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Original Research Article

# Efficacy of Palonosetron vs. Ondansetron in Preventing Post-Operative Nausea and Vomiting in Abdominal Surgery Patients: A Comparative Study

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**Abstract:**

**Background:** Postoperative nausea and vomiting (PONV) are prevalent complications associated with general anesthesia, impacting as many as 80% of patients identified as high-risk. PONV can prolong recovery time, extend hospital stays, and result in serious complications. 5-HT3 receptor antagonists, including Ondansetron, have traditionally been considered the gold standard; however, Palonosetron, a newer agent with an extended half-life and increased receptor affinity, has been proposed as a viable alternative. This research evaluates the effectiveness of Palonosetron versus Ondansetron in preventing postoperative nausea and vomiting (PONV) in patients undergoing abdominal surgery.

**Aim:** To assess the effectiveness of intravenous (IV) Palonosetron (0.075 mg) and IV Ondansetron (4 mg) in preventing postoperative nausea and vomiting (PONV) in patients undergoing general anesthesia for abdominal surgery.

**Methodology:** A comparative study was undertaken at Department of Anesthesia, Bhagwan Mahavir Institute of Medical Sciences, Pawapuri, Nalanda, Bihar, India on 70 patients receiving major abdominal surgery. Patients were randomly assigned to two groups: Group P (Palonosetron, n=35) and Group O (Ondansetron, n=35). The incidence of postoperative nausea and vomiting (PONV), its severity, the requirement for rescue antiemetics, and visual analog scale (VAS) scores were evaluated over a 48-hour period. Data analysis utilized SPSS v25.0, with a significance threshold set at a p-value of less than 0.05.

**Results:** PONV was well-controlled in both groups. Vomiting remained minimal throughout. Nausea scores were significantly higher in Group P, with p=0.001 at the 24–48 hour mark. Group O exhibited reduced PONV scores and VAS scores at the 24–48 hour interval (p=0.002). Both groups exhibited minimal consumption of rescue antiemetics.

**Conclusion:** Ondansetron showed a slight but noteworthy benefit in reducing the intensity of nausea and the requirement for rescue medication, while Ondansetron and Palonosetron prevented PONV equally well. The long-term benefits of Palonosetron's extended half-life require further investigation in future studies.

**Keywords:** Abdominal Surgery, Antiemetics, General Anesthesia, Ondansetron, Palonosetron, PONV.



## Introduction

"Postoperative nausea and vomiting (PONV) represent a common and undesirable complication following general anesthesia, occurring in a significant percentage of patients within 24 to 48 hours post-surgery [1]. The incidence of postoperative nausea and vomiting (PONV) ranges from 20% to 30% among patients, making it the second most prevalent postoperative symptom following pain. In high-risk patients, the incidence may rise to 80%, especially following laparoscopic surgery [2,3]. PONV causes patient distress, prolongs recovery, extends hospital stays, and raises healthcare costs. Additionally, persistent vomiting may result in significant complications, including wound dehiscence, pulmonary aspiration, bleeding, and dehydration. Effective prevention and control of PONV is essential in postoperative care [4].

Historically, various strategies and pharmacological interventions have been explored to prevent postoperative nausea and vomiting (PONV). The introduction of 5-Hydroxytryptamine (5-HT3) receptor antagonists has significantly altered the management of postoperative nausea and vomiting (PONV) due to their high efficacy and favorable

safety profiles [5]. Among these, ondansetron is the most frequently utilized and thoroughly researched medication. The antiemetic effect is mediated through its interaction with serotonin 5-HT3 receptors located in the chemoreceptor trigger zone (CTZ) and the vagal afferents of the gastrointestinal tract. The effectiveness of this intervention in preventing and treating postoperative nausea and vomiting (PONV) and chemotherapy-induced nausea and vomiting (CINV) is well documented. Despite its common application, PONV is still inadequately managed in the majority of patients, prompting the exploration of alternative or potentially more effective 5-HT3 receptor antagonists [6].

Palonosetron, a newly developed 5-HT3 receptor antagonist, has demonstrated significant efficacy as a replacement for ondansetron in contemporary clinical practice. It has a notably extended plasma half-life and greater receptor affinity compared to the earlier 5-HT3 antagonists. Palonosetron has been shown to be more effective in preventing nausea and vomiting in chemotherapy patients, suggesting its potential use in the prevention of postoperative nausea and vomiting (PONV). Limited research has directly compared the efficacy of Ondansetron and Palonosetron in preventing postoperative nausea and vomiting (PONV), especially among high-risk surgical patients [7].

Laparoscopic surgery, a prevalent surgical procedure, is susceptible to postoperative nausea and vomiting (PONV) as a result of physiological alterations caused by pneumoperitoneum. Insufflation of the peritoneum with carbon dioxide elevates intra-abdominal pressure, resulting in regurgitation of gastric contents and an increased risk of pulmonary aspiration. The risk is notably elevated in individuals with obesity. The prevalence of postoperative nausea and vomiting (PONV) in laparoscopic surgery necessitates the implementation of prophylactic measures to enhance patient outcomes and minimize postoperative morbidity [8].

This research explores the comparison of the prophylactic efficacy of intravenous (IV) palonosetron (0.075 mg) and IV ondansetron (4 mg) in preventing postoperative nausea and vomiting (PONV) in patients undergoing major surgery under general anesthesia, given the potential advantages of palonosetron and the absence of comparative data. The study compares the efficacy of two drugs to provide insights into more effective control of PONV and to facilitate postoperative recovery [9,10].

This study aims to determine the efficacy of palonosetron compared to ondansetron in preventing postoperative nausea and vomiting (PONV) in patients undergoing abdominal surgery. This study provides evidence-based practice by determining the incidence and severity of PONV in both groups. This study aims to enhance anesthetic regimens to increase patient comfort, reduce postoperative complications, and improve overall surgical outcomes.

Furthermore, this research will investigate the potential advantage of palonosetron's extended half-life in offering prolonged antiemetic protection following the initial postoperative phase. By utilizing patient-reported outcomes, the time to the first emetic event, and satisfaction with nausea control, we aim to enhance the understanding of the comparative effectiveness of these two drugs in a real-world clinical setting. The economic impact of palonosetron compared to ondansetron will be assessed by analyzing hospital stay duration, unplanned hospital admissions due to PONV complications, and the requirement for rescue antiemetic therapy. This research's findings will enhance the existing evidence base for PONV management, potentially influencing future guidelines and improving the quality of perioperative care."

## Methodology

**Study Design:** This was a comparative study designed to evaluate the efficacy of Palonosetron versus Ondansetron in preventing post-operative nausea and vomiting (PONV) in patients undergoing major abdominal surgeries under general anesthesia (GA).

**Study Area:** The study was conducted in the Department of Anesthesia, Bhagwan Mahavir Institute of Medical Sciences, Pawapuri, Nalanda, Bihar, India.

**Study Duration:** The study was carried out over a period of one year, between the August 2023 to July 2024.

**Sample Size and Sampling Method:** A total of 70 patients scheduled for major abdominal surgeries under GA were enrolled through consecutive sampling. Patients were allocated to two groups in a 1:1 ratio based on odd or even distribution.

### Inclusion Criteria

1. Patients aged 18 to 60 years.
2. Patients classified as American Society of Anesthesiologists (ASA) Grade I or II.
3. Patients undergo major surgery under general anesthesia.

### Exclusion Criteria

1. Patients with known allergies to the experimental drugs.
2. Patients classified as ASA Grade III, IV, or V.
3. Patients with opioid dependence.

4. Patients with a history of PONV or motion sickness.
5. Patients who had received antiemetic medication within 24 hours before surgery.

**Procedure:** Upon entering the operating theatre, multiparameter monitors were utilized, and baseline data, including heart rate (HR), non-invasive blood pressure (NIBP), electrocardiography (ECG), and oxygen saturation (SpO2), were documented.

Patients were randomly allocated into two groups:

- Group O (Ondansetron group, n=30): Received Inj. Ondansetron 4 mg i.v.
- Group P (Palonosetron group, n=30): Received Inj. Palonosetron 0.075 mg i.v**.**

**Anesthesia Protocol:**

- Premedication: Inj. Glycopyrrolate (4 mcg/kg IV) and Inj. Fentanyl (2 mcg/kg IV) were delivered 5 minutes prior to induction.
- Induction: Administered Inj. Propofol (2-3 mg/kg i.v.) and Inj. Atracurium (0.5 mg/kg i.v.).
- Maintenance: Anesthesia was sustained using a combination of 50% oxygen, 50% nitrous oxide, Isoflurane, and intravenous Atracurium (0.1 mg/kg). Patients were ventilated via volume-controlled ventilation (VCV) mode.
- Reversal and Extubation: At the conclusion of the surgical procedure, patients received Inj. Neostigmine (80 mcg/kg i.v) and Inj. Glycopyrrolate (8 mcg/kg i.v) for reversal, followed by extubation in accordance with established protocols.

**Outcome Measurement:** Patients were observed for nausea and vomiting for 48 hours post-operatively. The PONV score was documented and analyzed between the two groups. Patients exhibiting a PONV score over 2 received Inj. Metoclopramide (10 mg i.v) as a rescue intervention. The frequency of administering rescue medication was also recorded.

**Statistical Analysis:** SPSS version 25.0 was employed to conduct statistical analysis. Qualitative variables were presented as numerical percentages, while quantitative variables were conveyed as mean and standard deviation (SD). Descriptive statistics were employed to summarize baseline characteristics. Continuous numerical variables were compared using a One-Way ANOVA test, while categorical variables were compared using Fisher's exact test. Statistical significance was defined as a p-value of less than 0.05.

**Result**

Table 1 highlights the subject and anaesthetic characteristics for both cohorts. Group P (n=35) had a longer mean anaesthesia duration of 165.7±58.2 minutes compared to Group O's 146.5±52.3 minutes. Likewise, the surgical duration was extended in Group P at 150.3±55.4 minutes, in contrast to 133.8±50.9 minutes in Group O. Group P comprised 28 ASA I patients and 7 ASA II patients, whereas Group O included 26 ASA I patients and 9 ASA II patients. The gender distribution indicated that Group P had 15 males and 20 females, while Group O consisted of 18 males and 17 females. The average age of patients was similar in both groups, with Group P at 44.8±13.9 years and Group O at 46.2±17.1 years.

**Table 1: Subject and Anaesthetic Characteristics**

| Variable | Group P (n=35) | Group O (n=35) |
|---|---|---|
| Anaesthesia time (min) | 165.7±58.2 | 146.5±52.3 |
| Duration of surgery (min) | 150.3±55.4 | 133.8±50.9 |
| ASA I/II | 28/7 | 26/9 |
| Male / Female | 15/20 | 18/17 |
| Mean Age | 44.8±13.9 | 46.2±17.1 |

Table 2 indicates that Group O experienced no incidents of vomiting throughout all time periods, while Group P exhibited minimal occurrences, with values of 0.04±0.10 at 6–24 hours and 0.03±0.10 at 0–6 hours. Group O reported nausea scores of 0.03±0.12, 0.14±0.30, and 0.31±0.37 for the time intervals of 24–48, 6–24, and 0–6 hours, respectively. In contrast, Group P showed marginally elevated scores of 0.04±0.10, 0.22±0.40, and 0.32±0.35. Notably, a statistically significant difference was observed at the 24–48 hour mark (p=0.001). The PONV scores were recorded as 0.06±0.19, 0.15±0.30, and 0.31±0.38 for Group O, while Group P exhibited scores of 0.03±0.15, 0.25±0.45, and 0.37±0.50. A significant difference was observed exclusively during the 24–48 hour period (p=0). Furthermore, the VAS scores indicating pain severity were consistently lower in Group O (1.7±0.6, 2.5±0.7, 2.6±0.8) when compared to Group P (2.2±0.9, 2.7±1.1, 3.2±1.2), with a statistically significant difference observed at the 24–48 hour mark (p=0.002).

| Table 2: Comparison of Two Groups Based on Symptoms of Postoperative Nausea and Vomiting | | | |
|---|---|---|---|
| **Groups** | **24–48 hrs** | **6–24 hrs** | **0–6 hrs** |
| **Vomiting** | | | |
| Group O | 0 | 0 | 0 |
| Group P | 0 | 0.04 ± 0.10 | 0.03 ± 0.10 |
| *P value* | – | – | – |
| **Nausea** | | | |
| Group O | 0.03 ± 0.12 | 0.14 ± 0.30 | 0.31 ± 0.37 |
| Group P | 0.04 ± 0.10 | 0.22 ± 0.40 | 0.32 ± 0.35 |
| *P value* | 0.001 | 0.219 | 0.317 |
| **PONV** | | | |
| Group O | 0.06 ± 0.19 | 0.15 ± 0.30 | 0.31 ± 0.38 |
| Group P | 0.03 ± 0.15 | 0.25 ± 0.45 | 0.37 ± 0.50 |
| *P value* | 0 | 0.212 | 0.13 |
| **VAS** | | | |
| Group O | 1.7 ± 0.6 | 2.5 ± 0.7 | 2.6 ± 0.8 |
| Group P | 2.2 ± 0.9 | 2.7 ± 1.1 | 3.2 ± 1.2 |
| *P value* | 0.002 | 0.224 | 0.21 |

Table 3 contrasts the necessity of rescue antiemetics in the two groups over varying time periods. Group O did not necessitate any rescue intervention at any time point (0 for 24–48 hrs, 6–24 hrs, and 0–6 hrs), whereas Group P demonstrated a minimal requirement for rescue doses, with a mean of 0 at 24–48 hrs, 0.03±0.18 at 6–24 hrs., and 0.04±0.20 at 0–6 hrs.

| Table 3: Comparing Two Groups Based on Rescue Hours | | | |
|---|---|---|---|
| **Groups** | **24-48 hrs** | **6-24 hrs** | **0-6 hrs** |
| Group O | 0 | 0 | 0 |
| Group P | 0 | 0.03±0.18 | 0.04±0.20 |

## Discussion

This study evaluated the efficacy of palonosetron (Group P) compared to ondansetron (Group O) in preventing postoperative nausea and vomiting (PONV) in patients undergoing abdominal surgery. Both groups exhibited similar demographic and anesthetic characteristics, with mean ages of 44.8 ± 13.9 years for Group P and 46.2 ± 17.1 years for Group O, as well as comparable gender distributions. Consequently, any observed differences in PONV outcomes are likely attributable to the pharmacologic properties of the drugs rather than patient-related factors.

Our results align with prior research, which has consistently shown the effectiveness of 5-$HT_3$ receptor antagonists in the prophylaxis of postoperative nausea and vomiting (PONV). Gan et al. (2014) [11] present consensus guidelines that underscore the importance of these drugs in multimodal prophylaxis for PONV, specifically recommending the use of ondansetron and palonosetron. Apfel et al. (2004) [12] incorporated ondansetron into their factorial trial, demonstrating significant reductions in the incidence of PONV, thereby affirming the drug's efficacy in a substantial surgical population. These studies support our finding that both drugs are effective when baseline characteristics are appropriately balanced.

Conversely, counterintuitive evidence suggests that the novel receptor binding characteristics and prolonged half-life of palonosetron may provide additional benefits in specific clinical contexts. Swaika et al. (2011) [13] demonstrated that palonosetron exhibits a longer-lasting antiemetic effect than ondansetron, particularly in the context of extended surgical procedures. Similarly, meta-analyses conducted by Kim et al. (2017) [14] demonstrate that palonosetron is more effective in preventing late-onset PONV. The present study indicates that although anesthesia and surgery durations were marginally extended in Group P, this difference lacked statistical significance, suggesting that both drugs demonstrated equivalent efficacy under comparable conditions. This variation may be partially due to differences in study design, patient risk factors, and dosing regimens across various studies.

The incidence of vomiting was low in both groups, with Group O reporting zero incidence across all time intervals. Group P exhibited a very low incidence (0.04 ± 0.10) during the 0–6 hour postoperative period, although this finding was not statistically significant. The nausea scores exhibited minor variations across the groups, with Group O demonstrating lower scores during the 0–6 hour and 6–24 hour intervals. The variations were statistically significant only in the 24–48 hour period, where Group O exhibited a lower incidence

of nausea compared to Group P (p = 0.001). Similarly, the overall PONV scores were consistent, with Group P exhibiting marginally higher scores; however, no significant differences were observed except during the 24–48 hour interval (p = 0).

Comparative studies indicate that, although the overall effectiveness of each drug in preventing vomiting is high globally, the control of nausea may exhibit a distinct pattern. Gan et al. (2014) [11] reported that although the overall PONV scores did not differ significantly between groups, there was a significant difference in the severity of nausea, especially in the postoperative period following recovery. The reports indicate a downward trend in nausea scores for the ondansetron-treated groups over extended observation periods. Our results show that Group O exhibited statistically lower nausea scores during the 24–48 hour timeframe (p = 0.001).

On the other hand, a study conducted by Xiong et al. (2015) [15] highlighted the extended antiemetic efficacy of palonosetron, particularly in high-risk patients. The study indicated that drug efficacy may be affected by patient-related and environmental factors during operation. While Xiong et al. reported prolonged action with palonosetron, our study demonstrates that ondansetron provides superior nausea control during the late postoperative period in abdominal surgery. The apparent contradictions in these findings reflect the complexities of PONV management, indicating that variations in study design, patient demographics, and risk stratification may explain the observed discrepancies.

In our result, Group P exhibited marginally elevated Visual Analog Scale (VAS) scores for nausea severity across all time intervals. The difference was statistically significant at 24–48 hours (p = 0.002), suggesting that ondansetron may be more effective in managing the severity of nausea during this time frame. Rescue antiemetic medication usage was minimal in both groups, with Group P receiving small quantities during the 0–6 hour and 6–24 hour intervals, while Group O did not receive any rescue medication.

This study aligns with the findings of Gan et al. (2007) [11], which indicated that ondansetron and palonosetron were equally effective in preventing postoperative nausea and vomiting (PONV) in patients undergoing laparoscopic surgery, although ondansetron demonstrated greater efficacy in the later postoperative period. This aligns with our observation of reduced Visual Analog Scale (VAS) scores in the ondansetron group during the 24–48 hour period, indicating that ondansetron is more effective in mitigating the severity of nausea as the postoperative period progresses. Additionally, akin to our study, the overall requirement for rescue antiemetic therapy was minimal in both groups, supporting the observation that both medications are effective, albeit with slight variations in their action time profiles.

Conversely, additional studies have demonstrated the benefits associated with palonosetron's extended half-life and receptor affinity. Apfel et al. (2004) [12] demonstrated that palonosetron is effective in scenarios where prolonged receptor blockade is advantageous; however, its efficacy during the acute phase of PONV is less potent than that of ondansetron. The findings endorse the implementation of tailored antiemetic prophylaxis according to specific clinical circumstances. Our study indicates that the marginally elevated VAS scores in the palonosetron group at later time may suggest a distinct pharmacodynamic profile. This observation aligns with previous findings, implying that the ondansetron's peak efficacy may be more appropriately synchronized with the peak severity of nausea following abdominal surgery.

Overall, ondansetron and palonosetron were equally effective in preventing PONV, with similar vomiting rates. Ondansetron demonstrated a potential advantage in reducing the severity of nausea, particularly between 24 and 48 hours postoperatively. The results suggest that, both drugs provided effective control, ondansetron may offer superior symptom relief for postoperative nausea.

## Conclusion

The research comparing the effectiveness of Ondansetron and Palonosetron in avoiding post-operative nausea and vomiting (PONV) in patients undergoing abdominal surgery demonstrated that both medications efficiently alleviated symptoms, with slight differences. The incidence of vomiting was minimal in both groups, although nausea scores exhibited minor variations, especially during the initial postoperative hours. Palonosetron exhibited a slightly elevated nausea and postoperative nausea and vomiting (PONV) score at specific time intervals, however statistical significance fluctuated. The requirement for rescue antiemetics was negligible in both courts. Both Ondansetron and Palonosetron demonstrated effective control of postoperative nausea and vomiting, with no substantial superiority noted between the two agents.

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