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ORIGINAL RESEARCH

A comparative study between ramosetron and palonosetronin preventing postoperativenausea and vomitinginlaparoscopic surgeries

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Abstract

Background: Postoperative nausea and vomiting (PONV) are one of the most distressing symptoms that commonly seen after surgeries under general anesthesia. The present study was conducted to compare Ramosetron and Palonosetron in patients undergoing laparoscopic cholecystectomy.

Materials & Methods: 60 patients undergoing elective laparoscopic cholecystectomy surgeries under general anesthesia of both genders were divided into 2 groups of 30 each. Group I received injection ramosetron 0.3 mg and Group II received injection palonosetron 0.075 mg intravenous bolus immediately before the induction of anesthesia. Parameters such as weight, height, BMI, mean duration of surgery (min), duration of anesthesia (min), the incidence of PONV, adverse effects of the study drugs, and need for rescue antiemetics were recorded over the next 48 hours.

Results: The mean weight (Kg) in group I and II was 70.3 and 74.2, height (cm) was 162.8 and 163.2, BMI (kg/m2) was 20.4 and 21.7, duration of anesthesia (min) was 102.5 and 98.5 and duration of surgery (min) was 140.5 and 136.3 respectively. The difference was significant (P< 0.05). At 0-3 hours, complete response was seen in 82% and 90%, nausea in 10% and 7%, retching in 3% and 2%, vomiting in 5% and 1%. At 3-24 hours, complete response was seen in 80% and 85%, nausea in 12% and 5%, retching in 2% and 4%, vomiting in 6% and 6%. At 24-483 hours, complete response was seen in 67% and 92% in group I and II respectively. The difference was significant (P< 0.05).

Conclusion: Palonosetron is more effective than prophylactic therapy with ramosetron for the long-term prevention of PONV after laparoscopic surgery.

Key words: laparoscopic surgery, Palonosetron, ramosetron

Introduction

Postoperative nausea and vomiting (PONV) are one of the most distressing symptoms that commonly seen after surgeries under general anesthesia, the incidence being around 25% in adults.[1] Adverse consequences of PONV may range from delayed recovery to unexpected prolonged hospital stay. Prevention and treatment of PONV helps in accelerating postoperative recovery and early discharge and thereby increases patient satisfaction.[2]

Palonosetron is a second-generation 5-HT3 receptor antagonist with proposed higher efficacy and sustained action for prophylaxis of postoperative nausea and vomiting (PONV).[3]Recent

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receptor binding studies suggest that palonosetron is further differentiated from other 5-HT3 antagonists by interacting with 5-HT3 receptors in an allosteric, positively cooperative manner at sites different from those that bind with ondansetron and granisetron.[4]Palonosetron provides better protection against chemotherapy-induced nausea and vomiting than the older 5-HT3 drugs (including ondansetron) throughout the 5-day postchemotherapy period prompted the study of palonosetron as an antinausea and antiemetic drug with potentially long-lasting efficacy against postoperative nausea and vomiting (PONV) in at-risk patients.[5] Ramosetron is a newer long-acting selective 5-HT_3 receptor antagonist. It exhibits a higher affinity toward the serotonin receptors with a slower dissociation, resulting in a longer duration of action.[6]The present study was conducted to compare Ramosetron and Palonosetron in patients undergoing laparoscopic cholecystectomy.

Materials & Methods

The present study comprised of 60 patients undergoing elective laparoscopic cholecystectomy surgeries under general anesthesia of both genders. All gave their written consent for their participation in the study.

General information regarding name, age, gender etc. was recorded. Patients were divided into 2 groups of 30 each. Group I received injection ramosetron 0.3 mg and Group II received injection palonosetron 0.075 mg intravenous bolus immediately before the induction of anesthesia. Parameters such as weight, height, BMI, mean duration of surgery (min), duration of anesthesia (min), the incidence of PONV, adverse effects of the study drugs, and need for rescue antiemetics were recorded over the next 48 hours. Results were assessed using chi-m square test. P value less than 0.05 was considered significant.

Results

Table I Distribution of patients

Groups	Group I	Group II
Drug	0.3 mg ramosetron	0.075 mg palonosetron
M:F	20:10	16:14

Table I shows that group I had 20 males and 10 females and group II had 16 males and 14 females.

Table II Demographic data

Parameters	Group I	Group II	P value
Weight (Kg)	70.3	74.2	0.91
Height (cm)	162.8	163.2	0.82
BMI (kg/m2)	20.4	21.7	0.78
Duration of anesthesia (min)	102.5	98.5	0.94
Duration of surgery (min)	140.5	136.3	0.12

Table II, graph I shows that mean weight (Kg) in group I and II was 70.3 and 74.2, height (cm) was 162.8 and 163.2, BMI (kg/m2) was 20.4 and 21.7, duration of anesthesia (min) was 102.5 and 98.5 and duration of surgery (min) was 140.5 and 136.3 respectively. The difference was significant ($P< 0.05$).

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Graph IDemographic data

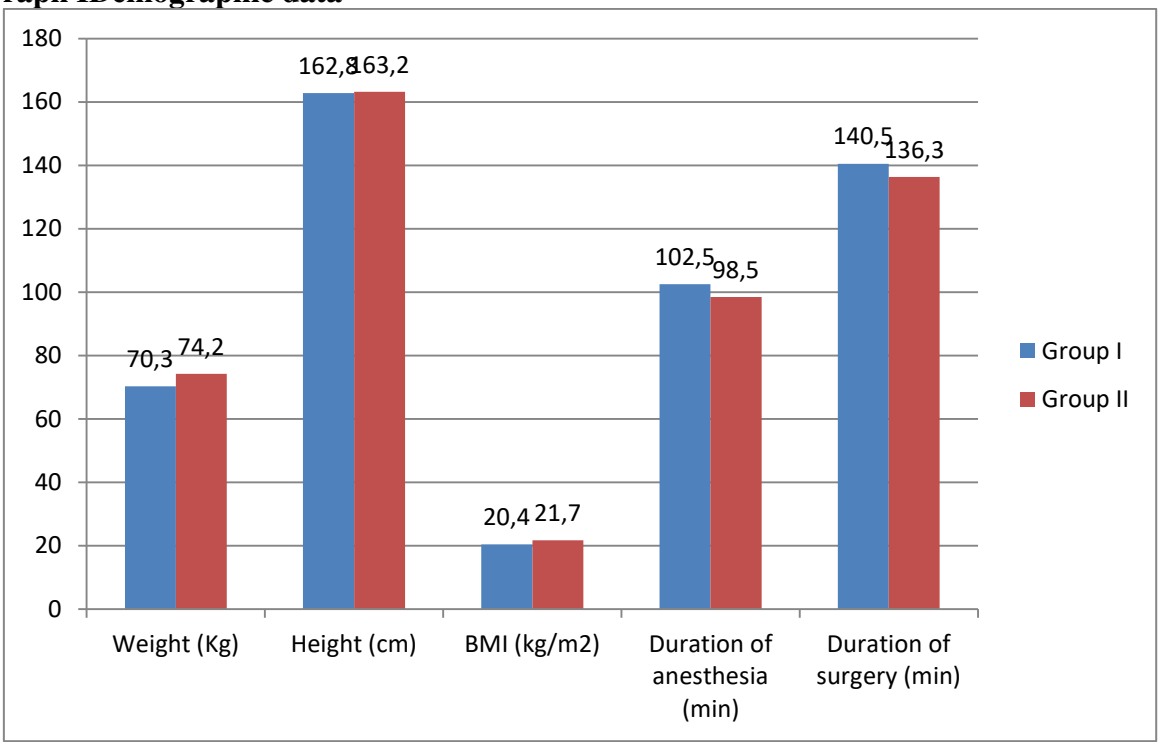

Table III Assessment of PONV

Post- operative period	Variables	Group I	Group II	P value
0-3 hours	Complete response	82%	90%	0.93
	nausea	10%	7%	0.81
	retching	3%	2%	0.75
	vomiting	5%	1%	0.94
	Rescue entiemetic	0	0	0
3-24 hours	Complete response	80%	85%	0.94
	nausea	12%	5%	0.04
	retching	2%	4%	0.15
	vomiting	6%	6%	1
	Rescue entiemetic	0	0	0
24-483 hours	Complete response	67%	92%	0.05

Table III, graph II shows that at 0-3 hours, complete response was seen in 82% and 90%, nausea in 10% and 7%, retching in 3% and 2%, vomiting in 5% and 1%. At 3-24 hours, complete response was seen in 80% and 85%, nausea in 12% and 5%, retching in 2% and 4%, vomiting in 6% and 6%. At 24-483 hours, complete response was seen in 67% and 92% in group I and II respectively. The difference was significant (P< 0.05).

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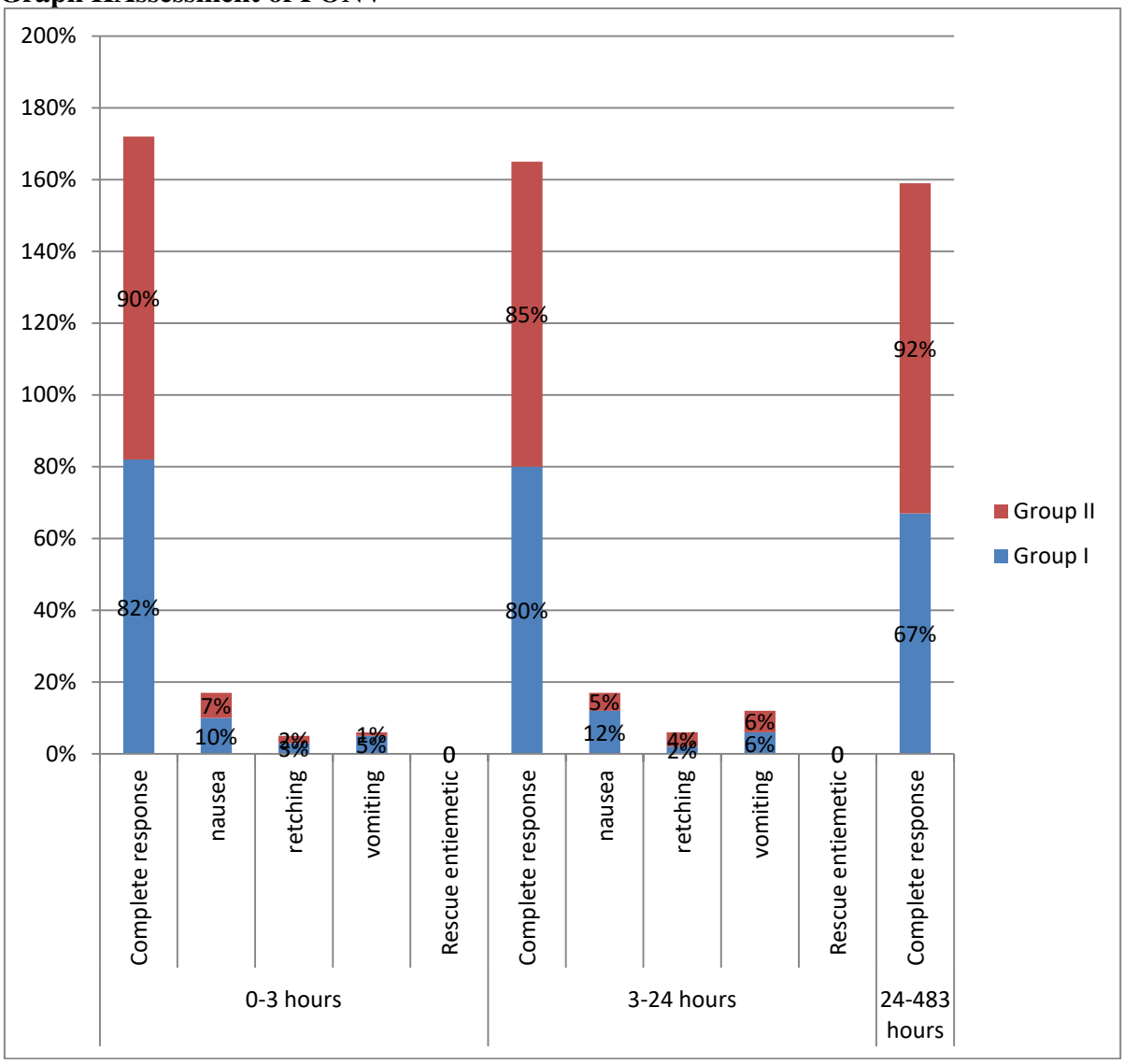
Graph IIAssessment of PONV



Discussion

Recently selective serotonin receptor (5-hydroxytryptamine type 3 [5-HT_3]) antagonists are considered first line in the management of PONV, due to their proven efficacy and favorable side effect profile.[7] 5-HT_3 antagonists act by preventing serotonin binding to 5-HT_3 receptors, which present on the vagus afferent nerve endings, which send signals directly to the vomiting center in the medulla oblongata and in the chemoreceptor trigger zone (CTZ) of the brain.[8] By preventing activation of these receptors, 5-HT_3 antagonists interrupt one of the pathways leading to vomiting.[9]The present study was conducted to compare Ramosetron and Palonosetron in patients undergoing laparoscopic cholecystectomy.

We found that group I had 20 males and 10 females and group II had 16 males and 14 females. Kovac et al[10]assessed the efficacy and safety of three doses of palonosetron, compared with placebo, on the incidence and severity of postoperative nausea and vomiting (PONV) in inpatients for 72 h after surgery. Female patients undergoing either elective gynecological or breast surgery were stratified according to two additional PONV risk factors: nonsmoking status and history of PONV and/or motion sickness. Five hundred forty-four patients with one or both of these risk factors were randomized to receive one of the three doses of IV palonosetron (0.025 mg, 0.050 mg, 0.075 mg) or placebo immediately before induction of anesthesia. The primary efficacy end-point was complete response

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evaluated at the 0–24 and 24–72 h time intervals after surgery. CR rates for placebo and palonosetron 0.075 mg were 36% and 56% for 0–24 h, 52% and 70% for 24–72 h and 36% and 52% for the 0–72 h postoperative interval. Palonosetron 0.075 mg was associated with less intense nausea (e.g., toward "mild" or "none") versus placebo during the 0–24 h (P 0.001) time interval and significantly delayed median time to emesis and treatment failure. Although CR rates for both the 0.025 mg and 0.050 mg palonosetron doses were not statistically superior to placebo for the 0–24 h or 24–72 h periods, both lower doses reduced nausea severity during the 0–24 h period.

We found that mean weight (Kg) in group I and II was 70.3 and 74.2, height (cm) was 162.8 and 163.2, BMI (kg/m2) was 20.4 and 21.7, duration of anesthesia (min) was 102.5 and 98.5 and duration of surgery (min) was 140.5 and 136.3 respectively. Reddy et al[11] in their study a total number of 80 patients, undergoing elective laparoscopic cholecystectomy surgeries under general anesthesia, were randomly assigned to one of the two equal groups to receive either of the following: Group R - received injection ramosetron 0.3 mg and Group P - received injection palonosetron 0.075 mg intravenous bolus immediately before the induction of anesthesia. The incidence of PONV, adverse effects of the study drugs, and need for rescue antiemetics were recorded over the next 48 h. Primary outcome was the incidence of PONV. Secondary outcomes were adverse effects of the study drugs and need for rescue. The incidence of a complete response (no PONV and no rescue medication) during 0-3 h in the postoperative period was 82.5% with ramosetron and 90% with palonosetron; the incidence during 3-24 h postoperatively was 80% with ramosetron and 87.5% with palonosetron. During 24-48 h, the incidence was 65% and 90%, respectively. The incidences of adverse effects were statistically insignificant between the groups.

We found that at 0-3 hours, complete response was seen in 82% and 90%, nausea in 10% and 7%, retching in 3% and 2%, vomiting in 5% and 1%. At 3-24 hours, complete response was seen in 80% and 85%, nausea in 12% and 5%, retching in 2% and 4%, vomiting in 6% and 6%. At 24-483 hours, complete response was seen in 67% and 92% in group I and II respectively. Chun et al[12]evaluated the efficacy of palonosetron, the latest 5-HT3 receptor antagonist, for the prevention of postoperative nausea and vomiting (PONV) during the first 72 h after operation. 204 healthy inpatients who were undergoing elective surgery with general anaesthesia were enrolled. Patients were divided into two groups: the palonosetron group (palonosetron 0.075 mg i.v.; n=102) and the placebo group (normal saline i.v.; n=102). The treatments were given after the induction of anaesthesia. The incidence of nausea, vomiting, severity of nausea, and the use of rescue anti-emetics during the first 72 h after surgery were evaluated. The incidence of PONV was lower in the palonosetron group compared with the placebo group during the 0-24 h (33% vs 47%) and 0-72 h period (33% vs 52%) but not during the 24-72 h postoperative period (6% vs 11%). The incidence of nausea was also significantly lower in the palonosetron group than in the placebo group during the 0-24 and 0-72 h period (P<0.05), but not during the 24-72 h postoperative period. However, there were no significant differences in the incidence of vomiting, and the use of rescue anti-emetics between the groups.

Conclusion

Authors found thatpalonosetron is more effective than prophylactic therapy with ramosetron for the long-term prevention of PONV after laparoscopic surgery.

References

1. Agarkar S, Chatterjee AS. Comparison of ramosetron with ondansetron for the prevention of post-operative nausea and vomiting in high-risk patients. *Indian J Anaesth.* 2015;59:222–7.

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2. Gan TJ, Diemunsch P, Habib AS, Kovac A, Kranke P, Meyer TA, et al. Consensus guidelines for the management of postoperative nausea and vomiting. *AnesthAnalg.* 2014;118:85–113.
3. Salmenperä M, Kuoppamäki R, Salmenperä A. Do anticholinergic agents affect the occurrence of postanaesthetic nausea? *ActaAnaesthesiol Scand.* 1992;36:445–8.
4. Islan S, Jain PN. PONV: A review article. *Indian J Anaesth.* 2004;48:253–8.
5. Mihara T, Tojo K, Uchimoto K, Morita S, Goto T. Reevaluation of the effectiveness of ramosetron for preventing postoperative nausea and vomiting: A systematic review and meta-analysis. *AnesthAnalg.* 2013;117:329–39.
6. Barrat A, Wyer PC, Hatala R, McGinn T, Dans AL, Keitz S, Moyer V, For GG. Evidence-Based Med Teaching Tips Working Group. Tips for learners of evidence-base medicine: 1. Relative risk reduction, absolute risk reduction and number needed to treat. Can Med Assoc J 2004;171:353–8.
7. Apfel CC, Korttila K, Abdalia M. A factorial trial of six interventions for the prevention of postoperative nausea and vomiting. N Engl J Med 2004;350:2441–51.
8. Apfel CC, La¨a¨ra¨ E, Koivuranta M, Greim C-A, Roewer N. A simplified risk score for predicting postoperative nausea and vomiting. Anesthesiology 1999;91:693–700.
9. Hirsch J. Impact of postoperative nausea and vomiting in the surgical setting. Anaesthesia 1994;49:30–3.
10. Kovac AL, Eberhart L, Kotarski J, Clerici G, Apfel C, Palonosetron 04-07 Study Group. A randomized, double-blind study to evaluate the efficacy and safety of three different doses of palonosetron versus placebo in preventing postoperative nausea and vomiting over a 72-hour period. Anesthesia & Analgesia. 2008 Aug 1;107(2):439-44.
11. Reddy GS, Manjusruthi B, Jyothsna G. Postoperative nausea and vomiting prophylaxis: A comparative study of ramosetron and palonosetron in patients undergoing laparoscopic cholecystectomy–A prospective randomized trial. Anesthesia, Essays and Researches. 2019 Jan;13(1):68.
12. Chun HR, Jeon IS, Park SY, Lee SJ, Kang SH, Kim SI. Efficacy of palonosetron for the prevention of postoperative nausea and vomiting: a randomized, double-blinded, placebo-controlled trial. British journal of anaesthesia. 2014 Mar 1;112(3):485-90.