



**ORIGINAL RESEARCH PAPER**

**Anesthesiology**

**“ROPIVACAINE 0.5% PLAIN AND LEVOBUPIVACAINE 0.5% PLAIN FOR LOWER ABDOMINAL SURGERY UNDER SPINAL ANAESTHESIA : A COMPARATIVE STUDY”**

**KEY WORDS:** Ropivacaine, levobupivacaine, sensory, motor, spinal

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**ABSTRACT**

**Background:** This study compare the anesthetic efficacy and safety of two local anesthetic agents ropivacaine 0.5% plain and levobupivacaine 0.5% plain, in patients undergoing lower abdominal surgery under spinal anaesthesia. Eighty patients, ASA I-II were randomized to receive an either of two local anesthetic solutions. Group L (n =40) received 3 ml of 0.5% plain levobupivacaine 5 mg/ml (15 mg) whereas Group R (n = 40) received 3 ml of 0.5% plain 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 effect like,nausea, vomiting, bradycardia, shivering, hypotension. Levobupivacaine has a longer duration of sensory and motor block than ropivacaine. Peak sensory level achieved by both is same (T6-T8).

**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.<sup>1</sup> 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.<sup>2</sup> Levobupivacaine is an amino-amide local anaesthetic drug belonging to the family of n-alkyl substituted pipercoloxylide. It is the S-enantiomer of bupivacaine. Compared to bupivacaine, levo-bupivacaine is associated with less vasodilatation and has a longer duration of action. It is approximately 13 percent less potent (by molarity) than racemic bupivacaine. Levobupivacaine the pure S-enantiomer of racemic bupivacaine, was developed as an alternative to bupivacaine, to achieve a lower risk of cardiotoxicity than bupivacaine.

Ropivacaine is a new amino-amide local anaesthetic drug. Ropivacaine is well tolerated after intrathecal use, and was found to have a shorter duration of action than bupivacaine.<sup>3</sup> Racemic bupivacaine and levobupivacaine, its S enantiomer, appear to produce a very similar pattern of the block.<sup>4</sup>

In equi-potent concentrations the degree of motor blockade is less pronounced with ropivacaine than bupivacaine and there is a greater propensity for blocking A and C fibres. If true, this may prove to be advantageous in obstetric patients in labour and in other suffering from acute and chronic pain.<sup>5</sup>

**Materials and method**

The present study entitled “Ropivacaine 0.5% plain, and levobupivacaine 0.5% plain for lower abdominal surgery-under spinal anaesthesia: A comparative study” has been conducted in the department of anaesthesiology after approval from the ethical committee. It was a prospective study conducted with a sample size of 80 patients undergoing lower abdominal surgeries. Patients were randomly allocated in group L receiving Levobupivacaine 0.5% plain 3ml and group R receiving Ropivacaine 0.5% plain 3ml with 40 patients in each group. Each patient received 15mg of the drug allotted.

**Inclusion criteria**

- ASA grade I& II, Age group 18-60 yrs, Patients undergoing elective lower abdominal surgeries

**Exclusion criteria –**

1. Patient with contraindication to spinal anaesthesia. Patients with cardiovascular, Renal, or Hepatic diseases.
2. Patient with known history of allergy to local anaesthetic, Incapability or refusing to be enrolled.
3. Bleeding and coagulation disorder.
4. Current psychiatric or respiratory disorders.
5. Patients with morbid obesity.

**Pre-operative Assessment**

Pre-operative assessment of the patient including history, clinical examination and relevant investigations (Hb%, TLC, DLC, Urine examination, BT, CT, Platelet count, Blood sugar, Blood Urea, Serum Creatinine and electrolytes, X-ray chest, ECG) were done. The patients were explained about the procedure and consent was taken from all the patients. All patients were kept fasting for 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.

**Technique & Monitoring**

IV access was established after the arrival of the patient in operation theatre. Baseline pulse rate, systolic blood pressure, diastolic blood pressure, mean blood pressure, respiratory rate, SpO<sub>2</sub> were checked and recorded and ECG monitoring were done by multipara monitor. All patients were preloading with one liter Ringer Lactate solution. Lidocaine 1% 3ml was used to infiltrate subcutaneous tissues at L3-L4 interspace for lumbar puncture. After all aseptic precautions a 25 G spinal Quincke needle was inserted and subarachnoid space was identified by sudden loss of resistance and free flow of CSF, 3ml of the study drug was injected intrathecally in lateral decubitus position and the patient was immediately changed to supine position.

Adequate block to initiate surgery was defined as sensory block bilaterally to dermatome T6. The time taken to achieve this level of anaesthesia is the primary efficacy measure. Secondary measures included: peak block height, time to reach peak block, time to two-segment regression and total duration of sensory block.

Sensory block was measured by using spirit swab or ice cold saline at 0, 2, 5, 10, 15, 20, 25, 30 and 60 min post injection and every 30 min thereafter until complete regression of sensory block was observed. The onset, degree and duration of motor block was measured in both legs by using a modified Bromage scale and scored as: grade 0-no paralysis, full flexion of hips, knees, and

ankles; grade 1-inability to raise extended leg, able to move knees; grade 2-inability to flex knees, able to flex ankles; or grade 3-inability to move any portion of the lower limb.

Motor block measured at 0, 10, 20 and 30 min post dose (pre surgery) and every 30 min post-surgery until the patient returned to a score of zero in both legs.

Hemodynamic variables were recorded at baseline (pre injection), at the end of injection, and at 30-min intervals until complete resolution of the sensory block. Hypotension was defined as a decrease in systolic blood pressure of at least 30%, of the baseline SBP and was treated with IV fluids or vasopressor drugs by the attending anesthesiologist. Bradycardia: It is defined as fall in pulse rate >20% of the base line will be treated with injection Atropine as per need. Any other adverse event was also recorded during the study.

**Rescue analgesia:** The degree of analgesia was determined by visual analogue score. It is a 10cm scale with a mark from 0-10 with 1 cm apart. The mark 0 denotes no pain and 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. When VAS will be  $\geq 4$ , inj. Diclofenac Sodium 1mg/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. A p value of 0.05 was considered significant and chi square test was used for categorical variables.

**Observations and results**

Total 80 patients participated in the study. Demographic features of both the groups were comparable. Both groups were comparable in terms of age, weight, gender, and ASA physical status and time of surgery was also comparable.

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

**Levobupivacaine Group (N=40) Ropivacaine Group (N=40)**

	Group L	Group R
Age (in years)	42.46± 11.20	41.6±11.1
Weight (kgs)	60.41±8.94	59.24±9.11
ASA I-II	30/10	30/10
Sex (M/F)	23/17	25/15
Duration of surgery (min)	67.4±17.9	67.6±18.92

**Table 2:** Characteristics of sensory & motor block on intrathecal administration of 15 mg of levobupivacaine and 15 mg of ropivacaine

Parameter	Group L	Group R	P value
Onset (min.) of sensory block	10.5±2.57	11.51±2.69	0.0249
Duration of sensory block	254.92±23.37	199.75±24.46	0.0012
Time to 2-segment regression ( T8-T10)	65.52±3.048	60.75±3.437	0.0154
Onset of motor block	10.5±2.048	11.75±2.43	0.0107
Duration of motor block	281.5±16.1	262.49±9.821	0.001

Onset of sensory blockade was significant faster in Group L (10.5 ± 2.571 min) as compared to Group R (11.512 ± 2.694). Duration of effective analgesia was 254.923 ± 23.378 min and 199.75 ± 24.467 min in Group L and Group R, respectively. It was significantly prolonged in Group L as compared and Group R (p=0.0012, <0.05), Two segment regression was significantly longer in Group L (65.52±3.048 min) as compared to Group R (60.75 ± 3.437min). (p=0.0154). Onset of motor blockade was significantly faster in Group L (10.5 ± 2.048 min) as compared to Group R (11.75 ± 2.437 min). Duration of motor blockade in Group L (281.5 ± 16.1)min had longer duration of block than group R (262.49 ± 9.821). It was significantly prolonged in Group L

as compared to group R (p=0.001, <0.05).

**Discussion**

The present study was carried out to compare safety and efficacy of ropivacaine and levobupivacaine in patients undergoing lower abdominal surgeries in respect to onset, duration, level of sensory and motor blockade produced by the two drugs. **Mantouvalou . M et al(2008)**<sup>6</sup> found that sensory onset time was 13 ± 9 min for the bupivacaine group, 12 ± 7 min for the ropivacaine group and 11±6 min for the levobupivacaine group. Duration of sensory block more in levobupivacaine (230±74)min as compared to ropivacaine (220±30)min. Onset of motor block faster in the bupivacaine group (group A) : 8 ± 5 min compared with 12 ± 5 min in the ropivacaine group (group B) and 11 ± 7 min in the levobupivacaine group (group C) (F < 0.05). Ropivacaine presented a shorter duration of motor block than bupivacaine and levobupivacaine (269 ± 20 min, 278 ± 70 mm and 273 ± 80 min, respectively) (P < 0.05). Maximum number of patients had T8 level of sensory blockade. But the highest level of sensory block achieved was T4 in both levobupivacaine and ropivacaine groups. Time for 2-segment regression of sensory blockade (from T8-T10) was 69 ± 16 for group bupivacaine, 60 ± 9 for group ropivacaine and 65 ± 11 for group levobupivacaine.

**Glaser C. et al(2001)**<sup>7</sup> found that mean onset time for plain levobupivacaine (11±6 min) was faster as compared to bupivacaine(13±8 min), duration of sensory block in isobaric levobupivacaine (228±77 min) was shorter than isobaric bupivacaine(237±88 min), onset time for motor block in the levobupivacaine group was 11±6 min, duration of motor block in levobupivacaine group (280±84 min) was shorter than bupivacaine group(284±80 min).

**Malinovsky J.M. et al(2000)**<sup>8</sup> found that the onset time for sensory blockade for ropivacaine (13±8min) was significantly longer than that of bupivacaine(11±7min), onset time for motor blockade for ropivacaine was in range of 25±12 min and for bupivacaine was in a range of 24±17 min, duration of motor blockade for ropivacaine was in range 165±62 min and for bupivacaine was in a range of 184±59 min. Mean time for two segment regression was faster in ropivacaine group (24±9) min as compared to Levobupivacaine group(33±16)min.

**Vanna O. et al (2006)**<sup>9</sup> found onset time for sensory block at T10 for levobupivacaine (10±4.3 min) was longer as compared to bupivacaine (7.3±3.6 min), duration of sensory blockade in group levobupivacaine (256±48.1min) was longer than bupivacaine group (215.1±50.8min). Duration of motor block in Levobupivacaine (232.1±51.8 min) was longer in comparison to bupivacaine group (192.9±50.9min). Highest level of block produced in the levobupivacaine group was T4 as compared to T6 in the bupivacaine group.

**Sen H. et al(2008)**<sup>10</sup> found sensory onset time was faster for plain levobupivacaine (15mg) group (7.5 min) as compared to plain levobupivacaine (12.5 mg) group (12. min) and hyperbaric levobupivacaine (13.5 mg) group. time for two segment regression was longer in the group 3 levobupivacaine (32.5 min) as compared to group 2 levobupivacaine (25min) and group 1 hyperbaric levobupivacaine (32.5min).

**Sen H. et al(2009)**<sup>11</sup> found sensory onset time for plain levobupivacaine (18.5 min) was longer than hyperbaric levobupivacaine (10 min), time for two segment regression for plain levobupivacaine (30 min) was similar to that of heavy levobupivacaine (30min).

**Fattorini F. et al(2006)**<sup>12</sup> found sensory onset time for levobupivacaine (12±6 min) was longer as compared to bupivacaine (9±5 min), duration of sensory block longer in the levobupivacaine(391±96min) group as compared to bupivacaine(381±105 min) group, motor onset time for levobupivacaine(11±6 min) was longer as compared to bupivacaine(8±4 min) group, duration of motor block was longer in levobupivacaine (256±86 min) group as compared to

bupivacaine(245±86 min) group, maximal upper spread of sensory block was T4 in both levobupivacaine and bupivacaine groups, and most patients had achieved block of level T8.

**Erdil F. et al(2009)<sup>13</sup>** found onset time of sensory block was longer in the levobupivacaine (26.4±7.2 min) group as compared to bupivacaine group (21.8±5.7 min). duration of sensory block was longer in the levobupivacaine group (245.5±30.1 min) as compared to bupivacaine group (239.7±32.9 min). Onset time for motor block was longer in the levobupivacaine group(19.1±5.4 min) compared to bupivacaine group(9.5±4.2 min). Duration of motor block was longer in the levobupivacaine group (145.6±18.5 min) as compared to bupivacaine group(139.9±22.4 mm). This difference is due to low dose of drug (7.5 mg) used while we used 15 mg in our study.maximum level of sensory block achieved by bupivacaine group (T4) was higher than levobupivacaine group (T5). Two segment regression was longer in the levobupivacaine group (80.3±9.9 mm) as compared to bupivacaine group (78.3±10.9 mm)

**Vimoluck S. et al(2011)<sup>14</sup>** found that time for onset for sensory block was longer in the plain levobupivacaine group(10±7.1 min) as compared to hyperbaric levobupivacaine group(9.1±3.7 min).

Duration of sensory block was longer in the isobaric levobupivacaine group (160±50.4 min) as compared to hyperbaric levobupivacaine group (158.9±60.9 min),onset time for motor block was longer in the isobaric levobupivacaine group (13.6±7.3 min) as compared to hyperbaric levobupivacaine group (8.2±6.8 min). both hyperbaric and isobaric levobupivacaine groups had maximal level of sensory block of T4,two segment regression was longer in the hyperbaric levobupivacaine group(110.8±42.9 mm) as compared to isobaric levobupivacaine group(98.3±29.5 min).

### Summary

Both the groups were comparable in demographic profile. Onset of sensory blockade was significantly faster in Group L as compared to Group R(p=0.0249). Most of the patients in group L and group R had T8 level sensory block. Maximum level of block was T4 in both the groups. Duration of effective analgesia was 254.923±23.378 min and 199.75±24.467 min in Group L and Group R, respectively. It was significantly prolonged in Group L as compared and Group R (p=0.0012, <0.05) Two segment regression was significantly longer in Group L as compared to Group R(p=0.0154).

Onset of motor blockade was significantly faster in Group L as compared to Group R(p=0.0107). Group L (281.5±16.1) min had longer duration of block than group R(262.49±9.821). It was significantly prolonged in Group L as compared to Group R (p=0.0010, <0.05)

Incidence of nausea/vomiting, bradycardia shivering and hypotension were comparable in both the groups.

### CONCLUSION

Intrathecal administration of either 15 mg ropivacaine or 15 mg of levobupivacaine was well tolerated and provided similar, effective anaesthesia for lower abdominal surgery. In equimilligram dose ropivacaine produced a shorter duration of motor block and sensory block than levobupivacaine.

Thus Levobupivacaine has a longer duration of sensory and motor block than ropivacaine. Intrathecal ropivacaine proved to be a better choice when surgical anaesthesia of similar quality but of a shorter duration than that of levobupivacaine is desired.

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