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Research Article

A COMPARATIVE STUDY BETWEEN 0.5% LEVOBUPIVACAINE AND 0.75% ROPIVACAINE IN PATIENTS UNDERGOING ELECTIVE LOWER LIMB SURGERIES UNDER SUBARACHNOID BLOCK

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ABSTRACT

Objective: The aim of the study was to compare the efficacy of 0.5% levobupivacaine and 0.75% ropivacaine after intrathecal administration in elective lower limb surgeries.

Methods: A prospective, randomized, controlled, and double-blind study was conducted on 100 patients undergoing elective lower limb surgeries under subarachnoid block using 0.5% levobupivacaine and 0.75% ropivacaine.

Results: Demographic characteristics of both groups are comparable. It is observed the onset of sensory blockade is earlier in ropivacaine group, Grade 4 bromage scale motor blockade onset is shorter in levobupivacaine and most of the parameters are comparable between two groups. Duration of sensory blockade is more in ropivacaine when compared to levobupivacaine. Levobupivacaine is more cardiostable with stable hemodynamic profile compared to ropivacaine.

Conclusion: Levobupivacaine is more cardiostable with stable hemodynamic profile compared to ropivacaine.

Keywords: Levobupivacaine, Ropivacaine, Subarchnoid block, Surgery.

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INTRODUCTION

James Corning was the first to attempt neuraxial blockade in humans. Later, August Bier performed first spinal anesthesia and it changed the perspective of anesthesia and its future.

Subarachnoid block is the anesthetic technique of choice for lower limb surgeries compared to general anesthesia, which has got more complications and prolonged recovery time.

Ropivacaine is synthesized by Ekenstam almost 50 years ago, and it was first launched in 1996, being the first pure enantiomer local anesthetic to be clinically introduced. Several experiments and clinical studies confirm ropivacaine has a lower toxic profile compared to bupivacaine.

Ropivacaine [1] is a new long-acting pure S enantiomer, amide local anesthetic with high pKa and low lipid solubility. It is considered to block sensory nerves to a greater degree compared to bupivacaine.

Levobupivacaine [2] is a chiral molecule with pure levo enantiomer of bupivacaine with similar properties and less cardiotoxic compared to bupivacaine.

This prospective, randomized, and control study was conducted to compare the efficacy of ropivacaine and levobupivacaine in patients undergoing elective lower limb surgeries under subarchnoid block.

Aim of the study

The aim of the study was to compare the efficacy of 0.5% Levobupivacaine and 0.75% ropivacaine in patients undergoing elective lower limb surgeries under subarchnoid block in terms of onset of sensory blockade and level of sensory blockade. Time for Grade 4 motor blockade, time for 2-segment regression, time for rescue analgesia, and hemodynamic stability.

METHODS

A prospective, randomized, controlled, and double-blindstudy was conducted on 100 patients undergoing elective lower limb surgeries under subarachnoid block a GITAM Institute of Medical Sciences and Research Hospital, Visakhapatnam, between August 2021 and September 2022, after the approval from the Institutional Ethics Committee.

Inclusion criteria

The following criteria were included in the study:

1. Patients under ASA Grade I and II
2. Patients undergoing elective surgeries
3. Patients undergoing lower limb surgeries
4. Patients giving valid informed consent
5. Patients with height ≥140 cm.

Exclusion criteria

The following criteria were excluded from the study:

1. Patient refusal
2. Patients of ASA Grade III and >Grade III
3. Patients having deformities of spine
4. Patients having infection at the site of insertion of spinal needle
5. Patients having bleeding disorders
6. Patients having coagulation abnormalities
7. Patients having raised ICP
8. Patients with height <140 cm
9. Patients posted for emergency surgeries
10. Patients having neurological deficits.

A total of 100 patients were randomly divided into two groups of 50 each.

Group R

Fifty patients received 3 mL of Inj. 0.75% Ropivacaine (without dextrose) intrathecally.

Group L
Fifty patients received 3 mL of Inj. 0.5% Levobupivacaine (without dextrose) intrathecally.

METHODS

Pre-anesthetic checkup was done 1 day before the surgery. Patients were evaluated with history, general physical examination, systemic examination of cardiovascular, respiratory, and central nervous system, and spine examination for deformity was also performed. Investigations such as hemogram, bleeding time, clotting time, blood glucose, blood urea, and serum creatinine were done. Electrocardiogram and chest X-ray were done wherever necessary. Patient's weight and height were also recorded before surgery. All patients were kept nil orally for 6–8 h. The procedure of spinal anesthesia was explained to the patients and written informed consent was obtained.

After shifting the patient to operating room, patients were monitored for heart rate (HR), non-invasive blood pressure, and percentage of oxygen saturation (SPO_2). Under all aseptic precautions, subarachnoid block was performed with the patient in the lateral or sitting position depending on the patient's comfort, using a 26G Quincke needle at the L3-L4 interspace. The study solution (3 mL) was administered over 10 s. Patient was repositioned gently to supine position without elevation of extremities and tested every 5 min until maximal spread of sensory blockade, and then every 15 min during the surgery.

Sensory blockade was assessed by loss of sensation to alcohol cotton swab on each side and patient was asked about the sensation. Pain was evaluated with visual analog scale (VAS) to assess the severity of the pain. Rescue analgesia was given if VAS is >5. The degree of motor block was assessed using "bromage scale." Motor blockade is assessed at 5 min and then for every 30 still Grade IV block is achieved. And then every 15 min until return of normal motor function. Mean arterial pressure (MAP), HR, SPO_2, and respiratory rate (RR) was recorded every 5 min for the first 30 min and then every 15 min for 1 h, later every 30 min throughout the surgery.

All the patients were kept under observation in the post-operative period for 24 h. HR, MAP, SPO_2, and RR were recorded at 15 min interval for the first 60 min, then every hourly for the first 8 h, then at 12 h and 24 h. All the patients are assessed for pain at regular intervals and rescue analgesia was given accordingly. Patients were also observed for the development of post dural puncture headache (PDPH) and were followed up for 3–4 days.

Statistical methods

This is a prospective, randomized, controlled, and double-blind study, where the patients were selected randomly. The demographic data were analyzed using either Student's t-test or Chi-square test. Quantitative data were analyzed by Student's t-test and qualitative data were analyzed by Chi-square test. All values were expressed as mean±standard deviation. $p<0.05$ was considered statistically significant.

RESULTS

Comparison of sensory blockade

The mean onset time for the sensory blockade, that is, the time to attain loss of sensation to alcohol cotton swab at L2 dermatomal level has shown a lot of variation between the groups (Table 1).

Level of sensory blockade at different time intervals (Tables 2-5).

Comparing the level of sensory block at different intervals, the attainment of the highest dermatomal level of sensory blockade is earlier in ropivacaine group when compared to levobupivacaine group (Table 2-5).

Bromage score

At 5, 15, and 20 min, the bromage scale is almost equal in both groups (Graph 1) but at 10 min, the mean score is more in L group compared to R group as depicted in the graph below.

Table 1: Comparison of time of onset of sensory blockade (in seconds)

Study group	Mean	SD
R	163.64	16.13
L	188.28	12.46

SD: Standard deviation

Table 2: Comparison of time of onset of sensory blockade

At 5 min		
Dermatome level	**R**	**L**
T8	1	0
T10	24	5
T12	25	39
L1	0	2
L2	0	4

Table 3: Comparison of time of onset of sensory blockade

At 20 min		
Dermatome level	**R**	**L**
T4	0	4
T6	29	30
T8	19	16
T10	2	0

Table 4: Comparison of time of onset of sensory blockade

At 15 min		
Dermatome level	**R**	**L**
T6	29	7
T8	16	37
T10	5	6

Table 5: Comparison of time of onset of sensory blockade

At 20 min		
Dermatome level	**R**	**L**
T4	0	4
T6	29	30
T8	19	16
T10	2	0

Table 6: Time for rescue analgesia

Study group	Mean	SD
R	192.6	16.81
L	174.16	12.29

SD: Standard deviation

Comparison for two segment regression

The time for two-segment regression is more or less similar in both groups. The above graph depicts it (Graph 2).

Comparison of time for rescue analgesia

This study observes that there is a significant difference that is mean time for rescue analgesia. The time for rescue analgesia is prolonged in Group R, compared to Group L.

The mean times for the rescue analgesia are 192.6 min with standard deviation (SD)±16.81 and 174.16 min with SD±12.29 for Group R and Group L, respectively Table 6.

Comparison of intraoperative mean arterial pressure

There is a significant difference in the mean pre-operative MAP between the two groups which reflected in the first 15 min with $p<0.05$ but later there is no significant difference was observed, with $p>0.05$.

It is observed that there is a significant fall in MAP in R group compared to L group in the first 15 min after subarachnoid block (Table 7).

Comparison of intraoperative HR

This study concludes that there is no significant difference that is observed in mean HRs in individual groups. Most of the time was the $p>0.05$ (Table 8).

Post-operative mean arterial pressure

There is no significant difference is seen in Mean arterial pressure between both groups in the post operative period for 24 hours.

Post-operative HR

As shown in the above graphs, there is not any significant effect of the drugs in the maintenance of the hemodynamics and other parameters postoperatively (Graphs 3 and 4).

DISCUSSION

Spinal anesthesia is one of the popular modality of the surgeries involving the lower limbs. Bupivacaine and Lignocaine are the drugs that are frequently used earlier for the attainment of subarachnoid block for lower limb surgeries. As Lignocaine and Bupivacaine are associated with increased risk of neurological and cardiovascular toxicity, respectively, there is a need for the new drugs for attaining subarachnoid block. Levobupivacaine and Ropivacaine are the newer drugs that are used instead of the earlier-mentioned drugs that can be used for spinal anesthesia.

The mean onset time for the sensory blockade, that is, the time to attain loss of sensation to alcohol cotton swab at L2 dermatomal level has shown a lot of variation between the groups.

Table 7: Intraoperative mean arterial pressure

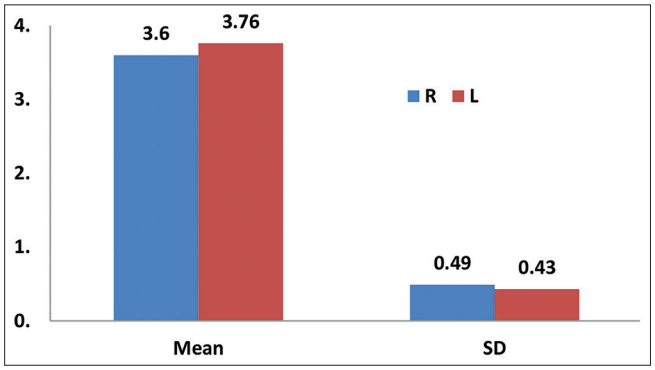
Time interval	Ropivacaine	Levobupivacaine	
	Mean±SD	Mean±SD	p-value
Pre-operative	106.24±9.86	96.36±13.66	<0.001
5 min	100.04±8.87	92.32±13.10	0.002
10 min	94.04±7.72	89.72±13.68	0.001
15 min	91.68±8.44	89.44±13.73	0.055
20 min	90.72±7.87	89.24±13.76	0.329
25 min	90.40±7.73	89.68±13.32	0.511
30 min	90.64±8.23	89.56±13.47	0.742
45 min	91.32±7.58	90.12±13.06	0.630
1 h	92.34±8.21	90.42±13.68	0.576
1 h 30 min	93.89±8.70	91.94±12.88	0.407
2 h	93.75±9.06	95.67±14.47	0.447
2 h 30 min	95.87±11.04	108.00±0	0.692
3 h	---	114.00±0	---

SD: Standard deviation

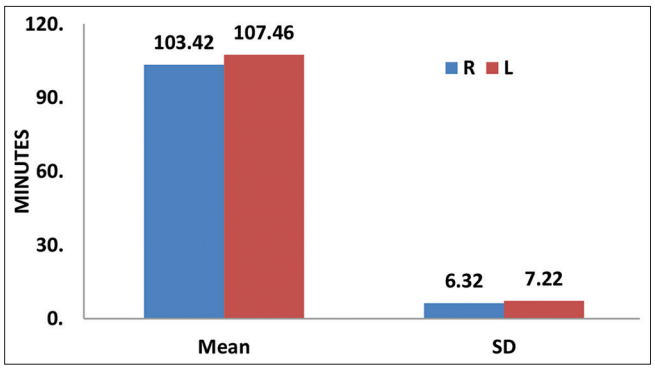
Table 8: Intraoperative heart rate

Time interval	Ropivacaine	Levobupivacaine	
	Mean±SD	Mean±SD	p-value
Preop	86.08±9.20	88.92±12.36	0.196
5 min	81.08±8.84	78.84±10.13	0.241
10 min	77.64±9.13	76.24±8.92	0.440
15 min	72.48±8.90	73.92±8.22	0.403
20 min	73.60±8.88	72.08±7.63	0.361
25 min	74.84±9.27	70.48±7.04	0.009
30 min	75.20±8.62	69.00±5.98	<0.001
45 min	76.16±8.84	69.48±5.11	<0.001
1 h	78.63±8.36	72.46±5.21	<0.001
1 h 30 min	79.54±8.13	74.87±6.37	0.008
2 h	79.38±9.95	76.00±6.66	0.293
2 h 30 min	81.20±8.65	80.00±0	--
3 h	--	82.00±0	--

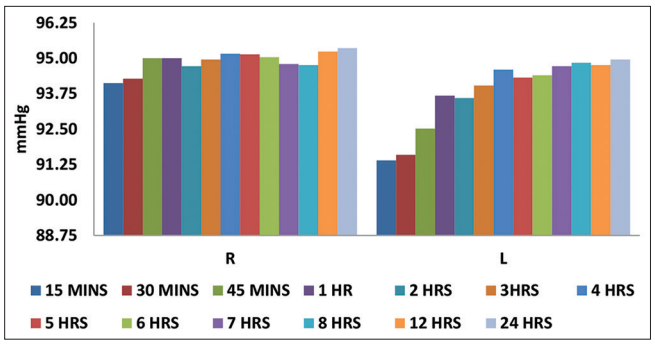
SD: Standard deviation



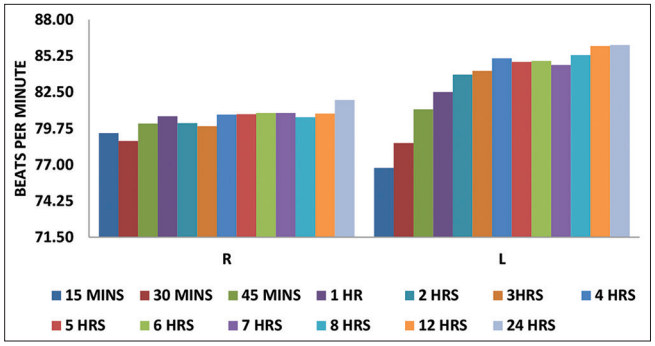
Graph 1: Bromage scale at 10 min



Graph 2: Time for 2-segment regression



Graph 3: Mean arterial pressure



Graph 4: Heart rate

This study is comparable to the study of Luck *et al*. [3] which compared Bupivacaine, Levobupivacaine, and Ropivacaine showed the mean onset time for sensory blockade at T10 dermatomal is about 5 min for both Levobupivacaine and Ropivacaine with p=0.99 which was statistically not significant. This study showed a p<0.001 which is highly significant. That study used hyperbaric solutions of the drugs with glucose compared to this study.

Bhat *et al*. [4] compared the efficacy of 0.75% isobaric ropivacaine and 0.5% isobaric bupivacaine for lower abdominal and lower limb surgeries, which showed the mean duration for the onset of sensory blockade for ropivacaine is 180±9.62 s, which is similar to that of this study. The sample size is 35 patients for that study compared to 50 of this study.

Comparing the level of sensory block at different intervals, the attainment of the highest dermatomal level of sensory blockade is earlier in ropivacaine group when compared to levobupivacaine group.

In this aspect, this study is comparable to Gautier *et al*. [5] in which it shows the mean time for attainment of the highest sensory level is short when compared to levobupivacaine. In that study, both the drugs used are hyperbaric and combined with sufentanil at equal dose.

Luck *et al*. [3] studied levobupivacaine, ropivacaine, and bupivacaine in elective surgeries which showed the time for attainment of the highest sensory blockade is earlier with ropivacaine when compared to bupivacaine and levobupivacaine.

This study observed a significant difference in the time for the attainment of the highest sensory blockade between the two groups. It observes that the attainment of the highest dermatomal level of sensory blockade is shorter with ropivacaine with a mean of 10.22 min and SD±3.47 when compared to levobupivacaine which showed a mean time of 17.49 min with SD±2.19 with p<0.001. This study also observes that there is no significant difference between the two groups as far as overall attainment of the highest dermatomal level of sensory blockade.

This study is in comparison with the study conducted by Gozaydin *et al*. [6] which showed the mean time to achieve maximum level of sensory blockade with hyperbaric levobupivacaine is 11 min.

Fettes *et al*., [7] studied plain and hyperbaric solutions of ropivacaine in spinal anesthesia which showed mean time for the highest level of sensory blockade with plain ropivacaine is 10 min which is comparable to this study.

This study shows that the mean time for the attainment of complete motor blockade is shorter with levobupivacaine, compared to ropivacaine. The mean time to achieve Grade 4 motor blockade with levobupivacaine and ropivacaine are 9.89 min±7.22 and 11.15 min±6.32, respectively, with p=0.01 which is statistically significant.

Gozaydin *et al*. [6] concluded that the mean time for Grade 4 bromage scale for levobupivacaine is 11 min which is comparable to this study, in spite of usage of hyperbaric levobupivacaine in that study.

Dizman *et al*. [8] compared two different doses of levobupivacaine in spinal anesthesia and concluded that the mean time for attainment of Grade 4 motor blockade is 8.1 min with SD ±6.5.

Gautier *et al*. [5] concluded that mean time for complete motor blockade is 13 min with levobupivacaine.

This study compared the mean time for two-segment regression in both groups and concluded that levobupivacaine is got a slight prolonged time compared to ropivacaine for two-segment regression.

The mean time for two-segment regression for ropivacaine is 103.42 min with SD ±6.32 and for levobupivacaine is 107.42 min with SD ±7.22.

Gozaydin *et al*. [6] concluded that the mean time for regression of motor block is 92.5 min for levobupivacaine.

Chari *et al*. [9] concluded that the duration for two-segment regression with ropivacaine is 108.5 min with SD ±10.61.

Baydilek *et al*. [10] compared single-dose levobupivacaine for spinal anesthesia with continuous spinal anesthesia with levobupivacaine for transurethral resection of prostate which concluded the mean time for two-segment regression with single-dose levobupivacaine is 90.08 min with SD ±14.66.

There is a significant difference in the mean pre-operative MAP between the two groups which reflected in the first 15 min with p<0.05 but later there is no significant difference was observed, with p>0.05.

It is observed that there is a significant fall in MAP in R group compared to L group in the first 15 min after subarachnoid block.

Gozaydin *et al*. [6] study shows that that there is no significant change in the MAP is observed in the intraoperative period with levobupivacaine.

Dizman *et al*. [8] study also concludes that there is no significant change in MAP is present during intraoperative period with levobupivacaine with p>0.05.

This study concludes that there is no significant difference is observed in mean HRs in individual groups. Most of the time was the p>0.05.

Gozaydin *et al*. [6] study shows that that there is no significant change in the HR that is observed in the intraoperative period with levobupivacaine.

Dizman *et al*. [8] study also concludes that there is no significant change in HR that is present during intraoperative period with levobupivacaine with p>0.05.

Luck *et al*. [3] observed that there is no significant difference in HR with ropivacaine and levobupivacaine.

Vanna *et al*. [11] study shows that there is no significant difference in HR in the intraoperative period with levobupivacaine.

Fattorini *et al*. [12] compared bupivacaine with levobupivacaine and concluded that there is no significant difference that is observed in the intraoperative HR.

CONCLUSION

Ropivacaine and levobupivacaine are the newest drugs that are used for neuraxial blockade. They got a better pharmacological safety profile when compared to racemic bupivacaine. It can be concluded from this study that levobupivacaine is more cardiostable with stable hemodynamic profile compared to ropivacaine.

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AUTHOR'S CONTRIBUTION

Conceptualization and Data collection.

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