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Original Research Article

A COMPARATIVE STUDY OF ONDANSETRON MONOTHERAPY AGAINST ONDANSETRON AND DEXAMETHASONE GIVEN AS ANTIEMETIC PROPHYLAXIS DURING LAPAROSCOPIC SURGERIES UNDER GENERAL ANESTHESIA

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ABSTRACT

Background: Post-operative nausea and vomiting (PONV) remains a significant complication following laparoscopic surgeries, affecting patient recovery, satisfaction, and healthcare costs. While ondansetron is widely used as a first-line antiemetic, combination therapy with dexamethasone may offer superior prophylaxis. **Objective:** To compare the efficacy of ondansetron monotherapy versus ondansetron and dexamethasone combination for preventing PONV during laparoscopic surgeries under general anesthesia. **Materials and Methods:** This prospective, randomized, comparative clinical study included 86 patients (ASA grade I-II, aged 18-60 years) scheduled for elective laparoscopic surgeries. Patients were randomly assigned to Group O (n=43): ondansetron 4 mg at surgery end + 2 ml distilled water as premedication, or Group OD (n=43): ondansetron 4 mg at surgery end + dexamethasone 4 mg as premedication. PONV incidence, severity (0-3 scale), hemodynamic parameters, and rescue antiemetic requirements were assessed at 0, 60 minutes, 3, 6, 12, and 24 hours post-operatively. **Results:** Demographic profiles were comparable between groups ($p>0.05$). Group OD demonstrated significantly lower vomiting severity at 3 hours (1.32±0.46 vs. 1.67±0.46, $p=0.0009$), 6 hours (1.41±0.49 vs. 1.76±0.42, $p=0.0007$), and 24 hours (1.20±0.73 vs. 1.48±0.54, $p=0.051$). Group O required significantly more rescue antiemetics (113 vs. 71, $p=0.002$). No significant differences were observed in hemodynamic parameters or oxygen saturation between groups. **Conclusion:** The combination of ondansetron and dexamethasone is significantly more effective than ondansetron monotherapy for preventing PONV following laparoscopic surgeries, with reduced severity and lower rescue antiemetic requirements.

INTRODUCTION

Post-operative nausea and vomiting (PONV) is one of the most distressing complications following surgery, with an estimated incidence of approximately 30% in the general surgical population and up to 70% in high-risk patients.[1-2] Laparoscopic surgeries, despite their minimally invasive nature, are particularly associated with an elevated risk of PONV due to pneumoperitoneum, abdominal organ manipulation, and the use of general anesthesia.[3]

The clinical and economic impact of PONV is substantial. It prolongs post-anesthesia care unit (PACU) stay, delays hospital discharge, increases healthcare costs, and significantly diminishes patient satisfaction.[4-5] Each episode of vomiting can delay recovery room discharge by approximately 20 minutes.[5] While rarely life-threatening, PONV can lead to serious complications including dehydration,

electrolyte imbalances, suture tension and rupture, increased venous pressure and bleeding, subcutaneous emphysema, esophageal rupture, and airway hazards.[6-10]

The pathophysiology of PONV involves multiple neurotransmitter pathways, including serotonergic (5-HT3), dopaminergic (D2), histaminergic, cholinergic, and neurokinin systems.[11-12] The chemoreceptor trigger zone (CTZ) and nucleus tractus solitarius (NTS) in the brainstem coordinate the vomiting reflex through complex neural networks.[13]

Ondansetron, a selective 5-HT3 receptor antagonist, is widely used as a first-line antiemetic for PONV prophylaxis and treatment. It acts by blocking serotonin receptors in both the CTZ and gastrointestinal tract, preventing the emetic response triggered by serotonin release during surgery and anesthesia.[14-15]

Dexamethasone, a potent corticosteroid, has demonstrated antiemetic properties through multiple mechanisms, including inhibition of prostaglandin synthesis, reduction of inflammation, and modulation of neurotransmitter release.[16-17] When combined with 5-HT3 antagonists, dexamethasone exhibits synergistic effects, providing more comprehensive PONV prophylaxis.[18]

The Apfel score, which identifies female gender, non-smoking status, history of PONV/motion sickness, and post-operative opioid use as independent risk factors, helps stratify patients for targeted prophylaxis.[19] Laparoscopic surgeries, gynecological procedures, and cholecystectomy are recognized as high-risk surgical categories.[20]

Several studies have demonstrated the superior efficacy of combination therapy over monotherapy. Kumar et al,[21] reported that ondansetron plus dexamethasone reduced PONV to 10% compared to 35% with ondansetron alone. Similarly, Chattopadhyay et al,[22] achieved complete response in 84.6% of patients receiving the combination versus 62% with ondansetron alone.

This study aims to compare the efficacy of ondansetron monotherapy versus ondansetron and dexamethasone combination for antiemetic prophylaxis during laparoscopic surgeries under general anesthesia, evaluating incidence and severity of PONV, rescue treatment requirements, and hemodynamic changes.

MATERIALS AND METHODS

Study Design and Setting

This prospective, randomized, comparative clinical study was conducted in the Department of Anesthesiology at GKGH, Gujarat Adani Institute of Medical Sciences (GAIMS), Bhuj, Gujarat, India, from July 2023 to December 2024. Institutional Ethical Committee approval was obtained (GAIMS/IEC/APPROVAL/2023/3), and the study was registered prospectively. All participants provided written informed consent.

Study Population

A total of 86 patients of either gender, aged 18-60 years, classified as American Society of Anesthesiologists (ASA) physical status I or II, scheduled for elective laparoscopic surgeries under general anesthesia were enrolled.

Sample Size Calculation

Sample size was calculated using the formula for finite population correction:

$n = [Z^2 \times P(1-P)] / C^2$

Where Z=1.96 (95% confidence level), P=0.5 (response distribution), C=0.1 (margin of error).

Adjusted for finite population: $n(adjusted) = (N \times n)/(N+n)$

Assuming 5% non-response rate, the final sample size was 86 patients (43 per group).

Randomization and Blinding

Patients were randomly allocated using computer-generated random number sequences into two groups. For blinding, Group O received 2 ml distilled water as premedication, while Group OD received dexamethasone 4 mg. The study was double-blinded; neither patients nor outcome assessors knew the group allocation.

Inclusion Criteria

1. Patients aged 18-60 years
2. ASA grade I or II
3. Scheduled for elective laparoscopic surgeries under general anesthesia
4. Willing to provide informed consent

Exclusion Criteria

1. Patient refusal
2. History of drug addiction
3. History of motion sickness or previous PONV
4. Known hypersensitivity to study drugs
5. Severe hepatic or renal impairment
6. Pregnancy or lactation
7. Emergency surgeries

Study Groups

Group O (n=43): Ondansetron 4 mg intravenously at the end of surgery + 2 ml distilled water as premedication (for blinding)

Group OD (n=43): Ondansetron 4 mg intravenously at the end of surgery + Dexamethasone 4 mg intravenously as premedication

Preoperative Assessment

All patients underwent thorough preoperative evaluation 24 hours before surgery, including:

- Complete history and physical examination
- Airway assessment
- Routine investigations: hemoglobin, blood sugar, liver function tests, serum creatinine, serology, chest X-ray, and electrocardiogram
- Baseline vital parameters (pulse rate, blood pressure, respiratory rate, SpO_2)
- Patients were familiarized with the PONV severity scale in their native language

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Anesthesia Protocol

Premedication:

- Inj. Glycopyrrolate 0.04 mg/kg IV slowly
- Inj. Midazolam 0.05 mg/kg IV slowly
- Inj. Fentanyl 2 mcg/kg IV slowly

Induction:

- Preoxygenation with 100% oxygen for 5 minutes
- Inj. Propofol 2.5 mg/kg IV slowly
- Inj. Succinylcholine 2 mg/kg IV bolus

Maintenance:

- O_2:N_2O = 50:50
- Isoflurane (1-2%)
- Inj. Atracurium 0.5 mg/kg loading, intermittent as required
- Intermittent positive pressure ventilation (IPPV)

Monitoring:

Continuous monitoring of pulse rate, blood pressure, respiratory rate, ECG, $ETCO_2$, SpO_2, and urine output was performed throughout the procedure.

Emergence:

At surgery completion, residual neuromuscular blockade was reversed with glycopyrrolate 8 mcg/kg and neostigmine 50 mcg/kg. Patients were extubated after meeting criteria for spontaneous breathing, adequate muscle tone, and following commands.

PONV Assessment

Patients were assessed for PONV at 0 minutes, 60 minutes, 3 hours, 6 hours, 12 hours, and 24 hours post-operatively using the following severity scale:

Score	Description
0	No nausea or vomiting
1	Nausea without vomiting
2	Nausea with vomiting (<3 times)
3	Vomiting (>3 times)

Rescue Antiemetic

Patients scoring 2 or 3 received rescue antiemetic therapy with Inj. Metoclopramide 10 mg IV single dose administered over 1-2 minutes.

Outcome Measures

Primary Outcomes:

1. Incidence of PONV at different time points
2. Severity of PONV using the 0-3 scale

Secondary Outcomes:

1. Need for rescue antiemetic treatment
2. Changes in vital parameters (heart rate, blood pressure, SpO_2)

Statistical Analysis

Data were analyzed using SPSS software version [version]. Quantitative data were expressed as mean ± standard deviation and analyzed using Student's t-test for intergroup comparisons. Qualitative data were analyzed using the Chi-square test. A p-value <0.05 was considered statistically significant.

RESULTS

Demographic Characteristics

A total of 86 patients (43 in each group) completed the study. The demographic profiles of both groups were comparable with no statistically significant differences. [Table 1]

Table 1: Demographic Profile of Patients

Parameter	Group OD (n=43)	Group O (n=43)	p-value
Age (years, mean±SD)	40.62 ± 11.99	36.88 ± 10.41	0.13 (NS)
Gender (Male/Female)	15/28	14/29	-
Weight (kg, mean±SD)	68.51 ± 8.03	66.11 ± 8.54	0.18 (NS)
ASA Grade (I/II)	8/35	11/32	-

Both groups were comparable in terms of age, gender, weight, and ASA grade, ensuring that any observed differences in outcomes were due to the intervention rather than baseline demographic variations.

Table 2: Comparison of Mean Pulse Rate at Different Time Intervals

Time	Group OD (Mean±SD)	Group O (Mean±SD)	p-value
Pre-Induction	81.48 ± 5.95	78.86 ± 5.07	0.01 (S)
Intra-op 0 Mins	79.44 ± 6.78	80.32 ± 4.06	0.24 (NS)
Intra-op 10 Mins	81.41 ± 6.20	80.51 ± 4.81	0.25 (NS)
Intra-op 30 Mins	80.23 ± 5.81	80.69 ± 4.79	0.34 (NS)
Intra-op 60 Mins	81.06 ± 5.50	79.90 ± 4.70	0.15 (NS)
Extubation	80.86 ± 6.31	80.25 ± 4.86	0.32 (NS)
Post-op 0 Mins	78.18 ± 6.25	80.30 ± 5.12	0.05 (NS)
Post-op 60 Mins	80.65 ± 6.18	80.02 ± 4.90	0.27 (NS)
Post-op 3hrs	80.58 ± 6.13	79.62 ± 4.29	0.20 (NS)
Post-op 6hrs	79.39 ± 6.10	80.76 ± 5.34	0.12 (NS)
Post-op 12hrs	80.67 ± 5.79	80.34 ± 5.16	0.39 (NS)
Post-op 24hrs	79.79 ± 6.19	78.69 ± 4.47	0.14 (NS)

S = Significant, MS = Marginally Significant, NS = Not significant

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A significant difference in mean pulse rate was observed only at pre-induction. At all other time points, including intra-operative and post-operative periods, no significant differences were noted between groups.

No significant differences in systolic blood pressure were observed between groups at any time point, with all p-values >0.05 except at 24 hours (p=0.056) which approached significance.

No significant differences in diastolic blood pressure were observed between groups at any time point.

Oxygen saturation remained stable throughout the perioperative period with no significant differences between groups.

Table 3: Incidence of PONV at Different Time Points

Time	Group OD (n)	Group O (n)
0 min	0	0
60 min	0	0
3 hrs	14	29
6 hrs	18	33
12 hrs	22	29
24 hrs	17	22

Group O consistently experienced a higher incidence of nausea and vomiting compared to Group OD at all time points. Both groups reported no vomiting at 0 and 60 minutes. At 3 and 6 hours, Group O had significantly more vomiting incidents than Group OD. At 12 and 24 hours, the difference narrowed though Group O still showed higher incidence.

Table 4: Comparison of Severity of PONV (0-3 Scale)

Time	Group OD (Mean±SD)	Group O (Mean±SD)	p-value
0 min	0.18 ± 0.38	0.32 ± 0.46	0.14 (NS)
60 min	0.25 ± 0.43	0.44 ± 0.49	0.07 (NS)
3 hrs	1.32 ± 0.46	1.67 ± 0.46	0.0009 (S)
6 hrs	1.41 ± 0.49	1.76 ± 0.42	0.0007 (S)
12 hrs	1.53 ± 0.69	1.65 ± 0.74	0.461 (NS)
24 hrs	1.20 ± 0.73	1.48 ± 0.54	0.051 (NS)

The combination group (OD) demonstrated significantly lower vomiting severity at 3 hours (p=0.0009) and 6 hours (p=0.0007). At 24 hours, the difference was marginally significant (p=0.051). No significant differences were observed at 0 minutes, 60 minutes, or 12 hours.

Table 5: Need for Rescue Antiemetic

Parameter	Group OD	Group O	p-value
Number of rescue doses required	71	113	0.002 (S)

Group O required significantly more rescue antiemetic doses (113) compared to Group OD (71), with a p-value of 0.002 indicating statistical significance. This suggests better overall PONV control in the combination group.

DISCUSSION

Laparoscopic surgeries, despite their minimally invasive advantages, are associated with a high incidence of PONV due to pneumoperitoneum, visceral manipulation, and anesthetic factors.[23-24] This study compared the efficacy of ondansetron monotherapy versus ondansetron combined with dexamethasone for PONV prophylaxis in patients undergoing laparoscopic surgeries under general anesthesia.

Demographic Comparability

The demographic characteristics of both groups were comparable (p>0.05), ensuring that observed differences in outcomes were attributable to the interventions rather than baseline variations. The mean age in Group OD was 40.62±11.99 years and in Group O was 36.88±10.41 years, both within the recognized risk age range of <50 years.[25] Female predominance in both groups (65.1% in Group OD, 67.4% in Group O) reflects the known gender-based risk for PONV, as females are 2-3 times more likely to experience PONV.[26]

Hemodynamic Stability

Our study found no significant differences in heart rate, blood pressure, or oxygen saturation between groups at most time points, suggesting that neither ondansetron nor dexamethasone adversely affected hemodynamic stability. A significant difference in heart rate was noted only at pre-induction (p=0.01), which likely represents baseline variation rather than drug effect. These findings align with those of Ravi et al,[27] who reported no significant differences in intra-operative hemodynamics between anesthetic regimens for middle ear surgeries.

Incidence of PONV

The combination group demonstrated consistently lower PONV incidence at all time points. At 3 hours, PONV occurred in 14 patients (32.5%) in Group OD versus 29 patients (67.4%) in Group O. At 6 hours, the incidence was 18 (41.8%) versus 33 (76.7%), respectively. These findings are consistent with Kumar et al,[21] who reported PONV incidence of

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10% with ondansetron-dexamethasone combination versus 35% with ondansetron alone.

Similarly, Chattopadhyay et al,[22] demonstrated complete response rates of 84.6% with combination therapy versus 62% with ondansetron alone ($p<0.05$). The superior efficacy of combination therapy can be attributed to the synergistic action of ondansetron (blocking 5-HT3 receptors) and dexamethasone (reducing prostaglandin synthesis and inflammation), targeting multiple pathways in the emetic reflex.[28]

Severity of PONV

Statistically significant differences in PONV severity were observed at 3 hours (1.32±0.46 vs. 1.67±0.46, $p=0.0009$) and 6 hours (1.41±0.49 vs. 1.76±0.42, $p=0.0007$). The 24-hour severity (1.20±0.73 vs. 1.48±0.54, $p=0.051$) showed a marginally significant difference. The peak severity in both groups at 12 hours (1.53±0.69 in Group OD vs. 1.65±0.74 in Group O) corresponds to the period of maximal opioid effect and delayed gastric emptying.[29]

The timing of peak PONV severity in our study (12 hours) aligns with observations by Chen et al,[31] who noted that PONV incidence was lowest during early morning hours and varied by surgical type. The persistent effect of dexamethasone beyond 24 hours, as demonstrated in our study, supports its role in preventing delayed PONV through its prolonged anti-inflammatory effects.[31]

Rescue Antiemetic Requirements

The significantly lower requirement for rescue antiemetics in Group OD (71 vs. 113, $p=0.002$) reflects the superior prophylactic efficacy of the combination. This finding has important clinical implications, as reduced rescue medication needs translate to improved patient comfort, shorter PACU stay, and decreased healthcare costs.[32]

Our results align with Karanicolas et al,[33] who demonstrated that dexamethasone significantly reduced the risk of nausea (RR 0.59) and vomiting (RR 0.41) in laparoscopic cholecystectomy. Similarly, Weibel et al,[34] in their network meta-analysis concluded that combinations of antiemetic drugs were generally more effective than single drugs, with high-certainty evidence supporting ondansetron and dexamethasone as effective standalone options and their combination preferred in high-risk patients.

Clinical Implications

The enhanced efficacy of the ondansetron-dexamethasone combination can be attributed to several mechanisms:

1. **Complementary receptor blockade:** Ondansetron targets 5-HT3 receptors in the CTZ and gastrointestinal tract, while dexamethasone modulates prostaglandin synthesis and inflammatory mediators, affecting different points in the emetic pathway,[35]
2. **Delayed effect coverage:** Ondansetron's half-life (3-4 hours) provides effective prophylaxis during the early post-operative period, while dexamethasone's longer duration of action (24-48 hours) provides protection against delayed PONV.[36]
3. **Anti-inflammatory action:** Dexamethasone reduces surgery-induced inflammation and serotonin release, thereby decreasing the substrate for ondansetron's target receptors.[37]
4. **Opioid-sparing effect:** Dexamethasone's analgesic properties may reduce post-operative opioid requirements, indirectly decreasing opioid-induced PONV.[38]

Comparison with Previous Studies

Our findings are consistent with multiple studies in the literature:

Bakri et al,[39] compared dexmedetomidine and dexamethasone in laparoscopic cholecystectomy, finding that dexamethasone reduced PONV incidence to 28%, similar to our findings.

Rajnikant et al,[40] compared palonosetron-dexamethasone with ondansetron-dexamethasone combinations, reporting higher PONV incidence with ondansetron-dexamethasone but no statistically significant difference.

Thapa et al,[41] reported a PONV prevalence of 14% in patients receiving ondansetron prophylaxis, consistent with the early (0-60 minute) period of our study where no vomiting occurred.

Sridharan et al,[42] in their network meta-analysis concluded that dexamethasone and ondansetron have the best evidence as stand-alone options, with combination therapy preferred in high-risk categories.

CONCLUSION

This randomized, double-blind comparative study demonstrates that the combination of ondansetron and dexamethasone is significantly more effective than ondansetron monotherapy for preventing post-operative nausea and vomiting in patients undergoing laparoscopic surgeries under general anesthesia.

The key findings are:

1. **Superior efficacy:** The combination therapy (Group OD) resulted in significantly lower PONV severity at 3 hours ($p=0.0009$) and 6 hours ($p=0.0007$), with marginally significant benefit at 24 hours ($p=0.051$).
2. **Reduced rescue medication:** Group OD required significantly fewer rescue antiemetic doses (71 vs. 113, $p=0.002$), indicating better overall PONV control.
3. **Favorable safety profile:** No significant differences in hemodynamic parameters or oxygen saturation were observed between groups, confirming the safety of both regimens.
4. **Clinical utility:** The ondansetron-dexamethasone combination provides comprehensive prophylaxis covering both early and delayed PONV, making it particularly suitable for high-risk patients undergoing laparoscopic procedures.

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Based on these findings, we recommend the use of ondansetron (4 mg) combined with dexamethasone (4 mg) as a prophylactic antiemetic regimen for patients undergoing laparoscopic surgeries under general anesthesia. This approach offers superior PONV control with reduced need for rescue therapy, potentially improving patient satisfaction, shortening hospital stay, and reducing healthcare costs.

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