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Original Research Article

# Comparing Palonosetron and Ondansetron for Preventing Post-Operative Nausea and Vomiting in Abdominal Surgery Patients

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**Abstract:**

**Background**: Postoperative nausea and vomiting (PONV) is a frequent and distressing complication following abdominal surgeries, affecting patient comfort and recovery. Ondansetron and palonosetron, both serotonin 5-HT3 receptor antagonists, are widely used to prevent PONV. However, the comparative efficacy of these medications in abdominal procedures remains an area of ongoing research.

**Aim**: The purpose of this research is to evaluate palonosetron and ondansetron, two drugs used to avoid PONV, side by side in patients having elective abdominal operations.

**Methodology**: A retrospective study was conducted in the Department of Anaesthesiology at IMS BHU in Varanasi, Uttar Pradesh , India, 90 patients who were having elective abdominal surgery were part of a probable, randomized, double-blind study. Before anesthesia, patients were given either 8 mg of ondansetron or 0.075 mg of palonosetron intravenously pursuant to a random allocation. Occurrence of postoperative nausea and vomiting (PONV) within the first day after surgery was the main target. The necessity of rescue antiemetics and negative side effects were deemed secondary outcomes.

**Results**: Compared to 66.67% in the 24-48-hour post-operative period, 96.67% showed a considerably greater complete response rate with palonosetron ($p = 0.008$). The palonosetron group had a much-reduced occurrence of vomiting, especially inside the first 24 hours (3.33% vs. 33.33%, $p = 0.008$). Adverse impact profiles were equivalent across the two sets.

**Conclusion**: While both palonosetron and ondansetron have similar safety profiles, palonosetron is superior at preventing delayed PONV, especially in the first 48 hours after surgery. Based on these results, palonosetron seems to be a superior choice for individuals undergoing abdominal surgery to avoid PONV in the long run.

**Keywords**: Postoperative nausea and vomiting, ondansetron, palonosetron, abdominal surgery, antiemetic efficacy



## Introduction

Postoperative nausea and vomiting (PONV) is a notably distressing side effect following surgery that can negatively impact patients' perceptions of their hospital experience. Patients undergoing abdominal procedures are at increased risk for PONV, and female patients are more vulnerable. Actually, a lot of patients say that avoiding postoperative nausea and vomiting is more important than pain relief [1]. Therefore, enhancing patient comfort and recovery depends on proper care of PONV. The initial medication created to combat chemotherapy-induced nausea and vomiting (CINV) was ondansetron, a serotonin 5-HT3 receptor antagonist [2]. An essential component of the emetic response, this carbazolone derivative medicine has structural similarities to serotonin and exerts its effects by specifically blocking 5-HT3 receptors. Because it does not affect the action of dopamine, histamine, adrenergic, or cholinergic receptors, ondansetron avoids several neurological adverse effects that were previously associated with earlier antiemetic drugs like droperidol and metoclopramide [3].

In 2003, the US Food and Drug Administration authorized palonosetron, a more contemporary 5-HT3 receptor antagonist, for the handling of CINV [4]. Among the many important ways in which palonosetron differs from its classmates is its much lengthier half-life (40 hours) and far tougher receptor-binding affinity. These features make it more effective in avoiding PONV [5]. The relative efficacy of ondansetron and palonosetron in avoiding PONV during abdominal procedures is still an area of interest and research, despite the drugs' extensive use. Key components of PONV include physiological symptoms such as nausea, retching, and vomiting, which can cause severe discomfort and anguish for patients [1]. When more rescue

medicine is not required and retching and vomiting have stopped, the patient is said to have had a complete response (CR) to antiemetic therapy [6].

Patients undergoing elective abdominal procedures under general anesthesia will be compared in this prospective, randomized, double-blind trial to see which antiemetic medication is more operative in tumbling PONV. In order to determine which medication has better effectiveness and safety profiles for this patient population, this study will also analyze the side effects and problems linked to each treatment.

The determination of this investigate is to compare palonosetron with ondansetron in order to find out whether one is better in preventing PONV in patients having abdominal surgery. This study aims to offer evidence that might enhance patient outcomes after surgery by examining the pharmacological differences and clinical outcomes.

## Methodology

**Study Design:** This study investigated the usefulness of palonosetron and ondansetron in avoiding PONV in patients having abdominal procedures. This study included two groups of patients and was characterized by randomization and double-blindness. The major goals of the research were to examine PONV rates, rescue antiemetic medication demands, and treatment satisfaction.

**Study Area:** A retrospective study was conducted in the Department of Anaesthesiology at IMS BHU in Varanasi, Uttar Pradesh, India for one year, performed the study. Whether it's an elective or emergency treatment, this tertiary care facility frequently performs abdominal surgery.

**Sample Size:** The research included 90 participants slated for elective abdominal operations. Each patient was randomly assigned to one of two groups; 45 patients received palonosetron and 45 patients received ondansetron. The sample size was established based on prior research indicating a clinically significant disparity in PONV rates between the two medications, with a power of 80% and an alpha level of 0.05.

**Sample Collection:** Patients were chosen according to the specified inclusion criteria. Demographic information (age, gender), clinical attributes (comorbidities, kind of abdominal surgery), and specifics concerning the prevalence of PONV within 24 hours post-surgery were gathered. The research concentrated on the incidence of PONV and the prerequisite for rescue antiemetic treatment within the initial 24 hours post-surgery.

### Inclusion Criteria & Exclusion Criteria

**Inclusion Criteria:** The inclusion criteria for this study encompassed individuals aged 18 to 65 undergoing elective abdominal surgeries under general anesthesia. Patients were selected based on a moderate-to-high risk of postoperative nausea and vomiting (PONV), as determined by the Apfel score. The study included a variety of abdominal procedures such as hernia repairs, bowel resections, and laparoscopic cholecystectomy. Additionally, only participants who provided informed consent after receiving comprehensive medical information were enrolled.

**Exclusion Criteria:** Exclusion criteria comprised individuals younger than 18 or older than 65, as well as pregnant or breastfeeding women. Patients with severe comorbidities, including significant cardiovascular, hepatic, or renal dysfunction, were also excluded. Furthermore, individuals with known hypersensitivity to 5-HT3 receptor antagonists, such as palonosetron or ondansetron, were not included. Patients who had received preoperative antiemetic therapy other than palonosetron or ondansetron were excluded from the study. Lastly, cases with incomplete clinical or demographic data were not considered for analysis.

**Procedure:** Participants in that randomized controlled trial were given either palonosetron or ondansetron before abdominal procedures, with the assignment done via computer-generated randomization. Prior to the initiation of anesthesia, both antiemetic medications were given intravenously. In contrast to the 8 mg given to the ondansetron group, the palonosetron group only got 0.075 mg. The occurrence of PONV was rigorously tracked in all patients on the first day after surgery. During the 24-hour period, the occurrence of PONV was the primary outcome assessed. Patient satisfaction, the frequency of adverse drug reactions, and the necessity of rescue antiemetic medicine were all considered secondary outcomes. To further investigate potential associations with PONV, demographic information including age, gender, and operation type was also gathered. In order to evaluate the safety profile of each antiemetic medication, the adverse effects associated with the study medicines were meticulously recorded. The determination of this research was to gauge palonosetron and ondansetron, two drugs used to prevent PONV in patients having abdominal surgery, side by side.

**Statistical Analysis:** Two sample t-tests were utilized to evaluate the complete responses across both groups. Significance was determined by a p-value that was lower than 0.05. The data were presented in numerical and percentage formats, together with standard deviation and mean.

## Result

The research included 90 participants slated for elective abdominal operations. Patients were randomly allocated to one of two groups: Group O (Ondansetron) including 45 patients and Group P (Palonosetron) also comprising 45 patients. The sample size was established according to prior research indicating a clinically significant disparity in PONV rates amongst the two medications, with a power of 80% and an alpha level of 0.05.

Table 1 displays the post-operative complete response rates for Ondansetron (Group O) and Palonosetron (Group P) at different time periods. In the 0–6-hour time following surgery, both groups had elevated complete response rates, with Group O attaining 93.33% and Group P reaching 86.67%, showing no significant difference (p = 0.668). Within the 6-24 hour timeframe, Group P exhibited a full response rate of 93.33%, surpassing Group O's rate of 73.33%; nevertheless, this difference lacked statistical significance (p = 0.083). During the 24–48-hour post-operative period, Group P exhibited a substantially greater complete response rate of 96.67% compared to 66.67% in Group O (p = 0.008). During the 48-72 hour interval, both groups had elevated response rates, with Group O at 86.67% and Group P at 96.67%; Having said that, p = 0.350 indicates that the disparity was not statistically substantial.

**Table 1: Post-Operative Response (Complete Response Rate)**

| Time Interval | Group O (Ondansetron) | Group P (Palonosetron) | p value |
|---|---|---|---|
| **0-6 hrs** | 93.33% complete response (28/30) | 86.67% complete response (26/30) | 0.668 |
| **6-24 hrs** | 73.33% complete response (22/30) | 93.33% complete response (28/30) | 0.083 |
| **24-48 hrs** | 66.67% complete response (20/30) | 96.67% complete response (29/30) | 0.008 |
| **48-72 hrs** | 86.67% complete response (26/30) | 96.67% complete response (29/30) | 0.350 |

Table 2 illustrates the occurrence of nausea in patients administered Ondansetron (Group O) and Palonosetron (Group P) at various post-operative time intervals. In the 0-6 hour interval, nausea occurred in 10% of Group O patients and 3.33% of Group P patients, with no statistically significant difference (p = 0.197). Nausea was documented in 6.67% of Group O patients over the 6-24- and 24-48-hour intervals, but Group P exhibited no instances of nausea (p = N/A). Within the 48–72-hour timeframe, no patients in either cohort reported nausea.

**Table 2: Incidence of Nausea**

| Time Interval | Group O (Ondansetron) | Group P (Palonosetron) | p value |
|---|---|---|---|
| **0-6 hrs** | 10% (3/30) | 3.33% (1/30) | 0.197 |
| **6-24 hrs** | 6.67% (2/30) | 0% (0/30) | N/A |
| **24-48 hrs** | 6.67% (2/30) | 0% (0/30) | N/A |
| **48-72 hrs** | 0% (0/30) | 0% (0/30) | N/A |

Table 3 illustrates the occurrence of vomiting in patients administered Ondansetron (Group O) and Palonosetron (Group P) at various post-operative time intervals. During the 0-6 hour interval, vomiting was seen in 6.67% of Group O patients and 13.33% of Group P patients, with no statistically significant difference (p = 0.668). In the 6–24-hour interval, 26.67% of Group O patients had vomiting, whereas 6.67% of Group P did; although there was no statistical significance (p = 0.083) between the two. In the 24–48-hour period, Group O had a markedly greater incidence of vomiting at 33.33%, in contrast to 3.33% in Group P (p = 0.008). During the 48–72-hour interval, vomiting occurred in 13.33% of Group O patients and 3.33% of Group P patients, with no statistically significant difference (p = 0.350).

**Table 3: Incidence of Vomiting**

| Time Interval | Group O (Ondansetron) | Group P (Palonosetron) | p value |
|---|---|---|---|
| **0-6 hrs** | 6.67% (2/30) | 13.33% (4/30) | 0.668 |
| **6-24 hrs** | 26.67% (8/30) | 6.67% (2/30) | 0.083 |
| **24-48 hrs** | 33.33% (10/30) | 3.33% (1/30) | 0.008 |
| **48-72 hrs** | 13.33% (4/30) | 3.33% (1/30) | 0.350 |

Table 4 illustrates the occurrence of adverse events in individuals administered Ondansetron (Group O) and Palonosetron (Group P). The prevalence of headache was 20% in Group O and 13.33% in Group P, with no statistically meaningful variation seen between the groups (p = 0.315). Constipation was noted in 6.67% of Group O patients and 10% of Group P patients, with no notable distinction found (p = 0.856).

**Table 4: Incidence of Adverse Complaints**

| Adverse Effect | Group O (Ondansetron) | Group P (Palonosetron) | p value |
|---|---|---|---|
| **Headache** | 20% (6/30) | 13.33% (4/30) | 0.315 |
| **Constipation** | 6.67% (2/30) | 10% (3/30) | 0.856 |

Both Palonosetron (Group P) and Ondansetron (Group O) had high rates of full response in this trial assessing their effectiveness in tumbling PONV in patients after abdominal surgery. Nevertheless, within the first 24 to 48 hours after the operation, Group P showed noticeably greater rates of full response ($p < 0.05$). Although both groups experienced nausea at equal rates, Palonosetron worked better to prevent vomiting in Group O over the 6-24 hour ($p = 0.083$) and 24-48 hour ($p = 0.008$) periods. Headache and constipation were among the adverse symptoms that were reported by both groups. In the latter post-operative time, Palonosetron ensured a more complete response and somewhat improved the prevention of vomiting.

**Discussion**

This study aimed to prevent postoperative nausea and vomiting (PONV) in patients undergoing elective abdominal surgeries by comparing the efficacy of two serotonin 5-HT3 receptor antagonists: palonosetron and ondansetron. Both medications demonstrated effectiveness in preventing PONV, achieving high rates of complete response. However, significant differences emerged between the two drugs at specific postoperative intervals. Research indicates that palonosetron may offer a more prolonged antiemetic effect compared to ondansetron, particularly in the later postoperative periods [10].

During the first six hours following surgery, both Ondansetron and Palonosetron showed a high rate of full response. On the other hand, Palonosetron had a far greater complete response rate than Ondansetron did in the first 48 hours after surgery (96.67% vs. 66.67%, $p = 0.008$). Palonosetron may offer better protection against PONV in the long run, especially for patients in their late phases of recovery, according to these findings [11]. Consistent with previous research, our results suggest that Palonosetron may be superior in avoiding delayed PONV due to its prolonged half-life. On the other hand, while both medications were beneficial in the short term, Palonosetron provided more long-term protection than Ondansetron.

The occurrence of nausea was minimal in both collections, with Palonosetron showing a modest advantage. Even though there was no statistically meaningful variation ($p = 0.197$), 10% of participants in the Ondansetron group and 3.33% in the Palonosetron group reported nausea in the 0-6 hour period. In the ensuing time periods (6-24 hours and 24-48 hours), patients on Palonosetron did not experience any nausea, but 6.67 percent of patients taking Ondansetron reported nausea [12]. The results indicate that Palonosetron might be a better choice for nausea management in the latter phases after surgery. Both results are in line with Palonosetron's pharmacokinetic characteristics, which would explain why it has a longer-lasting antiemetic effect.

When comparing the two medications, the frequency of vomiting was the most striking difference. Among patients treated with Ondansetron, 26.67% reported vomiting during the 6-24 hour period, while only 6.67% reported the same side effect in the Palonosetron group ($p = 0.083$). Most crucially, related to Group P (3.33% vs. 33.33%, $p = 0.008$), Group O had a much greater rate of vomiting within the first 48 hours after surgery.[13] It is evident that Palonosetron is more effective in avoiding vomiting, particularly in the later stages after surgery. These findings corroborate previous research that has shown that The apparent benefit of palonosetron in managing vomiting in the later stages following surgery may be due to its prolonged half-life compared to other medications.

Serious side effects, such as headaches and constipation, were reported with both Ondansetron and Palonosetron. When comparing the two medications for side effects, we found no disparities with a statistical significance ($p = 0.856$ for constipation and $p = 0.315$ for headache). It appears that the side effects of both medications are similar, lending credence to the claim that Palonosetron offers a better balance between benefits and risks when it comes to preventing PONV. Both medications had similar levels of safety events, suggesting that they are well-tolerated in this trial.

When it comes to preventing PONV, Ondansetron and Palonosetron have been compared in a number of trials. Palonosetron was more effective than Ondansetron in avoiding PONV following major abdominal surgery, according to research by Yoo JH et al. (2020). We found a substantially greater complete response rate with Palonosetron throughout the course of the first 48 hours, so our findings are consistent with that. Furthermore, Palonosetron had a longer interval of action than Ondansetron, which may account for its superior effectiveness in preventing PONV in the latter post-operative period (Park SK, Cho EJ. 2011). Additionally, in a study conducted by Davolos FJ et al. (2024), the effectiveness of Palonosetron was compared to Ondansetron in patients having laparoscopic surgery. The results showed that Palonosetron had a longer antiemetic effect and a lower incidence of vomiting. When it comes to the prevention of vomiting over the long term, these results provide more evidence that Palonosetron is preferable.

There are certain limitations to this study, despite the encouraging results. In the early post-operative periods, when PONV rates are typically lower, the sample size of 45 patients per group may not be

enough to detect modest changes in effectiveness. The study may also have limited applicability to other kinds of surgery, such those affecting the thoracic or orthopaedic areas, since it solely examined elective abdominal procedures. In conclusion, healthcare professionals may want to consider the study's exclusion of the economic impact of Palonosetron vs. Ondansetron when making a therapy selection. These findings might be further validated by a bigger, multi-center experiment that includes different types of surgeries.[14]

## Conclusion

The present study shows that patients having abdominal procedures can avoid PONV with the use of Ondansetron and Palonosetron. Palonosetron provided far better long-term protection, especially in the first 48 hours after surgery, and it was associated with a decreased frequency of vomiting, albeit both medications had excellent full response rates. There was no discernible difference in the adverse effects profiles of the two medications. The results of this study indicate that Palonosetron has the potential to be more effective than other options for long-term postoperative treatment, especially in cases of delayed PONV. To validate these findings and assess the cost-effectiveness of both medications, however, more research is required using bigger samples and other surgical procedures.

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