

# A study to compare ramosetron and ondansetron for prevention of post-operative nausea and vomiting in patients undergoing laparoscopic cholecystectomy under general anesthesia



Amit Dahiya<sup>1</sup>, Rashmi<sup>2</sup>, Vasudha Govil<sup>3</sup>, Suraj Garg<sup>4</sup>, Ruchika Singhmar<sup>5</sup>, Radhika Malik<sup>6</sup>

<sup>1</sup>Consultant Anaesthesia, Department of Cardiac Anaesthesia, Holy Heart Hospital, <sup>2</sup>Senior Resident, <sup>3</sup>Associate Professor, <sup>4,5,6</sup>Junior Resident, Department of Anesthesia and Critical Care, Pt. B. D. Sharma PGIMS, Rohtak, Haryana, India

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## ABSTRACT

**Background:** The incidence of nausea and vomiting following laparoscopic cholecystectomy is very high. 5-hydroxytryptamine receptor antagonists are drug of choice for prevention of post-operative nausea and vomiting (PONV) because of their good efficacy and very few side effects in comparison to other antiemetics. **Aims and Objectives:** This study was undertaken to compare the efficacy and safety of intravenous ramosetron 0.3 mg and ondansetron 8 mg for prevention of PONV in patients undergoing laparoscopic cholecystectomy under general anesthesia. **Materials and Methods:** One hundred patients between 18 and 70 years of age with American Society of Anesthesiology Grade I and II scheduled for elective laparoscopic cholecystectomy were randomly divided into two groups of 50 patients each. Group A patients were given injection ondansetron 8 mg and Group B patients were given injection ramosetron 0.3 mg approximately 5 min just before the induction of general anesthesia. **Results:** Difference in Nausea, vomiting/retching, and PONV score assessed at 4, 8, 12, and 24 h interval postoperatively in both groups was found to be statistically insignificant ( $P > 0.05$ ). The severity of nausea was assessed by visual analogue scale at various time intervals and use of rescue antiemetics in both the groups were found statistically insignificant. Incidence of side effects was also comparable in both the groups. **Conclusion:** Ramosetron and ondansetron are equally effective for prevention of PONV in patients who underwent elective laparoscopic cholecystectomy under general anesthesia when used prophylactically. Both drugs are safe and have low incidence of side effects.

**Key words:** Laparoscopic cholecystectomy; Ondansetron; Post-operative nausea and vomiting; Ramosetron; Visual analog scale

## INTRODUCTION

Nausea and vomiting in the post-operative period are one of the most common complications of anesthesia and surgery.<sup>1</sup> Incidence of post-operative nausea and vomiting (PONV) is 30–40% and in high risk group; it is up to 80%.<sup>2</sup> PONV is very distressing to patients and can also lead to a number of medical complications such as bleeding, wound dehiscence, electrolyte imbalance,

aspiration of gastric contents, and delayed discharge from hospital.<sup>3</sup>

Use of nitrous oxide, opioids, and volatile anesthetic agents are anesthesia-related risk factors which increases the risk of PONV.<sup>1</sup> Apfel's simplified score is one of the scoring systems which include risk factors like history of PONV or motion sickness, female sex, non-smoker, and use of opioids postoperatively.<sup>4</sup> These risk factors are associated

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### Address for Correspondence:

Dr. Vasudha Govil, Associate Professor, Department of Anesthesia and Critical Care, Pt. B. D. Sharma PGIMS, Rohtak, Haryana, India.

**Mobile:** +91-9466236862. **E-mail:** [vasudha\\_govil@yahoo.com](mailto:vasudha_govil@yahoo.com)

with increase in incidence of nausea and vomiting and presence of one, two, three, or all factors associated with 20%, 40%, and 60% increase in incidence of nausea and vomiting postoperatively.<sup>5</sup>

Laparoscopic cholecystectomy is treatment of choice for symptomatic cholelithiasis but the incidence of nausea and vomiting following laparoscopic cholecystectomy is as high as 46–72%.<sup>6</sup>

5-hydroxytryptamine (5HT<sub>3</sub>) receptor antagonists are drug of choice for prevention of PONV because of their good efficacy and very few side effects in comparison to other antiemetics.<sup>7</sup> Researches on 5HT<sub>3</sub> receptor antagonists were mainly focused on ondansetron and its antiemetic properties were well proven in chemotherapy induced nausea and in prevention and treatment of PONV.<sup>8</sup> Ramosetron is a recent drug in the 5HT<sub>3</sub> receptor antagonist group with greater affinity for the 5HT<sub>3</sub> receptors and slow rate of dissociation, proving it to be more potent and longer acting compared to other older drugs of this group.<sup>9</sup>

In the previous studies, it was proven that ramosetron is more potent and have longer duration of action than granisetron in the prevention of PONV, but there are few studies comparing ramosetron and ondansetron.<sup>10</sup> Hence, we had designed a prospective, randomized, and double blind study to compare the antiemetic efficacy of ramosetron and ondansetron in patients planned to undergo laparoscopic cholecystectomy under general anesthesia. The primary objective of the study is to compare the incidence and severity of nausea and vomiting postoperatively between the ramosetron and ondansetron groups and the secondary objective is to observe any side effects of drugs under study during and post-operative period.

### Aims and objectives

1. To compare the severity and incidence of post operative nausea and vomiting between Ramosetron and Ondansetron groups in patients of laparoscopic cholecystectomy under general anaesthesia.
2. To observe any side effects of drugs under study during and post operative period.

## MATERIALS AND METHODS

After obtaining approval from the Institutional Ethical Committee, the prospective, randomized, and double-blind study was conducted in our institute on 100 adult patients with ASA Grade I and II between 18 and 70 years of age planned to undergo elective laparoscopic cholecystectomy under general anesthesia.

Inclusion criteria included patient who had signed a written and informed consent form, 18–70 years old patients of either sex with ASA Grade I and II planned to undergo laparoscopic cholecystectomy and willing to complete the study until the end of 24-h postoperatively.

Exclusion criteria included patients with ASA Grade III, IV, or V, pregnant, breast feeding, taking opioids regularly or for more than 3 consecutive days before surgery, had persistent or recurrent nausea and/or vomiting due to other etiologies, history of retching, vomiting, or uncontrolled nausea within past 48 h before the administration of study drug or had received any medication with an antiemetic activity within 24 h before receiving the study drugs, patients with a history of uncontrolled diabetes mellitus, tuberculosis, and any other systemic infection. Immunocompromised patients with white blood cell count of <3000/mm<sup>3</sup>, and patients with a history of hypersensitivity or contraindication to any of the study drugs or any other 5-HT<sub>3</sub> receptor antagonist or to any scheduled anesthetic or analgesic agents.

Sample size of 100 patients was divided into two groups of 50 patients each. Group A patients received inj ondansetron 8 mg intravenously and Group B patients received inj ramosetron 0.3 mg intravenously 5 min prior to induction. Study drug was prepared and kept in number sealed envelopes by trained staff not participating in the study. Randomization was done by using chit and box method. Figure 1 shows the consort flow chart describing the study design.

### Procedure

On patients arrival in the operation theater fasting status, informed written consent and pre-anesthetic checkup of the patients were checked. Pre-operative vitals such as pulse, blood pressure, electrocardiogram, and saturation of the patients were recorded and an intravenous line was secured with 20 gauge cannula. Patients in Group A were given inj ondansetron 8 mg with the total volume 4 mL and patients in Group B were given inj ramosetron 0.3 mg with saline solution added to bring the total volume to 4 mL intravenously 5 min before induction. Premedication was given to patients with intravenous inj midazolam 0.02 mg/kg and inj glycopyrolate 0.004 mg/kg. Patients were preoxygenated with 100% oxygen for 3 min. Induction was done inj fentanyl 2 µg/kg and inj propofol 2 mg/kg. Inj succinylcholine 2 mg/kg was given as muscle relaxant and patient was intubated with appropriate size endotracheal tube. Anesthesia was maintained with isoflurane 1–2.5% and nitrous oxide in oxygen. During anesthesia, inj vecuronium bromide was used as intravenous boluses for muscle relaxation. Inj neostigmine 0.05 mg/kg and inj glycopyrrolate 0.008 mg/kg were used as reversal

at the end of surgery and patients were extubated. Inj diclofenac sodium 1 mg/kg intramuscularly was given to all the patients before shifting for post-operative analgesia. Patient's vitals were monitored postoperatively at the time intervals of 0<sup>th</sup>, 4<sup>th</sup>, 8<sup>th</sup>, 12<sup>th</sup>, and 24<sup>th</sup> h. Inj metochlopramide 10 mg intravenously was used as rescue medication when required.

Patients were assessed at the time intervals of 4 h till 24 h PONV. For the assessment of nausea; (visual analogue scale [VAS]; 0 – no nausea; 1, 2, 3 – mild nausea; 4, 5, 6 – moderate nausea; 7, 8, 9 – severe nausea; and 10 – worst nausea) was used. Retching and vomiting were assessed by simply questioning for yes or no. No retching or vomiting was given score 0, if present it was given score 1.<sup>11</sup>

Nausea was defined as an unpleasant sensation to vomit without any actual muscular contraction of gastrointestinal system but in vomiting, there was muscular contraction and expulsion of contents of the upper gastrointestinal system through mouth and retching was an attempt to vomit with no stomach contents expelled. Inj metoclopramide 10 mg intravenously was permitted as rescue medication for PONV. If no rescue medication was given, it was scored as 0 and if used then it was scored as 1.

Patient was said to have complete response if there was no episode of nausea and vomiting/retching and had not received any rescue medication during the whole study period. Side effects of the drugs such as headache, dizziness and constipation were recorded postoperatively.

The sample size was calculated at 80% study power at alpha level of 0.05 assuming incidence of PONV reduced to 0.4 from basal incidence of 0.7. For statistical calculations, Student's t-test and Chi-square test were used.  $P < 0.05$  was considered significant.

## RESULTS

Total 100 patients were included in the study, of which 50 patients receiving inj ondansetron 8 mg intravenously were included in Group A and 50 patients receiving inj ramosetron 0.3 mg intravenously were randomly allocated in Group B (Table 1).

Vitals of the patients (pulse and blood pressure) were recorded preoperatively, intraoperatively (at mid of surgery), and postoperatively on awakening and at 4, 8, 12, and 24 h for both the groups. P-value was calculated at each time interval and it was found statistically insignificant in both groups ( $P > 0.05$ ).

In the first 4 h (0–4 h) after recovery from anesthesia, 9 patients (18%) in Group A and 5 patients (10%) in Group B suffered from Nausea. 4–8 h post-anesthesia, 6 patients (12%) in Group A and 6 patients (12%) in Group B suffered from nausea. Whereas there were 6 patients (12%) in Group A and 4 patients (8%) in Group B who suffered from nausea in 8–12 h time period after recovery from anesthesia. Nine (18%) and 5 (10%) patients suffered from nausea in Group A and Group B, respectively, in 12–24 h time period after anesthesia. When total number of patients who suffered from nausea were counted, it was found statistically insignificant. There were 23 (46%) patients in Group A and 15 patients (30%) in Group B who suffered from nausea in whole 24 h study period after recovery from anesthesia with  $P = 0.099$  (Table 2).

In first 4 h (0–4 h) after recovery from anesthesia, 3 patients (6%) in Group A and 2 patients (4%) in Group B suffered from vomiting/retching. In 4–8 h time period after anesthesia, 4 patients (8%) in Group A and 3 patients (6%) in Group B suffered from vomiting/retching, whereas there were 5 patients (10%) in Group A and 3 patients (6%) in Group B who suffered from vomiting/retching in 8–12 h time period after recovery from anesthesia. Six (12%) and 2 (4%) patients suffered from vomiting/retching in Group A and Group B, respectively, in 12–24 h time period after anesthesia. When total number of patients who suffered from vomiting/retching was counted, it was found statistically insignificant. There were 18 (36%) patients in Group A and 10 patients (20%) in Group B who suffered from vomiting/retching in whole 24 h study period after recovery from anesthesia ( $P = 0.074$ ) (Table 3).

PONV score was also calculated at different time intervals. PONV score means the total number of the patients who suffered either from nausea or emesis (vomiting/retching) or if needed rescue medication. PONV score was calculated for whole 24 h period, it was 28 patients (56%) and 19 patients (38%) in Group A and Group B, respectively, and the difference was found statistically insignificant ( $P = 0.071$ ).

**Table 1: Demographic variables**

Observation	Group A Ondansetron	Group B Ramosetron	P-value
Male	18%	20%	0.798
Female	82%	80%	
Mean age (years)	42.5	42.96	0.840
Duration of surgery (minute)	53.38±4.90	53.36±5.07	0.984
Duration of anesthesia (minute)	65.54±5.01	65.64±5.06	0.921

**Table 2: 0–24 h comparison of nausea, vomiting/retching, PONV score**

Observation	Group A (Ondansetron) n*(%)	Group B (Ramosetron) n*(%)	P-value
Nausea	23 (46)	15 (30)	0.099
Vomiting/Retching	18 (36)	10 (20)	0.074
PONV score	28 (56)	19 (38)	0.071

(Chi-square test). \*Total no. of the patients is taken, PONV: Post-operative nausea and vomiting

**Table 3: Comparison of VAS score Mean±SD in both groups**

Observation time	Group A (Ondansetron)	Group B (Ramosetron)	P-value
0–4 h	4.11±1.36	3.80±0.84	0.654
4–8 h	3.83±0.98	4.33±1.21	0.450
8–12 h	4.00±2.19	4.00±0.82	1.000
12–24 h	4.44±1.01	3.80±0.84	0.251
0–24 h	5.39±2.23	5.33±2.35	0.939

(Unpaired student's t-test), VAS: Visual analogue scale

The above table clearly shows the 24 h comparison in both groups regarding nausea, emetic episodes (vomiting/retching) and overall PONV score. P-value calculated in all the cases was found to be statistically insignificant ( $P>0.05$ ).

The severity of nausea was also assessed and nausea was labeled according to VAS scale in both groups. Scores in between 0 and 4 were categorized as mild whereas score in between  $>4-6$  and  $>6-10$  categorized as moderate and severe, respectively.

The above table clearly shows that most of the patients had mild or moderate degree of nausea. P-value calculated at different intervals and it shows a statistically insignificant difference in these two groups regarding severity of nausea ( $P>0.05$ ).

Total number of patients who received rescue medication were 20 (40%) in Group A and 12 (24%) in Group B, difference is statistically insignificant ( $P=0.086$ ).

There were 22 (44%) patients in Group A and 31 patients (62%) in Group B who were having a complete response in whole 24-h study period ( $P=0.071$ ).

The common adverse events in both groups were headache and dizziness. One patient in Group A had constipation. Total number of patients who had adverse effects were 6 (12%) in Group A and 3 (6%) in Group B, difference was statistically insignificant ( $P=0.294$ ) (Table 4).

## DISCUSSION

PONV is very frequent complaint following surgery and anesthesia and causes a big distress to the patients. Etiology of PONV is still not understood properly, but it is suggested that multiple factors such as age, obesity, prior history of PONV, gender, non-smoker, anesthesia technique, surgical procedure, and duration, post-operative use of opioids, and ambulation are responsible for it and having one or more of these factors increases the incidence of PONV.<sup>4</sup>

Various drugs and regimens have been tried with variable success rates. The 5HT<sub>3</sub> receptor antagonists are an attractive option because of their effectiveness in prevention and treatment of PONV.<sup>12</sup> There is low incidence of side effects with 5HT<sub>3</sub> receptor antagonists and are safe to use.<sup>12</sup>

Ondansetron is a prototypical drug in this group and has been used over the years for prevention of PONV. For prevention of PONV, two doses of ondansetron have been recommended, that is, 4 mg and 8 mg intravenously. In our study, we had taken eight mg dose of ondansetron because there was meta-analysis by Tramer et al., in which they found out eight mg dose of ondansetron as an optimal dose for prevention of PONV.<sup>13</sup>

Ramosetron is more potent and has long receptor antagonizing effect.<sup>14</sup> It has a half-life of 9 h which is more in comparison to ondansetron 3.5 h, because of all these properties, it is more potent and long acting 5HT<sub>3</sub> receptor antagonist.<sup>9</sup> Fujii et al., conducted a study on PONV in patients who underwent major gynecological surgery and in their study; they found out 0.3 mg ramosetron as an effective dose for preventing PONV.<sup>15</sup> Manufacturers also recommended dose is 0.3 mg intravenously once daily. Hence, in our study, we used 0.3 mg dose of ramosetron with the eight mg dose of ondansetron to evaluate their efficacy in preventing PONV.

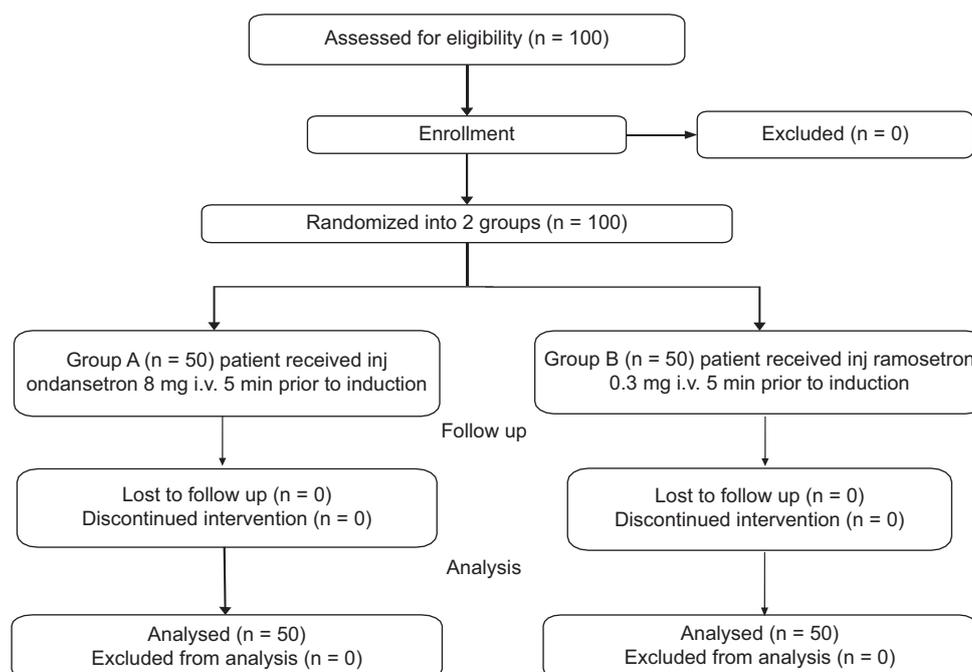
Nausea, vomiting/retching, and PONV score of patients assessed at different time intervals were found to be statistically insignificant in both the groups. To study overall efficacy of drugs, nausea, vomiting/retching, PONV score, and complete response (the total number of patients who had not suffered from PONV and had not required any rescue antiemetic) were measured and found to be statistically insignificant.

Our findings are consistent with meta-analysis done by Li et al., in which they found no difference in prevention of PONV in 0.3 mg ramosetron and 8 mg ondansetron in first 48 h after surgery but 0.3 mg ramosetron was found to be

**Table 4: Need of rescue medication in both groups in 24-h period and complete response**

No. of patients receiving rescue medication, complete response and adverse effects	Group A (Ondansetron) n*(%)	Group B (Ramosetron) n*(%)	P-value
No. of patients receiving rescue medication	20 (40)	12 (24)	0.086
No. of patients with complete response	22 (44)	31 (62)	0.071
No. of patients with adverse effects	6 (12)	3 (6)	0.294

(Chi-square test). \*Total no. of the patients is taken

**Figure 1:** Consort flow chart describing the study design

more effective than four mg ondansetron in reduction of post-operative nausea in 0–2-h period and post-operative vomiting in 24–48-h period.<sup>16</sup>

Similarly Opneja et al., did not found any statistical significant difference in the incidence of PONV in 0.3 mg ramosetron and 8 mg ondansetron group in first 24 h after surgery.<sup>17</sup>

These findings are in agreement with the findings of Ansari et al., in which ramosetron was compared with ondansetron for prevention of PONV in patients who underwent laparoscopic cholecystectomy.<sup>18</sup>

Our findings are also in corroboration with the findings of Kim et al., in which ramosetron 0.3 mg was not found superior to 8 mg of ondansetron.<sup>19</sup>

Similarly in a study on high risk patient of PONV by Agarkar and Chatterjee, 0.3 mg ramosetron was found equally effective to 8 mg ondansetron in reducing the incidence of PONV.<sup>20</sup>

Injection metochlopramide 10 mg intravenously was used as rescue medication for PONV in our study. According to current guidelines, it is recommended to use agent belonging to a different class when prophylaxis fails.<sup>8</sup> In our study, although apparently higher number of patients received rescue antiemetic in patients receiving ondansetron compared with ramosetron (20 vs. 12 patients, respectively), it was comparable on analysis. This finding was consistent with the findings of Agarkar and Chatterjee; Lee et al., who found no statistically significant difference in need for rescue antiemetic in first 24-h postoperatively.<sup>20,21</sup>

The severity of nausea was also assessed by VAS score at various time intervals. It was also found to be statistically insignificant at all the time intervals.

Headache and dizziness are the most commonly reported adverse effects of 5HT<sub>3</sub> receptor antagonists.<sup>22</sup> Statistical analysis of incidence of adverse effects in our study showed that in group ondansetron, three patients had headache, two patients had dizziness, one patient had constipation and in group ramosetron, two patients had headache and one

patient had dizziness. Most common side effect among both the groups was headache. The difference in incidence of side effects was found to be statistically insignificant. These findings were consistent with findings of other studies.<sup>12,18</sup>

For prediction of PONV in patients, many risk scoring systems have been developed.<sup>23</sup> These scoring systems can be used to assess the need for prophylactic use of antiemetic. For PONV prophylaxis combination therapy having drugs with different mechanism of action should be used as combination therapy that is superior to monotherapy.<sup>24</sup>

In future, one can hope that we will be able to understand pathophysiology of PONV better and newer drugs and combination regimens will help us to further decrease the problem of PONV.

### Limitations of the study

None.

## CONCLUSION

It was concluded that ramosetron 0.3 mg and ondansetron 8 mg were equally effective for prevention of PONV nausea and vomiting postoperatively in patients who underwent elective laparoscopic cholecystectomy under general anesthesia when used prophylactically. In both groups, severity of nausea and need for rescue antiemetic was not significantly different. Both drugs are safe and have low incidence of side effects.

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**Authors Contribution:**

**AD**- Definition of intellectual content, literature survey, prepared first draft of manuscript, implementation of study protocol, data collection, data analysis, manuscript preparation, and submission of article; **R**- Definition of intellectual content, literature survey, implementation of study protocol, data collection, data analysis, editing, manuscript preparation, and revision; **VG**- Implementation of study protocol, data collection, statistical analysis and interpretation, manuscript preparation, and submission of article; **SG**- Review manuscript and final approval of article; **RS**- Literature survey, prepared first draft of manuscript, implementation of study protocol, and review manuscript; and **RM**- Data collection, statistical analysis and interpretation, and final approval of article.

**Work attributed to:**

Pt. B. D. Sharma PGIMS, Rohtak, Haryana, India.

**Orcid ID:**

Amit Dahiya - <https://orcid.org/0009-0006-3254-360X>  
Rashmi - <https://orcid.org/0009-0005-7111-8457>  
Vasudha Govil - <https://orcid.org/0000-0001-6887-487X>  
Suraj Garg - <https://orcid.org/0009-0004-7171-7487>  
Ruchika Singhmar - <https://orcid.org/0009-0000-0589-8057>  
Radhika Malik - <https://orcid.org/0009-0007-8334-9820>

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