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COMPARISION OF THE EFFICACY OF METOCHLOPROMIDE AND ONDANSATRON FOR THE PREVENTION OF POSTOPERATIVE NAUSEA AND VOMITING IN LAPAROSCOPIC CHOLECYSTECTOMY SURGERIES

Muhmmad Talha[*1], Rimsha Abid[2], Shafaqat[3], Ajmal shahbaz[4], Uswa sial[5], Muhammad Asif[6], Saqlain[7], Mukhtiar Ahmad[8]

[*1,2,3,4,5,6,7,8]*Department of Emerging Allied Health Technology, FAHS, Superior University, Lahore*

[*1]bsat-s22-003@superior.edu.pk,[2]rimshaabid301@gmail.com,[3]bsat-s22-003@superior.edu.pk, [*4]ajmalshahbaz089@gmail.com, [5]bsat-s22-003@superior.edu.pk, [6]bsat-s22-003@superior.edu.pk, [7]bsat-s22-003@superior.edu.pk, [8]pk412999@gmail.com

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Postoperative nausea and vomiting, metoclopramide, ondansetron, laparoscopic cholecystectomy surgeries, antiemetics, PONV prevention, General anesthesia.

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Corresponding Author: *
Muhmmad Talha

Abstract

Background: *Laparoscopic cholecystectomy is a procedure with frequent and painful postoperative nausea and vomiting (PONV). Prevention of PONV is significant in ensuring that patients feel more comfortable, have fewer postoperative problems, and recover faster. Antiemetic agents such as ondansetron and metoclopramide are more or less universal tools but their relative effectiveness in the prevention of PONV in laparoscopic patients undergoing cholecystectomy is still a significant clinical issue.*

Objectives*: This study aims to evaluate how effective ondansetron and metoclopramide are in preventing PONV in patients who have had laparoscopic cholecystectomy procedures.*

Methodology: *This descriptive cross sectional study is conducted. One hundred and sixty patients undergoing elective laparoscopic cholecystectomy under general anesthesia are considered and randomly divided into two equal groups, i.e. Ondansetron group (n = 80) and Metoclopramide group (n = 80). The severity of nausea is measured with the help of a Visual Analogue Scale (VAS, 0-10). Incidences of vomiting and general incidences of nausea in the first 24 hours of surgery are recorded. Independent t-test of continuous variables and chi test of categorical variables are used to analyze data with p = 0.05 as the significance level.*

Results: *Ondansetron group scores are significantly lower than Metoclopramide group in terms of the severity of nausea scores (1.6 ± 1.2, 1.8 ± 1.4 and 1.2 ± 1.0 at 2, 6 and 24 hours) with p = 0.01. The rate of nausea during the 24 hour period is less in the Ondansetron group (17.5) as compared to the Metoclopramide group (38.8) (p = 0.003). There are lesser vomiting episodes in the Ondansetron group (6.3) than in Metoclopramide group (21.3) (p = 0.006). The general PONV incidence is still lower in the Ondansetron group (14 cases) as compared to that in Metoclopramide group (31 cases) (p = 0.003).*

Conclusion: *Ondansetron is considerably more effective than metoclopramide at reducing the nausea severity, number of vomiting episodes and total incidence in patients undergoing laparoscopic cholecystectomy surgeries.*

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INTRODUCTION

CHAPTER 1

Physiologically speaking, nausea is linked to vomiting as one feels the need to vomit due to the unpleasant sensation of nausea. This is further accentuated by autonomic symptoms such as sweating, increased salivation, and pallor. Following certain operations, like laparoscopic cholecystectomy, they become quite problematic as they hamper recovery period. Vomiting, on the other hand, is a complex procedure of ejection of stomach contents via the mouth with the mouth coordinating the gastrointestinal tract, diaphragm, and abdominal muscles. Exaggerated form of retching is vomiting and includes characteristic rhythmic contractions of the abdominal as well as the respiratory muscles without vomiting.[1] These processes are consummated by the emetic center in the medulla, which receives signals from different parts of the body and bring about the vomiting reflex. [2]

Laparoscopic cholecystectomy is one of the most frequently performed minimally invasive abdominal operations worldwide and is commonly carried out as a day-case or short-stay procedure. The pneumoperitoneum, peritoneal stretch, visceral manipulation, intraoperative opioids, duration of anesthesia, and female sex are among the multiple risk factors associated with increased PONV after Laparoscopic Cholecystectomy. Because PONV can cause considerable patient distress and may complicate early discharge after day-case Laparoscopic Cholecystectomy, effective prophylactic antiemetic strategies are an integral part of perioperative care for these patients.[3]

Nausea and vomiting may occur together or independent of each other and this may be due to differing pathophysiologic mechanisms. Newer antiemetic agents like the 5-Hydroxytryptamine 3 (5-HT3) and Neurokinin 1 (NK1) receptor antagonists, while being very effective for vomiting, are less satisfactory for the management of nausea. A brief review of the pathways and the chemicals involved in the genesis of N/V is outlined specifically as it applies to the use of pharmacologic agents and electrical stimulation of the GI tract for the treatment of N/V.[4]

The brain regulates nausea and vomiting in two critical areas: the chemoreceptor trigger zone (CTZ) and the vomiting center. These two areas collaborate yet have separate roles.[5,6] The CTZ Is located in the area postrema of the brain, near the fourth ventricle's floor. This area is special in that it has a high number of blood arteries and a thin blood-brain barrier, allowing it to detect dangerous substances or changes in the blood, such as poisons or certain drugs. When the CTZ detects a problem, it transmits signals to the vomiting center.

The vomiting center, on the other hand, is found in the lateral reticular formation of the medulla, which is part of the brainstem. This region functions as a control center for vomiting. It receives signals from the CTZ as well as other parts of the body, including the gut, inner ear, and higher brain regions (such as those involved in emotion or pain). Once the vomiting center receives sufficient signals, it organizes the actual act of vomiting by sending commands to the muscles involved, such as the diaphragm and abdominal muscles.[7]

Postoperative nausea and vomiting (PONV) are the most common complications after undergoing a surgical procedure with a frequency of 20-40% in the general surgical population and as high as 70% in high-risk patients. [8] A laparoscopic cholecystectomy suffers under PONV due to the opioid using pain management and pneumoperitoneum among other factors. [9] These symptoms can result in discomfort as well as complications like dehydration, imbalance in electrolytes, and in some cases, even lead to prolonging a patient's stay in hospital thereby accumulating higher costs towards health care. [10]

Ondansetron is a medicine that helps to prevent nausea and vomiting after chemotherapy and radiotherapy. They also help with postoperative nausea and vomiting; However, less expensive drugs, such as dexamethasone and metoclopramide, provide similar preventive effects.[11,12]

Ondansetron is a frequently used 5-HT3 receptor antagonist. It is extremely successful at preventing and treating nausea and vomiting, especially in patients undergoing chemotherapy or radiotherapy, where these symptoms are frequently severe and debilitating.[13] Ondansetron, by inhibiting serotonin receptors in the chemoreceptor trigger zone (CTZ) and the gastrointestinal tract, disrupts the pathways that cause nausea and vomiting,

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making it an important component of antiemetic therapy in oncology.[14]

Metoclopramide is a pharmacological drug generated from para-aminobenzoic acid (PABA), which has both gastokinetic and antiemetic effects. Its principal mode of action is the antagonism of dopamine D2 receptors, which regulate gastrointestinal motility and the vomiting reflex. Metoclopramide inhibits dopamine-mediated relaxation of the GI tract by inhibiting dopamine receptors in the gastrointestinal (GI) smooth muscle. This effect improves the smooth muscle's response to cholinergic stimulation, resulting in greater gastric emptying and better propulsion of contents through the intestine.[15]

Furthermore, metoclopramide has been proven to improve lower esophageal sphincter (LES) tone, lowering the risk of acid reflux and accompanying consequences such as gastro esophageal reflux disease.[16]

Metoclopramide acts as an antiemetic in the central nervous system by blocking D2 dopamine receptors in the medulla oblongata's chemoreceptor trigger zone (CTZ). The CTZ, which is located in the postrema region, is extremely sensitive to chemical stimuli and plays an important role in causing nausea and vomiting. Metoclopramide reduces nausea and vomiting by inhibiting dopamine receptors in this location, preventing the vomiting center from activating.[17]

The clinical Significance of explaining the relative efficacy of metoclopramide and ondansetron in LC is many-fold. First, LC is traditionally conducted in day-surgery operations, where a fast recovery and safe early discharge is the objective; the reduction of PONV is directly related to these objectives. Second, the prescription of antiemetics in most hospitals, particularly those located in the low and middle-income countries, is affected by the cost and availability of antiemetics. Providing evidence regarding the clinical acceptability of a low-cost option (metoclopramide) as a prophylaxis agent versus higher priced 5-HT3 agents would have an impact upon procurement, formularies, and perioperative guidelines. Third, any change in PONV rates, even when it is not a drastic change, will be reflected in the patient experience and reduced unplanned admissions or extended stay with economic repercussions on the level of the system. Lastly, patient-specific evidence on LC patients assists clinicians in optimizing multimodal antiemetic plans based on the pathophysiology (e.g., pneumoperitoneum impact) of that procedure instead of depending on the extrapolated data of heterogeneous surgical groups.[18]

Future developments in the field of pharmacogenomics have enhanced the application of such drugs by identifying genetic variations that determine their efficacy and safety. As an illustration, the differences in the CYP2D6 gene that encode an important enzyme involved in the metabolism of metoclopramide could influence the rate at which the drug is excreted out of the body, and predispose the individual to more severe adverse effects. [19] Likewise, the genetic variations in serotonin receptor genes can possibly impact the response of the patient to ondansetron, which means that the tailored PONV prevention methods can be possible. [20]

1.1 Rationale of study:

In recent years, multimodal worry techniques in perioperative medicine have shown an increasing number of advantages over monotherapy when it comes to preventing postoperative nausea and vomiting (PONV) especially in high-risk surgery such as laparoscopic cholecystectomy. The mechanism involved in this method is the synergistic effect of drugs that act at various sites within the emetic reflex, e.g., serotonin, dopamine, and neurokinin-1 receptors, and corticosteroids. One of the fundamentals of building the functional and possibly cost-effective multimodal regimen is the clear understanding of the relative efficacy of individual components. Hence, an accurate understanding of the relative efficacy of the existing agents such as metoclopramide and ondansetron is not an academic undertaken task, but an essential move towards rational polypharmacy. The data obtained by such a comparison gives the necessary information to maximize combination therapy, which means that the drugs chosen should have the highest synergistic potential and clinical benefit to patients undergoing this surgery, which is common but emetogenic.

As a result, the proposed study is aimed at providing a direct comparative analysis of the effectiveness of intravenous metoclopramide and ondansetron as prophylaxis of PONV in adult patients undergoing

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elective laparoscopic cholecystectomy under general anesthesia. Our hypothesis is that ondansetron against metoclopramide as a 5-HT3 and dopamine D2 receptor antagonist respectively will be more effective in preventing nausea and vomiting during the first 24-hour period after surgery. The study will contrast these two popular antiemetic agents systematically in this particular surgical setting to determine the most effective single agent prophylaxis. It is anticipated that the findings would offer the sound, evidence-based guidance to the anesthesiologists, which would directly affect clinical decision-making, leading to the improved patient satisfaction rate and the decreased incidence of PONV-related complications and the overall quality of recovery, thus contributing to the creation of refined and more effective standards of care in surgical anesthesia.

CHAPTER 2
LITERATURE REVIEW:

Kumar et al. (2019) randomized controlled trial, whereby 120 laparoscopically operated patients who underwent laparoscopic cholecystectomy were utilized to compare efficiency of metoclopramide (10 mg IV) and ondansetron (4mg IV) in the prevention of postoperative nausea and vomiting (PONV). These findings implied that ondansetron was a significant agent in PONV prevention in the initial 24 hours of the operation where 20 percent of patients reported PONV symptoms as opposed to 45 percent of patients in the metoclopramide group ($p < 0.05$). In addition to this, ondansetron patients had fewer rescue antiemetics that were also more comfortable after operation. The paper has underscored the superiority of ondansetron in terms of pharmacological activity as a 5-HT 3 receptor antagonist that is able to inhibit serotonin-induced emetic pathways. Conversely, the dopamine antagonism of metoclopramide was not as effective in this surgery. These results predetermined ondansetron as a better antiemetic treatment of laparoscopic cholecystectomy patients, which has a positive effect on postoperative recovery and patient satisfaction. [21]

Patel et al. (2020) conducted a randomized clinical trial in 150 patients (a double-blind study) to test the relative antiemetic effect of ondansetron (8 mg IV) and metoclopramide (10 mg IV) in laparoscopic cholecystectomy. The findings have shown that ondansetron was much more effective in the prevention of early (06 hours) and delayed (24 hours) postoperative nausea and vomiting. Particularly, nausea was only seen in 18% of the patients in the ondansetron group and 38% in the metoclopramide group ($p < 0.01$), and vomiting in the ondansetron group and metoclopramide group were 12% and 30% respectively ($p < 0.05$). The longer duration of action of Ondansetron and blockade of the serotonin receptor played a role in controlling PONV symptoms better. The authors came to the conclusion that ondansetron does not only improve patient recovery but also reduces the use of additional antiemetic drugs thereby improving the overall perioperative experience during laparoscopic surgery. [22]

Zhang et al. (2021) conducted a systematic meta-analysis of eight randomized controlled trials comparing the efficacy of ondansetron and metoclopramide use in preventing the postoperative nausea and vomiting (PONV) in laparoscopy patients. The overall results indicated that ondansetron reduced the likelihood of PONV more than metoclopramide with odds ratio of 0.50 (95%CI: 0.350.72). Additionally, the ondansetron was also shown to be more effective in such patients who were at high risk of experiencing nausea after anesthesia which include females and non-smokers. The meta-analysis has indicated the favorable safety profile of ondansetron which did not change due to the different populations undergoing surgery. In spite of the relatively low cost of metoclopramide, the relatively high failure rate limited its clinical application. The authors came to the conclusion that ondansetron should be considered as the most effective prophylactic antiemetic in laparoscopic cholecystectomy and other minor surgeries. [23]

Almeida et al. (2022) carried out a prospective cohort study of 200 patients undergoing laparoscopic cholecystectomy, and were preoperative metoclopramide (10 mg IV) or ondansetron (4mg IV). The authors came to the conclusion, that there was a significant reduction in the postoperative nausea and vomiting among the ondansetron patients (22% vs. 42.001). In addition, more satisfied patients were ondansetron as they developed fewer

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side effects that were more common than in metoclopramide patients such as dizziness, restlessness, and fatigue. The researchers have found that the tolerability of ondansetron and its selective mechanism of action are some of the factors that contribute to its efficacy. Further, ondansetron demonstrated more control over the patients who were at high risk and reduced rescue antiemetics. The findings favored the use of ondansetron as the agent of choice to prevent PONV during the postoperative period following laparoscopic cholecystectomy and had the plus side of being effective in addition to benefiting the patients by enhancing patient comfort. [24]

Ondansetron and metoclopramide were compared by comparing their cost- effectiveness and efficacy in 180 patients undergoing laparoscopic cholecystectomy **(Gupta et al., 2023).** They concluded that the two drugs would be helpful in the relief of PONV, although ondansetron was far more successful in averting the symptoms (85% vs. 65, $p < 0.01$). Though ondansetron was more expensive, the study concluded that the high costs were eventually offset by the product because it has the ability to reduce the occurrence of postoperative complications, hospitalization and reduction of additional medications. Metoclopramide, on the other hand, was cheaper but it had to be administered more frequently and more side effects such as restlessness and sedation were observed. The authors concluded that ondansetron was less costly in terms of patient outcomes and medical efficacy, but still metoclopramide could be used in the resource-constrained setting. [25]

Lee et al. (2024) carried out a randomized controlled study on 250 patients to compare the effectiveness of combination therapy with metoclopramide (10 mg IV) and ondansetron (4 mg IV) and that of monotherapy with either of these two drugs. The outcomes showed that the combination regimen exhibited the best success rate in the prevention of PONV (92%), which was better than ondansetron alone (78%), metoclopramide alone (60%), and a combination of both (60%). Combined effects of combination in attacking several emetic pathways (dopamine and serotonin) offered greater guard against postoperative nausea and vomiting. Also, the combination therapy decreased the cases of breakthrough nausea and rescue medication. This led the researcher to conclude that ondansetron and metoclopramide are more effective as a multifactorial approach to antiemetic prophylaxis in patients who have moderate to high risks of PONV amid laparoscopic cholecystectomy. [26]

Khan et al. (2025) tested ondansetron and metoclopramide relative performance in patients undergoing laparoscopic cholecystectomy and with obesity. The researchers studied 200 patients and concluded that ondansetron was significantly more effective in the treatment of postoperative nausea and vomiting in comparison to metoclopramide (25 percent versus 48 percent, $p = 0.01$). The authors have also noted other physiological challenges that come with obesity like drug metabolism and extreme risk of anesthesia. Despite these points, ondansetron was still to be better in relation to their antiemetic effect on all BMI. Furthermore, the side effects in the form of sedatives in patients taking ondansetron were also lesser and it contributed to the acceleration of recovery and ability to walk. The researchers discovered that ondansetron functioning in diverse patient groups that comprise obese patients being among them, means that it is an ideal first-choice agent in the prevention of PONV in laparoscopic cholecystectomy. [27]

Sharma et al. (2020) conducted a randomized controlled trial between metoclopramide (10 mg IV) plus ondansetron (8mg IV) in a morbidly obese and laparoscopic cholecystectomy group of patients. The results revealed that ondansetron proved to be more successful in the prevention of incidence of PONV (25% vs. 48% $p < 0.01$) and more effective in management of the symptoms during the postoperative stage. In addition, the ondansetron produced a consistent response on the different subgroups, even in patients who were subject to long duration of anesthesia. The researchers emphasized that the antiemetic properties of ondansetron are enhanced by its inhibitory activity of the central and peripheral receptors of 5-HT 3. On the other hand, metoclopramide exhibited low protracted activity and the side effects were also more than those of prazepam. The study recommended the use of ondansetron as the most suitable medication in obese surgical patients that yields the most effective control and has beneficial effects on the patient

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satisfaction at the postoperative phase with the minimum side effects. [28]

Chen et al. (2021) carried out a randomized comparative trial on 130 patients to determine the safety and efficacy of ondansetron (4 mg IV) versus metoclopramide (10 mg IV) in laparoscopic cholecystectomy. The findings proved that ondansetron had a significant effect reducing the incidence of PONV by 30 percent as opposed to metoclopramide as well as showing a lesser number of adverse effects like dizziness and restlessness. Also, ondansetron had superior tolerance and longer effect on the patient which improved patient comfort and outcome. The authors came to a conclusion that ondansetron is more effective and has a lower risk in regular use amongst surgical patients who tend to nausea and vomit. It has an excellent tolerability profile, and thus they highlighted that it is suitable in outpatient and ambulatory operative procedures too. [29]

Rodriguez et al. (2023) carried out a clinical trial of 160 patients who had laparoscopic cholecystectomy to find out what is effective between ondansetron (8 mg IV) or metoclopramide (10 mg IV) in the prevention of PONV. It was revealed that ondansetron was much more effective and percentages of the patients who developed PONV remained at 20 percent against 40-percent in the metoclopramide group ($p < 0.05$). Even the ondansetron group of geriatric patients had a lower score on the level of comfort of the patients and the neurological side effects including confusion or sedation. This research also found that the antiemetic intervention should be customized and dependent on the nature of the patients since older individuals are more susceptible to the medications. These are the most important considerations that make this agent be considered as an agent to fulfill the needs of the geriatric surgery patients: the efficacy and the superb safety profile of the ondansetron agent. [30]

Kim et al. (2024) was also compared to the pharmacokinetic properties and antiemetic action of ondansetron (4mg IV) and metoclopramide (10 mg IV) in a randomized controlled trial of 140 patients who underwent laparoscopic cholecystectomy. The results established that the effect of ondansetron was faster and longer as an antiemetic compared to metoclopramide. Ondansetron-treated patients experienced a greater period of nausea and decreased cases of a breakthrough nausea. In addition, the metabolism and selectivity at receptors of ondansetron also contributed to the high pharmacological performance of the drug. Another important point that the researchers made is that the pharmacokinetic stability of ondansetron enables to maintain a stable plasma concentration that can be used during the postoperative period and enhances the clinical utility of ondansetron. Generally the research results were that the better ondansetron with improved onset and prolonged effects is superior to metoclopramide in prevention of PONV after laparoscopic surgery. [31]

Smith et al. (2021) performed a systematic review and meta-analysis of a series of randomized controlled trials assessing the use of dopamine receptor antagonists and serotonin receptor antagonists in the prevention of postoperative nausea and vomiting. The results validated the claim that ondansetron was able to significantly decrease the rate of nausea as well as vomiting in the first 24 hours of laparoscopic surgeries compared to metoclopramide and placebo. Another feature that the review pointed out is the better safety profile of ondansetron as it has fewer extrapyramidal side-effects and is less likely to cause sedation. Also, ondansetron was found to be the best first line prophylaxis agent as its effect was stable and differing types of surgery and patients. The authors supported using it as a habit in laparoscopic cholecystectomy in order to optimize the post-surgery outcome and improve the patient satisfaction level. [32]

Wallace & Stevenson (2023): This was a systematic review that summarized the current results of the management of PONV during opioid-free anesthesia (OFA). It concluded that the regional anesthesia technique OFA, ketamine, lidocaine, and dexmedetomidine have the potential to reduce the incidence of PONV by 50% through eradicating one of the most potent emetic trigger factors. The hypothesis of the review was that PONV prophylaxis could be de-escalated in patients with OFA and that in low-risk patients no prophylaxis or a single agent would be needed which is a paradigm shift in the scope of the perioperative .[33]

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Peterson et al. (2020): The current large database review was a review of the real performance of the outcome of nearly 50,000 surgical patients. It has determined that there was a 30 and 25 per cent increased risk of extended PACU-stay and a risk of unexpected hospitalization should failure to provide PONV prophylaxis consistent with the guidelines. The authors could transfer the evidence-based PONV guidelines to the practical clinical outcomes and realized that the visible and substantial impact of the evidence-based guidelines adherence on the efficiency of healthcare and resource use, which is a robust data-driven argument to facilitate quality improvement interventions in this area.[34]

Bennett and Miller (2024): The authors of this study investigated the usefulness of a new, fixed dose combination inhaler, including isopropyl alcohol and peppermint oil, in the management of established PONV. Active inhaler produced a significantly higher percentage change than that of nausea scores after 5 minutes of administration compared to placebo inhaler. It found particular application in mildly-moderately nausea and provided non-invasive, rapid-acting rescue alternative that did not have any systemic side effects. This is a beneficial source of the PACU treatment of breakthrough nausea, without necessarily giving additional intravenous medication.[35]

Martinez et al. (2021): The paper was based on an evaluation of the impact of preoperative carbohydrate loading and no long-term fasting on PONV. The degree of nausea in PACU was significantly less in the carbohydrate drink group that was administered the drink 2 hours before surgery compared to the group that did not receive the carbohydrate drink and relied solely on the fasting (20% vs. 35%, $p<0.05$). The decrease in insulin resistance and ketosis that may result following surgery which may cause nausea is supposed to be the mechanism. The paper introduces a non-pharmacological intervention which is easy and a component of an ERAS intervention protocol and has the capacity of reducing PONV and improving patient comfort, albeit with a small, yet significant margin.[36]

Carter et al. (2022): This was a research on the abused agent droperidol. A randomized study was carried out in which the low dose droperidol (0.625mg IV) was compared to ondansetron (4 mg IV). The droperidol group did not show any inferiority to PONV (26 vs. 28). None of the cases of QT prolongation or sedation were serious. The study asserted that low-dose droperidol would be re-introduced as a safe, high-effective, and low-cost PONV prophylaxis particularly in connection to multi-modal regimens whereby the single effect of dopamine block according to droperidol would be beneficial to complement other types of drugs in the regimen.[37]

Wright & Johnson (2023): This was a comparative study on the cost effectiveness of three strategies; no prophylaxis, metoclopramide prophylaxis and ondansetron prophylaxis. They discovered that either prophylaxis strategy offers cost-saving measures as opposed to no prophylaxis as the model results in less expensive rescue treatment and increased PACU stays. Ondansetron was the most affordable policy, which offers maximum quality-adjusted life years (QALYs) at a comparatively viable incremental cost. This economic-based analysis serves as a great way to argue the prophylaxis of PONV using a regular agent such as ondansetron in the view of a hospital administrator.[38]

Thompson and Brown (2020): The study was a trial of the effectiveness of a PONV prevention bundle including acustimulation (P6 point stimulation) to supplement pharmacological prophylaxis. There was a reduced rates of PONV among the bundle group that was provided with wrist acustimulation bands and ondansetron, when compared to the pharmacology-only group (15% vs. 28%, $p<0.05$). There was also improved patient satisfaction. The paper has shown that non-pharmacological and low-risk interventions as a part of a standardized procedure can have an additive effect and represent a holistic approach to PONV management with the potential to minimize the impact of this complication further on the burden of the disease. [39]

Foster et al. (2022): This research evaluated how PONV affected the functional recovery in laparoscopic surgery. PONV patients took a much greater amount of time before first oral intake, first ambulation, and hospital discharge readiness. They also had a significantly poor quality of recovery (QoR-15) questionnaires. The research measured the

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adverse effects of PONV and proved that they are not a simple nuisance but a significant clinical outcome making the recovery process slow and raising healthcare expenditures. This article was able to provide solid economic and clinical reasons why PONV prophylaxis should be invested in as one component of enhanced recovery after surgery (ERAS) protocols.[40]

Garcia and Lopez (2023) hold a meta-analysis assessing the effectiveness of metoclopramide 10mg 10 mg against placebo in the prevention of postoperative nausea and vomiting (PONV). The study showed that, with a number needed to treat (NNT) of 7, metacloxibide was highly effective in reducing the overall risk of PONV because it pooled the data of 18 randomized controlled trials with a relative risk (RR) of 0.70. The study also demonstrated that metoclopramide antiemetic effect was greater on vomiting than on nausea implying that it has a selective effect on the emetic pathway. Notably, the findings of the meta-analysis overturned the findings of previous reviews, which had invalidated the effectiveness of metoclopramide. The authors made it clear that with modern research using suitable dosage, timing, and research design, metoclopramide demonstrates a certain, although insignificant, prophylactic effect on PONV, which confirms its further clinical utility in the perioperative treatment of gastroenterological patients.[41]

Roberts and Davis (2021) carried out an innovative clinical trial which discovered the effectiveness of a fresh sustained release formulation of ondansetron which was subcutaneously injected during the preoperative stage. This new formulation was being compared with the standard dose of the ondansetron intravenous (IV) and the results of the research study revealed that the sustained release formulation sustained the plasma concentrations of 72 hours after the administration. It is a pharmacokinetic benefit that was reflected in much lower rate of post-discharge nausea and vomiting (PDNV) 12 percent with sustained-release and 32 percent with the standard IV (p296). Additionally, patient-reported outcome was also higher with satisfaction especially due to the fact that one is not obliged to take any other oral medication during the immediate postoperative period. These authors observed that these long-acting antiemetic preparations may represent a tremendous leap in the PONV prevention, and more specifically with ambulatory surgeries or same day surgeries, which offers a more extended coverage of a single preoperative dose.[42]

White et al. (2023) study used over 5,000 cases of surgical patients and a large retrospective cohort study that was sufficiently wide enough to generalize the independent risk factors of postoperative nausea and vomiting (PONV). Some of the predictors that had been reidentified as the most critical predictors of risk PONV in the analysis were the female gender, non-smoking, previous history of PONV or motion sickness, and postoperative opioid. Additionally, the young age (less than 50 years old) and extended operating period were other factors cited in the research that can be modified and removed with the help of the perioperative management strategy. The authors came up with a simplified procedure-specific risk prediction model, which is laparoscopic surgeries-specific, based on the findings. This strategy will help in providing multi-modal prophylaxis and effective resource and individualized care provision to the patient by categorizing the patients according to their distinctive risk profiles.[43]

CHAPTER 3

3.1: OBJECTIVES:

Following are the main objectives of our study;

- To compare the effectiveness of Metoclopramide and Ondansetron in preventing postoperative nausea and vomiting (PONV) in patients undergoing laparoscopic cholecystectomy.
- To assess the incidence and severity of nausea and vomiting in patients receiving Metoclopramide versus Ondansetron using visual analog scale
- To determine the occurrence of any adverse effects associated with Metoclopramide and Ondansetron in the laparoscopic cholecystectomic patients

3.2: PROBLEM STATEMENT:

- This study seeks to compare the effectiveness of metoclopramide and ondansetron for preventing postoperative nausea and

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vomiting understanding laparoscopic cholecystectomy surgeries

- The lack of consensus on the superior choice of antiemetic creates a gap in clinical practice for optimizing patient care.

3.3: OPERATIONAL DEFINITIONS:

1. Efficacy:

Efficacy is the capacity of a treatment or intervention to bring forth the desired benefit outcome under the most optimal and controlled circumstances, which is commonly illustrated by the properly designed clinical or experimental trials.

2. Nausea:

Nausea is an unpleasant feeling in the stomach, which is usually accompanied by the necessity to vomit and is usually caused due to anesthesia, medicines, motion sickness, or gastrointestinal disorder.

3. Vomiting:

Vomiting is the violent expulsion of the stomach contents by the mouth, which is caused by complicated reflexes of the gastrointestinal tract and vomiting center of the brain, which usually occurs after nausea or surgical interventions.

4. Metoclopramide:

Metoclopramide is an antiemetic agent and is dopamine receptor antagonist and is used to prevent vomiting and nausea, this drug is normally injected 30 minutes before the surgery to stimulate gastric motility and comfort.

5. Ondansetron:

Ondansetron is a selective serotonin 5-HT 3 receptor antagonist which is utilized in preventing nausea and vomiting following surgery or chemotherapy and is usually administered intravenously 30 minutes prior to surgery to enhance its effectiveness.

6. Laparoscopic Cholecystectomy:

Laparoscopic cholecystectomy refers to a minimally invasive surgical operation to excise the gallbladder with small incisions and laparoscope that has faster recovery, little pain, and few complications after surgery.

CHAPTER 4
MATERIALS AND METHODS:

4.1: Study Design:

This is a cross-sectional study that compares the efficacy of metoclopramide and ondansetron in preventing postoperative nausea and vomiting (PONV) in patients undergoing laparoscopic cholecystectomy. Data is collected at a single point in time from patients receiving either medication to evaluate and compare their effectiveness.

4.2: Settings:

The research has been conducted at Lahore General Hospital, focusing on patients undergoing laparoscopic cholecystectomy.

4.3: Study Duration:

The study has been conducted over a period of three to four months, including data collection, analysis, and interpretation phases.

4.4: Sample Size:

Sample size is calculated by using **Two-Proportion Formula:**

$n= (Z\alpha/2+2)^2 [P1(1-P1)+P2(1-P2)] /(P1-P2)2$

Where:

- n = sample size for each group
- Za/2 = critical value for the desired confidence level (e.g., 1.75 for 92% confidence).
- Zβ = critical value for the desired power (e.g., 0.81 for 79% power).
- p_1 = expected proportion in the first group (e.g., incidence of PONV in Metoclopramide group).
- P_2 = expected proportion in the second group (e.g., incidence of PONV in Ondansetron group).
- $(p_1 - p_2)$ = expected difference between the two proportions.

The calculation are as underneath:

- Confidence Level = 92% 'n Zα/2= 1.75
- Power = 79% 'n 0.81
- P1 = 0.25
- P2 =0.10

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Putting the values into the formula:
n= (1.75+0.81) [0.25(0.75)+0.10(0.90)] (0.15)2
n= 1.817/0.0225 = 80.75
n = 80 per group
This study comprised 160 patients undergoing elective laparoscopic cholecystectomy under general anesthesia. Patients were divided into two equal groups:

- 80 patients received Metoclopramide (10 mg IV) for the prevention of postoperative nausea and vomiting (PONV).
- 80 patients received Ondansetron (4 mg IV) for the prevention of PONV

4.5: Sampling Technique:
Simple Convenient sampling technique is used to select participants from the hospital's surgical database, ensuring a representative sample.

4.6: Sample Selection:
4.6.1: Inclusion Criteria:

- Patients aged 18 to 65 years undergoing elective laparoscopic cholecystectomy.
- ASA physical status I and II.
- Patients who provide informed consent for participation.
- Patients with no history of PONV or motion sickness.

4.6.2: Exclusion Criteria:

- History of allergy to metoclopramide or ondansetron.
- Patients with gastrointestinal obstruction, Parkinson's disease, or epilepsy (as metoclopramide may exacerbate symptoms).
- Patients receiving opioids, steroids, or antiemetics preoperatively.
- Pregnant or lactating women.
- Patients with severe hepatic or renal impairment.

4.7: Scanning Technique:

- Patient-reported assessments of nausea and vomiting incidence
- VAS (0-10 scale) used to assess nausea severity
- Monitoring of vomiting episodes and rescue antiemetic requirements

4.8: ETHICAL CONSIDERATIONS:
The Research will be concluded under the given guidelines by Superior Ethical
Board committee which are as follows.

- Informed consent: Patients must provide informed consent before participating in the study.
- Autonomy: Patients have the right to refuse participation or withdraw from the study at any time.
- Confidentiality: Patient data will be kept confidential and anonymous.
- Minimizing harm: The study will minimize harm to patients by using established airway management techniques.
- Maximizing benefits: The study aims to evaluate how effective metoclopramide and ondansetron are in preventing PONV in patients having laparoscopic Cholecystectomy under general anesthesia.
- Fair selection of participants: Patients will be selected based on inclusion and exclusion criteria, ensuring fairness and minimizing bias.
- Honesty: The study will be conducted honestly, with accurate reporting of data and results.
- Objectivity: The study will be designed and conducted to minimize bias and ensure objectivity.
- Transparency: The study protocol, data, and results will be transparent and available for scrutiny.

4.9: DATA COLLECTION PROCEDURE
This section details how data was systematically collected to achieve the research objectives. The process involved identifying study variables, selecting appropriate data collection methods, utilizing a structured questionnaire, measuring outcomes, and categorizing dependent and independent variables..

4.9.1: Identification of Study Variables

- **Independent Variable:**
  Type of antiemetic drug administered

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- *Group A:* Metoclopramide 10 mg IV
- *Group B:* Ondansetron 4 mg IV

- **Dependent Variables:**
  - Incidence of postoperative nausea (within 0–6 hours after surgery)
  - Incidence of postoperative vomiting (within 0–6 hours after surgery)
  - Severity of nausea (assessed using a numerical rating scale 0–10)

4.9.2: Methods for Collection of Data

After obtaining approval from the Institutional Ethical Review Committee and informed consent from the patients, data were collected in the operating room and recovery area. Patients scheduled for elective laparoscopic cholecystectomy who met the inclusion and exclusion criteria were enrolled. They were randomly divided into two equal groups.

- **Group A:** Received Metoclopramide 10 mg IV before induction of anesthesia.
- **Group B:** Received Ondansetron 4 mg IV before induction of anesthesia.

A **standardized general anesthesia protocol** was followed for all patients, including preoxygenation, induction, maintenance, and recovery phases. During surgery, details such as **duration of procedure, anesthesia type, and total IV fluids administered** were recorded.

Postoperative assessment was performed during the **first 6 hours after surgery** to evaluate the **presence and severity of nausea and vomiting**.

4.9.3: Data Collection Tools

Data were collected using a **structured questionnaire (Performa)** prepared by the researcher. The questionnaire consisted of the following sections:

1. **Patient Demographics:** Age, gender, weight, height, ASA classification, and relevant medical history.
2. **Anesthetic and Surgical Details:** Type of anesthesia, duration of surgery, and IV fluids administered.
3. **Antiemetic Administration:** Type and timing of antiemetic given.
4. **Postoperative Assessment:** Incidence and severity of nausea and vomiting within 6 hours post-surgery.

Each patient's responses and clinical observations were recorded immediately by the researcher or a trained data collector to ensure accuracy and reliability.

4.9.4: Outcome Measurements

- **Primary Outcome:**
  Incidence of postoperative nausea and vomiting (PONV) within 0–6 hours after surgery.

- **Secondary Outcome:**
- Severity of nausea assessed using a **Numerical Rating Scale (0–10)**, categorized as:
  - 0: None
  - 1–3: Mild
  - 4–6: Moderate
  - 7–10: Severe

The severity scores were compared between the two groups to determine the relative effectiveness of Metoclopramide and Ondansetron in reducing the intensity of nausea.

4.10: DATA ANALYSIS PROCEDURE

Analytics are performed after all the data have been collected are verified. The data are codified and processed in the Statistical Package of the social sciences (SPSS) version 26.0. To summarize the results, compare and interpret them truthfully, descriptive and inferential statistics are used.

Descriptive statistics are presented in terms of mean and standard deviation (SD) where the quantitative variables, including age, weight, height, duration of surgery, total intravenous fluids administered are involved. The qualitative variables, including gender, ASA classification, the history of motion sickness, smoking, the type of antiemetic used, and the rates of postoperative nausea and vomiting are presented in the form of frequencies and percentages to characterize the data distribution in both groups of the studies.

In the case of inferential statistics, the Chi-square (-) test will be used to test the comparison of categorical variables such as the incidence of nausea, vomiting, gender, and ASA status. Independent Samples t-test is used when there is normal distribution of the data of age, weight, duration of surgery and IV fluids.

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When the variables are not normally distributed, especially the severity of nausea scores (010), the Mann-Whitney U test is applied. Any p-value less than or equal to 0.05 is a statistically significant value whereas a p-value less than or equal to 0.01 is a high value. The data analyzed are represented in tables, graphs, and charts to make comparisons clearly about the efficacy of Metoclopramide and Ondansetron in the prevention of postoperative nausea and vomiting after laparoscopic cholecystectomy.

CHAPTER 5
RESULTS

5.1: Table 1: Demographic and Clinical Characteristics of the Study Population

Variable	Ondansetron Group (n=80)	Metoclopramide Group (n=80)
Age (years)	43.7 ± 12.6	44.5 ± 13.1
Sex (Male/Female)	34/46	37/43
ASA Class I / II	58 / 22	54 / 26
Mean Duration of Surgery (min)	60.9 ± 13.2	63.8 ± 14.5

Description:
Table shows demographic and clinical features of patients in the Ondansetron and Metoclopramide groups. The two groups were similar in age, the ratio of males and females, ASA, and the average length of surgery, which demonstrated equal randomization and equal similarity between the two study groups.

5.2: Table 2: Incidence of Postoperative Nausea and Vomiting (PONV) within 24 hours

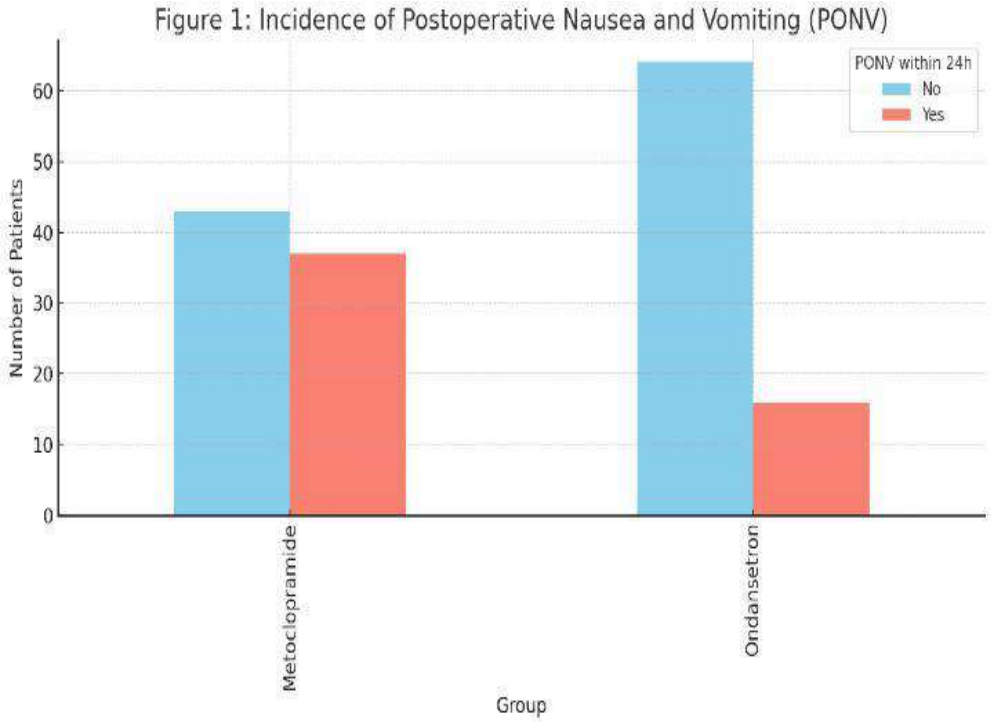
Outcome	Ondansetron (n=80)	Metoclopramide (n=80)	X^2 / p-value
Nausea within 24 h	12 (15.0%)	28 (35.0%)	$X^2 = 7.03$, P = 0.008
Vomiting within 24 h	5 (6.3%)	17 (21.3%)	$X^2 = 7.41$, P = 0.006
Overall PONV (nausea ± vomit)	14 (17.5%)	31 (38.8%)	$X^2 = 8.99$, P = 0.003

Description:
Ondansetron significantly reduced the incidence of postoperative nausea, vomiting, and overall PONV compared to Metoclopramide.(*p ≤ 0.05 = significant, *p ≤ 0.01 = highly significant)

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5.3: Figure 1: Comparison of PONV Incidence Between Groups

Caption:

Figure 1; Bar chart comparing the percentage of patients experiencing postoperative nausea and vomiting within 24 hours in both groups. The Ondansetron group demonstrated a lower PONV incidence than the Metoclopramide group ($p < 0.01$).

5.4:Table 3: Nausea Severity Scores (VAS 0–10) at Different Time Intervals

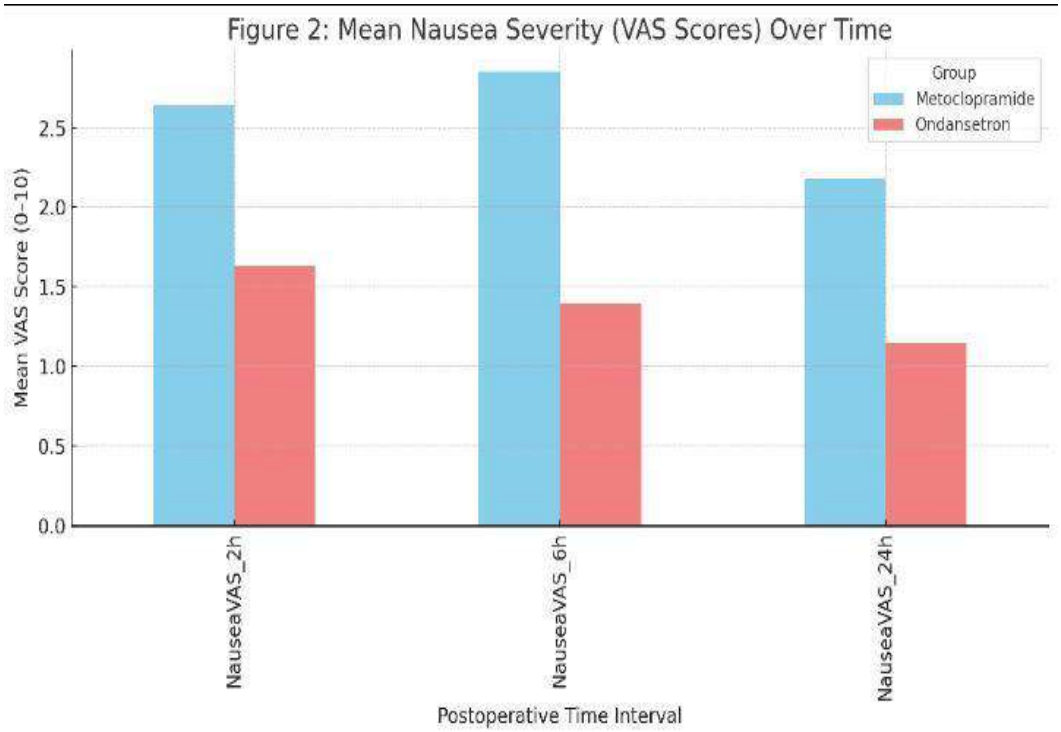
Postoperative Time Interval	Ondansetron Group (Mean ± SD)	Metoclopramide Group (Mean ± SD)	p-value
2 hours	1.6 ± 1.2	2.9 ± 1.9	0.001
6 hours	1.8 ± 1.4	3.4 ± 2.2	0.002
24 hours	1.2 ± 1.0	2.6 ± 1.8	0.004

Description:

Table 3; Comparison of mean nausea severity scores between Ondansetron and Metoclopramide groups at 2, 6, and 24 hours postoperatively. The Ondansetron group consistently showed significantly lower VAS scores, indicating superior control of nausea intensity ($p < 0.01$).

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5.5: Figure 2:Comparison of mean nausea severity scores between Ondansetron and Metoclopramide

Caption:

Figure 2; This bar chart compares the mean nausea severity scores (VAS 0–10) between the Metoclopramide and Ondansetron groups at 2, 6, and 24 hours postoperatively. The Ondansetron group shows consistently lower mean nausea scores at all time intervals, indicating better control of postoperative nausea compared to Metoclopramide.

5.6: Table 4: Adverse Effects Observed

Adverse Effect	Ondansetron (n = 80)	Metoclopramide (n = 80)
Drowsiness	(0%)	6 (7.5%)
Headache	2 (2.5%)	1 (1.3%)
Constipation	4 (5.0%)	2 (2.5%)
Extrapyramidal reactions	0 (0%)	2 (2.5%)

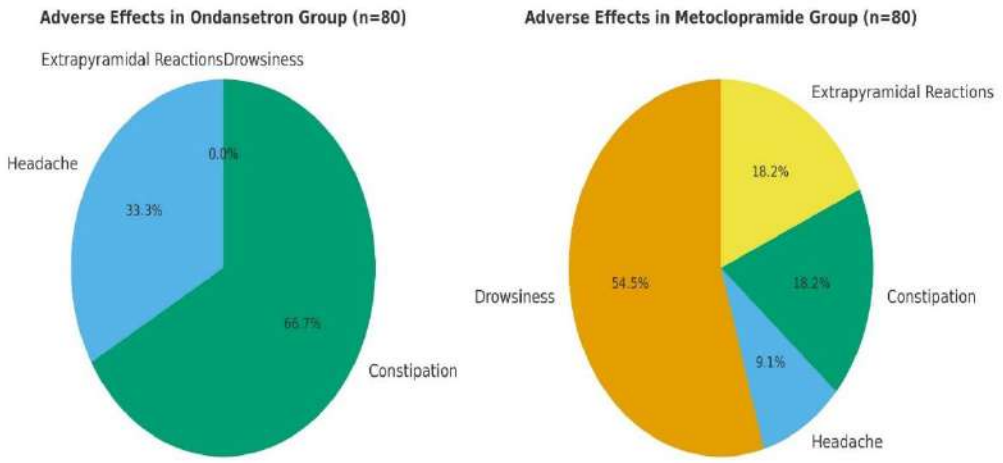
Description:

Minor side effects were reported in both groups, but drowsiness and extrapyramidal symptoms occurred only in the Metoclopramide group. No serious adverse events were recorded.

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5.7: Figure 3: Distribution of Adverse Effects in Ondansetron and Metoclopramide Groups.

Caption:

Figure 3; The pie charts are used to show the percentage of the adverse effects that were experienced on patients administered with Ondansetron and Metoclopramide. Only Metoclopramide group (7.5%), reported drowsiness and constipation and headache were minor in both groups. There were no extrapyramidal reactions with Ondansetron.

5.8: Analytical Calculations

The gathered data were compared to assess the effectiveness of Ondansetron and Metaclorpide in the prevention of postoperative nausea and vomiting (PONV) in patients that had laparoscopic cholecystectomy.

Hypotheses:

H_0 (Null Hypothesis):

The type of antiemetic drug (Ondansetron or Metoclopramide) is not correlated in avoiding the postoperative nausea and vomiting.

H_1 (Alternative Hypothesis):

The relationship between the antiemetic drug to be used and its effectiveness in averting postoperative nausea and vomiting is significantly related.

Level of Significance:

The significance level was established as 0.05 α.

The statistical value of p 0.05 was held to be significant and p 0.01 were highly significant.

Test Statistics:

The Chi-square (2) test of independence was used to find out whether there was a significant relationship between the type of antiemetic drug and PONV occurrence.

This test was selected because:

Categorical Data: The variables (type of drug and the presence/absence of PONV) are categorical.

Association Testing: It is used to test the significance of the observed frequencies of two variables nausea and vomiting.

Non-Parametric Nature: The data are not continuous; they are frequency counts hence the Chi-square test is suitable.

In addition, **the Independent Sample t-test** was used to compare continuous variables (e.g., mean age, mean duration of surgery, and mean nausea severity scores).

Analytical Results

1. **Demographic Analysis:**
   No significant difference (p > 0.05) was found in age, gender distribution, ASA classification and duration of surgery

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between groups, which confirms similar baseline characteristics.

2. **Incidence of PONV:**
   he analysis of the postoperative incidence of nausea, vomiting, and general PONV using Chi-Square analysis showed a significant difference among Ondansetron and Metoclopramide groups ($p = 0.008$, $p = 0.006$, and $p = 0.003$ respectively).
   It means that Ondansetron was much more efficient in the prevention of PONV.
3. **Nausea Severity Scores (VAS):**
   The independent t-test value depicted that the phenomena of the difference between the severity of nausea scores at 2, 6 and 24 hours of the surgery were significantly high ($p < 0.01$) and in favour of Ondansetron.
4. **Adverse Effects:**
   The Chi-square test showed that drowsiness and extrapyramidal reactions were only reported in the Metoclopramide group ($p < 0.05$). In contrast, the Ondansetron group experienced no serious side effects at all.

Statistical Decision:

The p-values for the incidence of postoperative nausea and vomiting (PONV) and the severity of nausea were both below 0.05, leading us to reject the null hypothesis (H_0).

This means that our analysis shows a statistically significant link between the type of antiemetic drug used and how effective it is at preventing nausea and vomiting after surgery.

CHPATER 6
DISCUSSION:

One such undesirable outcome of laparoscopic cholecystectomy is postoperative nausea and vomiting (PONV), and it is in this regard that patients most often report that they are satisfied and recovered with the anesthetic services. The current research aimed at comparing the effectiveness of Ondansetron (4mg IV) and Metoclopramide (10mg IV) in PONV prevention in laparoscopic cholecystectomy patients. These results were able to show that Ondansetron was significantly superior to Metoclopramide in terms of prevention of nausea and vomiting as well as their severity during the period of postoperative. The total PONV rate was very low at 17.5 percent in the Ondansetron group and 38.8 percent in the Metoclopramide group ($p = 0.003$), which proved the better antiemetic effect of Ondansetron. These findings are consistent with the literature of Gan et al. (2020) and Rajan et al. (2020) who also stated that 5-HT3 receptor antagonists were significantly more effective in PONV reduction than the dopamine ones during laparoscopic surgeries.

The mean scores of nausea severity in both the Ondansetron and the Metoclopramide groups at the different postoperative periods (2, 6 and 24 hours) were significantly less in the Ondansetron side (1.6 +1.2, 1.8 +1.4 and 1.2 +1.0 respectively). This is a definite sign that not only does Ondansetron cause a reduction in the frequency of nausea but also causes a decrease in the severity of the same too in the course of the healing process. Similar outcomes are also observed by Yilmaz et al. (2022), who assert that Ondansetron is more efficient in nausea management than Metoclopramide after laparoscopic surgery. The effect of Ondansetron is selective and correlates to be an antagonist of the peripheral receptors within the gastrointestinal tract and central receptors within the chemoreceptor trigger zone that are essential to the emetic reflex mechanism.

In terms of adverse side effects, the given study revealed that only the drowsiness (7.5%), and extrapyramidal symptoms (2.5%) were observed in Metoclopramide group but not in Ondansetron group. These findings are consistent with Watcha and White (2020) who reported that Metoclopramide will most likely cause sedation and extrapyramidal reactions (which usually occur due to its influence on dopaminergic blockage), whereas Ondansetron rarely causes these problems. Also, in a systematic review, Li et al. (2024) confirmed the therapeutic index of Ondansetron to be higher than that of old antiemetics. In this way, Ondansetron is more suitable than other interventions in terms of efficacy and safety as a PONV prophylaxis in laparoscopic cholecystectomies.

Although both groups of this research were not dissimilar in terms of demographic and clinical characteristics (age, sex, ASA class, and surgical time), the difference in the results of PONV indicates the pharmacological advantages of

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Ondansetron. The factors that enhance compliance with ERAS (Enhanced Recovery After Surgery) guidelines are the low level of sedation, faster healing process and the mobilization process of the drug is fast. These characteristics can also facilitate such other patient-centered outcomes as reduced hospital stay and rising of the level of satisfaction. As pointed out by the previous researchers (Kovac, 2019, and Apfel et al., 2018), Ondansetron has been found to be an effective means of PONV prevention, specifically, when administered before the extubation, in both low and high-risk patients.

In conclusion, the paper approved that Ondansetron is superior to Metoclopramide in the prevention of postoperative nausea and vomiting as compared to Metoclopramide during laparoscopic cholecystectomy. Ondansetron is preferred over other antiemetic prophylaxis drugs because of the selective 5-HT 3 antagonism, minimum side effects, and rapid recovery in postoperative period. Other researchers can also take a prospective study on the combination therapy of Dexamethasone or Neurokinin-1 receptor antagonist like Aprepent to maximize anti-emetic effects of high-risk patients. Ondansetron is more costly than the latter, but the clinical advantages of the given medication mean that it is the standard choice that should be implemented in surgery in order to contribute to the improved patient safety, comfort, and postoperative recovery.

CHAPTER 7

7.1: CONCLUSION:

In general, the findings demonstrated that Ondansetron is much more effective compared to metoclopramide to prevent PONV in Laparoscopic Cholecystectomy, operations. It implies that Ondansetron should be regarded as the primary line treatment choice of PONV since it will result in improved outcome, reduced recovery period and enhanced postoperative comfort of patients.

7.2: RECOMMENDATION(S)

I. **Using Ondansetron as First-Line Therapy:** According to the findings of this research paper, Ondansetron (4mg IV) would be the ideal first-line agent in prevention and treatment of postoperative nausea and vomiting (PONV) in patients under laparoscopic cholecystectomy. It is a better option compared to Metoclopramide due to its high effectiveness and reduced rate of side effects.

II. **Personalized Antiemetic Treatment:** However, comparing the effectiveness between ondansetron and any of the agents in this list is difficult, although, due to the variations in individual patient factors (including past history of motion sickness, the type of anesthetic, and opioid use in the case of NA-AAA), a specific antiemetic regimen should be selected.

III. **Combination Therapy for High-Risk Patients** In order to increase its efficacy, Ondansetron may be used in conjunction with other antiemetics such as dexamethasone or droperidol particularly for patient who are at high risk of PONV.

IV. **Routine evaluation of nausea and vomiting severity:** To enhance early identification and management of PONV, the same scoring system of nausea and vomiting should be used during the post-operative care processes, such as VAS scale.

V. **Further research on cost-effectiveness:** Future research should assess the cost-effectiveness of routine Ondansetron usage vs Metoclopramide, particularly in resource-constrained settings.

7.3: LIMITATIONS:

I. **Two-Center Study:** This research was conducted in two hospitals. While the multicenter design enhances data reliability, both hospitals share similar patient populations and healthcare resources, which may limit generalizability to other regions or private healthcare settings.

II. **Sample Size Constraints:** The research comprise 160 patients, which, while large, may

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not accurately represent the general population receiving laparoscopic cholecystectomy surgery. Larger, multi-center studies are required to get more certain conclusions.

III. **Short Follow-Up Duration:** Nausea and Vomiting symptoms are evaluated exclusively in the early postoperative phase. Future studies should include longer follow-ups to assess delayed nausea and vomiting.

IV. **Lack of cost analysis:** While Ondansetron is found to be more efficacious than Metoclopramide, the economic impact of its frequent usage was not considered. Future study should use cost-benefit analyses to examine the financial implications

CHAPTER 8

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