12.82	0.9
30	83.00±17.75	83.37±12.51	0.42
60	81.29±20.84	82.98±9.51	0.06
90	79.66±15.74	84.05±8.97	0.02
120	85.34±20.80	84.85±10.98	0.01
150	85.00±14.71	84.65±11.42	0.23
180	84.71±13.29	85.79±11.74	0.93

Table IV display MAP between 0 and180 minutes for Group R and L.

Table V: Arterial oxygen saturation from 0 to 180 minutes

Time	R	L	p value
Pre procedure	99.14±2.52	98.86±2.17	0.91
5	98.93±1.08	99±2.43	0.1
10	98.93±1.18	99.07±1.94	0.17
15	99.07±1.05	98.93±2.38	0.03
20	98.82±1.61	99.39±1.54	0.26
25	99±1.36	99.36±1.22	0.25
30	99.14±1.22	99.61±1.13	0.1
60	99.18±1.56	99.46±1.20	0.29
90	99.75±0.79	99.64±1.54	0.42
120	99.86±0.44	99.75±1.32	0.35
150	99.71±0.85	99.68±1.36	0.68
180	99.79±0.56	99.64±1.89	0.35

Table V show oxygen saturation between 0 and 180 minutes forGroup R and L.

minutes for Group L, with no significant difference (p>0.05) (Table II). Haemodynamic parameters such as heart rate (HR), mean arterial pressure (MAP), and oxygen saturation (SpO2) showed no significant differences between the two groups at various time intervals (Tables III, IV and V). These results suggest that while the onset of motor block was faster with levobupivacaine, the overall duration of motor block was similar for both anaesthetics. Additionally, both maintained stable hemodynamic profiles throughout the observation period.

DISCUSSION

The demographic profile and type of surgeries between the two groups were similar. In our study, the motor onset (MO) was 24.64 min in group R and 16.43 min in group L, (p=0.502), findings consistent with other studies.[4,7,8] Saha et al. found that the mean onset of motor block in group I (L) was 28.07±4.01 min and that of group II (R) was 23.07±2.77. (p<0.001)9Maheshwari et al. observed that the mean time for MO was significantly shorter in group II (R) (23.14±2.73 min) compared to group I (L) (31.43±2.59min) (p<0.05).[10] A study by Gandhi et al., compared the effects of epidural levobupivacaine 0.5% (group A) and ropivacaine 0.75% with fentanyl 100 mcg (group B) in patients undergoing orthopaedic surgeries and found that the MO and motor duration were comparable in both groups.[11]

Motor regression (MR) in our study was 170.54 min in group R and 177.14 min in group L, (p-value of 0.84). Our study suggests that the motor regression was faster in the R group, implying that this drug may be suitable for surgeries requiring early ambulation, postoperative analgesia, and obstetric analgesia. Olofsen Erik et al., recorded in their study that ropivacaine had a slower onset and offset than levobupivacaine.[12]

In the present study, the duration of motor block in group R was 146.25±48.58 min, while in group L it was 160.71±46.64 min. Brockway et al. demonstrated that the MO in ropivacaine group was slower and its duration of motor blockade was shorter than that of levobupivacaine.[13] Casati et al., compared epidural 0.5% of levobupivacaine and ropivacaine and found both groups had similar motor profiles.[8] Saha et al., found that the mean duration of Motor Block in group I (L) was 143.51±5.69 min and that of group II (R) patients was 141.78±3.35 min. (p=0.082).[9]

The mean motor block grade between the two groups (mean 2.86±0.35 in group R vs. 2.21±0.87 in group L) significantly differed, with a p<0.001. The time taken to reach maximum motor blockade was 40.18 minutes in group R and 17.86 minutes in group L (p=0.004). Additionally, 71.4% of patients achieved MBS 3 in motor block in group R, compared to 50% in group L, indicating a lower grade motor block in group L. Peduto et al. compared the effects of epidural administration of levobupivacaine 0.5% and ropivacaine 0.75% for lower limb procedures and observed that both drugs have similar clinical profiles.[2] This observation was also supported by Katz J A et al.[14] and Casati et al.[8] In our study the MO was shorter and duration of motor block lasted longer in group L compared to R. The time taken to obtain maximum motor grade was longer but denser in R group.

The intraoperative haemodynamic profiles of both groups were similar showing no significant statistical significance. Senard et al., observed similar efficacy with use of equal doses of levobupivacaine and ropivacaine postoperatively via PCEA, with the only difference being that patients receiving ropivacaine were able to ambulate earlier.[15] There were no significant differences in the total amount of intravenous fluids infused and ephedrine usage (4 instances in each group).

CONCLUSION

Our study demonstrates that both levobupivacaine 0.5% and ropivacaine 0.75% are effective and well-tolerated for providing epidural anaesthesia in patients undergoing surgeries below the umbilicus. The motor block characteristics, including the duration, onset, and regression, were comparable between the two groups. However, significant differences were noted in the motor block grade and the time to achieve maximum motor blockage, with ropivacaine taking longer (40.18 minutes) compared to levobupivacaine (17.86 minutes). Despite these differences, the overall duration of the motor block was similar between the two groups. Haemodynamic parameters such as heart rate, mean arterial pressure, and oxygen saturation remained stable and showed no significant differences

throughout the study. Therefore, both levobupivacaine and ropivacaine can be considered reliable options for epidural anaesthesia in lower abdominal surgeries.

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ETHICAL STATEMENTS
The study was approved by the ethical committee of Saveetha institute of medical and technological science (S.I.M.A.T.S) with number: 009/06/2023/IEC/SMCH.

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CONFLICT OF INTEREST
None

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