ORIGINAL RESEARCH

A Comparative clinical Study Between Ropivacaine 0.5% and Levobupivacaine 0.5% for Supraclavicular Brachial Plexus Block

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ABSTRACT

Introduction: Ropivacaineand Levobupivacaine are recently introducedand needs to be evaluated for the clinical efficacy and safety profile in regional anaesthesia. Aim of the study was toevaluate and compare the differences in onset, duration and quality of sensory and motor blockade of Ropivacaine withlevobupivacaine in supraclavicular brachial plexus block.

Materials and methods: The present study included 60 patients aged between 18-70 years, classified as American society of anesthesiologists(ASA) physical status I and II scheduled for elective orthopedic surgeries of upper limbs. The patients were randomly divided into two groups. Group R received 0.4 ml /kg of 0.5 % Ropivacaine and group L received 0.4 ml / kg of 0.5% of levobupivacaine for supraclavicular block. Onset,duration, quality of sensory and motor blockade and any adverse effects were noted.

Results: These results showed that there was no statistically significant difference between onset,duration and quality of sensory and motor blockade in both groups but there is slight prolongation of duration of sensory blockade in levobupivacaine group. Both groups showed stablehaemodynamic conditions and no complications were observed in either group.

Conclusion: It is concluded that ropivacaine or levobupivacaine for supraclavicular brachial plexus block produced satisfactory and comparable sensory and motor blockade

Keywords: Ropivacaine, Levobupivacaine, Supraclavicular block

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INTRODUCTION

Brachial plexus block provides useful alternative to general anaesthesia for upperlimborthopedic procedures and has been shown to provide effective and comfortable intra operative conditions. Regional anaesthetic techniques offer quicker recovery than general anaesthesia and produce minimal side effects.[1] Supraclavicular brachial plexus blockis preferred for any surgery in the upper extremity that doesnot involve the shoulder.[2] Such peripheral nerve blocks were generally performed with racemic bupivacaine.[3,4] However in recent years there has been a switch to ropivacaine owing to its more favorable clinical profile and lower toxicity.[5,6] Levobupivacaine an S-enantiomer of bupivacaine has become the favored drug for various other types of regional anaesthesia.[7] Clinical studies have shown that levobupivacaineandropivacaine have fewer adverse affects on the cardiovascular system and central nervous system than does bupivacaine.[8,9,10] However reports are conflicting in regard to the relative potencies of ropivacaine and levobupivacaine for use in peripheral nerve blocks.

Some clinical trials report that ropivacaine provides a sensory blockade similar to that of levobupivacaine, while in clinical practice many practitioners report dissimilar findings, therefore the purpose of this investigation was to compare the, onset, duration and quality of sensory and motor blockade between groups of patients receiving supraclavicular brachial plexus block with 0.5% ropivacaine or 0.5% levobupivacaine.

MATERIALS AND METHODS

It is double blind randomized prospective clinical study was carried out on 60 patientundergoing upper limb surgery under supraclavicular block. It was carried out for a period of one year, After ethical committee approval and written informed consent taken.

Inclusion criteria: American society of anaesthesiolo-

gists (ASA) Physical status l and ll patients of either sex, age 18 to 70 years undergoing upper limb surgery under supraclavicular block.

Exclusion criteria: Patients with physical status ASA lll and lV, history of allergy to local anaesthetic, central or peripheral neuropathies, coagulopathies,skin lesions at the site of the blockade,upper limb surgeries requiring bone graft,liver, kidney, neurological disease and patient refusal.

The patients were randomly assigned to either Group R: Ropivacaine o.5% (0.4 ml /kg) or group L: Levobupivacaine 0.5% (0.4 ml /kg) of 30 each using a computer generated random number.

On arrival to operation theatre, patients pulse rate, blood pressure and ECG were recorded, a 18 G intravenous line was established and infusion started with ringer lactate solution. Haemodynamicvariables was measured on arrival to operation theatre and every 5 min there after till the end of the surgery.

Patient was explained about the procedure and brachial plexus block performed through supraclavicular approach as described by Winne. With strict aseptic precautions supraclavicular brachial plexus block performed by an experienced anaesthesiologist other than one doing intra/post operative assessment. Both were blinded to the treatment groups.

On localization of the brachial plexus (with elicitation of paraesthesia) and after negative aspiration 0.4 ml / kg of the study drug was injected over one minute with repeat aspiration every 5 minutes. All the patients would be monitored for anaesthesia and analgesia postoperatively for 24 hrs. If the block turns out to be adequate,surgery was allowed to continue. Patients with complete failure of the block orunsatisfactory block were (patients requiring either intravenous sedation or general anaesthesia) excluded from our study.

Onset of sensory block was measured as loss of pin prick sensation using blunt end of 27 G hypodermic needle. Dermatomes C5-T1 wereassessed.Onset time was the time from completion of injection of study drug to first loss of pin prick sensation in any dermatome.

Time 0 minutes being the time of completion of injection

It was tested at every 5 min intervals until patient was unable to perceive pin prick. Sensory block was graded as Grade 0-sharp pain felt, Grade 1- analgesia,dull sensation felt, Grade 2- anaesthesia. Duration of sensory block was time from onset of sensory block to the time when the patient complains of pain at the site of surgery. Onset of the Motor block is the time required from completion of injection of study drug to first loss of motor power at the shoulder. Motor block graded as Grade 0- no blockade, Grade 1- loss of movement at elbow joint, grade 2- loss of movement at wrist joint, Grade 3- loss of finger movements. Duration of motor blockade is the time from onset of motor blockade to the complete recovery of abduction at shoulder joint against gravity. Overall assessment of the quality of the block was made on three point scale as follows; Grade 0- complete failure, Grade 1- unsatisfactory block, inadequate analgesia, inadequate relaxation or patient requires general anesthesia. G2- satisfactory block. For statistical analysis complete failure and unsatisfactory block were considered together as failure and compared with success (satisfactory block). Duration of surgery was noted.

Verbal rating scale (VRS) was used to assess the level of pain perceived by the patient. VRS from 0-4; 0- no pain, 1- mild pain, 2- moderate pain, 3- severe pain, 4- very severe pain. Injection diclofenac sodium could be given as rescue analgesic when patient complaints of pain.

Patient haemodynamics was monitored throughout the intra operative and postoperative period (Pulse rate, BP, ECG, SPO2). All patients were observed for any side effects and complications like central nervous system toxicity, cardiac arrhythmias, pneumothorax, hematoma and post block neuropathy in the intra and postoperativeperiod.

The results were presented as Mean±standard deviation (SD) for parametric data and as percentage for non parametric data.For statistical analysis of the data, continuous variables such as onset and duration of analgesia, anaesthesia, paresis and paralysis were tested using a Students “t” test or Wilcoxon rank Sum test (Mann-Whitney U test) if normality test fails. For categorical data were analysed with the x^2 test or Fishers exact test. A **P** value of less than 0.05 considered to represent statistical significance. The data were analysed by using Microsoft Excel for construction of graph and SPSS version 14 software for data analysis.

RESULTS

60 patients were randomly assigned to one of the 2 groups, 2 patients from the group R and 3 patients from group L were excluded from the study. As they have to be given general anaesthesia for inadequate block leaving R28 and group L 27 patients. Both the groups were comparable in terms of age, gender, weight and physical status. There was no significant difference between both the groups in duration and type of surgery p

>0.05(table.1). Onsetof sensory as well as motor block in group R was (sensory 3.65 ± 2.91 minutes, motor 4.63 ± 3.64 minutes) compared with levobupivacaine (sensory 4.23 ± 1.59 minutes, motor 4.4 ± 2.02 minutes) with p value > 0.05 making it statistically insignificant. Duration of sensory block was slightly high in levobupivacaine group which is 594.33 ± 158.73 minutes compared to 555±162.26 inropivacainegroup and the difference is statistically insignificant P > 0.05.The duration of motor block was 596.04 ± 154.14 minutes in group R as compared with 598.52 ± 141.13 minutes in group L, again duration of motor block was statistically insignificant P > 0.05(table.2, figure 1 & 2). The quality and overall quality of motor block were comparable and not statistically significant P > 0.05 (table.3, figure 3). The block was satisfactory in majority of patients in either group accounting for 93.33 in R group and 90% in Lgroup. The incidence of hematoma, pneumothorax,accidental intravascular injection, post blocknausea/vomiting/convulsions/neuralgia were nil in either group.

Haemodynamic parameters like BP/ECG/SPO2/HR were within normal limits in both groups. No patient required any intervention.

DISCUSSION

This prospective randomized double blind clinical trial demonstrates that ropivacaine has clinical profile that is similar to that of levobupivacaine when used for single dose supraclavicular block at 0.5 % concentration. The block onset time and duration of sensory and motor blockade and quality of the motor block in the two groups of the patients were similar.

There is mild prolongation of duration of sensory block was observed in our study but it is not statistically significant.

The onset of sensory and motor blockade is related to the physiochemical properties of individual drugs, mass of injected local anaesthetic (mass=concentration × volume) and PH of the tissues. Theoretically ropivacaine has lower lipid solubility compared to levobupivacaine. It should have produced faster onset of sensory and motor blockade. But according to minimal local anaesthetic concentration studies which are based on effective analgesia in 50% of patients, ropivacaine was found to have similar potency at higher doses and less potency thanlevobupivacaine at lower doses.[11] It is believed that ropivacaine is less potent because of its lower lipid solubility and that it has the advantage of stronger differentiation between sensory and motor blocks, a feature that is particularly useful when early mobilization is important to enhance recovery. Both levobupivacaine and ropivacaine are associated with lesser degree of motor block compared to bupivacaine when used for spinal anaesthesia.[12,13]

Clinical studies in various patient population suggest that levobupivacaine is less potent than bupivacaine and more potent than ropivacaine when used for epidural anaesthesia.[14,15] Animal studies on conduction blocks produced by bupivacaine, levobupivacaine and ropivacaine on isolated nerves showed that the onset and duration of nerve block induced by equimolar doses of these three agents were similar.[16]

In agreement with these findings several studies comparing ropivacaine with other local anaesthetics for different peripheral nerve blocks produced by ropivacaine have a clinical profile similar to that obtained with racemic bupivacaine and levobupivacainewhen used at similar concentrations and doses.[17-22]

Variable	0.5% Ropivacaine (R group)	0.5%Levobupivacaine (L group)	P-value
Age (Years)	38.97 ± 13.37	39.7 ± 15.49	0.7831
Sex (M/F)	19(63.3%)/11(36.7%)	16(53.3%)/14(46.7%)	0.601
Weight (Kg)	60.93 ± 6.65	57.7 ± 7.6	0.09
Duration of Surgery (Minites)	60 ±15	62 ±10	>0.05
Typeof Surgery	Open Reduction and internal fixation of both bones forearm	Open Reduction and internal fixation of both bones forearm	>0.05

Table-1: Demographic characteristic of study population.

Sl. No.	Parameter	0.5% Ropivacaine	0.5%Levobupivacaine	p-value
1	Onset of Sensory block nset	3.65 ±2.91 min	4.23±1.59 min	0.132
2	Onset of Motor block	4.63±3.64 min	4.4±2.02 min	0.76
3	Duration of Sensory block	555.14±162.26 min	594.33±158.73 min	0.369
4	Duration of Motor block	596.04±154.14 min	598.52±141.13 min	0.95

Table-2: Onset time and duration of sensory and motor blockade

TABLE 3: Overall quality of block

Grade	0.5% Ropivacaine	0.5% Levobupivacaine
Satisfactory block (2)	28 (93.33)	27 (90)
Unsatisfactory block(1)	2 (6.66)	3 (10)
Complete failure (0)	0	0

χ^2 = 0.2182, df=1, p=0.64, Not significant.

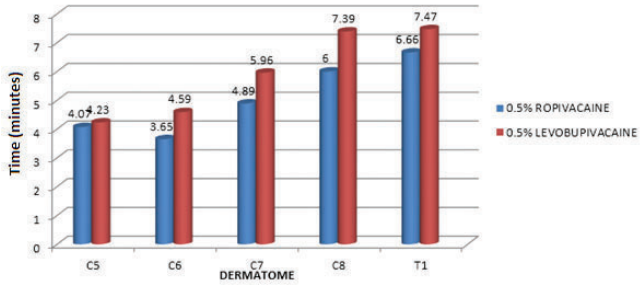

Figure-1: Onset of sensory blockade

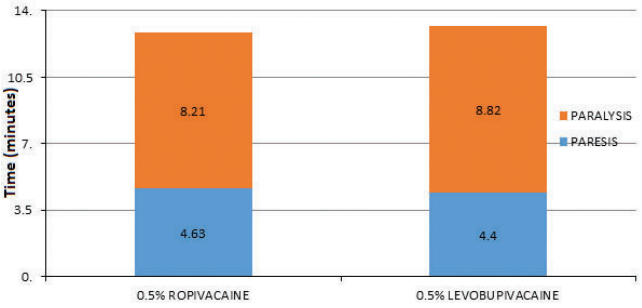

Figure-2: Onset of motor blockade

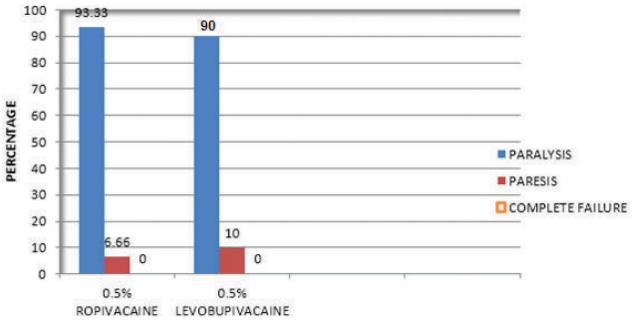

Figure-3: Quality of block

Casatiet al demonstrated that 30ml of 0.5% levobupivacaine produced an interscalene block of similar onset and quality as produced by the same volume of 0.5% of ropivacaine.[19] LiisanantiOetal concluded that axillary brachial plexes block with 45ml of 0.5% racemic bupivacaine, levobupivacaine and ropivacaine produced adequate anaesthesia without any clinically significant differences between the drugs.[20]

Recent studies revealed a substantially similar clinical profile when equal volume of levobupivacaine 0.5% and ropivacaine 0.5% compared for use in combined psoas compartment-sciatic nerve block in patients undergoing total hip arthroplasty and for ultra sound guided popliteal sciatic nerve block in undergoing unilateral hallux valgus surgery. At higher concentrations levobupivacaine might be more potent than ropivacaine[21,22]

Casatietalrevealed different clinical profiles in the sciatic nerve block when levobupivacaine 0.75% was compared to0.75%ropivacaine or 0.5%levobupivacaine.Levobupivacaine 0.75% provided a shorter onset time and longer duration of post operative analgesia than same volume of ropivacaine0.75% and reduced the total use of rescue opiod consumption during the first 24 hours after surgery[23]

Other studies however found prolongation of sensory analgesia with levobupivacaine compared to ropivacaine.[24,25] Our study has significant limitations.Followup was done only for 24 hours postoperatively.A more comprehensive study would have continued to evaluate the patients for extended period of time. Furthermorepresent findings apply only for single supraclavicular block. Additional studies should be done to evaluate the use of these drugs in continuous peripheral nerve catheters. Finally it would be advantageous to compare the clinical profile of the two local anaesthetics in other peripheral nerve blocks.

CONCLUSION

From the present study it can be concluded that ropivacaine 0.5% (0.4ml/kg) or 0.5% levobupivacaine(0.4ml/kg) for supraclavicular brachial plexus block produced satisfactory and comparable sensory and motor blockade. The reduced toxic potentials of both ropivacaine and levobupivacaine should be carefully considered when choosing the local anesthetic for regional anesthesia techniques requiring large volumes and infusion rates such as for epidural anaesthesia /analgesia, peripheral nerve blocks and local infiltration.

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