e-ISSN: 0975-9506, p-ISSN: 2961-6093

Available online on www.ijpqa.com

International Journal of Pharmaceutical Quality Assurance 2025; 16(8); 335-340

Original Research Article

Efficacy of Palonosetron versus Ondansetron in Preventing Postoperative Nausea and Vomiting Following Abdominal Surgeries: A Randomized Comparative Analysis

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Received: 10-07-2025 / Revised: 05-08-2025 / Accepted: 16-08-2025

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Conflict of interest: Nil

Abstract:

Background: Postoperative nausea and vomiting (PONV) are common and distressing complications following abdominal surgeries under general anesthesia. These symptoms can hinder recovery, prolong hospital stay, and adversely affect patient satisfaction. Among available prophylactic options, 5-HT_3 receptor antagonists are widely used—ondansetron being the conventional choice, and palonosetron, with its longer half-life, showing potential for improved outcomes.

Objectives: To compare the effectiveness of palonosetron and ondansetron in preventing postoperative nausea and vomiting in patients undergoing abdominal surgeries under general anesthesia.

Methods: In this prospective, hospital-based, comparative study, 100 patients aged 18–60 years with ASA physical status I or II, scheduled for elective abdominal surgery, were enrolled and randomly allocated into two groups of 50 each. Group A received a single intravenous dose of palonosetron 0.075 mg, while Group B received ondansetron 8 mg intravenously, 5–10 minutes before induction. All patients underwent standardized anesthetic and analgesic protocols. The incidence and severity of PONV were assessed during three postoperative intervals (0–6 h, 6–12 h, and 12–24 h), and rescue antiemetic requirements were recorded. Categorical data were analyzed using chi-square test and continuous variables by unpaired t-test; $p < 0.05$ was considered significant.

Results: The overall incidence of PONV over 24 h was significantly lower in the palonosetron group (10 of 50; 20 %) compared with the ondansetron group (37 of 50; 74 %) ($p < 0.001$). During the 0–6 h interval, nausea occurred in 5 of 50 patients (10 %) receiving palonosetron versus 12 of 50 (24 %) receiving ondansetron ($p = 0.18$). Between 6–12 h, nausea was reported by 3 of 50 (6 %) versus 15 of 50 (30 %) ($p = 0.01$), and during 12–24 h by 2 of 50 (4 %) versus 18 of 50 (36 %) ($p < 0.001$). Vomiting episodes followed a similar pattern, with 4 of 50 (8 %) versus 10 of 50 (20 %) in 0–6 h ($p = 0.12$), 2 of 50 (4 %) versus 12 of 50 (24 %) in 6–12 h ($p = 0.02$), and 0 of 50 (0 %) versus 17 of 50 (34 %) in 12–24 h ($p < 0.001$). Rescue antiemetic was required in 4 % of patients in the palonosetron group compared to 28 % in the ondansetron group ($p = 0.003$). Both drugs were well tolerated with minimal adverse effects.

Conclusion: Palonosetron demonstrated superior efficacy to ondansetron in preventing both early and late PONV, reduced the need for rescue antiemetics, and offered a favorable safety profile. Its prolonged duration of action makes it a preferred agent for single-dose prophylaxis in abdominal surgeries under general anesthesia.

Introduction

Postoperative nausea and vomiting (PONV) remain among the most frequent and distressing complications following surgical procedures under general anesthesia, with incidence rates ranging from 20 % to 30 % in the general surgical population and rising to 70 %–80 % in high-risk patients [1]. These symptoms not only impair patient comfort and satisfaction but can also precipitate serious sequelae such as wound dehiscence, electrolyte imbalance, dehydration, and prolonged hospital stays, thereby increasing healthcare costs [2].

Risk factors for PONV are multifactorial. Patient-related factors include female sex, non-smoking status, and a history of motion sickness or prior PONV [3]. Anesthetic-related factors encompass the use of volatile agents, nitrous oxide, and

perioperative opioids, while surgery-related factors such as the type and duration of the procedure further modulate risk. Abdominal surgeries, in particular, carry a heightened PONV risk due to visceral manipulation and frequent postoperative opioid use for analgesia [4,5].

Among prophylactic pharmacologic strategies, 5-hydroxytryptamine type 3 (5-HT_3) receptor antagonists have become first-line agents owing to their proven efficacy and favorable safety profiles. Ondansetron, the prototypical 5-HT_3 antagonist, achieves effective PONV control but is limited by a relatively short plasma half-life of 3–6 hours, necessitating repeated dosing [6]. In contrast, palonosetron a second-generation 5-HT_3 antagonist exhibits unique allosteric receptor binding, a plasma half-life of approximately 40 hours, and higher receptor affinity, enabling prolonged antiemetic coverage with a single preoperative dose [7,8].

Despite both agents being approved for PONV prophylaxis, direct comparative data specific to abdominal surgeries remain scarce, especially within the Indian clinical context. Given the high PONV risk associated with these procedures, optimizing prophylactic regimens is of paramount importance [9].

To address this gap, we conducted a hospital-based, prospective, randomized comparative study involving 100 adult patients (ASA I–II) scheduled for elective abdominal surgeries under general anesthesia. Patients were allocated to receive either palonosetron 0.075 mg IV or ondansetron 8 mg IV, administered 5–10 minutes before induction. The primary endpoint was the overall incidence of PONV over 24 hours; secondary endpoints included PONV severity at 0–6 h, 6–12 h, and 12–24 h intervals, as well as the need for rescue antiemetics.

Materials and Methods

Study Design and Setting: This prospective, randomized, comparative study was conducted in the Department of Anaesthesiology at Shaheed Nirmal Mahto Medical College, Dhanbad, Jharkhand, India. over a period of 12 months after obtaining Institutional Ethics Committee approval and written informed consent from all participants.

Sample Size Determination: Based on previous institutional data indicating a PONV incidence of approximately 50 % with ondansetron and anticipating a 30 % absolute reduction with palonosetron, a sample size of 46 per group was calculated to achieve 80 % power at $\alpha = 0.05$. To account for potential dropouts, 50 patients were enrolled in each group, yielding a total sample size of 100.

Patient Selection

Inclusion Criteria:

- Age 18–60 years
- American Society of Anesthesiologists (ASA) physical status I–II
- Scheduled for elective abdominal surgery under general anesthesia

Exclusion Criteria:

- Known allergy to 5-HT_3 antagonists
- History of chronic nausea, vomiting, or gastrointestinal disorders
- Use of antiemetic or steroid therapy within 24 h preoperatively
- Pregnancy or lactation
- Significant renal, hepatic, or cardiac dysfunction

Randomization and Blinding: Patients were randomized using computer-generated blocks of four into two equal groups (n = 50 each). Allocation concealment was ensured with sealed opaque envelopes. The study drugs were prepared and administered by an anesthesiologist not involved in data collection. Patients, surgeons, and outcome assessors were blinded to group assignment.

Anesthetic Protocol: All patients fasted overnight and received no premedication. Standard monitors (ECG, Noninvasive blood pressure, SpO_2) were applied. Anesthesia was induced with propofol 2 mg/kg and fentanyl 2 µg/kg, and muscle relaxation achieved with vecuronium 0.1 mg/kg. After tracheal intubation, anesthesia was maintained with isoflurane in a 50:50 oxygen–nitrous oxide mixture, and intermittent fentanyl boluses for analgesia. Mechanical ventilation settings were adjusted to maintain normocapnia. At the end of surgery, neuromuscular blockade was reversed with neostigmine and glycopyrrolate, and extubation performed when criteria were met.

Intervention

- **Group P (Palonosetron):** 0.075 mg IV palonosetron administered 5–10 minutes before induction.
- **Group O (Ondansetron):** 8 mg IV ondansetron administered 5–10 minutes before induction.

Outcome Assessment: The incidence and severity of nausea and vomiting were recorded at 0–6 h, 6–12 h, and 12–24 h postoperatively. Nausea was graded on a 0–3 scale (0 = none, 1 = mild, 2 = moderate, 3 = severe). Vomiting episodes were counted. Rescue antiemetic (metoclopramide 10 mg IV) was given for nausea ≥ grade 2 or any vomiting.

Statistical Analysis: Data were analyzed using SPSS version 25.0. Continuous variables are

presented as mean ± SD and compared using unpaired t-test. Categorical variables are expressed as number (%) and compared using chi-square or Fisher's exact test. A p-value < 0.05 was considered statistically significant.

Results

The demographic and perioperative characteristics were comparable between the two groups, ensuring homogeneity at baseline. The mean age and gender distribution did not differ significantly, nor did ASA physical status or duration of surgery. Palonosetron markedly reduced the incidence of both nausea and vomiting across all postoperative intervals compared to ondansetron. Early (0–6 h) nausea and vomiting rates were lower in the palonosetron group, but differences became highly significant in the later intervals (6–12 h and 12–24 h). Overall PONV over 24 h and the need for rescue antiemetics were significantly reduced with palonosetron ($p < 0.01$).

Table 1: Age distribution of patients

Group	Mean ± SD	p-value	Statistical test
Palonosetron (n=50)	45.2 ± 10.5		
Ondansetron (n=50)	44.8 ± 9.8	0.78	Unpaired t-test

Table 2: Gender distribution

Group	Male [n (%)]	Female [n (%)]	p-value	Statistical test
Palonosetron	28 (56%)	22 (44%)	0.81	Chi-square test
Ondansetron	26 (52%)	24 (48%)		

Table 3: ASA physical status

Group	ASA I [n (%)]	ASA II [n (%)]	p-value	Statistical test
Palonosetron	32 (64%)	18 (36%)	0.63	Chi-square test
Ondansetron	30 (60%)	20 (40%)		

Table 4: Duration of surgery

Group	Mean ± SD (min)	p-value	Statistical test
Palonosetron	110 ± 25		
Ondansetron	112 ± 27	0.68	Unpaired t-test

Table 5: Incidence of nausea (0–6 h)

Group	Patients with nausea [n (%)]	p-value	Statistical test
Palonosetron	5 (10%)		
Ondansetron	12 (24%)	0.18	Chi-square test

Table 6: Incidence of nausea (6–12 h)

Group	Patients with nausea [n (%)]	p-value	Statistical test
Palonosetron	3 (6%)		
Ondansetron	15 (30%)	0.01	Chi-square test

Table 7: Incidence of nausea (12–24 h)

Group	Patients with nausea [n (%)]	p-value	Statistical test
Palonosetron	2 (4%)		
Ondansetron	18 (36%)	< 0.001	Chi-square test

Table 8: Incidence of vomiting (0–6 h)

Group	Patients with vomiting [n (%)]	p-value	Statistical test
Palonosetron	4 (8%)		
Ondansetron	10 (20%)	0.12	Chi-square test

Table 9: Incidence of vomiting (6–12 h)

Group	Patients with vomiting [n (%)]	p-value	Statistical test
Palonosetron	2 (4%)		
Ondansetron	12 (24%)	0.02	Chi-square test

Table 10: Incidence of vomiting (12–24 h)

Group	Patients with vomiting [n (%)]	p-value	Statistical test
Palonosetron	0 (0%)		
Ondansetron	17 (34%)	< 0.001	Chi-square test

Table 11: Overall PONV incidence (0–24 h)

Group	Patients with PONV [n (%)]	p-value	Statistical test
Palonosetron	10 (20%)		
Ondansetron	37 (74%)	< 0.001	Chi-square test

Table 12: Rescue antiemetic requirement

Group	Patients requiring rescue [n (%)]	p-value	Statistical test
Palonosetron	2 (4%)		
Ondansetron	14 (28%)	0.003	Chi-square test

Table 1 demonstrates comparable mean ages between both groups. Table 2 and Table 3 confirm similar gender and ASA status distributions, while Table 4 shows no significant difference in surgery duration. Table 5, Table 6, and Table 7 outline progressively lower nausea rates in the palonosetron group across 0–6 h, 6–12 h, and 12–24 h intervals. Likewise, Table 8, Table 9, and Table 10 reveal reduced vomiting episodes with palonosetron. Table 11 highlights a significantly lower overall PONV incidence over 24 h in the palonosetron group, and Table 12 shows a markedly decreased need for rescue antiemetics compared to ondansetron.

Discussion

The present study demonstrates that a single preoperative dose of palonosetron 0.075 mg IV provides significantly better prophylaxis against postoperative nausea and vomiting (PONV) following elective abdominal surgery than ondansetron 8 mg IV. Over the 24-hour postoperative period, the overall incidence of PONV was reduced from 74 % with ondansetron to 20 % with palonosetron ($p < 0.001$) [10]. This marked reduction was evident not only in the cumulative incidence (Table 11) but also in each assessed interval: early (0–6 h), intermediate (6–12 h), and late (12–24 h) postoperative periods (Tables 5–7). Moreover, the need for rescue antiemetics was significantly lower in the palonosetron group (4 % vs 28 %, $p = 0.003$; Table 12), underscoring its superior efficacy in maintaining patient comfort and reducing additional medication requirements [11].

Pharmacologic Rationale: Palonosetron's prolonged half-life (approximately 40 h) and high receptor affinity likely underpin its sustained antiemetic effect. Unlike first-generation 5-HT_3 antagonists, which exhibit competitive inhibition at the serotonin receptor, palonosetron allosterically modulates receptor function and may induce receptor internalization [12]. These properties contribute to extended blockade of emetogenic pathways without the need for repeat dosing. In contrast, ondansetron's half-life of 3–6 h necessitates additional dosing to cover the 24-hour risk window, particularly during the late postoperative phase, where our data confirm a pronounced rebound in PONV incidence (36 % in ondansetron vs 4 % in palonosetron; $p < 0.001$) [13].

Comparison with Existing Evidence: The efficacy of palonosetron in reducing PONV has been reported across diverse surgical populations. Our findings align with these observations, while extending evidence specifically to abdominal procedures a cohort inherently at higher PONV risk due to visceral manipulation and opioid use [14]. The early differences in nausea and vomiting rates, although not statistically significant in the 0–6 h interval (Tables 5 and 8), become clinically and statistically robust in later time frames. This pattern underscores the importance of prolonged receptor blockade to prevent late-onset PONV, which often contributes most to patient dissatisfaction and unanticipated resource utilization [15].

Safety and Tolerability: Both study drugs were well tolerated, with no serious adverse events observed. Minor adverse effects such as headache and constipation occurred infrequently and at comparable rates in both groups, suggesting that the superior efficacy of palonosetron is not offset by increased toxicity. The single-dose regimen also simplifies administration and minimizes potential exposure to drug-related side effects [16].

Strengths and Limitations: Key strengths of this study include its randomized, double-blind design, adequate sample size powered to detect clinically meaningful differences, and standardized anesthetic protocols ensuring that drug effects were not confounded by variable perioperative management. However, limitations include the single-center setting and exclusion of high-risk patients (e.g., those with history of severe motion sickness), which may limit generalizability. Future multicenter trials involving broader patient populations and cost-effectiveness analyses would further validate these findings.

Clinical Implications: Given its superior efficacy, prolonged duration of action, and favorable safety profile, palonosetron 0.075 mg IV administered before induction should be considered the antiemetic of choice for PONV prophylaxis in elective abdominal surgeries under general anesthesia. Adoption of this regimen has the potential to enhance patient satisfaction, reduce ancillary antiemetic use, and decrease the burden of unanticipated extended postoperative care.

Conclusion

Palonosetron 0.075 mg IV administered preoperatively offers significantly superior prophylaxis against postoperative nausea and vomiting compared to ondansetron 8 mg IV in patients undergoing elective abdominal surgery. Its prolonged half-life and unique receptor binding profile result in sustained antiemetic coverage throughout the critical 24-hour postoperative period, markedly reducing both the incidence of PONV and the need for rescue antiemetics. The favorable safety and tolerability profile of palonosetron, coupled with the convenience of a single-dose regimen, support its routine use as the preferred antiemetic for PONV prophylaxis in this surgical population.

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