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Anesthesiology

A STUDY TO COMPARE THE EFFECT OF NALBUPHINE AND BUTORPHANOL AS AN ADJUVANT TO INTRATHECAL 0.5% HYPERBARIC BUPIVACAINE FOR LOWER LIMB SURGERY

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ABSTRACT **BACKGROUND:** Spinal Anesthesia is the preferred mode of anesthesia for surgeries performed on lower abdomen, pelvis and lower limbs. Adjuvants allow multiple benefits, most significant being longer duration of anesthesia and post-operative analgesia. **AIM:** A study to compare the effect of nalbuphine and butorphanol as an adjuvant to intrathecal 0.5% hyperbaric bupivacaine for lower limb surgery. **OBJECTIVE:** To compare the mean onset of sensory and motor blockade in both the groups, the duration of blockade and to assess the requirement of analgesia post operatively in both the groups. **MATERIALS AND METHODS:** Sixty participants between 25-55 years belonging to ASA grade I/II posted for elective surgery were assigned to : group N (n=30) : Bupivacaine (0.5%) hyperbaric (15mg) + nalbuphine 0.8mg (0.1ml) and group B (n=30) : Bupivacaine (0.5%) hyperbaric (15mg) + butorphanol 200mcg .Onset of motor and sensory blockade, mean period of sensory/motor blockade, hemodynamic parameters and postoperative analgesic requirement were compared. **RESULT:** The onset of sensory blockade was comparable in both the groups. The onset of motor blockade was earlier in Group N compared to Group B. Duration of block and post-operative analgesia was significantly higher for Group N. Hemodynamic parameters and adverse effects were comparable. **CONCLUSION:** When compared butorphanol , Nalbuphine as a adjuvant to spinal anesthesia provided prolonged the duration of block and postoperative analgesia

KEYWORDS : Spinal anesthesia, Nalbuphine, Butorphanol, Bupivacaine

INTRODUCTION

Spinal anaesthesia is the most commonly performed neuraxial blockade for surgeries involving lower abdomen, lower limbs, pelvis, ceaserean section. Subarachnoid block has higher safety and cost-effectiveness than general anaesthesia. Additionally, it prevents the use of several pharmaceuticals, airway manipulation, an increased risk of aspiration, hemodynamic changes linked to stress responses from laryngoscopy and intubation, and a lengthier recovery time.

To improve clinical effectiveness, duration of blockage, and post-operative analgesic properties, a number of intrathecal adjuvants to local anaesthetic drugs have been used. Opioids as adjuvants provide analgesic effect by a number of central and peripheral mechanisms, primarily by attenuating C-fibre associated nociception which is not dependent on supraspinal mechanism. This is coined as “synergistic analgesia”.

Nalbuphine is a kappa-opioid receptor agonist and a partial mu-opioid receptor antagonist. Analgesic properties are mediated through agonist activity at the kappa-opioid receptor. Because of this unique mixed agonist-antagonist opioid receptor activity of nalbuphine, it provides analgesia with less nausea, pruritus, and respiratory depression when compared to morphine. 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 Hrs. Used for management of moderate to severe pain, peri operative and post operative analgesia, supplement to balanced anaesthesia, obstetrical analgesia during labour and delivery. The most common side effects are sedation, sweating, nausea, vomiting, dizziness, vertigo, dry mouth, or a headache Butorphanol is a synthetic mixed 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 effect range from 2 to 3 Hrs.

Intrathecal Butorphanol potentiates Bupivacaine induced sensory block and reduces the analgesic requirement in the early post operative period without prolonging motor block recovery time.

MATERIAL AND METHODS:

A randomized comparative study was conducted in government general hospital, Kakinada over a period of august 2022 to September 2022. After attaining ethical committee approval 60 subjects were taken for the study with ASA grade I and II aged between 25-55 years belonging to both the genders.

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

GROUP B: Inj 0.5% hyperbaric bupivacaine (15mg)+ Inj Butorphanol 0.2mg intrathecally.

GROUP N: Inj 0.5% hyperbaric bupivacaine (15mg)+ Inj Nalbuphine 0.8mg intrathecally.

After taking informed consent. The patient was shifted to operation theatre. Standard monitors like were connected and baseline vitals were taken. Patient was pre-medicated with Inj. ondansetron 4mg and Inj. glycopyrrolate 0.2 mg was give intravenously and preloaded with ringer lactate solution at 10ml/kg.

GROUP B received Inj. 0.5% hyperbaric Bupivacaine(15mg) + Inj Butorphanol(0.2mg) intrathecally.

GROUP N(30) received Inj 0.5% Hyperbaric Bupivacaine(15mg) + Inj Nalbuphine (0.8mg) intrathecally HR, SBP, DBP, SpO2 were noted at 0, 2, 5, 10, 15, 20, 30, 60, 90, 120 mins.Mean onset time of sensory blockade was noted as point of drug administration to absence of appreciation of pin prick at T10 after which surgery was started. Total sensory blockade duration was considered from point of onset of sensory blockade to regression of level by two segments.

Mean onset time of motor blockade was assessed via Modified Bromage scale was noted from point of drug administration to complete grade 3 motor blockade. Total motor blockade time noted as the duration till effect reduced to grade 0 blockade pain score was assessed by visual analogue scale (VAS). Duration of analgesia was

considered from the time of intrathecal injection to when VAS ≥4. Inj diclofenac sodium 75mg intravenously was given for rescue analgesia.

STATISTICALANALYSIS

A sample size of 30 patients per group was selected randomly. The independent sample T – test was used to compare means for both 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.

RESULTS AND OBSERVATION:

Onset of sensory blockade

DRUG	MEAN	STANDARD DEVIATION	P VALUE
NALBUPHINE GROUP N	2.57	0.68	0.1
BUTORPHANOL GROUP B	2.8	0.66	0.1

Onset of motor blockade

DRUG	MEAN	STANDARD DEVIATION	P VALUE
NALBUPHINE GROUP N	5.33	0.46	0.005
BUTORPHANOL GROUP B	10.8	2.2	0.005

DURATION OF MOTOR BLOCKADE

DRUG	MEAN	STANDARD DEVIATION	P VALUE
NALBUPHINE GROUP N	301.8	15.8	0.005
BUTORPHANOL GROUP B	268.9	8.4	0.005

TWO SEGMENT REGRESSION

DRUG	MEAN	STANDARD DEVIATION	P VALUE
NALBUPHINE GROUP N	121.1	7.11	0.005
BUTORPHANOL GROUP B	102.7	7.57	0.005

DURATION OF ANALGESIA

DRUG	MEAN	STANDARD DEVIATION	P VALUE
NALBUPHINE GROUP N	403.8	15.25	0.0001
BUTORPHANOL GROUP B	373.1	18.94	0.0001

The hemodynamic parameters remained statistically non significant both intra and post operatively for both groups (p>0.05) The adverse event profile was comparable for both groups.

DISCUSSION

In our review of the literature, we found that butorphanol intrathecally was used very infrequently and that most trials ranged in butorphanol dosage from 25 to 200 mcg. Butorphanol was used as an adjuvant at a dose of 200mcg by N. Gopal Reddy et al. (2015), Kumkum Gupta et al. (2015), and B. Durga Venkatram et al. (2019), and 300 mcg was used by Vishva Darshanbhai Shah et al. (2020) without experiencing any negative side effects.

In the current study, we used 15 mg (3 ml) of hyperbaric bupivacaine (0.5%) in combination with 0.8 mg of nalbuphine and 0.2 mg of butorphanol as intrathecal adjuvants. We found that both groups were comparable in terms of age, gender, weight, and A.S.A. grade, and this difference was not statistically significant (p value > 0.05).

The time onset of sensory blockade was comparable & statistically non significant in both groups(p value > 0.1). The average period of sensory block (2 segment regression) was notably higher with nalbuphine which was statistically significant (p=0.005). The mean duration of analgesia was statistically significant and prolonged in nalbuphine group. (p=0.0001).

Sandip Sinha et al. (2018)[9] employed a lesser dose of butorphanol (25mcg) and nalbuphine (0.4mg) in infraumbilical operations and observed a similar onset of sensory blockage, with the duration of regression by two segments being significant and delayed with nalbuphine. Additionally, nalbuphine had a longer mean time to analgesia, which was very significant (p 0.05). According to B. Durga Venkatram et al. (2019), the duration of the sensory blockade was longer for nalbuphine (0.8mg), which was highly statistically significant, whereas the mean time of sensory onset between nalbuphine (0.8mg) and butorphanol (200mcg) was comparable and statistically non significant. While B. Durga Venkatram et al (2019) noted that the mean duration of analgesia with nalbuphine was significantly longer than butorphanol, Shahedha Parveen et al (2015)observed a similar duration of requirement of rescue analgesia with nalbuphine(1mg) as an adjuvant compared with plain bupivacaine in her study. When performing infraumbilical surgeries, Pallavi Ahluwalia et al. (2015) and Vishva Darshanbhai Shah et al. (2020) utilised similar drugs and saw that rescue analgesia took less time with nalbuphine (0.8mg) and butorphanol (300mcg) respectively as compared to our study.

In contrast to our observations, Sagar S M et al (2013) found that the two-segment regression time was non-significant in the nalbuphine (0.8mg) group compared to the butorphanol (25mcg) group and both having high significance (p0.001) against the group administered hyperbaric bupivacaine without adjuvant. The mean length of analgesia in both groups with the adjuvants employed in this trial was also comparable. Both the time period and the onset of the motor block were statistically significant in the current study, with the onset occurring faster in the nalbuphine group than the butorphanol group (p 0.0001) and the duration of the block lasting longer in the nalbuphine group than the butorphanol group (p 0.0001).

Similar findings on the onset and duration of motor blockade were made by Akash Nirmal et al. (2019), Pallavi Ahluwalia et al. (2015), Sandip Sinha et al. (2018), and B. Durga Venkatram et al. (2019). Sagar S. M. et al. (2013)found, in contrast to our study, that the difference in the mean duration of the onset of motor blockage between butorphanol and nalbuphine was statistically insignificant. Additionally, nalbuphine's motor block duration was statistically insignificant. Both preoperatively and postoperatively, the variation in vital parameters between the two groups in the current study was statistically insignificant. (p>0.05). Hypotension, bradycardia, nausea, and vomiting were comparable between the two groups for other intraoperative adverse events.

CONCLUSION

From overall observation and result after comparing with other studies, we can conclude that nalbuphine 0.8mg is found to be provide longer duration of analgesia compared to butorphanol 0.2mg as an adjuvant for spinal anaesthesia for elective lower limb surgeries.

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