RESEARCH PAPER

A Comparative Study of Intravenous Palonosetron Alone versus Palonosetron Combined with Dexamethasone for the Prevention of Postoperative Nausea and Vomiting in Patients Undergoing Laparoscopic Cholecystectomy

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ABSTRACT

Background: Postoperative nausea and vomiting (PONV) is one of the most common complications following general anaesthesia, particularly in patients undergoing laparoscopic cholecystectomy. It causes considerable postoperative discomfort, delays recovery and may prolong hospital stay. Palonosetron, a second-generation 5-hydroxytryptamine-3 (5-HT3) receptor antagonist, has a prolonged duration of action and is widely used for PONV prophylaxis. The addition of dexamethasone may further enhance its antiemetic efficacy through complementary mechanisms of action.

Aim and Objectives: To compare the efficacy of intravenous palonosetron alone with palonosetron combined with dexamethasone in preventing postoperative nausea and vomiting in patients undergoing laparoscopic cholecystectomy and to assess the requirement for rescue antiemetic medication.

Materials and Methods: This prospective comparative study was conducted in the Department of Anaesthesiology at Dr. PSIMS & RF, Gannavaram, Vijayawada, Andhra Pradesh, over a period of 24 months (April 2023 to March 2025). A total of 100 patients belonging to ASA physical status I and II, aged above 18 years and undergoing laparoscopic cholecystectomy under general anaesthesia, were included. Patients were divided into two groups of 50 each. Group P received intravenous palonosetron 0.075 mg, whereas Group PD received intravenous palonosetron 0.075 mg combined with dexamethasone 8 mg. Postoperative nausea, retching, vomiting, requirement for rescue antiemetics and haemodynamic parameters were assessed. Statistical analysis was performed using SPSS version 20, with p-value less than 0.05 considered statistically significant.

Results: The demographic characteristics, including age, gender, weight and ASA physical status, were comparable between the two groups. The mean age was 42.48 ± 10.70 years in Group PD and 43.32 ± 11.44 years in Group P. The mean duration of surgery was 59.08 ± 10.87 minutes in Group PD and 56.97 ± 10.69 minutes in Group P, with no statistically significant difference. Postoperative nausea was observed in 18% of patients in Group PD compared to 28% in Group P. Retching occurred in 8% and 12% of patients, respectively, while vomiting was reported in 16% of Group PD and 28% of Group P. Although the incidence of these symptoms was lower in the combination group, the differences were not statistically significant (p greater than 0.05). Rescue antiemetic medication was required in 24% of patients in Group PD compared to 28% in Group P. Haemodynamic parameters, including heart rate, systolic blood pressure and diastolic blood pressure, remained comparable between the groups throughout the observation period.

Conclusion: Both palonosetron alone and its combination with dexamethasone demonstrated effective prophylaxis against postoperative nausea and vomiting following laparoscopic cholecystectomy. Although the combination regimen showed a numerical reduction in the incidence of nausea, retching and vomiting, the differences were not statistically significant. Therefore, the addition of dexamethasone did not demonstrate a statistically significant improvement over palonosetron alone in the present study.

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Keywords: Postoperative nausea and vomiting, Palonosetron, Dexamethasone, Laparoscopic cholecystectomy, Antiemetic prophylaxis, General anaesthesia

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INTRODUCTION

Postoperative nausea and vomiting (PONV) is one of the most common and distressing complications encountered in patients undergoing surgical procedures under general anaesthesia. It is characterized by the occurrence of nausea, retching and vomiting during the postoperative period and remains an important concern in modern anaesthetic practice. Despite significant advancements in anaesthetic drugs, surgical techniques and perioperative patient care, PONV continues to affect a considerable proportion of surgical patients. Its incidence varies depending on patient-related factors, type and duration of surgery, anaesthetic technique and postoperative analgesic medications. Approximately 20–30% of patients undergoing general surgical procedures experience PONV, while the incidence may increase considerably in patients with multiple risk factors and those undergoing highly emetogenic procedures. PONV is not merely an unpleasant postoperative symptom but also an important determinant of patient satisfaction, recovery and overall quality of perioperative care [1].

The occurrence of PONV can have several adverse consequences, ranging from mild discomfort to serious postoperative complications. Persistent nausea and repeated vomiting may result in dehydration, electrolyte imbalance, acid-base disturbances and delayed resumption of oral feeding. In certain circumstances, forceful vomiting can lead to aspiration of gastric contents, wound disruption, bleeding, increased intra-abdominal pressure and prolonged postoperative recovery. It may also delay discharge from the post-anaesthesia care unit (PACU), increase the requirement for additional medications and nursing care, and contribute to unanticipated hospital admission following ambulatory surgery. Consequently, effective prevention and management of PONV have become essential components of contemporary anaesthetic practice, particularly with the increasing emphasis on enhanced recovery after surgery and early postoperative discharge [2].

Laparoscopic cholecystectomy is one of the most commonly performed minimally invasive surgical procedures for the treatment of symptomatic gallstone disease and other gallbladder disorders. Although laparoscopic surgery offers several advantages over conventional open surgery, including smaller incisions, reduced postoperative pain, shorter hospital stay and faster recovery, it is associated with a relatively high incidence of postoperative nausea and vomiting. The occurrence of PONV following laparoscopic cholecystectomy is influenced by several factors, including carbon dioxide pneumoperitoneum, peritoneal stretching, diaphragmatic irritation, manipulation of abdominal viscera and changes in intra-abdominal pressure. Furthermore, the use of inhalational anaesthetic agents and perioperative opioids may contribute to postoperative emetic symptoms. These factors collectively make laparoscopic cholecystectomy an important surgical model for evaluating the effectiveness of different antiemetic prophylactic regimens [3].

The pathophysiology of PONV is complex and involves the interaction of multiple neurotransmitters and neural pathways within the gastrointestinal tract and central nervous system. The vomiting reflex is regulated by several interconnected structures, including the nucleus tractus solitarius, area postrema, chemoreceptor trigger zone and central vomiting network in the medulla. Various neurotransmitters participate in the initiation and transmission of emetic signals, including serotonin, dopamine, histamine, acetylcholine, substance P and gamma-aminobutyric acid. Among these neurotransmitters, serotonin plays a particularly important role in the development of postoperative nausea and vomiting. Surgical manipulation and intestinal stimulation can promote serotonin release from enterochromaffin cells, which subsequently activates 5-hydroxytryptamine-3 (5-HT3) receptors located on vagal afferent nerve endings. These impulses are transmitted to the central nervous system and contribute to the initiation of the vomiting reflex [4].

The risk of developing PONV is determined by a combination of patient-related, anaesthesia-related and surgical factors. Female gender, a previous history of PONV or motion sickness, non-smoking status and postoperative opioid administration are among the most consistently recognized patient-related risk factors. Apfel and colleagues developed a simplified risk scoring system incorporating these four independent predictors to estimate the probability of postoperative nausea and vomiting. The incidence of PONV increases progressively with the number of risk factors present, making risk assessment an important component of perioperative planning. Anaesthesia-related factors include the use of volatile anaesthetic agents, nitrous oxide, opioids and prolonged anaesthesia, whereas surgical factors include the type, duration and extent of surgical manipulation. Identification of these risk factors allows anaesthesiologists to select appropriate prophylactic interventions and develop individualized antiemetic strategies [5].The management of PONV involves a combination of risk assessment, reduction of modifiable perioperative risk factors, pharmacological prophylaxis and timely administration of rescue antiemetics. [6].

Among the available 5-HT3 receptor antagonists, palonosetron has attracted considerable attention because of its distinctive pharmacological properties and prolonged duration of action. It is a second-generation serotonin 5-HT3 receptor antagonist that was initially introduced for the prevention of chemotherapy-induced nausea and vomiting and subsequently established an important role in the prevention of PONV. Compared with first-generation 5-HT3 receptor antagonists, palonosetron demonstrates a substantially higher receptor-binding affinity and a longer elimination half-life of approximately 40 hours. These characteristics contribute to its prolonged antiemetic activity and make it particularly useful in preventing both early and delayed postoperative nausea and vomiting [7].

The mechanism of action of palonosetron differs in certain respects from that of conventional 5-HT3 receptor antagonists. It interacts with the 5-HT3 receptor through a distinctive allosteric binding mechanism and demonstrates functional effects that may extend beyond conventional competitive receptor antagonism. Experimental studies have suggested that palonosetron can influence receptor internalization and inhibit receptor-mediated signalling for a prolonged period. Its high receptor affinity, sustained pharmacological activity and relatively favourable adverse-effect profile provide a scientific rationale for its use as an effective prophylactic antiemetic in patients undergoing laparoscopic cholecystectomy [8].

Clinical evidence has demonstrated the effectiveness of palonosetron in reducing postoperative nausea and vomiting across different surgical populations. Its prolonged duration of action is particularly advantageous in procedures associated with an increased risk of delayed postoperative emetic symptoms. Unlike shorter-acting antiemetic agents, palonosetron may provide sustained protection during the postoperative recovery period. Clinical trials evaluating palonosetron have reported reductions in the incidence of nausea, vomiting and the requirement for rescue antiemetic medication. Its efficacy, convenient single-dose administration and relatively low incidence of adverse effects have contributed to its increasing use in perioperative antiemetic prophylaxis [9].

Another important pharmacological agent used for the prevention of PONV is dexamethasone, a synthetic glucocorticoid with potent anti-inflammatory and immunomodulatory properties. Although its exact antiemetic mechanism is not completely understood, several mechanisms have been proposed, including inhibition of prostaglandin synthesis, modulation of serotonin release, reduction of inflammatory mediators and interaction with glucocorticoid receptors within the central nervous system. Dexamethasone may also influence the activity of other neurotransmitter pathways involved in the vomiting reflex. It is commonly administered intravenously during the peri-induction period because of its prolonged duration of action and established role in postoperative antiemetic prophylaxis [10].

The antiemetic effectiveness of dexamethasone has been evaluated in several randomized controlled trials and systematic reviews. Evidence suggests that dexamethasone can significantly reduce postoperative nausea and vomiting when administered either alone or in combination with other antiemetic medications. It is also associated with a relatively favourable safety profile when used as a single perioperative dose in appropriately selected patients. Its complementary mechanism of action makes it a suitable candidate for combination therapy with 5-HT3 receptor antagonists. The combination approach is based on the principle that targeting different pathways involved in the emetic response may provide better protection than using a single pharmacological agent [11].

Multimodal antiemetic prophylaxis has consequently become an important strategy in the contemporary management of patients at moderate or high risk of PONV. The Fourth Consensus Guidelines for the Management of Postoperative Nausea and Vomiting emphasize the importance of identifying individual risk factors, reducing baseline anaesthetic risks and administering prophylactic medications with different mechanisms of action when clinically indicated. Combining a 5-HT3 receptor antagonist with dexamethasone represents one such approach. However, the effectiveness of combination therapy depends on the individual drugs, their pharmacological properties, timing of administration and the risk profile of the patient [12].

The combination of palonosetron and dexamethasone is particularly interesting because both medications possess different but potentially complementary antiemetic mechanisms. Palonosetron primarily acts through inhibition of serotonin-mediated 5-HT3 receptor signalling, whereas dexamethasone may influence multiple inflammatory and neurochemical pathways involved in the development of nausea and vomiting. Their combined administration may therefore provide enhanced prophylactic protection, particularly in patients undergoing procedures associated with a high incidence of PONV. Nevertheless, the additional clinical benefit of administering dexamethasone along with palonosetron remains a subject of investigation, as available studies have reported variable findings [13,14].

Subsequent clinical investigations have also evaluated the comparative efficacy of these antiemetic regimens. A randomized comparative study involving patients undergoing laparoscopic cholecystectomy reported that the overall incidence of PONV was comparable between patients receiving palonosetron alone and those receiving the palonosetron-dexamethasone combination. Although the combination regimen showed a numerical reduction in postoperative symptoms and rescue antiemetic requirements, a statistically significant advantage over palonosetron alone was not established. Similarly, other randomized studies involving laparoscopic surgical patients have reported that the addition of dexamethasone does not consistently produce a significant reduction in postoperative nausea and vomiting [15].

In contrast, some clinical studies have reported improved complete response rates and reduced postoperative emetic symptoms with combination therapy. These differences may be related to variations in patient characteristics, baseline PONV risk, surgical procedures, anaesthetic techniques, timing of drug administration and postoperative observation periods. The variation in findings indicates that the superiority of combination therapy cannot be assumed in every clinical setting. Therefore, further evaluation in specific surgical populations is necessary to determine whether the additional administration of dexamethasone provides a clinically meaningful advantage over palonosetron monotherapy [16].

Laparoscopic cholecystectomy provides an appropriate clinical setting for evaluating these two antiemetic regimens because of its association with multiple risk factors for postoperative nausea and vomiting. The use of general anaesthesia, pneumoperitoneum, visceral manipulation and perioperative analgesic medications may collectively contribute to the development of PONV. Effective prophylaxis in these patients is important not only for improving postoperative comfort but also for facilitating early mobilization, oral intake and discharge. Furthermore, identifying an effective single-agent regimen may help reduce unnecessary medication exposure and treatment costs without compromising patient safety or recovery.

Considering the established antiemetic properties of palonosetron and dexamethasone, the present study was designed to compare the prophylactic effectiveness of intravenous palonosetron alone with that of intravenous palonosetron combined with dexamethasone in patients undergoing laparoscopic cholecystectomy under general anaesthesia. The study also aimed to assess the postoperative incidence of nausea, retching and vomiting, evaluate the requirement for rescue antiemetic medication and compare haemodynamic parameters between the two groups.

The findings of this study are expected to contribute to a better understanding of the role of combination antiemetic prophylaxis in laparoscopic cholecystectomy. By evaluating the clinical outcomes associated with both regimens, the study seeks to determine whether the addition of dexamethasone provides a statistically significant improvement over palonosetron alone. Such evidence may assist anaesthesiologists in selecting an appropriate, effective and economical prophylactic antiemetic strategy, ultimately improving postoperative patient comfort and quality of perioperative care.

MATERIALS AND METHODS

Study Design

The present study was conducted as a prospective, randomized comparative study to evaluate the efficacy of intravenous palonosetron alone versus a combination of palonosetron and dexamethasone for the prevention of postoperative nausea and vomiting (PONV) in patients undergoing laparoscopic cholecystectomy under general anaesthesia.

Study Setting

The study was conducted in the Operation Theatre, Department of Anaesthesiology at Dr. PSIMS & RF, Gannavaram, affiliated to Dr. NTRUHS, Vijayawada

Study Duration

The study was carried out over a period of 24 months, from April 2023 to March 2025.

Study Population

The study included male and female patients aged above 18 years, belonging to American Society of Anesthesiologists (ASA) physical status I and II, who were scheduled to undergo laparoscopic cholecystectomy under general anaesthesia and provided written informed consent.

Sample Size

A total of 100 patients were included in the study and randomly allocated into two groups, with 50 patients in each group.

The sample size was calculated by assuming a success rate of 80% for combination therapy (P1) and 50% for palonosetron monotherapy (P2), with a two-sided alpha error of 5% and statistical power of 80%. The calculated sample size was 36 patients in each group. Considering possible attrition and loss of data, the sample size was increased to 50 patients per group, resulting in a total sample size of 100 patients.

Inclusion Criteria

1. Patients aged above 18 years.
2. Patients belonging to ASA physical status I and II.
3. Patients scheduled to undergo laparoscopic cholecystectomy under general anaesthesia.
4. Patients of either gender.
5. Patients willing to participate in the study and providing written informed consent.

Exclusion Criteria

1. Patients who refused to participate in the study.
2. Patients outside the prescribed age limit.
3. Patients with a known history of allergy or hypersensitivity to palonosetron or dexamethasone.
4. Patients with anticipated complicated surgical conditions, such as gallbladder empyema, porcelain gallbladder, gallbladder carcinoma or biliary tract disease.
5. Patients with severe systemic comorbidities belonging to ASA physical status III and IV.
6. Patients receiving selective serotonin reuptake inhibitors (SSRIs) or medications known to cause QT interval prolongation.
7. Patients in whom laparoscopic cholecystectomy was converted into open cholecystectomy.

Ethical Considerations

The study was conducted after obtaining approval from the Institutional Ethics Committee. Written informed consent was obtained from all participants before enrolment. Patient confidentiality and privacy were maintained throughout the study, and all collected information was used exclusively for research purposes.

Study Procedure

Patients scheduled for laparoscopic cholecystectomy under general anaesthesia with endotracheal intubation were assessed preoperatively. A detailed medical history, clinical examination and routine pre-anaesthetic evaluation were performed. Eligible patients were enrolled after obtaining written informed consent.

The anaesthetic protocol included premedication with glycopyrrolate 0.005 mg/kg and fentanyl 2 µg/kg. Anaesthesia was induced using propofol 2 mg/kg, and neuromuscular blockade was achieved with vecuronium 0.12 mg/kg. Anaesthesia was maintained with sevoflurane, nitrous oxide and oxygen in a 2:1 ratio. A Ryle's tube was inserted for gastric

decompression during the procedure. At the completion of surgery, neuromuscular blockade was reversed using neostigmine 0.05 mg/kg and glycopyrrolate 10 µg/kg, followed by extubation after adequate recovery.

Group Allocation and Drug Administration

Patients were randomly allocated into two groups using computer-generated random numbers.

Group P (Palonosetron Group): Fifty patients received intravenous palonosetron 0.075 mg diluted in 2 mL of isotonic saline after removal of the gallbladder, approximately 30 minutes before the completion of surgery.

Group PD (Palonosetron + Dexamethasone Group): Fifty patients received intravenous palonosetron 0.075 mg combined with dexamethasone 8 mg, diluted in 5 mL of isotonic saline, after removal of the gallbladder.

Postoperative Assessment

Following surgery, patients were transferred to the post-anaesthesia care unit (PACU), where they were observed for the occurrence of postoperative nausea, retching and vomiting. The time of arrival in the PACU was recorded to correlate postoperative symptoms with the timing of administration of the study drugs.

Nausea was defined as an unpleasant subjective sensation associated with an urge to vomit. Retching was defined as rhythmic respiratory and abdominal muscular contractions without expulsion of gastric contents. Vomiting was defined as the forceful expulsion of gastric contents through the mouth.

Patients were assessed at regular postoperative intervals, and the incidence and severity of nausea, retching and vomiting were documented. The requirement for rescue antiemetic medication was also recorded.

Rescue Antiemetic Medication

Intravenous metoclopramide 10 mg was administered as rescue antiemetic therapy in patients developing moderate-to-severe nausea or any episode of vomiting. The number of patients requiring rescue medication was recorded and compared between the two study groups.

Postoperative Nausea and Vomiting Scoring System

The occurrence of postoperative nausea and vomiting was assessed using the following scoring system:

- Score 0: No symptoms.
- Score 1: Nausea.
- Score 2: Retching.
- Score 3: Vomiting.

The scores were recorded during the postoperative observation period to assess the severity and distribution of PONV in both groups.

Haemodynamic Monitoring

Heart rate, systolic blood pressure and diastolic blood pressure were monitored and recorded at regular intervals during the intraoperative and postoperative periods. Any significant haemodynamic variations or adverse events were documented and evaluated.

Outcome Measures

The primary outcome was the comparative incidence of postoperative nausea, retching and vomiting between the two groups.

The secondary outcomes included:

1. Comparison of the requirement for rescue antiemetic medication.
2. Assessment of postoperative PONV severity using the scoring system.
3. Comparison of intraoperative and postoperative haemodynamic parameters.
4. Assessment of the overall safety and tolerability of both antiemetic regimens.

Statistical Analysis

The collected data were entered into Microsoft Excel 2016 and analysed using Statistical Package for Social Sciences (SPSS), version 20. Continuous variables were expressed as mean ± standard deviation, while categorical variables were presented as frequencies and percentages.

The unpaired Student's t-test or Mann–Whitney U test was used for comparison of continuous variables between the two groups, as appropriate. Categorical variables were compared using the Chi-square test or

Fisher's exact test, wherever applicable. A p-value of less than 0.05 was considered statistically significant.

RESULTS

A total of 100 patients undergoing laparoscopic cholecystectomy under general anaesthesia were included in the study and divided into two groups of 50 patients each. Group P received intravenous palonosetron alone, whereas Group PD received a combination of intravenous palonosetron and dexamethasone. The postoperative incidence and severity of nausea, retching and vomiting were compared between the two groups.

The mean age of patients in Group PD was 42.48 ± 10.70 years, whereas in Group P it was 43.32 ± 11.44 years. The difference in mean age between the two groups was statistically insignificant (p=0.705), indicating comparable age distribution. Regarding gender distribution, Group PD consisted of 19 males (38%) and 31 females (62%), while Group P included 17 males (34%) and 33 females (66%). No statistically significant difference was observed between the groups with respect to gender (p=0.677). The mean body weight was 60.50 ± 3.81 kg in Group PD and 59.85 ± 2.98 kg in Group P, with no statistically significant difference (p=0.180).

The distribution of patients according to ASA physical status was comparable between the two groups. In Group PD, 30 patients (60%) belonged to ASA Grade I and 20 patients (40%) belonged to ASA Grade II. In Group P, 29 patients (58%) were classified as ASA Grade I and 21 patients (42%) as ASA Grade II. The difference in ASA physical status distribution was statistically insignificant (p=0.839). The mean duration of surgery was 59.08 minutes in Group PD and 56.97 minutes in Group P. Although the duration was slightly longer in Group PD, the difference was not statistically significant.

Postoperative nausea was observed in 9 patients (18%) in Group PD compared with 14 patients (28%) in Group P. Thus, a numerically lower incidence of nausea was observed among patients receiving the palonosetron–dexamethasone combination; however, the difference was not statistically significant. Retching was reported in 4 patients (8%) in Group PD and 6 patients (12%) in Group P. Similarly, vomiting occurred in 8 patients (16%) in Group PD compared with 14 patients (28%) in Group P. Although the incidence of retching and vomiting was numerically lower in Group PD, no statistically significant difference was reported between the two groups.

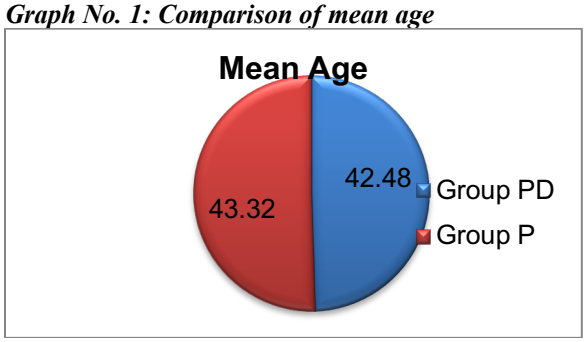
Rescue antiemetic medication was required in 12 patients (24%) in Group PD and 14 patients (28%) in Group P. The requirement for rescue medication was therefore slightly lower in the combination group, but the difference was not statistically significant. These findings indicate that the addition of dexamethasone to palonosetron was associated with numerically lower rates of postoperative nausea, retching, vomiting and rescue antiemetic requirement, although a statistically significant improvement was not demonstrated.Assessment of postoperative nausea and vomiting severity showed that 34 patients (68%) in Group PD and 33 patients (66%) in Group P were classified as Grade 0. Grade 1 was observed in 3 patients (6%) in each group. Grade 3 was reported in 12 patients (24%) in Group PD and 14 patients (28%) in Group P, while Grade 4 was observed in 1 patient (2%) in Group PD. Overall, the distribution of postoperative symptom grades was comparable between the two groups, with no statistically significant difference reported.

In summary, both intravenous palonosetron alone and the combination of palonosetron with dexamethasone demonstrated effectiveness in preventing postoperative nausea and vomiting following laparoscopic cholecystectomy. Although the combination group showed numerically lower incidences of nausea, retching, vomiting and rescue antiemetic requirement, these differences were not statistically significant. Therefore, the present study did not demonstrate a statistically significant additional benefit of dexamethasone when administered along with palonosetron.

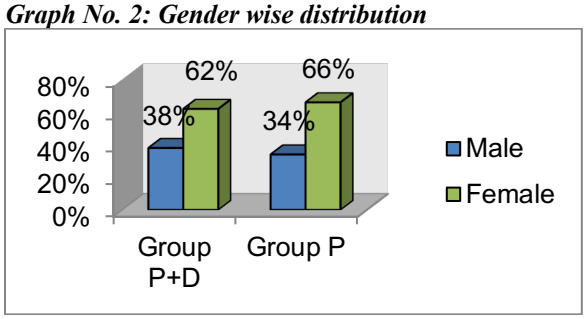
Table No. 1: Demographic Profile

Variable	Group PD (50)	Group P (50)	p-value
Age (Mean ± SD)	42.48 ± 10.70	43.32 ± 11.44	0.705
Gender (M/F)	19/31	17/33	0.677
Weight	60.5 ± 3.81	59.85 ± 2.98	0.180
ASA grade I	30 (60%)	29 (58%)	0.839
ASA grade II	20 (40%)	21 (42%)	

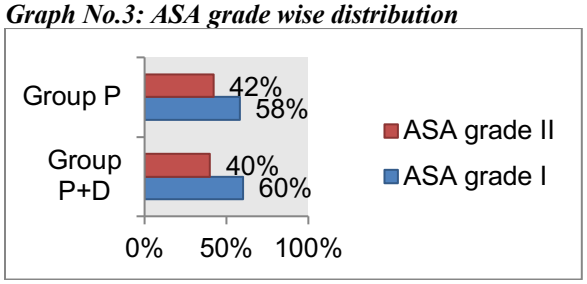
Graph No. 1: Comparison of mean age



Graph No. 2: Gender wise distribution



Graph No.3: ASA grade wise distribution



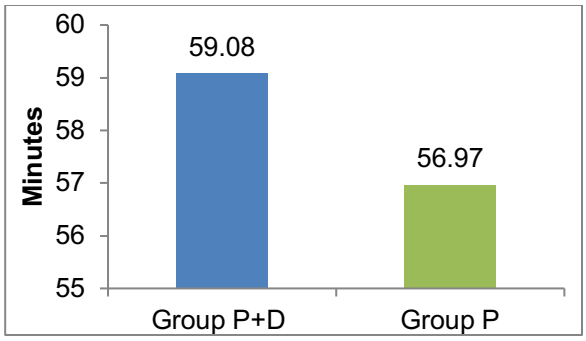
Mean duration of surgery:

The mean duration of surgery time in Group PD was 59.08 minutes and the mean duration of surgery in Group P was 56.97 minutes and the p-value between the 2 groups was 0.167, which is statistically not significant (p>0.05).

Table No. 2: Comparison of mean duration of surgery (min)

Group	Mean Min ± S.D	p-value
Group PD	59.08 ± 10.87	0.167
Group P	56.97 ± 10.69	

Graph No.4: Mean duration of surgery (min)

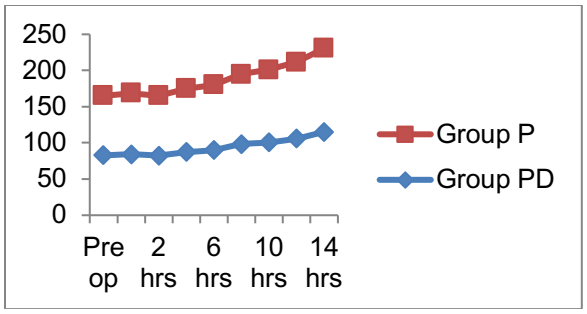


Mean heart rate:

Table No. 3: Comparison of mean heart rate between both the groups

Heart rate	**Group PD**	**Group P**	t-test value	p-value
Preop	82.97 ±1.40	82.1 ± 1.71	1.760	0.086
0 hrs	84.10 ± 1.05	84.48 ± 1.17	0.94	0.130
2 hrs	82.48 ± 0.58	82.58 ± 0.56	1.96	0.435
4 hrs	87.36 ± 0.49	87.32 ± 0.57	0.33	0.737
6 hrs	90.06 ±0.48	89.96 ± 0.59	0.83	0.408
8 hrs	98.45 ± 0.50	96.56 ± 0.38	1.10	0.271
10 hrs	100.45 ± 0.53	100.37 ± 0.38	0.77	0.440
12 hrs	105.75 ± 0.62	106.04 ± 0.77	1.85	0.067
14 hrs	115.19 ± 0.79	115.32 ± 0.87	0.69	0.486

Graph No.5: Mean heart rate between both the groups (min)



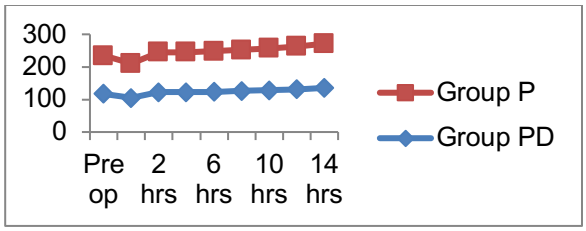
When the mean heart rates were measured between the two groups it was observed that the mean heart rate did not vary significantly in the two groups and this is consistent across different intervals of time (p>0.05) [Table no.3].

Mean SBP:

Table No. 4: Comparison of mean SBP between both the groups

SBP	Group PD	Group P	t-test value	p-value
Pre op	116.97 ± 1.40	117.1 ± 1.71	1.760	0.086
0 hrs	105.10 ± 1.15	105.30 ± 1.17	1.15	0.251
2 hrs	122.44 ± 0.58	122.56 ± 0.56	0.94	0.349
4 hrs	122.56 ± 0.49	122.60 ± 0.57	0.33	0.737
6 hrs	123.73 ± 0.48	123.95 ± 0.59	1.82	0.071
8 hrs	126.04 ± 0.50	126.19 ± 0.38	1.51	0.134
10 hrs	128.42 ± 0.53	128.45 ± 0.38	0.29	0.771
12 hrs	131.34 ± 0.62	131.52 ± 0.77	1.15	0.253
14 hrs	135.52 ± 0.79	135.72 ± 1.09	0.93	0.350

Graph No.6: Mean SBP between both the groups (min)



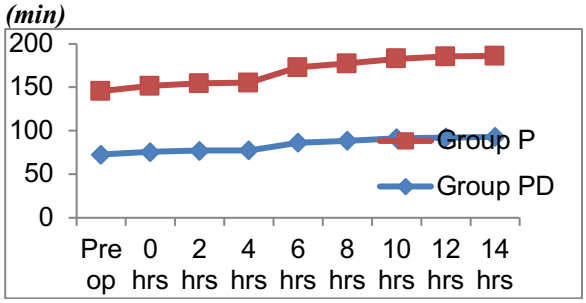
When the mean SBP was measured between the two groups it was observed that the values of SBP did not differ significantly at different intervals (p>0.05) [Table no.4]

Mean DBP:

Table No. 5: Comparison of mean DBP between both the groups

DBP	Group PD	Group P	t-test value	p-value
Pre op	72.81 ± 1.71	72.97 ±1.40	0.45	0.648
0 hrs	75.91 ± 0.18	75.84 ± 0.15	1.88	0.062
2 hrs	77.23 ± 0.56	77.48 ± 0.58	1.96	0.053
4 hrs	77.59 ± 0.57	77.61 ± 0.49	0.16	0.866
6 hrs	86.45 ± 0.59	86.53 ± 0.48	0.66	0.507
8 hrs	88.59 ± 0.38	88.74 ± 0.50	1.51	0.134
10 hrs	91.45 ± 0.38	91.42 ± 0.53	0.29	0.771
12 hrs	92.52 ± 0.77	92.84 ± 0.68	1.97	0.052
14 hrs	93.10 ± 0.91	93.17 ±0.30	0.46	0.645

Graph No.7: Mean DBP between both the groups (min)



When the mean DBP was measured between the two groups it was also observed that there were no significant differences between group P+D and group P at different time intervals (p>0.05) [Table no.5].

Incidence of Postoperative Nausea, Vomiting and Retching:

Table No. 6: Comparison of postoperative Nausea between two groups

Nausea	Group PD (N=50)	Group P (N=50)	p-value
0 hrs	3 (6%)	5 (10.0%)	0.461
2 hrs	2 (4%)	3 (6.0%)	0.307
4 hrs	2 (4%)	3 (6.0%)	0.646
6 hrs	1 (2%)	2 (4%)	0.558
8 hrs	1 (2%)	1 (2%)	1.0
10 hrs	-	-	-
12 hrs	-	-	-
24 hrs	-	-	-
0 – 24 hrs	9 (18%)	14 (28%)	0.235

Postoperative Nausea was more frequent in Group P (28%) compared to Group PD (18%), though the difference was not statistically significant ($p > 0.05$). The highest incidence occurred within the first 4 hours, with nausea reported in 6–10% of participants, gradually declining over time. By 8 hours, nausea was rare (2% in both groups), and no cases were reported beyond this point. The overall trend suggests a slightly higher occurrence of nausea in Group P, but with no significant difference between the groups at any time point ($p>0.05$).

Table No. 7: Comparison of postoperative Retching between two groups

Retching	Group PD (N=50)	Group P (N=50)	p-value
0 hrs	2 (4%)	3 (6%)	0.307
2 hrs	1 (2%)	2 (4%)	0.558
4 hrs	1 (2%)	1 (2%)	1.0
6 hrs	1 (2%)	1 (2%)	1.0
8 hrs	1 (2%)	2 (4%)	0.558
10 hrs	-	-	-
12 hrs	-	-	-
24 hrs	-	-	-
0 – 24 hrs	6 (8%)	9 (12%)	0.401

Retching was reported slightly more in Group P (12%) than in Group PD (8%), but the difference was not statistically significant ($p > 0.05$). The highest occurrence was within the first 8 hours, with a maximum incidence of 6% in Group P and 4% in Group PD at any given time. By 10 hours onward, no cases were reported in either group.

Table No. 8: Comparison of postoperative Vomiting between two groups

Vomiting	Group PD (N=50)	Group P (N=50)	p-value
0 hrs	2 (4%)	2 (4%)	0.401
2 hrs	2 (4%)	3 (6%)	0.558
4 hrs	2 (4%)	4 (8%)	0.401
6 hrs	1 (2%)	3 (6%)	0.307
8 hrs	1 (2%)	2 (4%)	0.558
10 hrs	-	-	-
12 hrs	-	-	-
24 hrs	-	-	-
0 – 24 hrs	8 (16%)	14 (28%)	0.148

Vomiting was more frequent in Group P (28%) compared to Group PD (16%), but the difference was not statistically significant ($p = 0.148$). The highest incidence occurred within the first 6 hours, with a peak of 8% in Group P and 4% in Group PD at 4

hours. Vomiting decreased over time, with only 2–4% of participants affected by 8 hours and no cases reported beyond this point. Overall, Group P had a higher occurrence of vomiting, but the difference was not statistically significant at any time point.

Graph No.8: Comparison of incidence of Nausea, Vomiting and Retching (%)

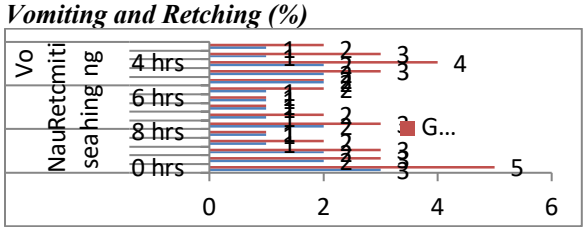


Table No. 9: Comparison of rescue medication usage

Rescue medication	Group P		Group PD		Total	
	N	%	N	%	N	%
Yes	14	28.0%	12	24.0%	26	26.0%
No	36	72.0%	38	76.0%	74	74.0%
Total	50	100.0 %	50	100.0 %	100	100.0 %
P = 0.761 (p>0.05)						

The comparison of rescue medication usage between Group P and Group PD showed no significant difference. In Group P, 28.0% of patients required rescue medication, compared to 24.0% in Group PD. The majority of patients in both groups did not require rescue medication, with 72.0% in Group P and 76.0% in Group PD. Overall, rescue medication was needed in 26.0% of the total study population. These results indicate similar rescue medication usage between the two groups.

Graph No.9: Comparison of rescue medication between both the groups

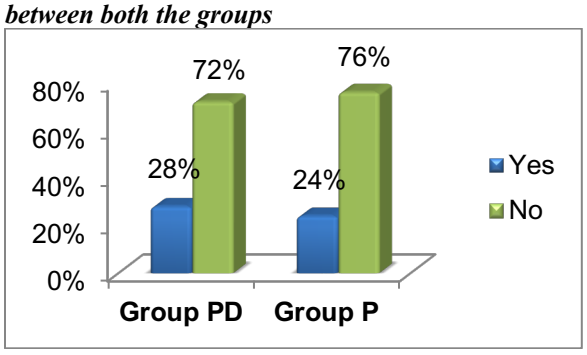


Table No. 10: Comparison of WHO grades

WHO grades	Group P		Group PD		Total	
	N	%	N	%	N	%
Grade 0	33	66.0%	34	68.0%	67	67.0%
Grade 1	3	6.0 %	3	6.0 %	6	6.0 %
Grade 3	14	28.0%	12	24.0%	26	26.0%
Grade 4	0	0.0 %	1	2.0 %	1	1.0 %
Total	50	100.0%	50	100.0%	100	100.0%
P = 0.761 (p>0.05)						

The comparison of WHO grades between Group P and Group PD revealed no statistically significant difference (p >0.05). Grade 0 was the most common category in both groups, accounting for 66.0% in Group P and 68.0% in Group PD. Grade 1 occurred at an equal frequency of 6.0% in both groups. Grade 3 was observed in 28.0% of patients in Group P and 24.0% in Group PD. Grade 4 was rare, reported only in 2.0% of Group PD patients. These findings suggest similar distributions of WHO grades between the two groups

DISCUSSION

The present study was conducted to compare the efficacy of intravenous palonosetron alone with intravenous palonosetron combined with dexamethasone for the prevention of postoperative nausea and vomiting (PONV) in patients undergoing laparoscopic cholecystectomy under general anaesthesia. A total of 100 patients were included and divided into two groups of 50 each. Group P received palonosetron 0.075 mg, whereas Group PD received palonosetron 0.075 mg combined with dexamethasone 8 mg. The incidence of postoperative nausea, retching, vomiting, requirement for rescue antiemetics and haemodynamic parameters were evaluated.Postoperative nausea and vomiting remains one of the most common complications following

general anaesthesia. It is associated with considerable patient discomfort, delayed recovery, prolonged hospital stay and increased healthcare expenditure. Laparoscopic cholecystectomy is associated with a relatively high incidence of PONV because of pneumoperitoneum, peritoneal stretching, visceral manipulation and the use of inhalational anaesthetic agents and opioids. Several studies have established the importance of identifying risk factors and administering appropriate prophylactic antiemetic medications to reduce postoperative complications [1–6].

In the present study, the mean age of patients was 42.48 ± 10.70 years in Group PD and 43.32 ± 11.44 years in Group P. The difference was statistically insignificant (p=0.705), indicating comparable age distribution between the groups. Apfel et al. identified important patient-related risk factors for PONV, including female gender, previous history of PONV or motion sickness, non-smoking status and postoperative opioid administration [5]. Similarly, Gan et al. emphasized the importance of individual risk assessment and multimodal prophylaxis in patients at increased risk of developing PONV [12].

Regarding gender distribution, Group PD consisted of 19 males (38%) and 31 females (62%), whereas Group P included 17 males (34%) and 33 females (66%). There was no statistically significant difference between the groups (p=0.677). The predominance of female patients in both groups is noteworthy because female gender is an established independent risk factor for PONV. The comparable distribution of gender between the two groups reduces the possibility that this factor substantially influenced the comparison of postoperative outcomes.

The mean body weight was 60.50 ± 3.81 kg in Group PD and 59.85 ± 2.98 kg in Group P, with no statistically significant difference (p=0.180). Similarly, the distribution of ASA physical status was comparable. In Group PD, 60% of patients belonged to ASA Grade I and 40% to ASA Grade II, while in Group P, 58% belonged to ASA Grade I and 42% to ASA Grade II (p=0.839). These findings indicate that the baseline demographic and clinical characteristics were comparable between the two groups.

The mean duration of surgery was 59.08 minutes in Group PD and 56.97 minutes in Group P. Although the duration was slightly longer in the combination group, the difference was not statistically significant. Surgical duration and anaesthetic exposure may influence the occurrence of PONV. The pathophysiology of PONV involves several neurotransmitter pathways, particularly serotonin-mediated stimulation of 5-hydroxytryptamine-3 (5-HT3) receptors located on vagal afferent nerve endings and within the central nervous system [3,4].

Incidence of postoperative nausea

In the present study, postoperative nausea was observed in 9 patients (18%) in Group PD compared with 14 patients (28%) in Group P. Thus, the combination of palonosetron and dexamethasone demonstrated a numerical reduction of 10 percentage points in the incidence of postoperative nausea. However, this difference was not statistically significant.

Palonosetron is a second-generation 5-HT3 receptor antagonist with a prolonged elimination half-life of approximately 40 hours and a high receptor-binding affinity. Its prolonged pharmacological action makes it useful in preventing both early and delayed postoperative nausea and vomiting [7,8]. Candiotti et al. demonstrated the efficacy and safety of palonosetron in preventing PONV in a randomized, double-blind clinical trial [9].

Dexamethasone has also been established as an effective prophylactic antiemetic agent. Its proposed mechanisms include modulation of inflammatory mediators, inhibition of prostaglandin synthesis and interaction with central glucocorticoid receptors [10,11]. The combination of palonosetron and dexamethasone is based on their complementary pharmacological actions. Nevertheless, the present study did not demonstrate a statistically significant additional benefit from adding dexamethasone.

Incidence of retching and vomiting

Retching was observed in 4 patients (8%) in Group PD and 6 patients (12%) in Group P. Vomiting occurred in 8 patients (16%) in Group PD compared with 14 patients (28%) in Group P.The combination group demonstrated a numerically lower incidence of both retching and vomiting. However, the differences were not statistically significant. These findings suggest that although combination therapy may provide some additional clinical benefit, the present study could not establish its statistical superiority over palonosetron alone.The findings are comparable with the study conducted by Ghosh et al., who compared palonosetron alone with palonosetron combined with dexamethasone in patients undergoing laparoscopic cholecystectomy. They reported no statistically significant difference in the complete

response rates between the two groups [14].Chatterjee et al. also evaluated palonosetron, dexamethasone and their combination in patients undergoing laparoscopic cholecystectomy. Their findings demonstrated comparable antiemetic efficacy between palonosetron alone and the combination regimen [15]. These observations support the findings of the present study.

In contrast, some studies have reported improved postoperative antiemetic outcomes with combination therapy. Bala et al. evaluated palonosetron alone against palonosetron combined with dexamethasone and reported improved complete response rates in patients receiving combination therapy [17]. Differences in study population, sample size, anaesthetic techniques and postoperative assessment periods may explain the variation in findings.

Requirement for rescue antiemetic medication

In the present study, rescue antiemetic medication was required in 12 patients (24%) in Group PD compared with 14 patients (28%) in Group P. Although the requirement was slightly lower in the combination group, the difference was not statistically significant.Rescue antiemetic requirement is an important indicator of the effectiveness of prophylactic treatment because it reflects breakthrough nausea and vomiting despite preventive medication. The lower numerical requirement in Group PD suggests a possible additional benefit of dexamethasone, although this was not statistically established.Ghosh et al. reported comparable antiemetic effectiveness between palonosetron alone and its combination with dexamethasone [14]. Chatterjee et al. also observed that combination therapy did not consistently provide a significant advantage over palonosetron monotherapy [15]. Sadhoo et al. evaluated different antiemetic regimens in patients undergoing laparoscopic surgery and reported variable findings regarding the additional benefit of combination therapy [16].Blitz et al. investigated palonosetron alone and palonosetron combined with dexamethasone in patients undergoing laparoscopic surgery with increased emetogenic risk. Their study provided further evidence regarding the role of combination prophylaxis in preventing postoperative and post-discharge nausea and vomiting [18].

Comparison with other antiemetic studies

Tahir et al. evaluated palonosetron and dexamethasone in patients undergoing laparoscopic abdominal surgery and reported differences in their antiemetic effectiveness during the postoperative period [19]. Khan et al. also investigated palonosetron and dexamethasone in female patients undergoing laparoscopic cholecystectomy, contributing further evidence regarding the effectiveness of these agents in preventing PONV [20].Gugale and Bhalerao compared palonosetron with granisetron for postoperative antiemetic prophylaxis and evaluated the effectiveness of palonosetron in controlling postoperative symptoms [21]. Jain et al. investigated different doses of palonosetron in patients undergoing laparoscopic gynaecological surgery, providing additional evidence regarding its dose-related antiemetic effectiveness [22].

Park and Cho compared palonosetron with ondansetron in patients undergoing gynaecological laparoscopic surgery and evaluated their efficacy in preventing postoperative nausea and vomiting [23]. Gan emphasized the importance of appropriate antiemetic prophylaxis and multimodal strategies in reducing the burden of PONV [24].

These studies collectively highlight the importance of selecting appropriate antiemetic agents according to patient risk factors, type of surgery and anaesthetic technique.

Postoperative nausea and vomiting severity

In the present study, assessment of postoperative symptom grades showed that Grade 0 was observed in 34 patients (68%) in Group PD and 33 patients (66%) in Group P. Grade 1 was observed in 3 patients (6%) in each group. Grade 3 was reported in 12 patients (24%) in Group PD and 14 patients (28%) in Group P, while Grade 4 was observed in one patient (2%) in Group PD.The distribution of postoperative symptom grades was broadly comparable between the two groups. Although the combination group demonstrated a slightly higher proportion of patients without symptoms and a lower proportion of patients with Grade 3 symptoms, the difference was not statistically significant.

These findings suggest that both regimens provided comparable postoperative symptom control. However, the interpretation of symptom severity should be based on the grading system used in the original study proforma.

Haemodynamic parameters

Haemodynamic stability is an important consideration when selecting prophylactic antiemetic medications. In the present study, heart rate, systolic blood pressure and diastolic blood pressure were

monitored during the perioperative period. The haemodynamic parameters remained comparable between the two groups, without any clinically significant differences.

Palonosetron has a relatively favourable safety profile and is generally well tolerated when administered in recommended doses [7–9]. Dexamethasone is also commonly used as a single perioperative dose for antiemetic prophylaxis [10,11]. The comparable haemodynamic findings in the present study suggest that both regimens were well tolerated in the studied population.

Overall interpretation

The present study demonstrated that intravenous palonosetron alone and palonosetron combined with dexamethasone were effective prophylactic regimens in patients undergoing laparoscopic cholecystectomy. Although the combination group showed numerically lower incidences of postoperative nausea, retching, vomiting and rescue antiemetic requirement, none of these differences was statistically significant.

The findings are consistent with studies by Ghosh et al. and Chatterjee et al., which demonstrated comparable efficacy between palonosetron alone and its combination with dexamethasone [14,15]. However, other studies have reported improved antiemetic outcomes with combination therapy [17,18]. These differences indicate that the additional benefit of dexamethasone may depend on patient characteristics, baseline PONV risk, anaesthetic technique, timing of drug administration and postoperative observation period.

Therefore, the present study suggests that palonosetron alone is a reasonable prophylactic option for patients undergoing laparoscopic cholecystectomy. Although the addition of dexamethasone demonstrated a numerical reduction in postoperative symptoms, a statistically significant improvement was not established. Further studies involving larger sample sizes and different risk categories are required to determine the additional clinical benefit of combination therapy.

CONCLUSION

The present study concluded that both intravenous palonosetron alone and palonosetron combined with dexamethasone were effective in preventing postoperative nausea and vomiting in patients undergoing laparoscopic cholecystectomy. Although the combination group showed a numerically lower incidence of nausea (18% vs 28%), retching (8% vs 12%), vomiting (16% vs 28%) and rescue antiemetic requirement (24% vs 28%), the differences were not statistically significant. Therefore, the addition of dexamethasone did not demonstrate a statistically significant improvement over palonosetron alone.

LIMITATIONS OF THE STUDY

1. The study was conducted in a single centre with a relatively small sample size of 100 patients.
2. The study was limited to patients undergoing laparoscopic cholecystectomy, limiting generalisation to other surgical procedures.
3. The postoperative observation period may not have been sufficient to assess all delayed episodes of PONV.
4. Individual patient-related risk factors and variations in susceptibility to PONV may have influenced the outcomes.
5. Larger multicentric studies with extended postoperative follow-up are required to establish the comparative efficacy of both regimens more conclusively.

DECLARATIONS:

Conflicts of interest: There is no any conflict of interest associated with this study

Consent to participate: There is consent to participate.

Consent for publication: There is consent for the publication of this paper.

Authors' contributions: Author equally contributed the work.

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