



A Comparative Study between Palonosetron and Granisetron to Prevent Postoperative Nausea and Vomiting after Laparoscopic Cholecystectomy

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KEYWORDS

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ABSTRACT:

Aim: This study aims to Compare Granisetron and Palonosetron for prevention of postoperative nausea and vomiting following laparoscopic surgery.

Materials and Methods: This study was conducted on 80 patients in the Department of Anesthesiology, Critical Care, and Pain Management. The inclusion criteria were patients with ASA physical class 1 and 2, patients in the Age between 20 to 70 yrs, patients who undergone Elective laparoscopic Cholecystectomy. Exclusion criteria included patients with ASA physical class 3 and above, patients with Inability to understand or co-operate with the study, The study design was prospective randomized, single blind comparative study. Group A: Received 40 mcg/kg Granisetron IV. Group B: Received 0.075 mg Palonosetron IV. At the completion of surgery patients received Neostigmine 0.05mg/kg and Glycopyrrolate 0.01mg/kg for several of Neuro muscular blockage. Nausea according to verbal descriptive scale (VDS) (0=no nausea, 1= mild nausea, 2=moderate nausea, 3= severe nausea) use of rescue antiemetic drug and adverse effect was monitored at 0- 2hrs, 2-6hrs and 6-24hrs.

Statistical Analysis and Results: SPSS software version 23.0 was used for our statistical analysis, Mean age in Granisetron group was 47±15 and in Palonosetron group was 45±14. The p-value is 0.667607. There was no significant difference in the mean age between the groups. Mean baseline SBP in Granisetron group was 123.4±13.5775 mmHg and in Palonosetron group was 128.425±13.013 mmHg. There was no significant difference in the SBP between two groups. In the study mean duration of surgery in Granisetron group was 1.22±13 hrs and in Palonosetron group was 1.2±22 hrs. There was no significant in episodes of vomiting between the two groups at 0 to 2 hrs, 2 to 6 hrs and 6 to 24 hrs. There was no significant difference in the use of rescue anti emetic drugs at 0 to 2 hrs, 2 to 6 hrs and 6 to 24 hrs between the both groups. The numbers of patients free of nausea at 24 hrs were more in Granisetron group as compared to Palonosetron.

Conclusion: Authors concluded that patients receiving Palonosetron had less incidence of vomiting than Granisetron group but the difference was not statistically significant during 0-2, 2-6 and 6-24 hours. The number of patients free of nausea vomiting was significantly lower in Palonosetron group than Granisetron at the end of 24 hrs. Therefore, both Granisetron and Palonosetron are equally effective in the immediate post operative period but palonosetron is more effective over 24 hour's period.



Introduction

Postoperative Nausea vomiting (PONV) are distressing symptoms that commonly occurs after laparoscopic surgery performed under general anesthesia. Vomiting may cause dehydration, electrolyte imbalance, disruption of surgical repair and increased perception of pain. It is usually felt in the back of the throat and Epigastrium, and is accompanied by the loss of gastric tone, duodenal contractions, and reflux of the intestinal contents into the stomach. Retching is defined as labored, spasmodic, rhythmic contraction of the respiratory muscle including the diaphragm, chest wall and abdominal wall muscle without the expulsion of gastric contents. The act of emesis includes Preejection, ejection, and post ejection phases. The preejection phase comprises prodromal symptoms of nausea, along with autonomic signs such as salivation, swallowing, pallor tachycardia, and licking in animals). The ejection phase comprises of retching and vomiting. Retching is characterized by rhythmic, synchronous, inspiratory movements of the diaphragm and abdominal and external intercostals muscles while the mouth and glottis are kept closed. Granisetron is a highly selective and potent 5-HT receptor on the Vagal nerve of the gut. Granisetron produces irreversible block of the 5HT receptors and it may account for the long duration of this drug. Palonosetron is 5-HT receptor antagonist used for preventing PONV and chemotherapy induced nausea and vomiting. This unique 5-HT receptor antagonist has a greater binding affinity and longer half life than older 5-HT antagonist like ondansetron.¹ Despite the advances in surgical technique and anesthetic technique the incidence of PONV has remained high. The incidence of PONV has been higher for certain procedures such as laparoscopic Cholecystectomies and Gynaecological surgeries. Unresolved PONV may result in prolonged post anesthesia care unit stay and unanticipated hospital re-admission that result in a significant increase in overall health care cost.²⁻⁴ PONV is influenced by numerous factors, which may be patient related, surgery related, and anesthesia related factors. Different Antiemetics, a combination of the same and even acupuncture has been in use to treat this distressing problem. Palonosetron and Granisetron newer 5-hydroxyptamines 3 (HT 3) receptor antagonist that have recently been introduced and have a longer half-life and a better safety profile when compared to the older generation of 5-HT3 receptor antagonists such as ondansetron.^{5,6} There is limited literature comparing the efficacy of Palonosetron with ondansetron especially when comparing laparoscopic operations.⁷⁻¹³ Our study was designed to assess and compare the efficacy of two drug regimens, Palonosetron and Granisetron in patients

undergoing laparoscopic cholecystectomy. A prospective randomized trial comparing the above-mentioned drugs was therefore constructed. The primary outcome that was studied was to compare the incidence of PONV between the two arms. Secondary objectives such as need for rescue antiemetic, dosage time of administering the same and the complications if any were study.

Aim

To Compare Granisetron and Palonosetron for prevention of postoperative nausea and vomiting following laparoscopic surgery.

Objectives

- To evaluate the effect of Palonosetron on incidence of nausea and vomiting in post operative care unit.
- To evaluate the effect of Granisetron on incidence of nausea and vomiting in post operative care unit.
- To compare the incidence severity of nausea and vomiting and complications in the studied group.

Materials and Methods

This study involved a total of 80 patients. This in vitro study was planned designed and executed in the Department of Anesthesiology, Critical Care, and Pain Management, Shri Ram Murti Smarak Institute of Medical Sciences, Bareilly. Approval from the institute ethical committee was taken vide notification number SRMS/IPS/ECC/2022/007 Dated 18.02.2022). Both male and female patients were included in the study and written informed consent was obtained from all participating patients. Sealed Envelope method sampling method was utilized for the accurate selection of samples. The sample size was calculated using G Power software (version 3.1.9.7; The G Power Team, Germany) with an alpha error probability of 0.05 and a power (1- β error probability) of 0.8. Eighty adult patients of class ASA 1 and 2 of either sex in age group between 20 to 70 yrs, scheduled for elective laparoscopic surgeries were selected for the study. The inclusion criteria were patients with ASA physical class 1 and 2, patients in the Age between 20 to 70 yrs, patients who undergone Elective laparoscopic Cholecystectomy. Surgery for which the duration is expected to last for at least 30 minutes or more also included in the study. Exclusion criteria included patients with ASA physical class 3 and above, patients with Inability to understand or co-operate with the study, patients who show Hypersensitivity to the drugs. Patients with Extremes of age also exclude from the study. Additional exclusion criteria were Emergency



surgeries, Patients suffering from motion sickness, severe, Patients who received Antiemetics 24 hrs prior to surgery or had emetic episode 24hrs prior to the study, Pregnant and lactating female patients. Prior to the study, informed consent was obtained from all patients. All such patients reported to us during the period of 2022 to 2023 were included in the study. The study design was prospective randomized, single blind comparative study. A complete preoperative evaluation of patient was done with history; physical examination and case relevant investigation were done. ASA physical classification was done on the basis of Preanaesthetic evaluation. Patients were enrolled in the study as per inclusion and exclusion criteria. Patients were randomly divided into two groups 40 each. Group 'G': Granisetron group (n=40), 40mcg/kg. Group 'P': Palonosetron (n=40), 0.075mg. Several side effects were monitored and checked during the study phase. They were predominantly Diarrhea, Constipation, Stomach pain, Weakness, Headache, Fever, Dizziness. Group A: Received 40 mcg/kg Granisetron IV. Group B: Received 0.075 mg Palonosetron IV. Baseline vital parameters were recorded and patients in group A were given 0.04 mcg/kg Granisetron iv and patients in group B were given 0.075mg Palonosetron diluted to 4 ml with sterile water iv just before induction. The person administering the drug and assessing the patient post operatively were blinded to the study drug. Anesthesia was induced with Fentanyl 2mcg/kg and Propofol 2mg/kg and tracheal intubation facilitated with Vecuronium 0.1mg/kg. The anesthesia was maintained on 1.0% - 1.5% Isoflurane & Nitrous Oxide in 50% O₂. At the completion of surgery patients received Neostigmine 0.05mg/kg and Glycopyrrolate 0.01mg/kg for several of Neuro muscular blockage. Nausea according to verbal descriptive scale (VDS) (0=no nausea, 1= mild nausea, 2=moderate nausea, 3= severe nausea) use of rescue antiemetic drug and adverse effect was monitored at 0- 2hrs, 2-6hrs and 6-24hrs. During 2-6 hrs, the episodes of vomiting and use of rescue antiemetic was not significantly different between the two groups but severity of nausea was significantly lower in Palonosetron group compared to Granisetron group. During the late post operative period (6-24), the episodes of vomiting had no significant different but the severity of nausea and need for rescue antiemetic was significant lower in Palonosetron group compared to Granisetron group. The number of patients free of nausea and vomiting over 24 hrs post operative period were significantly less in Palonosetron group than Granisetron group. The incidence of adverse effect namely headache was similar in both Palonosetron and Granisetron. Results thus obtained was compiled and sent for necessary statistical analysis. P value less than 0.05 was considered as significant (p<0.05).

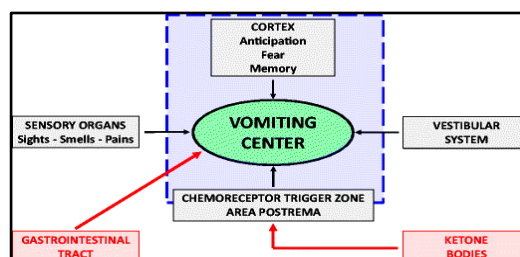


Fig 1:- Receptors Specific Antiemetics

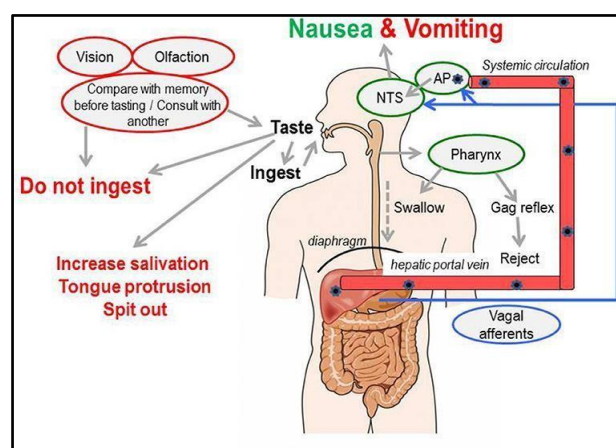


Fig 2:- Risk Factor for Post Operative Nausea and Vomiting

Statistical Analysis, Observations and Results

In this research, we utilized SPSS software version 23.0 for our statistical analysis, emphasizing the chi-square test to evaluate variances in proportions among different groups. This approach allowed for a comprehensive comparison of categorical data, guaranteeing that our findings truly represent the trends and connections within the dataset. Table 1 demonstrated about the Age distribution of patients according to Granisetron and Palonosetron drug uses. Mean age in Granisetron group was 47 ± 15 and in Palonosetron group was 45 ± 14 . The p-value is 0.667607. There was no significant difference in the mean age between the groups. Hence matching was ensured during selection of subjects. Table 2 demonstrated about the ASA status of subjects. There was no significant difference in ASA status between two groups. The p value is 1.000. Table 3 demonstrated about the Baseline blood pressure of subjects in the study Mean baseline SBP in Granisetron group was 123.4 ± 13.5775 mmHg and in Palonosetron group was 128.425 ± 13.013 mmHg. There was no significant difference in the SBP between two groups. Similarly, mean baseline DBP in Granisetron group was 78.375 ± 5.8164 mmHg and in Palonosetron group was 99.125 ± 7.80857 mmHg. There was no significant



difference in the DBP between two groups. Table 4 demonstrated about the Mean duration of surgery of and anaesthesia. In the study mean duration of surgery in Granisetron group was 1.22±13 hrs and in Palonosetron group was 1.2±22 hrs. There was no significant difference between two groups. Similarly the mean duration of anesthesia in Granisetron group was 1.35±12 hrs and in Palonosetron group was 1.33±12 hrs there was no significant difference between both groups. Table 5 demonstrated about the Episodes of vomiting. There was no significant in episodes of vomiting between the two groups at 0 to 2 hrs, 2 to 6 hrs and 6 to 24 hrs. Table 6 demonstrated about the severity of nausea In the study at 0 to 2 hrs, 2 to 6 hrs, 6 to 24 hrs. There was no significant difference in severity of nausea between the two groups. Table 7 demonstrated about the Use of Rescue Anti Emetic drug. There was no significant difference in the use of rescue anti emetic drugs at 0 to 2 hrs, 2 to 6 hrs and 6 to 24 hrs between the both groups. Table 8 demonstrated about the Number of

patients free of nausea / vomiting (in 24 hrs). In the study, the numbers of patients free of nausea at 24 hrs were more in Granisetron group as compared to Palonosetron. Also, the numbers of patients free of vomiting at 24 hrs were significant less in Palonosetron group as compared to Granisetron group. Table 9 demonstrated about the Number of patients with vomiting and requiring rescue medication (in 24 hrs). There was no significant difference in the use of rescue medication between the two groups in patients with vomiting in 24 hrs. Table 10 demonstrated about the Number of patients with vomiting and not requiring rescue medication (in 24 hrs). The patients with vomiting who did not require rescue antiemetic were 65% in Granisetron group and 57.5% in Palonosetron group. This difference was not statically significant. Table 11 demonstrated about the adverse effects There was significant difference in the incidence of adverse effect between the two groups at 0 to 2 hrs and to 6 hrs and 6 to 24 hrs.

Table 1:- Age distribution of Patients according to Granisetron and Palonosetron Drug uses

Age	Granisetron		Palonosetron		P value
	Frequency	in %	Frequency	in %	
<20	2	5%	2	5%	0.667607
20-40	9	23%	14	35%	
40-60	22	55%	18	45%	
60≤	7	18%	6	15%	
Total	40	100%	40	100%	
Mean±SD	47±15		45±14		

Table 2:- ASA status of Subjects

ASA	Granisetron		Palonosetron		P Value
	No. of Patients	%	No. of Patients	%	
I	12	30%	12	30%	1.000
II	28	70%	28	70%	
TOTAL	40	100%	40	100%	

Table 3:- Baseline Blood Pressure of Subjects in the study

	Granisetron (n=40)		Palonosetron (n=40)		P Value
	Mean±SD		Mean±SD		
SBP (mm Hg)	123.4±13.5775		128.425±13.013		0.097
DBP(mmHg)	78.375±5.8164		99.125±7.808567		.948

**Table 4:- Mean duration of Surgery of and Anesthesia**

	Granisetron (n=40)	Palonosetron (n=40)	P Value
	Mean±SD	Mean±SD	
Duration of surgery (mins)	1.22±13	1.2±22	.125
Duration of anesthesia (mins)	1.35±12	1.33±12	.929

Table 5:- Episodes of Vomiting

Episodes of Vomiting		Granisetron		Palonosetron		P Value
		No. of Patients	%	No. of patients	%	
0-2hrs	1 Episodes	0	0%	1	3%	0
	NO	40	100%	39	98%	
	Total	40	100%	40	100%	
2-6hrs	1 Episodes	2	5%	2	5%	1.000
	NO	38	95%	38	95%	
	Total	40	100%	40	100%	
24-Jun	1 Episodes	6	15%	5	13%	0.745441
	NO	34	85%	35	88%	
	Total	40	100%	40	100%	

Table 6:- Severity of Nausea

Severity of Nausea (VDS)		Granisetron		Palonosetron		p value
		No. of Patients	%	No. of Patients	%	
0-2 hrs	0 times	33	83%	33	83%	1.000
	1 time	6	15%	6	15%	
	2 times	1	3%	1	3%	
	3 times	0	0%	0	0%	
	Total	40	100%	40	100%	
2-6 hrs	0 times	31	78%	31	78%	1.000
	1 times	7	18%	7	18%	
	2 times	1	3%	1	3%	
	3 times	1	3%	1	3%	
	Total	40	100%	40	100%	
6-24 hrs	0 times	25	63%	22	55%	.837665
	1 times	8	20%	9	23%	



2 times	3	8%	5	13%
3 times	5	13%	4	10%
Total	40	100%	40	100%

Table 7:- Use of Rescue Anti Emetic Drug

Use of rescue antiemetic drug		Granisetron			Palonosetron		P Value
		No. Of Patients	No. Of Patients	%	NO. of patients	%	
0-2 hrs	No	40		100%	39	98%	0
	Yes	0		0%	1	3%	
	Total	40		100%	40	100%	
2-6 hrs	No	36		90%	37	93%	0.00005
	Yes	4		10%	3	8%	
	Total	40		100%	40	100%	
6-24 hrs	No	31		78%	29	73%	0.605577
	Yes	9		23%	11	28%	
	Total	40		100%	40	100%	

Table 8:- Number of Patients Free of Nausea/Vomiting (in 24 hrs)

	Granisetron (n=40)		Palonosetron (n=40)		p value
	No. of patients	%	No. of patients	%	
No nausea at 24 hrs	21	53%	16	40%	0.51238
No vomiting at 24 hrs	32	80%	32	80%	

Table 9:- Number of Patients with Vomiting and requiring Rescue Medication (in 24 hrs)

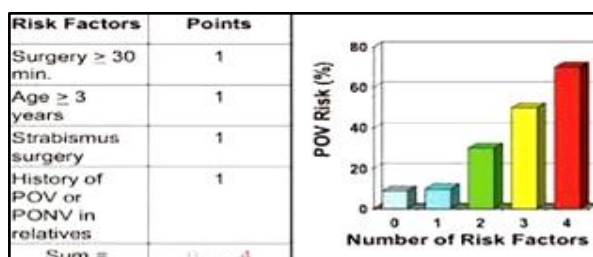
	Granisetron (n=40)	Palonosetron (n=40)	p value
NO. of patients with vomiting	8	7	0.867258
Number of patients requiring rescue antiemetic	4	3	

Table 10:- Number of patients with vomiting and not requiring rescue medication (in 24 hrs)

	Granisetron (n=40)	Palonosetron(n=40)	p value
No. of patients with vomiting	8	7	0.98527
No. of patients not requiring rescue antiemetic	26	23	

**Table 11:- Adverse Effects**

Adverse Effect		Granisetron		Palonosetron		P Value
		No. of Patients	%	No. of patients	%	
0-2 hrs	Headache	1	3%	1	3%	1.000
	Nil	39	98%	39	98%	
	Total	40	100%	40	100%	
2-6 hrs	Headache	3	8%	2	5%	.644167
	Nil	37	93%	38	95%	
	Total	40	100%	40	100%	
6-24 hrs	Headache	2	5%	3	8%	.644167
	Nil	38	95%	37	93%	
	Total	40	100%	40	100%	

Table 12:- Measurement of Nausea and Vomiting

Discussion

Common sequel of general anesthesia and a leading cause of delayed discharge of unanticipated hospital admission after ambulatory surgical procedure are postoperative nausea and vomiting (PONV).¹⁴⁻¹⁸ This is very frequent in abdominal surgeries leading to recommendation of routine prophylactic administration of Antiemetics. The etiology of nausea and vomiting after abdominal surgeries under general anesthesia is multifactorial in origin. Age type of surgery, anesthetic procedure and duration of surgery may influence PONV. PONV continues to be a –BIG LITTLE problem for surgical patients in spite of significant advances in general anesthesia. Incidence of PONV is 20-25% in addition to patient dissatisfaction, PONV may have other adverse consequences such as delayed recovery, and unexpected extended hospital stay and delayed return to work. PONV may lead to significant morbidity from dehydration, electrolyte imbalance, and aspiration of vomiting.¹⁹⁻¹⁶ We conducted a study to compare the efficacy of Granisetron (group A) and Palonosetron (group B) during laparoscopic surgery to prevent

PONV. Granisetron is a potent, highly selective 5-HT₃ receptor antagonist. The mechanisms of action of Granisetron are both central and peripheral. It blocks the 5-HT₃ in the area Postrema, nucleus Tractus solitarius (NTS) and adjacent areas in the brain, which are related to nausea and vomiting. Also, it blocks 5-HT₃ receptors in the mucosal Vagal afferents in the gastrointestinal tract. Palonosetron is a second generation 5HT₃ receptor binding agent newly approved by FDA for the prevention of PONV since March 2008. It has the highest binding affinity to the 5-HT₃ receptor and at approximately 40 hours, has the longest elimination half life. Unlike the representative of the first generation with competitive inhibition of the 5-HT₃ receptor, Palonosetron seems to exhibit Allosteric binding and positive cooperatively leading to effects persisting beyond the receptor binding time. Few researchers compared the efficacy of 40mcg/kg versus 80mcg/kg Granisetron for the prevention of PONV after laparoscopic Cholecystectomy and concluded that 80mcg/kg was more effective than 40mcg/kg.²⁷⁻³⁴ In our study 100% patients who received Granisetron did not have any vomiting in the first 2 hrs postoperatively compared to 98% patients who received Palonosetron. 95% patients and 85% patients in Granisetron group did not have vomiting between 2-6 hrs and 6-24hrs period respectively compared to 95% and 88% in Palonosetron group. Similarly, the frequencies of nausea, retching and vomiting episodes, when considered individually, did not show significant difference. Nausea score was comparable to our study but the frequently of nausea



and use of rescue Antiemetics, in our study, in our study were seen to be significantly higher in Granisetron group than Palonosetron Group In 6-24 Hour Period.

Limitation of the study

The efficacy of Granisetron and Palonosetron were compared based on the optimal doses, as equipotent doses are not known. The baseline incidence of PONV was not evaluated by the inclusion of a placebo group because it would be unethical to without prophylactic antiemetic drugs in patients at high risk for PONV. Also, the known difference in the half life of the two drugs could be one of the factors responsible for the difference in incidence of nausea and vomiting in the study period. In addition, Severity of headache and other adverse effects not graded.

Conclusion

Authors concluded and stated that when Palonosetron 0.075 mg was administered before induction of general anesthesia, the severity of nausea was significantly less compared to 0.04mcg/kg of Granisetron during 2-6 hrs and 6-24 hrs of post operative period. As far as vomiting is concerned, patients receiving Palonosetron had less incidence of vomiting than Granisetron group but the difference was not statistically significant during 0-2, 2-6 and 6-24 hours. The number of patients free of nausea vomiting was significantly lower in Palonosetron group than Granisetron at the end of 24 hrs. The number of rescue Antiemetics was also found to be significantly less in the Palonosetron group compared to Granisetron group in 6-24 hours of postoperative period. However, use of rescue antiemetic in patients with nausea and vomiting were compared, overall, in the 24 hrs period. Also, the number of patients with nausea and vomiting who did not require rescue antiemetic were comparable in both the group over 24 hrs period. The side effect profiles of the two drugs were comparable. Thus we conclude that the both Granisetron and Palonosetron are equally effective in the immediate post operative period but Palonosetron is more effective over 24 hour's period. Nevertheless, the overall performance and outcomes depends on numerous interconnected factors and patient responses. Recommendations of this study must be clinically correlated and verified prior to applying. However, authors expect few large scale studies to be conducted in these regards.

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