Bang Med J Khulna 2020; 53 : 27-30

ORIGINAL ARTICLE

Comparison of efficacy between intrathecal nalbuphine and fentanyl as adjuvant to hyperbaric bupivacaine for perianal surgery

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Abstract

Background: *Intrathecal opioids enhance the duration of action of local anasthetic drugs. Both nalpuphine and fentanyl enhance the action of hyperbaric bupivacaine when introduced intrathecally as adjuvant with bupivacaine.*

Objective: *Our study was aimed to compare the clinical efficiency of nalbuphine and fentanyl as adjuvant to hyperbaric bupivacaine for anal and perianal surgery.*

Methods: *In this prospective randomized clinical trial patients were included from January 2007 to June 2008 at Khulna Medical College & some private clinics in Khulna. Patients were ASA (American Society of Anaesthesiology) status I & II of both gender aged 18-70 years and was randomized into two groups. Each group received either nalbuphine, (Group I) or fentanyl (Group-II) with bupivacaine. After intrathecal use every patient was examined for sensory and motor block, drug related side effects like hypotension pruritus, nausea, vomiting respiratory depression for three hours and were recorded.*

Results: *Among two hundred study patients mean age was 49.5 and 5.2 in respective group I & II. Male female ratio was 16:14 in group I, whereas in group II it was 65:35. Mean duration of surgery was 46 and 43 minutes respectively in group I & II. Onset and cephalic extension of block was almost same in both groups. Time to recovery of sensory and motor block were significantly prolonged in Group 1. Duration of analgesia was also extended in group I. No significant drug related side effects were observed in either group.*

Conclusion: *Nalbuphine as adjuvant to bupivacaine was clinically more efficient than fentanyl for post--operative analgesia and duration of sensory and motor block in SAB (Sub Aracnoid Block) for anal and perianal surgery.*

Keywords : Nalbuphine Fertanyl, Bupivacaine, Adjuvant

Introduction

Opioid analgesics activate opioid receptors located on the primary afferent neurons, resulting in the activation of pain modulating systems. This activation may either directly decrease neuro transmission or inhibit the release of excitatory neurotrnsmitters. Opioids receptors are mu(μ), delta (s) and Kappa (k). Fentanyl is an opioid agonist and acts on μ receptor and Nelbuphine is a synthetic opioid with aganist antagonistic activity on μ receptor and agonist at k receptors.[1] Nalbuphine, when used as adjuvant to hyperbaric bupivacaine has improved the quality of perioperative analgesia with fewer side effects. Nalbuphine did not document any reports of neurotoxicity.[3,4]

There are relatively limited published data on the comparison between the effects of addition of nalbuphine and fentanyl as adjuvant to bupivacaine in spinal block for perianal surgery. The aim of the present study was comparing the effect of nalbuphine to fentanyl as an adjuvant to hyparbaric bupivacaine on the charateristics of spinal blockade post operative analgesia and effect

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on motor and sensory nerve and post operative haemodynamic effect.

Patients and Methods

This prospective randomised double blind study was conducted from January 2017 to June 2018 at Khulna Medical College Hospital and some Private Hospital, Khulna. Two hundred patients were included in the study, hundred in each group. ASA (American Society of Anaesthesiology) physical status I and II of both gender, aged 18 to 70 years, weighing 45-85 kg, scheduled for elective and emergency perianal surgery were selected. Patient aged below 18 and above 70 years or patient having neurological deficit were excluded from the study. The selected patients were randomised into two comparable groups regarding mean age, weight, height, gender ASA status and duration of surgery. Patient of group I were given 3ml of 0.5% hyperbaric bupivacaine with 2 mg nalbuphine and patients of group II were given 3 ml of 0.5% hypebaric bupivacaine with 25 µg fentanyl. Under all aseptic precuations SAB (Sub Aracnoid Block was given in all patients via L3-L4 intervertebral space, using 25G Quincke spinal needle as per group allocation and patient was placed in the supine 100 trendelenburg position. They were supplemented with Oxygen (02) at a rate of 4.5 L/min and adequate IV fluid to maintain blood volume to make patient haemodynamically stable.

The surgical anesthesia is considered to be achieved when sensory block reached to T10 dermatome level with complete motor block. Post operatively, the sensory and motor block levels where assessed at 15 minute intervals until normal sensations returned. Haemodynamic parameters, peripheral oxygen saturation were recorded just after spinal injection and continued in the post operative room for 3 hours. At the end of study demographic profile, sensory and motor blockade profile, haemodynamic status were compared using statistical parameter.

Results

The study was conducted in Khulna Medical College Hospital and different Private Hospital at Khulna City. Age, sex, physical status, weight and duration of surgery were demonstrated in Table I. Clinical efficacy of intrathecal Nalbuphine and Fentanyl as andjuvant to 0.5% hyperbaric bupivacaine in 100 patients in each group in anal and perianal surgery were compared. The onset of sensory block in both the groups was almost same and statistically not significant. Motor block also revealed no significant difference. Time to sensory regression was significantly extended in patients of group I as compared to group II and statistically significant.

Table I

Demographic profile of patient

Parameters	Group I	Group II
Mean Age (yrs)	49.5	51.3
Mean Weight (kg)	65.7	66.2
Mean Height (cm)	160.5	159.5
Male: Female	60.4	65.4
ASA I *	75	80
ASA II	25	20
Duration of surgery (minutes)	46	43

* ASA= American Society of Anaesthesiology

Duration of motor block also was more in group I then group II with P=0.002 and also statistically significant. There was significant difference in first dose of administration of analgesic. Group I reveal more duration then group II with P=0.001 and statistically significant (Table II).

Table II

Sensory and motor blockade profile

Parameter (min)	Group I	Group II	p
Time to achieve sensory blockage	7.1	7.5	0.075
Time to achieve motor block	8.5	9.3	0.042
Time taken for regression of sensory block	125	115	0.001
Duration of motor block	190	145	0.002
Time to administer first dose of analgesic	250	210	<0.001

Haemodynamic characteristics and Oxygen (02) saturation throughout the operation and post operative period were comparable in both the group and were of no significant difference (Fig.1 & Fig. 2). All the patients, in two groups were haemodynamically stable. Six patients in group II and three patients in group I reportedly had mild hypotension and was easily corrected by giving one or two litre of crystalloid i.v fluid. Incidence of hypotension and bradycardia was minimum and did not require any medication in any group. Mild pruritis was observed in 10 patients of fentanyl

group. No incidence of respiratory depression was observed in any group. None required supplemental analgesia during surgery.

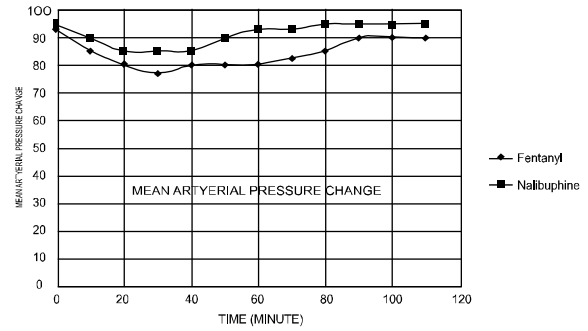

Figure 1. Mean arterial pressure changes in two groups

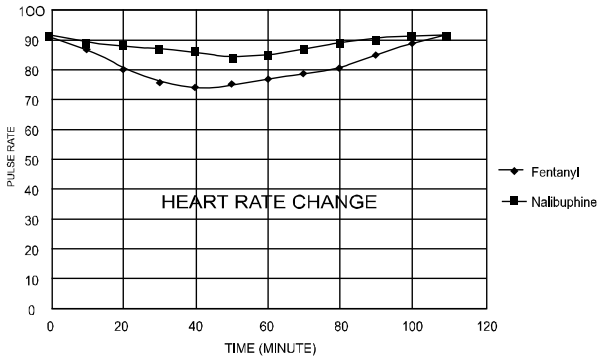

Figure 2. Mean pulse rate changes in two groups

Discussion

Both fentanyl and nalbuphine are opioid analgesics. Fentanyl is an opioid agonist and acts on μ opioid receptors. Nalbuphine is a synthetic opioid analgesic with agonist-antagonist activity and acts as antagonist at μ receptors and agonist at k receptors to provide reasonably potent analgesia. Nalbuphine, when used as adjuvant to hyperbaric bupivacaine, has improved the quality of perioperative analgesia with fewer side effects. Nalbuphine has been used intrathecally by various investigators to enhance the postoperative analgesia and they did not document any reports of neurotoxicity.

The clinical efficiency of intrathecal fentanyl and nalbuphine was compared as intrathecal adjuvant to 0.5% hyperbaric bupivacaine by assessing the sensory and motor blockade characteristics and duration of postoperative analgesia as the primary end points. Fentanyl are used as adjuvant to hyperbaric bupivacaine to prolong its clinical efficacy and minimize the requirement of postoperative analgesics, but they are associated with side effects of pruritus, nausea, vomiting, respiratory depression, constipation, and urinary retention. Nalbuphine, agonist-antagonist, is a synthetic highly lipid soluble opioid analgesic and possess an agonist action at the k opioid receptor and antagonist action at the μ opioid receptor to provide reasonably potent analgesia, of visceral nociception. It has the potential to maintain or even enhance μ-opioid based analgesia while simultaneously mitigating the μ opioid side effects. The duration of sensory block and motor block was significantly enhanced by the addition of intrathecal nalbuphine as compared to intrathecal fentanyl in the present study. The results of the present study correlates well with other studies where it was observed that addition of nalbuphine or Tramadol allowed a significant reduction in pain score.

There are only few studies available of central neuraxial administration of nalbuphine as intrathecal adjuvant, which concluded that nalbuphine, significantly enhanced the sensory analgesia with minimal pruritis and respiratory depression. Mukherjee et al studied the duration of analgesia with different dosages of intrathecal nalbuphin (0.2, 0.4, and 0.8mg) to find out the optimum dose of intrathecal nalbuphine which could prolong the postoperative analgesia without increasing the side effects. Their study concluded that effective analgesia was increased with increase in the doses of nalbuphine as adjuvant to 0.5% hyperbaric bupivacaine without any side effect.[4]

Yoon et al. studied sixty obstetric patients scheduled for cesarean section under spinal anesthesia. Patients received morphine 0.1 mg or nalbuphine 1 mg or morphine 0.1 mg with nalbuphine 1 mg in addition to 0.5% bupivacaine (10 mg) and concluded that effective analgesia was prolonged in the morphine group and morphine with nalbuphine group, but the incidence of pruritis, was significantly lower in the nalbuphine group.[7]

Those study are in accordance with the finding of our study. Sapate et al. observed the effects of intrathecal nalbuphine (0.5mg) with 0.5% spinal bupivacaine (3mL) for lower abdominal surgeries in elderly patients in a randomized control study. They concluded that nalbuphine provided better quality of SAB as compared to bupivacaine alone and also enhanced the postoperative analgesia. No patients in their study developed any side effects.6 Verma, et al. compared the postoperative analgesic efficacy of intrathecal tramadol (50mg) with nalbuphine (2mg) as adjuvant to hyperbaric bupivacaine (12.5mg) in spinal anesthesia for

lower limb orthopaedic surgery. Intrathecal tramadol could not make significant difference in postoperative analgesia as compared to bupivacaine when used alone.[5] The results of their study go well with the results of the present study. Ahmed et al. evaluated the potentiating effect of intrathecal nalbuphine with bupivacaine for postoperative analgesia in three different doses (0.8, 1.6 and 2.4mg) in a randomized control study. They concluded that the combination of intrathecal bupivacaine with significantly prolonged postoperative analgesia as compared to control group and a 1.6mg dose showed the best results.8 Recently Raghuraman et al reported that nalbuphine when added for sub aracnoid block provided a good quality and prolonged duration of postoperative analgesia with a valuable antishivering and antipruritic effect with decreased incidence of nausea and vomiting.[9]

The post operative pain was lower in group I as compared to group II and similar results were obtained in other studies.10,11 The effective relief of pain and less haemodynamic unstability is of principal importance for perinal surgery using SAB. Effect of nalbuphine and fentanyl in this study was comparable with results of Gamma et al.[12] The study and analysis of other study revealed that nalbuphine and fentanyl as an adjuvant to hyperbaric bupivacaine is useful in clinical practise but will need clinical judement to select the patient depending on duration of operation.

The principal limitation of the present study is lack of blinding eventhough randomised. Morever haemodynamic status of the study cases could not be monitored adequately with time during the operative procedure.

Conclusion

Nalbuphine as intrathecal adjuvant to hyperbaric bupivacaine, for subarachnoid blockage, was clinically more efficient than fentanyl for extending the duration of sensory and motor block and enhancing the postoperative analgesia in anal and perianal surgery with few side effects. Nalbuphine is a good adjuvant for prolonged surgery and fentanyl for surgery of short duration.

Acknowledgement

We are thankful to Syed Ahnaf Adib, Clinical Student of Sher E Bangla Medical College for participating in data collection and processing.

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