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Comparative Study of Epidural Levobupivacaine 0.5% and Ropivacaine 0.75% on Lower Limb Orthopaedic Surgeries

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Abstract: ***Background and Aims: The aim of the study was to compare the onset time and duration of epidural anaesthesia produced by levobupivacaine and ropivacaine for lower limb orthopaedic surgeries and to determine postoperative analgesia. Methods: 90 patients of ASA grade I and II planned for elective lower limb orthopedic surgeries were divided into two groups randomly. Group I (n=45): received 15ml 0.5% levobupivacaine; Group II (n=45): received 15ml 0.75% epidurally. Onset time and regression of motor and sensory block and postoperative analgesia were evaluated. Results: onset of sensory block with levobupivacaine was 18.51±2.77 minutes and with ropivacaine was 16.04±2.31 minutes (p<0.001). Duration of sensory block with levobupivacaine was 164.09±8.88 minutes and with ropivacaine was 172.26±4.03 minutes (p<0.0001). Onset of motor block with levobupivacaine was 28.07± 4.01 minutes and with ropivacaine was 23.07±2.77 minutes (p < 0.001). Duration of motor block with levobupivacaine was 143.51± 5.69 minutes and with ropivacaine was 141.78±3.35 minutes (p=0.0819). Time for first rescue analgesia with levobupivacaine was 276.82±41.29 minutes and for ropivacaine was 376.62±45.82 minutes (p<0.0001). Conclusion: Onset of sensory and motor block was faster and duration of sensory block was longer with ropivacaine than levobupivacaine. Postoperative analgesia was better with Ropivacaine.***

Keywords: Epidural Anaesthesia, levobupivacaine, ropivacaine

1. Introduction

For lower limb orthopaedic procedures, epidural anaesthesia is widely regarded as the gold standard anaesthetic approach. A spinal or general anaesthetic may be used in conjunction with an epidural block, which is often performed as a solo procedure utilising local anaesthetic drugs. Patient satisfaction and success rates for epidural anaesthesia are very good1. There is evidence that less blood is lost during orthopaedic procedures and there is a low risk of other complications, the epidural approach has recently become very popular and is well - liked by both patients and surgeons2.

The majority of anaesthetists' first - line local anaesthetic agent of choice for the regional, intrathecal, and epidural block over the past millennium has been bupivacaine. The search for a local anaesthetic agent comparable to bupivacaine but with lower cardiotoxicity began in the early 1970s, and the discovery of a relatively novel amide, ropivacaine, which was approved for use in 1996 but released in India only in 2009, was the outcome.3, 4 Because of its lower toxicity and clinical efficacy that is equivalent to bupivacaine, levobupivacaine was developed as another pure left isomer of bupivacaine for local anaesthetic usage.5

Levobupivacaine and ropivacaine are two more recent long - acting local anaesthetic medications that broaden the arsenal of local anaesthetics and were created in response to reports of serious toxicity linked to bupivacaine. Both of these substances are pure left isomers, and due to the three - dimensional nature of their structures, they are less hazardous to the heart and the central nervous system. Levobupivacaine and ropivacaine have clinical profiles that are comparable to racemic bupivacaine, and the few discrepancies between the three drugs are primarily due to the somewhat varying anaesthetic potencies. By temporarily preventing sodium ions from entering nerve fibres, they have effects that are comparable to those of other local anaesthetics. Due to the similarities between the two medicines, they favour using both of them.6

Hence this study is undertaken to compare the onset time and duration of epidural anaesthesia produced by levobupivacaine and ropivacaine for lower limb orthopaedic surgeries and to determine postoperative analgesia and adverse effects

2. Materials and Methods

Patients and study design:
This study includes 45 patients in each group, who underwent lower limb orthopaedic surgeries Group I: received 15 mL of 0.5% levobupivacaine (n =45), Group II: received 15 mL of 0.75% ropivacaine (n =45), who fulfilled the inclusion and exclusion criteria. The study was carried out under the department of Anaesthesiology, Jorhat Medical College and Hospital, Jorhat in the study period of one year from June 2021 to May 2022 with permission and approval from the Institutional Ethical Committee. The study design was a hospital based observational study. The sample size was calculated using sample size calculation formula. The inclusion criteria include patients who were

able to provide written informed consent, ASA Physical status I and II patients, Patients of either sex, between 18 - 60 years of age scheduled for lower limb orthopaedic surgeries. Exclusion criteria includes ASA grades III and higher, Age less than 18 years and more than 60 years, Bleeding diathesis, Patient with uncontrolled or labile hypertension, Patient with psychotic diseases, Patient with chronic low back pain, Patients with hepatic and renal impairment, Patient with known allergy to any local anaesthetic or opioid and patient's refusal. The operative procedures were performed following standard protocols, principles and approaches. An informed consent was taken from all the patients who underwent this study.

For statistical analysis data were entered into a Microsoft excel spreadsheet and then analyzed by SPSS (version 27.0; SPSS Inc., Chicago, IL, USA) and Graph Pad Prism version5. Data was presented in terms of mean +/ - SD and t test was applied for testing the significance

Technique of anaesthesia:
A detailed history of the patient was taken and a thorough clinical examination was done. Patients were kept fasting for 8 hours on the night before surgery. The base line vitals, heart rate, pulse rate, systolic blood pressure, diastolic blood pressure and mean arterial pressure, Sp02, ECG were recorded. IV line was secured with 18G cannula. Premedication was done in the pre anaesthetic room. The patients were shifted to operation room.

The study was carried out in 90 patients. Using, sealed - envelope assignment, patients were randomly allocated into 2 groups. Group I: to receive 15 mL of 0.5% levobupivacaine (n =45), Group II: to receive 15 mL of 0.75% ropivacaine (n =45). With the patient in the sitting position, under aseptic precautions, the L2–L3 or L3–L4 interspace was identified using the midline approach and infiltration was done with 2ml of 2% lidocaine. The epidural space was identified with an 18 - gauge Tuohy needle by the loss of resistance technique. A 20 - gauge epidural catheter was then inserted 3–5 cm into the epidural space. Test dose with 3 ml of 2% injection lignocaine hydrochloride with adrenaline 1: 200, 000 was given after a negative aspiration test to detect any intravascular or intrathecal placement of the catheter). Sterile syringes with the study drug were prepared. The sensory level was assessed using the pinprick method, and readiness to surgery was considered as the complete loss of pinprick sensation at T10. The degree of motor block was evaluated with a four - point modified Bromage score. The scale consists of the following four scores:
0 = No motor block (0% block)
1 = Unable to raise extended legs (33% block) 2 = Unable to flex knees (66% block)
3 = Unable to flex ankle joint (100% block)
Recovery of sensory levels to two dermatomal segments below the highest level was assessed. Postoperative pain score (VAS) was recorded.

3. Results and Observations

It was observed that the demographic profiles of the two groups for this study were comparable. The mean age in group I was (41.9 ± 11.5) years and in group II was (43.3± 13.03) years with p value 0.5787. In group I, 13 (28.89%) patients were female and 32 (71.11%) patients were male. In group II, 12 (26.67%) patients were female and 33 (73.33%) patients were male (p=0.8139). In group I, the mean Weight (mean± SD) of patients was 62.89± 9.4 and in group II, the mean Weight of patients was 64.84± 9.95 (p=0.3405). In Group I 35 (77.8%) patients were ASA I and 10 (22.2%) patients were ASA II. In Group II, 27 (60.0%) patients were ASA I and 18 (40.0%) patients were ASA II.

In group I, the mean onset of sensory block (Mins.) (mean± SD) of patients was 18.51± 2.76 and in group R, the mean onset of sensory block (Mins.) (mean± SD) of patients was 16.04±2.31. Distribution of mean onset of sensory block (Mins.) with group was statistically significant (p=<0.0001).

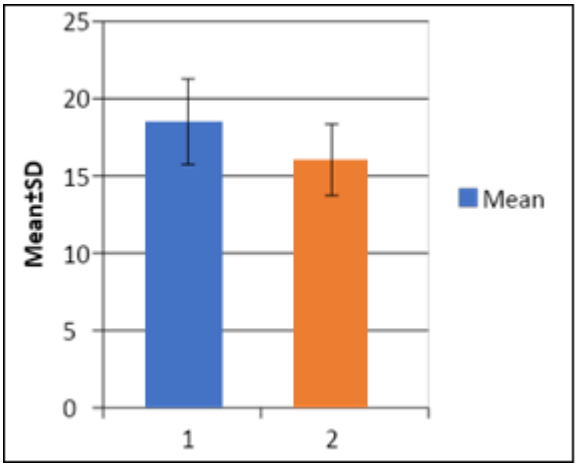

Figure 3.1: Mean Onset of Sensory Block

In group I, the mean onset of motor block (Mins) was 28.06± 4.0 and in group II, the mean onset of motor block (Mins) was 23.06±2.76. Distribution of mean onset of motor block (Mins) with group was statistically significant (p=<0.0001)

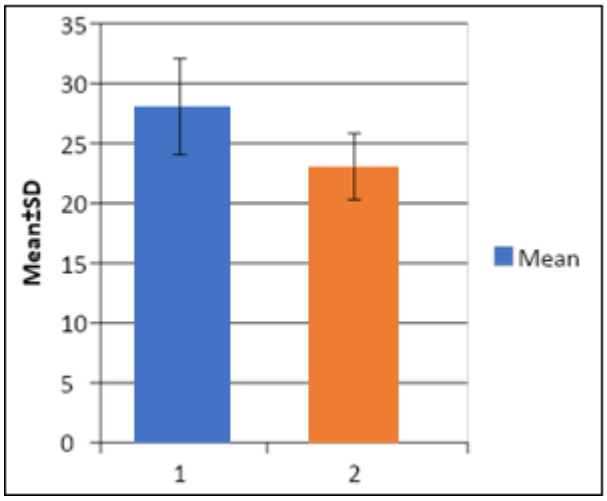

Figure 3.2: Mean Onset of Motor Block

In group I, the mean duration of sensory block (Mins) (mean± SD) was 164.08± 8.88 and in group II, it was 172.26±4.03. Distribution of mean duration of sensory block (Mins) with group was statistically significant (p=<0.0001)

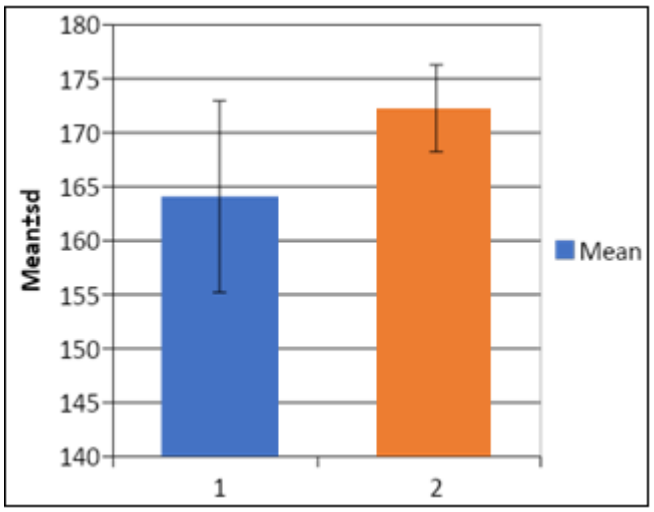

Figure 3.3: Mean Duration of Sensory Block

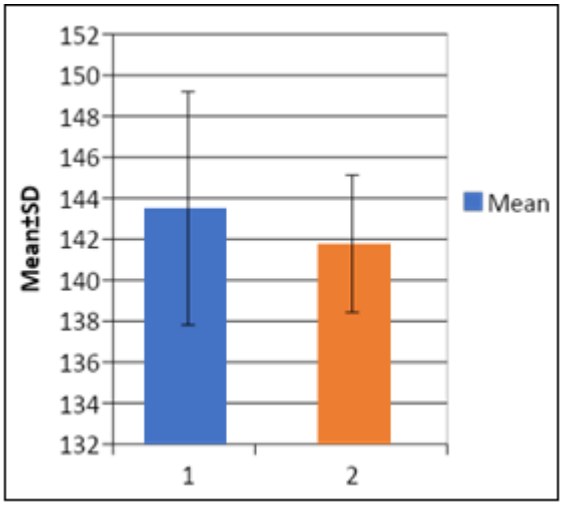

Figure: Mean Duration of motor block

In group I, the mean duration of motor block (Mins) (mean± SD) was 143.51± 5.69 and in group II, it was 141.77±3.35. Distribution of mean duration of motor block (Mins) with group was not statistically significant (p=0.0819).

In our study it is seen that VAS is significant (p<0.05) at 180 and 240 mins between both the groups. However, VAS is not significant (p>0.05) at B/L, 5mins and 10 mins between both the groups

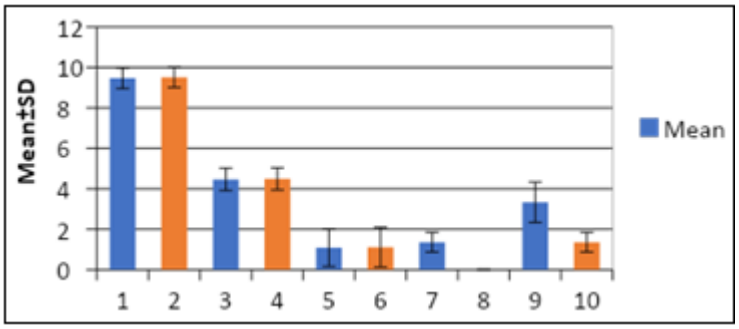

Figure: VAS of both the groups at different time intervals

In this study, it is seen that systolic blood pressure is significant (p<0.05) at 70 and 80 mins between both the groups. Whereas, systolic blood pressure is not significant (p>0.05) at B/L, 5 mins, 10 mins, 15 mins, 20 mins, 25 mins 30 mins, 40 mins, 50mins, 60mins, 90 mins, 100mins, 110 mins, 120 mins, 150 mins, 180 mins, 210 mins and 240 mins between both the groups

Also, it is seen that diastolic blood pressure is significant (p<0.05) at B/L, 15 mins, 20 mins, 25 mins, 30 mins, 40 mins, 50 mins, 60 mins, 80 mins, 90 mins, 100 mins, 110 mins and 240 mins between both the groups. However, diastolic blood pressure is not significant (p>0.05) at 5 mins, 10 mins, 70 mins, 120 mins, 150 mins, 180 mins and 210 mins between both the groups

In our study, it is seen that mean arterial pressure is significant (p<0.05) at 20 mins, 25 mins, 40 mins, 50 mins, 60mins, 80 mins and 90 mins between both the groups. Whereas, mean arterial pressure is not significant (p>0.05) at B/L, 5 mins, 10 mins, 15 mins, 30 mins, 70 mins, 100 mins, 110 mins, 120 mins, 150 mins, 180 mins, 210 mins and 240 mins between both the groups

It is found that heart rate was statistically significant (p<0.05) at all the intervals between both the groups

4. Discussion

Epidural anaesthesia and analgesia have the potential to reduce or eliminate the perioperative physiologic stress responses to surgery and thereby decrease surgical complications and improve outcomes7

The demographic data reveals that there was no significant difference between the two groups with respect to age, gender or ASA physical status.

In our study, we found that the mean time of onset of sensory block in group I was18.51 ± 2.77 minutes and that of group II to be 16.04 ± 2.31. We found a highly significant statistical difference (p value < 0.001) between the study groups with respect to the time for onset of sensory block

Maheshwari et al8 (2016) conducted a similar study to evaluate the efficacy of 15 mL of levobupivacaine 0.5% with that of 15 mL of ropivacaine 0.75% in patients undergoing lower limb orthopaedic surgeries under epidural anaesthesia. Time to achieve sensory onset was significantly lower in Group II (17.86 ± 2.51) as compared to Group I (26.14 ± 2.45) with p value (p<0.05) which is in accordance to our present study

Karki et al9 (2017), did a comparative study of epidural

levobupivacaine 0.5% and ropivacaine 0.75%. There was no significant difference in the sensory onset time between group R and L (p>0.05) which is in contrary to our present study

In our study we found that the mean duration of sensory block in minutes (mean± SD) in group I was 164.09± 8.88 and that of group II was 172.26 ± 4.03. (p=< 0.001) between the study groups with respect to the duration of sensory block

Maheshwari et al8 (2016) conducted a similar study and found that the duration of sensory block was significantly higher in Group II (173.29 ± 6.29 min) as compared to Group I (156.71 ± 6.96 min) with p value (p<0.05)

In our study we found that the mean onset of motor block in group I was 28.07± 4.01 mins and that of group II was 23.07±2.77. Thus, we found a significant statistical difference (p value < 0.001) between the study groups with respect to the onset of motor block. We also found that the mean duration of Motor Block in group I was 143.51± 5.69 mins and that of group II patients was 141.78±3.35 mins. Therefore, with respect to duration of motor block between both the groups the study is not statistically significant (p=0.0819).

Maheshwari et al8 (2016) conducted a similar study and found that time to achieve motor onset was significantly lower in group II (23.14 ± 2.73) as compared to group I (31.43± 2.59) (p<0.05) which is in accordance to our present study. while the duration of motor block in group I (142.43 ± 8.43 min) was higher than that of group II (141.43 ± 12.81 min), but this difference was not found to be statistically significant p (>0.05) which is in accordance to our study.

Gandhi et al10 (2020) conducted a similar study on epidural levobupivacaine 0.5% (group A) and ropivacaine 0.75% (group B) with fentanyl 100 mcg (2ml) on patients undergoing elective lower limb orthopaedic surgeries. Motor blockade mean onset time was 20+3.35 minutes and 20.2+3.64 minutes in group A and group B respectively which is statistically not significant (p>0.05) and is in contrary to our study. The mean duration of motor block in group A was 248.4+13.60 minutes and 247.8+13.29 minutes in group B which also was not statistically significant (p>0.05) and is in accordance to our present study

We found that the mean time for first rescue analgesia in group I patients was 276.82± and that for group II patients was 376.62±45.82. The time to first rescue analgesia for the patients receiving ropivacaine was longer and statistically highly significant (p<0.0001)

Maheshwari et al8 (2016) conducted a similar study and found that time for first rescue analgesia was significantly longer (p<0.001) in group II (6.43±2.12 hr) as compared to group I (4.97± 0.89 hr) which is in accordance to our study.

5. Conclusion

From our study comparing 0.5% Levobupivacaine and 0.75% Ropivacaine for epidural anaesthesia in patients undergoing elective lower limb orthopaedic surgeries, we came to the conclusion that Ropivacaine is more effective than Levobupivacaine, based on the following:

The onset of sensory block of 0.75% Ropivacaine was faster than 0.5% Levobupivacaine. Also, the duration of sensory block of 0.75% Ropivacaine was longer than 0.5% Levobupivacaine. The onset of motor block was faster with 0.75% Ropivacaine than 0.5% Levobupivacaine. The time to first rescue analgesia was prolonged in the Ropivacaine group.

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