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Original Research Article

Efficiency of nalbuphine as an adjuvant to bupivancaine in lower limb orthopaedic surgery-a prospective study

Kanhya Lal Gupta[1], Amit Gupta[1]*, Neeraj[2]

[1]Associate Professor, Department of Anesthesia, SMS & R, Greater Noida, Uttar Pradesh, India
[2]Assistant Professor, Department of Anesthesia, GS Medical College, Pilakhwa, Uttar Pradesh, India

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***Correspondence:**
Dr. Amit Gupta,
E-mail: dramitgupta63@gmail.com

ABSTRACT

Background: Spinal Anaesthesia is a well-known technique of performing lower limb orthopaedic surgeries. It has a shorter duration of action and early arising postoperative pain due to which various adjuvant needs to be added and their roles are being evaluated in various studies. Intrathecal opioids act synergistically with local anaesthetics and thus intensifying the sensory block without having any effect on sympathetic blockage. The main aim of present study is to investigate and evaluate the effectiveness of intrathecal nalbuphine (preservative free) as an adjuvant and also the efficacy of nalbuphine for postoperative analgesia and its complications if there are any.
Methods: A total of 60 patients were included in this study belonging to ASA I and ASA II score with normal coagulation profile. Patients were randomly divided into 2 groups of 30 patients each. Group I receiving 3 ml of hyperbaric bupivacaine 0.5%+1.0mgm of nalbuphine (preservative free) injection made in 0.5 ml normal saline intrathecally. Group II received 3 ml of hyperbaric bupivacaine 0.5%+0.5 ml injection Normal saline intrathecally. The following criteria were noted. The onset of sensory blockade and complete motor blockade highest level of sensory blockade, duration of sensory blockade, duration of motor and duration of effective analgesia were recorded. Any hemodynamic alterations were also noted.
Results: The mean time for the onset of sensory blockage was 56 sec in Group I and 59 sec in Group II (control). The difference were statistically insignificant ($p>0.05$). The mean onset of motor blockage was 106 sec in Group I and 208 sec in Group II (control). The difference was statically insignificant. The peak onset time in Group I and Group II was 372 sec and 220 sec respectively ($p>0.05$). Two segment regression times for sensory blockage was prolonged in Group I (118.20±8.56 min) compared to Group II (104.56±15.20 mins).
Conclusions: The duration of postoperative analgesia was 6-8 hours in Group I compared to 3-4 hours in Group II (p value= 0.0001, statistically significant).

Keywords: Bupivancaine, Efficiency, Nalbuphine

INTRODUCTION

Spinal anaesthesia is a well embraced technique for performing lower limb orthopaedic surgeries. It is simpler to perform with rapid onset of action and profound muscle relaxation. Spinal anaesthesia allows for lower drug dosage and lower incidence of failed block.[1,2] Every coin has two sides. Spinal anaesthesia has a shorter duration of action and early arising postoperative pain due to which various adjuvant need to be added and their roles are being evaluated in various studies. Intrathecal administration of adjuvant drugs to local anaesthesia improves quality and duration of spinal blockage and also prolongs postoperative analgesia. Moreover, the dose and amount of local anaesthetic drugs are also reduced during subarachnoid block.[3] Intrathecal opioids act synergistically with local anesthetics and thus intensifying the sensory block without having any effect

on sympathetic blockage. Opioids are commonly added to local anaesthesia for enhancing their effects, decreasing their dosage and therefore decreasing the potential side effects and complications. The duration of postoperative analgesia is also prolonged by them.[4] Nalbuphine, an agonist-antagonist opioid, has the ability to enhance the mu and kappa opioid effects. It was synthesized to produce analgesia without any unwanted mu agonist side effects. Its combination with mu agonist opoids was tried by many researchers in order to decrease the common mu agonist side effects like respiratory depression, undesirable sedation, nausea, vomiting and urinary retention.[5,6]

Only few studies have investigated intrathecal nalbuphine with bupivacaine. The main aim of present study is to investigate and evaluate the effectiveness of intrathecal nalbuphine (preservative free) as an adjuvant and also the efficacy of nalbuphine for postoperative analgesia and its complications, if there are any.

METHODS

The study was conducted in the Base hospital Delhi Cantt and all the selected patients were duly informed about the study and a written informed consent was obtained from all the patients. A total of 60 patients, ASA I and II with normal coagulation profile took part in the study. This study was conducted for a period of 6 months i.e. April 2014 September 2014. All the patients aged between 26-60 years and weighing 60-90 kgs participated in this study.

Exclusion criteria

Patients falling under ASA III or IV were not included in the study. Patients with infection at the injection site, coagulopathy, patients taking anticoagulants or with any preexisting neurological disease, cardiac or respiratory failure, any allergy to LA were also excluded from the study. Any unwilling or uncooperative patient was also excluded. Patients were randomly divided into 2 groups of 30 patients each. Group I receiving 3 ml of hyperbaric bupivacaine 0.5% + 1mgm of nalbuphine (preservative free) injection in 0.5 ml normal saline intrathecally. Group II received 3 ml of hyperbaric bupivacaine 0.5% + 0.5 ml injection Normal saline intrathecally. All the patients fastened for 6-8 hours before the procedure and were put in sitting position leaning forwards for injection. After complete asepsis, dural puncture was performed at L4- L5 interspace or L3-L4 interspace with a 25 gauge Quincke spinal needle.

Patient's blood pressure, ECG and oxygen saturation were monitored all the time after the arrival of the patient to operating room. Ringer lactate solution 10 ml/kg/15 min (preload) were given to all the patients before the procedure. Patients were placed in supine position after giving anaesthesia with head end elevated and an oxygen mask supplying oxygen at the rate of 5L/ min. Advanced equipments and drugs for resuscitation and airway management were kept ready at all the times.

The following criteria were noted. The onset of sensory blockade and complete motor blockade highest level of sensory blockade, duration of sensory blockade, duration of motor and duration of effective analgesia were recorded. The changes in pulse rate, systolic and diastolic blood pressure were recorded at 10-min intervals up to the end of treatment. Visual analog scale (VAS) was noted which ranged from 0 indicating no pain till 10 indicating severe intolerable pain. If general anesthesia was given and the patient was excluded. Complications related to spinal block or drug allergy (hypotension, bradycardia, pruritus, nausea, vomiting, shivering, rash and bronchospasm) were recorded and managed. SPSS software was used for data analysis; student t test was performed to estimate the significance. P value less than 0.05 was considered statistically significant.

RESULTS

A total of 60 patients took part in the study and the demographic data related to the patients like age, weight, height and the duration of surgery were comparable and statistically insignificant (Table 1).

Table 1: Demographic variables related to patients.

Variable	Group I (Bupivacaine + Nalbuphine) (Mean±SD)	Group II(Bupivacaine) (Mean±SD)	P value
Age (years)	27.33±7.01	26.87±6.21	Non-significant
Height (cm)	169.82±6.01	172.10±5.20	Non-significant
Weight (Killogram)	77.91±9.22	79.53±9.87	Non-significant
Duration of surgery (mins)	54.00±6.00	52.29±5.20	Non-significant

The mean time for the onset of sensory blockage (Table 2) was 56 sec in Group I and 59 sec in Group II (control). The difference were statistically insignificant (p>0.05). The mean onset of motor blockage was 106 sec in Group I and 208 sec in Group II (control). The difference also came out to be statically insignificant. The peak onset

time in Group I and Group II was 372 sec and 220 sec respectively (p>0.05). Two segment regression times for sensory blockage was prolonged in Group I (118.20±8.56 min) compared to Group II (104.56±15.20 mins). The duration of postoperative analgesia was 6-8 hours in Group I compared to 3-4 hours in Group II (p value= 0.0001, statistically significant).

Tale 2: Criteria's assessed.

	Group I (Bupivacaine + Nalbuphine) (Mean±SD)	Group II(Bupivacaine) (Mean±SD)	P value
Sensory blockage	56±3.2	59±2.9	>0.05
Onset of motor block	106±1.9	208±2.5	>0.05
Peak onset of motor block	372±2.4	220±2.2	>0.05

Table 3: Hemodynamic criteria's evaluated.

Parameters	Group I (Bupivacaine + Nalbuphine) (Mean±SD)	Group II (Bupivacaine) (Mean±SD)	p-value
Heart Rate	85.16±11.12	75.26±6.8	>0.001
Systolic BP	126.90±10.22	111±2.8	>0.001
Diastolic BP	74±10.02	63±6.1	>0.001

The hemodynamic parameters (Table 3) like heart rate, mean systolic blood pressure, diastolic blood pressure showed a statistically significant difference but they were within normal limits clinically and didn't require any intervention. No side effects or complications were noted in present study, either intraoperatively or postoperatively.

DISCUSSION

With the advancement in medical field, there has been a paradigm shift from the use of general anaesthesia to regional anaesthesia wherever possible. This paradigm shift is mainly due to the increased mortality rate associated with the general anaesthesia. Toxicity associated with high doses of Local anaesthesia is the commonest causes of mortality associated with regional blocks. In order to prevent this dose of Local anaesthesia needs to be reduced so that toxicity can be managed in a better way. In this prospective study, we compared and evaluated the effectiveness of intrathecal nalbuphine (preservative free) as an adjuvant and also the efficacy of nalbuphine for postoperative analgesia and its complications if there are any in patients undergoing lower limb orthopaedic surgery. Many adjuvant opioids have been tried with local anaesthesia to prolong the duration of postoperative analgesia but every opioid has its own set of complications.

Nalbuphine is a mixed agonist – antagonist drug that binds to the kappa receptors in the brain and spinal cord which are involved in nociception.[7] It prolongs the duration of analgesia without affecting the motor and autonomic nervous system.[8] The most common side effects with the use of opioids include pruritis, respiratory depression, nausea, vomiting, urine retention and sedation.[9]

Various animal studies have also been conducted to confirm that Nalbuphine was not neurotoxic. Rawal et al in a sheep model showed that even large doses of 15-24 mg of napbuphine were not associated with hypertensive changes in spinal cord.[10] Later human studies were also conducted to test the efficacy of nalbuphine which confirmed the same results. Lin et al compared the addition of 0.4 mg intrathecal nalbupine to hyperbaric tetracaine with 0.4 mg intrathecal morphine for subarachnoid block and the results showed an improved quality of intraoperative and postoperative analgesia with fewer side effects.[11] In a study by Tiwari et al, they showed that that addition of 0.4 mg nalbuphine significantly prolongs the duration of sensory block and postoperative analgesia.[12] There was no statistically significant difference between the sensory blockage, onset of motor blockage and the peak motor block between the two groups. Statistically significant difference was seen in the hemodynamic parameters but they were within normal limits. In a study by Culebrass et al and Mostafa there were no gross hemodynamic changes throughout the study.[13,14] No patient in our study reported with respiratory depression as it is predominantly mediated by mu receptors and nalbuphine is a mu receptor antagonist.

CONCLUSION

From this study we can conclude that addition of nalbuphine as an adjuvant to intrathecal bupivacaine improves intraoperative analgesia without causing any undue and undesirable side effects and complications.

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