Original Article

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A Comparison of Analgesic Effect of Different Doses of Intrathecal Nalbuphine Hydrocloride with Bupivacaine and Bupivacaine alone for Lower Abdominal and Orthopedic Surgeries

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Abstract

Objective: To compare the analgesic effect of different doses of nalbuphine when added to bupivacaine in spinal anaesthesia. To compare the onset of sensory blockade (time taken form 3, 5 min and then every 5 min until the end of the procedure.

Methods: 100 ASA grade 1 and 2 patients grouped into group A, group B, group C and group D randomly. Age group of 18-60 years. Patient undergoing elective lower abdominal and orthopedic surgery received with Group A : included 25patients with 0.5% hyperbaric bupivacaine 3 cc (15mg) + N.S. 0.2 ml. Group B: included 25 patients with 0.5% hyperbaric bupivacaine (3 cc) 15 mg + 0.8mg nalbuphine + N.S. 0.2 ml. Group C: included 25 patients with 0.5% hyperbaric bupivacaine (3 cc) 15 mg + 1.6mg nalbuphine + N.S. 0.2 ml. Group D: included 25 patients with 0.5% hyperbaric bupivacaine (3 cc) 15 mg + 2.4 mg nalbuphine + N.S. 0.2 ml.

Results: The mean sensory onset of study subjects in group A, B, C and D were 8.4±0.5, 5±0.9, 5.6±1 and 8.2±1.4 respectively and this difference was statistically significant. The mean motor onset of study subjects in group A, B, C and D were 10.2±0.7, 6.8±0.9, 6.1±1.2 and 8.6±1.1 respectively and this difference was statistically significant. The mean sensory duration of study subjects in group A, B, C and D were 176.8±29.3, 282±6.8, 300.2±6.6 and 286.2±9.8 respectively and this difference was statistically significant. The mean time for maximum sensory level of study subjects in group A, B, C and D were 11.5±1, 8.8±0.8, 5.6±1.6 and 8.2±1.2 respectively and this difference was statistically significant. The mean T 10 time of study subjects in group A, B, C and D were 8.5±0.5, 8.7±0.7, 5.6±1.6 and 8.6±1 respectively and this difference was statistically significant. The mean time for 2 segment regression of study subjects in group A, B, C and D were 76.6±2, 92.2±2.3, 95.8±3 and 90.6±4.4 respectively and this difference was statistically significant. The mean motor duration of study subjects in group A, B, C and D were 179.8±8.9, 184.6±6, 203.2±7 and 187±9.9 respectively and this difference was statistically significant. The mean analgesic duration of study subjects in group A, B, C and D were 175.8±4.1, 271.1±7.8, 303.8±9.9 and 279±10.7 respectively and this difference was statistically significant.

Conclusion: We came to conclusion that 0.5% hyperbaric bupivacaine (15mg) with nalbuphine (0.8mg, 1.6 mg, 2.4 mg) in subarachnoid block. Therefore addition of 1.6 mg nalbuphine to 15mg of 0.5% hyperbaric bupivacaine 15 mg in subarachnoid block can be considered safe with minimum complication, and provides excellent quality and longer duration of postoperative analgesia with good sedation compared with 0.8 mg and 2.4 of nalbuphine. So it is useful for prolonged duration of postoperative analgesia.

Keywords: Analgesic Effect; Intrathecal Nalbuphine; Orthopedic Surgeries.

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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 surgical stress response peaks during the postoperative period and has major effects on almost all body systems. A pain-free and stress free postoperative period definitely helps in early mobilization and recovery, thereby reducing morbidity and mortality.

Intrathecal opioid is widely used in treating intraoperative, postoperative, traumatic, obstetric, and chronic cancer pain. The technique of intrathecal opioid administration along with local anesthetics has been studied extensively and found to provide superior quality of analgesia in a variety of surgical procedures.[1,2]

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 solutions within the subarachnoid space determines the extent of neural blockade produced by spinal anaesthesia.

This study is designed to quantitatively examine the effects of adding nalbuphine 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 (25 in each group) were recruited. It was a double blind, prospective, randomized observational phase IV controlled study in patients undergoing lower limb orthopedic 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 Anesthesiologists (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 four groups i.e. Group – A (25), B (25), C (25) and D (25).

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, B, C and D to achieve optimum randomization.

Procedure

After the optimum randomization, the patients in four groups were given sitting/lateral position depending upon the operation to be performed. Spinal anaesthesia 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, 1.6 mg and 2.4 mg nalbuphine 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 (SpO_2) were recorded before and then after dural puncture every 2 minutes for first 10 minutes and there after 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 there after 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 (SpO_2), 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 4 mg.

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 four 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 in pulse rate, systolic blood pressure and diastolic blood pressure between the four groups. The mean sensory onset of study subjects in group A, B, C and D were 8.4±0.5, 5±0.9, 5.6±1 and 8.2±1.4 respectively

Table 1: Distribution of Parameters according to Study groups.

Parameters (Mean±SD)	Group A	Group B	Group C	Group D	p value
Sensory onset	8.4±0.5	5±0.9	5.6±1	8.2±1.4	<0.001*
Motor onset	10.2±0.7	6.8±0.9	6.1±1.2	8.6±1.1	<0.001*
Sensory duration	176.8±29.3	282±6.8	300.2±6.6	286.2±9.8	<0.001*
Time for max sensory level	11.5±1	8.8±0.8	5.6±1.6	8.2±1.2	<0.001*
T 10 time	8.5±0.5	8.7±0.7	5.6±1.6	8.6±1	<0.001*
Time for 2 seg regress	76.6±2	92.2±2.3	95.8±3	90.6±4.4	<0.001*
Motor block duration	179.8±8.9	184.6±6	203.2±7	187±9.9	<0.001*
Analgesia duaration	175.8±4.1	271.1±7.8	303.8±9.9	279±10.7	<0.001*

and this difference was statistically significant. The mean motor onset of study subjects in group A, B, C and D were 10.2±0.7, 6.8±0.9, 6.1±1.2 and 8.6±1.1 respectively and this difference was statistically significant. The mean sensory duration of study subjects in group A, B, C and D were 176.8±29.3, 282±6.8, 300.2±6.6 and 286.2±9.8 respectively and this difference was statistically significant. The mean time for maximum sensory level of study subjects in group A, B, C and D were 11.5±1, 8.8±0.8, 5.6±1.6 and 8.2±1.2 respectively and this difference was statistically significant.

The mean T10 time of study subjects in group A, B, C and D were 8.5±0.5, 8.7±0.7, 5.6±1.6 and 8.6±1 respectively and this difference was statistically significant. The mean time for 2 segment regression of study subjects in group A, B, C and D were 76.6±2, 92.2±2.3, 95.8±3 and 90.6±4.4 respectively and this difference was statistically significant. The mean motor duration of study subjects in group A, B, C and D were 179.8±8.9, 184.6±6, 203.2±7 and 187±9.9 respectively and this difference was statistically significant. The mean analgesic duration of study subjects in group A, B, C and D were 175.8±4.1, 271.1±7.8, 303.8±9.9 and 279±10.7 respectively and this difference was statistically significant.

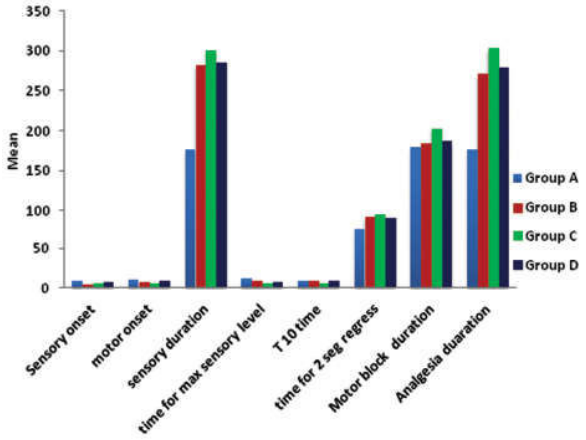

Fig. 1: Distribution of Parameters according to Study groups.

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. Nalbuphine as they have agonist and antagonist actions, have minimal respiratory depressant effects, while providing analgesic effect by agonist actions.

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] In addition it has ceiling effect on respiratory but not on analgesia.[6]

Manjula R et al[7] conducted a cross sectional study to evaluate the different characteristics in two groups. One Group received Bupivacaine only and other group received bupivacaine plus nalbuphine. The mean analgesia duration was 180 ± 5.85 and 260 ± 5.64 minutes in Group B and Group N respectively and this difference was statistically significant. This indicates that the duration of the analgesia is enhanced by using nalbuphine along with bupivacaine.

Gurunath BB et al[8] studied the post operative analgesic efficacy of intrathecal Fentanyl (Group C) compared to Nalbuphine (Group N) with bupivacaine in spinal anaesthesia for lower abdominal surgeries at their centre. Rescue analgesia was given at 268.33 ± 44.44 min in nalbuphine group which was significantly prolonged as compared to fentanyl group in which rescue analgesia was given at 220.91 ± 24.36 min.

Duration of Analgesia

The mean analgesic duration of study subjects in group A, B, C and D were 175.8±4.1, 271.1±7.8, 303.8±9.9 and 279±10.7 respectively and this difference was statistically significant. This shows that there was significant longer duration of analgesia with intrathecal 1.6 mg nalbuphine. This is considerably longer duration of analgesia when compared to using local anaesthetic alone.

Conclusion

After the above comparative study, we came to conclusion that 0.5% hyperbaric bupivacaine (15mg) with nalbuphine (0.8mg, 1.6 mg, 2.4 mg) in subarachnoid block.

Leads to prolonged duration of Sensory block as compared to 0.5%hyperbaric bupivacaine, which Leads to prolonged duration of analgesia as compared to 0.5% hyperbaric bupivacaine.

Therefore addition of 1.6 mg nalbuphine to 15mg of 0.5% hyperbaric bupivacaine 15 mg in

subarachnoid block can be considered safe with minimum complication, and provides excellent quality and longer duration of postoperative analgesia with good sedation compared with 0.8 mg and 2.4 of nalbuphine. So it is useful for prolonged duration of postoperative analgesia.

Advantages

- Longer duration of analgesia
- Better sedation
- Minimal side effect
- Reduced postoperative analgesic requirement.

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