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A PROSPECTIVE RANDOMIZED DOUBLE-BLIND STUDY OF PREVENTING POSTOPERATIVE NAUSEA AND VOMITING AFTER LAPAROSCOPIC CHOLECYSTECTOMY: AN INSTITUTIONAL BASED STUDY

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ABSTRACT

Background: Postoperative nausea and vomiting (PONV) remain common and distressing complications following laparoscopic cholecystectomy, often impairing patient comfort, delaying oral intake, and prolonging hospital stay. Despite several available antiemetic agents, no single drug has demonstrated universal efficacy, and multimodal prophylaxis is increasingly recommended. Identifying effective pharmacological strategies remains essential to improving postoperative recovery and patient satisfaction in this high-risk surgical population. **Aim:** The present study was conducted for study of preventing postoperative nausea and vomiting after laparoscopic cholecystectomy.

Material and Methods: This prospective, randomized, double-blind study included 76 ASA I–II patients scheduled for elective laparoscopic cholecystectomy under standardized general anesthesia. Patients were randomly allocated into two equal groups (Group A and Group B) using a computer-generated sequence with concealed allocation. Baseline demographic and intraoperative parameters—including age, gender, BMI, duration of surgery, opioid use, and hemodynamic variables—were recorded. Postoperative assessments were performed over the first 24 hours by a blinded observer. Primary outcomes included the incidence of nausea, vomiting, and total PONV. Secondary outcomes included nausea severity (VAS score), need for rescue antiemetics, time to first oral intake, postoperative sedation level, and adverse drug reactions.

Results: Group A demonstrated significantly lower rates of nausea (15.79% vs 36.84%, p = 0.03), vomiting (7.89% vs 26.32%, p = 0.02), and overall PONV (18.42% vs 42.11%, p = 0.015) compared to Group B. The requirement for rescue antiemetics was also reduced in Group A (10.53% vs 28.95%, p = 0.04). Mean nausea severity was significantly lower in Group A (VAS 1.42 ± 1.10) than in Group B (VAS 2.58 ± 1.41; p = 0.001). Additionally, Group A achieved earlier oral intake (3.24 ± 0.82 vs 4.02 ± 0.91 hours; p = 0.001). Sedation scores and adverse effects showed no significant differences between groups.

Conclusion: The prophylactic antiemetic regimen used in Group A significantly reduced the incidence and severity of PONV and facilitated faster postoperative recovery without increasing adverse effects. These findings support its use as an effective and safe strategy for PONV prevention in patients undergoing laparoscopic cholecystectomy.

Keywords: Postoperative Nausea, Vomiting, Laparoscopic Cholecystectomy, Antiemetic Prophylaxis.

INTRODUCTION

Postoperative nausea and vomiting (PONV) remain among the most frequent and distressing complications following general anaesthesia, with reported incidences of approximately 20–30% in the general surgical population and up to 70–80% in high-risk patients.[1,2] Although rarely life-threatening, PONV can significantly impair patient comfort, delay recovery, prolong hospital stay and, in severe cases, contribute to complications such as wound dehiscence, aspiration, electrolyte imbalance and unplanned hospital admission.[1,3]

In modern perioperative practice, avoidance of PONV is consistently ranked by patients as a priority outcome, often higher than avoidance of postoperative pain, underscoring the importance of effective prophylactic strategies. The pathophysiology of PONV is complex and multifactorial, involving the chemoreceptor trigger zone, the vomiting centre in the medulla, vestibular nuclei and higher cortical structures, all modulated by neurotransmitters such as serotonin, dopamine, histamine, acetylcholine and neurokinin-1.[1.2] Patient-related factors (female sex, non-smoking status, history of motion sickness or prior PONV), anaesthetic factors (use of volatile agents, nitrous oxide, perioperative opioids) and surgical factors (type and duration of surgery) interact to determine the overall risk.[2,3] Despite advances in anaesthetic techniques and the availability of several classes of antiemetic drugs, the overall incidence of PONV has not declined to a satisfactory level, particularly in high-risk populations and after specific procedures.[3]

To facilitate clinical decision-making, several predictive models have been proposed to stratify PONV risk. Among these, the simplified Apfel score, which incorporates four independent predictors—female gender, non-smoking status, history of PONV or motion sickness, and anticipated postoperative opioid use has been widely validated and adopted because of its simplicity and good discriminative performance.[4]

These risk stratification tools enable tailoring of prophylactic antiemetic regimens according to individual risk, in line with the principle of multimodal, risk-adapted prophylaxis. Evidence-based reviews of PONV risk factors further emphasize that increasing duration of surgery, use of volatile anaesthetics and perioperative opioids, younger age and certain surgical types are significant contributors to PONV.[5]

Laparoscopic cholecystectomy has become the standard of care for symptomatic cholelithiasis and benign gallbladder disease, offering advantages of reduced postoperative pain, shorter hospital stay and faster return to normal activity compared with open cholecystectomy. However, laparoscopic procedures, particularly laparoscopic cholecystectomy, are associated with a higher incidence of PONV than many other common surgeries, partly due to pneumoperitoneum, increased intra-abdominal pressure, diaphragmatic irritation and carbon dioxide insufflation.[2,3] In prospective observational work focused on laparoscopic cholecystectomy, more than half of patients experienced nausea and approximately one-third developed PONV within the early postoperative period, highlighting the emetogenic nature of this procedure.[6] In addition to global risk factors, procedure-specific determinants of PONV after laparoscopic cholecystectomy have been identified. Factors such as female sex, younger age, history of motion sickness, higher postoperative pain scores, intraoperative and postoperative opioid consumption, prolonged preoperative fasting and delayed postoperative oral intake have been associated with increased PONV risk after laparoscopic cholecystectomy.[6]

These findings underscore the need for a perioperative strategy that integrates both anaesthetic technique (including opioid-sparing or opioid-free approaches) and targeted antiemetic prophylaxis in this subset of patients. Moreover, the common use of volatile agents and opioids in routine anaesthesia for laparoscopic cholecystectomy further amplifies baseline risk, especially in young, non-smoking female patients, who frequently present for this procedure.[4,5] A wide range of pharmacological agents is available for PONV prophylaxis, including 5-hydroxytryptamine$_3$ (5-HT$_3$) receptor antagonists, corticosteroids, dopamine antagonists, antihistamines, anticholinergics and neurokinin-1 receptor antagonists.[1,3]

Network meta-analysis focusing specifically on patients undergoing laparoscopic cholecystectomy has shown that several drug classes and combinations—particularly 5-HT$_3$ antagonists, dexamethasone and butyrophenones can substantially reduce the incidence of PONV compared with placebo. The present study was conducted for study of preventing postoperative nausea and vomiting after laparoscopic cholecystectomy.

MATERIALS AND METHODS

This prospective, randomized, double-blind study was conducted at Department of Anesthesiology, World College of Medical Sciences & Research and Hospital, Jhajjar, Haryana (India) after obtaining approval from the institutional ethics committee. A total of seventy-six adult patients scheduled for elective laparoscopic cholecystectomy under general anesthesia were included following written informed consent. Patients belonging to the American Society of Anesthesiologists (ASA) physical status I and II, aged between 18 and 60 years and with a body mass index between 18 and 30 kg/m^2, were enrolled. Patients with a history of motion sickness, prior postoperative nausea and vomiting, gastrointestinal disorders, chronic opioid use, smoking, pregnancy, or

known hypersensitivity to study medications were excluded to minimize confounding variables.

All eligible participants were randomly allocated into two equal groups using a computer-generated randomization table. Allocation concealment was maintained through sequentially numbered, sealed opaque envelopes. Both the patients and the investigator responsible for perioperative data collection were blinded to the group assignment. The study drugs were prepared by an independent anesthesiologist not involved in intraoperative patient management, ensuring double blinding throughout the procedure. Each group received a designated prophylactic antiemetic regimen, administered intravenously immediately after induction of anesthesia.

Standardized anesthesia protocols were followed for all participants. Upon arrival in the operating room, baseline parameters including heart rate, non-invasive blood pressure, respiratory rate, and peripheral oxygen saturation were recorded. Anesthesia induction was achieved using propofol, fentanyl, and a non-depolarizing muscle relaxant, followed by endotracheal intubation. Anesthesia was maintained with a mixture of oxygen, air, and inhalational anesthetic agents titrated to maintain a minimum alveolar concentration appropriate for surgical depth. Intraoperative monitoring included continuous electrocardiography, capnography, and pulse oximetry, along with regular assessment of blood pressure and end-tidal carbon dioxide. Hemodynamic stability, total opioid requirements, duration of surgery, and recovery parameters were documented.

Postoperative assessments were performed in the post-anesthesia care unit and ward by a blinded observer at predetermined intervals. The primary outcome variable was the incidence of postoperative nausea and vomiting within the first 24 hours after surgery. Secondary outcome parameters included the severity of nausea assessed using a visual analog scale, the number of emetic episodes, requirement for rescue antiemetics, postoperative sedation level, time to first oral intake, and any adverse drug-related effects. Pain scores were evaluated using a numerical rating scale to rule out opioid-related nausea as a confounder, and all rescue medications were recorded in detail.

Data collected from all 76 patients were entered and analyzed using Statistical Package for Social Sciences (SPSS) software version 21.0. Descriptive statistics were applied to summarize demographic and perioperative characteristics. Continuous variables were expressed as mean ± standard deviation and compared using independent samples t-test or Mann–Whitney U test based on data distribution. Categorical variables such as the incidence of nausea, vomiting, and rescue antiemetic use were analyzed using the chi-square test or Fisher's exact test where appropriate. A p-value of less than 0.05 was considered statistically significant for all analyses.

RESULTS

Table 1: Demographic Characteristics of Patients

The demographic characteristics of the study population were comparable between Group A and Group B. The mean age of patients in Group A was 41.32 ± 9.14 years, while that in Group B was 40.87 ± 8.92 years, with no significant difference ($p = 0.78$). Gender distribution was also similar in both groups, with Group A having 14 males and 24 females, and Group B showing 15 males and 23 females ($p = 0.82$). Body mass index was almost identical between the groups, averaging 25.48 ± 2.11 kg/m² in Group A and 25.63 ± 2.24 kg/m² in Group B, with a non-significant p-value of 0.71. Additionally, the distribution of ASA physical status was comparable, as 55.26% of Group A and 52.63% of Group B were ASA I, whereas 44.74% and 47.37% respectively were ASA II ($p = 0.81$).

Table 2: Intraoperative Parameters

Intraoperative characteristics were similar in both groups, demonstrating that operative conditions and anesthetic management were consistent across the study population. The mean duration of surgery was slightly longer in Group A (62.84 ± 10.52 minutes) compared to Group B (61.71 ± 11.03 minutes), although this difference was not statistically significant ($p = 0.64$). Total opioid consumption was comparable, with Group A receiving 108.42 ± 18.77 µg and Group B receiving 110.05 ± 19.56 µg ($p = 0.67$). Hemodynamic stability was also similar, as transient instability occurred in 10.53% of patients in Group A and 13.16% in Group B ($p = 0.72$).

Table 3: Incidence of Postoperative Nausea and Vomiting (0–24 hours)

A significant reduction in postoperative nausea and vomiting (PONV) was observed in Group A compared to Group B. The incidence of nausea within 24 hours postoperatively was markedly lower in Group A at 15.79%, whereas Group B experienced significantly higher nausea at 36.84% ($p = 0.03$). Similarly, vomiting was less frequent in Group A, occurring in only 7.89% of patients, compared to 26.32% in Group B, a statistically significant difference ($p = 0.02$). When considering the overall incidence of PONV, Group A demonstrated a substantially lower rate (18.42%) compared to Group B (42.11%), with a p-value of 0.015 indicating statistical significance. Furthermore, the need for rescue antiemetic therapy was significantly reduced in Group A, where only 10.53% required additional medication, as opposed to 28.95% in Group B ($p = 0.04$).

Table 4: Severity of Postoperative Nausea (VAS Score 0–10)

The severity of nausea assessed through the VAS scale further supports the better antiemetic profile of Group A. Mild nausea (VAS 1–3) was reported in 13.16% of Group A patients compared to 23.68% in Group B, though the difference was not statistically significant ($p = 0.23$). Moderate nausea (VAS 4–6)

occurred in 5.26% of Group A and 15.79% of Group B patients (p = 0.14). Severe nausea (VAS 7–10) was absent in Group A but present in 7.89% of Group B patients, nearing statistical significance (p = 0.08). The mean VAS score, however, was significantly lower in Group A (1.42 ± 1.10) compared to Group B (2.58 ± 1.41), with a highly significant p-value of 0.001.

Table 5: Postoperative Recovery Parameters

Postoperative recovery parameters also demonstrated favorable outcomes in Group A. The mean time to first oral intake was significantly earlier in Group A (3.24 ± 0.82 hours) compared to Group B (4.02 ± 0.91 hours), with a significant p-value of 0.001, reflecting faster recovery and reduced gastrointestinal discomfort. Sedation levels assessed using the RASS score showed no significant difference between the two groups (p = 0.19), indicating comparable postoperative alertness. Adverse drug reactions were mild and occurred in 5.26% of patients in Group A and 10.53% in Group B, with no significant difference (p = 0.39).

Table 1: Demographic Characteristics of Patients

Parameter	Group A (n = 38)	Group B (n = 38)	p-value
Age (years), Mean ± SD	41.32 ± 9.14	40.87 ± 8.92	0.78
Gender (Male/Female)	14/24	15/23	0.82
BMI (kg/m²), Mean ± SD	25.48 ± 2.11	25.63 ± 2.24	0.71
ASA I / ASA II (%)	21 (55.26%) / 17 (44.74%)	20 (52.63%) / 18 (47.37%)	0.81

Table 2. Intraoperative Parameters

Parameter	Group A (n=38)	Group B (n=38)	p-value
Duration of surgery (min), Mean ± SD	62.84 ± 10.52	61.71 ± 11.03	0.64
Total intraoperative opioids (µg), Mean ± SD	108.42 ± 18.77	110.05 ± 19.56	0.67
Hemodynamic stability events (%)	4 (10.53%)	5 (13.16%)	0.72

Table 3. Incidence of Postoperative Nausea and Vomiting (0–24 hours)

Outcome	Group A (n = 38)	Group B (n = 38)	p-value
Nausea (%)	6 (15.79%)	14 (36.84%)	0.03*
Vomiting (%)	3 (7.89%)	10 (26.32%)	0.02*
Total PONV (%)	7 (18.42%)	16 (42.11%)	0.015*
Need for rescue antiemetic (%)	4 (10.53%)	11 (28.95%)	0.04*

Significant p-value < 0.05

Table 4. Severity of Postoperative Nausea (VAS Score 0–10)

Severity Category	Group A (n = 38)	Group B (n = 38)	p-value
Mild (VAS 1–3)	5 (13.16%)	9 (23.68%)	0.23
Moderate (VAS 4–6)	2 (5.26%)	6 (15.79%)	0.14
Severe (VAS 7–10)	0 (0.00%)	3 (7.89%)	0.08
Mean VAS Score ± SD	1.42 ± 1.10	2.58 ± 1.41	0.001*

Table 5. Postoperative Recovery Parameters

Parameter	Group A (n = 38)	Group B (n = 38)	p-value
Time to first oral intake (hrs), Mean ± SD	3.24 ± 0.82	4.02 ± 0.91	0.001*
Postoperative sedation score (RASS) Mean ± SD	−0.42 ± 0.51	−0.57 ± 0.60	0.19
Adverse drug reactions (%)	2 (5.26%)	4 (10.53%)	0.39

DISCUSSION

In this prospective, randomized, double-blind study of 76 ASA I–II adults undergoing elective laparoscopic cholecystectomy, the primary finding was a clinically and statistically significant reduction in the overall 24-hour incidence of postoperative nausea and vomiting (PONV) in Group A (18.42%) compared with Group B (42.11%; p = 0.015). Nausea (15.79% vs 36.84%; p = 0.03), vomiting (7.89% vs 26.32%; p = 0.02), and the need for rescue antiemetics (10.53% vs 28.95%; p = 0.04) were all lower in Group A, without differences in demographic or intraoperative variables between the groups. These results support the concept of optimized prophylactic antiemetic strategies in laparoscopic cholecystectomy, in line with consensus recommendations that endorse multimodal prophylaxis for patients with moderate to high PONV risk.[7] The baseline demographic and anesthetic characteristics were well matched between groups, with similar age, gender distribution, BMI, ASA status, duration of surgery, and opioid consumption (p > 0.05). This comparability minimizes confounding and suggests that differences in PONV outcomes are attributable to the prophylactic regimens rather than patient factors. Koivuranta et al. identified female sex, previous PONV, motion sickness, nonsmoking, and prolonged surgery as key risk factors, with predicted PONV rates increasing up to 74–87% when multiple factors are present.[8] In the present study, known high-risk factors such as previous PONV and motion sickness were excluded, yet Group B still exhibited a 42.11% overall PONV incidence, compatible with a moderate-risk profile and consistent with the risk strata described in Koivuranta's score.[8] The incidence of PONV observed in Group B (42.11%) is comparable to

control or minimal-prophylaxis arms in large factorial trials. Apfel et al. reported a baseline PONV incidence of approximately 52% in high-risk patients receiving no prophylaxis, which decreased to 37%, 28%, and 22% with one, two, and three prophylactic interventions, respectively. The 42.11% incidence in Group B lies between the control and single-intervention strata described by Apfel et al., suggesting that the comparative regimen in Group B provided only modest protection. By contrast, the 18.42% incidence in Group A is lower than the 22% reported for triple-agent prophylaxis in that trial, highlighting the effectiveness of the Group A regimen in this relatively homogeneous laparoscopic cholecystectomy cohort.[9] When compared with antiemetic trials specifically conducted in laparoscopic cholecystectomy, the present findings also demonstrate favorable efficacy. Erhan et al. observed cumulative 24-hour PONV incidences of 75% in placebo, 35% with ondansetron, 30% with granisetron, and 25% with dexamethasone in patients undergoing laparoscopic cholecystectomy. In that context, the 42.11% PONV rate in Group B is slightly higher than the single-agent 5-HT_3 antagonist arms but still within the expected range, whereas the 18.42% rate in Group A is clearly lower than any single-drug arm reported by Erhan et al., suggesting that the prophylactic strategy used in Group A achieved efficacy comparable to, or better than, standard monotherapy regimens.[10] Our PONV outcomes also align with studies evaluating combination antiemetic regimens in laparoscopic cholecystectomy. In a comparative trial of common antiemetics, Jehan et al. reported a 24-hour PONV incidence of 56.66% in patients receiving no prophylaxis, which decreased to 26.66% and 20.00% with two different combination regimens, accompanied by reduced rescue antiemetic use. In the present study, Group B (42.11% PONV; rescue antiemetic 28.95%) showed a lower incidence than the completely unprotected cohort in Jehan et al., whereas Group A (18.42% PONV; rescue 10.53%) achieved even better control than their combination arms (20–26.66%).[11] These comparisons reinforce that the regimen in Group A provides a degree of protection at least comparable to established combination strategies and translates into a clinically meaningful reduction in the need for rescue therapy. The magnitude of benefit observed in Group A is consistent with data on synergistic effects of combining corticosteroids with 5-HT_3 antagonists. Biswas and Rudra, in patients undergoing laparoscopic cholecystectomy, found that the 0–24-hour incidence of PONV was 25% with granisetron alone, 30% with dexamethasone alone, and only 7.5% with granisetron plus dexamethasone.[12] Our Group A PONV incidence of 18.42% falls between the single-agent and combination arms reported by Biswas and Rudra, whereas Group B (42.11%) exceeds those figures, suggesting that the antiemetic profile of Group A more closely resembles that of a synergistic combination regimen. The lower vomiting rate (7.89%) and reduced moderate-to-severe nausea in Group A in the present study further support this interpretation. Beyond incidence, the present study demonstrated significantly lower nausea severity and faster gastrointestinal recovery in Group A. The mean VAS nausea score was 1.42 ± 1.10 in Group A versus 2.58 ± 1.41 in Group B ($p = 0.001$), with an absence of severe nausea in Group A compared to 7.89% in Group B. This translated into earlier oral intake (3.24 ± 0.82 vs 4.02 ± 0.91 hours; $p = 0.001$). Coloma et al., evaluating dexamethasone as an adjunct to dolasetron in ambulatory laparoscopic cholecystectomy, reported that adding dexamethasone shortened time to meet discharge criteria (161 ± 32 vs 209 ± 39 minutes) and reduced late (at-home) nausea from 28% to 13%.[13] The earlier resumption of oral intake and improved nausea profile in Group A parallel these findings, suggesting that effective prophylaxis not only reduces PONV incidence but also enhances the overall quality of recovery. The pattern of reduced PONV and rescue antiemetic requirements in Group A is also comparable to combination regimens involving dexamethasone with other agents. Nesek-Adam et al. reported total 24-hour PONV incidences of 60% with placebo, 45% with metoclopramide, 23% with dexamethasone, and 13% with dexamethasone plus metoclopramide in laparoscopic cholecystectomy patients; rescue antiemetics were required in six placebo, four metoclopramide, one dexamethasone, and none of the combination-therapy patients.[14] In our study, Group B's overall PONV incidence (42.11%) is comparable to the metoclopramide arm (45%), whereas Group A (18.42% PONV; 10.53% rescue antiemetic use) approximates the dexamethasone and combination arms (23% and 13%, respectively). Importantly, pain control, hemodynamic stability, and sedation scores (RASS −0.42 ± 0.51 vs −0.57 ± 0.60; $p = 0.19$) were similar between our groups, suggesting that the improved PONV profile in Group A was not confounded by differences in analgesia or sedation. Finally, the safety profile in this study was favorable, with only mild adverse drug reactions occurring in 5.26% of Group A and 10.53% of Group B ($p = 0.39$), and no significant differences in hemodynamic instability or sedation. Hessami and Yari compared 3 mg granisetron with 8 mg dexamethasone in 104 patients undergoing laparoscopic cholecystectomy and reported PONV incidences of approximately 19.2% in the dexamethasone group and 15.4% in the granisetron group, with no significant difference in adverse effects between the two agents.[15]

CONCLUSION

The findings of this prospective, randomized, double-blind study demonstrate that the prophylactic antiemetic regimen used in Group A significantly reduced the incidence and severity of postoperative nausea and vomiting following laparoscopic

cholecystectomy compared with Group B. Group A also required fewer rescue antiemetics and achieved faster postoperative recovery, including earlier oral intake, without increasing adverse effects. These results support the use of an optimized multimodal antiemetic strategy in patients undergoing laparoscopic cholecystectomy. Overall, the regimen evaluated in Group A offers a safe, effective, and clinically superior approach to PONV prevention in this surgical population.

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