

Efficacy of Epidural Bupivacaine versus Ropivacaine in Lower Abdominal and Lower Limb Surgeries

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Abstract :

AIM: This study aims to compare epidural Ropivacaine's effectiveness with epidural Bupivacaine for anesthesia in the lower extremity, and lower abdominal surgeries with respect to the onset of sensory and motor blockade, degree of motor block (using Modified Bromage scale), duration of motor blockade, duration of sensory analgesia. **MATERIALS AND METHODS:** After taking institutional ethical committee approval and written informed consent, 60 patients aged between 18 to 60 years posted for elective lower limb and lower abdominal surgeries were selected. The study population was randomly divided into 2 groups with 30 patients in each group. Study group R- received 15ml of 0.5% Ropivacaine (isobaric) by the epidural route. Study group B- received 15ml of 0.5% Bupivacaine (isobaric) by the epidural route. The onset of sensory blockade, the onset of motor blockade, highest level of sensory blockade, degree of motor block was evaluated. **RESULTS:** There is no difference in the onset of sensory and motor block between 0.5% bupivacaine and 0.5% ropivacaine when administered through the epidural route.

The duration of motor blockade in Ropivacaine group R was significantly lower than the Bupivacaine group B.

CONCLUSION: It can be concluded that isobaric 0.5% Ropivacaine, when administered through the epidural route, provides adequate anaesthesia for lower abdominal and lower limb surgeries and 0.5% Ropivacaine has a shorter duration of motor blockade when compared with 0.5% Bupivacaine.

Keywords: Bupivacaine, Ropivacaine, Epidural anesthesia, Sensory block, Motor block

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I. Introduction

Regional anesthesia is noted for its safety, simplicity, effectiveness. Though spinal anesthesia provides an efficient block, it has some disadvantages like - level of the block cannot be controlled, the duration of the blockade is constant and cannot be prolonged, and it is associated with complications like post-dural puncture headache, neurological sequelae, etc. Epidural anesthesia is a regional technique for lower abdominal, lower extremity, vascular and pelvic surgeries where complications are less compared to spinal anesthesia. Also, there are no limitations for the duration of surgery if an epidural catheter is in place, it can be used as a modality for postoperative pain relief.

Bupivacaine has been the drug of choice for a long time in providing effective epidural anesthesia followed by postoperative analgesia for a considerable time.

Ropivacaine is a new, long-acting local anesthetic that is chemically homologous with Bupivacaine and Mepivacaine.¹ It is similar to the 'S' enantiomer of Bupivacaine, except that a propyl group is present in place of the butyl group on the piperidine ring's tertiary nitrogen atom.^{2,3} Ropivacaine exhibits less cardiotoxicity and CNS toxicity⁴. It produces effective analgesia similar to Bupivacaine, and that motor block appears to regress considerably more quickly than the sensory block.⁵ This makes Ropivacaine potentially well suited for administration through the epidural route for epidural anesthesia⁶.

This study aims to compare epidural Ropivacaine's effectiveness with epidural Bupivacaine for anesthesia in the lower extremity, and lower abdominal surgeries. Bupivacaine has been the drug of choice for a long time in providing adequate epidural anesthesia followed by postoperative analgesia for a considerable time.^{7,8}

II. Aims And Objectives Of The Study

To compare the following factors in the two groups - 15 ml of 0.5% Ropivacaine (isobaric) and 15 ml 0.5% Bupivacaine (isobaric) for epidural anesthesia in lower abdominal and lower extremity surgeries in adults aged 18 to 60 years, with respect to:

- The onset of sensory and motor blockade
- Degree of motor block (using Modified Bromage scale)
- Duration of motor blockade
- Duration of sensory analgesia

PATIENTS AND METHODS

This study was conducted on patients posted for elective lower limb and lower abdominal surgeries during the period from January 2019 to June 2020. After taking institutional ethical committee approval and written informed consent, 60 patients aged between 18 to 60 years posted elective lower limb and lower abdominal surgeries were selected. Among the selected individuals, those fulfilling the inclusion criteria were included in the study.

Inclusion criteria:

The age group of 18-60 years, ASA grade I or II, patients undergoing elective surgeries and patients of either sex are included in study.

Exclusion criteria: ASA grade III and IV, patient refusal, infection at the site of injection, Coagulopathy or anticoagulation, congenital abnormalities of the lower spine and meninges, active disease of CNS, history of allergy to local anesthetics.

The patient selection was made randomly by computer generated randomization table. Informed consent was obtained from all of these patients. A detailed pre-anesthetic examination, including history, general physical examination, the systemic examination of the cardiovascular, respiratory, central nervous system, spine examination for deformity, was performed.

Routine investigations like Haemogram, HB, BGT, BT, CT, RBS, BLOOD UREA, SERUM CREATININE, HIV & HBsAg, ECG, and CHEST X-RAY (if required) were done. The patient's weight and height were also recorded prior to surgery. The study population was randomly into 2 groups with 30 patients in each group. Study group R- received 15ml of 0.5% Ropivacaine (isobaric) by the epidural route.

Study group B- received 15ml of 0.5% Bupivacaine (isobaric) by the epidural route.

Premedication:

Tab. Alprazolam 0.5 mg orally was given the previous night. Patients were kept nil orally for 6-8 hours before surgery. Injection midazolam 0.03 mg/kg IV was given before insertion of the epidural catheter.

Procedure:

Drugs and equipment necessary for resuscitation and general anesthesia were kept ready. An autoclaved epidural tray was used. An IV line was secured using an 18G cannula, and the patient was preloaded with 500 ml Ringers lactate. Baseline blood pressure, heart rate, and spo2 were noted.

The patient was placed in the left lateral position or sitting position. With all aseptic precautions, a skin wheal was raised in L3-L4 interspace with 2ml of 2% Lignocaine. An 18 G Touhy needle was passed through this space for about 1cm. The stylet was removed, and a 10ml dry glass syringe with an air column of 5ml was firmly attached to the hub of the Touhy needle. The needle was slowly advanced until it entered the epidural space, which was identified by the loss of resistance to air. Once the epidural space was confirmed, the glass syringe was disconnected. The absence of blood or CSF was verified. An 18G epidural catheter was passed through the epidural space in cephalad direction until 3cm is in the space. 3ml of 2% Lignocaine with adrenaline 1:200000 was given a test dose. This is to exclude the presence of a needle in an epidural vein or subarachnoid space. 4 minutes later, 15 ml of the study drug was injected through the epidural catheter intermittently over 3 minutes. All the patients were monitored for cardiorespiratory problems, side effects if any, and were given supplemental oxygen. Fluid management was done according to requirements, including the fluid deficit, maintenance, blood loss, etc. The following factors were observed and recorded:

The onset of sensory blockade was tested by the pin-prick method using a 27 gauge hypodermic needle. The time of onset of sensory blockade was taken from the time of injection of the drug into epidural space to loss of pin-prick sensation. The time interval from the administration of the drug into epidural space to the patient's inability to raise the straight extended lower limb (Modified Bromage scale 1) is recorded as the onset time for the motor block. The highest level of the sensory block was assessed by the pin-prick method by using a hypodermic needle. The highest dermatomal level blocked was noted after the onset of motor block.

Degree of motor block: This was assessed by the modified Bromage scale.

Modified Bromage scale:

0- Able to raise leg straight, full flexion of knees and feet.

1- Inability to raise the leg, just able to flex knees, full flexion of feet.

2 - Unable to bend knees, but some flexion of feet possible.

3 - Unable to move legs or feet.

The duration of the motor block was taken from the time of injection to complete regression of the motor block. (modified Bromage scale - 0). Duration of sensory analgesia was recorded from the onset of sensory block to complete return of sensation to pin-prick. Hemodynamic changes: Monitoring of heart rate, blood pressure, and spo₂ was done at 0, 5, 10, 15, 20, 25, 30, 45, 60, 90, 120, and 180 minutes after administration of epidural block.

STATISTICAL ANALYSIS:

The data was compiled and analysed statistically by using student's 't' test and a 'p' value of < 0.05 was considered significant and p < 0.001 was considered as highly significant. All the scores in our study were analysed by using the student's 't' test and standard error of difference between the two means and chi-square test. Statistical analysis was done by using GraphPad prism software version 7.03 for windows (Inc., California Corporation).

III. Results:

The study sample comprised of 60 patients aged between 18 to 60 years belonging to ASA grade I and II, posted for elective lower abdominal and lower limb surgeries. Thirty of them (group R) received 20 ml of 0.75% Ropivacaine (isobaric) and the others (group B) received 20ml of 0.5% Bupivacaine (isobaric) for epidural anaesthesia.

Onset of Sensory Block:

TABLE 1: TIME OF ONSET OF SENSORY BLOCK

| Parameter | 0.5% Ropivacaine (group) | | 0.5% Bupivacaine (group) | | Mean Difference | P* Value, sig |
|------------------------------|--------------------------|-----|--------------------------|-----|-----------------|---------------|
| | Mean | SD | Mean | SD | | |
| Onset of Sensory Block (min) | 10.2 | 1.6 | 10.8 | 1.5 | 0.57 | 0.30 NS |

* Student's unpaired t test

The mean time for onset of sensory block in Ropivacaine group (group R) was 10.2 ±

1.6 minutes and 10.8 ± 1.5 minutes in Bupivacaine group (group B) (Table 1). The onset of sensory block in group B was delayed by only few seconds than group R (p= 0.30), so the difference was not statistically significant.

ONSET OF MOTOR BLOCK

TABLE 2: TIME OF ONSET OF MOTOR BLOCK

| Parameter | 0.5% Ropivacaine (group) | | 0.5% Bupivacaine (group) | | Mean Difference | P* Value, sig |
|----------------------------|--------------------------|-----|--------------------------|-----|-----------------|---------------|
| | Mean | SD | Mean | SD | | |
| Onset of motor Block (min) | 29.5 | 3.0 | 28.9 | 3.4 | 0.63 | 0.44 NS |

* Student's unpaired t test

The mean time for onset of motor block in Ropivacaine group (group R) was 29.5

± 3.0 minutes and in Bupivacaine group (group B) it was 28.9 ± 3.4 minutes (Table 2). There was no significant difference between the groups (p=0.44).

HIGHEST LEVEL OF SENSORY BLOCK

TABLE 3: HIGHEST LEVEL OF SENSORY BLOCK

| Highest level of sensory | 0.5% Ropivacaine (groupR) | | 0.5% Bupivacaine (group) | |
|--------------------------|---------------------------|----|--------------------------|----|
| | No. | % | No. | % |
| T6 | 18 | 60 | 18 | 60 |
| T7 | 10 | 33 | 8 | 27 |
| T8 | 0 | 0 | 1 | 3 |
| T10 | 2 | 7 | 3 | 10 |

$X^2 = 1.4$ P=0.7 NS

In patients of Ropivacaine group (group R), 60% attained T6 level, 33% attained T7 level and 7% attained T10 levels. In Bupivacaine group (group B) also 60% attained T6 levels, followed by 27% attaining T7 level and 10% attaining T10 level (Table 3). This implied that there was no difference in the highest level of sensory block achieved in both groups. (p=0.7)

DEGREE OF MOTOR BLOCK:

TABLE 4: DEGREE OF MOTOR BLOCK

| Degree of motor block | 0.5% Ropivacaine (group R) | | 0.5% Bupivacaine (group) | |
|-----------------------|----------------------------|----|--------------------------|----|
| | No. | % | No. | % |
| Grade 0 | 0 | 0 | 0 | 0 |
| Grade 1 | 0 | 0 | 0 | 0 |
| Grade 2 | 4 | 13 | 3 | 10 |
| Grade 3 | 26 | 87 | 27 | 90 |

$X^2 = 0.48$ P=0.6 NS

The degree of motor block was tested by modified Bromage scale. On comparison it was found that, in Ropivacaine group (group R) there were 4 patients (13%) who had grade 2 block and 26 patients (87%) who had grade 3 block. In Bupivacaine group (group B), 3 patients (10%) had grade 2 block and 27 patients (90%) had grade 3 block (Table 4). The percentage distribution of patients who had grade 2 and grade 3 block was similar in both the groups.

DURATION OF MOTOR BLOCK

TABLE 5: DURATION OF MOTOR BLOCK

| Parameter | 0.5% Ropivacaine (group) | | 0.5% Bupivacaine (group) | | Mean Difference | P* Value, sig |
|------------------------------|--------------------------|------|--------------------------|------|-----------------|---------------|
| | Mean | SD | Mean | SD | | |
| Duration of Motor Block(min) | 241.7 | 22.8 | 282.3 | 21.0 | 40.600 | <0.001 HS |

* Student's unpaired ttest

The mean duration of motor block in Ropivacaine group (group R) was 241.7± 22.8 minutes, whereas in Bupivacaine group (group B) it was 282.3 ± 21.0 minutes. The p value was <0.001, indicating that the difference was highly significant (Table 5). This implied that the duration of motor blockade in Ropivacaine group R was significantly lower than the Bupivacaine group B.

DURATION OF SENSORY ANALGESIA:

TABLE 6: DURATION OF SENSORY ANALGESIA

| Parameter | 0.5% Ropivacaine (group) | | 0.5% Bupivacaine (group) | | Mean Difference | P* Value . sig |
|------------------------------------|--------------------------|------|--------------------------|------|-----------------|----------------|
| | Mean | SD | Mean | SD | | |
| Duration of Sensory Analgesia(min) | 389.7 | 16.5 | 391.1 | 15.1 | 1.433 | 0.72 NS |

* Student's unpaired ttest

*

The mean duration of sensory analgesia in Ropivacaine group (group R) was 389.7

± 16.5 minutes. In Bupivacaine group (group B) the mean duration was 391.1 ±15.1 minutes (Table 6). The duration of sensory analgesia in group B was prolonged by only few minutes than group R (p= 0.72), so the difference was not statistically significant.

Haemodynamic parameters:

The mean pulse rate was compared between the two groups at 0, 5, 10, 15, 20,25,

30, 45, 60, 90, 120 and 180 minutes . There was no significant difference between the Ropivacaine and Bupivacaine group with respect to pulse rate when recorded at these time intervals. The mean systolic blood pressure changes over the time intervals between the Ropivacaine (group R) and Bupivacaine group (group B) was compared. It was found that the systolic blood pressure did not differ between the two groups. As with the systolic blood pressure, the mean diastolic blood pressure changes over the time intervals between Ropivacaine (group R) and Bupivacaine (group B) groups were similar. The difference was not statistically significant .

IV. Discussion:

In this study, the patients studied in both groups do not vary much with respect to sex, age, or weight. The majority of patients are in the age group between 18 to 60 years, with a mean age of 36.3+/-10.0 years in Group R and 39.2+/-11.8 years in Group B. The mean weight distribution and the mean sex in both groups were identical. These parameters were matched in both groups to avoid changes in the intraoperative and postoperative outcomes of the patients.

ONSET OF SENSORY AND MOTOR BLOCK

In the present study, the meantime of onset of sensory block in the Ropivacaine group was 10.2 ± 1.6 minutes and 10.8 ± 1.5 minutes in the Bupivacaine group. The mean time of onset of motor block in the Ropivacaine group was 29.5 ± 3.0 minutes, and in the Bupivacaine group, it was 28.9 ± 3.4 minutes. With regard to the onset of sensory block and motor block between the groups was not statistically significant which coincides with the study of **Brockway M S et al². and Finucane B T et al⁹.**

Katz et al¹⁰ also conducted a double-blind comparative study of epidural anaesthesia with 0.5% Bupivacaine versus 0.75% Ropivacaine. They found no significant difference in the onset of sensory or motor blockade, similar to our results.

Brown DL et al¹² designed a randomized, double-blind study to compare the clinical effectiveness of Ropivacaine and Bupivacaine in patients undergoing lower- extremity surgery. They also found no significant difference in the onset of sensory and motor block.

The above findings were similar to the findings of this study. Thus it can be concluded that there is no difference in the onset of sensory and motor block between 0.5% bupivacaine and 0.5% ropivacaine when administered through the epidural route.

HIGHEST LEVEL OF SENSORY BLOCK

The level of sensory block was assessed by the pin-prick method using a hypodermic needle after the onset of motor blockade. In the present study, patients of the Ropivacaine group attained the following level of sensory blockade: 60% attained T6 level, 33% attained T7 level, and 7% attained T10 level. In the Bupivacaine group, 60% attained T6 level, 27% attaining T7 level, 10% attaining T10 level. This implied that the sensory block levels achieved by both groups were similar and this coincides with study done by **Katz et al'**

DEGREE OF MOTOR BLOCK

The degree of motor blockade was tested by a modified Bromage scale. In the present study, there was no significant difference in the degree of the motor block between the two groups.

Brockway MS et al², Finucane B T et al⁹, Katz et al¹⁰, and Wolff A.P et al¹¹ found the degree of motor blockade to be grade 3 in both the bupivacaine and ropivacaine group. This was similar to the present study.

DURATION OF MOTOR BLOCK

In this study, the mean duration of the motor blockade in the Ropivacaine group was 241.7 ± 22.8 minutes, whereas in the Bupivacaine group it was ± 21.0 minutes. This difference was found to be statistically significant ($p < 0.001$).

Brockway et al², and Wolff A.P et al¹¹ compared 0.5%, 0.75% and 1% Ropivacaine 15ml versus 0.5% and 0.75% Bupivacaine 15 ml in 110 patients and found no significant difference in onset, spread, or duration of sensory block when similar concentrations were compared. However, Ropivacaine produced a slower onset, and shorter duration and less intense motor block than Bupivacaine. Similar to our study, they found that the return of motor function was earlier with Ropivacaine compared with that of Bupivacaine.

From the above studies, it can be concluded that the duration of the motor block is shorter with Ropivacaine than with Bupivacaine.

DURATION OF SENSORY ANALGESIA

In this study, the mean duration of sensory analgesia in the Ropivacaine group was 389.7 ± 16.5 minutes. In the Bupivacaine group, the mean duration of sensory analgesia was 391.1 ± 15.1 minutes, showing that there was no significant difference in the duration of sensory analgesia among the two groups which coincides with study

conducted by **Brockway M S et al², Finucane B T et al⁹, Katz et al¹⁰, Wolff A.P et al¹¹ and Brown DL¹² et al.**

HAEMODYNAMIC CHANGES

Heart rate and blood pressure:

In this study, the two groups did not significantly differ with respect to heart rate at any time interval. There were no bradycardia episodes in either group. The changes in the mean systolic blood pressure and diastolic blood pressure at any time interval were clinically and statistically insignificant. 2 patients in the Ropivacaine group experienced hypotension, whereas 3 patients experienced low blood pressure in Bupivacaine group, and it was corrected by small doses of Inj. Mephentermine.

From the above discussion, it can be concluded that the epidural administration of Ropivacaine produces similar changes in haemodynamic parameters as that of Bupivacaine. These findings are similar to the present study.

V. Conclusion

Based on the present comparative study, it can be concluded that isobaric 0.5% Ropivacaine, when administered through the epidural route, provides adequate anaesthesia for lower abdominal and lower limb surgeries. 0.5% Ropivacaine has a shorter duration of motor blockade when compared with 0.5% Bupivacaine. The onset of sensory and motor blocks, highest level of sensory block, degree of motor block, and duration of sensory analgesia are similar to that of Bupivacaine. The haemodynamic changes and side effect profile of Ropivacaine is also not significantly different from that of Bupivacaine.

Hence Ropivacaine is a safe alternative to Bupivacaine for epidural anaesthesia in lower abdominal and lower extremity surgeries. The shorter duration of motor block with Ropivacaine suggests that it can be effectively used for early mobilization of patients in the postoperative period.

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