

Original Research Article

COMPARATIVE STUDY OF PALONOSETRON AND GRANISETRON FOR THE PREVENTION OF POSTOPERATIVE NAUSEA AND VOMITING IN LAPAROSCOPIC CHOLECYSTECTOMY

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ABSTRACT

Background: Postoperative nausea and vomiting (PONV) remain one of the most common and distressing complications following laparoscopic cholecystectomy under general anaesthesia. Despite advances in anaesthetic techniques, the incidence of PONV remains high. Palonosetron and granisetron are selective 5-hydroxytryptamine-3 (5-HT₃) receptor antagonists widely used for PONV prophylaxis. Their comparative efficacy in preventing PONV following laparoscopic cholecystectomy requires further evaluation.

Aim: To compare the therapeutic efficacy of palonosetron and granisetron in the prevention of postoperative nausea and vomiting among patients undergoing laparoscopic cholecystectomy.

Materials and Methods: This prospective randomized single-blinded comparative study was conducted in the Department of Anaesthesiology, Lilavati Hospital & Research Center, Mumbai, from January 2020 to June 2021. A total of 88 patients undergoing elective laparoscopic cholecystectomy under general anaesthesia were included. Patients were randomized into two groups of 44 each. Group G received intravenous granisetron 45 µg/kg, while Group P received intravenous palonosetron 0.075 mg immediately before induction of anaesthesia. Standardized anaesthetic management was followed in all patients. PONV were assessed at 0–4 hours, 4–12 hours, and 12–24 hours postoperatively. Requirement of rescue antiemetic therapy was also recorded. Statistical analysis was performed, with $p < 0.05$ considered statistically significant.

Results: During the first 4 postoperative hours, complete response (Grade 0) was observed in 41 (93.2%) patients in the palonosetron group compared with 34 (77.3%) patients in the granisetron group ($p = 0.035$). Between 4–12 hours, complete response was noted in 41 (93.2%) patients receiving palonosetron and 37 (84.1%) patients receiving granisetron, with no significant difference ($p = 0.179$). During 12–24 hours, complete response was achieved in 42 (95.5%) patients in the palonosetron group compared with 35 (79.5%) patients in the granisetron group ($p = 0.024$). Rescue antiemetic therapy was required in 9 (20.5%) patients receiving granisetron, whereas none of the patients receiving palonosetron required rescue medication ($p = 0.001$).

Conclusion: Palonosetron demonstrated superior efficacy compared with granisetron in preventing postoperative nausea and vomiting following laparoscopic cholecystectomy. It provided a higher complete response rate during the early and late postoperative periods and significantly reduced the need for rescue antiemetic therapy.

Keywords: Anaesthesia, Granisetron, Laparoscopic Cholecystectomy, Palonosetron, Postoperative Nausea and Vomiting, Prophylaxis, Randomized Study.

INTRODUCTION

Postoperative nausea and vomiting (PONV) remain among the most common and distressing complications following anesthesia and surgery. Despite significant advances in anesthetic techniques and perioperative care, the incidence of PONV ranges from 20–30% in the general surgical population and may exceed 70% in high-risk patients.^[1,2] Although not usually life-threatening, PONV contributes substantially to patient discomfort, delayed recovery, prolonged hospital stay, increased healthcare costs, and reduced patient satisfaction. Furthermore, severe episodes may result in dehydration, electrolyte imbalance, wound dehiscence, aspiration pneumonitis, and postoperative bleeding.^[3]

Laparoscopic cholecystectomy has become the gold standard treatment for symptomatic gallstone disease because of its minimally invasive nature, reduced postoperative pain, shorter hospitalization, and faster recovery.^[4] However, patients undergoing laparoscopic procedures are particularly susceptible to PONV due to factors such as pneumoperitoneum, peritoneal stretching, carbon dioxide insufflation, use of volatile anesthetic agents, opioid administration, and manipulation of abdominal viscera.^[5] Consequently, effective prevention of PONV remains an important component of perioperative management in laparoscopic cholecystectomy.^[6]

The pathophysiology of PONV is complex and involves multiple neurotransmitter pathways, including serotonin (5-hydroxytryptamine, 5-HT), dopamine, histamine, acetylcholine, and neurokinin receptors. Among these, serotonin released from enterochromaffin cells in the gastrointestinal tract plays a pivotal role by stimulating vagal afferent fibers and activating the vomiting center through 5-HT₃ receptors. Therefore, selective 5-HT₃ receptor antagonists have become the cornerstone of pharmacological prophylaxis against PONV.^[7,8]

Granisetron is a highly selective 5-HT₃ receptor antagonist that has been widely used for the prevention and treatment of PONV.^[9] It provides effective antiemetic action with minimal adverse effects and has demonstrated favorable outcomes in various surgical procedures. However, its relatively shorter elimination half-life may limit prolonged protection against delayed postoperative nausea and vomiting.^[10]

Palonosetron is a second-generation 5-HT₃ receptor antagonist characterized by a significantly longer elimination half-life of approximately 40 hours and a higher receptor-binding affinity than older agents. In addition to competitive receptor blockade, palonosetron exhibits unique receptor internalization properties that may enhance and prolong its antiemetic efficacy.^[11] These pharmacological advantages suggest that palonosetron may offer superior protection against both early and delayed

PONV compared with first-generation 5-HT₃ antagonists such as granisetron.^[12]

Several studies have evaluated the efficacy of various antiemetic agents in preventing PONV; however, evidence comparing palonosetron and granisetron specifically in patients undergoing laparoscopic cholecystectomy remains limited and sometimes inconsistent. Direct comparison of these two agents is clinically relevant because both are commonly used in anesthetic practice, yet differences in efficacy, duration of action, and requirement for rescue antiemetics may influence therapeutic choice.

AIMS AND OBJECTIVES

- To compare the therapeutic effects of Palonosetron and Granisetron for the prevention of postoperative nausea and vomiting in laparoscopic cholecystectomy.

MATERIALS AND METHODS

This prospective randomized single-blinded comparative study was conducted in the Department of Anaesthesiology, Lilavati Hospital & Research Center, Mumbai, after obtaining approval from the Institutional Ethics Committee and written informed consent from all participants. The study was carried out over a period of 18 months from January 2020 to June 2021.

A total of 88 patients scheduled for elective laparoscopic cholecystectomy were enrolled in the study. Patients were randomly allocated into two equal groups of 44 each using a sealed-envelope randomization technique. The study was single blinded, with patients unaware of the antiemetic agent administered. Group G received intravenous granisetron 45 µg/kg, while Group P received intravenous palonosetron 0.075 mg. The study drug was administered immediately before induction of general anaesthesia.

Inclusion Criteria

- Patients aged more than 18 years.
- American Society of Anaesthesiologists (ASA) physical status I, II, or III.
- Patients undergoing elective laparoscopic cholecystectomy under general anaesthesia.
- Patients willing to participate and provide written informed consent.

Exclusion Criteria

- Known hypersensitivity or contraindication to palonosetron or granisetron.
- History of nausea or vomiting within 24 hours before surgery.
- Patients receiving antiemetic drugs or drugs with antiemetic properties within 24 hours before anaesthesia.
- Pregnant or lactating women.
- Patients with chronic opioid use.
- Patients with significant gastrointestinal, hepatic, or renal dysfunction.
- History of habitual nausea and vomiting.

All patients underwent detailed pre-anaesthetic evaluation including medical history, physical examination, and routine investigations such as complete blood count, liver function tests, renal function tests, chest radiography, electrocardiography, and urine examination. Patients received oral pantoprazole 40 mg two hours before surgery. Standard monitoring including electrocardiography, non-invasive blood pressure, pulse oximetry, end-tidal carbon dioxide, and airway pressure monitoring was instituted intraoperatively.

General anaesthesia was standardized for all patients. Premedication consisted of intravenous midazolam 0.03 mg/kg, fentanyl 2 µg/kg, and glycopyrrolate 5 µg/kg. Anaesthesia was induced with propofol 2–2.5 mg/kg and atracurium 0.5 mg/kg to facilitate endotracheal intubation. Anaesthesia was maintained with oxygen-air mixture and sevoflurane, with additional doses of atracurium administered as required. Intra-abdominal pressure during carbon dioxide insufflation was maintained between 10 and 12 mmHg. Intravenous paracetamol 15 mg/kg was administered for intraoperative analgesia, and port-site infiltration with 0.25% bupivacaine was performed at the conclusion of surgery.

After completion of surgery, neuromuscular blockade was reversed with neostigmine and glycopyrrolate. Patients were extubated after adequate recovery and transferred to the recovery room for monitoring. Postoperative assessment for nausea, retching, vomiting, and adverse effects was performed at predefined intervals of 0–4 hours, 4–12 hours, and 12–24 hours after surgery. PONV was

graded as: Grade 0 – none, Grade 1 – nausea, Grade 2 – nausea with retching, and Grade 3 – vomiting. Patients experiencing more than two episodes of nausea or vomiting within one hour received rescue antiemetic therapy with intravenous metoclopramide 10 mg. A complete responder was defined as a patient who experienced no nausea, retching, or vomiting and did not require rescue antiemetic medication during the 24-hour postoperative period.

Statistical Analysis

Data were entered into Microsoft Excel and analysed using Statistical Package for Social Sciences (SPSS) software version 25.0. Continuous variables were expressed as mean ± standard deviation (SD), while categorical variables were presented as frequency and percentage. Comparison of continuous variables between groups was performed using the independent Student's t-test. Categorical variables were compared using the Chi-square test or Fisher's exact test wherever appropriate. A p value of less than 0.05 was considered statistically significant.

RESULTS

A total of 88 patients undergoing elective laparoscopic cholecystectomy were enrolled and randomly allocated into two groups: Granisetron Group (Group G, n=44) and Palonosetron Group (Group P, n=44). The mean age, height, weight, and BMI were similar in both groups with no statistically significant differences ($p>0.05$). This confirms that both groups were comparable with respect to baseline demographic characteristics. (Table 1)

Table 1. Demographic Characteristics of Study Participants

Parameter	Granisetron (n=44) Mean ± SD	Palonosetron (n=44) Mean ± SD	p-value
Age (years)	51.18 ± 16.44	53.80 ± 14.15	0.425
Height (cm)	162.66 ± 7.66	164.48 ± 8.21	0.285
Weight (kg)	63.70 ± 11.39	64.39 ± 12.75	0.790
BMI (kg/m ²)	23.57 ± 3.45	24.34 ± 8.72	0.587

Females constituted the majority in both groups. Most patients belonged to ASA Grade II. No statistically significant difference was observed in gender distribution or ASA grading between the groups. (Table 2)

Table 2. Gender Distribution and ASA Grades

Variable	Granisetron n (%)	Palonosetron n (%)	p-value
Gender			
Male	20 (45.5)	16 (36.4)	0.385
Female	24 (54.5)	28 (63.6)	
ASA Grade			
Grade I	12 (27.3)	9 (20.5)	0.750
Grade II	25 (56.8)	30 (68.2)	
Grade III	7 (15.9)	5 (11.4)	

Hypothyroidism, diabetes, hypertension, and ischemic heart disease were observed in both groups. The prevalence of comorbid conditions did not differ significantly between the two groups ($p>0.05$). (Table 3)

Table 3. Distribution of Comorbidities

Comorbidity	Granisetron n (%)	Palonosetron n (%)	p-value
Hypothyroidism	7 (15.9)	12 (27.3)	0.195
Diabetes Mellitus	11 (25.0)	6 (13.6)	0.176
Hypertension	11 (25.0)	9 (20.5)	0.610
Ischemic Heart Disease	9 (20.5)	6 (13.6)	0.395

Baseline heart rate, systolic blood pressure, and diastolic blood pressure were comparable between the groups. No statistically significant differences were observed, indicating similar preoperative hemodynamic status. (Table 4)

Table 4. Baseline Vital Signs

Vital Parameter	Granisetron Mean $\pm$ SD	Palonosetron Mean $\pm$ SD	p-value
Heart Rate (bpm)	75.23 $\pm$ 10.08	76.95 $\pm$ 10.98	0.446
Systolic BP (mmHg)	125.89 $\pm$ 11.06	125.23 $\pm$ 7.31	0.742
Diastolic BP (mmHg)	77.27 $\pm$ 6.24	76.14 $\pm$ 6.89	0.422

During the first 4 postoperative hours, complete response was observed in 93.2% of patients receiving palonosetron compared to 77.3% receiving granisetron. The incidence of nausea, retching, and vomiting was lower in the palonosetron group, and the difference was statistically significant ($p=0.035$). (Table 5)

Table 5. Comparison of PONV Grades During 0–4 Hours Postoperatively

PONV Grade	Granisetron n (%)	Palonosetron n (%)	p-value
Grade 0 (No PONV)	34 (77.3)	41 (93.2)	0.035
Grade 1 (Nausea)	7 (15.9)	3 (6.8)	
Grade 2 (Nausea with Retching)	1 (2.3)	0 (0.0)	
Grade 3 (Vomiting)	2 (4.5)	0 (0.0)	

Between 4–12 hours, the incidence of PONV was lower in the palonosetron group, although the difference was not statistically significant ($p=0.179$). During 12–24 hours, palonosetron demonstrated superior protection against PONV with a significantly higher complete response rate (95.5% vs. 79.5%; $p=0.024$). (Fig 1, 2)

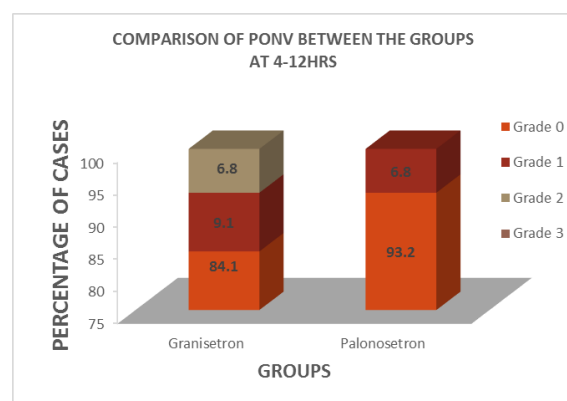


Fig 1: Comparison of PONV between the groups at 4-12hrs

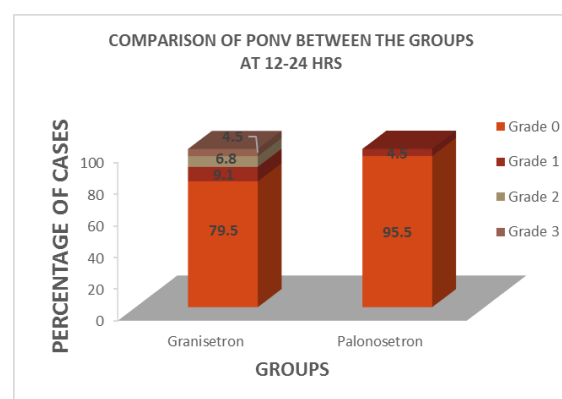


Fig 2: Comparison of PONV between the groups at 12-24 hrs

Rescue antiemetic therapy was required in 9 (20.5%) patients in the granisetron group, whereas none of the patients in the palonosetron group required additional antiemetic medication. This difference was highly statistically significant ($p=0.001$), indicating superior efficacy of palonosetron in preventing postoperative nausea and vomiting. (Table 6)

Table 6. Requirement of Rescue Antiemetic Therapy

Rescue Antiemetic	Granisetron n (%)	Palonosetron n (%)	p-value
Yes	9 (20.5)	0 (0.0)	0.001
No	35 (79.5)	44 (100.0)	

DISCUSSION

The present study demonstrated that palonosetron was more effective than granisetron in preventing PONV following laparoscopic cholecystectomy. Baseline demographic characteristics, ASA grades, comorbidities, and vital parameters were comparable between the groups, indicating that the observed differences in outcomes were attributable to the study drugs. Similar baseline comparability was reported by Aydin A et al.^[13] who found no significant differences in age, sex distribution, BMI,

ASA status, or duration of anaesthesia between patients receiving palonosetron and granisetron.

During the first 4 postoperative hours, complete response was achieved in 41 (93.2%) patients receiving palonosetron compared with 34 (77.3%) patients receiving granisetron ($p=0.035$). Nausea occurred in only 3 (6.8%) patients in the palonosetron group compared to 7 (15.9%) patients in the granisetron group; while retching and vomiting were observed only in the granisetron group. Monohar PS et al.^[14] reported an incidence of early PONV of 28% with palonosetron and 32% with granisetron, demonstrating comparable efficacy

during the immediate postoperative period. Similarly, Mamun MA et al.^[15] reported a significantly lower overall incidence of PONV with palonosetron (26.67%) compared to granisetron (63.33%), supporting the superior antiemetic efficacy observed in the present study.

Between 4 and 12 hours postoperatively, complete response was noted in 41 (93.2%) patients in the palonosetron group and 37 (84.1%) patients in the granisetron group, although the difference was not statistically significant. Comparable findings were reported by Aydin A et al.^[13] who observed similar PONV scores between the two drugs during the early postoperative period, indicating that both agents provide satisfactory short-term protection.

The superiority of palonosetron became more evident during the late postoperative period (12–24 hours), where complete response was observed in 42 (95.5%) patients compared with 35 (79.5%) patients receiving granisetron ($p=0.024$). No patient in the palonosetron group experienced retching or vomiting, whereas retching and vomiting occurred in 3 (6.8%) and 2 (4.5%) patients, respectively, in the granisetron group.

Makwana J et al.^[16] similarly reported that palonosetron provided better protection against delayed PONV, particularly during the 24–48-hour period following laparoscopic cholecystectomy. Kaur A et al.^[17] found that postoperative nausea occurred in 6 (12%) patients receiving palonosetron compared with 15 (30%) patients receiving granisetron, while vomiting occurred in 3 (6%) and 10 (20%) patients, respectively. Likewise, Kathuria R et al.^[18] reported a complete response rate of 95.6% with palonosetron compared to 73.3% with granisetron, demonstrating significantly better prophylaxis with palonosetron.

The requirement for rescue antiemetic therapy was significantly lower in the present study, with no patient in the palonosetron group requiring rescue medication compared with 9 (20.5%) patients in the granisetron group ($p=0.001$). Similar observations were reported by Govil V et al.^[19] who noted the lowest requirement for rescue antiemetics and highest patient satisfaction among patients receiving palonosetron. Mahrous M et al.^[20] also reported that additional rescue medication was required in only 45.1% of patients receiving palonosetron compared with 95.2% receiving granisetron, further supporting its prolonged antiemetic effect.

The findings of the present study were also consistent with those of Ryu JH et al.^[21] who demonstrated a lower incidence of PONV (22% vs. 41%), higher complete response rates (93% vs. 73%), and greater patient satisfaction with palonosetron. Similarly, Mekala AR et al.^[22] observed significantly lower incidences of retching and vomiting with palonosetron during the later postoperative period, emphasizing its long-lasting efficacy.

CONCLUSION

Palonosetron demonstrated superior efficacy compared to granisetron in preventing postoperative nausea and vomiting following laparoscopic cholecystectomy. Patients receiving palonosetron showed significantly higher complete response rates during the early and late postoperative periods, with lower incidences of nausea, retching, and vomiting. Furthermore, none of the patients in the palonosetron group required rescue antiemetic therapy, whereas a notable proportion of patients receiving granisetron required additional treatment. Both drugs were well tolerated and maintained stable perioperative hemodynamics. These findings suggest that palonosetron provides more sustained and effective prophylaxis against PONV and may be preferred for routine clinical use.

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Conflicts of Interest

There are no conflicts of interest.

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