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COMPARITIVE STUDY BETWEEN OF INTRARHECAL BUTORPHANOL AND INTRATHECAL NALBUPHINE AS ADJUVANTS TO 0.5% HYPERBARIC BUPIVACAINE

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ABSTRACT

BACKGROUND : spinal opiates have been of much interest in recent times as they potentiate the effect of local anaesthetic agent and provide prolonged post operative analgesia.

METHODS : A randomized clinical trial was conducted in Alluri Sitarama Raju academy of medical sciences, Eluru between 2017 to 2019. 60 patients scheduled for elective lower abdominal and orthopedic surgeries were randomly divided into two groups. Group B received 0.2 mg butorphanol and Group N received 0.8 mg Nalbuphine. Onset of sensory and motor blockade, duration of two segment regression and duration of analgesia were assessed.

RESULTS : It was found from our study that in nalbuphine group there was early onset of motor blockade, duration of analgesia, duration of motor blockade and time for two segment regression were significantly prolonged when compared to butorphanol group.

CONCLUSION: We conclude that nalbuphine is a better neuraxial adjuvant compared to butorphanol for providing early onset of sensory and motor blockade and prolonged duration of analgesia and motor blockade.

KEYWORDS : Spinal anaesthesia, 0.5 % Hyperbaric Bupivacaine , opiods

INTRODUCTION

Pain is "an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage".

Spinal anaesthesia provides profound muscular relaxation which is ideal for intra-abdominal and orthopedic procedures. Spinal anaesthesia with hyperbaric bupivacaine 0.5% is a popular method. Addition of opioids to local anesthetics is commonly practiced. Though the opioids reduce the toxicity and cardiovascular effects of local anaesthetics this type of combination may bring about additional undesirable problems like itching, nausea and vomiting or respiratory depression.

Bupivacaine is an amide local anesthetic. It blocks the generation and conduction of nerve impulses ,presumably by increasing the threshold for electrical excitation in the nerve, by slowing the propagation of the nerve impulse, and by reducing the rate of rise of the action potential.
Nalbuphine hydrochloride is a synthetic opioid agonist-antagonist analgesic. It has the potential to maintain or even enhance μ-opioid based analgesia while simultaneously mitigating the μ-opioid side effect. The plasma half-life of nalbuphine is 5 hours and in clinical studies the duration of analgesic activity has been reported to range from 3 to 6.

Butorphanol is a synthetic agonist antagonist opioid analgesic exhibiting partial agonist and antagonist activity at the μ- opioid receptor, as well as partial agonist activity at the κ-opioid receptor.

The plasma half-life of butorphanol is 2-3 hours. The duration of analgesic activity has been reported to range for 2-3 hours.

MATERIALS AND METHODS

The study was undertaken in Alluri Sitarama Raju Academy of Medical Sciences, after obtaining ethical committee clearance as well as informed consent from all patients.

Sixty patients of ASA grade 1 & 2, between the age of 25 to 55 years were allocated randomly into two groups in patients undergoing elective lower abdominal and orthopedic surgeries between 2017 to 2019.

Group B: Patients in this group were given Inj. Bupivacaine (15mg) + Inj. butorphanol (0.2 mg) intrathecally.

Group N: Patients in this group were given Inj. bupivacaine (15 mg) + Inj. nalbuphine (0.8mg) intrathecally.

INCLUSION CRITERIA

- ASA I & ASA II patients between age 25-55years, belonging to both sexes.
- No known history of allergy, sensitivity or other form of reaction to local anaesthetics.
- Patient willing to sign informed consent

EXCLUSION CRITERIA

- Patients not willing to participate in the study
- Those with known sensitivity to local anaesthetics
- Patients with local infection at the site of injection
- Uncooperative patients

PROCEDURE

Standard preanesthetic evaluation performed and informed consent was taken for spinal anaesthesia.

Pre-medication with Inj. ondansetron 4mg and Inj. glycopyrrolate 0.2 mg was given intravenously and preloaded with ringer lactate solution at 10ml/kg.

Patients monitored for oxygen saturation, ECG, heart rate, blood pressure and mean arterial pressure.

Under strict aspetic conditions ,Subarachnoid block was given with 25G quinckes needle in left lateral position at L3-L4 space. The study solution was administered over 10 seconds. Patient was repositioned to supine position immediately after injection and tested for level of sensory blockade. Sensory blockade was tested using pinprick method with a blunt tipped 27G needle at every minute for first 5 mins and every 5 mins for next 15 mins and every 10 mins for next 30 mins and every 15 mins till the end of surgery and thereafter every 30 mins until sensory block is resolved.

Quality of motor blockade was assessed by modified Bromage scale.

Group N (Nalbuphine hydrochloride group) :received 15 mg of 0.5% hyperbaric bupivacaine with0.8 mg of nalbuphine hydrochloride.

Group B(Butorphanol group):received 15 mg of 0.5% hyperbaric bupivacaine with 0.2 mg butorphanol.

STATISTICAL ANALYSIS

- A sample size of 30 patients per group was selected randomly. The independent sample T – test procedure compares means for two groups. Results are expressed as means and standard deviations. The comparison of normally distributed continuous variables between the groups was performed using one-way analysis of variance (ANOVA).
- P < 0.05 was considered to be significant.
- Statistical software used was SPSS 20, excel data analysis tool pack, MS word and excel has been used to generate graphs and tables.

PARAMETERS MEASURED

- ONSET OF SENSORY BLOCKADE
- ONSET OF MOTOR BLOCKADE
- DURATION OF ANALGESIA
- DURATION OF MOTOR BLOCKADE
- TWO SEGMENT REGRESSION

ONSET OF SENSORY BLOCKADE

DRUG	MEAN	STANDARD DEVIATION
NALBHUPHINE	2.57	0.68
BUTORPHANOL	2.8	0.66

t- value=1.17 & p>0.1

The mean time of onset of sensory blockade in group-N(Nalbuphine) was 2.57mins, and in group B (Butorphanolgroup) was 2.8mins. There was no statistically significant difference between group N and group B (p>0.1).

ONSET OF MOTOR BLOCKADE

DRUG	MEAN	STANDARD DEVIATION
NALBHUPHINE	5.33	0.48
BUTORPHANOL	10.80	2.2

t value=13.34 & p<0.0005

The mean time taken for the onset of motor blockade was 5.33 mins in group N and in group B 10.80mins.There was a statistically significant difference between group N and group B. (p<0.0005).

Duration of Analgesia

Drug	Mean	Standard deviation
NALBUPHINE	403.8	15.25
BUTORPHANOL	373.1	18.94

The mean duration of analgesia was 403.77 mins in group N ,313.10 mins in group B. There was a statistically highly significant difference between group N and group B(p<0.0001).

DURATION OF MOTOR BLOCKADE

Drug	Mean	Standard deviation
NALBUPHINE	301.8	15.8
BUTORPHANOL	268.9	8.4

t value =10.1 & p < 0.0005.

The minimum duration of motor block was 257 mins in group N, 255 mins in group B. The maximum duration of motor block was 322 mins in group N, 280 mins in group B. There was a statistically highly significant difference between group N and group B (p<0.0005).

TWO SEGMENT REGRESSION

DRUG	Mean	Standard deviation
NALBUPHINE	121.1	7.11
BUTORPHANOL	102.07	7.57

T value-10.07 and p <0.0001

The mean time taken for regression of sensory block by two segments was 121.10mins in group N,102.07 mins in group B. There was a statistically high significant difference between group N and group B.

DISCUSSION

Spinal anaesthesia has been commonly used for lower abdomen and lower limb surgeries because of its simplicity, speed, reliability and minimal exposure to depressant drugs.

Adding, an intrathecal adjuvant to local anesthetics forms a reliable method to prolong the duration of anaesthesia. They are commonly added to local anaesthetics for potentiating their effects, reducing their doses, thereby reducing their complications and side effects and offer haemodynamic stability. They also prolong the duration of postoperative analgesia.

There is a great similarity between butorphanol and nalbuphine regarding the chemical nature,also both have the same mode of action on Opioid receptors.

So we decided to compare the effects of nalbuphine hydrochloride (opioid) with butorphanol (opioid), when used intrathecally as an adjuvant to bupivacaine in spinal anaesthesia.

In our study 60 patients, of age between 20 and 55 years, were divided into two groups of 30 each. Group B was given Inj butorphanol 0.2mg with Inj. bupivacaine 15 mg intrathecally and Group N was given Inj. nalbuphine 0.8 mg with Inj. bupivacaine 15 mg intrathecally.

Demographic data comparing age, sex, height, weight shows no statistical difference among the groups.

The mean duration of onset of sensory blockade for nalbuphine was 2.57 min and butorphanol was 2.80 min (p>0.1) indicating that there was no significant difference between these two groups. Sandip Sinha et al , observed that the mean duration of onset of sensory blockade of nalbuphine was 2.60±0.77 min and butorphanol was 2.70±0.65min with the study of 0.4 mg of nalbuphine and 25 mcg of butorphanol as adjuvant to 2.8 ml of 0.5% isobaric levobupivacaine respectively indicating that there was no statistically significant difference between two groups(p=0.892). In this discussion we conclude that, both the drugs are equal in their action of onset of sensory blockade.

The mean duration of onset of motor blockade of nalbuphine was 5.33 min and butorphanol was 10.80 min (p<0.0005) indicating that there was highly significant difference between two groups. Shehla Shakooh et al , used nalbuphine 0.8 mg as an adjuvant to intrathecal hyperbaric bupivacaine (0.5%) for various lower abdominal surgeries and lower limb surgeries showed the mean duration of nalbuphine was 3.47±1.01concluded that nalbuphine shortens the onset of motor blockade. Hence, the results of our study are comparable to the above study.

In our study the mean time for two segment regression for nalbuphine was121.10 min and for butorphanol 102.07 min (p<0.0005) indicating that nalbuphine has prolonged time for two segment regression. Mukherjee et al, in his study shows that the mean time for two segment regression of nalbuphine 0.8 mg is 153.3±6.05 and concluded that time for two segment regression was prolonged in 0.8 mg nalbuphine group compared to 0.2 mg,0.4 mg of nalbuphine as adjuvant to 0.5% hyperbaric bupivacaine intrathecally. In this discussion we conclude that, time for two segment regression is prolonged with nalbuphine.

In our study, the mean duration of analgesia for nalbuphine 0.8 mg was 403.77 min and for butorphanol was 373.10min (p<0.0001) indicating that duration of analgesia is statistically higher in nalbuphine group. Neelam singh et al[27] compare the efficacy of intrathecal nalbuphine 0.6 mg and fentanyl 30 mcg as adjuvant to 2.8 mi of 0.5% hyperbaric bupivacaine shows the mean duration of analgesic for nalbuphine was 404.5±22.82 min and fentanyl was 295.5±21.82 min and concluded that nalbuphine has longer duration of analgesia. Thus, the results of our study are similar to above study.

Duration of motor blockade

In this study, the mean duration of motor blockade for nalbuphine group was 301.77 min and butorphanol was 268.50 min (p<0.0005) indicating that nalbuphine has prolonged duration of motor blockade. Pallavi Ahluwalia[11] compared 0.8 mg nalbuphine as adjuvant to 2.5 ml of 0.5% hyperbaric bupivacaine shows the mean duration of motor blockade of nalbuphine group was 256.41±33.41 min and for

bupivacaine group was 178.67±28.34min ($p<0.0001$) indicating that duration of motor block was significantly higher in nalbuphine group.

CONCLUSION

From the present study it can be concluded that comparison of intrathecal nalbuphine in the dose of 0.8 mg and intrathecal butorphanol in the dose of 0.2 mg along with 3 ml 0.5% heavy bupivacaine in patients undergoing elective lower abdominal and orthopedic surgeries.

- Decreases the onset time for motor blockade
- Increases the duration of analgesia
- Produces prolonged sensory blockade
- Produces prolonged motor blockade
- Increases time for two segment regression

It was not associated with cardiovascular side effects, respiratory depression. Since nalbuphine and butorphanol when used intrathecally along with bupivacaine significantly prolonged the duration of analgesia and there was also clinically significant difference between nalbuphine and butorphanol on spinal block characteristics, intrathecal nalbuphine was better than butorphanol with regards to onset and duration of both sensory and motor blockade as well as duration of analgesia. Hence, nalbuphine is a better neuraxial adjuvant compared to butorphanol for providing early onset of sensory and motor blockade, earlier onset of maximum level of sensory blockade and prolonged duration of analgesia.

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