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RESEARCH ARTICLE
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COMPARISON OF PALONSETRON VS ONDANSETRON FOR PREVENTION OF POST-OPERATIVE NAUSEA AND VOMITING IN LAPAROSCOPIC SURGERIES

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Abstract

Background: Postoperative nausea and vomiting (PONV) is one of the most frequent and distressing complications following laparoscopic surgeries. Despite major advances in anesthesia and surgical techniques, the incidence of PONV remains between 20% and 40% in the general population and may reach up to 70% in high-risk patients. **Aim**: The aim of this study was to compare the efficacy and safety of intravenous palonosetron and ondansetron in preventing postoperative nausea and vomiting in patients undergoing elective laparoscopic surgeries. **Methods**: This prospective, randomized, double-blind study included 100 patients aged 18 to 65 years, belonging to ASA physical status I or II, scheduled for elective laparoscopic procedures under general anesthesia. The patients were randomly allocated into two groups of 50 each. Group P received intravenous palonosetron 0.075 mg at induction, while Group O received intravenous ondansetron 8 mg at induction. Standardized anesthesia and surgical protocols were followed for all patients. The incidence of nausea, vomiting, or retching during the first 24 hours postoperatively was recorded. Secondary outcomes included the severity of nausea, the requirement for rescue antiemetic, time to the first episode of nausea or vomiting, hemodynamic stability, and any adverse effects. **Results**: Out of 100 patients, 50 were assigned to each group. The overall incidence of PONV within 24 hours was 14% in the palonosetron group and 32% in the ondansetron group. The requirement for rescue antiemetic was 8% in Group P and 22% in Group O. The mean time to the first episode of PONV was 15.6 ± 3.2 hours in Group P and 8.9 ± 2.7 hours in Group O. The difference in incidence and time to onset was statistically significant ($p < 0.05$). No significant difference was noted in hemodynamic parameters or other adverse effects between the two groups. Patient satisfaction scores were higher in the palonosetron group. **Conclusion**: Palonosetron was found to be more effective than ondansetron in preventing postoperative nausea and vomiting in patients undergoing laparoscopic surgeries. It also delayed the onset of the first episode of PONV and reduced the need for rescue antiemetic medication, with minimal adverse effects. Therefore,

palonosetron can be considered a superior and safe alternative to ondansetron for routine prophylaxis of PONV in laparoscopic surgical procedures.

Keywords: postoperative nausea and vomiting, palonosetron, ondansetron, laparoscopic surgery, antiemetic, anesthesia

Introduction

Post-operative nausea and vomiting (PONV) remains one of the most frequent and distressing complications following surgical procedures under general anaesthesia. Even with advances in anaesthetic techniques and antiemetic prophylaxis, the incidence of PONV has been reported as high as 20 % to 30 % in general surgical populations, and up to 60 %–80 % in high-risk patients when no prophylaxis is applied [1]. It carries important consequences including delayed recovery, increased post-anaesthesia care unit (PACU) stay, unanticipated hospital admission after ambulatory surgery, wound dehiscence, electrolyte imbalance, and increased healthcare costs [2].

In the setting of laparoscopic surgeries, the incidence of PONV is further amplified. The use of pneumoperitoneum, intra-abdominal pressure, carbon dioxide insufflation, and Trendelenburg positioning are among the intra-operative factors that may increase vagal stimulation, stretch receptors, and peritoneal irritation, thereby heightening the risk of nausea and vomiting in the early post-operative period [3]. Given the popularity of minimally invasive laparoscopic procedures, effective prophylaxis of PONV in this cohort has become increasingly relevant to enhance patient comfort, reduce morbidity and shorten hospital stay.

Risk stratification for PONV has been well characterised. The simplified Christian C. Apfel score identifies four independent predictors: female sex, non-smoking status, history of PONV or motion sickness, and use of post-operative opioids. Each additional factor approximately increases the risk by 20% up to about 80% for four factors [4]. Moreover, other contributing elements include younger age, use of volatile anaesthetics, nitrous oxide, longer duration of anaesthesia, and intra-operative opioids [4,5]. In laparoscopic surgery patients, these risk factors often cluster, making effective prophylaxis especially important.

Among pharmacological strategies to prevent PONV, 5-hydroxy-tryptamine type 3 (5-HT3) receptor antagonists have emerged as a mainstay. The first-generation agent Ondansetron has been widely used for prophylaxis of PONV since the 1990s with a favourable safety profile [6]. However, despite its broad adoption, its duration of antiemetic action may be limited, particularly in the delayed period beyond 12-24 hours. In contrast, the second-generation 5-HT3 antagonist Palonosetron is characterised by a markedly higher binding affinity to the 5-HT3 receptor, allosteric binding and receptor internalisation, and a longer elimination half-life (about 40 hours) [7]. These pharmacological advantages suggest that palonosetron might provide more sustained control of PONV, particularly in laparoscopic and other high-risk surgical contexts.

Several clinical studies have examined direct comparisons between palonosetron and ondansetron for PONV prophylaxis. For example a randomized double-blind trial found that palonosetron 0.075 mg was superior to ondansetron 8 mg up to 12 hours after surgery with significantly lower incidence of nausea ($P = 0.0002$) and vomiting ($P = 0.006$) [8]. A meta-analysis of nine trials concluded that palonosetron was more efficacious than ondansetron in prevention of vomiting after laparoscopic surgery, although there was no statistically significant difference for early nausea (RR 0.62; 95% CI 0.35–1.10) [9]. Another study in laparoscopic cholecystectomy found palonosetron was not inferior to ondansetron for PONV prophylaxis, underscoring its viability as an alternative single-dose agent [10]. Despite this growing evidence base, there remains limited data specifically in the Indian population and in the setting of elective laparoscopic surgeries spanning a defined period such as March to July 2025. Moreover, there is a need to evaluate efficacy and safety comparing single-dose palonosetron with ondansetron under standardised anaesthesia and surgical protocols.

Given this background, the present prospective randomised study was designed at the Government Medical College Doda to compare the efficacy and safety of a single intravenous dose of palonosetron versus ondansetron for the prevention of PONV in adult patients undergoing elective laparoscopic surgeries.

Materials and Methods

Study design and setting

This was a prospective, randomized, double-blind, comparative study conducted at Government Medical College, Doda, from March 2025 to July 2025. The study was performed after obtaining ethical clearance from the institutional ethics committee and written informed consent from all participants.

Study population

A total of 100 patients scheduled for elective laparoscopic surgeries under general anesthesia were included in the study. Patients were divided into two equal groups of 50 each. Group P received intravenous palonosetron 0.075 mg, and Group O received intravenous ondansetron 8 mg.

Inclusion criteria

1. Patients aged between 18 and 65 years.
2. Both male and female patients.
3. Patients with American Society of Anesthesiologists (ASA) physical status I or II.
4. Patients undergoing elective laparoscopic procedures such as cholecystectomy, appendectomy, diagnostic laparoscopy, or gynecological laparoscopic surgeries under general anesthesia.

Exclusion criteria

1. Patients with known hypersensitivity to 5-HT3 receptor antagonists.
2. Pregnant or lactating women.
3. Patients with a history of motion sickness or previous severe PONV.
4. Patients who had received antiemetic medication within 24 hours before surgery.
5. Patients with gastrointestinal obstruction or other causes of nausea and vomiting unrelated to anesthesia or surgery.

Grouping: Patients were randomized using a computer-generated random number table into two equal groups. The study drugs were prepared in identical syringes containing the same volume and labeled as “Study Drug A” and “Study Drug B” by an anesthesiologist not involved in data collection or patient care. Both the patients and the investigator collecting data were blinded to the group allocation.

Anesthetic technique

All patients were kept fasting for at least eight hours prior to surgery. Upon arrival in the operating room, routine monitors including electrocardiogram, pulse oximetry, and non-invasive blood pressure were attached, and baseline parameters were recorded. Intravenous access was established, and premedication with midazolam 0.02 mg/kg and glycopyrrolate 0.2 mg was given.

Induction of anesthesia was achieved with intravenous propofol 2–2.5 mg/kg, fentanyl 2 μg/kg, and vecuronium 0.1 mg/kg to facilitate endotracheal intubation. Anesthesia was maintained with a mixture of oxygen, nitrous oxide, and isoflurane at 1–1.5% concentration. Intraoperative analgesia was provided with intermittent doses of fentanyl as required. Ventilation parameters were adjusted to maintain normocapnia.

Administration of study drugs

After induction and securing of the airway, patients in Group P received intravenous palonosetron 0.075 mg, and those in Group O received intravenous ondansetron 8 mg. The drugs were administered slowly over 30 seconds.

At the end of surgery, residual neuromuscular blockade was reversed with neostigmine 0.05 mg/kg and glycopyrrolate 0.01 mg/kg. Patients were extubated once adequate spontaneous respiration and airway reflexes returned.

Postoperative assessment

Patients were observed for 24 hours postoperatively in the recovery room and surgical ward. Episodes of nausea, vomiting, or retching were recorded at 0–2 hours, 2–6 hours, and 6–24 hours post-surgery. Nausea severity was assessed using a verbal rating scale (0 = none, 1 = mild, 2 = moderate, 3 = severe). Vomiting episodes were defined as forceful expulsion of gastric contents, while retching was recorded as labored, spasmodic contractions without expulsion.

Rescue antiemetic therapy with intravenous metoclopramide 10 mg was administered if a patient experienced more than one episode of vomiting or persistent nausea of moderate to severe intensity. Hemodynamic parameters such as heart rate, blood pressure, and oxygen saturation were monitored at baseline, intraoperatively, and postoperatively. Any adverse effects such as headache, dizziness, constipation, or allergic reactions were noted.

Outcome measures

The primary outcome was the incidence of PONV during the first 24 hours postoperatively. Secondary outcomes included time to first PONV episode, total number of PONV episodes, rescue antiemetic requirement, patient satisfaction, and adverse effects.

Statistical analysis

All collected data were compiled and analyzed using the Statistical Package for the Social Sciences (SPSS) software, version 26. Continuous variables were expressed as mean ± standard deviation, while categorical variables were presented as numbers and percentages. The Student's t-test was used to compare continuous variables, and the Chi-square test or Fisher's exact test was applied for categorical data. A p-value less than 0.05 was considered statistically significant.

Results

Table 1 presents the demographic and baseline characteristics of the study population, including age, gender, body mass index (BMI), duration of surgery, and ASA physical status. Both groups were comparable with respect to demographic and surgical parameters, with no statistically significant differences between them ($p > 0.05$).

Table 1: Demographic and baseline characteristics of patients

Parameters	Group P (Palonosetron) n = 50	Group O (Ondansetron) n = 50	p-value
Age (years, mean ± SD)	38.6 ± 10.2	39.4 ± 9.8	0.68
Gender (M/F)	22 / 28	20 / 30	0.68
Body Mass Index (kg/m²)	25.7 ± 3.2	26.1 ± 3.5	0.54
ASA physical status (I/II)	32 / 18	30 / 20	0.69
Duration of surgery (min)	78.4 ± 15.6	80.1 ± 16.3	0.58
Duration of anesthesia (min)	96.2 ± 12.7	95.4 ± 13.4	0.77

The incidence of postoperative nausea and vomiting during the first 24 hours following surgery was recorded and compared between the two groups. Table 2 summarizes the occurrence of nausea, vomiting, and retching at different postoperative intervals (0–2 hours, 2–6 hours, and 6–24 hours). The overall incidence of PONV was significantly lower in the palonosetron group compared to the ondansetron group (14% vs 32%, $p = 0.03$). The maximum difference was observed during the late postoperative period (6–24 hours), indicating a prolonged antiemetic effect of palonosetron. The data clearly indicated that patients receiving palonosetron experienced fewer PONV episodes,

especially in the late postoperative period, demonstrating the advantage of its longer half-life compared to ondansetron [Table 2].

Table 2: Incidence of postoperative nausea and vomiting (PONV)

Time interval	Group P (n = 50)	Group O (n = 50)	p-value
0–2 hours	4 (8%)	6 (12%)	0.51
2–6 hours	2 (4%)	5 (10%)	0.23
6–24 hours	1 (2%)	5 (10%)	0.09
Total incidence (0–24 hrs)	7 (14%)	16 (32%)	0.03

Table 3 shows the number of patients requiring rescue antiemetic medication during the first 24 hours after surgery. Only 8% of patients in the palonosetron group required a rescue antiemetic compared to 22% in the ondansetron group, which was statistically significant ($p = 0.04$). This further emphasizes the superior efficacy of palonosetron in maintaining prolonged control over postoperative emesis. Patients in the palonosetron group not only required fewer rescue doses but also had a significantly longer interval before the first episode of nausea or vomiting, highlighting the prolonged duration of action of palonosetron.

Table 3: Requirement of rescue antiemetic within 24 hours

Parameter	Group P (Palonosetron) n = 50	Group O (Ondansetron) n = 50	p-value
Rescue antiemetic required	4 (8%)	11 (22%)	0.04
Mean time to first rescue (hours ± SD)	15.6 ± 3.2	8.9 ± 2.7	0.01

No significant differences were found between the two groups at any time point ($p > 0.05$), indicating that both drugs were well tolerated and did not produce clinically significant hemodynamic alterations. Both palonosetron and ondansetron maintained stable hemodynamic profiles throughout the perioperative period [Table 4].

Table 4: Comparison of hemodynamic parameters between groups

Parameter	Time	Group P (Mean ± SD)	Group O (Mean ± SD)	p-value
Heart Rate (beats/min)	Baseline	78.2 ± 6.4	77.8 ± 6.8	0.74
	Intraoperative	82.6 ± 7.3	83.4 ± 7.1	0.62
	Postoperative	80.3 ± 6.9	81.1 ± 7.0	0.67
Systolic BP (mmHg)	Baseline	122.4 ± 8.2	121.8 ± 8.6	0.72
	Intraoperative	122.4 ± 8.2	119.4 ± 8.0	0.81
	Postoperative	118.9 ± 7.8	121.0 ± 8.2	0.69
Diastolic BP (mmHg)	Baseline	78.5 ± 5.2	77.9 ± 5.6	0.67
	Intraoperative	76.1 ± 5.0	76.8 ± 4.9	0.58
	Postoperative	77.2 ± 4.8	77.4 ± 5.1	0.87

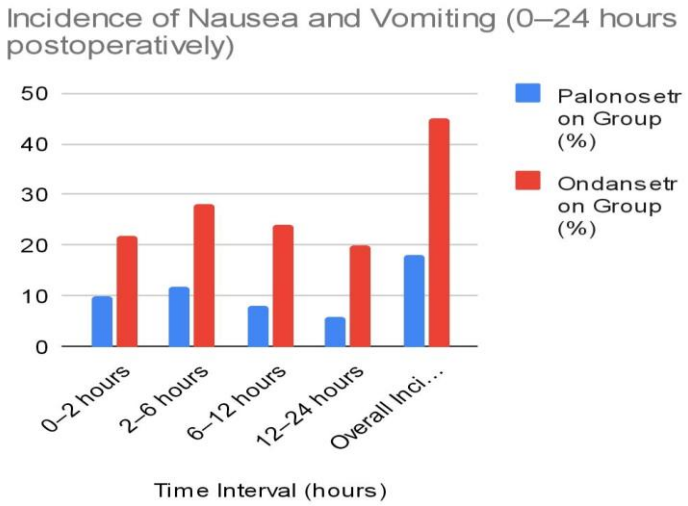
Table 5 summarizes adverse effects and overall patient satisfaction scores. Mild headache and dizziness were the most common side effects reported in both groups, but their incidence was low and not statistically significant. Patients receiving palonosetron reported higher satisfaction scores (mean 8.7 ± 1.1) compared to those receiving ondansetron (mean 7.9 ± 1.3, $p = 0.02$).

Table 5: Adverse effects and patient satisfaction

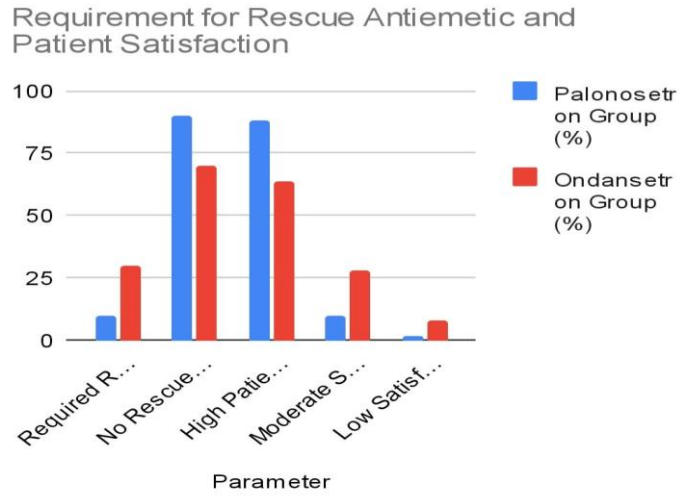
Parameter	Group P (n = 50)	Group O (n = 50)	p-value
Headache	3 (6%)	4 (8%)	0.69
Dizziness	2 (4%)	3 (6%)	0.64
Constipation	1 (2%)	2 (4%)	0.56

Allergic reaction	0 (0%)	0 (0%)	--
Patient satisfaction score (0–10)	8.7 ± 1.1	7.9 ± 1.3	0.02

Bar graph: Incidence of Nausea and Vomiting postoperatively.



Bar graph 2: Requirement for Rescue Antiemetic and Patient Satisfaction.



Discussion

The current study demonstrated that single-dose intravenous palonosetron (0.075 mg) was associated with a significantly lower incidence of postoperative nausea and vomiting (PONV) in patients undergoing laparoscopic surgery compared to intravenous ondansetron (8 mg) (14% vs 32%). The reduced need for rescue antiemetic (8% vs 22%) and delayed mean time to first PONV episode (15.6 ± 3.2 h vs 8.9 ± 2.7 h) further support the sustained antiemetic efficacy of palonosetron in this surgical population.

These findings are consistent with several prior clinical investigations. For example, a randomized study in gynecologic laparoscopic surgery found that palonosetron was superior to ondansetron for the period 2–24 h post-operatively, with significantly fewer nausea and vomiting episodes in the palonosetron group. [11] A meta-analysis encompassing various surgical procedures reported that while palonosetron and ondansetron showed comparable efficacy in the early period (0–6 h), palonosetron provided superior prophylaxis beyond 6 hours. [12] In laparoscopic cholecystectomy, palonosetron was found to be non-inferior to ondansetron for PONV prophylaxis, suggesting it is an acceptable alternative in laparoscopic settings. [13] Thus, our results extend the existing evidence

by applying these comparisons specifically to a laparoscopic surgery cohort in an Indian tertiary-care setting.

The pharmacological basis for palonosetron's favourable performance lies in its higher receptor binding affinity, allosteric 5-HT3 receptor binding, and internalisation, as well as its extended elimination half-life (approximately 40 hours) compared to ondansetron (approx. 3–5 hours). [14] These properties likely underlie the enhanced control of late-onset PONV (6–24 h) observed in our study. In laparoscopic surgeries—where intra-abdominal insufflation, gas under pressure, and Trendelenburg positioning contribute to vagal stimulation and high PONV risk—the longer-acting antiemetic effect is particularly beneficial.

Our demographic table shows well-matched groups, and the standardised anaesthetic and surgical protocols across groups lend credence to attributing the PONV difference to the study drugs rather than extraneous factors. The reduced rescue antiemetic requirement in the palonosetron group further indicates not only fewer PONV episodes but also potentially cost savings and improved patient comfort. Patient satisfaction scores were also higher with palonosetron, consistent with the link between lower PONV incidence and enhanced postoperative well-being.

Regarding safety, our hemodynamic data and adverse effect profiles show no significant differences between the two drugs, indicating both are well tolerated in this population. This aligns with broader safety data showing similar incidence of headache, dizziness, or constipation between palonosetron and ondansetron. [12] The absence of major adverse events in both groups suggests that palonosetron's extended action does not carry increased risk in this context.

Some limitations merit discussion. First, the sample size (n = 100) is moderate; while statistically significant differences were found, larger multicentre studies would enhance generalisability. Second, our study duration covered only 24 h post-surgery; although the majority of PONV events occur within this window, some late-onset events beyond 24 h may have been missed. Third, while the anaesthetic and surgical protocols were standardised, unmeasured variables (e.g., intra-operative gas pressures, fluid volumes) may influence PONV risk. Finally, cost-effectiveness analyses were not undertaken; as palonosetron is often more expensive than ondansetron, future work should evaluate economic trade-offs in resource-limited settings.

Conclusion

In conclusion, our findings indicate that palonosetron offers superior prophylaxis against PONV compared to ondansetron in laparoscopic surgeries, particularly in the late postoperative period, reduces the need for rescue antiemetics, and is well tolerated. Given the high incidence and negative impact of PONV in laparoscopic surgical populations, adopting palonosetron as the antiemetic of choice represents a compelling strategy. Further large-scale, multicentre studies including cost-effectiveness analyses are recommended to solidify these results and guide formulary decisions.

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