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# Dexamethasone versusOndansetron for prevention of postoperative nausea and vomiting Postoperative nausea and vomiting

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**ABSTRACT**
**Background:** postoperative nausea and vomiting (PONV) remains the second most common postoperative complaint after surgery
**Aims:**To compare Dexamethasone andOndansetron for prevention of postoperative nausea and vomiting.
**Settings and Design:** Prospective observational study conducted on 120 adult female patients
**Material and Methods:** Patients of ASA physical status I and IIwere randomly allocated to one of three groups and received antiemetic medication intravenously just before induction of anesthesia .Group 1 received dexamethasone 8 mg, Group 2 receivedondansetron 4 mg ,Group 3 received placebo normal saline. Hemodynamic variables, incidence of nausea, vomiting and pain was observed
**Results and Conclusion:** The overall incidence of PONV was significantly higher in the placebo group and was comparable in the dexamethasone and ondansetron group in this study.Prophylactic IV dexamethasone 8 mg is as effective as ondansetron 4 mg.
**Key Words –** Nausea, Vomiting, Anesthesia, Dexamethasone, Ondansetron

## I. INTRODUCTION:

**Despite advances in anaesthetic drugs and techniques, postoperative nausea and vomiting (PONV) remains the second most common postoperative complaint after surgery.**PONV, is defined as nausea and/or vomiting that occurs within 24 hours after surgery. The incidence of PONV can be very high following certain high-risk procedures, that is, procedures associated with an increased risk of developing nausea and vomiting postoperatively .

The determination of true incidence of PONV is difficult due to lack of a single stimulus of onset and multiple etiologies. In the absence of antiemetic treatment, the estimates put the incidence of PONV to 25 – 30 % for all surgical interventions and patient populations. The incidence of PONV is one of the most common causes of unanticipated hospital admissions in the adult surgical population.

Dexamethasone with ondansetron is an attractive combination, because ondansetron is most effective against early vomiting, whereas dexamethasone is effective against both early and late (2–24 h) nausea and vomiting, its late efficacy being pronounced. Female patients undergoing various surgical procedures are at high risk of PONV for whom multimodal strategies are most effective

## II. MATERIAL AND METHODS:

The protocol was practiced in premises of Sarojini Naidu Medical College, Agra on approval by Hospital Performa Committee and informed consent was obtained from each patient. One hundred twenty adult female patients of ASA physical status I and II, scheduled for major surgeries under general anesthesia were enrolled in this randomized controlled double blind study.

In the preoperative holding area, patients were allocated randomly to one of three groups (n = 40 each) by using a computer – generated random number table. The patients in each group received antiemetic medication intravenously just before induction of anesthesia.

Group D: received dexamethasone IV 8 mg
Group O: received ondansetron IV 4 mg
Group P: received a placebo (N saline) IV 2ml

anesthetic regimen was standardized for all patients. All patients received IV midazolam and fentanyl 2 mins before induction. Anaesthesia was induced by sodium pentothal, endotracheal intubation facilitated by vecuronium and maintained on oxygen, nitrous oxide and halothane

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on Bain circuit. The residual muscle paralysis was antagonized by standard doses of neostigmine and glycopyrrolate.

After end of surgery all patients were shifted to post anesthesia care unit (PACU) where patients were observed for first 2 hours and then transferred to the ward for further observation with standard analgesia in all.

The incidence of PONV was recorded by a person who was blind to the treatment groupat 2, 12 and 24 hours after operation. Nausea was measured using a10 - point numerical rating scale with 0 = no nausea and 10 = nausea as bad as can be.

Scoring was done as:

> = 8 - severe,

4 to 7 - moderate,

< = 3 - mild nausea

An emetic episode was defined as vomiting / retching events occurring in rapid sequence within a 1 min period. If the interval between 2 bouts of emesis exceed 1 min, they were considered separate episodes. If there were more than 4 episodes within 24 hours observation period, the emesis was considered severe.

End point was complete response defined as patients who stayed completely free from PONV and had no rescue antiemetic (metoclopramide) requirement during the first 24 hours observation period.

Pain intensity was rated by the patients using an 11 – point numerical rating scale similar to that used for nausea, where 0 symbolized no pain and 10 represented the worst pain imaginable.

Time of firstdemand of analgesia.

Other side effects such as restlessness, visual disturbance, headache or extrapyramidal symptoms were also considered at 2, 12 and 24 hours postoperatively.

## III. STATISTICAL METHODS

Sample size calculation was performed before starting the trials by using a statistical power analysis. Based on an alpha error of 0.05, 40patients were estimated in each group to have a 90% chance with a type I error of 5% to detect a decrease in total PONV incidence from 60% to 20% after treatment.

Statistical analysis was performed with ANOVA test for continuous variables expressed as mean ± SD (patient's age, weight, duration of surgery and anesthesia). Discrete variables, such as the incidence of complete response, nausea, or vomiting and pain were compared by using chi square, Fisher's exact tests. P values less than 0.05 were considered statistically significant.

**Ethical Consideration**

All patients received standard of care as per guidelines. No patient was treated with any non-standard or experimental therapy. Approval from institutional ethical and scientific committee has been obtained.

## IV. OBSERVATIONS:

This study was conducted on 120 adult female patients under general anesthesia at S.N medical College Agra. The patients all hemodynamic parameters like heart rate, diastolic and systolic blood pressure were comparable in all the three groups.

The patients were observed for post-operative nausea and vomiting, and rescue antiemetic requirement over 24 hours. Post-operative nausea in 0-2 hours was found in 9 patients ofgroup D and 8 patients of group O. It was found in 26 patients of placebo group. However in subsequent hours it was comparable in group D and O but was much higher in the placebo group. (Table 1)

Postoperative vomiting in 0-2 hours was found in 15%, 18% and 40% respectively in group D, O, and placebo group. In 2-12 and 12- 24 hours the incidence was comparable in group D and O. It was higher in placebo group but was not statistically significant. (Table 2)

The incidence of postoperative nausea and vomiting was significantly higher in placebo group, mid nausea was found in 9, 8 and 26 patients and moderate nausea was found in 3, 2 and 18 patients in group D, O and P respectively. However of severe nausea no case was reported in group D and O but 15 patients in placebo group had severe nausea. (Table 4)

For postoperative nausea and vomiting total rescue antiemetic requirement was much higher in the placebo group ( 55% ) as compared to 20% and 22.5% in the group D and group O respectively (p value = 0.008 versus O and 0.001 versus D ). (Table 5)

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| Postoperative interval and severity | | Group | | | P value |
|---|---|---|---|---|---|
| | | Group D (n=40) | Group O (n=40) | Group P (n=40) | |
| 0-2 hrs | Mild | 6 | 5 | 10 | D/O=0.98 |
| | Moderate | 3 | 3 | 7 | O/P=0.049 |
| | Severe | - | - | 9 | D/p=0.042 |
| | Total | 9/40 (23%) | 8/40 (20%) | 26/40(65%) | |
| 2-12 hrs | Mild | 4 | 4 | 10 | D/O=0.94 |
| | Moderate | 2 | 3 | 8 | O/P=0.1 |
| | Severe | - | - | - | D/p=0.89 |
| | Total | 6/40 (15%) | 7/40 (17.5%) | 18/40 (45%) | |
| 12-24 hrs | Mild | 10 | 8 | 12 | D/O=0.1 |
| | Moderate | - | - | 3 | O/P=0.89 |
| | Severe | - | - | - | D/p=0.53 |
| | Total | 10/40 (25%) | 8/40 (20%) | 15/40 (35%) | |

Table 1: **The number and percentage of nauseaat various postoperative intervals**

| Postoperative interval and severity | | Group | | | P value |
|---|---|---|---|---|---|
| | | Group D (n=40) | Group O (n=40) | Group P (n=40) | |
| 0-2 hrs | Yes | 6 | 7 | 16 | D/O=0.83 |
| | No | 34 | 33 | 24 | O/P=0.12 |
| | Total | 6/40 (15%) | 7/40 (18%) | 16/40 (40%) | D/P=0.08 |
| 2-12 hrs | Yes | 6 | 5 | 8 | D/O=0.82 |
| | No | 34 | 35 | 32 | O/P=0.52 |
| | Total | 6/40 (15%) | 5/40 (12.5%) | 8/40 (20%) | D/P=0.68 |
| 12-24 hrs | Yes | 5 | 4 | 10 | D/O=0.78 |
| | No | 35 | 37 | 30 | O/P=0.20 |
| | Total | 5/40 (12.5%) | 4/40 (10%) | 10/40 (25%) | D/P=0.31 |

Table 2: **The number and percentage of vomitingat various postoperative intervals**

| Grading of PONV | Group | | |
|---|---|---|---|
| | Group D (n=40) | Group O (n=40) | Group P (n=40) |
| Severity of Nausea | | | |
| Nil | 28 | 30 | 14 |
| Mild | 9 | 8 | 26 |
| Moderate | 3 | 2 | 18 |

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| | | | |
|---|---|---|---|
| Severe | - | - | 15 |
| Vomiting | | | |
| Nil | 34 | 33 | 24 |
| < 4 episodes in 24 hrs | 6 | 7 | 12 |
| >4 episodes in 24 hrs | - | - | 4 |

**Table 3: Severity of postoperative nausea and vomiting over 24 hrs**

| **Rescue antiemetic** | Groups | | | P value |
|---|---|---|---|---|
| | Group D | Group O | Group P | |
| 0 – 2 | 5 | 4 | 15 | |
| 2 - 12 | 3 | 5 | 6 | |
| 12 - 24 | - | - | 1 | |
| Overall | 8(20%) | 9(22.5%) | 22(55%) | D/O=0.78<br>O/P=0.008<br>D/P=0.001 |

**Table 4: Rescue antiemetic requirement over 24 hour**

## V. DISCUSSION

PONV is the most unpleasant common experience for a patient undergoing general anaesthesia. It is one of the most important factors that determines the length of hospital stay after ambulatory anaesthesia. It leads to patients dissatisfaction such that seventy percent of patient considered its avoidance as very important in postoperative period. In the present study, the effects of administration of dexamethasone (8 mgIV) and ondansetron (4 mg IV) were compared with placebo group (normal saline 2ml IV) given at the time of anesthetic induction in female patients undergoing various surgical procedures under general anaesthesia.

Dexamethasone was first reported to be an effective antiemetic agent in patients undergoing cancer chemotherapy in 1981[21]. The mechanism of antiemetic activity related to the use of dexamethasone is not fully understood but is believed to be due to either central inhibition of prostaglandin synthesis, a decrease in serotonin turnover in the central nervous system, or changes in the permeability of the blood-CSF barrier to serum proteins. It is also pointed out that steroids act to release endorphins and their antiemetic activity may therefore involve a psychological component.

The commoner class of antiemetics used for the prevention and treatment of PONV are the serotonin receptor antagonists / ondansetron. The antiemetic action of the 5-HT3 antagonists is due to simultaneous effects at both central and peripheral 5-HT3 receptor sites.

In our study, the incidence of post-operative nausea in early hrs was significantly higher in the placebo group 65% compared to 22.5% and 20% of patients in groups D and O respectively . There was no significant difference in the incidence of PONV between groups D and O. The rate of nausea did not differ between the three groups in the later hour; however the incidence was higher in the placebo group.

TugsanEgemenBilgin et al observed similar results in their comparative study on the antiemetic efficacy of dexamethasone, ondansetron, and metoclopramide in patients undergoing gynecologicalsurgery . Total rates of PON, POV ,and PONV were significantly higher in the placebo group at 0–2 hours and 2–12 hours as compared with the other three groups (P<.05). There was no significant difference in PON, POV, and PONV among these groups. They concluded that prophylactic dexamethasone is as effective as ondansetron 4 mg and metoclopramide 10 mg, and is more-effective than placebo.

In our study complete response was defined as patients who stayed completely free from PONV and had no rescue antiemetic requirement during the first 24 hr observation period .Complete response occurred in 65% of patients who received Dexamethasone and 67.5 %

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of the patients who received ondansetron.This was significantly higher compared to the placebo group where complete response was seen in only 35% of the patients .Gautam B et al in their study on antiemetic prophylaxis against postoperative nausea and vomiting with ondansetron-dexamethasone combination compared to ondansetron or dexamethasone alone for patients undergoing laparoscopic cholecystectomy reported that complete response occurred in 66.7, 66.0 and 89.4% in Groups O , D and OD respectively.

Postoperative pain is one of the etiologic factors of PONV. There is a positive correlation between postoperative pain and PONV. Effective management of pain may reduce the incidence of PONV.[50] In our study incidence of postoperative pain was comparable in both D and O groups (p value= 0.89) and was slightly higher in the placebo group (p value =0.29 versus D and 0.53 versus O ).

The present study showed that neither dexamethasone nor ondansetron were associated with any significant side effects. The most frequently reported adverse event during recovery from anaesthesia was headache followed by restlessness, dizziness, drowsiness, throat discomfort, muscle pain etc. There were no significant differences with regards to adverse events among the study groups.

## VI. CONCULSION

Postoperative nausea and vomiting is the most distressing side effect of naesthesia and surgery. Overall incidence of postoperative nausea and vomiting ranges from 40-60%. Prophylactic antiemetic in preventing this, without side effects is required. In our study prophylactic IV dexamethasone 8 mg is as effective as ondansetron 4 mg in reducing the PONV than placebo.

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