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A Comparative Study of Intrathecal 0.5% Isobaric Ropivacaine And 0.5% Isobaric Levobupivacaine In Patients Undergoing Elective Lower Limb Surgery

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Abstract

Background and Aims: Ropivacaine is replacing bupivacaine as drug of choice in epidural and regional anesthesia. 'Levobupivacaine' has been developed for clinical use as a long acting local anaesthetic. The present study has been undertaken to compare the efficacy and safety of isobaric ropivacaine and isobaric levobupivacaine for lower limb surgeries.

Methods: 60 patients of either sex aged between 19 to 60 years of ASA Grade I and II undergoing upper limb surgeries were included in this randomized double blind, interventional study, and allocated into 2 groups (n=60). Group A received 3 ml of isobaric 0.5% Levobupivacaine while Group B received 3ml of isobaric 0.5% Ropivacaine. Onset time and duration of sensory and motor block, duration of analgesia, time of 2-segment regression, VAS score, hemodynamics, and adverse effects were assessed.

Results: The onset of sensory and motor blockade were significantly earlier in Group A as compared to Group B with p-values of 0.002 and <0.001 respectively. Total duration of analgesia was longer in Group A (237.57±18.73 min) as compared to Group B (195.37±12.96 min) P<0.001.

Conclusion: Levobupivacaine provides earlier onset of sensory and motor blockade, significantly longer duration of analgesia and motor blockade as compared to Ropivacaine with both drugs providing stable hemodynamics.

Keywords: Isobaric, Levobupivacaine, Ropivacaine, Intrathecal, Duration of Analgesia

Introduction

Till recently mainly Bupivacaine 0.5% heavy was the only drug used for spinal anaesthesia. It is long acting amide local anaesthetic, compared to lignocaine, due to increased lipid solubility and protein binding. But it has lower therapeutic index with respect to cardiovascular toxicity. Bupivacaine is available as a racemic mixture of its enantiomers, dextro-bupivacaine and levo-bupivacaine [1, 2].

The S (-) enantiomer, 'Levobupivacaine' has been developed for clinical use as a long acting local

anaesthetic [3]. It has decreased affinity for cardiac sodium channels than bupivacaine. Thus it has an improved safety profile over bupivacaine. Ropivacaine is replacing bupivacaine as drug of choice in epidural and regional anesthesia. In several studies it was concluded that Ropivacaine was less cardiac depressant, less arrhythmogenic and less neurotoxic than bupivacaine.[4]

Many studies have been conducted comparing the hyperbaric bupivacaine with isobaric ropivacaine but limited literature is available on the comparison of the isobaric form of these drugs. Hence, the present study has been undertaken to compare the efficacy and safety of isobaric ropivacaine and isobaric levobupivacaine for lower limb surgeries.

Materials And Methods

A randomized single blinded study was conducted in SMS medical college and attached hospitals. Ethical clearance was obtained before Institutional Ethical review committee. An informed, bilingual and written consent was obtained from all the patients. 60 patients of either sex aged between 19 to 60 years of ASA Grade I and II undergoing upper limb surgeries were included in the study. Exclusion criteria comprised of patients who were unable to understand study protocol, patients with local infection, spinal deformity, increased intracranial tension, hypersensitivity to amide local anaesthetics, concomitant hematological diseases, pre-existing cardiovascular disease, deranged liver or renal functions and neurological or psychiatric disorders.The patients were randomly divided into two groups of 30 patients each by chit in box technique; Group A receiving 3ml of isobaric 0.5% Levobupivacaine and Group B: receiving 3ml of isobaric 0.5% Ropivacaine.

The patients were subjected for detailed pre anesthetic checkup. The patients were also subjected for detailed laboratory work up including complete haemogram and urine routine. Patients were also subjected for HIV and HBsAg, Chest X ray and ECG examination. Patients were shifted to the operating room following an overnight fasting. Standard monitoring was used (NIBP, Pulse oximetry and ECG). Preoperative baseline mean arterial pressure (MAP), pulse rate and SPO2 were recorded. Patients were secured with 18G intravenous cannula and preloaded with 10ml/kg of ringer lactate (Hartman's solution). Under all aseptic precautions, spinal anaesthesia was performed at the L_3-L_4 interspace with the patient in sitting position. A total of 3 ml study drug was administered over 30 seconds through a 25G spinal needle. The patients were placed in supine position immediately after injection and the time at which the drug administered was noted.

Sensory block was assessed by loss of sensation (pin prick sensation using 21 G sterile needles) bilaterally along the mid-clavicular line. Assessment started immediately after turning the patient to supine position and continued two minute till the peak block height was reached and the time noted. It was graded according to Gromley and Hill 1996, (Normal sensation - 0, Blunted sensation -1, No sensation -2) Grade 2 was taken as onset of sensory block. The onset of sensory block was defined as the time between the injection of anaesthetic solution and the absence of pain to pinprick at the T10 dermatome. The duration of sensory block was defined as the interval from intrathecal administration to the point of complete resolution of the sensory block or when the patient required first dose of rescue analgesia (for post-operative pain). Assessment of motor block was started immediately after placing the patient in

supine position and continued every minute till Bromage score of 3 was reached.

The onset of motor block was defined as the time to achieve Bromage score of 2 or 3 from the time of injection whichever is achieved. The duration of motor block will be taken as the time from subarachnoid injection to return of Bromage score to zero. If the level of analgesia was inadequate, the regimen was switched to general anaesthesia and excluded from the study. Systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), heart rate was recorded every two minutes for the first 10 mins and thereafter at every 5 mins interval until the end of surgery. SpO2 will be monitored continuously. Hypotension was defined as a decrease in mean blood pressure more than 20% from baseline or systolic blood pressure less than 90mm Hg. Hypotension will be managed by incremental doses of 6mg intravenous ephedrine. Bradycardia was defined as heart rate less than 50/min and managed by incremental doses of 0.5mg intravenous atropine. Vomiting, shivering and other complications (if any) were recorded.

Postoperative pain was assessed by the patient using the VAS (0-10). It was assessed every 30minutes. Patients were allowed to receive rescue analgesic IV Diclofenac 1.5mg/kg (max 75mg) on VAS score of ≥ 4. This time from intrathecal injection to first administration of rescue analgesic (duration of analgesia) was noted. Requirement of first dose of analgesia mark the end of post-operative observation.

Statistical Analysis

The sample size required was 23 in each group at 95% Confidence Interval and 80% power to verify the expected minimum difference of 43.2 (± 50.84) in duration of sensory block in both treatment groups (i.e. Group A: patients with isobaric 0.5% Levobupivacaine; Group B: patients with isobaric 0.5% Ropivacaine). This sample size is adequate to cover all the other study variables. Thus, sample size was enhanced to 30 in each group.

Statistical analysis was performed with the SPSS, version 20 for Windows statistical software package (SPSS inc., Chicago, il, USA). The Categorical data i.e. type of surgery and the incidence of adverse events (hypotension, bradycardia, respiratory depression, shivering and nausea) were presented as numbers (percent) and were compared among groups using Chi square test. Groups were compared for demographic data (age, weight), duration of surgery, time for two segment regression, VAS score, total duration of motor block and analgesia were presented as mean and standard deviation and were compared using by students t-test. P value <0.05 was considered statistically significant.

Results

60 patients were included in our study with demographic variables (age, weight, height, sex, ASA status, type of surgery) and duration of surgery comparable between both the groups. (P >0.05) (Table 1)

Variables	Levobupivacaine (n=30)	Ropivacaine (n=30)	p-Value
Age(years)	39.9±7.5	40.1±6.5	0.898
Weight(kg)	63.7±8.4	61.2±9.3	0.268
Sex (M/F)	21/9	20/10	0.781
ASA I/II	27/3	26/4	0.688
Duration of surgery (mins)	65.2±7	62.5±7.8	0.1636

Table 1: Demographic variables.

Variable	Levobupivacaine (n=30)	Ropivacaine (n=30)	P-value
Onset of sensory block (min)	4.87 ± 1.45	5.93 ± 1.06	0.002
Onset of motor block (min)	6.07 ± 1.09	7.97 ± 1.56	<0.001
Time to two segment regression (min)	183.13 ± 43.39	186.43 ± 42.531	0.7672
Duration of motor block (min)	306.1 ± 14	277.2 ± 14.1	<0.001
Duration of analgesia (hours)	237.57±18.73	195.37±12.96	<0.001

Age, weight and duration of surgery expressed in Mean±SD.

Table 2

The mean time to sensory onset (min) in patients who received Levobupivacaine was 4.87 minutes and those who received Ropivacaine was 5.93 minutes. There was statistically significant difference between the mean time to sensory onset (min) of the two groups.

The maximum sensory level achieved in two groups was T7 ie. 24(80%) in both the groups, level till T6 was achieved in 4(13.3%) and 3 (10%) for levobupivacine and ropivacaine respectively while a small proportional of study subjects had attained the level till T8 ie. 2(6.70%) and 3 (10%) for levobupivacine and ropivacaine respectively.

The mean time to motor onset (min) of patients who received Levobupivacaine (6.07 minutes) was significantly shorter when compared to those who received Ropivacaine (7.97 minutes). Levobupivacaine group showed a significantly longer motor blockade (306.1 minutes) in comparison to Ropivacaine group which was 277.2 minutes. The mean duration of total analgesia for levobupivacaine was 237.57 minutes, while for ropivacaine, it was 195.37 minutes; the difference was found to be statistically significant. (Fig.1) The mean time of two segment regression was 183.13 minutes and 186.43 minutes for levobupivacaine and ropivacaine respectively, which was not significant (p= 0.7672) (Table 2)

No significant mean difference was observed in mean intra operative and post-operative heart rate, SBP, DBP, MAP (Fig. 2) at different time interval between the two groups.

No significant difference was observed in mean VAS score noted till 90 mins and at first rescue analgesic among the two groups. (Fig. 3)

In the study 11 (36.6%) and 10 (33.3%) developed hypotension with Levobupivacaine and Ropivacaine respectively.The proprotion of study subjects developing bradycardia awas found to be similar ie. 4(13.3%) and 4(13.3%) for levobupivacaine and ropivacaine.The patient developing nausea / vomiting was 5(16.7%) and 4 (13.3.%) for levobupivacaine and ropivacaine respectively.The difference between the complication profile between the two groups was also observed to be statistically insignificant.(Table 3)

Complications	Levobupivacaine	Ropivacaine	p-value
Hypotension	11(36.6%)	10(33.3%)	0.778
Bradycardia	4(13.3%)	4(13.3%)	0.704
Nausea/Vomiting	5(16.7%)	4(13.3%)	1.000

Table 3: Comparison of complications among study groups

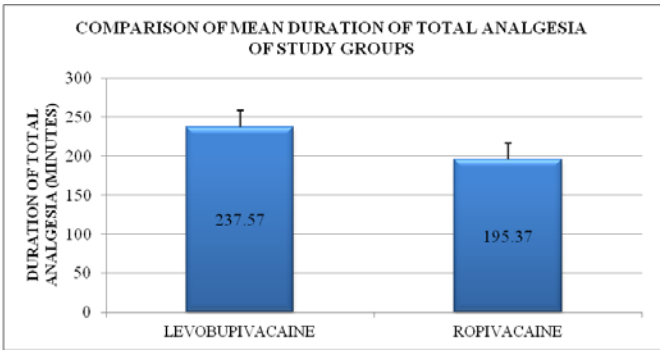

Fig. 1: Comparison of duration of analgesia (time to first request analgesia)

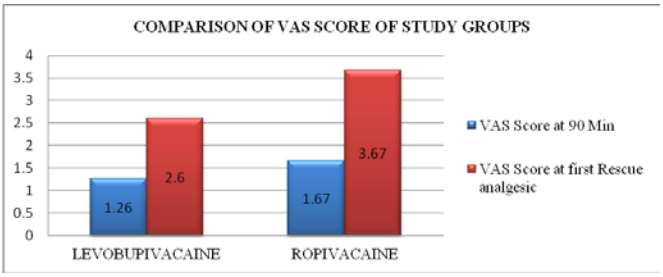

Fig. 2: Comparison of VAS score of study groups

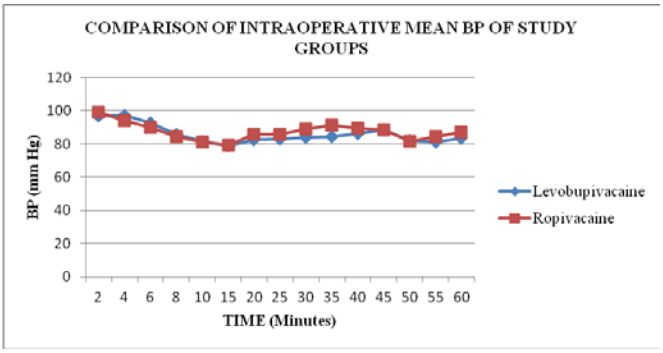

Fig. 3: Comparison of Intra Operative Mean Blood Pressure (mm Hg)

Discussion

The major clinical advantage of isobaric solution is that the patient's position during and after injection have no effect on the spread of local anaesthetic in cerebrospinal fluid.

We conducted our study with 60 patients undergoing lower limb orthopaedics surgery using isobaric levobupivacaine in group A and isobaric ropivacaine intrathecal in group B. In our study, the average duration of surgery was 65.2±7 min in levobupivacaine group and 62.5±7.8mins in ropivacaine group which was close to average duration of surgery in similar study Jindal R et al [5] in which it was 65±35 min in levobupivacaine group and 62±32 min in ropivacaine group. While in a similar study conducted by Ravishankar et al [6], the average duration of surgery was 98.8±26.95min in levobupivacaine group and 94.2±20.85 min in ropivacaine group. In a similar study conducted by A Mehta et al [7] the mean duration of surgery were 94.4 min in levobupivacaine group and 100.8 min in ropivacaine groups. The difference between average duration of surgery among two groups in our study was statistically not significant.

In our study, the mean onset of sensory blockade was 12.9±1.8 min in levobupivacaine group and 14.9±1.3min in ropivacaine group which was close to results came from similar study Jindal R et al [5] in which the time was 12.13 ± 3.71min and 14.4± 4.04 min respectively. But in similar study Ravishankar et al [6] this duration was 4.4± 1.51 min and 5.4± 1.05 min respectively, which was quite different from what we got in our study. There difference between average duration of surgery among two groups in our study was statistically significant. Onset of sensory blockade in Levobupivacaine group was significantly faster than ropivacaine group.

The average time for onset of motor blockade was 12.3±3.9 min and 12.6 ± 1.4 min respectively in the levobupivacaine and ropivacaine groups. In a similar study Jindal R et al [5] in which this time was 12.88 ± 3.99 and 12.8± 3.16 min respectively, which was close to our findings. However, in a study Ravishankar et al [6] this duration was 5.48± 1.7 and 6.48± 1.15 min respectively, which was quite different from what we got in our study. There difference between average time for

onset of motor blockade among two groups in our study was statistically not significant.

The duration of motor blockade was 306.1±14 min and 277.2±14.1 min respectively in the levobupivacaine and ropivacaine groups. In a similar study Jindal R et al [5] in which this time was 313.2 ± 40.11 and 274.06± 10.36min respectively, which was close to our findings. There difference between average duration of motor blockade among two groups in our study was statistically significant. Duration of motor blockade was significanly longer in levobupivacaine group in compare to ropivacaine group. Mantouvalou M et al[8] also noted similar results with ropivacaine having a shorter duration of motor blockade in comparison to bupivacaine and levo-bupivacaine. The average two segment regression time was 182.62±43.239 min and 185.85±42.597 min respectively in the levobupivacaine and ropivacaine groups. In a similar study conducted by Jindal R et al [5] this time was 69.8± 6.61 and 62.06±3.41 min respectively The difference between average two segment regression time among two groups in our study was statistically not significant.

The duration of sensory blockade was 264.83±44.75 min and 225.74±27.81 min respectively in the levobupivacaine and ropivacaine groups. In a similar study Jindal R et al [5] in which this time was 267.4 ± 50.84 and 224.2± 27.72 min respectively, which was close to our findings. There difference between average duration of sensory blockade among two groups in our study was statistically significant. Duration of sensory blockade was significantly longer in levobupivacaine group in comparision to ropivacaine group.

The average VAS score at 90 min was 0.11±0.47 and 2.43±9.94 respectively in the levobupivacaine and ropivacaine groups. The average VAS score at the time of rescue analgesia was 2.66±0.441 and 2.71±2.11 respectively in the levobupivacaine and ropivacaine groups. There difference between average average VAS score among two groups in our study was statistically not significant.

The average total duration of analgesia was 264.83±54.75 min and 257.74±37.81 minutes respectively in the levobupivacaine and ropivacaine groups. The difference between average total duration of analgesia among two groups in our study was statistically not significant. Levobupivacaine is said to produce equivalent spinal analgesia with a faster recovery period than that of Bupivacaine [9].

No significant difference was observed in heart rate, blood pressure and SpO2 intraoperatively in two groups. No significant difference in side effect profile was noted. This was similar to most of the similar studies conducted before.

Erdil F et al [10] in their study showed lesser incidence of hypotension and nausea with the use of levobupivacaine against bupivacaine. Our study demonstrated no clinically significant difference in the hemodynamic parameters and adverse effects amongst the two groups. In our study, there was no significant difference in the incidence of hypotension, bradycardia, nausea and vomiting. This was on the line with similar studies conducted before. Sızlan A et al showed levobupivacaine is better in terms of decreased risk of neurotoxicity and cardiotoxicity compared to bupivacaine. [11]

Conclusion

Levobupivacaine provided slightly faster onset of blockade and slightly longer motor and sensory blockade in comparison to ropivacaine. We found both intrathecal isobaric levobupivacaine and intrathecal

isobaric ropivacaine to be cardiostable drugs as they both have very stable intra and post-operative hemodynamics and less local anaesthetic toxicity. levobupivacaine has slightly faster onset of blockade and slightly longer motor and sensory blockade in comparison to ropivacaine.

Limitations: Further studies with large sample sizes are warranted to validate these findings

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