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A comparative study of nalbuphine and fentanyl for post operative pain relief in patient undergoing short surgical procedures

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Abstract: *Effective postoperative pain relief is an essential component of the peri-operative care of the surgical patient. Opioids are commonly employed analgesics for managing postoperative pain. The present study was aimed to compare the efficacy and safety of nalbuphine and fentanyl for postoperative pain relief in short surgical procedure. Sixty patients, scheduled for various short surgical procedures belonging to ASA I & II assigned randomly into two groups (n=30). Group N and Group F received nalbuphine 0.25 mg\kg and fentanyl 1.5 ug\kg respectively before 5 minutes of induction of anesthesia .The patient observed for post-operative analgesia, recovery criteria and side effects. Patients who received nalbuphine had significantly lower pain sores at 1 hour ($p<0.05$) and 2 hours ($p<0.05$) and required significantly ($p<0.05$) less postoperative analgesia. Duration of post operative analgesia was longer in group N than group F. No significant differences were found in recovery from anesthesia. No significant side effects were found among two groups. Freedom from controlled drug act regulations and improved analgesia without respiratory depression, nalbuphine, make it more suitable for day case surgeries.*

Keywords: *Analgesic, postoperative, anesthesia.fentanyl, nalbuphine.*

I. Introduction

Effective analgesia is an essential part of peri-operative management. Many techniques have been described use of short acting opioids eg. fentanyl for analgesia during short surgical procedures, but these drugs offer little pain relief in recovery period. Fentanyl is a synthetic opioid agonist related to phenylpiperidines. As an analgesic it is 100 times more potent than morphine. However, the use of fentanyl is associated with an increased risk of hypoxemia and apnea[1] which is undesirable for patients undergoing short surgical procedures. Nalbuphine is a synthetic partial kappa agonist/mu antagonist opioid of the phenanthrene series. It causes less respiratory depression than other opioids and has a safety profile with minimal effect on cardiovascular function[2-3].

The pharmacological profile of nalbuphine and its freedom from control by the *Misuse of Drugs Act* would appear to be useful properties in an analgesic for short surgical procedures. Fentanyl is one of the more commonly used analgesics in this situation and therefore we undertook a comparative study of nalbuphine and fentanyl for post operative pain relief in patients undergoing short surgical procedures.

The study was aimed to compare the efficacy and safety of nalbuphine and fentanyl for postoperative analgesia in short surgical procedures. The objectives are comparison of, analgesia, recovery criteria and side effects.

II. Material And Methods

A total of 60 patients of ASA grade I/ II, aged between 15-60 years of either sex scheduled for elective short surgical procedures under general anesthesia lasting <45 min were selected. They were randomly divided in to two groups(n=30), Group N and Group F received nalbuphine 0.25 mg\kg and fentanyl 1.5 ug\kg respectively before 5 minutes of induction of anesthesia.

Patients with history of asthma, drug allergy or sensitivity to opioids were excluded from study. Each patient was assessed preoperatively. A written informed consent was taken. Patients were kept nil orally for at least 6 hours pre-operatively & 4 hours post operatively. Intravenous cannula was inserted in to the patient's dorsum of hand. All patients were monitored with an electrocardiograph, NIBP, pulse oximeter and $ETCO_2$. Pre-operative baseline readings were recorded.

Premedication Inj. Glycopyrrolate 0.004 mg/kg IV was given.The selected opioid was given intravenously before 5 minutes of induction. After 5 minutes induction was done with thiopentone 5-6 mg/kg, and maintained using bain's breathing system with 66% nitrous oxide in oxygen supplemented with sevoflurane according to the clinical judgment. All vital parameters were monitored preoperatively, at the time

of induction, and then every 5 minutes during surgery and postoperatively 1, 2 and 4 hours. The duration of surgery and anesthesia and any untoward events were recorded. Recovery time was noted as the duration between the completion of surgery and patient responding to painful stimuli and follow verbal command. Postoperatively patients were observed for sedation, pain and nausea and vomiting. The patient's sedation was recorded as asleep, awake and calm and awake and restless as shown in table 2. Pain was assessed with visual analog score using 10 cm horizontal scale where no pain (0), mild pain (1-3), moderate pain (4-6) and severe pain (7-10). Duration of analgesia was noted and rescue analgesia was given intravenous diclofenac 75 mg. Side effects like nausea/vomiting, dizziness and headache was noted.

Statistical analysis of the data was undertaken using the student's t-test for demographic data, wilcoxon rank sum test for visual linear analogue scores and the chi-square test for patient scores for nausea.

III. Results

The two groups of patients were similar with respect to age, weight, ASA status, type of surgery and duration of surgery (table 1). Hemodynamic parameters were remained within normal limits in both the groups. Recovery time was 8.8 ± 1.0 minutes and 7.8 ± 1.5 respectively in group N and group F. No significant difference seen in recovery time.

Table -1 Demography of patients, expressed as mean (SEM)

	Nalbuphine (n=30)	Fentanyl (n=30)
Age, years	28.03 ± 1.3	29.3 ± 1.3
Weight, kg	55.7 ± 1.0	54.7 ± 1.2
ASA grade ½	28/2	28/2
Types of surgeries		
D & E/ MTP	10/6	9/5
D & C	4	6
I & D	10	10
Duration of surgery, minute	29.7 ± 1.3	24.5 ±1.5

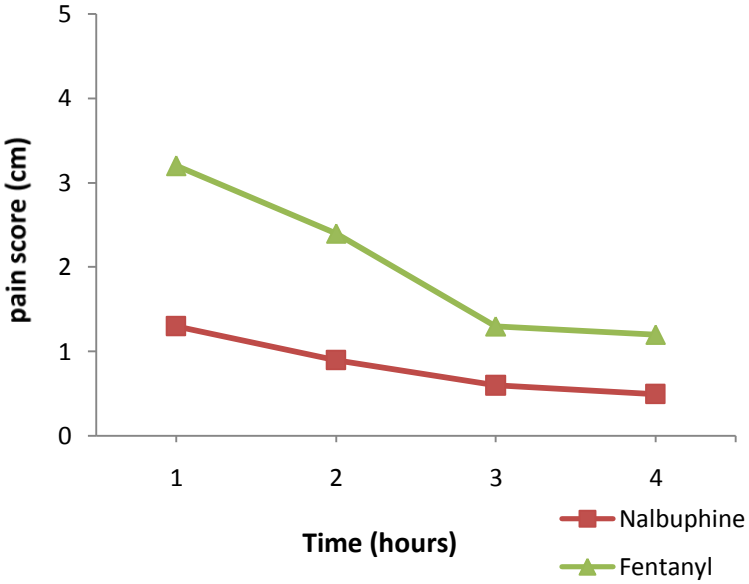
There were no significant differences between the observed sedation appearances of the 2 groups at any time postoperatively (table-2).

Table-2 Postoperative Sedation: Appearance of patient, expressed as number of patients

	Nalbuphine (n=30)	Fentanyl (n=30)
1 hour		
Asleep	6	5
Awake and calm	21	21
Awake and restless	3	4
2 hour		
Asleep	12	5
Awake and calm	12	10
Awake and restless	6	15
4 hour		
Asleep	3	2
Awake and calm	25	20
Awake and restless	2	8

There was significantly less pain postoperatively in the group N at 1 hour and 2 hours ($p < 0.05$) as seen in graph-1. 18 patients (60%) in the group N scored no pain at 1 hour, compared with 6 patients in group F. the number with no pain were 21 patients (70%) and 9 patients (30%), respectively at 2 hours. However there was no difference between groups at 4 hours.

Duration of analgesia was longer in group N than group F as 15 patients (50%) in group F required postoperative analgesia at mean time of 1.9 ± 0.17 hours, compared with group N, where 6 patients (20%) received postoperative analgesia at mean time of 3.2 ± 0.22 hours ($p < 0.05$).



Graph-1 Mean pain score with time, bars indicate SEM.

There were no significant differences in side effects like nausea and vomiting, headache, dizziness, drowsiness and respiratory depression between two groups.

IV. Discussion

Opioid analgesics are the corner stone for management of postoperative pain. Short surgical procedures required adequate depth of anesthesia with rapid recovery. The treatment of postoperative pain is frequently fortified to achieve this.

This study compared the efficacy and side effects of nalbuphine and fentanyl as intravenous analgesics in short surgical procedures. Hemodynamic parameters were remained within normal limits in both the groups.Collins *et al*[4] .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; it was 36% with halothane group and 27% with alfentanil group, overall 40% of patient required postoperative analgesia. Another study Hacket *et al*[5].compared techniques using fentanyl and enflurane in unpremedicated patients. The frequency of moderate to severe pain was similar in both groups, approximately 28%, and there was no difference in postoperative analgesics requirements.

Bone *et al*[6] compared nalbuphine and fentanyl for postoperative pain relief in patients undergoing termination of pregnancy. The incident of postoperative pain was significantly less in nalbuphine group and 45% of patient in fentanyl group required postoperative analgesia compared to 10% in nalbuphine group.

Our findings confirm this, since, there was a higher incidence of pain in group F and 50% required postoperative analgesia at mean time of 1.9 hours. The duration of analgesia was longer in group N only 20% of patients required postoperative analgesia at mean time o 3.2 hours and the pain score at 1 and 2 hours were significantly less than in group F ($p< 0.05$).

The use of longer acting opioid, such as nalbuphine with a half life of approximately 4 hours[7], may be expected to lengthen recovery time. However we found that the recovery time was not significantly different from group F. There was also no significant difference in observer assessments of postoperative sedation.

There were no significant differences in side effects like nausea and vomiting, headache, dizziness, drowsiness and respiratory depression between two groups.

Nalbuphine has been shown to provide adequate postoperative pain relief[8]. It has some advantages over pure agonists with a proven maximum respiratory depressant effect. Its 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.

V. Conclusion

Nalbuphine produces a significant reduction in the incidence of pain in first 2 hours compared to fentanyl and does not increase recovery time or incidence of side effects. Nalbuphine is as effective as fentanyl as intravenous analgesic during surgery. Nalbuphine also produces provides longer duration of postoperative analgesia with less respiratory depression and risk of chest wall rigidity and apnea. Freedom from controlled

drug act regulations and improved analgesia make it more safer alternative to more commonly used fentanyl as intravenous analgesic agent in short surgical procedures.

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