e-ISSN: 0975-5160, p-ISSN: 2820-2651

Available online on www.ijtpr.com

International Journal of Toxicological and Pharmacological Research 2022; 12(11); 99-108

Original Research Article

Comparative Study between 0.5% Levobupivacaine and 0.5% Ropivacaine in Ultrasound Guided Infraclavicular Brachial Plexus Block

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Received: 12-10-2022 / Revised: 08-11-2022 / Accepted: 25-11-2022
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Conflict of interest: Nil

Abstract

Background and Objectives: Infraclavicular Brachial plexus block is one of the most commonly used anaesthesia technique for any upper limb surgery specially orthopaedics surgery as it is very safe and also eliminates the risk of general anaesthesia. In one hand Use of ultrasound have made this block more safer and on the other hand use of Levobupivacaine and ropivacaine also reduces chances of Local Anaesthesia toxicity. This study was aimed at comparing effects of 0.5% Levobupivacaine and 0.5% Ropivacaine in USG guided Infraclavicular Brachial plexus block.
Materials and Methods: This is a randomized controlled trial done at a Tertiary care hospital in West Bengal in patients posted for Upper Limb surgery in patients aged more than 60 yrs of ASA 1 and ASA 2 status. Patient posted for upper limb surgery received USG guided Infra Clavicular Brachial plexus block with either 0.5% Ropivacaine or 0.5% Levobupivacaine.
Statistical Analysis: Statistical Analysis was done by SPSS software.Chi-square test or Fischer's exact test was used for analysis where applicable.
Results: The aim of our study was to compare the efficacy of 0.5% Levobupivacaine and 0.5%. Perioperative hemodynamic parameters were also compared and any obvious side effects noted.There was no statistically significant difference between the two groups in terms of demographic parameters like Age, Gender, Body Weight, Height and BMI. P value was >0.05. We found that there was no statistically significant difference between the two groups in terms of heart rate, systolic blood pressure, diastolic blood pressure and mean arterial pressure at different time intervals ($p>0.05$). We also found that mean duration of sensory block,motor block was almost similar and statistically nonsignificant. Also the duration of analgesia in both Ropivacaine and Levobupivacaine was statistically nonsignificant.
Conclusion: We conclude that for ultrasound guided infraclavicular brachial plexus block both the S enantiomer of Bupivacaine i.e. Levobupivacaine and Ropivacaine are similar for both sensory, motor block and duration of analgesia.

Introduction

Regional nerve block can provide effective surgical anaesthesia as well as postoperative analgesia. Ultrasound imaging techniques also enable the anaesthesiologist to secure an accurate needle position and monitor the distribution of the local anaesthetic in real time, with the potential advantage of improving the quality of nerve block, shortening onset of the block, and reducing the minimum volume required to obtain a successful nerve block [1].

The supra-clavicular block results in anaesthesia of dermatomes C5 through T1, making it suitable for anaesthesia or analgesia of entire upper extremity distal to shoulder, including the upper arm and elbow as well as forearm, wrist and hand [2] .Theinfraclavicular approach to a brachial plexus block was first described in the early 20th century by Bazy [3]. Brachial plexus block in the infraclavicular area offers excellent analgesia of the entire arm. Blockade occurs at the level of the cords and offers the advantages of avoiding pneumothorax while affording block of the musculocutaneous and axillary nerves. No special arm positioning is required. A nerve stimulator or ultrasound visualizationis required because there are no palpable vascular landmarks to aid in directing the needle [4].

The disadvantage is that plexus is situated deeper at this leveland the angle of approach is more acute making synchronised visualisation of the relevant anatomy and needle challenging in inexperienced hands and in obese patients [5].

Ropivacaine and Levobupivacaine are wellestablished long-acting amide local anaesthetic agent which is prepared as pure S (-) enantiomer of Bupivacaine. The cardiovascular adverse effect of Bupivacaine is associated with the R (+) isomer and thus these drugs have comparatively lesser side effects. In this context the present study has been undertaken to compare Levobupivacaine and Ropivacaine for ultrasound guided infraclavicular approaches of brachial plexus block.

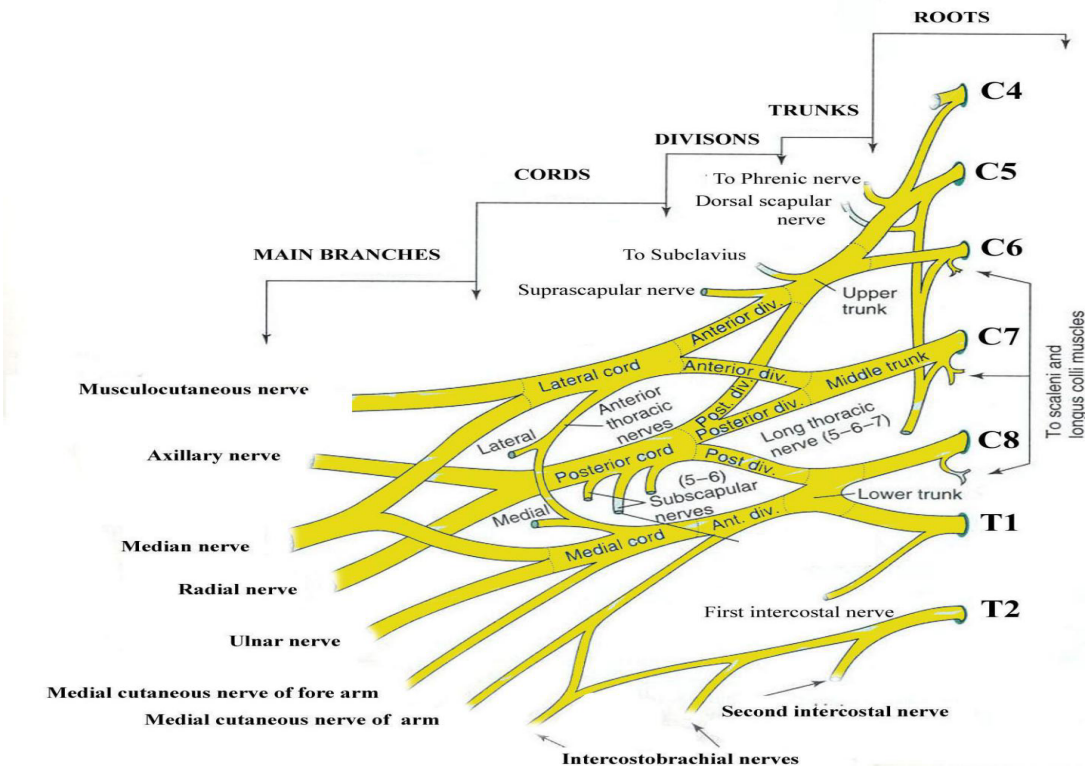


Figure 1: Schematic diagram of brachial plexus

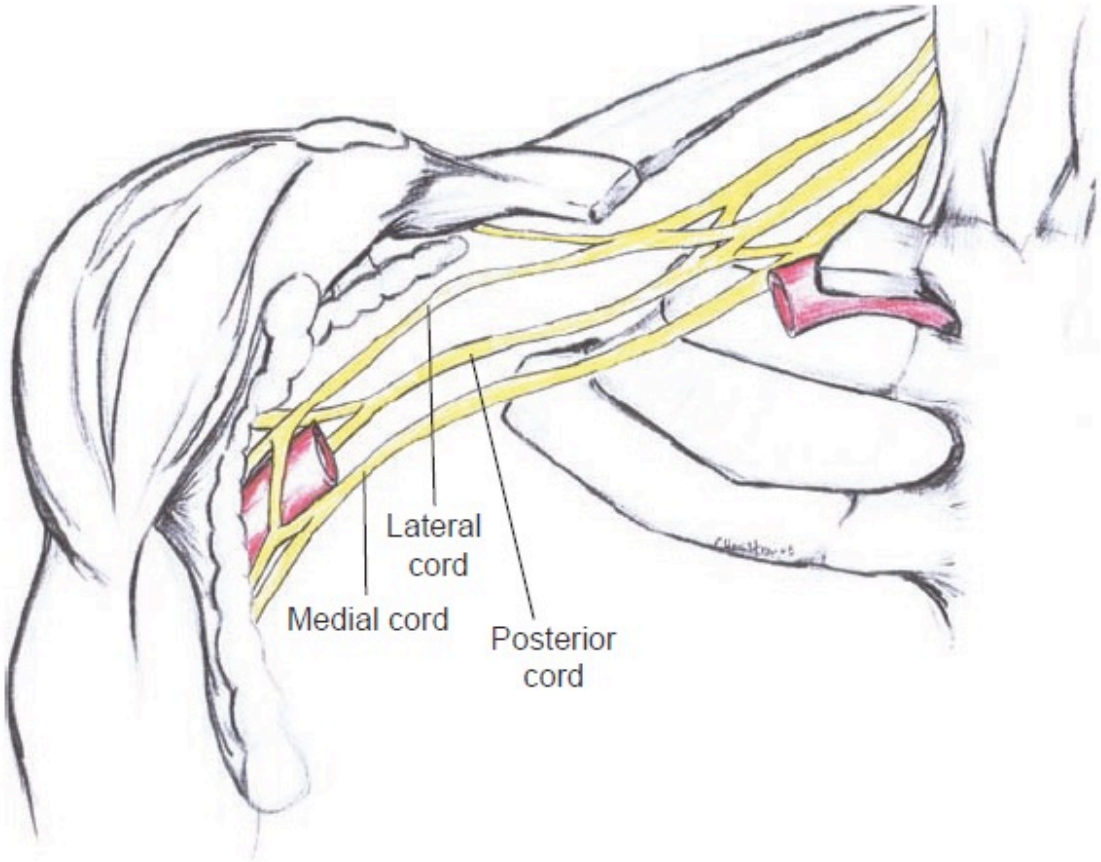


Figure 2: Infraclavicular brachial plexus block

Materials and Method

a. **Study Design:** Randomised Control Trial
b. **Place of study:** Vivekananda Institute of Medical Sciences (VIMS) 99, Sarat Bose Road, Kolkata 700026
c. **Study population:** Sixty two patients .

Study Period: January 2019 to January 2020

Study Design: It is a prospective, randomized, case control study.

Sample Size: We are to find the appropriate sample size for the study intending 1:1 allotment of patients between control (ropivacaine) and treatments (levobupivacaine),total sample size(n) is obtained as= 62. So, 31 patients are allocated to each group.

Sampling Techniques

Randomisation technique followed.

Statistical Analysis

If normally is valid then a t-test otherwise a Wilcoxon/Mann Whitney U test was carried out to test which drug performs better.

Methodology

Study Technique

Procedure explained, informed consent taken,visual analogue scale explained. Complete pre-anaesthetic evaluation was performed and fasting status noted. Sixtytwo patients were randomized to either to the levobupivacaine (L) group or ropivacaine (R) group using computer generated random numbers and standard ASA monitors attached and baseline parameters were recorded, Intravenous access was obtained and fluid started. The block was performed using Ropivacaine 0.5% or levobupivacaine 0.5%

making upto a volume of 30ml. The ultrasound machine frequency was set to 10MHz. The targets was axillary artery. Position of the patient was supine with head rotated to the contralateral side and the upper limb to be anesthetized was kept by the side of the patient. Antiseptic dressing and draping of the site was done. After anaesthetizing the skin and the subcutaneous tissue with 2–4 ml of lignocaine 20 mg/ml, a 5 cm stimuplex needle was inserted under the probe's long axis (in plane). The first half of the volume was injected posterior to the artery and the second half after repositioning the tip to obtain a posterolatero-medial, U-shaped LA spread.

The end of the injection is defined as time 'zero'. Systolic blood pressure, Diastolic blood pressure, 29 Mean arterial pressure heart rate and SPO2 were recorded 0 mins, 1min, 3mins, 5mins, 10mins, 15mins, 20mins, 30mins after brachial plexus block. Sensory block: Evaluation of sensory block was performed in musculocutaneous, median, radial, and ulnar nerve territories over a 30-min period beginning after the needle being withdrawn from the patient by comparing the Touch sensation and Pain sensation.Sensory block in the four nerve areas in the two groups was assessed in all the 4 nerve areas i.e. lateral side of the palm, thumb, second and third finger for Median Nerve; lateral side of the dorsum of the hand for Radial Nerve; medial side of the palm and the dorsum of the hand, fourth and fifth finger for Ulnar Nerve; lateral side of the forearm for Musculocutaneous Nerve and Onset of sensory block was estalished after the loss of sensation from all four areas. Duration of sensory block was defined as the time interval between the onset of sensory block of all four nerve (anesthesia, score-2) and complaining of first postoperative pain. Motor block was assessed by loss of thumb adduction for ulnar nerve; thumb abduction for radial nerve; thumb opposition for median nerve; flexion of the elbow and pronation of forearm for musculocutaneous nerve , and Onset of motor block was defined as the time after which all these movements were lost. Duration of motor block was defined as the time interval between the onset of motor block of all four nerve to complete recovery of motor function. All physiological variables and drugs used were recorded in a data collection chart. The anaesthesiologist who assessed the sensory and motor blockade was blinded to group allocation and type of drug given.

Post operative management and data collection

Patient transferred to PACU.The time of occurrence of first postoperative pain and the time of complete recovery of motor functions of the forearm and hand were duration of analgesia were recorded in each case. Pain was assessed by Visual Analogue Scale at skin closure and 30 minute interval till patient received first rescue analgesia.

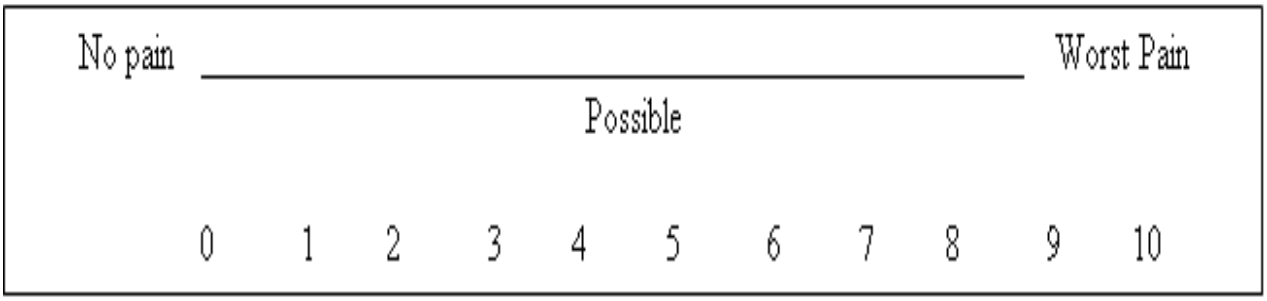
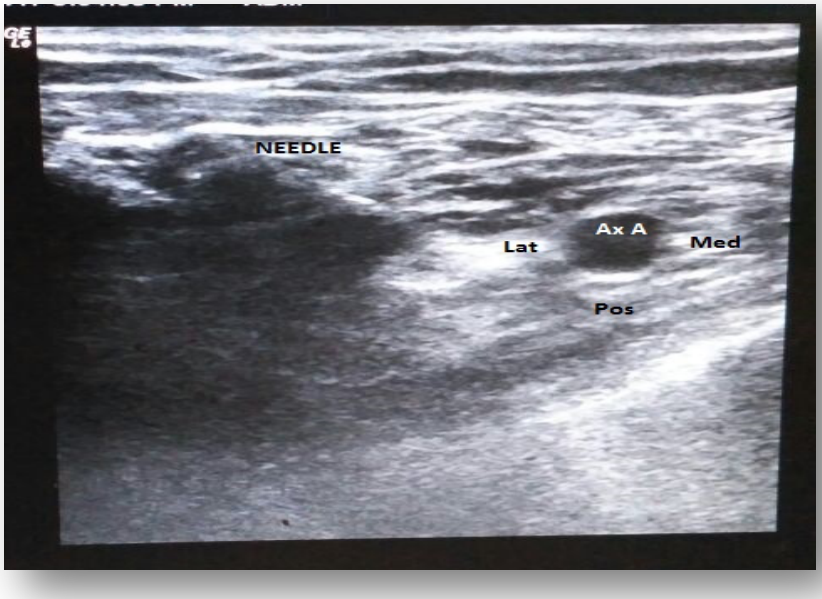


Figure 3: Visual analogue scale

Plan for analysis of data

Statistical Analysis was performed with help of Epi Info (TM) 3.5.3 which is a trademark of the Centres for Disease Control and Prevention (CDC). Chisquare test (2χ) test was used to test the association between categorical variables under study. Fisher's exact test was used in case of any one of cell frequency was found less than 5 in the bivariate frequency distribution. Test of proportion (Z-test) was used to test the significant difference between proportions. 't-test' was used to test the significant difference between means.



Posterolatero-medial, U-shaped Local Anesthetic spread

Figure 3: Lat-lateral cord Med-medial cord Pos-posterior cord Ax A- Axillary artery

Result and Analysis

Two-sample t-tests for a difference in mean involved independent samples or unpaired samples. A chi-squared test ($\chi 2$ test) was any statistical hypothesis test wherein the sampling distribution of the test statistic is a chi-squared distribution when the null hypothesis is true. Unpaired proportions were compared by Chi-square test or Fischer's exact test, as appropriate. Explicit expressions that can be used to carry out various t-tests are given below. In each case, the formula for a test statistic that either exactly follows or closely approximates a t-distribution under the null hypothesis is given. Also, the appropriate degrees of freedom are given in each case. Each of these statistics can be used to carry out either a one-tailed test or a two-tailed test. Once a t value is determined, a p-value can be found using a table of values from Student's tdistribution. If the calculated p-value is below the threshold chosen for statistical significance (usually the 0.10, the 0.05, or 0.01 level), then the null hypothesis is rejected in favour of the alternative hypothesis.p-value $\leq$ 0.05 was considered for Difference of mean Onset of sensory block (min) with both Group was not statistically significant (p=0.6713).

Table 1: Duration of mean Onset of sensory block (min): Group

	Groups	Number	Mean	SD	Minimum	Maximum	Median	Pvalue
Onset of sensory block (min)	Group-L	31	8.3226	2.5870	5.0000	15.0000	8.0000	0.6713
	Group-R	31	8.0645	2.1593	5.0000	13.0000	8.0000	

Table 2: Distribution of mean Onset of motor block (min): Group

	Groups	Number	Mean	SD	Minimum	Maximum	Median	pvalue
Onset of motor block (min)	Group-L	31	8.6452	2.4569	5.0000	15.0000	8.0000	0.7770
	Group-R	31	8.4839	1.9811	6.0000	13.0000	8.0000	

Difference of mean Onset of motor block (min) with both Group was not statistically significant (p=0.7770).

Table 3: Distribution of mean Duration of surgery (min): Group

	Groups	Number	Mean	SD	Minimum	Maximum	Median	pvalue
Duration of surgery (min)	Group-L	31	88.5806	5.5544	74.0000	99.0000	88.0000	0.3818
	Group-R	31	90.0323	7.3006	75.0000	105.0000	89.0000	

Difference of mean Duration of surgery block (min) with both Group was not statistically significant (p=0.3818).

Table 4: Distribution of mean duration of sensory block(min): Group

	Groups	Number	Mean	SD	Minimum	Maximum	Median	pvalue
Duration of sensory block (min)	Group-L	31	790.9677	33.0762	710.0000	830.0000	800.0000	0.9850
	Group-R	31	790.8065	34.1833	710.0000	835.0000	800.0000	

Difference of mean Duration of sensory block (min) with both Group was not statistically significant (p=0.9850).

Table 5: Distribution of mean duration of motor block (min): Group

	Groups	Number	Mean	SD	Minimum	Maximum	Median	pvalue
Duration of Motor Block(min)	Group-L	31	705.4839	40.3186	620.0000	760.0000	720.0000	0.8874
	Group-R	31	704.1935	30.4165	640.0000	770.0000	710.0000	

Difference of mean Duration of motor block (min) with both Group was not statistically significant (p=0.8874).

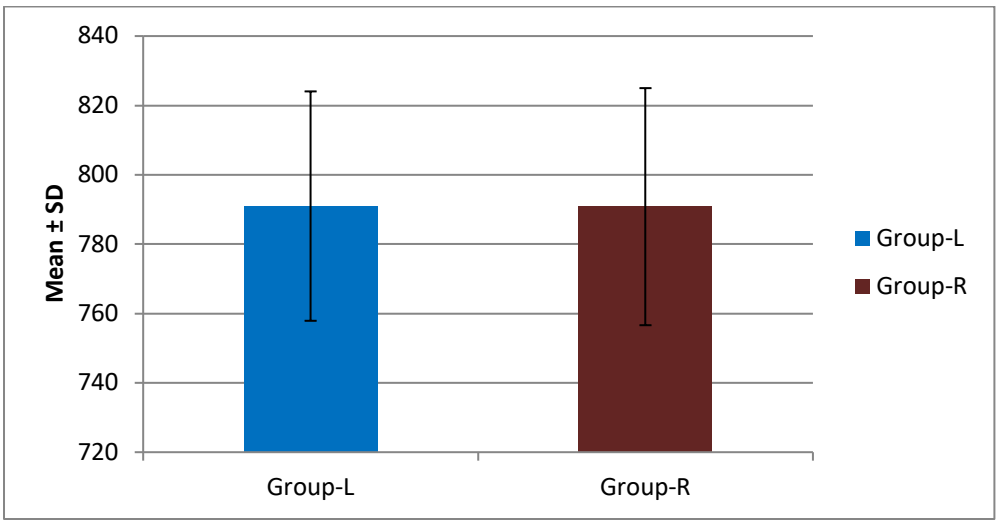


Figure 4

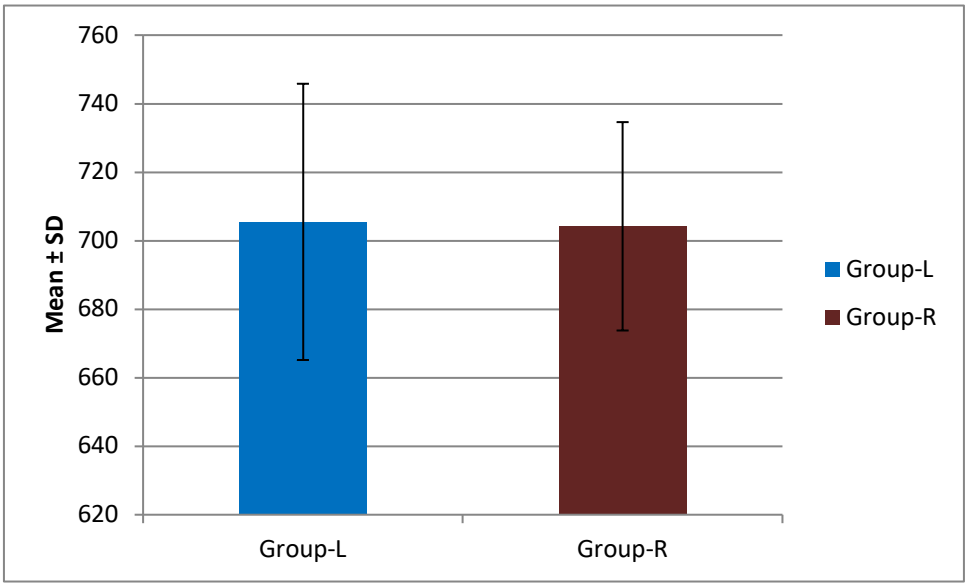


Figure 5

Table 6: Distribution of mean Block performance time (min): Group

		Number	Mean	SD	Minimum	Maximum	Median	pvalue
Block performance time (min)	Group-L	31	5.4839	0.6768	5.0000	7.0000	5.0000	0.8516
	Group-R	31	5.4516	0.6752	5.0000	7.0000	5.0000	

Difference of mean Block performance time (min) with both Group was not statistically significant (p=0.8516).

Table 7: Distribution of mean duration of analgesia: Group

		Number	Mean	SD	Minimum	Maximum	Median	pvalue
Duration of analgesia	Group-L	28	803.9286	35.7294	720.0000	840.0000	810.0000	0.6887
	Group-R	31	807.0968	24.1100	750.0000	840.0000	810.0000	

Difference of mean Duration of analgesia with both Group was not statistically significant (p=0.6887).

Discussion

The aim of our study was to compare the efficacy of 0.5% Levobupivacaine and 0.5% ropivacaine for producing infraclavicular brachaial plexus block for patients undergoing upper limb surgery. Perioperative hemodynamic parameters were also compared and any obvious side effects noted. In this study 62 adult patients of age between 18 and 60, with ASA physical status I & II were randomly allocated to receive USG guided infraclavicular brachial plexus block or either 0.5% levobupivacaine or 0.5% ropivacaine. 31(50.0%) patients were in the Group-L and rest 31(50.0%) patients were in the Group-R. It was seen that there was no statistically significant difference between the two groups in terms of demographic parameters like Age, Gender, Body Weight, Height and BMI. Chi-square ($2\ \chi$) test showed that there was no significant difference in the proportions of Gender (p= 0.4451) and ASA grade (P= 0.442) of the patients in the two groups. There was no significant difference between type of surgery in two groups (p=0.146).The mean duration of onset of sensory block for group L and group R are 8.32 min and 8.064 min respectively and the p value was >0.05, thus statistically non significant.The mean duration of onset of motor block for group L and group R are 8.64 and 8.48 min respectively and the p value was >0.05, thus statistically non significant, which is dissimilar to R Mangeswar and Y Choy [6] *et al* where there were significant differences in the onset of sensory and motor block as Levobupivacaine 0.5% (11.1 ± 2.6) had a faster onset of sensory and motor block compared to ropivacaine 0.5% (13.5 ± 2.9). Piangatelli *et al* [7,8] compared 0.5% levobupivacaine with 0.75% ropivacaine in the infraclavicular brachial plexuses block, showed that the onset time for motor block was greater in the ropivacaine group. The sensory block also was longer in the levobupivacaine group. Hickey *et al* [9-11] compared 0.25% ropivacaine with 0.25% bupivacaine for brachial plexus block for upper limb surgery, and showed that although motor onset was quicker in the bupivacaine group, there was no significant differences in terms of onset of sensory block. The difference in mean duration of sensory block in Group-L (790.96 min) and GroupR(790.80min) (p>0.05) were statistically non significant. [Table 4 and figure 4]. The difference in mean duration of motor block in Group-L(705.48min) Group-R(704.19min) (p>0.05) were statistically non significant. [Table 5 and figure 5]. In a study done by Cline E *et al* [10] comparing 0.5% levobupivacaine with 0.5% ropivacaine in patients undergoing 65 axillary brachial plexus block, the ropivacaine group had slightly higher verbal numerical rating scale (VNRS) scores at 8th and 10th hours post operative. However, in study done by RMangeshwar and Y Choy *et al*9 patients in both groups experienced no pain 6 hours after the block was given. In another study, Liisanantti *et al*9 concluded that axillary brachial plexus block with 45 ml of 0.5% racemic bupivacaine, levobupivacaine and ropivacaine produced adequate anaesthesia without any clinically significant differences between the drugs. The difference in mean duration of analgesia of Group-L(803.92 min) and Group-R (807.096

min) ($p>0.05$) are statistically non significant. [Tables 16 and figure 16] which corroborates with the study of Kunitaro *et al* [12] where the postoperative analgesic effects of levobupivacaine and ropivacaine used for brachial plexus blocks are similar. Based on the pharmacology, levobupivacaine is expected to be associated with a longer duration of analgesia compared with ropivacaine [13]. Liisanantti *et al* [9] reported that the duration of analgesia when using levobupivacaine for brachial plexus block was the same as that when using ropivicaine. Mageswaran and Choy6 reported that patients receiving levobupivacaine and ropivicaine reported almost the same pain level at 6 hours after the operation. Casati *et al* [8] reported that there were no difference in postoperative pain scores comparing levobupivacaine and ropivacaine. However, Cline *et al* [10] showed a longer analgesic effect of levobupivacaine compared with ropivacaine.Study done by Holmberg A *et al* [14] found that mean (SD) time to first rescue analgesic after emergence from general anaesthesia in infraclavicular group was 544 (±217) min.

Summary

This study was conducted to compare the efficacy of 0.5% Levobupivacaine and 0.5% Ropivacaine for ultrasound guided infraclavicular brachial plexus block for upper limb surgery.

There was no significant difference in haemodynamic parameters different time interval in both groups and there was difference in saturation in both groups at certain time interval.

We found no difference in onset and duration of sensory and motor block in two groups. Side effects of ultrasound guided infraclavicular block are less than ultrasound guided supraclavicular block as less patients in I group suffered from Suspected diaphragmatic paresis and Horner's syndrome.

Conclusion

We conclude that for ultrasound guided infraclavicular brachial plexus block both the S enantiomer of Bupivacaine i.e. Levobupivacaine and Ropivacaine are similar for both sensory and motor block.

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