Comparison of isobaric Ropivacaine and Levobupivacaine in patients undergoing lower abdominal surgery under spinal anesthesia

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ABSTRACT
This study was performed to compare the anesthetic efficacy and safety of two local anesthetic agents ropivacaine and levobupivacaine, in patients undergoing lower abdominal surgery. Thirty patients, ASA I-II were randomized to receive an intrathecal injection of either of two local anesthetic solutions. Group I (n = 15) received 3 ml of isobaric levobupivacaine 5 mg/ml (15 mg) whereas Group II (n = 15) received 3 ml of isobaric ropivacaine 5 mg/ml (15 mg). The onset and duration of sensory block at dermatome level T8, maximum upper spread of sensory block, time for 2-segment regression of sensory block as well as the onset, intensity and duration of motor block were recorded, as were any adverse effects. Levobupivacaine has a longer duration of sensory and motor block than ropivacaine. Peak sensory level achieved by both is same (T6-T8). No adverse events like nausea, vomiting, tremor, and decrease in oxygen saturation.

Keywords: Ropivacaine, levobupivacaine, sensory, motor, intrathecal.

INTRODUCTION
Spinal anesthesia is widely used, providing a fast onset and effective sensory and motor blockade. Bupivacaine a commonly used drug is available as a racemic mixture of its enantiomers, dextrobupivacaine and levobupivacaine [1]. In the last few years, its pure S-enantiomers, ropivacaine and levobupivacaine, have been introduced into clinical practice because of their lower toxic effects for heart and central nervous system [2]. The impetus for the development of these newer stereoselective, single enantiomer amide local anaesthetic agents, ropivacaine and levobupivacaine, came from reports of fatal cardiac toxicity in pregnant women receiving epidural bupivacaine and etidocaine for Caesarean section [3]. Ropivacaine is well tolerated after intrathecal use, and was found to have a shorter duration of action than bupivacaine [4]. Racemic bupivacaine and levobupivacaine, its S enantiomer, appear to produce a very similar pattern of the block [5].

AIMS AND OBJECTIVES
The present study was done to compare the safety and efficacy of either plain ropivacaine 15 mg or plain levobupivacaine 15 mg in patients undergoing lower abdominal surgery under spinal anesthesia.

METHODS
A randomised double blind study was carried out in 30 ASA grade1 and 2 adult patients of both sexes between 18-60 years of age under going lower abdominal surgery of 1.5 to 2 hours duration under spinal
anaesthesia at tertiary level hospital, after obtaining an informed written consent from every patient. Patients who met the inclusion criteria were divided into two groups randomly.

**Inclusion criteria:**
- Either sex
- ASA grade I and II
- Age group 18-60 years

**Exclusion criteria:**
1. Any contradiction for spinal anaesthesia
2. Bleeding disorder or an anticoagulant therapy
3. Local sepsis around spine.
4. Patient with increased intracranial tension
5. Spinal deformity
6. Psychiatric illness/uncooperative patients
7. Neurological deficits, history of epilepsy
8. Patient refusal
9. Patient not able to understand pain assessment test.
10. Patient with history of drug allergy
11. Patient with cardiovascular disease or mental retardation

**Pre-operative evaluation**
Thorough pre-operative checkup with detailed history and physical examination was done a day before surgery. All patients were thoroughly investigated as per the requirement of the surgery apart from routine investigations including the following:

- Haemoglobin
- Bleeding time
- Clotting time
- Blood sugar
- Complete urine routine
- ECG Chest X-Ray
  Special investigations were done as per need.
- A written informed consent was taken.
- Spinal block procedure and Visual analogue scale score for pain assessment was explained to the patient.
- All patients were kept fasting overnight.
- Tab Ranitidine (150mg) and Tab Alprax (0.25mg) was given to all the patients in night and repeated in early morning on day before surgery.

**Group allocation:** Using a sealed envelope technique, patients were randomly allocated to two groups:

a) Group I - 15 patients - isobaric laevobupivacaine (0.5%)
b) Group II - 15 patients - isobaric ropivacaine (0.75%)

Total drug volume injected: 3ml.

All injections were prepared in an adjacent room by a supervisor not involved in the subsequent evaluation of the study-patient.

**Anaesthetic Technique:** After taking the patient in operation theatre, a multipara vital monitor was attached and preoperative pulse rate, blood pressure and oxygen saturation were recorded and treated as baseline. Anaesthesia trolley, anaesthesia circuit and all the resuscitation equipments and drugs were kept ready. A
suitable wide bore i.v line was taken with 18G intracath. Preloading was done with ringer lactate 15 ml/kg body weight, 20 minutes before surgery.

Spinal anaesthesia was given in lateral position under all aseptic precautions at L,3-4 intervertebral space. After confirming the free flow of CSF, the patients were administered levobupivacaine (0.5%) in group I and ropivacaine (0.5%) in group II. The total volume injected was 3 ml. Then patient was reverted back to supine position immediately. Following observations were made:

- Time to onset of motor block (Bromage 3)
- Duration of motor block
- Onset of sensory block
- Duration of sensory block
- Peak sensory levels achieved
- Time taken to reach peak sensory level
- Time taken for two segment regression

All the patients will be given maintenance fluids. Blood loss will be replaced if excessive.

**Intraoperative monitoring:** The following vitals were recorded

- Blood pressure
- Pulse rate
- Oxygen saturation
- Respiratory rate.

Heart rate and arterial pressure were recorded before intrathecal injection, 5 minutes after the intrathecal drug administration, and thereafter every 10 minutes till the end of the operation and one hour after the end of the operation, at the ward. Any hypotension (mean arterial pressure lower than 60 mmHg) or bradycardia (heart rate< 50/min) incidents were treated with mepherteramine 5 mg or atropine 0.5 mg increments. A decrease in SpO2 to < 93% was defined as hypoxia and treated with supplemental oxygen via Venturi-mask 40% at 10l/min.

**Sensory blockade:** The level of sensory block was evaluated by loss of pinprick sensation. S1, L3, T12, T10, T8, T6 or higher (T4) dermatomes were checked bilaterally. C5-6 was used as baseline point for normal sensation. Sensory onset was taken as loss of pinprick sensations with 23 gauge needle at T10 level and the time was noted down. The test was performed every 5 minutes till loss of discrimination to pinprick for the first 60 minutes and then every 10 minutes until its full recovery. The duration of sensory blockade was defined as the interval from intrathecal administration to the point of complete resolution of the sensory block. Two segment regression of the block, peak sensory levels achieved and time taken to reach peak sensory level were also noted.

**Motor blockade:** Motor onset after the intrathecal administration will be taken as achievement of bromage score 1 and will be considered full after score reached grade 3. The duration of motor blockade was defined as the interval from intrathecal administration to the point in which the Bromage score was back to zero. Time taken to achieve both the grades was noted down with maximum Bromage grade and duration of motor blockade was also noted down.

Bromage score: Grade 0: no motor blockade, Grade 1: unable to raise extended leg, Grade 2: unable to flex knee, Grade 3: unable to flex ankle.

Bradycardia: It is defined as fall in pulse rate >20% of the base line will be treated with injection Atropine as per need.

Hypotension: it is defined as >20% fall in systolic and diastolic blood pressure from the baseline and will be treated with bolus i.v fluids (250ml) and if required will be treated with Mephentermine 5 mg intravenously.

**Post operative monitoring:** After the surgery is over, sensory levels were noted again for regression of the block and vitals were recorded.
Analgesia: The degree of analgesia was determined by visual analogue score. It is a 10 cm scale with a mark from 0-10 with 1 cm apart. The mark 0 denotes no pain and the mark 10 denotes worst pain. The patient will be asked to mark a point on the scale which corresponds with the intensity of pain he/she feels. 0 – No pain, 1-2 – Mild pain, 3-4- Moderate pain, 5-7– Severe pain, 8-10 – Worst pain. 

**Rescue analgesia:** When VAS will be ≥ 4, inj. Diclofenac Sodium 1.5mg/kg (max 75mg) was given intramuscularly as rescue analgesia. Inj. Diclofenac Sodium was repeated if the patient complained of pain(VAS=4) in next 24 hours. The total no. of doses of rescue analgesic required in 24 hr. will be compared in both the groups. The occurrence of adverse events, including bradycardia, hypotension, decrease in oxygen saturation SpO2 < 93%, tremor, as well as nausea and vomiting were also recorded. A p value of 0.05 was considered significant and chi square test was used for categorical variables.

**RESULTS**

Total 30 patients participated in the study. Demographic features of both the groups were comparable. Both groups were comparable in terms of age, height, weight, gender, body mass index (BMI), and ASA physical status [Table 1]. Time of surgery was also comparable.

**Table 1: Patient characteristics and duration of surgery for the two groups**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Levobupivacaine Group (N=15)</th>
<th>Ropivacaine Group (N=15)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (in years)</td>
<td>42±8</td>
<td>40±10</td>
<td></td>
</tr>
<tr>
<td>Weight (kgs)</td>
<td>67±11</td>
<td>72±9</td>
<td></td>
</tr>
<tr>
<td>Height (in cm)</td>
<td>172±7</td>
<td>176±9</td>
<td></td>
</tr>
<tr>
<td>ASA I-II</td>
<td>12/3</td>
<td>12/3</td>
<td></td>
</tr>
<tr>
<td>BMI (Kg/m²)</td>
<td>26±3</td>
<td>24±4</td>
<td></td>
</tr>
<tr>
<td>Sex (M/F)</td>
<td>10/5</td>
<td>11/4</td>
<td></td>
</tr>
<tr>
<td>Duration of surgery (min)</td>
<td>65±35</td>
<td>62±32</td>
<td></td>
</tr>
</tbody>
</table>

Peak sensory level achieved was similar in both the groups, i.e. T6-T8 [Table 2]. Time to reach onset and peak sensory level was delayed in Ropivacaine group but difference was insignificant (P> 0.05) [Table 2]. Duration of sensory block and time to 2-segment regression was more prolonged in Levobupivacaine group (P<0.05).

**Table 2: Characteristics of sensory block on intrathecal admiinstration of 15 mg of levobupivacaine and 15 mg of ropivacaine**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Levobupivacaine Group (N=15)</th>
<th>Ropivacaine Group (N=15)</th>
<th>Group</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Onset (min.)</td>
<td>12.13±3.71</td>
<td>14.4±4.04</td>
<td></td>
<td>0.62</td>
</tr>
<tr>
<td>Peak sensory level</td>
<td>T6-T8</td>
<td>T6-T8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time to reach peak sensory level</td>
<td>12.33±4.18</td>
<td>13.2±3.64</td>
<td></td>
<td>0.31</td>
</tr>
<tr>
<td>Duration of sensory block (mins)</td>
<td>267.4±50.84</td>
<td>224.2±27.72</td>
<td></td>
<td>0.01</td>
</tr>
<tr>
<td>Time to 2-segment regression (T8-T10)</td>
<td>69.8±6.61</td>
<td>62.06±3.41</td>
<td></td>
<td>0.01</td>
</tr>
</tbody>
</table>
Table 3 shows significantly more duration of motor block in Levobupivacaine group (P<0.05).

**Table 3: Characteristics of motor block on intrathecal administration of 15 mg of levobupivacaine and 15 mg of ropivacaine**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Levobupivacaine Group (N=15)</th>
<th>Ropivacaine Group (N=15)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Onset (min.)</td>
<td>12.88±3.99</td>
<td>12.8±3.16</td>
<td>0.19</td>
</tr>
<tr>
<td>Duration (min.)</td>
<td>313.2±40.11</td>
<td>274.06±10.36</td>
<td>0.00</td>
</tr>
</tbody>
</table>

**DISCUSSION**

This study shows that the intrathecal administration of either 15 mg ropivacaine or 15 mg levobupivacaine was well tolerated and an adequate block for lower abdominal surgery was achieved in all patients in each group.

In this study, Levobupivacaine had longer duration of sensory block and time to 2-segment regression (T8-T10) when compared with ropivacaine group. Similar results were observed by Kim et al [6] and Luck et al [7]. However, Lim et al didn’t find any difference between ropivacaine and levobupivacaine [8]. Longer duration of motor block was noticed with levobupivacaine group (p<0.05). Similar results were noted by others as well [7,9]. However, contradictory observations was recorded by others [6,8].

No adverse events like nausea, vomiting, tremor, and decrease in oxygen saturation SpO2 < 93% were noted. There was only a slight reduction in mean arterial blood pressures after the spinal injection in both groups similar to other studies [9]. None of the groups required the use of mephenteramine for hypotension.

**CONCLUSION**

Intrathecal ropivacaine may prove useful when surgical anesthesia of a similar quality but of a shorter duration than levobupivacaine is required in patients with cardiovascular instability in whom bupivacaine is undesirable.

The sample size of our study was small, more studies with larger sample size are required for comparison of intrathecal levobupivacaine and ropivacaine.

**REFERENCES**


