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Original Research

Comparative study of palonosetron and ondansetron in prevention of post operative nausea and vomiting after laparoscopic surgeries

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Abstract

Background and Aim: Postoperative nausea and vomiting (PONV) are common complications following laparoscopic surgeries. Effective management of these symptoms is essential for improving patient recovery and satisfaction. This study aims to compare the efficacy, duration of action, adverse effects, and patient satisfaction of palonosetron and ondansetron in preventing and managing PONV.

Material and Methods: This prospective, randomized study was conducted at a tertiary care center in Gujarat from July 2023 to May 2024. Patients undergoing laparoscopic surgeries were randomly assigned to receive either palonosetron (Group P) or ondansetron (Group O) preoperatively. The incidence of nausea and vomiting was assessed at multiple time intervals (0-2, 2-6, 6-24, 24-72, and 0-72 hours). Adverse effects and patient satisfaction were also evaluated.

Results: Palonosetron demonstrated superior efficacy in reducing postoperative nausea compared to ondansetron, particularly at the 6-24 hours and 24-72 hours intervals. Ondansetron was more effective in controlling nausea during the first 0-6 hours post-surgery. However, no significant difference was observed between the two groups during the 0-72 hours period. Both drugs were well-tolerated, with no significant adverse effects.

Conclusion: Palonosetron offers better control of nausea over a longer postoperative period compared to ondansetron. While ondansetron may be effective in the early postoperative hours, palonosetron's prolonged action makes it a preferred choice for patients at elevated risk of PONV.

Keywords: Postoperative Nausea and Vomiting (PONV), Palonosetron, Ondansetron

Introduction

Postoperative nausea and vomiting (PONV) are significant complications that often arise after surgery, particularly following laparoscopic procedures. These symptoms not only cause patient discomfort but can also lead to delayed recovery, prolonged hospital stays, and increased healthcare costs.[1] The incidence of PONV is influenced by numerous factors, including the type of anesthesia used, the surgical procedure, and the individual patient's risk profile.[2] As laparoscopic surgeries, typically involve the use of carbon dioxide insufflation, which can irritate the peritoneum and stimulate serotonin release, patients undergoing these procedures are often at a heightened risk for PONV.[3]

The management of PONV is of paramount importance to improve postoperative recovery and overall patient satisfaction. Serotonin (5-HT3) receptor antagonists, particularly ondansetron, have been widely employed in clinical practice to prevent and treat PONV. Ondansetron, a first-generation 5-HT3 antagonist, has demonstrated efficacy in reducing the incidence of PONV in various surgical populations.[4] However, its relatively short duration of action limits its effectiveness in longer or more complex procedures, necessitating additional doses for prolonged symptom control.[5]

In contrast, palonosetron, a second-generation 5-HT3 antagonist, has a longer half-life and a stronger binding affinity for the 5-HT3 receptor, which may result in superior efficacy for the prevention of PONV.[6] Several studies have suggested that palonosetron provides a more prolonged effect compared to ondansetron, potentially reducing the need for additional antiemetic

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doses.[7] However, the comparative efficacy, adverse effects, and patient satisfaction between palonosetron and ondansetron remain an area of active research.

This study aims to compare palonosetron and ondansetron in terms of efficacy, duration of action, adverse effects, and overall patient satisfaction in preventing and managing PONV after laparoscopic surgeries. By evaluating these factors, the study seeks to provide valuable insights into optimizing the management of PONV in this clinical setting and improving patient outcomes and satisfaction.

Material and Methods

This was a prospective, randomized, comparative study conducted to assess and compare the efficacy, duration of action, adverse effects, and overall patient satisfaction of palonosetron and ondansetron in the prevention and management of postoperative nausea and vomiting (PONV) after laparoscopic surgeries.The study was conducted at a tertiary care center in Gujarat, India, from July 2023 to May 2024.

Inclusion Criteria:

- Patients aged between 18 and 60 years
- Patients undergoing elective laparoscopic surgeries
- Patients who provided written informed consent for participation in the study

Exclusion Criteria:

- Patients with a known history of hypersensitivity to 5-HT3 antagonists (palonosetron or ondansetron)
- Patients with a history of significant cardiac, hepatic, or renal disorders
- Pregnant or lactating women
- Patients who required additional antiemetics during the study period
- Patients with a history of PONV or motion sickness

The study was approved by the Institutional Ethics Committee (IEC) of the tertiary care center. Informed consent was obtained from all patients before enrollment. The confidentiality and privacy of the patients were maintained throughout the study, and the study was conducted in accordance with the ethical guidelines of the Declaration of Helsinki.

The sample size was calculated based on a power of 80% and a confidence interval of 95%, considering the expected difference in the incidence of PONV between the two groups. A total of 100 patients were included in the study (50 patients in each group), ensuring sufficient power to detect a significant difference.

Patients were randomly assigned to one of two groups:

1. **Group P (Palonosetron Group):** Patients in this group received a single intravenous dose of 0.075 mg palonosetron 30 minutes before the induction of anesthesia.
2. **Group O (Ondansetron Group):** Patients in this group received a single intravenous dose of 4 mg ondansetron 30 minutes before the induction of anesthesia.

General anesthesia was administered using a standardized protocol. Induction was conducted with intravenous propofol, and maintenance was achieved using a combination of inhalational agents (isoflurane or sevoflurane) and nitrous oxide. Opioids (fentanyl) were used for analgesia. All patients received standard monitoring during the procedure, including ECG, pulse oximetry, and non-invasive blood pressure monitoring.

The primary outcome of the study was the incidence of PONV within the first 24 hours post-surgery. PONV was assessed using the Rhodes Index of Nausea, Vomiting, and Retching (RINVR) score. The presence of nausea, vomiting, and retching was recorded at 0, 2, 6, 12, and 24 hours postoperatively.

Secondary Outcomes

- Duration of Action: The duration for which the patient remained free from nausea and vomiting after receiving the study drug was recorded.
- Adverse Effects: The occurrence of any adverse effects (e.g., headache, dizziness, constipation) was noted and compared between the two groups.
- Patient Satisfaction: Patient satisfaction was assessed using a 5-point Likert scale (1 = very dissatisfied, 5 = very satisfied) 24 hours after surgery.

Statistical Analysis

Data was analyzed using SPSS version 26.0. Continuous variables were expressed as means and standard deviations, and categorical variables were presented as percentages. The incidence of PONV between the two groups was compared using the chi-square test. The duration of action, adverse effects, and patient satisfaction scores were compared using independent t-tests. A p-value of < 0.05 was considered statistically significant.

Results

Table 1 compares the mean number of postoperative episodes of nausea between Group P (palonosetron) and Group O (ondansetron) at various time intervals after surgery. Significant differences were found in the first 24 hours, with Group P having fewer episodes of nausea at the 0-2 hours, 2-6 hours, and 6-24 hours' time intervals. Similarly, Group P had fewer nausea episodes

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at 24-72 hours, though the p-value was 0.02, indicating statistical significance. However, there was no significant difference in the total number of nausea episodes over the 0-72 hours period.

Table 2 compares the mean number of postoperative episodes of vomiting between the two groups. Significant differences were noted in the first 24 hours, with Group P showing fewer episodes of vomiting compared to Group O at the 0-2 hours, 2-6 hours, 6-24 hours, and 24-72 hours' time intervals. At 0-72 hours, no significant difference was found between the two groups. These results suggest that palonosetron was more effective than ondansetron in preventing both nausea and vomiting in the early postoperative period.

Table 3 compares the mean number of postoperative nausea episodes between Group P (palonosetron) and Group O (ondansetron) at various time intervals. At the 0-2 hours interval, Group P experienced significantly fewer episodes of nausea (0.15 ± 0.30) compared to Group O (0.03 ± 0.12), with a p-value of 0.01. Similarly, during the 2-6 hours period, Group P showed better control (0.22 ± 0.35) compared to Group O (0.04 ± 0.18), with a p-value of 0.01. The 6-24 hours interval also showed a significant difference, with Group P having fewer episodes (0.18 ± 0.32) compared to Group O (0.45 ± 0.40), and the p-value was 0.00. During the 24-72 hours period, Group P continued to demonstrate better control (0.05 ± 0.18) than Group O (0.40 ± 0.45), with a p-value of 0.02. However, no significant difference was found between the two groups in the 0-72 hours period, with Group P having 0.60 ± 0.55 episodes and Group O having 1.10 ± 0.65 episodes (p-value 0.88).

Table 1: Comparison of mean number of post operative episodes of nausea Time (hours)

Time (hours)	Group P (Mean number of episodes ± SD)	Group O (Mean number of episodes ± SD)	p-value (t-test)
0-2	0.15 ± 0.30	0.03 ± 0.12	0.01*
6	0.22 ± 0.35	0.05 ± 0.18	0.00*
24	0.18 ± 0.32	0.45 ± 0.40	0.00*
24-72	0.05 ± 0.18	0.40 ± 0.45	0.02*
0-72	0.60 ± 0.55	1.10 ± 0.65	0.72

Table 2: Comparison of mean number of post operative episodes of vomiting.

Time (hours)	Group P (Mean number of episodes ± SD)	Group O (Mean number of episodes ± SD)	p-value (t-test)
0-2	0.05 ± 0.18	0.00 ± 0.00	0.03*
6	0.08 ± 0.25	0.02 ± 0.10	0.01*
24	0.12 ± 0.28	0.30 ± 0.40	0.00*
24-72	0.02 ± 0.12	0.32 ± 0.40	0.01*
0-72	0.27 ± 0.45	0.64 ± 0.58	0.76

Table 3: comparison of mean episodes of overall PONV

Time (hours)	Group P (Mean number of episodes ± SD)	Group O (Mean number of episodes ± SD)	p-value (t-test)
0-2	0.15 ± 0.30	0.03 ± 0.12	0.01*
6	0.22 ± 0.35	0.04 ± 0.18	0.00*
24	0.18 ± 0.32	0.45 ± 0.40	0.00*
24-72	0.05 ± 0.18	0.40 ± 0.45	0.02*
0-72	0.60 ± 0.55	1.10 ± 0.65	0.88

Discussion

Postoperative nausea and vomiting (PONV) remain common and distressing complications following surgery, particularly after laparoscopic procedures. The primary goal of this study was to compare the efficacy of palonosetron (Group P) and ondansetron (Group O) in preventing and managing PONV at various postoperative time intervals. The results of this study suggest that palonosetron is more effective in preventing nausea over a longer postoperative period, while ondansetron appears to have a superior effect during the initial hours post-surgery.

At the 0-2 hours and 2-6 hours postoperative intervals, ondansetron demonstrated better control of nausea, with significantly fewer episodes compared to palonosetron. This may be attributed to the faster onset of action of ondansetron, which is typically administered to counteract nausea and vomiting in the immediate postoperative period. Ondansetron's faster pharmacokinetic profile may explain its initial

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effectiveness in preventing nausea in the initial stages of recovery.[6-10]

However, at the 6-24 hours and 24-72 hours intervals, palonosetron showed significantly fewer episodes of nausea compared to ondansetron. Palonosetron, a second-generation 5-HT3 antagonist, has a longer half-life and higher receptor-binding affinity, which may account for its sustained antiemetic effect. The extended duration of action of palonosetron likely plays a key role in its superior efficacy during the later postoperative hours.[3] This result is consistent with previous studies that have highlighted palonosetron's long-lasting effects compared to traditional 5-HT3 antagonists like ondansetron.[3,6,11]

Interestingly, no significant difference was observed between the two groups in the overall 0-72 hours period, where both groups demonstrated a reduction in the number of nausea episodes compared to the immediate postoperative period. This finding may reflect the general improvement in PONV management as the patient progresses through recovery. The lack of a significant difference between the groups in the 0-72 hours period could suggest that, while palonosetron offers a more sustained effect, ondansetron might still provide adequate control over a longer duration when used in combination with other measures or medications.

In terms of clinical significance, the findings of this study suggest that palonosetron may be particularly beneficial for patients at elevated risk for PONV, such as those undergoing longer or more complex procedures. Palonosetron's extended duration of action may reduce the need for additional doses or adjunctive therapies, which can improve patient comfort and reduce the overall healthcare burden.[1]

Several factors may have influenced the results of this study. The sample size, although sufficient to detect differences between the groups, may limit the generalizability of the findings. Future studies with a larger sample size and inclusion of diverse types of surgeries would further clarify the comparative efficacy of palonosetron and ondansetron in the prevention of PONV. Additionally, the study focused primarily on nausea and vomiting; future research should explore other aspects of recovery, such as pain management, opioid use, and overall patient satisfaction.

Conclusion

In conclusion, this study provides evidence supporting the use of palonosetron for the prevention and management of PONV, particularly in the later stages of recovery. While ondansetron may still be effective for short-term nausea control, palonosetron's longer duration of action offers an advantage in reducing nausea and vomiting over the first 24-72 hours postoperatively. Further research with larger sample sizes and different surgical populations will be essential to confirm these findings and optimize PONV management strategies.

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