Original Research Article

Comparative study of intrathecal nalbuphine versus intrathecal buprenorphine as an adjuvant to intrathecal bupivacaine for post operative analgesia in patients undergoing lower limb surgeries

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Abstract

Background: To compare the efficacy of postoperative analgesia achieved between two opioids nalbuphine and buprenorphine when added to bupivacaine 0.5% heavy in spinal anaesthesia and to compare the onset of sensory blockade (time taken from 3, 5 minute and then every 5 minutes until the end of procedure). **Methods**: A total of 100 patients (50 in each group) , ASA I and ASA II, in the age range of30-60 years, posted for lower Limb surgeries received 0.5% Bupivacaine (hyperbaric) 3ml with either 0.8 mg nalbuphine (Group BN = 50) or 60 microgram of buprenorphine (Group BB = 50) injected intrathecally depending upon the randomization. **Results**: The mean duration of analgesia was more in BB group was 453.90 ± 60.50 minutes in comparison to 223.30± 57.63 minutes in BN group. Duration of postoperative analgesia for group BB was 324.50 ± 48.84 minutes and that of group BN was 86.30 ± 10.09 minutes which is statically significant. **Conclusion**: Our conclusion was both intrathecal buprenorphine and intrathecal nalbuphine act synergistically to potentiate bupivacaine induced sensory spinal block. Buprenorphine added to 0.5% bupivacaine heavy hyperbaric intrathecally prolongs the duration of sensory block and extend. the analgesia into early postoperative period compared to intrathecal nalbuphine.

Keywords: Inj.Bupivacaine heavy 0.5%, inj. Buprenorphine, inj. nalbuphine, 18G spinal needle, 5ml disposable syringe, lower abdominal surgeries.

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Received Date: 07/07/2021 Revised Date: 13/08/2021 Accepted Date: 25/09/2021
DOI: https://doi.org/10.26611/101519310

Access this article online	
Quick Response Code:	Website: www.medpulse.in
	Accessed Date: 26 September 2021

INTRODUCTION

Neuraxial blockade has a wide range of clinical applications for surgery, obstetrics, acute post-operative pain management and chronic pain relief. Single injection of spinal or epidural anaesthesia with local anaesthetic is most commonly used for surgery of lower abdomen, pelvic organ and lower limb and for caesarean delivery. The popularity of spinal block is that, the block has well defined end points and anaesthesiologist can produce block relatively with a single injection.[1] The spinal anaesthesia is so versatile because of presence of wide variety of local anaesthetic and variety of additives that help to achieve adequate level of block, time of onset and duration of spinal anaesthesia. The distribution of local anaesthetic

How to site this article: Pooja Chandak, D M Kokane, S S Chauhan. Comparative study of intrathecal nalbuphine versus intrathecal buprenorphine as an adjuvant to intrathecal bupivacaine for post operative analgesia in patients undergoing lower limb surgeries. *MedPulse International Journal of Anesthesiology.* September 2021; 19(3):96-99. http://medpulse.in/Anesthsiology/index.php

solutions within the subarachnoid space determines the extent of neural blockade produced by spinal anaesthesia. Spinal anaesthesia with 0.5% bupivacaine heavy is commonly performed procedure due to its longer duration of action compared to other local anaesthetics. At times certain surgeries demand to intensify and prolong the duration of blockade and thereby prolonging the duration of postoperative analgesia.[2] The addition of opioids as a method to accomplish these goals has been advocated. Use of intrathecal opioids can provide excellent pain relief after wide variety of surgical procedures. This study is designed to quantitatively examine the effects of adding nalbuphine and buprenorphine to hyperbaric bupivacaine hydrochloride spinal anaesthesia, to evaluate efficacy, duration of pain relief and complications if any.

MATERIALS AND METHODS

After obtaining institutional ethics committee approval and written informed consent from the patients involved in the study, 100 patients (50 in each group) were recruited. It was a double blind, prospective, randomized observational phase IV controlled study in patients undergoing lower limb orthopaedic surgery.

Inclusion criteria being, Patient undergoing lower limb orthopaedic procedure of < 120 mins, Patient of either sex, aging between 18 to 60 years and patients categorized under American society of Anaesthesiologists(ASA) classification as Class I or II.

Exclusion criteria being, any contraindications to spinal anaesthesia (e.g. coagulation defects, patients refusal, infection at puncture site, pre-existing neurological deficit, severe cardiovascular or respiratory disorders, severe neurological dysfunction, morbid obesity etc.), seriously or terminally ill patient of ASA classification III to VI , known case of allergy to any local anaesthetic drugs, Pregnant and lactating women, Obesity(BMI >/=29.9 Kg/m2) and neuromuscular diseases patients. Certain withdrawal criteria were set up, like when there will be deviation from protocol and If there is intolerance to study drug then patient will be excluded from study. Initially, we conducted a pre-anaesthetic evaluation comprising of history of previous medical and surgical illnesses, previous anaesthesia exposures, drug allergies along with General physical examination and complete systemic assessment. Airway examination was done. These patients were screened for routine investigation, viz. haemoglobin estimation, complete blood check-up, HIV/HCV/HBsAg detection, Renal Function Tests (RFTs), Liver Function Tests (LFTs),

Chest X Ray (CXR), Electrocardiography (ECG), Blood grouping and cross matching (BGCM), Random Blood Sugar Level (RBS) and Serum Electrolytes.

A written informed valid consent was obtained from all the patients included in this study just before the surgery after adequate starvation and patients were randomly assigned into two groups i.e. Group – BB (50) and Group – BN (50). Patients were taken to operation theatre. Intravenous access and Fluid preloading After intravenous insertion of an 18G intravenous canula in operating room all patients were given 500 ml of Ringer lactate for intravascular loading before spinal anaesthesia. Monitors were attached (e.g. Electrocardiography, non-invasive Blood Pressure, pulse oximetry). Selection of Patients was done using Lottery method. Patients were allotted into group A and group B to achieve optimum randomization.

Procedure: After the optimum randomization, the patients in both the groups were given sitting/lateral position depending upon the operation to be performed. Spinalanaesthesia was administered under strict aseptic precautions and after 2% lignocaine skin infiltration, dural puncture performed at L3-L4 inter vertebralspace using standard midline approach with Quincke's needle. Correct needle placement was identified by free flow of cerebrospinal fluid. 0.5% Bupivacaine (hyperbaric) 3ml with either o.8 mg nalbuphine or 60 microgram of buprenorphine injected intrathecally depending upon the randomization. After the injection of the drug the spinal needle was removed and the patient was placed in supine position.

Assessment: Patients were given oxygen 4 litres/min via facemask throughout the procedure. Standard monitoring was continued throughout the operation. Heart rate, systolic and diastolic blood pressure and oxygen saturation (SpO2) were recorded before and then after dural puncture every 2 minutes for first 10 minutes and thereafter every 10 minutes till 1st hour then every 30 minutes until full recovery.

Visual Analogue Scale[3]

Since perception of pain is highly subjective, this variable was standardised by using data from VAS. First advocated by Revill and Robinson in 1976, VAS consists of 10cm line anchored at one end by the label such as no pain and at end by label as worst pain ever imaginable or pain as bad as can be. The patient simply marks the line to indicate the pain intensity and the provider then measure the length to the mark on a pain scale.

Level of Sensory blockade was assessed by loss of pin prick sensation (25G hypodermic needle).The test was performed every 2 minutes for first 10 minutes and thereafter every 10 minutes till 1st hour then every 30 minutes until full recovery. It was checked bilaterally at dermatome levels S1, L2, L3, T12, T10, T8, T6 or higher (T4). We used dermatomes C5-C6 as baseline point for normal sensation.

Motor blockade was assessed by using Modified Bromage scale.[4]

The maximum Bromage score reached and duration of the motor block was registered every 2 minutes for first 10 minutes and thereafter every 10 minutes till 1st hour then every 30 minutes until full recovery. The duration of sensory blockade, maximum level of sensory block achieved and recovery from sensory block was measured. The interval from intrathecal administration to the point of complete resolution of the sensory block was recorded. The duration of motor blockade, a maximum score of Bromage score 3 and recovery from motor block was measured. The interval from intrathecal administration to the point in which the Bromage score was back to zero indicating complete motor recovery was measured. The occurrence of adverse events including bradycardia, hypotension, decrease in oxygen saturation (SpO2), nausea and vomiting were recorded. Any hypotension (mean arterial pressure lower than 60 mmHg) or bradycardia (heart rate < 50/min) incidents was treated with ephedrine 6 mg or atropine 0.6 mg in increments respectively. Nausea vomiting was treated with injection ondensetran 4mg. All the recorded data were statistically analyzed, and the significance was measured as a probability of occurrence by the t-test. Comparison of mean and SD between two groups will be done by using unpaired t test to assess whether the mean difference between groups is significant or not Descriptive statistics of each variable was presented in terms of Mean, standard deviation, standard error of mean. A p value of <0.05 was considered as statistically significant whereas a p value <0.001 was considered as highly significant.

RESULTS

There was no statistically significant difference between the demographic characteristics of both groups. The perioperative pulse rate variation in subjects of group A and group B shows highly significant variation in pulse rate reading at 1 hour, 2 hour, 3 hour, 5 hour and 6 hour readings postoperatively. Systolic blood pressure studies each hour till 6 hours shows no significant variation in between readings of subjects of group BB and group BN. Mean systolic blood pressure for group BB is 110.76±9.81 and mean systolic blood pressure for group BN is 114.80±7.15. Diastolic blood pressure variations in group BB and group BM shows no significant variation mean value was 70.08±5.30 in group A and that in group B was 69.68±4.52.

Total duration of analgesia in group BB 453.90±60.50 minutes and group BN is 223.30± 57.63 minutes. There is significant variation in duration of analgesia in group BB and group BN.

Table 1

Group		N	Mean	Std. Deviation	t	p	Inference
total duration of analgesia (min)	Buprenorphine	50	453.90	60.50	19.515	0.0001 (<0.001)	Highly significant
	Nalbuphine	50	223.30	57.63			

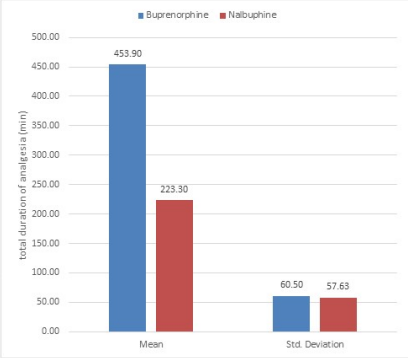

Figure 1

Duration of postoperative analgesia in group BB has a mean duration of 324.50±48.84 minutes and that in group BN was 86.30 ± 10.09 minutes.

Table 2

Group		N	Mean	Std. Deviation	t	p	Inference
duration of postop analgesia (min)	Buprenorphine	50	324.50	48.84	33.776	0.0001 (<0.001)	Highly significant
	Nalbuphine	50	86.30	10.09			

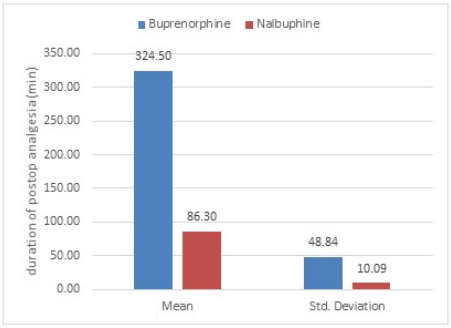

Figure 2

DISCUSSION

Subarachnoid block is a commonly employed anaesthetic technique for lower limb surgeries. Local anaesthetics commonly used for this purpose have various side effects and have less duration of analgesia. One of the disadvantage with subarachnoid block using local anaesthetic alone is that analgesia ends with regression of the block, which means there is immediate need for postoperative pain relief. In recent years, the use of intrathecal opioids has become widespread, albeit at the cost of an increased risk for respiratory depression. Buprenorphine and nalbuphine as they have agonist and antagonist actions, have minimal respiratory depressant effects, while providing analgesic effect by agonist actions. Although epidural buprenorphine and nalbuphine have been demonstrated to provide adequate postoperative analgesia in patients undergoing lower limb surgeries, their efficacy after intrathecal administration have not been studied sufficiently. Hence we thought it would be appropriate to study effects of intrathecally administered nalbuphine and buprenorphine along with bupivacaine hyperbaric. Nalbuphine is a synthetic opioid analgesic with agonist-antagonist activity and acts as antagonist at mu receptors and agonist at kappa receptors to provide reasonably potent analgesia[5] Buprenorphine is an agonist-antagonist opioid, about thirty times more potent than morphine. It is centrally acting lipid soluble analogue of the alkaloid thebaine with both spinal and supraspinal component of analgesia.[6,7] In addition it has ceiling effect on respiratory but not on analgesia[8]

Visual Analogue Scale

In the present study, there is significant reduction in the visual analogue score of the patients in group bb that is buprenorphine in comparison with higher VAS in group – BN that is nalbuphine.

Duration of analgesia

In the present study the duration of analgesia in group BB was 453.90± 60.50 minutes. Compared to 223.30±57.63 minutes in group BN which was statistically highly significant. This shows that there was significantly longer duration of analgesia with intrathecal buprenorphine. This is considerably longer duration of analgesia when compared to using local anaesthetic alone.

CONCLUSION

We can summarize that both intrathecal buprenorphine and intrathecal nalbuphine act synergistically to potentiate bupivacaine induced sensory spinal block. Buprenorphine added to 0.5 % bupivacaine hyperbaric intrathecally prolongs the duration of sensory block and extend the analgesia into early postoperative period compared to intrathecal nalbuphine. On the basis of our study we can draw conclusion that intrathecal buprenorphine 60 microgram along with bupivacaine 0.5% hyperbaric produces longer duration of analgesia as compared to nalbuphine 0.8 mg along with bupivacaine 0.5% hyperbaric in lower limb surgeries.

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Source of Support: None Declared
Conflict of Interest: None Declared