Section: Anaesthesia

Original Research Article

COMPARISON OF DURATION OF ANALGESIA AND BLOCK CHARACTERISTICS OF 0.375% LEVOBUPIVACAINE VERSUS 0.375% ROPIVACAINE IN ULTRASOUND-GUIDED SUPRACLAVICULAR BRACHIAL PLEXUS BLOCK FOR FOREARM ORTHOPAEDIC SURGERIES

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ABSTRACT

Background: Ropivacaine and Levobupivacaine are commercially available, intermediate-acting local anesthetics with similar anesthetic and analgesic potency. However, they differ in their risk profiles for cardiovascular and central nervous system (CNS) toxicity. In the context of brachial plexus blocks, which require relatively large doses, both Ropivacaine and Levobupivacaine offer a greater margin of safety. This study compares the onset of sensory and motor blockade between Levobupivacaine and Ropivacaine at a comparatively lower concentration of '0.375%' in Ultrasound guided supraclavicular brachial plexus block in upper limb orthopedic surgeries. **Materials and Methods:** A total of 62 adult patients undergoing elective forearm orthopedic surgeries were randomly assigned to one of two groups: Ropivacaine (Group R) or Levobupivacaine (Group L). Each group received 30 ml of 0.375% local anesthetic solution. Onset and duration of sensory and motor blockade, and duration of analgesia were assessed. **Result:** The mean onset of sensory block was similar and statically insignificant in both groups. The onset of motor blockade was 20±1.52 minutes in group L and that of group R was 11.94±1.34 minutes ($p<0.001$) and was statistically significant. The mean duration of sensory block was (10.18±0.44) hours in-group L when compared to group R (7.79±0.53). Group L had a significantly longer duration of analgesia (10.2±0.46) hours as compared to group R (7.8±0.51) Patient in group L had a longer duration of motor block (9.49±0.47) hours as compared to group R (6.47±0.44). **Conclusion:** 0.375% concentrations of both drugs provide excellent anesthetic properties while minimizing the risk of systemic toxicity associated with clinical doses of local anesthetics. Ropivacaine offers an advantage in facilitating early recovery of motor function in the postoperative period. Levobupivacaine provides a longer duration of analgesia.

INTRODUCTION

Regional anesthesia is an excellent adjunct or alternative to general anesthesia for extremity surgeries.[1] The advent of ultrasound imaging technology and safer drugs have made peripheral nerve blocks an integral part of anesthetist armamentarium. The supraclavicular level for the brachial plexus block is an ideal site for anesthesia of the upper extremity just distal to the shoulder. The plexus remains relatively tightly packed at this level, producing a rapid and high-quality block. For this reason, the supraclavicular block is often called the "spinal of the arm".[2] This block is performed at the level of the brachial plexus trunks where almost the entire sensory, motor, and sympathetic innervation of the upper extremity is carried in just three nerve structures confined to a very small surface area. Consequently, typical features of this block include its rapid onset, predictability, and density.[3,4] The increased availability of ultrasound in clinical practice has come with the ability to identify and avoid vascular and pleural structures as well as allow real-time visualization of the needle.

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An ideal local anesthetic should have a fast onset of sensory and motor blockade, differential offset, with an earlier offset of motor than sensory blockade, enabling early ambulation with prolonged analgesia.[5,6] The clinical profiles of Levobupivacaine and Ropivacaine are like that of racemic bupivacaine, and the minimal differences among the three agents are mainly related to the slightly different anesthetic potency.[7] They produce effects like other local anesthetics via reversible inhibition of sodium ion influx in nerve fibers. We prefer to use both drugs because of their similarity.[8] However higher concentrations of local anesthetics have not only been associated with increased direct neurotoxicity to the neurons but also the volume must be carefully selected to avoid exceeding the maximal dose.[9] Finding a lower concentration local anesthetic agent with quicker onset is important to anesthesiologists, especially in centers without a preparation room for performing blocks. However, previous literature usually compared Levobupivacaine and Ropivacaine at relatively higher concentrations and there is a paucity of data comparing lower concentrations of these drugs.[10-12] Therefore, in this study, we aimed to compare the analgesic effectiveness as primary outcome and nerve block characteristics of 0.375% Levobupivacaine and 0.375% Ropivacaine and procedural complication as secondary outcomes.

MATERIALS AND METHODS

This randomized controlled trial was conducted at a rural tertiary-level hospital in north India from November 2020 to 2022, following approval from the Institutional Ethics Committee and registration of the trial. The study included the American Society of Anesthesiologists (ASA) physical status I-II patients scheduled for elective upper limb surgery under ultrasound-guided supraclavicular brachial plexus block.

Written informed consent was obtained from all participants. Sixty-two patients were enrolled and randomly allocated to one of two groups using computer-generated randomization:

- Group L (n=31): Received 30 ml of 0.375% Levobupivacaine for supraclavicular block
- Group R (n=31): Received 30 ml of 0.375% Ropivacaine for supraclavicular block

To maintain double-blinding, the anesthesiologist preparing the study drugs remained independent of the study. Additionally, the clinician assessing outcomes was blinded to each patient's group allocation, ensuring a double-blinded, randomized controlled trial design. Patients with clinically significant coagulopathy, ASA ≥ 3, infection at the injection site, history of allergy to local anesthetics, history of drug abuse, preexisting neurological disorders and hepatic conditions, consent refusal, and age <18 years or >65 years were excluded from the study.

A comprehensive preoperative assessment was conducted a day before surgery. Patients received a detailed explanation of the brachial plexus block procedure in their native language. All patients were given a tablet of alprazolam 0.5mg orally on the night before surgery. In the operation theatre standard monitors were connected (Non-Invasive Blood Pressure (NIBP), Electrocardiogram, and Pulse-Oximeter) and the readings were taken as baseline recordings. 18 G intravenous cannula was secured in the contra-lateral hand. Appropriate equipment for procedures and drug-related complications was kept ready. Anxiolysis was established with intra-venous midazolam 0.03mg kg-1.

Sensory and motor block were assessed every 5 minutes till 30 minutes and or complete block is achieved. The degree of sensory block was assessed with response to an atraumatic prick with the blunt needle in the relevant dermatome innervated by radial, ulnar, and median nerves. Sensory block was graded according to a two-grade scale (0 = no sensory loss, 1 = loss of pinprick sensation).The Degree of motor block was assessed using the Modified Bromage scale (MBS; 0 = Normal muscle function, 1 = Elbow flexion, 2 = Wrist flexion, 3 = Full motor block).Sensory block onset time was taken as the time between injection of local anesthetic and loss of pain sensation with pinprick stimulus. Motor block onset time was taken as time between injection of local anesthetic and MBS 1 appearance.

Surgical anesthesia time was defined as sensory block grade 1 and motor block grade 2 or 3 in relevant dermatomes. When surgical anesthesia was achieved patient was assumed ready for surgery. The Time taken for achievement of surgical anesthesia was noted and surgery was started. If surgical anesthesia was not achieved in 30 minutes it was considered a “failed block” and the patient was operated under general anesthesia.

The quality of the block was compared to the need for intraoperative opioids. No analgesic requirement was considered a “complete block”. A 50 µg bolus of fentanyl was given to the patient if the patient complained of pain or VRS>4, if pain persisted after 5 minutes another bolus of 50 µg fentanyl was given. Intraoperative requirement of more than 100 µg of fentanyl was considered as “insufficient block”. If fentanyl supplementation was not sufficient to complete surgery, the block was considered a “failed block” and the patient was given General Anesthesia.

Sensory block duration was defined as the time elapsed between the sensory block onset to the first dull pain sensation (VAS<4). Motor block duration was the time between the onset of the motor block to the complete recovery of motor power (Bromage four-point score of 0).

The total duration of analgesia was defined as the time interval between the onset of the sensory block and the first request for additional analgesics, which occurred when the patient reported a pain score of 4 on the Visual Analog Scale (VAS). The VAS scale ranged from 0 (no pain) to 10 (worst pain

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imaginable). As part of standard postoperative care, patients received routine analgesics: - Injection of paracetamol 1g thrice daily. Additional analgesia was provided with an injection of diclofenac 75mg when patients reported a pain score of 4 or higher on the VAS, supplemental to their routine analgesic regimen.

Patients were evaluated hourly to assess the duration of postoperative analgesia, sensory blockade, and motor blockade. Vital parameters, like, systolic blood pressure (SBP), diastolic blood pressure (DBP), arterial saturation (SpO2), respiratory rate (RR), and heart rate (HR) were monitored at every 5 min intervals till 30 minutes of LA injection and then every 10 minutes till end of surgery. Adverse events such as hypotension (20% decrease in blood pressure from the baseline value), bradycardia (HR<60 bpm), hypoxemia (SpO2 <90%), and perioperative nausea and vomiting were recorded. After 24hour post-surgery patient was reassessed and patient satisfaction was evaluated using three-point scale "not satisfied, slightly satisfied, and satisfied.

RESULTS

Table 1: Distribution of patients concerning demographics

VARIABLE	GROUPS		P VALUE
	GROUP L (N=31)	GROUP R (N=31)	
Age (years)	31.90±11.42	34.16±13.46	0.479
Age group distribution			
10-20 years	5(16.1)	6(19.4)	0.650
21-30 years	11(35.5)	10(32.3)	
31-40 years	8(25.8)	4(12.9)	
41-50 years	5(16.1)	7(22.6)	
51-60 years	2(6.5)	4(12.9)	
Sex			
Male	24(77.4)	21(67.7)	0.570
Female	7(22.6)	10(32.3)	
ASA (American Society of Anesthesiologists) physical status			
ASA I	25(80.6)	25(80.6)	1.000
ASA II	6(19.4)	6(19.4)	
BMI-kg/m^2	24.06±4.27	25.65±2.90	0.092

Table 2: Sensory and motor block characteristics

	GROUP L (N=31) (MEAN±SD)	GROUP R (N=31) (MEAN±SD)	P-VALUE
Onset of Sensory blockade (minutes)	16.42±2.24	15.90±1.42	0.284
Onset of Motor blockade (minutes)	20.00±1.52	11.94±1.34	<0.001*
Onset of surgical anesthesia (minutes)	28.5±2.9	24.3±3.18	0.30
Duration of Sensory blockade (hours)	10.18±0.44	7.79±0.53	<0.001*
Duration of Motor blockade (hours)	9.49±0.47	6.47±0.44	<0.001*
Duration of analgesia (hours)	10.2±0.46	7.8±0.51	<0.001*
Patient satisfaction (Not satisfied, slightly satisfied, satisfied)	0,1,30	0,2,29	0.35

All values are shown as mean ± SD,

$ Patient satisfaction value represents the number of patients.

*Values showing clinical significance

The mean time for onset of motor block was 20.00±1.52 minutes in Group L and was 11.94±1.34 minutes in Group R (Table 2). Motor block was achieved earlier in Group R and the time difference was statistically significant (p<0.005). Time differences to achieve surgical anesthesia were not clinically significant between both groups (Table 2). The mean duration of sensory block was (10.18±0.44) hours in group L when compared to group R (7.79±0.53). [Table 2] Group L had a significantly longer duration of analgesia (10.2±0.46) hours as compared to group R (7.8±0.51) (Table 2). Patient's in-group L had a longer duration of motor block (9.49±0.47) hours as compared to group R (6.47±0.44). [Table 2] The quality of blockade was comparable between the two groups, with no significant differences observed. One patient in Group L required supplemental analgesia with 50µg of fentanyl, but no failed blocks were reported in either group. Hemodynamic parameters, including pulse rate, oxygen saturation, systolic blood pressure, and diastolic blood pressure, remained stable and showed no statistically significant differences between the two groups, both intraoperatively and postoperatively. [Figure 2]

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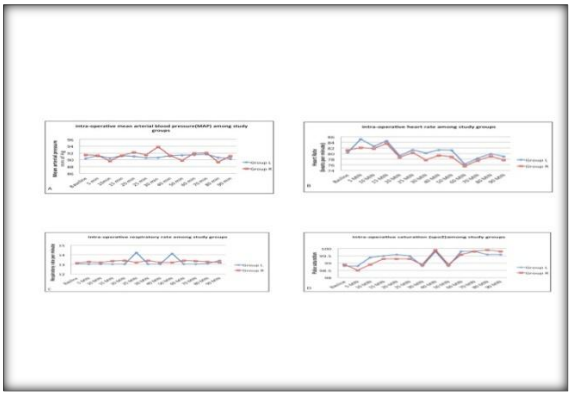

No episodes of hypotension, hypertension, nausea, or vomiting requiring pharmacological intervention were reported. Patient satisfaction was equally high in both groups. All patients experienced complete recovery of sensory and motor functions, with no reported complications.

Statistical Analysis: The sample size for this study was determined based on the results of a pilot study. Assuming a mean difference of 2 hours and a standard deviation of 2.8, a sample size of 31 patients per group was calculated to achieve adequate statistical power. Statistical analysis was performed using SPSS for Windows, version 22.0(SPSS Inc, Chicago, IL, USA) Quantitative variables were summarized using mean and standard deviation (SD). Categorical variables were represented using frequency and percentage. An Independent sample t-test was used to test the statistical significance of the difference between means of variables among different independent groups. Pearson Chi-square test was used for comparing categorical variables between groups. A p-value of <0.05 was considered statistically significant.

DISCUSSION

Levobupivacaine and Ropivacaine are two long - acting local anesthetics that have been developed as an alternative to Bupivacaine. Both of these agents are pure left isomers and due to their three-dimensional structure, seem to have less toxic effects on the central nervous system and the cardiovascular system.[13-16]

The use of 0.375% drug concentration is based on the conclusion of different studies.[17-20] Wonkyo et al,[17] compared the clinical effect of 0.375% Levobupivacaine with 0.5% Levobupivacaine for ultrasound (US) guided Axillary Brachial Plexus Block (ABPB). There was no clinically significant difference between these two concentrations of Levobupivacaine. The Study by Cox et al,[19] and Hickey et al,[20] concluded that the 0.25% concentration of local anesthetic for brachial plexus block is not sufficient to achieve surgical anesthesia because of slow onset and has a high rate of the inadequate block.

In our study, motor and sensory block onset time and surgical anesthesia time were shorter in Group R. Mean motor block onset time was 11 min in Group R and 20 min in Group L, while the mean sensory block onset time was 15 min in Group R and 16 min in Group L. Onset of surgical anesthesia took 24 min in Group R compare to 28 min in Group L. Even though there is a statistical difference between the two drugs regarding motor block onset time, it's not of significance in clinical application. Mankad et al,[21] in a similar study with 0.5% concentration of Levobupivacaine and Ropivacaine concluded that there was no statistical difference in the onset of sensory blockade among the two groups. In our study, we observed that the onset of sensory block was slower in the two groups (15 min in Group R and 16 min in Group L) than observed by Mankad et al. (11 min for Levobupivacaine and Ropivacaine). This may be because they have used a higher concentration (0.5%) of drugs. The study by Fournier et al,[22] and Agarwal et al,[23] also concluded that equal volumes and concentrations of either drug produce a similar pattern of sensory block but the motor block is faster in onset, less in intensity, and shorter in duration with Ropivacaine. Hetal et al,[24] compared the effect of 35 ml of 0.375% bupivacaine with 35 ml of 0.375% Ropivacaine in supraclavicular brachial plexus and obtained a similar result regarding the onset of sensory blockade.

The duration of analgesia was 10.2 hours in Group L and, was significantly longer than 7.8 hours in Group R ($P < 0.05$). Motor blockade and sensory blockade duration were significantly longer with Levobupivacaine (9.49 hours, 10.18 hours) when compared with Ropivacaine (6.4 hours, 7.79 hours) ($P < 0.05$). Similar results were observed by Ranjan et. al25. When they compared the effectiveness of supraclavicular brachial plexus anesthesia with two different concentrations of Ropivacaine (0.5% and 0.75%) and compared them with the standard 0.5% Bupivacaine. The onset of sensory and motor block was similar in all three groups. However, when compared to the Bupivacaine group, recovery of motor functions was faster in both the Ropivacaine groups. Cline et al,[26] observed similar results when he compared a higher concentration (0.5%) of Levobupivacaine with Ropivacaine in the supraclavicular block. He concluded duration of sensory analgesia was significantly longer in the Levobupivacaine group (831 minutes) than in the Ropivacaine group (642 minutes, $P = .013$). Return of motor activity was significantly faster in the Ropivacaine group (778 minutes) than in the Levobupivacaine group (1,047 minutes; $P = .001$). The relatively longer duration of the sensory and motor block as compared to our study could be attributed to the addition of epinephrine and the use of higher drug concentrations. Kaur et al,[27] observed that the mean duration of motor and sensory block was significantly longer in the Bupivacaine group (408.40±50.39, 450.40±54.50 minutes) as compared to the Ropivacaine group (365.60±34.29, 421.20± 38.33 minutes) ($p=0.001$). We got similar results but with a lower drug concentration. This may be

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attributed to the use of ultrasound-guided better anatomical coverage of the brachial plexus.

In our study, complete sensory and motor blocks were achieved in nearly all patients, except for one patient in group L who needed 50 µg of IV fentanyl intraoperative. This high success rate seems to be due to the use of USG, and and operator's skill. There was no clinical or statistical change in respiratory rate, arterial saturation, blood pressure, and heart rate at all measured intervals in the two groups. We did not find any hemodynamic side effects, which support their safety profile. Also with the usage of ultrasound guidance, we were able to prevent any incidences of pneumothorax, accidental intravascular injection, and other complications.

While this study provides valuable insights into the comparison of Levobupivacaine and Ropivacaine in ultrasound-guided supraclavicular blocks, it has some limitations and further research is necessary to expand our understanding of these drugs. The patient population was restricted to those with ASA I and II physical status scores. Therefore, further studies are needed to establish the safety and efficacy of Levobupivacaine and Ropivacaine in high-risk groups. Future studies should investigate the use of these drugs in other peripheral nerve blocks, such as femoral and sciatic nerve blocks and examine the impact of adding adjuvants to block character sticks. These future studies will help to further elucidate the properties of Levobupivacaine and Ropivacaine, ultimately guiding clinical practice and improving patient outcomes.

CONCLUSION

Our study demonstrates that 0.375% concentrations of both Ropivacaine and Levobupivacaine, in a 30ml volume, are sufficient to provide effective surgical anesthesia for ultrasound-guided supraclavicular brachial plexus block. Utilizing these safer local anesthetics at lower concentrations minimizes the risk of toxicity. Notably, while both drugs exhibit similar onset times for motor and sensory blocks, Ropivacaine offers an advantage in facilitating early recovery of motor function in the postoperative period. In contrast, Levobupivacaine provides a longer duration of analgesia, making it a preferable choice in certain long-duration surgeries.

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