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A COMPARATIVE STUDY OF FENTANYL 25MCG ADDED TO ROPIVACAINE 0.5% AND LEVOBUPIVACAINE 0.5% FOR SUPRACLAVICULAR BRACHIAL PLEXUS BLOCK EMPLOYING LANDMARK APPROACH FOR UPPER LIMB ORTHOPAEDIC SURGERIES.

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Abstract:

Background; Ropivacaine and Levobupivacaine are recently introduced drugs in Indian market and needs to be evaluated. Hence Ropivacaine and Levobupivacaine were selected as local anaesthetics in present study.

Aim; To evaluate and compare the onset, duration, quality of sensory and motor blockade of Ropivacaine versus levobupivacaine in supraclavicular brachial plexus block.

Materials and methods; The present study included 60 patients aged between 18-70 years of ASA grade 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 added to 25mcg of fentanyl for supraclavicular block. Time of onset, duration, sensory and motor blockade and any adverse effects were noted.

Results; The results showed that there was no statistically significant difference between, duration and quality of sensory and motor blockade in both groups. onset of action in Group R showed earlier but that was not statistically significant. Both groups showed stable hemodynamic conditions and no complications were observed.

Conclusion; The present study shows that 0.5% ropivacaine is equally potent as 0.5% levobupivacaine when compared with the onset, duration and quality of sensory and motor blockade.

Key words; Ropivacaine, levobupivacaine, fentanyl, supraclavicular block analgesia.

Introduction:

The brachial plexus block provides an alternative procedure to general anaesthesia for upper limb procedures. It provides more effective and comfortable intra operative condition. Regional anaesthetic techniques can be used for prolonged procedures. They offer quick recovery than general anaesthesia and produce minimal side effects. Supraclavicular brachial plexus block is preferred for any surgery in the upper extremity that does not involve the shoulder.

Bupivacaine a racemic mixture of the two stereo enantiomers dextro bupivacaine and levo bupivacaine, frequently used as local anaesthetic for brachial plexus anaesthesia because it offers the advantage of providing a long duration of action and a favorable ratio of sensory to motor neural block. However, with clinical use it was noted that this racemic mixture of bupivacaine resulted in cardiac and central nervous system toxic effects, in some patients which were attributed to dextro bupivacaine enantiomer. This prompted researchers to develope new local anaesthetic agents with a profile that contained all the desirable aspects of bupivacaine without the undesirable toxic effects. One of the local anaesthetic agents that emerged as a possible replacement for bupivacaine was ropivacaine.

Ropivacaine, the *S*-enantiomer of S-I- propyl- 2, 6 pipecoloxylidide is an amino amide local anaesthetic with a chemical structure similar to that of bupivacaine. Numerous comparative studies between bupivacaine and ropivacaine suggested that ropivacaine produced less cardiac and central nervous system toxic effects, less motor block, and similar duration of action of sensory analgesia.

Levobupivacaine the S- enantiomer of bupivacaine is the latest local anaesthetic agent introduced into clinical practice. Studies proved that (R – dextro bupivacaine and S- levobupivacaine) enantiomers of bupivacaine possessed anaesthetic activity but the S- enantiomer had significantly less cardiac and neural toxic effects than bupivacaine, while still possessing a similar duration of sensory blockade. levobupivacaine have shown to be safe and effective for spinal and epidural anaesthesia and blockade of the brachial plexus. Many clinicians began using levobupivacaine as agent of choice for neural blockade but a controversy exists in the literature and in clinical practice which agent (ropivacaine or levobupivacaine) is ideal for facilitating brachial plexus anaesthesia . 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

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was to compare the effectiveness, 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:

After ethical committee approval and written informed consent a double blind randomized prospective clinical study was carried out on 60 American society of anaesthesiologists (ASA) Physical status l and ll patients of either sex, age 18 to 70 years undergoing upper limb surgery under supraclavicular block.

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 list. The exclusion criteria were; 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. On arrival to operation theatre, patients pulse rate, blood pressure and ECG were recorded, an 18 G intravenous line was established and infusion started with ringer lactate solution

Haemodynamic variables were measured on arrival to operation theatre and every 5 min there after till the end of the surgery. The patient received brachial plexus block through landmark approach by an experienced anesthesiologist other than one doing intra/post operative assessment. Both were blinded to the treatment groups.

Then supra clavicular block performed: patient lies in the supine position with a pillow under his shoulder and his head turned away from the side to be injected. The arm to be anaesthetized should be adducted. In classical technique, the midpoint of the clavicle should be identified and marked the posterior border of the sternocleidomastoid can be palpated easily when the patient raises the head slightly. The palpating finger can then roll over the belly of the anterior scalene muscle into the interscalene groove, where a mark should be made approximately 1.5 to 2.0 cm the area behind the clavicle's midpoint. The land mark can be verified here by palpating the subclavian artery. After appropriate preparation and development of a skin wheal, the anaesthesiologist stands at the side of the patient facing the patient head.

A 22gauge, 4 cm needle is directed in a caudal, slightly medial and posterior direction until a paresthesia or motor response is elicited or the first rib is encountered. If the first rib is reached without inducing a paraesthesia, the plexus or the subclavian artery can be found by methodically walking a needle anteriorly and posteriorly down the rib. The artery's location serves as a helpful landmark, allowing the needle to be removed and reinserted further poster-laterally, which typically produces a paresthesia or motor reaction. On localization of the brachial plexus, aspiration for blood should be performed before incremental injections of a total volume of 32ml of the study drug. All the patients would be monitored for anesthesia and analgesia postoperatively for 24 hrs. If the block turns out to be adequate surgery was allowed to continue. Patient with complete failure of the block or unsatisfactory block were (patients requiring either iv sedation or GA) 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 were assessed. onset time was the time from completion of injection of study drug to first loss of pin prick sensation in any dermatome. 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 movement. 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 GA. 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 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 CNS toxicity, cardiac arrhythmias, pneumothorax, hematoma and post block neuropathy in the intra and post-operative period.

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 student's 't' test or Wilcoxon rank sum test (Mann-Whitney U test) if normality test fails. For

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categorical data were analyzed with the $\chi 2$ test or Fisher's exact test. A p-value of less than 0.05 considered to represent statistical significance. The data were analysed by using Microsoft Excel 2007 for construction of graph and SPSS version 14 software for data analysis.

Results:

60 patients fulfilling the inclusion criteria were randomly assigned to one of the 2 groups, 2 patients from the group R and 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). onset of sensory as well as motor block in group R was (sensory 3.55 ± 2.20 minutes, motor 4.53 ± 3.44 minutes) compared with levobupivacaine (sensory 4.13 ± 1.49 minutes, motor 4.3 ± 1.49 minutes) with p value more than 0.05 making it statistically insignificant. Duration of sensory block was 555 ±162.26 minutes, in R group compared to594.33 ± 158.73 in L group and the difference is statistically in significant P > 0.05.

The duration of motor block was 596.04 ± 154.14 minutes in group R as compared with 598.52 ± 141.13 min in group L. Again, duration of motor block was statistically insignificant in both groups, P > 0.05. The quality and overall quality of motor block were comparable and not statistically significant, P > 0.05. The block was satisfactory in majority of patients in either group accounting for 93.33 in group R and 90% in group L. The incidence of hematoma, pneumothorax, accidental intravascular injection, post block nausea/vomiting/convulsions/neuralgia were nil in either group.

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

Table 1: Demographic characteristics of study population (Mean SD)

Variable	**0.5% Ropivacaine + 25mcg Fentanyl** Mean ± Standard Deviation	**0.5% Levobupivacaine + 25mcg Fentanyl** Mean ± Standard Deviation	**P Value**
AGE	36.67 ± 13.37	37.7 ± 15.49	0.7831
SEX	19 (63.3%) / 11 (36.7%)	16 (53.3%) / 14 (46.7%	0.601
WEIGHT	60.93 ± 6.65	58.7 ± 7.6	0.09
Duration of Surgery (Minutes)	60 ± 15	62 ± 10	
Type of Surgery	Open Reduction and internal fixation of both bones forearm	Open Reduction and internal fixation of both bones forearm	

Table 2: Onset and Duration of Sensory and Motor Block:

S.No.	**Parameter**	**0.5% Ropivacaine + 25 mcg Fentanyl** Mean ± Standard Deviation	**0.5%Levobupivacaine + 25 mcg Fentanyl** Mean ± Standard Deviation	**p-value**
1	Sensory block Onset	3.55±2.20 min	4.13±1.49 min	0.132
2	Motor block Onset	4.53±3.44 min	4.3±1.49 min	0.76
3	Sensory block Duration	570.14±152.26 min	610.33±148.73 min	0.369
4	Motor block Duration	614.04±144.14 min	615.52±131.13 min	0.95

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Table 3: overall quality of block

Grade	0.5% Ropivacaine + 25 mcg Fentanyl	0.5% Levobupivacaine + 25 mcg Fentanyl
Satisfactory block (2)	28 (93.33)	27 (90)
Unsatisfactory block(1)	2 (6.66)	3 (10)
Complete failure (0)	0	0

X2 = 0.2182, df=1, p=0.64, not significant.

Figure 1:

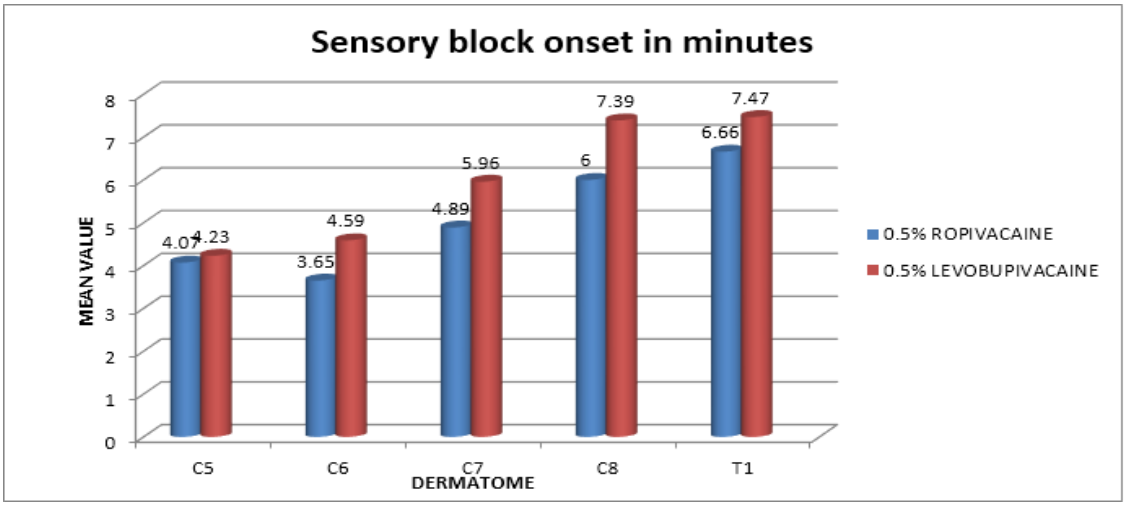

Figure 2:

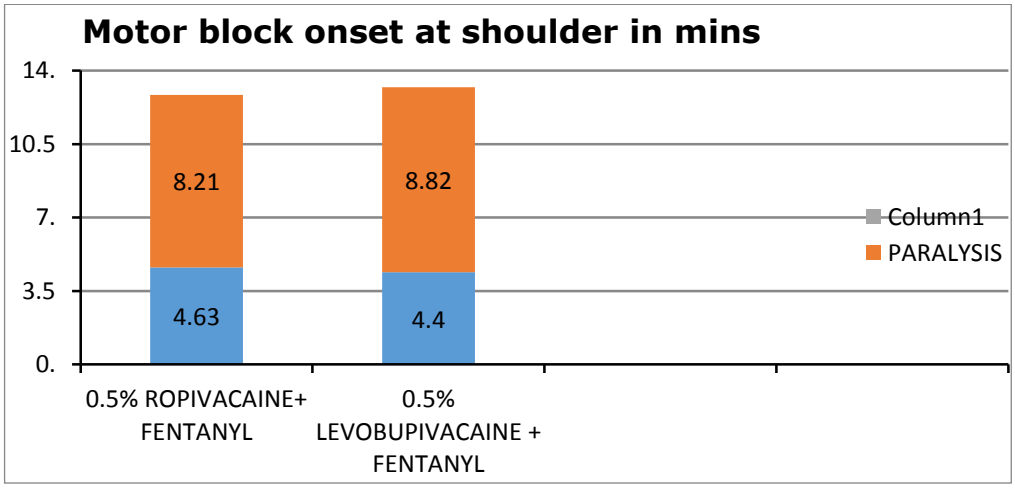

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Figure 3:

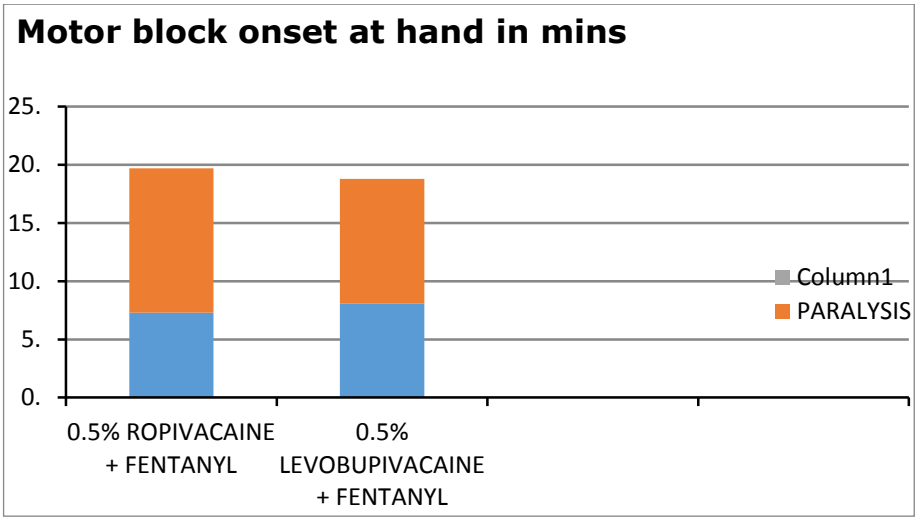
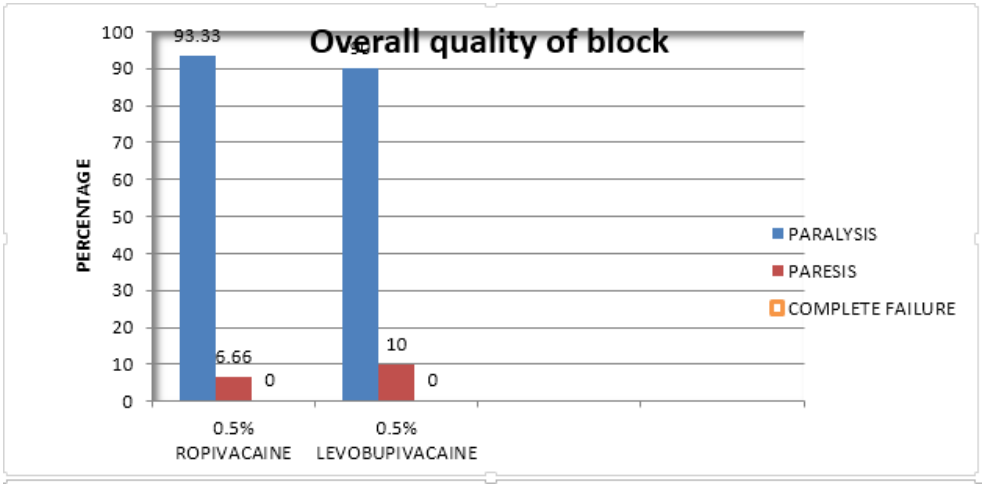


Figure 4:



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. 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 P^H 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 than levobupivacaine at lower doses. 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. Clinical studies in various patient population suggest that levobupivacaine is less potent than bupivacaine and more potent than ropivacaine when used for epidural anaesthesia. Animal studies on conduction block 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.

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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 levobupivacaine when used at similar concentrations and doses.

Casati etal when comparing 0.5% ropivacaine with 0.5% levobupivacaine for brachial plexus block injected through an interscalene catheter followed by a patient controlled inter scalene analgesia with 0.2% ropivacaine and 0.125% levobupivacaine. There is no difference in onset of time, quality of intraoperative anesthesia, efficacy of post operative analgesia and recovery of post operative analgesia and recovery of motor function.

Liisanantti O etal concluded that axillary brachial plexes block with 45ml of 0.5% racemic bupivacaine, levo bupivacaine and ropivacaine produced adequate anaesthesia without any clinically significant differences between the drugs.

Recent studies longer 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.

Casati etal revealed different clinical profiles in the sciatic nerve block when levobupivacaine 0.75% was compared to 0.75% or 0.5% levobupivacaine. levobupivacain 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 opioid consumption during the first 24 hours after surgery.

Other studies however found prolongation of sensory analgesia with levobupivacaine compared to ropivacaine.

Our study has significant limitations follow up was done only for 24 hours posoperatively. a more comprehensive study would have continued to evaluate the patients for extended period of time. Furthermore, present 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 present study it can be concluded that ropivacaine 0.5% (0.4ml/kg) or 0.5% levobupivacaine(0.4ml/kg) added to fentanyl 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 anesthesia /analgesia, peripheral nerve blocks and local infiltration.

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