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Comparison of Intrathecal Nalbuphine Versus Intrathecal Buprenorphine As An Adjuvant to Intrathecal Bupivacaine for Postoperative Analgesia in Patients Undergoing Lower Abdominal Surgeries,

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Abstract
Objective*: To evaluate and compare the characteristics of spinal block, its postoperative analgesic effects, using intrathecal inj. Bupivacaine 0.5% and its combination with nalbuphine or buprenorphine in patients undergoing lower abdominal surgery.*
Methods*: Sixty patients aged 30-60years scheduled for elective lower abdominal surgeries randomly received hyperbaric bupivacaine 0.5% 2.6 ml (group BN control, n = 30) with buprenorphine 60 micrograms [DOSAGE ERROR CORRECTED], or nalbuphine 0.8mg [DOSAGE ERROR CORRECTED] with hyperbaric bupivacaine 0.5% 2.6 ml(group BN, n = 30). Characteristics of spinal block, hemodynamic stability, postoperative analgesia.*
Results*: The mean time for Effective analgesia (VAS 0-3) was 285±94. 46 min in group BN as compared to 383.67 ± 79.20 min in group BB. This was statistically and clinically significant in this study (p<0.001). The mean duration of requirement of first rescue analgesia in Group BN (354±106.69) and Group BB (425±81.53) showed statistically significant difference (P=0. 0053), this has highlighted the fact that Group BB had prolonged post-operative analgesia.*
Conclusion*: Present study shows effective analgesia in BB group is 383.67 ± 79.20 min and time to rescue analgesia is 425 ± 81.53 min while compared to BN group effective analgesia is 285 ± 94.46 min and time to rescue analgesia is 354±106.69 min. Hence we concluded that intrathecal buprenorphine 60 μg when compared to intrathecal nalbuphine 0.8 mg causes prolonged duration of postoperative analgesia.*
Keywords*: Inj.Bupivacaine 0.5%, inj. Buprenorphine, inj. nalbuphine, 25G spinal needle, 5ml disposable syringe, lower abdominal surgeries*

I. Introduction

Opioids have been used along with bupivacaine in subarachnoid block to prolong its effect, to improve the quality of analgesia and minimize the requirement of postoperative analgesics[1,2]. The reason for mixing of opioids and local anaesthetics is that this combination will eliminate the pain by acting at two different locations, local anaesthetics acting at the nerve axon and the opioids at the receptor site in the spinal cord. Nalbuphine is a highly lipid soluble opioid with an agonist action at the kappa (κ) and an antagonist activity at the Mu (μ) opioid receptors[3]. Buprenorphine is also a highly lipid soluble thebaine derivative with a partial agonist activity at the μ-opioid recepto.This study was performed to compare intrathecal nalbuphine versus intrathecal buprenorphine as an adjuvant to spinal bupivacaine for postoperative pain relief.

II. Material And Method

The study was designed in the form of a prospective, randomized and double blinded study. After getting approval from Institutional Ethics Committee and written consent, 60 patients, ASA I and ASA II, in the age range of 30-60 years, posted for lower abdominal surgeries such as hernia repair were selected. The patients with cardiovascular, neurological, respiratory, renal or endocrine diseases, contraindications to spinal anaesthesia, those with a prior history of opioid and other substance abuse, allergy to any of the study drugs and pregnant patients were excluded from the study.
The patients were randomly allocated into one of 2 groups of 30 each using computer generated randomisation list.

Group BN : Inj. bupivacaine hyperbaric 0.5% 2.6 ml + inj. nalbuphine 0.4 ml [0.2 ml of nalbuphine (10mg/ml) taken in 1ml tuberculin syringe of BD brand and diluted to 1ml using normal saline(0.2mg/0.1 ml) and latter 0.4 ml (0.8 mg) of this solution used]

Group BB: Inj. bupivacaine hyperbaric 0.5% 2.6 ml + inj. buprenorphine 0.4 ml [0.4 ml (60 μg) of buprenorphine (150 μg/ml) taken 1ml tuberculin syringe of BD brand]In the pre-anaesthetic visit, all the patients were made familiar with the study plan and the different visual analogue scales (VAS) to be used in the assessment by the investigators.All the patients were kept nil orally for 6 hours prior to surgery. On entering the operation theatre all standard monitoring including non-invasive automatic blood pressure (NIBP), Pulse oximetry and ECG leads were attached to the patient. Baseline readings were recorded. Intravenous access was established using an 18 G cannula and preloading was done with Ringer's lactate solution at a dose of 10 ml/kg. SAB was performed with 3 ml of the study drug injected in L3-L4 or L4-L5 interspace using a 25 G Whitacre spinal needle in lateral position. Recordings of pulse rate, blood pressure, SPO2, respiratory rate were done at 1, 3, 5 min and then every 5 min until the end of the procedure. The onset of sensory blockade (time taken from the end of injection to loss of pin prick sensation at L1 dermatome), highest level of sensory blockade, duration of sensory blockade (two segment regression time from highest level of sensory blockade), and complete motor blockade (time taken from the end of injection to development of grade IV motor block, modified Bromage's criteria 5), duration of motor blockade (time required for motor blockade return to Bromage's grade I from the time of onset of motor blockade) and duration of effective analgesia were recorded.

Intensity of pain was assessed by VAS [6] at 0, 10, 15, 30 and 60 min and then at 30-min until the patient received a rescue analgesic. The duration of effective analgesia was measured as time from the intrathecal drug administration to the patient's VAS score <3 either in the recovery room or in the ward, and was recorded in minutes. The patient's VAS score>3 and administration of rescue analgesia constituted the end point of the study. Patients reporting a VAS score >3 or more received rescue analgesics in the form of injection (Inj) Diclofenac 1.5 mg/kg IM. All the recorded data were statistically analyzed, and the significance was measured as a probability of occurrence by the t-test.

III. Result

There was no statistically significant difference between the demographic characteristics of both groups. The mean time of onset of sensory block at L1 was 2.74 ± 0.659 min in group BN while it was 2.69 ± 0.672 min in group BB. This difference was not statistically significant ($p > 0.05$). Maximum height of sensory block achieved in group BN was T 6.77±1.10 whereas in group BB it was T 6.40±1.43. This difference was not statistically significant ($p > 0.05$). Two-segment regression time of sensory blockade was 112.33 ± 14.78 min in Group BN compared to 115 ± 16.14 min Group BB. This difference was not statistically significant ($p > 0.05$). The mean time for Effective analgesia (VAS 0-3) was 285±94. 46 min in group BN as compared to 383.67 ± 79.20 min in group BB. This was statistically and clinically significant in this study ($p<0.001$). The mean duration of requirement of first rescue analgesia in Group BN (354±106.69) and Group BB (425±81.53) showed statistically significant difference (P=0.0053), this has highlighted the fact that Group BB had prolonged post-operative analgesia.

	GROUP BN	**GROUP BB**	**P Value**
Onset Of Sensory Block At L1(Min)	2.74±0.659	2.69±0.672	0.74
2 Segment Regression(Min)	112.33±14.78	115±16.14	0.5071
Maximum Height Of Sensory Block	T 6.77±1.10	T 6.40±1.43	0.27
Effective Analgesia (Min) (VAS 0-3)	285±94. 46	383. 67±79. 20	<0.001
Rescue Analgesia (Min) (VAS >3)	354±106. 69	425±81. 53	0. 0053

IV. Discussion

Subarachnoid block is common technique for lower abdominal surgeries. The combination of local anaesthetics with adjuvant enables us for use of lesser dose of local anaesthetics and increase the success of anaesthesia. Intrathecal opioids have been used as an adjunct to local anaesthetic bupivacaine vary widely. The demonstration of opioid receptors in the substantia gelatinosa of spinal cord (Yakash and Rudy 1976) has created interest in the intrathecal administration of opiates in the management of Chronic Pain and Pain following surgery[7]. Spinal opioids can provide profound post-operative analgesia with fewer central and systemic adverse effects than with opioids administered systemically.

Nalbuphine is an opioid structurally related to oxy-morphone. It is a highly lipid soluble opioid with an agonist action at the k opioid receptor and an antagonist activity at the mu opioid receptor[8,9]. There are few studies done previously on intrathecal nalbuphine as an adjuvant. Various dose of intrathecal nalbuphine compared by Arghya Mukherjee et al[10], Manisha Sapate et al. compare effect of adding 0.5 mg of nalbuphine to spinal bupivacaine[11]. Lin et al. found that the addition of intrathecal nalbuphine 0.4 mg to hyperbaric tetracaine, compared with intrathecal morphine 0.4 mg for SAB, improved the quality of intraoperative and postoperative

analgesia, with fewer side effects[12]. These studies found that postoperative analgesia prolong around 200 -600 minute by adding various dose of intrathecal nalbuphine.

Our study shows effective analgesia in BN group is 285±94.46 min and time to rescue analgesia is 354±106.69 min. This prolongation of postoperative analgesia supported by previous studies mention above.
Buprenorphine is a centrally acting lipid soluble analogue of alkaloid thebaine. It exhibits analgesic property both at spinal and supraspinal levels[13]. It is highly lipid soluble and diffuses quickly into neural tissue, decreasing the chances of rostral spread leading to lesser side effects in the post-operative period. There are few studies done previously on intrathecal buprenorphine as an adjuvant. Dixit et al stated that 60 µg buprenorphine given intrathecally to pregnant patients prolonged the duration of analgesia with negligible side effects[14]. Khan et al. compared analgesia after spinal anaesthesia between fentanyl plus bupivacaine and bupivacaine plus buprenorphine and bupivacaine alone. They concluded that adding buprenorphine to bupivacaine could induce longer pain-free periods[15]. In a study by Capno G. et al, the duration of analgesia obtained with 45 µg of bupronorphine intrathecally in patients undergoing supra pubic prostatectomy ranged from 7-12hrs[16]. These studies found that postoperative analgesia prolong by adding bupronorphine intrathecally.

Our study shows effective analgesia in BB group is 383.67 ± 79.20 min and time to rescue analgesia is 425 ± 81.53 min. This prolongation of postoperative analgesia supported by previous studies mention above.
There are no studies in the literature comparing postoperative analgesia of the drugs buprenorphine and nalbuphine as adjuvant to bupivacaine for lower abdominal surgeries. Our study shows no statistically significant difference between onset of sensory block, maximum height of sensory block and Two-segment regression time among both groups. Intrathecal buprenorphine 60 µg as an adjuvant provide significantly longer duration of postoperative analgesia when compare to 0.8 mg nalbuphine.

V. Conclusion

Present study shows effective analgesia in BB group is 383.67 ± 79.20 min and time to rescue analgesia is 425 ± 81.53 min while compared to BN group effective analgesia is 285 ± 94.46 min and time to rescue analgesia is 354±106.69 min. Hence we concluded that intrathecal buprenorphine 60 µg when compared to intrathecal nalbuphine 0.8 mg causes prolonged duration of postoperative analgesia.

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