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Ropivacaine a better alternative to bupivacaine: A comparative study of 0.75% ropivacaine vs 0.5% bupivacaine for analgesic efficacy under supraclavicular brachial plexus block

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Abstract

Background and Objectives: Patients undergoing forearm surgeries have benefited considerably with the widespread use of brachial plexus block instead of general anaesthesia. This study was conducted to investigate the efficacy of 0.75% Ropivacaine in supraclavicular brachial plexus block and to compare the results with 0.5% bupivacaine, which is already established as local anaesthetic for regional anaesthesia.
Methods: Sixty patients of ASA-I and II consenting adult patients undergoing elective upper limb surgeries were randomly divided into Group A and Group B. Group A received 30 ml of 0.5% Bupivacaine and Group B received 0.75% Ropivacaine in supraclavicular block after authenticating the position of brachial plexus with nerve stimulator. Patients were monitored for peak onset and duration of sensory and motor blockade and post-operative analgesia using visual analogue scale. Patients were also observed for any complications during the surgery and in the postoperative period. Sensory and motor block peak and duration of analgesia were evaluated statistically using unpaired t-test and p-value <0.05 was considered significant.
Results: There were no significant differences between the study groups with respect to pattern of changes in Heart rate, Systolic blood pressure, Diastolic blood pressure, Mean arterial pressure perioperatively.
Peak sensory blockade was attained faster in Group B (Ropivacaine) i.e. 13.10 ±2.5 minutes compared to Group A (Bupivacaine) i.e. 23.33 ±3.1 minutes which is statistically significant. Duration of sensory blockade was also longer in Group B (Ropivacaine) i.e. 720.66 ±38.09 minutes compared to Group A (Bupivacaine) i.e. 672.66 ±105.95 minutes and is statistically significant. Onset of Motor blockade was faster in Group B (Ropivacaine) i.e. 18.03 ±2.4 minutes compared to Group A (Bupivacaine) i.e. 24.76±3.1 minutes which is statistically significant. Duration of Motor blockade in Group A (Bupivacaine) was 637.100 ±88.72 minutes compared to Group B (Ropivacaine) i.e. 646.17 ±38.07 minutes and is statistically

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not significant. Also, the time for demand of rescue analgesics was prolonged in Group B (Ropivacaine) i.e. 752.66 ±40.33 minutes compared to Group A (Bupivacaine) i.e. 694.56 ±106.14 minutes and this difference is statistically significant.
Conclusion: Ropivacaine 0.75% has an added advantage over Bupivacaine 0.5% for Supraclavicular Brachial Plexus block in terms of early onset of sensory and motor blockade, prolonged duration of sensory blockade, and prolonged duration of analgesia leading to lesser requirement of rescue analgesic. The side effects and complications rate are almost negligible in both groups. Thus Ropivacaine even at higher concentrations of 0.75% and 30 ml volume has proven to be an absolutely safe local anaesthetic. So on the basis of our study we conclude that Ropivacaine 0.75% is an excellent choice for local anaesthetic, which provides better and safer regional anaesthesia.

Keywords: Supraclavicular brachial plexus block, ropivacaine, bupivacaine

Introduction

Regional anaesthesia is undeniably advantageous for any branch of surgery, because it's perfect combination of anesthesia and long lasting postoperative analgesia.
Bupivacaine due to its long duration of action and high quality sensory and motor blockade has been the most commonly used local anaesthetic for peripheral nerve block. Bupivacaine is racemic mixture of (R)-and (S)-stereoisomers [1]. Bupivacaine is highly lipid soluble. So its uptake into nerves is very high. Thus it has high potency, and increased toxicity [2-4].
Ropivacaine is a newer, long acting local anaesthetic whose neuronal blocking potential used in peripheral nerve blockade seems to be equal or superior to Bupivacaine [5]. Ropivacaine is less lipophilic than bupivacaine, this together with its stereo-selective properties [6], contribute towards a significantly higher threshold for cardiotoxicity and CNS toxicity than bupivacaine in healthy volunteers [7, 8, 9].
This study was conducted to compare Ropivacaine with Bupivacaine in supraclavicular brachial plexus block.

Aims and Objectives

This study is designed to compare 30 ml of Bupivacaine 0.5% and 30 ml of Ropivacaine 0.75% for supraclavicular brachial plexus block by using nerve stimulator in upper limb surgeries.

- Onset time of Sensory blockade.
- Onset time of Motor blockade.
- Duration of Sensory blockade.
- Duration of Motor blockade.
- Duration of Analgesia.

Materials and Methods

1. Study area

Command Hospital (Eastern Command), Alipore, Kolkata 60 patients of ASA Grade-I and Grade-II were allocated randomly into two groups. Permission of the Hospital Ethical Committee was obtained.

2. Study population

Patients scheduled for elective orthopaedic upper limb surgeries.

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Inclusion criteria

a) Patients in the age range 18-60 years of either sex.
b) ASA risk category I and II.
c) With no known history of allergy, sensitivity or other form of reaction to local anaesthetics of the amide type.

Exclusion criteria

a) Patients who had not given consent.
b) Patients with severe pulmonary, cardiac, renal or endocrine disease.
c) Patients in physical status ASA grade 3 or higher.
d) Patients with local skin infections at site of injection.
e) Patients with coagulopathy, on potent antiplatelets, or on anticoagulants.
f) Patients allergic to the trial drugs.
g) Patients with hemidiaphragmatic paralysis on contralateral side of surgery.
h) Patients with psychological disorder.

3. Study period

February 2016 to April 2017.

4. Sample size

60 patients (30 in each group).

5. Sample and Study design

A prospective, randomised clinical Study:
The patients were divided into 2 groups of 30 each and were administered local anaesthetic drugs via supraclavicular brachial plexus block as noted below:
a) Group A were given 30 ml of 0.5% injection Bupivacaine.
b) Group B were given 30 ml of 0.75% injection Ropivacaine.

Parameters studied

a) Onset time of Peak Sensory blockade.
b) Onset time of Peak Motor blockade
c) Duration of Sensory blockade
d) Duration of Motor blockade
e) Duration of Analgesia

Preanaesthetic preparations

a) A detailed pre-anaesthetic evaluation of each case was done after noting the medical history. A thorough systemic examination was carried out to detect the presence of any systemic disorder. Routine and special investigations were carried out accordingly. Local examination of block site was done to exclude any sign of sepsis, previous injury or previous deformity. Patients were kept nil orally 6-8 hours prior to regional block.
b) Premedication and anaesthetic procedures. The patients were reassured, the procedure of block was explained and a written informed consent was obtained from them. On arrival

of the patient in the operation theatre, Multiparameter monitors were applied and base line respiratory rate, pulse rate, non-invasive blood pressure, SPO2 and ECG were recorded. Intravenous line was secured with 18G venous cannula and I.V. Fluids administered according to the requirement of the patient. Premedication with Midazolam 0.2mg/kg and Fentanyl 0.5-1µg /kg IV were given.

6. Landmarks and Patient positioning

The patient was placed in a semi-sitting position with the head rotated away from the site to be blocked and the shoulder pulled down. The arm rested comfortably on the side. The main anatomical landmarks for this block are the lateral insertion of the sternocleidomastoid muscle onto the clavicle and the clavicle itself

7. Technique

a) After appropriate positioning of the patient the subclavian artery was palpated 1cm above the midpoint of the clavicle. An insulated 1.5 inch 25G needle was introduced just lateral to the subclavian pulsation in backward, downward and medial direction. The nerve stimulator is connected to the stimulating needle and set to deliver a 0.8 to 1.0 mA current at 1 Hz frequency and 0.1 ms of pulse duration. Once the contraction of muscle below the deltoid in the upper extremity was observed, intensity of current was decreased in 0.02mA decrements while advancing the needle, until maximum contraction was elicited with minimal possible current. This technique ensures close proximity of the needle tip to the brachial plexus. At this point, 30 ml of the drug was injected after gentle aspiration as per the group assigned.
b) All patients were incessantly monitored for heart rate, BP, respiratory rate and oxygen saturation. After completion of the surgery patients were observed in the recovery room and ward.

Assessment of the block

a) Onset of Sensory and Motor Blockade was monitored every two minutes for first 15 minutes then every five minutes till 30 minutes.

b) Sensory blockade

i) Assessment of sensory block was done after completion of drug injection in the dermatomal areas of median, radial, ulnar and musculocutaneous nerves.
ii) Sensory block was evaluated by Hollmen scale [10] measured with pin prick test at a three-point scale: 0-Sharp pain; 1-Dull pain (analgesia); 2-No pain (anaesthesia).
iii) Peak of sensory blockade was considered when there was complete loss of sensation to pin prick.
iv) The duration of sensory blockade was considered from complete loss of pin prick sensation to reappearance of pain.

c) Motor blockade

i) A modified Bromage Scale [11] for the upper extremity was used to evaluate Motor function. This scale consists of the following four scores:
1) Able to raise the extended arm to 90 for a full 2 sec.
2) Able to flex the elbow and move the fingers but unable to raise the extended arm.

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3) Unable to flex the elbow but able to move the fingers.
4) Unable to move the arm, elbow or fingers.

Motor block was assessed every two minutes for first 15 minutes. Peak motor block was considered when there was Grade 3 motor blockade. The duration of motor blockade was defined as the time interval between peak motor blockade and complete movement of wrist and fingers.

d) The duration of analgesia was taken as time interval between onset of sensory blockade and the first dose of rescue analgesic. Postoperatively, pain was assessed using visual analog scale (VAS) score explained to the patient preoperatively where 0 represented no pain and 10 meant worst possible pain. Postoperatively, whenever VAS score was more than 5, injection diclofenac sodium 1 mg/kg was given intravenously as rescue analgesic.

Statistical analysis

For statistical analysis data were entered into a Microsoft excel spreadsheet and then analyzed by SPSS 20.0 and Graph Pad Prism version 5. Data had been summarized as mean and standard deviation for numerical variables and count and percentages for categorical variables. Demographic and hemodynamic data were analyzed by student's *t*-test. For statistical analysis of onset time and duration of sensory and motor blocks, duration of analgesia unpaired t-test was applied, $p<0.05$ was considered as statistically significant.

Results

Total number of patients enrolled for the study were 60, 30 in each group. None of the patients had failed or partial blocks. Both the groups were comparable in terms of age, weight and gender.

Table 1: Demographic profile

Parameters	Group A (N=30)	Group B (N=30)
Age	39.83 ± 16.91	32.60 ± 10.47
Weight	70.93 ± 8.45	70.90 ± 6.49
Sex (M:F)	22: 8	27: 3

Table 2: Comparison of mean Heart rate in two groups

	Group-A		Group-B		p-value
	Mean	±SD	Mean	±SD	
PR 0 Mins	80.2667	5.1924	80.4667	1.7167	0.8419
PR 15 Mins	78.6000	4.9869	78.4667	1.4559	0.8887
PR 30 Mins	79.8000	6.5464	75.0667	3.3107	0.0868

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Heart rate variation between two groups at 0 mins, 15 mins and 30 mins was not statistically significant (p>0.05)

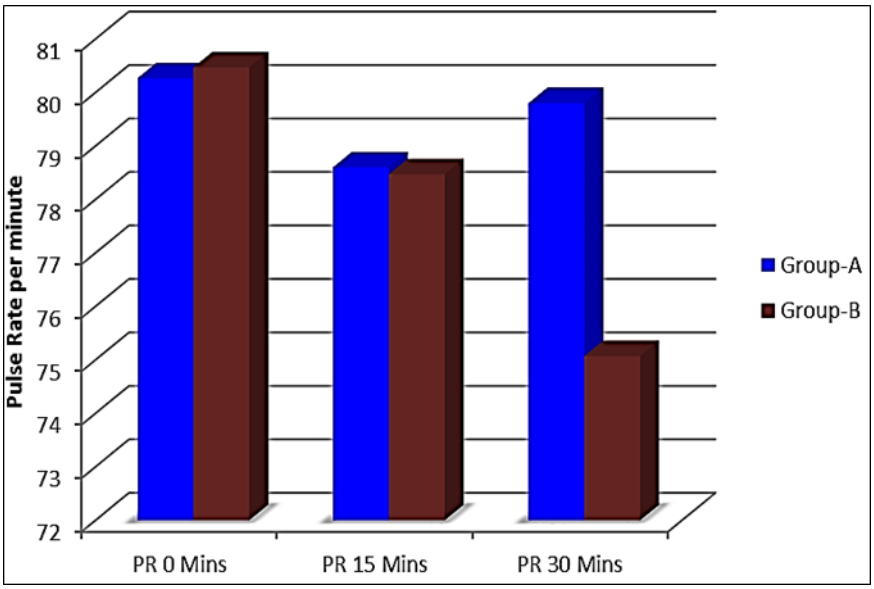

Fig 1: Comparison of mean Heart rate in two groups

Table 3: Comparison of mean SBP (mmHg) in two groups

	Group-A		Group-B		p-value
	Mean	±SD	Mean	±SD	
SBP 0 Mins	128.6667	10.9712	125.3333	7.4154	0.1733
SBP 15 Mins	129.2667	12.2894	117.7333	6.5964	0.8861
SBP 30 Mins	124.1333	12.3281	115.8000	5.9966	0.5100

Systolic blood pressure variation between two groups at 0 mins, 15 mins and 30 mins was not statistically significant (p>0.05)

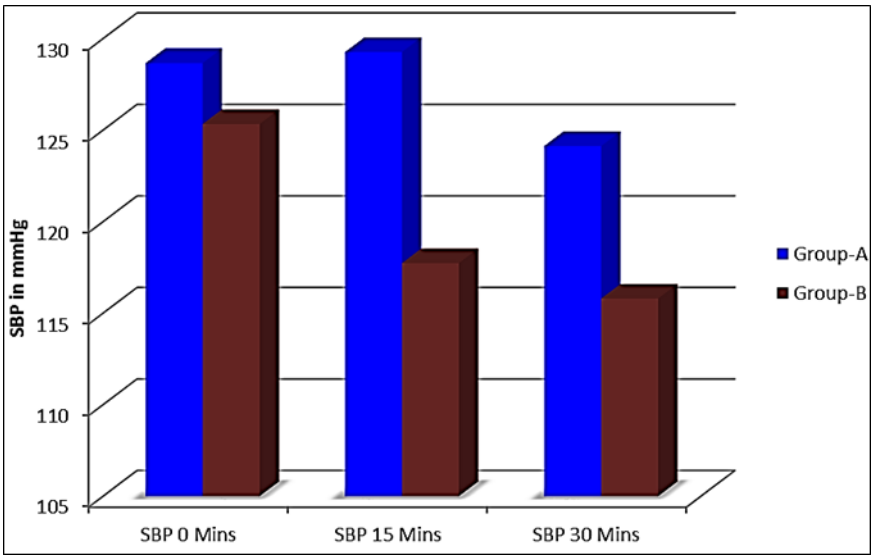

Fig 2: Comparison of mean SBP in two groups

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Table 4: Comparison of groups based on peak sensory block time (mins)

		Number	Mean	SD	Minimum	Maximum	Median	p-value
PST Min	Group-A	30	23.3333	3.1441	18.0000	30.0000	23.0000	<0.0001
	Group-B	30	13.1000	2.5237	10.0000	20.0000	13.0000	

Peak sensory block time in two groups was statistically significant (p<0.0001)

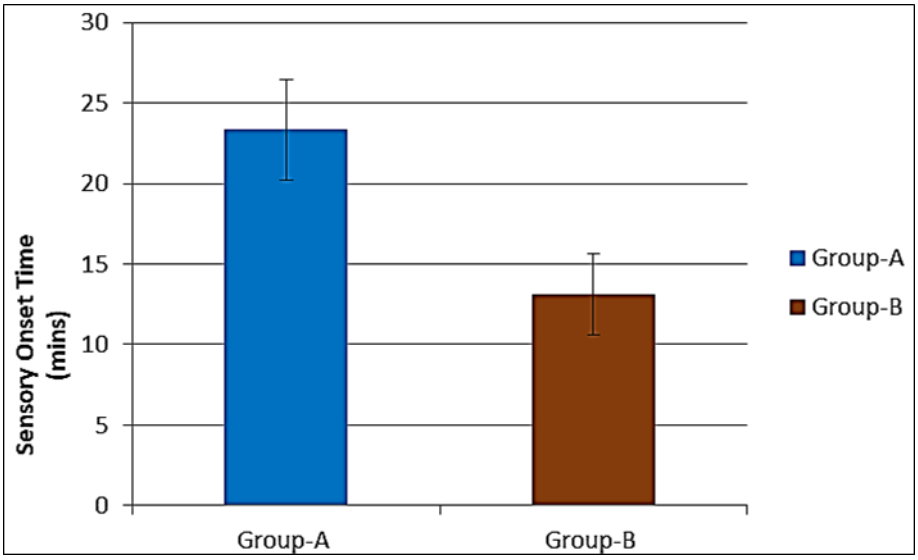

Fig 3: Comparison of Peak Sensory Block Time (mins) in two groups

Table 5: Comparison of Peak Motor Block Time (mins) in two groups

		Number	Mean	SD	Minimum	Maximum	Median	p-value
PMT Min	Group-A	30	24.7667	3.1588	20.0000	30.0000	25.0000	<0.00001
	Group-B	30	18.0333	2.3995	13.0000	22.0000	18.0000	

Difference of peak motor block time in two groups is statistically significant (*p*<0.0001)

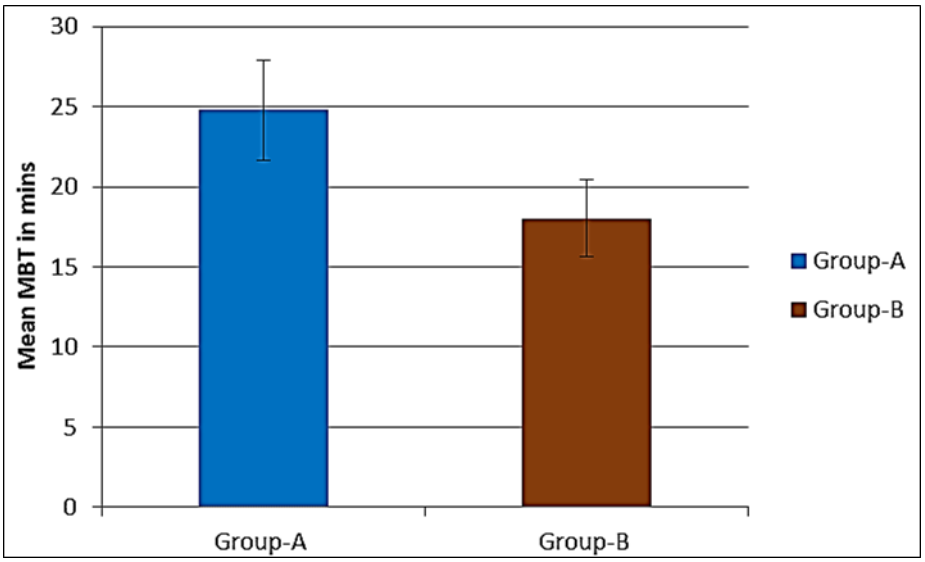

Fig 4: Comparison of Mean Peak Motor Block Time (mins) in two groups

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Table 6: Comparison of Group based on Mean Duration of Sensory Block (mins)

		Number	Mean	SD	Minimum	Maximum	Median	p-value
Duration of sensory block min	Group-A	30	672.6667	105.9500	420.0000	960.0000	662.5000	0.0230
	Group-B	30	720.6667	38.0955	650.0000	790.0000	720.0000	

Difference of mean duration of sensory block in two groups was statistically significant (p=0.0230)

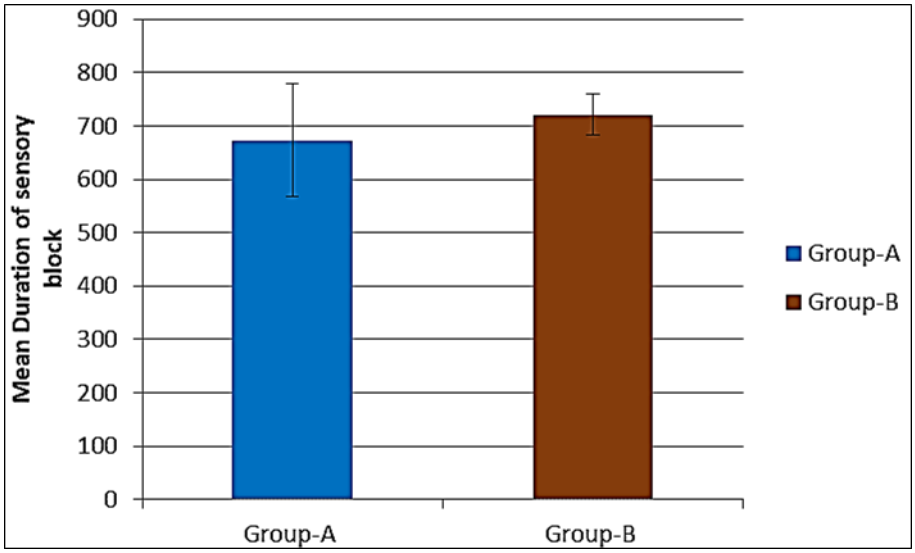

Fig 5: Comparison of Mean Duration of Sensory Block (mins) in two groups

Table 7: Comparison of Mean Duration of Motor Block (mins) in two groups

		Number	Mean	SD	Minimum	Maximum	Median	p-value
Duration of motor block in min	Group-A	30	637.1000	88.7202	405.0000	790.0000	630.0000	0.6089
	Group-B	30	646.1667	38.0717	550.0000	700.0000	647.5000	

Difference of Mean Duration of Motor Block in two groups was not statistically significant (p=0.6089)

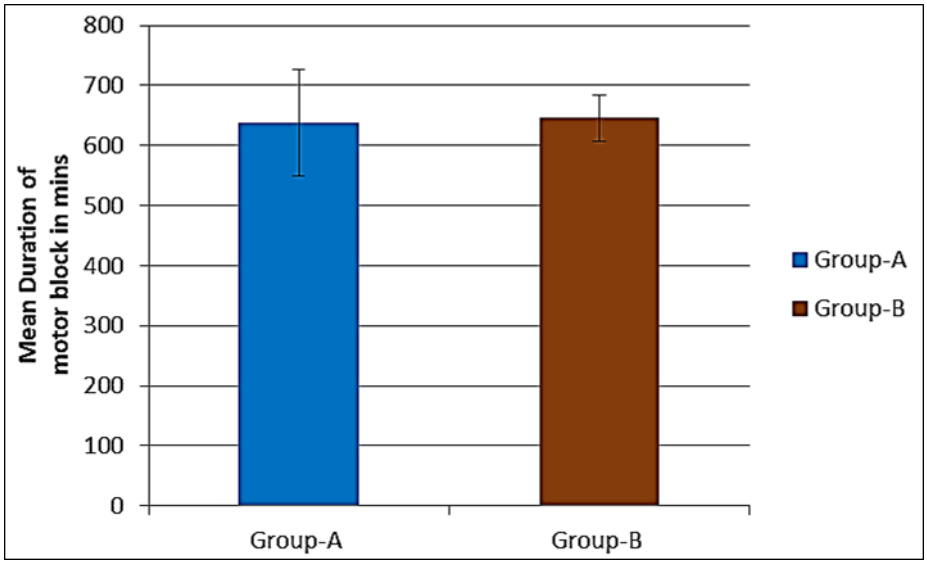

Fig 6: Comparison of Mean Duration of Motor Block (mins) in two groups

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Table 8: Comparison of Mean Duration of Analgesia (mins) in two groups

		Number	Mean	SD	Minimum	Maximum	Median	p-value
Duration of post-operative analgesia min	Group-A	30	694.5667	106.1494	430.0000	990.0000	685.0000	0.0069
	Group-B	30	752.6667	40.3377	680.0000	820.0000	750.0000	

Difference of mean duration of analgesia in two groups was statistically significant (p=0.0069)

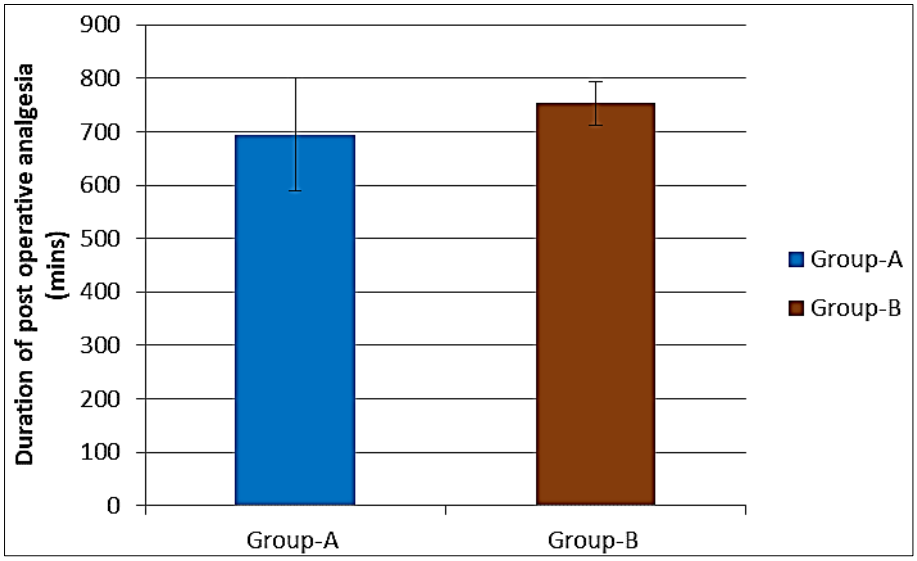

Fig 7: Comparison of Mean Duration of analgesia (mins) in two groups.

Discussion

Peripheral nerve blocks have revolutionized the practice of anaesthesia because of their role in intraoperative and postoperative pain relief, shortening of patient recovery time and avoiding risks and adverse effects of General Anaesthesia.

Brachial plexus blockade for upper limb surgeries is the most widely practiced major peripheral nerve block technique. The supraclavicular approach to brachial plexus is carried at the level of trunks of brachial plexus. It provides most effective blockade since plexus is blocked at the level of trunks, resulting in homogenous spread of anaesthetic drug [12].

The discovery of Ropivacaine has ended our search for a local anaesthetic with longer duration of action, better nerve selectivity, lesser degree of motor blockade and lower incidences of systemic toxicity. It is a newer local anaesthetic found to be equally efficacious to Bupivacaine, but with a better safety profile when used in Brachial plexus block. Ropivacaine is enantiomerically pure (S-enantiomer) amide local anaesthetic with a high pKa (ionization constant) and low lipid solubility which blocks nerve fibers involved in pain transmission (A delta and C fibers) more than those controlling motor function (A-beta fibers). Thus, it is similar to bupivacaine with regard to pain relief but has less propensity to cause motor blockade at low concentrations [13, 14]. Furthermore, the drug is less cardio toxic than equal concentrations of bupivacaine and has a much higher threshold for CNS toxicity than bupivacaine [15].

The patients demographic profiles did not vary much with respect to Age, Sex and Weight. The type of surgeries performed were almost identical in both the groups. The study groups did not vary much with respect to duration of surgery (Statistically not significant).

D Tripathi *et al*. [16] observed that there were no significant differences between the two study groups with respect to pattern of changes in Heart rate, Systolic blood pressure, Diastolic blood pressure and mean arterial pressure preoperatively. Similar trend of hemodynamic

parameters was observed in our study. There is no difference between Bupivacaine 0.5% and Ropivacaine 0.75% with respect to variation in hemodynamic parameters when used at equal volumes for supraclavicular Brachial plexus block.

Peak Sensory and Motor block

In Ropivacaine group (Group B) the mean value of peak sensory onset time was 13.10±2.5 minutes in comparison to Bupivacaine group (Group A) having a mean value of 23.33.10±3.1 minutes, which is statistically significant?
Onset time of Peak Motor block is earlier in Ropivacaine group (Group B) having a mean value of 18.03±2.4 minutes in comparison with Bupivacaine group (Group A) having a mean value of 24.76±3.1 minutes which is statistically significant.
The above observations are similar to studies conducted by Singelyn FJ. and Himatvaghadia *et al*..[17, 18] Early onset of peak sensory and motor blockade with 0.75% Ropivacaine justifies that using Ropivacaine at this concentration is of added advantage to anaesthesiologist and patient in terms of pain relief.

Duration of Sensory block and Motor block

Mcglade D.P, Kalpokas M.V, Mooney P.H [19] reported that the quality of sensory block was similar in both drugs, however the motor blockade lasted significantly longer when Bupivacaine was used. But in our study the Duration of sensory block was 720.66±38.09 minutes with Ropivacaine group and 672.66±105.95 minutes with Bupivacaine group. The quality of sensory block in Ropivacaine group was comparable to Bupivacaine group but duration of sensory block was longer in Ropivacaine, which was statistically significant. Longer duration of sensory block could be due to higher concentration of Ropivacaine used in our study.
Reader JC *et al*. [20] Found that motor blockade with 0.75% Ropivacaine was comparable to 0.5% Bupivacaine. Mclellan KJ, Faulds D [21] found that Ropivacaine is a well-tolerated regional anaesthetic with similar anaesthetic efficacy to that of bupivacaine but has a lower propensity to produce Motor block. We found that the mean onset of peak motor block is 18 mins which is statistically significant and duration of Motor block was 646.16 minutes with Ropivacaine group as compared to Bupivacaine which is 24.7 mins and 637mins respectively. This shows that onset of motor block and weaning of motor block, both were early in the Ropivacaine group. Quality of muscle relaxation was excellent and the duration of motor block was comparable in both the groups.
Reader J.C, Drosahl S, Klaastad O [20] showed that 0.75% Ropivacaine resulted in better sensory block when compared with same volume of 0.5% Bupivacaine, however the onset and duration of blockade were similar in both groups and concluded that Ropivacaine at a concentration of 7.5 mg/ml was required to produce similar effects with respect to onset and Duration of Sensory and Motor blockade as compared to Bupivacaine 0.5% at equal volumes.

Duration of analgesia

Mcglade D. P, Kalpokas M. V, *et al*. compared 0.5% Ropivacaine and 0.5% Bupivacaine (30 ml) for brachial plexus block noted that the quality of anaesthesia and was similar in both the groups [19]. Hickey. R, Rowley. C.L, Ramamurthy. S *et al*. concluded that Ropivacaine and Bupivacaine 0.5% appeared equally effective in providing brachial plexus anaesthesia. Both were similar in terms of Incidence of analgesia, anaesthesia, paresis, paralysis and the need for supplementation [23]. However we analyzed that the Duration of Analgesia was 752.66±40.33 minutes with Ropivacaine group (Group B) which is very significant in terms

of pain relief and statistically, in comparison to 694.56±106.14 minutes with Bupivacaine group. Longer duration of analgesia can be attributed to higher concentration of Ropivacaine in our study. Thus Ropivacaine 0.75% is of added advantage for postop analgesia.

Adverse effects/complications

No patient in our study developed any significant Side effects. This signifies that adverse effects were not significant in both the groups. Singelyn FJ [10] in his study Clinical application of Ropivacaine for the upper extremity concluded that Ropivacaine is at least as efficient as bupivacaine in terms of quality, duration of analgesia, anesthesia and motor block. Because of lower CNS and cardiac toxicity, Ropivacaine is safer than bupivacaine.
Mclellan KJ, Faulds D [15, 21] concluded that Ropivacaine is a well-tolerated regional anaesthetic with an efficacy broadly similar to that of bupivacaine. However, it may be a preferred option because of its reduced Central nervous system and cardiotoxic potential.
Vaghadia H, Mckenna J, chan V [18] *et al*. suggested that the lower CNS and cardiotoxicity of ropivacaine reduces the risk to the patient due to inadvertent intravenous injection.

Conclusion

We analyzed that Ropivacaine 0.75% has an added advantage over Bupivacaine 0.5% for Supraclavicular Brachial Plexus block in terms of early onset of sensory and motor blockade, prolonged duration of sensory blockade, and prolonged duration of analgesia leading to lesser requirement of rescue analgesic. The side effects and complications rate are almost negligible in both groups. Thus Ropivacaine even at higher concentrations of 0.75% and 30 ml volume has proven to be an absolutely safe local anaesthetic. So on the basis of our study we conclude that Ropivacaine 0.75% is excellent choice for local anaesthetic, which provides better and safer regional anaesthesia.

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