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# A prospective, double-blind, randomized controlled study comparing the efficacy of dexamethasone and nalbuphine as additives to 0.5% ropivacaine in ultrasound-guided supraclavicular brachial plexus block

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## ABSTRACT

### Background and objectives:

There are number of studies available regarding the use of ropivacaine with adjuvants like dexamethasone or nalbuphine individually in supraclavicular brachial plexus block with variable results. Thus we are comparing both dexamethasone and nalbuphine with ropivacine on following objectives. Primary objectives: Onset and duration of sensory blockade, Onset and duration of motor blockade and duration of analgesia. Secondary objectives: Adverse effects and analgesics consumption in post-operative period.

### Materials and methods:

The study was conducted after ethical committee clearance prospectively in 90 patients of 18 to 60 years of age undergoing upper limb surgeries. The patient selected as per the criteria for the study were randomly placed into following 3 groups and block was performed using the following drugs.

Group RD: using 30ml of 0.5% ropivacaine and 1ml of dexamethasone.

Group RN: using 30ml of 0.5% ropivacaine and 1ml of nalbuphine.

Group RS: using 30ml of 0.5% ropivacaine and 1ml of normal saline.

### Results and conclusion:

Perineural dexamethasone or nalbuphine added to ropivacaine in supraclavicular brachial plexus block is extremely effective in reducing the time of motor block onset and prolonging the duration of sensory and motor blockade. It is also effective in providing prolonged postoperative analgesia. No side effects were evidenced.

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**Keywords:** Nalbuphine, Dexamethasone, Ropivacaine 0.5%, USG guided supraclavicular brachial plexus bloc

## INTRODUCTION:

Regional anesthesia techniques offer significant advantages over general anesthesia and systemic analgesia, including effective pain control, reduced side effects, and a shortened post-anesthesia care unit stay. However, these initial benefits may be short-lived due to the limited duration of action of current local anesthetics, potentially leading to block resolution before the peak postoperative pain period. Although increasing the volume (dose) of local anesthetics prolongs analgesia, it also poses the risk of systemic toxicity.

Various perineural adjuvants, such as buprenorphine, clonidine, dexamethasone, magnesium sulfate, and midazolam, have been employed to extend the duration of analgesia in nerve blocks, with varying degrees of success. [1-5] Combining adjuvants with local anesthetics in brachial plexus blocks aims to achieve a rapid, dense, and prolonged block. [1,6,7,8]

The supraclavicular brachial plexus block is the preferred regional anesthesia for upper limb surgeries [9], as it targets the brachial plexus most compactly at the proximal division or trunk level, providing reliable anesthesia for median, radial, and ulnar nerves over 80% of the time. [10]

Dexamethasone, a corticosteroid, exerts its perineural effects by directly inhibiting signal transmission in nociceptive C-fibers. It also possesses local anti-inflammatory effects and induces vasoconstriction locally, prolonging the action of local anesthetics [11]. Nalbuphine, a mixed agonist-antagonist at opioid receptors, provides analgesia with less addictive potential and respiratory depression. It extends the duration of sensory and motor blockade while reducing the need for rescue analgesics [12].

Numerous studies have investigated the combination of ropivacaine with adjuvants like dexamethasone or nalbuphine individually. Consequently, this study aims to compare the effects of both dexamethasone and nalbuphine with ropivacaine on various objectives.

## METHODS:

The research was carried out prospectively following clearance from the ethical committee, involving 90 patients aged between 18 to 60 years undergoing upper limb surgeries. Patient inclusion and exclusion criteria were applied to determine eligibility for participation in the study.

*Inclusion criteria:*

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1. Age group: 18 – 60 years of either sex.
2. Patients belonging to ASA – class 1 and class 2.
3. Upper limb surgeries

*Exclusion criteria:*

1. Patient's declined consent for the procedure.
2. Patients presenting with notable coagulopathies or other contraindications for supraclavicular brachial plexus block.
3. Patients with pre-existing significant systemic illnesses.
4. Patients exhibiting allergies to amide local anesthetics.
5. Presence of any local infection at the block site.

A prospective, double-blind, randomized controlled study was conducted at a tertiary heath care center from December 2021 to June 2023. Approval was secured from the institutional ethical committee. Patients and their accompanying individuals were briefed about the procedure in a language comprehensible to them, and written informed consent was obtained. Randomization was carried out using a computer-generated random number series. The supraclavicular brachial plexus block was administered by an experienced anesthesiologist proficient in ultrasound-guided techniques. Both the principal investigator and the patients remained blinded to the drugs used. Patients meeting the study criteria were randomly assigned to one of the three groups, and the block was performed using the specified drugs.

Group RD: 30ml of 0.5% ropivacaine and 1ml of dexamethasone.
Group RN: 30ml of 0.5% ropivacaine and 1ml of nalbuphine.
Group RS: 30ml of 0.5% ropivacaineand 1ml of normal saline.

Patients underwent standard pre-anesthetic assessment, involving a physical examination and pertinent laboratory investigations. NPO guidelines were adhered to. Pre-medication included T. Alprazolam 0.5mg at bedtime and T. Metoclopromide 10mg at bedtime and on the morning of the surgery. The patient was transferred to the operating theater, positioned in a supine manner, and an intravenous cannula was placed in the non-operative limb. Standard monitors such as electrocardiography, pulse oximeter, and non-invasive blood pressure were applied to the patient.

The patient positioned in a supine position with the head turned away from the limb. The injection site was meticulously prepared and draped with sterile coverings. Utilizing a Sonosite ultrasound machine and a linear ultrasound probe with a frequency range of 6-13 MHz, positioned over the supraclavicular region, a sterile water-based gel served as an acoustic couplant between the probe and the skin. The plexus

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was accessed using an in-plane (IP) technique with an insulating needle. Upon reaching the nerve sheath and confirming negative aspiration for blood/air, 31 ml of the study drug was injected around the plexus under visual guidance.

Onset of Sensory Blockade: The time from the injection of the local anesthetic to the loss of prick sensation in radial, median, and ulnar dermatomes on the ipsilateral upper limb.

Onset of Motor Blockade: The time from drug administration to the loss of movements in the ipsilateral upper limb.

Duration of Sensory Block: The interval between the loss and reappearance of prick sensations.

Duration of Motor Block: The interval between the loss and reappearance of movements in the ipsilateral upper limb.

Duration of Analgesia: The time from the onset of sensory blockade to the administration of the first dose of rescue analgesic to the patient.

Sensory block is graded into three; Grade 0: Sharp prick felt; Grade 1: Analgesia, dull sensation felt; Grade 2: Anaesthesia, no sensation felt.

Evaluation: Sensory block assessment involved testing prick sensation every 3 minutes until the onset of loss of sensation or attainment of grade 2, followed by hourly assessments up to 24 hours from the time of complete block onset.

Motor block is be graded using modified bromage scale for upper extremities. Grade 0: Able to raise extended arm to 90 degree; Grade 1: Unable to extend arm, able to flex elbow and fingers. Grade 2: Unable to flex elbow, able to move fingers. Grade 3: Unable to move arm, elbow or fingers.

Finger movements were restored during the postoperative period. In the event of block failure, general anesthesia was administered, and such cases were excluded from the study. For postoperative pain, intravenous injection of diclofenac 75mg diluted in 10ml normal saline was provided as rescue analgesia. The number of rescue analgesic doses was documented and compared across different groups. Additionally, injection ondansetron 4mg was administered at the conclusion of the surgery. Hypotension (defined as a systolic blood pressure drop of more than 20% from the baseline value), bradycardia (heart rate <50/min), and postoperative complications such as nausea and vomiting were observed and managed accordingly. Postoperative analgesia was evaluated using a visual analogue scale ranging from 1 (no pain) to 10 (worst

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| Time from induction of block to | RS group | | RD group | | RN group | | F-value | P-value |
|---|---|---|---|---|---|---|---|---|
| | Mean | SD | Mean | SD | Mean | SD | | |
| Onset of sensory block | 11.43 | 15.20 | 8.33 | 10.00 | 8.87 | 8.80 | 0.6052 | 0.5483 |
| Onset of motor block | 19.07 | 10.01 | 12.50 | 11.53 | 14.83 | 9.03 | 3.1693 | 0.0469* |

pain). The duration of analgesia, measured as the time to the first request for postoperative analgesic, was recorded.

Stastical analysis: The onset, duration of sensory and motor blockade, and duration of analgesia were compared among the three groups using analysis of variance (ANOVA). Chi-square analysis was

**RESULTS:**

*p<0.05

**Table 1**: A one-way ANOVA was utilized to compare the mean changes in the time from the induction of block to the onset of sensory block and the onset of motor block among the three groups (RS, RD, RN).

| Variables | RS group | | RD group | | RN group | | F-value | P-value |
|---|---|---|---|---|---|---|---|---|
| | Mean | SD | Mean | SD | Mean | SD | | |
| Duration of motor block | 511.93 | 125.25 | 721.17 | 165.30 | 678.43 | 148.84 | 16.8787 | 0.0001* |
| Duration of sensory block | 615.70 | 132.20 | 842.67 | 179.42 | 795.37 | 151.86 | 17.7430 | 0.0001* |
| Duration of analgesia | 694.97 | 130.48 | 1004.97 | 221.82 | 895.23 | 161.41 | 24.0967 | 0.0001* |

*p<0.05 indicates significant

**Table 2**: A one-way ANOVA was employed to compare the mean duration of motor block, duration of sensory block, and duration of analgesia among the three groups (RS, RD, RN).

| No. of doses of | RS group | % | RD group | % | RN | % | Total | % |
|---|---|---|---|---|---|---|---|---|
| **0** | 1 | 3.33 | 7 | 23.33 | 1 | 3.33 | 9 | 10.00 |
| **1** | 6 | 20.00 | 18 | 60.00 | 16 | 53.33 | 40 | 44.44 |
| **2** | 22 | 73.33 | 5 | 16.67 | 13 | 43.33 | 40 | 44.44 |
| **3** | 1 | 3.33 | 0 | 0.00 | 0 | 0.00 | 1 | 1.11 |
| **Total** | 30 | 100.00 | 30 | 100.00 | 30 | 100.00 | 90 | 100.00 |
| Chi-square= 142.338 P = 0.0634 | | | | | | | | |

**Table 3**: Comparison of three groups (RS, RD, RN) with rescue analgesic requirement i.e., number of doses of diclofenac 75mg.

In our study, no side effects such as nausea, vomiting, pruritus, hypotension, hypoxemia, pneumothorax, or hematoma were observed.

**DISCUSSION:**

**Onset of sensory and motor blockade**

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In the investigation led by Dar FA et al involving 80 patients, the onset of sensory blockade in group R was recorded as 17.5 ± 4.2 minutes, whereas in group RD, it was 14.6 ± 3.3 minutes. Similarly, the onset of motor block in group R and group RD was 20.6 ± 3.0 minutes and 18.0 ± 4.5 minutes, respectively. The study revealed a faster onset of sensory and motor blockade in the dexamethasone additive group, indicating statistical significance. However, our study did not identify a statistically significant difference in the onset of sensory blockade. Nonetheless, a comparable accelerated onset of motor block was observed in the RD group in our study [7].

Bindal et al, in their study with 120 participants, found that the onset of sensory blockade in the control group (group R) with ropivacaine alone was 16.00 ± 1.438 minutes, while in the ropivacaine with dexamethasone (RD) additive group, it was 9.27 ± 0.980 minutes. The onset of motor blockade in the control group (group R) with ropivacaine was 20.27 ± 1.799 minutes, and in the RD group, it was 14.07 ± 1.929 minutes. The dexamethasone additive group exhibited a statistically significant faster onset of both sensory and motor blockade. Contrary to our study, there was no statistically significant difference in the onset of sensory blockade, but a parallel faster onset of motor block was observed in the RD group [8].

In the randomized controlled study by Nazir et al involving 60 patients, the onset of sensory blockade in the control group with bupivacaine alone was 14.62 ± 1.73 minutes, while in the bupivacaine with nalbuphine additive group, it was 4.89 ± 1.5 minutes. Similarly, the onset of motor blockade in the control group with bupivacaine alone and in the nalbuphine additive group was 18.86 ± 1.75 minutes and 8.83 ± 1.9 minutes, respectively. The nalbuphine additive group exhibited a statistically significant faster onset of both sensory and motor blockade. Notably, our study aligns with theirs in terms of motor onset, but the sensory onset in our study did not show a significant difference. [14]

Gupta K et al, in their study involving sixty adult patients, reported a mean onset of sensory blockade in group 1 as 10.36 ± 1.7 minutes and in group 2 as 9.57 ± 1.5 minutes. The mean onset of motor blockade in group 1 and group 2 was 18.16 ± 1.3 minutes and 14.10 ± 1.24 minutes, respectively. Surprisingly, there was no significant difference in the onset of sensory and motor blockade between the two groups, contradicting our study findings. [15]

**Duration of sensory and motor blockade**

In the investigation conducted by Dar FA et al, the duration of sensory blockade in group R was 483 minutes, while in group RD, it extended to 762 minutes. The duration of motor block in group R was 402 minutes, and in the RD group, it was 522 minutes. A statistically significant prolongation of both sensory

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and motor blockade was observed in the RD group compared to group R. These findings mirrored the outcomes of our study. [7]

In the study led by Bindal et al, the duration of sensory blockade in the control group with ropivacaine alone was 222.5 ± 8.78 minutes, whereas in the ropivacaine with dexamethasone additive group, it remarkably increased to 1084.73 ± 11.91 minutes. The duration of motor blockade in the control group with ropivacaine alone was 182.5 ± 10.48 minutes, and in the ropivacaine with dexamethasone additive group, it was 976.0 ± 24.7 minutes. These results were in alignment with our study.[13]

Nazir et al, in their study, discovered that the mean duration of sensory blockade with nalbuphine additive was 373.17 ± 15.56 minutes, compared to 157.82 ± 11.05 minutes in the control group with bupivacaine alone. The duration of motor block in the nalbuphine additive group was 313.92 ± 16.22 minutes, as opposed to 121.87 ± 16.62 minutes in the control group with bupivacaine alone. These outcomes were consistent with our study. [14]

Gupta K et al, in their investigation, identified that the duration of motor block in group 1 (20 mL of 0.5% bupivacaine with 1 mL of normal saline) was 257.69 ± 30.19 minutes, while in group 2 (20 mL of 0.5% bupivacaine with 1 mL of nalbuphine 10 mg), it significantly prolonged to 278.53 ± 34.61 minutes. This statistically significant prolongation in the duration of motor blockade in group 2 was in line with our study. [15]

**Duration of analgesia**

In the study by Bindal et al involving 120 patients, the duration of analgesia in group R was recorded as 283.17 ± 7.71 minutes, while in group RD, it significantly extended to 1211.83 ± 32.86 minutes. The observed statistically and clinically significant prolongation in the duration of analgesia in the dexamethasone additive group was in concordance with our study. [13]

In the randomized controlled study conducted by Nazir et al with 60 patients, the duration of analgesia in group C was 171.65 ± 19.79 minutes, and in group N, it notably increased to 389.3 ± 14.52 minutes. A statistically significant prolongation in the duration of analgesia was evident in group N, aligning with parallel results observed in our study. [14]

Gupta K et al, in their study involving sixty adults, reported a mean duration of analgesia in group 1 as 341.31 ± 21.42 minutes, whereas in group 2, it significantly prolonged to 481.53 ± 42.45 minutes. The

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statistically significant prolongation in the duration of analgesia in group 2 mirrored parallel results identified in our study. [15]

**Analgesic consumption in the post-operative period**

Bindal et al conducted a study with 120 patients, and the median first 24-hour analgesics consumption in group R was 3 (interquartile range: 3-4) doses of diclofenac 75mg, while in group RD, it was 0 (interquartile range: 0-1) dose of diclofenac 75mg. A statistically significant reduction in the postoperative requirement of diclofenac dose was observed in the RD group. [13]

In the study by Das A et al involving seventy-eight patients, Group LN (n = 39) received 30 ml 0.5% levobupivacaine + 10 mg (diluted in 2 ml 0.9% saline) nalbuphine hydrochloride, and Group LC (n = 39) received 30 ml 0.5% levobupivacaine + 2 ml normal saline (0.9%) in a supraclavicular block. In the 24-hour postoperative follow-up period, Group LC had received 110.21 ± 8.32 mg diclofenac, while group LN received 80.34 ± 6.7 mg diclofenac, showing a statistically significant difference. [16]

**Adverse effects**

In our study, no side effects such as nausea, vomiting, pruritis, hypotension, hypoxaemia, pneumothorax, or hematoma were observed. Dar FA et al, in their study with 80 patients, reported that no side effects were noted in their study participants. [7]

In the study by Gupta K et al, there were no observed side effects such as sedation, pruritis, pneumothorax, nausea, vomiting, and no significant hemodynamic fluctuations were present. [15]

Das A et al, in their study involving seventy-eight patients, identified nausea, vomiting, sedation, and pruritus in both study groups. However, the incidence was comparable between the two groups ($p > 0.05$). For nausea, active management was unnecessary except for increasing the fluid transfusion rate. Two patients in the LN Group and one patient in the LC Group experienced vomiting, all of whom were successfully managed with slow intravenous metoclopramide 10 mg. Although sedation was higher in the nalbuphine group, it was easily reversible and did not lead to respiratory depression. Similarly, pruritus was more prevalent in the nalbuphine group but was self-limiting. [16]

**CONCLUSION:**

In summary, our findings indicate that the addition of perineural dexamethasone or nalbuphine to ropivacaine in supraclavicular brachial plexus block is highly effective. This approach significantly reduces the onset time of motor block while extending the duration of both sensory and motor blockade. Moreover,

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it proves to be an effective means of ensuring prolonged postoperative analgesia. Importantly, no side effects were observed in our study.

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