

Postoperativenauseavomitingand sedation with fentanyl and nalbuphine: a comparative study

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Abstract

Background: Both nalbuphine and fentanyl are opioids used for perioperative analgesia. Postoperative sedation and nausea and vomiting are one of the most common complications seen with the perioperative use of opioids. The aim of this study was to compare the postoperative sedation and postoperative nausea and vomiting with both the drugs.

Material and methods: It was a prospective double blind randomized study. After obtaining approval of institutional ethical committee, eighty patients aged 20-60 years of either sex, ASA physical status I or II, scheduled for elective surgery were studied and they were randomly assigned to one of the two groups of 40 patients each in a double blind manner to receive any of the two drugs.

Group I (n=40) received fentanyl 2 microgram per kg body weight 5 minutes prior to intubation

Group II (n=40) received nalbuphine 0.2 mg per kg body weight 5 minutes prior to intubation

Patients in both the groups were assessed for post operative sedation and nausea and vomiting immediately after extubation. The statistical package used was SPSS version 11.0.

Results: Both the groups were well matched for their demographic data.

After extubation, sedation was reported in 2(5%) cases in fentanyl group and in 21(52.5%) cases in nalbuphine group. The difference was found to be statistically significant ($p < 0.001$) However, on comparison of post operative nausea and vomiting in both the groups, the values were not found to be statistically significant.

Conclusion: Incidence of sedation was found to be more with nalbuphine than with fentanyl. However, post operative nausea and vomiting was comparable in both the groups.

Keywords: nalbuphine, fentanyl, sedation, nausea and vomiting

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I. Introduction

Opioids offer a combination of analgesic potency and acceptable profile of adverse effects matched with no other class of drugs.¹

They have the advantage of having perioperative role in anaesthesia. These can be used as a sole or supplementary agent for induction of anaesthesia. They are very commonly used for intraoperative analgesia; therefore, there is no additional cost involved.²

Despite this, use of opioids has generally been limited due to a number of well documented adverse effects including nausea, vomiting, drowsiness, dry mouth, respiratory depression, histamine release and neuro excitatory and gastrointestinal effects.³

Fentanyl, a mu opioid receptor antagonist³ is an exception characterized by high potency, rapid onset, short duration of action and an apparent absence of the serious side effects normally associated with opioids.

Nalbuphine is an agonist antagonist opioid that is structurally related to oxymorphone and naloxone. Its cardiovascular stability, long duration of analgesia, no respiratory depression, less nausea and vomiting and potential safety on overdose makes it an ideal anaesthetic for use in balanced anaesthesia.

This study was undertaken to compare the sedation and post operative nausea and vomiting with both the drugs in the postoperative period.

II. Material and Methods

This prospective comparative study was carried out in the patients undergoing elective surgery at Vivekananda Polyclinic and Institute of Medical Sciences, Lucknow, Uttar Pradesh from December 2009 to December 2010. A total of 80 subjects of either sex aged 20 to 60 years were included in the study.

Study design: Prospective double blind randomised study.

Study location: Vivekananda Polyclinic and Institute of Medical Sciences, Mahanagar, Lucknow, Uttar Pradesh, India

Study duration: December 2009 to December 2010

Sample size: 80 patients

Subjects and selection method: Eighty patients aged 20 to 60 years of either sex, ASA physical status I or II, scheduled for elective surgery were included in the study and they were randomly assigned to one of the two groups of 40 patients each in a double blinded manner to receive any of the two drugs.

Group I (n=40) received fentanyl 2 microgram per kg body weight 5 minutes prior to intubation

Group II (n=40) received nalbuphine 0.2 mg per kg body weight 5 minutes prior to intubation

Exclusion criteria:

1. Patient refusal
2. Patients under 20 and over 60 years.
3. ASA physical status III or higher.
4. Patients with any cardiac ailment (IHD, VHD, arrhythmias)
5. Patients with hypersensitivity to study drugs.
6. Patients with pulmonary diseases like asthma or COPD and/or respiratory insufficiency.
7. Pregnancy
8. Patients on any cardiac drugs

Procedure methodology

After obtaining approval of the institutional ethical committee, written informed consent was taken from the patients included in the study. Patients scheduled for elective surgery were randomly allocated to any of the two groups to receive either fentanyl 2 microgram/kg body wt (group I) or nalbuphine 0.2 mg/kg body wt (group II) 5 minutes prior to intubation. The observer was totally blind about the groups or medications received by the patients. Group sizes of 40 were determined by power analysis based on standard deviation data.

Preoperative orders:

- Nil orally 8 to 10 hours prior to surgery.
- Written informed consent.
- Tablet alprazolam 0.5 mg in the preceding night.

On patient arrival in the operation theater, monitors were attached and baseline vital parameters were recorded. Injection glycopyrolate 0.2 mg given intravenously and study drugs fentanyl (0.2 microgram per kg body weight) or nalbuphine (0.2 milligram per kg body weight) were administered to the patients. After induction with injection propofol 2 milligram per kg body weight and muscle relaxation with injection succinylcholine 2 mg per kg body weight, endotracheal intubation was performed and anaesthesia was maintained with 33% oxygen and non-polarizing muscle relaxant vecuronium bromide 0.06 mg/kg body wt and 0.4% healthcare were used.

Muscle relaxation was achieved by intermittent doses of vecuronium bromide. Just 30 minutes prior to surgery injection ondansetron in the dose of 0.1 mg per kg body weight was administered. At the end of the surgery, neuromuscular block was reversed with appropriate dose of IV neostigmine and IV glycopyrolate and patient was extubated. During the entire surgery no other drug was administered that could confound with the sedation in the post-operative period.

The following parameters were recorded from the time immediately after extubation.

- Sedation
- Post-operative nausea and vomiting

The primary objective of the study was to compare the incidence of sedation and post-operative nausea and vomiting in fentanyl and nalbuphine groups.

Statistical analysis

For the purpose of evaluation of the results of the present study, data has been managed using MS Excel software and for statistical analysis, statistical package for social sciences (SPSS 11.0) has been used.

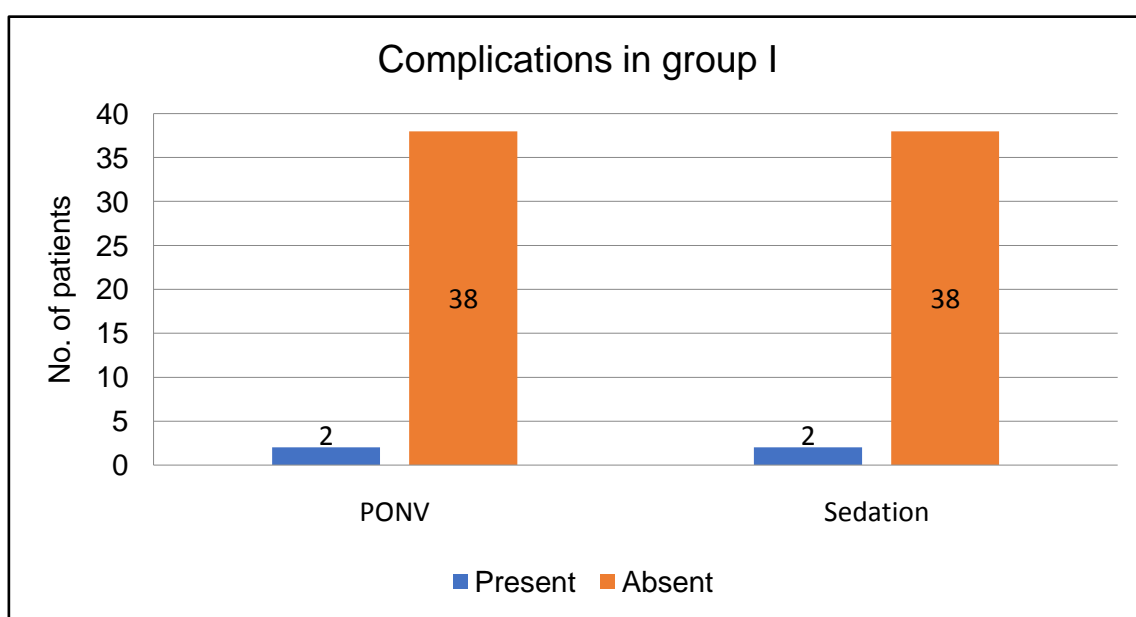
The statistical tools used in the study are mean, standard deviation, chi-square test for proportions , t test for independent samples and confidence level.

III. Results

The groups were well matched for their demographic data, gender wise distribution and ASA grade. The surgeries routinely performed in our institution such as laparoscopic cholecystectomy, tympanoplasty, mastectomy, functional endoscopic sinus surgery were included in this study. After extubation post operative nausea and vomiting was reported in 2/40 patients and sedation was also reported in 2/40 patients in group 1.(table no 1)

Table no 1: Complications in group I

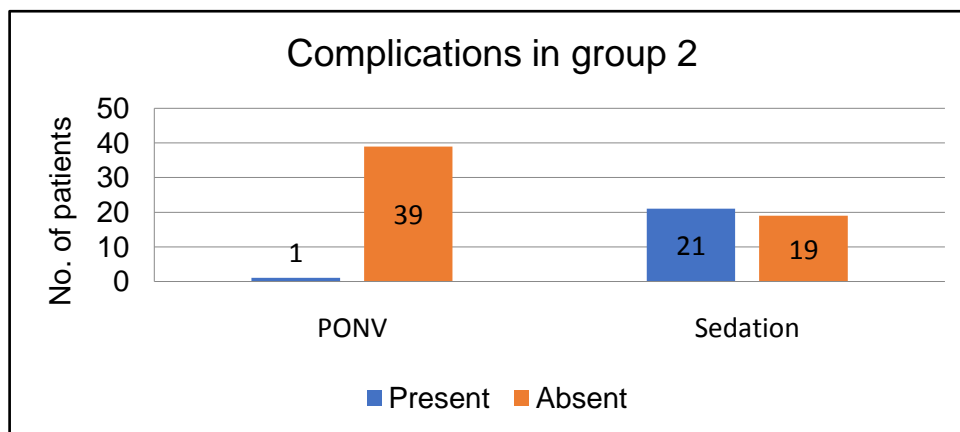
	Present	Absent
Post operative nausea and vomiting (PONV)	2	38
Sedation	2	38



In group 2, post operative nausea and vomiting was reported in 1/40 patients while sedation was reported in 21/40 patients in the post operative period. (table no 2)

Table no 2: Complications in group II

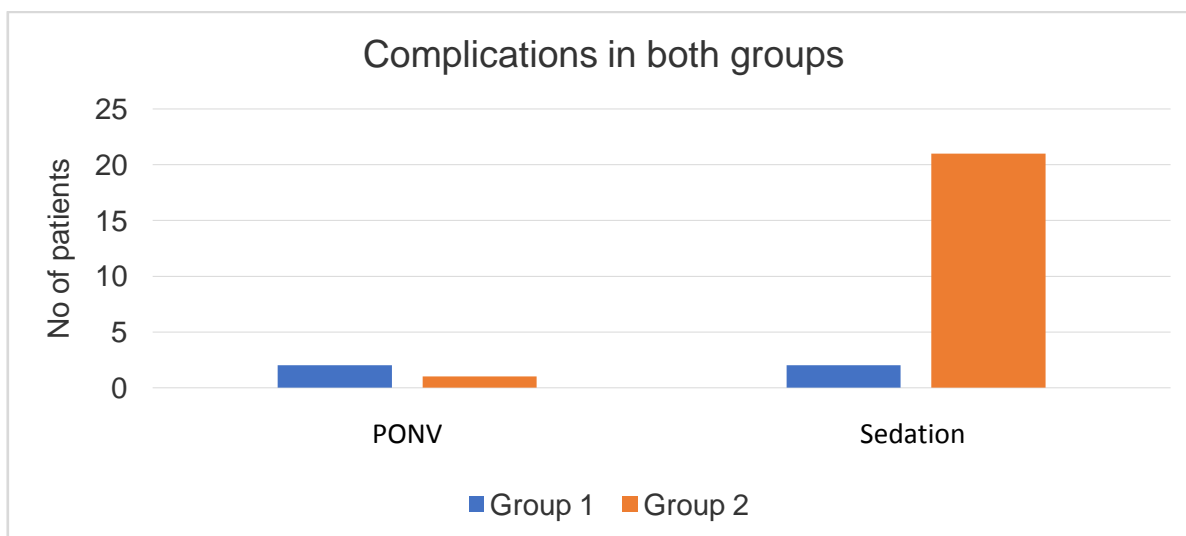
	Present	Absent
Post operative nausea and vomiting(PONV)	1	39
Sedation	21	19



On comparison of data in both the groups, sedation was reported in 2/40 (5%) cases in group 1 and in 21/40(52.5%) cases in group 2. On analysis, the values were of definite statistical significance. ($p < 0.001$). There was episode of postoperative nausea and vomiting in 2/40(5%) cases in group 1 and in 1/40(2.5%) cases in group 2. The values were not found to be statistically significant. ($p > 0.1$)(table no 3)

Table no 3: Complications in group I and group II

	Group I	Group II	p value
Post operative nausea and vomiting	2	2	$p > 0.1$
Sedation	2	21	$p < 0.001$



IV. Discussion

Till date no pharmaceutical agent is available that has been absolutely free of complications.

Fentanyl is a synthetic opioid. It binds to mu receptors; most of its effects typical of opioids especially analgesia, euphoria or respiratory depression are through its agonist actions on mu receptors.⁴

Nalbuphine is an agonist antagonist opioid that binds to mu receptors as well as kappa and delta receptors, with potent analgesic effects due to its agonist action on kappa receptors in the central nervous system.

Chestnut, Clarke and Dundee⁵ studied the effects of nalbuphine, pethidine and placebo group and noticed that nausea and vomiting at the end of surgery was more in pethidine group.

Garcia et al⁶ performed a pilot study with nalbuphine and tramadol given via continuous intravenous infusion for post operative pain control in children. They concluded that nausea and vomiting was in 2 (16.7%) cases in nalbuphine group and in 4(33.3%) cases in tramadol group. This finding is similar to our study where incidence of nausea and vomiting has been observed less in nalbuphine group.

Bone, Dawson and Smith⁷ compared nalbuphine and fentanyl for post operative pain relief. Congruous to the finding in the present study, no significant differences were found between the groups for the incidence of nausea and vomiting.

Siddiqui and Chohan⁸ in their comparative study of nalbuphine versus tramadol concluded that mean time to orientation as well as mean time to eye opening at the end of total intravenous anaesthesia was less with nalbuphine as compared to tramadol.

Vandenberg et al⁹ studied clinical comparison of the intraoperative recovery and post operative effects of nalbuphine, buprenorphine, fentanyl, morphine and pethidine given intravenously with induction of anaesthesia in ENT surgery. Following discontinuation of the inhalational anaesthetic agents and administration of neostigmine and atropine at the end of anaesthesia, the mean time to extubation was prolonged for buprenorphine, fentanyl, morphine and pethidine compared to nalbuphine.

Chung et al¹⁰ observed that pure mu receptor agonists such as remifentanyl can cause complications such as respiratory depression which can be dangerous in the recovery room. On the other hand, nalbuphine which is an agonist-antagonist, causes less respiratory depression by activating the supra-spinal and spinal kappa receptors.

Mitterschiffthaler et al¹¹ compared nalbuphine with pethidine for post operative pain therapy. Akin to the present study, sedation was significantly more pronounced in the nalbuphine group.

Graham, McCaughey and Bell¹² in their study found that 2 patients in nalbuphine and 3 patients in pentazocine group were fast asleep at 5 minutes and 1 patient in each group remained fast asleep at 20 minutes.

In the study by Rawal and Wennhager¹³, within the first 15 minutes following recovery, increased PaCO₂ and ETCO₂ as well as respiratory rates below 10 minute were reported in 8 patients who all belonged to fentanyl group; in 4 of these patients intravenous naloxone had to be administered to reverse respiratory depression. Prolonged sedation was a common feature in patients receiving nalbuphine. However, fentanyl was associated with respiratory depression in considerable number of patients. In our study, there was no episode of respiratory depression in any of the two groups.

V. Conclusion

Nalbuphine caused much greater sedation in the postoperative period as compared to fentanyl. However, the incidence of post operative nausea and vomiting was comparable in both the drugs.

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