



Comparative Study on the Effectiveness of Palonosetron Versus Granisetron in Preventing Postoperative Nausea and Vomiting (PONV)

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Abstract

Background: Palonosetron is a potent, single stereoisomeric 5-HT₃RA, with a structure based on a fused tricyclic ring system attached to a quinuclidine moiety - unique and different from first-generation 5-HT₃RA, therefore aim of our study was to find out betterment of palonosetron as PONV management in comparison to granisetron. **Objectives:** The purpose of the present study was to evaluate the effectiveness of Palonosetron in comparison with Granisetron in preventing Postoperative nausea and vomiting. **Methodology:** The patient with ASA grade I, II and age between (20-50) years undergoing surgery under general anaesthesia having no pathology or deformity causing vomiting were selected after their admission in Bangladesh Medical college and hospital from November 2019 to May 2020, Department of Anaesthesiology & ICU, Bangladesh Medical College & Hospital, Dhaka. The selected patients were divided in two groups. Both the group was given a prospective randomized trial were conducted on a total of 60 patients of ASA grade I and II and mallampati I & II of either sex between age group of 20 to 50 years, scheduled for general anaesthesia were selected at random. **Results:** The overall incidence of PONV was 26.67 % for group A and 63.33% for group B. The number of complete responders to drugs at 24 hr after the surgery was 22 (73.33 %) for palonosetron and 11 (36.67%) for granisetron representing statistical difference (P = 0.035). **Conclusion:** Palonosetron is more effective in the prevention of PONV in patients undergoing elective surgeries under general anaesthesia as compared to granisetron, especially in the 2-24 h period postoperatively. [Journal of National Institute of Neurosciences Bangladesh, January 2025;11(1):52-57]

Keywords: PONV; Palonosetron; Granisetron; VAS for nausea.

Introduction

Postoperative nausea and vomiting (PONV) are among the most common complications of general anaesthesia, affecting (30-40) % of patients, and up to 80% in high-risk populations. Post operative nausea and vomiting (PONV) are hazardous symptoms that commonly occur after surgery performed under general anaesthesia¹. Vomiting can cause dehydration, disruption of surgical repair, electrolyte imbalance, other complications, including increased hospital costs and increase the perception of pain². A number of

pharmacological agents (butyrophenones, dopamine receptor antagonists, antihistamines) have been tried for prevention and treatment of PONV but adverse effects such as excessive sedation, hallucinations, hypertension, dry mouth, dysphoria and extra pyramidal symptoms have been noted³. 5-hydroxytryptamine type-3 (5HT₃) receptor antagonists are devoid of such side effects and highly effective in prevention and treatment of PONV. Granisetron is a highly selective & potent 5-HT₃ receptor antagonist⁴. It acts specifically at 5-HT₃ receptors on the vagal afferent nerves of the gut.

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Granisetron produces irreversible block of 5-HT₃ receptors and it may account for the long duration of this drug^{5,6}. Palonosetron is a 5-HT₃ receptor antagonist used for preventing chemotherapy induced nausea and vomiting. This unique 5-HT₃ receptor antagonist has a greater binding affinity and longer half-life than older 5-HT₃ antagonists like ondansetron. Recent receptor binding studies suggest that palonosetron is further differentiated from other 5-HT₃ by interacting with 5-HT₃ receptors in an allosteric, positively cooperative manner at sites different from those that bind with ondansetron and granisetron⁷.

We designed this randomized clinical study to assess and compare the antiemetic efficacy of granisetron and palonosetron to prevent PONV in patients undergoing Surgery under General Anaesthesia.

Methodology

Study Settings and Population: The patient with ASA grade I, II and age between (20-50) years undergoing surgery under general anaesthesia having no pathology or deformity causing vomiting were selected after their admission in Bangladesh Medical college and hospital from November 2019 to May 2020, Department of Anaesthesiology & ICU, Bangladesh Medical College & Hospital, Dhaka.

Study Procedure: Patients were randomly selected for the study from admitted patient scheduled to undergo elective surgical procedures under general anaesthesia at BMCH, Dhaka. The selected patients were divided into two groups. Both the group was given a prospective randomised trial were conducted on a total of 60 patients of ASA grade I and II and mallampati I & II of either sex between age group of 20 to 50 years, scheduled for general anaesthesia were selected at random.

Statistical Analysis: Statistical analyze were carried out by using the Statistical Package for Social Sciences version 23.0 for Windows (SPSS Inc., Chicago, Illinois, USA). Appropriate statistical test was applied. P values <0.05 was considered as statistically significant.

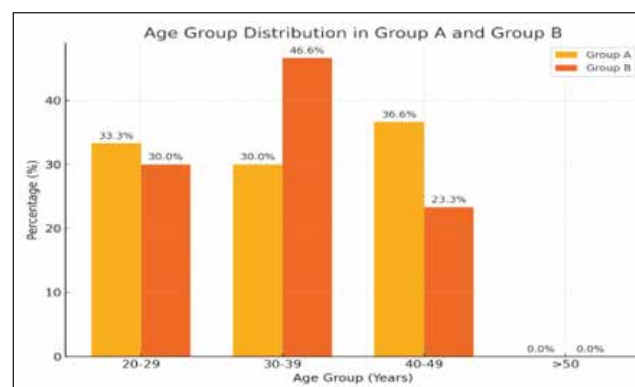
Ethical implications: Ethical clearance were taken from the Institutional ethical body. The purpose and effects of the study was clearly explained to each of the subjects and the confidentiality was ensured. The study was done after taking proper informed written consent.

Results

The results of this study were to brought the true picture of patient's post-operative nausea and vomiting.

The majority of the patients were in the age range of

30-39 years in Group B and 40-49 years old in Group A. The mean age was found 36.0 ± 9.1 years in group A and 35.4 ± 7.8 years in group B. The difference was not statistically significant ($p>0.05$) between two groups. No statistical difference between mean ages of the groups ($p>0.05$) (Figure 1)



ns= not significant; P value reached from Pearson's correlation test; Group A= Palonosetron group; Group B= Granisetron group

Figure 1: Distribution of the study patients by age (n=60)

The majority of the patients mean weight were found 72.3 ± 14.1 kg in group A and 70.5 ± 13.8 kg in group B. No statistically significant difference was found when correlated (Table 1).

Table 1: Distribution of the study patients according to weight (n=60)

	Group A	Group B	P value
	Mean \pm SD	Mean \pm SD	
Weight (kg)	72.3 \pm 14.1	70.5 \pm 13.8	0.614 ^{ns}
Range (min-max)	45-105	45-105	

ns= not significant; P value reached from Pearson's correlation test

The mean duration of anaesthesia was found 78.6 ± 25.1 minute in group A and 77.6 ± 22.9 minute in group B. The difference was not statistically significant ($p>0.05$) between two groups (Table 2).

Table 1: Distribution of the study patients according to weight (n=60)

	Group A	Group B	P value
	Mean \pm SD	Mean \pm SD	
Duration of anaesthesia (min)	78.6 \pm 25.1	77.6 \pm 22.9	0.91 ^{ns}
Range (min-max)	40-140	40-130	

ns= not significant; P value reached from Pearson's correlation test

After the end of surgery Group B experienced slightly more nausea, but they also experienced more vomiting, with a statistically significant $P=0.035$ (Table 3).

Table 1: Distribution of the study patients according to weight (n=60)

	Group A	Group B	P value
No PONV (0-2) hours	22 (73.3%)	11 (36.6%)	
Nausea	5 (16.6%)	6 (20%)	
Vomiting	1 (3.3%)	5 (16.6%)	
VAS	0.73 ± 1.43	0.83 ± 1.49	
(2-24) hours			
Nausea	1 (3.3%)	2 (6.6%)	
Vomiting	1 (3.3%)	6 (20%)	
VAS	0.27 ± 0.78	0.27 ± 0.78	
Total			0.03 ^s
Nausea	6 (20%)	8 (26.6%)	
Vomiting	2 (6.6%)	11 (36.6%)	

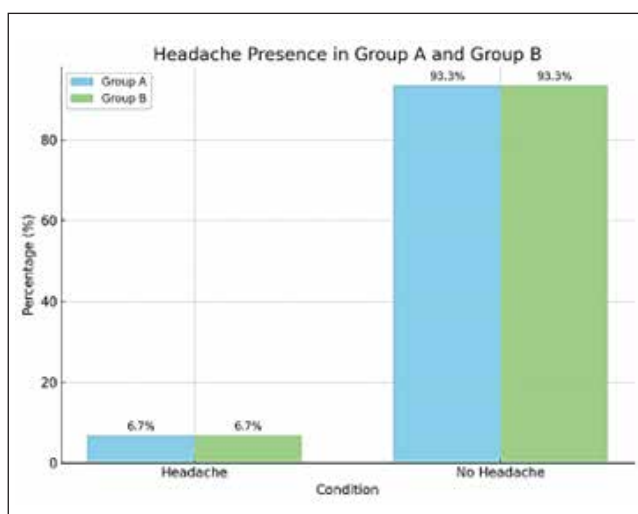
S= Significant, ns= not significant, P value reached from Chi-Square test, VAS value reached from t-test, Data are mean ± SD or number of patients (%). VAS: visual analogue scale. *VAS score for nausea (0: none, 10: the worst imaginable nausea).

Both Groups A and B used Ondansetron more frequently and Group B required more rescue medication. The difference between these two groups were statistically significant (Table 4).

Table 4: Rescue medication. (n=60)

	Group A	Group B	P value
No Rescue medicine	28 (46.6%)	19 (31.6%)	
Metoclopramide 10mg I.V.	0	3 (16.6%)	0.01 ^{ns}
Ondansetron 4mg I.V.	2 (3.3%)	8 (13.3%)	

Headache was equal in both group 6.7% and statistically not significant. (Figure 2)

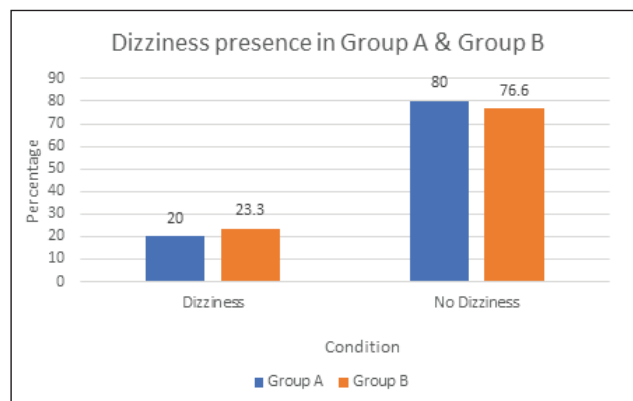


S= Significant, ns= not significant, P value reached from chi square test.

Figure 2: Headache in postoperative period (n=60)

Dizziness was more in Group B 23.3% but statistically

it was not significant. (Figure 3)



ns= not significant, P value reached from chi square test.

Figure 3: Dizziness in postoperative period

Discussion

This prospective randomized clinical study was conducted in Department of Anaesthesiology & ICU, Bangladesh Medical College & Hospital, Dhaka from November 2019 to May 2020. Total of 60 patients fulfilling inclusion/exclusion criteria were studied to determine the effectiveness of pretreatment with Palonosetron and Granisetron.

In this study observed that the mean age was found 36.0 ± 9.1 years in group A and 35.4 ± 7.8 years in group B & was not statistically significant ($p > 0.05$) between two groups. Similar observation was found Tong J. Gan, MB.²¹ they showed the mean age in group Granisetron was 34.3 ± 8.3 years and in group Promethazine was 33 ± 6.5 years. The difference was not statistically significant ($p > 0.05$) between two groups.

In present study observed that the majority (53.3%) patients were female in group A and equal in group B & was not statistically significant ($p > 0.05$) between two groups. Cho et al²³ showed the distribution of sex was 51 male and 45 female in Group P and 45 male and 51 female in Group PD & was not statistically significant ($p > 0.05$) between two groups.

In this study observed that the mean weight was found 72.3 ± 14.1 kg in group A and 70.5 ± 13.8 kg in group B & was not statistically significant ($p > 0.05$) between two groups. Gan et al²¹ study reported similar observation they showed that the mean weight was found 79.5 ± 25.3 kg in group Granisetron and 77.0 ± 19.6 kg in group Promethazine & was not statistically significant ($p > 0.05$) between two groups. Jigisha Makwana.²² also reported the mean weight in group Palonosetron was 60.1 ± 4.9 kg and in group

Granisetron was 59.3 ± 5.1 kg & was not statistically significant ($p > 0.05$) between two groups. Cho et al²³ reported the mean body weight of group P was 66.5 ± 12.3 kg and group PD was 65.0 ± 13.3 kg & was not statistically significant ($p > 0.05$) between two groups.

In this study observed that the mean duration of operation was found 68 ± 23.47 minute in group A and 67.3 ± 23.3 minute in group B & was not statistically significant ($p > 0.05$) between two groups. Cho et al²³ studied the mean duration of surgery was found 80.8 ± 47.8 minute for group P, 76.8 ± 40.1 minute in group PD & was not statistically significant ($p > 0.05$) between two groups. Our observation was supported different studies, in study of Makwana et al²² reported the mean duration of surgery was found 100.2 ± 34.1 minute in group palonosetron and 99.4 ± 25.3 minute in group Granisetron & was not statistically significant ($p > 0.05$) between two groups. Gan et al²¹ also reported that the mean duration of surgery was found 109.6 ± 54.2 minute in group granisetron and 106.2 ± 62.5 minute in group palonosetron & was not statistically significant ($p > 0.05$) between two groups.

In this study observed that the mean duration of anaesthesia was found 78.6 ± 25.1 minute in group A and 77.6 ± 22.9 minute in group B & was not statistically significant ($p > 0.05$) between two groups. Cho et al²³ reported the mean duration of anaesthesia in group P was 123.4 ± 53.3 minute and in the group, PD was 118.4 ± 49.6 minute were comparable and an insignificant 'p' value. Park et al²⁴ found the mean duration of anesthesia was found 117.1 ± 42 minute in group P and 123.1 ± 45.5 minute in group C & was not statistically significant ($p > 0.05$) between two groups. Makwana et al²² reported the duration of anesthesia in both groups was comparable with duration in palonosetron group was 128.1 ± 47.5 hour and in granisetron group was 123.5 ± 35.1 hour & was not statistically significant ($p > 0.05$) between two groups.

In this study observed that almost two third 19(63.3%) patients was found ASA grade I in group A and 19(63.3%) in group B & was not statistically significant ($p > 0.05$) between two groups. Park et al²⁴ observed that the ASA grade ratio was 39:2 in group P and 40:3 in group C & was not statistically significant ($p > 0.05$) between two groups. Makwana et al²² reported that the ASA grade ratio was 23:12 in group Palonosetron and 24:11 in group Granisetron & was not statistically significant ($p > 0.05$) between two groups.

In this study observed at the end of surgery, patient with no post operative nausea and vomiting was found to be 22(36.6%) in group A and 11(18.3%) in group B. 0 to 2 hours nausea in group A was 5(8.3%) and group B was 6(10%), whereas vomiting was 1(1.6%) in group A and 5(8.3%) in group B. 2 to 24 hours nausea post operatively was 1(1.6%) in group A and 2(3.3%) in Group B & vomiting was 1(1.6%) in Group A and 6(10%) in Group B. VAS for Nausea in 0 to 2 hours mean and SD was 0.73 ± 1.43 for Group A and 0.8 ± 1.4 for Group B. VAS for Nausea in 2 to 24 hours was 0.2 ± 0.7 for Group A and 0.27 ± 0.78 for Group B. There is statistically significant ($p = 0.035$) difference in the patients in both the groups with relation to above factors. Cho et al²³ observed that in 0-6 hours after surgery in group P nausea was 60 (62.5%) and in group PD was 47 (49%). Vomiting was 10 (10.4%) for group P and 8 (8.3%) for group PD and $p = 0.042$. 6 to 24 hours nausea was 62 (64.9%) for group P and 52 (54.2%) for group PD, vomiting was 11(11.5%) for group P and 11(11.5%) for group PD & $p = 0.142$. Makwana et al²² found in study that 0 to 6 hours nausea for Palonosetron group was 2 out of 35 and 3 out of 35 for Granisetron group & vomiting was 1 out of 35 for Palonosetron group and 1 out of 35 for Granisetron group & $p = 0.5$ & 1 respectively. 6-24 hours postsurgical observation was nausea was 2 out of 35 for Palonosetron group and 4 out of 35 for Granisetron group & $p = 0.336$, vomiting was 0 for palonosetron group and 1 out of 35 for granisetron group, overall $p = 0.311$. Gan et al²¹ found that nausea for first 2 hour granisetron group was 17(37%) and promethazine group was 23(49%) & Vomiting incidence for 0-2 hours was 5(11%) for granisetron group and 6(13%) for promethazine group (& $p = 0.17$), 2-6 hours nausea in granisetron group was 12 (26%) and promethazine group was 16(34%) & 2-6 hours vomiting in granisetron group was 5 (11%) and promethazine group was 3(6%) (& $p = 0.041$), 6-24 hours granisetron group was 12(26%) and promethazine group was 12(26%), 6-24 hours granisetron group was 2(4%) and promethazine group was 2(4%) (& $p = 0.024$).

In this study 4 (13.3%) patients needed rescue medicine postoperatively in group A whereas group B needed more rescue medicine and that was 10(33.3%). There was statistically significant difference in the patients in both the groups with relation to above factors. Makwana et al²² found to have rescue medicine given in 0-6 hours was 1 out of 35 for palonosetron

group and 1 out of 35 for granisetron group. For 6-24 hours duration postoperatively, the number was 0 for palonosetron group and it was 1 out of 35 for granisetron group. Gan et al²¹ found that granisetron group needed rescue medicine postoperatively 0-2 hours was 10(22%), 2-6 hours was 1(2%) and 6-24 hours was 0, whereas Promethazine group needed in 0-2 hours postoperatively was 17(37%), 2-6 hours was 3(7%) and 6-24 hours was 2(4%).

In this study 2(6.7%) patients had headache in postoperative period in group A and 2(6.7%) in group B. There was no statistically significant ($p>0.05$) between two groups. R. A. Johns study reported that the headache was found 13% in group Cyclizine and 15% in group Granisetron & was not statistically significant ($p=0.79$) between two groups.

In this study 6(20%) patients had dizziness in postoperative period in group A and 7(23.3%) in group B. There is no statistically significant ($p>0.05$) between two groups. R. A. Johns study reported that the dizziness was found 40% in group Cyclizine and 32% in group Granisetron & was statistically significant ($p=0.04$) between two groups.

Conclusion

Present study demonstrated that addition of palonosetron to combat post operative nausea and vomiting results in markedly prolonged duration of antiemetic property with minimum unwanted effects. And palonosetron have few requirements of rescue medication. So, it is concluded that palonosetron can be used to prevent post operative nausea and vomiting. The limitation of our study was small sample size and short duration of study period.

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Data Availability

Data supporting the findings of this study are available from the corresponding author upon reasonable request.

Ethics Approval and Consent to Participate

Ethical approval was obtained from the Institutional Review Board of Bangladesh Medical College & Hospital. Written informed consent was obtained from all participants prior to inclusion in the study. All procedures were conducted in accordance with relevant ethical guidelines and regulations.

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