e-ISSN: 0975-1556, p-ISSN:2820-2643

Available online on www.ijpcr.com

International Journal of Pharmaceutical and Clinical Research 2024; 16(2); 265-270

Original Research Article

Comparison between Bupivacaine V/S Bupivacaine Plus Nalbuphine in Supraclavicular Brachial Plexus Block: Double Blind Randomized Controlled Trial

Vatsal Shah[1], Anjali Tripathi[2], Divyang Sutaria[3], Komal Shah[4]

[1]MD Anesthesiology, Ahmedabad, Gujarat, India

[2,3]Senior Resident, Department of Anesthesia, Smt. NHL Municipal Medical College, Ahmedabad, Gujarat, India

[4]Associate Professor, Department of Anesthesia, Govt. Medical College, Bhavnagar, Gujarat, India

Received: 25-11-2023 / Revised: 23-12-2023 / Accepted: 26-01-2023

Corresponding Author: Dr. Komal Shah

Conflict of interest: Nil

Abstract:

Background and Aim: Brachial plexus block is frequently performed for ambulatory upper limb surgery as an alternative to general anesthesia. It can significantly reduce pain, reduce post-operative nausea, and vomiting and allowing for faster discharge from hospital. Our current study was designed to test the hypothesis that nalbuphine when added as an adjuvant to bupivacaine in supraclavicular brachial plexus block enhanced the onset, duration of sensory and motor blocks, duration of analgesia, and quality of block for the patients undergoing ambulatory forearm and hand surgery.

Material and Methods: Present prospective, randomized, double blind study was carried out in 60 patients in Department of Anaesthesiology, Sir T. Hospital, Bhavnagar. Patients were randomly allocated to one of the two groups of 30 patients each by distributing sealed envelopes.

1. Group – A (Bupivacaine alone)- 30 patients received 29 ml of 0.375% Bupivacaine with 1ml of normal saline. 2. Group–B (Bupivacaine + Nalbuphine)- 30 patients received 29ml of 0.375% Bupivacaine with 1ml Nalbuphine (10 mg). Onset and duration of sensorimotor blockade, hemodynamic variables, duration of analgesia, and adverse effects were recorded.

Results: Mean time to onset was significantly shorter in Group B compared to Group A and duration of sensory blockade was prolonged in group B which is statistically significant in favor of group B. Mean time of onset and duration of motor blockade was significantly changed in both groups showing shorter onset and prolonged duration in Group B. The duration of effective analgesia was significantly prolonged with addition of nalbuphine to bupivacaine.

Conclusion: Addition of Nalbuphine 10mg to 0.375% Bupivacaine in supraclavicular brachial plexus block significantly shortens the onset of both sensory and motor blockades, prolongs the duration of sensory and motor blockade and the duration of analgesia but does not significantly reduce the frequency of rescue analgesic required in postoperative period.

Keywords: Brachial plexus block, Bupivacaine, Motor Blockade, Nalbuphine.

Introduction

The prime duty of any anesthesiologist is to relieve pain in the perioperative period; the anesthesiologist adopts various types of techniques to alleviate pain, like general or regional anesthesia. Today regional anesthesia is well established as equal to general anesthesia in effectiveness and patient's acceptability. Regional anesthesia is blocking of peripheral nerve conduction in a reversible way using local anesthetic agents thereby one region of the body is made insensitive to pain and is devoid of response to surgical stimuli. In this the CNS effect is spared, so that the patient is conscious, fully awake during the surgical procedure without recognizing pain. For surgeries on upper extremities, particularly in emergency surgeries, regional anesthesia has many advantages over general anesthesia. Brachial plexus block (BPB) is a routinely performing regional anesthesia technique for surgeries involving upper limb, especially below mid-arm orthopedic procedures. The BPB not only provides good intraoperative anesthesia but also produces very good postoperative analgesia, thereby reducing the incidence of complications and providing early mobilization. [1] Orthopaedic upper limb surgeries are quite common and routine encounter for the

anaesthesiologist and brachial plexus block is an established regional anaesthetic technique for these surgeries. It is a better alternative to general anaesthesia in most of the patients because it is economical, requires minimal preoperative preparation, causes minimal physiological and metabolic alterations, less stress response, provides longer postoperative analgesia, less postoperative nausea & vomiting, early ambulation and hence reduced hospital stay.

Local anesthetics alone for supraclavicular BPB provide good intraoperative conditions but produce a shorter duration of postoperative analgesia. Various adjuvants to local anesthetics were used to prolong postoperative analgesia with variable results and advantages. [2] Drugs such as epinephrine, morphine, pethidine, dexamethasone, clonidine, dexmedetomidine, butorphanol, and midazolam are used along with local anesthetics for this purpose. Addition of adjuvants to local anesthetics improves the onset and duration of the blockade, gaining patient satisfaction and maintaining proper hemodynamics, together with reducing the need for postoperative analgesics. [3]Nalbuphine is 14-hydroxymorphine derivative with a strong analgesic effect with mixed κ agonist and μ antagonist. [4] The analgesic effect of nalbuphine has been found to be equal to the analgesic effect of morphine but unlike it has a ceiling effect on respiration. Nalbuphine has the potential to maintain or even enhance μ-opioid-based analgesic effect while simultaneously mitigating the μ-opioid side effects. [5]

Our current study was designed to test the hypothesis that nalbuphine when added as an adjuvant to bupivacaine in supraclavicular brachial plexus block enhanced the onset, duration of sensory and motor blocks, duration of analgesia, and quality of block for the patients undergoing ambulatory forearm and hand surgery.

Material and Methods

After institutional review board approval and written informed consent from patient, this prospective, randomized, double blind study was carried out in 60 patients in Department of Anaesthesiology, Sir T. Hospital, Bhavnagar. After thorough pre-anaesthetic evaluation patients were included or excluded according to following criteria:

Inclusion Criteria

1. American Society of Anesthesiologists (ASA) physical status I to II of either gender
2. Age: 18–58 years
3. Patients scheduled for elective forearm and hand surgeries in orthopaedic operation theaters.
4. A written informed consent obtained from patient.

Exclusion Criteria

1. Patients with clinically significant coagulopathy
2. Infection at the injection site
3. Allergy to local anesthetics
4. Refusal to technique
5. Patients taking psychotropic medications.

The study drug was prepared and coded by an anaesthesiologist who was not involved in the study. Principal Investigator performed the brachial plexus block and monitored the patient. So, PI remained blinded for the study. The time for onset of sensory & motor blockade, hemodynamic changes, regression time for sensory and motor block, duration of analgesic effect and side effect were recorded by PI. All the patients were assured and explained about the procedure to be performed and informed consent was obtained before performing the block. A standard regional anaesthesia trolley was prepared. Resuscitation equipment was kept ready.

Patients were randomly allocated to one of the two groups of 30 patients each by distributing sealed envelopes.

1. Group – A (Bupivacaine alone)- 30 patients received 29ml of 0.375% Bupivacaine with 1ml of normal saline.

2. Group–B (Bupivacaine + Nalbuphine)- 30 patients received 29ml of 0.375% Bupivacaine with 1ml Nalbuphine (10 mg).

In pre-anaesthetic preparation room standard monitoring for Heart Rate (ECG), Systolic and Diastolic Blood Pressure (NIBP), Peripheral Oxygen Saturation (Pulse Oxymeter) was established and baseline vital parameters were recorded. An appropriate size i.v. cannula was secured and DNS infusion was started at the rate of 8 ml/kg/hr. Inj. Ondansetron 0.08 mg/kg was given as premedication 15 minutes before induction. Sedation in the form of inj. Midazolam 0.02mg/kg was given intravenously.

After shifting the patient into operation theater, noninvasive monitors such as blood pressure (noninvasive blood pressure), oxygen saturation (SPO_2), and ECG were applied and their baseline values were measured. IV access was established using 22 G cannula. •A marker was placed 3 cm from the tip of the needle and the plexus was located using the supraclavicular approach. The current was initially set to deliver 1.0 milli amperes at 2 Hz stimulation frequency. •End of the injection was taken as Time '0'. Immediately after the block, sensory and motor characteristics of blockade, hemodynamic variables, SpO2 were assessed by

the PI at 1,5,10,15,30 minutes and then at hourly interval till offset of sensory and motor blockade and then at four hourly interval for 24 hours.

The territories supplied by following nerves were evaluated by pin prick for presence or absence of pain sensation with 25 gauge needle. The block was tested for both sensory and motor block and was compared with the contralateral side. The sensory block was graded using a 3-point scale. Assessment of the motor block was carried out according to the modified Bromage scale for upper extremities. The quality and duration of analgesia were assessed every hour postoperatively in the recovery room and in the surgical ward using visual analog scale (VAS) graded from 0 to 10. All the patients were monitored for Heart rate (ECG), Blood Pressure (NIBP), Respiratory rate, SpO2 and for complications if any in intraoperative and postoperative period for next 24hrs. Post operatively, the time of first rescue analgesic required at Numerical rating scale≥ 4 and total doses of analgesic given in 24 hours will also be noted. Diclofenac sodium 75 mg i.v. will be given as rescue analgesic whenever required (NRS≥ 4) Any complications or adverse event were also noted.

Statistical analysis: The recorded data was compiled and entered in a spread sheet computer program (Microsoft Excel 2007) and then exported to data editor page of SPSS version 15 (SPSS Inc., Chicago, Illinois, USA).

Quantitative variables were described as means and standard deviations or median and interquartile range based on their distribution. Qualitative variables were presented as count and percentages. For all tests, confidence level and level of significance were set at 95% and 5% respectively.

Results

Table 1: Demographic data of study participants

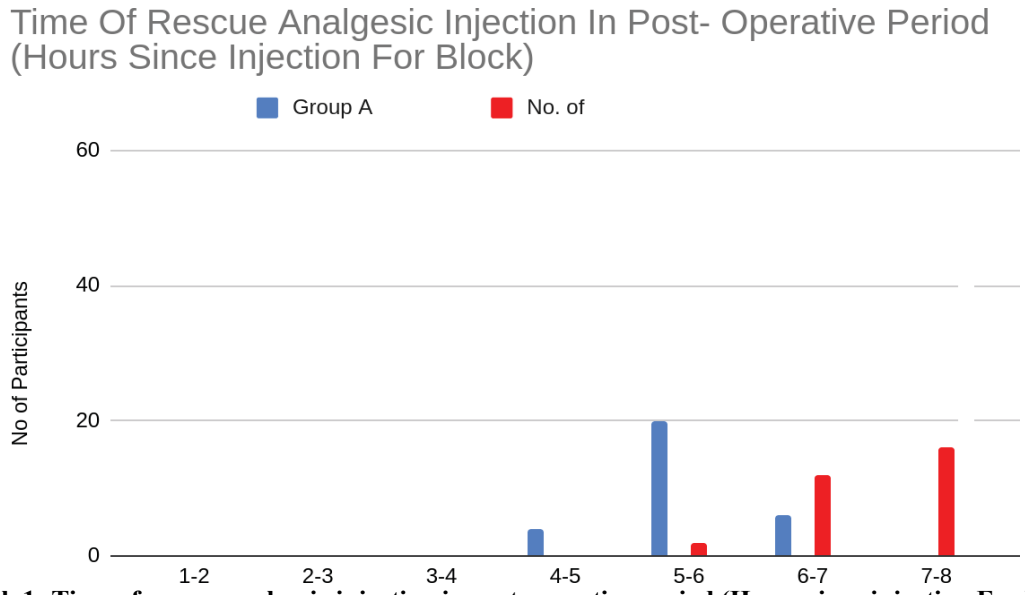
Patient's Characteristics	Group A (Mean±SD)	Group B (Mean±SD)	P value
Age(years)	38.4±12.37	37.3±12.77	0.73
Gender(M/F)	23/7	21/9	0.77
Weight(kg)	57.0±7.24	57.37±7.34	0.85

Patient characteristics in terms of age, gender, weight, ASA Grade were comparable among both the groups (p>0.05). On comparison, between group A and group B there is statistically significant difference in onset and duration of motor blockade. This shows that addition of Nalbuphine to Bupivacaine has significant effect on onset and duration of the motor blockade. On comparing the total duration of analgesia between Group A and Group B, it was observed that addition of 10 mg Nalbuphine to bupivacaine (Group B) produced statistically significant prolonged duration of analgesia than addition of Normal Saline to bupivacaine (Group A)

Table2:Duration ofEffectiveAnalgesia

Variable	Group A (n=30) (Mean ± SD)	Group B (n=30) (Mean ± SD)	P Value
Effective analgesia (minutes)	346±30.77	429.33±30.73	0.0001*

* indicate statistically significance at p≤0.05. On comparing the total duration of analgesia between Group A and Group B, it was observed that addition of 10mg Nalbuphine to bupivacaine (Group B) produced statistically significant prolonged duration of analgesia than addition of Normal Saline to bupivacaine (Group A)



Graph 1: Time of rescue analgesic injection in post-operative period (Hours since injection For Block

In group A, majority of the participants required rescue analgesics between 5-6 hours (66.67%), 06 participants between 6-7 hours (20%) and 4 participants between 4-5 hours (13.33%) of brachial plexus blockade. In group B, majority of the participants required rescue analgesics between 7-8 hours (53.33%), 12 participants between 6-7 hours (40%) and 02 participants between 5-6 hours (6.67%) of brachial plexus blockade.

Table 3: Doses of Rescue Analgesics Required Within 24 Hours

No. of analgesic doses	Group A(n=30)		Group B(n=30)	
	No. of participants	%	No. of participants	%
1	0	0	0	0
2	0	0	0	0
3	28	93.33	30	100%
4	2	6.67%	0	0

The analgesic requirement within 24 hrs was comparable in both the groups. In group A 2 patients (6.67%) required four injections of rescue analgesic and 28 patients (93.33%) required three injections in 24 hours. While 30 patients (100%) required three injections of rescue analgesic in group B

In comparison to group A and group B, there were no significant changes in Heart Rate, blood pressure, respiratory rate between the two groups during various times of recording after giving brachial plexus block. (P>0.05). No complications were observed in any two groups throughout the study period.

Discussion

Regional anaesthesia is the gold standard in anaesthetic management for orthopaedic surgeries. In many clinical studies, it has been reported that regional anaesthesia technique provided important advantages when compared with general anaesthesia in terms of safety, adequate anaesthesia, excellent postoperative pain control, reduced side effects, decreased blood loss, extreme patient satisfaction and shorten stay in the post anaesthesia care unit and early discharge from recovery room.

In this prospective, randomized, double-blinded trial, we had compared the effect of nalbuphine hydrochloride 10 mg (1ml) and the same volume of normal saline (as control) as an adjuvant to 29 ml 0.375% bupivacaine in supraclavicular brachial plexus block, on the onset and duration of sensory and motor blocks as well as on the postoperative rescue analgesic requirement for the patients undergoing ambulatory forearm and hand surgery post-operatively and occurrence of side effects such as labored breathing, flushing, dizziness, sweating, skin itching or burning.

Historically, the Supraclavicular approach to the brachial plexus can provide excellent anaesthesia for upper-extremity surgery. Dr. Sheetal Shah et al [6] in 2013, did a prospective, randomized study, comparison of Infraclavicular brachial plexus block with Supraclavicular brachial plexus block in upper limb surgeries in 100 patients aged between 18- 66 years. They compared block performance time and quality of block between two groups. They have found that quality of block was better in group receiving Supraclavicular block than group receiving Infraclavicular block. So, we have chosen

Supraclavicular approach of brachial plexus block.There are many adjuvants used with LA for potentiating the quality of the block and increasing the duration of post-operative analgesia. Hence, there is constant search for effective adjuvants to bupivacaine to shorten the onset of action and to prolong the duration of postoperative analgesia.Nalbuphine is a semisynthetic opioid with mixed κ agonist and μ antagonist properties. Nalbuphine has been proven to prevent hemodynamic stress response associated with endotracheal intubation. Like fentanyl and propofol, nalbuphine is also popular in producing analgesia during monitored anesthesia care. The drug is also very effective in subarachnoid as well as epidural route for prolonging sensory and motor block duration and also postoperative analgesia. Success and nontoxicity of the drug in subarachnoid and epidural route ensure that the drug can safely be used perineurally in any peripheral nerve block. [7]

In the present study the mean time for onset of sensory block is 12.6 ± 2.23 and 8.2 ± 1.91 mins in group A and group B respectively. The duration of sensory blockade was 323.17 ± 30.83 and 407.6 ± 29.9 in group A and group B respectively. This shows that Nalbuphine shortens the onset of sensory blockade but it prolongs duration of sensory blockade when given along with bupivacaine for brachial plexus block.

The results were comparable with the study done by Nazir et al [8] in which it was observed that in Nalbuphine Group, there was a statistically significant shorter time to onset of sensory blockade and longer duration of sensory block compared to control group.

In the present study the time taken for onset of motor block is 16.35±1.67 mins and 12.2 ± 1.67 mins in group A and group B respectively. These findings show that there is a significant difference in the time of onset of motor blockade in both the groups. The duration of motor blockade was 301.17 ± 22.96 and 373.67 ± 28.70 in group A and group B respectively. This shows that Nalbuphine shortens the onset of motor blockade as well as prolongs the duration of motor blockade when given along with bupivacaine for brachial plexus block.The results were also comparable to another similar study conducted by Mohammed et al [9] in which it was observed that Nalbuphine group showed significant increase in the duration of motor block, when compared to control group (p-value < 0.001).

In our study the duration of analgesia was 346 ± 30.77 mins and 429.33 ± 30.73 mins in group A and group B respectively which was statistically significant with a p value of <0.0001. In another study conducted by Parveen et al [10] evaluating the effect of intrathecal nalbuphine as an adjuvant to spinal bupivacaine in abdominal hysterectomy it was observed that the total duration of effective analgesia was also significantly prolonged in Nalbuphine Group compared to Control Group.

In this study on comparison of mean heart rate changes between group A and group B during and after the block, the changes are not significant as the p value is >0.05. Hence the changes in heart rates recorded at different times are not statistically significant between the two groups. This was in consonance with another study conducted by Sunil Chiruvella et al [11] which showed no significant changes in mean heart rate between both the groups.

On comparison of changes in mean arterial blood pressure between the two groups during various times of recording, it is also found that it is statistically not significant, as the p value is >0.05. This was comparable with another study conducted by Sunil Chiruvella et al [11] which showed no significant changes in mean arterial blood pressure between both the groups.

On comparison of changes in Respiratory Rate between the two groups during various times of recording, it is also found that it is statistically not significant, as the p value is >0.05. This was comparable with another study conducted by Sunil Chiruvella et al [11] which showed no significant changes in mean Respiratory Rate between both the groups.

In our study there were no incidences of any complications like laboured breathing chest pain, flushing, dizziness, sweating or skin itching in either of the groups.

Conclusion

Addition of Nalbuphine 10 mg to 0.375% Bupivacaine in supraclavicular brachial plexus block significantly shortens the onset of both sensory and motor blockades, prolongs the duration of sensory and motor blockade and the duration of analgesia but does not significantly reduce the frequency of rescue analgesic required in postoperative period.

Hence, addition of Nalbuphine to Bupivacaine is a better choice than plain Bupivacaine for Supraclavicular Brachial Plexus Block for upper limb surgeries.

Also addition of Nalbuphine to Bupivacaine for supraclavicular brachial plexus block is an economically affordable choice for upper limb surgeries.

References

1. Bruce BG, Green A, Blaine TA, Wesner LV. Brachial plexus blocks for upper extremity or-

thopaedic surgery. J Am Acad Orthop Surg. 2012; 20:38–47.
2. Murphy DB, McCartney CJ, Chan VW. Novel analgesic adjuncts for brachial plexus block: A systematic review. Anesth Analg. 2000; 90:1122–8.
3. Kayser EF (2002) Local anesthetics and additives. Anesth Analg 92:32–36.
4. Ahmed F, Narula H, Khandelwal M, Dutta D. A comparative study of three different doses of nalbuphine as an adjuvant to intrathecal bupivacaine for postoperative analgesia in abdominal hysterectomy. Indian J Pain. 2016; 30:23–8.
2. Gunion MW, Marchionne AM, Anderson TM. Use of the mixed agonist-antagonist nalbuphine in opioid based analgesia. Acute Pain. 2004; 6:29–39.
3. Sheetal Shah et al. Dr. Sheetal Shah, Dr. Kamla Mehta, Dr. Kirti Patel, Dr. Khyati Patel. Dept. of anaesthesia, Smt. SCL Hospital, Ahmedabad.NHL journal of medical sciences/ January2013/Vol 2/ Issue 1. Comparison of Infraclavicular brachial plexus block with Supraclavicular Brachial plexus block in upper limb surgeries.
4. Chatrath V, Attri JP, Bala A, Khetarpal R, Ahuja D, Kaur S, et al. Epidural nalbuphine for postoperative analgesia in orthopedic surgery. Anesth Essays Res. 2015; 9:326–30.
5. Nazia Nazir, Shruti Jain Randomized Controlled Trial for Evaluating the Analgesic Effect of Nalbuphine as an Adjuvant to Bupivacaine in Supraclavicular Block under Ultrasound Guidance, 10.4103/0259-1162.194590
6. Mohamed Mohamed Abdelhaq, Mohamed Adly Elramely, Effect of Nalbuphine as Adjuvant to Bupivacaine for Ultrasound-Guided Supraclavicular Brachial Plexus Block, 10.4236/ojanes.2016.63004
7. Shahedha Parveen1, P Krishna Prasad2, B Sowbhagya Lakshmi3, Evaluation of the Effect of Intrathecal Nalbuphine as an Adjuvant to Spinal Bupivacaine for Postoperative Analgesia in Patients Undergoing Abdominal Hysterectomy: A Randomized, DoubleBlinded Control Trial, 10.17354/ijss/2015/527
8. Sunil Chiruvella, Suresh Kumar Konkyana, Srinivasa Rao Nallam, Gokul Sateesh, Supraclavicular Brachial Plexus Block: Comparison of Varying Doses of Nalbuphine Combined with Levobupivacaine: A Prospective, Doubleblind, Randomized Trial, 10.4103/aer.AER_197_17.