

Ramosetron versus Ondansetron for Prevention of Postoperative Nausea and Vomiting in Women Undergoing Laparoscopic Cholecystectomy: A Prospective Randomised Double-Blind Comparative Study

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Abstract

Background: Postoperative nausea and vomiting (PONV) is common after laparoscopic cholecystectomy, particularly in women. Serotonin 5-hydroxytryptamine-3 receptor antagonists are commonly used for prophylaxis. This study compared the efficacy of intravenous ramosetron and ondansetron for prevention of PONV in women undergoing laparoscopic cholecystectomy under general anaesthesia.

Methods: This prospective, randomised, double-blind comparative study included 100 women undergoing laparoscopic cholecystectomy at Maharishi Markandeshwar Medical College & Hospital, Kumarhatti-Solan, India. Participants were allocated equally to Group O, which received ondansetron 8 mg intravenously, or Group R, which received ramosetron 0.3 mg intravenously, 5 minutes before induction of anaesthesia. PONV was assessed using the Bellville score at 0, 2, 6, 12, 18 and 24 hours postoperatively. Severity of nausea was assessed using an 11-point scale. Requirement for intravenous metoclopramide 10 mg as rescue antiemetic was recorded.

Results: Mean age was 38.74 ± 10.92 years in Group O and 40.02 ± 8.56 years in Group R ($p=0.516$), while mean body mass index was 26.04 ± 2.01 and 26.28 ± 2.12 kg/m², respectively ($p=0.570$). At 0 hours, 28/50 (56%) patients in Group O and 46/50 (92%) in Group R had a Bellville score of 0 ($p=0.001$). At 2 hours, corresponding proportions were 94% and 100% ($p=0.079$), and at 6 hours they were 96% and 100% ($p=0.360$). No PONV was recorded in either group at 12, 18 or 24 hours. Nausea-severity scores differed significantly between groups at 0 hours ($p<0.001$) but not at 2 or 6 hours. Rescue metoclopramide was required by 24/50 (48%) patients receiving ondansetron and 4/50 (8%) receiving ramosetron ($p<0.001$). No significant adverse effects were reported with either drug.

Conclusion: Ramosetron 0.3 mg provided better control of immediate postoperative PONV than ondansetron 8 mg and markedly reduced the requirement for rescue antiemetic therapy. Differences in PONV were not statistically significant at 2 and 6 hours, and no events were recorded in either group from 12 to 24 hours.

Keywords: Laparoscopic Cholecystectomy; Postoperative Nausea and Vomiting; Ramosetron; Ondansetron; Antiemetic Prophylaxis.

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Introduction

Laparoscopic cholecystectomy is widely performed for gallbladder disease and offers advantages including reduced postoperative pain, earlier mobilisation, shorter hospital stay and improved postoperative recovery compared with open surgery. [1] Despite these advantages, postoperative nausea and vomiting (PONV) remains an important adverse effect following

laparoscopic procedures. The incidence of PONV following laparoscopic cholecystectomy has been reported to be particularly high, with rates ranging from approximately 46% to 75% in susceptible patients. [2] The development of PONV is multifactorial. Patient-related factors include female sex, younger age, non-smoking status, a previous history of PONV and motion sickness.

Anaesthetic factors include exposure to volatile anaesthetic agents, nitrous oxide and perioperative opioids, while surgical factors include the type and duration of surgery. [3] Women undergoing laparoscopic procedures therefore constitute a population with several recognised risk factors for PONV.

PONV can cause considerable postoperative discomfort and may contribute to delayed recovery, dehydration, electrolyte disturbance and prolonged stay in the post-anaesthesia care unit. Prevention is therefore an important component of perioperative management. Pharmacological prophylaxis commonly includes serotonin 5-hydroxytryptamine-3 (5-HT₃) receptor antagonists and agents from other antiemetic classes. [4]

Ondansetron is a commonly used 5-HT₃ receptor antagonist for prevention and treatment of PONV. Ramosetron is another selective 5-HT₃ receptor antagonist with high receptor affinity and a longer duration of action. [5] Comparative studies have evaluated ramosetron and ondansetron for PONV prophylaxis in laparoscopic procedures, although findings have differed according to drug dose, surgical population and postoperative assessment period. [6] A meta-analysis of randomised trials reported that ramosetron 0.3 mg was more effective than ondansetron 4 mg and broadly comparable with ondansetron 8 mg for PONV prophylaxis following laparoscopic surgery. [7]

The aim of this study was to evaluate the efficacy of intravenous ramosetron 0.3 mg for prophylaxis of PONV in women undergoing laparoscopic cholecystectomy and to compare it with intravenous ondansetron 8 mg.

Materials and Methods

Study Design and Setting: This prospective, randomised, double-blind comparative study was conducted in the Department of Anaesthesiology, Maharishi Markandeshwar Medical College & Hospital, Maharishi Markandeshwar University, Kumarhatti-Solan, and Himachal Pradesh, India.

Study Duration: The study was conducted between 2019–2022.

Participants: The study included 100 female patients scheduled for laparoscopic cholecystectomy under general anaesthesia. Patients were allocated equally to two groups of 50 participants each.

Inclusion Criteria: Women aged 18–55 years with American Society of Anesthesiologists physical status I or II who were scheduled for laparoscopic cholecystectomy and provided informed consent were eligible.

Exclusion Criteria: Patients were excluded if they declined participation; belonged to ASA physical status III or IV; had received opioids, non-steroidal anti-inflammatory drugs, steroids or antiemetic agents during the preceding 24 hours; had a previous history of PONV or motion sickness; had known allergy or another contraindication to either study drug; had cardiac rhythm abnormalities or were receiving antiarrhythmic medication; or had symptoms suggestive of gastro-oesophageal reflux disease.

Sample Size: A total of 100 patients were included, with 50 patients in each study group.

Patient allocation, randomisation and blinding: The enrolled patients were randomly allocated in a 1:1 ratio to one of two study groups using a computer-generated random number sequence. The allocation sequence was placed in sealed envelopes, which were opened before induction of anaesthesia by a trained staff member who was not involved in postoperative assessment.

Group O received ondansetron 8 mg intravenously, whereas Group R received ramosetron 0.3 mg intravenously. The assigned study drug was administered 5 minutes before induction of anaesthesia. The patients and investigators responsible for postoperative assessment and data collection were blinded to group allocation.

Preoperative Assessment: Patients were evaluated on the day before surgery. Clinical history included symptoms of gastro-oesophageal reflux, previous operations, drug allergy, prolonged medication use, previous PONV, motion sickness and previous antiemetic treatment.

General physical examination, systemic examination and airway assessment were performed, and appropriate preoperative investigations were obtained.

Patients remained nil per oral from midnight. Tablet alprazolam 0.25 mg and tablet pantoprazole 40 mg were administered on the night before surgery and again 2 hours before surgery.

Study interventions

After transfer to the operating theatre, intravenous access was established and Ringer lactate infusion was started. Standard monitoring included electrocardiography, non-invasive blood pressure and peripheral oxygen saturation.

Patients in Group O received ondansetron 8 mg intravenously as a single dose 5 minutes before induction of anaesthesia. Patients in Group R received ramosetron 0.3 mg intravenously as a single dose 5 minutes before induction.

All patients received midazolam 0.02 mg/kg, glycopyrrolate 0.01 mg/kg and tramadol 1 mg/kg as

premedication. Patients were preoxygenated with 100% oxygen. Anaesthesia was induced with propofol 2 mg/kg. Vecuronium 0.1 mg/kg was administered to facilitate endotracheal intubation. Anaesthesia was maintained using oxygen, nitrous oxide and isoflurane with controlled ventilation.

Intraoperative monitoring included end-tidal carbon dioxide, systolic and diastolic blood pressure, mean arterial pressure and electrocardiography. At completion of surgery, neuromuscular blockade was reversed with neostigmine 0.05 mg/kg and glycopyrrolate 0.01 mg/kg. After suction and extubation, patients were transferred to the post-anaesthesia care unit and subsequently to the ward.

Outcome Measures: The primary outcome was postoperative nausea, retching and vomiting assessed using the Bellville grading system at 0, 2, 6, 12, 18 and 24 hours after surgery. Bellville scores were graded as 0=no nausea, retching or vomiting; 1=nausea; 2=retching; and 3=vomiting. [8]

Severity of nausea was assessed using an 11-point scale from 0 to 10, where 0 represented no nausea and 10 represented the worst possible nausea. Scores below 5 were classified as mild, a score of 5 as moderate and scores above 5 as severe nausea. [9] Assessments were performed at 0, 2, 6, 12, 18 and 24 hours.

Intravenous metoclopramide 10 mg was used as rescue antiemetic therapy in patients requiring treatment for postoperative nausea or vomiting when the Bellville score was >1 and the severity of

nausea on the 11-point visual analogue scale was ≥ 5 . The requirement for rescue treatment was recorded. Adverse effects related to the study drugs were also observed.

Statistical Analysis: Data were expressed as mean $\pm$ standard deviation, median, range, frequency and percentage as appropriate. Distribution of quantitative data was assessed for normality. Quantitative variables were compared between the two groups using appropriate parametric or non-parametric methods according to data distribution. Categorical variables were compared using methods for proportions, with exact testing when expected frequencies were below 5. A p value <0.05 was considered statistically significant. Statistical analysis was performed using SPSS version 21 (SPSS Inc., Chicago, IL, USA).

Ethical Considerations: The study was approved by the Institutional Ethics Committee of Maharishi Markandeshwar Medical College & Hospital, Kumarhatti-Solan, and Himachal Pradesh, India (IEC reference: MMMCH/IEC/20/305; Project No. 18). Written informed consent was obtained from all participants before enrolment.

Results

Participant Characteristics: The analysed study population comprised 100 women, with 50 participants each in the ondansetron and ramosetron groups. Mean age, body mass index and duration of surgery were comparable between groups.

Table 1: Baseline demographic and operative characteristics

Variable	Group O: Ondansetron (n=50)	Group R: Ramosetron (n=50)	Statistic	p value
Age, years	38.74 $\pm$ 10.92	40.02 $\pm$ 8.56	t = -0.652	0.516
Body mass index, kg/m ²	26.04 $\pm$ 2.01	26.28 $\pm$ 2.12	t = -0.571	0.570
Duration of surgery, min	41.30 $\pm$ 7.94	40.90 $\pm$ 8.85	Z = -0.320	0.749

Values are presented as mean $\pm$ standard deviation.

Postoperative Nausea, Retching and Vomiting: At 0 hours, 28 patients (56%) in Group O and 46 patients (92%) in Group R had no nausea, retching or vomiting. In Group O, nausea occurred in 16 patients (32%), retching in five (10%) and vomiting in one (2%).

In Group R, four patients (8%) experienced nausea, while no retching or vomiting was recorded. The distribution of Bellville scores differed significantly between groups at this assessment (p=0.001). At 2 hours, 47 patients (94%) in Group

O and all 50 patients (100%) in Group R had a score of 0. Three patients (6%) in Group O had nausea.

The difference between groups was not statistically significant (p=0.079). At 6 hours, 48 patients (96%) in Group O and all patients in Group R had a score of 0. One patient (2%) in Group O experienced nausea and one (2%) experienced retching.

The difference was not statistically significant (p=0.360). No nausea, retching or vomiting was recorded in either group at 12, 18 or 24 hours.

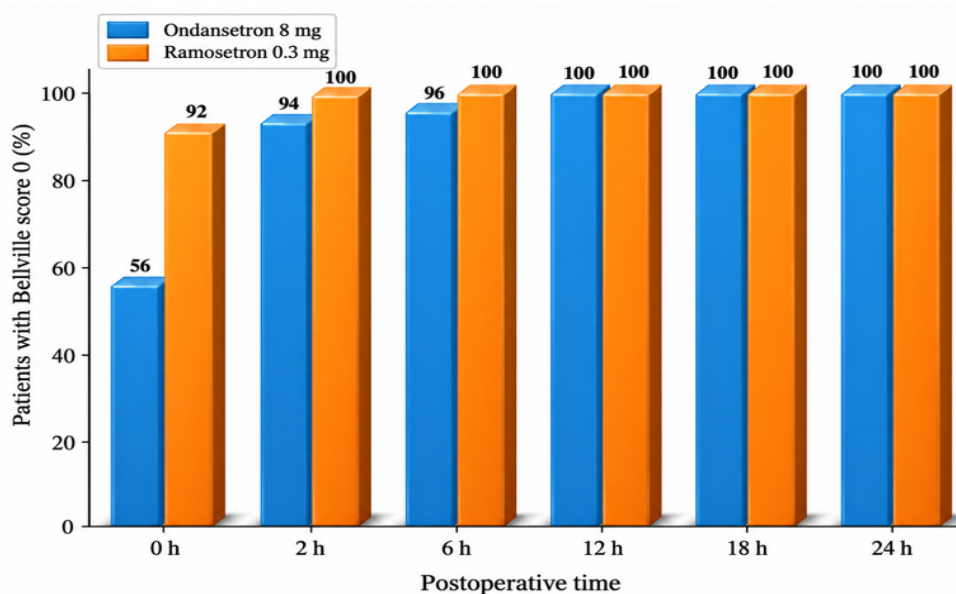


Figure 1: Proportion of patients with Bellville score 0 at each postoperative assessment in the ondansetron 8 mg and ramosetron 0.3 mg groups

Table 2: Bellville scores for postoperative nausea, retching and vomiting

Time	Bellville score	Group O, n (%)	Group R, n (%)	Test statistic	p value
0 h	0	28 (56)	46 (92)	17.578	0.001
	1	16 (32)	4 (8)		
	2	5 (10)	0 (0)		
	3	1 (2)	0 (0)		
2 h	0	47 (94)	50 (100)	3.093	0.079
	1	3 (6)	0 (0)		
6 h	0	48 (96)	50 (100)	2.041	0.360
	1	1 (2)	0 (0)		
	2	1 (2)	0 (0)		
12 h	0	50 (100)	50 (100)	—	—
18 h	0	50 (100)	50 (100)	—	—
24 h	0	50 (100)	50 (100)	—	—

Bellville score: 0=no nausea, retching or vomiting; 1=nausea; 2=retching; 3=vomiting.

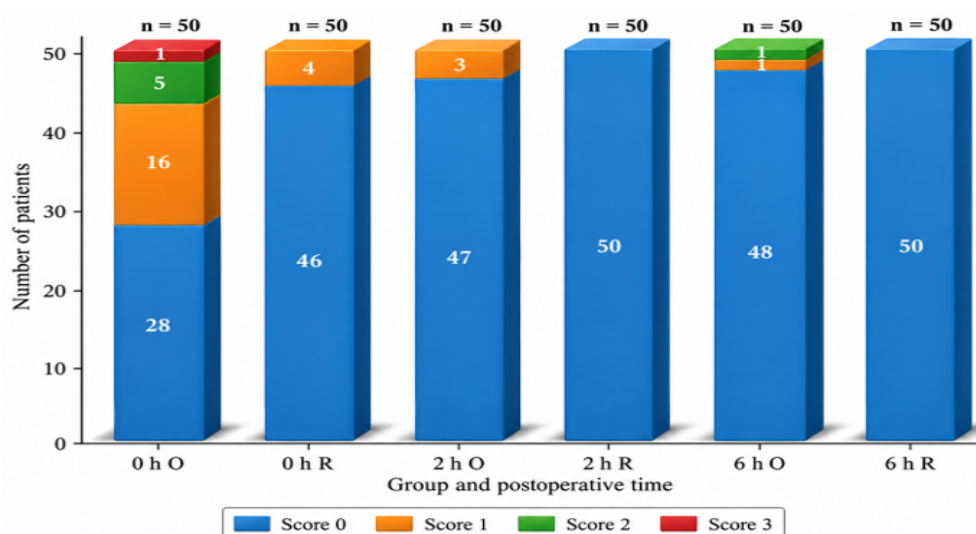


Figure 2: Distribution of Bellville scores at 0, 2 and 6 hours in the ondansetron and ramosetron groups. O, ondansetron; R, ramosetron

Severity of Nausea: At 0 hours, nausea-severity scores were lower in the ramosetron group. In Group O, 28 patients (56%) had a score of 0, three (6%) had a score of 2, 14 (28%) had a score of 3, four (8%) had a score of 5 and one (2%) had a score of 7.

In Group R, 46 patients (92%) had a score of 0, three (6%) had a score of 1 and one (2%) had a score of 2. The difference between groups was statistically significant ($p < 0.001$). At 2 hours, 47

patients (94%) in Group O and all patients in Group R had a score of 0. One patient (2%) in Group O had a score of 2 and two (4%) had a score of 3. The between-group difference was not statistically significant ($p = 0.213$). At 6 hours, 48 patients (96%) in Group O and all patients in Group R had a score of 0. One patient (2%) in Group O had a score of 3 and another (2%) had a score of 4. The difference was not statistically significant ($p = 0.360$). All patients in both groups had a score of 0 at 12, 18 and 24 hours.

Table 3: Distribution of postoperative nausea-severity scores

Time	Nausea score	Group O, n (%)	Group R, n (%)	Test statistic	p value
0 h	0	28 (56)	46 (92)	27.378	<0.001
	1	0 (0)	3 (6)		
	2	3 (6)	1 (2)		
	3	14 (28)	0 (0)		
	5	4 (8)	0 (0)		
	7	1 (2)	0 (0)		
2 h	0	47 (94)	50 (100)	3.093	0.213
	2	1 (2)	0 (0)		
	3	2 (4)	0 (0)		
6 h	0	48 (96)	50 (100)	2.041	0.360
	3	1 (2)	0 (0)		
	4	1 (2)	0 (0)		
12 h	0	50 (100)	50 (100)	—	—
18 h	0	50 (100)	50 (100)	—	—
24 h	0	50 (100)	50 (100)	—	—

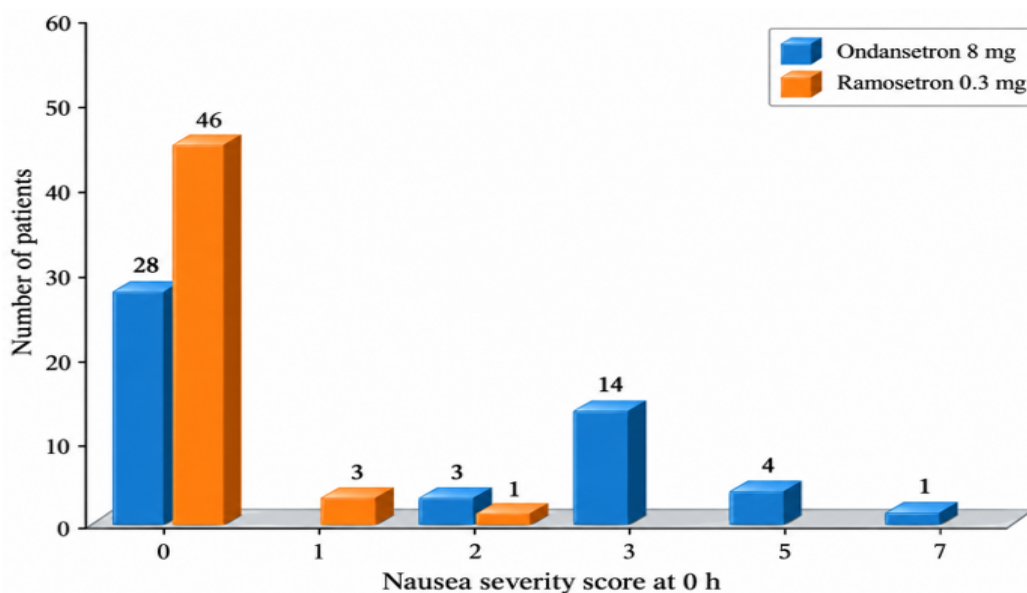


Figure 3: Distribution of nausea-severity scores at 0 hours in the ondansetron 8 mg and ramosetron 0.3 mg groups.

Requirement for rescue antiemetic: Metoclopramide was required by 24 patients (48%) in Group O compared with four patients (8%) in Group R. The difference was statistically significant ($p < 0.001$). No patient required more than one dose of rescue antiemetic.

Table 4: Requirement for rescue metoclopramide

Rescue metoclopramide	Group O, n (%)	Group R, n (%)	Total	Test statistic	p value
Not required	26 (52)	46 (92)	72	19.841	<0.001
One dose required	24 (48)	4 (8)	28		

No patient required more than one dose.

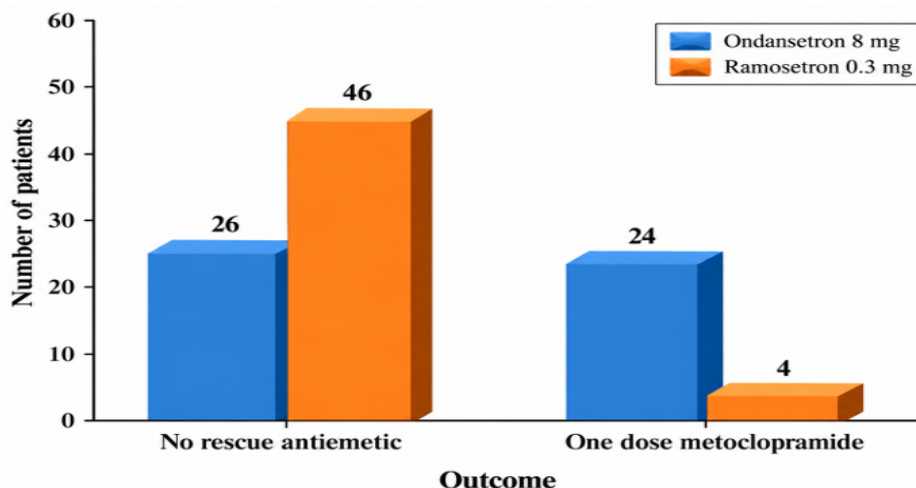


Figure 4: Requirement for rescue antiemetic treatment in the ondansetron 8 mg and ramosetron 0.3 mg groups

Adverse Effects: No adverse effects were reported in either group during the observation period.

Discussion

In this prospective randomised comparison of ramosetron 0.3 mg and ondansetron 8 mg in women undergoing laparoscopic cholecystectomy, ramosetron was associated with lower immediate postoperative PONV. At 0 hours, 92% of patients receiving ramosetron had no nausea, retching or vomiting compared with 56% receiving ondansetron, and the difference in Bellville-score distribution was statistically significant.

The difference was most evident during the immediate postoperative assessment. At 2 hours, 100% of patients in the ramosetron group and 94% in the ondansetron group were free of PONV, but this difference did not reach statistical significance. Similarly, at 6 hours the corresponding proportions were 100% and 96%, with no statistically significant difference. No PONV was recorded in either group at 12, 18 or 24 hours.

A significant difference was observed in the requirement for rescue antiemetic therapy. Metoclopramide was required in 48% of patients receiving ondansetron compared with 8% receiving ramosetron. Thus, although the between-group differences in categorical PONV scores were no longer statistically significant at 2 and 6 hours, the overall requirement for additional antiemetic treatment remained substantially lower in the ramosetron group. Ryu et al. compared ramosetron 0.3 mg with ondansetron 4 mg and 8 mg in patients

undergoing laparoscopic cholecystectomy and reported that ramosetron 0.3 mg and ondansetron 8 mg were similarly effective for prevention of PONV. [6] The present findings differ in showing a significant immediate postoperative difference between ramosetron 0.3 mg and ondansetron 8 mg, although the subsequent 2- and 6-hour comparisons were not significant.

A meta-analysis by Li et al. found that ramosetron 0.3 mg was superior to ondansetron 4 mg but comparable with ondansetron 8 mg for prophylaxis of PONV after laparoscopic surgery. [7] This pooled evidence is compatible with the absence of significant differences at the later assessment periods in the present study, while the significant difference at 0 hours indicates a greater immediate antiemetic effect in the studied population. Ansari et al. reported favourable antiemetic efficacy of ramosetron compared with ondansetron following laparoscopic cholecystectomy and observed a lower requirement for rescue antiemetic treatment in patients receiving ramosetron. [9] The marked difference in rescue metoclopramide use in the present study is consistent with that finding. Kim et al. compared ramosetron 0.3 mg with ondansetron 8 mg for prevention of PONV in women undergoing gynaecological surgery and found comparable control of PONV. [10] Differences between surgical populations and assessment intervals may contribute to variation among individual studies. Swaika et al. evaluated ondansetron, ramosetron and palonosetron in patients undergoing laparoscopic cholecystectomy

and reported favourable early postoperative control with ramosetron 0.3 mg. [11] Banerjee et al. also reported greater efficacy of ramosetron compared with ondansetron for PONV prophylaxis after ambulatory surgery. [12] These findings are consistent with the lower immediate PONV burden observed with ramosetron in the present study.

Gao et al., in a meta-analysis of randomised clinical trials, reported favourable efficacy of ramosetron compared with ondansetron for prevention of PONV after general anaesthesia. [13] Similarly, Pandharpurkar et al. reported better PONV prevention with ramosetron following laparoscopic cholecystectomy. [14] Agarkar and Chatterjee also observed lower PONV and rescue antiemetic requirements with ramosetron in patients at increased risk of PONV. [15]

Not all published comparisons have demonstrated superiority of ramosetron. Choi et al. compared ramosetron and ondansetron for treatment of established PONV after laparoscopic surgery and found similar treatment efficacy. [16] That study addressed treatment of established PONV rather than prophylaxis, and direct comparison with prophylactic studies is therefore limited.

The absence of significant adverse effects with either study drug is consistent with the established clinical use of 5-HT₃ receptor antagonists. Jamwal et al. compared the safety of ondansetron, ramosetron and palonosetron in women undergoing laparoscopic cholecystectomy and reported generally comparable safety profiles among the three agents. [17] An updated systematic review and meta-analysis by Yokoi et al. also examined comparative efficacy of ramosetron and ondansetron for prevention of PONV and reported differences favouring ramosetron in several postoperative outcomes. [1] The principal difference between the two regimens occurred during the immediate postoperative period. The 0-hour Bellville and nausea-severity distributions both favoured ramosetron. By 2 and 6 hours, however, the numerical differences were small and statistically non-significant, and no PONV was observed in either group after 12 hours.

The between-group difference was mainly observed during the immediate postoperative assessment. At 2 and 6 hours, the differences were not statistically significant, and no PONV was recorded in either group from 12 to 24 hours. Rescue metoclopramide was required in 48% of patients receiving ondansetron compared with 8% receiving ramosetron. Both groups received the same anaesthetic technique and perioperative medications apart from the prophylactic antiemetic.

Strengths and Limitations: The prospective randomised double-blind design, equal group sizes, standardised anaesthetic technique and assessment

of PONV at predefined postoperative intervals were strengths of the study. The use of both a categorical PONV score and a nausea-severity scale allowed assessment of both occurrence and severity of postoperative symptoms.

The study was conducted at a single centre and included only women undergoing laparoscopic cholecystectomy with ASA physical status I or II, limiting generalisability to other surgical populations and to male patients. Follow-up was restricted to the first 24 postoperative hours. The absence of PONV in both groups from 12 hours onwards also limited comparison of delayed postoperative efficacy. Adverse effects were reported as absent without a detailed quantitative adverse-event distribution.

Conclusion

In women undergoing laparoscopic cholecystectomy under general anaesthesia, prophylactic ramosetron 0.3 mg intravenously was associated with lower PONV at the immediate postoperative assessment compared with ondansetron 8 mg intravenously. Ramosetron also significantly reduced the requirement for rescue metoclopramide. Between-group differences in PONV were not statistically significant at 2 or 6 hours, and no PONV was recorded in either group at 12, 18 or 24 hours. No adverse effects were reported in either group during the observation period.

Declarations

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Author Contributions: Dr Gurdarshan Kaur was the principal investigator and was involved in study conduct, patient recruitment, data collection, data analysis and preparation of the manuscript. Dr Ravnit Kaur contributed to manuscript preparation, interpretation of the findings and critical revision of the manuscript. Dr R. S. Thakur supervised the study, provided scientific and methodological guidance and critically revised the manuscript. All authors reviewed and approved the final manuscript.

Ethics Approval and Consent to Participate: The study was approved by the Institutional Ethics Committee of Maharishi Markandeshwar Medical College & Hospital, Kumarhatti-Solan, and Himachal Pradesh, India (IEC reference: MMMCH/IEC/20/305; Project No. 18).

Written informed consent was obtained from all participants before enrolment. The study was conducted after institutional ethical approval and with written informed consent from all patients.

Availability of Data and Materials: The data supporting the findings of this study are available from the corresponding author on reasonable request, subject to institutional and ethical requirements.

Guarantor: Dr Gurdarshan Kaur, Principal Investigator, Department of Anaesthesia, Maharishi Markandeshwar Medical College & Hospital, Maharishi Markandeshwar University, Kumarhatti-Solan, Himachal Pradesh, India, is the guarantor of the work.

The study was carried out by Dr Gurdarshan Kaur under the supervision of Dr R. S. Thakur

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