Section: Miscellaneous

Original Research Article

COMPARISON OF PALONOSETRON WITH ONDANSETRON FOR PROPHYLAXIS OF POSTOPERATIVE NAUSEA AND VOMITING AFTER LAPAROSCOPIC GYNAECOLOGICAL SURGERIES: A PROSPECTIVE, RANDOMISED, DOUBLE BLIND STUDY

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Abstract

Background: Postoperative nausea and vomiting (PONV) is a commonly seen in the recovery room area. It is a major cause of patient dissatisfaction and distress postoperatively, second only to pain. Palonosetron is a second generation 5-HT3 receptor antagonist with a greater binding affinity and a longer plasma half-life (mean elimination t1/2 ~40hours) than other drugs in the same class. It has been shown to be effective in PONV and chemotherapy induced nausea and vomiting. We conducted this study in patients undergoing elective laparoscopic gynaecological surgeries, to compare the incidence of PONV in the first 24 hours post surgery following administration of intravenous Palonosetron and ondansetron by assessing nausea score , postoperative vomiting score and postoperative nausea and vomiting score. We also compared the incidence of adverse effects in both the groups and requirement of additional rescue antiemetics. **Materials and Methods:** Hundred female patients of ASA physical status I or II, non smokers, in the age group 18-60 years posted for elective laparoscopic gynaecological surgeries were enrolled as participants. Patients were randomly divided into two groups (n=50 each) by a computer generated randomisation list. Group A (n=50) patients received inj ondansetron 0.1mg/kg (maximum 8mg) and Group B (n=50) patients received inj Palonosetron 1mcg/kg (maximum 75mcg) intravenously just before induction. The incidence of postoperative nausea, vomiting and PONV after administration of either of the study drugs in the first 24 hours following surgery using nausea score , postoperative vomiting score and postoperative nausea and vomiting score. The incidence of adverse effects , requirement of additional rescue antiemetics, complete response to study drugs and patient satisfaction score in both the groups was also noted. **Result:** Both the study groups were comparable with regards to patient characteristics and anaesthesia timeThe postoperative nausea score was comparable in both the groups in 0-2 hours ($p>0.05$). However, Group B patients experienced significantly lesser nausea in 2-24 hours postoperative period ($p<0.05$) as compared to Group A patientsThe overall postoperative vomiting score was significantly less in Group B as compared to Group A ($p<0.05$) in both 0-2 hours and 2-24 hours postoperative period. The PONV Score was comparable in both the study groups in first 2 hours postoperative period ($p>0.05$). However, Group A subjects reported higher PONV scores in 2-24 hour postoperative period as compared to Group B ($p<0.05$)The use of first line rescue antiemetic (ondansetron) in Group A was significantly higher as compared to Group B ($p<0.05$) in 2-24 hours postoperative period. The incidence of adverse effects was comparable in both

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the study groups. **Conclusion:** We conclude that Palonosetron demonstrated better antiemetic profile with significantly lesser incidence of postoperative nausea, vomiting and PONV scores in 2-24 hours postoperative period. Additionally, it significantly reduced the dose of first line antiemetic required in the postoperative period as compared to ondansetron group. Also, the adverse effects in both the groups were comparable.

INTRODUCTION

Postoperative nausea and vomiting (PONV) are a commonly seen in the recovery room area. It is a major cause of patient dissatisfaction and distress postoperatively, second only to pain.[1] This perioperative complication has a multifactorial etiology and results in electrolyte abnormalities, wound dehiscence, subcutaneous emphysema, delayed nutrition, prolonged hospital stay, and reduced patient satisfaction.

Due to the multifactorial etiology, no single drug can achieve 100% results for control of PONV. With the advancements in anaesthesia practice and drug therapy over the past few years, different class of antiemetics are available and have been used with variable efficacy. These include anticholinergics (atropine, scopolamine), dopamine antagonists (metoclopramide, promethaxine), antihistaminics (diphenhydramine), steroids (dexamethasone), 5-HT3 receptor antagonists (ondansetron, granisetron, dolasetron). The 5-HT3 receptor antagonists are routinely used in prophylaxis of PONV as they are effective and cause fewer side effects.

Palonosetron is a second generation 5-HT3 receptor antagonist with a greater binding affinity and a longer plasma half-life (mean elimination t1/2 ~40hours) than other drugs in the same class.[2,3] It has been shown to be effective in PONV,[4,5] and chemotherapy induced nausea and vomiting.[2,3] The superiority of palonosetron compared to other 5HT-3 receptor antagonists for the prevention of PONV in patients undergoing general anesthesia has been reported in some studies.

Recent literature comparing the use of ondansetron and Palonosetron for prevention of PONV following laparoscopic surgeries have shown conflicting results.[6,7] The antiemetic efficacy and potency of Palonosetron in the late postoperative period in patients with high risk factors is controversial.[8,9]

So, we conducted this study in patients undergoing elective laparoscopic gynaecological surgeries, to compare the incidence of PONV in the first 24 hours post-surgery following administration of intravenous Palonosetron and ondansetron by assessing nausea score, postoperative vomiting score and postoperative nausea and vomiting score. We also compared the incidence of adverse effects in both the groups and requirement of additional rescue antiemetics.

MATERIALS AND METHODS

This study was carried out in Govt Doon Medical College, Dehradun over a period of 6 months from October 2023 to March 2024. Hundred female patients of ASA physical status I or II, non-smokers, in the age group 18-60 years posted for elective laparoscopic gynaecological surgeries were enrolled as participants. Patients with known history of PONV, motion sickness, pregnant or lactating females, hypersensitive to serotonin receptor antagonists, ongoing gastrointestinal disease, disorders of major organ systems like heart, lung or liver, those who had received chemotherapy in past few weeks and who were already on antiemetics or steroids were excluded from our study.

Primary objective of the study was to compare the incidence of postoperative nausea, vomiting and PONV after administration of either of the study drugs in the first 24 hours following surgery using nausea score, postoperative vomiting score and postoperative nausea and vomiting score. Secondary objective was to compare the incidence of adverse effects, requirement of additional rescue antiemetics, complete response to study drugs and patient satisfaction score in both the groups.

Patients fulfilling the inclusion criteria, were enrolled in the study, after obtaining an informed written consent. For All the study participants, the preanaesthetic regime, conduct of anaesthesia and surgical technique was kept uniform. The patients were allowed to take light and non-residual meals in the evening of one day prior to surgery. Nil per oral as per American Society of Anaesthesiologists (ASA) task force guidelines was followed by the patients for preoperative fasting.

On arrival to the operating room, standard ASA monitoring in the form of electrocardiography (ECG), noninvasive blood pressure (NIBP), pulse oximetry (SpO2) was attached to the patients. Intravenous fluid (ringer lactate) was started and patients were premeditated with intravenous Inj Glycopyrolate 0.004mg/kg, inj fentanyl 2mcg/kg and inj midazolam 0.02mg/kg body weight.

Patients were randomly divided into two groups (n=50 each) by a computer-generated randomisation list. Patients, the anaesthetist involved in administration of the study drug and making observations in the postoperative period were all blinded to the allocated group.

Group A (n=50) patients received inj ondansetron 0.1mg/kg (maximum 8mg) and Group B (n=50) patients received inj Palonosetron 1mcg/kg (maximum 75mcg) intravenously just before

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induction. The syringes of study drugs were labelled as 'antiemetic' diluted with normal saline upto 5ml volume and will be prepared by an anaesthesiologist not involved in the study.

Anaesthesia was induced with inj propofol (1%) 1.5-2mg/kg intravenous. Endotracheal intubation was facilitated by inj vecuronium 0.1mg/kg IV. Maintenance of anaesthesia was done with Intermittent positive pressure ventilation with 0.8-1.0 MAC of sevoflurane and intermittent boluses of inj vecuronium. Intraoperatively vitals were monitored and endtidal CO2 was maintained in the range of 30-40 mmHg. Inj Paracetamol 15mg/kg IV was given 20minutes prior to completion of surgery. Stomach decompression was done by inserting nasogastric tube. At the end of surgery, Tracheal extubation and residual neuromuscular blockade was reversed with inj neostigmine 0.05mg/kg and inj glycopyrrolate 0.001mg/kg.

Oxygen was administered at FiO2 =1 for 5 minutes post extubation. Postopratively, Inj Paracetamol 15mg/kg IV tds and inj diclofenac was used as rescue analgesic.

An episode of PONV was defined as either a spell of nausea (unpleasant sensation with an urge to vomit), retching (involuntary, laboured, spasmodic contractions of respiratory muscles without expulsion of gastric contents), or vomiting (forceful expulsion of stomach contents from mouth) scored on a scale of 0-3 as per scoring system [Table 1].[10,11]

The data was collected in PACU for 0-2hour and in postoperative ward for 2-24 hour. 'Complete response' was labelled if there was no need of administration of rescue antiemetics and absence of PONV. While, 'treatment failure' meant patients experienced PONV despite receiving antiemetics.

Ondansetron 4mg IV was given for PONV as first line rescue antiemetic in both the groups and repeated after 30 minutes if symptoms persisted, which was treated by second line rescue antiemetic dexamethasone 4mg IV. Ondansetron was used as first line rescue antiemetic as dexamethasone has a slow onset of action. Adverse effects like dizziness, drowsiness, headache, ECG changes were also recorded. Patients were enquired about the overall satisfaction (satisfied, neutral, dissatisfied) after surgery.

We calculated the sample size based on observed incidence of PONV during 24 h. Using an alpha value (0.05) and power 80%, 50 patients per group were found to be adequate to detect a significant difference of 25% in incidence of PONV between the palonosetron and ondansetron groups.[2] We performed statistical testing with SPSS [Version 17.0, Chicago: SPSS Inc.]. Categorical variables were expressed as absolute numbers and percentages and Continuous variables as mean ± SD. Normally distributed continuous variables were compared using Student's t-test. Chi-square test or Fisher's exact test were used to compare nominal categorical data as deemed appropriate. P-value <0.05 was observed as statistically significant.

RESULTS

A total of 100 patients were enrolled for the study with no dropouts. Both the study groups were comparable with regards to patient characteristics and anaesthesia time.

The postoperative nausea score was comparable in both the groups in 0-2 hours (p>0.05). However, Group B patients experienced significantly lesser nausea in 2-24 hours postoperative period (p<0.05) as compared to Group A patients. [Table 3]

The overall postoperative vomiting score was significantly less in Group B as compared to Group A (p<0.05) in both 0-2 hours and 2-24 hours postoperative period. [Table 4]

The PONV Score was comparable in both the study groups in first 2 hours postoperative period (p>0.05). However, Group A subjects reported higher PONV scores in 2-24 hour postoperative period as compared to Group B (p<0.05). [Table 5]

The use of first line rescue antiemetic (ondansetron) in Group A was significantly higher as compared to Group B (p<0.05) in 2-24 hours postoperative period. [Table 6] However, the use of second line antiemetic (dexamethasone) was comparable in both groups.

The incidence of adverse effects was comparable in both the study groups. [Table 7] Group B patients reported high satisfaction as compared to Group A (85% vs 70% respectively); 8% and 5% patients were dissatisfied in Group A and B respectively; and rest patients were neutral.

Table 1: Scoring system used for assessing postoperative nausea, vomiting and PONV

Score	Postoperative nausea score	Postoperative vomiting score	Ponv score
0	None	None	No nausea/vomiting/retching/ requirement of rescue antiemetic
1	Mild, intermittent nausea	One vomit only	Nausea
2	Constant, moderate nausea	Several vomits	Retching
3	Severe nausea	Repeated retching/ Vomiting	Vomiting

Table 2: Patient characteristics and duration of anaesthesia

	GROUP A	GROUP B	p- value
Age (years)	35.62±5.24	34.25±6.50	0.24
Weight (kg)	69.22±4.67	67.80±5.65	0.17
ASA grade			
I	22 (44%)	27 (54%)	0.32
II	28 (56%)	23 (46%)	0.32

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Duration of anaesthesia (minutes)	160.72±35.88	152.43±40.56	0.28

Table 3: Postoperative nausea score

Time (hours)	Nausea score	Group A (frequency %)	Group B (frequency %)	p-value
0-2	0	35 (70)	40 (80)	0.25
	1	8 (16)	7 (14)	0.78
	2	1 (2)	0 (0)	0.31
	3	6 (12)	3 (6)	0.29
2-24	0	26 (52)	38 (76)	0.01
	1	18 (36)	9 (18)	0.04
	2	2 (4)	1 (2)	0.55
	3	4 (8)	2 (4)	0.40

Table 4: Postoperative vomiting score

Time (hours)	Vomiting score	Group A (frequency %)	Group B (frequency %)	p- value
0-2	0	37 (74)	45 (90)	0.03
	1	10 (20)	3 (6)	0.03
	2	3 (6)	2 (4)	0.64
	3	0 (0)	0 (0)	
2-24	0	35 (70)	44 (88)	0.02
	1	9 (18)	2 (4)	0.02
	2	4 (8)	4 (8)	1
	3	2 (4)	0 (0)	0.31

Table 5: Postoperative Nausea and Vomiting (PONV) score

Time (hours)	PONV Score	Group A (frequency %)	Group B (frequency %)	p-value
0-2	0	40 (80)	44 (88)	0.28
	1	5 (10)	4 (8)	0.72
	2	0 (0)	0 (0)	
	3	5 (10)	2 (4)	0.24
2-24	0	32 (64)	42 (84)	0.02
	1	8 (16)	5 (10)	0.37
	2	5 (10)	0 (0)	0.02
	3	3 (6)	3 (6)	1

Table 6: First line Rescue Antiemetic (ondansetron) requirement

Time (hours)	Rescue antiemetics used	Group A (frequency %)	Group B (frequency %)	p-value
0-2	Yes	10 (20)	8 (16)	0.60
	No	40 (80)	42 (84)	0.60
2-24	Yes	20 (40)	7 (14)	0.003
	No	30 (60)	43 (86)	0.003

Table 7: Incidence of adverse effects

Adverse effects	Group A (frequency %)	Group B (frequency %)	p-value
Headache	5 (10)	4 (8)	0.73
Dizziness	2 (4)	3 (6)	0.64
Drowsiness	7 (14)	5 (10)	0.54
Allergic Reaction	0 (0)	0 (0)	
ECG changes	0 (0)	0 (0)	

DISCUSSION

PONV is a very common perioperative complaint reported by patients after general, regional and local anaesthesia. Nausea has been reported in 22-38% patients and vomiting in 12-26% patients in the postoperative period.[12] Incidence of PONV can be as high as 60-70% in susceptible subjects.[13] Apfel scoring system identifies four risk factors for PONV each of which increases the probability by 18-22%. These risk factors are female gender, history of PONV and motion sickness, non-smoker and predicted opioid use.[14] Other risk factors include laparoscopic surgery (40-70% incidence), duration of surgery and use of volatile anaesthetics.[15,16]

Vomiting reflex is caused by the stimulation of 5-HT3 receptors present in the chemoreceptor trigger zone (CTZ) in the area prostema and the nerve terminals of vagus nerve in the periphery (caused by release of serotonin from enterochromaffin cells).[11] 5-HT3 receptor antagonists have been used commonly for prevention of PONV owing to their efficacy and better safety profile as compared to other antiemetics.[17,18] Palonosetron, is a potent 5-HT3 receptor antagonist with unique pharmacology, structure and clinical effects. It interacts with 5-HT3 receptors in allosteric and positively cooperative fashion at different sites.[19] It blocks substance P associated response, has negative cooperation with Neuro kin in-1 by crosstalk and prolonged effects due to receptor ligand binding and responsiveness to serotonin.[20] Its elimination half-life in adults is 40 hours.

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With the increasing emphasis on early discharge and enhanced recovery protocol, PONV may prove to be a limiting factor by delaying the discharge and prolonging recovery. Therefore, use of a potent and longer acting drug will benefit the patients and prove economical too. Also, Liu et al in their meta analysis have stated the need for more high-quality RCTs to obtain superior clinical evidence for rational clinical decisions regarding precise and effective choice for PONV prophylaxis in patients posted for laparoscopic surgeries.[7] So, we conducted this study to compare the efficacy of ondansetron and Palonosetron for PONV in patients posted for laparoscopic gynaecological surgeries.

In our study, the patients in Palonosetron group had significantly lesser postoperative nausea,vomiting and PONV scores in 2-24 hours period which is explainable by its longer elimination t1/2, better potency and greater affinity to the 5-HT3 receptors. Our results are consistent with Balyan et al, who in their study also observed that Palonosetron resulted in superior antiemetic effect with significantly lesser need of rescue antiemetics and lower PONV scores at 2-24 hours postoperatively and comparable effects to ondansetron at 0-2 hours and 24-48 hours postoperative period in high risk patients posted for laparoscopic gynaecological surgeries. They explained that the comparable effects in 0-2 hours and 24-48 hours resulted due to lesser exposure to risk factors (like washout of inhalation agents, no surgical exposure, metabolism of opioids and use of non-emetogenic analgesics) during these periods.[21] Moon et al also reported comparable results between the study groups in 0-2 hours postoperatively but lower PONV scores in 2-24 hours postoperative period following thyroidectomy in Palonosetron (42%) versus ondansetron (62%) groups.[22,23] This is in consensus with our study. Sharma et al in their study comparing ondansetron and Palonosetron in patients posted for middle ear surgeries also observed that PONV score and nausea score in ondansetron group were significantly higher that Palonosetron group 2-12 hour postoperatively. However, in their study they administered Palonosetron just before induction and ondansetron at time of skin closure and explained this difference in timing of administration on basis of shorter half-life (3.5-4 hours) of ondansetron which may result in its lesser antiemetic efficacy in procedures lasting more than 2hours.[24]

We found that the rate of 'complete response' during 2-24 hours was greater in Palonosetron group as compared to ondansetron groups, which was consistent with findings of Balyan et al.[21] This also corroborates with the finding that there was lesser requirement of first line rescue antiemetic during 2-24 hours period in Palonosetron group versus ondansetron group ($p<0.05$). However, the amount of second line antiemetic (dexamethasone) was comparable in both groups.

We found that the incidence of adverse effects in both the groups were comparable and more patient satisfaction was reported in Palonosetron group as compared to ondansetron group, which was consistent with the results of Balyan et al who observed similar findings and concluded that Palonosetron possess better antiemetic profile with similar safety profile.[21]

Limitations of our study include: inability to exclude medications for comorbidities (hypertension, diabetes mellitus) that are continued in peri operative period, inability to standardize peri operative antibiotic regime, no placebo group taken in the study due to ethical considerations of withholding antiemetics for PONV prophylaxis, subjectivity in assessment of patient satisfaction, administration of optimal doses rather than equipotent doses of study drugs. We recommend larger sample size and more multicentric studies to address these limitations.

CONCLUSION

We concluded that Palonosetron demonstrated better antiemetic profile with significantly lesser incidence of postoperative nausea, vomiting and PONV scores in 2-24 hours postoperative period. Additionally, it significantly reduced the dose of first line antiemetic required in the postoperative period as compared to ondansetron group. Also, the adverse effects in both the groups were comparable. All these findings reflect the better efficacy and potency of Palonosetron especially in long duration surgeries and also indicates it's beneficial role in day care surgeries and enhanced recovery after anaesthesia (ERAS) settings. Owing to its longer duration of action, it may prove economical as compared to other antiemetics in long term.

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