DOI: 10.7860/JCDR/2026/87375.23910

Original Article

Anaesthesia Section

# Effect of Nalbuphine as an Adjuvant to 0.5% Levobupivacaine in Ultrasound-guided Supraclavicular Brachial Plexus Block for Upper Limb Surgery: A Randomised Controlled Study

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## ABSTRACT

**Introduction:** Ultrasound-guided supraclavicular brachial plexus block is a preferred regional anaesthesia technique for upper limb surgeries due to its rapid onset and high efficacy. Levobupivacaine is widely used for its prolonged action and reduced cardiotoxicity. Nalbuphine, a mixed opioid agonist-antagonist, has emerged as a promising adjuvant with potential to enhance the analgesic effects of local anaesthetics without increasing opioid-related side-effects.

**Aim:** To evaluate the clinical efficacy of nalbuphine as an adjuvant to 0.5% levobupivacaine in ultrasound-guided supraclavicular brachial plexus block.

**Materials and Methods:** This randomised, double-blind controlled trial was conducted in the Department of Anaesthesiology, Sharda School of Medical Sciences and Research (SSMS&R), Sharda University, Greater Noida, Uttar Pradesh, India, over 18 months from May 2023 to November 2024. It includes 90 American Society of Anesthesiologists (ASA) physical status I-II patients undergoing elective upper limb surgeries were divided into two groups (n=45). Group N received 20 mL of 0.5% levobupivacaine with 10 mg nalbuphine; Group S received 20 mL of 0.5% levobupivacaine with saline. Ultrasound-guided supraclavicular brachial plexus block was administered, and duration of analgesia, onset, duration of sensory and motor block, VAS scores, haemodynamic parameters and complications were recorded over 24 hours. Statistical analyses such as Student's t-test, Chi-square test and Mann-Whitney U test were used.

**Results:** Group N had significantly longer duration of analgesia (725.16±29.42 vs. 550.73±20.30 min), faster onset of sensory (6.93±0.94 min) and motor (11.40±1.48 min) block than group S (9.42±0.72 min and 15.29±1.85 min respectively; $p<0.0001$). Duration of sensory and motor block was prolonged in group N (602.58±18.93 min and 525.56±15.94 min) as compared to group S (473.42±13.19 min and 420.58±15.50 min; $p<0.0001$). Rescue analgesic requirement was lower (75.00 vs. 113.33±37.91 mg; $p<0.0001$) in the nalbuphine group. No complications were reported in either group.

**Conclusion:** Nalbuphine as an adjuvant to levobupivacaine significantly improves the onset and duration of anaesthesia and postoperative analgesia without affecting haemodynamic stability or increasing side-effects. It appears to be a safe and effective agent for enhancing the quality of supraclavicular brachial plexus blocks.


**Keywords:** Haemodynamic stability, Local anaesthesia, Peripheral nerve block, Postoperative analgesia

## INTRODUCTION

Regional anaesthesia has emerged as a cornerstone of anaesthetic practice in upper limb surgeries. This provides several advantages over general anaesthesia, including reduced systemic drug exposure, enhanced intraoperative conditions, decreased postoperative opioid consumption, and shorter hospital stays [1-3]. Among the various regional techniques available, the supraclavicular approach to brachial plexus blockade is preferred for surgeries involving the distal upper extremity due to its rapid onset, dense sensory and motor block and relatively straightforward anatomical target [4,5]. As described by Liu SS (2016), the compact arrangement of the trunks in the supraclavicular region allows for reliable blockade with a single injection. This makes it highly effective for achieving complete anaesthesia in the upper limb [6].

The evolution of imaging technologies has refined the application of this technique. Williams SR et al., (2003) demonstrated that ultrasound guidance enhances the accuracy, efficacy and safety of supraclavicular blocks compared to landmark-based and nerve stimulator-guided approaches [7-10]. With the ability to directly visualise neural structures, vascular anatomy and local anaesthetic spread in real time, ultrasound not only improves success rates but also minimises the risk of complications such as pneumothorax or inadvertent intravascular injection, as supported by the findings of Chan VWS and Chung FF (1996) [11]. These advancements have led to ultrasound-guided supraclavicular blocks becoming the standard of care in many institutions.

Levobupivacaine, the S-enantiomer of racemic bupivacaine, is increasingly favoured in regional anaesthesia due to its lower potential for cardiotoxicity and neurotoxicity [12-15]. Its long-acting nature provides prolonged intraoperative anaesthesia and postoperative analgesia. This makes it suitable for procedures requiring extended block duration [16]. However, the effect of levobupivacaine, while enduring, is still constrained by its pharmacokinetic profile, prompting the exploration of adjuvants to enhance and prolong its clinical utility [12].

Opioids have traditionally been employed as adjuvants to local anaesthetics in regional blocks to extend analgesia and improve patient comfort. While agents like morphine and fentanyl have shown efficacy in this regard, their use is tempered by concerns over side-effects such as respiratory depression, nausea, pruritus and urinary retention. Nalbuphine, described by Gunion MW et al., (2004) as a mixed opioid agonist-antagonist, provides an appealing alternative

[17]. It acts primarily on κ-opioid receptors to deliver analgesia while antagonising μ-opioid receptors, thereby reducing the incidence of typical opioid-related adverse effects. This pharmacological profile makes nalbuphine suitable for use in ambulatory and regional settings where safety is paramount.

Several clinical investigations have explored the use of nalbuphine as an adjuvant in regional anaesthesia. Abdelhaq MM and Elramely MA reported that adding nalbuphine to bupivacaine in supraclavicular blocks significantly prolonged both sensory and motor block duration and improved postoperative analgesic profiles [18]. Similarly, Madhusudhanan R et al., observed a 42% increase in analgesic duration with nalbuphine in comparison to controls, highlighting its potential for clinical benefit [16]. Data on the efficacy and safety of nalbuphine in combination with levobupivacaine remain limited [14,19].

In light of these findings, the purpose of the current study was to evaluate the efficacy of nalbuphine as an adjuvant to levobupivacaine in ultrasound-guided supraclavicular brachial plexus block. The primary objective was to compare the duration of analgesia between two groups. The secondary objective was to compare the onset and duration of sensory and motor block, rescue analgesic requirements in 24 hours, and any associated adverse effects.

## MATERIALS AND METHODS

This randomised, double-blind controlled trial was conducted in the Department of Anaesthesiology, Sharda School of Medical Sciences and Research (SSMS&R), Sharda University, Greater Noida, Uttar Pradesh, India, over 18 months from May 2023 to November 2024. After obtaining approval from the Institutional Ethical Committee of the School of Medical Sciences and research (Ref. No. SU/SMS&R/76-A/2023/84), the trial was registered in Clinical Trial Registry-India (CTRI/2023/07/055741). Written informed consent was obtained from all participants.

**Sample size calculation:** The sample size for this study was based on Das A et al., (2017) [15], who reported the duration of analgesia of the block in two groups as 531.45±41.23 min and 501±42 min. Using formula given by Snedecor and Cochran, sample size (N)=1+2(Zα+Z1-β)2σ2/δ2 and assuming significance level of 0.05 (Zα=1.96) and 90% power {Z(1-β) =1.28} the sample size was calculated.

i.e., N=1+2(1.96+1.282)21737/30.432=40.

To cater to patients dropping out of the study, a larger sample of 45 patients in each group was taken.

**Inclusion criteria:** Patients with ASA physical status I or II of either gender, aged 18 to 60 years, scheduled for elective upper limb surgery were enrolled.

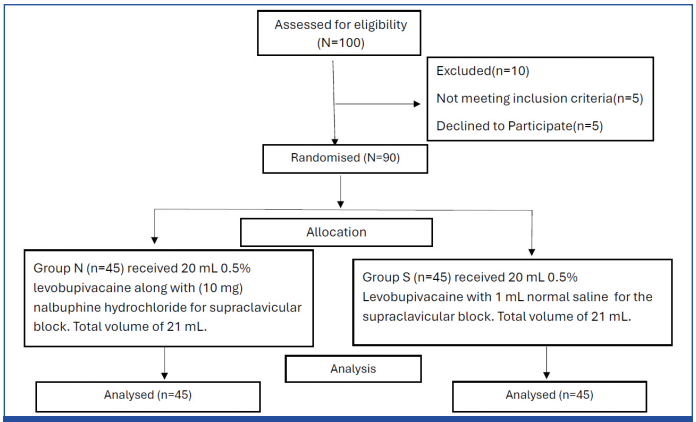
**Exclusion criteria:** Patients with known hypersensitivity to study drugs, coagulation disorders, infection at the injection site or those on antipsychotic medications were excluded.

### Study Procedure

Participants were randomised into two groups (n=45 each) using a computer-generated random number table [Table/Fig-1].

- Group N (Nalbuphine group) received 20 mL of 0.5% levobupivacaine with 10 mg (1 mL) nalbuphine, and
- Group S (control group) received 20 mL of 0.5% levobupivacaine with 1 mL of normal saline [20].

Under sterile precautions and ultrasound guidance, the supraclavicular brachial plexus was identified using a high-frequency linear probe. Following skin infiltration with lignocaine, a 22-G needle was introduced in-plane, and the drug mixture was administered adjacent to the plexus. The study drug was prepared and labelled in sequential numbers (as per the randomisation chart) by an independent anaesthesiologist who was not involved in the study. Both the patient and investigator were blinded to ensure double blinding.




**[Table/Fig-1]:** Consolidated Standard of Reporting Trials (CONSORT) flowchart of the participants.

Vitals monitoring {Heart Rate (HR), Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP), Mean Arterial Pressure (MAP), Oxygen Saturation ($SpO_2$)} was monitored throughout the surgery and recorded at every 10-minute interval. The primary outcome measured was the duration of analgesia, defined as the interval between the onset of a complete sensory block and the time of request for the first rescue analgesic.

Secondary outcomes measured were the onset and duration of sensory and motor block. The onset of sensory block was defined as the time interval between the end of local anaesthetic administration and the loss of pinprick sensation in the upper limb dermatomes (C5-T1), recorded in minutes.

**For assessment of the sensory block,** a 25-G needle was used for pinprick testing, and the sensory block was graded as follows:

- Grade 0: normal sensation (sharp pain felt),
- Grade 1: blunted sensation (dull sensation or slight heaviness),
- Grade 2: no pain perception (state of anaesthesia).

**For assessment of the onset of motor block** the modified Bromage scale for the upper extremities were used as follows:

- Grade 0: normal motor function with full flexion/extension of elbow, wrist, and finger,
- Grade 1: decreased motor strength with the inability to move fingers,
- Grade 2: complete motor blockade with the inability to move fingers. The motor block was assessed by thumb abduction (radial nerve), thumb adduction (ulnar nerve), and thumb opposition (median nerve).

The onset of the sensory and motor block was assessed at three-minute intervals initially and then every minute till the Grade 2 (sensory block) and Grade 2 (motor block) complete block was achieved.

Duration of the sensory block was defined as the time interval between the onset of the sensory block and the return of the sensation to a pinprick. The duration of the motor block was taken from the onset of motor block to complete recovery of full muscle power and was determined by noting the time for the first appearance of finger movement in the blocked limb. The patient was observed for any incidences of nausea, vomiting, sedation, or pruritus.

Postoperatively all the patients were kept under observation for 24 hours for assessment of pain and other parameters, and detection and management of any complications. The intensity of pain was evaluated by the Visual Analogue Scale (VAS) where 0 represents no pain, and 100 represents the worst possible pain. First rescue analgesic (inj. Diclofenac 75 mg in 100 mL NS over 10 minutes) was given if the VAS score was>30.

## STATISTICAL ANALYSIS

Data was coded and recorded in MS Excel spreadsheet program. The Statistical Package for Social Sciences (SPSS) version 23.0 (IBM Corp.) was used for data analysis. Descriptive statistics were elaborated in the form of means/standard deviations for continuous variables and frequencies and percentages for categorical variables. Data was presented graphically wherever appropriate for data visualisation using histograms/column charts for continuous data and bar charts/pie charts for categorical data. Independent Student's t-test was used for normally distributed continuous variables, Mann-Whitney U test for non normally distributed continuous variables and the Chi-square test for categorical variables. Statistical significance was kept at p<0.05.

## RESULTS

Both groups were comparable in terms of age, height, weight, gender distribution, ASA grade and duration of surgery, with no statistically significant differences observed (p>0.05 for all variables).

Duration of analgesia was prolonged in group N (Nalbuphine) as compared to group S (control). Group N demonstrated extended analgesia duration, which was statistically significant [Table/Fig-2].

| Characteristics | Group N | Group S | p-value |
|---|---|---|---|
| Age (in years) | 41.78±13.85 | 38.49±12.27 | 0.238 |
| Gender (Male/Female) | 19/26 | 17/28 | 0.700 |
| Duration of Surgery (in minutes) | 69.56±23.18 | 66.89±19.40 | 0.578 |
| Height (in cm) | 171.18±11.81 | 171.18±12.24 | 1.00 |
| Weight (in kg) | 78.10±16.00 | 79.36±13.68 | 0.706 |
| ASA Grade (I/II) | 35/10 | 35/10 | 1.00 |
| Duration of analgesia (minutes) | 725.16±29.42 | 550.73±20.30 | <0.0001** |

**[Table/Fig-2]:** Demographics and baseline characteristics (N=90).
(p-value< 0.05* statistically significant, p-value<0.001** statistically highly significant.); t-test for age, weight, height, duration of surgery and Chi-square test for gender and ASA grade

The onset of sensory block was significantly shorter in group N compared to group S. Similarly, the onset of motor block was faster in group N than in group S, with statistically significant differences in both parameters [Table/Fig-3].

| Variables | Group N | Group S | p-value |
|---|---|---|---|
| Onset of sensory block (minutes) | 6.93±0.94 | 9.42±0.72 | <0.0001** |
| Onset of motor block (minutes) | 11.40±1.48 | 15.29±1.85 | <0.0001** |
| Duration of sensory block (minutes) | 602.58±18.93 | 473.42±13.19 | <0.0001** |
| Duration of Motor Block (minutes) | 525.56±15.94 | 420.58±15.50 | <0.0001** |
| Rescue Analgesia requirement (mg) | 75.00±0.00 | 113.33±37.91 | <0.0001** |

**[Table/Fig-3]:** Comparison of onset and duration of sensory and motor block between Group N and Group S.
(p-value< 0.05* statistically significant, p-value <0.001** statistically highly significant);
An Unpaired Student's t-test is used

Group N exhibited a significantly prolonged sensory and motor blockade compared to group S, which was statistically significant.

The total rescue analgesia requirement was significantly lower in group N as compared to group S, demonstrating a statistically significant difference.

VAS scores were consistently lower in the group N at all-time intervals, with statistically significant differences observed from nine hours onward (p<0.0001). These findings confirm the prolonged analgesic effect of Nalbuphine as an adjuvant, demonstrating its efficacy in extending the duration of postoperative analgesia [Table/Fig-4].

Haemodynamic parameters in both groups demonstrated comparable values with no statistically significant differences at critical time points. Thus, the results indicate that all patients in both groups remained haemodynamically stable throughout the procedure.

| Time point | Group N | Group S | p-value |
|---|---|---|---|
| VAS_0-5_h | 1.33±3.44 | 1.33±3.44 | 1 |
| VAS_6_h | 13.33±4.77 | 15.33±5.05 | 0.0565 |
| VAS_9_h | 18.89±5.32 | 42.89±9.44 | < 0.0001** |
| VAS_12_h | 17.56±4.35 | 38.44±9.28 | < 0.0001** |
| VAS_24_h | 17.56±4.35 | 16.22±4.90 | 0.1757 |

**[Table/Fig-4]:** Comparison of postoperative pain score (VAS) in group N and group S at different time intervals.
(p-value< 0.05* statistically significant, <0.001** statistically highly significant.) Unpaired Student's t-test is used

No side-effects or complications were observed in either group. There were zero recorded cases of intravascular injection, local anaesthetic toxicity, phrenic nerve palsy, subcutaneous emphysema, pneumothorax, nausea, vomiting, sedation or pruritus in both group N and group S.

## DISCUSSION

In the present study, the duration of analgesia was prolonged in group N (levobupivacaine with nalbuphine) as compared to group S (levobupivacaine with saline). Similarly, Abdelhaq MM and Elramely MA noted duration of analgesia 835.18±42.45 min in the group N vs. 708.14±54.57 min in the control group S (p<0.001) [18]. In agreement with these results, Madhusudhanan R et al., observed a 42% increase in analgesia duration with nalbuphine (687.50±6.28 min vs. 444.30±38.19 min; p<0.001) [16]. Das A et al., also found prolonged analgesia in ambulatory forearm surgery with nalbuphine as compared to the control group (531.45 min vs. 501.02 min; p=0.0019) [15]. Gupta K et al., and Aggarwal S et al., similarly demonstrated significantly longer analgesia with nalbuphine compared to control groups, which favours the present study [21,22].

In the current study, the sensory and motor block onset was significantly faster in group N, as compared to group S (p<0.0001). These findings corroborate the observations of Madhusudhanan R et al., who reported a 36% faster sensory onset and 16% faster motor onset with nalbuphine, supporting its role in rapid block establishment [16]. According to Abdelhaq MM and Elramely MA, the onset of sensory and motor block in group N was earlier (8.64±0.717 minutes and 17.4±1.14 minutes) as compared to the control group (9.18±1.37 minutes and 18±1.5 minutes) [18]. Similar to the present study, Das A et al., also reported faster onset of sensory and motor block (15.46±3.44 and 20.34±4.76 minutes) in comparison to the control group (16.10±4.08 and 21.86±5.34 minutes) [15]. Studies conducted by Gupta K et al., and Chiruvella S et al., support findings of the present study [20,21].

In the present study, the duration of both sensory and motor block was significantly extended in the group N as compared to the control group S. Similar to the present study, Abdelhaq MM and Elramely MA also documented a significant prolongation of both blocks with nalbuphine, reporting over 100 minutes of added duration [13,18]. Madhusudhanan R et al., found that the duration of sensory and motor block was longer in the nalbuphine group as compared to the control group, concurrent with the current study [16]. Abdelhamid BM et. al., also found that adding nalbuphine to levobupivacaine significantly prolongs the duration of sensory and motor block, which is comparable to this study [13]. Nazir N and Jain S added nalbuphine to bupivacaine and revealed that it prolonged the duration of sensory and motor block, which favours the findings of the present study [23].

The requirement for rescue analgesia was reduced in the levobupivacaine with nalbuphine group in the present study. The analgesic requirement remained constant at 75 mg. In contrast, the levobupivacaine with saline group required rescue analgesia ranging from 75 to 150 mg. Aggrawal S et al., reported that the requirement for rescue analgesia was reduced in the nalbuphine

group (127.5±34.96 mg) as compared to the control group (150±37.5 mg). This finding is concurrent with the present study [22]. Similarly, studies conducted by Abdelhaq MM and Elramely MA and Chiruvella S et al., demonstrated that adding nalbuphine to bupivacaine reduces the need for rescue analgesia [18,20]. Das A et al., suggested that the rescue analgesic drug requirement was lower in the group N (80.34±6.78 mg) compared to the group S (110.21±8.32 mg), which is in favour of the study [15].

Visual Analogue Scale (VAS) scores were significantly lower in the nalbuphine group in comparison to the control group in the present study. Similar to the study finding, Gupta K et al., reported lower VAS scores in the nalbuphine group at multiple postoperative time points. Patients receiving nalbuphine reported significantly lower pain levels (mean VAS 18.89±5.32) compared to those in the saline group (mean VAS 42.89±9.44), with a p-value <0.0001 [21]. These findings are consistent with those of Abdelhaq MM and Elramely MA, who reported significantly reduced pain scores and prolonged analgesic effect with nalbuphine in peripheral blocks [18]. Similarly, Madhusudhanan R et al., observed that nalbuphine extended analgesia by approximately 42%, which supports the present study [16].

In the present study, no postoperative complications or side-effects were observed in either group. Addition of nalbuphine did not compromise haemodynamic parameters. The HR, SBP, DBP, MAP, and $SpO_2$ remained within normal physiological limits in both groups. No statistically significant or sustained deviations were observed. In contrast to the current study, Madhusudan R et al., reported clinically manageable side-effects in 3.3% of patients in the nalbuphine group, with mild bradycardia (10%) and hypotension (10%) [16]. Gupta K et al., reported no major side-effects associated with nalbuphine, similar to the current study [21]. No complications such as local anaesthetic toxicity, pneumothorax, sedation, pruritus or respiratory depression were reported in the present study, emphasising the excellent safety profile of nalbuphine in the present study setting. Thus, it was observed that nalbuphine as an adjuvant to levobupivacaine extends the duration of analgesia, significantly accelerates block onset, prolongs sensory and motor blockade, reduces rescue analgesic requirements and maintains haemodynamic stability. These results align with and reinforce previous studies. This makes nalbuphine a safe and effective option in regional anaesthesia for upper limb surgeries.

### Limitation(s)

The study was conducted at a single centre with a relatively small sample size. Long-term follow-up was not performed, patient satisfaction and quality-of-life outcomes were not assessed, and comparisons with other commonly used adjuvants were not undertaken. These factors may limit the generalisability of the findings. Comparative studies with alternative opioid adjuvants such as buprenorphine or fentanyl are needed to establish superiority. Furthermore, patient-reported outcomes and quality of life assessments were not included in the current evaluation and should be considered in future research.

## CONCLUSION(S)

Nalbuphine as an adjuvant to 0.5% levobupivacaine in supraclavicular brachial plexus block was associated with improved block characteristics and prolonged postoperative analgesia in the present study. Patients receiving nalbuphine demonstrated a faster onset of sensory and motor blockade, prolonged duration of analgesia and reduced requirement for rescue analgesics compared to levobupivacaine alone. Haemodynamic parameters remained stable, and the incidence of adverse effects was minimal and manageable, indicating a favourable safety profile.

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**PLAGIARISM CHECKING METHODS:** [Jain H et al.]
- Plagiarism X-checker: Jan 22, 2026
- Manual Googling: Apr 09, 2026
- iThenticate Software: Apr 11, 2026 (6%)

**ETYMOLOGY:** Author Origin

**EMENDATIONS:** 6

**AUTHOR DECLARATION:**
- Financial or Other Competing Interests: None
- Was Ethics Committee Approval obtained for this study? Yes
- Was informed consent obtained from the subjects involved in the study? Yes
- For any images presented appropriate consent has been obtained from the subjects. NA

Date of Submission: **Jan 19, 2026**
Date of Peer Review: **Feb 21, 2026**
Date of Acceptance: **Apr 13, 2026**
Date of Publishing: **Jul 01, 2026**