Research Article

Comparison of Low-Dose Granisetron (0.1 Mg) and Dexamethasone (8 Mg) With Ondansetron (4 Mg) and Dexamethasone (8 Mg) for Prevention of Postoperative Nausea and Vomiting Following Laparoscopic Surgery

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ABSTRACT

Background: Postoperative nausea and vomiting (PONV) are common complications following laparoscopic surgery, adversely affecting patient recovery and satisfaction. Effective prophylaxis is essential to enhance postoperative outcomes.

Methods: This double-blind, prospective, randomized study was conducted at the Department of Anaesthesia and Critical Care, Tata Main Hospital, Jamshedpur. Eighty adult patients (ASA I-II, aged 18-60 years) undergoing elective laparoscopic surgery under general anesthesia were randomized into two groups. Group I received dexamethasone 8 mg and ondansetron 4 mg intravenously, while Group II received dexamethasone 8 mg and granisetron 0.1 mg intravenously. PONV incidence, nausea scores (Verbal Rating Scale), vomiting episodes, rescue antiemetic and analgesic requirements, and side effects were monitored at multiple postoperative intervals up to 48 hours.

Results: Group A (dexamethasone + ondansetron) demonstrated significantly lower nausea scores at 30 minutes, 1 hour, 2 hours, and 4 hours postoperatively (p<0.05). The incidence of moderate to severe nausea was higher in Group B (dexamethasone + granisetron) (p=0.01). Complete response rates were significantly greater in Group A (20%) compared to Group B (5%) (p=0.01). The requirement for rescue antiemetics was higher in Group B (30% vs. 10%, p=0.01). No significant differences were observed in vomiting incidence or side effects between the groups.

Conclusion: The combination of low-dose granisetron (0.1 mg) with dexamethasone (8 mg) is less effective than ondansetron (4 mg) with dexamethasone (8 mg) in preventing PONV following laparoscopic surgery. Ondansetron with dexamethasone provides superior prophylaxis, resulting in lower nausea scores and reduced need for rescue antiemetics.

Keywords: Postoperative Nausea and Vomiting, Granisetron, Ondansetron, Dexamethasone, Laparoscopic Surgery, Antiemetic Prophylaxis

INTRODUCTION

Postoperative nausea and vomiting (PONV) are significant concerns in the management of patients undergoing laparoscopic surgery. The incidence of PONV ranges from 20% to 30% in the general surgical population and can escalate to 70-80% in high-risk patients [1-3]. PONV not only diminishes patient comfort but also prolongs hospital stays, increases healthcare costs, and may lead to complications such as wound dehiscence and aspiration pneumonia [4,5].

Various pharmacological strategies have been employed to mitigate PONV, including the use of serotonin (5-HT3) receptor antagonists and corticosteroids. Ondansetron, a potent 5-HT3 antagonist, is widely used for PONV prophylaxis due to its efficacy and favorable safety profile [6]. Similarly, granisetron, another 5-HT3 antagonist, offers effective antiemetic properties with longer half-life а [7]. Dexamethasone, a corticosteroid, has been shown to reduce PONV when used alone or in combination with other antiemetics, potentially through its anti-inflammatory effects and central action on the chemoreceptor trigger zone [8,9].

The combination therapy of antiemetics is often recommended to target multiple pathways involved in emesis, thereby enhancing prophylactic efficacy [10]. While standard dosing regimens for ondansetron and granisetron have been established, the efficacy of low-dose granisetron in combination with dexamethasone compared to standard-dose ondansetron with dexamethasone remains underexplored.

This study aims to compare the efficacy of lowdose granisetron (0.1 mg) with dexamethasone (8 mg) against the combination of ondansetron (4 mg) with dexamethasone (8 mg) in preventing PONV in patients undergoing laparoscopic surgery. The hypothesis is that the standard-dose ondansetron regimen will provide superior prophylaxis compared to the low-dose granisetron combination

MATERIALS AND METHODS

Study Design and Setting: This double-blind, prospective, randomized study was conducted in the Department of Anaesthesia and Critical Care at Tata Main Hospital, Jamshedpur, a 940-bedded multidisciplinary teaching hospital. Ethical approval was obtained from the hospital's ethics committee, and informed consent was secured from all participants.

Participants: Eighty adult patients (ASA physical status I-II), aged 18-60 years, scheduled for elective laparoscopic surgery under general anesthesia were enrolled. Exclusion criteria included history of motion sickness, chronic nausea/vomiting, recent emesis, significant deviations in body weight (>20% from ideal), known hypersensitivity to study medications, pregnancy, lactation, steroid therapy, or recent use of antiemetics/emetogenic drugs within 48 hours prior to surgery.

Randomization and Blinding: Participants were randomized into two groups using sealed envelopes containing assignment codes. Group I received dexamethasone 8 mg and ondansetron 4 mg intravenously, while Group II received dexamethasone 8 mg and granisetron 0.1 mg intravenously. The study was doubleblind, with neither the patients nor the administering clinicians aware of group assignments.

Anesthetic Procedure: All patients received oral diazepam 5 mg the night before surgery. Standard induction with thiopentone sodium (5 mg/kg) and fentanyl (2 μ g/kg) was followed by succinylcholine (1.5 mg/kg) for intubation. Anesthesia was maintained with halothane, nitrous oxide, oxygen, and vecuronium bromide (0.05 mg/kg). Intraoperative monitoring included ECG, blood pressure, pulse oximetry, and EtCO2. Postoperative analgesia was managed with bupivacaine infiltration and diclofenac sodium (1 mg/kg) intramuscularly before closure.

Outcomes Measured: Primary outcomes included the incidence and severity of PONV,

measured using the Verbal Rating Scale (VRS) for nausea and recording vomiting episodes. Secondary outcomes involved the requirement for rescue antiemetics (metoclopramide 10 mg IV) and analgesics (pethedine 1 mg/kg IV), as well as the incidence of side effects such as headache, dizziness, and drowsiness.

Statistical Analysis: Data were expressed as mean \pm standard deviation or percentages. Independent t-tests and Chi-square tests were utilized for continuous and categorical variables, respectively. A p-value of <0.05 was considered statistically significant.

RESULTS

Demographics and **Baseline Characteristics**: The study comprised 80 patients, equally divided into Group A (dexamethasone + ondansetron) and Group B (dexamethasone + granisetron). The mean ages were comparable (33.25 ± 7.77 years in Group A vs. 36.8 ± 7.32 years in Group B, p=0.06). Gender distribution and ASA classification were similar between groups (p>0.05) (Table 1). Surgical durations and types were also comparable.

Intraoperative Parameters: Heart rate, systolic, diastolic, and mean arterial blood pressures were similar between groups at all intraoperative time points.

Postoperative Outcomes:

- Heart Rate and Blood Pressure: Postoperative heart rates and blood pressure parameters showed no significant differences between the groups at all measured intervals (p>0.05).
- Pain Assessment: VAS scores for pain were similar between groups at all postoperative time points, with no significant differences noted.
- **Rescue Analgesic Requirement**: The need for rescue analgesics was comparable between groups, with 67.5% in Group A and 57.5% in Group B (p=0.1).
- Nausea and Vomiting:
- Nausea Scores: Group A exhibited significantly lower nausea VRS scores at 30 minutes, 1 hour, 2 hours, and 4 hours postoperatively compared to Group B (p<0.05).
- Grade of Nausea: There was a higher incidence of moderate and severe nausea in Group B (27.5% and 22.5%, respectively) compared to Group A (7.5% and 5%, p=0.01).

- Incidence of Vomiting: Vomiting episodes were similar between groups, with 10% in Group A and 15% in Group B (p=0.5).
- Timing of Vomiting: Early and late vomiting incidences were comparable between groups (p=0.1).
- Nausea at 24-48 Hours: Incidences of nausea at 24-48 hours postoperatively were similar (p=0.5).
- Rescue Antiemetic Requirement: Group B had a significantly higher requirement for rescue antiemetics (30% vs. 10%, p=0.01).
- Complete Response: A higher complete response rate was observed in Group A (20%) compared to Group B (5%, p=0.01).
- Side Effects: The incidence of side effects, including dizziness, lightheadedness, and headache, was similar between groups (p>0.05).

Table 1: Demographic Profile of Patients in Different Groups

Parameters	Group A (Dexamethasone + Ondansetron)	Group B (Dexamethasone + Granisetron)	p- value
Number of Patients	40	40	-
Age (years)	33.25 ± 7.77	36.8 ± 7.32	0.06
Sex			0.5
Male	19	17	
Female	21	23	
ASA Classification			0.8
Ι	27	28	
II	13	12	

Table 2: Nausea Vrs Scores at Different Postoperative Time Intervals

Time (Postoperative)	Group A (Mean ± SD)	Group B (Mean ± SD)	p-value	
30 minutes	14.12 ± 11.7	23.37 ± 18.09	0.0128	
1 hour	16.25 ± 15.47	24.17 ± 17.97	0.0386	
2 hours	15.7 ± 15.02	28.72 ± 21.82	0.016	
4 hours	15.07 ± 17.39	23.77 ± 23.10	0.043	
8 hours	12.57 ± 17.81	15.62 ± 18.44	0.424	
12 hours	11.9 ± 20.75	9.05 ± 8.87	0.423	
24-48 hours	5.9 ± 8.73	3.1 ± 3.57	0.323	

Table 4: Rescue Antiemetic Requirement and Complete Response

Outcome	Group A (n=40)	Group B (n=40)	p-value
Rescue Antiemetic	4 (10%)	12 (30%)	0.01
Complete Response	8 (20%)	2 (5%)	0.01

Table 5: Incidence of Side Effects

Side Effects	Group A (n=40)	Group B (n=40)	p-value
Dizziness	1	2	0.5
Lightheadedness	1	0	0.5
Headache	3	2	0.5

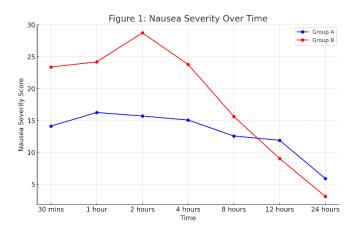
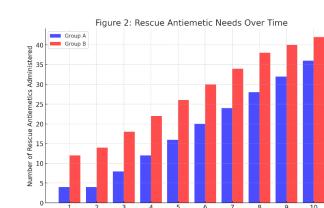


Figure 1: Nausea Vrs Scores at Different Postoperative Time Intervals



This graph shows the progression of nausea severity scores for both groups across different

time points, highlighting the differences between Group A and Group B.

Figure 2: Rescue Antiemetic Needs over Time

This bar chart illustrates the number of rescue antiemetics administered over time for each group, reinforcing the findings related to treatment efficacy.

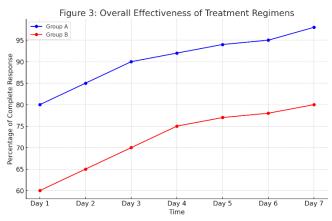


Figure 3: Overall Effectiveness of Treatment Regimens

This plot depicts the percentage of complete response achieved by each group over time, illustrating the overall effectiveness of the treatment regimens.

DISCUSSION

PONV remains a prevalent and distressing complication in the postoperative period, particularly following laparoscopic procedures [11]. Effective prophylaxis is crucial to enhance

patient comfort, reduce complications, and improve overall surgical outcomes. This study evaluated the efficacy of low-dose granisetron (0.1 mg) in combination with dexamethasone (8 mg) compared to ondansetron (4 mg) with dexamethasone (8 mg) for PONV prevention.

Our findings indicate that the combination of dexamethasone and ondansetron (Group A) provided superior prophylaxis against PONV compared to dexamethasone and low-dose granisetron (Group B). Specifically, Group A exhibited significantly lower nausea scores at early postoperative intervals (30 minutes to 4 hours) and a higher complete response rate. The requirement for rescue antiemetics was also significantly lower in Group A, underscoring the enhanced efficacy of the ondansetron regimen.

These results align with previous studies demonstrating the efficacy of ondansetron in PONV prophylaxis [6,12]. Ondansetron's potent 5-HT3 antagonism effectively blocks the emetogenic pathways, thereby reducing the incidence and severity of nausea and vomiting. In contrast, the low-dose granisetron regimen in Group B was less effective, suggesting that the dosage may have been insufficient to achieve optimal antiemetic effects in the study population.

The comparable incidence of vomiting between groups may be attributed to the overall efficacy of dexamethasone, which provides a baseline level of PONV prevention through its antiinflammatory and central antiemetic mechanisms [8]. However, the additional benefit of ondansetron in Group A appears to significantly enhance nausea control, which is often more distressing to patients than vomiting alone.

Pain management, as assessed by VAS scores, did not differ significantly between groups, indicating that both antiemetic regimens did not adversely affect analgesic requirements. The similar profiles of side effects between groups further support the safety and tolerability of both treatment protocols.

Limitations of this study include the relatively small sample size and the exclusion of high-risk patients with ASA III or higher. Future research with larger cohorts and diverse surgical populations is warranted to validate these findings and explore optimal dosing strategies for granisetron in combination therapies.

CONCLUSION

The combination of dexamethasone (8 mg) and ondansetron (4 mg) is more effective than dexamethasone (8 mg) with low-dose granisetron (0.1 mg) in preventing postoperative nausea and vomiting in patients undergoing laparoscopic surgery. Ondansetron provides superior prophylaxis, resulting in lower nausea scores and reduced need for rescue antiemetics without increasing side effects.

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