

ORIGINAL RESEARCH

COMPARISON OF EFFICACY OF 0.5% LEVOBUPIVACAINE AND 0.5% ROPIVACAINE IN ULTRASOUND GUIDED BRACHIAL PLEXUS BLOCK BY SUPRACLAVICULAR APPROACH IN UPPER LIMB ELECTIVE PROCEDURES: A COMPARATIVE, CLINICAL STUDY

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ABSTRACT

Introduction: Supraclavicular block is preferred for its rapid onset, reliability and a safe technique for surgeries involving the upper limb. Several local anaesthetics have been used and proven effective with various efficacies.

Aims: To study and compare the efficacy of 0.5% Ropivacaine with 0.5% Levobupivacaine in supraclavicular brachial plexus block in patients undergoing elective upper limb surgeries.

Materials and methods: In our prospective clinical study, we compared Levobupivacaine and Ropivacaine for providing supraclavicular block in 60 patients. We demonstrated that a volume of 30 ml of Levobupivacaine and Ropivacaine was sufficient to provide a satisfactory and a successful supraclavicular block with the help of ultrasound-guided technique keeping in mind the toxic doses.

Results: There were no observable changes in both the groups on comparing the vitals which included heart rate, systolic blood pressure, diastolic blood pressure and oxygen saturation. Sensory block onset and duration in Ropivacaine group was statistically significant. Motor block onset of both were comparable and did not show any statistical significance. The mean duration of motor blockade were found to be significant statistically. The duration of analgesia were found to be statistically significant. Levobupivacaine providing a longer duration of analgesia. There were no significant changes in baseline parameters, heart rate, blood pressure and saturation in both the groups.

Conclusion: Levobupivacaine would be a better option to choose in supraclavicular brachial plexus block where prolonged postoperative analgesia is required.

Keywords: Ropivacaine, Levobupivacaine, Supraclavicular Brachial Plexus Block, Elective Upper Limb Surgeries.

INTRODUCTION:

According to the International association for the study of pain - Pain is defined as "An unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage"¹. Peripheral nerve blocks are often considered to be the best anaesthetic choice for procedures limited to the extremities with relatively rare complications when good technique and reasonable precautions are employed. They are becoming a well-accepted component of comprehensive anaesthetic care, also expanding outside the operating theatre for postoperative pain relief and control of chronic pain. The use of regional anaesthesia techniques has increased over the past decade, while

patients who previously received a regional block often prefer regional anaesthesia for subsequent surgery.

The trend towards regional anaesthesia began in the late 18th century when William Halsted and Richard Hall experimented with cocaine as a local anaesthetic for upper and lower limb procedures. Regional anaesthesia of the upper limb can be achieved by blocking the brachial plexus at varying stages along the course of the trunks, divisions, cords and terminal branches. The four most common techniques used in the clinical setting are the interscalene block, supraclavicular block, infraclavicular block and axillary block. Each approach has its own unique set of advantages and indications for use. The supraclavicular block is most effective for anaesthesia of the mid-humerus and below².

MATERIAL AND METHODS

This study was a hospital based randomized comparative study about efficacy of Ropivacaine and Levobupivacaine over the patients fulfilling the predetermined inclusion and exclusion criteria. Study included patients admitted at Gandhi Hospital for upper limb surgeries after the predetermined inclusion criteria were fulfilled. Such cases were enrolled throughout the study period of 12 months (October 2017 to October 2018). A sample size of 60 was taken and patients posted for upper limb surgeries from Departments of orthopedics and Plastics surgery and were categorized into either of the two groups (R & L) using computer generated randomization.

Sample size has been calculated using Open Epi version 3.0 and considering the percent of exposed with the outcome as 41% as obtained from the data collected from the medical record section department of the institute.

Inclusion criteria: Patient with age between 18-60 years, either of Gender, to ASA grade I and II and Who have been electively posted for upper limb procedures.

Exclusion

Patients with known hypersensitivity to local anaesthetics, Infection at the site of block, with significant bleeding/coagulation abnormalities or patient on anticoagulant therapy, severe systemic disorder (respiratory, cardiac, hepatic, renal diseases neurological, psychiatric, neurovascular disorders and contra lateral diaphragmatic paralysis), morbid obesity, peripheral neuropathy, Pregnant and lactating women.

The final study protocol, including the final version of the subject information and consent forms, was approved in writing by the ethics committee of the institute before the enrolment of any subject into the study. The study was performed in accordance to the guidelines of good clinical practice. Only subject number was used in the sourced documents to identify subjects. Patients to be included in the study were provided with detailed information about this study. A patient was enrolled in this study after careful application of inclusion and exclusion criteria and after the written informed consent was obtained from the patient and attendant.

A study proforma as appended to the thesis was used for the collection of patient related information which included General data, Pre-operative evaluation, Investigations, Pre-medications, Onset of sensory and motor blockade, Intra operative monitoring and Duration of analgesia and motor blockade.

Patients posted for upper limb surgeries from Department of Orthopaedics and Plastic Surgery were categorized into either of the two groups (R & L of 30 each) using computer generated randomization. General data and preoperative evaluation will be done for all the patients and premedication will be given to all the patients.

A standard routine pre anaesthetic evaluation was made on the day before surgery. Baseline vital parameters (heart rate, oxygen saturation, non-invasive blood pressure) were documented. The procedure to be performed was explained in detail and informed written consent was obtained from each patient before the procedure. Patients were premedicated on the night before surgery with Tab. Alprazolam 0.25 mg and Tab. Ranitidine 150 mg.

On the day of procedure, Intravenous access was secured and all patients were pre-medicated with Inj. Ondansetron 0.1 mg/kg I.V. and Inj. Midazolam 0.05 mg/kg IV.

Procedure was done with patients being randomly allocated into two groups by drawing lots labelled Group R and Group L, and documenting their hospital number on the lot assigned. The lots were retrospectively used to find out the group to which the patient was allocated to.

Group R - will receive 30 ml of 0.5% Ropivacaine

Group L - will receive 30 ml of 0.5% Levobupivacaine.

Drugs will be prepared by an Anaesthesiologist not involved in the study. The syringe with patient's name will be given to another Anaesthesiologist who is giving the block. Baseline heart rate, Noninvasive blood pressure and oxygen saturation are monitored and recorded in the preoperative holding area. In the operating room after proper positioning, with ultrasound guidance block will be performed. Patient is placed in the supine position with face turn towards the contralateral shoulder. Both the sensory and motor blockade were obtained within 20 minutes, it is considered as a successful block. Block was considered to have failed if sensory anaesthesia was not achieved in 30 min, general anaesthesia will be given subsequently to these patients and will be excluded from the study. Any complications such as pneumothorax, haematoma, tinnitus, circumoral numbness, dizziness and seizures were observed. Surgery was allowed to begin after successful block was confirmed and established.

Pain was assessed using visual analogue scale:

Graded from 0 to 10 which will be explained to the patient preoperatively.

0 - Represents no pain

10 - Represents worst pain possible

Adverse effects: Patients will be monitored for any signs of cardiovascular or central nervous system toxicity (changes in BP, heart rate, rhythm, signs or symptoms of CNS stimulation).

Patients will also be looked for any hypersensitivity reaction for the drug and evidence of pneumothorax.

STATISTICAL ANALYSIS

Results were statistically analyzed using Un-paired t test and Fisher exact test and Chi-square test. A 'p' value of <0.05 was considered as significant and calculated by Graphpad software. All the values are mentioned as Mean +/- standard deviation.

RESULTS

There were no clinical or statistically significant differences in the demographic profile of patients and the two groups were comparable.

	Group R	Group L	P-value
Age in mean	36.43	35.47	0.788
SD	14.862	12.792	
Males	23(76.7%)	20(66.7%)	>0.05
Females	7(23.3%)	10(33.3%)	
ASA-1	16(53.3%)	24(80%)	
ASA-11	14(46.6%)	6(20%)	

The mean age in group R was 36.43 years and in group L was 35.47 years. The two groups did not differ significantly with respect to their age. In group R there were 23 males (76.7%) and 7 females (23.3%). Group L had 20 (71.7%) males and 10 females (33.3%). The groups were comparable with respect to gender.

In group R there were 16 ASA I cases (53.4%) and 14 ASA II cases (46.6 %). In group L there were 24 ASA I cases (80.0%) and 6 ASA II cases (20.0%). There was no statistically significant difference between the two groups.

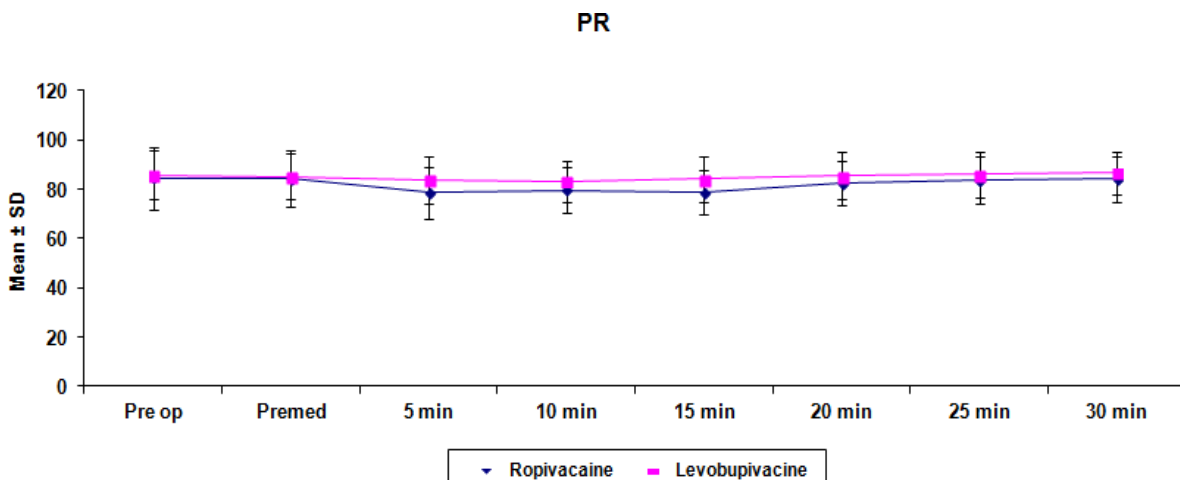
Table-2: Comparison of sensory and motor block variables in groups

Onset of sensory blockade	Mean	Standard deviation	pvalue
Group R	5.22	1.280	0.0002
Group L	6.88	1.944	
Onset of motor blockade			
Group R	7.90	1.689	0.0763
Group L	8.94	2.666	
Onset of peak sensory onset			
Group R	14.93	2.149	0.1936
Group L	15.71	2.436	
Peak motor onset			
Group R	18.82	3.019	0.8880
Group L	18.93	3.005	
Duration of sensory blockade			
Group R	8.64	1.315	0.0014
Group L	10.29	2.351	
Duration of motor blockade			
Group R	8.323	1.2398	0.0010
Group L	9.837	2.0351	
Duration of analgesia			
Group R	8.33	1.130	0.0001
Group L	10.23	2.092	

Sensory onset is much earlier in Ropivacaine which was statistically significant. Both groups were comparable with respect to onset of motor blockade and were not statistically significant. Levobupivacaine group had statistically significant longer duration of sensory blockade.

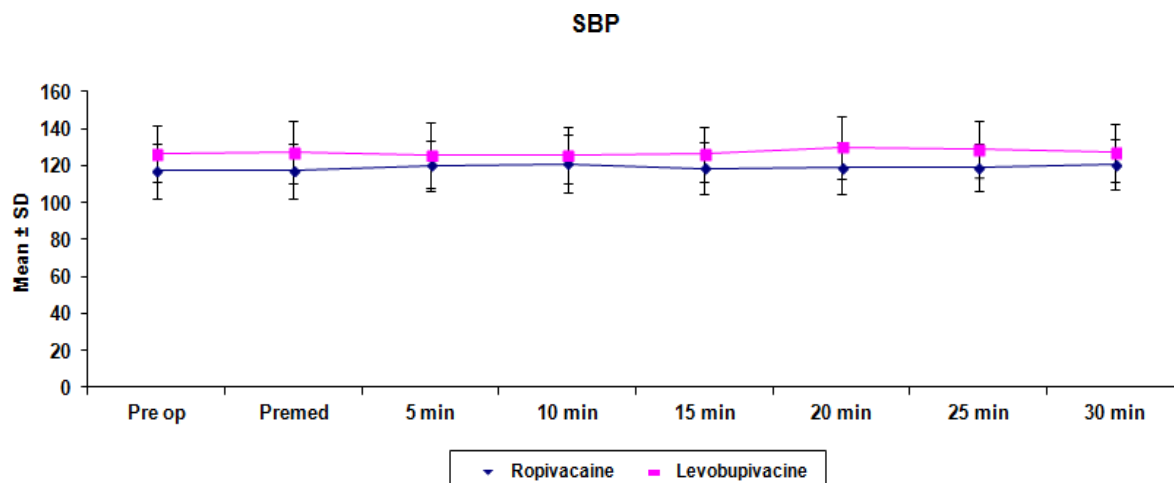
Duration of motor blockade was found to be longer in Levo-bupivacaine group and it was statistically significant. Duration of analgesia was found to be longer in Levobupivacaine group and it was found to be highly significant statistically.

Figure-1: Changes in heart rate in comparison in groups



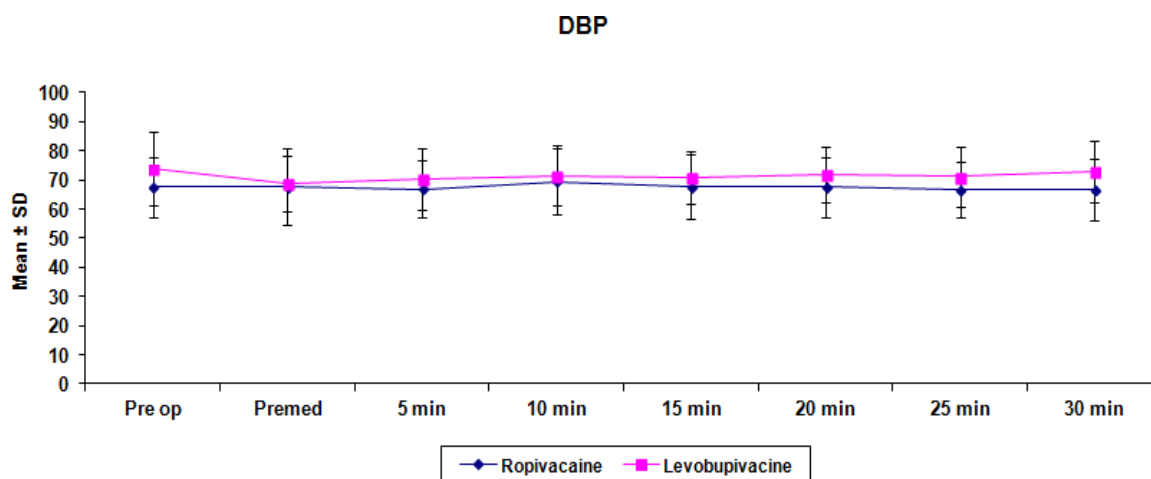
Both groups were comparable with respect to changes in heart rate and statistically significant change was found only at 15 mins after administration of the block.

Figure-2: Changes in systolic blood pressure



At 15 mins, it was 118.70 in group R and 126.47 in group L with a p value of 0.040 which was also significant statistically. At 20 mins it was 118.87 in group R and 130.20 in group L with a p value of 0.006 which was statistically significant. At 25 mins it was 119.23 in group R and 129.10 in group L with a p value of 0.009 which was significant statistically. At 30 mins, the mean values were found to be 120.70 in group R and 127.10 in Group L with a p value of 0.096 which was not significant statistically.

Figure-3: Changes in diastolic blood pressure



At 25 mins, it was 66.83 in group R and 71.17 in group L with a p value of 0.100 which was not significant statistically. At 30 mins, it was 66.70 in group R and 72.83 in group L with a p value of 0.027 which was significant statistically.

There was no statistically significant difference in oxygen saturation levels between the two study groups.

Table-3: Comparison of adverse events

Drug	Adverse events	Percentage
Group R	2	3.3%
Group L	0	0%

On observing for any adverse events, two patients in Group R had an episode of vomiting. On total it contributed to 3.3% out of the total number of patients participating in group R. Patients in group L had no adverse events.

DISCUSSION

Among various types of brachial plexus block the supraclavicular approach has been considered the most efficacious. It is often described as "spinal anaesthesia for upper extremity" because of its ubiquitous application for upper extremity surgery characteristically associated with a rapid onset of anaesthesia, high success rate, complete and predictable anaesthesia for upper extremity. Bupivacaine is commonly used local anaesthetic drug for brachial plexus block because of its long duration of action and a favorable ratio of sensory to motor neural block. However, its toxicity is a concerning issue especially when larger doses are used in peripheral nerve blocks or prolonged infusions for postoperative analgesia.

Hence, the present study was on new drug with wider safety margin, and desirable pharmacokinetic properties of Bupivacaine. The decreased toxicity of Levobupivacaine is attributed to its S- enantiomer and faster protein-binding rate. Ropivacaine, a long acting pure S- enantiomer is considered to be less cardiotoxic profile compared to Bupivacaine with similar pharmacodynamic properties. Use of Ultrasound guidance for supraclavicular brachial plexus block also reduces amount of volume required and hence less risk of local anaesthetic systemic toxicity.

This is the rationale for our study on comparison of effectiveness of Ropivacaine and Levobupivacaine for ultrasound guided brachial plexus block by supraclavicular approach. After Approval from ethical committee of Gandhi Medical College, Telangana. Written informed consent obtained from all the 60 adult patients (30 for each group) who are mentally stable and / or attendant, participating in present study undergoing elective surgery for upper limb procedures.

Previous studies were performed with higher doses of local anaesthetics ranging from 30 to 40 ml^{16,38}. With the effective use of ultrasound we were able to come down on the volume of local anaesthetic and thereby bringing down the drug related side effects without compromising on the quality of the block⁵. Our hypothetical assumption is that 0.5% Ropivacaine will produce less intense and shorter duration of motor block than 0.5% Levobupivacaine as Ropivacaine is less potent due to its lesser lipid solubility compared to Levobupivacaine.

There was even distribution of age in both groups. The patients selected in the present study belonged to the age between 18-60 yrs. A random allocation of the patient was done in both groups. However, as is evident of the observation the mean age was 36.43 ± 14.86 in group R (Ropivacaine) and 35.47 ± 12.79 in group L (Levobupivacaine) did not vary significantly. Therefore, clinically insignificant

variations in ages simply helped us to alleviate these confounding factors, like distribution, metabolism, excretion and action of different drugs.

In our study majority of patients were male with 76.7% and 66.7% in group R and group L respectively. They belong to Orthopaedic and Plastic surgery groups in our institution in this study period. However, this male preponderance had no clinical relevance on the results of the study. Based on the values derived from the descriptive and inferential statistical data, it was evident that the parameters of the subjects like, Age, Sex, Type of surgery and the ASA status are not significantly associated with the study group to which they belong to viz. Ropivacaine and Levobupivacaine groups. This also indicates that the subjects are

well matched as far as these basic Demographic parameters are concerned and both the groups, viz. Ropivacaine and Levobupivacaine groups are comparable.

Kulkarni Setal³ in 2016 conducted a prospective randomized double blind comparative study of 60 patients with ASA I and II of either sex between the ages of 18-60 years. They were enrolled and randomly divided into two groups. Supraclavicular brachial plexus block was given for upper limb surgeries using 0.5% Levobupivacaine (Group L) and 0.5% Ropivacaine (Group R). The results of demographic variables like sex, age, ASA status are similar to our study.

In our study Ropivacaine had earlier onset of sensory block. The mean onset of sensory block was (5.22 ± 1.28 min) with Ropivacaine and (6.88 ± 1.94 min.) in Levobupivacaine, with a p value of 0.0002 which was statistically significant. Tripathi Detal.⁴ in their study on comparison of Ropivacaine and Bupivacaine for supraclavicular brachial plexus block found that the mean onset time of sensory block was (4.22 ± 1.52 min) with 0.75% Ropivacaine and (13.83 ± 3.49 min) with 0.5% Bupivacaine respectively, P < 0.01 which was significant statistically. This was almost similar to present study but the earlier onset for them may be due to usage of higher concentration of 0.75% Ropivacaine. Mangeswaran R et al⁵ in their study on Comparison of 0.5% Ropivacaine and 0.5% Levobupivacaine for Infra-clavicular brachial plexus block observed that the mean onset time for sensory block with Ropivacaine was (13.5 ± 2.9 min.) compared to Levobupivacaine at (11.1 ± 2.6 min.) with p value 0.003, so, statistically significant. The faster onset with Ropivacaine in our study might be due to use of ultrasound guidance and by supraclavicular approach. In a study done by Jyothi Detal.⁶ the onset of sensory block with Levobupivacaine was earlier compared to Bupivacaine.

The difference between onset time for motor block with Ropivacaine and Levobupivacaine in our study was not statistically significant.

We found that the mean onset of motor blockade was (7.90 ± 1.68 min.) in Ropivacaine and was (8.94 ± 2.66 min.) in Levobupivacaine with p value of 0.763 which was statistically insignificant. Mangeswaran R et al⁵ in their study on Comparison of 0.5% Ropivacaine and 0.5% Levobupivacaine for infra-clavicular brachial plexus block observed that the onset time for motor block was (19.0 ± 2.7 min.) in Ropivacaine group compared to (17.1 ± 2.6 min.) in Levobupivacaine group which is significant statistically. (p = 0.013). The faster onset of motor block in our study might be due to supraclavicular approach and ultrasound guided block. Mankand P et al.⁷ found in their study the mean onset of motor blockade was significantly faster with Ropivacaine (9.50 ± 2.403 min) as compared to levobupivacaine (12.33 ± 2.537 min) with P < 0.05 which is statistically significant. In our study, Ropivacaine had a similar onset of motor blockade as in the study done by Tripathi Detal.⁴ and Bhatia Retal.⁸. But in comparison with Shobaba Getal⁹ a faster onset of motor blockade was obtained. As for Levobupivacaine onset of motor blockade was longer in comparison to the study done by Jyothi D etal.⁶. However, the results of our study was almost similar to the study done by Pandya Cetal¹⁰.

Kulkarni D et al³. in their study observed significant earlier onset of sensory blockade (8.60 ± 1.52 min.) with Levobupivacaine (p = 0.027) and onset of motor blockade (13.13 ± 2.01 min) with Levobupivacaine. (p = 0.01). In our study we observed earlier onset of sensory in Ropivacaine group which was statistically significant. Though earlier motor onset also observed in Ropivacaine group in present study, it was not significant statistically.

In present study, the peak onset of sensory blockade was earlier in the Ropivacaine group with mean value of (14.93 ± 2.14 min), when compared to the Levobupivacaine group with mean value of (15.71 ± 2.43 min). The p value obtained was 0.1936 and the values were not statistically significant. The peak onset of sensory blockade by Ropivacaine was midway between studies done by Tripathi Detal.⁴ and Bhatia Retal.⁸.

The peak motor onset time for groups R (Ropivacaine) and L (Levobupivacaine) were 18.82 ± 3.019 and 18.93 ± 3.005 mins. The p value was 0.8880 and the results were not statistically significant. The peak onset of motor blockade was not different between Ropivacaine and Levobupivacaine in study done by Bhatia Retal.⁸. Tripathi Detal.⁴. in their study observed that peak motor onset developed in 27.26 ± 8.93 min. with Ropivacaine and 23.43 ± 3.89 min with Levobupivacaine respectively

and was not statistically significant. ($P < 0.05$) The differential onset time for sensory and motor blockade can be explained by the mechanism of action of local anaesthetics on the nerve fibres.

The duration of sensory blockade in-group R (Ropivacaine) was 8.64 hours and in-group L (Levobupivacaine) was 10.29 hours. The standard deviation values of both the groups were 1.315 and 2.351 for group R and L respectively. The p value was 0.0014. So, Levobupivacaine group had statistically significant longer duration of sensory blockade. Kulkarni S et al³ in their study observed that duration of sensory block was (9.53±1.65 hrs) with Ropivacaine and (8.60±1.52hrs) with levobupivacaine and p value of 0.027 which is statistically significant. The mean duration of motor block for Ropivacaine (14.6±2.25hrs) and Levobupivacaine (13.13±2.01hrs) with p value of 0.01 which is insignificant.

Mankand Petal⁷ in their study found that the mean duration of sensory block was (10.93±1.96hrs) with Levobupivacaine and (8.67±1.09hrs) with Ropivacaine, p value of < 0.001 which is statistically significant. The mean duration of motor block was (10.87±1.13hrs) in Levobupivacaine group and (7.13±1.25hrs) in Ropivacaine group with a p value of < 0.05 which is significant statistically. The duration of sensory blockade was more in Levobupivacaine group than the Ropivacaine group. However, in our study the duration of sensory blockade was less for both drugs when compared with Tripathi Det al⁴ and Pandya C et al¹⁰. The difference might be attributed to the amount of drug used.

The Mean duration of motor blockade in-group R (Ropivacaine) was 8.323 hours and in-group L (Levobupivacaine) was 9.837 hours. The standard deviation values of both the groups were 1.2398 and 2.0351. Duration of motor blockade was found to be longer in Levobupivacaine group and it was statistically significant with a p value of 0.0010. In our study, the duration of motor blockade was not different between the two groups, which is similar to the findings of study done by Lisnatti O et al¹¹, Mangeswaran R et al⁵. In comparison to our study on Ropivacaine, Tripathi D et al⁴ in his study had a similar duration of motor blockade while in the study done by Shobaba G et al⁹ the motor duration was relatively shorter. As for Levobupivacaine the duration of motor blockade was shorter on comparison with the study done by Pandya C¹⁰.

Kulkarni D et al³ in their prospective study on comparison of Levobupivacaine and Ropivacaine observed that the prolonged duration of sensory 12.11±0.71hrs and motor blockade 11.31±1.02 hrs ($p=0.0001$) was observed in group of patients receiving Levobupivacaine compared to Ropivacaine (11.26±0.75hrs) and (8.50±0.41hrs) respectively.

Similarly, our study findings show prolonged duration of sensory and motor block with Levobupivacaine. The duration of analgesia in Group R (Ropivacaine) was 8.33 hours and group L (Levobupivacaine) had a mean value of 10.23 hours. Standard deviation values of Group R and L were 1.130 and 2.092. Duration of analgesia was found to be longer in Levobupivacaine group and it was found to be highly significant statistically with p value 0.0001. Kulkarni D et al³ in their study found the time for first rescue analgesia required postoperatively was much longer in Group L (13.2333±1.1651hr) as compared to Group R (10.8667±0.91852hr) and the difference was statistically significant ($P=0.0001$). Which is similar to present study.

Cline E et al¹² in their study on Analgesia and effectiveness of Levobupivacaine compared with ropivacaine in patients undergoing axillary brachial plexus block observed that duration of analgesia was prolonged with Levobupivacaine with 13.85hrs and with Ropivacaine was 10.70hrs with a p value of 0.013, which is statistically significant. In our study with Levobupivacaine the duration of analgesia was also shorter in comparison with the study done by Cline E et al¹². This difference could be attributed to trans-axillary technique used by Cline E et al¹². In our study also when 0.5% Ropivacaine and 0.5% Levobupivacaine are compared, we found Levobupivacaine produced longer duration of analgesia than Ropivacaine group which is highly statistically significant ($p < 0.001$). This was similar to the study done by Cline E et al¹², Mankad P et al⁷ and Kulkarni S et al³.

In the present study, we observed that the mean heart rate during premedication was 84.47 in Group R and 85.23 in Group L, with a p value of 0.774, which was not statistically significant. At 15 mins, the mean heart rate was 78.93 in-group R and 84.13 in Group L, with a p value of 0.035, which was statistically significant.

In the present study, the mean systolic blood pressure during premedication in-group R was 117.27 mm Hg and in Group L was 127.43 mm Hg, which was statistically significant with a p value of 0.016. Our study observed that although systolic blood pressure during pre-medication was significant, the mean difference values between two groups were comparable and no major blood pressure fluctuations observed in the study groups. The systolic blood pressure values between both the groups are significant at 15 min (p = 0.040), 20 min (p = 0.006), 25 min (p = 0.009) respectively after the administration of the block.

In our study, we found that during premedication the mean baseline diastolic blood pressure was 67.90 mm Hg in-group R and 69.77 mm Hg in-group L with a p value of 0.532, which was not statistically significant. There was no statistical significant difference in oxygen saturation levels between the two study groups at any point of time. Kulkarni D et al³ in their study observed intraoperative heart rate (HR), systolic blood pressure (SBP) and diastolic blood pressure (DBP) which were comparable in both the groups and found no statistically significant difference (P > 0.05) between Levobupivacaine and Ropivacaine.

In the present study, we observed that in Ropivacaine group HR was decreased by 6 beats/min compared to baseline HR however it was statistically significant at 15 min. interval when compared to the HR fluctuations in the Levobupivacaine group and SBP showed significant difference at 15 min, 20 min, 25 min time intervals. However, the mean values were comparable between the groups.

In our study, except for 2 episodes of vomiting in the Ropivacaine group there were no major adverse events. Mankad Petal⁷, Kulkarni Setal³ showed no significant intraoperative and postoperative complications with both the drugs which were similar to our study. Few studies had adverse outcomes like, bradycardia, Horner's syndrome and pneumothorax.¹³ The incidence of adverse effect was probably low in our study due to the decreased amount of local anaesthetics used and the use of ultrasound for guiding the deposition of the drug at the correct anatomical location. This study demonstrated that patients receiving Levobupivacaine had a comparative late onset of sensory and motor blockade but the duration of action was longer, and postoperative analgesic requirements were delayed with lesser VAS scores. While the Ropivacaine group had earlier onset of sensory and motor blockade but the duration of action was shorter compared to group Levobupivacaine. Hence, Levobupivacaine would be a better option to choose in supraclavicular brachial plexus blocks where prolonged post-operative analgesia is required.

CONCLUSIONS

We thus conclude from the present study that 0.5% Levobupivacaine on comparison with 0.5% Ropivacaine in patients undergoing elective supraclavicular block have slower onset of sensory block, longer duration of sensory and motor blockade, longer duration of analgesia and no major hemodynamic variations or adverse events.

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