I J C R M
International Journal of Contemporary Research In Multidisciplinary

Research Article

Comparative Effectiveness of Palonosetron and Ondansetron in Preventing Chemotherapy-Induced Nausea and Vomiting in Solid Tumors: An Observational Study

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DOI: https://doi.org/10.5281/zenodo.17154655

Abstract

Introduction: Chemotherapy-induced nausea and vomiting (CINV) remain a major barrier to effective cancer care, often impairing quality of life and treatment adherence. While ondansetron has been widely used as a first-generation 5-HT3 receptor antagonist, palonosetron, with a longer half-life, may offer superior protection, particularly in the delayed phase of CINV.

Materials and Methods: This prospective observational study was conducted at Osmania Medical College, Hyderabad, between January 2024 and January 2025. A total of 180 adult patients with histologically confirmed solid tumors receiving moderately or highly emetogenic chemotherapy were included. Patients received either palonosetron (0.25 mg IV) or ondansetron (8 mg IV) along with dexamethasone as per institutional practice.

Results: Complete response over 0–120 h was significantly higher with palonosetron (78.9%) compared to ondansetron (61.1%; p = 0.01). Palonosetron provided superior delayed-phase control (81.1% vs. 64.4%; p = 0.02), reduced nausea (77.8% vs. 60.0%; p = 0.01), and decreased rescue antiemetic use (20.0% vs. 37.8%; p = 0.01). Both drugs had similar safety profiles, with mild headache and constipation being the most common adverse events. Patient satisfaction was higher in the palonosetron group (57.8% delighted vs. 38.9%; p = 0.03).

Conclusion: Palonosetron was more effective than ondansetron, particularly in the delayed phase, while maintaining comparable safety. Its use may improve patient satisfaction and adherence to chemotherapy.

Manuscript Information

- **ISSN No:** 2583-7397
- **Received:** 26-07-2025
- **Accepted:** 06-09-2025
- **Published:** 18-09-2025
- **IJCRM:**4(5); 2025: 110-113

- **Plagiarism Checked:** Yes
- **Peer Review Process:** Yes

How to Cite this Article

Subrahmanyam N, Jaju S, Mantri A, Yasarapu M. Comparative Effectiveness of Palonosetron and Ondansetron in Preventing Chemotherapy-Induced Nausea and Vomiting in Solid Tumors: An Observational Study. Int J Contemp Res Multidiscip. 2025;4(5):110-113.

Access this Article Online

www.multiarticlesjournal.com

KEYWORDS: Palonosetron, Ondansetron, CINV

1. INTRODUCTION

Chemotherapy-induced nausea and vomiting (CINV) remain among the most common adverse effects experienced by patients undergoing cancer treatment [1]. Despite significant advances in supportive care, inadequate control of CINV not only impairs quality of life but can also compromise adherence to chemotherapy schedules, thereby reducing treatment efficacy [2]. The incidence and severity depend on both chemotherapy's emetogenic potential and individual patient-related risk factors, making effective prophylaxis a critical component of comprehensive cancer care [3].

Among the various classes of antiemetic agents, 5-HT3 receptor antagonists are central to the prevention of acute CINV [4]. Ondansetron, one of the earliest and most widely used 5-HT3 antagonists, has been a standard of care for decades. However, its relatively short half-life and limited efficacy in controlling delayed CINV pose important clinical challenges [5-7]. In contrast, palonosetron has a prolonged $t_{1/2}$ and unique allosteric properties that may confer superior protection against both acute and delayed phases of CINV [8, 9].

Evidence from randomized clinical trials and meta-analyses suggests that palonosetron is associated with improved delayed-phase control and reduced need for rescue antiemetics compared with first-generation agents [10, 11]. Nevertheless, in routine oncology practice within resource-limited settings, ondansetron continues to be frequently used due to wider availability and lower cost. Comparative data on the effectiveness of palonosetron versus ondansetron in real-world patient populations, particularly within the Indian context, remain limited [12]. Therefore, the present study aimed to evaluate and compare the effectiveness, safety profile, and patient-reported satisfaction of palonosetron and ondansetron in the prevention of CINV.

2. MATERIALS AND METHODS

This prospective observational study was conducted in Osmania Medical College, Hyderabad, between January 2024 and January 2025. Adult patients with histologically confirmed solid tumors scheduled to receive single-day moderately or highly emetogenic intravenous chemotherapy were enrolled. Patients with adequate performance status and no baseline nausea or vomiting were included, while those with known hypersensitivity to study drugs, significant cardiac disease, or severe hepatic or renal impairment were excluded. A total of 180 patients meeting eligibility criteria were observed for antiemetic outcomes following administration of either palonosetron or ondansetron as part of routine institutional practice.

On the day of chemotherapy, all patients received standard prophylaxis with IV dexamethasone. Patients in one group received palonosetron 0.25 mg intravenously, while the other group received ondansetron 8 mg intravenously, both administered 30 minutes before chemotherapy. It was guided by treating oncologists and institutional availability. Rescue antiemetics were permitted for breakthrough symptoms, and their use was documented as treatment failure for the primary endpoint.

Participants were followed for five days (0–120 hours) after chemotherapy. The primary outcome was complete response, defined as the absence of emesis and no rescue medication use during the 0–120-hour period. Secondary outcomes included complete response in the acute and delayed phases, incidence of clinically significant nausea, time to first emetic episode, and overall patient satisfaction with antiemetic therapy. Adverse effects such as headache, constipation, and dizziness were recorded.

Sample size was calculated to detect a 20% difference in complete response rates between groups (expected 80% vs 60%) with 80% power and 5% significance, requiring 82 participants per group. Allowing for dropouts, 90 patients were enrolled in each group, totalling 180. Data was entered in an Excel sheet, and chi-square tests were applied for categorical outcomes, and t-tests for continuous variables, depending on distribution. A p-value of <0.05 was considered statistically significant.

3. RESULTS

The baseline demographic and clinical characteristics were well balanced between the palonosetron and ondansetron groups. (Table 1).

Table 1: Baseline Demographic and Clinical Characteristics

Characteristic	Variable	Palonosetron (n = 90)	Ondansetron (n = 90)	p-value
Age group	< 50 years	34 (37.8%)	36 (40.0%)	0.62
	≥ 50 years	56 (62.2%)	54 (60.0%)	
Gender	Male	42 (46.7%)	45 (50.0%)	0.78
	Female	48 (53.3%)	45 (50.0%)	
ECOG performance status	0–1	71 (78.9%)	69 (76.7%)	0.72
	2	19 (21.1%)	21 (23.3%)	
Tumor type	Breast	28 (31.1%)	25 (27.8%)	0.94
	Lung	24 (26.7%)	26 (28.9%)	
	Colorectal	20 (22.2%)	18 (20.0%)	
	Other solid tumors	18 (20.0%)	21 (23.3%)	
Chemotherapy regimen	Moderately emetogenic	52 (57.8%)	50 (55.6%)	0.78
	Highly emetogenic	38 (42.2%)	40 (44.4%)	

Assessment of the primary endpoint revealed a significantly higher CR rate in the palonosetron group. Over the 0–120 h evaluation period, 78.9% of patients receiving palonosetron achieved a complete response, versus 61.1% in the ondansetron arm ($p = 0.01$). Treatment failure was correspondingly lower in the palonosetron group (21.1% vs. 38.9%) (Table 2).

Table 2: Primary Outcome – Complete Response (CR)

Outcome (0–120 h)	Palonosetron (n = 90)	Ondansetron (n = 90)	p-value
Complete Response	71 (78.9%)	55 (61.1%)	0.01
Failure (emesis or rescue use)	19 (21.1%)	35 (38.9%)	

Secondary outcomes reinforced the superiority of palonosetron. Although CR during the acute phase (0–24 h) was not

statistically significant with palonosetron (88.9% vs. 80.0%). In contrast, complete response in the delayed phase (24–120 h) favored palonosetron significantly (81.1% vs. 64.4%, p = 0.02). Patients on palonosetron also reported less significant nausea (77.8% vs. 60.0%, p = 0.01), longer time to first emesis (93.5 ± 18.4 h vs. 72.1 ± 20.2 h, p = 0.001), and lower use of rescue antiemetics (20.0% vs. 37.8%, p = 0.01) (Table 3).

Table 3: Secondary Outcomes

Variable	Palonosetron (n = 90)	Ondansetron (n = 90)	p-value
CR in Acute Phase	80 (88.9%)	72 (80.0%)	0.12
CR in Delayed Phase	73 (81.1%)	58 (64.4%)	0.02
No Significant Nausea (VAS ≤10 mm)	70 (77.8%)	54 (60.0%)	0.01
Time to First Emesis (hr)	93.5 ± 18.4	72.1 ± 20.2	0.001
Rescue Antiemetic Use	18 (20.0%)	34 (37.8%)	0.01

Both regimens were well tolerated, with no statistically significant differences in adverse events. Headache and constipation were the most commonly reported toxicities in both groups, while dizziness and QTc prolongation were less frequent. The overall incidence of treatment-related adverse events was comparable (26.7% in the palonosetron group vs. 31.1% in the ondansetron group, p = 0.54), suggesting that improved efficacy of palonosetron was not associated with an increased toxicity burden (Table 4).

Table 4: Adverse Events

Adverse Event	Palonosetron (n = 90)	Ondansetron (n = 90)	p-value
Headache	10 (11.1%)	12 (13.3%)	0.65
Constipation	8 (8.9%)	9 (10.0%)	0.81
Dizziness	6 (6.7%)	8 (8.9%)	0.59
QTc prolongation (>450 ms)	3 (3.3%)	6 (6.7%)	0.30
Total	24 (26.7%)	28 (31.1%)	0.54

Patient satisfaction was higher among those treated with palonosetron. More than half of patients in this group reported being very satisfied with antiemetic control (57.8% vs. 38.9%), with significantly fewer patients expressing dissatisfaction or uncertainty compared with the ondansetron group (p = 0.03). Overall, palonosetron provided better patient-perceived benefit in addition to objective clinical efficacy (Table 5).

Table 5: Patient Satisfaction with Antiemetic Control

Satisfaction Level	Palonosetron (n = 90)	Ondansetron (n = 90)	p-value
Very satisfied	52 (57.8%)	35 (38.9%)	0.03
Satisfied	28 (31.1%)	33 (36.7%)	
Unsure	6 (6.7%)	10 (11.1%)	
Dissatisfied/Very dissatisfied	4 (4.4%)	12 (13.3%)	

4. DISCUSSION

In this study, palonosetron demonstrated superior efficacy in the prevention of CINV among patients with solid tumors. The CR rate was significantly higher in the palonosetron group, with notable improvements in delayed-phase control, reduced need for rescue antiemetics, and greater patient satisfaction. Importantly, the safety profile of palonosetron was comparable to that of ondansetron. These findings reinforce the pharmacological advantages of palonosetron and suggest its clinical utility as a preferred 5-HT3 antagonist for CINV prophylaxis.

Our results are consistent with previous randomized controlled trials and meta-analyses. A pivotal phase III trial by Aapro et al. demonstrated that palonosetron provided superior complete response rates in the delayed phase compared to ondansetron in patients receiving moderately emetogenic chemotherapy [13]. Similarly, Eisenberg et al. reported that palonosetron achieved better delayed CINV control and reduced need for rescue medication, findings closely aligned with our observations [14]. A review further confirmed that palonosetron significantly reduces delayed vomiting compared with first-generation 5-HT3 antagonists [15].

An important aspect of our findings is the higher patient-reported satisfaction associated with palonosetron, which may be attributed to sustained symptom relief during the delayed phase. Similar observations have been made in studies conducted in Asian and Indian cohorts, where palonosetron was associated with improved quality of life outcomes compared with ondansetron [16, 17]. Given that poor CINV control is a major factor leading to treatment non-adherence, better patient satisfaction with palonosetron highlights its potential role in ensuring optimal chemotherapy delivery.

The safety findings in our study are also in line with previously published evidence. Both agents were well tolerated, and no significant increase in adverse events, including headache, constipation, or QTc prolongation, was observed with palonosetron. Prior comparative studies have consistently reported a similar tolerability profile [15, 18], further supporting its safe use in routine practice. While cost considerations continue to limit the widespread adoption of palonosetron in many resource-constrained settings, the superior delayed-phase control and patient-perceived benefits underscore its potential for improving supportive cancer care.

5. CONCLUSION

Palonosetron demonstrated superior efficacy to ondansetron in preventing CINV among patients with solid tumors, particularly in achieving higher complete response rates during the delayed phase, reducing the need for rescue antiemetics, and improving patient satisfaction, while maintaining a comparable safety profile. Hence, palonosetron may be a better and well-tolerated option for CINV prophylaxis in routine oncology practice, with

the potential to enhance treatment adherence and overall quality of care.

ACKNOWLEDGEMENT: None

CONFLICT OF INTEREST: None declared

FUNDING: None

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Dr. Shubham Jaju is an MD in Pharmacology and currently serves as an Assistant Professor. He has a deep research interest and has contributed to several scientific publications, showcasing strong skills in academic research and study execution. Dr. Jaju is recognized for his expertise in research and his dedication to advancing both medical education and pharmacological knowledge. His active engagement in research underlines his dedication to innovation and evidence-based medical science.