



EFFICACY OF ONDANSETRON ALONE VERSUS ONDANSETRON WITH DEXAMETHASONE IN PREVENTING POSTOPERATIVE NAUSEA OR VOMITING IN PATIENTS UNDERGOING ENT SURGERY

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ABSTRACT

Background: Postoperative nausea and vomiting (PONV) are common after Ear, Nose, and Throat (ENT) surgeries due to various factors. Addressing PONV effectively is crucial for patient recovery and satisfaction.

Objective: This study compared the efficacy of ondansetron alone versus ondansetron with dexamethasone in preventing PONV in ENT surgery patients.

Methodology: A six-month prospective study enrolled 138 ENT surgery patients, randomly assigning them to receive ondansetron alone (Group A) or ondansetron with dexamethasone (Group B). Efficacy was assessed by nausea and vomiting occurrence within six hours post-surgery.

Results: Group B showed significantly higher efficacy in preventing PONV compared to Group A (Group A: 62.3% vs. Group B: 84%, $p=0.004$). While nausea occurrence was lower in Group B, vomiting occurrence did not significantly differ between groups. Group B had fewer multiple vomiting episodes, indicating better efficacy.

Conclusion: Combining ondansetron with dexamethasone provides superior PONV prophylaxis in ENT surgery patients compared to ondansetron alone. This highlights the potential for optimizing perioperative care and patient outcomes in ENT surgeries. Further research is needed to validate these findings.

Keywords: Ondansetron, Dexamethasone, Postoperative Nausea, Vomiting, ENT Surgery

INTRODUCTION

The management of postoperative nausea and vomiting (PONV) remains a major concern in the patients undergoing surgeries for Ear, Nose, and Throat (ENT). Postoperative nausea and vomiting (PONV) is described as any nausea, retching, or vomiting that occurs during the span of first 24–48 hrs. post-surgery in inpatients (Pierre & Whelan, 2013). Although the anesthetic techniques have

advanced, the surgeries for ENT remain one of the most high risk procedures in terms of postoperative nausea and vomiting (Yosief *et al.*, 2022). There are a number of factors that play role in PONV occurrence including anesthesia factors (use of general anesthesia, nitrous oxide), surgical factors (duration and type of surgery), and patient-specific predictors (e.g., age, gender, obesity, history of motion sickness, smoking) (Murdoch, 2022; Shaikh *et al.*, 2016).

PONV incidence in patients undergoing ENT surgeries is reported as 36-76% and 80% for Adenotonsillectomy and Middle ear surgery, respectively, when prophylactic antiemetic was not given. PONV is not only the cause of discomfort to the patients rather is a crucial aspect of postoperative care that needs to be addressed effectively as it may be responsible for delayed recovery, potential complications, prolonged hospital stay and increased healthcare costs (B Sridevi *et al.*, 2015; Gan, 2002). PONV can be the cause exacerbate dehydration, anorexia and disturb electrolyte balance, that further contribute to complicate the postoperative course (Öbrink *et al.*, 2015; Wang *et al.*, 2015). Also, there is a risk of catastrophic outcomes such as wound dehiscence or esophagus rupture in severe cases due to the forceful nature of vomiting (Shaikh *et al.*, 2016).

Ondansetron, a selective serotonin 5-HT₃ receptor antagonist, among other pharmacological agents utilized for PONV prevention, has been demonstrated to be safe and efficacious in various surgical settings. However, recent studies suggest that the combination of ondansetron with dexamethasone, a potent antiemetic agent and anti-inflammatory agent, might be able to provide better prophylaxis against PONV in comparison with the utilization of ondansetron alone (Bhattarai *et al.*, 2011; Song *et al.*, 2011).

The complementary mechanisms of action of ondansetron and dexamethasone back the rationale behind utilizing them in combination. While ondansetron primarily targets serotonin receptors in the central nervous system and gastrointestinal tract to prevent nausea and vomiting, antiemetic effects by dexamethasone are exerted that inhibit the inflammatory pathways and modulate the release of neurotransmitter (Chu *et al.*, 2014).

The efficacy of ondansetron alone in comparison with ondansetron with dexamethasone has not been widely explored despite the growing interest in combination therapy, particularly in the context of surgeries related to ENT. Therefore, the aim of the study is to evaluate and compare the efficacy of these two regimens in preventing PONV in patients undergoing ENT surgical procedures.

This is the first study conducted for the purpose of providing evidence-based insights into the optimal pharmacological approach for PONV prophylaxis in ENT surgery, and ultimately aims to enhance patient satisfaction and outcomes.

MATERIALS AND METHODS

Setting and Duration

The study was conducted at the Department of Anaesthesiology, Liaquat National Hospital, Karachi, over a period of six months from December 23rd, 2020, to June 22nd, 2021.

Sample Selection

The study included patients fulfilling the inclusion criteria which was as follows; age between 18 and 55 years, undergoing any ENT surgery and categorized as ASA I and II. The exclusion criteria included the following: pregnant patients, pre-operative emesis, patients taking anti-emetic drugs 24 hours prior to surgery, menstruation at the time of surgery, and individuals with vertigo. Patients with BMI exceeding 30 kg/m², ASA grade III and IV and neurological problems were also not made part of the study.

Data Collection Procedure

Ethical approval from the ethical committee of LNHMC, and informed consent from all participants was obtained prior. Pre-anesthesia assessments were conducted without administering pre-medication, and patients were kept nil per oral (NPO) for 6 hours before surgery. Patients were

randomly assigned to two groups: Group A received ondansetron 4mg intravenously, while Group B received a combination of ondansetron 4mg and dexamethasone 8mg intravenously before induction. Anesthesia was induced with propofol (2mg/kg) and tracheal intubation achieved with atracurium (0.5mg/kg). Intraoperative muscle relaxation was maintained with atracurium (0.1mg/kg), and anesthesia was maintained with isoflurane/sevoflurane and 50% oxygen. By the end of surgery, anesthesia was discontinued, and residual neuromuscular blockage was antagonized by administering Neostigmine (0.06 mg/kg) mixed with Glycopyrrolate (0.01 mg/kg). Patients were kept under observation for the presence of nausea/vomiting and blood pressure in the recovery room for the initial half an hour after surgery, then moved to the ward for further monitoring. Data were collected through structured proforma, and antiemetic efficacy was determined on the basis of number of vomiting episodes during the span of 6 hours post-operatively. The drug was considered effective if patients experienced two or less than two episodes of nausea or vomiting within a 6 hrs timeframe after the surgery.

Data Analysis Procedure

Data analysis was performed using the Statistical Package for the Social Sciences (SPSS-21). Frequency and percentages for categorical variables and mean and standard deviation for continuous variables were computed. Chi-square test was used to compare efficacy between groups, with stratification performed for age, gender, BMI, duration of procedure, and hypertension to assess the modification in efficacy. Fisher's exact test was used to compare the number of episodes of nausea and vomiting between both groups. A p-value of <0.05 was considered statistically significant.

RESULTS

The study encompassed 138 patients aged 18-55 undergoing ENT procedures, with an equal distribution of 69 patients in each group: Group A received ondansetron alone, while Group B received a combination of ondansetron and dexamethasone. Group demographics revealed a slight male predominance in both groups, with 88.4% males in Group A and 82.6% in Group B. The mean ages were 48.97 ± 5.31 years for Group A and 48.81 ± 4.49 years for Group B. Results revealed similar distributions of comorbidities and smoking status between the two groups. For example, 7.2% of patients in Group A were obese compared to 4.3% in Group B, and 49.3% of patients in Group A were smokers compared to 43.5% in Group B. While characteristics such as weight, height, and BMI showed comparable means between the two groups, procedure duration was slightly longer in Group B, with mean times of 135.36 ± 104.22 minutes compared to 119.78 ± 123.56 minutes in Group A (Table 1). In Group A, 75.4% experienced post-therapy nausea, while in Group B, it was 56.5% ($p=0.03^*$). Vomiting occurred in 69.6% of Group A and 55.1% of Group B, with no significant difference ($p=0.11$). However, Group B had fewer multiple vomiting episodes ($p=0.05^*$), suggesting enhanced efficacy with the addition of dexamethasone to ondansetron therapy (Table 2). Overall efficacy was significantly higher in Group B (84%) than in Group A (62.3%) (Table 3 and Fig 1). Stratification by various factors such as gender, age, comorbidities, and procedure duration consistently favoured combination therapy (Table 4).

Table 1. Demographic characteristics, baseline data and procedural feature of the patients of both groups [Group A (ondansetron IV alone) and Group B (ondansetron and dexamethasone IV combination)]

Variable	Group A (n=69)	Group B (n=69)
Gender		
Male	61 (88.4%)	57 (82.6%)
Female	8 (11.6%)	12 (17.4%)
Age (years), Mean $\pm$ SD	48.97 ± 5.31	48.81 ± 4.49
Weight (Kg), Mean $\pm$ SD	72.88 ± 8.58	71.20 ± 8.39

Height (cm), Mean ± SD	168.59 ± 5.22	167.65 ± 5.21
Body Mass Index (kg/m²), Mean ± SD	25.64 ± 3.04	25.31 ± 2.67
Comorbidities		
Obesity	5 (7.2%)	3 (4.3%)
Diabetes Mellitus	20 (29.0%)	18 (26.1%)
Hypertension	44 (63.8%)	46 (66.7%)
Smoking	34 (49.3%)	30 (43.5%)
ASA Status		
ASA-I	32 (46.4%)	37 (53.6%)
ASA-II	37 (53.6%)	32 (46.4%)
Procedure Duration (minutes), Mean ± SD	119.7 ± 123.5	135.3 ± 104.2

Table 2. Comparison of Frequency of nausea and vomiting and their number of episodes post therapy.

Variable	Group A (n=69)	Group B (n=69)	P value
Nausea Occurrence	52 (75.4%)	39 (56.5%)	0.03*
Nausea Episodes			
1	38 (73.1%)	33 (84.6%)	
2	4 (7.7%)	0 (0%)	
3	5 (9.6%)	2 (5.1%)	0.07
4	3 (5.8%)	3 (4.3%)	
5	2 (3.8%)	1 (2.6%)	
Vomiting Occurrence	48 (69.6%)	38 (55.1%)	0.11
Vomiting Episodes			
1	23 (47.9%)	28 (73.7%)	
2	5 (10.4%)	3 (7.9%)	
3	11 (22.9%)	2 (5.3%)	0.05*
4	6 (12.5%)	4 (10.5%)	
5	3 (6.3%)	1 (2.6%)	

*Statistically significant

Note: The p values of number of episodes of nausea and vomiting and calculated using Fisher's exact test and occurrences are calculated using chi-square test.

Table 3. Comparison of Efficacy of the drugs used in respective groups.

Efficacy	Study Group		P value
	Group A (n = 69)	Group B (n = 69)	
Yes	43 (62.3%)	58 (84%)	0.004*
No	26 (37.7%)	11 (15.9%)	

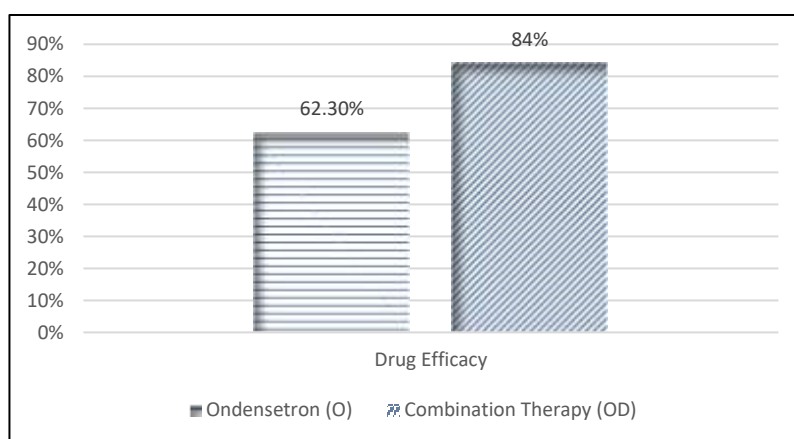


Figure 1. Comparison of Efficacy of the ondansetron vs combination therapy (ondansetron + dexamethasone)

*Statistically significant

Table 4. Comparison of efficacy of drugs used in each group stratified over different demographic, baseline, and procedural variables.

Variable	Group A (n=69)		Group B (n=69)		P-Value
	N	Efficacy	N	Efficacy	
Gender					
Male	n = 61	38 (62.3%)	n = 57	48 (84.2%)	0.007*
Female	n = 8	5 (62.5%)	n = 12	10 (83.3%)	0.292
Age					
≤45 years	n = 20	13 (65%)	n = 19	18 (94.7%)	0.02*
>45 years	n = 49	30 (61.2%)	n = 50	40 (80%)	0.04*
Co-Morbidities					
Obesity					
Yes	n = 5	4 (80%)	n = 3	3 (100%)	0.40
No	n = 64	39 (61%)	n = 66	55 (83.3%)	0.004*
Diabetes Mellitus					
Yes	n = 20	15 (75%)	n = 18	14 (77.7%)	0.841
No	n = 49	28 (57.1%)	n = 51	44 (86.2%)	0.001*
Hypertension					
Yes	n = 44	29 (66%)	n = 46	38 (82.6%)	0.06
No	n = 25	14 (56%)	n = 23	20 86.9%	0.01*
Smoking					
Yes	n = 34	21 (61.7%)	n = 30	24 (80%)	0.11
No	n = 35	22 (62.8%)	n = 39	34 (87.2%)	0.01*
ASA Status					
ASA-I	n = 32	22 (68.7%)	n = 37	32 (86.4%)	0.07
ASA-II	n = 37	21 (56.7%)	n = 32	26 (81.2%)	0.02*
Procedure Duration					
≤90 minutes	n = 32	24 (75%)	n = 19	18 (94.7%)	0.07
61-180 minutes	n = 20	12 (60%)	n = 32	25 (78.1%)	0.16
>180 minutes	n = 17	7 (41.2%)	n = 18	15 (83.3%)	0.01*

*Statistically significant

DISCUSSION

Postoperative nausea and vomiting (PONV) accounts as one of a commonly encountered distressing complication subsequent to Ear, Nose, and Throat (ENT) surgeries. PONV tends to cause anorexia, electrolyte imbalance and dehydration. Extremely forceful vomiting may also be responsible for esophagus rupture and wound dehiscence (Ashfaq, 1998), which necessitates the need for effective prophylactic strategies for improving patient satisfaction and procedural outcomes. The current study evaluated the efficacy of ondansetron alone versus a combination therapy with ondansetron and dexamethasone for the prevention of PONV in patients undergoing ENT surgeries. The findings of the study indicated the combination therapy (ondansetron with dexamethasone) to be significantly more effective for decreasing the PONV incidence in comparison with ondansetron alone, as lower frequency of occurrence of nausea and vomiting episodes along with higher rate of overall efficacy were observed.

The patients' demographic characteristics in both the groups were well-matched, that minimized the chance of biasness due to confounding factors in the study outcomes. Although, the demographic variables such as gender, age, and comorbidities differed slightly between the two groups, the difference did not seem to impact the efficacy of the interventions significantly. This observation was found consistent with previously conducted studies that also indicate that demographic factors may have an impact on PONV susceptibility for individual patient, but the treatment response remain relatively limitedly influenced by them particularly when interventions are standardized and administered appropriately. In a study conducted by Henzi et al. (2000), consistent antiemetic efficacy with dexamethasone was reported across various patient demographics, highlighting the

robustness of certain antiemetic agents in PONV risk mitigation regardless of patient-specific factors (Henzi *et al.*, 2000).

The results of the current study are found to be consistent with previous research that has reported the superiority of combination therapy using ondansetron and dexamethasone in the prevention of PONV across various surgical settings. The findings from the studies conducted by Bano *et al.* (2008), Ahmed *et al.* (2012), and Imam (2004) demonstrated the consistent efficacy of the combination therapy with ondansetron and dexamethasone in postoperative nausea and vomiting (PONV) prevention across diverse surgical populations. Bano *et al.* (2008) reported 81.6% of patients with no nausea and vomiting and 60.4% of patients with PONV who received the combination therapy and dexamethasone alone, respectively, underscoring a significant reduction in the incidence of PONV. Similarly, Ahmed *et al.* (2012) observed a notable high rate for combination therapy in preventing PONV, where 85% of patients remained free from nausea and vomiting. The findings were further corroborated by another study conducted by Imam (2004) which demonstrated a significant decrease in the incidence of PONV in patients who received the combination therapy with ondansetron and dexamethasone in comparison with ondansetron alone. Among the combination therapy group, 77.5% of the patients experienced no nausea and vomiting and only 47.5% of the patients remained free from PNOV who had received ondansetron alone. Moreover, ondansetron, dexamethasone and a combination therapy of both were compared by Chitta *et al.* (2022) for assessing their efficacy in postoperative nausea and vomiting (PONV) reduction in elective surgeries. The incidence of PONV was reported as 13.2% with the use of combination therapy which was lower compared to the incidence of 36.3% with ondansetron alone. In another study conducted by Shivanna *et al.* (2022), ondansetron monotherapy and a combination therapy with ondansetron and dexamethasone were investigated in breast surgeries, the findings revealed a significantly lower incidence of PONV in the combination therapy group (13.9%) in comparison with the ondansetron alone group (38.9%) within the span of initial 6 hours post-surgery. Further research and a few meta-analyses (Awad *et al.*, 2016; Wang *et al.*, 2015) have also provided additional insights into the optimal use of these medication combinations in different surgical contexts, enhancing patient care and outcomes.

Additionally, the findings from the studies conducted by Panda *et al.* (2004) and Rajeeva *et al.* (1999) that relate to reduced antiemetic requirements in patients receiving combination therapy aligns with the results of our study. This consistency in the results suggests that the combination therapy not only benefits for reducing PONV incidence, rather also decrease the reliance on rescue medications, therefore, enabling to enhance the postoperative comfort and satisfaction of the patients.

Ondansetron and dexamethasone, when used in combination act synergistically and target different pathways that play role in the emetic response, thereby offering enhanced antiemetic efficacy. Ondansetron, which is a selective serotonin 5-HT₃ receptor antagonist, work in the inhibition of emetic signals in the central nervous system and dexamethasone, which is a potent corticosteroid, works in the suppression of pro-inflammatory cytokines and help modulate the release of neurotransmitter. The combination therapy provides superior prophylaxis against PONV by addressing multiple emesis mechanisms (Fujii & Uemura, 2002).

Moreover, in the subgroup analysis, the efficacy of the interventions was found consistent across different variables related to demographics and the procedure that included gender, age, comorbidities, duration of the procedure and ASA Status. These findings demonstrate that the advantages of combination therapy with ondansetron and dexamethasone extend across diverse patient population who undergo ENT surgeries, regardless of procedural factors or baseline characteristics.

The current study, which is the first of its kind as it has focused particularly on patients undergoing ENT surgeries, underscores the efficacy of ondansetron and dexamethasone combination therapy in the prevention of postoperative nausea and vomiting (PONV) exclusively in the context of ENT surgery. While combination therapy has previously been investigated extensively in various surgical

settings, there is scarcity of literature regarding its application in ENT surgery. Our findings fill a critical gap in the literature, offering practical implications for optimizing perioperative care in ENT patients. Despite the significance of our results, limitations such as the single-center design and small sample size necessitate further validation through multicenter studies with larger cohorts to enhance generalizability. Additionally, variations in antiemetic agents and dosing regimens among institutions may impact the external validity of our findings.

CONCLUSION

The use of ondansetron in combination with dexamethasone is superior to the ondansetron used alone in the prophylaxis of PONV in patients who are undergoing ENT surgeries. This implies the value of combination therapy in the field of enhanced perioperative care and better patient results in ENT surgical settings.

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