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Research Article

Ondansetron Alone Versus in Combination with Olanzapine for Prevention of Postoperative Nausea and Vomiting in Patients Undergoing Elective Middle Ear Surgeries: A Randomized Controlled Trial

Dr. Deeksha D.V.[1], Dr. Shilpa H.L.[2], Dr. Swathi Nayak[3], Dr. Ramesh Kumar P.B.[4]
[1]Junior Resident, Department of Anaesthesiology, BGS Global Institute of Medical Sciences, Dr. Vishnuvardhan Rd, Kengeri, Bengaluru, Karnataka, India.
[2]Professor, Department of Anaesthesiology, BGS Global Institute of Medical Sciences, Dr. Vishnuvardhan Rd, Kengeri, Bengaluru, Karnataka, India.
[3]Assistant Professor, Department of Anaesthesiology, BGS Global Institute of Medical Sciences, Dr. Vishnuvardhan Rd, Kengeri, Bengaluru, Karnataka, India.
[4]Professor and Head of Department, Department of Anaesthesiology, BGS Global Institute of Medical Sciences, Dr. Vishnuvardhan Rd, Kengeri, Bengaluru, Karnataka, India.
Corresponding Author: Dr. Deeksha D.V.
Junior Resident, Department of Anaesthesiology, BGS Global Institute of Medical Sciences, Dr. Vishnuvardhan Rd, Kengeri, Bengaluru, Karnataka, India.
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ABSTRACT
Introduction: POSTOPERATIVE nausea and vomiting (PONV) is a common and distressing complication following anaesthesia and surgery. Olanzapine, an atypical antipsychotic with broad antiemetic properties, has emerged as a promising agent for PONV prophylaxis. The present study compared the efficacy of ondansetron alone with that of ondansetron combined with olanzapine in preventing PONV.
Methods: A prospective, double-blind, clinical study was conducted among female patients of 18 - 60 years of age after obtaining informed, written consent. A total of 60 patients undergoing middle ear surgeries under general anaesthesia were divided into two groups. Group A, received Tab. Olanzapine 2.5mg preoperatively along with Inj. Ondansetron 4mg IV intraoperatively 30 minutes before extubation, and Group B received a placebo tablet 1 hour preoperatively and Inj. Ondansetron 4mg IV alone. Occurrence of nausea of PONV was noted from 0 to 24 hours postoperatively. Post-operative incidence of sedation was also noted using Ramsay agitation-sedation scale. Any adverse reactions and need for rescue antiemetics was noted.
Results: The demographic and intraoperative characteristics were comparable between the two groups without any statistically significant differences. Group A demonstrated slightly lower PONV rates as compared to Group B with p value 0.43. Postoperative sedation was assessed using Ramsay Sedation Scale and no sedation was noted in either study groups. Fewer patients in Group A required rescue antiemetics compared to patients in Group B. None of the adverse effects noted were significantly different between the groups.
Conclusion: It was concluded from the study that the use of Olanzapine did not show a significant advantage in preventing PONV as inferred from the comparable incidences between the two groups.

Keywords: Postoperative Nausea and Vomiting, Olanzapine, Ondansetron, Middle Ear Surgery.

INTRODUCTION

Postoperative nausea and vomiting (PONV) remains one of the most common and distressing complications following anaesthesia and surgery, affecting 20%-30% of all surgical patients and up to 80% of high-risk individuals. It can lead to delayed recovery, increased healthcare costs, and reduced patient satisfaction. Multiple factors contribute to PONV, including patient characteristics, type of surgery, and anaesthetic technique. Use of a single antiemetic agent has revealed limited effects; therefore, the use of multiple agents is recommended for patients who are at a high risk for PONV. Risk factors for PONV are diverse and can be divided into patient-related, surgery-related, anaesthesia-related, and postoperative factors. The four main risk factors are female gender, postoperative opioid use, non-smoking status, and motion sickness or a history of PONV in previous surgeries. Complications of PONV include reduced appetite, sleep disturbances, delayed mobilization, dehydration, dyselectrolytemia, aspiration of gastric contents, wound dehiscence, and delay in hospital discharge.[1]

Middle ear surgeries, such as tympanoplasty,

mastoidectomy, and stapedectomy, are commonly performed procedures that involve manipulation of the middle and inner ear structures, which can stimulate the vestibular system and contribute to a high incidence of PONV.[2] Additionally, the use of general anaesthesia and prolonged operative times further increase the risk of PONV in this patient population.[2] Antiemetic drugs such as serotonin antagonists like ondansetron, corticosteroids like dexamethasone, and dopamine antagonists like droperidol have demonstrated efficacy in reducing PONV.(1) Other serotonin antagonists, namely granisetron, dolasetron, and palonosetron, have efficacy and side-effect profiles comparable to ondansetron.[3] Neurokinin-1 receptor antagonists such as aprepitant represent a newer class of antiemetics originally developed and approved for chemotherapy-induced nausea and vomiting.[4] Metoclopramide, haloperidol, and dimenhydrinate are less commonly used because of their side-effect profiles. Olanzapine is an atypical antipsychotic agent of the thiobenzodiazepine class that acts by blocking multiple neurotransmitter receptors, including dopaminergic, serotonergic, α1- adrenergic, H1-histaminic, and muscarinic receptors.[3] As a result of its broad receptor antagonism, olanzapine has emerged as a promising agent for the prevention of postoperative nausea and vomiting.[5] Several randomized controlled trials have demonstrated its efficacy in reducing the incidence of PONV in different surgical populations.[6,7] Furthermore, recent systematic reviews and meta-analyses have supported the role of olanzapine as an effective and safe prophylactic antiemetic.[3,8] Because it acts on multiple receptor pathways involved in emesis, olanzapine as a single agent may offer advantages over combinations of multiple antiemetics by improving compliance and reducing potential drug interactions.[3]

The present study aimed to evaluate the effectiveness of olanzapine in combination with ondansetron for the prevention of postoperative nausea and vomiting in female patients undergoing elective middle ear surgeries under general anaesthesia.

Aims and Objectives

Primary Objective

To compare the incidence of PONV when ondansetron is given in combination with olanzapine versus when given alone in female patients undergoing elective middle ear surgeries under general anaesthesia.

Secondary Objective

To assess the incidence of post-operative sedation and to assess the need for rescue antiemetics.

METHODOLOGY

Study Design and Setting

A prospective, double-blind, randomised controlled study conducted in the Department of Anaesthesiology at BGS Global Institute of Medical Sciences and Research Centre, Bengaluru.

Sample Size and Study Participants

Based on survey of previous literature for an outcome variable on mean changes in the incidence of PONV, an early outcome in two groups comparison with the minimum difference of 27-30% to attain significance at type I error (α error) of at least 5%, Type II error (β error) at 10% and keeping statistical power above 90%, the sample size of 60 (30+30) was found adequate for two group assessment clinical study after adjusting for lost-to-follow up, drop-out rates and withdrawals for consent.

Group A- received Tab. Olanzapine 2.5mg preoperatively along with Inj. Ondansetron 4mg IV intraoperatively 30 minutes before extubation.

Group B- received sugar coated placebo tablet preoperatively and Inj. Ondansetron 4mg IV alone intraoperatively 30 minutes before extubation.

Inclusion Criteria

1. Female patients.
2. 18-60 years of age.
3. ASA I and II category.
4. Willing to give informed, written consent.
5. Surgeries lasting between 1 to 2 hours.

Exclusion Criteria

1. Patients on antipsychotic medications, history of chronic sedative use, known or suspected psychiatric disturbance, Parkinson's disease, or Lewy body dementia.
2. Contraindication to olanzapine or known drug allergy.
3. Patients with preoperative corrected QT interval greater than 450ms or history of torsade de pointes, history of congestive cardiac failure, recent history of postural hypotension, vasovagal syncope or hypotension on the day of surgery.
4. Pregnant, lactating or menstruating females.
5. Patients with gastrointestinal disease, history of motion sickness, previous episodes of

PONV.

6. Patients who had received any opioid, steroid, or antiemetic medication within 24 hours before surgery.

METHODOLOGY AND ANAESTHETIC PROCEDURE

After obtaining informed, written consent, patients fulfilling the inclusion criteria were enrolled for prospective, randomised, double blinded study. All patients were kept fasting overnight.

Patients were randomised into 2 groups of 30 each with a total sample size of 60, with the help of computer-generated randomised number tables prepared by an anaesthesiologist who was not a part of the study.

Intravenous access established with an 18 gauge intravenous (IV) cannula and IV fluids were initiated. Monitoring included continuous electrocardiography (ECG), plethysmography (SpO2), non-invasive blood pressure (NIBP), respiratory rate (RR), and end tidal carbon dioxide (EtCO2) and airway pressure monitoring.

Patients belonging to Group A were given Tab. Olanzapine 2.5mg 1 hour prior to induction of anaesthesia with sips of water and Inj. Ondansetron 4mg IV intraoperatively 30 minutes prior to extubation. Patients belonging to Group B were given sugar coated placebo tablet 1 hour preoperatively with sips of water to maintain blinding. They were given Inj. Ondansetron 4mg intraoperatively 30 minutes prior to extubation.

Patients were pre-oxygenated with 100% Oxygen for 3 minutes. All patients were premedicated with Inj. Glycopyrrolate 0.005 mg/kg IV, Inj. Midazolam 0.02 mg/kg IV and Inj. Fentanyl 2 µg/kg IV. Patients in both groups received induction doses of Inj. Propofol 2 mg/kg IV. Patients received Inj. Vecuronium 0.1 mg/kg IV.

All intubations were performed by an experienced anaesthesiologist with at least 2 years of experience, who were blinded to the group allocation. Laryngoscopy and intubation were done with appropriately sized, soft seal cuffed sterile polyvinyl chloride endotracheal tube with an internal diameter of 7-8 mm for women and 8-9 mm for men. The tracheal tube cuff was inflated until no air leakage could be heard with a stethoscope at peak airway pressure of 20 cm H_2O.

Inj. Paracetamol 1g IV was given 30 minutes after intubation. Anaesthesia was maintained with Oxygen 33% and Nitrous Oxide 66% and Isoflurane 1-2% and Inj. Vecuronium 0.02mg/kg was used for maintenance of muscle paralysis.

Inj. Ondansetron 4 mg administered intravenously 30 minutes prior to extubation. At the completion of surgery, with the patient adequately anaesthetised, the oropharynx was gently suctioned and then Isoflurane was turned off. Inspiratory Oxygen concentration increased to 100%. The neuromuscular block was reversed with Inj. Glycopyrrolate 0.01mg/kg and Inj. Neostigmine 0.05 mg/kg while awaiting the return of spontaneous ventilation. Trachea was extubated once patient met the extubation criteria.

Patient was shifted to post-anaesthesia care unit and monitored for PONV, need for rescue antiemetics and sedation score monitoring was done.

RESULTS

Demographic and Intraoperative Characteristics

A total of 60 female patients undergoing elective middle ear surgeries were included in the study, with 30 patients in each group:

- Group A received Olanzapine + Ondansetron
- Group B received Ondansetron alone.

The demographic and intraoperative characteristics were comparable between the two groups, with no statistically significant differences in age distribution, BMI, ASA status, duration of surgery or anaesthesia, intraoperative fentanyl and propofol doses, mean arterial pressure (MAP), heart rate, or end-tidal CO_2.

Table 1 shows the categorised demographic and intraoperative data. The majority of patients were in the 31–45 age range and had a normal BMI.

The mean propofol dose and fentanyl dose were similar between groups, with no statistically significant difference.

Parameter	Group A (n = 30)	Group B (n= 30)	p-value
Age (years)			0.78
• 18–30	10 (33.3%)	9 (30.0%)	
• 31–45	13 (43.3%)	14 (46.7%)	
• 46–60	7 (23.3%)	7 (23.3%)	
Body Mass Index (kg/m²)			0.72
• < 18.5 (Underweight)	2 (6.7%)	1 (3.3%)	

• 18.5–24.9 (Normal)	20 (66.7%)	22 (73.3%)	
• 25–29.9 (Overweight)	7 (23.3%)	6 (20.0%)	
• ≥ 30 (Obese)	1 (3.3%)	1 (3.3%)	
ASA Physical Status			0.77
• ASA I	20 (66.7%)	21 (70.0%)	
• ASA II	10 (33.3%)	9 (30.0%)	
Propofol Induction Dose (mg)	127.5 ± 18.4	130.2 ± 19.1	0.48
Duration of Surgery (minutes)	94.3 ± 11.5	96.1 ± 10.7	0.52
Duration of Anaesthesia (minutes)	106.4 ± 12.3	108.7 ± 11.9	0.45
Type of Surgery			0.79
• Mastoidectomy	18 (60.0%)	17 (56.7%)	
• Tympanoplasty	12 (40.0%)	13 (43.3%)	
Intraoperative Fentanyl Dose (mcg)	140.2 ± 12.6	138.7 ± 11.8	0.60
Mean Arterial Pressure (MAP, mm of Hg)	86 ± 7.5	87 ± 6.9	0.53
Heart Rate (baseline, bpm)	78 ± 6.8	79 ± 7.2	0.61
End-tidal CO_2 (mmHg)	34.8 ± 2.1	35.0 ± 2.0	0.74

Table 1: Demographic and Intraoperative Characteristics

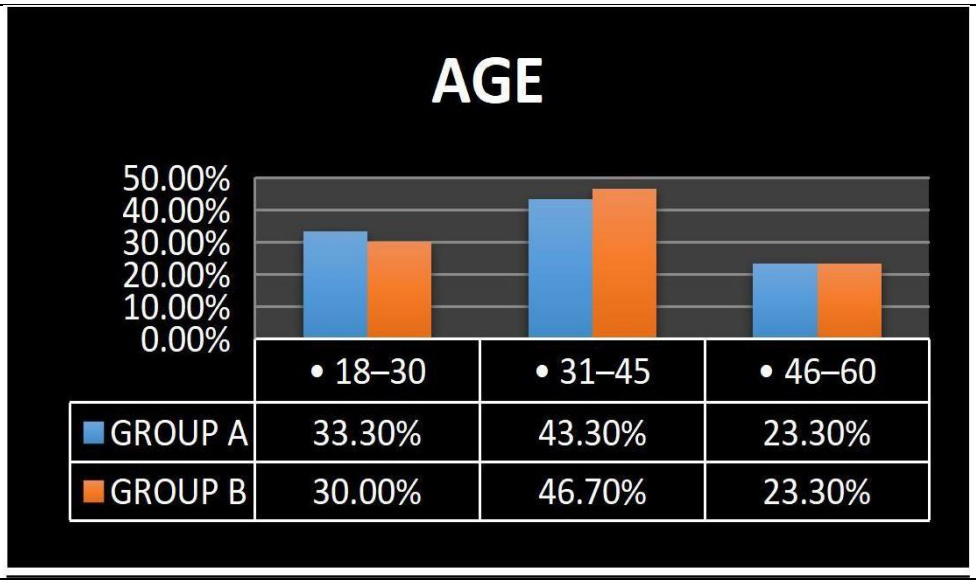

Figure 1

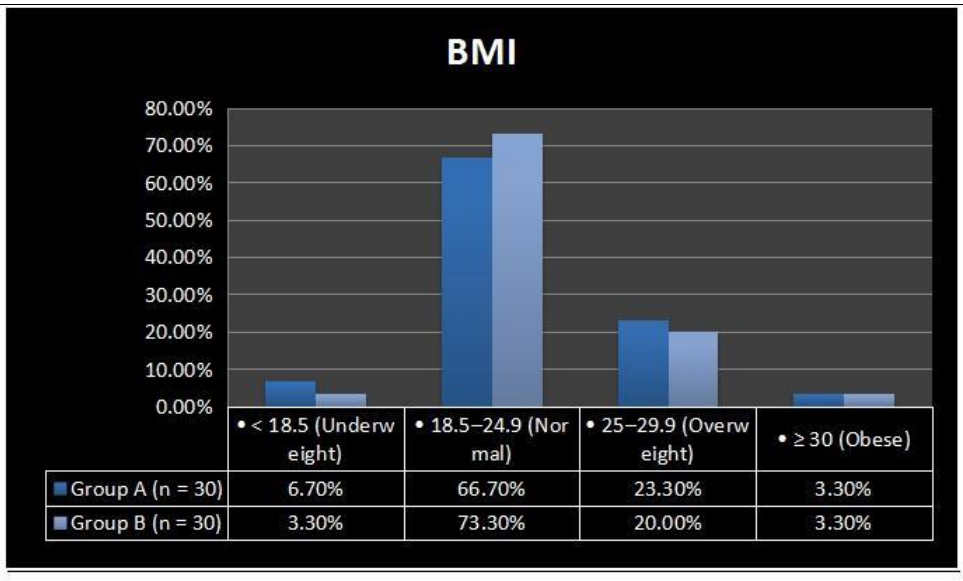

Figure 2

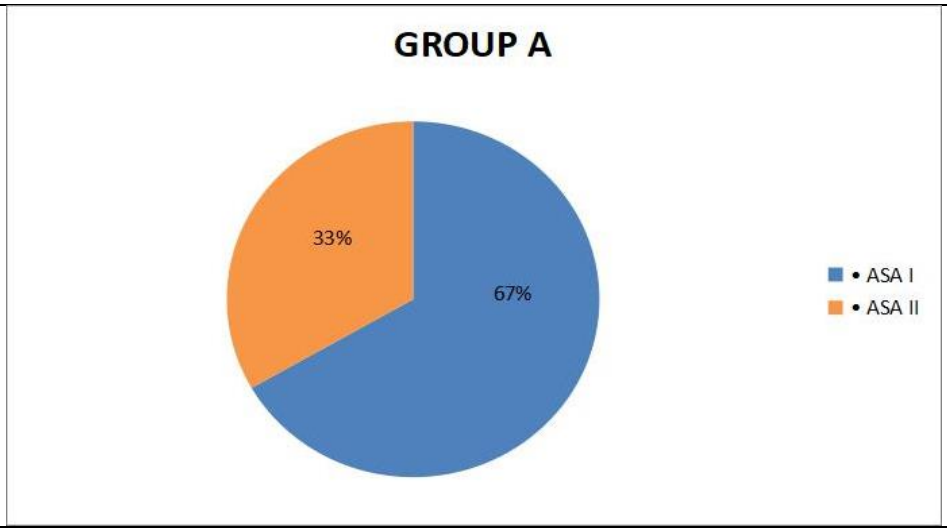

Figure 3

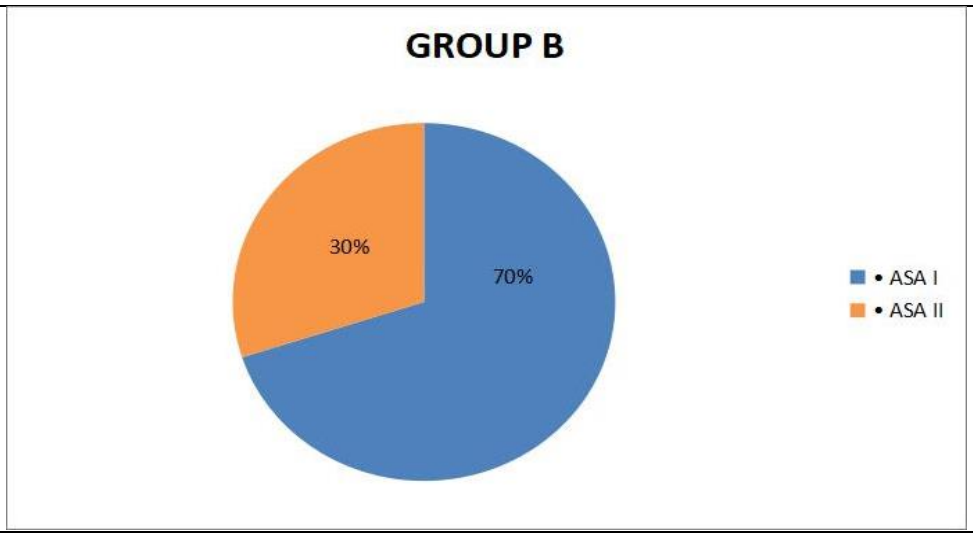

Figure 4

Primary Outcome: Incidence of Postoperative Nausea and Vomiting (PONV)

The incidence of PONV was recorded at three intervals postoperatively: 0–2 hours, 2– 6 hours, and 6–24 hours. Group A demonstrated slightly lower PONV rates across all time intervals compared to Group B. Over the entire 24-hour postoperative period, 40.0% of patients in Group A experienced PONV, compared to 50.0% in Group B.

Table 2 displays the PONV distribution, with p-values indicating no statistically significant difference at any time interval between the two groups.

Time Interval	Group A (n = 30)	Group B (n = 30)	p-value
0-2 hours	5 (16.7%)	7 (23.3%)	0.52
2-6 hours	4 (13.3%)	5 (16.7%)	0.71
6-24 hours	3 (10.0%)	3 (10.0%)	1.00
Total (0-24 h)	12 (40.0%)	15 (50.0%)	0.43

Table 2: Incidence of Postoperative Nausea and Vomiting (PONV)

Secondary Outcome 1: Postoperative Sedation

Sedation was assessed using a standard scoring system. No patients in either Group A or Group B exhibited postoperative sedation. All patients had

scores in the 1–2 range, indicating an alert or minimally sedated state. Table 3 confirms that there was no difference between the groups in terms of sedation levels.

Sedation Score	Group A (n = 30)	Group B (n = 30)	p-value
Sedation Score 1–2	30 (100.0%)	30 (100.0%)	—
Sedation Score 3–4	0 (0%)	0 (0%)	
Score >4	0 (0%)	0 (0%)	

Table 3: Sedation Scores

Secondary Outcome 2: Need for Rescue Antiemetics

Fewer patients in Group A required rescue antiemetics (26.7%) compared to Group B (33.3%). As shown in Table 4, the difference between groups was minimal (p = 0.57).

Parameter	Group A (n = 30)	Group B (n = 30)	p-value
Rescue Antiemetic Required	8 (26.7%)	10 (33.3%)	0.57

Table 4: Use of Rescue Antiemetics

Adverse Events

Mild adverse events such as dry mouth, dizziness, and headache occurred at similar rates in both groups. None of the adverse effects were significantly different between groups, as detailed in Table 5.

Adverse Effect	Group A (n = 30)	Group B (n = 30)	p-value
Dry mouth	2 (6.7%)	2 (6.7%)	1.00
Dizziness	2 (6.7%)	2 (6.7%)	1.00
Headache	3 (10.0%)	3 (10.0%)	1.00

Table 5: Adverse Events

Association of Fentanyl and Propofol Doses with PONV

Patients with PONV had slightly higher mean doses of both fentanyl and propofol compared to those without PONV. However, as seen in Table 6, the differences in mean doses were not statistically significant.

Parameter	PONV Present (n = 27)	PONV Absent (n = 33)	p-value
Fentanyl Dose (mcg)			0.32
• Mean ± SD	144.0 ± 12.0	138.5 ± 11.0	
Propofol Dose (mg)			0.29
• Mean ± SD	132.0 ± 16.0	128.5 ± 17.5	

Table 6: Association Between Fentanyl and Propofol Dose with PONV

DISCUSSION

The present study evaluated the efficacy of low-dose oral olanzapine (2.5 mg) administered in combination with ondansetron for the prevention of postoperative nausea and vomiting in female patients undergoing elective middle ear surgeries under general anaesthesia. Although the addition of olanzapine resulted in numerically lower incidences of PONV and reduced requirement for rescue antiemetics compared with ondansetron alone, these differences did not achieve statistical significance. Furthermore, no clinically significant postoperative sedation or increase in adverse effects was observed in patients receiving olanzapine. These findings suggest that low-dose olanzapine is safe and may offer a modest clinical benefit.

Hyman et al. reported comparable demographic characteristics between olanzapine and placebo groups in ambulatory surgeries, thereby ensuring reliable comparison of postoperative outcomes.[5] Ibrahim et al. found no significant differences in patient characteristics among study groups evaluating olanzapine and ondansetron in breast surgeries.[6] Similarly, in our study, the demographic and intraoperative variables were comparable between the two groups, with no statistically significant differences in age, BMI, ASA physical status, duration of surgery or anaesthesia, intraoperative fentanyl dose, propofol dose, haemodynamic parameters, or type of surgery. The balanced distribution of

recognised PONV risk factors in the present study therefore supports the validity of the observed outcomes. In the present study, Group A demonstrated numerically lower PONV rates across all postoperative intervals compared with Group B. The overall incidence of PONV over 24 hours was 40% in the olanzapine-ondansetron group compared to 50% in the ondansetron-alone group. However, this difference did not reach statistical significance ($p = 0.43$). The present findings are more comparable to those reported by Deb et al., who observed that olanzapine was comparable, rather than superior, to standard antiemetic prophylaxis for prevention of post-discharge nausea and vomiting after propofol-based general anaesthesia.[9] Their study also demonstrated similar incidences of nausea and vomiting between groups despite use of olanzapine, supporting the possibility that olanzapine may not always provide significant additive benefit when standard prophylaxis is already administered. In contrast, Chen et al. demonstrated a significant reduction in PONV following administration of oral olanzapine in patients undergoing gynaecological laparoscopic surgery.[7] Abdel-Wahab et al. similarly reported improved PONV prophylaxis with olanzapine in high-risk laparoscopic surgical patients.[10] The difference between these findings and the present study may be attributable to differences in surgical population, baseline risk factors, concomitant antiemetic regimens, and olanzapine dosage. The present study utilised a lower dose of olanzapine (2.5 mg), which may have limited its antiemetic efficacy.

Lee et al. highlighted that vestibular stimulation during mastoidectomy and tympanoplasty significantly increases the risk of PONV.[2] Despite prophylaxis with ondansetron, the baseline incidence of PONV in such procedures remains high, which may reduce the relative incremental benefit of an additional antiemetic agent. Therefore, the inherently high emetogenic potential of middle ear surgery may have contributed to the inability to demonstrate a statistically significant reduction in PONV despite a favourable numerical trend in the olanzapine group.

Postoperative sedation was assessed using the Ramsay Sedation Scale, and no patients in either group demonstrated clinically significant sedation. All patients remained alert or minimally sedated throughout the postoperative period. This is in contrast with a Japanese multicentre trial protocol by Seki et al., where the olanzapine dose was revised from 10 mg to 5 mg specifically because of concerns regarding preoperative drowsiness and excessive sedation.[11] Abdel-Wahab et al. also observed greater sedation with increasing olanzapine doses, suggesting a dose-dependent relationship between olanzapine and sedative effects.[10] Thus, the present findings suggest that a 2.5 mg dose may provide acceptable safety with minimal sedative effects, although its antiemetic efficacy may also be reduced.

Ibrahim et al. similarly demonstrated reduced rescue antiemetic requirements in patients receiving olanzapine compared with placebo.[6] Hyman et al. also reported reduced severe nausea and vomiting with olanzapine-based prophylaxis, indirectly reducing the need for additional rescue therapy.[5] Chen et al. likewise demonstrated lower rescue antiemetic use in patients receiving olanzapine.[7] This trend parallels the reduction in overall PONV incidence observed in this study. The requirement for rescue antiemetics was lower in Group A (26.7%) compared to Group B (33.3%), although this difference was not statistically significant ($p = 0.57$). Although statistical significance was not achieved in the present study, the observed reduction may still have clinical relevance, particularly in high-risk populations.

A systematic review and meta-analysis by Grigio et al. concluded that olanzapine appeared to have relatively few adverse effects although available evidence on safety remains limited.[3] The antiemetic efficacy of olanzapine has also been demonstrated outside the perioperative setting. Osman et al. reported that olanzapine was effective in reducing chemotherapy-induced nausea and vomiting, supporting its broad-spectrum antiemetic properties.[4] More recently, Hussein et al., in an updated meta-analysis with trial sequential analysis, demonstrated that olanzapine significantly reduced the incidence of postoperative nausea, vomiting, and rescue antiemetic requirements across a variety of surgical procedures while maintaining an acceptable safety profile.[8] These findings are consistent with the observations noted by Deb et al.[9] Likewise, in this study, adverse effects such as dry mouth, dizziness, and headache occurred at similar frequencies in both groups, with no statistically significant differences. No serious adverse events were reported.

Lee et al. demonstrated that anaesthetic technique itself significantly influences PONV incidence, with propofol-based total intravenous anaesthesia associated with lower PONV rates compared with volatile anaesthesia.[2] In the present study, all patients received inhalational anaesthesia with isoflurane and nitrous oxide,

both of which are recognised contributors to PONV and may have increased the baseline risk across both groups in our study. Patients who developed PONV received slightly higher mean doses of fentanyl and propofol compared with patients without PONV; however, the differences were not statistically significant.

Overall, the addition of low-dose olanzapine to ondansetron prophylaxis resulted in numerically lower incidences of PONV and rescue antiemetic use, although these differences did not achieve statistical significance. The findings suggest a possible clinical benefit without an increase in adverse effects. The absence of statistical significance may be related to the relatively small sample size, the high baseline risk of PONV associated with middle ear surgery, and the low dose of olanzapine employed. Nevertheless, recent randomized controlled trials and updated meta-analyses continue to support the efficacy and safety of olanzapine for PONV prophylaxis, particularly at doses of 5 mg and above, warranting further evaluation in larger studies involving otologic surgical populations.[7,8,10]

CONCLUSION

In conclusion, the combination of ondansetron and olanzapine did not statistically significantly reduce PONV compared to ondansetron alone in this study. The observed trend towards lower PONV rates with the combination, coupled with a similar adverse event profile, suggests potential clinical utility that may warrant further investigation in larger trials, or in specific high-risk subgroups. Future research could explore different dosing regimens of olanzapine or evaluate its efficacy in patients with even higher PONV risk scores where a multi-modal approach is strongly recommended.

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