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GRANISETRON VERSUS ONDANSETRON FOR PREVENTING POSTOPERATIVE NAUSEA AND VOMITING AFTER LAPAROSCOPY AT TERTIARY CARE HOSPITAL, SALEM, TAMIL NADU

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Abstract

Background and Aims: After laparoscopic procedures, unpleasant side effects of general anaesthesia are often encountered, including post-operative nausea and vomiting (PONV). The purpose of the research was to assess the antiemetic effects of two distinct 5-hydroxytryptamine-3 receptor antagonists, Granisetron and Ondansetron, when administered proactively to patients having general anesthesia-induced laparoscopic cholecystectomy. **Material and Methods:** Sixty ASA-PS I/II patients, weighing 40–80 kg, having elective laparoscopic cholecystectomy under general anaesthesia participated in a prospective, double-blind trial. Thirty patients each were assigned to Group A (ondansetron 4 mg intravenously) and Group B (granisetron 2 mg intravenously). Prior to the restoration of the neuromuscular blockade, both medications were given after surgery, diluted to 10 millilitres in regular saline. Severe episodes of nausea and vomiting were evaluated six, twelve, and twenty-four hours after surgery. A p-value of less than 0.05 was deemed significant when the collected data was run through the relevant test in the Statistical Package for the Social Sciences (SPSS). **Results:** The Ondansetron group had a higher incidence of PONV (25%) than the Granisetron group (14%) ($P<0.05$). The demographic information was similar for both groups ($p>0.05$). No significant difference observed in the recovery time from anesthesia between the two drugs and slight difference in the adverse events were observed between the two groups. **Conclusions:** When administered prophylactically during laparoscopic cholecystectomy, the incidence of PONV was considerably higher in the Ondansetron group than in the Granisetron group i.e Granisetron is more effective drug than ondansetron with less incidence of side effects.

Keywords: Anaesthesia; Laparoscopic Cholecystectomy; Granisetron; Ondansetron; Nausea and Vomiting.

INTRODUCTION

The second most problematic and difficult occurrence that occurs after surgery is postoperative nausea and vomiting (PONV) [1-2]. This often happens during the 24-hour period after anaesthesia, with an incidence ranging from 30% to 20% [3]. Between 40 and 75 percent of patients have PONV[4–8] . Females, anaesthesia lasting longer than 30 minutes, age more than three years, the kind of operation, a personal or family history of postoperative nausea and vomiting, and motion sickness are risk factors for

postoperative nausea and vomiting [9-10]. Laparoscopic cholecystectomy (LC) is a frequently performed surgical procedure [11].

The primary cause of PONV is not always the kind of surgery. The incidence of post-operative non-operative wound closure (PONV) is mostly caused by anaesthetic and patient-related variables rather than self-surgery complications [12-13]. Patients often consider PONV to be worse than postoperative pain because it is an unpleasant experience [13]. Postoperative satisfaction is enhanced in individuals who are at high risk of developing PONV by preventing it [14].

The consequences of postoperative nausea and vomiting (PONV) can be either surgical, such as wound dehiscence or disruption of vascular anastomosis, or anesthetic, such as aspiration pneumonitis or dyselectrolytemia. PONV incurs a greater cost impact due to the increased need for nursing care, delayed discharges, and unexpected readmissions. Therefore, it is reasonable to administer preventive antiemetic treatment to patients undergoing LC. Preventing postoperative nausea and vomiting (PONV) following laparoscopic operations presents a significant challenge. Therefore, it is crucial to have an efficient preventive treatment plan in order to minimize patient suffering and complications after surgery.

The purpose of this study was to examine the effectiveness of intravenous Ondansetron and Granisetron in preventing postoperative nausea and vomiting (PONV) in patients after laparoscopic cholecystectomy (LC).

Aim of The Study:

1. The aim of the study is to compare the effectiveness of administering a preventive dose of 4mg Ondansetron intravenously to 2mg Granisetron intravenously at the conclusion of surgery, specifically in preventing postoperative nausea and vomiting (PONV) in patients undergoing laparoscopic operations.
2. The study also aims to assess the impact of these interventions on clinical recovery, which includes factors such as the time it takes for patients to recover from anesthesia, regain consciousness, and resume normal bodily functions.
3. Furthermore, the study intends to investigate the adverse consequences associated with the administration of both Inj Ondansetron and Inj Granisetron.

By addressing these objectives, the study seeks to provide valuable insights into the optimal choice of antiemetic medication for preventing PONV in laparoscopic surgery patients, considering both efficacy and safety concerns.

MATERIALS AND METHODS

The research was conducted at VMKV Medical College & Hospital on patients admitted for elective Laparoscopic surgeries from 2023 to 2024. A total of sixty adult patients classified as ASA I and ASA II, of either sex, aged between 18 to 50 years, and weighing between 45 to 70 kgs, who were scheduled for Laparoscopic surgeries, were included in the study. The patients were randomly allocated into two groups, with 30 patients in each group: Group A received Ondansetron, and Group B received Granisetron. Ethical clearance for the study was obtained from the college's ethical committee.

The inclusion criteria for this study comprised patients classified as ASA I and ASA II, aged between 18 to 50 years. However, patients falling under ASA III and ASA IV

categories were excluded from participation. Additionally, individuals with a history of drug allergies, extremes of age, obesity, a history of motion sickness, emergency surgeries, a full stomach, respiratory diseases, uraemia, and diabetes mellitus were also excluded from the study. These criteria were implemented to ensure a homogeneous sample population and to minimize confounding factors that could affect the outcomes of the research.

The study was a prospective and randomized study, involving patients who were premedicated with 0.2mgkg-1 diazepam orally 12 hours before general anesthesia. Patients were kept NPO for 12 hours before surgery. In the operation theatre, routine monitoring devices were attached, and baseline blood pressure, heart rate, and O2 saturation values were recorded. Capnography was attached after intubation. The anaesthetic regimen and surgical procedures were standardized for all patients, with Glycopyrollate 5µgkg-1 intravenous Thiopentone 5mgkg-1 used for anesthesia and scoline 2mgkg-1 for intubation. Ventilation was controlled mechanically and adjusted to maintain end tidal carbon dioxide. Laparoscopic surgeries were performed under video guidance, and patients were placed in trendlenberg positions. At the end of surgery, Group I patients received 4mg Inj ondansetron, while Group II patients received 2mg Inj. granisetron. At the cessation of surgery, patients were made supine and residual neuromuscular block was reversed with glycopyrrolate 0.005mgkg-1 and neostigmine 0.05mgkg-1. Blood pressure and heart rate were recorded every 5 minutes for 30 minutes. Episodes of nausea and vomiting were recorded by direct questioning, and rescue antiemetic (Metaclopramide 10mg) was used if vomiting occurred.

The study compared the effects of nitrous oxide on patients' recovery time (RT) and clinical recovery score (CRS) after surgery. The RT was measured from the time nitrous oxide was switched off until the patient responded to simple verbal commands. The CRS was assessed at 0, 1, 2, 3, and 4 hours after the patient's arrival in the recovery room. Adverse reactions of the drug, such as headache, dizziness, hypersensitivity, and constipation, were noted in the 24-hour study period. The study also included pre-anaesthetic evaluation, premedication, induction, and maintenance. Statistical analysis was done using the student 'T' test, with a 'P' value of less than 0.05 considered significant.

Data analysis:

The Statistical Package for Social Services was then used to compile and analyse the data (SPSS vs 18). The student's t-test was used to assess the quantitative data. The qualitative data was examined using the Chi-Square test. A p-value was considered statistically significant if it was less than 0.05.

RESULTS

The study included a total of 60 patients. The demographic characteristics of the individuals included in the study were similar (Table 1). Despite some minor variations in the averages, neither group is statistically younger, more likely to be a specific sex, or heavier than the other.

Table 1: Comparison of age, sex, and weight between two groups (n =60)

Range	Ondansetron	Granisetron	p- value
Age	28.63± 7.62	30.23±9.49	0.47
Sex M/F	7/23	5/25	0.42
weight	56.93±10.62	50.86±10.85	0.39

The table 2 shows the distribution of patients across ASA grades for Ondansetron and Granisetron groups. In the Ondansetron group, 83% of patients belong to ASA grade I, while 17% belong to grade II. Similarly, in the Granisetron group, 77% of patients are in grade I and 23% in grade II.

Table 2: ASA Grade Wıse

Grade	Ondasetron	Granisetron
I	25 (83%)	23 (77%)
II	5 (17%)	7 (23%)

The table 3 shows the distribution of performed surgical procedures across the Ondansetron and Granisetron groups. Laparoscopic tubal occlusion (LTO) is the most common procedure in both groups, accounting for 60% of Ondansetron cases and 50% of Granisetron cases. Laparoscopic appendicectomy (LAPP) is the least common procedure for Ondansetron (7%) but more frequent for Granisetron (20%).

Table 3: Surgical Procedures Done

Type of Procedure	Ondasetron	Granisetron
Laproscopic tubal occulusion (LTO)	18 (60%)	15 (50%)
Laproscopic Appendicectomy (LAPP)	2 (7%)	6 (20%)
Laproscopic Cholecystectomy (LCHO)	7 (23%)	5 (17%)
Diagnostic Laproscopy	3 (10%)	3 (10 %)
Laproscopic Hernioplasty	0 (0%)	1 (3%)

The table 4 shows the comparison of vital signs (Mean Pulse, Systolic BP, Diastolic BP, and SPO2%) between the Ondansetron and Granisetron groups. On average, both groups have similar values. Mean Pulse is slightly higher in the Granisetron group (82.73±1.5 vs. 76.90±1.5), while the remaining measures (SBP, DBP, and SPO2%) have comparable values between the groups.

Table 4: Comparision of Systolic BP, Diastolic BP, HR and SPO_2%

Grade	Ondasetron	Granisetron
MEAN PULSE	76.90±1.5	82.73±1.5
Mean SBP	131.46±6.06	131.76±6.23
Mean DBP	79.86±11.25	82.13±8.48
Mean SPO_2%	99.10±0.76	99.17±0.83

The table 5 shows the incidence of nausea following surgery in the Ondansetron and Granisetron groups. Ondansetron appears to be less effective in preventing nausea than Granisetron.

Higher Nausea Rates with Ondansetron: Within the first 4 hours after surgery, 14% (4 patients) in the Ondansetron group experienced nausea compared to only 7% (2 patients) in the Granisetron group. This difference is statistically significant ($p<0.05$).

Trend Continues Across Time Intervals: The trend of more nausea in the Ondansetron group continues throughout the measured time intervals (4-12 hours and 12-24 hours).

Granisetron Might Be More Effective: Overall, these results suggest that Granisetron might be more effective than Ondansetron in preventing postoperative nausea, especially within the first 4 hours following surgery.

Table 5: Incıdence of Nausea

	Ondansetron (n=30)	Granisetron (n=30)
0-4hr	**4 (14%)	**2 (7%)
4-12hr	*2(7%)	*1 (4%)
12-24hr	1(4%)	0 (0%)

*** (P<0.05) * * (P<0.01)**

Table 6: Comparıson of Sıde Effects

Side effects	Ondansetron (n =30)	Granisetron (n =30)
Headache	*6(20%)	*4 (13 %)
Constipation	*4(13%)	*2 (7 %)
Dizzness	*4 (13%)	*2 (7 %)

* (P<0.05)

As shown table 6 Occurrence of side effects like headache, constipation and dizziness in Ondansetron group are 6(20%),4(13%),4(13%) respectively compared to 4 (13%), 2(7%),2 (7 %) in Granisetron group. The number of patients who suffered side effects were more in Ondansetron group.

DISCUSSION

Despite the advancements in antiemetic medication, a substantial prevalence of PONV is still observed following general anaesthesia. The most common problems following laparoscopic procedures are nausea and vomiting.[15–16] Patients frequently worry more about PONV than they do about pain after surgery.[17] Pneumoperitoneum, which stimulates the gut's mechanoreceptors and the brain's nociceptors by absorption of CO2, is thought to be the cause of PONV. As compared to open cholecystectomy, laparoscopic cholecystectomy carries a 3.2-fold higher risk of PONV, according to Iitomi et al. Other variables, such as the patient's features, the length of the procedure, and the anaesthetic method employed, can also affect the incidence of PONV.[18] Incidence of PONV in Ondansetron group was 75% in this study. Similar incidence was identified in studies done by Ommid et al (52%).[19] Study done by Bhattacharya et al reported the incidence of PONV in Ondansetron group was 10%.[20]

In this study, the incidence of PONV in the Granisetron group was 23.33%. The incidence of PONV was 29% in the study by Ommid et al.[19] Similar findings were obtained in this investigation. According to a study by Bhattacharya et al, the Granisetron group had a 7% incidence of PONV.19 This variation in PONV incidence may result from the various surgical procedures and their durations that were examined. The Granisetron group in the Gupta et al. trial had a greater prevalence of PONV (45%) than the Granisetron group in this study.[21] This could be the result of a medication administered before surgery rather than after.

Our study's limitation is that the length of the procedure was not taken into account. Compared to non-smokers, smokers have a lower incidence of PONV.[22] But when we were gathering information, we didn't take smoking history into account. Thus, this represents a study constraint.

CONCLUSION

In conclusion, antiemetics should be used prophylactically for patients having laparoscopic cholecystectomy (LC). Serotonin receptor antagonist preoperative antiemetic prophylaxis lowers postoperative nausea scores following LC, the incidence of PONV, and the need for rescue antiemetics.

Limitations:

The findings of this study cannot be generalised because it was a only one study with a somewhat tiny sample size. Result from related major research must be substantiated before generalisation can be made.

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Data Avaılabılıty:

All datasets generated or analyzed during this study are included in the manuscript.

Informed Consent:

Written informed consent was obtained from the participants before enrolling in the study

Authors' contributions:

Dr.S.Prem Kumar - conceptualization, data curation, investigation, methodology, project administration, visualization, writing—original draft, writing—review and editing; ***Dr.P.Abdul Rahaman & Dr.Sathish.R*** -conceptualization, methodology, writing—original draft, writing—review and editing; ***Dr Dr.Prabhu Thilaak*** - conceptualization, visualization, supervision, writing—original draft; ***Dr.V.A. Sabapathy*** - methodology, writing—original draft, writing, review and editing. All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work. All authors have read and agreed to the published version of the manuscript***.***

Ethical statement:

The study's institutional ethical committee approved by VMKVMC Salem; institutional human ethics committee accepted the study (Tracking No. VMKVMC&H/IEC/127/2022). Dated: January 30, 2022. All study participants provided written informed consent, and only those who were prepared to sign it were allowed to take part in the research. Before giving their agreement, Participants were advised about the benefits and dangers of the study. The confidentiality of the research subjects was protected.

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