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A Comparative Study of Intrathecal Bupivacaine & Bupivacaine with Nalbuphine for Lower Limb Major Orthopaedic Surgery

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Abstract

Introduction: *Opioids as adjuvant to local anesthetics used intrathecally provides very good analgesia. Explanation behind this combination is that these two drugs act at different sites and provide better analgesia.*

Aim & Objective: *To evaluate the efficacy of nalbuphine as adjuvant to intrathecal bupivacaine on onset, duration of sensory & motor blockade and its side effects.*

Materials & Methods: *The study was a prospective randomized controlled study, done in Katihar Medical College for a period of 1 year after approval from Institutional ethical committee. Sample size of the study was 60. Patients were divided into two groups (A and B). Both the study and control groups were comparable in demographic parameters like age, weight and height. Group A (n=30) received 3ml (15mg) 0.5% Hyperbaric bupivacaine + 0.5mg (0.5ml) nalbuphine. Group B (n=30) received 3ml (15mg) 0.5% Hyperbaric Bupivacaine+ 0.5 ml normal saline.*

Results: *The mean onset time of sensory block (T10) in the nalbuphine group was found to be 1.93±0.45 mins whereas in the control group it was found to be 3.30±0.54 mins. The mean onset time of motor block was found to be 2.97±0.56 mins in the nalbuphine group whereas in the control group it was found to be 4.50±0.63mins. The statistical analysis showed significantly faster onset of sensory and motor blockade in nalbuphine group (p value of 0.0001). The meantime of regression of sensory block in the nalbuphine group was 4.65±1.03 hours, whereas in the control group it was 3.21±0.57 hours. Mean duration of motor blockade in the nalbuphine group was 2.87±0.39hours and in the control group was2.05±0.34hours. Statistical analysis was done and p value (0.0002) was found significant.*

Conclusion: *Nalbuphine added to bupivacaine has an earlier onset of action, prolonged sensory and motor blockade compared to bupivacaine alone. Nalbuphine has lesser side effects as compared to other adjuvants in use now a days.*

Introduction

Subarachnoid blocks are mostly preferred for lower limb and infra-umbilical surgeries. To prolong the duration of block, addition of various adjuncts to local anesthetics have been tested for intrathecal use. The combination of opioid and local anesthetics used intrathecally is found to provide better analgesia and prolonged duration of block as these two drugs act at different sites. Pure mu agonists like morphine and fentanyl are the

commonly used opioid adjuncts. It's not been long since nalbuphine, a mixed opioid, kappa agonist and mu antagonist, has been in use, hence the topic of our study.

Aim & Objective

Aim of the study is to evaluate the efficacy of nalbuphine as adjuvant to intrathecal bupivacaine. The Primary Objective is to observe effect on time of onset and duration of sensory & motor blockade when nalbuphine is added to bupivacaine. The secondary objective is to observe the side effects of nalbuphine as an additive.

Materials & Methods

The study was a prospective randomized controlled study, done in Katihar Medical College for a period of 1 year after approval from Institutional ethical committee. Written informed consent was taken from all the patients. Sixty patients of either sex aged 30-60 years of American Society of Anesthesiologists (ASA) class 1 or 2 posted for lower limb major orthopedic surgeries (Total hip arthroplasty, Total knee replacement, Pelvic fracture, Ankle repair) were included. Patient refusal, infection at subarachnoid injection site, patients with neurological & musculoskeletal disease, patients with bleeding disorders, patients on anticoagulants, pregnancy, history of allergy to local anesthetics were excluded.

Patients were randomized 1:1 using computer generated series into two groups of 30 each. Allocation concealment was done using sealed opaque envelope technique and study drug was prepared by an anesthesiologist not involved in the study. Group A (n=30) received 3ml (15mg) 0.5% Hyperbaric bupivacaine + 0.5mg (0.5ml) nalbuphine. Group B (n=30) received 3ml (15mg) 0.5% Hyperbaric Bupivacaine+ 0.5 ml normal saline.

Thorough pre-anesthetic check-up was done a day prior to surgery that is, detailed history, general physical examination, systemic examination, airway assessment and lumbar spine examination. Patients were kept nil by mouth for 8 hours prior to surgery.

Anesthesia workstation, equipment for subarachnoid block and equipment for resuscitation were kept ready. Patient was shifted to operation room and counseled regarding the procedure. Multipara monitor was attached. Baseline heart rate, blood pressure, oxygen saturation were recorded and monitored throughout the procedure. Intravenous line was secured with 18G/20G intravenous cannula and injection ringer lactate was administered according to Holliday-Segar formula.

The patient was put in lateral decubitus position. Under all aseptic precautions, lumbar puncture was done in the midline at L3-L4 intervertebral space with 27G Quincke needle. After confirmation by free aspiration of cerebrospinal fluid, the predetermined volume of the study drug was injected intrathecally and the patient was turned supine.

Sensory block was assessed by pinprick method in the mid-clavicular line using 27G needle, every minute until the block reached T6dermatome. After that, level was checked every 2 mins until maximal sensory block was attained.

Grades of Sensory Blockade

Grade 0 - Sharp pain felt
Grade 1 -Analgesia, dull sensation felt
Grade 2 -Anesthesia, no sensation felt

Quality of motor block was assessed by **modified Bromage scale.**

Grade 0-no motor blockade, able to lift the leg at the hip.
Grade 1 -Able to flex the knee and ankle but not able to lift the leg at the hip (hip blocked)
Grade 2-Able to move the foot only (hip and knee blocked)
Grade 3 - Unable to move even the foot (hip, knee and ankle blocked).

Surgery was started when complete anesthesia was attained. After the completion of the surgery,

both sensory and motor level were noted. Two segment regression time from the maximal level and regression to level L1 was also noted.

Data was recorded in Microsoft Excel software. Group comparisons were made using t-test. Chi-square test was used for categorical variables. Statistical Package for Social Sciences (SPSS) version 21 was used for analysis. $P < 0.05$ was taken as the cut off for statistical significance.

Results

In our study, the demographic characteristics age, sex, height and weight were comparable. Significant differences were not seen between the two groups in terms of ASA class, type & duration of surgery.

The mean on set time of sensory block (T10) in the nalbuphine group was found to be 1.93±0.45 mins whereas in the control group it was found to be 3.30±0.54 mins. The mean onset time of motor block was found to be 2.97±0.56 mins in the nalbuphine group whereas in the control group it was found to be 4.50±0.63 mins. The statistical analysis showed significantly faster onset of sensory and motor blockade in nalbuphine group (p value of 0.0001). The meantime of regression of sensory block in the nalbuphine group was 4.65±1.03 hours, whereas in the control group it was 3.21±0.57 hours. Mean duration of motor blockade in the nalbuphine group was 2.87±0.39 hours and in the control group was 2.05±0.34 hours. Statistical analysis was done and p value (0.0002) was found significant.

Conclusion

Nalbuphine added to bupivacaine has an earlier onset of action, prolonged sensory and motor blockade compared to bupivacaine alone. Nalbuphine has lesser side effects as compared to other adjuvants in use now a days.

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