

Effect of Nalbuphine as an Adjuvant to 0.5% Bupivacaine for Supraclavicular Brachial Plexus Block in Upper Limb Surgeries**Anandu M.¹, Jayshri Prajapati², Priyank D. Patel³, Ketu Patel⁴**^{1,3}Senior Resident, Department of Anaesthesiology, GMERS Medical College, Himmatnagar²Professor, Department of Anaesthesiology, GMERS Medical College, Gandhinagar⁴Assistant Professor, Department of Anaesthesiology, GMERS Medical College, Gandhinagar

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Conflict of interest: Nil

Abstract

Background: Ultrasound-guided brachial plexus block offers distinct advantages by enabling anesthesiologists to visualize anatomical variations and the spread of local anesthetics accurately. This study aimed to evaluate the effect of adding nalbuphine to 0.5% bupivacaine for supraclavicular brachial plexus block for the potential benefits and safety profile.

Material & Methods: This prospective observational study was conducted at GMERS Medical College and Hospital, Himmatnagar in patients aged 18 years and above, scheduled for upper limb surgeries requiring supraclavicular brachial plexus block as the primary anesthesia technique. 60 participants were divided into two equal-sized groups using randomization. Group B: received 25 ml of 0.5% bupivacaine along with 1 ml of normal saline and Group N: received 25 ml of 0.5% bupivacaine combined with 1 ml (10 mg) of nalbuphine. The duration of both motor and sensory blockade and the duration of postoperative analgesia and side effects were compared in both the groups.

Results: The mean duration of surgery in the group B was 125.6±17.1 min whereas it was 104.6±9.8 min for the group N (p<0.001). The mean time of onset for sensory blockade in the group B was 13.7±2.3 min whereas it was 3.6±2.1 min for the group N (p<0.001). The mean time of onset for motor blockade in the group B was 20.3±3.6 min whereas it was 4.6±3.6 min for the group N (p<0.001). The mean duration sensory blockade in the group B was 345.6±14.6 min whereas it was 375.4±79.4 min for the group N (p=0.047). The mean duration of motor blockade in the group B was 298.6±35.8 min whereas it was 336.4±72.9 min for the group N (p=0.014). No significant differences were observed in post-operative complications or sedation scores between the two groups.

Conclusion: This study concludes that nalbuphine may be a valuable adjunct to bupivacaine for enhancing the quality and duration of brachial plexus blockade while minimizing intra operative complications.

Keywords: Nalbuphine, Supraclavicular, Brachial Plexus, Bupivacaine.

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Introduction

Effective pain management is a critical aspect of anesthesia care, as it contributes to various favorable outcomes including earlier mobilization, reduced risk of complications such as deep venous thrombosis and cardiac issues, shorter hospital stays, and enhanced patient satisfaction [1]. Ultrasound-guided brachial plexus block offers distinct advantages by enabling anesthesiologists to visualize anatomical variations and the spread of local anesthetics accurately. Particularly, the supraclavicular approach offers significant advantages, ensuring comprehensive anesthesia for upper limb surgeries by targeting the densely packed trunk level of the plexus [2]. Ultrasound guidance improves success rates and minimizes the risk of injury to adjacent structures. Additionally, it enables the use of smaller volumes of local

anesthetic, thereby reducing the likelihood of systemic toxicity [2]. Anesthetists continually seek to enhance the efficacy of local anesthetics while minimizing their toxicity. Various adjuncts, including opioids, dexamethasone, and clonidine, are commonly employed to prolong block duration and reduce adverse reactions [3]. Nalbuphine, a derivative of 14-hydroxymorphine, has emerged as a promising adjunct in regional anesthesia. Studies across spinal, epidural, and intravenous blocks consistently demonstrate its effectiveness in prolonging block duration [4]. Nalbuphine, known for its mixed kappa agonist and mu antagonist properties, offers potent analgesia comparable to morphine while exhibiting a ceiling effect on respiratory depression. This unique characteristic enables nalbuphine to maintain or

enhance mu-opioid analgesia while mitigating associated side effects [5]. Moreover, nalbuphine has been found effective in preventing the hemodynamic stress response linked with endotracheal intubation [6]. Although nalbuphine may induce side effects such as sedation, clamminess, nausea and vomiting, dizziness, xerostomia, and headache, these are notably less pronounced compared to other additives commonly used in anesthesia. Overall, nalbuphine stands out as a valuable analgesic option with favorable characteristics for pain management in various clinical settings [7,8].

The addition of nalbuphine as an adjuvant to 0.5% bupivacaine for supraclavicular brachial plexus block in upper limb surgeries is a subject of interest due to its potential to enhance the quality and duration of anesthesia while minimizing adverse effects. Previous studies have demonstrated the efficacy of nalbuphine as an adjuvant in various regional anesthesia techniques, including spinal, epidural, and local intravenous blocks, with favorable outcomes in terms of prolonged block duration and reduced toxicity [9]. However, its specific impact when combined with bupivacaine for supraclavicular brachial plexus block in upper limb surgeries warrants further investigation. Hence, this study aimed to evaluate the effect of adding nalbuphine to 0.5% bupivacaine for supraclavicular brachial plexus block for the potential benefits and safety profile.

Material and Methods

Study Design: Prospective comparative study.

Study Site: GMERS Medical College and Hospital, Himmatnagar.

Study Duration: January 2023 to January 2024.

Sample Size: Using formula $n = 2 * (Z_{1-\alpha/2} + Z_{1-\beta})^2 * \sigma^2 / d^2$; sample size in each group was minimum 30. Where σ is standard deviation, d is mean difference (which were taken from previous study) [10], $Z_{1-\alpha/2} = 1.96$ for 95% confidence interval and $Z_{1-\beta} = 80\%$ power.

Inclusion Criteria:

- Patients aged 18 years and above
- Patients scheduled for upper limb surgeries requiring supraclavicular brachial plexus block as the primary anesthesia technique
- American Society of Anesthesiologists (ASA) physical status classification I-III
- Patients provided informed consent

Exclusion Criteria:

- Patients with known allergy or hypersensitivity to local anesthetics (bupivacaine) or nalbuphine
- Patients with a history of significant

respiratory insufficiency or chronic obstructive pulmonary disease (COPD)

- Patients with pre-existing neurological deficits or neuropathies affecting the upper limb
- Pregnant or breastfeeding women
- Patients with coagulopathy or bleeding disorders
- Patients with significant hepatic or renal impairment
- Patients unable to communicate effectively or cooperate with the study procedures

Allocation of groups: Patients who met the inclusion criteria were provided with detailed information about the risks and benefits associated with participating in the study. After obtaining valid informed consent from those willing to enroll, the 60 participants were divided into two equal-sized groups. The allocation of participants to these groups was achieved through a randomization method utilizing even and odd numbers.

Group B: received 25 ml of 0.5% bupivacaine along with 1 ml of normal saline.

Group N: received 25 ml of 0.5% bupivacaine combined with 1 ml (10 mg) of nalbuphine.

Ethics: Ethical clearance was obtained from the Institutional Ethical Committee before the commencement of the study. Written informed consent was collected from all study participants, ensuring that the consent was given voluntarily was fully informed.

Pre anesthetic evaluation: Prior to the surgery, all patients underwent a comprehensive preoperative examination, including detailed history taking, physical assessment, and relevant investigations. Additionally, an 18G venflon was inserted into a peripheral vein in the opposite forearm, and intravenous midazolam at a dose of 0.01-0.05 mg/kg was administered for sedation. Intravenous fentanyl at a dose of 1 microgram/kg was provided if necessary to achieve moderate sedation, ensuring the patient remained arousable upon command. Basic monitoring, including electrocardiography, non-invasive blood pressure monitoring, and pulse oximetry was applied to all patients.

Anesthetics technique: Baseline measurements of heart rate, blood pressure, and oxygen saturation were recorded prior to the block procedure with the patient lying supine. The patient's head was turned 45 degrees to the opposite side, and ultrasound guidance using a Mindray M7 machine with a 10 MHz linear probe was employed. Aseptic measures were strictly adhered to, including skin cleansing and draping, followed by local anesthetic infiltration. The supraclavicular fossa was scanned to identify anatomical landmarks such as the subclavian artery, 1st rib, pleura, and brachial plexus cluster. Using an echogenic 22 Gauge, 5 cm

B. Braun needle, insertion was directed from lateral to medial along the long axis of ultrasound beams. The needle was advanced towards the "corner pocket," where the lower trunk of the brachial plexus typically resides. Half of the prepared local anesthetic mixture, either with 1ml of normal saline or 10mg of nalbuphine, was injected. The needle was then repositioned cranially to infiltrate the remaining volume of the local anesthetic just above and lateral to the subclavian artery. Intraoperative monitoring included noting the patient's heart rate and mean arterial pressure every 5 minutes for the first 15 minutes and subsequently every 15 minutes until the surgery concluded. If sensory and motor blockade remained inadequate after 30 minutes, the block was deemed unsuccessful.

Following local anesthetic administration, surgery commenced, and the onset of motor and sensory blockade was recorded. The duration of both motor and sensory blockade and the duration of postoperative analgesia were assessed in the early postoperative period. Patient side effects were monitored routinely. In the postoperative period, if patients reported pain (VAS>3), rescue analgesia was administered- intravenous paracetamol 1 gram infusion, or intramuscular diclofenac sodium 75 mg, until the pain score decreased to VAS<3.

Data Collection: Following the administration of the block, motor and sensory evaluations were conducted every 5 minutes until complete sensory and motor block were achieved or 30 minutes elapsed, whichever came earlier. Sensory block assessment involved using a 23 G hypodermic needle to assess pinprick sensation in the distribution areas of the ulnar, median, musculocutaneous, and radial nerves. A 3-point scale was utilized, where zero represented normal sensation, one indicated loss of prick sensation, and two signified loss of touch sensation.

Motor block evaluation included assessing thumb adduction (radial nerve), opposition of thumb (median nerve), adduction of thumb (ulnar nerve), and elbow flexion (musculocutaneous nerve). Similar to sensory evaluation a 3-point scale was used to grade motor function.

The time from the end of local anesthetic infiltration to the complete motor and sensory block was defined as the onset time for motor and sensory block, respectively. Complete sensory block was indicated by anesthesia across all four nerve territories, while the absence of voluntary

movements of the hand and forearm indicated complete motor block.

The quality of anesthesia was assessed at the conclusion of surgery using a grading system: excellent (4) for no complaints from the patient, good (3) for vague complaints not requiring supplementation, moderate (2) for complaints necessitating supplemental analgesics and unsuccessful (1) indicating the need for general anesthesia.

Postoperatively, patients rated their pain on a 10-point visual analogue scale. Pain assessments were conducted regularly every 30 minutes for the first two hours post-discharge from the recovery room and then hourly for 24 hours. Sensory and motor regression was monitored every 15 minutes until complete resolution. The duration of motor block was recorded as the time from the end of local anesthetic infiltration until full motor power recovery of the hand and forearm, while the duration of analgesia was measured from the end of local anesthetic administration until the first request for rescue analgesia.

Statistical Analysis: It was conducted using Microsoft Excel and Epi Info 7.2 software. The means of continuous variables were compared between the two groups utilizing a unpaired t-test. Demographic data for categorical variables were compared using the chi-square test. A significance level of $p < 0.05$ was considered to determine statistical significance.

Results

The mean age of the group B was 34.5 ± 10.1 years whereas it was 41.1 ± 12.9 years for the group N. Significant difference in age was found between the two groups ($p = 0.032$). Majority of the study participants were males in both groups ($n=23$, 76.7%). No significant difference was found between the two groups ($p = 1.000$). 26 (86.7%) patients in group B and 20 (66.7%) in group N were ASA I whereas the remaining were ASA II. No significant difference was found between the two groups ($p = 0.067$). The mean BMI of group B was 22.5 ± 2.1 whereas it was 22.9 ± 1.9 for the group N. No significant difference was found between the two groups ($p=0.423$). The mean duration of surgery in the group B was 125.6 ± 17.1 min whereas it was 104.6 ± 9.8 min for the group N. A significant difference was found between the two groups ($p < 0.001$). (Table 1)

Table 1: Demographic characteristics of both the groups

Variable	Group B (n=30)	Group N (n=30)	P value
Age (in years)	34.5±10.1	41.1±12.9	0.032*
Sex (M/F)	23/7	23/7	1.000
ASA status (I/II)	26/4	20/10	0.067
Weight (in kgs)	60.6±5.8	59.2±6.8	0.417
Height (incms)	164.4± 5.5	163.8± 5.8	0.667
BMI (in kg/m ²)	22.5±2.1	22.9±1.9	0.423
Duration of Surgery (Min)	125.6±17.1	104.6± 9.8	<0.001*

*Significant

The mean time of onset for sensory blockade in the group B was 13.7±2.3 min whereas it was 3.6±2.1 min for the group N. Significant difference was found between the two groups ($p < 0.001$). The mean time of onset for motor blockade in the group B was 20.3±3.6 min whereas it was 4.6±3.6 min for the group N. Significant difference was found between the two groups ($p < 0.001$). The mean

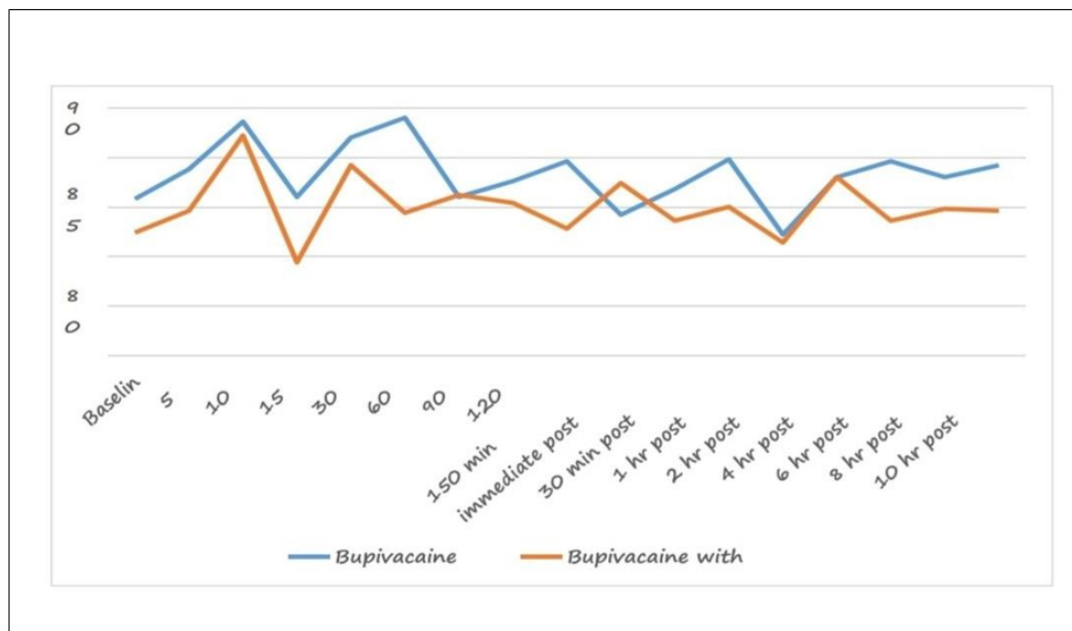
duration sensory blockade in the group B was 345.6±14.6 min whereas it was 375.4±79.4 min for the group N. Significant difference was found between the two groups ($p = 0.047$). The mean duration of motor blockade in the group B was 298.6±35.8 min whereas it was 336.4±72.9 min for the group N. Significant difference was found between the two groups ($p = 0.014$). (Table 2)

Table 2: Sensory and motor characteristics in both the groups

Variable (in minutes)	Group B (n=30)	Group N (n=30)	P value
Onset time Sensory blockade	13.7±2.3	3.6±2.1	<0.001*
Onset time Motor blockade	20.3±3.6	4.6±3.6	<0.001*
Duration Sensory blockade	345.6±14.6	375.4±79.4	0.047*
Duration Motor blockade	298.6±35.8	336.4±72.9	0.014*

*Significant

The mean value of heart rate was generally higher in Bupivacaine alone (Group B) as compared to Bupivacaine with Nalbuphine (Group N). The mean variation of heart rate values between the two groups was statistically significant at 15 minutes and 60 minutes pre-operatively. (Figure 1)

**Figure 1: Comparison of heart rates in Bupivacaine (group B) and Bupivacaine with Nalbuphine (group N)**

The mean value of Mean Arterial Pressure (MAP) was comparable throughout the duration in both the groups. The mean variation of MAP values between the two groups was statistically significant at 8 hour and 10 hour post-operatively. (Figure 2)

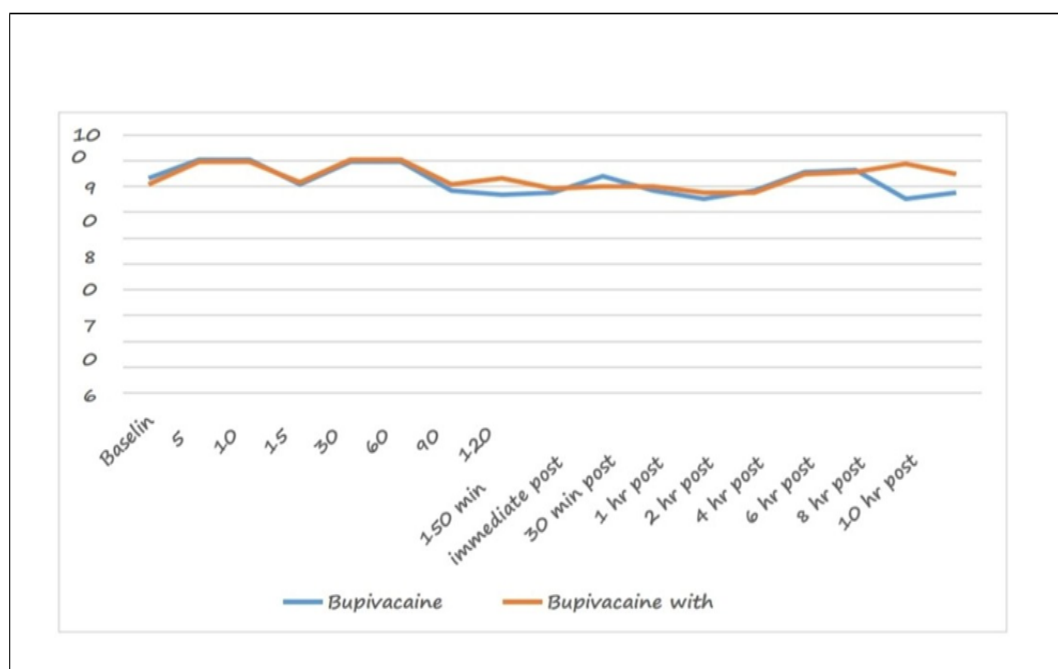


Figure 2: Comparison of Mean Arterial Pressure in Bupivacaine (group B) and Bupivacaine with Nalbuphine (group N)

The mean value of Systolic Blood Pressure (SBP) was generally higher in Bupivacaine alone (Group B) as compared to Bupivacaine with Nalbuphine (Group N) from 10 to 60 minutes pre-operatively.

The mean variation of SBP values between the two groups was statistically significant at 10-min pre-operatively and after 4-hours post-operatively. (Figure 3)

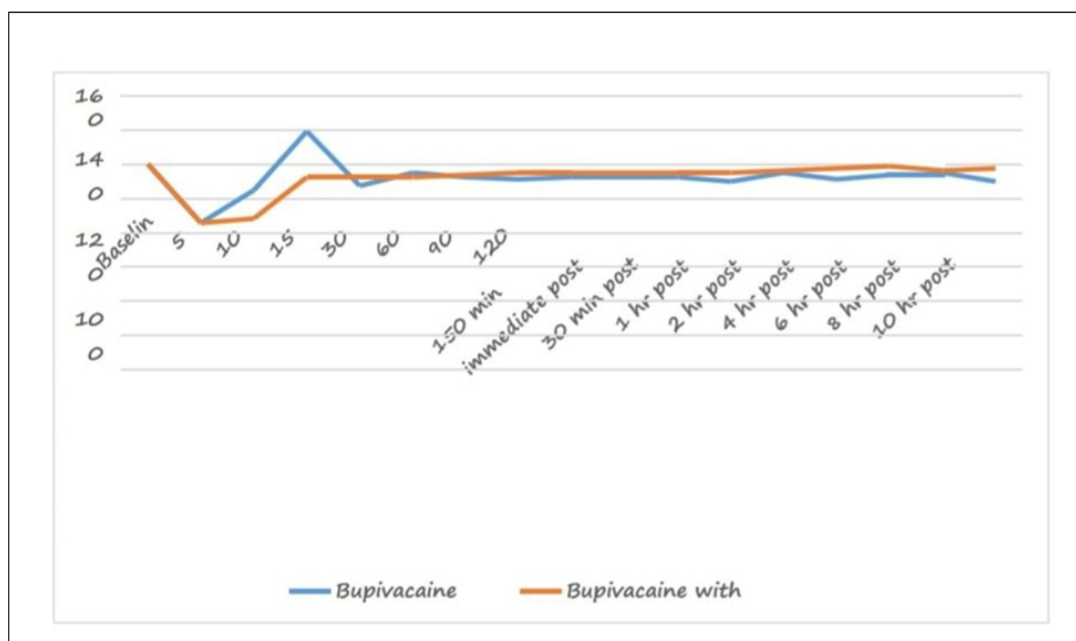


Figure 3: Comparison of Systolic Blood Pressure in Bupivacaine (group B) and Bupivacaine with Nalbuphine (group N)

The mean value of Diastolic Blood Pressure (DBP) was generally higher in Bupivacaine alone (Group B) as compared to Bupivacaine with Nalbuphine (Group N) from 5 to 60 minutes pre-operatively and there after comparatively lower. The mean variation of DBP values between the two groups was statistically significant at 15-min pre-operatively and 2-hour to 6-hours post-operatively. (Figure 4)

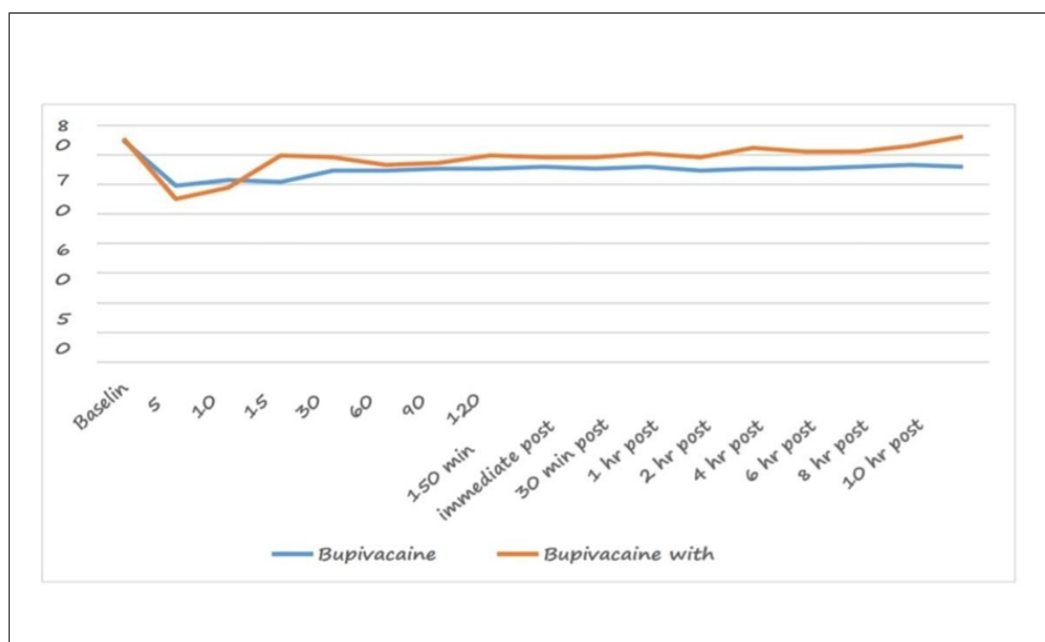


Figure 4: Comparison of Diastolic Blood Pressure in Bupivacaine (group B) and Bupivacaine with Nalbuphine (group N)

The mean value of Visual Analogue Score (VAS) was comparable throughout the duration in both the groups. The mean variation of VAS values between the two groups was not statistically significant at any point of time.

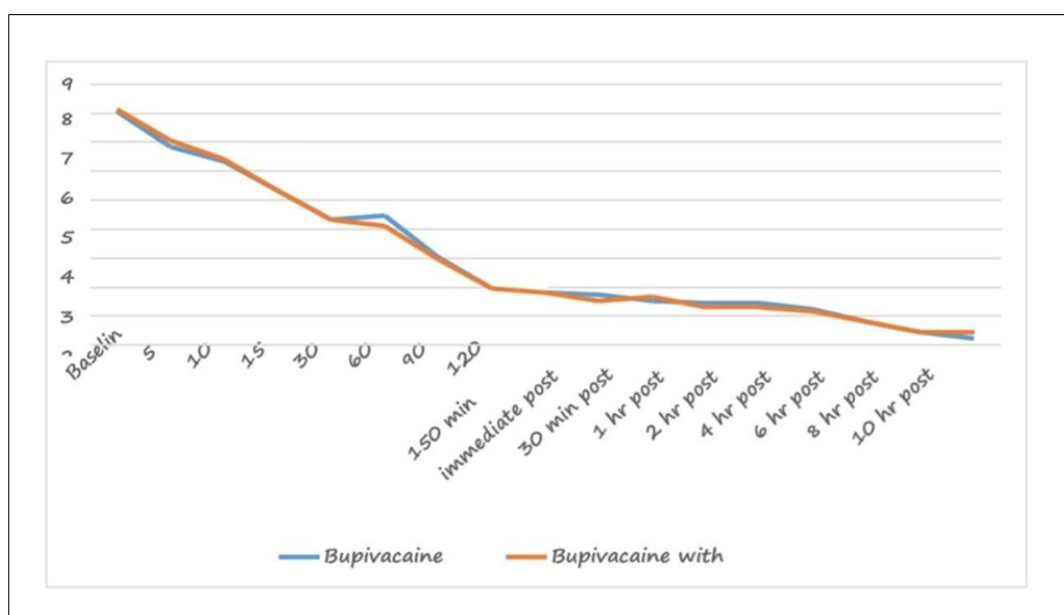


Figure 5: Comparison of Visual Analogue Score in Bupivacaine (group B) and Bupivacaine with Nalbuphine (group N)

Intra-operatively more patients in Bupivacaine alone (group B) had complications (n=18; 60%) as compared to Bupivacaine with Nalbuphine (group N) (n=2; 6.7%).

Bradycardia was the most common complication followed by hypotension and vomiting. Significant difference was found between the two groups ($p < 0.001$). Post-operatively group B had

complications (n=15; 50%) as compared to group N (n=14; 46.7%). Nausea was the most common complication followed by dizziness and vomiting. No significant difference was found between the two groups ($p = 0.989$). (Table 3)

Campbell Sedation Score were comparable in the two groups. No significant difference was found between the two groups ($p = 0.639$). (Table 3)

Table 3: Comparison of complications and Campbell Sedation Score in both the groups

	Group B (n=30)	Group N (n=30)	P value
Intraoperative complications			
None	12(40%)	28(93.3%)	<0.001 *
Bradycardia	5(16.7%)	2(6.7%)	
Hypotension	6(20.0%)	0	
Shivering	3(10.0%)	0	
Vomiting	4(13.3%)	0	
Post-operative complications			
None	15(50%)	16(53.33%)	0.989
Dizziness	5(16.7%)	5(16.7%)	
Nausea	6(20.0%)	5(16.7%)	
Vomiting	4(13.3%)	4(13.3%)	
Campbell Sedation Score			
1.00	28(93.3%)	27(90%)	0.693
2.00	2(6.7%)	3(10.0%)	

*Significant

Discussion

The mean age comparison across different studies involving the use of bupivacaine alone versus bupivacaine with nalbuphine as an adjuvant reveals some variability in findings. In the present study, the mean age of patients receiving bupivacaine alone was 34.5 ± 10.1 years, while those receiving bupivacaine with nalbuphine had a higher mean age of 41.1 ± 12.9 years. This suggests that, in this particular study, patients receiving the combination therapy were generally older. Abdelhaq et al study reported mean ages of 44 ± 6.5 and 48 ± 5.4 years for the respective groups, indicating a higher mean age overall compared to the present study [11]. Conversely, Gupta et al study documented mean ages of 34.6 ± 14.3 in the bupivacaine group and 33.7 ± 17.2 in the bupivacaine with nalbuphine group, suggesting a younger patient population in both groups compared to the present study [12]. Overall, while there is some variability in the mean age of patients across different studies, the present study's findings suggest a trend towards older patients receiving bupivacaine with nalbuphine compared to those receiving bupivacaine alone. However, further investigation and analysis would be needed to understand the potential implications of age differences on the outcomes of the supraclavicular brachial plexus block in upper limb surgeries.

The predominance of males in both groups of the present study, constituting 76.7% of the total study subjects, was consistent with findings from previous conducted studies [10,12-14].

The consistent observation of male predominance across multiple studies suggests that there may be inherent demographic or sociocultural factors contributing to this gender distribution in patients undergoing supraclavicular brachial plexus block for upper limb surgeries. Possible explanations

could include occupational or lifestyle factors leading to a higher incidence of upper limb injuries or conditions requiring surgical intervention among males, or differences in healthcare-seeking behavior between genders. Understanding the gender distribution in patients undergoing regional anesthesia procedures is important for tailoring healthcare services and optimizing patient care. Further research may be warranted to explore the underlying factors contributing to the observed gender disparities and their potential implications for clinical practice and patient outcomes.

The distribution of ASA physical status grades among participants in the present study, as well as in studies conducted previously revealed some interesting trends [10,12-14]. In the present study, two-thirds of the total participants were categorized as ASA I, indicating that the majority of patients were in good health with no systemic disease or functional limitations. Specifically, in the bupivacaine alone group, a high proportion (86.7%) were ASA I, suggesting that this group consisted primarily of patients with minimal or no systemic disease. In contrast, in the bupivacaine with nalbuphine group, while the majority (66.7%) were still ASA I, there was a higher representation of ASA II patients compared to the bupivacaine alone group. This indicates that patients receiving the combination therapy may have had slightly more systemic comorbidities or functional limitations compared to those receiving bupivacaine alone. Madhusudhanan study reported 40% of patients were ASA I, and 60% were ASA II in group N, while in Group C, 33% had ASA I, and 67% had ASA II [10]. This suggests a higher proportion of patients with systemic comorbidities or functional limitations in both groups compared to the present study. Mishra et al study also showed balanced distribution [15]. Yadav et al study showed ASA grade I predominance in both groups, indicating

that the majority of patients were in good health [14]. Overall, while there are some variations in the distribution of ASA grades across studies, the majority of patients undergoing supraclavicular brachial plexus block for upper limb surgeries tend to be in good health, with a smaller proportion having systemic comorbidities.

Mean weight and height was similar in both the groups. Mean duration of Surgery was significantly less in group N which may be due to fast effect in patients receiving the combination therapy.

In present study the mean time of onset of sensory blockade and motor blockade was significantly earlier in Nalbuphine group which was similar to other studies [12-14]. In present study mean duration of sensory blockade and motor blockade was significantly long in Nalbuphine group which was similar to other studies [12-15]. In the present study the mean heart rate was consistently higher in the Bupivacaine alone group compared to the Bupivacaine with Nalbuphine group. Madhusudhanan study had showed similar results [10]. In the present study the mean values of Mean Arterial Pressure (MAP) remained comparable throughout the duration in both groups. In a study by Madhusudhanan, MAP variation between the two groups was found to be statistically significant at 45, 60, 75, and 90 minutes, with a p-value of <0.05 [10]. During these intervals, Group N also exhibited a dip in Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP), indicating what could be considered the peak effect of nalbuphine.

In the present study the mean Systolic Blood Pressure (SBP) was generally higher in the Bupivacaine alone group compared to the Bupivacaine with Nalbuphine Group from 10 to 60 minutes preoperatively. The mean variation of SBP values between the two groups reached statistical significance at 10 minutes preoperatively and after 4 hours postoperatively. The mean diastolic Blood Pressure (SBP) was generally higher in the Bupivacaine alone group compared to the Bupivacaine with Nalbuphine Group from 5 to 60 minutes preoperatively, and thereafter, it was comparatively lower. Similar results were reported by Mishra et al study [15].

The mean value of VAS was comparable throughout the duration in both the groups. The mean variation of VAS values between the two groups was not statistically significant at any point of time. In a study by Madhusudhanan, the VAS score in Group Bupivacaine alone had four patients with mild pain at 2 hours and 30 patients with moderate pain at 3 hours [10]. More patients in Bupivacaine alone group had complications (50%) as compared to Bupivacaine with Nalbuphine group (46.7%). Nausea was the most common

complication followed by dizziness and vomiting. In a study by Gupta et al, there was no complaint of difficulty in breathing or any clinical evidence of diaphragmatic palsy or pneumothorax in any patient [12]. No complications of anesthetic technique or drug-related adverse effects such as nausea, vomiting, pruritus, or dry mouth were observed in any patient. In a study by Mehta et al, no complications and adverse events were observed in either group [15]. In a study by Aggarwal et al, most common complication in the nalbuphine group was nausea vomiting and pruritis, in the bupivacaine group it was vomiting and dry eyes [16].

The Campbell Sedation Score were comparable in both groups. This finding aligns with a study by Mehta et al, where the majority of total patients also had a score of 1 [15].

Conclusion

In conclusion, the addition of nalbuphine to bupivacaine for supraclavicular brachial plexus block resulted in faster onset times for sensory and motor blocks, as well as prolonged durations of sensory and motor blockade compared to bupivacaine alone. While the Bupivacaine with nalbuphine group showed lower diastolic blood pressure values during certain time intervals, intraoperative complications were significantly reduced in this group compared to the Bupivacaine alone group.

These findings suggest that nalbuphine may be a valuable adjunct to bupivacaine for enhancing the quality and duration of brachial plexus blockade while minimizing intra operative complications.

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