The impact of preinduction fentanyl dosing strategy on postoperative nausea and vomiting in patients undergoing laparoscopic cholecystectomy: A concept evaluation of equi-dose fentanyl given as a single-bolus or divided intermittent boluses or continuous infusion administration technique.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21891

Source
NTR

Health condition

Post operative nausea & vomiting (PONV) in patients undergoing laparoscopic cholecystectomy.

Keywords- Post operative nausea & vomiting (PONV) , laparoscopic cholecystectomy

Trefwoorden-Post-operatieve misselijkheid en braken (PONV), laparoscopische cholecystectomie

Sponsors and support

Primary sponsor: Department of Anaesthesiology, Pain and Perioperative Medicine. Sir Ganga Ram Hospital, Old Rajinder Nagar ,New Delhi-110060 .India

Source(s) of monetary or material Support: Department of Anaesthesiology, Pain and Perioperative Medicine Sir Ganga Ram Hospital, Old Rajinder Nagar ,New Delhi-110060. India

Intervention

Outcome measures

Primary outcome

1. The impact of pre-induction IV fentanyl dosing methodology on reduction of PONV incidence;

2. Reduction in the use of postoperative antiemetics.

Secondary outcome

The effect of different methods of pre-induction intravenous fentanyl administration method on patient response profile including:

1. Hemodynamics: Heart rate (HR), noninvasive blood pressure (NIBP);

2. Respiration: Respiratory rate (RR), depth of breathing, oxygen saturation (SpO2);

3. Central nervous system: Orientation, consciousness (level of sedation), bispectral index (BIS).

Study description

Background summary

This concept-oriented study aims determine the impact of the three equidose pre-induction intravenous fentanyl citrate administration strategies on reduction of the incidence and magnitude of postoperative nausea and vomiting (PONV) in patients undergoing laparoscopic cholecystectomy. In addition, the patient's clinical response to different fentanyl administration methods will be studied. The outcome of this research is expected to help bring down patient morbidity secondary to the PONV and related effects. It will also help us determine if there is a decrease in the incidence of PONV. The study is being undertaken with the sole intent to reduce patient morbidity by simple utilization of intravenous fentanyl

pharmacokinetics at clinically acceptable analgesic doses.

Study objective

Fentanyl, a synthetic opioid agent, is the most common opioid used during general anaesthesia (GA) owing to its analgesic efficacy and selective action.However, it is associated with significant side effects, most notably postoperative nausea and vomiting (PONV). PONV is one of the most common complaints following GA. Not only it may lead to wound dehiscence, pulmonary aspiration, fluid – electrolyte disturbances but also patient dissatisfaction, delayed discharge and inadvertent readmission (in outpatients). Opioid induced nausea and vomiting are caused by direct stimulation of chemoreceptor trigger zone (CTZ) in the floor of the fourth ventricle. Opioid administered IV reaches the vomiting center as rapidly as it reaches the CTZ. The inconsistencies involving the IV opioid administration during pre-induction period may affect the above stated balance may result in over-stimulation of the CTZ center along with subsequent PONV. Since it is unclear as to how long the CTZ-activation lasts, it may encroach the postoperative period, especially in surgical intervention of shorter duration, resulting in PONV.

Although emetogenic action of opioids may vary in different individuals it is possible to reduce PONV severity by selection of a different opioid. The mechanism of PONV following opioid use involve direct CTZ stimulation, increased vestibular sensitivity and decreased GI (stomach, small/large intestine) motility. The strategies of opioid selection in reducing PONV are primarily postoperative opioid use-oriented. Despite opioids being administered prior to anaesthesia induction in almost all patients in receipt of GA, the emetic action specific to immediate pre-induction opioid use pattern has been unexplored. Our premise that bolus dose fentanyl administration gives a pharmacokinetic peak that causes CTZ activation, which, in turn, adds upon the incidence of PONV and consonant antiemetic use, thus increasing cost. This increases patient morbidity; increases medication cost (use of antiemetic) and may have a negative administration impact (delay discharge).

Laparoscopic cholecystectomy is a common standardized laparoscopic procedure done under general anaesthesia. It is increasingly being done on an outpatient/short hospital stay (<24-hrs) basis. It is commonly associated with PONV (64% in one study).

We postulate that intravenous fentanyl administered during the pre-induction period can be given in favorable dosing patterns that may help preclude CTZ activation (and thereby a reduced PONV incidence postoperatively), a mechanism that is a possibility following random IV bolus dosing of fentanyl. This will also help in reducing costs related to antiemetic use, overstay-readmission, and manpower loss.

Study design

Time of extubation to 48 hours postoperatively or patient discharge from the hospital, whichever is later.

Intervention

All the patients scheduled for laparoscopic cholecystectomy under general anaesthesia will be randomly (simple computer generated random number table) allocated to one of the following three groups:

Group.I: Single 3µg/kg IV bolus pre-induction fentanyl;

Group.II: Intermittent 1µg/kg fentanyl IV (total-3µg/kg) given thrice during the pre-induction period (3 minutes apart; i.e., 0, 3, 6 minutes);

Group.III: Continuous intravenous infusion of 3µg/kg fentanyl over 6 minutes prior to induction.

Patients will be extubated once wide-awake. Any regurgitation during the peri-extubation period will be considered as 'non-emesis' but will be recorded. PONV parameters will be recorded after patient is shifted to the recovery room. In addition, demographic and haemodynamic data, surgery details and pre-induction patient response profile to fentanyl administration [hypopnoea, desaturation, sedation, cough (if any)] will be noted and recorded.

Rescue Anti-emetic: Ondansetron (5-HT3-receptor antagonist), a standard antiemetic used in the postoperative period will be administered to the patients @0.1 mg/kg following a confirmed nausea and/or vomiting episode.

Contacts

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Eligibility criteria

Inclusion criteria

1. Male or female gender;

2. Aged 20-60 years age;

3. Scheduled surgery: Laparoscopic cholecystectomy;

4. General anaesthesia;

5. Elective nature of intervention;

6. Consenting for surgery;

7. ASA physical status I-II.

Exclusion criteria

1. Patients with uncompensated systemic co-morbidity [cardiac (hypertension, coronary artery disease, cardiomyopathy, arrhythmias), respiratory (bronchial asthma, COPD), endocrinology (diabetes mellitus, thyroid disease), hepato-renal, CNS];

2. Allergy to opioid drugs;

3. History of substance abuse;

4. Psychiatric illness;

5. Acute nature of gall bladder pathology (cholecystitis);

6. Those with a tendency/recent history of hyperemesis;

7. H/o postoperative emesis.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-03-2011
Enrollment:	270
Type:	Anticipated

Ethics review

Positive opinion

Date:	19-02-2011
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2634

Register	ID
NTR-old	NTR2762
Other	METC Sir Ganga Ram Hospital, New Delhi, India : EC01/11/208
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A