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Comparison Of Granisetron Versus Ramosetron In Preventing Postoperative Nausea And Vomiting In Laparoscopic Surgeries

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Abstract
Introduction: *The incidence of postoperative nausea and vomiting (PONV) following laparoscopic surgeries is very high without antiemetic prophylaxis. 5HT3 receptor antagonists are the most commonly used drug for prevention of PONV.*
Aims: *To compare the effectiveness of intravenous (IV) Granisetron versus Ramosetron in prevention of PONV during the 24 hour period in patients undergoing laparoscopic surgeries.*
Materials and Methods: *Sixty patients enrolled for the study were randomly allotted into two groups of thirty each. Group I received 1mg of IV Granisetron and Group II received 0.3 mg of IV Ramosetron, two minutes before induction of anaesthesia. Both the Groups were similar with respect to age, sex, duration and types of surgery and anaesthetic management. Patients were assessed for the incidence of nausea, retching, vomiting, need for rescue antiemetic and adverse effects at 0-2 hour and 2-24 hours interval following surgery. Students 't' test and chi-square test were used for comparing the parameters. A p-value <0.05 was considered significant.*
Results: *There was no significant difference between the groups with respect to incidence of nausea, retching and vomiting. The incidence of nausea in group I at 0-2 hours was 3.3% and 6.7% in Group II without a statistically significant difference (p=0.5) and at 2-24 hour interval Group I had 3.3% while Group II had 10% incidence of vomiting with p=0.3 and statistically non- significant. There was no significant difference with respect to incidence of retching, vomiting, need for rescue antiemetic and adverse effects between the two groups.*
Conclusion: *Both Granisetron and Ramosetron are equally effective in prevention of PONV in laparoscopic surgeries.*
Keywords: *Granisetron, Ramosetron, Postoperative nausea and vomiting.*

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I. Introduction

Postoperative Nausea and Vomiting (PONV) are common distressing complications of surgery and anaesthesia. The syndrome of nausea, retching and vomiting is known as 'sickness' and each part of it can be distinguished as a separate entity. In the present scenario it is estimated that 22% to 30% of adult patients will develop post operative emesis which is consistently lower when compared to 75% - 80% incidence reported during the 'ETHER ERA'. It is one of the causes of delayed discharge from the hospital. It also causes patient dissatisfaction, dehydration, electrolyte imbalance, higher pain perception and wound dehiscence in the postoperative period. Numerous antiemetics have been studied to prevent and treat PONV after laparoscopic abdominal surgery, including antihistamines, anticholinergics and benzamide. However, these agents can cause undesirable side effects such as sedation, dry mouth and hypotension. Selective serotonin 5-hydroxytryptamine type 3 (5-HT_3) receptor antagonists have a well-established role in the prophylaxis and treatment of PONV due to their efficacy and fewer side effects compared to other antiemetics. Most 5-HT_3 receptor antagonist research has focused on Ondansetron, and the antiemetic efficacy of these com- pounds has been well established for the prevention and treatment of chemotherapy-induced emesis, as well as for PONV. Granisetron selectively blocks the 5-HT_3 receptor with a relatively short half-life of 4 to 9 hrs. Ramosetron is a recently developed selective 5-HT_3 receptor antagonist, which exhibits a significantly greater binding affinity for 5-HT_3 receptors and a slower dissociation rate com- pared to older 5-HT_3 receptor antagonists, resulting in more potent and longer effects. The purpose of this study was to prospectively evaluate the efficacy of Granisetron, and Ramosetron in the prevention of PONV in patients undergoing laparoscopic surgery.

II. Materials and Methods

Sixty patients of ASA grade I & II are scheduled to undergo laparoscopic surgeries electively, both males and females 18 to 60 years of age under general anaesthesia were included in the study. Informed written consent from the patients and institutional ethical committee approval were obtained. Patients with gastrointestinal disorders, advanced liver disease, cardiovascular disorders, morbid obesity, history of drug allergy and antiemetic use in 24 hours before surgery were excluded from the study.

30 patients were randomly allotted in each group.

1. In Group I 1 mg intravenous (IV) Granisetron. was administered
2. In Group II 0.3 mg intravenous (IV) Ramosetron was administered.

A preoperative evaluation and routine laboratory investigations which included complete hemogram, blood urea and serum creatinine, blood sugars, electrocardiogram, bleeding time and clotting time were done on the day prior to the scheduled surgery. Tablet Alprazolam 0.5 mg and tablet Ranitidine 150mg was given the night prior to surgery and were kept nil by mouth from 10 PM onwards. On shifting to the operating table, IV line was secured and Ringer lactate was started. Non-invasive blood pressure {NIBP}, SPO2 monitor and ECG were connected. Basal readings were recorded. The study drugs were given by intravenous route two minutes before induction of anaesthesia. Induction of anesthesia was done with injection propofol 2mg/kg IV and injection succinylcholine 2mg/kg IV was administered for muscle relaxation and patients were intubated with appropriate sized cuffed endotracheal tubes. Injection Tramadol 1mg/kg IV was used for analgesia and injection Atracurium Besylate 0.5mg/kg IV was used for maintenance of muscle relaxation during surgery. Nitrous oxide (66%) and oxygen (33%) with isoflurane 1% along with intermittent positive pressure ventilation was used for maintenance of anaesthesia. Continuous ECG, pulse oximetry and NIBP were monitored every 5^{th} minute during the intra operative period. Glycopyrrolate 0.008mg/kg IV and Neostigmine 0.05 mg/kg IV was administered for reversing the neuromuscular block and extubation was done after meeting the extubation criteria and shifted to recovery room. On meeting the Aldrette score of nine or above patients were shifted from the recovery room.

Patients were observed for postoperative nausea, retching and vomiting during the 24 hours following surgery, at 0-2 hours and 2-24 hours. Spontaneous complaints from the patient or by questioning the patient about the same was used for assessment.

1. Patients expelling gastric contents forcefully from the mouth was considered as vomiting.
2. Patients trying to vomit with a feeling that was unpleasant was considered as nausea.
3. Patients having contraction of the respiratory muscles in a laboured manner that was rhythmic, with spasm and without the gastric contents being expelled was considered as retching.

The necessity for rescue antiemetic was noted and injection Ondansetron 4mg IV, was given if the patient had episodes of vomiting during the postoperative period if felt necessary by the observer. Patients were asked about headache and dizziness. Data obtained was analyzed and comparison done between the two groups. Data was analyzed using SPSS for windows, SPSS Inc. New York. Mean ± SD was used for calculating continuous measurement and categorical measurement results were presented in number (%) and 5% level is considered significant. Student 't' test (two tailed independent) was used for comparison of continuous scale parameters and chi- square / Fisher exact test for comparing parameters on categorical scale between the two groups. A p-value <0.05 is considered significant while <0.01 is strongly significant.

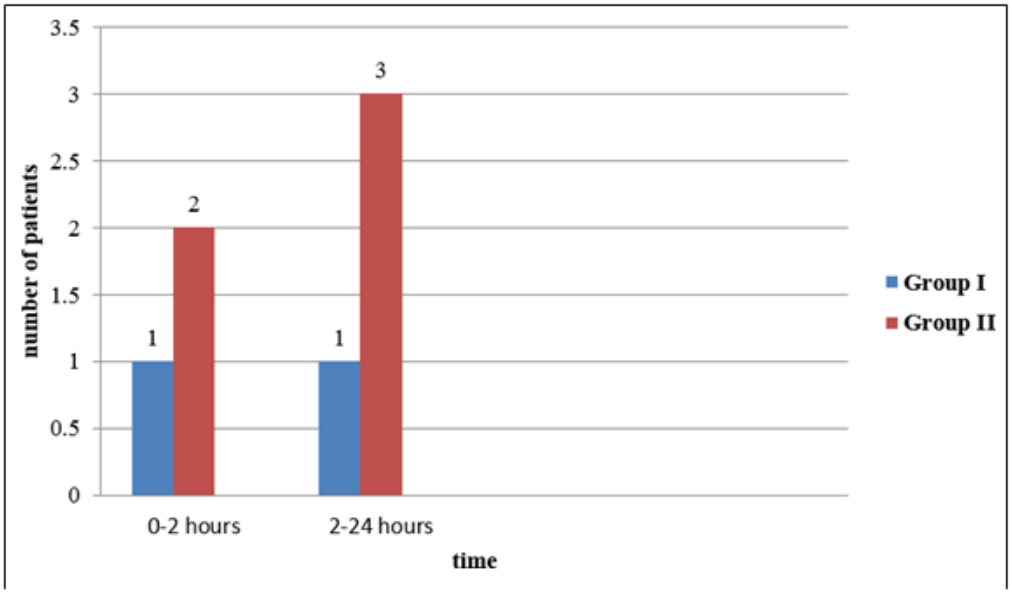
Table 1: Age, sex, weight of patients and duration of surgery

Parameter	**Group I (G)**		**Group II (R)**		**p-value**
Mean age	32.7		37.43		0.179
Weight in kilograms	**Male**	**Female**	**Male**	**Female**	0.184
	61.47	52.6	59.2	54.2	
Sex of patients	**Male**	**Female**	**Male**	**Female**	0.436
	15	15	12	18	
Mean duration of surgery in minutes	70.83		81.90		0.118

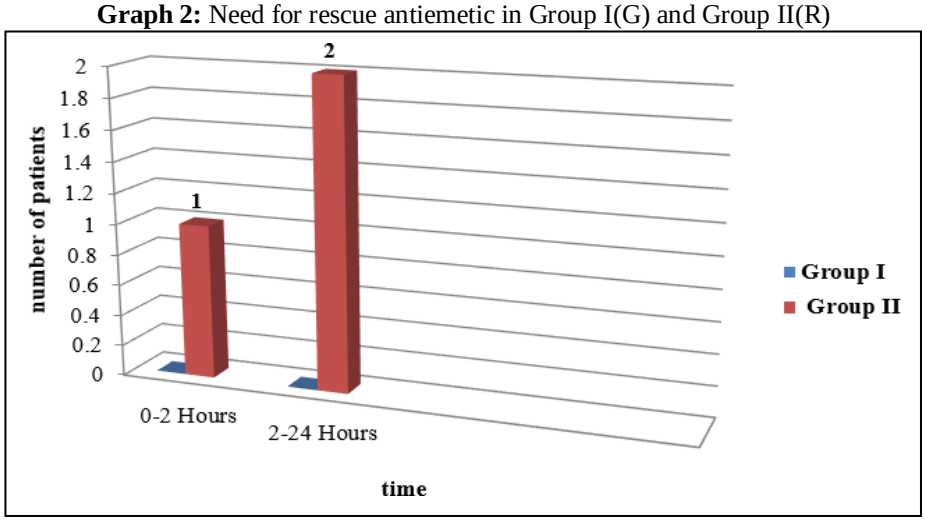
Table 2: Incidence of nausea, retching, vomiting, need for rescue antiemetic and adverse effects

Parameter		Group I (G)	Group II (R)	p-value
Nausea	0-2 hours	1 (3.3%)	2 (6.7%)	0.554
	2-24 hours	1 (3.3%)	3 (10%)	0.306
Retching	0-2 hours	0	0	-
	2-24 hours	0	1 (3.3%)	0.313
Vomiting	0-2 hours	0	2 (6.7%)	0.15
	2-24 hours	0	2 (6.7%)	0.15
Need for rescue antiemetic	0-2 hours	0	1 (3.3%)	0.313
	2-24 hours	0	2 (6.7%)	0.15
Adverse effects	Headache	0	1 (3.3%)	0.3
	Dizziness	0	1 (3.3%)	0.3

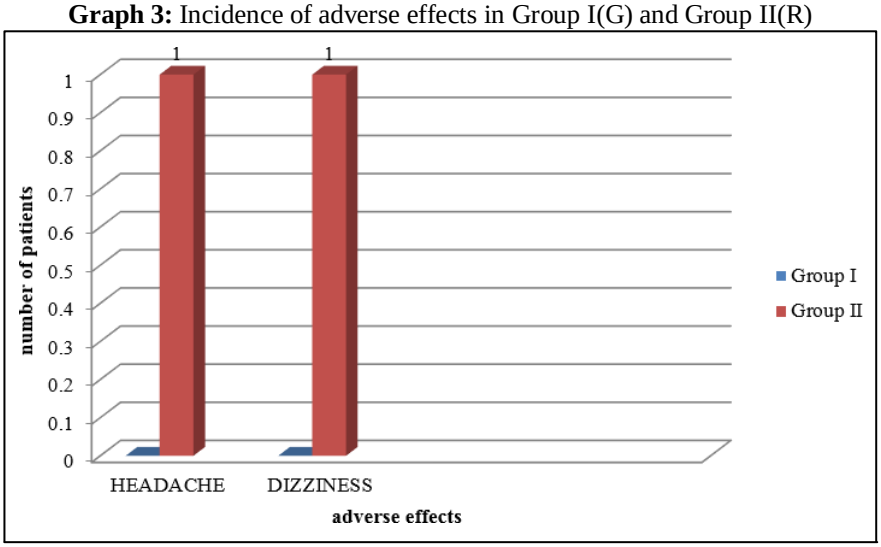
Graph 1: Incidence of nausea in Group I(G) and Group II (R)



Graph 2: Need for rescue antiemetic in Group I(G) and Group II(R)



Graph 3: Incidence of adverse effects in Group I(G) and Group II(R)



III. Results

Study was completed by all the patients. Age, weight, sex, type of surgery and duration of surgery was same in both groups. During the 0-2 hour interval single patient (3.3%) in group I and two patients (6.7%) in group II had complaints of nausea and was statistically non significant (p=0.55). In the 2-24 hours interval one patient (3.3%) in group I and three patients (10%) in group II had a sensation of nausea which was statistically non significant (p=0.30).

No patients in either group I or group II had complaints of complaints of retching in the 0-2 hour period. In the 2-24 hours interval, not even a single patient in group I and single patient (3.3%) in group II complained of retching and was statistically non significant (p=0.313). In group I no patient had vomiting while two patients (6.7%) in group II had vomiting during the 0-2 hour interval and was statistically non significant (p=0.15). During the 2-24 hour interval no patient in group I and two patients (6.7%) in group II had vomiting and was statistically non significant (p=0.15). Out of two patients who complained postoperative nausea in group I none of them received rescue antiemetic while out of five patients who complained of vomiting, retching or nausea in group II, three patients received rescue antiemetic (one during the 0-2 hour interval and two during the 2-24 hour interval) and was statistically non significant (p=0.56). Headache or dizziness was not seen in any patients in group I and one patient in group II complained of headache and one patient complained of dizziness and was statistically non significant (p=0.3).

IV. Discussion

Although laparoscopic surgeries decreased surgical morbidity and have become an accepted procedure for the treatment of many surgical procedures, the high incidence of PONV remains a major clinical problem.

The incidence of PONV on an average is between 20% to 30% but can be very high upto 72% after laparoscopic cholecystectomy and up to 80% in gynecological laparoscopic surgeries. Numerous patient and surgical factors are responsible for PONV[6,7]. 5HT3 receptors stimulation in the chemoreceptor trigger zone caused by the anaesthetic agents, intestinal ischemia due to pneumoperitoneum and subsequent serotonin release and mechanoreceptors mediated stimulation of the gut due to creation of pneumoperitoneum results in an increased incidence of PONV[7]. Granisetron is effective for the treatment of emesis induced by cancer chemotherapy. The precise mechanism of Granisetron for the prevention of PONV remains unclear, but it has been suggested that Granisetron may act on sites containing 5-HT $_3$ receptors with demonstrated antiemetic effects. Ramosetron which is a newly developed 5HT3 receptor antagonists and used in cisplatin induced emesis because of its high potency and bio-availability has been found to be very effective. It acts by exerting its effects on area postrema and nucleus tractus solitaries both of which are rich in 5HT3 receptors. The effective dose of Ramosetron needed to prevent of PONV was 0.3mg according to Fuji et al[1] in patients being operated for gynecological surgery.[18] The dose recommended by the manufacturer is also 0.3mg once in a day. Therefore we used the same dose of Ramosetron in our study. An incidence of 3.3% nausea was found in palonosetron group during 0-2 hour period (1 out of 30 patients) and in the Ramosetron group was 6.7% (2 out of 30 patients) and at 2-24 hours period 3.3% (1 out of 30 patients) reported nausea in the palonosetron group and 10% (3 out of 30 patients) in the Ramosetron group. In the 0-2 hour period vomiting was not seen in any patients in palonosetron group and seen in 6.7% in Ramosetron group. At 2-24 hours, vomiting was not observed in any patients in palonosetron group and observed in 6.7% in Ramosetron group. Won-Suk Lee,[3] in patients scheduled to

undergo laparoscopic hysterectomy, found that the number of patients having PONV was same in the palonosetron, Granisetron and Ramosetron at 0-6 and 6-24 hour period and corresponds to our results.. The findings of this study correlate to those observed by Firdous Ahmed Yatoo et al[2] who concluded that no significant difference was present between Granesetron and Ramosetron in PONV prevention in patients who underwent laparoscopic procedures. In a study done Y K Khan et al[8] in order to compare 0.3mg Granisetron and 0.3mg Ramosetron for the prevention of Cisplatin induced Emesis shows both drugs appear to have equivalent efficacy and tolerability profiles the effects of Ramosetron on the prevention of acute vomiting in patients undergoing cisplatin chemotherapy were long lasting , no difference was observed between the two drugs that corresponds to our finding.

Patients with a requirement of rescue antiemetic was higher in Ramosetron group 10% compared to 0% in Granesetron group (p=0.56) but was not statistically significant and is similar to the results obtained by Firdous Ahmed Yatoo et al[2.] Headache and dizziness were seen in 0% in Granisetron and 6% in Ramosetron p=0.13 and no clinically serious adverse effects caused by the study drug were observed in either of the groups.

V. Conclusion

Both the drugs are effective in preventing nausea and vomiting in first 24 hours. The incidence of PONV in Granisteron group was less compared to Ramosetron group, but was statistically non-significant.hence, there is not much difference between the two drugs in preventing PONV after laproscopic surgeries.

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