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A COMPARATIVE STUDY OF EFFICACY OF ROPIVACAINE AND BUPIVACAINE FOR SUPRACLAVICULAR BRACHIAL PLEXUS BLOCK.

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ABSTRACT

Aims: To compare the efficacy of ropivacaine and bupivacaine in supraclavicular block, for upper limb orthopaedic surgeries.

Study design: Prospective randomized double blinded study

Material and Methods: Sixty American Society of Anesthesiologists physical status grades I-II patients, posted for upper limb orthopaedic surgery under supraclavicular block, were randomized to two groups. Group R received 0.4ml/kg of ropivacaine 0.75%; Group B received 0.4ml/kg of 0.5% bupivacaine. Outcome measured in term of onset, duration and quality of sensory and motor block along with overall quality of the block. Adverse effects were also studied.

Results: Onset times and duration of Sensory and Motor blockade were comparable between the two groups. The mean onset time of sensory blockade was 3.66±2.91 min in Group R and 4.23±1.59 min in Group B.(*P*=0.132).Onset time of motor blockade was 4.63 ±3.64 min in Group R and 4.40 ± 2.03 min in Group B. (=0.76). Quality of motor blockade was comparable between the two groups. (*P* = 0.64). Overall quality of blockade was satisfactory in 93.3% (n=28) of the patients in Group R and 90.0% (n=27) of the patients in Group B. (*P*=0.64). Duration of sensory and motor blockade was also comparable in both the group. No adverse effects were noted in either group.

Conclusion: The use 0.75% ropivacaine at 0.4ml/kg dose in supraclavicular brachial plexus block is equally effective as using 0.5% bupivacaine at 0.04ml/kg.

KEYWORDS :

INTRODUCTION

Peripheral nerve blocks are increasingly being used for extremity surgeries to provide optimum surgical anaesthesia along with postoperative pain relief. Supraclavicular brachial plexus block is a popular technique for upper limb surgeries as it provides sympathetic block, better perioperative analgesia and patient satisfaction along with cost effectiveness while avoiding many disadvantages of general anesthesia. Technical advancements and availability of safer clinical profile long-acting local anaesthetics has increased the use of peripheral nerve block tremendously in past years. Racemic bupivacaine, a long-acting local anesthetic agent is being used widely for regional nerve blocks but concerns have been raised over its potential cardiotoxicity and central nervous system toxicity. Ropivacaine, pure L-isomer of bupivacaine with less lipophilicity and quite similar physicochemical properties is having significantly less potential for cardiotoxicity and CNS toxicity, offers a safer alternative to bupivacaine. Hence, we designed this study to compare bupivacaine with its pure L- enantiomer, ropivacaine in terms of their efficacy and adverse effects in supraclavicular block.

MATERIALS AND METHODS

This Prospective, randomized, double blind clinical study was conducted after the approval from Institutional Ethical committee and taking written informed consent from all patients. Sixty patients of either gender aged between 18 to 70 years with the ASA physical status grade I or II, weighing between 45 to 65 kg, posted for elective upper limb orthopaedic surgery were included in this study.

All the patients underwent a thorough pre anaesthetic check-up, including history, general physical examination and required blood investigations. Patients with known allergy to the study drug, cardio-respiratory, hepato-renal disease, coagulopathies, unwilling patients, patients having infection at local site and any neural injury were excluded from the study.

The study population was randomized into two groups using computer generated random number table. Random group assigned was enclosed in a sealed opaque envelope. After shifting the patient in the operation theatre, the sealed envelope was opened by an anaesthesiologist not involved in the study. The anaesthesiologist involved in randomization and drug preparations as well as patient were blinded to the drug solution administered. The visual analogue scale (VAS) was explained to all the patients during the pre-operative assessment. All patients were given tab. Alprazolam 0.5 mg and Ranitidine 150 mg the night before surgery, and kept nil orally for more than eight hours. In the operating room, an 18 gauge intravenous cannula was inserted under local anaesthetic infiltration on the non operating hand, and an infusion of normal saline was started. The patients were connected to Siemens SC 7000, multi-channel monitor, which recorded the heart rate (HR), non invasive blood pressure, continuous electrocardiogram (ECG) and peripheral oxygen saturation (SPO_2), baseline values were recorded. All patients were pre-medicated with Inj. midazoalm (0.02 mg/kg) IV.

The patients were placed in the dorsal recumbent position, with the head turned away from the site of injection. Under aseptic precautions, skin infiltration was done with Lignocaine 2% at the site of block, supraclavicular Subclavian perivascular Brachial plexus blocks were performed as described by Winnie[6], using 22G, a 50mm insulated, blunt needle (Stimuplex B Braun) with an extension tubing, and a B Braun Nerve Stimulator. The Inter-scalene groove was indentified at the level of cricoid cartilage, and traced downwards till the clavicle. Subclavian arterial pulsations were felt in the groove just above the clavicle. The needle entry point was just above the finger palpating the subclavian artery in the inter-scalene groove. The positive electrode of the nerve stimulator was connected to an ECG electrode placed on the chest of the patient. The negative electrode was connected to the needle. The intensity of stimulating current was initially set to deliver 1mA, with impulse duration of 0.1ms. The needle was introduced parallel to midline and to the table. A motor response was sought distal to elbow in fingers/ hand. The current was gradually decreased to < 0.5 mA, after the proper motor response (flexion of the thumb and index finger). After an appropriate response was localized with a current <0.5mA, 0.4ml/kg of the study drug was injected in 3ml increments.

Group R (n=30) received 0.4ml/kg of 0.75% Ropivacaine

Group B (n=30) received 0.4ml/kg of 0.5% Bupivacaine

An Intercosto-brachial nerve block was then performed separately,

using 5ml of lignocaine with adrenaline 1%, to provide anaesthesia for the possible placement of the tourniquet.

Immediately after block placement, patients were evaluated every 1 minute, for the assessment of onset of sensory and motor blockade, quality of motor blockade, overall quality of the block, duration of sensory and motor blockade and hemodynamic variables. Assessments were carried out every 1 minute till the achievement of motor and sensory blocks until 30 minutes

Overall quality of block[1] was assessed on a three point scale: 0 = Complete failure, 1 = Unsatisfactory block (inadequate analgesia, inadequate relaxation, or patient requiring general anaesthesia because of agitation and restlessness), 2 = Satisfactory block.

After 30 minutes if the block was considered to be adequate, surgeons were allowed to apply the tourniquet and start the surgery. If the block was considered to be inadequate for surgery, the patient was given General Anaesthesia with endotracheal intubation.

Intraoperatively hemodynamic variables, SPO_2 and ECG were monitored at 2, 5 and 10 minutes after drug injection, and every ten minutes thereafter intra-operatively, and every thirty minutes post-operatively for the next twelve hours and every 60 minutes until complete recovery.

Patients were monitored for any signs of cardiovascular or central nervous system toxicity and any other adverse effect throughout the study. Dermatomes located in the surgical field could not be tested during the operative procedure. Because all patients were applied plaster of Paris cast after the procedure, individual dermatomes could not be assessed. Instead, to evaluate sensation, patients were asked to document the time when incisional discomfort began, and the time when full power returned to the shoulder. When the patient complained of pain at the operative site, inj. ketorolac 30 mg IV was given and the study was concluded at this point.

Statistical data analysis was done using SPSS version 17.Quantitative data were represented as mean ± standard deviation; number and percentage were used for qualitative data. *P* value < 0.05 was considered as statistically significant.

RESULTS

Demographic data comparing age, sex and body weight showed no statistically significant difference between both the groups. (Table 1) Duration of surgery was also comparable in the both groups.

TABLE 1: Distribution of demographic variables

Variable	Group R (n=30)	Group B (n=30)	P value
Age (years)	38.67 ± 13.371	39.70 ± 15.492	0.783
Sex (M/F) (No./ percentage)	19(63.3%)/ 11(36.7%)	16(53.3%)/ 14(46.7%)	0.601
Weight (Kg)	60.93 ± 6.65	57.70 ± 7.66	0.086
Duration of surgery (min.)	60 ± 12	62 ± 13	>0.05

Values presented as mean±SD, n (%).Group R-Ropivacaine; B-Bupivacaine. SD-Standard deviation Onset of sensory block was assessed by pin prick sensation using the blunt needle. Dermatomes C5-T1 was assessed. Onset time defined as the time from the completion of injection of study drug to first loss of pin prick sensation in each of these dermatomes. There was no statistically significant difference between the two groups in terms of onset of sensory blockade at all the dermatomes (C5- T1) [P > 0.5].In the ropivacaine group, onset of sensory blockade was earliest in the C6 dermatome (3.66 min), whereas in the bupivacaine group, it was earliest in the C5 dermatome (4.23 min). After 6.66 minutes, all the dermatomes were blocked in the R group and by 7.47 minutes in the B group, this difference was statistically insignificant. (Table 2)

TABLE 2: Sensory block onset (minutes) in each dermatome in the two groups

LEVEL	Group R (minutes)	Group B (minutes)	P value
C5	4.07 ± 2.32	4.23 ± 1.59	0.747
C6	3.66 ± 2.91	4.59 ± 1.52	0.132
C7	4.90 ± 2.91	5.96 ± 2.95	0.179
C8	6.00 ± 4.29	7.39 ± 3.75	0.202
T1	6.66 ± 5.14	7.47 ± 2.76	0.451

Values are presented as mean±SD, n (%).Group R-Ropivacaine; B-Bupivacaine. SD-Standard deviation Onset of motor block was defined as the time required from completion of injections of study drug to loss of motor power at the shoulders. Motor block at the shoulder was assessed by asking the patient to elevate the arm while keeping the elbow straight (superior trunk function) and at the hand by grip strength (middle and inferior trunk function) and its quality was graded as (0 = no weakness, 1 = paresis, 2 = paralysis).Time of onset of motor block was 4.63 min. in the R group and 4.40 min. in the B group. Complete motor blockade was achieved in 12.41 min. in the R group and 10.70 min. in B group. There was no statistically significant difference between the two groups in terms of paresis or paralysis of either shoulder (P > 0.05) or hand (P > 0.05). (Table 3)

TABLE 3: Motor block onset (minutes) of the two groups

SHOULDER (Grade)	Group R (minutes)	Group B (minutes)	P value
1 (Paresis)	4.63 ± 3.64	4.40 ± 2.03	0.760
2 (Paralysis)	8.21 ± 5.45	8.82 ± 3.93	0.635
HAND			
1 (Paresis)	7.29 ± 5.34	8.07 ± 4.06	0.531
2 (Paralysis)	12.41 ± 8.77	10.70 ± 2.83	0.341

Values are presented as mean±SD, n (%).Group R-Ropivacaine; B-Bupivacaine. SD-Standard deviation Duration of sensory blockade was defined as the time from the onset of sensory blockade to onset of pain at the surgical site. No statistically significant difference was observed between the two groups. (P > 0.05). The duration ranged from 210 – 1037 min. in group R and 250 – 987 min. in group B.(Table 4)The duration of motor block was defined as the time form the onset of motor blockade to the complete recovery of abduction at shoulder joint against gravity. It ranged from 263 – 1140 minutes in group R and 330 – 990 minutes in group B.(Table 4)

TABLE 4: Sensory and Motor block duration (min.) in the two groups

Parameter	R group (minutes)	B group (minutes)	P value
Sensory Block	555.71 ± 162.29	588.41 ± 159.23	0.454
Motor Block	595.96 ± 153.30	595.60 ± 140.63	0.993

Values are presented as mean±SD, n (%).Group R-Ropivacaine; B-Bupivacaine. SD-Standard deviation The overall quality of block was satisfactory in 93.3% (n=28) of the patients in the R group and 90.0% (n=27) of the patients in the B group. Two patients in group R and three patients in group B had unsatisfactory block and required general anaesthesia, were excluded from the study. The difference was not statistically significant (P > 0.05). (Figure 1) No adverse effects observed in both the group.

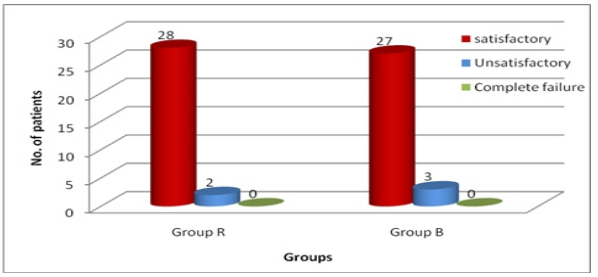

Figure 1: Overall quality of motor block in both group

DISCUSSION

In all, this study we observed that these two drugs are comparable

with regards to the onset time of sensory block and motor block, duration and quality of sensory-motor block and patient satisfaction.

A volume of 0.4ml/kg of local anaesthetic was chosen by consensus in order to ensure that the study did not expose patients in the lower weight ranges to an unexpectedly high dose of local anaesthetic, so that it did not reach the toxic plasma concentration of Bupivacaine (3µg/ml) and that of Ropivacaine (4µg/ml)[2], and to facilitate blinding. Cox CR et al[1] has used 0.4ml/kg dose for bupivacaine and levobupivacaine for brachial plexus block.

In this study, the onset of sensory block was studied at various dermatomal levels. The onset of sensory block was earlier at C6 dermatome (3.66 min) and delayed at T1 dermatome (6.66 min) in R group while in Group B; it was earlier in C5 dermatome (4.23 min) and delayed at T1 dermatome (7.47 min). There was no statistically significant difference was found between 0.75% ropivacaine and 0.5% bupivacaine regarding the onset of sensory block. Similar observations were made in the studies[3,4,5,6,7,8,9,10,11,12,13]

The time of onset of sensory block is comparable with study conducted by Klein SM et al[6] (< 6, < 6 minutes) and Raeder JC et al[8] (5, 5 minutes).In our study, the duration of sensory block was 555.71 minutes in the ropivacaine group and 588.41 minutes in the bupivacaine group, which was not statistically significant. These findings are in line with the studies.[7,8,17,14,15,16]

The onset of motor block in this study was studied at shoulder and hand. The onset of motor block in the ropivacaine group was 4.63 minutes and in bupivacaine group was 4.40 minutes. Complete motor block was achieved in 12.41 minutes in ropivacaine group and 10.70 minutes in bupivacaine group. No statistically significant difference was observed among both the groups. Our observations are in accordance with the studies.[3,4,7,8,17,9,15]

Regarding the quality of motor blockade, we observed that 93.3% (n=28) of the patients in ropivacaine group and 90.0% (n=27) in bupivacaine group had complete paralysis of both shoulder and hand, which was not statistically significant. There were two (6.7%) partial blocks in ropivacaine group and three (10.0%) partial blocks in bupivacaine group along with few dermatomal sparing. Similar observation was made in the study conducted by Hickey et al[3], being 83.0% in ropivacaine and 91.0% in bupivacaine group, which were also not statistically significant.

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