



## A COMPARISON OF UNILATERAL INTRATHECAL 0.75% ROPIVACAINE HEAVY WITH 0.5% LEVOBUPIVACAINE HEAVY FOR DIABETIC FOOT SURGERY : A CLINICAL STUDY

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### ABSTRACT

**Introduction:** The low cardiovascular and neurological toxicity of levobupivacaine has made it suitable for use as a local anaesthetic in numerous specialized procedures. This study aimed to assess the effectiveness of levobupivacaine 0.5% and compare the quality of the block with that of ropivacaine 0.75%. **Aims And Objectives:** To study the onset and duration of sensory and motor block and to compare intraoperative quality of anaesthesia. **Material And Method:** The study was conducted in 70 female patients of age between 30-60 years of ASA grade I and II undergoing elective modified radical mastectomy surgeries. Patients were randomly divided into two groups. Group R - patients received 1ml intrathecal 0.75% Ropivacaine Heavy and group L - patients received 1ml intrathecal 0.5% Levobupivacaine Heavy. **Result:** The mean Onset of Sensory and motor Block (in min) was significantly higher in group R as compared with Group L. The above association found to be significant among both study groups ( $p < 0.05$ ). **Conclusion:** Based on the present study we have concluded that Levobupivacaine (0.5%) has better anaesthetic properties with respect to 0.75% ropivacaine

**KEYWORDS :** Levobupivacaine, Ropivacaine, intrathecal, diabetic foot surgery

### INTRODUCTION

Diabetic foot ulcers, a major complication of diabetes mellitus, are a leading cause of non-traumatic amputations worldwide, due to the development of diabetic neuropathy, a common condition among people with diabetes. It is estimated that around 40% of older adults with type 2 diabetes have risk factors that heighten their chances of developing foot ulcers.<sup>(1)(2)</sup>

Spinal anaesthesia is a widely used regional anaesthesia technique, offering benefits such as lower anaesthetic doses, ease of administration, quick onset, muscle relaxation, effective postoperative pain relief, and cost-efficiency. It might lead to certain complications, including post-dural puncture headache, nausea, vomiting, low blood pressure, back pain, complete spinal anaesthesia, neurological damage, spinal hematoma, and temporary neurological issues.<sup>(3)(4)(5)</sup>

Ropivacaine and levobupivacaine are local anaesthetics with better safety profiles than bupivacaine, regardless of the method of administration. These drugs were developed in response to the severe toxicity linked to bupivacaine. We are using these medications in our research due to their reduced cardiotoxicity. Their duration of action (1-4 hours) is ideal for diabetic foot surgery.<sup>(6)(7)(8)</sup>

Unilateral spinal anaesthesia is a cost-effective anaesthetic technique that targets the sensory, motor, and sympathetic functions on one side of the body. It provides the advantages of a spinal block while avoiding the common side effects linked to a bilateral block. This method is particularly suitable for patients with cardiovascular risk factors, such as aortic valve stenosis or coronary artery disease, as it does not lead to hypotension.<sup>(9)(11)(12)</sup>

Ropivacaine is used therapeutically due to its lower cardiotoxic and neurotoxic effects. It is similar to bupivacaine in terms of onset, effectiveness, and pain relief duration but causes shorter muscle paralysis. Ropivacaine heavy is considered safe for spinal anaesthesia.<sup>(10)</sup>

Levobupivacaine is a long-acting amide local anaesthetic

that blocks motor and sensory nerve function by inhibiting voltage-gated sodium channels. It is the left-handed enantiomer of dextropropivacaine and is considered a safe option for local anaesthesia. Although generally well-tolerated, dosage adjustments may be needed for children and the elderly. Hyperbaric levobupivacaine leads to a faster onset of sensory and motor block compared to isobaric levobupivacaine.<sup>(2)(11)</sup>

### AIMS AND OBJECTIVES

1. To study the onset and duration of sensory and motor block and to Compare intraoperative quality of anaesthesia.
2. To study and compare perioperative hemodynamic effects by intrathecal Anaesthesia.
3. To study the post operative analgesia

### MATERIAL AND METHODS

The present study was carried out in Department of Anaesthesiology, J.A. Group of hospitals G.R. Medical College, Gwalior (M.P). 70 patients with ASA grade I and II, who fulfilled the eligibility criteria were studied with informed and written consent, subsequently patients were randomized into two groups of each have 35 patients.

Group R = patients received 1ml intrathecal 0.75% Ropivacaine Heavy

Group L = patients received 1ml intrathecal 0.5% Levobupivacaine

Heavy

Patients were in lateral decubitus position for 10 minutes then made supine. Level checked.

### Inclusion Criteria:

- Patients of ASA I and ASA II.
- Age group 18-70 years of both sexes.
- All patients posted for diabetic foot surgeries

### Exclusion Criteria:

- Patients of ASA III AND ASA IV
- Parents/guardian refusal or not giving consent.
- Patients with neurological disease
- Local skin infections or disease at site of SAB.
- Patients with bleeding diathesis.
- History of drug allergies to Levobupivacaine and Ropivacaine.
- Coagulopathy.
- Severe liver or kidney diseases.

After thorough routine preanesthetic assessment, patient were taken in Operation theatre. DragerScio Four Plus Monitor was attached and baseline parameters recorded (Pulse rate, SBP, DBP, MBP and SPO<sub>2</sub>). Intravenous lines were secured. A total of 70 diabetic foot patients undergoing amputation of diabetic foot surgery were enrolled in this study. Under all aseptic conditions cleaning painting and draping done in lateral decubitus position. Subarachnoid block induced at L3-L4 intervertebral space by 25 gauge Quincke spinal needle. After confirming free flow of CSF injection levobupivacaine heavy or injection Ropivacaine heavy administration done.

#### Parameters Of Study:

- Time for onset of sensory block
- Peak level of sensory block
- Time to reach peak level of sensory block
- Time to achieve maximum motor block
- Time for 2 segment regression
- Time for complete motor regression
- Time for complete sensory regression
- Assessment of hemodynamic parameters (PR, SBP, DBP and MAP) Quality of analgesia
- Observation and recording of side effects and complication of the study drugs and technique.

The statistical analysis of this study was carried out by paired t-test and Pearson chi-square test. P value > 0.05 was statistically insignificant while p value < 0.05 was considered statistically significant and p value < 0.01 was statistically highly significant. The statistical analysis was done using SPSS software

#### OBSERVATIONS AND RESULTS

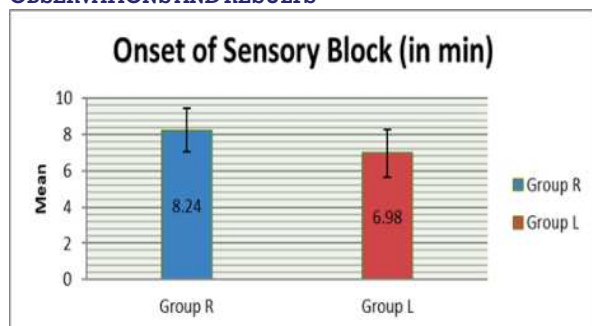


Fig 1: Mean Onset of Sensory Block (in min)

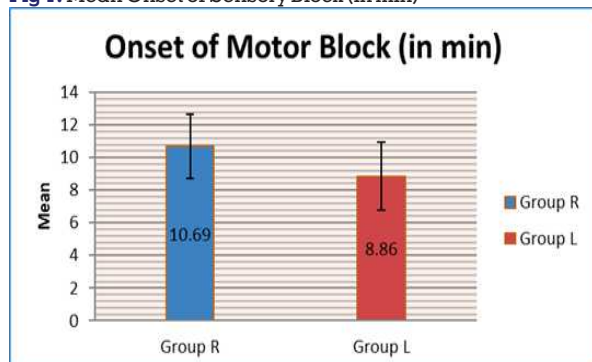


Fig 2: Mean Onset of Motor Block (in min)

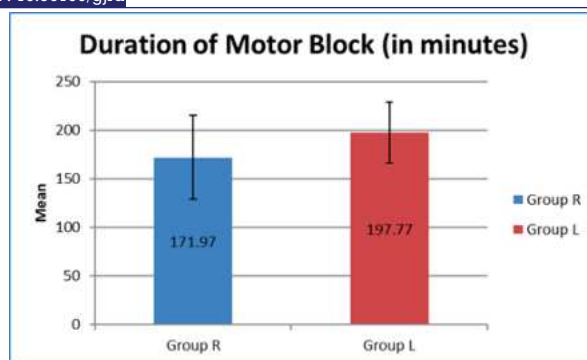


Fig 3: Mean Duration of Motor block (in min)

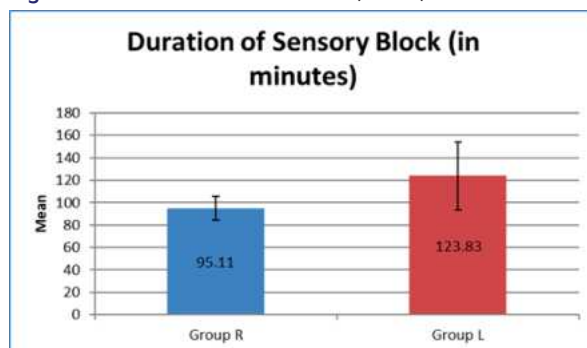


Fig 4: Mean Duration of Sensory block (in min)

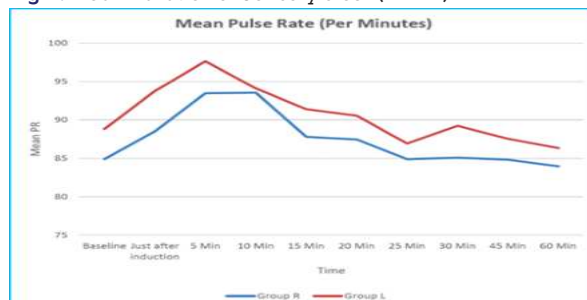


Fig 5: Mean Pulse Rate (Per Minutes) in the two groups

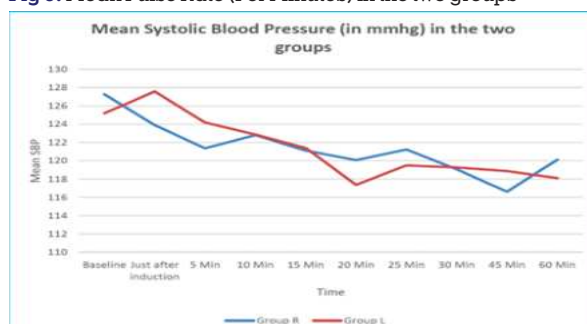


Fig 6: Mean Systolic Blood Pressure (in mmhg) in the two groups

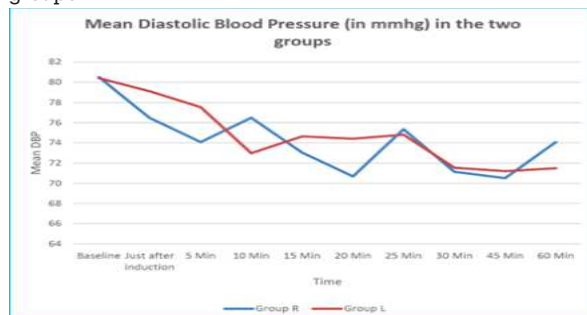


Fig 7: Mean Diastolic Blood Pressure (in mmhg) in the two groups

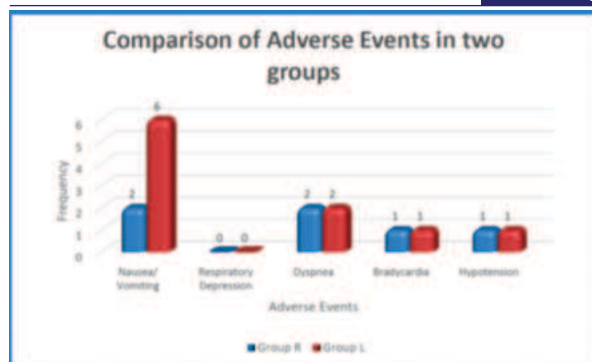


Fig 8: Comparison of Adverse Events in two groups

Table 1: Anthropometric Distribution (Mean  $\pm$ SD) Of The Patients

| Demographic/<br>Anthropometric<br>Data | Group R<br>(Mean $\pm$ SD) | Group L<br>(Mean $\pm$ SD) | t Value | P value | Remark |
|----------------------------------------|----------------------------|----------------------------|---------|---------|--------|
| Age (years)                            | 47.91 $\pm$ 8.06           | 46.54 $\pm$ 6.25           | 0.796   | 0.429   | NS     |
| Height (cm)                            | 163.31 $\pm$ 6.26          | 164.86 $\pm$ 5.92          | -1.320  | 0.191   | NS     |
| Weight (kg)                            | 60.23 $\pm$ 13.18          | 64.49 $\pm$ 13.79          | -1.060  | 0.293   | NS     |

Table 2 : VAS Score At Time For First Rescue Analgesics

|              | Group R<br>(Mean<br>$\pm$ SD) | Group L<br>(Mean $\pm$ SD) | t<br>Value | P<br>value | Remar<br>k |
|--------------|-------------------------------|----------------------------|------------|------------|------------|
| VAS<br>Score | 4.83 $\pm$ 0.38               | 4.06 $\pm$ 0.24            | 10.16      | 0.000      | S          |

## DISCUSSION

Efficient anaesthesia and careful postoperative pain management measures are necessary for successful recovery and comfort in lower limb procedures. Levobupivacaine and ropivacaine are frequently used as local anaesthetics in these procedures due to their strong effectiveness, safe characteristics, and unique pharmacokinetic qualities. A diabetic foot ulcer is a significant consequence of diabetes mellitus and is the primary cause of non-traumatic limb amputations worldwide, due to the development of diabetic neuropathy.<sup>(1)(2)</sup>

A unilaterally exclusive block specifically impacts the sensory, motor, and sympathetic functioning on one side of the body, while avoiding the usual negative side effects associated with a bilateral block.<sup>(11)</sup>

Levobupivacaine and ropivacaine are commonly used in clinical settings for regional anaesthesia procedures, including epidural, spinal, and peripheral nerve blocks, particularly for surgery involving the lower limbs. These procedures not only deliver exceptional surgical anaesthesia, but also reduce the occurrence of systemic adverse effects.

As per table no.1 The patients in both groups had similar characteristics in terms of age, weight, and ASA grade distribution. There was no statistically significant disparity in demographic data, sex, or ASA grade distribution between the groups. The study conducted by Samar P et al.[22] showed similar results, with a  $P > 0.05$ . Studies of casati et al[16], Cappelleri et al[15] and Kazak et al[21] also have similar findings in demographic data distribution.

**Onset Of Sensory Motor Response:** As shown in figure no. 1, the current study found that the beginning of Sensory Block

was substantially longer in group R ( $8.24 \pm 1.20$  min) compared to Group L ( $6.98 \pm 1.32$  min). Additionally, the mean onset of motor block was significantly longer in group R ( $10.69 \pm 1.95$  min) compared to group L ( $8.86 \pm 2.11$  min). Unlike our study, Bhat et al<sup>12</sup> noted a faster onset of sensory blockade in group ropivacaine. Cappelleri et al<sup>13</sup> found that onset on sensory blockade was similar with ropivacaine and levobupivacaine.

**The average duration of the sensory block:** as seen in figure 4, was significantly longer in the L Group ( $123.83 \pm 30.38$  min) compared to the R Group ( $95.11 \pm 10.34$  min). Similarly, the average duration of the motor block was significantly longer in the L Group ( $197.77 \pm 31.23$  min) compared to the R Group ( $171.97 \pm 43.01$  min). Our study was similar to the study done by Bhat et al<sup>12</sup> who observed that the duration of the blockade was much shorter in the ropivacaine group. Thalamati et al<sup>14</sup> found that Levobupivacaine group exhibited a statistically significant increase in the duration of sensory blockage.

**Duration Of Motor Blockage:** as in figure 3, we found that in group R, the average duration of motor blockade was 8.323 hours, whereas in group L it was 9.837 hours. The levobupivacaine group had a significantly longer duration of motor blockade. Our study was in concordance with the study done by Athar et al<sup>15</sup> who found that levobupivacaine produced significantly longer duration of motor block than ropivacaine.

**Post operative Analgesia:** In our study the average duration of postoperative pain relief (in minutes) was substantially longer in group L compared to group R in the current investigation. The p-value is less than 0.05. Our study was similar to the study done by Athar et al<sup>15</sup> who found that the post operative analgesia was longer in levobupivacaine group that ropivacaine group.

**VAS score -** VAS Score was significantly higher in Group R ( $4.83 \pm 0.38$ ) compared to Group L ( $4.06 \pm 0.24$ ), with a t-value of 10.16 and a p-value of 0.000, indicating statistical significance ( $p < 0.01$ ).

## Hemodynamic parameter:

**Heart rate:** as seen in figure 5, there is no statistically significant difference in pulse rate between Group R and Group L at any of the specified time points (Baseline, shortly after induction, 5 Min, 10 Min, 15 Min, 20 Min, 25 Min, 30 Min, 60 Min) with a p-value greater than 0.05. These results are similar to studies done by Athar et al<sup>15</sup> and Hashimoto et al<sup>16</sup>

**Blood pressure:** As seen in figure 6 and 7, there is no statistically significant difference in systolic (SBP), diastolic (DBP) and mean arterial blood pressures (MAP) between Group R and Group L at several time points, including Baseline, shortly after induction, 5 Min, 10 Min, 15 Min, 20 Min, 25 Min, 30 Min, and 60 Min ( $P$  Value  $> 0.05$ ). These findings were similar to those found by Hashimoto et al<sup>16</sup> who found that There were no significant changes in mean arterial pressure and heart rate during the research in either group. In study of Athar et al<sup>15</sup> Baseline haemodynamic parameters were comparable in both the groups.

The mean MAP decreased significantly in both the groups compared to baseline/preoperative values ( $p < 0.05$ ) but overall incidence of hypotension was not significantly different which is similar to our study. There was no significant difference between the groups in terms of any of the adverse events. These findings indicate that both groups had comparable frequencies of negative occurrences during the trial, as illustrated in Figure 13. In their study, Athar et al<sup>15</sup> found that ropivacaine is a viable drug for procedures with a low threshold for hypotension due to its efficacy, minimal toxicity,

and favourable haemodynamic profile.

## CONCLUSION

The study compared Unilateral Intrathecal 0.75% Ropivacaine Heavy and 0.5% Levobupivacaine Heavy anesthesia in diabetic foot surgeries, with 35 patients in each group. We concluded that both anaesthetics were effective, but levobupivacaine demonstrated quicker onset, longer block durations, and extended analgesia, suggesting potential advantages in anesthesia management for diabetic foot surgeries.

**Conflict Of Interest – NIL**

## REFERENCES

1. Yazdanpanah L, Nasiri M, Adarvishi S. Literature review on the management of diabetic foot ulcer. *World J Diabetes*. 2015 Feb 15;6(1):37-53. doi: 10.4239/wjd.v6.i1.37. PMID: 25685277; PMCID: PMC4317316.
2. Ahmed O. Almobarak1, HeithamAwadalla2, MugtabaOsman3, Mohamed H. Ahmed4.
3. Brown DL, Spinal, Epidural and Caudal anesthesia, In: Ronald D Miller[']s Anesthesia, 5th edition Philadelphia, Churchill Livingstone 2000; 1491-1508.
4. Halpern S, Preston R. Postdural puncture headache and spinal needle design. *Metaanalyses. Anesthesiology*. 1994 Dec;81(6):1376-83.
5. Zaric D, Pace NL. Transient neurologic symptoms (TNS) following spinal anaesthesia with lidocaine versus other local anaesthetics. *Cochrane Database Syst Rev*. 2009 Apr 15;(2):CD003006.
6. Sia AT, Tan KH, Sng BL, Lim Y, Chan ES, Siddiqui FJ. Use of hyperbaric versus isobaric bupivacaine for spinal anaesthesia for caesarean section. *Cochrane Database Syst Rev*. 2013 May 31;(5):CD005143. doi: 10.1002/14651858.CD005143.pub2. PMID: 23728652.
7. Colombian Journal of Anesthesiology Volume 44, Issue 2, April-June 2016, Pages 97-104
8. 5. Lee YY, NganKee WD, Fong SY, Liu JT, Gin T. The median effective dose of bupivacaine, levobupivacaine, and ropivacaine after intrathecal injection in lower limb surgery. *Anesth Analg*. 2009 Oct;109(4):1331-4. doi: 10.1213/ane.0b013e3181b1912b. PMID: 19762766.
9. Kalpana R Kulkarni, Sunetra Deshpande, [...], and KonarkKondilya
10. Spinal Ropivacaine for Lower Limb Surgery: A Dose-Response Study Lee, Ying Y. FFARCSI, MScPainM\*†; NganKee, Warwick D. MD\*; Chang, Hang K. MBBSt; So, Chi L. MBBSt; Gin, Tony MD
11. Gupta R, Bogra J, Singh PK, Saxena S, Chandra G, Kushwaha JK. Comparative study of intrathecal hyperbaric versus isobaric ropivacaine: A randomized control trial. *Saudi J Anaesth*. 2013 Jul;7(3):249-53. doi: 10.4103/1658-354X.115326. PMID: 24015125; PMCID: PMC3757795
12. Bhat, Sonal N et al. "Comparison of efficacy and safety of ropivacaine with bupivacaine for intrathecal anesthesia for lower abdominal and lower limb surgeries." *Anesthesia, essays and researches* vol. 7,3 (2013): 381-5. doi:10.4103/0259-1162.123252
13. Cappelleri, G., Aldegheri, G., Danelli, G., Marchetti, C., Nuzzi, M., Iannandrea, G., & Casati, A. (Year). *Spinal Anesthesia with Hyperbaric Levobupivacaine and Ropivacaine for Outpatient Knee Arthroscopy: A Prospective, Randomized, Double-Blind Study*. Department of Anesthesiology, Vita-Salute University of Milan, IRCCS H. San Raffaele, Milan, Italy; Department of Anesthesiology, University of Parma, Azienda Ospedaliere di Parma, Parma, Italy.
14. Thalamati, Dwarakesh et al. "Comparison of Ropivacaine and Levobupivacaine in Supraclavicular Brachial Plexus Blocks-A Double Blinded Randomized Control Study." *Turkish journal of anaesthesiology and reanimation* vol. 49,4 (2021): 278-283. doi:10.5152/TJAR.2021.266
15. Athar, Manazir, et al. "Levobupivacaine or Ropivacaine: A Randomised Double Blind Controlled Trial Using Equipotent Doses in Spinal Anaesthesia". *Colombian Journal of Anesthesiology*, vol. 44, no. 2, Apr. 2016, pp. 97-104.
16. Hashimoto T, Iwasaki T, Takahashi Y, Kimura Y, Nagao M, Yamaguchi S, et al. Comparison of Bupivacaine, Ropivacaine, and Levobupivacaine in an Equal Dose and Concentration for Sympathetic Block in Dogs. *Reg Anesth Pain Med*. 2010 Aug 1;35(5):409-11.