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Post Operative Analgesia: A Prospective, Comparative Study With Intrathecal Nalbuphine And Fentanyl.

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Abstract:
Introduction*: Post operatively Various adjuvants have been used along with local anaesthetics for prolongation of analgesia post operatively in neuraxial blockade. Opioids are most commonly used analgesics for managing postoperative pain. The aims of the present study was to compare the efficacy and safety of nalbuphine and fentanyl for postoperative pain relief in surgical procedure. Nalbuphine is an opioid drug with mixed μ antagonist and κ agonist properties.*
Materials and methods*: Ninety patients who were posted for various surgical procedures belonging to ASA I & II were taken into the study. They were assigned randomly into two groups, group A and group B, each group has allocated 45 patients each (n=45). Group A received nalbuphine 0.25 mg\kg and Group B received and fentanyl 1.5 ug\kg before 5 minutes of induction of anesthesia .The patient observed for recovery criteria, post-operative analgesia, and side effects.*
Results: *The duration of post-operative analgesia and the effective analgesic time were more prolonged in Group A than in Group B with no statistically significant difference.*
No significant differences were found in recovery from anesthesia. No significant side effects were found among two groups.
Conclusion: *Nalbuphine is a better adjuvant than Fentanyl because of its prolonged post operative analgesia and effective analgesia time and lesser side effects for intrathecal injections in surgeries undergoing spinal anaesthesia. with no statistically significant difference.*
Keywords*: Nalbuphine, postoperative, fentanyl, analgesia.*

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I. Introduction

Nalbuphine avidly binds to Kappa opioid receptors in these areas to produce analgesia. This pattern of binding and effects defines Nalbuphine as a mixed agonist-antagonist.[1] It causes less respiratory depression than other opioids and has a safety profile with minimal effect on cardiovascular function[2-3]. Fentanyl is a synthetic opioid agonist related to phenylpiperidines. As an analgesic it is 100 times more potent than morphine.

Various types of medications can be used to overcome pain but opioids provide the most effective pain relief and are a standard of care. Fentanyl is one of the most commonly used analgesics and therefore we undertook a comparative study of nalbuphine and fentanyl for post operative pain relief in patients undergoing surgical procedures.

There are a very few studies of Intrathecal Nalbuphine for postoperative analgesia. The present prospective study was aimed to compare the efficacy and safety of nalbuphine and fentanyl for postoperative analgesia in surgical procedures. The objectives of the study are comparison of group A (nalbuphine) and Group B (fentanyl), analgesia, recovery criteria and side effects.

II. Materials And Methods

In this study a total of 90 patients of ASA grade I/ II, aged between 20-60 years who were scheduled for elective surgical procedures under general anesthesia lasting <60 min were selected. They were randomly divided in to two groups(n=45), Group A and Group B received nalbuphine 0.25 mg\kg and fentanyl 1.5 ug\kg respectively before 5 minutes of induction of anesthesia.

Patients with history of hypersensitivity to any of the drugs, with history of asthma and on long term analgesic therapy, those having peripheral neuropathy, drug allergy or sensitivity to opioids, local skin infections and spinal deformities or coagulation abnormalities were excluded from the study. Each patient was assessed preoperatively. A written informed consent was taken.

Patients were kept nil orally pre-operatively for at least 6 hours and post operatively for 4 hours. A suitable peripheral vein was cannulated and 10 ml/kg/15 min I.V. Ringer solution (preload) was given to all surgical patients before the procedure. Baseline pulse rate , Blood pressure, ECG , oxygen saturation and Respiratory rate was recorded. Pre-operative baseline readings were recorded. The selected opioid was given intravenously according to the gropus before 5 minutes of induction. The induction was done with thiopentone 5-6 mg/kg, and maintained with 66% nitrous oxide in oxygen supplemented with sevoflurane using bain's breathing system according to the clinical judgment.

Postoperatively these 90 patients who were divided into two groups were observed for sedation, pain , nausea and vomiting. The patient's sedation was recorded as X,Y and Z. X is asleep, Y is awake and calm and Z is awake and restless which was shown in table 1. Recovery time was noted as the duration between patient responding to painful stimuli and the completion of surgery and follow verbal command. Duration of analgesia was noted and rescue analgesia was given intravenous diclofenac 75 mg. Visual analog score using 10 cm horizontal scale Pain was assessed, where no pain (0), mild pain (1-3), moderate pain (4-6) and severe pain (7-10). Side effects like nausea/vomiting, dizziness and headache was noted. Using the student's t-test for demographic data Statistical analysis of the data were done.

III. Results

Both groups were compared in various demographic data like age, weight and duration of surgery and there was no significant statistical difference. The two groups of patients were similar with respect to age, weight, ASA status, type of surgery and duration of surgery.

There were no significant differences between the observed sedation appearances of the two groups at any time postoperatively which was shown in (table-1).

Table :1 showing the Appearance of Postoperative Sedation.

		Group A (Nalbuphine)	Group B (Fentanyl)
1 hour	Asleep (X)	9	7
	Awake and clam (Y)	27	28
	Awake and restless(Z)	9	10
2 hour	Asleep (X)	11	9
	Awake and clam (Y)	27	25
	Awake and restless(Z)	7	11
4 hour	Asleep (X)	5	4
	Awake and clam (Y)	36	34
	Awake and restless(Z)	4	7

The duration of post-operative analgesia and the effective analgesic time were more prolonged in nalbuphine group than in fentanyl group but with no statistically significant difference. Hemodynamic parameters were remained within normal limits in both the groups. Recovery time was 7.9 ± 1.0 minutes and 7.8 ± 1.5 respectively in group A and group B. No significant difference seen in recovery time.

IV. Discussion

Intrathecal opioids have advantages like sympathetic and motor nerve sparing activities, rapid onset of action, technical ease of administration and simplicity of postoperative management. These Opioid analgesics are the corner stone for management of postoperative pain. This prospective study compared the side effects and efficacy of nalbuphine and fentanyl as intravenous analgesics in surgical procedures dividing and comparing them in two groups.

Nalbuphine is an opioid which is proven and having agonist activity at kappa receptors and antagonistic activity at mu receptors. Nalbuphine if given systemically will reduce the incidence of respiratory depression and has been used to antagonize the side effects[4]. Nalbuphine has some advantages over pure agonists with a proven maximum respiratory depressant effect and has been shown to provide adequate postoperative pain relief[5]. Nalbuphine analgesic potency is similar to morphine. Nalbuphine is not subject to the restriction of the Misuse of Drugs Act and therefore it is readily available in peripheral units. Similarly in the present prospective and comparative study Nalbuphine showed that it can provide longer duration of postoperative analgesia with less respiratory depression and risk of chest wall rigidity and apnea.

Fentanyl is a μ receptor agonist opioid, with a rapid onset following intrathecal injection. In patients undergoing termination of pregnancy Bone et al[6] compared nalbuphine and fentanyl for postoperative pain relief. The incident of postoperative pain was significantly less in nalbuphine group and compared to 10% in nalbuphine group 45% of patient in fentanyl group required postoperative analgesia. Similarly in our study, the findings are there was a higher incidence of pain in group B (Fentanyl) and 40% required postoperative analgesia at mean time of 1.8 hours. The duration of analgesia was longer in group A (Nalbuphine) only 20% of patients required postoperative analgesia at mean time of 3.4 hours and the pain score at 1 and 2 hours were

significantly less than in group B ($p< 0.05$). Hemodynamic parameters were remained within normal limits in both the groups.

Mukherjee et al did a study to determine whether nalbuphine prolongs analgesia by comparing with control and to find out the optimum dose of intrathecal nalbuphine by comparing the 0.2, 0.4 and 0.8mg doses which prolonged post operative analgesia and without increased side effects. It was observed that effective analgesia increased with increase in concentration and the ultimate observation of prolongation of analgesia was with 0.4mg of nalbuphine with 0.5% hyperbaric bupivacaine without any side effects.[7] The use of longer acting opioid, such as nalbuphine with a half life of approximately 4 hours[8], may be expected to lengthen recovery time. However in our study we found that There were no significant differences in side effects like nausea and vomiting, headache, dizziness, drowsiness and respiratory depression between two groups. The recovery time was not significantly different from group B. There was also no significant difference in observer assessments of postoperative sedation.

In review of literature, It was found that Collins et al[9] .compared inhalational anesthesia using halothane with a technique using alfentanil in unpremedicated patients. The incident of postoperative moderate to severe pain was not significantly different between the groups; overall 40% of patient required postoperative analgesia. it was with halothane group 36% and with alfentanil group 27%. From our study it was observed nalbuphine as an adjunct prolongs the postoperative analgesia with minimal side effects and with desirable sedation intraoperatively which also helps in taking care of psychological impact of patient in operation theatre environment.

V. Conclusion

As compared to Fentanyl, Nalbuphine produces a significant reduction in the incidence of pain in first 2 hours and does not increase incidence of side effects or recovery time. Nalbuphine is as effective as fentanyl as intravenous analgesic during surgery. To conclude Nalbuphine with comparatively prolonged post operative analgesia and effective analgesia time and lesser side effects is a better adjuvant than Fentanyl.

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