Original Research Article

Indian Journal of Anesthesia and Analgesia
November – December 2020;7(6)
DOI: http://dx.doi.org/10.21088/ijaa.2349.8471.7620.78

Levobupivacaine vs Ropivacaine in Spinal Anesthesia for Lower Abdominal and Lower Limb Surgeries: A Comparative Study

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How to cite this article:

Mohammed Yahya, Vikas Joshi, Abdul Azim Makandar. Levobupivacaine vs Ropivacaine in Spinal Anesthesia for Lower Abdominal and Lower Limb Surgeries: A Comparative Study. Indian J Anesth Analg. 2020;7(6):1411–1415.

Abstract

Background: Till recently Bupivacaine 0.5% Heavy was the only drug used for spinal anesthesia after the discontinuation of Lidocaine's intrathecal use. The last few years, its pure S (-) enantiomers, ropivacaine and levobupivacaine, have been introduced into clinical practice because of their lower cardiac and central nervous system toxic effects. This study was performed to compare the anesthetic efficacy and safety of the ropivacaine and levobupivacaine, in patients undergoing lower abdominal and lower limb surgery.

Methods: 60 patients of ASA physical status I–II between the ages of 20–60 years, scheduled for spinal anesthesia were prospectively enrolled in our randomized controlled trial. They were divided into 2 groups, R and L, of 30 pts each. 3.0ml (15mg) of 0.5% isobaric ropivacaine in study group R and 3.0ml (15mg) of 0.5% isobaric levobupivacaine in study group L was given.

Results: The mean Time of onset sensory blockade and Time of onset of Motor Blockade was significantly high in Group R as compare to Group L, whereas mean Duration of sensory blockade, mean Duration of motor blockade and mean Duration of analgesia were significantly less in Group R as compare to Group L ($P<0.001$).

Conclusion: Intrathecal administration of either 15 mg ropivacaine or 15 mg levobupivacaine was well-tolerated and provided similar, effective anesthesia for lower limb and lower abdominal surgery. Intrathecal ropivacaine may prove useful when surgical anesthesia of a similar quality but of a shorter duration is desired.

Keywords: Levobupivacaine; Ropivacaine; Spinal Anesthesia.

Introduction

Spinal anesthesia is a safe, reliable and inexpensive technique with the advantage of providing surgical anesthesia and prolonged post operative pain relief by using various adjuvant drugs along with local anesthetic agents.[1] Bupivacaine is available as a racemic mixture of its enantiomers, dextrobupivacaine and levobupivacaine.[2] 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.[3–5] Ropivacaine is an amide local anesthetic agent, less lipophilic than bupivacaine and is less likely to penetrate large myelinated motor fibres, resulting in a relatively reduced motor blockade. The reduced lipophilicity is also associated with decreased potential for central nervous system toxicity and cardiotoxicity,[6] and when compared to bupivacaine, the lower lipid solubility of ropivacaine would predict that it is likely to produce a greater differential block

of sensory and motor function than bupivacaine.[7] This feature is particularly useful when early mobilization is important to enhance recovery. Levobupivacaine is an S (-) enantiomer of the long acting local anesthetic bupivacaine having less cardiotoxic and central nervous system effects in comparison with both R (+) bupivacaine and bupivacaine. Clinical studies have shown that ropivacaine and levobupivacaine are effective in providing analgesia and anesthesia when used for upper or lower limb surgery, but little information is available regarding their comparable clinical profile, with regards to onset time and duration of sensory and motor blockade, and any side effects. In the present study we have compared the spinal effects of isobaric levobupivacaine 15mg, with isobaric ropivacaine 15mg in patients undergoing lower abdominal and lower limb surgeries.

Material and Methods

After approval of the Institutional Ethical Committee and written informed consent, 60 patients of ASA physical status I-II between the ages of 20–60 years, scheduled for elective lower abdominal and lower limb surgery under spinal anesthesia were prospectively enrolled in our randomized controlled trial.

Patients with ASA physical status III or more, patients on any opioid or any sedative medication in the week prior to the surgery, patients who have known allergies to any of test drugs, patients with coagulation disorders or on anti coagulant drugs, patients with spinal deformities, and patient with refusal were excluded from the study.

Sixty patients undergoing elective lower limb and lower abdominal surgeries under spinal anesthesia were selected randomly after applying the already mentioned stringent inclusion and exclusion criteria. All the patients were divided into two groups, group L and R. Group L received isobaric levobupivacaine 15mg, and group R recieved isobaric ropivacaine 15mg. An informed written consent was taken for every case selected for the study. Using computer generated random allocation chart, patients randomly allocated to one of the two groups according to the drug to be used. Each patient was assessed in detail preoperatively and baseline readings of pulse rate, blood pressure and oxygen saturation were recorded.

The patient was placed in left lateral position on a horizontal table. Under strict aseptic precautions, a lumbar puncture was performed at L_3-L_4 intervertebral space with 23G Quincke spinal needle. After ensuring free flow of CSF, 3.0ml (15mg) of 0.5% ropivacaine in study group R and 3.0ml (15mg) of 0.5% levobupivacaine in study group L was given. After the intrathcal injection patients were immediately turned to supine position. Heamodynamic parameters such as heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP) and respiratory rate (RR) , oxygen saturation (spo_2) of the patients were recorded.

- Onset of analgesia was assessed by loss of sensations to pin prick every 30 seconds till the levels of T_{10} dermatome was achieved.
- Intensity of motor blockade was assessed by modified bromage scale every 2 minutes for first 10 minutes

Intra operative, non invasive blood pressure (NIBP), electrocardiogram (ECG), Pulse oximeter were used. HR, SBP, DSP, MAP, RR were recorded at 0min, 2min, 5min, 10min, 20min, 30min, 60min, 90min, 120min, 150min and 180min. The patients were carefully monitored for any untoward effects like inadequate block, hypotension, bradycardia, respiratory distress, nausea, vomiting, restlessness, shivering, anaphylactic reaction.

Definitions used:

1. *Onset of sensory block:* It is defined as the time taken from time of injection of drug into subarachnoid space to loss of pin-prick sensation.
2. *Quality of motor block assessed by Modified Bromage scale:*

   Grade 0: Free movements of legs,feet,with ability to raise extended legs.

   Grade 1: Inability to raise extended leg and knee flexion is decreased but full flexion to feet and knee present.

   Grade 2: Inability to raise leg or flex knees, flexion of ankle and feet present.

   Grade 3: Inability to raise legs,flex knees,ankle or move toes.
3. *Duration of sensory blockade:* This is defined as the time interval from completion of intrathecal drug injection to time of return of pin prick sensation to L2 dermatomal area.
4. *Duration of motor blockade:* This is taken as the time interval from complete motor block Bromage grade 3 to complete motor recovery Bromage grade 0.

Hypotension is defined as decrease in systolic blood pressure by 20% of baseline or any value <90mmHg. Hypotension was treated by rapid infusion of IV fluids, inj mephentramine 6mg increments.

Bradycardia (HR <60/minute) was treated by inj atropine 0.6mg IV.

Nause and vomiting were treated with inj ondensetron 4mg IV.

Shivering was treated with warm drapes and warm IV fluids.

The mean comparison between the two groups was done using unpaired t test. Two group proportions were compared using Chi square test for two sample proportion. A P-value of <0.05 was taken as statistically significant, P-value of <0.005 was taken as highly significant and P-value of <0.0005 was taken as very highly significant.

Results

Study observes that, maximum number of patients in the two groups, 22 (36.7%) cases were belongs to the age group of 21–30, followed by 17 (28.3%) and 12 (20.0%) cases were belongs to the age groups of 31–40 and 41–50 respectively. But there was no statistical significant difference of mean age between the groups Group L (Levobupivacaine) and Group R (Ropivacaine) (P>0.05). (Table 1)

In the present study, Male patients were dominant 42 (70.0%) in two groups L and R, female patients were 18 (30.0%). But there was no statistical significant difference of gender between the groups L and R (P>0.05). The mean height of patients in group L was 159.00 ± 5.21 and the mean height of patients in group R was 161.67 ± 5.46. There was no statistical significant difference of mean height between the groups L and R (P>0.05). The mean weight of patients in group L was 59.51 ± 5.35 and the mean weight of patients in group R was 61.80 ± 5.20. There was no statistical significant difference of mean weight between the groups L and R (P>0.05).

Table 1: Age wise distribution of patients.

Age in years	Group L		Group R		Total	
	No.	%	No.	%	No.	%
21–30	12	40.0	10	33.3	22	36.7
31–40	9	30.0	8	26.7	17	28.3
41–50	4	13.3	8	26.7	12	20.0
51–60	5	16.7	4	13.3	9	15.0
Total	30	100.0	30	100.0	60	100.0
Mean ± SD	37.07 ± 10.44		37.67 ± 10.60		37.34 ± 10.52	
t-test and P-value	t = 0.432 P = 0.921 NS					

NS = not significant, S=significant, HS=highly significant, VHS=very highly significant.

The mean sensory block onset time in levobupivacaine group was 4.00±1.91 min, while it was 6.67±0.78 min in ropivacaine group. The mean duration of sensory block in levobupivacaine group was 218.8±15.7 min, while it was 168.3±11.1 min in ropivacaine group. The mean motor block onset time in levobupivacaine group was 6.00±1.86 min, while it was 9.67±0.97 min in ropivacaine group. The mean duration of motor block in levobupivacaine group was 206.0±16.5 min, while it was 142.2±9.5 min in ropivacaine group.(Table 2)

The mean Time of onset sensory blockade and Time of onset of Motor Blockade was significantly high in Group R as compare to Group L, whereas mean Duration of sensory blockade, mean Duration of motor blockade and mean Duration of analgesia were significantly less in Group R as compare to Group L. Duration of analgesia was 227.9±15.9 min in levobupivacaine group and it was 175.9±11.3 min in ropivacaine group.

Study reveals that, there was no statistical significant difference of distribution of side effects of patients between the groups L and R (P>0.05). Two patients in each group developed nausea and vomiting, which were treated with inj ondensetron 4mg IV. Two patients in levobupivacaine group and five patients in ropivacaine group had hypotension, which were treated wth inj mephenteramine 6mg IV bolus. One patient in levobupivacaine group and two patients in ropivacaine group had bradicardia, which were treated with inj atropine 0.6 mg IV. One patient in each group had shivering, which

Table 2: Comparison of sensory and motor variables between the groups.

Variables	Group L Mean ± SD	Group R Mean ± SD	t-test value	P- Value and Significance
Time of onset sensory blockade	4.00 ± 1.91	6.67 ± 0.78	t = 47.97	P= 0.000, VHS
Time of onset of Motor Blockade	6.00 ± 1.86	9.67 ± 0.97	t = 15.37	P= 0.000, VHS
Duration of sensory blockade	218.8 ± 15.7	168.3 ± 11.1	t = 17.21	P= 0.000, VHS
Duration of motor blockade	206.0 ± 16.5	142.2 ± 9.5	t = 21.87	P= 0.000, VHS
Duration of analgesia	227.9 ± 15.9	175.9 ± 11.3	t = 23.92	P= 0.000, VHS

NS= not significant, S=significant, HS=highly significant, VHS=very highly significant.

was treated with inj tramadol 25 mg slow IV after dilution.

Discussion

Spinal anesthesia is safe reliable technique with an effective treatment for operative pain and blunts autonomic, somatic and endocrine responses.[8] Till recently Bupivacaine 0.5% Heavy was the only drug used for spinal anaesthesia after the discontinuation of Lidocaine's intrathecal use. The last few years, its pure S (-) enantiomers, ropivacaine and levobupivacaine, have been introduced into clinical practice because of their lower cardiac and central nervous system toxic effects. They have been developed as safer alternative to racemic bupivacaine having desirable blocking property with greater margin of safety.[9] Many clinical studies have showed that bupivacaine is the most potent local anesthetic equivalent to levobupivacaine followed by ropivacaine.[10–12]

The present study demonstrates that levobupivacain and ropivacaine are effective local anesthetics for spinal applications. Levobupivacaine presented a faster onset of sensory and motor blockade compared to the ropivacaine group, and levobupivacaine produced a prolonged duration of sensory and motor block and prolong duration of analgesia than ropivacaine.

The study done by S.Vani et al.[13] on 100 pts for infra umbilical surgeries showed faster onset of sensory and motor block in levobupivacaine group compared to ropivacaine group, which approximates our findings. It also showed a more rapid postoperative recovery of sensory and motor function in the ropivacaine group compared with the levobupivacaine group, which is also in accordance with our findings. In their study the mean duration of sensory block (186.4±26.86 min) and motor block (154.6±36.04 min) in levobupivacaine group was less than in our study group (sensory 218.8±15.7 min, motor 206.0±16.5 min). The reason for the observed differences is not apparent, but it could be attributed to methodological differences, such as difference in the population studied, or in the potency.

Sunita Jain et al.[14] conducted a study on patients posted for elective gynecological surgeries. In their study also, there was faster onset of sensory and motor blockade in levobupivacaine group compared to ropivacaine group. The mean duration of sensory and motor blockade was shorter in ropivacaine group compared to levobupivacaine group. These findings are similar to the findings in our study. In their study, the mean duration of sensory and motor block in both the groups, (levobupivacaine and ropivacaine group) was more than in our study group. This could be attributed to the higher dose (17.5mg) used in Sunita Jain et al. study.

Prem Swarup et al.[15] done a study on patients undergoing various lower abdominal and lower limb surgeries, and found that there was no statistically and clinically significant difference in mean time for onset of peak sensory block between ropivacaine group (8.28±2.2 mins) and levobupivacaine group (7.98±2.2 mins), with p=0.49. In their study, the mean time for onset of motor block (Bromage 3), in ropivacaine group (13.9±2.9 mins) and levobupivacaine group (12.9±3.9 mins) was similar, with p=0.16, which was clinically and statistically not significant. This is in contrast to our study. This may be due to the additive they have used in their study, that is fentanyl 25µg added to 3ml of ropivacaine and levobupivacaine each. In their study Ropivacaine group was associated with the shorter duration of sensory and motor block compared to levobupivacaine group. This correlates with the findings in our study.

In a study done by Ashton et al.[1] for elective lower abdominal surgery there was no significant difference between ropivacaine and levobupivacaine group with respect to median onset of sensory block at T_{10} (P Value < .05/3 i.e. ≈ .02). Time for onset of Bromage 3 Motor block was significantly different between Levobupivacine group, with a median time of 5 min, and ropivacaine group, with a median time of 18 minutes. This difference in the onset of a dense motor block is due to the differential sensory blockade by ropivacaine. In Median Duration of Sensory and Bromage 3 motor Block, there was no difference between ropivacaine and levobupivacaine group. This is in contrast with our study. The reason for the observed differences between our results and those seen in their study, is not apparent, but can be attributed to methodological differences, such as a difference in the percent use, in the population studied, or in the potency.

M. Mantouvalou et al.[16] showed, in a study, statistically significant differences in sensory block onset between the ropivacaine and the levobupivacaine groups($P < 0.05$). The duration of sensory block was significantly shorter in patients receiving ropivacaine than in those receiving bupivacaine or levobupivacaine (220 ± 30 min, 237 ± 88 min and 230 ± 74 min, respectively). Ropivacaine presented a shorter duration of motor block than

bupivacaine and levobupivacaine (269 ±20 min, 278 ± 70 min and 273 ± 80 min, respectively) ($P < 0.05$).

Conclusion

Intrathecal administration of either 15 mg ropivacaine or 15 mg levobupivacaine was well-tolerated and provided similar, effective anesthesia for lower limb and lower abdominal surgery. The onset of sensory and motor block is faster in levobupivacaine group compared to ropivacaine group. In an equal milligram dose, ropivacaine produced a shorter duration of motor and sensory block than levobupivacaine. So intrathecal ropivacaine may prove useful when surgical anesthesia of a similar quality but of a shorter duration is desired like in ambulatory surgeries.

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