

Comparative Evaluation Of Ondansetron Plus Dexamethasone Versus Ondansetron And Dexamethasone In Preventing Postoperative Nausea And Vomiting In Laparoscopic Cholecystectomy

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Abstract

Background: Postoperative nausea and vomiting (PONV) is a common distressing experience in patients following laparoscopic surgeries. This study was aimed at comparing the efficacies of Ondansetron-Dexamethasone combination with each drug alone as a prophylaxis against PONV in patients after elective laparoscopic cholecystectomy done under general anaesthesia.

Materials and methods: This prospective study was conducted in the Department of Anaesthesia from December 2022 to May 2023. After obtaining the Institutional Ethical Committee clearance written informed consent was obtained from the patients. Patients aged 18 to 65 years weighing about 50-60 kg undergoing laparoscopic cholecystectomy under general anesthesia were included in the present study. A total of 60 patients were included in the present study which were grouped into three of 20 each.

For Group A participants, Ondansetron 4 mg and Dexamethasone 8 mg; for Group B Ondansetron 4 mg and for Group C Dexamethasone 8 mg were administered within 30 minutes prior to completing the surgery. After preoxygenation, general anesthesia was administered, pneumoperitoneum was created, and laparoscopic cholecystectomy was done. All patients were observed postoperatively by noting vital signs and complications. All episodes of PONV were recorded 12 hours postoperatively and data was obtained.

Results: The incidence of **retching** was less in group A i.e. Ondansetron 4 mg and Dexamethasone 8 mg administered group than in group B (Ondansetron 4 mg) and C (Dexamethasone 8 mg) and is found significant with $P < 0.05$ ($P=0.001$). The incidence of **nausea** was less in group A i.e. Ondansetron 4 mg and Dexamethasone 8 mg administered group than in group B (Ondansetron 4 mg) and C (Dexamethasone 8 mg) and is found significant with $P < 0.05$ ($P=0.000$). The incidence of **vomiting** was less in group A i.e. Ondansetron 4 mg and Dexamethasone 8 mg administered group than in group B (Ondansetron 4 mg) and C (Dexamethasone 8 mg) and is found significant with $P < 0.05$ ($P=0.000^*$)

Conclusion: Combination of Ondansetron and Dexamethasone is better than each drug alone in preventing PONV after laparoscopic cholecystectomy. Dexamethasone alone is significantly less effective in preventing early vomiting compared to its combination with Ondansetron; whereas Ondansetron alone is less effective against late PONV as compared with combination therapy.

Keywords: Laparoscopic Cholecystectomy, preventing PONV, Ondansetron, Dexamethasone

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I. Introduction

Postoperative nausea and vomiting (PONV) are common and distressing complications for patients undergoing laparoscopic cholecystectomy. These symptoms can lead to a range of adverse effects, including anxiety, dehydration, metabolic abnormalities, wound disruption, and delayed recovery, significantly impacting patient outcomes and satisfaction. The incidence of PONV in laparoscopic cholecystectomy patients varies widely, ranging from 20% to 80%, highlighting the need for effective prophylactic measures¹.

The economic and social burden of PONV is considerable. Increased healthcare costs due to prolonged hospital stays and additional treatments, along with the decreased quality of life for patients, underscore the importance of optimal PONV management. Prophylactic strategies that effectively prevent PONV can thus alleviate these burdens and improve patient care.

Ondansetron, a selective 5-HT₃ receptor antagonist, is widely used for its potent antiemetic properties. It works by blocking serotonin receptors in the brain and gastrointestinal tract, thereby preventing vomiting signals from being transmitted. This mechanism makes Ondansetron a reliable choice for PONV prevention in various surgical settings, including laparoscopic cholecystectomy. Dexamethasone, a corticosteroid, also demonstrates antiemetic effects, though its precise mechanism of action remains unclear. Despite this, it has been shown to be effective in reducing the incidence of PONV. Dexamethasone's anti-inflammatory properties may play a role in its ability to mitigate nausea and vomiting. In deciding on prophylactic antiemetic therapy, cost-benefit analyses are crucial. While Ondansetron is highly effective, it is also more expensive, leading to a high cost-to-benefit ratio. Dexamethasone, being less costly, presents a potential cost-effective alternative. However, its efficacy relative to Ondansetron in preventing PONV specifically in laparoscopic cholecystectomy patients requires further evaluation.

This study aims to fill this gap by comparing the efficacy of Ondansetron alone, Dexamethasone alone, and their combination in preventing PONV in patients undergoing laparoscopic cholecystectomy under general anesthesia. By examining both clinical outcomes and cost implications, we seek to identify the most effective and economical approach to managing PONV in this patient population.

II. Materials & Methods

This prospective, randomized, double-blind study was conducted in the Department of Anaesthesia from December 2022 to May 2023. The study aimed to compare the effectiveness of three different antiemetic regimens in preventing postoperative nausea and vomiting (PONV) in patients undergoing laparoscopic cholecystectomy.

Ethical Considerations

Prior to commencement, the study protocol received approval from the Institutional Ethical Committee. All participants provided written informed consent, ensuring adherence to ethical standards and patient rights.

Study Population

The study included patients aged 18 to 65 years, with body weights ranging between 50 and 60 kg, who were scheduled for elective laparoscopic cholecystectomy under general anesthesia. Patients were classified as ASA I or II, indicating they were healthy or had mild systemic disease, respectively.

Inclusion and Exclusion Criteria (Paragraph)

Inclusion Criteria:

- Age: 18 to 65 years
- Weight: 50 to 60 kg
- Undergoing elective laparoscopic cholecystectomy
- Classified as ASA I or II

Exclusion Criteria:

- History of adverse reactions to study medications
- Pregnant or breastfeeding women
- Patients with significant cardiovascular, hepatic, or renal diseases
- Patients on concurrent antiemetic therapy

Randomization and Group Allocation

A total of 60 patients were enrolled and randomly assigned to one of three groups, with 20 patients in each group:

- Group A:** Received 4 mg Ondansetron plus 8 mg Dexamethasone
- Group B:** Received 4 mg Ondansetron
- Group C:** Received 8 mg Dexamethasone

Randomization was performed using a computer-generated randomization table to ensure equal distribution and minimize bias.

Drug Administration

The assigned medications were administered intravenously within 30 minutes prior to the completion of surgery. This timing was chosen to ensure optimal drug efficacy during the immediate postoperative period.

Anesthetic Technique

All patients underwent a standardized general anesthetic technique. Preoxygenation was followed by the induction of general anesthesia. A balanced anesthesia approach was utilized, which included the use of:

- Induction agents (e.g., Propofol)
- Muscle relaxants (e.g., Vecuronium)
- Maintenance agents (e.g., Isoflurane)
- Analgesics (e.g., Fentanyl)

Pneumoperitoneum was created to facilitate the laparoscopic procedure, and the cholecystectomy was performed according to standard surgical protocols.

Postoperative Monitoring and Data Collection

Postoperatively, all patients were closely monitored in the recovery area and later in the surgical ward. Vital signs, including heart rate, blood pressure, respiratory rate, and oxygen saturation, were continuously monitored.

Outcome Measures

Primary Outcome:

Incidence of PONV: Episodes of nausea and vomiting were recorded at 6, 12, and 24 hours postoperatively.

Secondary Outcomes:

- Requirement for rescue antiemetics:** The use of additional antiemetic medication was documented.
- Complete response rate:** Defined as no PONV and no need for rescue antiemetics within the first 24 hours.
- Pain scores:** Assessed using a Visual Analog Score.
- Time to first analgesia demand:** Time elapsed until the patient first requested pain relief.
- Total Meperidine consumption:** The amount of Meperidine administered postoperatively.
- Adverse events:** Any complications or side effects related to the study medications.
- Duration of hospital stay:** Time from surgery completion to patient discharge.

Data Analysis

Data were analyzed using appropriate statistical methods to compare the efficacy of the three antiemetic regimens. Incidence rates of PONV, the need for rescue antiemetics, and secondary outcomes were compared between groups using chi-square tests and analysis of variance (ANOVA) where applicable. A p-value of less than 0.05 was considered statistically significant.

This detailed methodology ensures that the study's findings are robust, reliable, and applicable to clinical practice in preventing PONV in patients undergoing laparoscopic cholecystectomy.

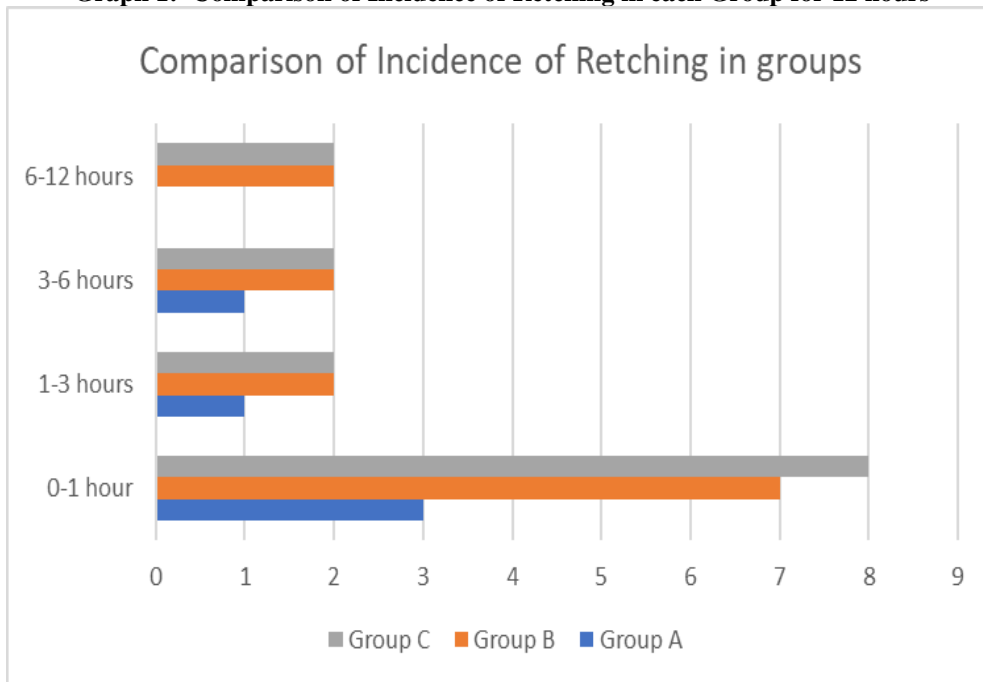
III. Results

The incidence of **retching** was less in group A i.e. Ondansetron 4 mg and Dexamethasone 8 mg administered group than in group B (Ondansetron 4 mg) and C (Dexamethasone 8 mg) and is found significant with $P < 0.05$ ($P = 0.001$)

Table 1: Incidence of Retching in each Group for 12 hours

	0-1 hour	1-3 hours	3-6 hours	6-12 hours
Group A	3	1	1	0
Group B	7	2	2	2
Group C	8	2	2	2

Graph 1: Comparison of Incidence of Retching in each Group for 12 hours

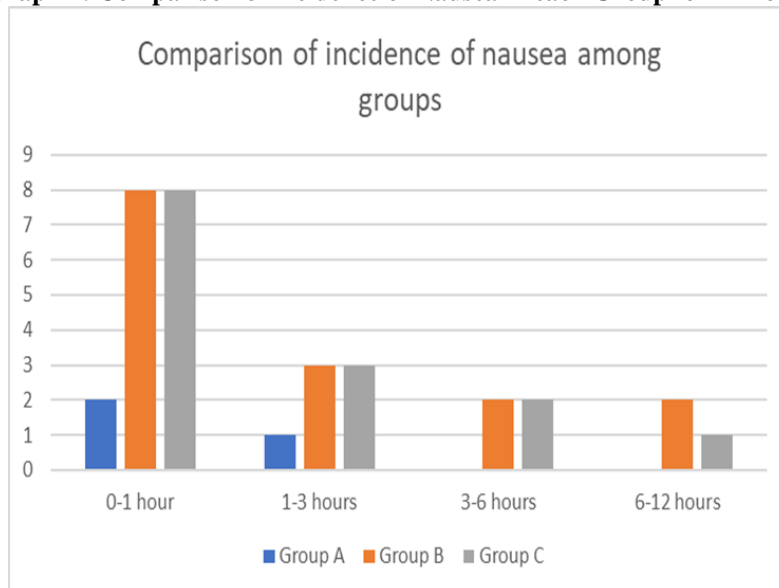


The incidence of nausea was less in group A i.e. Ondansetron 4 mg and Dexamethasone 8 mg administered group than in group B (Ondansetron 4 mg) and C (Dexamethasone 8 mg) and is found significant with $P < 0.05$ ($P=0.000$)

Table 2: Incidence of Nausea in each Group for 12 hours

	0-1 hour	1-3 hours	3-6 hours	6-12 hours
Group A	2	1	0	0
Group B	8	3	2	2
Group C	8	3	2	1

Graph 2: Comparison of incidence of Nausea in each Group for 12 hours

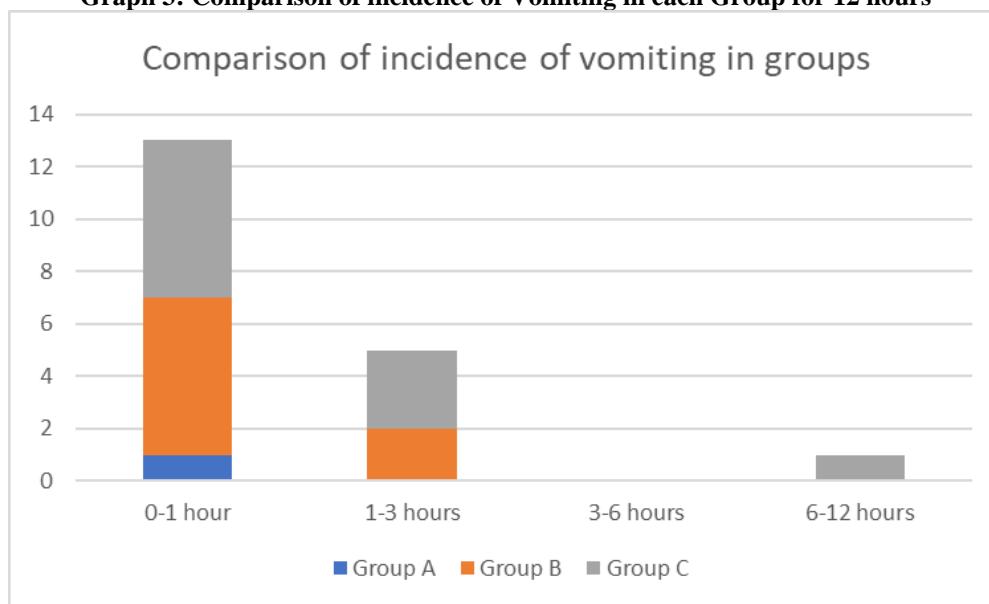


The incidence of vomiting was less in group A i.e. Ondansetron 4 mg and Dexamethasone 8 mg administered group than in group B (Ondansetron 4 mg) and C (Dexamethasone 8 mg) and is found significant with $P < 0.05$ ($P=0.000^*$)

Table 3: Incidence of Vomiting in each Group for 12 hours

	0-1 hour	1-3 hours	3-6 hours	6-12 hours
Group A	1	0	0	0
Group B	6	2	0	0
Group C	6	3	0	1

Graph 3: Comparison of incidence of Vomiting in each Group for 12 hours



IV. Discussion

Nausea and vomiting in the postoperative period are the most distressing and unpleasant experiences for a patient. Severe post-operative emesis results in dehydration, and electrolyte imbalance, which may lead to a life-threatening complication like aspiration pneumonitis and alter the overall outcome of the entire surgical procedure. Incidences of postoperative nausea and vomiting are more with laparoscopic surgery due to manipulation of abdominal viscera which is a strong emetic stimulus along with pain, anxiety, and use of drugs like opioids and NSAID. The drugs commonly used are Metoclopramide, Domperidone, Phenothiazine, and anticholinergics drugs. As these drugs have effective side effects, alternative drugs are much needed². In this study we compared the Ondansetron and Dexamethasone versus Ondansetron versus Dexamethasone. The combination of Ondansetron and Dexamethasone was found more effective in preventing PONV than administering them alone.

Wang, et al³, 2013, a meta-analysis that reviewed multiple randomized controlled trials to evaluate the effectiveness of Dexamethasone and Ondansetron in preventing PONV. The study concluded that the combination of dexamethasone and Ondansetron significantly reduces PONV incidence compared to each drug alone. Comparison with Study Results: Our study's findings align with this meta-analysis. We observed that the combination of Ondansetron 4 mg and Dexamethasone 8 mg (Group A) significantly reduced the incidence of nausea ($P=0.000$), vomiting ($P=0.000^*$), and retching ($P=0.001$) compared to Ondansetron or Dexamethasone alone. This reinforces the conclusion that combination therapy is more effective in PONV prevention.

Qasemi F, et al⁴ (2024) study specifically focused on laparoscopic cholecystectomy patients and found that the combination of Ondansetron and Dexamethasone significantly lowered the incidence of PONV compared to each drug alone. Similar to our results, this study highlighted the superior efficacy of combination therapy. In our study, Group A showed significantly lower incidence of nausea, vomiting, and retching

compared to Groups B (Ondansetron alone) and C (Dexamethasone alone). Both studies strongly support the use of combination therapy in laparoscopic cholecystectomy to improve patient outcomes.

V. Conclusion

Combination of Ondansetron and Dexamethasone is better than each drug alone in preventing PONV after laparoscopic cholecystectomy. Dexamethasone alone is significantly less effective in preventing early vomiting compared to its combination with Ondansetron; whereas Ondansetron alone is less effective against late PONV as compared with combination therapy.

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Nil

CONFLICTS OF INTEREST

There are no conflicts of interest.

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