

How to Cite:

Kyizom, T., Parag, K., Negi, A. S., Khandelwal, H., & Govil, N. (2022). Ultrasonography guided supraclavicular brachial plexus block, comparison of sensori-motor blockade and duration of postoperative analgesia between ropivacaine and levo-bupivaine: A prospectivetriples blind randomized control study. *International Journal of Health Sciences*, 6(S3), 4157–4168. <https://doi.org/10.53730/ijhs.v6nS3.6750>

Ultrasonography guided supraclavicular brachial plexus block, comparison of sensori-motor blockade and duration of postoperative analgesia between ropivacaine and levo-bupivaine: A prospectivetriples blind randomized control study

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Abstract---The study was conducted to compare the onset time, duration and quality of analgesia between 0.5% levo-bupivacaine and 0.5% ropivacaine given in brachial plexus. This prospective, triple blind randomized controlled trial was conducted between January 2020 to December 2021. Seventy patients were randomly allocated into two groups of 35 patients each to receive USG guided brachial plexus block with 30 ml of 0.5% levo-bupivacaine or 30 ml of 0.5%ropivacaine. Blinded observer recorded the onset time and duration of brachial plexus block. Patient characteristics regarding

age, weight, and surgical time were comparable in the two groups. The mean onset time of sensory blockade with 0.5% ropivacaine and 0.5%levo-bupivacaine was clinically comparable in our present study. The mean duration of sensory block with 0.5% ropivacaine and 0.5% levo-bupivacaine was also comparable in study. The mean onset time for motor block with 0.5%levo-bupivacaine was lesser than 0.5% ropivacaine. The mean duration of motor block observed in present study with 0.5% ropivacaine was lesser than 0.5% levo-bupivacaine. Mean duration of post operative analgesia of 485.0 ± 76.90 mins (8.08 hrs) was noted with 0.5%ropivacaine and 491.91 ± 92.99 mins (8.2 hrs) with 0.5%levo-bupivacaine which was clinically comparable and the difference was statistically insignificant. With the results of our study, we arrived to conclusion that 0.5%levobupivacaine has a shorter motor onset time and longer duration of motor blockade than 0.5%ropivacaine while the onset, duration of sensory block and post operative analgesia was found to be similar and comparable with both 0.5% levo-bupivacaine and 0.5%ropivacaine.

Keywords---brachial plexus block, ultrasonography, ropivacaine, levo-bupivacaine, supraclavicular.

Introduction

Brachial plexus block has become an established and popular technique in modern anaesthesia practice for most upper limb surgeries. The advantages offered by the brachial plexus block include lesser complications and side effects of polypharmacy with general anaesthesia.^[1] Brachial plexus can be blocked at different sites depending upon the site of surgery and extent of surgery in upper limb. The different sites are interscalene, superior trunk, supraclavicular, infraclavicular and axillary.^[2] All approaches have their own specific advantages and disadvantages. Generally, blocks above clavicle (interscalene and supraclavicular) are considered to have faster block than infraclavicular blocks (infraclavicular and axillary). Anatomically above the clavicle brachial plexus nerves are tightly grouped as compared to infraclavicular. This anatomical advantage facilitates a single point injection and rapid onset.^[3]

Ultrasound-guided Supraclavicular brachial plexus blocks have the potential to improve efficacy and/or safety compared with landmark and tactile techniques. Many complications have been reported with the classic approach of brachial plexus block. One of the commonest complication is subclavian vessel puncture and haematoma formation. A 22% incidence of subclavian vessel puncture and consequent 1.4% incidence of hematoma formation have been reported. An incidence of 6.1% and 25 % pneumothorax has been published by Brand and Papper.^[4] All these complications probably has been avoided with the use of ultrasonography guided (USG) blocks.

Local anaesthetics used in brachial plexus blocks like Bupivacaine has advantage as the local anaesthetic, as it has a long duration of sensori-motor blockade, making it an ideal local anaesthetic in terms of providing longer duration of

postoperative analgesia. However, bupivacaine has been reported to be associated with cardiac and central nervous system toxicity which has led to the search of other drugs.^[5] Ropivacaine is also a long acting local anaesthetic with motor sparing effect and is reported to be associated with lesser cardiotoxicity compared to bupivacaine. Levo-bupivacaine (S-bupivacaine), a more recently introduced local anaesthetic is an S-enantiomer of racemic bupivacaine and also reported to be less toxic to the heart and CNS.^[6] Very few studies are present in literatures about the nerve block characteristics of 0.5% levobupivacaine and 0.5% ropivacaine in brachial plexus. Thus, in this prospective randomized triple blind study, we aimed to investigate and compare the efficacy of levobupivacaine and ropivacaine local anaesthetics by comparing onset time of sensory-motor block and duration of sensory-motor block in supraclavicular brachial plexus using ultrasonography.

Materials and Methods

Ethics

After getting permission from the institutional ethical committee of Shri Guru Ram Rai Institute of Medical Sciences Dehradun (SGRR/IEC/69/18 dated 26/12/2018) this study was done by Department of Anaesthesia and Intensive Care in the Department of Orthopaedics of the institute.

Study design

This single center prospective, randomized triple blinded trial was conducted over a period of 2 years (January 2020 to December 2021) as per the Helsinki declaration on human experimentation. The study design and reporting conforms to the consolidated standards of reporting trials (CONSORT) standards.

Study participants

A total of 75 patients were enrolled for the study. Patients of age between 18 and 65 years of either sex, American Society of Anesthesiologists (ASA) grade I-II scheduled for upper limb orthopaedic surgeries (arm, elbow, forearm and hand). Exclusion criteria were infection at the site of injection, shoulder surgeries, history of allergy to study medication, bleeding dyscrasias, neuropathy or neurological disorders and failure of block.

Study intervention

Written and informed consent was obtained from all the patients after explaining the details of the procedure. Pre-anesthetic checkup was done in all the patients included for the study. They were pre-medicated with oral diazepam 10 mg at night before surgery and kept fasting overnight. 75 patients were randomly allocated into two groups. The allocation sequence was generated by a random number table, and group allocation was concealed in sealed opaque envelopes that were not opened until patient consent had been obtained. The patients, the investigators performing the block and evaluator in postoperative care were blinded to group assignment. Out of 75 patients enrolled, 5 patients had to be

excluded from the study due to inadequate block. In the operation theatre, pre-operative parameters including heart rate (HR), Non-invasive Blood pressure (NIBP) and oxygen saturation (SpO₂) were recorded and an intravenous access established.

Technique of Supra-Clavicular Brachial Plexus Block

Position

The patients were placed supine, with the head turned away from the side to be blocked. The arm to be anaesthetized was adducted and the hand extended towards the ipsilateral knee as far as possible.

Technique

The midpoint of the clavicle was identified and marked. After sterile preparation and draping, the ultrasound guided block was performed after real time visualization of nerves, vessels, pleura and bones. In plane approach with USG probe using 20G cannula stylet was done in order that needle tip and shaft was continuously visualized. After reaching the brachial plexus and careful aspiration to exclude vascular puncture, study solution was injected all around the plexus. Patients were given supra-clavicular brachial plexus block using an ultrasound system (Sonosite micro-maxx) using a 8–13 MHz linear HFL38 transducer.

- Group I: Patients received 30 ml of 0.5% ropivacaine (n=35)
- Group II: Patients received 30 ml of 0.5% levo-bupivacaine (n=35)

Surgical anaesthesia was considered to be achieved when the patient reported no sensations and was not able to move limbs. Any sensation or motor response in the desired area was considered as failure of block.

Outcomes measured

Primary outcomes measured were:

- Onset time and sensory block duration: assessed by Ice test method
- Onset time and motor block duration: assessed by modified Bromage score

Secondary outcomes measured were duration of post operative analgesia, intraoperative and postoperative hemodynamics status in both the groups.

- Sensory block duration: evaluated from onset of sensory block till VAS<4
- Motor block duration: evaluated from onset of motor block till flickering of fingers.
- Sensory-motor block was assessed every 2 hours for the initial 8 hours and thereafter every 4 hours till the recovery.

The following observations were also made:

- Duration of post-operative analgesia: Assessed by the time for the need of 1st rescue analgesia after shifting patient to PACU.
After the recovery of sensations, pain was assessed using VAS score (0= no pain to 10 = worst pain) every two hours for the first 8 hours and thereafter every 4 hours till the need for rescue analgesia.
Inj. Tramadol 1mg/kg intravenously was given as rescue analgesia. Rescue analgesia was administered at a VAS of ≥ 4 .
- ECG and SpO₂ was monitored continuously throughout the surgery. Heart rate, NIBP was recorded every 5mins for the first 15mins and thereafter every 15mins throughout the surgery. In post operative period also, HR and NIBP was monitored every 2 hours for the first 8 hours and thereafter every 4 hours till the need for rescue analgesia.

Statistical analysis

The data was collected and analysed using SPSS Statistics ver. 23 (IBM Corp., Armonk, NY). For the quantitative data, (haemodynamic changes, duration of sensori-motor blockade and the onset and post operative analgesia), unpaired student t-test was used. Non Parametric Mann Whitney U test was applied in case the data did not follow normal distribution. Chi-square test or Fisher Exact test was used for the comparison of categorical variables (side effects). p value <0.05 was taken as level of statistical significance. Sample size was calculated considering the mean onset of motor block in ropivacaine group as 19.0 ± 2.7 mins and mean duration of onset of motor block in levo-bupivacaine as 17.1mins, assuming 95% Confidence Interval and 85% as power of study.^[7] The sample size for the study was calculated to be 64 with 32 participants in each group but we took 35 participants in each group in our study.

Results

There was no statistical significant difference regarding age, ASA physical status, sex ratio and duration of surgery [Table 1]. Baseline oxygen saturation, mean blood pressure and HR between the groups were comparable. The mean sensory block onset in Group I was noted to be 14.37 ± 3.77 mins and 14.06 ± 4.46 mins in Group II. This was comparable and the difference was statistically insignificant ($p = 0.751$). The mean onset of motor block was faster in Group II (15.66 ± 5.54 mins) as compared to Group I (19.63 ± 3.96 mins). This difference was significant statistically ($p=0.001$). [Table: 2, Fig.1]. The sensory blockade in group I lasted for 435.3 ± 77.28 mins and for 429.71 ± 91.87 mins in group II. Therefore, the mean total duration of sensory blockade in both the groups were similar and comparable statistically. The difference between the two groups was also noted to be insignificant statistically ($p= 0.785$). [Table 3, Fig.1]

The duration of motor blockade was lesser in group I as compared to group II. While the motor block extended to a mean duration of 440.29 ± 98.55 mins in group II, it lasted for only 371.43 ± 77.59 mins in group I. This difference of over 68mins was both clinically and statistically significant ($p = 0.002$). [Table 3,4 Fig.1]. A difference of less than 7 minutes in the mean duration of post operative

analgesia was noted between the two groups, the values being 485.0 ± 76.90 mins in Group I and 491.91 ± 92.99 mins in Group II. This was clinically and statistically insignificant. [Table: 5]. All patients were either pain free or had mild pain and did not request for rescue analgesia for the first 6 hours after surgery. Only 4 patients each in both the study groups reported VAS scores 4 between 6th to 8th postoperative hour. The number of patients reporting VAS score 4 increased four fold in both the groups between 8th and 12th postoperative hour, the number being 18 in group I and 17 in group II. [Table 6 Fig 2,3]

The mean systolic blood pressure ranged between 118.91 ± 8.35 mmHg and 125.66 ± 9.50 mmHg in group I and between 116.53 ± 9.38 mmHg to 126.17 ± 10.63 mmHg in group II. These values were well within normal limits. When the two groups were compared, the difference in mean SBP at various time intervals was found to be statistically insignificant. In both the groups, mean heart rate remained normal at all times during the surgery. Mean heart rate at baseline and at various intervals specified in the table were found to be clinically and statistically comparable between the two groups. ($p > 0.05$). Throughout the intraoperative period, no ECG abnormalities were noted in any patient, at any time and oxygen saturation remained between 98–100%.

Table 1
Demographic Data

	GROUP I	GROUP II	p value
Age	36.6 $\pm$ 12	37.8 $\pm$ 10	0.35
Sex (Male:Female)	25:10	23:12	0.76
ASA (I:II)	30:5	29:6	0.54
Duration of surgery (mins)	110 $\pm$ 28	102 $\pm$ 32	0.67

Table 2
Mean onset of block

VARIABLE (mins)	GROUP I	GROUP II	p VALUE
Sensory block	14.37 $\pm$ 3.77	14.06 $\pm$ 4.46	0.751
Motor block	19.63 $\pm$ 3.96	15.66 $\pm$ 5.54	0.001

Table 3
Duration of Block

VARIABLE	GROUP I	GROUP II	p VALUE
Sensory block (mins)	435.3 $\pm$ 77.28	429.71 $\pm$ 91.87	0.785
Motor block (mins)	371.43 $\pm$ 77.59	440.29 $\pm$ 98.55	0.002

Table 4
Median Duration of Post Operative Motor Block

BROMAGE SCORE (POST OP)	Ropivacaine Median (IQR)	Levo- bupivacaine Median (IQR)	p-value
IMMEDIATELY	3(3-3)	3(3-3)	0.99
2 HOUR	3(3-3)	3(3-3)	0.99
4 HOUR	3(3-3)	3(3-3)	0.94
6 HOUR	3(2-3)	3(3-3)	0.00
8 HOUR	2(2-2)	2(2-3)	0.86
12 HOUR	2(2-2)	2(2-2)	0.99

Table 5
Mean Duration of Post Operative Analgesia

VARIABLE	GROUP I	GROUP II	p VALUE
Post-operative analgesia (mins)	485.0 ± 76.90	491.91 ± 92.99	0.737

Table 6
Median Duration of Post Operative Analgesia

VAS SCORE (POST OP)	Ropivacaine Median (IQR)	Levo-bupivacaine Median (IQR)	p-value
IMMEDIATELY	0(0-0)	0(0-0)	0.99
2 HOUR	0(0-1)	0(0-0)	0.18
4 HOUR	1(1-2)	1(1-2)	0.23
6 HOUR	3(2-3)	2(2-3)	0.70
8 HOUR	4(2-4)	4(3-4)	0.97
12 HOUR	4(4-4)	4(4-4)	0.99

Discussion

Supraclavicular brachial plexus block is a popular and widely employed regional nerve block technique for perioperative anaesthesia and analgesia for surgery of the upper extremity. The present study was conducted in the department of Anaesthesiology, Shri Guru Ram Rai Institute of Medical & Health Sciences to compare the time of onset and duration of sensory block, motor block and the duration of post-operative analgesia between 0.5% ropivacaine and 0.5% levobupivacaine using USG guided Brachial plexus block. Hickey et al [8] compared the efficacy of 40 ml of 0.25 % ropivacaine with 0.25% bupivacaine for brachial plexus block. They reported that despite virtually identical efficacy in terms of the onset and duration of sensory block between the two drugs, the block was inadequate for surgical anesthesia with a high failure rate and a frequent need for intra-operative supplementation of the blocks or conversion into general anesthesia. They further recommended the use of 0.5% concentration of both the

drugs. In the present study, both ropivacaine and levobupivacaine were used in a concentration of 0.5% and a bolus dose of 30 ml.

Onset time of sensory block

In our study, the mean onset time of sensory blockade with 0.5% ropivacaine and 0.5 % levo-bupivacaine was clinically comparable, with no statistically significant differences between the two groups. However, in other literatures Gonzalez et al.^[9] reported a high mean onset time for sensory block with 0.5% ropivacaine as well as 0.33% levobupivacaine used for brachial plexus block. The result of Gonzalez et al could be explained by the fact that they used lesser concentration of levobupivacaine and different approach of brachial plexus block in their study. Our observations were comparable to those of Cline et al,^[10] and Piangatelli et al^[11] even though Piangatelli et al had used a higher concentration of 0.75 % ropivacaine. Mageswaran and Choy^[7] however reported a lower mean onset time of sensory block of with 0.5 % levobupivacaine when used for infraclavicular brachial plexus block. In a recent study, Thalamati D et al^[12] reported very early onset of sensory block even with lower volumes of local anaesthetics as they used combined approach using ultrasonography and nerve stimulator for supraclavicular block.

Onset time for motor block

In the present study, we found that the onset of motor blockade was faster with 0.5% levobupivacaine than with 0.5% ropivacaine ($p = 0.001$). Our findings concur with the observations of Mageswaran and Choy,^[7] Gonzalez et al^[9] and Piangatelli et al^[11] This is in contrast that Gonzalez et al has used lower concentration 0.33% levobupivacaine in their study where as Piangatelli et al had used a higher concentration of 0.75% ropivacaine. Thalamati D et al^[12] reported very early onset of motor probably by increasing the accuracy of block as they used combined approach using ultrasonography and nerve stimulator for supraclavicular block.

Duration of sensory block

The mean duration of sensory block with 0.5% ropivacaine and 0.5% levobupivacaine was comparable in our study. The observations of Cline et al,^[10] Piangatelli et al^[11] and Liisananti et al^[13] differ from those of the present study. They reported a much higher duration of sensory block. Cline et al^[10] had added 1:200,000 epinephrine as an adjuvant to local anaesthetic, Liisananti et al used higher volumes (45ml) of local anaesthetics where as Piangatelli et al used higher conc. (0.75%) of ropivacaine but used same conc. of levobupivacaine as in our study. The findings from our study with comparison to other studies suggest addition of adjuvants, higher conc. and higher volumes do prolong sensory block duration.

Duration of motor block

In our study, the duration of motor block was found to be higher with 0.5% levobupivacaine as compared to 0.5% ropivacaine. This difference was statistically

significant ($p = 0.002$). The mean duration of motor block observed in our study with 0.5% ropivacaine was much less than the duration of motor block reported by others. Piangatelli et al^[11] reported a longer mean duration of motor blockade with 0.75% ropivacaine. Cline et al^[10] and Hannah and Sloan^[14] also noted that motor block with 0.5% ropivacaine with epinephrine lasted much longer. These results may be consistent as adding adjuvants and using higher concentration of local anaesthetic could prolong the motor block. A mean duration of motor block in our study with 0.5% levobupivacaine findings are in agreement with those of Piangatelli et al, Cline et al and Hannah and Sloan. The above findings and inference from other studied reveals that higher conc. and adding adjuvant to ropivacaine significantly increases motor blockage time as compared to levobupivacaine.

Duration of post operative analgesia

Our study used Visual Analogue Scale (VAS) to quantify the post-operative pain and determine the mean duration of post operative analgesia. Mean duration of post operative analgesia of 485.0 ± 76.90 mins (8.08 hrs) was noted with 0.5% ropivacaine and 491.91 ± 92.99 mins (8.2 hrs) with 0.5% levobupivacaine in our study. This was clinically comparable and the difference was statistically insignificant ($p = 0.737$). Mageswaran and Choy,^[14] Casati et al^[15] and Hannah and Sloan,^[12] also reported comparable duration of postoperative analgesia with both 0.5% ropivacaine and 0.5% levobupivacaine. The limitations of this study, we used only fixed conc. and dose of drug. Further studies are required with different conc. and volume to determine the minimum conc. and volume of the drug for the desired block. We did not study addition of adjuvants in the block for search of ideal adjuvants which prolongs the analgesic effect without prolonging motor block duration. We did not use nerve stimulator for blocks which could have further enhanced quality of block.

Conclusion

The onset of sensory block, duration of sensory block and postoperative analgesia are similar and comparable with both 0.5% ropivacaine and 0.5% levobupivacaine. The motor blockade onset was faster and the motor block duration was longer with 0.5% levobupivacaine in comparison to 0.5% ropivacaine. In our study 0.5% ropivacaine and 0.5% levobupivacaine, in a dose of 30 ml are safe for supraclavicular brachial plexus block in adults, and not associated with any side effects. In orthopaedic surgeries, early return of muscle power with good postoperative pain relief is desirable. Early active finger movements reduce post-operative oedema, and allow assessment of nerve integrity so 0.5% ropivacaine seems to offer an advantage over 0.5% levobupivacaine in this respect, for brachial plexus block. So in present study, we see similar onset and duration of sensory block and different onset and duration of motor blockade with two drugs but further studies are required to confirm and establish this fact.

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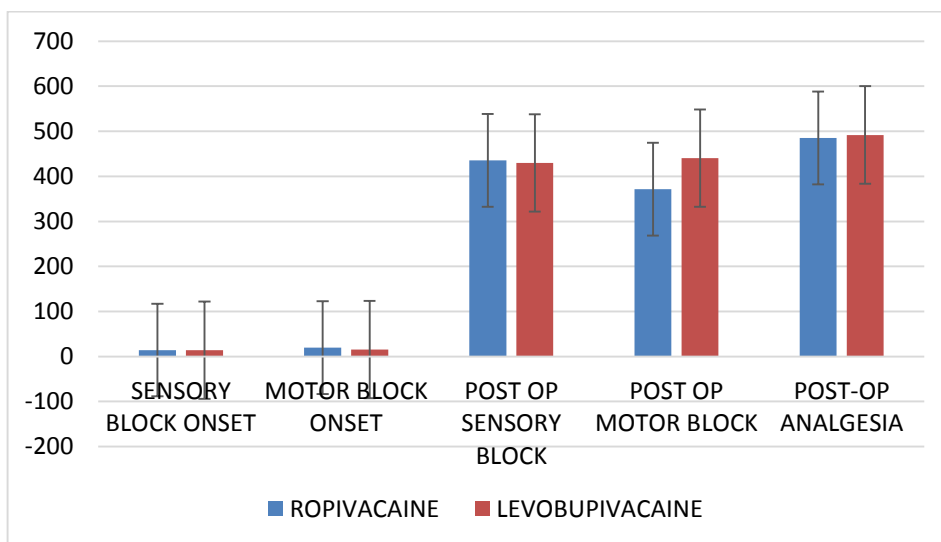


Fig 1. Time of onset of block and duration of block and post operative analgesia

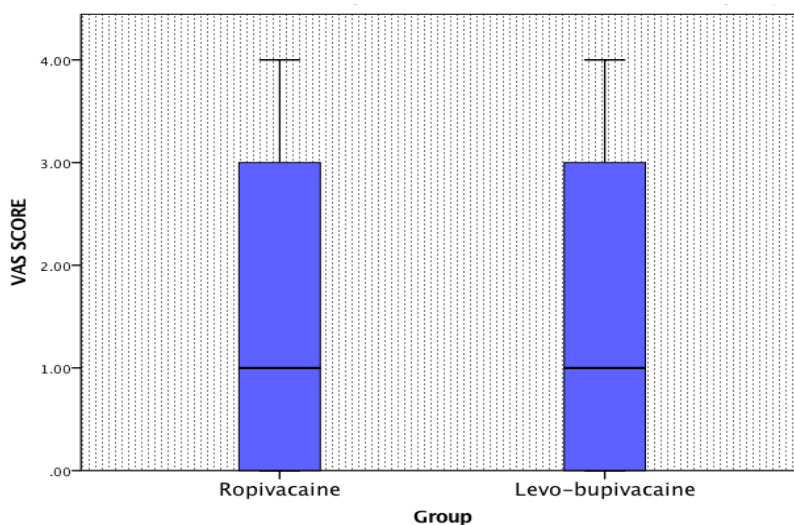


Fig 2. BOX-WHISKER PLOT showing distribution of VAS Score in two groups

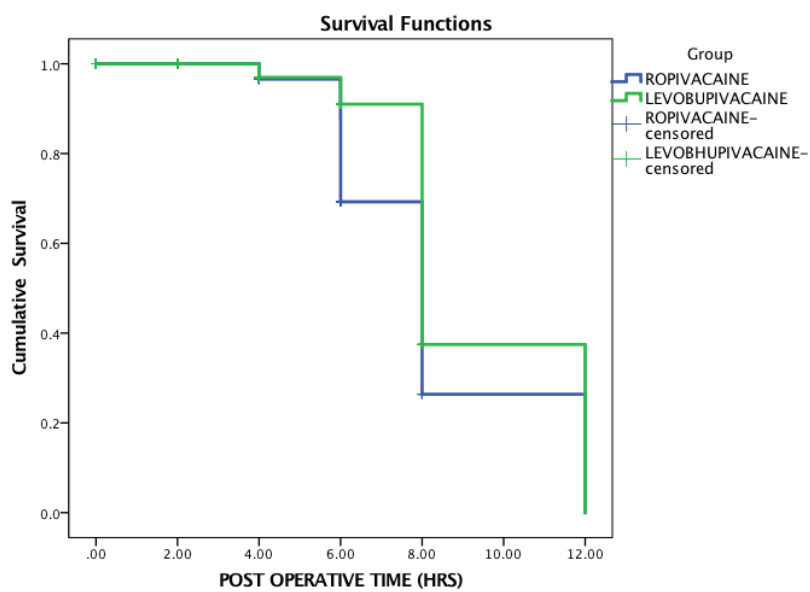


Fig 3. Kaplan-miere graph