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Original Research Article

THE EFFICACY OF ONDANSETRON V/S PALONOSETRON IN POSTOPERATIVE NAUSEA AND VOMITING

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ABSTRACT

Background: Despite the availability of newer anesthetic agents and advanced surgical techniques, the management of postoperative nausea vomiting (PONV) remains a challenge. The present study was conducted to compare the antiemetic efficacy of two commonly used $5HT_3$ antagonists, Ondansetron and Palonosetron, in patients undergoing elective surgery under general anesthesia.

Materials and Methods: This was a randomized comparative clinical study included a total of 110 subjects and were grouped into two, Group O received 4mg of intravenous ondansetron and Group P received 75 mcg of intravenous palonosetron. Incidence of post-operative nausea vomiting were analysed in both groups.

Results: Group O and Group P, both had comparable baseline demographic characteristics and hemodynamic parameters. In Group P, emesis was seen in 2.2% of patients at 2hours, 8.9% at 6 hours, 15.6% at 12 hours, and 4% at 24 hours. In Group O, the emesis was seen in 26.7% of patients at 2 hours, 35.5% at 6 hours, 40% at 12 hours, and 33.3% at 24 hours. This difference was statistically significant from the 2nd hour. The experience of nausea in the Group P was 3.6% at 2 hours, 14.5% at 6 hours, 20% at 12 hours, and 10.9% at 24 hours. In contrast, the Ondansetron group exhibited a much higher incidence of nausea, with 20% at 2 hours, 41.8% at 6 hours, 49% at 12 hours, and 41.8% at 24 hours. There was a statistically significant difference in the incidence of nausea between the two groups from the second hour onward.

Conclusion: The present study conclude that Palonosetron is superior to Ondansetron in managing postoperative nausea and vomiting (PONV) in patients undergoing elective surgery under general anesthesia.

Keywords: General Anaesthesia, Postoperative nausea and vomiting, Palonosetron, Ondansetron.

INTRODUCTION

After general anaesthesia, postoperative nausea and vomiting (PONV) is a significant complication often contributing to patient dissatisfaction with their surgical experience.[1]

The occurrence of PONV can extend a patient's time in the recovery area, resulting in postponed discharge from the hospital. These symptoms typically arise within the initial 24 hours after surgery, with incidence rates soaring to 80% among patients with certain risk factors who do not receive preventive antiemetic treatment.[2] The causes of PONV are diverse, with a notably high prevalence in individuals undergoing middle ear procedures.[3] This highlights the necessity of recognizing and managing PONV to enhance postoperative recovery and outcomes for patients.

In managing PONV, a range of antiemetic medications are employed, with 5-HT3 receptor antagonists being the preferred choice due to their higher effectiveness in both prevention and treatment of PONV, along with their favorable side effect profiles.[4] Common examples of drugs in this

category include Ondansetron, Granisetron, and Ramosetron. Although these drugs are available, no single medication is effective for all patients, underscoring the necessity for a customized strategy in the prevention and management of PONV.[5] Palonosetron is a novel and highly effective second-generation 5-HT3 receptor antagonist, recognized for its strong binding affinity to receptors and a prolonged plasma half-life of about 40 hours. These characteristics make it more effective and economical compared to earlier agents in its class.[6] Unlike other 5-HT3 receptor antagonists, Palonosetron binds to 5-HT3 receptors in an allosteric fashion, exhibiting positive cooperation at sites that differ from those used by ondansetron.[7] Given these differences, this study aims to compare the antiemetic effects of intravenous Ondansetron and Palonosetron in patients undergoing elective surgeries under general anesthesia and to evaluate whether Palonosetron offers a superior profile in terms of nausea score, vomiting score, and overall PONV score compared to Ondansetron.

MATERIALS AND METHODS

Study Design

The present study was a randomized comparative clinical study conducted over 12 months at a tertiary care center, focusing on patients undergoing elective surgeries under general anesthesia. Approval from the Institutional Ethics Committee (IEC) was obtained and informed consent was also obtained from the patients.

Inclusion Criteria

Patients between the ages of 18 and 60 who were undergoing elective procedures under general anesthesia and who gave their informed agreement to participate were included in the study. These patients were categorized as American Society of Anaesthesiology (ASA) grade I or II.

Exclusion Criteria

The exclusion criteria for the study were patients with a known allergy to Ondansetron or Palonosetron, those who had used antiemetic medications within 48 hours prior to surgery, and patients diagnosed with prolonged QT syndrome.

Sample size

The sample size was calculated based on a previous study by Jyothi Bhalla et al,[5] resulting in an estimated 50 patients per group. However, to ensure adequate power and account for potential dropouts, 55 patients were enrolled in each group, selected through random sampling.

Study Procedure

The study groups were designated as Group O wherein the study participants received 4 mg of intravenous Ondansetron and Group P in which the subjects received 75 mcg of intravenous Palonosetron. Prior to being transferred to the operating room, an intravenous line was secured using an 18-gauge (G) IV cannula. Standard anesthetic monitoring methods, such as electrocardiography, temperature, peripheral oxygen saturation (SpO2), and non-invasive blood pressure (NIBP), were used in the operating room. SpO2, heart rate (HR), mean arterial pressure (MAP), and blood pressure (BP) were measured at baseline. After that, the patients received intravenous premedication in the form of fentanyl (1.5 µg/kg), midazolam (0.05 mg/kg), and glycopyrrolate (0.01 mg/kg). Ten minutes before general anesthesia was induced using Propofol at a dose of 2 mg/kg, patients received an intravenous injection of either Palonosetron (75 mcg) or Ondansetron (4 mg). Vecuronium Bromide (0.1 mg/kg) was then administered to ease tracheal intubation. Intermittent positive pressure ventilation (IPPV) with a 50:50 oxygen and nitrous oxide combination, 2% isoflurane in a closed-circuit system, and extra vecuronium bromide (0.05 mg/kg) when needed were used to maintain anesthesia. The patient's hemodynamic stability was continuously tracked and maintained during the procedure. Neostigmine (0.05 mg/kg) and Glycopyrrolate (0.01 mg/kg) were injected to reverse neuromuscular inhibition after surgery. Intravenous Paracetamol (1 g infusion) was used to guarantee adequate postoperative analgesia. Other emetogenic analgesics and medications were avoided for 24 hours in order to reduce the incidence of postoperative nausea and vomiting (PONV).

During the first, second, sixth, twelve, and twenty-four hours after surgery, the number of episodes of nausea, vomiting, and any other side effects were counted and documented. The Visual Analogue Scale (VAS), with 0 denoting no pain and 10 denoting the worst discomfort, was used to assess the degree of postoperative pain.

Statistical Analysis

All statistical analyses were conducted using the Statistical Package for the Social Sciences (SPSS) Version 20. The chi-square test was applied to analyse categorical variables such as sex, and ASA classification. The independent t-test was employed to compare continuous variables including age, heart rate, respiratory rate, oxygen saturation, systolic blood pressure, diastolic blood pressure, as well as the incidence, grading of nausea and emesis, and the use of rescue antiemetics. A p-value of less than 0.05 was considered statistically significant.

RESULTS

The present study included 110 participants divided into two study groups, i.e., Group O (Ondansetron) and Group P (Palonosetron). Both the study groups were comparable in gender distribution with slight male preponderance (In Group O, males accounted for 64.2%, while 35.8% were female. Similarly, in Group P, males constituted 57.6%, with the remaining 42.4% being female).

The mean age of patients in Group O was slightly lower (31.6 years) in comparison to Group P (36.4 years), however, the difference was statistically not significant (p value 0.067). Height, weight, and BMI of participants in both the study groups were also comparable with statistically no significant difference (p-value >0.05). [Figure 1]

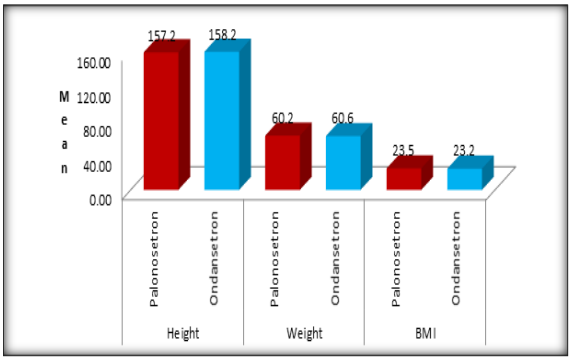

Figure 1: Baseline parameters in Group P and Group O

Table 1: The blood pressure and heart rate in Group P and Group O

Group		Mean	Std. Deviation	t value	p value
Systolic Blood Pressure (in mm of Hg)					
Pre-operative	Palonosetron	120.58	11.88	1.61	0.106
	Ondansetron	118.56	8.89		
During induction of anesthesia	Palonosetron	126.07	10.38	1.70	0.091
	Ondansetron	120.12	10.91		
Intra operative	Palonosetron	118.47	5.33	0.14	0.885
	Ondansetron	118.22	6.57		
Postoperative	Palonosetron	127.62	7.39	0.46	0.642
	Ondansetron	128.89	7.39		
Diastolic Blood Pressure (in mm of Hg)					
Pre-operative	Palonosetron	76.64	6.99	1.68	0.065
	Ondansetron	72.91	5.15		
During induction of anesthesia	Palonosetron	80.20	8.29	1.59	0.115
	Ondansetron	76.09	7.26		
Intra operative	Palonosetron	71.36	5.05	0.27	0.787
	Ondansetron	71.76	6.82		
Post-operative	Palonosetron	81.62	9.07	0.40	0.688
	Ondansetron	81.87	8.69		
Heart rate (in beats/ minute)					
Pre-operative	Palonosetron	87.51	10.50	0.74	0.457
	Ondansetron	85.87	10.27		
During induction of anesthesia	Palonosetron	80.58	4.58	0.06	0.949
	Ondansetron	80.67	8.15		
Intra operative	Palonosetron	82.04	3.53	0.33	0.736
	Ondansetron	82.49	6.55		
Post-operative	Palonosetron	91.27	6.44	0.11	0.908
	Ondansetron	91.13	6.47		

There was no significant difference observed in vital parameters such as systolic blood pressure (SBP), diastolic blood pressure (DBP), and heart rate (HR) during the preoperative, induction, intraoperative, and postoperative periods (table 1).

The mean VAS score for the Palonosetron group was 5.96 with a standard deviation of 1.02, while the Ondansetron group had a mean VAS score of 6.20 with a standard deviation of 1.47. The t-test analysis revealed a t-value of 0.91, with a p-value of 0.362 indicating no statistically significant difference in postoperative pain scores between the two groups.

Table 2: Comparison of anti-emetic effect and other symptoms among study groups

Parameters	Group		Chi-square value	p value
	Palonosetron	Ondansetron		
Headache *No* *Yes*	44(80%) 11(20%)	32 (58.1%) 23(42.2%)	5.18	**0.023**
Sedation *No* *Yes*	53 (96.3%) 2(3.6%)	48 (87.2%) 7(12.7%)	2.19	0.138
Rescue anti-emetic required *No* *Yes*	39(70.9%) 16(29%)	10(18.1%) 45(81.8%)	25.92	**<0.001**
Grading of control of emesis over 24 hours *No episode*				

1-2 episodes *3-5 episodes* *>5 episodes*	2 (3.6%) 39(70.9%) 16 (29%) 16 (29%)	7(12.7%) 10(18.1%) 45 (81.8%) 40 (72.7%)	26.03	**<0.001**

Table 2 presents the comparison of anti-emetic effects and other symptoms between the Palonosetron and Ondansetron groups.

With a p-value of 0.023, which indicates statistical significance, the Palonosetron group experienced fewer headaches (20%) than the Ondansetron group (42.2%). In contrast to the Ondansetron group (12.7%), only 2 (3.6%) of the Palonosetron group experienced sedation; however, this difference was not statistically significant (p = 0.138). Compared to the Ondansetron group (18.1%), 39 (70.9%) of the 55 patients in the Palonosetron group did not require rescue anti-emetics, with a p-value of less than 0.001. Over 24 hours, the palonosetron group demonstrated improved emesis control. Only 1-2 episodes of vomiting were reported by about 70.9% of patients, compared to 18.1% in the Ondansetron group. In contrast to 29% in the Palonosetron group, 81.8% of the Ondansetron group had three to five episodes.

These differences were statistically significant, with a p-value of <0.001. Overall, the findings suggest that Palonosetron was superior to Ondansetron.

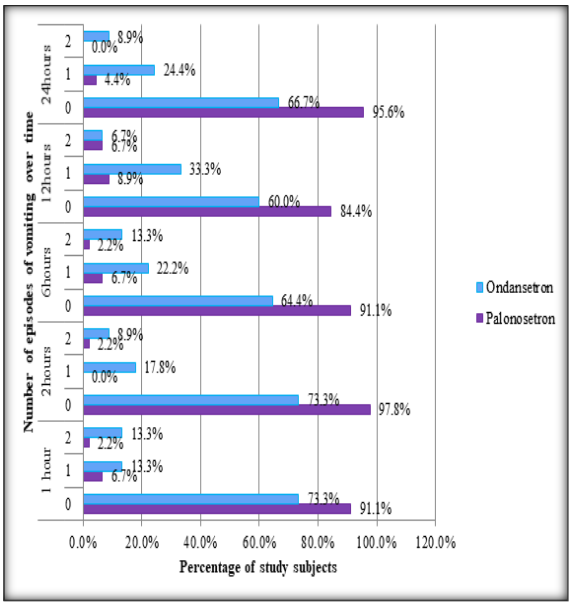

Figure 2: Comparison of the number of episodes of emesis over time among the study groups

Figure 2 shows a comparison of the number of emesis events. With a p-value greater than 0.05, the analysis showed no significant correlation between the study groups and the number of emesis events one hour after surgery. However, just 2.2% of patients in the Palonosetron group reported emesis at 2 hours, while 26.7% of patients in the Ondansetron group did so (p-value of 0.003). At six hours, this pattern persisted, and the correlation was still significant (p = 0.009); 8.9% of patients in the Palonosetron group experienced emesis, whereas 35.5% of patients in the Ondansetron group did the same. With 15.6% of patients in the Palonosetron group suffering emesis at 12 hours, compared to 40% in the Ondansetron group, the link was significant once more (p = 0.016).

Lastly, the substantial connection remained at 24 hours (p = 0.009), with just 4% of patients experiencing emesis in the Palonosetron group and 33.3% in the Ondansetron group. According to these results, Palonosetron outperformed Ondansetron in lowering the incidence of emesis at different postoperative time periods

Significant differences were found at several time points when the number of nausea episodes in the Palonosetron and Ondansetron groups was compared. At one hour, there was no discernible (p = 0.078) correlation between the Palonosetron group and the Ondansetron group reporting no nausea. By two hours, however, there was a strong correlation (p = 0.012), with 69% of patients in the Ondansetron group reporting no nausea and 94.5% of patients in the Palonosetron group. With 81.8% of patients in the Palonosetron group and just 45.4% in the Ondansetron group reporting no nausea at 6 hours, the difference became more noticeable (p = 0.006). At 12 hours, 76.3% of Palonosetron patients reported no nausea, compared to 41.8% in the Ondansetron group (p = 0.009), continuing the trend. 89% of Palonosetron patients and 49% of Ondansetron patients reported no nausea by the 24-hour mark, indicating that the difference was still significant (p = 0.022). Over the course of the day, the Palonosetron group experienced noticeably fewer instances of nausea than the Ondansetron group. (Table 3).

Table 3: Comparison of number of episodes of nausea among the study groups

Timeline Nausea (episodes)	Groups Palonosetron	 Ondansetron	Chi-square value	p value
1st hour • 0 • 1 • 2	 48 (87.2%) 5 (9%) 2 (3.6%)	 37 (67.2%) 11 (20%) 7 (12.7%)	5.097	0.078
After 2 hours • 0 • 1 • 2	 52 (94.5%) 2 (3.6%) 1 (1.8%)	 38 (69%) 11 (20%) 6 (10.9%)	8.799	0.012
After 6 hours				

• 0 • 1 • 2	45 (81.8%) 8 (14.5%) 2 (3.6%)	25 (45.4%) 23 (41.8%) 7 (12.7%)	7.563	0.006
After 12 hours • 0 • 1 • 2	42(76.3%) 11 (20%) 2 (4.4%)	23 (41.8%) 27 (49%) 5 (9%)	9.557	0.009
After 24 hours • 0 • 1 • 2	49 (89%) 6(10.9%) 0(0%)	27 (49%) 23 (41.8%) 5 (9%)	8.211	0.022

DISCUSSION

The present study compared the antiemetic efficacy of two commonly used 5HT$_3$ antagonists, Ondansetron and Palonosetron, in patients undergoing elective otorhinolaryngology surgery under general anesthesia.

Age, gender, BMI, and ASA grading were among the baseline demographics that were similar across the two groups in the current study. Hemodynamic parameters also did not significantly change throughout the follow-up period. However, between the second and twenty-four hours after surgery, there was a significant difference in the incidence of emesis between the Palonosetron and Ondansetron groups. At 2.2%, 8.9%, 15.6%, and 4% at 2, 6, 12, and 24 hours, respectively, the Palonosetron group experienced a considerably lower incidence of emesis than the Ondansetron group, which experienced rates of 26.7%, 35.5%, 40%, and 33.3% during the same periods. Except the first hour, when there was no discernible variation in emesis, this difference was statistically significant.

Compared to the Ondansetron group, which saw 3-5 episodes, the Palonosetron group had greater control over 24 hours, with 71.1% of patients experiencing only 1-2 episodes. Although there are significant discrepancies, our results are consistent with those of other studies. With an incidence of vomiting of 18.8% in the Ondansetron group and 9.4% in the Palonosetron group 24 hours postoperatively (p = 0.474), Vinit Kumar Srivastava et al. found no statistically significant difference in the frequency and intensity of vomiting between the Ondansetron and Palonosetron groups during the study period.[6] This is consistent with our finding that the Palonosetron group experienced a lower incidence of vomiting, even if Srivastava's study did not detect a statistically significant difference.

In contrast to our findings, which demonstrated a definite advantage in lowering the incidence of emesis, Jyoti Bhalla et al. similarly discovered similar vomiting occurrences between the Ondansetron and Palonosetron groups.[5] In contrast to our data, which showed a significant difference, FJ Davolos et al. reported that the largest incidence of vomiting occurred in both groups between 2 and 6 hours following surgery, with no significant difference between the two groups.[1] Our conclusion that the Palonosetron group had a reduced incidence of emesis was corroborated by J Sambasiva Rao et al., who reported an overall incidence of vomiting of 31.11% in the Ondansetron group and 3.33% in the Palonosetron group.[11] Our findings of less vomiting in the Palonosetron group during this period are also supported by Shubhangi Sharma et al.'s report of a statistically significant difference in postoperative vomiting scores between 2 and 12 hours, with 94% of Group Palonosetron patients having a score of 0 compared to 72% in the Ondansetron group.[4]

From the second to the twenty-fourth hour after surgery, the Palonosetron group experienced a considerably reduced incidence of nausea than the Ondansetron group. At 2, 6, 12, and 24 hours, the Palonosetron group had nausea at rates of 3.6%, 14.5%, 20%, and 10.9%, respectively. At the same time points, however, the Ondansetron group showed a significantly greater incidence of nausea. Statistical significance was found.

Our results are in line with those of Vinit Kumar Srivastava et al,[6] who found a significant difference (p = 0.032) in the occurrence of nausea 24 hours after surgery, with 34.4% of the Ondansetron group experiencing nausea and 9.4% of the Palonosetron group experiencing it. This closely reflects our finding that palonosetron is more effective than ondansetron at controlling nausea. Our study's results were supported by Jyoti Bhalla et al., who discovered that the Ondansetron group experienced a noticeably greater incidence of postoperative nausea than the Palonosetron group.[5] J. In close agreement with our findings, Sambasiva Rao et al. likewise observed an overall incidence of nausea of 55.56% in the Ondansetron group and 7.78% in the Palonosetron group.[11]

Additionally, Shubhangi Sharma et al,[4] reported that, with a statistically significant p-value (<0.05), 72% of patients in the Palonosetron group experienced a nausea score of 0 during the 2- and 12-hour postoperative period, compared to 32% in the Ondansetron group.

Comparing the Palonosetron group to the Ondansetron group, it has been found that the overall incidence of PONV is much reduced, which is consistent with several recent studies.[12-15] In our study, there was a statistically significant difference (p = 0.023) in the occurrence of headaches between the Palonosetron group (20%) and the Ondansetron group (42.2%). Although the Palonosetron group experienced sedation less frequently (3.6%) than the Ondansetron group (12.7%), the difference was not Furthermore, with a p-value of <0.001, indicating

strong statistical significance, a significantly higher percentage of patients in the Palonosetron group (70.9%) did not require rescue anti-emetics than in the Ondansetron group (18.1%). This suggests that Palonosetron offered better postoperative symptom management with fewer side effects than Ondansetron.

In line with our findings that the Palonosetron group had a considerably lower number of patients in need of rescue drugs, Jyoti Bhalla et al. discovered that the need for rescue anti-emetics was 32% in the Ondansetron group compared to 16% in the Palonosetron group.[5] Similarly, Sambasiva Rao et al, reported no statistical significance in the incidence of headaches, though the rates were 57% and 40% for Ondansetron and Palonosetron, respectively.[11]

Their research further supported our findings of Palonosetron's higher efficacy by demonstrating that, when it came to rescue antiemetic use, only 10% of the Palonosetron group needed extra antiemetic medication, compared to 53% in the Ondansetron group. Interestingly, our results show a significant incidence of headaches, especially in the Ondansetron group, but FJ Davolos et al,[1] did not record any adverse events like headaches in their trial. Overall, our research confirms the mounting data that Palonosetron is a better-tolerated and more efficient treatment for postoperative nausea and vomiting than Ondansetron.

Limitations: The study was conducted at a single institution with a restricted number of cases, limiting the generalizability of the findings. Multi-centric trials would be beneficial to confirm the external validity of the results.

CONCLUSION

Palonosetron is better than Ondansetron at treating postoperative nausea and vomiting (PONV) in patients having elective otorhinolaryngology surgery while under general anesthesia, according to the current study. Palonosetron was linked to a markedly decreased incidence of nausea and vomiting between two and twenty-four hours after surgery. Additionally, compared to patients in the Ondansetron group, fewer patients in the Palonosetron group needed rescue anti-emetics. With fewer headaches and no discernible change in sedation, palonosetron also showed a more favorable side-effect profile. According to these results, palonosetron is a useful supplement to the postoperative care of patients who are at risk of PONV since it provides a more efficient and well-tolerated choice for PONV prevention. Additional research with diverse patient populations and bigger sample sizes would be beneficial to confirm and expand upon these results.

Conflicts of Interest: Nil

Funding: Nil

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