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Granisetron Versus Ondansetron for Prevention of Post-operative Nausea and Vomiting (PONV) in Patients Undergoing Laparoscopic Cholecystectomy

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Authors' contributions

This work was carried out in collaboration among all authors. Authors MN and RT designed the study, Authors AHA and MN performed the statistical analysis, Authors MM wrote the protocol, and wrote the first draft of the manuscript. Authors MSK, RI and RT managed the analyses of the study. Author MN managed the literature searches. All authors read and approved the final manuscript.

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ABSTRACT

Aim: To determine the efficacy of single dose Granisetron versus ondansetron in preventing PONV in patients undergoing elective laparoscopic cholecystectomy.
Methodology: A total of 100 patients were included in this study after the ethical approval of PUMHSW. Patients were randomly divided into two groups, in (Group G) 50 patients were given Granisetron and in (group O) 50 patients were given Ondansetron. Every patient was evaluated for PONV at one hour, two hours, three hours, six hours, twelve hours and 24 hours post operatively.
Results: A sample of 100 patients with age between 20-60 years (mean age 43.72±5.67 years), were included in this study. Patients were received granisetron 1 mg I/V and other patients received ondansetron 4mg I/V before induction.
Conclusion: we concluded that there was no significant difference between efficacy of granisetron and ondansetron as the p-value is found to be ≤0.05.

Keywords: Efficacy; postoperative nausea and vomiting; PONV; granisetron; ondansetron; laparoscopic cholecystectomy.

1. INTRODUCTION

PONV leads to serious surgical complications like wound dehiscence, surgical site bleeding which result in delayed wound healing and prolong hospital stay ultimately lead to increase burden over country's economy [1]. The Postoperative nausea and vomiting (PONV) are common sequelae of general anaesthesia and a leading cause of delayed discharge and unanticipated hospital admission after ambulatory surgical procedures [2]. A lot of drugs have been used for prevention of PONV. Most act as antagonist at the receptors which are involved in emesis. The traditional antiemetics include antihistamines, anticholinergics and dopamine-receptor antagonists [3]. Newer drugs like Serotonin Receptor Antagonists (granisetron and ondansetron) provide better efficacy and safety as compared to the traditional drugs [4]. They bind to the 5-Hydroxytryptamine subtype-3 (5HT3) receptors, selectively blocking the emetogenic stimuli during anesthesia and surgery. They have proven efficacy and is recommended as a prophylactic antiemetic at the time of induction of anesthesia [5]. Further, the combination of 5HT3 receptor antagonists with dexamethasone has better control of PONV than administration of single drug therapy in high risk cases [6]. In a recent study conducted at India, observed that granisetron better than ondansetron as a prophylaxis against PONV following laparoscopic procedures, with incidence of nausea 36% in Group O and 12% in Group G, which was significantly low [7]. Another researcher revealed that the frequency for need of overall rescue antiemetics were more in Group O (20%) when compared to Group G (2%) [8]. A considerable proportion of patients experience PONV despite the widespread use of prophylactic antiemetics, including 5-HT3receptor antagonists [9]. Another study by Sanjowal et al revealed that complete response of 92% with ondansetron and dexamethasone combination [10].

The rationale of study was to determine the use of Granisetron versus ondansetron as more effective antiemetic drug in terms of reduced number of emetic episodes, for prevention of PONV in our setting, where no such study had been conducted so in our country. Although the mode of action of both drugs is same but one better drug in preventing PONV reduce the hospital stay and thereby reduce the cost during post-operative care.

2. MATERIALS AND METHODS

This study was conducted for the time period of six months from June 2018 to November 2018 at department of Anaesthesia and SICU, PUMHSW, Sindh, Pakistan. 100 those patients were included in this study who give their written consent with age 20-60 years of both sexes and ASA type I and II while those patients have history of motion sickness, previous exposure to general anesthesia, pregnancy, menstruation, upper gastro intestinal disease and taken antiemetic drugs pre operatively within 24 hours of operation were excluded from this study. Patients were randomly allocated into two cohorts, G & O for each drug, each group consisting of 50 patients. Cohort G received granisetron 1 mg I/V before induction whereas

Cohort O received ondansetron 4 mg I/V before induction.

Research instrument was predesigned proforma, which incorporate clinical examination, relevant laboratory investigations, ASA score and post-operative outcome/ nausea & vomiting according to study design. All patients were kept nil by mouth for 8 hours before surgery.

All the patients were re-examined and assessed preoperatively in the operating room. Intravenous (I/V) access was established with an 18G I/V cannula and for Premedication inj. Alprazolam 0.1mg/kg, inj. Ranitidine 50mg,inj. Glycopyrolate 0.2mg I/V was used and for analgesia inj. acetaminophen 10mg/kg infusion and inj. ketarolac 30mg diluted I/V was used. All monitoring equipments like pulse oximeter, noninvasive blood pressure &ECG monitors were checked and applied to each patient on arrival to the operating room.

Induction of anesthesia done with Inj. Propofol 2 mg/kg, Inj. Succinylcholine 1.5 mg/kg. Inj. Nalbuphine 0.1 mg/kg I/V were used for analgesia and inj. atracurium 0.5 mg/kg I/V were used to provide maintenance of muscle relaxation during surgery depending on the type and duration of the procedure.

Maintenance of anesthesia done isoflurane 1.20% and Oxygen mixture using controlled ventilation. On completion of surgery, the residual paralysis was reversed with Inj. Neostigmine 0.035 mg/kg I/V and glycopyrrolate 0.01 mg/kg IV. Patients were transported to the recovery room and later to the ward after confirming an adequate level of consciousness and intact reflexes. Postoperative analgesia was given with acetaminophen infusion 10mg/kg I/V 6 hourly& inj.ketarolac 30 mg bid.

The PONV cases were recorded within the first 24 hours after surgery at intervals of 0-2 hours, 3 hours, 6 hours, 12 hours and 24 hours. Episodes of PONV were identified by spontaneous complaints by the patients or by direct questioning. “Complete response” was defined as the absence of nausea or vomiting and no need for rescue anti-emetics during the 24-hour observation period. Whenever any of the intervention drug under study fails to prevent PONV, the rescue antiemetic single dose were provided with Inj. Metoclopramide 10 mg and Inj. Dexamethasone 8 mg I/V after event of 1st episodes of nausea or vomiting.

The results were analyzed by using latest SPSS-21 version and level of significance was kept at ***p***-value <0.05.

3. RESULTS

A total of 100 patients were included in this study. Patients were randomly divided into two groups. Cohort G received granisetron 1 mg I/V before induction whereas Cohort O received ondansetron 4 mg I/V before induction. Each group contains 50 patients. Regarding frequency of post operative complications (PONV) there was no significant difference between efficacies of granisetron and ondansetron groups as p-value is found to be ≤0.05.

The patient were distributed by their age and gender.

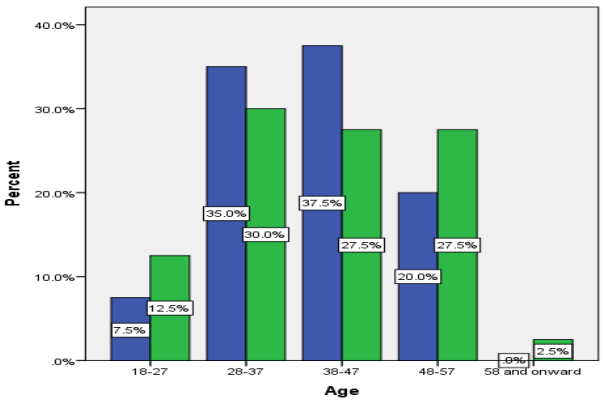

Fig. 1. Age Distribution Of The Patients

Cohort Group O

Cohort Group G

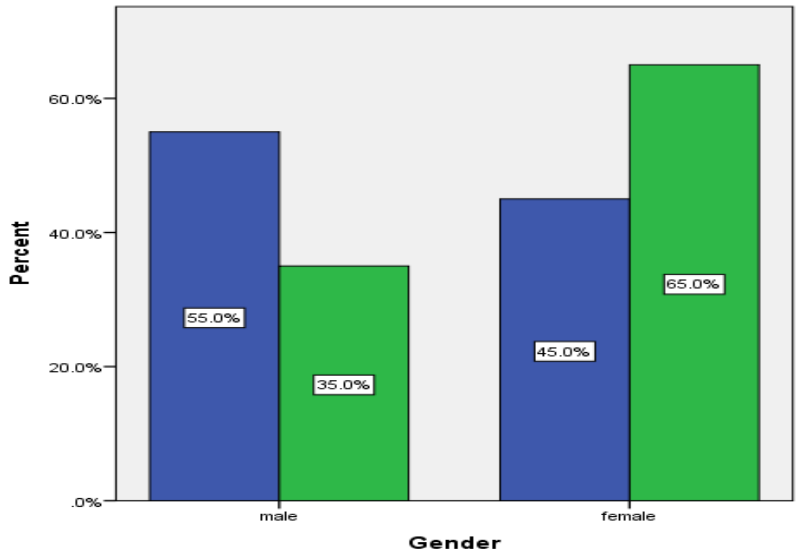

Fig. 2. Gender Distribution Of The Patients

Cohort Group O

Cohort Group G

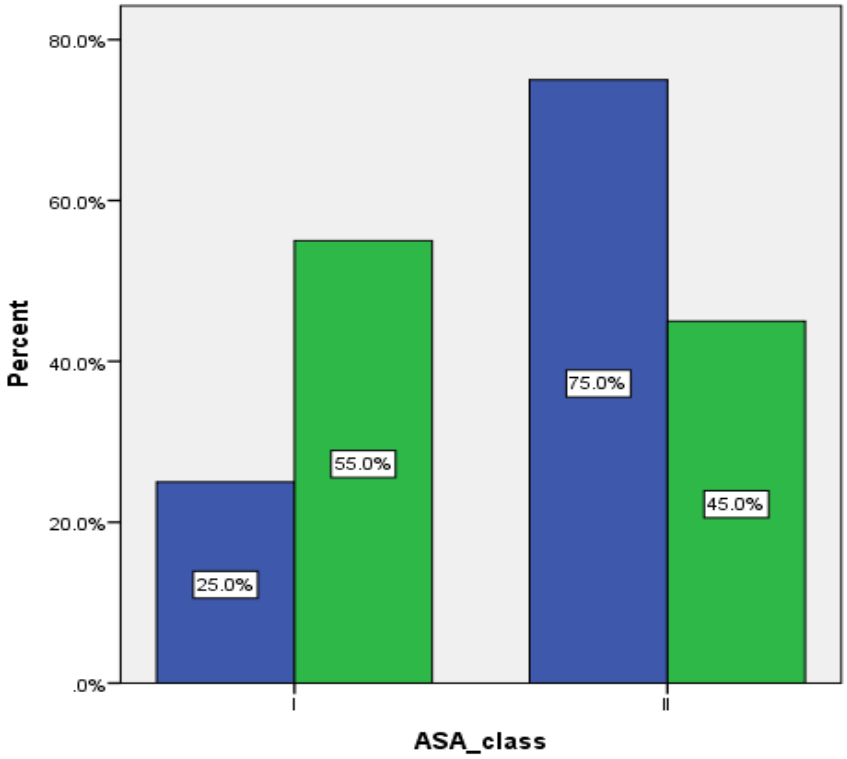

Fig. 3. Asa Status Distribution of The Patients

Cohort Group O

Cohort Group G

Table 1. Comparison of the frequency of post operative complications between groups

Time	Groups	NO PONV	Nausea	Vomiting	P-Value
Within 1 Hour	G	49	Nil	Nil	Not Computed
	O	51	Nil	Nil	
After 1 Hour	G	48	0	1	0.524
	O	48	1	2	
Two Hours	G	46	3	0	0.207
	O	44	4	3	
Three Hours	G	46	2	1	0.859
	O	47	2	2	
Six Hours	G	46	2	1	0.557
	O	45	3	3	
Twelve Hours	G	47	1	1	0.859
	O	48	2	1	
Twenty Four Hours	G	49	Nil	Nil	Not .Computed
	O	51	Nil	Nil	

Results are presented as n (%) Chi-Square test applied

The patients of both groups were also distributed according to ASA status.

PONV within 1 hour, PONV after1 hour. PONV after 2 hour, PONV after 3 hour, PONV after 6 hour, PONV after 12 hour and PONV after 24 hour is shown in Table. Demographic variables distribution of the patients is presented in Figures where as Table 1 is showing post operative complications among groups.

4. DISCUSSION

A total of 100 patients were included in this study. Regarding complications there was not significant difference between efficacy of granisetron and ondansetron groups as the value was found to be ≤0.05. Yoshitaka Fujii [11] et al,. in 2008 reported that Antiserotinins (ondansetron, granisetron, and ramosetron) are highly effective in decreasing the incidence of PONV for 24 h postoperatively, compared with traditional antiemetics alike present study [11]. DryBerg et al reported dissimilar results with present study as they found significant difference between ondansetron and placebo group (p=0.001 and p=0.054) respectively [12], whereas Fujii *et al*. showed similar insignificant with present study, results showed there is no significant difference between granisetron group with placebo group i.e p=0.292 [11].

Nisar Ahmedet al in 2012 conducted a descriptive study over a period of 8 months from May 2010 to December 2010 in the Department of Surgery, Khyber Teaching Hospital, Peshawar. The study shows that with the administration of ondansetron 4 mg and dexamethasone 8 mg, 15% of the patients experienced PONV during the first 24 hours alike present study which shows no nausea and vomiting in both G and O groups at 24 hours. Without prophylactic anti-emetics, the incidence of nausea and vomiting after laparoscopic cholecystectomy has been more than 70% [13].

PARK et al in 2011 evaluated the relative efficacy of palonosetron (a new, selective 5-hydroxytryptamine type 3 [5-HT3] receptor antagonist) and ondansetron in preventing postoperative nausea and vomiting (PONV) in patients undergoing gynaecological laparoscopic surgery. Patients received either palonosetron 0.075 mg (*n* = 45) or ondansetron 8mg (*n* = 45), I/V, immediately before induction of general anaesthesia [14].

The occurrence of nausea and vomiting and the severity of nausea according to avisual analogue scale were monitored immediately after the end of surgery and during the following 24 h. The incidence of PONV was significantly lower in the palonosetron group compared with the ondansetron group (42.2% vs 66.7%,respectively). There were no significant statistical differences for PONV similar to present study. In conclusion, palonosetron 0.075 mg was more effective than ondansetron 8 mg in preventing PONV.

5. CONCLUSION

Our results showed that Group G and group O regarding frequency of post operative complications (PONV) showed insignificant results as no value is found to be ≤0.05.

DISCLAIMER

The products used for this research are commonly and predominantly use products in our area of research and country. There is absolutely no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation but for the advancement of knowledge. Also, the research was not funded by the producing company rather it was funded by personal efforts of the authors.

CONSENT

All authors declare that 'written informed consent was obtained from the patient.

ETHICAL APPROVAL

As per international standard or university standard written ethical approval has been collected and preserved by the authors.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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