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Study of Efficacy of Ondansetron and Granisetron in Patients Undergoing Surgery Under General Anesthesia

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ABSTRACT

Background: Postoperative nausea and vomiting (PONV) remain prevalent complications following general anaesthesia. Although 5-HT_3 receptor antagonists are widely used for prophylaxis, variability exists in dosing practices and reported efficacy. This study aims to compare the efficacy of ondansetron and granisetron in preventing PONV among patients undergoing surgery under general anaesthesia.

Methods: The present study was included 110 patients undergoing elective surgery under general anaesthesia, allocated into Group A (ondansetron 8 mg IV) and Group B (granisetron 3 mg IV), prior to induction. Postoperative nausea was assessed using a visual analogue scale, while vomiting episodes, rescue antiemetic requirements, haemodynamic parameters, and adverse effects were recorded over the first 24 postoperative hours.

Results: Baseline demographic and clinical characteristics were comparable between groups. Within the first four postoperative hours, nausea occurred in 52.7% of patients in Group B and 70.9% in Group A; this difference did not reach statistical significance ($p = 0.07$). Vomiting incidence was similar between the groups (47.3% vs. 43.6%; $p = 0.85$). No episodes of nausea or vomiting were observed beyond four hours. Adverse effects were mild and comparable in both groups.

Conclusion: In this study, no statistically significant difference was detected between ondansetron and granisetron in the prevention of PONV at the doses administered. Although granisetron demonstrated a lower numerical incidence of early postoperative nausea, the study was underpowered to establish equivalence or superiority. These findings should therefore be interpreted cautiously.

Keywords: Ondansetron, Granisetron, Postoperative nausea and vomiting, General anaesthesia, 5-HT3 receptor antagonists, PONV prevention

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INTRODUCTION

Postoperative nausea and vomiting (PONV) remain one of the most common and distressing complications following general anaesthesia, despite advances in anaesthetic techniques and pharmacological prophylaxis. Recent systematic reviews report an overall incidence ranging from 20% to 40% in the general surgical population, increasing to 70-80% in high-risk patients when no prophylactic measures are employed. [1,2] PONV is associated with patient discomfort, delayed recovery, prolonged hospital stays, and increased healthcare costs. [2]

Multiple patient-related, anaesthetic, and surgical factors contribute to the risk of PONV. Female gender, non-smoking status, use of volatile anaesthetic agents and opioids, and certain types of surgery are well-established risk factors.[3,4] Contemporary consensus guidelines emphasize the importance of multimodal prophylaxis and individualized risk-based antiemetic strategies to reduce the burden of PONV.[5]

Among the available antiemetic agents, selective 5-hydroxytryptamine-3 (5-HT_3) receptor antagonists remain the cornerstone of prophylaxis due to their favorable efficacy and safety profile. Ondansetron and granisetron are the most commonly used drugs in this class, differing primarily in receptor affinity, elimination half-life, and duration of action.[6,7] With a plasma half-life approximately 2 to 3 times longer than that of ondansetron, granisetron may provide more sustained 5-HT_3 receptor blockade, potentially offering greater protection against delayed PONV.[8]

Several randomized trials and meta-analyses have compared ondansetron and granisetron for the prevention of PONV, with inconsistent findings some demonstrating superior efficacy of granisetron, while others report comparable outcomes and no definitive consensus on the preferred agent.[9-11] Moreover, most available studies originate from urban or specialized centres, and data from rural tertiary care settings in developing countries remain limited.

Therefore, this study was undertaken to compare the efficacy of ondansetron and granisetron for the prevention of PONV in patients undergoing surgery under general anaesthesia in a rural tertiary care hospital in India. The study aims to provide context-specific evidence while acknowledging the constraints imposed by the COVID-19 pandemic.

MATERIALS AND METHODS

This study was conducted at a tertiary rural healthcare centre over a period of two years, from November 2019 to October 2021. Approval for conducting the study was obtained from the institutional authority (ARMCH/IEC/03/2019 Dated: 23/10/2019), and permission was secured from the concerned departmental authority prior to its commencement. Written informed consent was obtained individually from all participants before their inclusion in the study.

All patients scheduled to undergo elective surgical procedures under general anaesthesia were screened for eligibility according to predefined inclusion and exclusion criteria. Patients with American Society of Anesthesiologists (ASA) physical status I and II, aged between 25 and 60 years, and planned for elective surgery were included in the study. Patients were excluded if they had ASA physical status III or IV, were pregnant or lactating, were younger than 20 years or older than 60 years, or had a known allergy to any of the study drugs.

Study sample

The study sample size was calculated using the standard formula for comparing two proportions. The formula used was:

$$n = \frac{\{z_1\sqrt{2P(1-P)}+z_2\sqrt{P_1(1-P_1)+P_2(1-P_2)}\}^2}{(P_1-P_2)^2}$$

where P_1represents the probability of the outcome in Group A intervention (0.25), P_2represents the probability of the outcome in Group B intervention (0.11), and $P$is the arithmetic mean of $P_1$and P_2(0.18). The value of $z_1$corresponds to the set level of alpha for a one-sided test (1.6449), while $z_2$represents the z-value associated with the set level of beta (0.8416). Based on this calculation, the minimum required sample size for the study was determined to be 93 participants.

Thus, the sample size calculated was186 that is 93 patients in each group of the study. However, due to limited patient availability during the COVID-19 pandemic, data from a total of 110 patients, with 55 in each group, were collected. This modification was undertaken with formal approval from the respective institutional authority.

An equal number of chits were prepared, half labelled as Group A (ondansetron) and the other half as Group B (granisetron). When a patient was deemed eligible for the study after applying the inclusion and exclusion criteria, allocation to either group was carried out by randomly picking a chit. The anaesthetist administering the drug documented the intervention as either Study Drug A (granisetron) or Study Drug B (ondansetron) without revealing the actual identity of the drug.

Ondansetron (8 mg IV) and granisetron (3 mg IV) were selected based on evidence from previous studies suggesting improved prophylactic efficacy at higher doses in patients at moderate to high risk of postoperative nausea and vomiting. Tramer et al. demonstrated superior control of PONV with ondansetron doses greater than 4 mg, while Mikawa et al. identified 3 mg granisetron as an effective dose for PONV prophylaxis [6,7]. The use of higher-than-standard doses in both groups was intended to ensure adequate antiemetic coverage; however, this approach may have reduced the ability to detect subtle differences between the two drugs.

Data collection procedure: Patients meeting the inclusion criteria underwent demographic and medical history assessments, including age, sex, weight, height, comorbidities, and drug allergies. A general physical examination, airway assessment, and systemic evaluation were conducted, along with laboratory investigations such as CBC, BSL, LFT, RFT, ECG, serum electrolytes, and urine examination. Preoperative baseline vitals, including pulse rate and blood pressure, were recorded, and all patients were kept nil per month for six hours before surgery.

Following intravenous cannulation, patients received 7 mL/kg Ringer's lactate for rehydration. Premedication with glycopyrrolate 0.2 mg IV was administered ten minutes before induction. Patients in Group A received ondansetron 8 mg IV, while those in Group B received granisetron 3 mg IV. Three minutes later, midazolam 0.04 mg/kg and fentanyl 50 mcg IV were given. After five minutes of preoxygenation, anaesthesia was induced with propofol 2 mg/kg IV over 30-60 seconds, followed by succinylcholine 2 mg/kg IV for intubation.

Endotracheal intubation was performed using an appropriately sized tube, and its position was confirmed. Anaesthesia was maintained with 60% nitrous oxide, 40% oxygen, and sevoflurane, along with propofol infusion at 15 mL/hour. Muscle relaxation was maintained with intermittent doses of vecuronium bromide 0.04 mg/kg IV. If surgery exceeded 60 minutes, fentanyl 50 mcg was repeated. Sevoflurane was discontinued five minutes before the end of surgery, and nitrous oxide was stopped before extubation.

At the end of surgery, spontaneous respiration was assessed through clinical parameters. Once the patient was fully awake, vitals were stable, and sustained head lift was achieved, reversal of neuromuscular blockade was performed with neostigmine 0.05 mg/kg and glycopyrrolate 0.01 mg/kg IV. After oropharyngeal suctioning, extubation was performed, and 100% oxygen was administered via a face mask until full recovery, after which the patient was transferred to the recovery room for postoperative monitoring.

Postoperatively, patients were observed for nausea, vomiting, and adverse drug reactions such as headache, dizziness, and drowsiness. Pain was managed with an intramuscular injection of diclofenac sodium 75 mg. Nausea was assessed using an 11-point Visual Analogue Scale (VAS), with scores above 5 classified as severe and scores of 4 or less as minimal. The number of vomiting episodes was recorded, and if needed, metoclopramide 5 mg IM was administered as rescue antiemetic therapy.

Outcome measures and definitions: Postoperative nausea, vomiting, and adverse effects were assessed during the first 24 hours following surgery at predefined intervals of 0-4 hours, 4-12 hours, and 12-24 hours.

Nausea was defined as a subjective unpleasant sensation associated with the urge to vomit and was assessed using an 11-point Visual Analogue Scale (VAS), where a score of 0 indicated no nausea and 10 indicated worst imaginable nausea. VAS scores >5 were considered clinically significant nausea. Vomiting was defined as any forceful expulsion of gastric contents.

Complete response was defined as the absence of nausea, vomiting, and the need for rescue antiemetic medication during the observation period. Rescue antiemetic therapy consisted of intramuscular metoclopramide 5 mg and was administered upon patient request or in the presence of persistent nausea or vomiting. All postoperative assessments were performed by nursing staff who were blinded to group allocation.

Statistical Analysis:

For continuous variables, data were presented as mean and standard deviation, while categorical variables were expressed as numbers and percentages. The comparison between groups was conducted using an independent t-test for normally distributed data and the Mann-Whitney U test for non-normally distributed data. The chi-square test was employed to analyse categorical variables. A p-value of less than 0.05 was considered statistically significant. Data analysis was performed using SPSS software version 20.0.

RESULTS

There were no statistically significant differences between the two groups in terms of age, gender, height, and weight, confirming comparable baseline characteristics. The majority of patients in the granisetron group were aged 50-59 years (34.6%), while most in the ondansetron group were aged 40-49 years (47.3%), with no significant age difference ($p = 0.27$). Female patients comprised 78.2% of the granisetron group and 90.9% of the ondansetron group, but the gender distribution difference was not statistically significant ($p = 0.07$). Height distribution was similar, with most patients in the 160-169 cm range (45.5% in the granisetron group and 41.8% in the ondansetron group), and no significant difference was found ($p = 0.64$). The weight distribution was also comparable, with most patients weighing 60-69 kg (36.4% in the granisetron group and 27.3% in the ondansetron group), and no significant difference was observed ($p = 0.72$). (table 1)

The proportion of hypertension was slightly higher in the granisetron group (5.4%) than in the ondansetron group (3.6%), but the difference was not statistically significant ($p = 1.0$). Diabetes mellitus was equally present in both groups (7.3%, $p = 0.71$). The incidence of hypothyroidism, COPD, and motion sickness was low, with no significant differences between the groups ($p = 0.47$). Smoking was slightly more common in the granisetron group (5.4%) compared to the ondansetron group (3.6%), but this was not statistically significant ($p = 1.0$). A history of postoperative nausea and vomiting (PONV) was reported in 3.6% of patients in both groups, with no significant difference ($p = 0.61$). (Table 2)

Table 1: Basic characteristics

Characteristics	Granisetron group (%)	Ondansetron group (%)	p-value
Age (years)			
20-29	7 (12.7)	5 (9.1)	0.27
30-39	14 (25.5)	7 (12.7)	
40-49	12 (21.8)	26 (47.3)	
50-59	19 (34.6)	14 (25.5)	
60-69	3 (5.4)	3 (5.4)	
Gender			
Male	12 (21.8)	5 (9.1)	0.07
Female	43 (78.2)	50 (90.9)	
Height (cm)			
150-159	16 (29.1)	15 (27.3)	0.64
160-169	25 (45.5)	23 (41.8)	
170-179	14 (25.4)	17 (30.9)	
Weight (Kg)			
40-49	7 (12.7)	8 (14.5)	0.72
50-59	10 (18.2)	12 (21.8)	
60-69	20 (36.4)	15 (27.3)	
70-79	11 (20)	11 (20)	
80-89	7 (12.7)	9 (16.4)	

Table 2: Distribution of the cases in two groups according to the presence of history of comorbid illnesses

History	Granisetron Group (%)	Ondansetron Group (%)	p-value
Hypertension	3 (5.4)	2 (3.6)	1
DM	4 (7.3)	4 (7.3)	0.71
Hypothyroid	1 (1.8)	1 (1.8)	0.47
COPD	1 (1.8)	1 (1.8)	0.47
Smoking	3 (5.4)	2 (3.6)	1
PONV	2 (3.6)	2 (3.6)	0.61
Motion sickness	2 (3.6)	1 (1.8)	1

DM – Diabetes Mellitus
COPD – Chronic Obstructive Pulmonary Disease
PONV - Postoperative nausea and vomiting

Baseline demographic characteristics and known PONV risk factors, including gender distribution, smoking status, and history of PONV or motion sickness, were comparable between the two groups.

The mean pulse rate was slightly higher in the granisetron group (79.9 ± 16.6 bpm) than in the ondansetron group (76.6 ± 13.6 bpm), but the difference was not statistically significant (p = 0.28). Similarly, the mean systolic blood pressure (SBP) was marginally higher in the granisetron group (125.1 ± 10.8 mmHg) compared to the ondansetron group (122.3 ± 6.9 mmHg), with a near-significant p-value of 0.06, though the confidence interval suggests limited clinical relevance. The mean diastolic blood pressure (DBP) was comparable between the two groups (73.3 ± 8.3 mmHg vs. 74.1 ± 8.2 mmHg, p = 0.70). The mean respiratory rate was slightly lower in the granisetron group (18.7 ± 2.1 breaths per minute) than in the ondansetron group (19.2 ± 2.3 breaths per minute), but this difference was also not statistically significant (p = 0.23).

Nausea was less frequent in the granisetron group (52.7%) than in the ondansetron group (70.9%) within the first four hours postoperatively, though the difference was not statistically significant (p = 0.07). No nausea was reported in either group between 4-12 hours and 12-24 hours postoperatively. Vomiting occurred in 47.3% of patients in the granisetron group and 43.6% in the ondansetron group within the first four hours, with no significant difference (p = 0.85), and no vomiting was observed beyond this period.

The incidence of postoperative side effects was comparable between the two groups. Headache was reported in 7.3% of the granisetron group and 10.9% of the ondansetron group (p = 0.74).

Table 3: Comparison of Pulse, SBP-systolic blood pressure, DBP- diastolic blood pressure and RR- respiration rate between two groups (Mean ± SD)

Parameters	Granisetron Group (Mean ± SD)	Ondansetron Group (Mean ± SD)	Mean difference	95% CI of difference	p- value
Pulse (/min)	79.9 ± 16.6	76.6 ± 13.6	3.34	-2.38 - 9.07	0.28
SBP (mmHg)	125.1 ± 10.8	122.3 ± 6.9	2.78	-0.66 - 6.23	0.06
DBP (mmHg)	73.3 ± 8.3	74.1 ± 8.2	0.82	-3.95 - 2.31	0.70
RR (/min)	18.7 ± 2.1	19.2 ± 2.3	0.53	-1.37 - 0.31	0.23

Constipation occurred in 3.6% of granisetron patients and 7.3% of ondansetron patients (p = 0.67), while dizziness was observed in 3.6% and 7.3% of patients, respectively (p = 0.67), with no significant differences.

DISCUSSION

The incidence of early postoperative nausea and vomiting observed in the present study was higher than that reported in several previous trials despite prophylactic antiemetic administration. This finding may be explained by the predominance of female patients, perioperative opioid use, and inclusion of patients undergoing moderate-risk surgical procedures. Additionally, formal risk stratification using validated tools such as the Apfel score was not performed, which may have contributed to variability in observed PONV rates. The reduced sample size, necessitated by recruitment constraints during the COVID-19 pandemic, further limited the ability to perform meaningful subgroup analyses based on individual risk factors.

PONV remains a major concern for both patients and clinicians, with an incidence ranging from 20% to 80% in the absence of prophylaxis. [1,2,12] Several risk factors contribute to PONV, including patient-related factors such as female gender, history of PONV, motion sickness, non-smoking status, and opioid use.

Table 4: Incidences in both groups

Incidences	Granisetron Group (%)	Ondansetron Group (%)	p-value
Nausea			
0-4 hrs	29 (52.7)	39 (70.9)	0.07
4-12 hrs	0	0	-
12-24 hrs	0	0	-
Vomiting			
0-4 hrs	26 (47.3)	24 (43.6)	0.85
4-12 hrs	0	0	-
12-24 hrs	0	0	-
Side effects			
Headache postop_24hr	4 (7.3)	6 (10.9)	0.74
Constipation postop 24hr	2 (3.6)	4 (7.3)	0.67
Dizziness_postop_24hr	2 (3.6)	4 (7.3)	0.67

Anaesthesia-related factors, such as premedication, induction agents, and maintenance drugs, also play a role [6]. As prevention is more effective than treatment, various anaesthesia societies recommend selective prophylaxis for high-risk patients using validated risk scores such as the Apfel and Koivuranta scores.[13]

In the present study, both groups were comparable in terms of demographics, comorbidities, and risk factors, ensuring that any differences in PONV incidence were drug-related. The lack of a placebo group was a limitation, but previous studies have already established that ondansetron and granisetron are superior to placebo.[14] The selected doses were based on existing literature, with 8 mg of ondansetron used, as study Tramer et al. demonstrated its superiority over 4 mg doses. [6] Similarly, 3 mg of granisetron was chosen based on recommended dosages for PONV prevention.[7]

The timing of drug administration plays a crucial role in PONV prevention. Studies have shown that administering ondansetron and granisetron at induction ensures peak plasma levels within 30 minutes, providing an optimal postoperative antiemetic effect. In the present study, both drugs were given three minutes before induction, aligning with these recommendations.

The incidence of nausea within the first four hours postoperatively was 52.7% in the granisetron group and 70.9% in the ondansetron group, but this difference was not statistically significant. Similar findings were reported by Neufeld SM et al. [9]. Beyond 4-12 hours and 12-24 hours, no nausea was observed in either group.

The incidence of vomiting within four hours was 47.3% in the granisetron group and 43.6% in the ondansetron group, with no significant difference. Similar findings have been reported in recent comparative studies where granisetron and ondansetron did not differ significantly in early post-operative vomiting rates. [15,16] Furthermore, meta-analytic evidence suggests a trend toward lower overall vomiting incidence with granisetron within the first 12-24 hours. [8] Recent randomized data also indicate comparable early vomiting outcomes between the two drugs in various surgical populations.[17]

The requirement for rescue antiemetics was minimal, with 3.6% of patients in both groups requiring additional treatment. This finding is consistent with contemporary evidence indicating low rescue antiemetic requirements when 5-HT_3 receptor antagonists are used for prophylaxis, as reported in recent consensus guidelines and randomized studies.[2,8] Study by Savant KS et al. showed no significant difference in rescue antiemetic use between ondansetron and granisetron.[14]

A complete response, defined as the absence of nausea, vomiting, and need for rescue antiemetics, has been reported more frequently with granisetron than ondansetron in recent randomized studies, a finding attributed to its longer duration of action.[8] However, contemporary literature remains inconsistent, with some studies demonstrating superior complete response rates with granisetron [15], while recent systematic reviews and meta-analyses report no statistically significant difference between the two agents, which is consistent with the findings of the present study.[16]

Regarding adverse effects, headache was the most common, occurring in 7.3% of the granisetron group and 10.9% of the ondansetron group, with no significant difference. Constipation and dizziness were also comparable between the groups.

CONCLUSION

In conclusion, no statistically significant difference was observed between ondansetron and granisetron in the prevention of postoperative nausea and vomiting following general anaesthesia. Although granisetron showed a lower numerical incidence of early postoperative nausea, the study was underpowered to establish equivalence or superiority. Both drugs were well tolerated with comparable safety profiles. These findings should be interpreted cautiously, and larger, adequately powered studies are required to more definitively determine their comparative efficacy.

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Availability of data: The data that support the findings of this study are available from the corresponding author on reasonable request.

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