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Original Research Article

Comparative Study between Amisulpride and Ondansetron for Prevention of Postoperative Nausea and Vomiting in Patients Undergoing Laparoscopic Cholecystectomy

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Abstract

Background: Laparoscopic cholecystectomy is now a procedure of choice for cholelithiasis and chronic cholecystitis. Laparoscopic procedures are being done under general anaesthesia with muscle relaxants and controlled ventilation. Postoperative nausea and vomiting (PONV) is a common and a distressing complication after surgery. PONV may be mild or transient, but its impact on patients can be much more severe, it can cause inability to mobilize after surgery, restricted oral intake, complications of protracted vomiting and delayed recovery and discharge after surgery.

Methods: Sixty patients, of either sex, ASA physical status I or II, undergoing elective laparoscopic cholecystectomy, were randomly allocated into two groups containing thirty patients each. Group A received intravenous inj. Amisulpride 5 mg i.v. over 1-2 minutes before induction of anaesthesia. Group O received intravenous inj. Ondansetron 4 mg i.v. over 1-2 minutes before induction of anaesthesia.

Results: In Group A, total 4 patients had nausea and/or vomiting, while other 26 patients were asymptomatic, while in Group O, total 13 patients had nausea and/or vomiting, while 17 other patients were asymptomatic.

Conclusion: Amisulpride can be considered as a safe and a promising alternate option for PONV in place of Ondansetron.

Keywords: Amisulpride, Ondansetron, PONV.

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Introduction

Postoperative nausea vomiting is the second most common complaint after pain in post-surgical procedure.[1] 5 main receptor pathways are involved in PONV, amongst which CHEMORECEPTOR TRIGGERING ZONE is one. Ondansetron and dexamethasone are routinely used for PONV prevention; however, ondansetron has been associated with an increased risk of QT prolongation and arrhythmias, particularly in individuals over 50 years of age.[2]

Amisulpride, a dopamine (D2, D3) receptor antagonist, has demonstrated safety and efficacy in managing PONV in non-neurosurgical settings.[3–5] Previous studies primarily focussed on its enteral administration, but the recent Food and Drug Administration (FDA) approval of intravenous (IV) amisulpride has opened new possibilities for its use. This randomized study was therefore undertaken to assess and compare the effectiveness of Amisulpride and Ondansetron in alleviating postoperative nausea vomiting after laparoscopic cholecystectomy.

Materials and Methods

This was a randomized, comparative interventional clinical study performed in KPC Medical College and Hospital, Jadavpur from November 2025 till March 2026.

After getting approval from the institutional ethical committee, an informed consent was taken from every patient enrolled in the study.

Sixty patients aged ⩾18–⩽60 years, ASA physical status I and II, planned for elective laparoscopic cholecystectomy were included.

The exclusion criteria included the following: Age less than 18 years and more than 60 years, known allergy to anaesthetic agents, history of substance

abuse and current opioid use, pheochromocytoma, pregnancy, lactation, patient on drugs that prolong the QT interval, movement disorders, Severe renal impairment and unwilling patients.

Method of randomization: Patients were allocated randomly by a computer-generated list of random permutations to one of two equal groups (30 patients each): group A and group O.

Group A – 30 patients were given intravenous inj. Amisulpride 5 mg i.v. over 1-2 minutes before induction of anaesthesia.

Group O – 30 patients were given intravenous inj. Ondansetron 4 mg i.v. over 1-2 minutes before induction of anaesthesia.

In the operation theatre, the patient's body weight, fasting, consent, and pre-anaesthetic checkup was checked, i.v access was established and IV fluids started @ 2ml/kg/hr. Standard monitors like ECG, Pulse oximeter, NIBP connected to the patients and baseline heart rate, systolic blood pressure, diastolic blood pressure, mean arterial blood pressure were noted.

After pre-oxygenation with O2 100% for 3 min, anaesthesia was induced with a standard anaesthetic protocol using midazolam 0.05 mg/kg, fentanyl 2 µg/kg, propofol 2 mg/kg, and tracheal intubation was facilitated by atracurium 0.5 mg/kg intravenously. Lungs were mechanically ventilated with N2O:O2 3:2 and anaesthesia was maintained with isoflurane 0.8% and atracurium 0.1 mg/kg every 25 min. Ventilation was adjusted to maintain normocapnia (end-tidal carbon dioxide 40 ± 5 mmHg). Post intubation, both the groups received inj. Dexamethasone 8 mg i.v. as standard institutional prophylaxis.

Pneumoperitoneum was created by insufflations of CO2 and operation table was tilted to about 15° reverse Trendelenburg. Intra-abdominal pressure was not allowed to exceed more than 14 mmHg. After 1 h of surgery, each patient received 1 g paracetamol infused over 30 min intravenously. During surgery, Ringer's lactate solution was administered in maintenance dose as per Holliday-Segar formula. Any hypotension (MAP < 20% preoperative) was managed with a fluid bolus of normal saline 250–300 ml. If hypotension did not respond to fluid administration, Mephentermine 6 mg i.v. was ready to be administered. Any incidence of bradycardia (HR < 50/min) was treated with atropine 0.6 mg i.v. At the end of surgery, residual neuromuscular block was reversed by the injection of neostigmine 0.05 mg/kg and glycopyrrolate 0.01 mg/kg i.v. and patient was extubated when spontaneous respiration was adequate, and they were able to obey commands. Patients were transferred to the post-anaesthesia care unit (PACU) where they were strictly monitored for any evidence of complications or adverse events, PONV. ECG 12 leads done in all patients after 6 hours postoperatively.

The primary outcome was to evaluate the incidence of PONV following intra-operative administration of amisulpride (5 mg) versus ondansetron (4 mg) in adult patients undergoing elective laparoscopic cholecystectomy within the first 24 hours post-operatively. PONV was defined as any episode of nausea (subjective unpleasant sensation associated with the urge to vomit) or vomiting (forceful expulsion of gastric contents) reported by the patient or observed by staff. In such cases, rescue antiemetic was given with inj. Metoclopramide 10 mg i.v. Treatment-related adverse events were noted which was defined as any drug-attributable events (e.g. QTc prolongation >500 ms on the electrocardiogram (ECG), bradycardia <50 beats per minute requiring intervention, allergic reactions like rash/itching, extrapyramidal symptoms, or psychological disturbances), monitored continuously via vital signs, ECG, and clinical observation in the first 24 hours, with documentation in the patient's record.

Statistics: Categorical variables were summarized as Number of patients and percentage of patients and compared across the groups using Pearson's Chi Square test for Independence of Attributes/ Fisher's Exact Test as appropriate.

Continuous variables were summarized as Mean and Standard Deviation and compared across the groups using Unpaired t-test. The statistical software SPSS version 30 was used for the analysis.

An alpha level of 5% been taken, i.e. if any p value is less than 0.05 it was considered as significant.

Sample size: Sample size was calculated with reference to a previous study by Ravindranath S et al [6]. As per that study, where the incidence of postoperative nausea and vomiting was 36% in the ondansetron group and 22% in the amisulpride group and considering $\alpha = 0.05$ and power of 80%, the calculated sample size of 30 patients per group was considered adequate for this study, including possible dropouts.

Results: Total 60 patients were studied after applying exclusion criteria. Analysis of demographic profiles showed no statistically significant difference for age, sex and BMI.

Table 1:

Parameter	Mean + SD		P Value
	Group O	Group A	
Age	44.53 + 11.96	44.8 + 11.35	0.93
Male/Female	16/14	15/15	0.79
Bmi	24.27 + 4.94	23.72 + 4.22	0.65

In the initial hour post-op, none of the patients developed any signs of nausea or vomiting. After 1st hour, one patient from group A developed nausea and one patient developed vomiting. At the end of 5 hours, another patient from Group A developed vomiting while one other patient developed nausea. So total 4 patients were affected from Group A, while remaining 26 patients were asymptomatic. While in group O, after 1st hour, 3 patients developed nausea and 2 patients vomited. At the end of 6 hours, 6 patients developed nausea and 2 other patients vomited. So total 13 patients were affected, while remaining 17 patients were asymptomatic.

Table 2:

Group/ Parameter	Group O (N=30)	Group A (N=30)
Vomiting	**4**	**2**
Nausea	**9**	**2**
No Nausea Or Vomiting	**17**	**26**

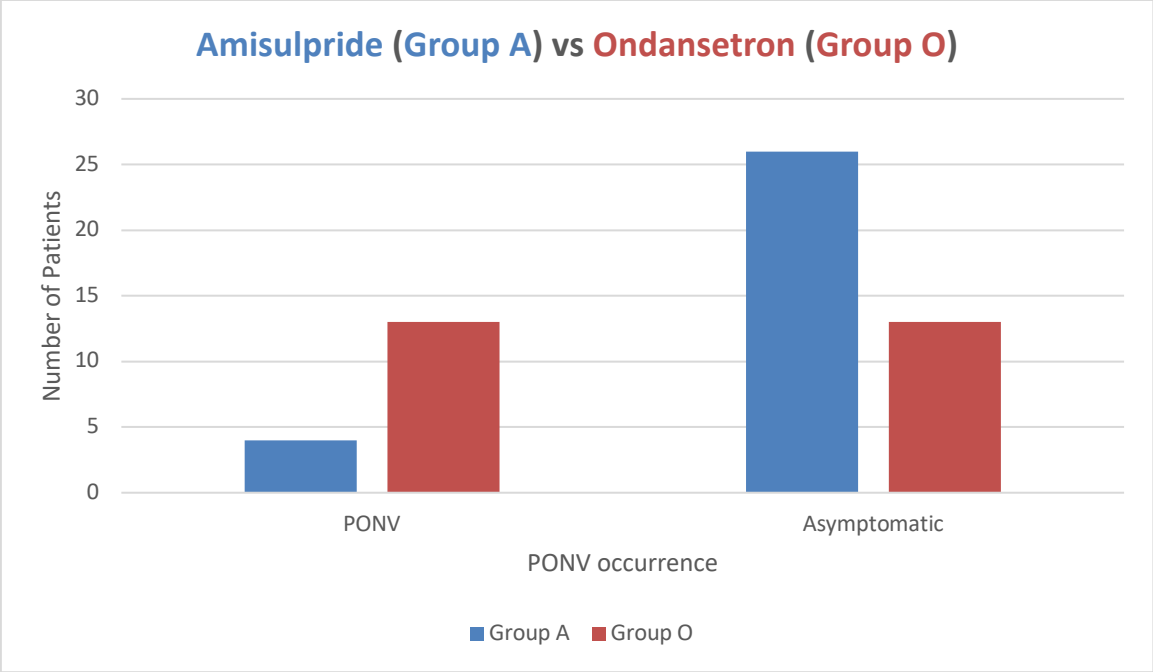

Figure 1: Amisulpride (Group A) vs Ondansetron (Group O)

So, $\chi^2 = 6.6486$. The p-value is 0.00998. The result is significant at $p < 0.05$.

The incidence of vomiting was significantly lower in Group A compared to Group O ($p = 0.00998$), indicating better efficacy of the intervention in reducing postoperative vomiting.

Discussion

Our study found that a single intra-operative prophylactic dose of IV amisulpride significantly reduced the incidence of PONV compared to ondansetron in patients undergoing elective laparoscopic cholecystectomy. There are several classes of antiemetic drugs, including 5-hydroxytryptamine 3 (5-HT3), D2, and neurokinin-1 (NK1) receptor antagonists, corticosteroids, antihistamines, and anticholinergics. [7–13] The most commonly reported electrocardiographic abnormalities include ST-T changes and prolonged QTc, which can progress to lethal arrhythmias like torsades de pointes and cardiac arrest. [14,15] While ondansetron remains a commonly used antiemetic in laparoscopic settings, it is known to increase the risk of arrhythmias in patients with pre-existing QTc prolongation.[16]

Despite prophylactic administration of IV ondansetron, a significant proportion of patients undergoing laparoscopic cholecystectomy continue

to experience PONV. PONV can contribute to events like intravascular volume depletion, electrolyte imbalances, pulmonary aspiration, and prolonged hospital stay.[17] Amisulpride, a dopamine receptor antagonist which was initially used as an atypical antipsychotic in the dose range 600–1200 mg/day, orally, was approved by the FDA in 2020 as an antiemetic. Amisulpride offers a longer duration of action, with a half-life of approximately 12 hours, compared to 6 hours for ondansetron. IV amisulpride (5 mg) has been shown to be more effective than placebo in reducing nausea and vomiting.[18]

Amisulpride is not associated with sedation, extrapyramidal side effects, or QTc prolongation at antiemetic doses.[4] When used in combination with other antiemetics, it demonstrates a favourable safety profile comparable to a placebo. Moreover, IV amisulpride has not shown significant drug interactions and does not induce or inhibit cytochrome P450 liver enzymes.[13]

Kranke et al. [4] evaluated different doses of IV amisulpride administered at anaesthesia induction for PONV prevention in non-neurosurgical patients and concluded that 5 mg was the optimal and safest dose. A 2022 survey among anaesthesia providers reported that IV amisulpride has a superior safety profile compared to IV ondansetron.[19]

Conclusion

A single intra-operative IV dose of amisulpride (5 mg) demonstrated significantly lower incidence of PONV compared to ondansetron and may be considered a promising alternative to ondansetron in patients undergoing laparoscopic cholecystectomy.

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