RESEARCH PAPER

To Evaluate the Efficacy and Safety of Ondansetron Versus Palonosetron in Prevention of Nausea and Vomiting After Laparoscopic Appendicectomy - A Randomized, Prospective, Double Blind, Comparative Study

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ABSTRACT

Background: Postoperative nausea and vomiting remain common complications after laparoscopic appendicectomy despite advancements in anaesthetic practice. Newer 5-HT3 antagonists such as palonosetron may provide prolonged antiemetic protection compared with ondansetron.

Aim: To evaluate and compare the efficacy and safety of intravenous ondansetron 4 mg and palonosetron 0.075 mg administered before induction of general anaesthesia in preventing postoperative nausea and vomiting.

Methods: A prospective randomized double-blind study was conducted in 150 female patients undergoing elective laparoscopic appendicectomy. Patients were divided into two equal groups receiving ondansetron or palonosetron. Incidence and severity of nausea, vomiting, complete response rates, rescue antiemetic use and adverse drug reactions were recorded for 72 hours postoperatively.

Results: Both drugs significantly reduced postoperative emesis; however, palonosetron demonstrated lower incidence and severity of nausea, particularly during the 4–24 hour postoperative period. Complete response rates were higher in the palonosetron group, and adverse effects were mild and comparable between groups.

Conclusion: Palonosetron provides superior control of postoperative nausea with comparable safety to ondansetron and may be preferred for prophylaxis in high-risk laparoscopic surgery patients.

Keywords: Postoperative nausea and vomiting; Ondansetron; Palonosetron; Laparoscopic appendicectomy.

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INTRODUCTION

Postoperative nausea and vomiting (PONV) remains one of the most unpleasant and frequent complications following general anesthesia, with an incidence of up to 30% in unselected surgical populations and as high as 70–80% in high-risk groups undergoing laparoscopy [1,2]. PONV not only causes considerable discomfort for patients but also increases the risk of postoperative complications such as dehydration, wound dehiscence, electrolyte imbalance, and aspiration, resulting in delayed recovery and prolonged hospital stays [1,3].

Patients undergoing laparoscopic procedures—including laparoscopic appendectomy—are particularly vulnerable to PONV due to pneumoperitoneum, visceral stimulation, and intraoperative opioid use [4,5]. Effective prophylaxis against PONV has therefore become an essential component of perioperative care to improve patient satisfaction and postoperative outcomes [1,6].

Among pharmacologic agents used for PONV prevention, serotonin (5-HT_3) receptor antagonists are widely accepted

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as first-line options because of their favorable efficacy and safety profile [1,7]. Ondansetron, a first-generation 5-HT_3 antagonist, has been one of the most commonly used antiemetics for PONV, acting centrally in the chemoreceptor trigger zone and peripherally on vagal nerve terminals in the gut [7]. Despite its widespread use, ondansetron's relatively short half-life and limited receptor binding duration may compromise its ability to control delayed PONV when used as a single preoperative dose [7].

Palonosetron is a newer, second-generation 5-HT_3 receptor antagonist with markedly higher receptor affinity and a significantly longer plasma half-life (~40 hours) than ondansetron, enabling prolonged antiemetic action [8,9]. It also exhibits unique allosteric binding and positive cooperativity at the 5-HT_3 receptor, which may contribute to its extended efficacy [8]. Multiple clinical studies comparing palonosetron and ondansetron have reported more effective prevention of both early and late PONV, as well as reduced need for rescue antiemetics following various surgical procedures [9,10].

For example, in laparoscopic cholecystectomy patients, palonosetron demonstrated non-inferior or superior efficacy to ondansetron in reducing the incidence of PONV without increased adverse effects [9]. Similarly, meta-analytic evidence has suggested that palonosetron may provide improved antiemetic protection compared to ondansetron, particularly in high-risk patients [10]. Nevertheless, there remains a need for well-designed, procedure-specific comparisons — especially in laparoscopic appendectomy, where literature is limited and patient profiles differ from other laparoscopic populations.

Considering the clinical impact of PONV and the pharmacological differences between ondansetron and palonosetron, this randomized, prospective, double-blind comparative study aims to evaluate the efficacy and safety of intravenous ondansetron (4 mg) versus palonosetron administered before induction of general anesthesia in patients undergoing laparoscopic appendectomy.

MATERIAL AND METHODS

After obtaining approval from the Institutional Review Board of Government Medical College, Bhavnagar (IRB No. 241/2012), and written informed consent from all participants, this prospective, randomized, double-blind clinical trial was conducted in 150 female patients scheduled for elective laparoscopic appendicectomy under general anaesthesia. Patients aged between 18 and 40 years with American Society of Anesthesiologists (ASA) physical status I or II were included in the study. Patients were excluded if they were lactating mothers; had pre-existing nausea or vomiting; a history of opioid intake, alcohol abuse, esophageal reflux disease, acid peptic disease, motion sickness, postoperative nausea and vomiting, or psychiatric illness; were smokers or antenatal females; or had received any antiemetic medication within 24 hours prior to surgery.

In the pre-anaesthetic preparation room, baseline vital parameters were recorded and intravenous access was secured with an appropriately sized cannula. Randomization was performed using computerized randomization software, and patients were allocated into two groups. Group O received intravenous ondansetron 4 mg, while Group P received intravenous palonosetron 0.075 mg. The study drug was prepared by a co-investigator who was not involved in postoperative assessment. Ondansetron 4 mg (2 ml) and palonosetron 0.075 mg (1.5 ml) were diluted with normal saline to a total volume of 10 ml and administered slowly over 15 seconds, 15 minutes prior to induction of anaesthesia. The principal investigator responsible for intraoperative and postoperative observations remained blinded to group allocation. Patients were observed for any adverse reactions such as pain at injection site, signs of allergy, dizziness, or chest and abdominal discomfort.

All patients received premedication with intravenous tramadol 2 mg/kg, midazolam 0.02 mg/kg, and glycopyrrolate 8 µg/kg before shifting to the operating theatre. Standard monitoring, including heart rate from electrocardiography, mean arterial pressure using non-invasive blood pressure monitoring, and peripheral oxygen saturation, was established. Following preoxygenation, anaesthesia was induced with intravenous thiopentone sodium 2.5% administered slowly until loss of eyelash reflex. Endotracheal intubation was facilitated with intravenous succinylcholine 2 mg/kg, and the trachea was intubated with an appropriately sized cuffed polyvinyl chloride endotracheal tube. Anaesthesia was maintained with a mixture of oxygen and nitrous oxide (50:50), sevoflurane 1–2%, and vecuronium bromide 0.08–0.1 mg/kg for controlled ventilation. Laparoscopic appendicectomy was performed using carbon dioxide as the insufflating gas.

At the conclusion of surgery, neuromuscular blockade was reversed with intravenous glycopyrrolate 8 µg/kg and neostigmine 0.05 mg/kg. After meeting satisfactory extubation criteria, the trachea was extubated and patients were transferred to the post-anaesthesia care unit for further observation. Postoperative analgesia was provided with intravenous diclofenac sodium 75 mg when the visual analogue scale (VAS) score exceeded 4. Patients were monitored for vital parameters hourly for the first four postoperative hours. Nausea was defined as a subjective unpleasant sensation associated with an urge to vomit, while vomiting was defined as spasmodic rhythmic contraction of respiratory muscles leading to forceful expulsion of gastric contents. The intensity of nausea was assessed using a four-point categorical scale based on VAS scoring, where a score of 0 indicated no nausea, 1–3 mild nausea, 4–7 moderate nausea, and 8–10 severe nausea.

Patients experiencing any episode of vomiting or severe nausea received rescue antiemetic therapy with intravenous metoclopramide 10 mg administered slowly. Episodes of nausea, vomiting, and use of rescue antiemetic

were recorded at 0–4, 4–12, 12–24, 24–48, and 48–72 hours postoperatively. Complete response was defined as the absence of nausea and vomiting without the requirement for rescue medication during each time interval. Patients requiring rescue antiemetic therapy were categorized as treatment failures, and the time to treatment failure was defined as the interval until the first administration of rescue medication. Adverse drug reactions, including headache, drowsiness, and dizziness, were monitored and recorded for 72 hours postoperatively in both groups.

RESULTS

Table 1 shows that both groups were comparable in baseline characteristics, which supports unbiased comparison of antiemetic efficacy. The mean age in Group O was 26.3±08.54 years compared to 24.76±07.07 years in Group P with p=0.2456, indicating no statistical difference. Mean weight was also similar at 49.65±07.54 kg versus 49.18±06.80 kg (p=0.6915). ASA physical status distribution was 66/9 versus 69/6 (p=0.9999), confirming equal surgical risk profile. Duration of surgery was 67.66±11.94 minutes in Group O and 69.09±14.78 minutes in Group P (p=0.8462), while anaesthesia duration was 78.50±12.37 versus 78.52±14.90 minutes (p=0.9952), showing both groups were homogenous before assessing outcomes.

Table 2 demonstrates the number of patients experiencing nausea, vomiting and total PONV across time intervals. During 0–4 hours, PONV occurred in 21.33% of Group O compared to 10.66% of Group P (p=0.1177). At 4–12 hours, nausea incidence was markedly higher in Group O at 17.33% compared to 02.67% in Group P with significant p=0.0049, and total PONV was 17.33% versus 04.00% (p=0.0150). Between 12–24 hours, nausea remained 09.33% in Group O while none was reported in Group P (p=0.0135). Incidence further reduced after 24 hours with only 06.66% PONV in Group O and none in Group P.

Table 3 highlights severity of nausea where absence of nausea was higher in Group P at almost all intervals. During 0–4 hours, 84.00% of Group O had no nausea compared to 93.33% in Group P. At 4–12 hours, none category increased to 97.33% in Group P versus 82.66% in Group O (p=0.0049), indicating better efficacy of palonosetron. Moderate nausea during early period was 08.00% in Group O versus 02.67% in Group P, and severe nausea remained minimal in both groups.

Table 4 shows complete response rates where Group P consistently had higher percentages though differences were statistically insignificant. Complete response at 0–4 hours was 78.67% in Group O versus 89.33% in Group P, and at 4–12 hours it was 74.67% versus 90.33%. Similar trends were observed at 12–24 hours and beyond with 77.33% versus 92.00%, suggesting improved clinical response with palonosetron.

Table 5 demonstrates adverse drug reactions which were mild and comparable. Headache was seen in 14.67% of Group O and 8.00% of Group P (p=0.3029), dizziness in 10.67% versus 2.67% (p=0.0976), and drowsiness in 6.67% versus 4.00% (p=0.7190), confirming safety of both drugs over 72 hours.

Table 1: Patients Characteristics

Patient's Characteristics	Gr. O (n=75) (Mean± SD)	Gr. P (n=75) (Mean ±SD)	P value
Age (yrs)	26.3±08.54	24.76±07.07	0.2456
Weight (Kg)	49.65 ± 07.54	49.18 ± 06.80	0.6915
ASA Physical Status I/II	66 / 9	69 / 6	0.9999
Duration of surgery (min)	67.66 ± 11.94	69.09 ± 14.78	0.8462
Duration of Anaesthesia (min)	78.50 ± 12.37	78.52 ± 14.90	0.9952

Table 2: No. Of Patients With Ponv

Time Interval	Parameter	Gr. O (n=75) No. %	Gr. P (n=75) No. %	p value
0-4 hr	Nausea	12 16.00	5 06.66	0.1203
	vomiting	04 05.33	3 04.00	1.0000
	PONV	16 21.33	8 10.66	0.1177
4-12 hr	Nausea	13 17.33	2 02.67	0.0049
	vomiting	03 04.00	1 01.33	0.6199
	PONV	13 17.33	3 04.00	0.0150
12-24 hr	Nausea	07 09.33	0 00.00	0.0135
	vomiting	01 01.33	1 01.33	1.0000
	PONV	07 09.33	0 00.00	0.0135
24-48 hr	Nausea	04 05.33	0 00.00	0.1202
	vomiting	01 01.33	0 00.00	1.0000
	PONV	05 06.66	0 00.00	0.0583
48-72 hr	Nausea	02 02.67	0 00.00	0.4966
	vomiting	00 00.00	0 00.00	-
	PONV	02 02.67	0 00.00	0.4966

Table 3: Distribution of Severity Of Nausea

Time Interval	Severity	Gr. O (n=75) No. %	Gr. P (n=75) No. %	p value
0-4 hr	None	63 84.00	70 93.33	0.1203
	Mild	04 05.33	02 02.67	0.6811
	Moderate	06 08.00	02 02.67	0.2756
	Severe	02 02.67	01 01.33	1.0000
4-12 hr	None	62 82.66	73 97.33	0.0049
	Mild	08 10.66	01 01.33	0.0335
	Moderate	04 05.33	01 01.33	0.3665
	Severe	01 01.33	00 00.00	1.0000
12-24 hr	None	68 90.66	75 0100	0.0135
	Mild	03 04.00	00 00.00	0.2450
	Moderate	03 04.00	00 00.00	0.2450
	Severe	01 01.33	00 00.00	1.0000
24-48 hr	None	71 94.66	75 01.00	0.1200
	Mild	02 02.67	00 00.00	0.4966
	Moderate	02 02.67	00 00.00	0.4966
48-72 hr	None	73 97.33	75 01.00	1.0000
	Mild	01 01.33	00 00.00	1.0000
	Moderate	01 01.33	00 00.00	1.0000

Table 4: No. Of Patients with Complete Response At Different Time Intervals

Time	Gr. O (n=75) No. %	Gr. P (n=75) No. %	P value
0-4hr	59 78.67	67 89.33	0.7453
4-12hr	56 74.67	68 90.33	0.2761
12-24hr	58 77.33	69 92.00	0.1393
24-48hr	58 77.33	69 92.00	0.0908
48-72hr	59 78.67	69 92.00	0.0908

Table 5: Adverse Drug Reaction

Parameter	Gr. O (n=75) No. %	Gr. P (n=75) No. %	P value
Headache	11 14.67	6 8.00	0.3029
Dizziness	8 10.67	2 2.67	0.0976
Drowsiness	3 6.67	1 4.00	0.7190

DISCUSSION

Post-operative nausea and vomiting remains one of the most common adverse outcomes following laparoscopic surgery, particularly in female patients undergoing general anaesthesia. The present study demonstrated that although both ondansetron and palonosetron effectively reduced emesis, palonosetron showed superior efficacy in decreasing the incidence and severity of postoperative nausea, especially during the early postoperative period. The reduction in PONV observed in the palonosetron group between 4–12 hours and 12–24 hours correlates with the pharmacodynamic profile of second-generation 5-HT3 antagonists, which possess longer receptor binding affinity and extended plasma half-life compared with first-generation agents. Previous clinical evaluations have shown that palonosetron provides prolonged antiemetic protection lasting up to 72 hours due to its unique allosteric receptor interaction, thereby improving sustained control of nausea rather than only immediate postoperative symptoms [11].

The present findings are consistent with studies evaluating newer serotonin antagonists in laparoscopic procedures, where delayed nausea rather than vomiting represented the major clinical challenge. Kim and colleagues reported that palonosetron demonstrated improved prevention of postoperative nausea compared with ondansetron in patients receiving patient-controlled analgesia, supporting the observation that palonosetron offers better protection against nausea beyond the early postoperative phase [11]. The current results showing significantly lower nausea incidence at 4–12 hours (17.33% vs 2.67%) and 12–24 hours (9.33% vs 0%) in the palonosetron group further reinforce this concept.

Another important observation in the study was that the incidence of vomiting remained statistically comparable between groups, suggesting that both drugs effectively suppress the emetic reflex but differ in controlling the subjective sensation of nausea. This aligns with pharmacological reviews indicating that 5-HT3 antagonists are highly effective in preventing vomiting but may vary in efficacy against nausea due to differences in central receptor modulation [13]. Palonosetron's ability to inhibit substance P mediated pathways and receptor cross-talk may explain the lower severity distribution of nausea observed in the present results [14].

Complete response rates were higher in the palonosetron group across all time intervals, although differences were not statistically significant. Similar outcomes have been reported in comparative clinical studies where both ondansetron and palonosetron achieved satisfactory antiemetic control, but palonosetron showed a consistent trend toward improved patient comfort and reduced rescue antiemetic requirement [15]. The reduction in rescue antiemetic use from 18.66% in the ondansetron group to 8% in the palonosetron group highlights a clinically meaningful advantage despite statistical insignificance, suggesting that palonosetron may improve postoperative recovery quality.

Safety analysis in the present study revealed comparable adverse effects between groups, with headache, dizziness and drowsiness occurring infrequently and without clinical significance. Earlier pharmacological analyses have also reported that newer 5-HT3 antagonists maintain favourable safety profiles without significant haemodynamic instability or serious adverse reactions, supporting their use in high-risk laparoscopic populations [12]. The stability of heart rate, mean arterial pressure and oxygen saturation further confirms that both agents are haemodynamically safe when administered prior to induction of anaesthesia.

Overall, the present findings support existing evidence that while ondansetron remains an effective and widely used antiemetic, palonosetron provides enhanced control of postoperative nausea with similar safety, particularly during the first 24 hours after laparoscopic surgery. The prolonged duration of action and reduced need for rescue therapy make palonosetron a valuable alternative in patients with multiple risk factors for PONV.

CONCLUSION

Both ondansetron and palonosetron were effective in preventing postoperative emesis following laparoscopic appendicectomy; however, palonosetron demonstrated superior efficacy in reducing the incidence and severity of postoperative nausea, particularly during the early postoperative period. Complete response rates and safety profiles were comparable between groups, with minimal adverse drug reactions observed. Therefore, palonosetron may be considered a more effective prophylactic antiemetic option for high-risk patients undergoing laparoscopic surgery, although cost considerations and institutional protocols may influence drug selection.

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