

Comparison of anti-emetic efficacy of various 5 hydroxy tryptamine-3 receptor antagonists in PONV

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Abstract

Introduction: Post operative nausea and vomiting (PONV) continues to be a significant challenge following many type of anesthetics in modern day anesthesia practice despite the latest advances in anesthesia and the introduction of new class of antiemetic. PONV is defined as nausea, retching and vomiting occurring during first 24-48 hrs after surgery, the three symptoms may occur separately or in combination. Overall incidence of PONV has been reported to between 20% and 30% but can increase up to 80% in patients high risk for PONV. **Aims and objectives:** To study and compare the antiemetic efficacy of 5 Hydroxy Tryptamine₃ Receptor Antagonists (5HTR₃RA) i.e. Ondansetron, Ramosetron and palonosetron in patients who are at high risk for PONV undergoing laparoscopic cholecystectomy. **Material and method:** The present study was conducted in the postgraduate Department of Anesthesiology and Intensive Care GMC Jammu. The study population of 150 patients was randomly selected to compare the antiemetic efficacy of Ondansetron, Ramosetron, Palonosetron in patients undergoing Laparoscopy cholecystectomy under general anesthesia. All the patients enrolled in the study belonged to either ASA class I or II. Patients were divided into 3 groups of 50 each. Group O patients received ondansetron 4 mg, Group R patients received ramosetron 0.3 mg and Group P patients received palonosetron 0.075 mg. our study did not have a control group receiving placebo since we thought that placebo controlled trials may be unethical if active drugs are available because postoperative nausea and vomiting is common and distressing symptom against which effective treatment should be given. It was decided to administer the study drug three minutes before the induction of anaesthesia. Postoperative patients were observed for 48 hrs. Injection Metocloramide 10 mg i/v was used as rescue antiemetic. During first 48 hrs after anaesthesia all episodes of nausea, vomiting, retching, complete response at various time intervals 0-2hrs, 2-6hrs, 6-12hrs, 12-24hrs, 24-48hrs were analyzed statistically. **Results:** It was observed that all the three groups Ondansetron (Group O), Ramosetron (Group R) and Palonosetron (Group P) were clinically matched with respect to patients demographic data (Age in years' and weight in kg) and duration of surgery ($P > 0.05$) in our study. It was seen that 83.6% patients in Group O, 89.2% in Group R and 98.4% in Group P had no incidence of Nausea. It was evident from the table that the control over vomiting was significantly better in group P patients as compared to group O and R. In 82.0% Group O and 87.6% in Group R no incidence of Retching was observed. Use of rescue medicine was more in group O and group R as compared to group P. Mean percentage of use of rescue medication in Group O, Group R and Group P was 22.8%, 14.8% and 2.4% respectively. The difference observed in use of rescue medicine in group P was statistically significant as compared to group O and group R. **Conclusion:** Thus we concluded that a single injection of 0.075 mg of Palonosetron was more effective in preventing PONV and reduced the need of use rescue antiemetic compared to an injection of 4 mg of ondansetron or 0.3 mg of Ramosetron in patients who are at high risk for PONV scheduled for laparoscopic cholecystectomy. **Key words:** PONV, laparoscopic cholecystectomy, 5 Hydroxy Tryptamine-3 Receptor Antagonists.

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Received Date: 26/05/2015 Revised Date: 03/06/2015 Accepted Date: 05/06/2015

Access this article online

Quick Response Code:



Website:

www.statperson.com

DOI: 07 June 2015

INTRODUCTION

Post operative nausea and vomiting (PONV) continues to be a significant challenge following many type of anesthetics in modern day anesthesia practice despite the latest advances in anesthesia and the introduction of new class of antiemetic. PONV is defined as nausea, retching and vomiting occurring during first 24-48 hrs after surgery, the three symptoms may occur separately or in combination¹. Overall incidence of PONV has been

reported to between 20% and 30% but can increase up to 80% in high risk patients.² Laparoscopic Cholecystectomy has emerged as a popular alternative to traditional open cholecystectomy in the management of cholelithiasis and Post operative nausea and vomiting is one of the main complaints after laparoscopy (40-75% of patients)³ and the most important factor determining the length of hospital stay after ambulatory anesthesia. Although PONV is almost always self limiting and non fatal, it can cause significant morbidity and remains an unpleasant and persistent clinical problem. In addition it has potential to adversely affect the patient in the form of delayed recovery, unexpected hospital stay, thereby increasing hospital cost patient⁴. At times it can lead to serious complications like aspiration of gastric contents, suture dehiscence, hematomas formation, dehydration and electrolyte imbalance. In fact many adult find PONV more distressing than postoperative pain⁵. Apfel *et al.*² identified female gender, non smoking status, previous history of PONV or motion sickness and use of opioids as the major risk factors. If none, 1,2,3 or 4 these factors are present, the incidence of PONV were 10%, 21%, 39%, 61% and 79% respectively. An ideal antiemetic medication for treatment of PONV should have quicker onset and longer duration of action and should have least undesirable side effects⁶. Clinical experience with Selective 5HT₃ receptor antagonists (Ondansetron, Granisetron, Ramosetron, Dolasetron, Tropisetron and Palonosetron) has demonstrated superior efficacy, safety and tolerability over conventional anti emetics. Selective 5HT₃ receptor antagonists block serotonin binding at vagal afferents in the gut and in the region of CNS involved in emesis including CTZ. The commonly used drug of 5HT₃ receptor antagonist group is Ondansetron. Ondansetron considered as a gold standard for the treatment of PONV. The studies have shown that it is more effective in preventing early but not late PONV. This may be due to its shorter duration of action though it claims to have duration of action of 4-12 hrs.⁷

AIMS AND OBJECTIVES

To study and compare the antiemetic efficacy of 5 Hydroxy Tryptamine -3 Receptor Antagonists (5HT₃RA) i.e. Ondansetron, Ramosetron and palonosetron in patients who are at high risk for PONV undergoing laparoscopic cholecystectomy.

MATERIAL AND METHOD

The present study was conducted in the postgraduate Department of Anesthesiology and Intensive Care at GMC Jammu. The study was initiated after getting clearance from the institutional ethics committee. For the purpose of study 150 female patients aged 20-55yrs with American Society of anesthesiology (ASA) -

physical status I or II scheduled for elective laparoscopic cholecystectomy of duration < 1 hour with known high risk of PONV were included in the study. Apfel simplified risk score was used to identify appropriate patient for enrolment in this study.

Risk factors that were considered were female gender, non smoking status, previous history of PONV or motion sickness and use of post operative opioids. Each risk factor carries a score of 1. Only patients with at least 2 risk factors (risk score 2-4) were enrolled. The patients enrolled were randomly allocated to 3 study groups according to simple random sampling and each group consist of 50 patients.

- Group O : patients received Ondansetron 4 mg i/v stat
- Group R : patients received Ramosetron 0.3 mg i/v stat
- Group P : patients received Palonosetron 0.075 mg i/v stat

Pre-aesthetic check-up was done one day before surgery and it included detailed history, thorough physical examination (General and systemic) and relevant investigation as per the Performa. Demographic profile including age, sex, height and weight were recorded and BMI calculated. An informed written consent was taken from all patients at the time of preanesthetic examination. Post operatively close monitoring was done for 48 hrs for either complete response of PONV or complain of nausea, retching, vomiting and need for rescue antiemetic at intervals of 0-2, 2-6, 6-12, 12-24 and 24-48 hours post surgery by direct questioning to the patient or to her attendant by the same anesthetist. Complete response is defined as no PONV and no need for rescue antiemetic medication within post operative 48 hours. Nausea was measured by using an 11 point numerical visual rating scale (VRS) with 0= no nausea and 10= nausea as bad as can be. A score of >5 was considered severe, 5= moderate and < 5 = minimal. The Moderate and severe nausea was considered as major nausea. Vomiting or retching episodes of > 2 was considered severe, 2 as moderate and <2 as mild. Rescues antiemetic in the form of injection Metoclopramide 10 mg i/v stat was given when nausea severity attained 5 or more on VRS, on patient request and after vomiting. If metoclopramide treatment was ineffective then injection Dexamethasone 8 mg i/v was given. The patients were also observed for side effects like headache, dizziness drowsiness and myalgia for 48 hours post operatively. Results were studied in terms of Figures and Proportions and comparisons were made. Statistical analysis of the data was done using Chi-Square test using SPSS-16 software.

RESULTS

Table 1: Demographic distribution of patients

	Group O	Group R	Group P
Age	38.32±10.59	38.36±9.15	38.94±9.99
Weight	58.94±5.09	59.04±4.81	58.08±5.84
Duration of surgery (min)	65.20±12.90	71.22±12.39	69.50±11.92

It was observed that the mean age of patients in the group O, R and P was 38.32±10.59yrs, 38.36±9.15 yrs and 38.94±9.99 yrs respectively. The mean weight of patients in the group O, R and P was 58.94±5.09kg, 59.04±4.81kg and 58.08±5.84kg respectively. The mean duration of surgery was 65.20±12.90min, 71.22±12.39min and 69.50±11.92 min in group O, R and P respectively. The difference observed in age, weight and duration of surgery was not significant in the three groups. Thus all the three groups were comparable with each other.

Table 2: Comparison according to visual rating scale for nausea

Post Operative Duration	Group	No	Mild	Moderate	Severe
0-2 hrs	Group O	45	5	0	0
	Group R	46	4	0	0
	Group P	48	2	0	0
2-6 hrs	Group O	46	4	0	0
	Group R	48	2	0	0
	Group P	48	2	0	0
6-12 hrs	Group O	42	8	0	0
	Group R	44	6	0	0
	Group P#§	50	0	0	0
12-24 hrs	Group O	37	9	4	0
	Group R	44	4	2	0
	Group P #§	50	0	0	0
24-48 hrs	Group O	39	9	2	0
	Group R	41	3	5	1
	Group P#§	50	0	0	0

* Statistically significant difference between Group O and Group R

Statistically significant difference between Group O and Group P

§ Statistically significant difference between Group R and Group P

It was observed that in group O, nausea was increasing with increase in post operative time. However in group P it was decreasing with increase in time. In group R nausea was more between 6 to 24hrs post operative duration. It was seen that 83.6% patients in Group O, 89.2% in Group R and 98.4% in Group P had No incidence of Nausea.

Table 3: Comparison of Vomiting in the groups

Post Operative Duration	Group	No	Mild	Moderate	Severe
0-2 hrs	Group O	46	3	1	0
	Group R	40	10	0	0
	Group P§	48	2	0	0
2-6 hrs	Group O	48	2	0	0
	Group R	46	4	0	0
	Group P	49	1	0	0
6-12 hrs	Group O	47	3	0	0
	Group R	43	7	0	0
	Group P	48	2	0	0
12-24 hrs	Group O	33	17	0	0
	Group R*	44	5	1	0
	Group P#	50	0	0	0
24-48 hrs	Group O	31	12	6	1
	Group R*	37	2	8	3
	Group P#§	50	0	0	0

* Statistically significant difference between Group O and Group R

Statistically significant difference between Group O and Group P

§ Statistically significant difference between Group R and Group P

It was evident from the table that the control over vomiting was significantly better in group P patients as compared to group O and R. No incidence of vomiting in 82.0% Group O, 84% in Group R and 98% in Group P.

Table 4: Comparison of Retching in the groups

Post Operative Duration	Group	No	Mild	Moderate	Severe
0-2 hrs	Group O	44	6	0	0
	Group R	48	2	0	0
	Group P	50	0	0	0
2-6 hrs	Group O	39	11	0	0
	Group R*	46	4	0	0
	Group P#§	50	0	0	0
6-12 hrs	Group O	42	8	0	0
	Group R	44	5	1	0
	Group P#§	50	0	0	0
12-24 hrs	Group O	40	10	0	0
	Group R	42	8	0	0
	Group P#§	50	0	0	0
24-48 hrs	Group O	40	8	2	0
	Group R	39	4	4	3
	Group P#§	50	0	0	0

No patient of retching was observed in the group P. In 82.0% Group O and 87.6% in Group R no incidence of Retching was observed. The difference observed in group P was statistically significant as compared to group O and group R.

Table 5: Comparison of use of rescue medicine in the groups

Post Operative Duration	Group	Yes	No
0-2 hrs	Group O	10	40
	Group R	5	45
	Group P#	2	48
2-6 hrs	Group O	4	46
	Group R	3	47
	Group P	2	48
6-12 hrs	Group O	7	43
	Group R	3	47
	Group P	2	48
12-24 hrs	Group O	18	32
	Group R	10	40
	Group P#§	0	50
24-48 hrs	Group O	18	32
	Group R	16	34
	Group P#§	0	50

It was observed that use of rescue medicine was more in group O and group R as compared to group P. Mean percentage of use of rescue medication in Group O, Group R and Group P was 22.8%, 14.8% and 2.4% respectively. The difference observed in use of rescue medicine in group P was statistically significant as compared to group O and group R.

DISCUSSION

It was observed that all the three groups Ondansetron (Group O), Ramosetron (Group R) and Palonosetron (Group P) were clinically matched with respect to patients demographic data (Age in years’ and weight in kg) and duration of surgery ($P > 0.05$) in our study. The risk of PONV is associated with various risk factors that include age, sex, smoking, prior history of PONV or motion sickness, postoperative use of opioids, anaesthetic techniques, type and duration of surgery and other as given by simplified risk score of PONV by Apfel *et al.*²

these factors were well balanced between the three groups in the present study. All enrolled patients were females, non smoker and underwent laparoscopic surgery, so all of them had at least 3 risk factors for PONV. So far as nausea is concerned we found that comparing the three groups 98.4%, 89.2% of patients in group P, Group R and Group O respectively did not have any incidence of nausea. Only 1.6% patients in palonosetron (Group P) had mild nausea at 0-6 hours post operatively. No patient had nausea of moderate or severe intensity. In Ramosetron (Group R) mild nausea was present in 7.6%

of patients, moderate in 2.8% and severe in 0.4%. Similarly in Ondansetron (group O) mild nausea was present in 14% and moderate in 2.4%. Nausea during early postoperative period may be attributable to the use of N₂O and CO₂ insufflation of peritoneal cavity during intraoperative period. On inter group comparison of Ondansetron (group O) with Ramosetron (Group R) number of patients having complete control of nausea were almost similar with 42, 44 patients respectively, till 12 hours period. The difference in the incidence of nausea was found to be statistically significant at 12-24 hours interval, where 13 patients in Ondansetron (group O) had nausea as compared to only 6 patients in Ramosetron (Group R). The severity of nausea according to VRS score was also more in Ondansetron (Group O) 16% as compared to Ramosetron (Group R) 10.4%. Our results were in accordance with results obtained by Hahm TS *et al.*⁸ and Banarjee D *et al.*⁹ who showed that Ramosetron was superior to Ondansetron as antiemetic both regarding frequency and severity. Similarly comparing Ondansetron (Group O) with Palonosetron (Group P) number of patients having complete control of nausea was almost similar with 9 and 4 patients respectively at 0-6 hrs interval and difference was statistically insignificant. The difference in incidence of nausea was statistically insignificant at 6-48 hours intervals ($P < 0.05$). No patient in group P suffers from moderate or severe nausea. Only 1.6% patients had an episode of mild nausea in Ondansetron (group O). Our results are in accordance with observation of Kim Y Y *et al.*¹⁰ who reported that the incidence of nausea was lower in the Palonosetron group than in the Ondansetron group (34% vs 56% $P = 0.027$). Our results are also in accordance with observations of Park S K *et al.*⁷ who showed the incidence of nausea and its severity were significantly lower in Palonosetron group than Ondansetron during 0-24hr.

On comparing Ramosetron (Group R) with palonosetron (Group P) we found that both faired equally well from 0-6 hours post operatively. However at 6-12 hours no nausea was seen in all 50 patients in Palonosetron (Group P) as compared to 44 patients in Ramosetron (Group R). After 12 hours of surgery again no patient complained of nausea in Palonosetron (Group P) whereas in Ramosetron (Group R) 7.6% patients had mild and 2.8% patients had moderate episode of nausea. The possible mechanism of Palonosetron and Ramosetron for prevention of PONV was similar but Palonosetron is further differentiated from other 5HT₃R antagonists by interacting with receptors in allosteric manner¹¹ and thus as expected we found lesser incidence of postoperative nausea in Palonosetron (Group P) than Ramosetron (Group R). Our study is in accordance Chattopadhyaya S *et*

*al.*¹² who showed that the severity of nausea was a lesser with Palonosetron than with Ramosetron during the 2-24 and 24-48 h. On comparing the three groups with respect to vomiting 98%, 84% and 82% in Group P, Group R and Group O respectively did not have any episode of vomiting. Only 2% patients in Palonosetron (Group P) had mild vomiting up to 12 hours post operatively and no patient had vomiting of moderate or severe intensity. Our results are in accordance with observation by Kim S H *et al.*¹⁰ who observed that the incidence of vomiting was lower in Palonosetron than in Ondansetron and Ramosetron. In Ramosetron (Group R) 11.2% patients presented with mild vomiting at all the study intervals up to 48 hours post operatively. Similarly in Ondansetron (Group O) 14.8% presented with mild vomiting, 2.8% with moderate and 0.04% with severe vomiting. On inter group comparison of Ondansetron (Group O) with Ramosetron (Group R) at 0-2, 2-6, 6-12, 24-48 hours the difference was statically insignificant. However the difference in incidence of vomiting was found to be statistically significant at 12-24 hours intervals where 17 patients had vomiting in Ondansetron (Group O) as compared to only 6 patients in Ramosetron (Group R). The severity of vomiting was also more in Ondansetron (Group O) 18% as compared to Ramosetron (Group R) 16%. Our Results are also in accordance with observation of Kim S I *et al.*¹⁰ who reported no significant difference in the incidence of vomiting between the Ramosetron 0.3mg and ondansetron 8mg.

Our results are also match those of Choi *et al.*¹³ who observed, overall incidence of vomiting at 6 to 24 hours after surgery was significantly lower in the Ramosetron group than Ondansetron. Similarly comparing the Ondansetron (Group O) with Palonosetron (Group P) we found the incidence of vomiting to be statistically significant at 12-24 hours and 24-48 hours ($P < 0.05$). No Patient in Palonosetron (Group P) Suffered moderate or severe vomiting, only 2% patient had episode of mild vomiting and that too from 0-12 hours intervals as against 14.8% of severe vomiting in Ondansetron (Group O) at all intervals from 0-48 hours. Our results are in accordance with observation of Moon Y E *et al.*¹⁴ who showed the incidence of vomiting was significantly lower in Palonosetron group than Ondansetron during 2-24 hr. Our results are also in accordance with those of Candotii K A *et al.*¹⁵ who observed less emesis in the 0-72 h time period favouring Palonosetron. On comparing Ramosetron (Group R) and Palonosetron (Group P) we found the incidence of vomiting was only 2% in Palonosetron (Group P) as compared to Ramosetron (Group R) where 11% had mild vomiting, 36% had moderate and 1.2% had severe vomiting however the difference was not statistically significant from 0-12

hours post operatively. At 12-24 hours intervals complete control of vomiting was seen in all the patients in Palonosetron (Group P) as compared to only 44 patients in Ramosetron (Group R) this difference was found to be statistically significant.

Similarly the results were also statistically significant at 24-48 hours as no patient complained of vomiting in Palonosetron (Group P) as compared to 37 patients in Ramosetron (Group R). Our results are in accordance with Kim SH *et al.*¹⁰ who observed that incidence of vomiting was lower in Palonosetron 5.6% that in Ondansetron 28.6% and Ramosetron 18.4% during 48 hours period. Our results are also in accordance with Park S K *et al.*⁷ who reported the incidence of vomiting was significantly lower in the Palonosetron group than in the Ramosetron group during 0-6 hr and 0-48 hr. No patient in the Palonosetron (Group P) complained of retching as compared to 18% in Ondansetron (Group O) and 12.4% in Ramosetron (Group R). On inter group comparison of Ondansetron (group O) with Ramosetron (Group R) at different time intervals, we found the difference to be statistically significant at 2-6, 6-12, 24-48 hours interval. Our results were in accordance with She Y *et al.*¹⁶ who observed that Ramosetron was a long-lasting better than ondansetron so far as control of retching was concerned. Similarly on comparing Ondansetron (Group O) with Palonosetron (Group P) we found the difference in incidence of retching to be statistically significant at all intervals from 0-48 hours ($P < 0.05$) as no patient in Palonosetron (Group P) suffers from retching compared to 19% patients having mild to moderate retching in Ondansetron (Group O). Likewise on comparing Palonosetron (Group P) with Ramosetron (Group R) the difference in incidence of retching was statistically significant at all time intervals ($P < 0.05$) as against 11.4% patients in Ramosetron (Group R) had mild to severe retching. Our Results are in accordance with Kim S H *et al.*¹⁰ who observed that the incidence of Retching was lower in Palonosetron than Ondansetron and Ramosetron. In Palonosetron (Group P) only 2.4% patient require rescue antiemetic where as in Ramosetron (Group R) 14.8% and in Ondansetron (Group O) 22.8% had need of rescue antiemetic. The difference observed in use of rescue medicine in group P was statistically significant as compared to group O and group R. Our results were in accordance with Lee W K *et al.*¹⁷ and Laha B *et al.*¹⁸

CONCLUSION

Thus we concluded that a single injection of 0.075 mg of Palonosetron was more effective in preventing PONV and reduced the need of use rescue antiemetic compared to an injection of 4 mg of ondansetron or 0.3 mg of

Ramosetron in patients who are at high risk for PONV scheduled for laparoscopic cholecystectomy.

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Source of Support: None Declared
Conflict of Interest: None Declared