

Comparison of Efficacy of Palonosetron-Dexamethasone Combination with Palonosetron Alone or Dexamethasone Alone for Prophylaxis Against Post-Operative Nausea and Vomiting in Patients Undergoing Laparoscopic Abdominal and Pelvic Surgeries

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Abstract

Background: Postoperative nausea and vomiting (PONV) is a common complication following laparoscopic surgery. This study compared the efficacy of palonosetron-dexamethasone combination with palonosetron or dexamethasone alone for PONV prophylaxis.

Materials and Methods: This prospective, randomised, double-blind study included 135 patients undergoing elective laparoscopic abdominal and pelvic surgeries, randomly allocated into three groups (n=45 each). Group PD received palonosetron 0.075 mg with dexamethasone 8 mg, Group P received palonosetron 0.075 mg, and Group D received dexamethasone 8 mg intravenously. PONV incidence, severity and rescue antiemetic requirements were assessed over 24 hours postoperatively.

Results: Baseline characteristics were comparable across groups. PONV incidence was significantly lower in Group PD (4.4%) than in Groups P (22.2%) and D (28.9%) at 1 hour (p=0.005). Similar findings were observed at 2 hours (4.4%, 15.6% and 26.7%, respectively; p=0.010). Rescue antiemetic requirements were significantly lower in Group PD at 1 hour (p<0.001) and 2 hours (p=0.010). Differences at 6 hours were statistically insignificant.

Conclusion: Palonosetron-dexamethasone combination demonstrated greater efficacy in preventing early PONV and reducing rescue antiemetic requirements compared with either drug alone.

Keywords: Palonosetron, Dexamethasone, PONV, Laparoscopic surgery, Antiemetic prophylaxis.

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Introduction

Postoperative nausea and vomiting (PONV) remains one of the most common and distressing complications following anaesthesia and surgery, second only to postoperative pain in terms of patient discomfort. Despite advances in anaesthetic techniques and pharmacological prophylaxis, PONV continues to be a significant challenge in modern anaesthesia practice. Its incidence is estimated to be approximately 20–30% in the general surgical population and may reach 80% among high-risk patients [1,2].

PONV adversely affects postoperative recovery and patient satisfaction and may lead to dehydration, electrolyte imbalance, pulmonary aspiration, wound dehiscence, delayed mobilisation, prolonged hospitalisation and increased healthcare costs [1,3]. Patients undergoing

laparoscopic abdominal and pelvic surgeries are particularly susceptible to PONV due to pneumoperitoneum, carbon dioxide insufflation, peritoneal stretching and manipulation of abdominal and pelvic organs. Additional contributing factors include volatile anaesthetic agents, perioperative opioid administration and prolonged surgical duration. Female sex, non-smoking status, previous history of PONV and motion sickness are recognised independent risk factors [2,3].

The pathophysiology of PONV is multifactorial, involving several neurotransmitter pathways, including serotonin (5-HT₃), dopamine (D₂), histamine (H₁), acetylcholine (M₁) and substance P (neurokinin-1). Consequently, multimodal antiemetic prophylaxis targeting different receptor

pathways is increasingly recommended, particularly in high-risk patients [3,4]. Palonosetron is a second-generation, highly selective 5-HT₃ receptor antagonist with greater receptor-binding affinity and a substantially longer elimination half-life of approximately 40 hours compared with conventional first-generation agents such as ondansetron and granisetron [5,6]. Its distinctive pharmacological properties provide prolonged antiemetic activity, making it effective in preventing both early and delayed PONV. However, its action is predominantly limited to the serotonergic pathway, which may restrict its effectiveness as a single agent in patients with multiple emetic risk factors [5,6]. Dexamethasone, a synthetic glucocorticoid, is another widely used and cost-effective antiemetic agent. Although its exact mechanism remains incompletely understood, its antiemetic activity is attributed to inhibition of prostaglandin synthesis, reduction of inflammatory mediators and modulation of central and peripheral emetic pathways [7]. Owing to its different mechanism of action and prolonged duration of effect, dexamethasone is frequently combined with 5-HT₃ receptor antagonists to improve prophylactic efficacy [4,7]. The combination of palonosetron and dexamethasone offers a multimodal approach by targeting different emetic pathways, potentially providing superior and sustained protection compared with either agent alone. Previous studies involving laparoscopic procedures have reported reduced PONV incidence and rescue antiemetic requirements with combination therapy; however, findings remain inconsistent regarding its additional benefit over monotherapy [8,9]. The rationale behind this combination therapy lies in the synergistic effect of targeting different emetic pathways, potentially leading to a lower incidence of PONV, enhanced patient comfort, and faster post-operative recovery [10]. Although various studies have evaluated antiemetic prophylaxis in laparoscopic cholecystectomy, comparative evidence encompassing a broader spectrum of laparoscopic abdominal and pelvic surgeries remains important. Variations in surgical procedures, patient characteristics and anaesthetic exposure may influence antiemetic efficacy. Therefore, the present study was designed to compare the efficacy of palonosetron–dexamethasone combination therapy with palonosetron alone and dexamethasone alone for prophylaxis against PONV in patients undergoing laparoscopic abdominal and pelvic surgeries.

Materials and Methods

This prospective, randomised, double-blind, controlled study was conducted at Paras Hospital, Gurugram, a tertiary healthcare centre, over a period of one year. The study was initiated after

obtaining approval from the Institutional Ethics Committee and Scientific Committee.

Study Population: A total of 135 patients of either sex, aged 18–60 years, belonging to American Society of Anesthesiologists Physical Status (ASA-PS) I or II and scheduled for elective laparoscopic abdominal and pelvic surgeries under general anaesthesia were enrolled.

Inclusion Criteria: Patients aged 18–60 years, classified as ASA-PS I or II, undergoing elective laparoscopic surgery and having a simplified Apfel risk score ≤ 2 were included.

Exclusion Criteria: Patients with ASA-PS III/IV, BMI greater than 30 kg/m², Apfel score greater than 2, emergency surgery, known hypersensitivity to study medications, renal or hepatic diseases, intestinal pathologies, immunocompromised status or chronic steroid therapy were excluded. Patients receiving oral hypoglycaemics, antidepressants, anticonvulsants, antipsychotics or oral contraceptives were also excluded, along with those who had received antiemetics within 24 hours, chemotherapy within four weeks or emetogenic radiotherapy within eight weeks before surgery.

Randomisation, Allocation and Blinding:

Eligible patients were randomly allocated into three equal groups (n=45 each) using a computer-generated randomisation sequence and opaque sealed envelopes. An independent investigator prepared the study medications in identical 5 mL syringes, maintaining blinding of both patients and the anaesthesiologist responsible for outcome assessment.

Study Groups and Drug Administration: Patients received one of the following prophylactic regimens:

- Group PD (n=45): Palonosetron 0.075 mg + dexamethasone 8 mg intravenously.
- Group P (n=45): Palonosetron 0.075 mg intravenously.
- Group D (n=45): Dexamethasone 8 mg intravenously.

All study medications were diluted to a total volume of 5 mL using normal saline and administered slowly intravenously over 30 seconds immediately before induction of anaesthesia.

Preoperative Assessment: All patients underwent detailed pre-anaesthetic evaluation, including clinical history, physical examination and routine investigations. PONV risk stratification was performed using the simplified Apfel scoring system. Patients were instructed to maintain a minimum fasting period of eight hours and received intravenous pantoprazole 40 mg on the morning of surgery.

Standardised Anaesthetic Technique: All participants received a uniform anaesthetic protocol. Premedication included intravenous glycopyrrolate 0.004 mg/kg, midazolam 0.02 mg/kg and fentanyl 2 µg/kg. Anaesthesia was induced using propofol 2 mg/kg, and endotracheal intubation was facilitated with atracurium 0.5 mg/kg. Anaesthesia was maintained with isoflurane in a mixture of 50% oxygen and 50% nitrous oxide under controlled mechanical ventilation.

Standard intraoperative monitoring included five-lead ECG, SpO₂, EtCO₂ and non-invasive blood pressure. Intravenous paracetamol 1 g and diclofenac 75 mg were administered for analgesia.

At the completion of surgery, neuromuscular blockade was reversed using neostigmine 0.05 mg/kg and glycopyrrolate 0.008 mg/kg, followed by extubation after ensuring adequate recovery.

Postoperative Monitoring and Follow-up: Following extubation, patients were transferred to

the post-anaesthesia care unit (PACU), where vital parameters were monitored continuously for two hours. After fulfilling PACU discharge criteria, patients were shifted to their respective wards. Postoperative nausea and vomiting were assessed by a blinded anaesthesiologist at 0, 1, 2, 6, 12 and 24 hours following surgery.

Outcome Measures

Primary Outcome: The primary outcome was the incidence of postoperative nausea and vomiting (PONV) during the first 24 postoperative hours and the duration of antiemetic protection provided by the study medications.

Secondary Outcome: The secondary outcome was the requirement for rescue antiemetic medication during the first 24 postoperative hours.

Assessment of PONV: PONV was assessed using a three-point grading system:

Grade	Clinical interpretation
PONV 1	No nausea or vomiting
PONV 2	Nausea without vomiting
PONV 3	Nausea with vomiting

Failure of prophylaxis was defined as any episode of nausea, retching or vomiting and/or the requirement for rescue antiemetic medication. Intravenous metoclopramide 10 mg was administered as the rescue antiemetic when required. The incidence of PONV and number of rescue antiemetic doses were recorded at each predefined observation interval.

Statistical Analysis: Data were analysed using SPSS version 22.0 (IBM Corp., Armonk, NY, USA) according to the intention-to-treat principle. Continuous variables were expressed as mean ± standard deviation, while categorical variables were presented as frequencies and percentages. One-way ANOVA followed by Tukey's post hoc test was used to compare continuous variables, whereas the Chi-square test or Fisher's exact test was applied to categorical variables, as appropriate. Kaplan–Meier survival analysis and the log-rank test were used to compare time to the first PONV episode.

Cox proportional hazards regression was used to adjust for potential confounders, including age, sex, ASA grade and duration of surgery. Effect sizes were expressed as odds ratios or Cohen's d, wherever applicable. Subgroup analyses were performed according to age, sex, ASA grade and duration of anaesthesia. A two-tailed p-value less than 0.05 was considered statistically significant.

Results

A total of 135 patients undergoing elective laparoscopic abdominal and pelvic surgeries were randomly allocated into three equal groups: Group PD (palonosetron–dexamethasone, n=45), Group P (palonosetron, n=45), and Group D (dexamethasone, n=45). Baseline characteristics were comparable across the three groups. The mean age was 40.7 ± 8.4, 42.3 ± 7.5, and 42.6 ± 6.9 years in Groups PD, P, and D, respectively (p=0.451). Male patients predominated in all groups (68.9%, 64.4%, and 66.7%; p=0.886). No significant intergroup differences were observed in BMI (p=0.782), ASA-PS classification (p=0.977), or duration of anaesthesia (p=0.524) (Table 1).

The incidence of PONV was significantly different among the groups at 1 hour (4.4%, 22.2%, and 28.9%; p=0.005) and 2 hours (4.4%, 15.6%, and 26.7%; p=0.010), with the lowest incidence observed in Group PD. At 6 hours, the corresponding incidences were 6.7%, 13.3%, and 22.2%, without a statistically significant difference (p=0.096). No PONV episodes occurred at 0, 12, or 24 hours (Table 2, Figure 1). At 1 hour, the proportion of patients with a PONV score of 1 (absence of nausea and vomiting) was 95.6% in Group PD, 77.8% in Group P, and 71.1% in Group D (p=0.005). The corresponding proportions at 2 hours were 95.6%, 84.4%, and 73.3% (p=0.010), and at 6 hours were 93.3%, 86.7%, and 77.8% (p=0.096). All reported PONV episodes were

limited to score 2 (nausea without vomiting), with no score 3 events recorded (Table 3, Figure 2).

At 1 hour, rescue antiemetics were required by 0%, 22.2%, and 28.9% of patients in Groups PD, P, and D, respectively ($p < 0.001$). At 2 hours, the corresponding requirements were 4.4%, 15.6%, and 26.7% ($p = 0.010$), while at 6 hours they were 6.7%, 13.3%, and 22.2% ($p = 0.096$). No rescue antiemetic administration was recorded at 0, 12, or 24 hours (Table 4, Figure 3).

Kaplan–Meier analysis demonstrated significant overall intergroup differences in both time to first PONV episode and time to first rescue antiemetic administration (log-rank $p = 0.002$ for each). The reported median time for both outcomes was 6.0 hours (95% CI: 1.0–11.0 hours) in Group D, whereas the median was not reached in Groups PD and P.

Table 1: Comparison of baseline demographic and clinical characteristics among the three study groups (N=135)

Characteristic	Group PD (n=45)	Group P (n=45)	Group D (n=45)	p-value	Statistical Test
Age category (years), n (%)				0.885	Chi-square test
≤30	2 (4.4)	2 (4.4)	3 (6.7)		
31–40	18 (40.0)	18 (40.0)	14 (31.1)		
41–50	20 (44.4)	20 (44.4)	23 (51.1)		
>50	5 (11.1)	5 (11.1)	5 (11.1)		
Age (years), mean ± SD	40.7 ± 8.4	42.3 ± 7.5	42.6 ± 6.9	0.451	One-way ANOVA
Sex, n (%)				0.886	Chi-square test
Male	31 (68.9)	29 (64.4)	30 (66.7)		
Female	14 (31.1)	16 (35.6)	15 (33.3)		
BMI (kg/m ²), mean ± SD	26.2 ± 2.8	26.4 ± 2.4	26.6 ± 2.5	0.782	One-way ANOVA
ASA-PS, n (%)				0.977	Chi-square test
ASA I	23 (51.1)	22 (48.9)	23 (51.1)		
ASA II	22 (48.9)	23 (51.1)	22 (48.9)		
Duration of anaesthesia (min), mean ± SD	93.7 ± 18.9	89.3 ± 17.5	91.1 ± 18.2	0.524	One-way ANOVA

Table 2: Comparison of postoperative nausea and vomiting incidence at different postoperative intervals

Postoperative interval	Group PD (n=45)	Group P (n=45)	Group D (n=45)	p-value	Statistical Test
0 hour	0 (0.0)	0 (0.0)	0 (0.0)	1.000	Not applicable*
1 hour	2 (4.4)	10 (22.2)	13 (28.9)	0.005	Fisher–Freeman–Halton exact test
2 hours	2 (4.4)	7 (15.6)	12 (26.7)	0.010	Fisher–Freeman–Halton exact test
6 hours	3 (6.7)	6 (13.3)	10 (22.2)	0.096	Fisher–Freeman–Halton exact test
12 hours	0 (0.0)	0 (0.0)	0 (0.0)	1.000	-
24 hours	0 (0.0)	0 (0.0)	0 (0.0)	1.000	-

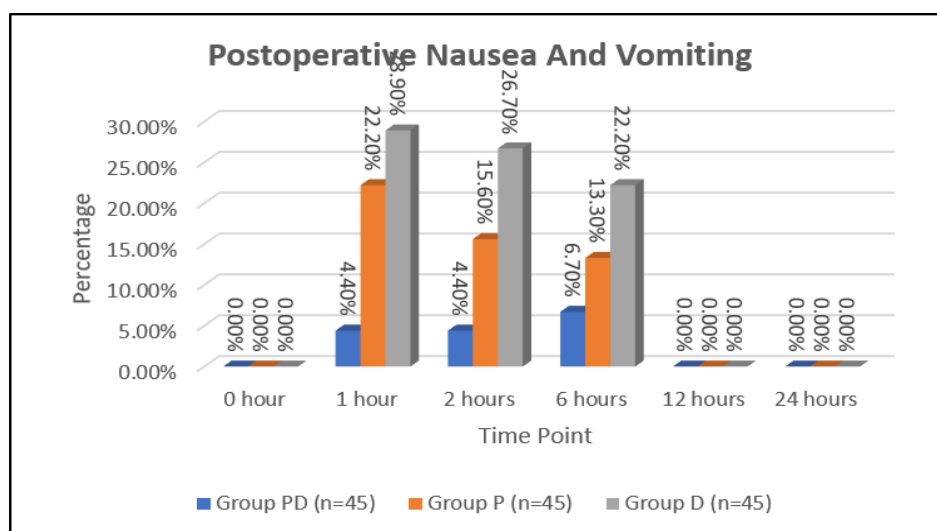
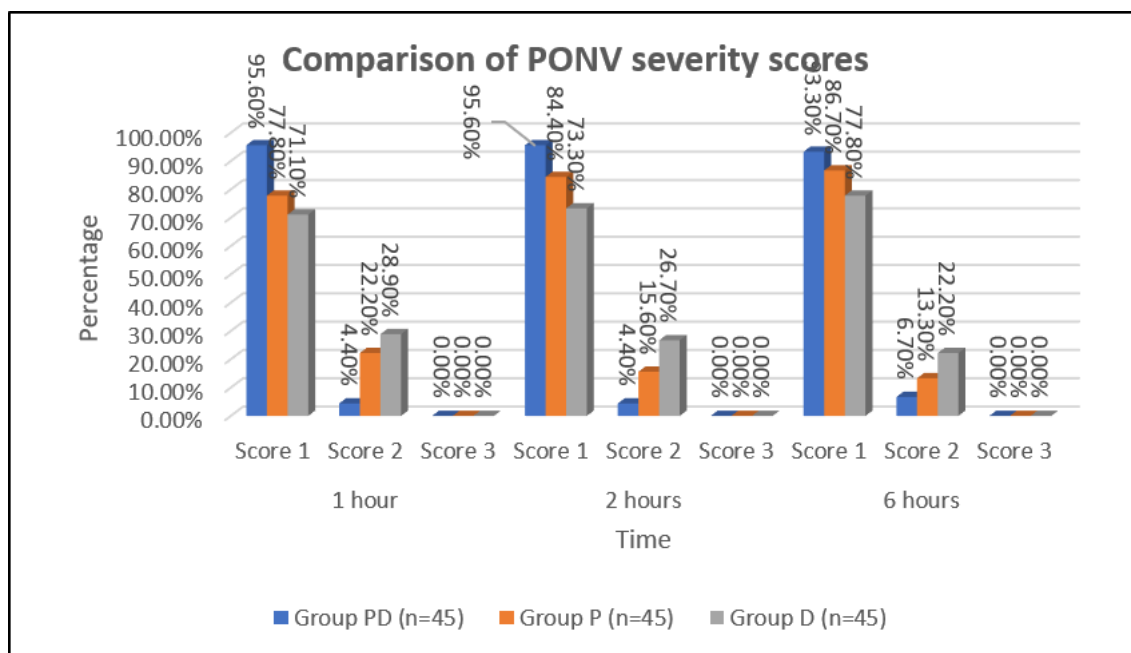


Figure 1: Comparison of postoperative nausea and vomiting incidence at different postoperative intervals

Table 3: Comparison of PONV severity scores among the three study groups

Time interval	PONV score	Group PD (n=45)	Group P (n=45)	Group D (n=45)	p-value	Statistical Test
1 hour	Score 1	43 (95.6)	35 (77.8)	32 (71.1)	0.005	Fisher–Freeman–Halton exact test
	Score 2	2 (4.4)	10 (22.2)	13 (28.9)		
	Score 3	0 (0.0)	0 (0.0)	0 (0.0)		
2 hours	Score 1	43 (95.6)	38 (84.4)	33 (73.3)	0.010	Fisher–Freeman–Halton exact test
	Score 2	2 (4.4)	7 (15.6)	12 (26.7)		
	Score 3	0 (0.0)	0 (0.0)	0 (0.0)		
6 hours	Score 1	42 (93.3)	39 (86.7)	35 (77.8)	0.096	Fisher–Freeman–Halton exact test
	Score 2	3 (6.7)	6 (13.3)	10 (22.2)		
	Score 3	0 (0.0)	0 (0.0)	0 (0.0)		

**Figure 2: Comparison of PONV severity scores among the three study groups****Table 4: Comparison of rescue antiemetic requirements among the three study groups**

Postoperative interval	Group PD (n=45)	Group P (n=45)	Group D (n=45)	p-value	Statistical Test
0 hour	0 (0.0)	0 (0.0)	0 (0.0)	1.000	-
1 hour	0 (0.0)	10 (22.2)	13 (28.9)	<0.001	Fisher–Freeman–Halton exact test
2 hours	2 (4.4)	7 (15.6)	12 (26.7)	0.010	Fisher–Freeman–Halton exact test
6 hours	3 (6.7)	6 (13.3)	10 (22.2)	0.096	Fisher–Freeman–Halton exact test
12 hours	0 (0.0)	0 (0.0)	0 (0.0)	1.000	-
24 hours	0 (0.0)	0 (0.0)	0 (0.0)	1.000	-

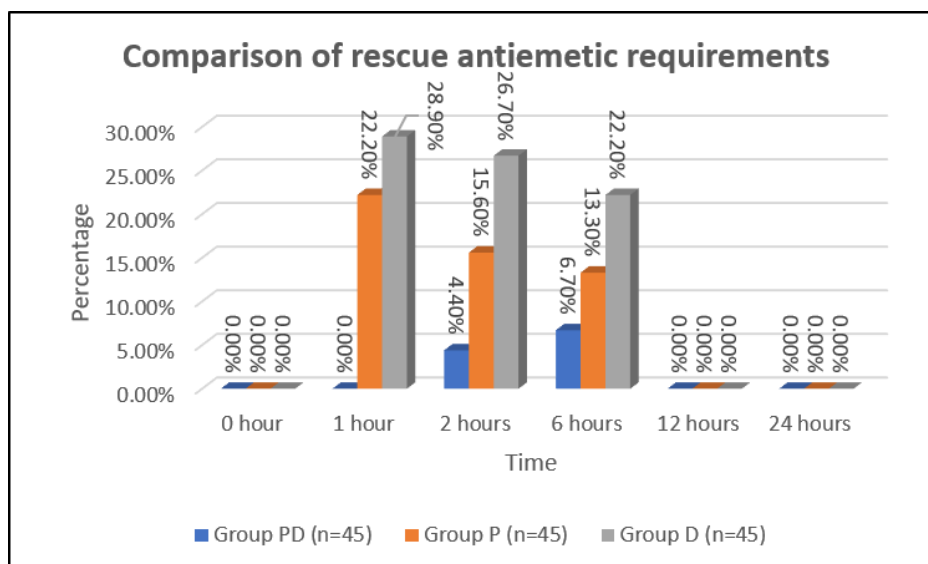


Figure 3: Comparison of rescue antiemetic requirements among the three study groups

Discussion

Postoperative nausea and vomiting (PONV) remains an important complication of anaesthesia, contributing to patient discomfort, delayed recovery, prolonged hospital stay and increased healthcare utilisation [2]. The present study compared palonosetron–dexamethasone combination (PD) with palonosetron alone (P) and dexamethasone alone (D) for PONV prophylaxis in patients undergoing laparoscopic abdominal and pelvic surgeries. The principal finding was that combination therapy reduced PONV and rescue antiemetic requirements, particularly during the early postoperative period. The three groups were comparable with respect to age, sex, BMI, ASA-PS classification and duration of anaesthesia, with no statistically significant baseline differences. This comparability is important because several patient- and anaesthesia-related characteristics influence PONV risk [11]. Apfel et al. identified female sex, non-smoking status, previous PONV or motion sickness and postoperative opioid use as major predictors of PONV [1]. Thus, comparable baseline characteristics reduced the potential influence of these confounding factors. At 1 hour, PONV occurred in 4.4% of patients in Group PD compared with 22.2% in Group P and 28.9% in Group D ($p=0.005$). At 2 hours, the corresponding incidences were 4.4%, 15.6% and 26.7%, respectively ($p=0.010$). Although PONV remained lower in Group PD at 6 hours (6.7%) compared with Groups P (13.3%) and D (22.2%), the difference was not statistically significant ($p=0.096$). No PONV was recorded at 12 or 24 hours in any group. These findings are consistent with the meta-analysis by Xiong et al., who reported that palonosetron–dexamethasone significantly reduced PONV compared with palonosetron alone (OR=0.51, 95% CI: 0.39–0.67)

and dexamethasone alone (OR=0.44, 95% CI: 0.31–0.62) [12].

Their analysis of 10 randomised controlled trials involving 1,827 patients also demonstrated better protection with combination therapy at 24 and 48 hours. Although later PONV was absent in our study, the significantly lower early PONV incidence similarly supports the benefit of combination prophylaxis. Bala et al. studied 150 patients undergoing laparoscopic cholecystectomy and reported a significantly lower 24-hour PONV incidence with palonosetron–dexamethasone (13.3%) than with palonosetron (33.3%) or dexamethasone (40%) alone [13]. They also reported lower nausea, vomiting and rescue antiemetic requirements with combination therapy. These observations are in agreement with the present study, although differences in absolute incidence may reflect variations in patient characteristics, surgical procedures, anaesthetic techniques and baseline PONV risk. PONV severity scores also favoured combination therapy. At 1 hour, 95.6% of patients in Group PD remained free from nausea and vomiting compared with 77.8% in Group P and 71.1% in Group D ($p=0.005$). At 2 hours, the corresponding proportions were 95.6%, 84.4% and 73.3% ($p=0.010$). At 6 hours, 93.3%, 86.7% and 77.8% of patients, respectively, remained symptom-free, although this difference was not significant. Thus, combination prophylaxis provided better control of early postoperative symptoms.

A similar pattern was observed for rescue antiemetic requirements. At 1 hour, none of the patients in Group PD required rescue antiemetics compared with 22.2% in Group P and 28.9% in Group D ($p<0.001$). At 2 hours, rescue treatment was required in 4.4%, 15.6% and 26.7% of patients, respectively ($p=0.010$). Park et al.

similarly reported significantly lower rescue antiemetic use with palonosetron–dexamethasone (13.3%) compared with palonosetron (37.8%) and dexamethasone (35.6%) and observed a higher complete response rate with combination therapy [14]. These findings support the clinical benefit of multimodal prophylaxis in reducing additional antiemetic requirements. Kaplan–Meier analysis demonstrated significant overall differences in time to first PONV episode and time to first rescue antiemetic administration (both log-rank $p=0.002$). The median event time was reported as 6 hours in Group D, whereas the median was not reached in Groups PD and P. Kim et al., however, found no significant difference in time to first PONV between palonosetron–dexamethasone and dexamethasone ($p=0.447$) in patients undergoing thyroidectomy [15]. Nevertheless, they reported significantly lower 24-hour PONV (22.2% vs. 47.2%) and rescue antiemetic use (13.9% vs. 36.1%) with combination therapy. Differences in surgical populations and baseline emetic risk may explain the variation between studies. The greater efficacy of combination therapy has a plausible pharmacological basis. Palonosetron is a second-generation 5-HT₃ receptor antagonist with high receptor affinity and a prolonged half-life compared with first-generation agents [4]. Its allosteric receptor binding and positive cooperativity may contribute to sustained antiemetic activity [16]. Dexamethasone acts through complementary mechanisms, including modulation of serotonin release, inhibition of prostaglandin synthesis and reduction of inflammatory and central emetic signalling [16,17].

Combining these agents therefore targets different components of the emetic pathway and may explain the improved prophylactic efficacy observed. The strengths of the present study include its prospective, randomised, double-blind design, standardised anaesthetic technique and direct comparison of combination therapy with both individual drugs. However, the study was single-centre with a relatively modest sample size and included only ASA-PS I–II patients with Apfel scores ≤ 2 . Follow-up was limited to 24 hours; therefore, delayed PONV beyond this period could not be evaluated. Adverse effects and cost-effectiveness were also not systematically assessed. Tang et al. highlighted the relevance of economic evaluation of combination antiemetic strategies in laparoscopic surgery [18]. Future multicentre studies with larger and higher-risk populations, longer follow-up and assessment of safety and cost-effectiveness are warranted.

Conclusion

The palonosetron–dexamethasone combination demonstrated greater efficacy in preventing early postoperative nausea and vomiting compared with

palonosetron or dexamethasone alone in patients undergoing laparoscopic abdominal and pelvic surgeries. Combination therapy significantly reduced PONV incidence and rescue antiemetic requirements during the first two postoperative hours. These findings support its use as an effective multimodal strategy for PONV prophylaxis.

Limitations

The study was limited by its single-centre design, relatively small sample size and inclusion of patients with an Apfel score ≤ 2 , potentially limiting generalisability. Follow-up was restricted to 24 hours, and delayed PONV, drug-related adverse effects and cost-effectiveness were not systematically evaluated.

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