A “COMPARATIVE STUDY BETWEEN BUPIVACAINE 0.5% AND ROPIVACAINE 0.75% IN EPIDURAL ANALGESIA IN PATIENTS UNDERGOING ELECTIVE LOWER ABDOMINAL AND LOWER LIMB SURGERIES”

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R. S. Sachidanand, G. Shravan Kumar, B. Srinivas Rao, Praveen Kumar Devulapalli, Laxmi Kanth, M. Srinath. “A Comparative Study between Bupivacaine 0.5% and Ropivacaine 0.75% in Epidural Analgesia in Patients Undergoing Elective Lower Abdominal and Lower Limb Surgeries”. Journal of Evolution of Medical and Dental Sciences 2015; Vol. 4, Issue 78, September 28; Page: 13699-13714, DOI: 10.14260/jemds/2015/1956

ABSTRACT: BACKGROUND: Regional anaesthesia is noted for its simplicity, safety and effectiveness. Though spinal anaesthesia provides an efficient block it has some limitations. Epidural anaesthesia is one of regional techniques for lower abdominal and lower limb surgeries. Bupivacaine is the drug of choice for providing effective epidural analgesia. Ropivacaine is new long acting local anaesthetic with similar chemical structure but with less cardio toxicity and CNS toxicity. We did a Prospective Randomised control study to compare between two groups- 20ml of 0.75% Ropivacaine (Isobaric) and 20ml 0.5% Bupivacaine (Isobaric) for epidural anaesthesia in lower abdominal and lower limb surgeries in adults aged 18 to 60 years. AIM: To compare in two groups- 20 ml of 0.75% Ropivacaine (Isobaric) and 20 ml 0.5% Bupivacaine (isobaric) for epidural anaesthesia in lower abdominal and lower limb surgeries in adults DESIGN: A Prospective randomized control study. METHODS: The study population was randomly divided into 2 groups with 30 patients in each group. Study group R- received 20ml of 0.75% Ropivacaine (Isobaric) by epidural route Study group B- received 20ml of 0.5% Bupivacaine (isobaric) by epidural route and compared 1. Onset of sensory and motor block, 2. Highest level of sensory block, 3. Degree of motor blockade (Using Modified Bromage scale) 4. Duration of motor blockade. 5. Duration of sensory analgesia. 6. Haemodynamic changes heart rate, blood pressure, respiratory rate. 7. Side effects if any. RESULTS: 0.75% Ropivacaine has a shorter duration of motor block 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 CONCLUSION: Based on the present clinical comparative study, we conclude that Ropivacaine can be used as a safe alternative to Bupivacaine for epidural anaesthesia in lower abdominal and lower limb surgeries. The shorter duration of motor block with Ropivacaine suggest that it could be effectively used for early mobilization of patients in the post-operative period. KEYWORDS: Bupivacaine, Epidural analgesia, Motor blockade Ropivacaine, Sensory blockade.

INTRODUCTION: Regional anaesthesia is noted for its simplicity, safety, and effectiveness. Anaesthesia with an efficient block, having least onset time and which can be prolonged with least complications is one of the challenges faced by the anaesthesiologist.

Though spinal anaesthesia provides an efficient block, it has some disadvantages such as height of block cannot be controlled, duration of block is constant and cannot be prolonged and it is associated with complications such as postdural puncture headache, neurological sequelae etc.
Epidural anaesthesia is one of the regional techniques for lower abdominal, lower limb, pelvic and vascular surgery, it has some definite advantages over spinal anaesthesia like there is no limitation for the duration of surgery if an epidural catheter is in place. It can also be used as a modality for post-operative pain relief. Bupivacaine has been the drug of choice in providing effective epidural anaesthesia followed by post-operative analgesia for a considerable time. The recognition of acute life-threatening cardiotoxicity of bupivacaine, led to the search for a local anaesthetic agent comparable with bupivacaine but with lower cardiotoxicity resulting in development of a relatively new amide, ropivacaine, registered for use in 1996 but introduced in India only in 2009.

Ropivacaine is a new, long acting local anaesthetic which is chemically homologous with Bupivacaine and Mepivacaine. It is similar to the ‘S’ enantiomer of Bupivacaine, except that a propyl group is present in place of butyl group on the piperidine ring’s tertiary nitrogen atom. Ropivacaine exhibits less cardio toxicity and CNS toxicity. It produces effective analgesia as that of Bupivacaine and that motor block appears to regress considerably more rapidly than sensory block, this makes Ropivacaine potentially well suited for administration through epidural route for epidural anaesthesia.

Hence this is Prospective Randomised control study to compare in two groups- 20ml of 0.75% Ropivacaine (Isobaric) and 20ml 0.5% Bupivacaine (Isobaric) for epidural anaesthesia in lower abdominal and lower limb surgeries in adults aged 18 to 60 years

METHODS: This study was conducted on patients undergoing elective lower limb and lower abdominal surgeries in M.G.M Hospital, attached to Kakatiya Medical College, Warangal during the academic year from December 2012 to July 2014. After ethical committee approval and written informed consent, 60 patients aged between 18 to 60 years undergoing elective lower limb and lower abdominal surgeries were selected.

Inclusion Criteria:
- Age group of 18-60 years. ASA grade I or II.
- Patients undergoing elective surgeries.

Exclusion Criteria:
- ASA grade III and IV.
- Infection at the site of injection.
- Coagulopathy or anti coagulation.
- Congenital abnormalities of lower spine and meninges.
- Active disease of CNS.
- History of allergy to local anaesthetics.

The selection of the patients was done randomly. A detailed preanaesthetic evaluation including history, general physical examination, systemic examination of various systems& spine examination for deformity was performed.

Routine investigations like Haemogram, TLC, DLC, ESR, BT, CT, RBS, BLOOD UREA, SERUM CREATININE, URINE for albumin, sugar and microscopy, HIV & HBsAg, ECG and CHEST X-RAY (If required) were done. Patient’s weight and height was also recorded prior to surgery.
The study population was randomly divided into 2 groups with 30 patients in each group. Study group R- received 20ml of 0.75% Ropivacaine (Isobaric) by epidural route. Study group B- received 20ml of 0.5% Bupivacaine (isobaric) by epidural route.

The following parameters were observed and recorded:

**Onset of Sensory Block:** The onset of sensory block was tested by pin-prick method using a 27 gauge hypodermic needle. The time of onset was taken from the time of injection of drug into epidural space to loss of pin prick sensation.

**Onset of Motor Block:** The time interval between administration of drug into epidural space and the patient's inability to lift the straight extended leg (Modified Bromage scale 1) was recorded as onset time for motor block.

**Highest level of Sensory Block:** The highest level of sensory blockade was assessed by pin prick method using a hypodermic needle. The highest dermatomal level blocked was noted and recorded after the onset of motor block.

**Degree of Motor Block:** This was assessed by Modified Bromage scale.

**Modified Bromage scale:**

0. Able to raise leg straight, full flexion of knees and feet.
1. Inability to raise leg, just able to flex knees, full flexion of feet.
2. Unable to flex knees, but some flexion of feet possible.
3. Unable to move legs or feet.

**Duration of Motor Block:** The duration of motor block was taken from time of injection to complete regression of motor block. (Ability to lift the extended leg i.e. modified Bromage scale- 0).

**Duration of Sensory Analgesia:** Duration of sensory analgesia was noted and recorded from the onset of sensory block to complete return of sensation to pin prick.

**Haemodynamic Changes:** Patients were monitored for heart rate, blood pressure and respiratory rate at 0, 5,10, 15, 20, 25, 30, 45, 60, 90, 120 and 180 minutes after administration of epidural block.

**Side Effects:** Such as nausea, vomiting, backache, retention of urine, respiratory depression were observed for, recorded and treated accordingly.
Statistical Analysis:4,5

The following list of formulae was used for analyzing the data:

1. Arithmetic mean = Sum of all the values =\( \frac{\sum X}{\text{No. of values}} \)
2. Standard deviation, \( s = \sqrt{\frac{\sum (X - \bar{X})^2}{n-1}} \)
3. Student's unpaired t test

\[ t = \frac{\text{Difference of means}}{\text{S.E of difference of means}} \]

Fisher's Exact Test:

<table>
<thead>
<tr>
<th>Cases</th>
<th>T1</th>
<th>T2</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abnormal</td>
<td>A</td>
<td>B</td>
<td>A+B</td>
</tr>
<tr>
<td>Normal</td>
<td>C</td>
<td>D</td>
<td>C+D</td>
</tr>
<tr>
<td></td>
<td>A+C</td>
<td>B+D</td>
<td>N=A+B+C+D</td>
</tr>
</tbody>
</table>

Fisher's test = (A+B)! (C+D)! (A+C)! (B+D)!
N! A! B! C! D!

OBSERVATIONS AND 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. The Demographic data like age, gender, and weight were compared and there was no statistical significant difference between the two groups as shown in the table.

Age:

<table>
<thead>
<tr>
<th>Age (Years)</th>
<th>0.75% Ropivacaine (Group R)</th>
<th>0.5% Bupivacaine (Group B)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No</td>
<td>%</td>
</tr>
<tr>
<td>18-29</td>
<td>6</td>
<td>20</td>
</tr>
<tr>
<td>30-39</td>
<td>12</td>
<td>40</td>
</tr>
<tr>
<td>40-49</td>
<td>8</td>
<td>27</td>
</tr>
<tr>
<td>50-59</td>
<td>4</td>
<td>13</td>
</tr>
<tr>
<td></td>
<td>30</td>
<td>100</td>
</tr>
<tr>
<td>Mean+/_SD</td>
<td>36.3+/_10.0</td>
<td>39.2+/_11.8</td>
</tr>
<tr>
<td>P*Value, significance</td>
<td>0.29NS</td>
<td></td>
</tr>
</tbody>
</table>

* Student's unpaired
**Sex Distribution:**

<table>
<thead>
<tr>
<th>Sex</th>
<th>0.75% Ropivacaine (Group R)</th>
<th>0.5% Bupivacaine (Group B)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No.</td>
<td>%</td>
</tr>
<tr>
<td>Male</td>
<td>15</td>
<td>50</td>
</tr>
<tr>
<td>Female</td>
<td>15</td>
<td>50</td>
</tr>
</tbody>
</table>

*Table 2: Sex Distribution*

**Weight:**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>0.75% Ropivacaine (group R)</th>
<th>0.5% Bupivacaine (group B)</th>
<th>Mean Difference</th>
<th>P* Value, sig</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
<td>SD</td>
</tr>
<tr>
<td>Weight (kgs)</td>
<td>53.8</td>
<td>5.6</td>
<td>54.6</td>
<td>5.8</td>
</tr>
</tbody>
</table>

* Student's unpaired t test

**Onset of Sensory Block:**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>0.75% Ropivacaine (Group R)</th>
<th>0.5% Bupivacaine (Group B)</th>
<th>Mean Difference</th>
<th>P* Value, sig</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
<td>SD</td>
</tr>
<tr>
<td>Onset of Sensory Block(min)</td>
<td>10.2</td>
<td>1.6</td>
<td>10.8</td>
<td>1.5</td>
</tr>
</tbody>
</table>

* 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 9). 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>
<thead>
<tr>
<th>Parameter</th>
<th>0.75% Ropivacaine (Group R)</th>
<th>0.5% Bupivacaine (Group B)</th>
<th>Mean Difference</th>
<th>P* Value, sig</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
<td>SD</td>
</tr>
<tr>
<td>Onset of motor Block(min)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* 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 10). There was no significant difference between the groups (p=0.44)

**Highest level of sensory block:**

<table>
<thead>
<tr>
<th>Highest level of sensory block</th>
<th>0.75% Ropivacaine (group R)</th>
<th>0.5% Bupivacaine (group B)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No.</td>
<td>%</td>
</tr>
<tr>
<td>T6</td>
<td>18</td>
<td>60</td>
</tr>
<tr>
<td>T7</td>
<td>10</td>
<td>33</td>
</tr>
<tr>
<td>T8</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>T10</td>
<td>2</td>
<td>7</td>
</tr>
</tbody>
</table>

Table 6: Highest Level of Sensory Block

\[ X^2 = 1.4 \ P=0.7 \text{ NS} \]

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 11). 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>
<thead>
<tr>
<th>Degree of motor block</th>
<th>0.75% Ropivacaine (group R)</th>
<th>0.5% Bupivacaine (group B)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No.</td>
<td>%</td>
</tr>
<tr>
<td>Grade 0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Grade 1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Grade 2</td>
<td>4</td>
<td>13</td>
</tr>
<tr>
<td>Grade 3</td>
<td>26</td>
<td>87</td>
</tr>
</tbody>
</table>

Table 7: Degree of Motor Block

\[ X^2 = 0.48 \ P=0.6 \text{ NS} \]

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 12). The percentage distribution of patients who had grade 2 and grade 3 block was similar in both the groups.
Duration of Motor Block:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>0.75% Ropivacaine (group R)</th>
<th>0.5% Bupivacaine (group B)</th>
<th>Mean Difference</th>
<th>P* Value, sig</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>241.7</td>
<td>282.3</td>
<td>40.600</td>
<td>&lt;0.001 HS</td>
</tr>
<tr>
<td>SD</td>
<td>22.8</td>
<td>21.0</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 8: Duration of Motor Block

* Student’s unpaired t test

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 (Table13). 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>
<thead>
<tr>
<th>Parameter</th>
<th>0.75% Ropivacaine (Group R)</th>
<th>0.5% Bupivacaine (Group B)</th>
<th>Mean Difference</th>
<th>P* Value, sig</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>389.7</td>
<td>391.1</td>
<td>1.433</td>
<td>0.72 NS</td>
</tr>
<tr>
<td>SD</td>
<td>16.5</td>
<td>15.1</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 9: Duration of Sensory Analgesia

* Student’s unpaired t test

The mean duration of sensory analgesia in Ropivacaine group (group R) was389.7±16.5 minutes. In Bupivacaine group (group B) the mean duration was 391.1±15.1 minutes (Table 14). 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: Haemodynamic parameters like Pulse rate, SBP& DBP were compared at 0, 5, 10, 15, 20,25, 30, 45, 60, 90, 120 and 180 minutes and found no statistically significant difference between the two groups with respect to changes in the mean PR, mean SBP& DBP.
**Pulse Rate:**

<table>
<thead>
<tr>
<th>Pulse Rate</th>
<th>0.75% Ropivacaine (group R)</th>
<th>0.5% Bupivacaine (group B)</th>
<th>Mean Difference</th>
<th>P* Value</th>
<th>Sig</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
<td>SD</td>
<td></td>
</tr>
<tr>
<td>0 min</td>
<td>74.6</td>
<td>4.8</td>
<td>75.6</td>
<td>5.1</td>
<td>0.97</td>
</tr>
<tr>
<td>5 min</td>
<td>86.8</td>
<td>5.5</td>
<td>87.9</td>
<td>5.2</td>
<td>1.03</td>
</tr>
<tr>
<td>10 min</td>
<td>89.9</td>
<td>4.0</td>
<td>92.4</td>
<td>4.2</td>
<td>2.43</td>
</tr>
<tr>
<td>15 min</td>
<td>90.1</td>
<td>4.1</td>
<td>91.4</td>
<td>5.0</td>
<td>1.57</td>
</tr>
<tr>
<td>20 min</td>
<td>83.4</td>
<td>5.1</td>
<td>86.4</td>
<td>6.0</td>
<td>2.93</td>
</tr>
<tr>
<td>25 min</td>
<td>79.6</td>
<td>4.1</td>
<td>80.2</td>
<td>5.6</td>
<td>0.67</td>
</tr>
<tr>
<td>30 min</td>
<td>77.8</td>
<td>3.6</td>
<td>78.9</td>
<td>4.9</td>
<td>1.07</td>
</tr>
<tr>
<td>45 min</td>
<td>77.5</td>
<td>3.3</td>
<td>78.5</td>
<td>4.4</td>
<td>1.00</td>
</tr>
<tr>
<td>60 min</td>
<td>76.7</td>
<td>1.9</td>
<td>77.0</td>
<td>2.5</td>
<td>0.30</td>
</tr>
<tr>
<td>90 min</td>
<td>76.0</td>
<td>1.7</td>
<td>76.1</td>
<td>2.3</td>
<td>0.13</td>
</tr>
<tr>
<td>120 min</td>
<td>75.3</td>
<td>1.7</td>
<td>75.6</td>
<td>2.3</td>
<td>0.33</td>
</tr>
<tr>
<td>180 min</td>
<td>74.5</td>
<td>2.1</td>
<td>75.3</td>
<td>2.5</td>
<td>0.83</td>
</tr>
</tbody>
</table>

*students unpaired t test*

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 (Table 15). There was no significant difference between the Ropivacaine and Bupivacaine group with respect to pulse rate when recorded at these time intervals.

**Systolic blood Pressure:** 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.
**ORIGINAL ARTICLE**

**Table 11: Systolic Blood Pressure Comparison**

<table>
<thead>
<tr>
<th>SBP (mm/Hg)</th>
<th>0.75% Ropivacaine (group R)</th>
<th>0.5% Bupivacaine (group B)</th>
<th>Mean Difference</th>
<th>P* Value</th>
<th>Sig</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0 min</td>
<td>119.6 (7.4)</td>
<td>118.7 (7.8)</td>
<td>0.93</td>
<td>0.63</td>
<td>NS</td>
</tr>
<tr>
<td>5 min</td>
<td>113.5 (7.6)</td>
<td>111.6 (6.4)</td>
<td>1.87</td>
<td>0.31</td>
<td>NS</td>
</tr>
<tr>
<td>10 min</td>
<td>110.4 (8.5)</td>
<td>107.4 (6.5)</td>
<td>3.00</td>
<td>0.13</td>
<td>NS</td>
</tr>
<tr>
<td>15 min</td>
<td>105.8 (8.1)</td>
<td>102.5 (8.0)</td>
<td>3.30</td>
<td>0.12</td>
<td>NS</td>
</tr>
<tr>
<td>20 min</td>
<td>107.5 (7.7)</td>
<td>103.5 (7.1)</td>
<td>4.07</td>
<td>0.06</td>
<td>NS</td>
</tr>
<tr>
<td>25 min</td>
<td>108.6 (7.6)</td>
<td>105.1 (6.7)</td>
<td>3.53</td>
<td>0.06</td>
<td>NS</td>
</tr>
<tr>
<td>30 min</td>
<td>110.3 (7.0)</td>
<td>107.5 (6.7)</td>
<td>2.87</td>
<td>0.11</td>
<td>NS</td>
</tr>
<tr>
<td>45 min</td>
<td>111.5 (6.8)</td>
<td>108.7 (6.7)</td>
<td>2.73</td>
<td>0.12</td>
<td>NS</td>
</tr>
<tr>
<td>60 min</td>
<td>112.3 (6.8)</td>
<td>110.2 (7.1)</td>
<td>2.13</td>
<td>0.24</td>
<td>NS</td>
</tr>
<tr>
<td>90 min</td>
<td>113.9 (7.2)</td>
<td>111.3 (6.9)</td>
<td>2.57</td>
<td>0.16</td>
<td>NS</td>
</tr>
<tr>
<td>120 min</td>
<td>114.4 (6.0)</td>
<td>112.3 (6.7)</td>
<td>2.07</td>
<td>0.22</td>
<td>NS</td>
</tr>
<tr>
<td>180 min</td>
<td>115.5 (5.7)</td>
<td>113.6 (6.9)</td>
<td>1.93</td>
<td>0.24</td>
<td>NS</td>
</tr>
</tbody>
</table>

*Students unpaired t test*

**Diastolic Blood Pressure:**

**Table 12: Diastolic Blood Pressure Comparison**

<table>
<thead>
<tr>
<th>DBP (mm/Hg)</th>
<th>0.75% Ropivacaine (group R)</th>
<th>0.5% Bupivacaine (group B)</th>
<th>Mean Difference</th>
<th>P* Value</th>
<th>Sig</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0 min</td>
<td>74.9 (6.1)</td>
<td>75.3 (5.8)</td>
<td>0.47</td>
<td>0.76</td>
<td>NS</td>
</tr>
<tr>
<td>5 min</td>
<td>70.9 (5.5)</td>
<td>70.9 (4.8)</td>
<td>0.07</td>
<td>0.96</td>
<td>NS</td>
</tr>
<tr>
<td>10 min</td>
<td>68.2 (5.5)</td>
<td>68.9 (5.3)</td>
<td>0.67</td>
<td>0.63</td>
<td>NS</td>
</tr>
<tr>
<td>15 min</td>
<td>65.5 (6.4)</td>
<td>65.4 (6.3)</td>
<td>0.13</td>
<td>0.94</td>
<td>NS</td>
</tr>
<tr>
<td>20 min</td>
<td>65.7 (4.6)</td>
<td>65.6 (5.3)</td>
<td>0.13</td>
<td>0.92</td>
<td>NS</td>
</tr>
<tr>
<td>25 min</td>
<td>65.9 (5.0)</td>
<td>66.3 (4.7)</td>
<td>0.40</td>
<td>0.75</td>
<td>NS</td>
</tr>
<tr>
<td>30 min</td>
<td>68.3 (5.5)</td>
<td>67.8 (5.7)</td>
<td>0.53</td>
<td>0.71</td>
<td>NS</td>
</tr>
<tr>
<td>45 min</td>
<td>69.6 (6.1)</td>
<td>69.0 (6.3)</td>
<td>0.60</td>
<td>0.71</td>
<td>NS</td>
</tr>
<tr>
<td>60 min</td>
<td>71.0 (5.7)</td>
<td>70.1 (5.7)</td>
<td>0.87</td>
<td>0.56</td>
<td>NS</td>
</tr>
<tr>
<td>90 min</td>
<td>72.4 (6.1)</td>
<td>71.7 (5.9)</td>
<td>0.73</td>
<td>0.64</td>
<td>NS</td>
</tr>
<tr>
<td>120 min</td>
<td>73.7 (5.3)</td>
<td>72.5 (5.9)</td>
<td>1.20</td>
<td>0.41</td>
<td>NS</td>
</tr>
<tr>
<td>180 min</td>
<td>72.9 (5.3)</td>
<td>72.1 (5.7)</td>
<td>0.73</td>
<td>0.61</td>
<td>NS</td>
</tr>
</tbody>
</table>
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.

**Respiratory Rate:**

<table>
<thead>
<tr>
<th>Respiratory rate</th>
<th>0.75% Ropivacaine (group R)</th>
<th>0.5% Bupivacaine (group B)</th>
<th>Mean Difference</th>
<th>P* Value</th>
<th>Sig</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
<td>SD</td>
<td></td>
</tr>
<tr>
<td>0 min</td>
<td>14.3</td>
<td>1.3</td>
<td>14.1</td>
<td>1.1</td>
<td>0.13</td>
</tr>
<tr>
<td>5 min</td>
<td>14.4</td>
<td>1.2</td>
<td>14.4</td>
<td>1.2</td>
<td>0.03</td>
</tr>
<tr>
<td>10 min</td>
<td>15.1</td>
<td>1.3</td>
<td>15.1</td>
<td>1.3</td>
<td>0.03</td>
</tr>
<tr>
<td>15 min</td>
<td>14.8</td>
<td>1.2</td>
<td>14.9</td>
<td>1.2</td>
<td>0.10</td>
</tr>
<tr>
<td>20 min</td>
<td>15.0</td>
<td>0.8</td>
<td>15.0</td>
<td>0.9</td>
<td>0.07</td>
</tr>
<tr>
<td>25 min</td>
<td>14.8</td>
<td>0.8</td>
<td>14.9</td>
<td>0.9</td>
<td>0.07</td>
</tr>
<tr>
<td>30 min</td>
<td>14.4</td>
<td>1.1</td>
<td>14.5</td>
<td>1.1</td>
<td>0.10</td>
</tr>
<tr>
<td>45 min</td>
<td>15.0</td>
<td>1.0</td>
<td>15.0</td>
<td>1.0</td>
<td>0.03</td>
</tr>
<tr>
<td>60 min</td>
<td>15.0</td>
<td>1.1</td>
<td>14.9</td>
<td>1.0</td>
<td>0.13</td>
</tr>
<tr>
<td>90 min</td>
<td>15.0</td>
<td>0.9</td>
<td>14.9</td>
<td>0.8</td>
<td>0.10</td>
</tr>
<tr>
<td>120 min</td>
<td>14.6</td>
<td>0.9</td>
<td>14.6</td>
<td>0.9</td>
<td>0.07</td>
</tr>
<tr>
<td>180 min</td>
<td>14.5</td>
<td>0.9</td>
<td>14.5</td>
<td>0.9</td>
<td>0.00</td>
</tr>
</tbody>
</table>

Table 13: Respiratory Rate Comparison

The mean respiratory rate at 0, 5, 10, 15, 20, 25, 30, 45, 60, 90, 120 and 180 minutes in Ropivacaine group was compared to that of Bupivacaine group. The difference was not statistically significant at any of the time intervals with respect to respiratory rate.

**Side Effects:**

<table>
<thead>
<tr>
<th>Side Effects</th>
<th>0.75% Ropivacaine (group R)</th>
<th>0.5% Bupivacaine (group B)</th>
<th>P* Value, sig</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No.</td>
<td>%</td>
<td>No.</td>
</tr>
<tr>
<td>Nausea</td>
<td>1</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Vomiting</td>
<td>1</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Hypotension</td>
<td>2</td>
<td>7</td>
<td>3</td>
</tr>
</tbody>
</table>

Table 14: Side Effects

* Fisher, exact test
In Ropivacaine group (group R), 7% patients had hypotension, 3% had nausea and 3% had vomiting. In Bupivacaine group (group B), 10% patients had hypotension, 7% had nausea and 3% had vomiting. There was no significant difference between the two groups with regard to these side effects.

**DISCUSSION:** Epidural anaesthesia is widely practiced regional anaesthesia technique for many lower abdominal and lower limb surgeries. When compared to spinal anaesthesia, advantages of epidural anaesthesia lies in its decreased frequency of hypotension, no limitation on duration of surgery and effective post-operative analgesia.

The local anesthetic drugs currently available for epidural anaesthesia offer a varied degree of efficacy, from drugs of low potency such as Procaine to much potent drugs such as Etidocaine and Bupivacaine. Unfortunately, as the potency of local anesthetics increases so does their toxicity. Bupivacaine, one of the most widely utilized local anesthetics, has been the subject of intense investigation because of reports of sudden cardiovascular collapse in some patients.7-9

Ropivacaine (LEA-103) is a new amino-amide local anesthetic agent similar in structure to Bupivacaine. Ropivacaine is prepared as the s-isomer rather than a racemic mixture such as Bupivacaine. Previous studies involving the isomers of local anesthetics suggest that the systemic toxicity of the S-isomer of various compounds may be less than that of racemic preparations. Pharmacologic studies in isolated nerves,10 and intact animals have indicated that Ropivacaine possesses an anesthetic profile similar to that of Bupivacaine but with less potential for cardio toxicity than Bupivacaine.11,12

The aim of this study was to compare the effects of 0.75% Ropivacaine (Isobaric) with that of 0.5% Bupivacaine (isobaric) for epidural anaesthesia in elective lower abdominal and lower limb surgeries. Our study design consisted of 60 patients aged between 18-60 years, ASA physical status I, II undergoing epidural anesthesia for lower abdominal and lower limb surgeries. They were randomly divided into two groups. Group R (Ropivacaine group) patients received 20ml of 0.75% Ropivacaine and Group B (Bupivacaine group) received 20 ml of 0.5% Bupivacaine through epidural route. The following parameters were observed:

1. Sensory and motor blockade Onset, duration, highest level of sensory blockade.
2. Degree of motor blockade.
3. Recovery parameters- Time for complete sensory and motor recovery.
4. Haemodynamic changes over various time intervals.

In the present study the patients studied in both the groups did not vary much with respect to age, sex or weight. Majority of patients were in the age group between 18 to 60 years, with mean age of 36.3+/=10.0 years in Group R and 39.2+/=11.8 years in Group B. The mean sex distribution and the mean weight in both groups were also identical. These parameters were matched in both the groups to avoid changes in intraoperative and postoperative outcome of patients.

**ONSET OF SENSORY AND MOTOR BLOCKADE:** In our study, the mean time for onset of sensory block in Ropivacaine group was 10.2±1.6 minutes and 10. ±1.5 minutes in Bupivacaine group. The mean time for onset of motor block in Ropivacaine group was 29.5±3.0 minutes and in Bupivacaine group it was 28.9 ± 3.4 minutes. There was no statistically significant difference with regard to onset of sensory and motor block between the groups.
Brockway M S et al.\textsuperscript{5} who conducted a study comparing 0.5\%, 0.75\% and 1\% Ropivacaine with 0.5\% and 0.75\% Bupivacaine found no significant differences in the onset time of sensory or motor block.

Finucane B T et al.\textsuperscript{13} found no clinical difference in the onset of sensory or motor block when comparing 0.5\%, 0.75\% and 1\% Ropivacaine with 0.5\% Bupivacaine for epidural anaesthesia in patients undergoing abdominal hysterectomy.

Katz et al.\textsuperscript{14} also conducted a double blind comparison study of 0.5\% Bupivacaine with 0.75\% Ropivacaine administered epidurally. They found no difference in the onset of sensory or motor blockade similar to our results.

Wolff A P et al.\textsuperscript{15} found no difference in onset of sensory or motor block when comparing 0.5\%, 0.75\%, 1.0\% Ropivacaine or 0.5\% Bupivacaine administered extradurally in patients undergoing elective hip surgery.

Brown DL et al. 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 difference in onset of sensory or motor block.

The above findings were similar to that of our study. Thus we can conclude that there is no variation in the onset of sensory or motor blockade between 0.75\% Ropivacaine and 0.5\% Bupivacaine when administered through epidural route.

**HIGHEST LEVEL OF SENSORY BLOCK:** Highest level of sensory block was assessed by pin prick method using a blunt needle after the onset of motor block. In our study, patients of Ropivacaine group attained the following level of sensory block: 60\% attained T6 level, 33\% attained T7 level and 7\% attained T10 levels. In Bupivacaine group also 60\% attained T6 levels, followed by 27\% attaining T7 level and 10\% attaining T10 level. This implied that the sensory block level achieved by both groups were similar.

Brockway M S et al.\textsuperscript{5} conducted a study comparing 0.5\%, 0.75\% and 1\% Ropivacaine with 0.5\% and 0.75\% Bupivacaine. They found the mean upper limit of sensory block to be T6.

Katz et al.\textsuperscript{16} conducted a double blind comparison study of 0.5\% Bupivacaine with 0.75\% Ropivacaine administered epidurally. They found the median sensory block height to be between T4 for Bupivacaine and T5 for Ropivacaine. The higher block compared to our study could be related to higher volume of the drug used in their study.

From the above studies we can conclude that the highest level of sensory block is similar between Ropivacaine and Bupivacaine. These findings are similar to our study.

**DEGREE OF MOTOR BLOCKADE:** The degree of motor block was tested by modified Bromage scale. In our study, there was no difference in the degree of motor block between the two groups.

Brockway M S et al.\textsuperscript{5} Finucane B T et al.\textsuperscript{15} Katz et al.\textsuperscript{16} and Wolff A P et al.\textsuperscript{17} found the degree of motor blockade assessed by modified Bromage scale to be grade 3 in both the Ropivacaine and Bupivacaine group. This finding was similar to our study.

**DURATION OF MOTOR BLOCK:** Duration of motor blockade was assessed from the time of administration of the drug to complete motor recovery (Bromage scale- 0). In our study, the mean duration of motor block in Ropivacaine group was 241.7±22.8 minutes, whereas in Bupivacaine group it was 282.3 ± 21.0 minutes. This difference was statistically significant (\(p < 0.001\))
Brockway et al.\textsuperscript{5} compared 0.5%, 0.75% and 1% Ropivacaine 15ml with 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, shorter duration and less intense motor block than Bupivacaine.\textsuperscript{19}

Wolff A.P et al.\textsuperscript{17} studied 126 patients undergoing elective hip surgery; they received 20ml of 0.5%, 0.75%, 1.0% Ropivacaine or 0.5% Bupivacaine extradurally in a double-blind design. Similar to our study, they found that return of motor function was earlier with Ropivacaine compared to Bupivacaine.

From the above studies we can conclude that the duration of motor block is shorter with Ropivacaine than Bupivacaine.

**DURATION OF SENSORY ANALGESIA:** In our study, the mean duration of sensory analgesia in Ropivacaine group was \(389.7 \pm 16.5\) minutes. In Bupivacaine group the mean duration was \(391.1 \pm 15.1\) minutes, indicating that there was no difference in the duration of sensory analgesia among the two groups. In studies conducted by Brockway M S et al.\textsuperscript{5}, Finucane B T et al.\textsuperscript{13} Katz et al.\textsuperscript{14} Wolff A.P et al.\textsuperscript{15} and Brown DL\textsuperscript{16} et al it was found that there was no significant difference in duration of sensory analgesia when comparing Ropivacaine with Bupivacaine.

**HAEMODYNAMIC CHANGES (HEART RATE AND BLOOD PRESSURE):** In our study, the two groups did not differ significantly with respect to heart rate at any time interval. There were no episodes of bradycardia in either group. The changes in mean systolic blood pressure and diastolic blood pressure at any time interval were statistically and clinically insignificant. 2 patients in Ropivacaine group experienced hypotension, whereas 3 patients experienced hypotension in Bupivacaine group. Hypotension was corrected by small doses of Inj. Ephedrine.

In the study conducted by Brockway M S et al.\textsuperscript{5} the systolic and diastolic blood pressures decreased by about 20% from the baseline values over the first 20 minutes, whereas the heart rate tended to increase over first 15 minutes and there after decrease to slightly less than the baseline. This was similar to our study. There was no significant difference between the two groups.

A study by Wolff A.P et al.\textsuperscript{17} comparing extradural Ropivacaine and Bupivacaine in hip surgery showed that Systolic and diastolic arterial pressures decreased in all groups. Treatment with ephedrine or atropine was required more often in the 0.75% Ropivacaine group and in the 1% Ropivacaine group compared with the 0.5% Ropivacaine group and the 0.5% Bupivacaine group.

Finucane B T et al.\textsuperscript{13} and Brown DL\textsuperscript{14} et al and cekmen et al.\textsuperscript{15} found that the cardiovascular changes with respect to heart rate and blood pressure were similar in both Bupivacaine and Ropivacaine group.

From the above discussion we can conclude that epidural administration of Ropivacaine produces similar changes in haemodynamic parameters as that of Bupivacaine. These findings are similar to our study.

**Respiratory Rate:** None of our patients experienced respiratory depression and the mean RR between both the groups was statistically insignificant. Our study found no changes in the respiratory rates between the two groups which corroborated with the other studies conducted by Brockway M S et al.\textsuperscript{5} Finucane B T et al.\textsuperscript{15} Katz et al.\textsuperscript{16} Wolff A.P.\textsuperscript{17} and Brown DL et al.\textsuperscript{18} cekmen et al.\textsuperscript{19}
SIDE EFFECTS: In Ropivacaine group, 7% patients had hypotension, 3% had nausea and 3% had vomiting. In Bupivacaine group, 10% patients had hypotension, 7% had nausea and 3% had vomiting indicating no significant difference between the two groups with regard to these side effects.

Brockway M S et al.\(^5\) found similar number of side effects in each group, the commonest being backache (23%) followed by nausea (14%) and vomiting (2%). The most common adverse events reported in the study conducted by Finucane B T et al.\(^1\) were nausea, vomiting, hypotension, headache and backache.

The reported side effects in the above studies were similar in both groups as was noticed in to our study.

CONCLUSION: Based on the present clinical comparative study, we conclude that Isoobaric 0.75% Ropivacaine, when administered through epidural route, provides adequate anaesthesia for lower abdominal and lower limb surgeries and has a shorter duration of motor block 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, with no significant differences between the two groups with respect to haemodynamic changes.

Hence Ropivacaine can be used as a safe alternative to Bupivacaine for epidural anaesthesia in lower abdominal and lower limb surgeries. The shorter duration of motor block with Ropivacaine suggest that it could be effectively used for early mobilization of patients in the post-operative period.

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13. Finucane B T, Sandler A N et al, A double blind comparison of Ropivacaine 0.5%, 0.75%, 1% and Bupivacaine 0.5%, injected epidurally in patients undergoing abdominal hysterectomy. Can J Anaesth, 1996; 43; 5:442-9.
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