Original Article

A comparative double blinded study of levobupivacaine and ropivacaine in USG guided supraclavicular brachial plexus block

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Abstract

Introduction: Existing local anaesthetics are known for its wide and unpredictable latency of nerve block, as well as its propensity for neuro and cardiotoxicity. Ropivacaine has a potential clinical advantage during neural blockade. Bupivacaine possessed the same anaesthetic activity but had less cardiac and neural toxic effects than bupivacaine. The purpose of this clinical study was to compare the onset, duration and quality of sensory and motor blockade and postoperative analgesia between groups of patients receiving supraclavicular brachial plexus block with 0.5% ropivacaine and 0.5% levobupivacaine under USG guidance. **Material and Methods:** The study was conducted in two groups of 30 patients each. The patients were randomly allocated in two groups by sealed envelope technique as – Group R (received 30 ml of 0.5% Ropivacaine) and Group L (received 30 ml of 0.5%Levobupivacaine).The onset of sensory and motor block, their duration, and duration of postoperative analgesia were recorded and compared for both groups. **Results:** The mean onset time and mean peak time for sensory and motor block was significantly faster in Group R as compared to Group L.The mean duration of sensory and motor block was 8.13 hours and 10.05 hrs in group R as compared to 10.06 hours and 11.79 hrs in group L respectively.The mean duration of postoperative analgesia was significantly higher in group L (13.20±1.61) hours as compared to (9.50±1.43) hours in group R. **Conclusion:** The onset of action of sensory, motor was early in ropivacaine group with faster recovery of motor function as compared to equivalent dose of levobupivacaine. Ropivacaine offers an advantage where early recovery of motor function is desired in postoperative period. Levobupivacaine has a better profile in terms of duration of analgesia and should be considered when postoperative analgesia is a concern but not when early return of motor activity is required.

Keywords: Levobupivacaine, Ropivacaine, Supraclavicular brachial plexus block.

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Received Date: 02/01/2017 Revised Date: 28/01/2017 Accepted Date: 22/02/2017

Access this article online

Quick Response Code:

Website: www.medpulse.in

DOI: 06 March 2017

INTRODUCTION

Regional anaesthesia with supraclavicular brachial plexus block is a useful technique for upper limb orthopaedic surgery. Brachial plexus block offers many advantages over general anaesthesia for upper limb surgeries such as sympathetic block, better post-operative analgesia and no systemic side effects. Existing local anaesthetic, bupivacaine is known for its wide and unpredictable latency of nerve block when small volume of local anaesthetic solution is injected, as well as its propensity for neuro and cardiotoxicity when large volume of the drug is required[1-3]. This prompted the researchers to develop new local anaesthetic agents with a profile that contained all the desirable aspects of bupivacaine without the undesirable toxic effects. One of the first local anesthetic agents that emerged as a replacement of bupivacaine was ropivacaine. It is a long acting amide local anesthetic agent with potentially improved safety profile when compared to bupivacaine[1-2]. Human trials have demonstrated less cardiac depression and fewer central nervous system toxic effects, less motor block and similar duration of action of sensory analgesia with ropivacaine. Hence, ropivacaine may offer advantage of reduced toxicity with accidental intravascular injection. It suggests a potential clinical advantage of this drug during neural blockade when large amount of local anaesthetic is required. This property

How to site this article: Anuja A Rathore, Jyotsna P Bhosale. A comparative double blinded study of levobupivacaine and ropivacaine in USG guided supraclavicular brachial plexus block. *MedPulse – International Medical Journal.* March 2017; 4(3): 320-324. http://www.medpulse.in (accessed 08 March 2017).

may also enable the use of the solution with a higher concentration to enhance the speed of onset and to prolong the duration. Levobupivacaine, the S-enantiomer of bupivacaine, is the latest local anaesthetic agent introduced into the clinical practice. Studies have revealed that R-dextrobupivacaine and S-levobupivacaine enantiomers of bupivacaine possessed the same anaesthetic activity but the S-enantiomer had less cardiac and neural toxic effects than bupivacaine[4],while still possessing similar duration of sensory blockade[5-7]. Technology and clinical understanding of anatomical ultrasonography (USG) has greatly evolved over the past decade and has reduced the complications of conventional peripheral nerve block techniques. Recent studies have shown that direct visualization of the distribution of local anaesthetic with high frequency probes can improve the quality of peripheral nerve block and avoid complications such as intravascular and intraneural injection. Ultrasound guidance enables the anaesthetist to secure an accurate needle position and monitor the distribution of local anesthetic in real time. This prompted us to undertake the study between these two local anesthetic agents under USG guidance in supraclavicular brachial plexus block. It also has been noticed that there are no direct comparative trials that have been performed between these two agents in patients receiving supraclavicular brachial plexus block. Therefore, the purpose of this clinical study was to compare the onset, duration and quality of sensory and motor blockade and postoperative analgesia between groups of patients receiving supraclavicular brachial plexus block with 0.5% ropivacaine and 0.5% levobupivacaine under USG guidance.

MATERIAL AND METHODS

After the institutional ethical committee approval and written informed consent, a double blinded randomized clinical study was carried out in 60 American society of Anesthesiologists (ASA) grade 1 and 2 patients undergoing various bony orthopaedic surgeries on upper limb under supraclavicular brachial plexus block. The study was conducted in two groups of 30 patients each. The patients were randomly allocated in two groups by sealed envelope technique as – Group R (received 30 ml of 0.5% Ropivacaine) and Group L (received 30 ml of 0.5%Levobupivacaine). Patients between 18 to 60 years with bone or soft tissue lesion of the upper limb were included and patients with coagulation disorder, pre-existing peripheral neuropathy, skin lesion or infection at the site of blockade, pregnant women and un-cooperative patients were excluded from the study. At the preoperative visit, on the evening before surgery the visual analogue scale (VAS) scoring system was explained to all the patients. On arrival in the operative room baseline heart rate, blood pressure and oxygen saturation was recorded. An intravenous line was secured in the unaffected limb and ringer lactate was started. All the patients received USG guided supraclavicular brachial plexus block by perivascular subclavian approach by an experienced anaesthesiologist different from the one assessing the patient intra and post-operatively. Both were blinded to the treatment groups. Brachial plexus localization was done under USG guidance. Following negative aspiration and visualizing proper spread of local anaesthetic, 30 ml of solution containing local anaesthetic was injected. Sensory block was assessed by pin prick method. Assessment of sensory block was done at one-minute interval after completion of drug injection in the dermatomal areas corresponding to median nerve, radial nerve, ulnar nerve and musculocutaneous nerve till complete sensory blockade. Sensory onset was considered when there is a dull sensation to pinprick along the distribution of any of the above mentioned nerves. Complete sensory block was considered when there is complete loss of sensation to pin prick. Sensory block was graded as - Grade 0 (Sharp pain felt); Grade 1 (Analgesia, dull sensation felt) and Grade 2 (Analgesia, no sensation felt). Assessment of motor block was carried out by the same observer at each minute till complete motor blockade after drug injection. Onset of motor blockade was considered when there is Grade 1 motor blockade. Peak motor block was considered when there is Grade 2 motor blockade. Motor block was determined according to a modified Bromage scale of upper limb extremity on a 3-points scale. (Grade 0: Normal motor function with full flexion and extension of elbow, wrist and fingers; Grade 1: Decreased motor strength with ability to move the fingers only; Grade 2:Complete motor block with inability to move the fingers). This block was considered incomplete when any of the segments supplied by the median, radial, ulnar and musculocutaneous nerve had no analgesia even after 30 minutes of drug injection. These patients were supplemented with intravenous fentanyl (1 microgram/kg) and midazolam (0.02mg/kg). When more than one nerve remains unaffected, it was considered as a failed block. In such case, general anaesthesia was given intraoperatively. Patients were monitored for hemodynamic variables such as heart rate, blood pressure and oxygen saturation at regular interval intraoperative and thereafter till the 6th hour (post block).Patients were also assessed for the duration of postoperative analgesia using visual analogue scale (VAS) with grade 0 (no pain) to 10 (worst pain). VAS scale was recorded postoperatively every 60 mins till the score 4. The rescue analgesia was given in the form of injection diclofenac sodium (1.5 mg/kg) intramuscularly at the VAS of 4. The duration of sensory block was

defined as the time interval between the end of local anaesthetic administration to feeling of dull sensation in any of the concerned nerve distribution. The duration of motor block was defined as the time interval between the end of local anaesthetic administration to the wearing off of the motor effect in any of the concerned nerve distribution.

Statistical Analysis

The statistical significance of difference of qualitative characteristics across two study groups was tested using Chi-Square test. The statistical significance of inter-group difference of mean of quantitative characteristics is tested using independent sample 't' (unpaired Student 't' test) test, after confirming the underlying normality assumption. p-values <0.05 were considered to be statistically significant. All the hypotheses were formulated using two tailed alternatives against each null hypothesis (hypothesis of no difference). The entire data was statisticallyanalyzed using statistical Package for Social Sciences (SPSS version 16.0, Inc. Chicago) for MS Windows.

RESULTS

The study was carried out in 60 adult patients scheduled to receive supraclavicular brachial plexus block for upper limb orthopaedic surgery with either Ropivacaine 0.5% or Levobupivacaine 0.5%. These patients were divided into two groups of 30 patients each by sealed envelope technique as Group R (received 30 ml of 0.5% Ropivacaine) and Group L (received 30 ml of 0.5% Levobupivacaine). The demographic distribution of our study population were comparable. There was statistically no significant difference found in the two interventional groups in age, gender and weight distribution (Table 1).

Table 1: Demographic distribution of cases

Variables	Group R (n=30) (Ropivacaine)	Group L (n=30) (Levobupivacaine)	p value
Age (yrs) (Mean±SD)	38.93 ± 13.57	40.33 ± 12.59	>0.05
Sex (M:F)	21:9	20:10	>0.05
Weight (Kgs) (Mean±SD)	57.73 ± 5.03	59.77 ± 4.31	>0.05

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In both the groups, forearm surgery was done on 22 patients. Arm surgery was done on 5 patients from Group R and 4 patients from Group L, whereas, hand surgery was done on 3 and 4 patients from Group R and L respectively. The average duration of surgery was significantly higher in Group L (169.0±68.09 mins) compared to Group R (123.5±36.79 mins) ($p < 0.05$). In our study the mean onset time for sensory and motor blockade was significantly faster in Group R (Ropivacaine) as compared to Group L (Levobupivacaine) (8.24 and 10.6 mins v/s 11.0 and 13.5mins respectively) ($p<0.05$). The mean peak time for sensory and motor blockade was significantly faster in Group R (Ropivacaine) as compared to Group L (Levobupivacaine) (13.3 and 15.72 mins v/s 17.5 and 20.8 mins respectively) (Table 2).

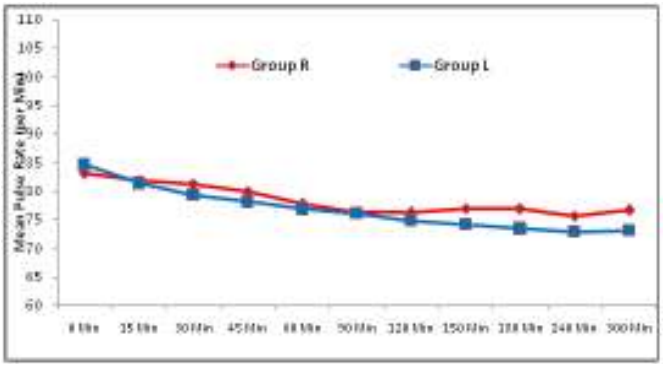
Table 2: Comparison of onset and peak time of sensory and motor block

	Group R (Ropivacaine) Mean±SD	Group L (Levobupivacaine) Mean±SD	Test statistics
Sensory Block			
Onset time (min)	8.24±2.26	10.6±3.19	p=0.015
Peak time (min)	13.37±2.98	15.72±4.79	p=0.029
Motor Block			
Onset time (min)	11.0±2.57	13.5±4.27	p=0.091
Peak time (min)	17.5±3.88	20.8±4.63	p=0.018

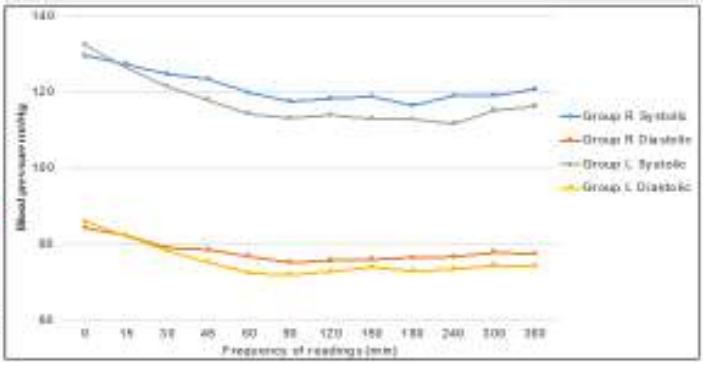
Table 3: Comparison of Duration of sensory and motor block

	Group R (Ropivacaine) Mean±SD	Group L (Levobupivacaine) Mean±SD	Test statistics
Duration of Sensory Block (hrs)	8.13±1.12	10.06±2.93	t=3.3046 p=0.001
Duration of Motor Block (hrs)	10.05±1.19	11.79±3.40	t=2.598 p=0.012

The mean duration for sensory and motor blockade was significantly shorter in Group R as compared to Group L(8.13 and 10.06 hours v/s 10.05 and 11.79 hours respectively). The average time duration to post-operative analgesia after VAS ≥4 was significantly higher in Group L (13.20±1.61 hrs) compared to Group R (9.50±1.43 hrs)($p<0.05$)



Graph 1: Comparison of pulse rate between two study groups



Graph 2: Comparison of Blood pressure between two study groups

The average pulse rate, systolic and diastolic blood pressure readings at frequent intervals did not differ significantly between two intervention groups (p >0.05 for all) (Graph 1, 2). No significant difference observed between two intervention groups (p >0.05 for all) in mean arterial pressure and oxygen saturation readings taken at different time intervals.

DISCUSSION

Regional anaesthesia, particularly peripheral nerve blockade, are often used to provide not only anaesthesia but also postoperative analgesia after limb surgery. Brachial plexus block offers many advantages over general anaesthesia for upper limb surgeries such as sympathetic block, better postoperative analgesia and fewer side effects[8]. Existing local anaesthetic bupivacaine is known for its wide and unpredictable latency of nerve block when smaller volume of local anaesthetic solution is injected, as well as its propensity for neuro and cardiotoxicity, with potentially fatal arrhythmias when large volume of drug is required. Levobupivacainehas less cardiac and central nervous system toxic effects than bupivacaine, while possessing similar duration of sensory blockade[9]. Ropivacaine is a long acting amide local anaesthetic agent with potentially improved safety profile when compared with bupivacaine. Human trials have demonstrated less cardiac depression and fewer CNS side effects when ropivavcaine in injected intravenously. Hence, it may offer advantage of reduced toxicity with accidental intravascular injection. It suggests potential clinical advantage of this drug during neural blockade when large volume of local anaesthetic is required. This favourable clinical profile prompted many clinicians to switch from bupivacaine to ropivacaine for all types of neural blockade[9]. Ropivacaine is in routine use abroad like USA and UK. It is recently introduced in the Indian market and needs to be evaluated from the Indian perspective. The application of ultrasound technique has revolutionized the regional anaesthesia field where ultrasound probe of suitable frequencies is used. It also offers an improved success rate of block with excellent localization and improved safety profile. Only a few trials have been conducted in order to compare the effects of ropivacaine and levobupivacaine to come to a conclusion for a better choice between the two for supraclavicular brachial plexus block. This prompted us to study these two local anaesthetics in our study. The demographic distribution of our study population were comparable. There was statistically no significant difference found in the two interventional groups in age, gender and weight distribution (p>0.05). (Table 1). Theropivacaine and levobupivacaine groups were compared with respect to the time for onset of sensory and motor block. It was found that in group R, mean time required for onset of sensory block was (8.24±2.26) mins as compared to (10.6±3.19) mins in group L. This difference was statistically significant (p<0.05). The mean time required for onset of motor block in group R was (11.0. ± 2.57) mins as compared to (13.5±4.27) mins in group L. This difference was statistically significant with (p < 0.05). Kaur *et al*[10] concluded that the onset of motor blockade was earlier in ropivacaine group (5 min) as compared to bupivacaine group (20 min), higher levels of motor blockade, mean onset time for motor block was significantly shorter in ropivacaine group (14.88±3.35 min) as compared to bupivacaine group (22.92±3.79 min). Onset of sensory block was observed from 5 min itself in ropivacaine group as compared to bupivacaine group (10 min).Thus, they concluded that onset of action of sensory, motor block was early in ropivacaine group with faster recovery of motor functions as compared to bupivacaine group. Mankad *et al* [11] observed no statistically significant difference in the onset of sensory block in both the groups. Onset of motor blockade was significantly faster with ropivacaine (9.50 ± 2.403 min) as compared to levobupivacaine (12.33 ± 2.537 min; p<0.05). The mean peak time required for sensory block was significantly faster in group R (13.37±2.98) mins as compared to (15.72±4.79) mins in group L. This difference was statistically significant (p<0.05). The

mean peak time for motor blockade in group R was (17.5±3.8) mins as compared to (20.8±4.63) min in group L. This difference was statistically significant ($p<0.05$). The mean duration of sensory blockade in group R was (8.13±1.12) hrs as compared to (10.06±2.93) hrs in group L.The mean duration of motor blockade in group R was (10.05±1.19) hrsas compared to (11.79±3.40) hrs in group L. This difference was statistically significant($p<0.05$).Cline *et al* [9] found that the duration of sensory analgesia was significantly longer in the levobupivacaine group (831 minutes) than in the ropivacaine group (642 minutes, p=.013) and return of motor activity was significantly faster in the ropivacaine group (778 minutes) than in the levobupivacaine group (1,047 minutes; p=.001). The result of their study demonstrated that the brachial plexus block produced by 0.5% levobupivacaine resulted in an increased duration of time until supplemental analgesia was required and an increase in duration of motor block compared with analgesia and motor block produced by the same volume and concentration of ropivacaine. Hence, they considered levobupivacaine when postoperative analgesia is a concern but not when an early return of motor activity is required.Kaur *et al* [10] observed that the mean duration of block was significantly longer in bupivacaine group (408.40±50.39 min) as compared to ropivacaine group (365.60±34.29 min) ($p=0.001$). Duration of sensory block was significantly longer in bupivacaine group (450.40±54.50 min) as compared to ropivacaine group (421.20±38.33 min). InMankad *et al* [11] study, duration of sensory block was observed to be longer in levobupivacaine group (10.93 hours) as compared to ropivacaine group (8.67 hrs). Duration of motor block was observed to be shorter for ropivacaine (7.13 hours) as compared to levobupivacaine (10.87 hrs). It was found that duration of postoperative analgesia was significantly higher in group L (13.20±1.61) hours as compared to (9.50±1.43) hours in group R. This difference was statistically significant ($p<0.05$).Mankad *et al* [11] observed that the duration of postoperative anlagesia was significantly longer in levobupivacaine group (12.56±1.30) hours as compared to (9.93±1.70) hours in ropivacaine group. This difference was statistically significant.There was no statistical difference found in comparison of haemodynamic variables (Mean PR, SBP, DBP, MAP, $SPO_{2)}$ in both the groups ($p>0.05$). In our study, we made an attempt to compare the onset, duration of action of sensory and motor and post-operative analgesia in 0.5% ropivacaine and 0.5% levobupivacaine drugs. We found that onset of action of sensory and motor block of ropivacaine was faster than levobupivacaine but ropivacaine had shorter duration of action than levobupivacaine. However, there were no significant side effects noted in both the interventional groups.

In conclusion, the onset of action of sensory, motor was early in ropivacaine group with faster recovery of motor function as compared to equivalent dose of levobupivacaine. Ropivacaine offers an advantage where early recovery of motor function is desired in postoperative period as compared to motor recovery profile of levobupivacine. Levobupivacaine has a better profile in terms of duration of analgesia, with a considered disadvantage of delayed wearing off of the motor blockade. Levobupivacaine should be considered when postoperative analgesia is a concern but not when early return of motor activity is required.

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Source of Support: None Declared
Conflict of Interest: None Declared