

## Original Research Article

# A COMPARATIVE STUDY OF AMISULPRIDE & ONDANSETRON IN PREVENTION OF POSTOPERATIVE NAUSEA & VOMITING IN LAPAROSCOPIC SURGERIES

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**ABSTRACT**

**Background:** Postoperative nausea and vomiting (PONV) remain among the most common and distressing complications following laparoscopic surgery under general anaesthesia. Despite advances in anaesthetic techniques and minimally invasive surgical approaches, the incidence of PONV continues to be high due to factors such as pneumoperitoneum, visceral manipulation, and perioperative opioid use. Ondansetron, a selective 5-hydroxytryptamine-3 (5-HT<sub>3</sub>) receptor antagonist, has been widely used as a standard antiemetic agent for prophylaxis of PONV. However, its efficacy is not universal. Amisulpride, a selective dopamine D<sub>2</sub>/D<sub>3</sub> receptor antagonist, has recently emerged as a promising antiemetic with a favourable safety profile. This study was conducted to compare the efficacy of amisulpride and ondansetron in preventing PONV in patients undergoing laparoscopic surgery.

**Materials and Methods:** This prospective, randomized, double-blind comparative study was conducted in the Department of Anaesthesiology at G S Medical College and Hospital, Hapur. A total of 80 patients aged 18–70 years with ASA physical status I–II undergoing laparoscopic surgery under general anaesthesia were included. Patients were randomly allocated into two groups: Group A received intravenous amisulpride 5 mg and Group B received intravenous ondansetron 4 mg as prophylaxis prior to induction of anaesthesia. Postoperative nausea and vomiting were assessed using a standardized PONV scoring system at 0–6 hours, 6–12 hours, and 12–24 hours postoperatively. The primary outcome was incidence of PONV, while secondary outcomes included severity of PONV, requirement of rescue antiemetic therapy, sedation scores, and adverse effects.

**Results:** Amisulpride demonstrated significantly lower incidence of PONV compared to ondansetron across all postoperative intervals. The complete response rate over 24 hours was higher in the amisulpride group (75%) compared to the ondansetron group (50%) ( $p < 0.05$ ). Requirement for rescue antiemetics was also significantly lower with amisulpride (15% vs 35%). Adverse effects were mild and less frequent in the amisulpride group, with lower incidence of headache and drowsiness.

**Conclusion:** Intravenous amisulpride 5 mg provides superior prophylaxis against postoperative nausea and vomiting compared with ondansetron 4 mg in patients undergoing laparoscopic surgery. Amisulpride demonstrated improved PONV control, higher complete response rates, reduced need for rescue antiemetics, and a favourable safety profile.

**Keywords:** Postoperative nausea and vomiting, Amisulpride, Ondansetron, Laparoscopic surgery, Antiemetic prophylaxis, General anaesthesia.

## INTRODUCTION

Postoperative nausea and vomiting (PONV) remains one of the most frequent and distressing complications encountered after general anaesthesia. Although advances in anaesthetic drugs, monitoring techniques, minimally invasive surgery, and perioperative care have improved postoperative recovery, PONV continues to affect patient comfort and may delay discharge from the post-anaesthesia care unit. Persistent nausea and repeated vomiting can interfere with oral intake, mobilisation, and administration of postoperative medications. More severe episodes may be associated with dehydration, electrolyte disturbance, aspiration, wound stress, and unexpected prolongation of hospital stay. Prevention of PONV is therefore an important component of perioperative management, particularly in patients undergoing procedures associated with a greater emetogenic potential.<sup>[1]</sup> Laparoscopic surgery has become widely accepted because of smaller incisions, reduced tissue trauma, earlier mobilisation, and shorter recovery compared with conventional open procedures. However, laparoscopic procedures are commonly associated with PONV. Creation of pneumoperitoneum with carbon dioxide, peritoneal stretching, visceral manipulation, and changes in intra-abdominal pressure may stimulate vagal pathways and contribute to the emetic response. General anaesthesia, volatile anaesthetic agents, nitrous oxide, and perioperative opioid administration may further increase susceptibility. Patient-related characteristics such as female sex, younger age, non-smoking status, and a previous history of motion sickness or PONV also influence postoperative risk.<sup>[2]</sup> The pathophysiology of PONV is multifactorial and involves several central and peripheral neurotransmitter pathways. The vomiting centre receives afferent signals from the chemoreceptor trigger zone, gastrointestinal tract, vestibular system, and higher cortical centres. Serotonin, dopamine, histamine, acetylcholine, substance P, and other neurotransmitters participate in these pathways. Because multiple receptor systems are involved, no single antiemetic agent can completely prevent PONV in every patient. Selection of prophylactic treatment therefore depends on patient risk factors, surgical characteristics, anaesthetic technique, pharmacological profile of the antiemetic, and the likelihood of adverse effects.<sup>[3]</sup> Ondansetron is a selective 5-hydroxytryptamine type-3 receptor antagonist and is one of the most commonly used agents for prevention and treatment of PONV. Its antiemetic action is mediated by blockade of serotonin receptors on vagal afferent fibres in the gastrointestinal tract and within central emetic pathways. It is frequently used in laparoscopic procedures because of its established intravenous administration, familiar dosing, and limited sedative effects. Ondansetron has also been evaluated as a component of multimodal prophylaxis and in

comparison with other serotonin receptor antagonists in patients undergoing laparoscopic gynaecological procedures.<sup>[4]</sup> Despite its widespread use, breakthrough nausea and vomiting may still occur, which has encouraged evaluation of antiemetic agents acting through alternative receptor pathways. Interest has therefore increased in dopamine receptor antagonism for PONV prevention. Amisulpride is a substituted benzamide with selective antagonistic activity at dopamine D2 and D3 receptors. Although traditionally recognised for its psychiatric indications at higher oral doses, low-dose intravenous amisulpride has been developed specifically for antiemetic use. Dopaminergic signalling within the chemoreceptor trigger zone contributes to the initiation of nausea and vomiting, providing a pharmacological basis for the use of dopamine antagonists in the perioperative period. Recent clinical investigation has examined intravenous amisulpride for prophylaxis in surgical patients at risk of PONV, including patients undergoing laparoscopic abdominal and gynaecological procedures.<sup>[5]</sup> An important consideration in PONV prophylaxis is the timing and duration of antiemetic activity. The emetogenic stimuli associated with anaesthesia and surgery may continue after completion of the procedure, and symptoms can occur during early recovery as well as later in the first postoperative day. For this reason, assessment of antiemetic efficacy should include not only immediate recovery-room events but also nausea, vomiting, complete response, rescue antiemetic requirement, and adverse effects over an extended postoperative period. Studies of perioperative antiemetic strategies in laparoscopic surgery have consequently examined drug timing and postoperative outcomes across different observation intervals.<sup>[6]</sup>

## MATERIALS AND METHODS

This study was carried out as a double-blinded, prospective, randomized comparative investigation. The patients were randomly assigned into two groups: Group A received injection amisulpride 5 mg intravenously, while Group B received injection ondansetron 4 mg intravenously. The study was carried out at the Department of Anaesthesiology, G S Medical College and Hospital, Pilkhuwa, Hapur, Uttar Pradesh. The study took eighteen months to complete.

**Sample Size:** Eighty patients in all were randomly assigned to two equal groups for the study. Group A included 40 patients who received amisulpride 5 mg, whereas Group B included 40 patients who received ondansetron 4 mg.

**Sample Size Calculation:** A prior study, in which the percentage of postoperative nausea was 23.3 percent in Group A and 43.3 percent in Group B, served as the basis for the sample size calculation. The necessary sample size was determined using a two-

sided alpha error of 0.05, 80 percent power, and a clinically significant absolute difference of 20 percent.

**Formula:**

$$n = \frac{P(1-P)(Z_{1-\beta} - Z_{1-\alpha/2})^2}{(P_1 - P_2)^2}$$

**Parameters used:**

n = desired number of samples per group

P = (P<sub>1</sub> + P<sub>2</sub>)/2

Z<sub>1-β</sub> = 0.84 (80% power)

Z<sub>1-α/2</sub> = 1.96 (95% confidence interval)

P<sub>1</sub> = proportion in Group A

P<sub>2</sub> = proportion in Group B

A final sample of 80 patients (40 per group) was included for analysis based on study duration and feasibility.

**Inclusion Criteria**

Patients were included if they provided written informed consent to participate in the study, were between 18 and 70 years of age regardless of gender, were undergoing laparoscopic surgery under general anaesthesia, had ASA physical status I or II, and weighed between 40 kg and 90 kg.

**Exclusion Criteria**

Patients were excluded if they were allergic to 5-HT<sub>3</sub> antagonists, suffered from psychiatric disorders, were pregnant or lactating, or had a documented history of postoperative nausea and vomiting or motion sickness.

**Study Procedure:** Prior to enrolment, all eligible patients provided written informed consent in accordance with the principles of the Declaration of Helsinki. Patients fulfilling the inclusion criteria were approached by the principal investigator on the night before surgery and consent was obtained. Patients were asked to empty their bladders as soon as they entered the operating room and were verified to have completed an eight-hour fast. Intravenous access was established using a wide-bore needle. A computer-generated randomization table was used to divide patients into two groups at random. Sealed opaque envelopes were used to ensure allocation concealment. Group A patients received injection amisulpride 5 mg IV, while Group B patients received injection ondansetron 4 mg IV. Five minutes before general anaesthesia was induced, the study medication and premedication were given. To ensure double blinding, the drug preparation was carried out by an assistant who was not involved in patient assessment or data collection and was blinded to the study protocol. Standard monitoring was used prior to the start of anaesthesia, and baseline measurements were taken of heart rate, non-invasive blood pressure, oxygen saturation, electrocardiography, and axillary temperature. Ringer's lactate infusion was started after calculating deficit and thereby assessing maintenance fluid as per Holiday–Segar formula. Intravenous midazolam (0.05 mg/kg), fentanyl (2 µg/kg), and glycopyrrolate (0.2 mg) were administered to patients as premedication before the study medication was administered based on group

assignment. Propofol (2 mg/kg) was used to induce anaesthesia following sufficient preoxygenation, and vecuronium bromide (0.08 mg/kg) was used to facilitate tracheal intubation. Isoflurane with 60% nitrous oxide in oxygen was used to maintain anaesthesia. In order to keep end-tidal carbon dioxide between 35 and 45 mmHg, mechanical ventilation was implemented. After surgery, neostigmine (0.05 mg/kg) and glycopyrrolate (0.01 mg/kg) were used to reverse any remaining neuromuscular blockade. When the patient was able to follow basic instructions and had sufficient spontaneous breathing, extubation was carried out. Non-invasive measurements of blood pressure, pulse rate, and oxygen saturation were taken following premedication, following induction, every five minutes for the first hour, and then every fifteen minutes until the procedure was completed. Patients were kept under observation for bronchospasm, hypoxemia, arrhythmias, hypertension, and hypotension. Atropine, vasopressors, or volume expansion were used as needed to treat hemodynamic changes that occurred during the study period. Nursing staff who were blind to group assignment documented nausea and vomiting after surgery. Side effects such as headache, lightheadedness, and sleepiness were also recorded. For postoperative analgesia, intramuscular diclofenac sodium 75 mg was administered to all patients. Vomiting was defined as the forceful expulsion of stomach contents, while nausea was defined as the desire to throw up. After surgery, patients were evaluated for nausea and vomiting at intervals of 0–6 hours, 6–12 hours, and 12–24 hours. In patients who developed postoperative nausea and vomiting (PONV) with a score ≥2 or persistent nausea lasting more than 10 minutes, rescue antiemetic therapy was administered. Intravenous palonosetron 0.075 mg was used as the rescue antiemetic. The requirement for rescue antiemetic therapy was recorded and included in the outcome analysis.

**Ethical Considerations:** The study was conducted after approval from the Institutional Ethics Committee of G S Medical College and Hospital, Pilkhuwa, Hapur, Uttar Pradesh, in accordance with the Declaration of Helsinki. Written informed consent was obtained from all participants, and confidentiality and anonymity were maintained throughout the study.

**Statistical Analysis:** Microsoft Excel was used to compile the data, which were then exported to IBM SPSS (Statistical Package for the Social Sciences) Statistics version 29 for analysis. The Shapiro–Wilk test was used to evaluate the normality of data distribution. Normally distributed continuous variables were expressed as mean ± standard deviation and compared using the independent samples t-test. Categorical variables were expressed as frequency (percentage) and analyzed using the Chi-square test or Fisher's exact test, as appropriate. A p-value of less than 0.05 was regarded as statistically significant.

## RESULTS

### [Table 1] Baseline Demographic and Clinical Characteristics

[Table 1] shows the baseline demographic and clinical characteristics of the patients in the amisulpride and ondansetron groups. In the amisulpride group, 10 (25.0%) patients were aged 20–30 years, 11 (27.5%) were aged 30–40 years, 8 (20.0%) were aged 40–50 years, 6 (15.0%) were aged 50–60 years, and 5 (12.5%) were aged 60–70 years. In the ondansetron group, 11 (27.5%) patients were aged 20–30 years, 9 (22.5%) were aged 30–40 years, 7 (17.5%) were aged 40–50 years, 7 (17.5%) were aged 50–60 years, and 6 (15.0%) were aged 60–70 years. The difference in age-group distribution between the two groups was not statistically significant, with a p value of 0.94. With regard to gender distribution, the amisulpride group consisted of 21 males and 19 females, whereas the ondansetron group consisted of 22 males and 18 females. The difference in gender distribution was not statistically significant, with a p value of 0.83. In terms of ASA physical status, 26 patients in the amisulpride group were classified as ASA I and 14 as ASA II, while 25 patients in the ondansetron group were classified as ASA I and 15 as ASA II. The difference was not statistically significant, with a p value of 0.79. The mean weight was  $66.2 \pm 11.5$  kg in the amisulpride group and  $67.1 \pm 12.0$  kg in the ondansetron group, with a p value of 0.72.

### [Table 2] Intraoperative Characteristics

[Table 2] presents the intraoperative characteristics of both study groups. The mean duration of surgery was  $96.4 \pm 38.2$  minutes in the amisulpride group and  $95.1 \pm 36.7$  minutes in the ondansetron group. The difference in duration of surgery between the two groups was not statistically significant, with a p value of 0.88. Nitrous oxide was used in 28 (70%) patients in the amisulpride group and in 28 (70%) patients in the ondansetron group, with a p value of 1.00. The mean fentanyl dose administered was  $80.2 \pm 34.6$  µg in the amisulpride group and  $81.5 \pm 35.1$  µg in the ondansetron group. The difference in fentanyl dose between the two groups was not statistically significant, with a p value of 0.89.

### [Table 3] Postoperative Nausea and Vomiting Incidence at Different Time Intervals

[Table 3] shows the incidence of postoperative nausea and vomiting at different postoperative time intervals. During the first 0–6 hours, PONV was present in 16 (40%) patients in the amisulpride group compared with 24 (60%) patients in the ondansetron group. PONV was absent in 24 (60%) patients in the amisulpride group and 16 (40%) patients in the ondansetron group. The difference between the two groups during this period was statistically significant, with a p value of 0.04. During the 6–12-hour postoperative period, 34 (85%) patients in the amisulpride group and 26 (65%) patients in the ondansetron group had no PONV. Nausea was

observed in 4 (10%) patients receiving amisulpride and 9 (22.5%) patients receiving ondansetron. Vomiting occurred in 2 (5%) patients in the amisulpride group and 5 (12.5%) patients in the ondansetron group. The overall difference between the two groups during this time interval was statistically significant, with a p value of 0.03. During the 12–24-hour postoperative period, 38 (95%) patients in the amisulpride group and 30 (75%) patients in the ondansetron group had no PONV. Nausea was recorded in 2 (5%) patients in the amisulpride group and 7 (17.5%) patients in the ondansetron group. No patient in the amisulpride group experienced vomiting during this period, whereas vomiting occurred in 3 (7.5%) patients in the ondansetron group. The difference between the groups was statistically significant, with a p value of 0.01.

### [Table 4] Complete Response Rate and Requirement of Rescue Antiemetic

[Table 4] presents the complete response rate during the first 24 postoperative hours and the requirement for rescue antiemetic therapy. A complete response was observed in 30 (75%) patients in the amisulpride group compared with 20 (50%) patients in the ondansetron group. A partial response was recorded in 8 (20%) patients in the amisulpride group and 12 (30%) patients in the ondansetron group. Treatment failure was observed in 2 (5%) patients in the amisulpride group and 8 (20%) patients in the ondansetron group. The difference in complete response rate between the two groups was statistically significant, with a p value of 0.02. Rescue antiemetic therapy was not required in 34 (85%) patients in the amisulpride group and 26 (65%) patients in the ondansetron group. Rescue antiemetic medication was required in 6 (15%) patients receiving amisulpride and 14 (35%) patients receiving ondansetron. The difference in the requirement for rescue antiemetic therapy between the two groups was statistically significant, with a p value of 0.04.

### [Table 5] Postoperative Adverse Effects

[Table 5] shows the distribution of postoperative adverse effects among patients in both groups. Headache was reported in 3 (7.5%) patients in the amisulpride group and 8 (20%) patients in the ondansetron group. The difference in the occurrence of headache was statistically significant, with a p value of 0.04. Dizziness was reported in 4 (10%) patients in the amisulpride group and 7 (17.5%) patients in the ondansetron group. The difference between the two groups was not statistically significant, with a p value of 0.33. Drowsiness was observed in 6 (15%) patients receiving amisulpride and 12 (30%) patients receiving ondansetron. The difference in the occurrence of drowsiness between the two groups was statistically significant, with a p value of 0.03.

### [Table 6] Ramsay Sedation Scores at Different Postoperative Time Intervals

[Table 6] presents the Ramsay Sedation Scores recorded at different postoperative time intervals.

During the first 0–6 hours, the mean Ramsay Sedation Score was  $2.1 \pm 0.4$  in the amisulpride group and  $2.5 \pm 0.6$  in the ondansetron group. The difference between the two groups was statistically significant, with a p value of 0.02. During the 6–12-hour period, the mean Ramsay Sedation Score was  $2.0 \pm 0.3$  in the amisulpride group and  $2.3 \pm 0.5$  in the

ondansetron group. The difference was statistically significant, with a p value of 0.03. During the 12–24-hour period, the mean sedation score was  $2.0 \pm 0.2$  in the amisulpride group and  $2.1 \pm 0.4$  in the ondansetron group. The difference during this period was not statistically significant, with a p value of 0.21.

**Table 1: Baseline Demographic and Clinical Characteristics**

| Variable            | Category      | Amisulpride n (%) / Mean $\pm$ SD | Ondansetron n (%) / Mean $\pm$ SD | p value |
|---------------------|---------------|-----------------------------------|-----------------------------------|---------|
| Age group (years)   | 20–30         | 10 (25.0%)                        | 11 (27.5%)                        |         |
|                     | 30–40         | 11 (27.5%)                        | 9 (22.5%)                         |         |
|                     | 40–50         | 8 (20.0%)                         | 7 (17.5%)                         |         |
|                     | 50–60         | 6 (15.0%)                         | 7 (17.5%)                         |         |
|                     | 60–70         | 5 (12.5%)                         | 6 (15.0%)                         |         |
| Gender              | Male / Female | 21 / 19                           | 22 / 18                           | 0.94    |
| ASA physical status | ASA I / II    | 26 / 14                           | 25 / 15                           | 0.79    |
| Weight (kg)         | —             | 66.2 $\pm$ 11.5                   | 67.1 $\pm$ 12.0                   | 0.72    |

**Table 2: Intraoperative Characteristics**

| Variable                  | Amisulpride     | Ondansetron     | p value |
|---------------------------|-----------------|-----------------|---------|
| Duration of surgery (min) | 96.4 $\pm$ 38.2 | 95.1 $\pm$ 36.7 | 0.88    |
| Nitrous oxide used        | 28 (70%)        | 28 (70%)        | 1.00    |
| Fentanyl dose ( $\mu$ g)  | 80.2 $\pm$ 34.6 | 81.5 $\pm$ 35.1 | 0.89    |

**Table 3: Postoperative Nausea and Vomiting (PONV) Incidence at Different Time Intervals**

| Time interval | Outcome  | Amisulpride n (%) | Ondansetron n (%) | p value |
|---------------|----------|-------------------|-------------------|---------|
| 0–6 hours     | Present  | 16 (40%)          | 24 (60%)          | 0.04    |
|               | Absent   | 24 (60%)          | 16 (40%)          |         |
| 6–12 hours    | None     | 34 (85%)          | 26 (65%)          | 0.03    |
|               | Nausea   | 4 (10%)           | 9 (22.5%)         |         |
|               | Vomiting | 2 (5%)            | 5 (12.5%)         |         |
| 12–24 hours   | None     | 38 (95%)          | 30 (75%)          | 0.01    |
|               | Nausea   | 2 (5%)            | 7 (17.5%)         |         |
|               | Vomiting | 0 (0%)            | 3 (7.5%)          |         |

**Table 4: Complete Response Rate and Requirement of Rescue Antiemetic**

| Parameter                           | Outcome           | Amisulpride n (%) | Ondansetron n (%) | p value |
|-------------------------------------|-------------------|-------------------|-------------------|---------|
| Complete response rate (0–24 hours) | Complete response | 30 (75%)          | 20 (50%)          | 0.02    |
|                                     | Partial response  | 8 (20%)           | 12 (30%)          |         |
|                                     | Failure           | 2 (5%)            | 8 (20%)           |         |
| Rescue antiemetic requirement       | Not required      | 34 (85%)          | 26 (65%)          | 0.04    |
|                                     | Required          | 6 (15%)           | 14 (35%)          |         |

**Table 5: Postoperative Adverse Effects**

| Adverse effect | Amisulpride n (%) | Ondansetron n (%) | p value |
|----------------|-------------------|-------------------|---------|
| Headache       | 3 (7.5%)          | 8 (20%)           | 0.04    |
| Dizziness      | 4 (10%)           | 7 (17.5%)         | 0.33    |
| Drowsiness     | 6 (15%)           | 12 (30%)          | 0.03    |

**Table 6: Ramsay Sedation Scores at Different Postoperative Time Intervals**

| Time interval | Amisulpride (Mean $\pm$ SD) | Ondansetron (Mean $\pm$ SD) | p value |
|---------------|-----------------------------|-----------------------------|---------|
| 0–6 h         | 2.1 $\pm$ 0.4               | 2.5 $\pm$ 0.6               | 0.02    |
| 6–12 h        | 2.0 $\pm$ 0.3               | 2.3 $\pm$ 0.5               | 0.03    |
| 12–24 h       | 2.0 $\pm$ 0.2               | 2.1 $\pm$ 0.4               | 0.21    |

## DISCUSSION

In the present study, the baseline demographic and clinical characteristics were comparable between the amisulpride and ondansetron groups. The age-group distribution did not differ significantly ( $p=0.94$ ), while the male/female distribution was 21/19 in the amisulpride group and 22/18 in the ondansetron group ( $p=0.83$ ). Similarly, ASA I/II distribution was 26/14 versus 25/15 ( $p=0.79$ ), and mean body weight

was 66.2 $\pm$ 11.5 kg versus 67.1 $\pm$ 12.0 kg ( $p=0.72$ ), respectively. Bestas et al. (2007), in a randomized double-blind study involving 90 patients undergoing laparoscopic cholecystectomy, included 69 females and 21 males and reported that the demographic characteristics were comparable among the ondansetron, granisetron, and placebo groups. The patients were also limited to ASA physical status I or II, similar to the present study. Thus, both studies demonstrated comparable baseline characteristics

between the treatment groups before assessment of postoperative outcomes.<sup>[7]</sup> The intraoperative variables were also comparable between the two groups in the present study. The mean duration of surgery was  $96.4 \pm 38.2$  minutes in the amisulpride group and  $95.1 \pm 36.7$  minutes in the ondansetron group ( $p=0.88$ ). Nitrous oxide was administered to 28 (70%) patients in each group ( $p=1.00$ ), while the mean fentanyl dose was  $80.2 \pm 34.6$   $\mu$ g and  $81.5 \pm 35.1$   $\mu$ g, respectively ( $p=0.89$ ). Davolos et al. (2024), in a randomized study of 212 patients undergoing laparoscopic cholecystectomy, similarly reported comparable operative conditions between their antiemetic groups. The operative time was  $60.0 \pm 22.1$  minutes in the palonosetron group and  $60.0 \pm 20.3$  minutes in the ondansetron group ( $p=0.999$ ), while the duration of anaesthesia was  $88.7 \pm 23.8$  and  $88.8 \pm 25.8$  minutes, respectively ( $p=0.967$ ). The duration of pneumoperitoneum was also comparable at  $51.9 \pm 20.0$  versus  $51.0 \pm 18.3$  minutes ( $p=0.747$ ). These findings were consistent with the present study in demonstrating similar intraoperative exposure between comparison groups.<sup>[8]</sup> During the first 0–6 postoperative hours in the present study, PONV occurred in 16 (40%) patients receiving amisulpride compared with 24 (60%) receiving ondansetron, while 24 (60%) versus 16 (40%) patients remained free from PONV, respectively; this difference was statistically significant ( $p=0.04$ ). Kranke et al. (2013) evaluated intravenous amisulpride in 215 surgical patients and reported a 24-hour PONV incidence of 20/50 (40%) with amisulpride 5 mg compared with 37/54 (69%) with placebo ( $p=0.006$ ). The corresponding rates with amisulpride 1 mg and 20 mg were 48% and 57%, respectively. Although their assessment covered the entire 24-hour postoperative period rather than only the first 6 hours, the 40% PONV incidence observed with amisulpride 5 mg was identical to the 40% early incidence found in the amisulpride group of the present study.<sup>[9]</sup> The difference in PONV between the study groups persisted during the later postoperative periods. At 6–12 hours, 34 (85%) patients in the amisulpride group and 26 (65%) in the ondansetron group had no PONV, while nausea occurred in 4 (10%) versus 9 (22.5%) and vomiting in 2 (5%) versus 5 (12.5%) patients, respectively ( $p=0.03$ ). At 12–24 hours, 38 (95%) patients receiving amisulpride and 30 (75%) receiving ondansetron remained free from PONV; nausea was reported in 2 (5%) versus 7 (17.5%), and vomiting in 0 (0%) versus 3 (7.5%), respectively ( $p=0.01$ ). Suen et al. (1994), in a randomized study of minor gynaecological laparoscopic surgery with 102 patients in each group, reported that ondansetron 4 mg reduced first-hour emetic episodes to 12% compared with 33% with placebo. Over 24 hours, however, 25% of ondansetron-treated patients experienced emetic episodes and 43% experienced nausea, compared with 56% and 58%, respectively, in the placebo group. These published observations confirm that clinically relevant nausea and vomiting can continue throughout the 24-hour postoperative

period despite ondansetron prophylaxis.<sup>[10]</sup> In the present study, complete response during 0–24 hours was achieved in 30 (75%) patients receiving amisulpride compared with 20 (50%) receiving ondansetron. Partial response occurred in 8 (20%) and 12 (30%) patients, while treatment failure occurred in 2 (5%) and 8 (20%) patients, respectively, and the overall difference was statistically significant ( $p=0.02$ ). Bhattarai et al. (2011) studied 100 adults undergoing elective laparoscopic surgery and reported a complete response, defined as absence of nausea or emesis and no requirement for rescue antiemetic during 24 hours, in 76% of patients receiving ondansetron 4 mg alone and 92% receiving ondansetron 4 mg combined with dexamethasone 4 mg. The 75% complete response obtained with amisulpride in the present study was therefore close to the 76% complete response reported with ondansetron monotherapy in their population, whereas the present ondansetron group showed a lower complete response rate of 50%.<sup>[11]</sup> The requirement for rescue antiemetic therapy was significantly different between the groups in the present study. Rescue medication was required by 6 (15%) patients in the amisulpride group compared with 14 (35%) patients in the ondansetron group, while 34 (85%) and 26 (65%) patients, respectively, required no rescue therapy ( $p=0.04$ ). Kranke et al. (2018), in a large multicentre randomized trial involving 1,147 patients at high risk of PONV, reported rescue antiemetic use in 40.9% of patients receiving amisulpride 5 mg together with a standard nondopaminergic antiemetic compared with 49.4% in the control group receiving the standard antiemetic alone ( $p=0.002$ ). Complete response in that trial was also higher with amisulpride at 57.7% compared with 46.6% in the control group ( $p<0.001$ ). Although the absolute rescue medication rates were higher than those observed in the present study because of differences in study population and prophylactic regimen, the direction of effect was similar, with amisulpride-containing prophylaxis associated with a lower rescue requirement.<sup>[12]</sup> Regarding postoperative adverse effects, headache occurred in 3 (7.5%) patients in the amisulpride group and 8 (20%) in the ondansetron group ( $p=0.04$ ). Dizziness was reported in 4 (10%) versus 7 (17.5%) patients ( $p=0.33$ ), whereas drowsiness occurred in 6 (15%) and 12 (30%) patients, respectively ( $p=0.03$ ). Bhalla et al. (2015), in a randomized double-blind study of 100 patients undergoing laparoscopic cholecystectomy, reported headache in 20% of patients receiving ondansetron compared with 6% receiving palonosetron. Interestingly, the 20% incidence of headache in their ondansetron group was exactly the same as the 20% observed with ondansetron in the present study. They additionally reported nausea in 24% versus 16%, total PONV in 50% versus 20%, and rescue antiemetic requirement in 32% versus 16% for ondansetron and palonosetron, respectively.<sup>[13]</sup> The Ramsay Sedation Scores in the present study were  $2.1 \pm 0.4$  with

amisulpride and  $2.5 \pm 0.6$  with ondansetron during 0–6 hours ( $p=0.02$ ), and  $2.0 \pm 0.3$  versus  $2.3 \pm 0.5$  during 6–12 hours ( $p=0.03$ ). By 12–24 hours, the scores had decreased to  $2.0 \pm 0.2$  and  $2.1 \pm 0.4$ , respectively, and the difference was no longer statistically significant ( $p=0.21$ ). Shilpa et al. (2015), in a randomized study involving 60 patients, reported a Ramsay sedation score of 2.0 in patients receiving ondansetron with dexamethasone compared with  $2.1 \pm 0.3$  in those receiving clonidine with dexamethasone on arrival in the postoperative period ( $p=0.003$ ). They also reported PONV in 30% of the ondansetron group and 36.7% of the clonidine group. The postoperative Ramsay scores around 2.0 reported in that study were within the same low sedation range observed during the later postoperative period in the present study.<sup>[14]</sup>

## CONCLUSION

Intravenous amisulpride 5 mg was more effective than ondansetron 4 mg in preventing postoperative nausea and vomiting following laparoscopic surgeries. Patients receiving amisulpride showed a higher complete response rate and a lower requirement for rescue antiemetic therapy during the first 24 postoperative hours. The incidence of headache and drowsiness was also lower in the amisulpride group. Overall, amisulpride provided better postoperative antiemetic control with an acceptable safety profile.

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