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To Compare The Efficacy of Dexamethasone With and Without Ondensatreon in Prevention of Post Operative Nausea and Vomiting in Elective Laproscopic Surgeries

Medical Science

KEYWORDS : Bacteremia, *Enterobacter*, Underlying Disease, Intravascular Catheter

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AIM AND OBJECTIVES-To compare the efficacy of dexamethasone with and without ondensatron in prevention of post operative nausea and vomiting (PONV) in elective laparoscopic surgeries like laparoscopic Hysterectomy and Diagnostic laparoscopy

MATERIALS AND METHOS This study was conducted at Swatantra Multispeciality Hospital Rajahmundry; from the period January 2012 to December 2012. All patients were selected and after matching our inclusion criteria we finalized to a total of 100 patients. We took 50 in each group, with informed consent. We did a randomized controlled trial in which, study was done after taking approval from the ethics committee. Written informed consent was taken from all patients, who were **American Society of Anesthesiologists** (ASA) physical status 1 and 2 patients undergoing laparoscopic surgery. The study had 2 groups; Group I and Group II They were then randomly divided into their respective groups with sealed envelope technique of 50 patients in each group.Group I had received 4 mg of Ondansetron intravenously (i.v.) Group II had received 4 mg of Ondansetron intravenously (i.v.)with 8 mg of Dexamethasone intravenously (i.v.)

The inclusion criteria:

1. Patients of ASA Grade I and II undergoing laparoscopic surgery.
2. Patients between 20 and 55 years of age.
3. Patients weighing between 30 and 75 kg.
4. Elective laparoscopic surgeries
5. Diagnostic
6. Cholycystectomy
7. Appendicectomy

The exclusion criteria :

1. Patients belonging to ASA Grade III and IV.
2. Patients who had received opioids, nonsteroidal anti-inflammatory drugs, steroids, and antiemetic agents during the previous and post 24 h.
3. Patients with a history of motion sickness and previous PONV
4. Any rescue analgesic administered along with fentanyl for a VAS score of >5
5. Co-morbidities ; Diabetes Mellitus, Disturbed pituitary adrenal axis ex. Cushing's syndrome, Obesity with BMI > 20, etc.
6. Surgeries
7. Requiring Ryle's tube
8. Gynaecological
9. any other laparoscopic surgery
10. Lactating mothers
11. Intra-operative **Conversion** into open surgery due to unforeseeable circumstances
12. post operative **Pain** on patients (VAS >5) were excluded from our study.

Randomization

(1) Pre operative methodology A day prior to surgery, preoperative evaluation of the patients was done. Necessary preoperative investigations based on the diagnosis were done. All the patients received Tab diazepam 10 mg at night and 5 mg in the morning of surgery and also Tab ranitidine 150 mg on the night of the surgery. Patients were kept nil per oral from midnight. After shifting the patient to the operation theatre, normal saline infusion was started. Preinduction monitors were connected, which included electrocardiography, non-invasive blood pressure monitoring, and oxygen saturation through pulse oxymetry. The patients were then given study medication based on groups they belonged. Group I received 4 mg of ondansetron intravenously (i.v.), whereas Group II received ondansetron 4 mg and dexamethasone 8 mg i.v. just before the induction of anesthesia

(2) Intra operative methodology; the patients were then preoxygenated for 3 min and premedicated with 0.2 mg/kg of Inj. Midazolam and 2 mcg/kg of 2) Intra operative methodology; the patients were then preoxygenated for 3 min and premedicated with 0.2 mg/kg of Inj. Midazolam and 2 mcg/kg of Inj. Fentanyl. Anesthesia was then induced with Inj Propofol at 2mg/kg to the loss of verbal command and eyelash reflex neuromuscular blockade achieved, which was achieved with inj vecuronium, 0.1 mg/kg after 3 min of assisted ventilation, endotracheal intubation was done with an appropriate-sized endotracheal cuffed tube. General anesthesia was maintained with air in oxygen and Isoflurane 0.5%–1% MAC with controlled ventilation through closed circuit absorber system. Postinduction monitoring included end-tidal carbon dioxide maintained at 35 – 45 mm Hg and temperature. After completion of the surgery, the respective drugs were given according to randomization just before the extubation. The residual paralysis was antagonised with Inj. Neostigmine 0.05 mg/kg and Inj. Glycopyrolate 0.02 mg/kg. The patients were then transported to the recovery room after extubation and later to the ward after confirming that there was adequate level of consciousness and intact reflexes.

(3) Post operative Observation methodology Post operatively Inj Fentanyl 1mcg/kg i/v every 6 hourly for a 24hr period was used as a routine analgesic under due observation of vitals.

PONV monitoring

The incidence of PONV was recorded at regular intervals within the first 24 hours of surgery only. Episodes of PONV were identified by spontaneous complaints by the patients or by direct questioning**.** Complete or Incomplete response was recorded.

Complete response was defined as the absence of any nausea or vomiting and no need for rescue antiemetic during the whole observation period.

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Incomplete response was defined as the presence of any nausea or vomiting, for which rescue antiemetic was provided with inj. Ondansetron 4 mg i.v.

Outcome variables monitored

Presence of Nausea and Vomiting in the post operative period of up to 24 hours at regular intervals.Administration of rescue medication (number of times). Anesthesia was then induced with Inj Propofol at 2mg/kg to the loss of verbal command and eyelash reflex neuromuscular blockade achieved, which was achieved with inj vecuronium, 0.1 mg/kg after 3 min of assisted ventilation, endotracheal intubation was done with an appropriate-sized endotracheal cuffed tube. General anesthesia was maintained with air in oxygen and Isoflurane 0.5%–1% MAC with controlled ventilation through closed circuit absorber system. Postinduction monitoring included end-tidal carbon dioxide maintained at 35 – 45 mm Hg and temperature. After completion of the surgery, the respective drugs were given according to randomization just before the extubation. The residual paralysis was antagonised with Inj. Neostigmine 0.05 mg/kg and Inj. Glycopyrolate 0.02 mg/kg. The patients were then transported to the recovery room after extubation and later to the ward after confirming that there was adequate level of consciousness and intact reflexes.

RESULTS AND OBSERVATIONS

Patients were interviewed and assessed for the first 24 hours as per our protocol and the results were tabulated and the data was analyzed accordingly.

AGE DISTRIBUTION

The age was tabulated and Both the groups were comparable in terms of Age (P=0.14)

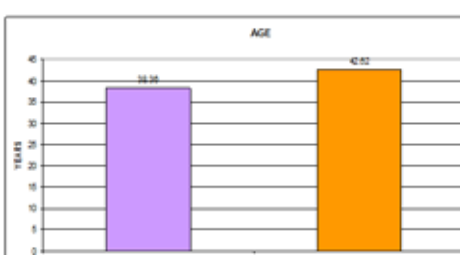


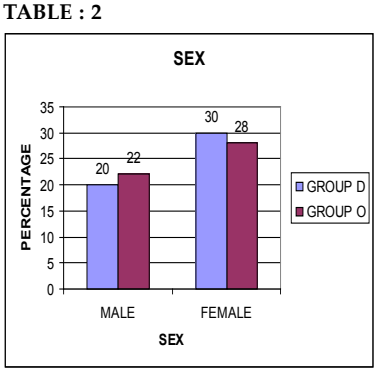
TABLE : 1

Group		N	Mean	Std. Deviation	Std. Error Mean
Age	Group I	50	38.36	13.708	1.939
	Group II	50	42.62	12.081	1.709

SEX DISTRIBUTION

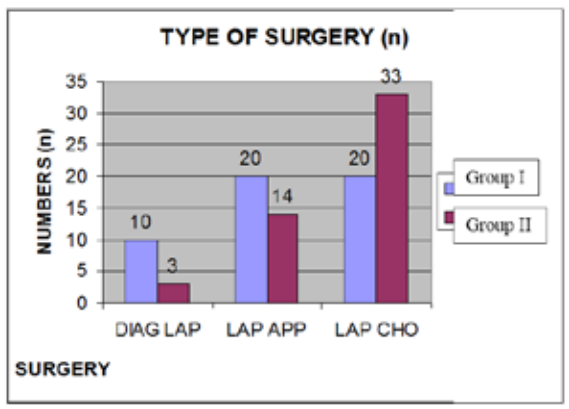
Both the groups were comparable in terms of sex distribution.

TABLE : 2



SEX	Group I	Group II
FEMALE	22%	28%
MALE	20%	30%

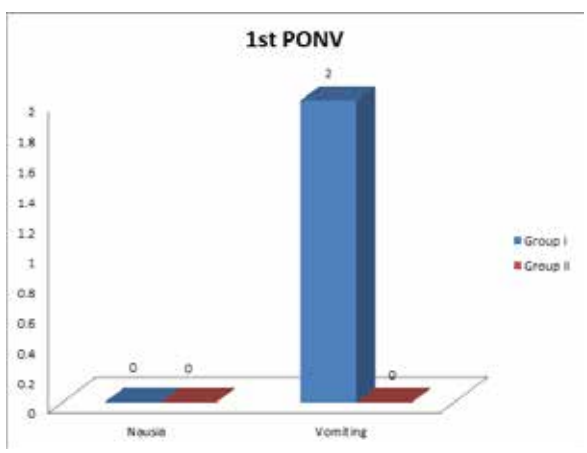
SURGERY DISTRIBUTION



Surgery	Group I	Group II
LAP APP : Laporoscopic Appendisectomy	20	14
LAP CHO : Laparoscopic Cholecystectomy	20	33
DIAG LAP: Diagnostic Laparoscopy	10	3

TIME DISTRIBUTION

1ST PONV DISTRIBUTION



1st PONV	Group I	Group II
Nausia	0	0
Vomiting	2	0

2ND PONV DISTRIBUTION

2nd PONV	Group I	Group II
Nausia	10	0
Vomiting	3	2

3RD PONV DISTRIBUTION

3rd PONV	Group I	Group II
Nausia	0	0
Vomiting	0	0

4TH PONV DISTRIBUTION

4th PONV	Group I	Group II
Nausia	26	4
Vomiting	22	4

DISSCUSION

one of the main complaints in patients undergoing surgery under general anesthesia. The incidence of PONV in patients undergoing laparoscopy ranges from 40% to 75%. It is the one of the most important factors that determines the length of hospital stay after ambulatory anaesthesia. In fact its contribution to patient dissatisfaction is such that over 70% of patients considered avoidance of PONV to be very important Numerous factors can affect PONV, such as age, gender, obesity, motion sickness, history of PONV, duration of the procedure, anesthetic technique, use of opioids, and pain. In our study, the majority of these factors (age, gender, weight, duration of the procedure, anesthetic technique, and medication) were not significant among both the study groups [12]. The selection of drug dosages was based on the previous work that demonstrated that these doses were effective .In our study he had an overall incidence of PONV of 35% in the first24 hours after surgery. Our study however did not include gynaecological procedures which have highest incidence of PONV.

Dexamethasone being a long acting steroid and it's long half-life, between 36 and 72 hours, extends its antiemetic efficacy up to 24 hours post surgery ; as our study also extends upto 24 hours we did not find any specific time set pattern of maximum prophylaxis in the 12 cases of PONV .Ondansetron, a selective 5 HT_3 receptor antagonist, has been shown to be effective in the prevention and treatment of PONV in many studies . Role of steroids as antiemetics was established in 1980, and dexamethasone as an antiemetic was introduced later. Many studies have shown that dexamethasone alone or in combination with other antiemetics used prophylactically prevents PONV.Although $5HT_3$ antagonists are potent antiemetics, no single drug has been successful in effectively controlling PONV. This has led to a number of studies investigating the efficacy of combination of various antiemetics with an assumption that using a combination of antiemetics acting on different receptors can further reduce the incidence of PONV.The mechanism of action of corticosteroids is unknown; however, there have been some suggestions, such as central and peripheral inhibition of production of 5HT, central inhibition of synthesis of prostaglandins, or changes in permeability of the blood–brain barrier to serum proteins. It was shown that dexamethasone was most effective when adminstered at the time of induction of anesthesia. As for ondansetron, it was suggested that in operative procedures lasting more than 2 h, it might be relevant to administer the drug toward the end of the surgery as the half-life of ondansetron is approximately 3.5-4 h in adults . Since the mean duration of the procedure in our study was about an hour, we assumed that the timing of antiemetic combination before induction would not affect the outcome. A complete response to the prophylaxis of antiemetic therapy was defined as no nausea or vomiting and no need for rescue antiemetic during the 24 h observation period postoperatively. It was duly observed and noted. In our study, the complete repsonse occurred in 76% of the cases in ondansetron group and 92% in ondansetron and dexamethasone group. In our study, 12 cases in Group I had complaints of PONV of which 11 cases (22%) needed rescue antiemetic. This can be compared with 4 cases (8%) in Group II who had complaints of PONV and all of them needed rescue antiemetic. The need for rescue antiemetic is more in Group I (22%) than in Group II (4%),Dexamethasone lacks the sedative, dysphoric and extrapyramidal signs associated with the traditional antiemetics, droperidol, and metoclopramide. The long-term administration of dexamethasone may cause undesirable adverse effects, such as an increased risk of infection, glucose intolerance, delayed wound healing, superficial ulceration of gastric mucosa, and adrenal suppression In our study we decided to administration of fentanyl as a routine analgesic under due observation of respiration and vitals to eliminate the pain as a cause of emesis.However, in the present study, there were no adverse effects that we could specifically attribute to the single dose of dexamethasone we had administered. Thus, prophylactic antiemetics therapy with dexamethasone is considered to be relatively free of side effects. In the present study, the patients who had been treated for PONV within the first 24 hrs had only one episode of nausea and vomiting after treatment and did not require a repeat dose.The incidence of PONV and pain was less in Group II than in Group I. Though all with VAS>5 were excluded from our study. This probably reflects the strong anti-inflammatory action of dexamethasone, which has been shown to decrease postoperative pain Considering the side effects profile of ondansetron and dexamethasone, both the drugs are well tolerated. A single dose of dexamethasone is considered safe. Two cases had minor side effects that included headache, heartburn, and transient chest pain. These side effects were statistically insignificant.In our study we have compared the efficacy of ondansetron 4 mg alone with the combination of ondansetron 4 mg and dexamethasone 4 mg i.v. given prophylactically just before induction of anesthesia in adult patients undergoing elective laparoscopic surgery under general anaesthesia.

Conclusion

It has been concluded from this study that the combination of ondansetron 4 mg with dexamethasone 8 mg is more effective than ondansetron 4 mg alone in preventing PONV. Both the monotherapy and the combination therapy have a very good safety profile and are well tolerated among patients. The combination therapy has a better patient response in preventing PONV.

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