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A Comparitive Study Of Palonosetron Versus Ondansetron And Dexamethasone Combination For Prevention Of Postoperative Nausea And Vomiting In Patients Undergoing Laparoscopic Surgery.

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Abstract
Background: *Postoperative Nausea And Vomiting (Ponv) Are Common Sequeal Of General Anaesthesia. Ponv Is An Unpleasant, Distressing And Exhausting Experience For Patients Undergoing Surgery. Laparoscopy Compared To Conventional Surgery Reduces The Patient Morbidity Significantly, But Ponv Are The Most Common Distressing Symptoms.*
Aim: *To Analyze The Effect Of Palonosetron Alone And Combination Of Ondansetron And Dexamethasone In Prevention Of Postoperative Nausea And Vomiting In Patients Undergoing Laparoscopic Surgery.*
Methods: *This Is Prospective, Double Blind Study Comprising Of Sixty Four Patients Of Asa Grade I And Ii Of Either Sex, Aged 18-60 Years And Scheduled For Laparoscopic Surgery Under General Anesthesia. Patients Were Randomly Divided Into Group P (Intravenous Palonosetron 0.075 Mg) And Group Od (Intravenous Ondansetron 4 Mg + Intravenous Dexamethasone 8 Mg). The Drug Was Administered Just Before The Induction. All The Vital Parameters Of Patients Were Observed During Intraoperative Period. Episodes Of Nausea, Vomiting And Any Side Effects Were Noted For 48 Hours Post-Operative Period. Intravenous Metoclopramide Was Administered As Rescue Antiemetic In A Patient Who Experienced One Or More Episodes Of Vomiting And Nausea With Visual Analogue Score(Vas) >4 .*
Results: *Incidence Of Nausea During 48hours Of Postoperative Period Is More Group Od Than Group P.*
Conclusion: *The Use Of Palonosetron Evidenced Better Control Of Nausea And Vomiting Than The Combination Of Ondansetron And Dexamethasone Among The Patients Undergoing Laparoscopic Surgery.*
Keywords: *Ponv, Palonosetron, Ondansetron, Dexamethasone.*

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I. INTRODUCTION

Post-operative nausea and vomiting (PONV) is most common complication encountered after laparoscopic surgery under general anaesthesia.[1] The PONV incidence ranges between 20% and 30% in first 24 h, but its incidence can be as frequent as 63%–80% in the high-risk patients when no prophylactic antiemetic used such as laparoscopic surgery.[2-6] It often causes pulmonary aspiration electrolyte imbalance, dehydration and esophageal rupture.[7] The incidence of is influenced by various patient related factors, anaesthesia technique, type of surgery, drugs used and post-operative factors such as pain, dizziness, ambulation etc.[8-11]

Laparoscopic surgeries have been emerged as an alternative to open surgeries in recent times. Increased patient discomfort due to post-operative nausea and vomiting remains as a concern for surgeons as well as anaesthesiologists and has some definite implication on the recovery.[12] PONV may prolong patient recovery, delay patient discharge, and increase hospitalization costs. The goal of PONV prophylaxis is to decrease the incidence of PONV, patient related distress and reduce health care costs.[13]

The 5-hydroxytryptamine 3 (5HT3) receptor antagonists are generally accepted as first-line drugs to prevent PONV.[14] The ondansetron and palonosetron are the first and second generation of 5- HT3 receptor antagonists which are commonly used for the prevention of PONV.[15] Dexamethasone is another class of drug which is a corticosteroid and has recently emerged as a potentially useful antiemetic for the prophylaxis of PONV with minimal side effects after a single dose administration.[16] The multimodal approach is described as the best way to decrease PONV. However, studies comparing the effects on preventing PONV between palonosetron alone and combination of dexamethasone and ondansetron are sparse. Hence, the study was planned to compare the efficacy of palonosetron alone and combination of ondansetron and dexamethasone in the prevention of post-operative nausea and vomiting in patients undergoing laparoscopic surgery.

AIMS

To analyze the effect of palonosetron alone and combination of ondansetron and dexamethasone in prevention of postoperative nausea and vomiting in patients undergoing laparoscopic surgery.

II. MATERIALS AND METHODS

This is prospective, double blind study comprising of sixty four patients of ASA grade I and II of either sex, aged 18-60 years and scheduled for laparoscopic surgery under general anesthesia. Patients were randomly divided into Group P (Intravenous Palonosetron 0.075 mg) and Group OD (Intravenous Ondansetron 4 mg+ Intravenous Dexamethasone 8 mg). The drug was administered just before the induction. All the vital parameters of patients were observed during intraoperative period. Episodes of nausea, vomiting and any side effects were noted for 48 hours post-operative period. Intravenous metoclopramide was administered as rescue antiemetic in a patient who experienced one or more episodes of vomiting and nausea with visual analogue score (VAS) >4.

PRE-OPERATIVE ASSESSMENT

After taking detailed history and systemic examination, Standard pre-anaesthetic check-up with relevant investigations was done. Patients were kept fasting for 8 hours on the night before surgery. Patients were included or excluded for the study on the basis of following criteria:

Inclusion Criteria :

Patients belongs to ASA Grades I & II and aged between 18-60 irrespective of gender scheduled for laparoscopic surgery under general anesthesia.

Exclusion criteria : Pregnant and lactating women, patient with hypersensitivity to palonosetron, dexamethasone or ondansetron. Patients with history of motion sickness and significant neurological, psychiatric, or neuromuscular disorders. Patients on steroid therapy, antiemetics or on treatment with other medication known to produce nausea and vomiting. Any hepatic, renal or cardio-pulmonary abnormality, alcoholism, diabetes mellitus.

TECHNIQUE OF ANAESTHESIA

All patients were pre-oxygenated for three minutes and induced with thiopentone sodium 5 mg/kg and succinylcholine 1.5 mg/kg i.v was used as muscle relaxant to facilitate laryngoscopy and intubation. Oxygenation was continued by positive pressure mask ventilation. At the onset of apnea, using a laryngoscope with a macintosh blade, intubation was performed with well lubricated, appropriate size cuffed oral endotracheal tube. After confirmation of the tube position, the cuff was inflated, and the tube fixed. Injection vecuronium bromide 0.1 mg/kg i.v was used to provide muscle relaxation during surgery depending on the type and duration of the procedure. Capnography was attached after intubation for monitoring end tidal carbon dioxide(ETCO2).

Anaesthesia was maintained with nitrous oxide (N2O), oxygen (O2), isoflurane, and controlled ventilation with the appropriate fresh gas flow. Paracetamol was administered intravenously for analgesia based on requirements. At the end of surgery, when patients had respiratory attempts, the residual neuromuscular blockage was reversed with injection neostigmine and glycopyrrolate. Recovery assessed and extubation was done after thorough throat suction. After complete clinical recovery, patients were shifted to the post-anaesthesia care unit.

In the postoperative period, the patients was observed for PONV during 48 h follow-up with interval of 0-2 hours, 2-6 hours, 6-24 hours and 24-48 hours. Rescue antiemetic metoclopramide 10 mg i. v. was given for patients with visual analogue score (VAS) ≥4 score in nausea and in the events of one or more episodes of vomiting. Any adverse effects like headache, dizziness, constipation, QT prolongation and allergic reactions during 48 hours postoperative period were noted. Cardio-respiratory parameters were recorded continuously, and recordings were made pre-op, 0 minutes and every 30 minutes interval till 120 minutes. Intravenous fluids were given as per body weight and operative loss requirement.

STATISTICAL TOOLS

Statistical Package for Social Sciences (SPSS) version 20 was employed to analyze data. Continuous data was analyzed for its mean, median and standard deviation (summary statistics). Categorical variable was analyzed using chi-square test, student-test was used to analyze the significant difference on the mean value of selected variables. All statistical significance was tested at 5% level.

III. RESULTS AND OBSERVATION

Demographic data of both groups were comparable. There were no statistically significant differences between the groups with respect to sex, ASA-grading, age, weight and height distribution(table-1). The mean duration of surgery, anesthesia, duration of CO2 insufflation, and total i. v. fluid used intraoperatively were also comparable among both groups (table 2) and type of surgery(table 3).

Table no : 1

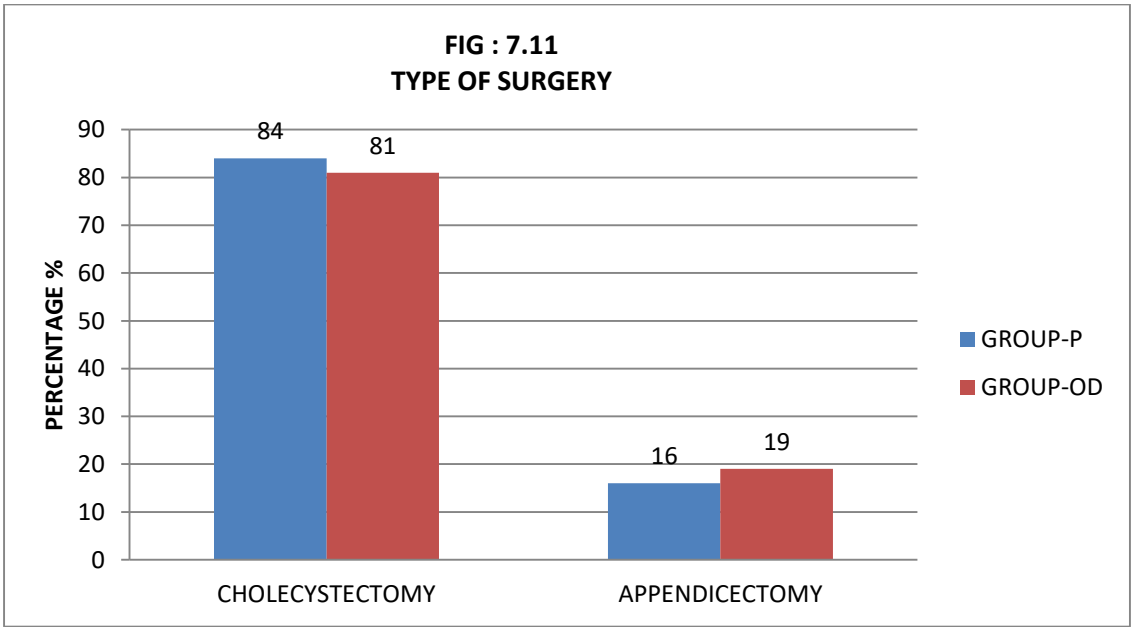
PARAMETERS	Group-P	Group-OD	p-value
AGE	38.25 ±11.1	37.68 ±11.7	0.84
SEX (male:female)	5:25	6:24	0.74
ASA(I:II)	17:13	18:12	0.80
WEIGHT(kg)	50.25 ±8.30	51.28 ±8.36	0.62
HEIGHT(cm)	154.53 ±2.42	153.91 ±2.67	0.33

Table no : 2

PARAMETERS	Group-P	Group-OD	p-value
DURATION OF ANESTHESIA(min)	107±32.3	99.3±29.8	0.34
DURATION OF SURGERY(min)	87.8±32.4	81±31.2	0.40
DURATION OF CO2INFLATION(min)	74.8±31.9	82±30.6	0.44
TOTAL IVF(ml)	837±166	847±174	0.82

TYPE OF SURGERY (LAPAROSCOPIC SURGERY)

Table :3



The intraoperative hemodynamic parameter such as, heart rate (HR), mean arterial pressure(MAP) and oxygen saturation (SpO2) were similar with no statistically significant difference between the groups (Figures 1-3).

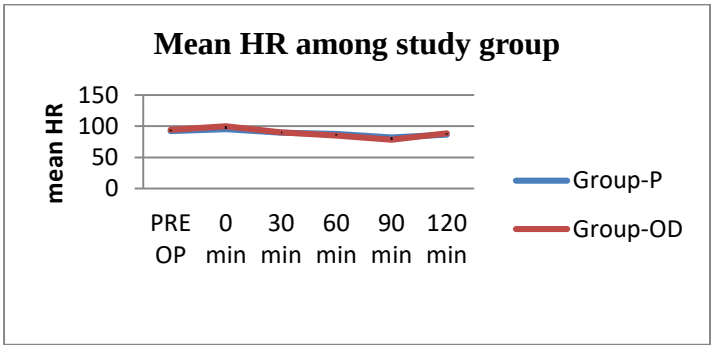


FIGURE : 1

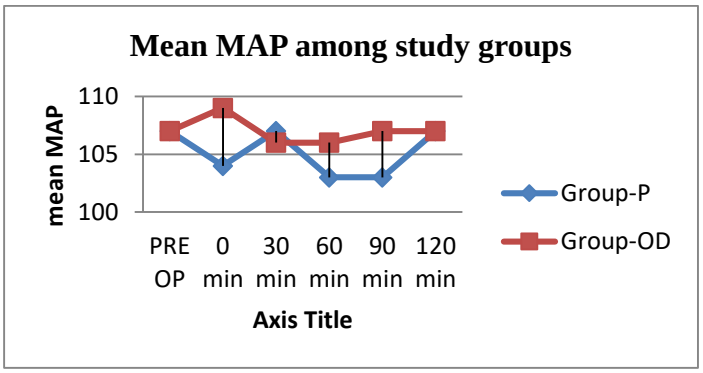


FIGURE : 2

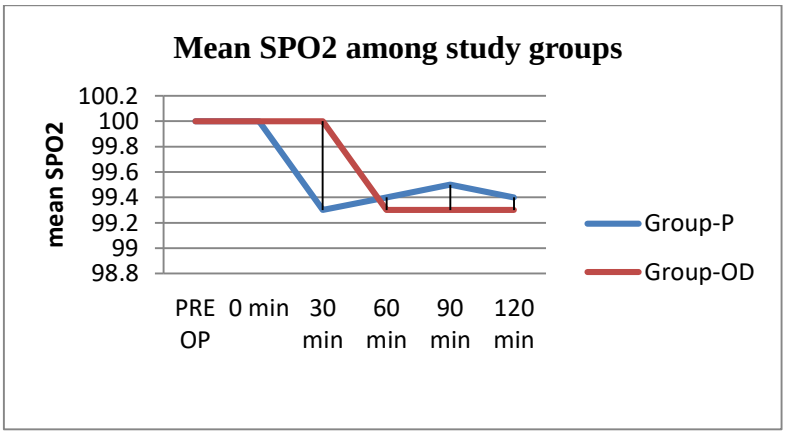


FIGURE : 3

INCIDENCE OF NAUSEA

One patient(3.3%) in group P and five patients (15.6%) had nausea within 2 hours after surgery. Two patients (6.2%) group P and six patients (18.7%) felt nauseating during 2-6 hours of post operative period. During 6-24 hours of postoperative period one patient(3.3%) in Group P and 6 patients(18.7%) in Group OD experienced nausea. Four patients (12.25%) in Group OD had nausea during 24-48 hours of postoperative period (Figure 4).

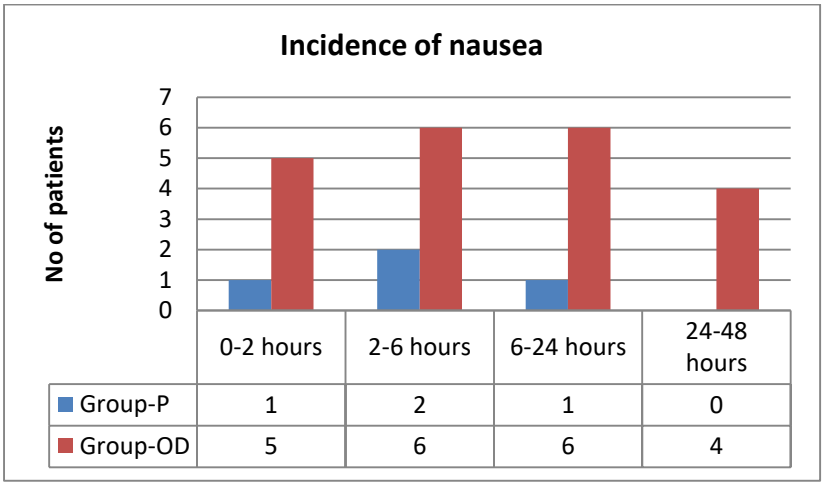


Figure 4 : Bar diagram showing incidence of nausea during 0-2,2-6,6-24,24-48 hours of postoperative period

INCIDENCE OF VOMITING

Two patients(6.2%) in group P and four patients(12.25%) in group OD had vomiting within 2 hours after surgery. Three patient(9.4%) in Group P and eight patients(25%) in group OD had vomiting during 2-6 hours of post operative period. One patient(3.3%) in Group P and seven patients(21.9%) in Group OD had vomiting during 6-24hours of postoperative period. One patient(3.3%) group P and six patients (18.75%) had vomiting during 24-48 hours of postoperative period(Figure 5).

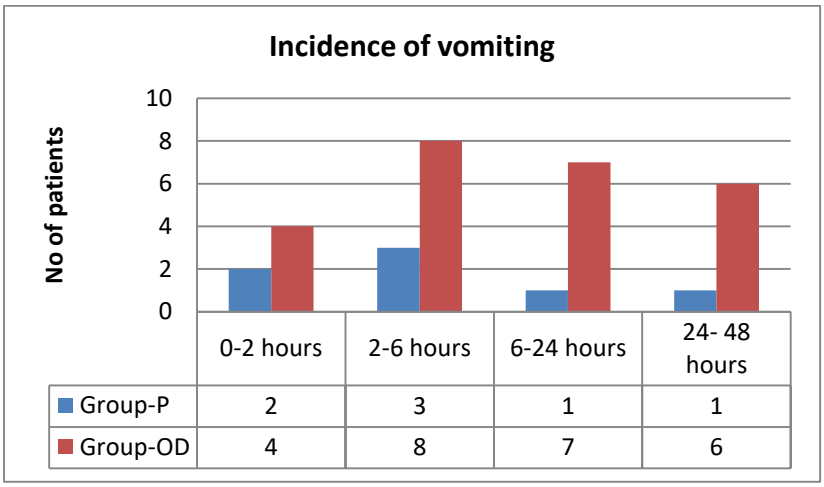


Figure 5 : Bar diagram showing incidence of vomiting during 0-2,2-6,6-24,24-48 hours of postoperative period

REQUIREMENT OF ANTIEMETIC AMONTH THE STUDY GROUP

Two patients(6.2%) in Group P and four patients(12.25%) in Group OD required rescue antiemetic during first two hours of postop period. Three patient(9.4%) in Group P and ten patients(32%) in group OD needed rescue drugs during 2-6 hours. . One patient(3.3%) in Group P and eight patients(25%) in Group OD treated with rescue measures during 6-24hours of postoperative period. One patient(3.3%) in group P and seven patients (22%) in group OD required antiemetics during 24-48 hours of postoperative period(Figure 5).

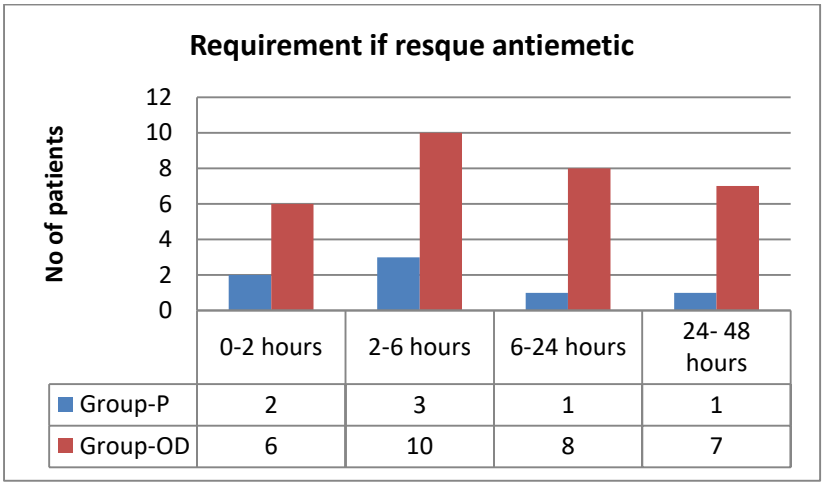


Table 3 : Requirement of rescue antiemetics among the study groups.

IV. DISCUSSION

Postoperative nausea and vomiting (PONV) are common sequel of general anaesthesia. PONV is an unpleasant, distressing and exhausting experience for patients. Laparoscopy compared to conventional surgery reduces the patient morbidity significantly, but PONV are the most common distressing symptoms occurring after laparoscopic surgeries. PONV increases the duration of hospital stay, the readmission rates after discharge, which negate the advantage of laparoscopy. Hence control of PONV after laparoscopic surgeries is of utmost importance. The incidence of PONV varies from 36-82 % during immediate postoperative recovery.[5] Because of this high incidence of PONV, we decided to conduct our study in patients undergoing Laparoscopic surgery.

Numerous factors can affect PONV such as age, gender, obesity, history of motion sickness and / or PONV, use of opioids, anaesthetic technique and its duration, duration and type of the surgical procedure and postoperative pain. In the present study, majority of these factors (age, gender, weight, height, duration of anaesthesia and surgery, type of the procedure) were statistically insignificant between both the groups (p> 0.05).

In our study, during first 2 hours of postoperative period, in group P only one patient had nausea and two patients had vomiting whereas in group OD three patients had vomiting and among them 2 had nausea. In the next 2-6 hours five patients in total experienced nausea in which two of them were from group P and three from group OD, six patients in group P and eight patients in group OD had vomiting in the same time period.

During 6-24 hours of post operative period, one patient had nausea and vomiting in group P whereas in group OD six patients had nausea and seven had vomiting. In 24-48 hours period, no episodes nausea was seen among patients in group P, however one episode of vomiting was noted. Among group OD four patients had nausea and among them six had vomiting.

In the first six hour of the study there is no significant difference in preventing nausea have been observed among the study groups but in the next fourty two hours the effectiveness of palonosetron is found to be statisfactory in the prevention of nausea with p value 0.045 during 6-24 hours and 0.039 during 24-48 hours respectively.

As far as the vomiting is concerned, no significant difference is noticed during the first six hours. However, palonosetron showed a significant difference in reducing vomiting than the combination of ondansetron and dexamethasone during 6-24 and 24-48 hours time period with p value 0.023 and 0.045 respectively.

No difference has been noted in the necessity of rescue antiemetics in the first two hours of the post operative period whereas a significant reduction in requirement of recue measure has noted among the patients given palonosetron in the remaining period of the study.

V. CONCLUSION

To conclude, the use of palonosetron evidenced better control of nausea and vomiting than the combination of ondansetron and dexamethasone among the patients undergoing laparoscopic surgery.

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