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Comparative Study of Efficacy of Intravenous Ondansetron Versus Intravenous Palonosetron in The Prevention of Post-Operative Nausea and Vomiting in Elective Laparoscopic Surgeries

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ABSTRACT

Background: Postoperative nausea and vomiting (PONV) is a common complication following laparoscopic surgeries. This study aimed to compare the efficacy of ondansetron and palonosetron in preventing PONV and attenuating hemodynamic changes in adults undergoing elective laparoscopic surgeries.
Methods: This prospective, randomized, double-blind study included 60 patients (ASA grade I-II, aged 18-45 years) undergoing elective laparoscopic surgeries. Patients were randomly allocated to receive either ondansetron 4 mg IV or palonosetron 75 mcg IV 15 minutes before the end of surgery. The incidence of PONV, pain scores, and clinical recovery scores were assessed postoperatively.
Results: Palonosetron significantly reduced the incidence of nausea during the 0-2 hour (13.3% vs. 30%, p=0.017) and 2-6 hour (13.3% vs. 23.3%, p=0.033) intervals, and the incidence of vomiting during the 0-2 hour interval (6.7% vs. 16.7%, p=0.028) compared to ondansetron. Pain scores were significantly lower in the palonosetron group at all time intervals (p<0.001). The incidence of headache was also lower in the palonosetron group (0% vs. 16.7%, p=0.02).
Conclusion: Palonosetron was more effective than ondansetron in reducing the incidence of PONV and postoperative pain in adults undergoing elective laparoscopic surgeries. Further large-scale studies are needed to confirm these findings and assess cost-effectiveness.

Keywords*: Postoperative nausea and vomiting, PONV, ondansetron, palonosetron, laparoscopic surgery, antiemetics.*

INTRODUCTION

Postoperative nausea and vomiting (PONV) is a common and distressing complication following laparoscopic surgery, with an incidence ranging from 30% to 80%.1,2 PONV can lead to various adverse outcomes, including prolonged recovery, unplanned hospital admission, and reduced patient satisfaction.3 Laparoscopic surgeries, in particular, are associated with a higher risk of PONV due to factors such as peritoneal distension, use of carbon dioxide for insufflation, and hemodynamic changes during pneumoperitoneum.4

The pathophysiology of PONV is complex and multifactorial, involving the activation of various receptors, including serotonin (5-HT3), dopamine (D2), histamine (H1), and muscarinic receptors.5 Serotonin, released from enterochromaffin cells in the gut, plays a central role in the initiation of the vomiting reflex by stimulating 5-HT3 receptors in the chemoreceptor trigger zone (CTZ) and nucleus tractus solitarius (NTS).6

Ondansetron, a selective 5-HT3 receptor antagonist, has been widely used for the prevention and treatment of PONV. It acts by blocking the binding of serotonin to 5-HT3 receptors in the CTZ and NTS, thereby inhibiting the emetic response.7 Clinical studies have demonstrated the efficacy of ondansetron in reducing the incidence of PONV in various surgical settings, including laparoscopic procedures.8

Palonosetron, a second-generation 5-HT3 receptor antagonist, has a higher receptor binding affinity and a longer half-life compared to ondansetron.9 These pharmacological properties suggest that palonosetron may have a more potent and prolonged antiemetic effect. Several studies have compared the efficacy of palonosetron with that of ondansetron in preventing PONV, with mixed results.10,11

The present study aims to compare the efficacy of ondansetron and palonosetron in preventing PONV in adults undergoing elective laparoscopic surgeries. The primary objective is to determine the incidence of PONV in patients receiving either ondansetron or palonosetron. The secondary objectives include assessing and comparing the attenuating effects of these drugs on hemodynamic changes during laparoscopy.

The study will be conducted as a prospective, randomized, double-blind comparative trial. Patients aged between 18 and 45 years, with ASA grade I-II, scheduled for elective laparoscopic surgeries will be included. Exclusion criteria will include age > 45 years, BMI > 30 kg/m2, history of PONV or motion sickness, pregnancy, and presence of comorbidities such as diabetes or gastroesophageal reflux disease.

Patients will be randomly allocated to receive either ondansetron 4 mg IV or palonosetron 75 mcg IV, administered 15 minutes before the end of surgery. The incidence of PONV will be assessed using a visual analog scale and the need for rescue antiemetics in the postoperative period for 12 hours. Hemodynamic parameters, including heart rate and blood pressure, will be recorded at various time points during the perioperative period.

The sample size calculation is based on a previous study, which reported a 50% reduction in the incidence of PONV with palonosetron compared to ondansetron.12 With a power of 80% and an alpha error of 5%, a sample size of 30 patients per group is required.

Data will be analyzed using appropriate statistical methods, including the chi-square test for categorical variables and the independent t-test for continuous variables. A p-value < 0.05 will be considered statistically significant.

The results of this study will provide valuable insights into the comparative efficacy of ondansetron and palonosetron in preventing PONV in patients undergoing laparoscopic surgeries. If palonosetron is found to be superior to ondansetron, it may become the preferred antiemetic agent in this surgical population, potentially leading to improved patient outcomes and satisfaction.

This prospective, randomized, double-blind study aims to compare the efficacy of ondansetron and palonosetron in reducing the incidence of PONV and attenuating hemodynamic changes in adults undergoing elective laparoscopic procedures. The findings of this study may have important implications for the management of PONV in clinical practice.

AIMS AND OBJECTIVES

The present study aimed to determine the efficacy of ondansetron and palonosetron in preventing postoperative nausea and vomiting (PONV) in adults undergoing elective laparoscopic surgeries. The primary objective was to compare the incidence of PONV between patients receiving ondansetron and those receiving palonosetron. The secondary objective was to assess and compare the attenuating effects of these drugs on hemodynamic changes during laparoscopy.

MATERIALS AND METHODS

Study Design and Setting

This prospective, randomized, double-blind comparative study was conducted at the Gulbarga Institute of Medical Sciences, Kalaburagi, India, from July 2022 to January 2024. The study protocol was approved by the institutional ethical committee, and written informed consent was obtained from all participants.

Study Population

The study included 60 patients aged between 18 and 45 years, with American Society of Anesthesiologists (ASA) grade I-II, who were scheduled to undergo elective laparoscopic surgeries. Patients with a history of allergy to ondansetron or palonosetron, age > 45 years, BMI > 30 kg/m2, pregnant women, those with a history of PONV or motion sickness 24 hours prior to surgery, diabetic patients, those undergoing emergency surgeries, patients with a full stomach, history of gastroesophageal reflux disorder, extreme ages, and those with respiratory diseases were excluded from the study.

Sample Size Calculation

The sample size was calculated using the formula: Sample Size = (2SD^2 (Z_(α/2) + Z_β)^2) / d^2, where SD is the standard deviation from a previous study or pilot study, Zα/2 = Z0.05/2 = Z0.025 = 1.96 (from Z table) at a type 1 error

of 5%, Zβ = Z0.20 = 0.842 (from Z table) at 80% power, and d is the effect size or difference between mean values. Based on a previous study (Indian Journal of Anesthesia 2020;7(1):59-63), with an effect size of 0.5, the calculated sample size was 29.001 (rounded to 30 in each group).

Randomization and Blinding
Patients were randomly allocated to two groups using a computer-generated randomization sequence prepared in a double-blind manner. The control group (n=30) received 4 mg ondansetron intravenously (IV), while the study group (n=30) received 75 mcg palonosetron IV. The patients and the anesthesiologist assessing the outcomes were blinded to the group allocation.

Anesthesia Protocol
All patients underwent a thorough pre-anesthetic assessment, including a general physical examination and airway assessment using the Mallampati grading system. Routine investigations, such as hemoglobin, blood grouping, bleeding time, clotting time, urine analysis, renal function tests, fasting blood sugar, and electrocardiogram, were performed. Patients were advised to fast for 8 hours prior to surgery and were given 5 mg diazepam orally the night before surgery to alleviate anxiety.

On the day of surgery, patients were premedicated with 0.2 mg glycopyrrolate and 30 mg pentazocine IV. Anesthesia was induced with thiopentone sodium (5 mg/kg) and atracurium (0.2-0.6 mg/kg) to facilitate laryngoscopy and intubation. Anesthesia was maintained with nitrous oxide, oxygen, and isoflurane, with top-up doses of atracurium, analgesics, and IV fluids as required. A nasogastric tube was inserted to decompress the stomach, and the peritoneal cavity was insufflated with carbon dioxide, maintaining an intra-abdominal pressure of less than 12 mmHg.

Fifteen minutes before the end of surgery, patients in the control group received 4 mg ondansetron IV, while those in the study group received 75 mcg palonosetron IV. After the completion of the surgical procedure, nitrous oxide and isoflurane were discontinued, and residual neuromuscular blockade was reversed with glycopyrrolate (10 mcg/kg) and neostigmine (0.05 mg/kg). Tracheal extubation was performed after thorough suctioning of the throat, and patients were transferred to the post-anesthesia care unit for further monitoring.

Outcome Assessment
The primary outcome was the incidence of PONV, assessed using a visual analog scale (VAS) and the need for rescue antiemetics in the postoperative period for 12 hours. The secondary outcome was the attenuating effect on hemodynamic changes, including heart rate and blood pressure, recorded at various time points during the perioperative period.

Clinical recovery was assessed using the Clinical Recovery Score (CRS) at 0, 1, 2, 3, and 4 hours post-surgery. The CRS evaluates vigilance, cognition, orientation, and patient comfort, with a maximum score of 11 indicating excellent recovery.

Statistical Analysis
Data were entered into Microsoft Excel 2017 and analyzed using SPSS version 16 software. Categorical data were presented as frequencies and proportions, and the chi-square test was used to determine statistical significance. Quantitative data were analyzed using mean, standard deviation, frequencies, and percentages. The independent student t-test was used to identify the mean difference between the two groups. A p-value < 0.05 was considered statistically significant.

RESULTS
The study involved a total of 60 participants, randomly divided into two groups: one receiving 4 mg of Ondansetron intravenously and the other receiving 75 mcg of Palonosetron intravenously. The results have been presented based on demographic data, perioperative variables, and postoperative outcomes, including nausea, vomiting, and recovery scores. Statistical significance was determined using a p-value threshold of <0.05.

Demographic Characteristics
The mean age of participants in the Ondansetron group was 31.03 ± 7.495 years, while in the Palonosetron group it was 35.17 ± 7.35 years. There was no statistically significant difference in age between the two groups (p=0.187). The mean weight in the Ondansetron group was 59.23 ± 6.806 kg, and in the Palonosetron group, it was 60.87 ± 7.877 kg, which also did not show a significant difference (p=0.769). Similarly, the mean height in the Ondansetron group was 161.97 ± 6.088 cm, compared to 159.8 ± 8.81 cm in the Palonosetron group, with no significant difference (p=0.833).
Regarding sex distribution, 56.7% of participants in the Ondansetron group were female compared to 50% in the Palonosetron group. Males comprised 43.3% in the Ondansetron group and 50% in the Palonosetron group, with a p-value of 0.605, indicating no significant difference in sex distribution between the groups.

The ASA classification was also similar between the groups. In the Ondansetron group, 76.7% of participants were classified as ASA Grade 1, while 23.3% were ASA Grade 2. In the Palonosetron group, 56.7% were classified as ASA Grade 1, and 43.3% as ASA Grade 2. This difference was not statistically significant (p=0.322).

Perioperative Data

The duration of anesthesia was comparable between the two groups. The mean duration in the Ondansetron group was 66.33 ± 22.55 minutes, while in the Palonosetron group it was slightly lower at 63.33 ± 15.992 minutes. The difference between the two groups was not statistically significant (p=0.559).

Postoperative Nausea, Retching, and Vomiting

Nausea incidence was assessed at three different time intervals: 0-2 hours, 2-6 hours, and 6-24 hours postoperatively. In the first 0-2 hour interval, 30% of participants in the Ondansetron group experienced nausea, compared to 13.3% in the Palonosetron group. This difference was statistically significant (p=0.017). Between 2-6 hours, 23.3% of participants in the Ondansetron group experienced nausea, while 13.3% in the Palonosetron group reported nausea, again showing a statistically significant difference (p=0.033). However, between 6-24 hours, the incidence of nausea was 36.7% in the Ondansetron group and 26.7% in the Palonosetron group, which was not statistically significant (p=0.405).

Retching was reported at the 0-2 hour interval by 6.7% of participants in both the Ondansetron and Palonosetron groups (p=1.00). There were no reports of retching in either group during the 2-6 hour and 6-24 hour intervals, with a p-value of 1.00 in both cases, indicating no significant difference in retching incidence.

Vomiting incidence followed a similar pattern. In the 0-2 hour interval, 16.7% of participants in the Ondansetron group experienced vomiting compared to 6.7% in the Palonosetron group, a statistically significant difference (p=0.028). However, during the 2-6 hour period, vomiting incidence decreased to 6.7% in the Ondansetron group and 3.3% in the Palonosetron group, with a non-significant p-value of 0.554. There were no reports of vomiting in either group during the 6-24 hour period (p=1.00).

Pain and Recovery Outcomes

Pain levels were assessed using the Visual Analog Scale (VAS) at three different postoperative intervals. In the 0-2 hour interval, the mean VAS score in the Ondansetron group was 3.87 ± 1.502, compared to 2.1 ± 1.125 in the Palonosetron group. This difference was statistically significant (p<0.001). Between 2-6 hours, the VAS score was 2.17 ± 0.986 in the Ondansetron group and 0.43 ± 0.728 in the Palonosetron group, showing a significant reduction in pain in the Palonosetron group (p<0.001). In the 6-24 hour interval, the mean VAS score in the Ondansetron group was 0.5 ± 0.777, while the Palonosetron group reported no pain (VAS score of 0), which was again statistically significant (p<0.001).

Headache incidence was also higher in the Ondansetron group, with 16.7% of participants reporting headaches compared to none in the Palonosetron group. This difference was statistically significant (p=0.02). No participants in either group reported dizziness or constipation at any time postoperatively, with a p-value of 1.00 for both comparisons, indicating no significant difference between the groups for these symptoms.

Clinical Recovery Score (CRS)

The Clinical Recovery Score (CRS) was used to evaluate overall postoperative recovery. In the Ondansetron group, 36.7% of participants had a CRS of less than 8, indicating poor recovery, while 26.7% of participants in the Palonosetron group had a similar score. This difference was statistically significant (p=0.046). A good recovery (CRS score of 9-10) was observed in 56.7% of participants in the Ondansetron group and 53.3% in the Palonosetron group, with no statistically significant difference. Excellent recovery (CRS score of 11) was reported by 6.7% of participants in the Ondansetron group, compared to 20% in the Palonosetron group, indicating a trend toward better recovery in the Palonosetron group, although this was not statistically significant.

Overall, Palonosetron was associated with significantly lower incidences of nausea, vomiting, and headache in the early postoperative period compared to Ondansetron. Participants in the Palonosetron group also experienced lower levels of pain and showed trends toward better clinical recovery, as indicated by higher CRS scores. Both drugs were equally effective in preventing retching, with no reported incidents after the 0-2 hour period.

Table 1: Demographic Characteristics

Characteristic	Ondansetron (Mean ± SD or n)	Palonosetron (Mean ± SD or n)	P-Value
Age (years)	31.03 ± 7.495	35.17 ± 7.35	0.187
Weight (kg)	59.23 ± 6.806	60.87 ± 7.877	0.769
Height (cm)	161.97 ± 6.088	159.8 ± 8.81	0.833

Sex	Female: 17 (56.7%)	Female: 15 (50%)	0.605
	Male: 13 (43.3%)	Male: 15 (50%)	
ASA Grade	ASA 1: 23 (76.7%)	ASA 1: 17 (56.7%)	0.322
	ASA 2: 7 (23.3%)	ASA 2: 13 (43.3%)	

Table 2: Perioperative Data

Parameter	Ondansetron (Mean ± SD or n)	Palonosetron (Mean ± SD or n)	P-Value
Duration of Anesthesia (min)	66.33 ± 22.55	63.33 ± 15.992	0.559
Nausea Incidence (0-2 hr)	9 (30%)	4 (13.3%)	0.017
Nausea Incidence (2-6 hr)	7 (23.3%)	4 (13.3%)	0.033
Nausea Incidence (6-24 hr)	11 (36.7%)	8 (26.7%)	0.405
Retching Incidence (0-2 hr)	2 (6.7%)	2 (6.7%)	1.00
Retching Incidence (2-24 hr)	0 (0%)	0 (0%)	1.00
Vomiting Incidence (0-2 hr)	5 (16.7%)	2 (6.7%)	0.028
Vomiting Incidence (2-6 hr)	2 (6.7%)	1 (3.3%)	0.554
Vomiting Incidence (6-24 hr)	0 (0%)	0 (0%)	1.00

Table 3: Pain and Recovery Outcomes

Outcome	Ondansetron (Mean ± SD or n)	Palonosetron (Mean ± SD or n)	P-Value
VAS Score (0-2 hr)	3.87 ± 1.502	2.1 ± 1.125	<0.001
VAS Score (2-6 hr)	2.17 ± 0.986	0.43 ± 0.728	<0.001
VAS Score (6-24 hr)	0.5 ± 0.777	0	<0.001
Headache Incidence	5 (16.7%)	0 (0%)	0.02
Dizziness Incidence	0 (0%)	0 (0%)	1.00
Constipation Incidence	0 (0%)	0 (0%)	1.00

Table 4: Clinical Recovery Score (CRS)

CRS	Ondansetron (n)	Palonosetron (n)	P-Value
< 8 (Poor Recovery)	11 (36.7%)	8 (26.7%)	0.046
9-10 (Good Recovery)	17 (56.7%)	16 (53.3%)	
11 (Excellent Recovery)	2 (6.7%)	6 (20%)	

Table 5: Summary of Nausea, Retching, and Vomiting Incidence

Time Interval	Nausea Incidence (n, %)	Retching Incidence (n, %)	Vomiting Incidence (n, %)
Ondansetron (0-2 hr)	9 (30%)	2 (6.7%)	5 (16.7%)
Palonosetron (0-2 hr)	4 (13.3%)	2 (6.7%)	2 (6.7%)
Ondansetron (2-6 hr)	7 (23.3%)	0 (0%)	2 (6.7%)
Palonosetron (2-6 hr)	4 (13.3%)	0 (0%)	1 (3.3%)
Ondansetron (6-24 hr)	11 (36.7%)	0 (0%)	0 (0%)
Palonosetron (6-24 hr)	8 (26.7%)	0 (0%)	0 (0%)

DISCUSSION

The present study compared the efficacy of ondansetron and palonosetron in preventing postoperative nausea and vomiting (PONV) and attenuating hemodynamic changes in adults undergoing elective laparoscopic surgeries. The results demonstrated that palonosetron was associated with significantly lower incidences of nausea, vomiting, and headache in the early postoperative period compared to ondansetron.

The incidence of nausea in the palonosetron group was significantly lower than in the ondansetron group during the 0-2 hour (13.3% vs. 30%, p=0.017) and 2-6 hour (13.3% vs. 23.3%, p=0.033) intervals. These findings are consistent with a meta-analysis by Xiong et al., which reported that palonosetron was more effective than ondansetron in preventing PONV, with a relative risk of 0.63 (95% CI: 0.45-0.89, p=0.008) for nausea and 0.51 (95% CI: 0.37-0.71, p<0.0001) for vomiting.13

Similarly, vomiting incidence in the palonosetron group was significantly lower than in the ondansetron group during the 0-2 hour interval (6.7% vs. 16.7%, p=0.028). This is in line with a study by Park and Cho, which found that the incidence of vomiting was significantly lower in the palonosetron group compared to the ondansetron group (3.3% vs. 20%, p=0.048) in patients undergoing gynecological laparoscopic surgery.14

Pain scores were also significantly lower in the palonosetron group at all time intervals ($p<0.001$). This finding is supported by a study by Kim et al., which demonstrated that palonosetron was more effective than ondansetron in reducing postoperative pain in patients undergoing laparoscopic cholecystectomy, with mean VAS scores of 3.2 ± 1.3 vs. 4.1 ± 1.5 ($p=0.015$) at 1 hour and 2.4 ± 0.9 vs. 3.3 ± 1.2 ($p=0.002$) at 6 hours postoperatively.15

The incidence of headache was significantly lower in the palonosetron group (0% vs. 16.7%, $p=0.02$). This is consistent with a study by Sharma et al., which reported a lower incidence of headache in the palonosetron group compared to the ondansetron group (2% vs. 10%, $p=0.204$) in patients undergoing laparoscopic cholecystectomy, although the difference was not statistically significant.16

The Clinical Recovery Score (CRS) showed a trend towards better recovery in the palonosetron group, with 20% of participants achieving an excellent recovery score compared to 6.7% in the ondansetron group, although this difference was not statistically significant. A study by Singh et al. also found no significant difference in the postoperative recovery score between palonosetron and ondansetron groups ($p=0.548$) in patients undergoing laparoscopic cholecystectomy.17
In contrast to our findings, a study by Laha et al. found no significant difference in the incidence of PONV between palonosetron and ondansetron groups in patients undergoing laparoscopic cholecystectomy, with an overall incidence of 20% in both groups ($p=1.00$).18 This discrepancy may be attributed to differences in sample size, anesthesia protocol, and patient characteristics.

The current study has several limitations. First, the sample size was relatively small, which may have limited the power to detect significant differences in some outcomes. Second, the study was conducted at a single center, which may limit the generalizability of the findings. Third, the study did not include a placebo group, which could have provided additional insights into the efficacy of the antiemetic drugs.

In conclusion, palonosetron was found to be more effective than ondansetron in reducing the incidence of PONV, pain, and headache in adults undergoing elective laparoscopic surgeries. These findings suggest that palonosetron may be a preferred choice for preventing PONV in this patient population. However, further large-scale, multicenter studies are needed to confirm these results and assess the cost-effectiveness of palonosetron compared to other antiemetic agents.

CONCLUSION

In this prospective, randomized, double-blind study comparing the efficacy of ondansetron and palonosetron in preventing postoperative nausea and vomiting (PONV) in adults undergoing elective laparoscopic surgeries, palonosetron demonstrated superior antiemetic effects. Palonosetron significantly reduced the incidence of nausea during the 0-2 hour (13.3% vs. 30%, $p=0.017$) and 2-6 hour (13.3% vs. 23.3%, $p=0.033$) intervals, as well as the incidence of vomiting during the 0-2 hour interval (6.7% vs. 16.7%, $p=0.028$) compared to ondansetron. Additionally, palonosetron was associated with significantly lower pain scores at all time intervals ($p<0.001$) and a lower incidence of headache (0% vs. 16.7%, $p=0.02$).

Although the Clinical Recovery Score (CRS) showed a trend towards better recovery in the palonosetron group, with 20% of participants achieving an excellent recovery score compared to 6.7% in the ondansetron group, this difference was not statistically significant. The study's findings suggest that palonosetron may be a more effective choice for preventing PONV and reducing postoperative pain in patients undergoing laparoscopic surgeries.

However, the study has limitations, including a relatively small sample size, single-center design, and the absence of a placebo group. Further large-scale, multicenter studies are needed to confirm these results and assess the cost-effectiveness of palonosetron compared to other antiemetic agents. Despite these limitations, the current study provides valuable insights into the comparative efficacy of ondansetron and palonosetron in the prevention of PONV and management of postoperative pain in the context of laparoscopic surgeries.

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