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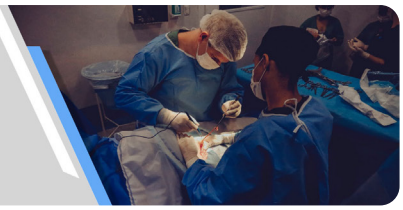

Comparative Evaluation of Ondansetron and Palonosetron for Postoperative Nausea and Vomiting In Abdominal Laparoscopic Surgeries: A Prospective Observational Comparative Study

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Abstract

Background and Aims: The incidence of PONV remains high despite recent advances in practice of anaesthesia and in management of PONV. Having a multifactorial etiology, multiple neurotransmitters involved in PONV includes serotonin, dopamine, acetylcholine, histamine, opioids and neurokinin-1. The present study is designed to evaluate the efficacy of palonosetron compared with ondansetron for preventing PONV in patient undergoing elective abdominal laparoscopic surgeries.

Materials and methods: A prospective observational study was conducted in which eighty patients receiving general anaesthesia for laproscopic abdominal surgery were randomised into group O (n = 40) and group P (n = 40). In Group O all patients receive 4 mg of ondansetron intravenously and in Group P all patients receive palonosetron 0.075 mg intravenously prior to induction. In the post anesthesia care unit, the occurrence of nausea, vomiting, severity of nausea is assessed with the help of verbal descriptive scale (VDS). Rescue antiemetic drug is monitored at the end of the surgery at 0-2 hours, 2-6 hours. and 6-24 hours. Inj. Ondansetron 4 mg iv. is used as a rescue antiemetic. Details of any adverse effects is recorded.

Results: In 2-6hrs post procedure, incidence of retching and vomiting between the 2 groups were comparable with insignificant p value but the incidence of nausea and requirement of rescue antiemetic came to be statistically significant. In 6-24hr post procedure,3 patients (7.5%) in group P suffered from vomiting whereas group O showed a higher incidence of vomiting i.e.30%.5 patients in group P suffered from nausea whereas 20 patients in group O suffered from nausea with p value of .001 which was statistically significant. During this period only 2 patients (5%) required rescue antiemetic in group P while 8 patients (20%) in group O required rescue antiemetic making the difference statistically significant. The severity of PONV measured in terms of VDS score was higher in group O as compared to group P patients in 2-6hrs (p=0.05) and 6-24hrs (p=0.001) postoperative period.

Conclusion: Palonosetron is more efficacious in preventing PONV than ondansetron in patients undergoing elective abdominal laparoscopic surgeries.

Keywords: Ondansetron; Palonosetron; PONV; Laparoscopic surgeries

Introduction

Post-operative nausea and vomiting (PONV) is a common problem following general anaesthesia and one of the most unpleasant side effect which

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can affect the patient after surgery and is the worst memory of their hospital stay. The incidence of PONV remains high despite recent advances in practice of anaesthesia [1]. The incidence of PONV following general anaesthesia is about 20-30% [2,3] and 80% in patient who has increased risk factors for PONV. [3,4] The etiology of PONV is multifactorial, involving anaesthetic factors, surgical factors and patient factors. The factors which predict the incidence are the patient age, gender, smoking habits, duration and the type of surgery, pain, opioid requirement and anaesthetic inhalation agent. [4,5] The incidence of PONV is very high in abdominal surgeries and especially the female patient are at high risk. [6,7] A study from India stated that Palanosetron has got better anti-nausea effect, less need of rescue antiemetics, favourable side effect profile and a decrease in the incidence of total PONV as compared to ondansetron in 24 h post operative period in patients undergoing laproscopic cholecystectomy under general anesthesia [8]. While another study stated that Palonosetron is comparable to ondansetron for PONV prophylaxis in elective laparoscopic cholecystectomy when administered as single pre-induction dose[9]. A number of pharmacological agents (antihistaminic, butyrephenones, dopamine receptor antagonist) have been tried but undesirable adverse effects such as excessive sedation, hypertension, dry mouth, dyspnea, hallucinations and extrapyramidal symptoms have been noted [2]. Most clinical research with the 5-HT3 receptor antagonists has used ondansetron and its antiemetic efficacy is well established in chemotherapy induced emesis and in the treatment of PONV.[10] The 5-HT3 receptor antagonist belongs to CIS loop superfamily ligand gated ion channel and are the first line therapies in the prevention of PONV. [11,12] Recently palonosetron have been reported to be effective in prevention of PONV. Palonosetron is unique from other 5HT3 receptor antagonists by its unique chemical structure, greater binding affinity and substantially longer half-life (approx.40 hours). [13-16] Palonosetron has been compared with placebo for PONV, but comparison with other anti-emetic drugs is still limited. Various studies have been done to evaluate the effect of drugs but at different setting. [17-25]

The present randomized double blinded study is designed to evaluate the efficacy of palonosetron compared with ondansetron for preventing PONV in patient undergoing elective abdominal laparoscopic surgeries. The essence of this study was to accept or refuse the theories given by researchers working on the same drug under the limitation of same timeline (i.e. 24 hours). The aim of the study was to evaluate whether palonosetron is more efficacious in preventing PONV than ondansetron in patients undergoing elective abdominal laparoscopic surgeries with the objectives of to document the complete response of ondansetron and palonosetron on PONV, to estimate and compare the incidence of nausea, retching and vomiting between ondansetron group and palonosetron group, to compare and document the need for rescue medication between ondansetron group and palonosetron group and to compare the side effect profile between ondansetron group and palonosetron group.

Methodology

This prospective observational research was conducted in the Department of Anesthesiology, Paras hospitals Gurugram, Haryana over a period from July 2016 to May 2017,after an institutional Ethics Committee approval. After acquiring written informed consent, aged 18–65 years, of either sex, of American Society of Anaesthesiologists (ASA) physical status I & II, receiving general anaesthesia for abdominal laparoscopic surgery were included in the study

Exclusion criteria: Patients undergoing emergency surgeries, surgeries which involves major hemodynamic changes, with known allergy to study drug, with history of motion sickness, migraine, Gastro esophageal reflex disease, PONV, pregnant patients and those who refuse to participate in the study were excluded from the study.

Sample Size: Sample size is calculated using the following formula:

$$M\ (size\ per\ group) = \frac{C\ x\ \pi1(1-\pi1) + \pi2(1-\pi2)}{(\pi1-\pi2)2}$$

Where C = 7.9 for 80% power, π1 and π2 are the proportional estimates

π1 = Anticipated proportion of prevalence of PONV in Ondansetron group

π2 = Anticipated proportion of prevalence of PONV in Palonosetron group

π1 = 0.50 (50%) π2 = 0.20 (20%) (Bhalla J et al)8

M = 7.9 x 0.50 (1-0.50) + 0.20 (1-0.20)/ (0.50-0.20)

M = 7.9 x 0.50 (0.50) + 0.20 (0.80)/ 0.09

M = 3.239/0.09

M = 36

Giving a sample size of 36 in each arm

10% non-response rate so 40 in each arm.

Patients were randomly allocated through chit system to each group consisting of 40 patients each.

Group O: (n=40) All patients in this group will receive 4 mg of ondansetron intravenously.

Group P: (n=40) All patients in this group will receive palonosetron 0.075 mg intravenously.

After detailed pre anaesthetic check-up (PAC), taking written informed consent and ensuring adequate fasting. Patient was shifted to precheked operation theatre & baseline

parameters like systolic blood pressure (SBP), diastolic blood pressure (DBP), Mean arterial pressure (MAP), heart rate, & SpO2 were recorded. After securing appropriately sized cannula and randomizing into one of the two groups, patient was premeditated with Inj. Midazolam 1mg iv, Inj. Glycopyrrolate 0.2mg iv, Inj. Fentanyl 2µg/Kg. The study drug was given to patient prior to induction. General anaesthesia was induced with propofol 1-2 mg/kg iv titrated to the loss of verbal response. Inj. Vecuronium 0.1 mg/kg iv was administered to facilitate endotracheal intubation. The patient's lungs were mechanically ventilated with N2O:02(2:1) and isoflurane at tidal volume of 7-10ml/Kg maintaining intraoperative systolic blood pressure, diastolic blood pressure and heart rate within 20% of baseline value. Arterial oxygen saturation (SpO2) was kept above 95% and end tidal carbon dioxide (EtCO2) was maintained between 35-40 mmHg. Muscle relaxation was maintained by appropriate doses of vecuronium. Multimodal analgesia was provided, in addition to opioid given before induction, Inj diclofenac sodium 1.5mg/Kg im was given intraoperative just after intubation. At the end of surgery residual neuromuscular blockade was antagonized with neostigmine 50µg/Kg and Glycopyrrolate 10µg/Kg. Patient was extubated after adequate reversal of neuromuscular blockade. During laparoscopy, care was taken to maintain the intra-abdominal pressure equal or less than 12 mmHg and CO2 were carefully released at the end of the procedure. Any untoward event like bradycardia or hypotension requiring active intervention were recorded.

Postoperative Assessment

In the post anesthesia care unit, the occurrence of nausea, vomiting, severity of nausea was assessed with the help of verbal descriptive scale (VDS) (0=no nausea, 1=mild nausea, 2 = moderate nausea, 3 = severe nausea). Rescue antiemetic drug was monitored at the end of the surgery at 0-2 hours, 2-6 hours. and 6-24 hours. Inj. Ondansetron 4 mg iv. was used as a rescue antiemetic, when 2 episodes of vomiting has occurred or VDS equal to 2 or more than 2 or if the patient request for it. Details of any adverse effects were recorded.

Statistics

Data was entered on Epi-Info version 3.5.4 (Distributed by Centers for Disease Control and prevention (CDC), Atlanta, USA). Data was then transferred into Microsoft Excel 2010. Data cleaning was done in Microsoft Excel 2010. Analysis was done in Stata 11 (StataCorp LP, Lakeway Drive, College Station, Texas, USA). Results of descriptive analysis was presented as proportions with 95% confidence intervals or as mean (SD) wherever applicable. The means was compared using t test and p value stated. Categorical data was analysed using chi square test. Non-normal distribution continuous variables was compared using Wilcoxan ranksum test. For all statistical tests, a p value less than 0.05 was taken to indicate a significant difference.

Results

A clinical study of 80 patients of ASA I & II undergoing abdominal laparoscopic surgery under general anesthesia was designed to compare the effectiveness of palonosetron over ondansetron for postoperative nausea and vomiting over 24hr period.

Incidence of vomiting and retching across various time intervals

Incidence of vomiting at various time interval is demonstrated in table 1. During 6-24 hour time interval, 3 patient (7.5%) in group P and 12 patients (30%) in group O suffered from vomiting episode with p value .01 which is statistically significant

Table 1: Incidence of vomiting and retching across various time intervals

	Interval (hours)	Group P	Group O	p Value
Vomiting	0 - 2	3 (7.50%)	6 (15%)	0.209
	02-Jun	3 (7.50 %)	6 (15%)	0.28
	Jun-24	3 (7.50%)	12 (30%)	0.01
Retching	0 - 2	1 (2.50%)	2 (5%)	0.56
	02-Jun	0 (0 %)	2 (5%)	0.15
	Jun-24	0 (0%)	2 (5%)	0.15

Table 2: Severity of nausea during 0-2 hours post operativity

Interval (hours)	VDS	Group P	Group O	Total	P Value
0 - 2	0	36(90%)	30(75%)	66	0.18
	1	3(7.5%)	6(15%)	9	
	2	1(2.5%)	4(10%)	5	
	3	0(0%)	0(0%)	0	
02-Jun	0	33(82.5%)	22(55%)	55(68.8%)	0.05
	1	6(15%)	13(32.5%)	19(23.8%)	
	2	1(2.5%)	4(10%)	5(6.2%)	
	3	0(0%)	1(2.5%)	1(.01%)	
Jun-24	0	35(87.5%)	20(50%)	55	0.001
	1	4(10%)	15(37.5%)	19	
	2	1(2.5%)	5(12.5%)	6	
	3	0(0%)	0(0%)	0	

Table 3: Number of patients requiring rescue antiemetic 0-2 hours post operativity

Interval (hours)	RAE	Group P	Group O	Total	P Value
0-2	No	38 (95%)	36 (90%)	74 (92.5%)	0.39
	Yes	2 (5%)	4 (10%)	6 (7.5%)	
02-Jun	No	37 (92.5%)	35 (87.5%)	72 (90%)	0.0456
	Yes	3 (7.5%)	5 (12.5%)	8 (10%)	
Jun-24	No	38 (95%)	32 (80%)	70 (75%)	0.043
	Yes	2 (5%)	8 (20%)	10 (25%)	

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Severity of nausea across various time intervals post operativity

None of the patient had severe nausea in group P and group O. the p value is .18 which is statistically nonsignificant. None of the patient in group P had episode of severe nausea whereas 1 patient (2.5%) in group O experienced severe nausea with VDS score of 3. The overall p value came to be .05 that is statistically significant. None of the patients had severe nausea episode in 6-24 hour period. Overall p value came to be .001 that is statistically significant (table 2).

Need for rescue antiemetic across various time intervals post operativity

During 2-6hrs time interval, 3patients (7.5%) out of 40 required rescue antiemetics in group P, while 5 patients (12.5%) out of 40 required rescue antiemetic in group O. The p value came to be .0456 which is statistically significant. During 6-24hrs time interval, 2patients (5%) out of 40 required rescue antiemetics in group P, while 8 patients (20%) out of 40 required rescue antiemetic in group O. The p value came to be .043 which is statistically significant.

Adverse Effects

Table 4 shows comparison of the incidence of adverse effects in the postoperative period in group P and group O. However, the occurrence of these adverse effects when compared statistically were found to be not significant; p=0.57 (p>0.05).

Table 4: Comparison of the incidence of adverse-effects between both the groups in the postoperative period

Adverse-Effects	Group P	Group O	Total	P Value
None	35(87.5%)	36(90%)	71(88.8%)	
Drowsiness	0 (0%)	1 (2.5%)	1 (1.25%)	0.57
Headache	2 (5%)	2 (5%)	4 (5%)	
Constipation	3 (7.5%)	1 (2.5%)	4 (5%)	

Table 5: Complete response for the drug over 24hour interval

Drug response	Yes/ no	Group P	Group O	Total	P Value
Complete Response	No	14 (35%)	28 (70%)	42 (52.5%)	0.002
	Yes	26 (65%)	12 (30%)	38 (47.5%)	
Nausea	No	26 (65%)	12 (30%)	38 (47.5%)	0.002
	Yes	14 (35%)	28 (70%)	42 (52.5%)	
Vomiting	No	31 (77.5%)	19 (47.5%)	50 (62.5%)	0.006
	Yes	9 (22.5%)	21 (52.5%)	30 (37.5%)	
Retching	No	39 (97.5%)	34 (85%)	73 (91.25%)	0.048
	Yes	1 (2.5%)	6 (15%)	7 (8.75%)	

Complete response for the drug over 24hour interval

Table 5 shows complete responders between the groups. 30% in group O and 65% in group P showed complete response with p value of .002 that is statistically significant. Nausea over 24 hrs in group P 14 patients (35%) experienced nausea whereas in group O 28 patients (70%) experienced nausea with a p value of .002 which is statistically significant. Incidence of vomiting over 24 hrs period, 9 patients (22.5%) had vomiting in group P where as in group O 21 patients (52.5%) had vomiting with p value of .006 that is statistically significant. Overall incidence of retching over 24 hrs, only 1 patient (2.5%) had retching in group P whereas 6 patients (15%) had retching in group O with p value .048 that is statistically significant.

Discussion

Nausea and vomiting are among the most common postoperative complaints. These are frequently the cause of great distress to patients and it is often the worst memory of their hospital stay [22]. The consequences of prolonged postoperative nausea and vomiting (PONV) range from unexpected admission of day patients, with its economic implications to physical, metabolic and psychological effect on the patients [23]. Better anesthetic technique, identification of precipitating factors, use of new generation of antiemetics and improvement in operative techniques reduce the incidence and severity of PONV has been decreasing over the last 10 years. Despite these changes, there is still unacceptable frequency of PONV with incidences up to 85% reported in some studies [24]. A study suggests that the incidence of postoperative nausea and vomiting has remained constant for decades with 20-30% of patients suffering from these unpleasant side effects [3]. Thus, PONV is likely to create considerable extra cost for health care system. The aetiology of PONV is complex and multifactorial. Factors associated with an increased risk of postoperative emesis include age, gender, obesity, a history of motion sickness and/or previous postoperative emesis, anxiety, menstruation, gastroparesis, pain, hypoxia, type of anaesthetic, hypotension and type and duration of the surgical procedure [25]. The present study was undertaken to evaluate and compare the effects of prophylactic intravenous palonosetron, and ondansetron on PONV in patients undergoing abdominal laparoscopic surgeries. Eighty adult ASA grade I/II patients scheduled to undergo elective abdominal laparoscopic surgery under general anesthesia were chosen. Patients were randomly divided into two groups using permuted blocks method and envelope method. Group P patients received intravenous palonosetron 0.075 mg, and group O received intravenous ondansetron 4mg. Studies show that inj. Ondansetron 4 mg is effective for prevention of PONV14. We chose .075mg palonosetron, since the study done by Candiotti K et al concluded that .075mg of palonosetron effectively reduced the incidence of

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PONV when compared to .025mg and .050mg. The drugs were given immediately prior to induction. In our study the overall incidence of nausea, retching & vomiting at 24hrs post procedure in ondansetron group are 70%,15% & 52.5% respectively, whereas it is 35%,2.5%, 22.5% in palonosetron group with p value of .002,.048,.006 respectively making the difference statistically significant.

The results of our study are comparable to the results of various studies done from time to time.[17] found palonosetron to be more effective then ondansetron for high risk patients receiving fentanyl based controlled analgesia after thyroidectomy in 2 -24hrs period following surgery. The incidence of PONV at 24hrs period is 42% in palonosetron group whereas it is 62% in ondansetron group. There was not much difference in both the groups at 2hrs. Similarly in our study, there was no significant difference between 2 groups post procedure. But during 2-24hrs interval there was a significant difference between the 2 groups in respect to nausea and vomiting with p value of .002 and .006 respectively.[18] compared the incidence of PONV using ondansetron and palonosetron among patients undergoing middle ear surgery. The incidence of nausea and vomiting in ondansetron group was higher than palonosetron group (38% vs 12%) and (28% vs 4%) respectively. Similar in our study the incidence of nausea and vomiting is higher in ondansetron group i.e. (70% vs 35%) and (52.5% vs 22.5%) respectively. This concludes that palonosetron to be better antiemetic than ondansetron. [1] compared the incidence of PONV using ondansetron (4mg) and palonosetron(.075mg) among patients undergoing laparoscopic cholecystectomy. The incidence of nausea and vomiting is higher in ondansetron group than in palonosetron group i.e. (38% vs 12%) and (28% vs 4%) which is similar to our study i.e. (70% vs 35%) and (52.5% vs 22.5%). The incidence of nausea and vomiting is more at period between 6hrs and 24hrs which is consistent with our study. Complete responder in ondansetron and palonosetron group are 62% and 88% whereas in our study it was found to be 30% and 65%. [19] compared the antiemetic efficacy of palonosetron, ondansetron and granisetron in laparoscopic cholecystectomy. The incidence of nausea was 10% in palonosetron, while 60% in ondansetron group which is similar to our finding i.e. 35% in group P and 70% in group O. The incidence of vomiting was 6.7% in palonosetron group and 53.3% in ondansetron group which was statistically significant. In our study, it is 22.5% in palonosetron group and 52.5% in ondansetron group similar to their study. The requirement of rescue antiemetic was 13.3% in palonosetron group and 46.7% in ondansetron group. Similarly, in our study 17.5% required antiemetic in group P and 42.5% required antiemetic in group O. They concluded that palonosetron is more efficacious in comparison to granisetron and ondansetron in prevention and treatment of PONV after laparoscopic cholecystectomy [21] compare the effect of ondansetron(4mg) and palonosetron(.075mg) for PONV in laparoscopic surgery. The incidence of nausea during 1st 6hrs post-surgery were 4% in palonosetron and 20% in ondansetron group which was not significant whereas late nausea during 6-24hr was 12% in palonosetron and 40% in ondansetron was statistically significant. Similarly, in our study nausea during 0-2hrs was insignificant but it was significant during 6-24hr post procedure. Incidence of vomiting was insignificant in 1st 6hrs i.e. consistent with our study. Whereas vomiting was significant in the later hours i.e.6-24hrs similar to our study. They concluded that palonosetron is more effective then ondansetron in prevention of PONV during 6-24hrs post procedure after laparoscopic surgery. [20] concluded that palonosetron is better than ondansetron in preventing PONV in laparoscopic cholecystectomy. The complete control of palonosetron and ondansetron over 24hrs was 90% and 30% respectively. In our study, it is 65% and 30% in palonosetron and ondansetron group which is similar to our study. The safety profile was better in palonosetron group whereas it is statistically insignificant in our study.

To conclude palonosetron .075mg i.v. is more effective than ondansetron 4mg i.v. to prevent postoperative nausea and vomiting in patients undergoing abdominal laparoscopic surgery under general anesthesia as the overall incidence of postoperative nausea, vomiting number of patients with incomplete response and requirement of rescue antiemetics were less in palonosetron group as compared to ondansetron.

The limitations of the study are that the study was not powered for adverse effect for the drugs, hence we were not able to the adverse events between the two drugs, inclusion of small sample size, premorbid conditions which could effect the nausea and vomiting were also not assessed which can effect the incidence of nausea and vomiting.

Conclusion

A study was conducted to compare the efficacy of palonosetron and ondansetron in prevention of PONV. Incidence of nausea, retching, vomiting and requirement of rescue antiemetic in the 2 groups during 0-2hours were comparable as the difference in these parameters were found to be statistically insignificant. In 2-6hours post procedure, incidence of retching and vomiting between the 2 groups were comparable and statistically insignificant. But the incidence of nausea and requirement of rescue antiemetic was statistically significant and greater in the O group during the 2-6hour interval and the 6-24 hour interval. The severity of PONV measured in terms of VDS score was higher in group O as compared to group P patients in 2-6 hours and 6-24hours postoperative period. The complete response was less in group O as compared to group P. The different adverse effects observed in the two groups upto 24 hours in the postoperative period (headache, drowsiness, constipation) were similar in incidence and not serious from clinical point of view. Hence palonosetron is more efficacious in preventing PONV than

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ondansetron in patients undergoing elective abdominal laparoscopic surgeries.

Recommendations

Palonosetron is more efficacious in preventing PONV than ondansetron in patients undergoing laparoscopic surgery hence it is recommended that to use Palonosetron at a dose of .075mg. Further research is required to study the adverse effect of the drug as the sample size was not powered for the adverse events. Further research with inclusion of wide variety of surgery cases and use of Palonosetron in them should be explored. To give Inj ondansetron i.v. as rescue antiemetic in case there is nausea vomiting at a dose of 4mg. Careful monitoring of patient for headache, constipation and drowsiness.

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