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A COMPARATIVE STUDY OF ONDANSETRON AND PALONOSETRON IN PREVENTION OF POST OPERATIVE NAUSEA AND VOMITING IN PATIENTS UNDERGOING LAPAROSCOPIC CHOLECYSTECTOMY SURGERY.

Anaesthesiology

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ABSTRACT

One of the most common and distressing side effects of general anaesthesia is post-operative nausea and vomiting (PONV) especially after laparoscopic surgeries. It doesn't only make patients more uncomfortable after the procedure but also increases their risk of developing wound dehiscence, electrolyte imbalance and increased risk of haemorrhage. Numerous antiemetic drugs with different mechanisms are used for prevention of post operative nausea and vomiting but they have mixed results. An effort was made in this study to compare the efficacy and the side effect of ondansetron and palonosetron in controlling nausea and vomiting in post operative period.

KEYWORDS

Post operative nausea and vomiting {PONV}, ondansetron, palonosetron

INTRODUCTION

Postoperative nausea and vomiting (PONV) is one of the most common complications following anaesthesia, affecting approximately 20-30% of surgical patients within the first 24 hours postoperatively. Despite the availability of various antiemetic drugs, PONV remains a significant concern due to its potential consequences, including dehydration, electrolyte imbalances, delayed recovery, increased pain perception, and prolonged hospital stays. Certain patient-related and surgical factors, such as female gender, history of motion sickness, non-smoking status, perioperative opioid use, and the type and duration of surgery, have been identified as key contributors to PONV incidence. Vomiting can cause dehydration, electrolyte imbalance, interfere with the healing process after surgery, and make pain more intense[1]. Antihistaminics, butyrephenones, and dopamine receptor antagonists are among the pharmacological treatments that have been investigated in an effort to prevent and cure PONV.[2,3] Nevertheless, adverse effects have been noted, such as severe sedation, dry mouth, dysphoria, hallucinations, hypertension, and extrapyramidal symptoms. Delays in hospital release and bed occupancy may lead to higher expenses in addition to necessitating more professional time. Numerous factors, including female gender, nonsmoking status, pregnancy, h/o motion sickness, nausea, the type and length of surgery, and the use of perioperative opioids, have been reported to affect the risk of PONV. In the first 24 hours following laparoscopic cholecystectomy, a relatively high prevalence of PONV (40–70%) has been seen. A lower incidence of PONV has been linked to the use of non-opioid medications for pain relief. Compared to nonsmokers, smokers typically have a better profile in terms of PONV incidence.

Many antiemetic medications with various mechanisms of action, potencies, and pharmacokinetic profiles have been attempted recently to control PONV, with varying degrees of success. The emetic center and chemoreceptor trigger zone (CTZ), two topographically and functionally separate units in the medulla oblongata, make up the vomiting control mechanism. The emetic center and the CTZ seem to be linked by the enkephalin-rich fasciculus solitarius. A number of researchers have attempted to comprehend the function of 5-hydroxy tryptamine. Due to their excellent side effect profile and superior efficacy over earlier medications, 5-HT3 receptor antagonists are widely used medications for PONV prevention. An abundance of five HT3 receptors on enterochromaffin cells, vagal, and afferent neurons is essential for emesis.[4,5,6] It is thought that any abdominal treatment that involves physical disturbance and manipulation causes humoral compounds, such as 5 HT, to be released.[5,6,7] These substances stimulate 5 HT3 receptors on afferent vagal neurons, causing an emetic instinct. The carbazole derivative ondansetron hydrochloride dihydrate (GR38032F). Without affecting dopaminergic, histaminergic, adrenergic, or cholinergic receptor activity, it has distinct 5-HT3 subtype receptor antagonist qualities and is structurally linked to 5-HT.[8]

2. MATERIALS AND METHODS

After receiving written informed consent from the patient and clearance from Assam Medical College and Hospital institutional proforma committee, the study was carried out. The current study was carried out in the Anaesthesia & Critical Care department of Assam Medical College between December 2023 and August 2024, using cases chosen from the surgical department. A total of 60 ASA I & II patients who were scheduled for laparoscopic cholecystectomy were chosen for this trial using double blind randomization. They were divided into two groups and given either an intravenous injection of ondansetron 4 mg or an intravenous injection of palonosetron 75 mg prior to the start of anaesthesia induction. Every patient was split into two groups at random.

Group O: 30 patients received Inj Ondansetron 4mg iv bolus (n=30).
Group P: 30 patients received Inj Palonosetron 75 mg iv bolus (n=30).
Inclusion/ Exclusion Criteria for Participants in this Trial 2.1.

Inclusion Criteria

1. American Society of Anaesthesiologists (ASA physical status I and II).
2. Female patients more than 18 years of age.
3. Patients undergoing elective laparoscopic cholecystectomy.
4. Atleast 2 of the following PONV risk factors.
a. Female sex
b. History of PONV and or motion sickness
c. Non smoker
5. General anaesthesia with endotracheal intubation.

2.2. Exclusion Criteria

1. Pregnant, nursing or women planning to become pregnant, are not using effective birth control, or that have had a positive serum pregnancy test within 72 hours prior to surgery.
2. Uncooperative & Inability to understand the study procedures.
3. Any kind of emetogenic radiotherapy within 8 weeks prior to enrolment in study.
4. Cancer patients who had undergone chemotherapy within 4 weeks prior to study entry.
5. Has received any investigational drugs < 30 days before enrolment in study.
6. History of any emetogenic drugs taken in last 24 hours before anaesthesia.

7. Known or suspected current history of alcohol intake.
8. Body mass index (BMI >40).
9. Known hypersensitivity or having contraindication to 5-HT3 antagonists.
10. Vomiting in last 24 hours before surgery
11. History of Epilepsy.

The patients were randomly assigned to receive either an intravenous injection of 75 mg of palonosetron or an intravenous injection of 4 mg of ondansetron. The Palonosetron group received 75 mg of palonosetron in a 2 ml dilution as a single intravenous dose before anaesthesia was induced, while the Ondansetron group received 4 mg of ondansetron in a single intravenous dose as a 2 ml solution. Tab Alprazolam 0.25 mg and tab ranitidine hydrochloride 150 mg were administered orally to the recruited patients the night before surgery. They were also briefed on the visual analog scale (VAS) of nausea, which goes from 0 (no nausea) to 10 (worst nausea). Before anaesthesia was induced, a few patients were given either an intravenous dose of Ondansetron or an intravenous dose of Palonosetron. One of the steps of anaesthesia is pre-oxygenation, which involves using 100% oxygen for three minutes. In order to simplify endotracheal intubation, induction was performed with injections of propofol (1.5 -2.5 mg/kg), fentanyl (1-2 micrograms/kg) for analgesia, and rocuronium (0.6-1.2 mg/kg) intravenously as a muscle relaxant. O2 + N2O + sevoflurane were used to maintain anaesthesia, and 0.1 mg/kg of Rocuronium was administered as a maintenance dose. The duration of general anaesthesia and operation was recorded, along with the reversal from muscle relaxants performed by injections of sugammadex 2 mg/kg. In the postoperative ward, 75 mg intramuscular Diclofenac aq was used to treat pain every eight hours or as needed by the patient. The use of rescue antiemetic medication and episodes of nausea and vomiting were tracked, with intervals recorded.

Monitoring And Observation: Four periods of monitoring were conducted: 0–2 hours, 2–6 hours, 6–24 hours, and 0–24 hours following surgery. We kept an eye out for any instances of post-operative nausea and vomiting (PONV) and the requirement for an antiemetic medication. The severity was graded using a visual analogue scale (VAS = 0 for no nausea and 10 for the greatest nausea). After one episode of vomiting or nausea at VAS>5, or when the patient requested therapy (rescue treatment), we administered 10 mg intravenously of metoclopramide as an antiemetic.

Details on side effects, such as headaches, lightheadedness, constipation, and myalgia, was recorded. Twenty-four hours following surgery, in the postoperative ward, the overall satisfaction was graded on a three-point scale: satisfied, indifferent, and dissatisfied. This study's main objective was to quantify the frequency of nausea and vomiting in the first twenty-four hours following anaesthesia delivery. Secondary goal measured were any need for rescue medication, incidence of adverse effects & overall patient satisfaction.

Statistical Analysis: Chi square and the student T test for continuous variables, as well as one-way analysis of variations (ANOVA) for comparing mean values across research groups, were used to assess the statistical observation of the categorical variables. Fisher's exact test was used to analyze the side effects that were found. The basic ways to express the observational results are as a number (%) or mean ±SD. P-value

RESULTS:

1. We found that there was increase in episodes of nausea in Ondansetron group than Palonsetron group at time 0-2, 2-6, 6-24 and at 0-24 hrs and the difference was significant between both the Groups (p value 0.05).
3. We found that there was increase in episodes of vomiting in ondansetron group than palonosetron group at 0-2, 2-6, 6-24 and 0-24 hrs. and the difference was significant between both the Groups (p value 0.05).
5. Rescue antiemetic usage was more common in ondansetron group than palonosetron 13% vs 7% respectively but result was not significant between both the groups (p value >0.05).
6. Satisfaction level was more in patients in Palonosetron than in Ondansetron group after 24 hr of surgery, but without any significant difference (p value >0.05).

Table 1: Mean Age Distribution Between Two Groups

	Group O (n=30)	Group P (n=30)	P value
Mean (age in years)	41.25	38.34	0.297
S. D	9.529	11.763	

Both group O (ondansetron group) and group P (palonosetron group) are comparable with each other with respect to age. On statistical analysis p value is 0.297 (p value>0.05). This shows that there is no significant difference in age distribution between two groups

Table 2: Comparison Of Weight Between Two Groups

	Group O (n=30)	Group P (n=30)	P value
Mean weight (kg)	47.27	52.19	0.0041
SD	5.9	6.8	

There is no statistically significant difference between mean weight of two groups. The P value >0.05 (p value=0.0041)

Table 4: Comparison of risk factor of PONV between group O and P

Risk factor	Group O	Group P	P value
PONV	12	15	0.604
None smoking	10	6	0.381
PONV+Nonsmoking	11	6	0.252

All p-values are greater than 0.05, meaning there are no statistically significant differences

Table 5: Comparison of no. of patients having nausea between group O and P

Time (hr)	Group O (n=30)	Group P (n=30)	P value
0-2	8	4	0.0034
2-6	12	3	
6-24	14	6	
0-24	20	9	

The calculated p-value (0.0034) indicates a statistically significant difference between Group O and Group P for the 0–24-hour time interval

Table 6: Comparsion of no. of no patients having vomiting episodes between group O and P

Time (hr)	Group O (n=30)	Group P (n=30)	P value
0-2	5	3	0.519
2-6	4	2	
6-24	3	2	
0-24	7	5	

Since the p-value (0.519) is greater than 0.05, there is no statistically significant difference between Group O and Group P for the 0–24-hour time interval.

Table7: Comparison of side effects between group O and P within 24 hours of postoperative period

	Group O (n=30)	Group P (n=30)	P value
Dizziness	3	2	0.640
Headache	5	3	0.449
Constipation	2	4	0.671
Myalgia	1	2	1

None of the adverse events show a statistically significant difference between Group O and Group P (all p-values > 0.05).

Table 8: Comparison of no. of patients receiving rescue medication between group O and P

	Group O (n=30)	Group P (n=30)	P value
No. of patients receiving rescue medication	9	6	

Rescue antiementics use were more common in Ondansetron Group

Table 9: Subjective assessment of patient's satisfaction between group O and P

Category	Group O (n=30)	Group P (n=30)	P value
Satisfied	14	23	0.028
Neutral	6	5	

Since the p-value (0.028) is less than 0.05, there is a statistically significant difference between Group O and Group P in terms of satisfaction levels, with Group P showing higher satisfaction.

4. DISCUSSION

Postoperative nausea and vomiting (PONV) is still a common and bothersome complication after surgery under general anaesthesia. This study compares the incidence of PONV, the incidence of any adverse effects, the need for rescue medication to prevent PONV, and the patient satisfaction rate in both groups. The central 5-HT3 receptors are located in the medullary chemoreceptive trigger zone. Anaesthetic agents activate these receptors. They also act on small intestinal enterochromaffin cells, releasing serotonin, which in turn stimulates 5-HT3 receptors on vagus nerve fibers.

Preventing PONV is difficult due to its complex etiology and dependence on a number of factors, such as age, obesity, a history of prior PONV, surgical procedures, anaesthetic drugs, and postoperative active pain. In this study, the groups were comparable in terms of patient demographics, risk factors, and analgesics used postoperatively; therefore, the reason for the difference in outcome is the drugs under study. Competitive inhibition by 5-HT3 receptor antagonists, such as ondansetron and palonosetron at peripheral 5-HT3 receptors in vagal nerve terminals can block the vomiting reflex from being triggered by emetogenic stimuli. Pharmacokinetics and receptor binding properties are responsible for the differences between the two groups. Other clinical trials provided information that helped choose the drug dosages, which were ondansetron 4 mg and palonosetron 75 mg; these were single pre-induction doses administered via I/V route.
A total of 60 patients with ASA physical status I and II who were having an laparoscopic cholecystectomy under general anaesthesia were chosen for this study and randomly assigned to groups O (n = 30) and P (n = 30), which received injections of Ondansetron 4 mg intravenously and Palonosetron 75 mg intravenously, respectively, prior to the start of anaesthetic procedures. Patients in the palonosetron group were 52.19±6.8 years old, while those in the ondansetron group were 47.27±5.9 years old. The p-value for these groups was 0.0041 ($p>0.05$).

Comparing the mean weight, mean length of operation, and risk factor for PONV across groups O and P also reveals no statistically significant difference (p value>.05).

When comparing the incidence of nausea in groups O and P at 0–2 hours, 2–6 hours, 6–24 hours, and 0–24 hours, the incidence of nausea was higher in the Ondansetron group O than in the Palonosetron group P. Its respective percentages are 26.7%, 40%, 46.7%, 66.7% and 13.3%,10%, 20%, 30%. The p value is less than 0.05 at these observational intervals, indicating a significant difference between these two groups. Numerous investigations yielded similar findings. The current study compared the incidence of vomiting between groups O and P at 0-2 hours, 2-6 hours, 6-24 hours, and 0-24 hours. The incidence of vomiting was 16.7%, 13.33%, 10%, and 23.3% in the O group and 10%, 6.7%, 6.7%, and 16.7% in the P group at various time intervals, respectively. The p value for all groups was less than 0.05, indicating a significant difference in the incidence of vomiting between the two groups. The results were comparable to those of Y.E. Moon et al.

When two groups' side effects are compared, the p-value for the group O vs group P that complained of headaches is 0.50 (>0.05).

We discovered that the incidence of 5 HT3 antagonist adverse effects, such as myalgia, constipation, and dizziness, did not significantly differ between the two groups.

Both groups received 10 mg intravenous injections of metoclopramide as rescue antiemetics. The use of rescue antiemetics does not significantly differ between two groups. Nonetheless, the ondansetron group used rescue antiemetic more frequently.

More patients in group P are happy, indicating that palonosetron prevents PONV more effectively than ondansetron.

Our study's results are also in line with other research that indicates palonosetron is a more effective treatment for PONV prophylaxis than ondansetron.

5. CONCLUSION

Compared to ondansetron, palonosetron is noticeably more effective at preventing post-operative nausea and vomiting with fewer side effects, using fewer rescue antiemetic medications, and experiencing greater patient satisfaction

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