

Supraclavicular Brachial Plexus Block for Upper Limb Orthopedic Surgery: A Randomized , Double Blinded Comparison Between Ropivacaine And Bupivacaine

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Citation

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Abstract

Background: Ropivacaine is recently introduced in Indian market and needs to be evaluated for its clinical efficacy and safety profile in regional anesthesia. We evaluated ropivacaine for its anesthetic and safety profile in brachial plexus block for upper limb orthopedic surgery and its clinical comparison with bupivacaine. Patients and method: This prospective, randomized, double blind clinical study was carried out in 60 consenting adults of either sex, aged 20-40 yrs, scheduled for elective upper limb orthopedic surgery. Patients were randomly allocated to one of the two groups of 30 patients each. Group B received 30 ml of 0.5% bupivacaine and Group R received 30ml of 0.75% ropivacaine in Supraclavicular brachial plexus block after confirming the proximity of brachial plexus with nerve locator. Patients were observed for onset, peak and duration of sensory and motor blockade, post-operative analgesia using visual analogue scale and complications if any. Results- In comparison to equal volume of 0.5% bupivacaine, 0.75% ropivacaine provides earlier onset and peak of sensory blockade ($p < 0.05$) with comparable duration of postoperative analgesia ($P > 0.05$). Though, it provides earlier onset of motor blockade ($p < 0.05$), there is statistically significant delay in achieving peak effect as compared to bupivacaine ($p < 0.05$). Haemodynamic remained stable and no complications were encountered in both the groups. Conclusion – We conclude that 30ml of 0.75% ropivacaine has effective anaesthetic and safety profile in Supraclavicular brachial plexus block with excellent post operative analgesia. We recommend this dose of ropivacaine against equal volume of 0.5% bupivacaine for achieving earlier onset of sensory and motor blockade.

INTRODUCTION

Regional anesthesia with supraclavicular brachial plexus block is a useful technique for upper limb surgery. Existing local anesthetic, bupivacaine, is known for its wide and unpredictable latency of nerve block when small volume of local anesthetic solution is injected as well as its propensity for neuro and cardio toxicity when large volume of the drug is required.¹⁻³ ropivacaine is a long acting amide local anesthetic agent with potentially improved safety profile when contrasted to bupivacaine.^{1,2} Human trials have demonstrated less cardiac depression and fewer CNS effects when ropivacaine is injected intravenously. Hence, ropivacaine may offer advantage of reduced toxicity with accidental intravascular injection. It suggests a potential clinical advantage of this drug during neural blockade when large volume of the local anesthetic is required. This property may also enable the use of the solution with a higher concentration to enhance the speed of onset and to

prolong duration.

Ropivacaine is in routine use abroad like USA and UK. It is recently introduced in Indian market and needs to be evaluated in Indian perspective. This prompted us to study this new local anesthetic ropivacaine in brachial plexus block for upper limb orthopedic surgery and its comparison with bupivacaine.

MATERIAL AND METHOD

After institutional review board approval and informed written consent, this prospective randomized double blind study was carried out in 60 patients of sex, aged 20-40 years of physical status I or II, and posted for upper limb orthopedic surgery.

After thorough preanaesthetic evaluation, patients receiving chronic analgesic therapy, on anticoagulants, with severe broncho pulmonary diseases, diabetes, neuropathy, bleeding

disorders, and psychiatric illness were excluded from the study.

In the preoperative preparation room, after recording the baseline vital parameters and securing intravenous access, midazolam in 0.5 mg increments titrated to moderate sedation (arousal on command) was given intravenously as premedication. Monitoring consisted of non-invasive blood pressure, pulse Oximeter and electrocardiogram. Patients were randomly allocated, by distributing sealed envelopes, to one of the two groups of 30 patients each. Group R received 30 ml of 0.75% Ropivacaine and group B, 30 ml of 0.5% bupivacaine in supraclavicular brachial plexus block. In the operation theatre, a supraclavicular brachial plexus block was performed using nerve locator (B Braun, Germany) with all aseptic precautions. After appropriate positioning of the patient for supra clavicular block, subclavian artery was palpated 1 cm 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. Needle is connected to nerve locator and 0.5 mA current at 1 Htz was applied for stimulation. Once the contraction of the muscle below the deltoid in the upper extremity was observed, intensity of current was decreased in 0.02 mA 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 as per the group assigned. End of the injection was considered time 0. Patients were evaluated for sensory and motor characteristics of the block (onset, peak and duration), hemodynamic variables and side effects if any at 1, 3, 5, 10, 15, 30, 60 minutes and then, at hourly interval till sensory and motor block were offset. Thereafter, patients were monitored at four hourly intervals for hemodynamic variations and side effects for next 24 hours. Sensory and motor effects were evaluated using Grading shown in Table 1. Patients were assessed for sensory blockade by using pinprick. The palmer surface of Index and little fingers were used to test the median and ulnar nerve in the hand respectively. The dorsal surface of thumb was used to test the radial nerve .The motor block was assessed by asking the patients to move the thumb as per the grading mentioned in Table 1.

Heart rate (HR), non invasive blood pressure (NIBP), and peripheral oxygen saturation (SpO₂) were measured as per

the time interval shown above. Variation in hemodynamic more than 20% from base line was considered significant. 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. Post operatively, when VAS score was equal to or more than 5 (duration of analgesia), Inj. Diclofenac 100 mg IV was given as rescue analgesics. Surgeon was asked to rate his experience as satisfactory, neutral or unsatisfactory.

STATISTICAL ANALYSIS

Data collected were subjected to statistical analysis using Graph pad prism software. Data are presented in the tabulated form and expressed as mean \pm SD. Comparison between the groups was made using student unpaired t test and Mann- Whitney test. After allowing α error to be 0.2, power of study stands out to be 80%.

OBSERVATION AND RESULTS

All patients (n- 60) completed the study. Patient characteristics were comparable in both the

Groups in Table II. Table III shows the sensory characteristics of the block. The mean onset time of sensory block was 4.22 ± 1.52 min and 13.83 ± 3.49 min ($P < 0.01$), peak developed in 11.70 ± 6.40 min and 18.46 ± 3.55 min ($P < 0.01$), in group R and group B respectively. In-group R, two patients developed onset of sensory block within a minute and in one patient, onset was as late as 7 min. In-group B, onset of sensory block was 8 minutes in three patients while 6 patients developed sensory onset as late as 18 minutes. All the patients with successful block had loss of pin prick Sensation over the dermatome of radial, median and ulnar nerve over hand before the skin incision. The duration of sensory block was 9.72 ± 2.73 hrs and 8.77 ± 0.75 hrs respectively in group R and group B. ($P > 0.05$) All the patients in both the groups required rescue analgesic within 11 hours. Thus, Ropivacaine provided earlier onset and peak of sensory effect with comparable duration of post operative analgesia when compared to bupivacaine.

Table IV shows motor characteristic of the block. The mean onset time of motor block was 8.92 ± 2.92 minutes and 15.86 ± 3.72 min ($P < 0.05$), peak developed in 27.26 ± 8.93 minutes and 23.43 ± 3.89 min ($P < 0.05$) and duration of 8.53 ± 1.02 hrs and 8.77 ± 0.75 hrs ($P > 0.05$) in group R and group B respectively. Thus, ropivacaine provided earlier onset and comparable duration of motor blockade but required considerable delay in achieving peak effect when

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compared to bupivacaine.

Table V shows the surgeons assessment of quality of block. Surgeons rated quality of block as satisfactory in 29 patients in group R while one patient needed supplementation with fentanyl. No patient in-group B needed supplementation. Figure 1 and 2 depict changes in heart rate, and mean arterial pressure. Haemodynamic and Spo2 remained stable and no side effects were encountered in either group.

Figure 1

TABLE I: SENSORY and MOTOR BLOCK GRADIN

GRADE	SENSORY CHARACTERISTICS	MOTOR CHARACTERISTICS
0	Normal sensation to pinprick	Normal movement of thumb.
1	Dull response to pinprick (Onset)	Decreased movement of thumb. (Onset)
2	No response to pinprick (Peak)	No movement of thumb. (Peak)

Figure 2

TABLE II: DEMOGRAPHIC PROFILE

Variable	GROUP R Mean ± S.D	GROUP B Mean ± S.D	P VALUE
Age (Year)	35.92 ± 10.80	33.60 ± 11.70	
Sex (M: F)	16: 09	20: 10	
Weight (Kg)	56.64 ± 11.10	55.83 ± 8.89	
Duration of surgery (hrs)	1.03 ± 0.54	1.95 ± 0.95	

Figure 3

TABLE III: Sensory Characteristic of neural blockade

	GROUP R Mean ± S.D	GROUP B Mean ± S.D	P VALUE
Onset (MIN)	4.22 ± 1.52	13.83 ± 3.49	< 0.01
Peak (MIN)	11.70 ± 6.40	18.46 ± 3.55	< 0.01
Duration (hrs.)	9.72 ± 2.73	8.77 ± 0.75	>0.05

		GROUP R Mean±S.D.	GROUP B Mean±S.D.	P Value
Onset	Sensory	4.22 ± 1.52	13.83 ± 3.49	< 0.01
	Motor	8.92 ± 2.92	15.86 ± 3.72	< 0.05
Peak	Sensory	11.70 ± 6.40	18.46 ± 3.55	< 0.01
	Motor	27.26 ± 8.925	23.43 ± 3.89	< 0.05
Duration	Sensory	9.72 ± 2.73	8.77 ± 0.75	>0.05
	Motor	8.53 ± 1.02	8.77 ± 0.75	>0.05

Figure 4

TABLE VI: Motor Characteristic of neural blockade

	GROUP R Mean ± S.D	GROUP B Mean ± S.D	P VALUE
Onset (MIN)	8.92 ± 2.92	15.86 ± 3.72	< 0.05
Peak (MIN)	27.26 ± 8.925	23.43 ± 3.89	< 0.05
Duration (hrs.)	8.53 ± 1.02	8.77 ± 0.75	>0.05

Figure 5

TABLE V: Surgeon’s rating of neural blockade

	Satisfactory	Neutral	Unsatisfactory
GROUP R	29	00	01
GROUP B	30	00	00

Figure 6

FIGURE 1 CHANGES IN HEART RATE

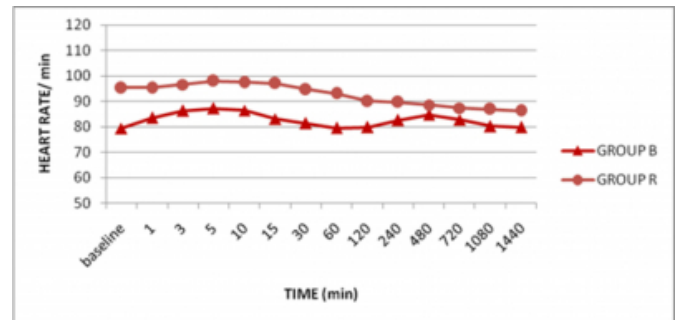
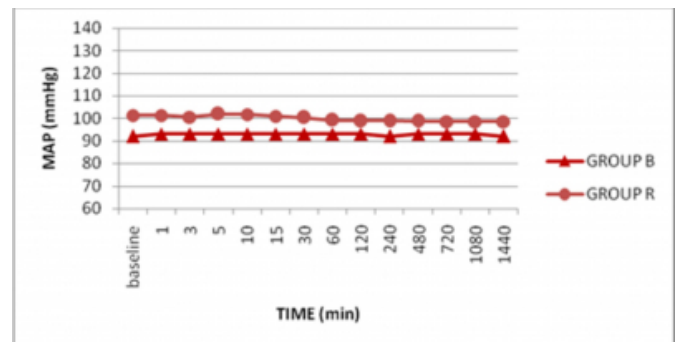


Figure 7

FIGURE 2 CHANGES IN MEAN ARTERIAL PRESSURE



DISCUSSION

The selection of optimal long acting anesthetics for brachial plexus block must take into consideration the available anesthetics, the time to onset and duration of blockade and side effect of each drug. The drug with fast onset, long duration and minimal toxic profile could be an advantage. Numerous studies abroad have compared ropivacaine 0.5% or 0.75% in brachial plexus block for upper limb surgery and

results suggest comparable clinical profile with bupivacaine 0.5% or levobupivacaine with remarkable safety in favor of ropivacaine^{4,9}. Bupivacaine, with its wide and unpredictable latency of nerve block and enhanced neuro and cardio toxicity^{8,9} needed replacement with a drug of better anaesthetic and safety profile. Ropivacaine is a new long acting local anaesthetic and the first single enantiomeric anesthetic to be introduced clinically¹⁰. The introduction of ropivacaine in the medical field became necessary due the toxic profile of bupivacaine. Ropivacaine, a pipercolonylidides group of local anesthetics, showed a remarkable safety profile and greater degree of separation between motor and sensory blockade in extradural block¹¹. Although, this might be more a result of relative potency, this property could be clinically useful in other areas like brachial plexus block. Another advantage of ropivacaine is its reduced toxic potential as compared with bupivacaine not only at equivalent but also at equipotent doses.¹² Recent availability of ropivacaine in Indian market prompted us to evaluate this new drug in brachial plexus block for its anesthetic and safety profile and its clinical comparison with bupivacaine.

In this study, 0.75% 30ml Ropivacaine was given in supraclavicular brachial plexus block. It was hoped that ropivacaine would provide fast onset, long lasting pain relief extending into postoperative period with less motor blockade. In majority of the patients (96%) with this concentration of Ropivacaine, mean onset time of sensory block was < 5 min and peak effect achieved in < 15 min. However, the onset of motor blockade delayed with mean onset time 8.91 ± 2.9 min and peak achieved in 27.2 ± 8.9 min. Hence, there was considerable delay in establishing the complete motor blockade. In contrast to ropivacaine, bupivacaine required statistically significant delay in onset of sensory and motor blockade with mean time of 13.83 ± 3.49 min and 15.86 ± 3.72 .min respectively, though the peak effect of motor blockade established earlier as compared to ropivacaine. ($P < 0.05$)

The data from this study reveal a time to onset for sensory and motor blockade similar to that of Klein et al⁽¹³⁾ where a mean onset time for sensory blockade < 6 min and motor blockade between 7 to 9 min was observed with the same volume and concentration of Ropivacaine in inter scalene brachial plexus block which is comparable to this study. In another study using 20 ml of 0.75 % ropivacaine⁽⁴⁾ author demonstrated onset of sensory and motor blockade within 15

min. Smaller volume of drug used in the study may be responsible for the delay observed. Hickey et al⁽¹¹⁾ used 30 ml of 0.5% Ropivacaine for subclavian perivascular brachial plexus block and found onset of peak sensory blockade delayed substantially for 28 minutes. This difference may be attributable to the lower concentration used in the study as well as to the difference in the technique used for the localization of brachial plexus. They used elicitation of parasthesia for localization of nerve plexus, which is not as accurate as use of nerve locator used in our study.

It is reported by various investigators that the total volume and concentration of local anesthetic used are crucial factors for the speed with which the neural blockade begins.^{14, 15, 16, 17}

In this study, large volume and higher concentration of ropivacaine was used and in addition, close deposition of drug in the vicinity of nerve plexus using nerve locator may be the major factors in increasing the rate of satisfactory block. It is striking to note that except one patient in ropivacaine group, none of the patient in either group-required supplementation. Though bupivacaine is claimed to be more cardio and neuro toxic, none of the patient developed any complication and haemodynamics remained fairly stable and comparable in both the groups.

Studies comparing acute toxicity of ropivacaine to bupivacaine found that ropivacaine was at least 25% less toxic than bupivacaine with regard to tolerated doses¹ with the threshold for CNS toxicity for ropivacaine being twice that of Bupivacaine.¹⁸ In many studies, maximum dose of ropivacaine up to 5mg/kg was reported to be safe without any toxic effect.^{13,19,20} A case of convulsion has been reported after unintentional intravascular injections of ropivacaine 2.3 mg/kg during inter scalene brachial plexus block.²¹ However, Geiger and colleagues²² reported safe use of 1% ropivacaine up to 500 mg. In this study, 225 mg (0.75%) of ropivacaine was found to produce satisfactory sensory and motor blockade with stable hemodynamic profile and no sign of neuro and cardio toxicity. We did not determine plasma concentration of ropivacaine in our patients but studies of systemic disposition of ropivacaine after brachial plexus injection have demonstrated that plasma concentration increases slowly^{19,20} and up to 250 mg have been injected in peripheral nerve block without concern.²³

The addition of epinephrine to ropivacaine or bupivacaine did not alter pharmacokinetic properties²⁴ we therefore chose

plain local anesthetic. Ropivacaine has mild vasoconstrictive property of its own.²⁵ Ropivacaine and bupivacaine, both provided prolonged duration of sensory and motor blockade extending into the postoperative period and are comparable in this respect. Although, prolonged sensory blockade provides excellent postoperative analgesia, extended motor blockade is not desirable as it limits patient's ability to be self-caring.

In this study, identification of brachial plexus was done with the help of nerve locator. This technique was specifically chosen as evaluation of any drug for neural blockade needs close deposition of drug in the vicinity of nerve plexus .We specially selected forearm orthopedic surgery as contraction of muscles due to nerve stimulation is unwanted in arm fractures. Another technique for administration of local anesthetic in close proximity of nerve plexus is ultrasonography guided block, which is more acceptable and useful but needs availability of sonography and experience in the technique.

CONCLUSION

As rapid onset of sensory block and prolonged post operative analgesia with stable hemodynamic without neuro and cardio toxicity are important goals in regional anesthesia, we conclude that 0.75% 30 ml of ropivacaine in supraclavicular brachial plexus block is a safe dose, allowing practitioner to produce a fast onset of sensory block and long duration of peripheral nerve block with excellent post operative analgesia and stable hemodynamic. In comparison to bupivacaine, ropivacaine provides earlier onset of sensory and motor blockade with comparable duration of the same. However, long duration of motor block for surgery of limited duration of 1 to 2 hours as in our study is surely a disadvantage. Long duration of motor blockade can be made an advantage by selecting the surgery of longer duration.

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