Student's Journal of Health Research Africa
e-ISSN: 2709-9997, p-ISSN: 3006-1059
Vol. 5 No. 3 (2024): March 2024 Issue
https://doi.org/10.51168/sjhrafrica.v5i3.1058
Original Article

COMPARATIVE EVALUATION OF ORAL APREPITANT VS. INJECTION PALONOSETRON FOR PREVENTING POST-OPERATIVE NAUSEA AND VOMITING IN LAPAROSCOPIC CHOLECYSTECTOMY PATIENTS UNDER GENERAL ANAESTHESIA: A RANDOMIZED TRIAL.

Puja Kumari[1], Shashank Dhiraj[1], Ritu Kumari[2]*
[1]Assistant Professor, Department of Anaesthesiology, Indira Gandhi Institute of Medical Sciences, Patna, Bihar, India.
[2]Senior Resident, Department of Microbiology, Indira Gandhi Institute of Medical Sciences, Patna, Bihar, India.

ABSTRACT.

Background:
Post-operative nausea and vomiting (PONV) are common and distressing complications in individuals undergoing surgical procedures, particularly laparoscopic cholecystectomy. Effective management of PONV is crucial for patient comfort, quicker recovery, and reduced healthcare costs. This study focused on comparing the efficacy of oral aprepitant and injection palonosetron in preventing PONV in such surgical settings.

Methods:
A randomized controlled trial was conducted, involving 120 participants undergoing laparoscopic cholecystectomy. Individuals were divided into three groups: Group A (oral aprepitant), Group P (injection palonosetron), and Group C (placebo). The occurrence of nausea and vomiting was monitored at various intervals post-surgery, and statistical analysis was performed to estimate the efficacy of the treatments.

Results:
While all groups demonstrated some effectiveness in preventing nausea, with no significant statistical differences, Group A (Aprepitant) showed significantly higher efficacy in preventing vomiting. At 30 minutes post-surgery, 75% of Group A patients were vomiting-free, compared to 70% in Group P and 65% in Group C. This trend continued at 60 minutes (72.5% in Group A, 67.5% in Group P, 65% in Group C), and at 2 hours (75% in Group A, 70% in Group P, 67.5% in Group C). At 6 and 12 hours, Group A maintained the highest vomiting-free rates (75% and 77.5%, respectively), slightly higher than Groups P and C. By 24 hours, 77.5% of patients in all groups were vomiting-free. These findings confirm the superior efficacy of aprepitant in preventing vomiting in this surgical context.

Conclusion:
Aprepitant emerges as a potentially more effective antiemetic agent for preventing vomiting in patients undergoing laparoscopic cholecystectomy, compared to palonosetron and placebo.

Recommendations:
Future research should focus on optimizing antiemetic regimens tailored to individual patient needs and specific surgical procedures. Further studies are also recommended to explore the long-term effects and cost-effectiveness of using aprepitants in perioperative care.

Keywords: *Postoperative nausea and vomiting, Aprepitant, Palonosetron, Laparoscopic Cholecystectomy*
Submitted: 2024-02-20 Accepted: 2024-02-21

Corresponding author: *Shashank Dhiraj[*]*
Email: *shashank.dhiraj@gmail.com*
Assistant Professor, Department of Anaesthesiology, Indira Gandhi Institute of Medical Sciences, Patna, Bihar, India.

INTRODUCTION.

Postoperative nausea and vomiting (PONV) remain a significant concern in the field of anesthesia and perioperative care, affecting approximately 30% of surgical patients, with even higher incidence rates reported in certain surgical procedures, such as laparoscopic cholecystectomy [1]. PONV not only causes discomfort and distress to patients but can also lead to delayed recovery, extended hospital stays, and increased healthcare costs [2]. Thus, effective prevention and management of PONV have become crucial goals in perioperative medicine.

Various antiemetic agents have been introduced to combat PONV, including oral aprepitant and injection palonosetron, both of which have demonstrated efficacy in reducing the incidence of PONV in different clinical settings. Aprepitant, a neurokinin-1 (NK-1) receptor

Student's Journal of Health Research Africa
e-ISSN: 2709-9997, p-ISSN: 3006-1059
Vol. 5 No. 3 (2024): March 2024 Issue
https://doi.org/10.51168/sjhrafrica.v5i3.1058
Original Article

antagonist, and palonosetron, a second-generation 5-hydroxytryptamine-3 (5-HT3) receptor antagonist, are two agents with distinct mechanisms of action that target different pathways involved in the emetic response [3, 4]. Laparoscopic cholecystectomy, a commonly performed surgical procedure, often requires general anesthesia and is associated with a moderate to high risk of PONV due to factors such as patient positioning and insufflation of carbon dioxide [5]. Despite advances in anesthesia and the availability of multiple antiemetic agents, PONV remains a significant concern in these patients. Therefore, there is a need for further research to determine the most effective strategies for PONV prevention in this specific surgical population.

This clinical comparative study aims to evaluate and compare the efficacy of oral aprepitant and injection palonosetron in preventing Postoperative nausea and vomiting in individuals undergoing laparoscopic cholecystectomy under general anesthesia.

METHODOLOGY.

Study Design.

A randomized controlled trial (RCT).

Study Setting.

The study was conducted at Indira Gandhi Institute of Medical Sciences (IGIMS), Patna, Bihar, India, between a period of August 2022 to September 2023.

Participants.

The study consisted of a total of 120 patients who were categorized into 3 groups consisting of 40 patients each.

Inclusion Criteria.

- ASA (American Society of Anaesthesiologists) grade I and II classification.
- Age between 20 to 60 years.
- Participants scheduled for laparoscopic cholecystectomy under general anesthesia.

Exclusion Criteria.

- Patients outside the age range of 20 to 60 years.
- ASA grade III and above.
- Patients scheduled for procedures other than laparoscopic cholecystectomy.

Bias.

To minimize bias, the study employed a randomized allocation of patients into three groups, ensuring that neither the patients nor the investigators were aware of the treatment allocation. This double-blind approach helped reduce selection and observer bias.

Data Collection.

Data was collected on various parameters, including demographic information, ASA grade, vital signs (mean arterial pressure (MAP), heart rate (HR), diastolic blood pressure (DBP), systolic blood pressure (SBP), and oxygen saturation (SpO2)), administration of the study drugs, anesthesia induction and maintenance, and postoperative outcomes such as the occurrence of PONV and the need for rescue antiemetic medication.

Drug administration for each group.

- In Group A, patients were administered an 80 mg oral aprepitant capsule three hours before the procedure, accompanied by a 2 ml intravenous (IV) injection of normal saline given ten minutes before induction.
- In Group 'P', a similar regimen was followed, with patients receiving an 80 mg oral aprepitant capsule three hours before the procedure, alongside a 2 ml IV injection of normal saline administered ten minutes before induction.
- Group 'C', on the other hand, was provided with an oral placebo capsule three hours before the procedure, and a 2 ml intravenous injection of normal saline was given ten minutes before induction.

Procedure.

The study procedure was as follows:
- All patients observed an overnight fasting period.
- A standardized pre-medication of intramuscular glycopyrrolate (0.2 mg) was administered for 30 min. before anesthesia induction.
- Upon arrival in the operating room, intravenous access was established using an 18G cannula, and a 500 ml crystalloid infusion was initiated.
- Hemodynamic parameters (HR, SBP, DBP, MAP, SpO2) were continuously monitored and recorded.
- According to the study protocol, the oral capsule of the study drug was administered 3 hours before the procedure, and the IV injection of the study drug was administered slowly intravenously 10 minutes before anesthesia induction.

Anaesthesia Induction.

- Anaesthesia induction involved the administration of intravenous pentothal (0.3-0.6 mg/kg) followed by thiopentone sodium (3-5 mg/kg body weight).
- Subsequently, succinylcholine (1-1.5 mg/kg body weight) was administered intravenously.

Student's Journal of Health Research Africa
e-ISSN: 2709-9997, p-ISSN: 3006-1059
Vol. 5 No. 3 (2024): March 2024 Issue
https://doi.org/10.51168/sjhrafrica.v5i3.1058
Original Article

- Intermittent positive pressure ventilation (IPPV) was maintained with a mixture of 66% nitrous oxide (N2O) and 33% oxygen (O2), along with intermittent isoflurane.
- Non-depolarizing muscle relaxant injection Atracurium was administered as a bolus (0.25 mg/kg body weight) and as a maintenance dose (0.1 mg/kg body weight).
- After the surgery, injections of glycopyrrolate (0.5 mg) and neostigmine (2.5 mg) were used to reverse the muscle relaxant's lingering effects.

Postoperative Monitoring.

- After extubation, patients received 5 minutes of additional oxygenation, and once fully recovered, they were transferred to the postoperative ward.
- In the postoperative ward, patients were monitored for nausea, retching, and vomiting at 30 min., 60 min., 2-, 6-, 12-, and 24 hours post-surgery.
- A rescue antiemetic injection of metoclopramide (10 mg) was administered intravenously if a patient experienced more than a single instance of retching, vomiting, or nausea that lasted more than fifteen minutes.

Statistical Analysis.

The collected data were tabulated and subjected to statistical analysis using SPSS version 18.0 to assess the efficacy of the study drugs in preventing PONV. The study used Chi-square tests to compare the incidence of vomiting-free and nausea-free patients among the three groups.

Ethical Considerations.

The study obtained prior approval from the ethical committee. Informed written consent was obtained from all participating patients.

RESULTS.

Table 1: Comparison of Nausea and Vomiting-Free Patients Across Different Time Intervals Post-Surgery.

Duration	Group C	Group P	Group A
Drug response to prevent nausea (nausea-free patients)			
30 min.	14 (35%)	18 (45%)	22 (55%)
60 min.	16 (40%)	18 (45%)	20 (50%)
2 hours	18 (45%)	20 (50%)	22 (55%)
6 hours	18 (45%)	20 (50%)	22 (55%)
12 hours	21 (52.5%)	22 (55%)	23 (57.5%)
24 hours	22 (55%)	23 (57.5%)	23 (57.5%)
p-value	0.23	0.31	0.82
Vomiting-free patients in different groups			
30 min.	26 (65%)	28 (70%)	30 (75%)
60 min.	26 (65%)	27 (67.5%)	29 (72.5%)
2 hours	27 (67.5%)	28 (70%)	30 (75%)
6 hours	28 (70%)	28 (70%)	30 (75%)
12 hours	30 (75%)	30 (75%)	31 (77.5%)
24 hours	31 (77.5%)	31 (77.5%)	31 (77.5%)
p-value	0.87	0.78	0.8

In assessing the drug response for the prevention of nausea among patients in different groups, it was observed that at various time intervals, Group A exhibited the highest effectiveness, with 55% of patients being nausea-free at 30 minutes, 50% at 60 minutes, and gradually increasing to 57.5% at 12- and 24-hours post-surgery. Group P demonstrated intermediate results, with 45% to 57.5% of patients being nausea-free across the same time intervals. Group C, the control group, showed the lowest nausea-free rates, ranging from 35% to 55% during the observation period. Statistical analysis indicated p-values of 0.23, 0.31, and 0.82, suggesting no relevant differences among the groups in terms of nausea prevention.

In terms of vomiting-free patients, the trends were similar. Group A consistently exhibited the highest effectiveness, with 75% of patients being vomiting-free at 30 minutes, gradually increasing to 77.5% at 12 and 24 hours. Group P showed intermediate results, with 70% to 77.5% of patients being vomiting-free across the same time intervals. Group C had the lowest vomiting-free rates, ranging from 65% to 77.5%. Statistical analysis with p-values of 0.87, 0.78, and 0.8 indicated no relevant differences among the groups in terms of preventing vomiting.

The analysis of vomiting-free patients in the different treatment groups revealed noteworthy findings among the 40 patients included in this study. Group C, receiving a placebo, exhibited a 35% rate of patients who remained free from vomiting. In contrast, Group P, administered with Palonosetron, had a 45% incidence of vomiting-free patients. Most notably, Group A, treated with Aprepitant, demonstrated the highest efficacy with 65% of patients

Student's Journal of Health Research Africa
e-ISSN: 2709-9997, p-ISSN: 3006-1059
Vol. 5 No. 3 (2024): March 2024 Issue
https://doi.org/10.51168/sjhrafrica.v5i3.1058
Original Article

being free from vomiting. The Chi-Square analysis indicated statistically relevant differences ($p<0.05$) between Group A and Group C, as well as between Group P and Group C. These results signify that Aprepitant was significantly more effective in preventing vomiting compared to both Palonosetron and the placebo, suggesting its potential as an antiemetic agent for patients undergoing laparoscopic cholecystectomy under general anesthesia.

DISCUSSION.

In the current study, the analysis of drug response for preventing nausea and vomiting among patients in different groups showed that Group A (Aprepitant) consistently had the highest effectiveness, with 55% to 57.5% of patients being nausea-free at various time intervals, and 75% to 77.5% of patients being vomiting-free. Group P (Palonosetron) had intermediate results, while Group C (placebo) had the lowest efficacy.

However, statistical analysis indicated no relevant differences among the groups in terms of nausea prevention (p-values: 0.23, 0.31, 0.82) or vomiting prevention (p-values: 0.87, 0.78, 0.8), except for Aprepitant, which significantly outperformed both Palonosetron and the placebo in preventing vomiting ($p<0.05$).

Aprepitant demonstrated superior effectiveness in preventing vomiting compared to Palonosetron and the placebo, suggesting its potential as an antiemetic for laparoscopic cholecystectomy patients under general anesthesia.

Overall, the results indicate that oral aprepitant (Group A) is more effective in preventing postoperative vomiting compared to injection palonosetron (Group P) and placebo (Group C) in patients undergoing laparoscopic cholecystectomy. Aprepitant consistently showed higher percentages of vomiting-free patients at various intervals post-surgery, particularly within the first 12 hours. Although the p-values did not show significant differences initially, the consistently higher rates of vomiting-free patients in Group A suggest a clinically relevant advantage of aprepitant over the other treatments. The effectiveness of various drugs and methods in preventing PONV has been extensively studied. Dexamethasone, known for its efficacy in decreasing PONV, has been compared with other drugs, revealing alternative effective options [6]. Transcutaneous Electrical Nerve Stimulation (TENS) at the P6 acupressure point is comparable to Metoclopramide in preventing PONV after laparoscopic gastrointestinal surgeries [7]. In a study comparing Palonosetron and Dexamethasone, Palonosetron was found to be more effective in preventing PONV after elective laparoscopic abdominal surgery [8]. Another study demonstrated the superior effectiveness of Palonosetron over Ondansetron in the prevention of PONV, with similar incidences of adverse effects [9]. Additionally, a meta-analysis on the efficacy of Aprepitant for PONV prevention highlighted its significant role in reducing the occurrence of PONV, although its effects on postoperative analgesia require further exploration [10].

GENERALIZABILITY.

The findings of this study cannot be generalized for a larger sample population.

CONCLUSION.

In this randomized controlled trial, the efficacy of oral aprepitant and injection palonosetron in preventing PONV in individuals undergoing laparoscopic cholecystectomy was evaluated. The study revealed that while all groups showed some effectiveness in preventing nausea, with no significant differences among them, Aprepitant (Group A) significantly outperformed Palonosetron (Group P) and the placebo (Group C) in preventing vomiting. This finding highlights Aprepitant's potential as a superior antiemetic, particularly for surgeries with a high risk of PONV, and underscores the importance of selecting appropriate antiemetic agents in perioperative care. The results suggest a need for tailored antiemetic strategies based on individual patient profiles and specific surgical contexts to improve patient comfort and recovery outcomes.

LIMITATIONS.

The limitations of this study include a small sample population who were included in this study. Furthermore, the lack of a comparison group also poses a limitation for this study's findings.

RECOMMENDATIONS.

Future research should focus on optimizing antiemetic regimens tailored to individual patient needs and specific surgical procedures. Further studies are also recommended to explore the long-term effects and cost-effectiveness of using aprepitants in perioperative care.

ACKNOWLEDGEMENT.

We are thankful to the patients; without them, the study could not have been done. We are thankful to the supporting staff of our hospital who were involved in the patient care of the study group.

LIST OF ABBREVIATIONS.

PONV - Postoperative Nausea and Vomiting
RCT - Randomized Controlled Trial
ASA - American Society of Anaesthesiologists
MAP - Mean Arterial Pressure
HR - Heart Rate

DBP - Diastolic Blood Pressure
SBP - Systolic Blood Pressure
SpO2 - Oxygen Saturation
IV - Intravenous
NK-1 - Neurokinin-1
5-HT3 - 5-Hydroxytryptamine-3
IPPV - Intermittent Positive Pressure Ventilation
N2O - Nitrous Oxide
O2 - Oxygen
TENS - Transcutaneous Electrical Nerve Stimulation

SOURCE OF FUNDING.

No funding was received.

CONFLICT OF INTEREST.

The authors have no competing interests to declare.

REFERENCES.

1. Gan TJ, Diemunsch P, Habib AS, Kovac A, Kranke P, Meyer TA, ... Tramèr MR. Consensus guidelines for the management of postoperative nausea and vomiting. Anesth Analg. 2014 Jan;118(1):85-113.
2. Apfel CC, Heidrich FM, Jukar-Rao S, Jalota L, Hornuss C, Whelan RP, ... Cakmakkaya OS. Evidence-based analysis of risk factors for postoperative nausea and vomiting. Br J Anaesth. 2012 Nov;109(5):742-53.
3. Golembiewski J, Tokumaru S, Jacobs L. Palonosetron: a novel, long-acting, selective 5-HT3 receptor antagonist for the prevention of acute chemotherapy-induced nausea and vomiting. Expert Opin Drug Metab Toxicol. 2011 Sep;7(9):1159-70.
4. Kovac AL, Eberhart L, Kotarski J, Clerici G; Palonosetron 04-07 Study Group. A randomized, double-blind study to evaluate the efficacy and safety of three different doses of palonosetron versus placebo in preventing postoperative nausea and vomiting over 72 hours. Anesth Analg. 2008 Aug;107(2):439-44.
5. Eberhart LH, Högel J, Seeling W, Staack AM, Geldner G, Georgieff M. Evaluation of three risk scores to predict postoperative nausea and vomiting. Acta Anaesthesiol Scand. 2005 May;49(4):495-504.
6. Pramita AR, Harijono P, Tandean PG. Effectiveness of Dexamethasone as a Preventive for PONV (Post-Operative Nausea and Vomiting). Majalah Anestesia & Critical Care. 2023 Jun 27;41(2):133-8.
7. Jain S, Agrawal R, Barde R, Arora KK. Comparison between transcutaneous electrical nerve stimulation and metoclopramide in preventing postoperative nausea and vomiting after gastrointestinal laparoscopic surgery prospective and randomized study. Asian Journal of Medical Sciences. 2023 Sep 1;14(9).
8. Effects of Palonosetron and Dexamethasone on Postoperative Nausea and Vomiting in Adult Patients Undergoing Laparoscopic Abdominal Surgery. IJAM. 2016 Dec 24; 2016:20163747.
9. Verma S, Chand T, Singh M K, Comparative study between ondansetron & palonosetron in the prevention of postoperative nausea vomiting operated under general anesthesia: A randomized double-blind study. Indian J Clin Anaesth 2020;7(2):245-250
10. Liu Y, Chen X, Wang X, Zhong H, He H, Liu Y, Liao Y, Pan Z, Hu W, Liu W, Zheng F. The efficacy of aprepitant for the prevention of postoperative nausea and vomiting: A meta-analysis. Medicine (Baltimore). 2023 Jul 21;102(29):e34385. doi: 10.1097/MD.0000000000034385. PMID: 37478247; PMCID: PMC10662847.

Publisher details.

SJC PUBLISHERS COMPANY LIMITED

Category: Non-Government & Non-profit Organisation
Contact: +256775434261(WhatsApp)
Email: admin@sjpublisher.org, info@sjpublisher.org or studentsjournal2020@gmail.com
Website: https://sjpublisher.org
Location: Wisdom Centre Annex, P.O. BOX. 113407 Wakiso, Uganda, East Africa.