

Comparative Evaluation of Ropivacaine Alone with Ropivacaine Nalbuphine Combination in Supraclavicular Brachial Plexus Block for Upper Limb Surgery

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Abstract

Background and Aims: The benefit of post-operative analgesia in regional block is short lived due to limited duration of the action of local anesthetics. Various adjuvants have been tried to enhance the duration of analgesia. The aim of this study was to evaluate the analgesic efficacy and safety of nalbuphine as an adjuvant to 0.5% ropivacaine for supraclavicular brachial plexus block.

Materials and Methods: A prospective, randomized, double-blind study was conducted on 60 patients of American Society of Anesthesiologists physical Status I/II aged 18–60 years scheduled for upper limb surgeries under supraclavicular brachial plexus block. The patients were randomly allocated into two groups of 30 each to receive either 30 ml of 0.5% ropivacaine with 1 ml of normal saline (Group R) or 30 ml of 0.5% ropivacaine with 1 ml (10 mg) of nalbuphine (Group RN). The onset and duration of sensory and motor block, duration of analgesia, and side effects were noted.

Results: The mean onset time for a complete sensory and motor block in Group RN was shorter (8.37 ± 0.79 min; 17.67 ± 1.07 min) as compare to Group R (10.9 ± 1.11 min; 19.17 ± 0.86 min). The mean duration of sensory and motor block in Group RN was longer (725.67 ± 16.06 min; 420.33 ± 14.94 min) as compare to Group R (473.0 ± 22.67 min; 359.67 ± 26.89 min). The mean duration of analgesia in Group RN was 846.33 ± 72.50 min and in Group R was 588.0 ± 27.37 min. All results were statistically significant ($P < 0.0001$). No significant side effects were observed in any of the two groups ($P > 0.05$).

Conclusion: Nalbuphine as an adjuvant to ropivacaine in the supraclavicular brachial block significantly shortens the onset time for sensory and motor block and prolongs the duration of sensory and motor blocks with longer duration of post-operative analgesia.

Key words: Analgesia, Nalbuphine, Ropivacaine, Supraclavicular brachial plexus

INTRODUCTION

Regional anesthesia is an important part of the anesthesiologist's armamentarium. Regional anesthesia is particularly indicated for patients undergoing peripheral

limb surgery because it provides effective intraoperative anesthesia and post-operative pain control. Brachial plexus block is a versatile and reliable regional anesthetic technique and a suitable alternative to general anesthesia for upper limb surgical procedures. Supraclavicular approach of brachial plexus block is the most commonly used approach and provides the most complete and reliable anesthesia for upper limb surgery. For brachial plexus block, a drug that has a fast onset, long duration, and minimal toxicity could be an advantage. The quest for safer local anesthetics began toward the end of the 19th century. Ropivacaine is a long-acting local anesthetic drug belonging to aminoamide group. They are pure S(-) enantiomer, unlike bupivacaine

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which is a racemic mixture. These S enantiomers are considered to produce less neurotoxicity and cardiotoxicity than racemic mixtures or the R-enantiomers of local anesthetics.^[1] Local anesthetics alone for supraclavicular brachial plexus block provide good operative conditions but have a shorter duration of post-operative analgesia. Hence, various drugs such as opioids,^[2] clonidine,^[3] dexamethasone,^[4] midazolam,^[5] and magnesium^[6] were used as an adjuvant with local anesthetics in brachial plexus block.

Nalbuphine, an opioid agonist-antagonist, is used as adjuvant to local anesthetic for various regional anesthetic techniques due to its affinity to κ -opioid receptors to enhance the duration of analgesia. It is widely studied as an adjuvant to local anesthetics in central neuraxial techniques by epidural, caudal, and intrathecal routes. However, after research in literature, we did not find much published data studying the effect of nalbuphine as an adjuvant to local anesthetics in peripheral nerve blocks.^[7]

The aim of our study was to assess the characteristics of supraclavicular brachial plexus block using 0.5% ropivacaine and to study the effect of nalbuphine as an adjuvant.

MATERIALS AND METHODS

After approval of the institutional ethical committee, this prospective, double-blind, randomized trial was conducted on 60 patients of the American Society of Anesthesiologists physical Status I and II of both genders, aged 18–60 years, scheduled for various upper limb surgeries after obtaining written informed consent from each patient. Patients who had not given consent, patients with coagulopathy, infection at the site of block, preexisting peripheral neuromuscular disease, and allergy to any of the study drugs, i.e., nalbuphine or ropivacaine were excluded from the study.

The patients were randomly allocated into two groups of 30 each using computer-generated table of random numbers. The allocation concealment was done using sequentially numbered closed opaque-sealed envelope technique. Group R received 30 ml of 0.5% ropivacaine with 1 ml of normal saline and Group RN received 30 ml of 0.5% ropivacaine with 1 ml (10 mg) of nalbuphine (total volume of study drug is 31 ml in both groups). A resident anesthesiologist, who was not involved in the study process, prepared the syringes loaded with the study drugs for supraclavicular block and the another anesthesiologist who performed the block and observed the patient thereafter was unaware of the contents of the loaded syringes for the

purpose of double blinding so both the anesthesiologists who prepared the drugs and the observer who performed the block as well as assessed the results, were blinded.

Pre-anesthetic assessment was done on evening before surgery. A routine examination was done by assessing general condition, nutritional status, weight, airway assessment, complete examination of cardiovascular, respiratory system, site of block, and investigation in all patients. All patients were kept electively nil per oral 6 h before surgery and before operation patients were explained about the procedure and a written informed consent taken. Intravenous line secured. Standard monitors such as electrocardiogram, pulse oximeter, and blood pressure cuff were applied, and patient's baseline parameter such as pulse, blood pressure, respiratory rate, and SpO₂ was recorded. All patients were premedicated with (on operation table):

- Injection glycopyrrolate 4 µg/kg intravenous
- Injection ondansetron 80 µg/kg intravenous
- Injection midazolam 20 µg/kg intravenous.

For performing brachial plexus blockade through supraclavicular approach, we used classical technique. The patients were placed in the dorsal recumbent position with the head turned away from the site of brachial block, under all aseptic and antiseptic precautions midclavicular point, external jugular vein, and subclavian artery pulsation were identified. About 1 cm above the midclavicular point just lateral to subclavian artery pulsation, a 23G 1.5 inch needle was introduced and directed caudal, downward, and medially toward the first rib until paresthesia was noted along radial and ulnar distribution or motor response was elicited. Here, local anesthetic solution is injected. Before every incremental dose, negative aspiration for blood was performed to avoid any intravascular injection.

End of the injection was taken as time “0.”

Immediately after the block, sensory and motor characteristics of blockade, hemodynamic variables, and SpO₂ were assessed at 1, 3, 5, 10, 15, and 30 min and then at hourly interval till offset of sensory and motor blockade and then at 2 hourly interval for 24 h.

Sensory block was assessed by pinprick test using a needle at each minute after the completion of drug injection in the corresponding dermatomal areas till complete blockade.

The sensory and motor characteristics of the blockade were assessed as per the criteria mentioned below:

Sensory Characteristics

- Onset – It was taken as time duration from the end of injection to dull response to pinprick

- Peak – It was taken as time duration from the onset of sensory block to no response to pinprick
- Duration – It was taken as time duration from complete sensory block to feeling of pinprick sensation.

Motor Characteristics

- Onset – It was taken as time duration from the end of injection to decreased thumb movement
- Peak – It was taken as time duration from the end of injection to complete abolition of thumb movement
- Duration – It was taken as time duration from complete motor block to reappearance of thumb movement.

Duration of post-operative analgesia was taken as time duration from the onset of sensory block to first rescue analgesic requested by the patient at visual analog scale (VAS) ≥ 4 .

If the block was considered to be adequate, surgeons were allowed to apply tourniquet and start the surgery. If the block was considered to be inadequate for surgery, the patient was given general anesthesia and excluded from the study.

Patients were monitored for nausea, vomiting, hypersensitivity reaction, any sign of cardiovascular system (CVS) or central nervous system (CNS) toxicity, evidence of pneumothorax, hematoma, and post-block neuropathy during the study.

The patients were educated regarding reporting of pain using VAS which is of 10 points where “0” indicates no pain and “10” indicates worst possible pain.

In post-operative period, when patient complained of pain at operative site, inj. diclofenac sodium 1.5 mg/kg intravenously and the time for rescue analgesia noted (VAS ≥ 4). Injection tramadol 1 mg/kg intravenously was used as a second analgesic when required.

Both groups were compared for complete onset time and total duration of sensory blockade, complete onset time and total duration of motor blockade, and total duration of analgesia. All the data were filled in pro forma and were statistically analyzed by GraphPad instant 3.0 software. Intergroup comparison of the quantitative data among the different groups was done using the unpaired *t*-test and of the qualitative data was done by Chi-square test. Intragroup comparison of the quantitative data was done using unpaired *t*-test where baseline value was used as control. $P < 0.05$ was taken as statistically significant.

RESULTS

As shown in Table 1, demographic data in terms of age, sex, and weight were comparable in both the groups ($P > 0.05$

is not statistically significant). The duration of surgery was also comparable in both groups ($P > 0.05$).

On comparing both the groups, Group RN produced statistically significant earlier onset and peak with prolonged duration of sensory blockade as compared to Group R ($P < 0.0001$) [Table 2].

On comparing both the groups, Group RN produced statistically significantly earlier onset and peak with prolonged duration of motor blockade as compared to Group R ($P < 0.0001$) [Table 3].

On comparing both the groups, Group RN produced significantly prolonged the duration of analgesia as compared to Group R ($P < 0.0001$) [Table 4].

In Group RN, most of the patients required rescue analgesics between 14 and 16 h of giving brachial plexus

Table 1: Patient characteristics

Patient characteristics	Group R (n=30) (Mean±SD)	Group RN (n=30) (Mean±SD)	P value
Age (in years)	36.8±14.16	33.5±13.33	0.3565
Weight (in kg)	56.2±4.08	57.23±4.37	0.3551
Gender (M/F)	24/6	24/6	1.0000
Duration of surgery (in min)	71.5±36.27	78±40.32	0.5141

SD: Standard deviation

Table 2: Sensory characteristics of brachial plexus blockade

Sensory characteristics (min)	Group R (n=30) (Mean±SD)	Group RN (n=30) (Mean±SD)	P value
Onset	4.47±1.34	2.47±0.76	<0.0001
Peak	10.9±1.11	8.37±0.79	<0.0001
Duration	473±22.67	725.67±16.06	<0.0001

SD: Standard deviation

Table 3: Motor characteristics of brachial plexus blockade

Motor characteristics (min)	Group R (n=30) (Mean±SD)	Group RN (n=30) (Mean±SD)	P value
Onset	9.9±1.11	6.6±1.11	<0.0001
Peak	19.17±0.86	17.67±1.07	<0.0001
Duration	359.67±26.89	420.33±14.94	<0.0001

SD: Standard deviation

Table 4: Duration of effective analgesia

Variable	Group R (n=30) (Mean±SD)	Group RN (n=30) (Mean±SD)	P value
Effective analgesia (min)	588±27.37	846.33±72.50	<0.0001

SD: Standard deviation

blockade. In Group R, most of the patients required rescue analgesics between 10 and 12 h [Figure 1].

On comparing Group RN with Group R, 29 patients required one injection of rescue analgesia and 1 patient required two injections in 24 h in Group RN while in Group R, 24 patients required one injection and 6 patients required two injections in 24 h. The analgesic requirement and total dose of analgesics were reduced in Group RN as compared to Group R [Table 5].

Figure 2 shows that changes in the heart rate were comparable in both the groups without any statistical significance ($P > 0.05$) except at 10 h (Group R) and 14 h (Group RN), when it shows a significant increase in heart rate ($P = 0.0002$ and 0.006 , respectively).

Figure 3 shows that changes in the mean arterial pressure were comparable in both the groups without any statistical significance ($P > 0.05$) except at 10 h (Group R) and 14 h (Group RN), when it shows significant changes in heart rate ($P = 0.0001$ and < 0.0001 , respectively).

Figure 4 shows that SpO₂ remained stable and comparable to baseline in both the groups throughout the study period ($P > 0.05$).

Table 5: Doses of rescue analgesics required in 24 h

Number of analgesic doses	Group R		Group RN	
	Number of patients	%	Number of patients	%
1	24	80	29	97
2	6	20	1	3
3	0	0	0	0

DISCUSSION

Regional anesthesia is practiced in most developing countries. Regional nerve blocks are based on the concept that pain is conveyed by nerve fibers, which are amenable to interruption anywhere along their pathway. Supraclavicular blocks are performed at the level of the brachial plexus trunks. As with other fields, regional anesthesia has undergone major developments both in technique and drugs availability. Gradually, ropivacaine was introduced into clinical practice. Local anesthetics alone for supraclavicular brachial plexus block provide good operative conditions but have a shorter duration of post-operative analgesia. Recently, nalbuphine has been reported as an effective adjuvant for regional anesthetic agents. On reviewing literature, the present study was undertaken to compare analgesia and effectiveness regarding onset and duration of complete motor and a sensory block of 0.5% ropivacaine alone versus 0.5% ropivacaine with nalbuphine in patients undergoing supraclavicular brachial plexus block.

Onset

The mean time of onset of sensory blockade (2.47 ± 0.76 min in Group RN vs. 4.47 ± 1.34 min in Group R) and the motor blockade (6.6 ± 1.11 min in Group RN vs. 9.9 ± 1.11 min in Group R) was faster in Group RN compared to Group R and was statistically significant ($P < 0.0001$).

The peak of sensory block was achieved in 8.37 ± 0.79 min in Group RN versus 10.9 ± 1.11 min in Group R and of motor block was achieved in 17.67 ± 1.07 min in Group RN versus 19.17 ± 0.86 min in Group C which was statistically significant ($P < 0.0001$).

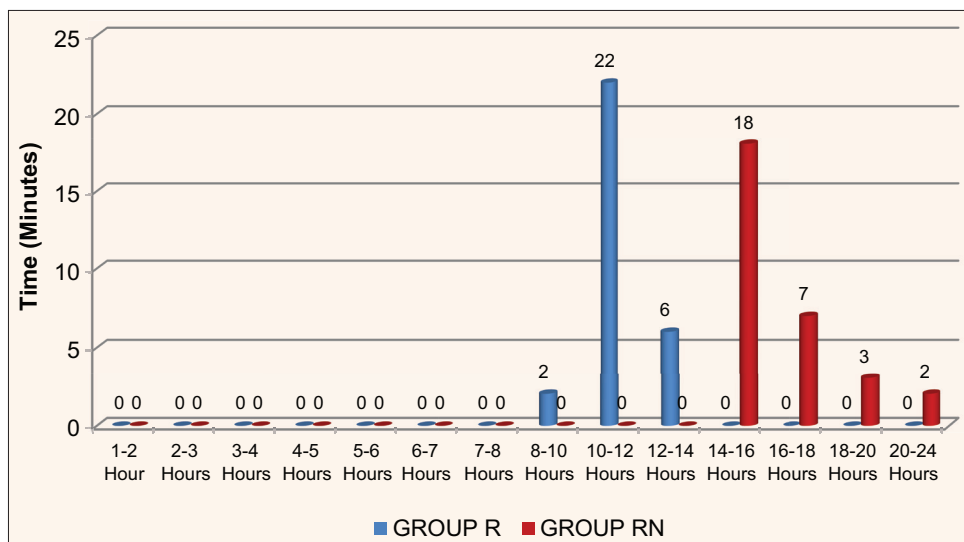


Figure 1: Time of first rescue analgesic required

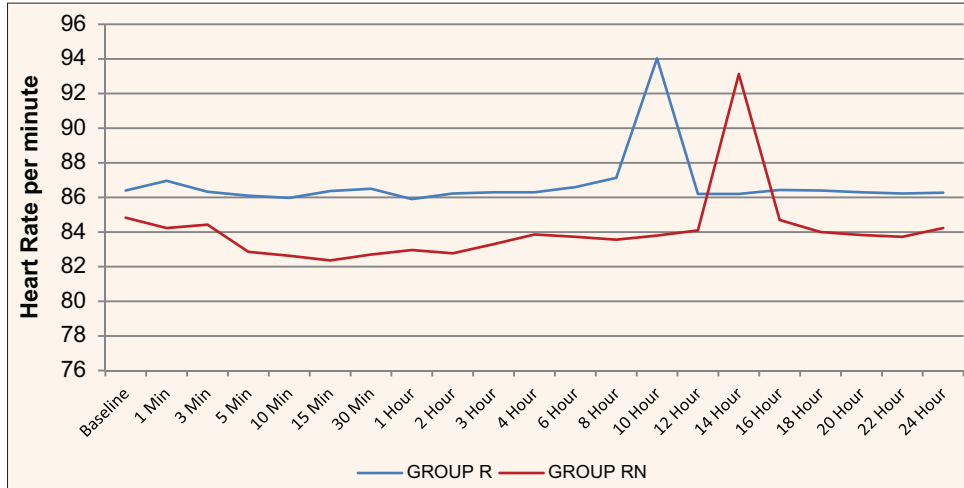


Figure 2: Heart rate at various specified intervals

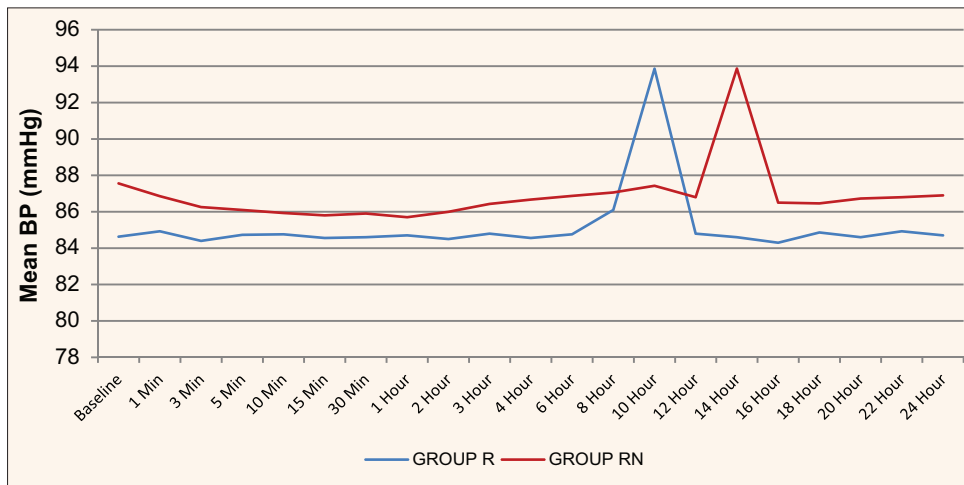


Figure 3: Mean arterial blood pressure

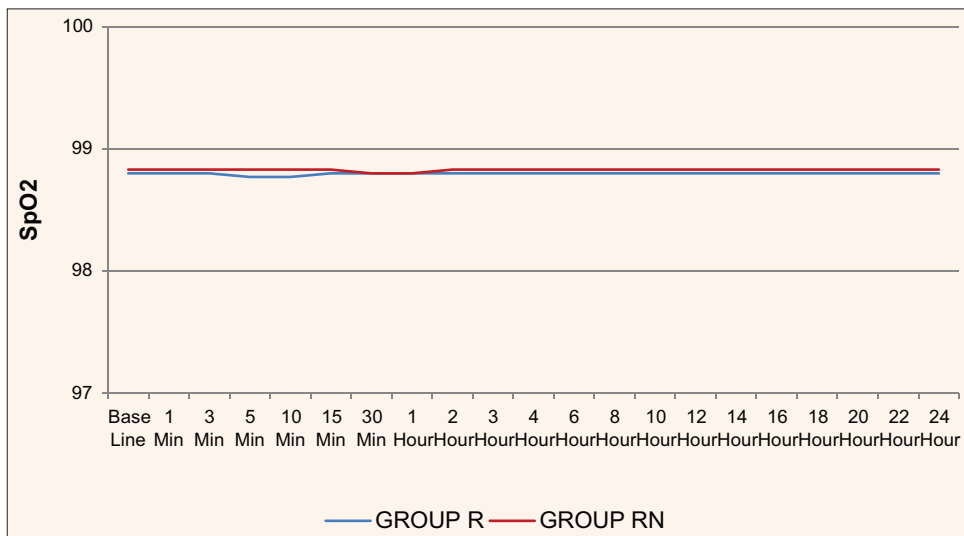


Figure 4: SpO₂ at various specified time period

These results are comparable to other studies:

In a study of Akhtar *et al.*,^[7] they found that Group 2 (0.5% ropivacaine 28 ml + 100 mg tramadol 2 ml) had a rapid onset of both sensory and motor block (sensory onset: 9.40 ± 2.22 min of Group 2 vs. 10.93 ± 2.90 min of Group 1 [0.5% ropivacaine 28 ml + normal saline 2 ml] and motor onset: 13.15 ± 3.64 of Group 2 vs. 13.65 ± 2.17 min of Group 1) but without a statistically significant difference (P value sensory onset 0.10 and motor onset 0.20).

In the study done by Gupta *et al.*,^[8] they found that onset of sensory and motor block was rapid in patients of Group 2 (0.5% bupivacaine 20 ml + 10 mg nalbuphine 1 ml) as compare to Group 1 (0.5% bupivacaine 20 ml + normal saline 1 ml). Sensory onset: 9.57 ± 1.5 min of Group 2 versus 10.36 ± 1.7 min of Group 1; $P = 0.76$ and motor onset: 14.10 ± 1.24 min of Group 2 versus 18.16 ± 1.30 min of Group 1; $P = 0.49$ but showed no statistically significant difference ($P > 0.05$).

Duration of Sensory and Motor Blockade

In the present study, the mean duration of the sensory blockade (725.67 ± 16.06 min in Group RN vs. 473 ± 22.67 in Group R) and the motor blockade (420.33 ± 14.94 min in Group RN vs. 359.67 ± 26.89 min in Group R) was also prolonged and was statistically significant ($P < 0.0001$) which was comparable to the study of Akhtar *et al.*^[7] They found that addition of 100 mg (2 ml) tramadol with 0.5% ropivacaine 28 ml in Group 2 results in significant increase in the duration of sensory (5.27 ± 2.01 h) and motor block (4.38 ± 1.57 h) when compared to control Group 1 (0.5% ropivacaine 28 ml + normal saline 2 ml) (3.9 ± 2.05 h) and (3.19 ± 0.69 h), respectively ($P < 0.05$).

In the study done by Gupta *et al.*,^[8] they found that the mean duration of motor block was 257.69 ± 30.19 min in patients of Group 1 when compared to 278.53 ± 34.61 min in Group 2 and difference was statistically significant ($P = 0.038$).

This study correlates well with the study done by Youssef and ElZayyat^[9] where they compared the efficacy of nalbuphine and tramadol as separate adjuvants to lidocaine in intravenous regional anesthesia (Bier's block) with lignocaine alone. They found that nalbuphine in Group LN causes statistically significant faster onset of sensory (3.8 ± 1.38 min) and motor blockade (5.2 ± 1.51 min) as compared to Group L (4.8 ± 1.15 min and 7.1 ± 1.45 min, respectively) but statistically insignificant faster onset than tramadol in Group LT (3.7 ± 1.14 min and 5.5 ± 1.71 min, respectively). They also found that the duration of sensory (82.7 ± 8.02 min) and motor block (92.9 ± 10.15 min) was prolonged in Group LN as compared to Group L (75.3 ± 4.13 min and 82.1 ± 3.94 min, respectively)

and Group LT (80.7 ± 5.19 min and 91.4 ± 7.59 min, respectively).

Duration of Analgesia

In the present study, the duration of analgesia was prolonged in Group RN (846.33 ± 72.50 min) as compared with Group R (588 ± 27.37 min) which was statistically significant ($P < 0.0001$).

Akhtar *et al.*^[7] also observed that there was a significant increase in the duration of analgesic effect in tramadol group when compared to control group (7 ± 2.77 h vs. 5.4 ± 2.83 h) ($P = 0.03$).

Gupta *et al.*^[8] also observed that the duration of analgesia in patients of Group 2 was 481.53 ± 42.45 min and in patients of Group 1 was 341.31 ± 21.42 min with $P < 0.001$.

Hemodynamic Changes

Regarding the hemodynamic changes, in this study, there were no significant changes in heart rate, mean arterial blood pressure, and SpO₂ at all hours except at 10 and 14 h which are due to pain. Changes were comparable to the study done by Akhtar *et al.*^[7] as well as with Gupta *et al.*^[8]

Complications

There was no incidence of headache, nausea, vomiting, hypotension, bradycardia, chest pain, coughing, convulsion and respiratory depression, and procedure-related complication. There were no CNS and CVS toxicity seen in either group in our study.

CONCLUSION

Nalbuphine as an adjuvant to ropivacaine in the supraclavicular brachial block for upper limb surgery significantly shortens the onset time for sensory and motor block, prolongs the duration of sensory and motor blocks with longer duration of post-operative analgesia, and causes a decrease in need for rescue analgesia in patients with no side effects.

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