A Comparative Study of Palonosetron and Ondansetron for Prevention of Post-Operative Nausea and Vomiting in Patients undergoing Thyroidectomy Held at Central Kerala

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ABSTRACT

BACKGROUND

Nausea and vomiting are very frequently encountered with the use of anaesthetic techniques for surgical procedure. This study was done to compare the efficacy of palonosetron and ondansetron for prevention of post-operative nausea and vomiting in patients undergoing thyroidectomy under general anaesthesia.

METHODS

This one year observational study was conducted in the Department of Anaesthesiology, Government Medical College, Thrissur, Kerala state undergoing thyroidectomy under general anaesthesia and getting antiemetic interventions of either palonosetron or ondansetron. A total of 68 patients were included in this study in two groups of 34 patients each. The patients who received iv palonosetron were included in Group A (Palonosetron group) and patients who received iv ondansetron were included in Group B (Ondansetron group). Patients with previous history of postoperative nausea and vomiting (PONV), gastro oesophageal reflux disease, motion sickness, and obese patients were excluded. Incidence of postoperative nausea and vomiting was recorded for 24 hours and recorded in the following intervals. 0 - 4 hours, 5 - 8 hours, 9 - 12 hours and 13 - 24 hours in the postoperative period.

RESULTS

Although the incidence of postoperative nausea and vomiting was lower in the palonosetron group compared with the ondansetron group for 24 hours (5.9 - 11.8 %), the results were statistically not significant.

CONCLUSIONS

Incidence of postoperative nausea and vomiting is statistically not different in patients who had received palonosetron in comparison to those who had received ondansetron in patients undergoing thyroidectomy surgeries under general anaesthesia. From the study we conclude that palonosetron is similar to ondansetron in prevention of postoperative nausea and vomiting in patients undergoing thyroidectomy under general anaesthesia.

KEYWORDS

Post-Operative Nausea and Vomiting, Palonosetron, Ondansetron

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DOI: 10.18410/jebmh/2021/651

How to Cite This Article:
Randeep AM, Sunilkumar TS, Beegum TSS, et al. A comparative study of palonosetron and ondansetron for prevention of post-operative nausea and vomiting in patients undergoing thyroidectomy held at central Kerala. J Evid Based Med Healthc 2021;8(42):3596-3601. DOI: 10.18410/jebmh/2021/651

Submission 10-10-2021,
Peer Review 18-10-2021,
Acceptance 12-11-2021,
Published 30-11-2021.

BACKGROUND

Postoperative nausea and vomiting is defined as any nausea, retching or vomiting occurring during the first 24 – 48 hours after surgery.[1] Postoperative nausea and vomiting occurs in 20 % to 30 % of patients and are the second among the most common complaints reported, pain being the most common.[2] It limits an early discharge in ambulatory surgery and leads to unexpected hospital admission.[3] It may delay a patient's discharge and can be the leading cause of unanticipated hospital admission after ambulatory anesthesia.[4]

Postoperative nausea and vomiting became the most commonly used clinical term after the review by Watcha and White in 1992.[5] PONV led to delayed recovery, increased need for nursing care, and potential hospital admission thereby increasing total health care associated costs. High level patient discomfort is also associated with PONV. Some patients used to describe PONV as their greatest fear of subsequent anesthetics.[6] PONV can be such an unpleasant experience that patients often rate it worse than postoperative pain[7] and the avoidance of PONV is of greater concern than avoidance of postoperative pain.

Prevention of PONV in high-risk patients improves postoperative ratings of patient satisfaction.[8] Other concerns include risk of increased abdominal pressure, increased central venous pressure and sympathetic nervous system response as well as parasympathetic responses. PONV can also lead to complications such as aspiration of gastric contents, suture dehiscence, rupture of oesophagus, subcutaneous emphysema, or pneumothorax.[9]

GanTJ, Meyer T, Apfel CC, et al. reviewed the medical literature and formed guidelines for managing postoperative nausea and vomiting. They concluded that reducing baseline risk factors is the first step to reduce PONV. They recommended drugs for prophylaxis of PONV for adults should be used as monotherapy or a combination of drugs for patients at moderate risk for PONV. Combination drug therapy should be used for patients at high risk for PONV. An emetic episode 6 h after surgery can be treated with any antiemetic drugs used for prophylaxis except dexamethasone and transdermal scopolamine.[10]

Chen, Yi-Fan, Yeh, Wen-Lin Lee et al. showed that, in shoulder arthroscopy, intravenous injection of ondansetron 30 minutes before completion of the procedure decreases the incidence of PONV. Also, the patients using ondansetron showed to have lower pain intensity and analgesic injection needs.[11]

C. Rojas, M. Stathis, A. Thomas et al. found out that palonosetron showed allosteric binding and positive cooperativity when binding to the 5HT3 receptor. This was the first report showing palonosetron's unique interaction with the 5-HT3 receptor at the molecular level, differentiating it from older 5-HT3 receptor antagonists.[12]

AbdEl-Hamid, Ahmed M, Afifi, Ehab E, Othman, Mohamed S, K. compared palonosetron versus ondansetron for prevention of PONV during middle ear surgery. They recommended palonosetron as a good antiemetic alternative during the postoperative period with minimal adverse effects.[13]

Y. E. Moon, J. Joo, J. E. Kim and Y. Lee studied the anti-emetic effect of ondansetron and palonosetron in thyroidectomy with post operative fentanyl based patient controlled analgesia and found palonosetron is more effective than ondansetron for high-risk patients receiving fentanyl-based patient controlled analgesia (PCA) after thyroidectomy, especially 2 – 24 h after surgery.[14]

Antiemetic effect of intravenous palonosetron and intravenous ondansetron in laparoscopic cholecystectomy was studied by Baduni, Neha, Bansal, Pooja, Bhalla, Jyoti. The conclusion being palanosetron has got better anti-nausea effect, less need of rescue antiemetics, favourable side effect profile and a decrease in the incidence of total PONV as compared to ondansetron in 24 h post-operative period.[15]

A. Arya, S Jain, S Dulara et al. compared ondansetron and palonosetron for prevention of PONV in elective abdominal surgery patients under general anaesthesia. They found that 6 hours postoperatively bolus dose of palonosetron was better in prevention of PONV.[16]

Taninder Singh, Nilam Shah, Chinar Patel and R.M. Upadhayay compared the efficacy of prophylactic palonosetron with ondansetron, in patients undergoing middle ear surgeries under general anaesthesia. They found that the efficacy of prophylactic administration of palonosetron 0.075 mg IV is superior to that of ondansetron 8mg IV for PONV in patients after middle ear surgeries under general anaesthesia.[17]

Yu Yil Kim, SooYeong Moon, Dong Un Song et al. compared the efficacy of palonosetron and ondansetron in preventing postoperative nausea and vomiting in patients receiving IV opioid-based patient-controlled analgesia undergoing high risk gynaecological laparoscopic surgery. They concluded that a bolus of palonosetron 0.075 mg had similar effect as a bolus of ondansetron 8 mg and a continuous i.v. administration of ondansetron 16 mg along with IV-PCA in high-risk patients who were using IV-PCA after gynaecological laparoscopic surgery.[18]

Hasan, M. M., Islam, M. S., Ara, A., Fazilatunnesa et al. conducted a comparative study between ondansetron vs palonosetron for controlling postoperative nausea and vomiting. They found that during the first 24 hours the antiemetic efficacy of palonosetron is similar to that of ondansetron in patients who undergo surgery under general anaesthesia. But after 72 hours, nausea and vomiting were statistically lower in palonosetron group than ondansetron group.[19] The objective of the study is to observe the effects of palonosetron and ondansetron in preventing postoperative nausea and vomiting in thyroidectomy patients. Thereby to compare the efficacy of palonosetron and ondansetron in preventing PONV.

METHODS

This prospective observational study was conducted in a tertiary care hospital in Central Kerala over a period of 1 year. After obtaining approval of institutional research and

ethical committee, 68 patients belonging to The American Society of Anaesthesiologists Physical Status classification system (ASA PS) I & II, of either sex in the age group of 20 - 55 years, scheduled to undergo elective thyroidectomy under general anaesthesia with controlled ventilation were considered in this study. Patients were divided randomly into two groups (Group A and Group B) of thirty four each.

A comparison of ondansetron and palonosetron for prevention of post-operative nausea and vomiting in patients undergoing elective abdominal surgeries under general anaesthesia by Arya A, Jain S, Dulara SC, et al. was taken as the reference study for taking the values of incidences of PONV in both groups (p1 - 66.67 and p2 - 96.67, Za + Zb 2.8, p - 81.67, q - 18.33) and used the formula $[(Z_{\alpha/2} + Z_{\beta})^2 \times 2 \times p \times q]/(p_{1-}p_2)^2\ p = (p_1 + p_2)/2q = 1 - p\ Z_{\alpha/2} = 1.96$ (alpha error 5%) Z_{β} = 0.84 (beta error 20 %) to calculate the sample size and expected a 25 % dropout rate, hence included 34 in each group. Patients with previous history of postoperative nausea and vomiting, gastro oesophageal reflux disease, motion sickness and obese patients (BMI 30 or more) were excluded. Patients who received palonosetron were included in Group A (0.075 mg intravenously in 10 ml NS over 30 s along with premedications before induction of anaesthesia). Patients who received ondansetron were included in Group B (4 mg intravenously in 10 ml NS over 30 s along with premedications before induction of anaesthesia).

Detailed pre anaesthetic check-up was done before surgery. An informed written consent was obtained after giving sufficient information. Tab alprazolam (0.25 mg) was given on the night before surgery day.

On arrival in the operation theatre, an intravenous infusion line was started with 18 G cannula and ringer lactate. Electrocardiogram (ECG), non invasive blood pressure (NIBP) and oxygen saturation were attached for monitoring till the end of the surgery. Inj. midazolam (0.05 mg/kg) and Inj. glycopyrrolate (0.2 mg) intravenously as premedication were given.

Heart rate, ECG, non invasive blood pressure and oxygen saturation were recorded just before, during and after the administration. The patients also received Inj. fentanyl (1µg/kg) intravenously. The patients were pre-oxygenated for 3 minutes and induced with Inj. thiopentone sodium (4 – 6 mg/kg), Inj. succinylcholine (1.5 mg/kg) intravenously and the patients were intubated with an oral cuffed endotracheal tube of appropriate size.

Anaesthesia was maintained with nitrous oxide: oxygen (2 : 1), Isoflurane (0.4 – 1 %) and neuromuscular blockade by Inj. Vecuronium (0.08 mg/kg) and repeated (0.02 mg/kg) whenever needed. At the end of the procedure, the patients were reversed with Inj. neostigmine (0.05 mg/kg) and Inj. glycopyrrolate (0.2 mg/1mg neostigmine). The patients were extubated after adequate neuromuscular reversal. Following extubation, the patients were maintained on supplemental oxygen in the recovery room. The duration of surgery was recorded. Hemodynamic parameters heart rate, ECG, blood pressure and oxygen saturation were monitored throughout the procedure and recorded every 15 minute until the end of surgery. Patients received Inj. paracetamol (1 g) intravenous infusion for postoperative analgesia before shifting the patient to postoperative ward and Inj. diclofenac (75 mg) intramuscular every 12th hourly for 24 hours. They were given an intravenous infusion of Inj. paracetamol 1 g as a second-line of treatment when their pain is refractory to diclofenac.

Post operative patients were advised to take rest and remain in the bed at least for the first 24 hours. Other emetogenic analgesics and drugs were not given for 24 hours.

The number of episodes of nausea, retching and vomiting were assessed postoperatively for 24 hours and recorded in the following intervals, 0 - 4 hours, 5 - 8 hours, 9 - 12 hours and 13 - 24 hours in the postoperative period. An intravenous Inj. metoclopramide 10 mg was given to the patients with vomiting as a rescue antiemetic.

Statistical Analysis

Data entered in Microsoft Excel were analyzed in Statistical Package for Social Sciences (SPSS) version 12. Qualitative variables were expressed in percentage and frequencies and the distribution compared between the groups using chi square test or Fisher's exact test depending on the expected cell counts. Age was summarized as mean with standard deviation. P value < 0.05 was taken as statistically significant.

RESULTS

	Group A (Palonosetron)	Group B (Ondansetron)	p Value
Mean age	42.47 (8.6)	42.94 (9.2)	.83
BMI: Normal weight	88.2 %	82.3 %	
Over weight	11.8 %	17.7 %	
Gender: Male	6 (17.6 %)	5 (14.7 %)	.74
Female	28 (82.4 %)	29 (85.3 %)	
ASA PS: 1	28 (82.4 %)	26 (76.5 %)	.55
2	6 (17.6 %)	8 (23.5 %)	

Table 1. The Patients in the Two Groups were Compared with Respect to Age, sSex, Weight and ASA PS and Found no Significant Difference between the Groups

		Group A (Palonosetron)	Group B (Ondansetron)	Total	p Value
Nausea	Yes	0 (0 %)	5 (14.7 %)	5 (7.4 %)	.053
	No	34 (100 %)	29 (85.3 %)	63 (92.6 %)	
Retching	Yes	0 (0 %)	0 (0 %)	0 (0 %)	NA
	No	34 (100 %)	34 (100 %)	68 (100 %)	
Vomiting	Yes	0 (0 %)	0 (0 %)	0 (0 %)	NA
	No	34 (100 %)	34 (100 %)	68 (100 %)	
Rescue antiemetic	Yes	0 (0 %)	0 (0 %)	0 (0 %)	NA
	No	34 (100 %)	34 (100 %)	68 (100 %)	

Table 2. Incidence of PONV in 0 - 4 Hours in Each Group

		Group A (Palonosetron)	Group B (Ondansetron)	Total	p Value
Nausea	Yes	0 (0 %)	4 (11.8 %)	4 (5.9 %)	.11
	No	34 (100 %)	30 (88.2 %)	64 (94.1 %)	
Retching	Yes	0 (0%)	2 (5.9%)	2 (2.9%)	.49
	No	34 (100 %)	32 (94.1 %)	66 (97.1 %)	
Vomiting	Yes	0 (0 %)	4 (11.8 %)	4 (5.9 %)	.11
	No	34 (100 %)	30 (88.2 %)	64 (94.1 %)	
Rescue antiemetic	Yes	0 (0 %)	4 (11.8 %)	4 (5.9 %)	.11
	No	34 (100 %)	30 (88.2 %)	64 (94.1 %)	

Table 3. Incidence of PONV in 5 - 8 Hours in Each Group

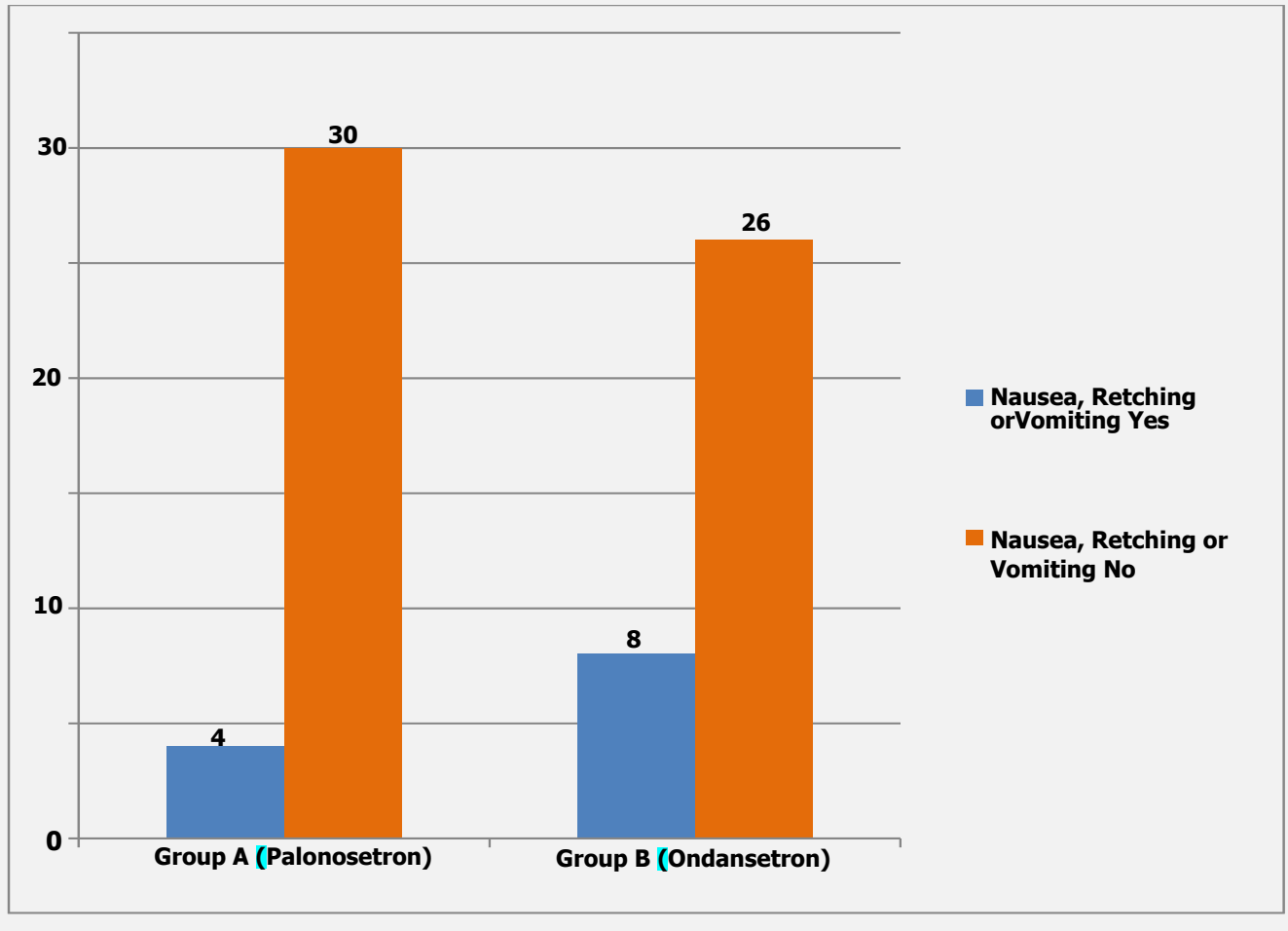

Figure 1. Incidence of PONV in 0 - 24 Hours in Each Group

		Group A (Palonosetron)	Group B (Ondansetron)	Total	p Value
Nausea	Yes	0 (0 %)	2 (6.7 %)	2 (3.1 %)	.22
	No	34 (100 %)	28 (93.3 %)	62 (96.9 %)	
Retching	Yes	0 (0 %)	1 (3.3 %)	1 (1.6 %)	.47
	No	34 (100 %)	29 (96.7 %)	63 (98.4 %)	
Vomiting	Yes	0 (0 %)	2 (6.7 %)	2 (3.1 %)	.22
	No	34 (100 %)	28 (93.3 %)	62(96.9 %)	
Rescue antiemetic	Yes	0 (0 %)	2 (6.7 %)	2 (3.1 %)	.22
	No	34 (100 %)	28 (93.3 %)	62 (96.9 %)	

Table 4. Incidence of PONV in 9 - 12 Hours in Each Group

		Group A (Palonosetron)	Group B (Ondansetron)	Total	p Value
Nausea	Yes	4 (11.8 %)	2 (7.1 %)	6 (9.7 %)	.68
	No	30 (88.2 %)	26 (92.9 %)	56 (90.3 %)	
Retching	Yes	1 (2.9 %)	2 (7.1 %)	3 (4.8 %)	.58
	No	33 (97.1 %)	26 (92.9 %)	59 (95.2 %)	
Vomiting	Yes	2 (5.9 %)	2 (7.1 %)	4 (6.5 %)	1.0
	No	32 (94.1 %)	26 (92.9 %)	58 (93.5 %)	
Rescue antiemetic	Yes	2 (5.9 %)	2 (7.1 %)	4 (6.5 %)	1.0
	No	32 (94.1 %)	26 (92.9 %)	58 (93.5 %)	

Table 5. Incidence of PONV in 13 - 24 Hours in Each Group

		Group A (Palonosetron)	Group B (Ondansetron)	Total	p Value
Nausea, retching or vomiting 0 - 24 hours	Yes	4 (5.9 %)	8 (11.8 %)	12 (17.7 %)	.20
	No	30 (44.1 %)	26 (38.2 %)	56 (82.3 %)	

Table 6. Incidence of PONV in 0 - 24 Hours in Each Group

DISCUSSION

Post-operative nausea and vomiting (PONV) is a very common sequelae of general anaesthesia and is very unpleasant and distressing for the patient. It is the leading cause of delayed discharge and unanticipated hospital admission after ambulatory surgical procedure. Incidence of postoperative nausea and vomiting in an untreated adult surgical population receiving general anaesthesia is around 20 – 30 %, but it increases up to 80 % in patients with high risk for PONV. PONV is very frequent in abdominal surgeries leading to the recommendation of routine prophylactic administration of antiemetics. The aetiology of nausea and vomiting after abdominal surgeries under GA are multifactorial in origin. Age, anaesthetic procedure, type and duration of surgery may influence PONV.

The complex act of vomiting involves coordination of respiratory, gastrointestinal tract and abdominal musculature and is controlled by the emetic center situated in the lateral reticular formation close to the tractussolitarius in the brain stem. Stimuli from areas within the central nervous system may affect the emetic center.

These include afferents from the pharynx, gastrointestinal tract and mediastinum, also afferents from the higher cortical center and the chemoreceptor trigger zone within the area postrema. The area postrema of the

brain is rich in dopamine, opioid and 5-HT3 receptors. Major neurotransmitter systems which play an important role in mediating emetic reflex are dopaminergic, histaminic (H1), muscarinic and 5-HT3. So an ideal antiemetic agent should be able to block all these 4 receptors. But the present antiemetic agents have prominent action at one or two receptors only.

Numerous interventional methods have been studied for the prevention of nausea and vomiting. Non pharmacological methods include acupuncture, electro puncture, transcutaneous electrical nerve stimulation, acupoint stimulation and acupressure. Pharmacological methods include dopamine receptor antagonists (phenothiazines, butyrophenones and benzamides), histamine receptor antagonists (dimenhydrinate), muscarinic receptor antagonists (Scopolamine), and serotonin receptor antagonists (ondansetron). Miscellaneous drugs like propofol, clonidine, dexamethasone and ephedrine are also tried for prevention of nausea and vomiting. These drugs are effective in reducing PONV with varying efficacy and are associated with unwanted side effects.

Hence introduction of 5-HT3 receptor antagonists in 1990s was considered as the major advance in prophylaxis of PONV as they lack the major adverse effects which were observed commonly with traditionally used antiemetic drugs. These 5-HT3 receptor antagonists produced no sedation, extra pyramidal reactions, adverse effects on vital signs or laboratory tests or drug interactions.

5-HT3 receptor antagonists are routinely used nowadays to prevent postoperative nausea and vomiting to the patients undergoing abdominal surgeries under general anaesthesia. Currently available 5-HT3 antagonists include ondansetron, granisetron, dolasetron, tropisetron and palonosetron.

FDA has approved the administration of palonosetron for prophylaxis of PONV in 2008 and is now available for use in India. All 5- HT3 receptor antagonists have the basic double nitrogen ring backbone for their chemical structure. This may be the clinical site of action of the 5-HT3 receptor antagonists on serotonin.

Half-life of ondansetron is 3.5 to 5.5 hours and that of palonosetron is 40 hours, this confers palonosetron prolonged duration of action and less frequent dosing as compared to ondansetron. The binding affinity of palonosetron to 5- HT3 receptor is 100 times that of ondansetron which makes it unlikely that palonosetron will produce unwanted effects at the other receptor sites. Present study was done to compare the efficacy of palonosetron 0.075 mg and ondansetron 4 mg for prevention of PONV administered prior to the induction of anaesthesia in the patients undergoing thyroidectomy surgeries under general anaesthesia. The study was designed in such a way as to control all the factors that can interfere with the interpretation of the results of the study with a standardized anaesthesia regimen like (avoiding use of propofol for induction, avoiding use of opioids for post-operative analgesia). The duration of anaesthesia, surgery and the anaesthetic used were similar in both the groups.

Therefore it is likely that the difference in the incidence of emetic episodes in both the groups were attributable to ondansetron and palonosetron.

In this study, during 0 - 4 hours in the palonosetron group, no patients had nausea, retching and vomiting. But in the ondansetron group, 14.7 % had nausea. Rescue antiemetics were needed for no patients in either group during 0 - 4 hours postoperatively.

During 5 - 8 hours in the palonosetron group, no patient had nausea, retching and vomiting. But in the ondansetron group, 11.8 % had nausea, 5.9 % had retching and 11.8 % had vomiting (p value is > 0.05). Rescue antiemetics were needed for 11.8 % of patients in the ondansetron group during 5 - 8 hours postoperatively. None of the palonosetron group of patients required rescue antiemetics during 5 - 8 hours postoperatively.

During 9 - 12 hours in the palonosetron group, no patient had nausea, retching and vomiting. But in the ondansetron group, 6.7 % had nausea, 3.3 % had retching and 6.7 % had vomiting (p value > 0.05). Rescue antiemetics were needed for 6.7 % of patients in the ondansetron group during 9 - 12 hours postoperatively. None of the palonosetron group of patients required rescue antiemetics during 9 - 12 hours postoperatively.

During 13 - 24 hours in the palonosetron group, 11.8 % had nausea, 2.9 % had retching and 5.9 % had vomiting. But in the ondansetron group, 7.1 % had nausea, 7.1 % had retching and 7.1 % had vomiting (p value > 0.05). Rescue antiemetics were needed for 7.1 % of patients in the ondansetron group during 13 - 24 hours postoperatively. Rescue antiemetics were needed for 5.9 % of patients in the palonosetron group during 13 - 24 hours postoperatively.

During 0 - 24 hours, 5.9 % of the palonosetron group had nausea, retching or vomiting whereas 11.8 % of the ondansetron group had similar incidents (p value > 0.05).

In ASA PS I patients, only 16.7 % had nausea/retching/vomiting in 0 - 24 hours whereas in ASA PS II patients, 21.4 % had nausea/retching/vomiting in 0 - 24 hours. 16.7 % of patients with normal body mass index (BMI) had nausea/retching/vomiting in 0 - 24 hours whereas 25 % of overweight patients had nausea/retching/vomiting in the same period.

CONCLUSIONS

From the study we conclude that the efficacy of palonosetron is similar to ondansetron for prevention of PONV for 24 hours in patients undergoing thyroidectomy under general anaesthesia.

Limitations of the Study

The study included patients scheduled for thyroidectomy surgery under general anaesthesia only. This emphasizes the importance of conducting more studies in patients scheduled for other surgeries under general anaesthesia, for better results.

Data sharing statement provided by the authors is available with the full text of this article at jebmh.com.
Financial or other competing interests: None.
Disclosure forms provided by the authors are available with the full text of this article at jebmh.com.

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