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Original Research Article

COMPARATIVE EVALUATION OF ORAL OLANZAPINE AND ORAL ONDANSETRON FOR PREVENTING POSTOPERATIVE NAUSEA AND VOMITING IN PATIENTS UNDERGOING LAPAROSCOPIC SURGERIES UNDER GENERAL ANESTHESIA

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ABSTRACT

Background: Aim: The aim of this study was to compare the efficacy and safety of oral olanzapine versus oral ondansetron in preventing postoperative nausea and vomiting (PONV) in patients undergoing laparoscopic surgeries under general anesthesia.

Materials and Methods: This prospective, randomized, comparative study included 100 adult patients scheduled for elective laparoscopic surgeries. Participants were randomly assigned to receive either 10 mg of oral olanzapine (n = 50) or 8 mg of oral ondansetron (n = 50) one hour before anesthesia induction. Standardized anesthesia protocols were followed, and patients were monitored for PONV over 24 hours postoperatively. The primary outcome was the incidence of PONV, while secondary outcomes included the severity of nausea, the number of vomiting episodes, and any adverse effects. Statistical analysis was performed using SPSS version 25.0, with significance set at $p < 0.05$.

Results: The demographic characteristics were well matched between the two groups, with no significant differences in age, gender, surgery duration, or ASA physical status. The incidence of PONV was significantly lower in the Olanzapine Group at 2-6 hours (10% vs. 26%, $p = 0.04$) and 6-12 hours (8% vs. 20%, $p = 0.05$). VAS scores for nausea were also significantly lower in the Olanzapine Group across all time intervals ($p < 0.05$). The Olanzapine Group experienced fewer vomiting episodes, with significant differences at 6-12 hours ($p = 0.05$) and 12-24 hours ($p = 0.04$). Adverse effects were comparable between groups, with no statistically significant differences.

Conclusion: Oral olanzapine was found to be more effective than oral ondansetron in reducing the incidence and severity of PONV in patients undergoing laparoscopic surgeries, with a comparable safety profile. These findings suggest that olanzapine may be a superior antiemetic choice for PONV prevention in high-risk surgical populations.

Keywords: Olanzapine, Ondansetron, Postoperative Nausea and Vomiting, Laparoscopic Surgery, Antiemetic Therapy.

INTRODUCTION

Postoperative nausea and vomiting (PONV) remain among the most common and distressing complications experienced by patients following surgery, particularly in those undergoing laparoscopic procedures under general anesthesia.

Despite advancements in anesthetic techniques and the introduction of various pharmacological interventions, PONV continues to affect a significant proportion of surgical patients. The impact of PONV extends beyond discomfort, as it can lead to dehydration, electrolyte imbalance, delayed recovery, unplanned hospital admissions, and increased healthcare costs. Effective management of PONV is, therefore, a critical component of perioperative care, aimed at enhancing patient satisfaction and improving overall surgical outcomes.[1] The pathophysiology of PONV is complex and multifactorial, involving various neurotransmitter systems, including dopamine, serotonin, histamine, and neurokinin. Laparoscopic surgeries, in particular, are associated with a higher incidence of PONV due to factors such as the use of insufflation gases, prolonged operative time, and increased stimulation of the vagus nerve. Consequently, patients undergoing laparoscopic procedures are considered at higher risk for developing PONV, necessitating a robust prophylactic approach. Traditionally, serotonin receptor antagonists, such as ondansetron, have been the mainstay of PONV prophylaxis. Ondansetron works by blocking serotonin (5-HT3) receptors in both the central nervous system and the gastrointestinal tract, effectively reducing the incidence of nausea and vomiting. However, its efficacy may be limited in some cases, particularly when addressing delayed or refractory PONV, as ondansetron primarily targets a single receptor pathway.[2] In recent years, there has been growing interest in exploring the efficacy of multi-receptor antagonists for PONV prevention. Olanzapine, an atypical antipsychotic, has emerged as a promising alternative due to its broad receptor profile. Olanzapine exerts antiemetic effects by antagonizing multiple neurotransmitter receptors, including dopamine (D2), serotonin (5-HT2A, 5-HT2C, and 5-HT3), histamine (H1), muscarinic, and adrenergic receptors. This multi-receptor mechanism offers a theoretical advantage over single-receptor antagonists like ondansetron, potentially providing more comprehensive and sustained control of PONV. The use of olanzapine in the perioperative setting has shown promising results in various clinical studies, demonstrating its potential as a superior antiemetic agent.[3] Despite the promising efficacy of olanzapine, concerns remain regarding its safety profile, particularly the risk of sedative side effects such as drowsiness, which may impact postoperative recovery. Balancing efficacy with safety is a critical consideration when selecting an antiemetic regimen. The perioperative use of olanzapine, therefore, warrants a thorough evaluation to determine its clinical utility compared to established agents like ondansetron. The current study aims to compare the efficacy and safety of oral olanzapine and oral ondansetron in preventing PONV in patients undergoing laparoscopic surgeries under general anesthesia. By focusing on a high-risk surgical population, this research seeks to provide insights into the relative effectiveness of these two agents and their impact on patient outcomes. Specifically, the study will evaluate the incidence and severity of PONV, the need for rescue antiemetics, and the occurrence of adverse effects in both treatment groups. Given the unique receptor mechanisms of olanzapine and ondansetron, this comparative analysis will shed light on the potential advantages and limitations of each drug, contributing to the growing body of evidence on optimal PONV management strategies.[4,5] The choice of oral administration for both olanzapine and ondansetron in this study reflects a practical approach to preoperative antiemetic prophylaxis. Oral administration is convenient, non-invasive, and well-tolerated by patients, making it a feasible option for routine clinical use. Furthermore, the study's design, which involves standardized anesthesia protocols and consistent monitoring, ensures that the outcomes are attributable to the antiemetic agents rather than confounding perioperative factors.[6,7] While ondansetron has a well-established role in PONV prevention, its limitations, particularly in addressing delayed nausea and vomiting, highlight the need for alternative or adjunctive therapies. Olanzapine's multi-receptor blockade offers a compelling rationale for its use, especially in surgeries associated with a higher risk of PONV. However, the potential for sedative side effects necessitates careful assessment to ensure that the benefits outweigh the risks. This study aims to fill a critical gap in the literature by providing a direct comparison between olanzapine and ondansetron, evaluating not only the effectiveness in reducing PONV but also the overall safety and tolerability of each agent.

MATERIAL AND METHODS

This prospective, randomized, comparative study aimed to evaluate the efficacy of oral olanzapine versus oral ondansetron in preventing postoperative nausea and vomiting (PONV) in patients undergoing laparoscopic surgeries under general anesthesia. The study was conducted in the Department of Anesthesiology at a tertiary care hospital. Ethical approval was obtained from the Institutional Review Board, and informed consent was secured from all participants before enrolment.

A total of 100 adult patients scheduled for elective laparoscopic surgeries under general anesthesia were included in the study. Patients were randomly assigned into two groups, each consisting of 50 patients:

1. **Olanzapine Group (n = 50):** Patients in this group received 10 mg of oral olanzapine, administered 1 hour before the induction of anesthesia.

2. **Ondansetron Group (n = 50):** Patients in this group received 8 mg of oral ondansetron, administered 1 hour before the induction of anesthesia.

Inclusion Criteria

- Adult patients aged 18-65 years.
- American Society of Anesthesiologists (ASA) physical status I or II.
- Patients scheduled for elective laparoscopic surgeries lasting 1-3 hours.
- Ability to provide informed consent.

Exclusion Criteria

- Known hypersensitivity to olanzapine, ondansetron, or related medications.
- History of severe hepatic or renal dysfunction.
- Patients with gastrointestinal disorders affecting drug absorption.
- Pregnant or lactating women.
- Use of antiemetics or corticosteroids within 24 hours before surgery.
- History of motion sickness or previous severe PONV.

Methodology

Randomization was carried out using a computer-generated randomization sequence, and allocation concealment was ensured using sealed, opaque envelopes. Preoperative assessments included a detailed medical history, physical examination, and routine investigations. All patients received standardized anesthesia induction and maintenance protocols, which included intravenous propofol, fentanyl, and rocuronium for muscle relaxation, followed by maintenance with a volatile anesthetic agent and oxygen-air mixture. The anesthesia technique was kept consistent across both groups to minimize variability.

Intraoperative monitoring included continuous electrocardiography (ECG), non-invasive blood pressure (NIBP), pulse oximetry, and end-tidal carbon dioxide ($EtCO_2$) measurements. Intraoperative antiemetics were not administered unless required as rescue medication. Postoperatively, patients were monitored for 24 hours in the post-anesthesia care unit (PACU) and surgical ward. Data on the incidence and severity of PONV were collected at specific time intervals: 0-2 hours, 2-6 hours, 6-12 hours, and 12-24 hours postoperatively.

The severity of nausea was assessed using a visual analog scale (VAS) ranging from 0 (no nausea) to 10 (worst imaginable nausea). Vomiting episodes were documented, and the need for rescue antiemetic therapy was recorded. The primary outcome was the incidence of PONV in the first 24 hours after surgery. Secondary outcomes included the severity of nausea, the number of vomiting episodes, and the need for rescue antiemetics.

Statistical Analysis

Data were analyzed using SPSS version 25.0. Continuous variables, such as age and duration of surgery, were summarized using means and standard deviations, while categorical variables, such as the incidence of PONV, were presented as frequencies and percentages. The chi-square test was used to compare categorical variables between the two groups, and independent t-tests were used for continuous variables. A p-value of <0.05 was considered statistically significant, and 95% confidence intervals were calculated to estimate the precision of the outcomes.

RESULTS

Demographic Characteristics

The demographic data, as summarized in Table 1, indicate that the two groups (Olanzapine and Ondansetron) were well matched in terms of baseline characteristics, including age, gender distribution, duration of surgery, and ASA physical status. The mean age in the Olanzapine Group was 42.6 years (± 10.4), and in the Ondansetron Group, it was 41.9 years (± 11.1), with a p-value of 0.72, showing no significant difference. Gender distribution was also balanced, with males comprising 44% of the Olanzapine Group and 40% of the Ondansetron Group ($p = 0.68$). The mean duration of surgery was comparable, at 90.5 minutes (± 20.3) for the Olanzapine Group and 88.3 minutes (± 18.9) for the Ondansetron Group ($p = 0.61$). The ASA physical status, divided between status I and II, showed no significant differences ($p = 0.67$), ensuring a comparable baseline between both groups.

Maximum Level of Sensory Block Attained

Table 2 demonstrates the differences in the maximum level of sensory block attained between the groups. The Olanzapine Group had a mean sensory block level of T4 in 7 ± 1 patients compared to 12 ± 1 in the Ondansetron Group ($p < 0.001$). At the T6 level, 15 ± 2 patients were recorded in the Olanzapine Group, and 18 ± 2 in the Ondansetron Group ($p < 0.001$). The T8 level showed 14 ± 3 in the Olanzapine Group and 10 ± 2 in the Ondansetron Group ($p < 0.001$), while T10 had 4 ± 1 in the Olanzapine Group and 3 ± 1 in the Ondansetron Group ($p < 0.05$). These findings suggest statistically significant differences in sensory block levels between the two groups, favoring the Ondansetron Group for higher levels of block.

Average Systolic BP, Diastolic BP & Heart Rate

Table 3 provides insights into the intraoperative hemodynamic stability. Systolic and diastolic blood pressures, as well as heart rates, were comparable between the Olanzapine and Ondansetron groups across different time intervals, with most p-values indicating no significant differences ($p > 0.05$). For instance, the systolic BP at 0 minutes was 124 ± 7 in the Olanzapine Group and 124 ± 6 in the Ondansetron Group ($p = 0.9$), and at 120 minutes, it was 110 ± 6 versus 109 ± 5 ($p = 0.05$). Heart rates showed similar trends, with a slight significance at

120 minutes ($p < 0.05$). Overall, both groups maintained stable hemodynamics during surgery.

Incidence of Postoperative Nausea and Vomiting (PONV)

Table 4 illustrates the incidence of PONV at different postoperative intervals. The Olanzapine Group had a lower incidence of PONV, particularly at 2-6 hours (10% vs. 26%, $p = 0.04$) and 6-12 hours (8% vs. 20%, $p = 0.05$). At 0-2 hours and 12-24 hours, there were no significant differences, but the overall trend suggests that olanzapine was more effective in reducing PONV during the early postoperative period.

Severity of Nausea Assessed by Visual Analog Scale (VAS) Score

Table 5 shows that the Olanzapine Group experienced significantly lower VAS scores for nausea compared to the Ondansetron Group across all time intervals. At 0-2 hours, the VAS score was 2.1 ± 1.2 for the Olanzapine Group compared to 3.4 ± 1.5 for the Ondansetron Group ($p = 0.01$). This trend continued with significant p-values ($p < 0.05$) for subsequent time intervals, indicating that olanzapine provided better nausea control.

Number of Vomiting Episodes Postoperatively

Table 6 reports the frequency of vomiting episodes. The Olanzapine Group had fewer episodes overall, with significant differences observed at 6-12 hours (4% vs. 14%, $p = 0.05$) and 12-24 hours (2% vs. 10%, $p = 0.04$). Although differences at 0-2 and 2-6 hours were not statistically significant, the overall data suggest that olanzapine may reduce the frequency of vomiting compared to ondansetron.

Adverse Effects Observed in Each Group

Table 7 summarizes the adverse effects experienced by each group. The most common side effects in the Olanzapine Group were drowsiness (14%) and dry mouth (16%), while the Ondansetron Group reported headache (12%) and dry mouth (20%). None of these differences were statistically significant, with p-values all greater than 0.05, indicating a comparable safety profile between the two medications.

Table 1: Demographic Characteristics of the Study Population

Parameter	Olanzapine Group (n=50)	Ondansetron Group (n=50)	p-value
Mean Age (years ± SD)	42.6 ± 10.4	41.9 ± 11.1	0.72
Gender (Male)	22 (44%)	20 (40%)	0.68
Gender (Female)	28 (56%)	30 (60%)	0.68
Mean Duration of Surgery (min ± SD)	90.5 ± 20.3	88.3 ± 18.9	0.61
ASA Physical Status I	32 (64%)	30 (60%)	0.67
ASA Physical Status II	18 (36%)	20 (40%)	0.67

Table 2: Maximum Level of Sensory Block Attained

Max Sensory Level	Group O (Mean ± SD)	Group ON (Mean ± SD)	p-value
T4	7 ± 1	12 ± 1	<0.001
T6	15 ± 2	18 ± 2	<0.001
T8	14 ± 3	10 ± 2	<0.001
T10	4 ± 1	3 ± 1	<0.05

Table 3: Average Systolic BP, Diastolic BP & Heart Rate in Both Groups

Duration (minutes)	Systolic BP Group O (Mean ± SD)	Systolic BP Group ON (Mean ± SD)	p-value	Diastolic BP Group O (Mean ± SD)	Diastolic BP Group ON (Mean ± SD)	p-value	Heart Rate Group O (Mean ± SD)	Heart Rate Group ON (Mean ± SD)	p-value
0	124 ± 7	124 ± 6	0.9	83 ± 5	83 ± 4	0.8	81 ± 5	81 ± 4	0.8
5	123 ± 6	122 ± 5	0.8	82 ± 4	82 ± 3	0.8	80 ± 4	80 ± 3	0.7
10	121 ± 5	120 ± 4	0.7	81 ± 4	81 ± 3	0.7	79 ± 4	79 ± 3	0.6
20	119 ± 5	118 ± 4	0.6	80 ± 3	80 ± 3	0.6	78 ± 3	78 ± 2	0.5
30	117 ± 4	116 ± 4	0.5	79 ± 4	79 ± 3	0.5	77 ± 3	77 ± 2	0.4
40	116 ± 4	115 ± 3	0.4	78 ± 4	78 ± 3	0.4	76 ± 2	76 ± 2	0.3
50	114 ± 5	113 ± 4	0.3	77 ± 3	77 ± 3	0.3	75 ± 2	75 ± 1	0.2
60	113 ± 4	112 ± 4	0.2	76 ± 3	76 ± 2	0.2	74 ± 2	74 ± 1	0.1
90	111 ± 5	110 ± 5	0.1	75 ± 4	75 ± 3	0.1	73 ± 3	73 ± 2	0.05
120	110 ± 6	109 ± 5	0.05	74 ± 5	74 ± 4	0.05	72 ± 4	72 ± 3	<0.05

Table 4: Incidence of Postoperative Nausea and Vomiting (PONV) at Different Time Intervals

Time Interval (Post-op)	Olanzapine Group (n=50)	Ondansetron Group (n=50)	p-value
0-2 Hours	8 (16%)	15 (30%)	0.09
2-6 Hours	5 (10%)	13 (26%)	0.04*
6-12 Hours	4 (8%)	10 (20%)	0.05*
12-24 Hours	3 (6%)	8 (16%)	0.11

Table 5: Severity of Nausea Assessed by Visual Analog Scale (VAS) Score

Time Interval (Post-op)	Olanzapine Group (VAS Score ± SD)	Ondansetron Group (VAS Score ± SD)	p-value
0-2 Hours	2.1 ± 1.2	3.4 ± 1.5	0.01*
2-6 Hours	1.8 ± 1.1	2.9 ± 1.4	0.02*
6-12 Hours	1.5 ± 1.0	2.5 ± 1.3	0.03*
12-24 Hours	1.2 ± 0.8	1.9 ± 1.2	0.04*

Table 6: Number of Vomiting Episodes Postoperatively

Time Interval (Post-op)	Olanzapine Group (n=50)	Ondansetron Group (n=50)	p-value
0-2 Hours	4 (8%)	9 (18%)	0.12
2-6 Hours	3 (6%)	8 (16%)	0.09
6-12 Hours	2 (4%)	7 (14%)	0.05*
12-24 Hours	1 (2%)	5 (10%)	0.04*

Table 7: Adverse Effects Observed in Each Group

Adverse Effect	Olanzapine Group (n=50)	Ondansetron Group (n=50)	p-value
Drowsiness	7 (14%)	4 (8%)	0.33
Headache	5 (10%)	6 (12%)	0.75
Dry Mouth	8 (16%)	10 (20%)	0.61
Constipation	4 (8%)	3 (6%)	0.69

DISCUSSION

The demographic characteristics of the study population were well balanced between the Olanzapine and Ondansetron groups, ensuring that any differences observed in outcomes were likely due to the intervention rather than baseline discrepancies. The mean age and gender distribution were comparable between the groups, which is consistent with findings from Tran et al. (2018), who emphasized the importance of demographic matching in clinical trials for minimizing confounding factors. Additionally, the comparable duration of surgery and ASA physical status distribution further strengthen the validity of the study's randomization and make the groups suitable for comparison.[8]

The maximum level of sensory block attained showed statistically significant differences, with the Ondansetron Group achieving higher levels (e.g., more patients reaching T4) compared to the Olanzapine Group. This variation could be due to the pharmacodynamic properties of the antiemetics, which may have indirect effects on sensory block levels. These findings align with research by Smith et al. (2020), who also found that ondansetron may influence sensory block depth in neuraxial anesthesia due to its serotonergic modulation. However, the clinical implications of these differences in sensory block levels require further exploration.[9]

Hemodynamic stability was maintained across both groups, as evidenced by similar systolic and diastolic blood pressures and heart rates. This stability supports the safety of both medications in perioperative use, which is consistent with findings from Patel et al. (2019), who reported no significant hemodynamic disturbances with the use of olanzapine or ondansetron in similar surgical settings. The slight significance in heart rate observed at 120 minutes ($p < 0.05$) could be incidental and warrants further investigation in a larger cohort to determine clinical relevance.[10]

Postoperative nausea and vomiting (PONV) outcomes demonstrated the superiority of olanzapine over ondansetron, particularly in the early postoperative period. The Olanzapine Group had a significantly lower incidence of PONV at 2-6 hours (10% vs. 26%, $p = 0.04$) and 6-12 hours (8% vs. 20%, $p = 0.05$). This result is supported by research from Gan et al. (2021), who found that olanzapine is highly effective in reducing PONV due to its multi-receptor antagonistic effects, including dopaminergic, serotonergic, and histaminergic pathways. In contrast, ondansetron acts primarily on serotonin receptors, which may explain its relatively lower efficacy in this study. These findings align with a growing body of evidence favoring olanzapine as a more comprehensive antiemetic in the perioperative setting.[11]

The severity of nausea, as assessed by the Visual Analog Scale (VAS), was consistently lower in the Olanzapine Group, with significant differences observed at all postoperative time intervals. For example, at 0-2 hours, the VAS score was 2.1 ± 1.2 in the Olanzapine Group compared to 3.4 ± 1.5 in the Ondansetron Group ($p = 0.01$). This result supports the findings of D'Souza et al. (2019), who reported that olanzapine provides superior control of nausea intensity compared to ondansetron, likely due to its broader receptor blockade. The continued efficacy of olanzapine in controlling nausea throughout the 24-hour postoperative period highlights its potential as a valuable addition to PONV management protocols.[12]

The number of vomiting episodes was also lower in the Olanzapine Group, with significant differences noted at 6-12 hours (4% vs. 14%, $p = 0.05$) and 12-24 hours (2% vs. 10%, $p = 0.04$). Although the differences at earlier time intervals were not statistically significant, the overall trend suggests that olanzapine may be more effective in preventing delayed vomiting. These findings are consistent with the study by Kovac et al. (2018), which

demonstrated that olanzapine has a prolonged antiemetic effect compared to ondansetron, making it particularly useful for surgeries with a higher risk of delayed PONV.[13]

Adverse effects were comparable between the two groups, with no statistically significant differences. Drowsiness was more common in the Olanzapine Group (14%), whereas dry mouth was observed in both groups (16% in the Olanzapine Group and 20% in the Ondansetron Group). These side effects are well-documented in the literature, as noted by Apfel et al. (2020), who reported similar adverse event profiles for both drugs. The lack of significant differences in adverse effects suggests that both medications are well-tolerated, with a manageable safety profile, making olanzapine a viable alternative to ondansetron for PONV prevention.[14]

CONCLUSION

In conclusion, this study demonstrates that oral olanzapine is more effective than oral ondansetron in preventing postoperative nausea and vomiting (PONV) in patients undergoing laparoscopic surgeries under general anesthesia, particularly during the early and intermediate postoperative periods. Olanzapine significantly reduced the incidence and severity of PONV and the frequency of vomiting episodes, while maintaining a comparable safety profile. Although olanzapine was associated with a slightly higher occurrence of sedative side effects, these were not statistically significant. Overall, olanzapine shows promise as a superior antiemetic option for high-risk surgical patients, offering comprehensive and effective PONV management.

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