

**A COMPARATIVE STUDY BETWEEN 0.5% BUPIVACAINE AND 0.5% ROPIVACAINE
IN SUPRACLAVICULAR BRACHIAL PLEXUS BLOCK****Dr. Kirti Kundalwal^{1*}, Dr. Anandkumar Pande² and Dr. Nanasheeb Bhangare³**¹Assistant Professor, Department of Anaesthesia, B. J. Govt. Medical College, Pune, Maharashtra, India.²Associate Professor, Department of Anaesthesia, B. J. Govt. Medical College, Pune, Maharashtra, India.³Assistant Professor, Department of Pharmacology, B. J. Govt. Medical College, Pune, Maharashtra, India.***Corresponding Author: Dr. Kirti Kundalwal**

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ABSTRACT

Introduction: Brachial plexus blocks are among the most commonly performed peripheral neural blocks for upper extremity surgeries in clinical practice. This study compared the effectiveness of 0.5% Bupivacaine and 0.5% Ropivacaine for brachial plexus block. **Methods:** For this prospective randomized double blind study we enrolled, after approval by institutional ethical committee and informed consent from patients, total 100 patients scheduled for upper limb surgeries under supraclavicular brachial plexus block. Patients were randomly divided into two groups. Group B received 30 ml of 0.5% bupivacaine while Group R received 30ml 0.5% ropivacaine. Onset and duration of sensory and motor blockade, Intraoperative opioid requirement and adverse effects were noted. **Result:** The onset time of sensory block in group B was 840 ± 21.95 seconds while it was 780.6 ± 21.45 seconds in group R. Duration of sensory action in group B was 572.94 ± 7.29 min and in group R it was 563.22 ± 7.16 min. In case of motor action, onset was 1228.8 ± 30.34 seconds in group B while it was 1245.6 ± 23.41 seconds in group R while motor duration time was 529.56 ± 5.80 min and 427.12 ± 8.79 min in group B and group R respectively. Most of the patients in group R had good to excellent satisfaction as compared to bupivacaine. **Conclusion:** We can conclude that ropivacaine is better choice of local anaesthetic compared to bupivacaine, in equal dose and concentration, in terms of better analgesia and subsequently patient satisfaction when used for supraclavicular brachial plexus block.

KEYWORDS: Bupivacaine, Ropivacaine, Supraclavicular brachial plexus block.**INTRODUCTION**

As far as history can go back man has always sought to avoid pain and its unpleasant effects. Anaesthesia can either be general anaesthesia or involve a small area of the body (regional anaesthesia). Regional anaesthesia avoids the complications of general anaesthesia and also intubation while providing adequate analgesia and muscle relaxation in the operative area. It thus is a good alternative to general anaesthesia. In addition it provides the advantages of early ambulation and decreased incidence of thromboembolic complications. It also provides post-operative analgesia-a highly important factor which is to be addressed by the anaesthetist.

Nerve blocks are an integral part of regional anaesthesia. The brachial plexus block is useful in surgeries of the upper extremity. There are various techniques to block the brachial plexus. The supraclavicular approach is technically easy and provides intense anaesthesia for forearm surgeries. This is because the three trunks are clustered over the first rib just lateral and cephaloposterior to the subclavian artery where they can be easily blocked. Blocks are performed by using various

local anaesthetics. Among them bupivacaine provides longer duration of action but it shows more cardiac complications than most other commonly used local anaesthetics and marked cardiovascular depression may occur at plasma concentrations only slightly above those for central nervous system toxicity. Simultaneous seizures and cardiovascular collapse may develop rapidly after inadvertent intravascular injection and even prompt oxygenation and blood pressure support might not prevent cardiac arrest.^[1]

Ropivacaine is a new amino-amide local anaesthetic with a structure closely related to Bupivacaine, the butyl group being replaced by a propyl group. It differs also in that it is prepared as the pure S-isomer rather than a racemic mixture.^[2] Animal studies have shown that it is an effective, long-acting agent devoid of serious adverse effects when used for infiltration anaesthesia, peripheral and central neural block.^[3] Additionally, in vitro and in vivo animal experiments have suggested that ropivacaine may be approximately 50% less cardiotoxic than bupivacaine and possesses a greater safety margin between convulsant and lethal doses.^[4]

In clinical studies conducted with ropivacaine versus bupivacaine in brachial plexus block, ropivacaine was found superior in terms of early motor recovery, reduction of intra-operative opioids, less CVS and CNS complications and hence, greater patient satisfaction.^[5,6]

The present study was aimed to study safety and efficacy of ropivacaine over bupivacaine in supraclavicular brachial plexus block for upper limb surgeries.

METHODS

After approval from institutional ethics committee, this prospective randomized double blind study included total 100 patients belonging to ASA grade I-II of either sex with age between 18-50 years and weight 50-80 kg. A written informed consent was obtained from all patients posted for upper limb surgeries under brachial plexus block. Patients having own refusal for block, patients with significant cardiopulmonary disease, hepatic or renal failure, neuromuscular disorder, allergic to local anaesthetics, massive trauma with destruction of brachial plexus region, bleeding and coagulation disorders, patients on oral anticoagulants or antiplatelet agent, infection at the site of block, pregnant women and lactating mothers were excluded from the study. Patients were randomly divided into two groups of 50 each. Randomization was done by a computerized chart. Group B received 30ml of 0.5% bupivacaine while Group R received 30ml 0.5% ropivacaine. Local anaesthetic solution was prepared by an anaesthetist not involved in the study.

Anaesthesia Technique

Patients under the study were undergone thorough preoperative assessment including detailed case history, clinical examination, local examination of supraclavicular area & all necessary investigations a day before surgery. On the day of surgery after confirming nil by mouth status of 8 hours and written informed consent, patient was taken inside the operation theatre. After applying all ASA standard monitors, baseline parameters like pulse rate, blood pressure, respiratory rate, oxygen saturation (SPO2) were noted. Procedure was explained to the patient. Intravenous line was secured with 18G intracath and IV fluids were given according to the requirement. Premedication of inj ondansetron 4mg and inj midazolam 1mg were given before procedure.

The patient was placed in supine position with head turned about 30 degree to opposite side. Ipsilateral shoulder and arm was depressed. A 22 gauge 50mm blunt needle and a nerve stimulator was used to identify brachial plexus. The site that triggered muscular response to a stimulus equal to or lower than 0.4mA was identified and 30 ml of study drug was administered. The needle was removed and gentle massage was given for the spread of drug around nerves.

Evaluation of sensory block: Onset time of Sensory blockade was defined as the time between the local anaesthetic administration & total abolition of pinprick sensation. It was evaluated at distribution sites of radial, ulnar, median and musculocutaneous nerve. It was evaluated at every 30seconds. Duration of Sensory blockade was defined as the time of total abolition of pinprick sensation to return of pinprick sensation. It was evaluated every 15minutes intraoperatively and every 30minutes postoperatively.

Evaluation of Motor Blockade

A modified Bromage Scale^[7] for the upper extremity was used to assess motor function. This scale consists of the following four scores.

- 0-able to raise the extended arm to 90° for a full 2 sec
- 1-able to flex the elbow and move the fingers but unable to raise the extended arm.
- 2-Unable to flex the elbow but able to move the fingers
- 3-Unable to move the arm, elbow or fingers

Onset time of motor blockade was defined as the time between the local anaesthetic administration & grade 1 motor block. It was evaluated every 30seconds. Duration of motor blockade was defined as the time from grade 3 motor block to the complete recovery of wrist and hand movement. It was evaluated every 15minutes intraoperatively and every 30minutes postoperatively.

Complications associated with bupivacaine are mainly CVS related. These are hypotension; arrhythmia & cardiac depression. CNS complications are ranging from confusion to convulsion. Incidence of complications were recorded & compared with ropivacaine.

When patient experienced mild pain (Visual Analogue Scale<3) intraoperatively, supplementation of opioid like inj fentanyl 1µg/kg or inj pentazocine 0.3mg/kg were given intravenously. Ropivacaine & bupivacaine groups were compared for intraoperative need of opioids.

Patient's satisfaction was taken in consideration after brachial plexus block for hand surgeries with two drugs under study. Satisfaction was graded as- Excellent Good Not Satisfactory.

STATISTICAL METHODS

Both the groups were compared for onset and duration of sensory and motor block, intraoperative opioid requirement, patient satisfaction and complications due to drug or procedure if any. The data was expressed in Mean±SD or SEM and analysed statistically by using GraphPad Prism 7, statistics software published by GraphPad Software, Inc. Fisher's exact test was used for analysis of Categorical data including demographic parameters. Numerical data was analysed by using student's unpaired 't' test. The results were considered significant if P value was <0.05.

RESULTS

The study was successfully carried out in 100 patients who were divided into 2 groups. Group B received 30ml of 0.5% bupivacaine while Group R received 30ml 0.5% ropivacaine. Both the groups were comparable with respect to age, weight, sex and ASA status (Table 1). Onset of sensory block in group B was 840 ± 21.95 seconds while in group R it was 780.6 ± 21.45 seconds. Duration of action of sensory block in group B was 572.94 ± 7.29 min and in group R it was 563.22 ± 7.16 min. Both the time periods were slightly longer in group B than Group R but these were not significant statistically (Table 2). In case of motor action, onset was

1228.8 ± 30.34 seconds in group B while it was 1245.6 ± 23.41 seconds in group R which was statistically not significant but the duration of motor action was statistically highly significant (p value = 0.0001) which was 529.56 ± 5.80 min in group B and 427.12 ± 8.79 in group R as shown in (Table 3). Out of 50 patients only 6 patients of group R required opioids intraoperatively as against 16 patients in group B which showed statistically significant (p value = 0.0283) result (Fig 1). Most of the patients in group R had good to excellent satisfaction as compared to bupivacaine which was statistically significant (p value = 0.0228) as shown in Fig 2.

Table 1: Age, Weight and Sex distribution in Ropivacaine and Bupivacaine group.

Drugs	Age (Years) Mean \pm SEM	Weight (Kgs) Mean \pm SEM	SEX		ASA	
			Male	Female	I	II
Ropivacaine (n = 50)	36.86 ± 1.03	58.06 ± 0.75	35	15	42	8
Bupivacaine (n = 50)	39.64 ± 1.08	57.8 ± 0.91	38	12	40	10
P Value	0.0655 *	0.8261 *	0.6529 †		0.7953 †	

*Descriptive level of unpaired 't' test

†Descriptive level of Fisher's Exact test

Table 2: Evaluation of Sensory blockade: Onset (in seconds) and Duration of action (in minutes).

Drugs	Onset of Action (Sec.) Mean \pm SEM	Duration of Action (Mins.) Mean \pm SEM
Ropivacaine (n = 50)	780.6 ± 21.45	563.22 ± 7.16
Bupivacaine (n = 50)	840 ± 21.95	572.94 ± 7.29
P Value	0.0559 *	0.3440 †

* $P > 0.05$; Not Significant

† $P > 0.05$; Not Significant

Table 3: Evaluation of Motor blockade: Onset (in seconds) and Duration of action (in minutes).

Drug	Onset of Action (Sec.) Mean \pm SEM	Duration of Action (Mins.) Mean \pm SEM
Ropivacaine (n = 50)	1245.6 ± 23.41	427.12 ± 8.79
Bupivacaine (n = 50)	1228.8 ± 30.34	529.56 ± 5.80
P value	0.6621 *	0.0001 †

* $P > 0.05$; Not Significant

† $P < 0.001$; Highly Significant

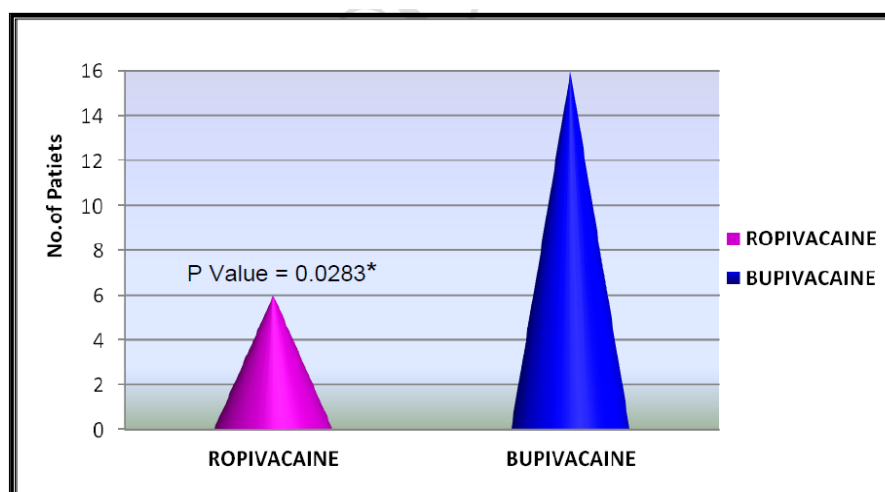


Fig. 1: Intra-operative Opioid requirement with Ropivacaine and Bupivacaine.

* $P < 0.05$; Statistically Significant.

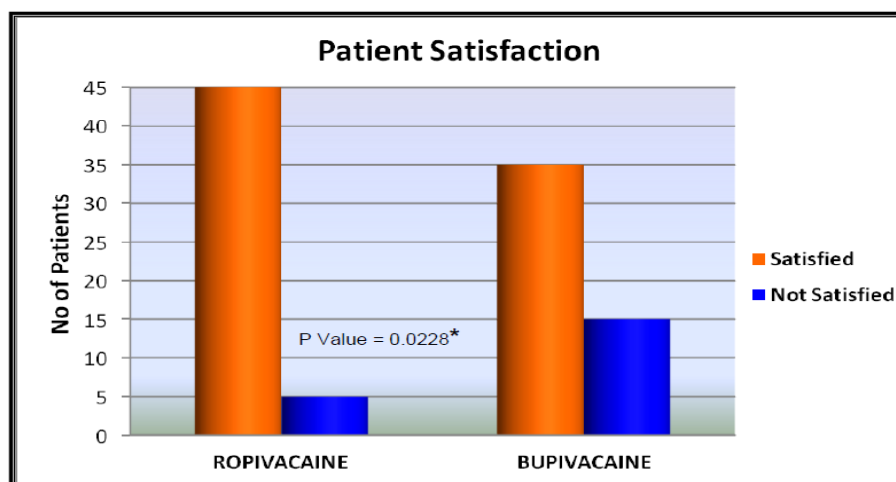


Fig. 2: Patients satisfaction with Ropivacaine and Bupivacaine.

* $P < 0.05$; Statistically Significant.

DISCUSSION

Regional anaesthesia is better alternative to general anaesthesia in upper extremity surgeries as it confers better patient safety, minimizes stress response and avoids opioid related complications. In the present study we preferred to block brachial plexus for upper extremity surgeries. Brachial plexus is blocked by various approaches like interscalene, supraclavicular and axillary. However each has its own limitations. But supraclavicular approach has been considered the most efficacious approach to brachial plexus block because in this approach we block the trunks of brachial plexus and is associated with a rapid onset of anaesthesia, high success rate, complete and predictable anaesthesia for entire upper extremity.^[8] Use of nerve stimulator for localization of peripheral nerves helps in accurate placement of drug around nerves and reduce the chances of failure which ultimately improves the success rate of the procedure. Considering these facts, we used classical approach technique of supraclavicular brachial plexus block with the aid of the nerve stimulator. The selection of optimal local anaesthetic agent for brachial plexus block is done by considering its time of onset, duration of action and its side effects. Bupivacaine is frequently used local anaesthetic for brachial plexus block because of its longer duration of action and favourable ratio of sensory to motor block. But its toxicity is concerning issue especially when larger doses are used. Hence, it led to a need for a drug which can have all the advantages of bupivacaine without its toxicity.

The present study was conducted to compare efficacy and safety of bupivacaine with ropivacaine in supraclavicular brachial plexus block. Both of these drugs act by blocking nerve conduction by decreasing the entry of Na^+ ions during upstroke of action potential. Ropivacaine has less cardiac complications than bupivacaine. These complications are because of very slow reversal of sodium channel blockade after cardiac action potential by bupivacaine. In case of ropivacaine, the reversal is faster. Negative inotropic potency on isolated cardiac tissue is less with ropivacaine. These

both electrical and mechanical differences in toxic profiles may arise from selective inhibition of calcium current by bupivacaine.^[9]

Different concentrations of ropivacaine were studied and compared with 0.5% bupivacaine in different studies by many authors yet and found that 0.5% ropivacaine is equipotent to 0.5% bupivacaine in providing brachial plexus block.^[5,6] The present study compared ropivacaine with bupivacaine in similar concentration of 0.5% and volume of 30ml in brachial plexus block in total 100 patients which were allocated randomly into 2 groups i.e. GROUP B- received 0.5% of 30ml bupivacaine and GROUP R - received 0.5% of 30ml ropivacaine.

Both groups were comparable in terms of age, weight, sex and ASA grade. Average age of the patient was 39.64 ± 7.60 years in bupivacaine group and 36.86 ± 7.32 years in ropivacaine group. Average weight of the patient was 58.06 ± 5.29 Kg in bupivacaine group and 57.80 ± 6.46 Kg in ropivacaine group. The sex distribution and ASA distribution were comparable in both the groups.

The mean onset of sensory block (defined as the time between administering the block to the absence of pinprick sensation) was 840 ± 155.24 seconds with bupivacaine and 780.6 ± 151.70 seconds with ropivacaine. Mean duration of sensory blockade was 572.94 ± 51.57 minutes with bupivacaine and 563.22 ± 50.64 minutes with ropivacaine. The difference was not statistically significant ($p > 0.05$).

The study done by McGLADE DP et al; 1998^[5] on comparison of 0.5% ropivacaine with 0.5% bupivacaine for axillary brachial plexus block using 40ml volume of each Median sensory onset time for ropivacaine was 10-20min and for bupivacaine was 10-30min. Median duration for sensory block was 5.3-8.7hour for ropivacaine and 6.9-20.3hour for bupivacaine. In another study done by HICKEY R et al:1991^[10] on comparison

of 0.5% ropivacaine with 0.5% bupivacaine for brachial plexus block using 175mg dose of both median sensory onset time for ropivacaine was 13-31min and that for bupivacaine was 18-58min. Median duration of sensory block for both drugs was 9-11hours. Similar observations were found in the studies conducted by Himat Vaghadia *et al*^[11], Stephen M Klein *et al*^[8] where there was no statistically significant difference between the onset of sensory block among ropivacaine group and bupivacaine group ($p>0.05$). In the above studies sensory onset and duration for ropivacaine and bupivacaine were comparable and statistically not significant. These results were in line with our study.

The mean onset of motor blockade was 1228.8 ± 214.54 seconds with bupivacaine and 1245.6 ± 165.57 seconds with ropivacaine. But the difference between these two groups was not statistically significant ($p>0.05$). Mean duration of motor blockade was 529.56 ± 41.01 minutes with bupivacaine and 427.12 ± 62.18 minutes with ropivacaine. The difference was statistically highly significant ($p<0.001$). This property of prolonged motor block interferes self-care ability of the patient. Study done by McGLADE DP *et al*; 1998^[5] on comparison of 0.5% ropivacaine with 0.5% bupivacaine for axillary brachial plexus block using 40 volume of each showed partial motor block of significantly longer duration with bupivacaine (6.8 Vs 16.4 Hrs at the wrist and 6.7 Vs 12.3 hrs at the hand). Vainionpaa *et al*^[12] compared 0.5% ropivacaine with 0.5% bupivacaine in axillary brachial plexus block and found no statistically significant differences in the clinical (and pharmacokinetic) comparisons. They used a slightly different dose of drug depending on patient body weight: 30 mL (weight <70 kg), 35 mL (weight 70–80 kg), or 40 mL (weight >80 kg).

The theoretic advantage of ropivacaine over bupivacaine is its lesser potential for cardiac toxicity. Intact animal studies have also demonstrated that the ropivacaine is associated with lesser arrhythmogenic potential than bupivacaine.^[13,14] In a human volunteer study, Scott *et al*.^[15] reported that volunteers subjectively accepted a significantly greater dose of ropivacaine than bupivacaine when it was infused intravenously. In our study though there were no complications^[16,17,18] related to the drug like signs of CNS toxicity (like restlessness, anxiety, incoherent speech, lightheadedness, dizziness, blurred vision, tremors, drowsiness and convulsion) or CVS toxicity (hypotension, bradycardia, hypertension, tachycardia, vasovagal reaction, arrhythmias like extrasystoles, atrial fibrillation, ST segment changes and myocardial infarction), nausea, vomiting noted intraoperatively in both the groups, still ropivacaine is a well-tolerated regional anaesthetic with an efficacy broadly similar to that of bupivacaine because of its reduced CNS and cardiotoxic potential and its lower propensity for motor block as concluded by Mclellankj, Faulds D, in 2000.^[19]

In present study, only 12% of patients from ropivacaine group, required opioids intraoperatively. These results are statistically significant in comparison with bupivacaine group where 36% patient required intraoperative opioids. The most common used opioids during surgery were fentanyl and pentazocine. The overall patient satisfaction with the supraclavicular block was rated as Excellent, Good and Not Satisfactory. The rating was done in consultation with expert team of Department of Anaesthesia, in our tertiary care hospital. Criteria used for rating was perception of pain during procedure. Pain relief was regularly assessed by using a visual analogue scale and the patients were asked to rate their satisfaction at the end of the study. Patient satisfaction was higher with ropivacaine as compared to bupivacaine.

These results are in line with the study conducted by Bertini L, *et al*, 1999.^[6] Clinical comparison of 0.75% and 0.5% ropivacaine with 0.5% bupivacaine was done for axillary brachial plexus block. The dose of local anaesthetics used by Bertini was 32 mL. The quality of anesthesia was found higher with ropivacaine. An additional observation was noted by them that the 0.75% concentration of ropivacaine did not add any benefit. Therefore 0.5% of ropivacaine was recommended for axillary brachial plexus blocks.

CONCLUSION

In the present study 30ml of 0.5% bupivacaine was compared with 30ml 0.5% ropivacaine in supraclavicular block in upper limb surgery. Both of these produced satisfactory anaesthesia for surgery with comparable onset of sensory and motor block. Though duration of sensory block was comparable that of motor block was prolonged in bupivacaine group. The quality of anaesthesia was better with ropivacaine with less analgesic supplementation intraoperatively, considering this property and safety profile of ropivacaine compared to bupivacaine, ropivacaine will be a better choice of local anaesthetic in peripheral block.

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