Section: Anesthesiology

Original Research Article

ANALYSIS OF COMPLICATIONS FOLLOWING ADMINISTRATION OF DIFFERENT DOSES OF NALBUPHINE USED AS ADJUVANT IN PATIENTS UNDERGOING SURGERY UNDER SUB ARACHNOID BLOCK WITH 0.5% HYPERBARIC BUPIVACAINE AT A TERTIARY CARE HOSPITAL

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Abstract

Background: Various adjuvants have since been added to local anaesthetics to increase the quality and duration of spinal blockade as well as prolongation of postoperative analgesia. The present study was conducted to observe complications following administration of different doses of nalbuphine used as adjuvant in patients undergoing surgery under sub arachnoid block with 0.5% hyperbaric Bupivacaine. **Materials and Methods:** Patients in Group A received 3 ml of 0.5% hyperbaric bupivacaine with 0.4mg Nalbuphine in 1ml Saline. Patients in Group B received 3 ml of hyperbaric 0.5% bupivacaine with 0.8mg of Nalbuphine in 1ml saline. Complications in patients in the two study groups at various time intervals were noted. The data was analysed statistically using student t test, Chi-Square test. A P value less than 0.05 was considered statistically significant. **Result:** In both groups, male patients were more in comparison to female patients. In group A 24(80%) patients whereas in group B 21(70%) patients were having ASA grade I. The mean±SD age of patients in group A was 41.90±8.79 years whereas mean±SD age of patients in group B is 44.30±8.86 years. The mean±SD weight of patients in group A was 57.5±4.29 Kg whereas mean±SD weight of patients in group B was 59.40±3.92 Kg. The difference in presence of side effects among the two groups was found to be statistically significant (p=0.012). **Conclusion:** The present study concluded that adverse effects were less with 0.4 mg nalbuphine in 1ml NS with 3ml 0.5% Hyperbaric Bupivacaine.

INTRODUCTION

Spinal anaesthesia is the most popular and effective regional anaesthetic technique used for lower limb surgeries.[1] Since spinal anesthesia provided postoperative analgesia for a short time, many intrathecal adjuvants to local anesthetic have been addressed to augment the clinical efficiency and duration of analgesia. Among various adjuvants, intrathecal opioid has provided an effective prolongation of postoperative analgesia after orthopedic surgical procedures.[2,3] Various local anaesthetics commonly used for spinal anaesthesia are lignocaine, bupivacaine, levobupivacaine and ropivacaine.[1,4] The combination of adjuvants to local anesthetic is synergetic for producing the analgesia of prolonged duration without measurably increasing sympathetic or motor blockade, thus allows early ambulation of patients and reduction in dosages of local anesthetics, hence the decline of their systemic side effects.[5] Nalbuphine is a synthetic highly lipid-soluble opioid analgesic and possesses an agonist action at the κ-opioid receptor and antagonist action at the μ-opioid receptor to provide reasonably potent analgesia of visceral nociception.[5] Intrathecal nalbuphine produces lesser adverse effects like pruritus, nausea, and vomiting when compared to intrathecal morphine and does not cause any significant hemodynamic or respiratory complications.[6,7] Nalbuphine has been used intrathecally by various investigators to enhance the postoperative analgesia and they did not document

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any reports of neurotoxicity.[6,8] Morphine, fentanyl, and other μ-opioids come under Narcotics Act, thus their availability is a major concern in many hospitals in India, while nalbuphine is easily available and devoid of side effects.[5] Hence, this prompt us to conduct a study to observe complications following administration of different doses of nalbuphine used as adjuvant in patients undergoing surgery under sub arachnoid block with 0.5% hyperbaric Bupivacaine.

MATERIALS AND METHODS

The prospective study was conducted among ninety patients admitted to Department Of Anaesthesiology, Heritage Institute of Medical Sciences, Bhadvar, Varanasi for elective surgery undergoing various infra umblical surgery from year 2020 to 2022. American Society of Anaesthesiologists (ASA) I and II patients, age group of 15-55 years, patient with written valid consent, patient undergoing elective lower abdominal and orthopedic surgery were included in the study. Infection at the site, cardiac arrhythemias, heart blocks, bradycardia, allergic reaction to any anesthetic drug, ASA III and IV grade, patients with bleeding disorders, head injury, raised intracranial pressure were excluded from the study. The patients were allocated in two groups of 45 patients each.

- **Group A:** Recieving 0.4 mg nalbuphine in 1ml NS with 3ml 0.5% Hyperbaric Bupivacaine
- **Group B:** Recieving 0.8 mg nalbuphine with 1ml NS with 3ml 0.5% Hyperbaric Bupivacaine

Patient was premedicated with tablet alprazolam 0.25mg and tablet ranitidine 150mg orally the night before surgery and fasted for 6-8hours before procedure of spinal anesthesia. On the day of surgery after securing intravenous (18G) access in dorsum of the left hand, all the routine monitor was attached, patient was preloaded with Ringer's lactate solution 15 ml/kg over 10 min. Under all aseptic precautions after putting the patient in sitting position, using 25-guage Quincke spinal needle, spinal block was performed at lumbar third and fourth interspace through a midline approach and the patient was put to supine position after giving the drug. Patients in Group A received 3 ml of 0.5% hyperbaric bupivacaine with 0.4mg Nalbuphine in 1ml Saline. Patients in Group B received 3 ml of hyperbaric 0.5% bupivacaine with 0.8mg of Nalbuphine in 1ml saline. The time of intrathecal injection was considered as 0. SpO2, respiratory rate, pulse rate, blood pressure was recorded. The patients was observed for onset of sensory blockade; the height of sensory blockade, motor blockade as per bromage scale, total duration of sensory and motor blockade, quality of analgesia{visual analogue score},two segment sensory regression time, time to first rescue analgesia and the number of rescue analgesics in 24 hrs. Complications observed in patients in the two study groups at various time intervals were noted. The data was analysed statistically using student t test, Chi-Square test. A P value less than 0.05 was considered statistically significant.

RESULTS

In both groups, male patients were more in comparison to female patients but the difference in distribution is statistically non-significant (p=0.791). In group A 24(80%) patients whereas in group B 21(70%) patients were having ASA grade I but the difference in distribution was statistically non-significant (p=0.371). The mean±SD age of patients in group A was 41.90±8.79 years whereas mean±SD age of patients in group B is 44.30±8.86 years. The difference in mean age was statistically non-significant (p=0.296). The mean±SD weight of patients in group A was 57.5±4.29 Kg whereas mean±SD weight of patients in group B was 59.40±3.92 Kg. The difference in mean weight was statistically nonsignificant (p=0.078).

Among group A, 3(10%) patients reported hypertension and NV whereas 2(6.7%) patients reported NV as side effect. Among group B, 6(20%) patients reported NV as side effect. This difference in presence of side effects among the two groups was found to be statistically significant (p=0.012).

Table 1: Demographic characteristics and ASA grade of patients in the two study groups

Parameter		Group A		Group B		Chi square value	p value
		Frequency	Percent	Frequency	Percent		
Gender	Male	19	63.3	18	60.0	0.071	0.791
	Female	11	36.7	12	40.0		
ASA Grade	1	24	80.0	21	70	0.800	0.371
	2	6	20.0	9	30		
		Mean	SD	Mean	SD	t test value	p value
Age (Years)		41.90	8.79	44.30	8.86	-1.054	0.296
Weight (Kg)		57.50	4.29	59.40	3.92	-1.791	0.078

Table 2: Comparison of frequency distribution of adverse effects observed in patients in the two study groups at various time intervals

Adverse effects	Group A		Group B		Chi square value	p value
	Frequency	Percent	Frequency	Percent		
HTN, NV	3	10.0	0	0	11.020	0.012*
NV	2	6.7	6	20.0		
None	25	83.3	24	80.0		

Statistically significant

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DISCUSSION

Intrathecal opioids are quite commonly used as adjunct to local anaesthetics in regional anaesthesia with multiple advantages. The most common causes of mortality in regional anaesthesia are high spinal and local anaesthetic toxicity. Hence, reduction in the doses of local anaesthetics and better management of local anaesthetic toxicity is possible in this way.[9]

In both groups, male patients were more in comparison to female patients but the difference in distribution was statistically non-significant (p=0.791). In group A 24(80%) patients whereas in group B 21(70%) patients were having ASA grade I but the difference in distribution were statistically non-significant (p=0.371).

Gupta K et al (2016) compared the clinical efficiency of intrathecal fentanyl with nalbuphine as adjuvant to 0.5% hyperbaric bupivacaine for orthopedic surgery of lower limbs. Sixty-eight adult patients of American Society of Anesthesiologist physical status I and II of both gender aged 25-65 years were included in the study.[5] Pradhan A et al. (2021) intends to compare three different doses of intrathecal nalbuphine as an adjuvant to 0.5 % hyperbaric bupivacaine and determine the optimal dose in knee joint surgeries. One hundred and twenty American Society of Anaesthesiologists (ASA) I and II patients undergoing knee joint surgeries were included in the study.[10]

The mean±SD age of patients in group A was 41.90±8.79 years whereas mean±SD age of patients in group B was 44.30±8.86 years. The difference in mean age was statistically non-significant (p=0.296). The mean±SD weight of patients in group A was 57.5±4.29 Kg whereas mean±SD weight of patients in group B was 59.40±3.92 Kg. The difference in mean weight was statistically non-significant(p=0.078).

Among group A, 3(10%) patients reported hypertension and NV whereas 2(6.7%) patients reported NV as side effect. Among group B, 6(20%) patients reported NV as side effect. This difference in presence of side effects among the two groups was found to be statistically significant (p=0.012).

Ban M et al (2022) compared the effects of intrathecal morphine injection and low-dose bupivacaine with morphine injection. In total, 90 patients were divided into 3 groups: (1) sham injection for the control group; (2) morphine 400 mcg for the morphine group (M); and (3) morphine 400 mcg and bupivacaine 5 mg for the morphine and bupivacaine group (M + B). Although time to first rescue was significantly shorter in the control group compared to group M and group M + B ($p < 0.001$), both groups (M and M + B) were comparable to each other. Pruritus and tingling were more prevalent in the M + B group ($p = 0.023$; $p = 0.010$). The addition of 5 mg bupivacaine may be insufficient in providing further analgesic benefits; however, higher doses may aggravate side effects.[11]

Borah TJ et al (2018) performed a prospective, randomised double blind study to find the optimal dose of intrathecal nalbuphine with isobaric 0.75% ropivacaine for elective lower limb surgeries. Patients were divided into four groups randomly: groups A, B, C and D, who received 0.5 mL normal saline or 0.4, 0.8 and 1.6 mg nalbuphine made up to 0.5 mL normal saline added to 22.5 mg (total volume 3.5 mL) isobaric 0.75% ropivacaine, respectively. Incidence of adverse effects was highest in the 1.6 mg group when compared with others, although it was statistically insignificant ($P > 0.05$).[12]

Mishra PR, et al (2017) compared Nalbuphine in different doses as adjuvant to hyperbaric bupivacaine with bupivacaine alone in subarachnoid block. Patients were randomly allocated into four groups with 30 patients in each group. Group I (control group) received hyperbaric bupivacaine 0.5%, 3 mL (15 mg) with 0.5 mL of 0.9% normal saline. Group II, III, IV each received 0.5% hyperbaric bupivacaine 3 mL (15 mg) with 0.5 mg, 0.75 mg and 1 mg Nalbuphine respectively with added normal saline 0.9% making the total volume 3.5 mL in each group. Addition of Nalbuphine produce conscious sedation with minimal side effects.[13]

Tiwari AK et al (2013) performed this randomized, prospective double-blind study to evaluate the effects of 2 different doses of intrathecal nalbuphine on the onset, duration of action, side effects, and complication produced by intrathecal hyperbaric 0.5% bupivacaine in lower abdominal, urologic and lower limb surgeries. Group A (n = 25) received 2.5 mL of 0.5% hyperbaric bupivacaine + 1 mL sterile water intrathecally; group B (n = 25) received 2.5 mL of 0.5% hyperbaric bupivacaine + 1 mL (200 mg) nalbuphine intrathecally; group C (n = 25) received 2.5 mL of 0.5% hyperbaric bupivacaine + 1 mL (400 mg) nalbuphine intrathecally. One patient in group A had nausea and vomiting, 2 patients in each group developed shivering ($P<0.05$). No other side effect or complication was observed.[7]

CONCLUSION

The present study concluded that 10% patients receiving 0.4 mg nalbuphine in 1ml NS with 3ml 0.5% Hyperbaric Bupivacaine had hypertension and NV whereas 6.7% patients reported NV as side effect. 20% patients receiving 0.8 mg nalbuphine with 1ml NS with 3ml 0.5% Hyperbaric Bupivacaine had NV. Overall, adverse effects were less with 0.4 mg nalbuphine in 1ml NS with 3ml 0.5% Hyperbaric Bupivacaine.

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