How to Cite:
Chauhan, D., Sharma, T., & Naik, G. C. (2022). Antiemetic effect of intravenous palonosetron and ondansetron for the prevention of postoperative nausea and vomiting following laparoscopic surgeries under general anaesthesia, a randomised observational study. *International Journal of Health Sciences*, *6*(S2), 2778–2784.
https://doi.org/10.53730/ijhs.v6nS2.5694

Antiemetic effect of intravenous palonosetron and ondansetron for the prevention of postoperative nausea and vomiting following laparoscopic surgeries under general anaesthesia, a randomised observational study

Dinesh Chauhan
Professor and Head, Department of Anaesthesiology, Shrimati Bhikhiben Kanjibhai Shah, Medical Institute & Research Centre, Sumandeep Vidyapeeth (An Institute Deemed to be **U**niversity), Piparia, Vadodara, Gujarat, India

Tejash Sharma
Associate Professor, Department of Anaesthesiology, Shrimati Bhikhiben Kanjibhai Shah, Medical Institute & Research Centre, Sumandeep Vidyapeeth (An Institute Deemed to be University), Piparia, Vadodara, Gujarat, India

Ganesh C. Naik
3rd year resident, Department of Anaesthesiology, Shrimati Bhikiben Kanjibhai Shah, Medical Institute & Research Centre, Sumandeep Vidyapeeth (An Institute Deemed to be University) Piparia, Vadodara, Gujarat, India
Email: ganeshnaik888@gmail.com

***Abstract*---**Post-operative nausea and vomiting(PONV) is one of the common complications in patients undergoing laparoscopic surgeries under general anaesthesia. This study compares efficacy of prophylactic palonosetron and ondansetron in the prevention of PONV. After obtaining the approval of institutional ethical committee, a prospective randomised study was conducted on 60 patients belonging to American Society of Anaesthesiologists Grade I and II, patients of either sex, aged between 18 to 60 years, fulfilling the inclusion criteria were divided into two groups receiving inj. ondansetron 8 milligrams i.v. or inj. palonosetron 75 micrograms i.v. Incidence of PONV and need of rescue antiemetic was recorded post operatively. Data were evaluated statistically using Graph Pad Prism computer software version 6.04.It was found that inj. palonosetron 75mcg i.v. was more efficient in the prevention of PONV and required lesser rescue antiemetic when compared inj. ondansetron 8mg i.v. At conclusion of

International Journal of Health Sciences ISSN 2550-6978 E-ISSN 2550-696X © 2022.
***Corresponding author**: Naik, G. C.; Email: ganeshnaik888@gmail.com*
Manuscript submitted: 18 Feb 2022, Manuscript revised: 09 March 2022, Accepted for publication: 01 April 2022

the study it was found that the prophylactic usage of inj. palonosetron 75 mcg i.v. is more effective than inj. ondansetron 8mg i.v. in the prevention of PONV in patients undergoing laparoscopic surgery (p value < 0.05).

***Keywords*---**ondansetron, palonosetron, laparoscopic surgeries, general anaesthesia.

Introduction

Postoperative nausea and vomiting (PONV) continues to be one of the most common postsurgical complications in modern anaesthetic practice, with incidence ranging from 20 to 30 %[1]. In patients undergoing laparoscopic surgeries the incidence of post operative nausea and vomiting reaches up to 70 percent [2]. PONV is found to decrease satisfaction of patients and may cause rare but severe consequences like pulmonary aspiration, wound dehiscence, oesophageal rupture, subcutaneous emphysema and bilateral pneumothorax [3].

The 5- hydroxytryptamine (5HT3) receptor antagonist like ondansetron and palonosetron are commonly used as they are more effective in prevention and treatment of PONV than other antiemetics such as metoclopramide, ranitidine etc. and have comparatively less side effects [4]. It prevents nausea and vomiting by antagonizing the receptors of 5HT3 in vagal efferents of intestinal tracts and central chemoreceptor trigger zone. Ondansetron the first available 5HT3 receptor antagonist, is being widely used in prevention of PONV and it may be related to its lower cost compared to other agents in the same class [5,6].

Palonosetron newly developed 5-HT3 receptor antagonist differs from others by having greater binding affinity and longer half life than others of the same class [7]. Other antagonists directly compete with serotonin, but palonosetron has indirect effect by its allosteric binding with 5HT3 receptors at sites different than of ondansetron or others of the same class [7]. It has long lasting effects on receptor binding and functional response to serotonin [8].

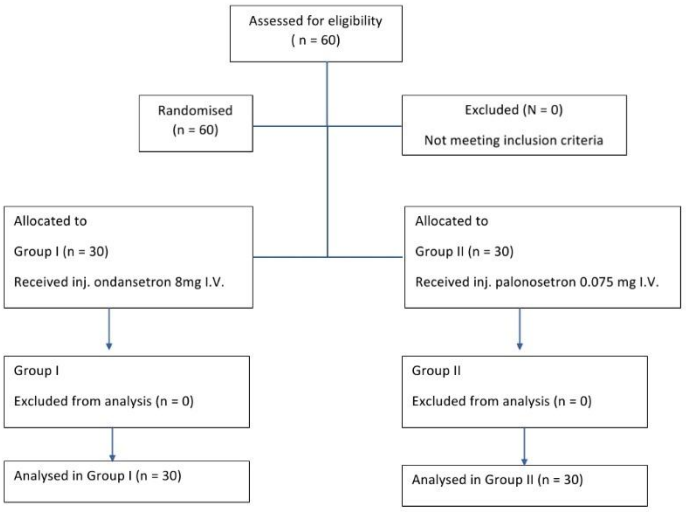
Material and Methods

This prospective randomised observational study was performed on 60 patients admitted in tertiary care center, Dhiraj hospital under the Department of anaesthesiology. After obtaining the approval from the institutional ethical committee (approval number SVIEC/ON/MEDI/BNG18/D19180) the study was performed among 60 patients belong to either gender, aged between 18 to 60 years, belonging to ASA grade I and II who were posted for laparoscopic surgery under general anaesthesia. Patients who had used anti emetic medication in past 24 hours, having history of allergic reaction to serotonin antagonists in the past were excluded from the study.

The patients were allocated in a randomised manner by chit method into two equal groups of 30 patients. Patients belonging to Group I, received inj. ondansetron 8 mg intravenously before the induction of anaesthesia. Patients belonging to

Group II, received inj. palonosetron 0.075 mg intravenously before the induction of anaesthesia.

(Table/Figure II): Study flow diagram



Pre operative examination was done and vitals namely: Pulse rate, Blood pressure, Respiratory rate, Temperature and SpO2 were measured and noted. After arrival of the patient in the operation theatre an 18 gauge venous cannula was inserted into a vein on the dorsum of the patient's non-dominant hand and intravenous fluid namely Ringer's lactate infusion was started. Baseline hemodynamic parameters namely heart rate, electrocardiograph (ECG), pulse oximetry (SPO_2), systolic blood pressure(SBP), diastolic blood pressure(DBP), and mean arterial pressure(MAP) were measured and recorded before the induction of anaesthesia. Each of the two groups (Group I and Group II), along with either ondansetron or palonosetron respectively, were premedicated with inj. glycopyrrolate 0.004 mg/kg i.v., inj. midazolam 0.05 mg/kg i.v, inj. tramadol 2 mg/kg. Patient were preoxygenated with 100% oxygen for 3 mins and induction of anaesthesia was facilitated with inj.propofol (2mg/kg) i.v. and inj. succinylcholine (2 mg/kg) i.v. Patients were intubated and airway secured with appropriate size endotracheal tube. Maintenance of anaesthesia was done using oxygen, nitrogen (at 50% each), isoflurane (inhalational anaesthetic agent) and atracurium (muscle relaxant). After the completion of the surgery reversal of muscle relaxant was achieved by using inj. glycopyrrolate 0.008mg/kg i.v. and inj. neostigmine 0.05mg/kg i.v. For postoperative analgesia, inj. diclofenac 75 mg i.v. was given. Patients were observed in surgical intensive care unit and wards for 24 hours and number of episodes of nausea, retching, vomiting and side effects of the drugs were recorded at 0-4 hours, 4-8 hours, 8-12 hours, 12 to 24 hours at regular time interval.

Observation and Results

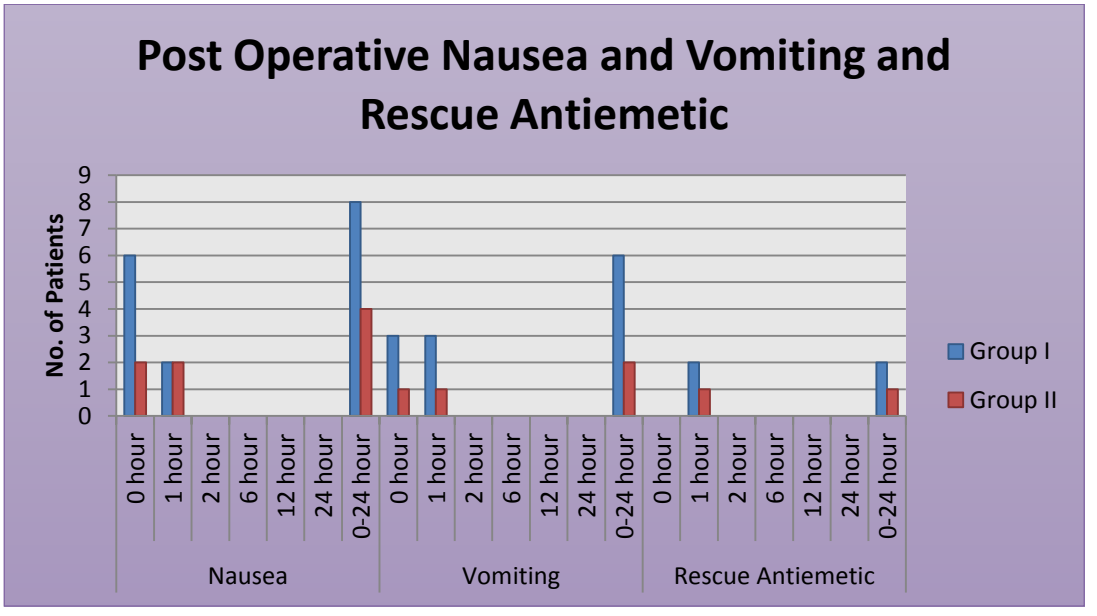
Entire data were collected and tabulated. Numerical variables were represented as mean and standard deviation. Frequency and percentage were used to present the categorical variables. For between groups comparison with regards to numerical variable, whereas for categorical variables chi- square test was used and value less than 0.05 was considered statistically significant.

(Table/Figure II): Demographic parameters between the two groups

Demographic Parameters	Group I (Ondansetron) (N=30)	Group II (Palonosetron) (N=30)	P-Value	**Significance**
Age (years)	41.8 ±4.89	42.07 ±5.28	0.8379	Not significant
Gender				
Male	15 (50%)	13 (43.33%)	0.9785	Not significant
Female	15 (50%)	17 (56.67%)	0.9821	Not significant
Weight (Kg)	64.6 ±5.44	64.2 ±4.8	0.7637	Not significant

Demographic profile of patients were similar in both the study group population as shown above (Table/Figure II).

Table/Figure III: Graph showing Incidence of Post-Operative Nausea and Vomiting and Rescue Antiemetic between the two groups



Six (20%) patients belonging to group I had nausea at 0 hour as compared to two (6.67%) patients belonging to group II. No statistically difference (p value 0.5109) in the prevention of nausea was noted in 0 hours between both the groups (Table/Figure III). Two (6.67 %) and one (3.33%) patients belonging to group I and II had nausea in the 1st hour of post operative period. There was statistically significant difference (p value 0.0451) in the prevention of nausea between the two groups in 1st hour post operative period (Table/Figure III).

There was no incidence of nausea in both the groups after 1 hour. Three (10%) patients belonging to group I had vomiting at 0 and 1 hour as compared to One (3.33%) patient belonging to group II. Statistically significant difference (p value 0.04) in the prevention of vomiting was noted in 0 and 1 hours between both the groups (Table/Figure III).

There was no incidence of vomiting in both the groups after 1 hour.Two (6.67%) patients in group I received rescue anti emetic in the 1st hour where as one (3.33%) patient in group II received rescue anti emetic in 1st hour. There was statistically significant difference (p value 0.0106) in patients belonging to group II when compared with group I in the requirement of rescue anti emetic (Table/Figure III).

Discussion

Post operative nausea and vomiting (PONV) is one of the most common adverse effect in patients undergoing laparoscopic surgeries under general anaesthesia. It can lead to aspiration pneumonia, dehydration, increased intra ocular and intra cranial pressure, wound dehiscence, increased recovery time and increased healthcare cost. 5 HT3 receptor antagonists introduced in 1990s provided a major breakthrough in the prevention of PONV. Food and drug administration (FDA) agency approved the usage of palonosetron for the prevention of PONV in 2008 [9].

Palonosetron binds to allosteric site present in 5HT3 receptor. Once palonosetron binds to allosteric site of 5HT3 receptor, serotonin receptor undergoes conformational transition leading to indirect inhibition of serotonin binding. It has greater affinity of binding to 5HT3 receptor responsible for its greater potency and longer duration of action. Both groups in this study had similar demographic profile, that is age, sex, weight and ASA grading was similar in both the groups.

In 2001 S **P**aventi et al[10], studied the efficacy of ondansetron 4mg vs 8 mg in prevention of PONV and found that 8mg when given as a premedication was more effective in prevention of PONV. In our study Ondansetron group received 8mg intravenously before induction of anaesthesia for prevention of PONV[10]. In 2008 Kovac AL et al[11] compared different dosage of palonosetron that is 0.025mg, 0.05mg and 0.075mg intravenously. The study showed that statistically significant difference in the prevention of PONV was obtained when 0.075mg intravenously for the prevention of PONV. In our study 0.075mg intravenous palonosetron was used as a premedication in the prevention of PONV in patients undergoing laparoscopic surgery.

In this study the overall incidence of nausea in 24 hours was 26.67 % in patients among group I and 13% in patients belonging to group II. Patients receiving

ondansetron had statistically significant higher incidence of nausea when compared to patients receiving palonosetron. Similar results were obtained by SK Park et al[12] and YE Moon et al[13] where the incidence of nausea in ondansetron and palonosetron group was 30% and 15% , 30% and 14% respectively.

The overall incidence of vomiting in group I and group II was 20% and 6.6% respectively . The difference between the two being statistically significant (p value 0.04). Similar result were found in the study done by YE Moon[13] where 24% and 8% of patients had vomiting in ondansetron and palonosetron group respectively. In the study made by SK Park[12] 28% and 10% respectively had incidence of vomiting . This study is in accordance with the other two study.

6.67% of patients in group I and 3.33% of patients in group II required rescue anti emetic medication. From the result of the present study it can be concluded that inj. palonosetron 0.075mg given intravenously is better than inj. ondansetron 8mg intravenous injection in the prevention of PONV in patients undergoing laproscopic surgeries under general anaesthesia.

Conclusion

To conclude this, inj. palonosetron (0.075mg) given intravenously is better than inj. ondansetron (8mg), when given intravenously before induction of general anaesthesia in patients undergoing various laparoscopic surgery for the prevention of post operative nausea and vomiting, in the form of less episodes of nausea, vomiting and the requirement of rescue anti emetic, is also less in palonosetron group when compared to ondansetron group.

Limitations

Absence of measurement of plasma level of ondansetron and palonosetron. A larger study group could have been beneficial for better understanding of role of both drugs in prevention of PONV.

References

1. Miller R. Miller's anesthesia. Philadelphia PA: Elsevier Saunders; 2015.
2. Elsaid R, Namrouti A, Samara A, Sadaqa W, Zyoud S. Assessment of pain and postoperative nausea and vomiting and their association in the early postoperative period: an observational study from Palestine. BMC Surgery. 2021;21(1).
3. Nagarekha D, Shaikh S, Hegade G, Marutheesh M. Postoperative nausea and vomiting: A simple yet complex problem. Anesthesia: Essays and Researches. 2016;10(3):388.
4. Nanavati A, Prabhakar S. Fast-track surgery: Toward comprehensive peri-operative care. Anesthesia: Essays and Researches. 2014;8(2):127.
5. Islam S, Jain PN. Post-operative nausea and vomiting (PONV): A review article. Indian Journal of Anaesthesia. 2004;48(4):253-8.
6. Bunce KT, Tyers MB. The role of 5-HT in postoperative nausea and vomiting. British Journal of Anaesthesia. 1992;69(7 Suppl 1):60S-2S.

7. Gan TJ, Meyer T, Apfel CC, Chung F, Davis PJ, Eubanks S, Kovac A, Philip BK, Sessler DI, Temo J, Tramèr MR. Consensus guidelines for managing postoperative nausea and vomiting. Anesthesia & Analgesia. 2003;97(1):62-71.
8. Tramer M, Reynolds D, Moore R, McQuay H. Efficacy, Dose-Response, and Safety of Ondansetron in Prevention of Postoperative Nausea and Vomiting. Anesthesiology. 1997;87(6):1277-1289.
9. Bednarz S, Filipovic M, Schoch O, Mauermann E. Gastric rupture after bag-mask-ventilation. Respiratory medicine case reports. 2015;16:1-2.
10. Paventi S, Santevecchi A, Ranieri R. Efficacy of a single-dose ondansetron for preventing post-operative nausea and vomiting after laparoscopic cholecystectomy with sevoflurane and remifentanil infusion anaesthesia. European review for medical and pharmacological sciences. 2001;5:59-64.
11. Kovac AL. Prevention and treatment of postoperative nausea and vomiting. Drugs. 2000;59(2):213-43.
12. Park SK, Cho EJ. A Randomised, double-blind trial of palonosetron compared with ondansetron in preventing postoperative nausea and vomiting after gynaecological laparoscopic surgery. Journal of International Medical Research. 2011;39(2):399-407.
13. Moon YE. Postoperative nausea and vomiting. Korean journal of anesthesiology. 2014;67(3):164.