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Comparison of Oral Ondansetron and Metoclopramide in Reducing Postoperative Nausea and Vomiting in Gynecological Laparoscopic Procedures

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ABSTRACT

Background: Postoperative vomiting and nausea frequently occur after gynecological laparoscopic surgeries, adversely affecting rehabilitation and patient satisfaction. Although metoclopramide and ondansetron are often utilized antiemetics, their relative efficacy in avoiding postoperative nausea and vomiting continues to be investigated. **Objective:** To compare the efficacy of oral ondansetron and metoclopramide in reducing postoperative nausea and vomiting in gynecology laparoscopic procedure. **Study Design:** Randomized controlled trial. **Duration and Place of Study:** The study was conducted from June 2024 to December 2024 at the Department of Obstetrics and Gynecology, Lady Reading Hospital, Peshawar. **Methodology:** A total of 194 female patients, aged 18 to 50 years, scheduled for gynaecological laparoscopic procedures, were assigned at random into two separate categories: Group A (ondansetron) & Group B (metoclopramide), having 97 patients in each group. Patients were administered either 4 mg of ondansetron with 8 mg of dexamethasone (Group A) or 10 mg of metoclopramide with 8 mg of dexamethasone (Group B) before surgery. The efficacy was assessed by the lack of vomiting and nausea within 24 hours following surgery. **Results:** The mean age of participants was 34.82±7.83 years for Group A and 35.75±8.69 years for Group B. The efficacy of ondansetron was significantly higher, with 55.7% of patients in Group A showing effectiveness, compared to 33% in Group B (p=0.001). Stratified analysis revealed that younger patients (≤40 years), married patients, and those with a BMI ≤25 showed a greater response to ondansetron. **Conclusion:** Ondansetron was found to be more effective than metoclopramide in preventing postoperative nausea and vomiting following gynecological laparoscopic surgery..

INTRODUCTION

Postoperative nausea and vomiting (PONV) is a distressing and prevalent postoperative syndrome that is more common with general anesthesia.[1] It is associated with patient discomfort, extended recovery times, extended hospital stay, and increased costs.[2] PONV is a multifactorial interplay of multiple patient-related and type of surgery and type of administered anesthesia-related factors.[3] Depending on these factors, the development of PONV can be quite variable and can be exacerbated with some operations.[4] Treatment modalities are aimed to minimize these effects and facilitate recovery and patient comfort.

Postoperative nausea and vomiting is very prevalent in laparoscopic surgery, especially in gynecology.[5] Laparoscopy with insufflation of abdomen with carbon dioxide gas leads to PONV by mechanisms of insufflated gas effects and organ manipulation. Postoperative nausea and vomiting is caused by general anesthesia and opioids used for surgery.[6] Laparoscopic gynecologic surgeries for conditions such as endometriosis or excision of ovarian cysts is more prone to cause increased incidence of PONV based on nature of surgery and patient population.[7] With increased risk involved, prevention and treatment are necessary to improve patient outcome. Oral ondansetron demonstrates high efficacy in preventing postoperative nausea and vomiting and specifically treats nausea and vomiting during laparoscopic operations.[8] Ondansetron functions as a receptor-specific antagonist blocking 5-HT3 receptors which reduces nausea and vomiting challenges within gastrointestinal tissues and the central nervous system. Extensive clinical trials have documented this agent's ability to prevent PONV in laparoscopic surgery patients.[9] Postoperative nauseas and vomiting prevention is achieved effectively and safely through Ondansetron use despite its limited side effect profile.[10] The prophylactic application of this drug before surgeries is common practice and the oral dosage

provides simple administration for ongoing prevention after surgical procedures.

Metoclopramide is used as a dopamine receptor blocker as well as to prevent post-operative nausea and vomiting, especially in gynecology laparoscopic surgery.[11] This effect is produced by the metoclopramide to block dopamine receptors in the central nervous system in order to suppress nausea and vomiting by increasing gastric motility and stomach emptying.[12] The effect is especially useful to reduce nausea associated with delayed gastric emptying such as this is observed following laparoscopic surgery. Although metoclopramide works, as well as it does it produces side effects such as sedation, and extrapyramidal effects if used for extended periods of time. Metoclopramide, however, is a useful treatment with caution, for the postoperative nausea and vomiting.[13]

A study by Khan A et al. demonstrated that ondansetron and metoclopramide exhibited efficacy rates of 63.3% and 43.3%, respectively, in reducing postoperative nausea and vomiting (PONV) following gynecological laparoscopic procedures.[14]

Postoperative nausea and vomiting remain common complications following gynecological laparoscopic procedures, leading to patient discomfort and prolonged recovery. While various antiemetic medications are available, there is limited consensus on the most effective oral treatments for managing PONV in this specific patient group. This study aims to evaluate the efficacy of oral ondansetron and metoclopramide in reducing PONV, providing valuable insights to optimize postoperative care and improve patient outcomes in gynecological laparoscopic surgeries.

METHODOLOGY

A randomized controlled trial in LRH Peshawar's Department of Obstetrics and Gynaecology from June 2024 to December 2024 was conducted. In the study a total of 194 female patients aged 18 to 50 years subjected for gynecological laparoscopic procedures were included. Therefore, participants were randomly assigned to two groups: one group received oral metoclopramide (Group B), and the other oral ondansetron (Group A). Blocked randomization was applied such that 97 patients each were in each group.

The sample size was calculated using a 95% confidence level, alpha = 5% (two-sided), and power = 80%, based on the anticipated efficacy rates of ondansetron (63.3%) and metoclopramide (43.3%). This calculation determined a total sample size of 194, with 97 patients assigned to each group.

The inclusion criteria were women above of age 18 to 50 years, married or otherwise unmarried, with ASA grade I/II. Patients having gynecological laparoscopic procedure defined as ovarian cyst removal via laparoscopic method were chosen. Exclusion criteria included a history of diabetes, motion sickness, gastroesophageal reflux disease, opioid use or drug addiction. All participants were asked to provide demographic information including age, marital status, BMI, residential status, educational level, socioeconomic status and profession. This was after explaining the purpose of the study, the risks and benefit of the study.

Upon entering the surgical area, an IV (intravenous) line was initiated, and monitoring apparatus was affixed. Fluid therapy was modified according to preoperative fasting, duration of surgery, and intraoperative fluid losses. Anaesthesia was initiated using fentanyl, propofol, and atracurium, and maintained with oxygen and isoflurane. Fifteen minutes before to the completion of the surgery, the assigned groups were administered their respective antiemetic therapies: Group A received 4 mg of ondansetron in conjunction with 8 mg of dexamethasone, whereas Group B received 10 mg of metoclopramide along with 8 mg of dexamethasone. Postoperatively, patients were observed in the postanesthesia care unit, receiving supplementary doses of metoclopramide as required for severe nausea or vomiting persisting beyond 5 minutes.

The effectiveness of the treatments was assessed based on the absence of postoperative nausea and vomiting within 24 hours after surgery. Nausea was defined as the sensation of needing to vomit, lasting for at least 15 minutes, while vomiting was characterized by the forceful ejection of stomach contents with more than three episodes within 24 hours, separated by no more than two minutes. Data were analyzed using SPSS version 26, with categorical variables assessed using frequencies and percentages, while quantitative data were summarized using means or medians. The efficacy between groups was compared using the chi-square test, and stratified analysis was performed based on demographic factors such as age, BMI, and socioeconomic status. Statistical significance was set at $p \leq 0.05$.

RESULTS

In Group A (ondansetron group, n=97), the mean age was 34.82±7.83 years and the mean BMI was 25.71±3.82 kg/m². In Group B (metoclopramide group, n=97), the mean age was 35.75±8.69 years, and the mean BMI was 25.94±3.97 kg/m². Regarding marital status, 100% of patients in Group A were married, while 93.8% in Group B were married and 6.2% unmarried. The residential status showed 54.6% of patients in Group A and 45.4% in Group B resided in rural areas, while 45.4% of Group A and 54.6% of Group B lived in urban areas. Educationally, 11.3% of patients in Group A were uneducated, 60.8% had primary education, 21.6% had secondary education, and 6.2% had higher education. In

Group B, 15.5% were uneducated, 48.5% had primary education, 32% had secondary education, and 4.1% had higher education. Socioeconomic status was similar in both groups, with most patients being from middle-class backgrounds (52.6% in both groups), followed by low and high socioeconomic status categories as shown in Table-I.

Table I

Demographics of the patients (n=194)

Demographics		Group A n=97 Mean±SD	Group B n=97 Mean±SD
Age (years)		34.824±7.83	35.752±8.69
BMI (kg/m²)		25.714±3.82	25.937±3.97
Marital Status	Married n(%)	97 (100%)	91 (93.8%)
	Unmarried n(%)	0 (0%)	6 (6.2%)
Residential Status	Rural n(%)	53 (54.6%)	44 (45.4%)
	Urban n(%)	44 (45.4%)	53 (54.6%)
Educational Level	Uneducated n(%)	11 (11.3%)	15 (15.5%)
	Primary n(%)	59 (60.8%)	47 (48.5%)
	Secondary n(%)	21 (21.6%)	31 (32%)
	Higher n(%)	6 (6.2%)	4 (4.1%)
Socioeconomic Status	Low n(%)	32 (33%)	33 (34%)
	Middle n(%)	51 (52.6%)	51 (52.6%)
	High n(%)	14 (14.4%)	13 (13.4%)

Table-II compares the efficacy between the two groups. In Group A, 55.7% of patients reported efficacy, while in Group B, only 33% showed efficacy (p=0.001), indicating a significant difference in favor of the ondansetron group.

Table II

Comparison of efficacy between the two groups (n=194)

Efficacy	Group A n=97 n (%)	Group B n=97 n (%)	P value
Yes	54 (55.7%)	32 (33%)	
No	43 (44.3%)	65 (67%)	0.001
Total	97 (100%)	97 (100%)	

Table-III and Graph-I shows the stratification of efficacy based on demographic variables. For patients aged ≤40 years, 60.3% in Group A experienced efficacy compared to 35.4% in Group B (p=0.004). For those aged >40 years, there was no significant difference in efficacy between the groups (p=0.175). Regarding marital status, 55.7% of married patients in Group A showed efficacy, compared to 35.2% in Group B (p=0.005). No efficacy differences were observed in unmarried patients. For BMI ≤25, 57.1% in Group A and 33.3% in Group B showed efficacy (p=0.019), while for BMI >25, 54.2% in Group A and 32.7% in Group B showed efficacy (p=0.032).

Table III

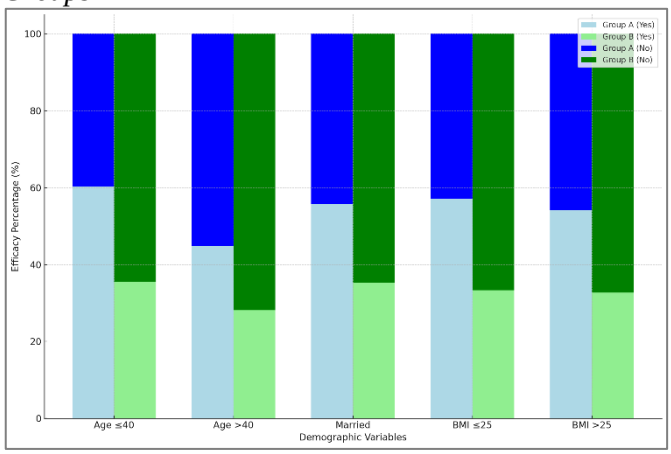
Association of Efficacy with Demographic Variables

Demographics variables		Group	Efficacy Yes (n, %)	Efficacy No (n, %)	P-value
Age (years)	≤40	A	41 (60.3%)	27 (39.7%)	0.004
		B	23 (35.4%)	42 (64.6%)	
	>40	A	13 (44.8%)	16 (55.2%)	0.175
		B	9 (28.1%)	23 (71.9%)	
Marital Status	Married	A	54 (55.7%)	43 (44.3%)	0.005
		B	32 (35.2%)	59 (64.8%)	
	Unmarried	A	0 (0%)	0 (0%)	1.000*
		B	0 (0%)	6 (100%)	
BMI (kg/m²)	≤25	A	28 (57.1%)	21 (42.9%)	0.019
		B	16 (33.3%)	32 (66.7%)	
	>25	A	26 (54.2%)	22 (45.8%)	0.032
		B	16 (32.7%)	33 (67.3%)	

*Fischer Exact Test

Graph I

Efficacy Stratification Based on Demographics Across Groups



DISCUSSION

These findings are indicative of much greater efficacy in Group A (55.7%) compared with Group B (33%), reflecting the fact that ondansetron is more effective in the prophylaxis of PONV. Perhaps the two drugs differ in their pharmacologic mechanism; ondansetron, as a selective 5-HT3 receptor antagonist, acts more specifically on serotonin-mediated emesis pathways that are typically more prevalent in the context of laparoscopic procedures.

Further age subdivision by marital status and BMI also showed that patients ≤40 years old in both groups also showed enhanced reduction in PONV, where Group A (60.3%) showed significantly greater efficacy than Group B (35.4%) (p=0.004). This might have been due to the better pharmacokinetic profile in younger patients potentially leading to better drug absorption and effect. However, among patients >40 years old, the two groups were not significantly differentiated in terms of efficacy (p=0.175), which suggests that other factors such as the health status or the comorbid conditions that accompany increasing age may influence the efficacy of antiemetics.

Also contributing towards the result was marital status; married patients within Group A reported greater efficacy (55.7%) than Group B (35.2%) (p=0.005). Marital status may indirectly suggest more stable lifestyle or less stress, which may have implications for the reaction of the body towards drugs, though more work would need to be done.

Finally, BMI analysis also indicated that patients ≤25 BMI showed significantly higher efficacy in Group A (57.1%) than Group B (33.3%) (p=0.019), while patients >25 also showed higher efficacy in Group A (54.2%) than Group B (32.7%) (p=0.032). The variance observed might be due to the variability in drug distribution among patients with higher body fat that would affect the efficacy and the absorption of the drug.

Group A (ondansetron group) in our study demonstrated significantly greater efficacy (55.7%) than Group B (metoclopramide group) at the level of 33% (p=0.001). This agrees with the work by Vasantha Kumar et al. [15] who reported that ondansetron was significantly better than metoclopramide in the prevention of vomiting and retching post-operatively in patients who underwent caesarean section in the lower segment by spinal anaesthesia. Their result demonstrated the superiority of ondansetron in the prevention of vomiting episodes as the postoperative period progressed. Khan et al. [16] also reported that ondansetron (2mg) caused fewer vomiting episodes (40%) than metoclopramide (53.3%) after laparoscopic cholecystectomy and that the efficacy difference was statistically significant.

In a larger meta-analysis involving four trials involving 979 patients by Alhaaj et al.,[17] no significant overall difference between the effectiveness of ondansetron (41%) and that of metoclopramide (43%) in the prevention of PONV was observed. Ondansetron was slightly superior in preventing vomiting, which is consistent with our finding where patients in Group A had reduced rates of nausea and vomiting, the difference being significant among the younger patients as well as the patients having the lower BMI.

Another significant study conducted by Alexander and Fennelly [18] proved that ondansetron (8mg) reduced the incidence of vomiting significantly (26%) when compared with that of metoclopramide (43%) and placebo (55%) in patients undergoing major orthopaedic surgery of the lower limb. They also concluded that ondansetron worked best in patients at risk of PONV by reducing the incidence to 29% in the ondansetron group compared with that in the metoclopramide and placebo groups at 68% and 67% respectively (p=0.035). These findings are in accordance with our study in which married patients in Group A showed higher efficacy at 55.7% compared with that in Group B at 35.2%, further validating the hypothesis that the efficacy of ondansetron would be higher in specific subgroups of patients.

This differential effectiveness between the two drugs was also seen in the study by Mithun et al.[15] where ondansetron was most effective in the prevention of PONV, vomiting being significantly less in the ondansetron group (5%) than that in the case of metoclopramide (35%) and placebo (60%). Our findings also agreed where Group A performed better in nausea and vomiting (55.7% efficacy) than Group B (33%).

A study by Alhaaj et al. [17] proved that the efficacy of ondansetron was slightly better than that of metoclopramide even though there wasn't any significant overall difference between the two groups in the frequency of PONV. That minor difference would arise from the more selective nature of the action by ondansetron as an antagonist at the 5-HT3 receptor while the action by the dopamine and serotonin receptors by the metoclopramide would not prove as effective in preventing pathways by serotonin-induced nausea and vomiting that are most specific in the case of PONV following surgery. Our study's similarly good but marginally better performance by ondansetron lends support to this mechanism.

Also, both the result from Alexander and Fennelly [18] and Khan et al. [16] suggest that the superior efficacy of ondansetron results from the fact that it controls vomiting episodes better, which we also observed in the study where vomiting severity in Group A was less. It's important because vomiting can lead to dehydration, delayed recovery, and longer hospital stays.

Compared to the variability in results between the various studies, the consistent trend in our study and that in other studies suggests the higher efficacy of ondansetron in specific patient populations such as young patients, low BMI patients, and patients with history of PONV. These results also emphasize the patient-specific and surgical-specific nature of antiemetic therapy.

There are several limitations in our study. Because the study was single-center based, the results cannot be generalized totally to large populations because patient characteristics and treatment results might vary in other practice environments. Our sample size was small and

potentially decreased the statistical power to detect subtler differences between the two drugs. Side effects, long-term outcomes, and cost-effectiveness were not considered in the study. Future study based on a larger multi-center cohort would prove valuable in providing a better overall assessment about the comparative efficacy and safety between these two antiemetics.

CONCLUSION

Our study has demonstrated that ondansetron is comparable to metoclopramide in preventing postoperative nausea and vomiting across varied patient populations. Our findings agree with the literature and point out the superior effectiveness of ondansetron among patients who are young, have low BMI, and have PONV history. These findings support the use of ondansetron as the treatment of choice for the management of PONV depending on patient characteristics and surgical considerations.

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Author Contributions

The authors have played key roles in the creation of this manuscript, as outlined below:
Dr. Muhammad Kamil Qadeer spearheaded the development of the study, wrote the initial draft of the article, and oversaw the collection of hospital data.
Dr. Roheena Wadud contributed significantly to refining the article, helping shape the study's framework, and providing crucial input in data analysis and interpretation.

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