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# Comparative Study between Dexamethasone and Dexmedetomidine as an Adjuvant to Ondansetron for the Prevention of Post Operative Nausea and Vomiting Following Laparoscopic Surgeries - A Randomised Clinical Trial

Dr.Kiran B. Patel, Dr S.M. Suresh Babu, Dr.Hiren D. Patel, Dr Hrishikesh M Shah

*Associate professor ,Department of Anesthesiology ,B J Medical college, Ahmedabad-380016*
*Resident doctor Department of Anesthesiology ,B J Medical college ,Ahmedabad – 380016*
*Resident doctor Department of Anesthesiology ,B J Medical college ,Ahmedabad – 380016*
*Resident doctor Department of Anesthesiology ,B J Medical college ,Ahmedabad – 380016*

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**ABSTRACT**

**Introduction** : Postoperative nausea and vomiting (PONV) are the most common annoying events and complications following general anesthesia and surgery. Emetic incidents can lead to aspiration of gastric contents, wound unsealing, psychological distress, and delayed recovery from anesthesia and discharge times. **Methods**: This study is a prospective randomized single-blind study. The study involved 75 patients with American Society of Anesthesiologists physical status I and II, of both sexes, between 18 and 65 years of age, undergoing elective laparoscopic surgery . At the end of surgery, patients were randomly allocated to receive an intravenous single dose of either 0.1 mg/kg of ondansetron as a control group, or 8mg of dexamethasone following 0.1 mg/kg of ondansetron, or dexmedetomidine 0.1 μ/kg following 0.1 mg/kg ondansetron. Postoperatively, all the incidents of nausea, retching and/or vomiting were recorded and patients were asked if vomiting had occurred or if the patients felt nauseated with only two possible answers (yes or no**). Results**: incidence of PONV during the first 24 h postoperatively, with a slight difference in the ondansetron dexmedetomidine (ondan–dexmed) group, which was less infrequency in relation to the other groups (P<0.001). Regarding the PONV incidence in relation to intraoperative and postoperative medications, there was a highly significant difference among the three groups regarding the severity of PONV. The PONV severity was lower in the ondan–dexmed group in relation to the other groups (P<0.001). The rescue drug dose during the following 24 h was significantly low in ondan–dexmed group in relation to the other groups (P<0.05). **Conclusion**: A single dose of dexmedetomidine combined with ondansetron is superior to ondansetron alone or ondansetron combined with dexamethasone for preventing PONV in patients undergoing laparoscopic surgery under general anaesthesia.

**Key words- dexamethasone, dexmedetomidine, ondansetron, postoperative nausea and vomiting**

## I. INTRODUCTION

Postoperative nausea &vomiting (PONV) are the most common annoying events & complications following general anesthesia. Anesthesia is provided worldwide to more than 75 million patients every year. If it is not performed appropriately, one third of patients will experience postoperative vomiting, nausea or both (PONV). Emetic incidents can lead to aspiration of gastric contents, wound dehiscence, psychological distress, and delayed recovery from anesthesia. PONV is defined as any retching, nausea or vomiting that happens during the first 24 h following surgery.

Ondansetron, one of the most common antiserotonins is available for the prevention and treatment of PONV in patients undergoing different types of surgical procedures.

Dexmedetomidine is a potent α2-adrenergic agonist with probable usage in anesthesia because of its broad-spectrum effects, which include sympatholytic, sedative, analgesic, anxiolytic, anesthetic sparing, and hemodynamic-stabilizing advantages.

In prospective randomized control study, we have tried to compare both dexamethasone and dexmedetomidine as adjuvants when given with ondansetron for prophylaxis of PONV in patients

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undergoing laparoscopic surgery and to assess if there is any advantage of one drug over the other.

## II. MATERIAL AND METHODS

After obtaining institutional ethical approval from Institutional ethical committee, BJ Medical college and civil Hospital, Ahmedabad. 75 patients aged 18-65 years of either sex having ASA 1 and 2, BMI 35 below who are undergoing for elective laparoscopic surgeries under general anesthesia selected. Patients who refused for study, with ischemic heart disease, Hypertension, diabetes, gastroesophageal-reflux disease, chronic renal disease (serum creatinine level >2.0 mg/dl) or on replacement therapy(dialysis), allergy to study medication, those receiving antiemetics medication during the past 24h before surgery and patients with BMI above 35kg/m2 were excluded.

All patients were thoroughly examined preoperatively. Routine investigations were advised and verified on the day of surgery. After getting the written informed consent, Patient were taken on OT table and ASA standard monitors attached, baseline vitals were recorded.

Patients were premedicated with glycopyrrolate 4 microgram/kg, fentanyl 2 microgram/kg and ondansetron 0.15 mg/kg IV 20 minutes prior to induction. After monitoring the hemodynamics for 10 minutes, the anaesthetic procedure was started. General anaesthesia technique was selected, Patients were induced with Inj. propofol 2mg/kg and Inj.Succinyl Choline 2mg/kg intravenously to endotracheal tube size. Patients were maintained under controlled ventilation with O2, sevoflurane and atracurium besylate 0.5 mg/kg as maintenance anaesthesia. At the end of surgery, patients were randomly allocated by sealed envelope to receive an intravenous single dose of either 0.1 mg/kg of ondansetron (control group, N=25) or 8-mg dexamethasone following 0.1 mg/kg ondansetron [ondansetron–dexamethasone (ondan–dexa) group, N=25] or dexmedetomidine 0.1 μ/kg following 0.1 mg/kg ondansetron [ondansetron–dexmedetomidine (ondan–dexmed) group, N=25]. The study drug was diluted to a total of 100 ml normal saline solution and infused over a 15-min period. After surgery, reversal was achieved with Inj. neostigmine 0.05 mg/kg IV and Inj. glycopyrrolate 8 mcg/kg IV and tracheal extubation was done when the patients were fully awake. Postoperatively, all the incidents of nausea, retching and/or vomiting were recorded and patients were asked if nausea, retching, or vomiting had occurred with only two potential answers (yes or no). Occurrence of emetic incidents, need for supplemental antiemetic medications, sedation, need of analgesia, or any adverse effects were recorded for 24 h (in ward) after operation. Rescue antiemetic (metoclopramide 0.2 mg/kg) was given slowly intravenously if more than two episodes of nausea, retching, and/or vomiting had occurred or the patient had persistent nausea.

**Data and Statistical Analysis**

Data were analyzed using Statistical Program for Social Science, version20.0 Quantitative data were displayed as mean±SD. Qualitative data were exhibited as frequency and percentage.

The following tests were done:

(1) A one-way analysis of variance when comparing between more than two means.

(2) Analysis of variance test was used to estimate the difference between groups, and any results should be followed by Benferroni test to detect which group showed this significant difference in comparison with the other groups.

(3) $\chi$2-Test of significance was used to compare proportions between two qualitative parameters.

(4) Probability (P value).

a) P value of less than or equal to 0.05 was considered significant.

b) P value of less than or equal to 0.001 was considered as highly significant.

c) P value greater than 0.05 was considered insignificant

## III. RESULT

**DEMOGRAPHIC DATA**

There were no significant differences among the three groups with regarding mean age, sex, height, BMI, type of surgical procedure, length of surgical procedures, or length of anesthesia. Table1 shows the difference among the three groups according to study population data

Table 1 Comparison among groups according to characteristics of the study population (N=25)

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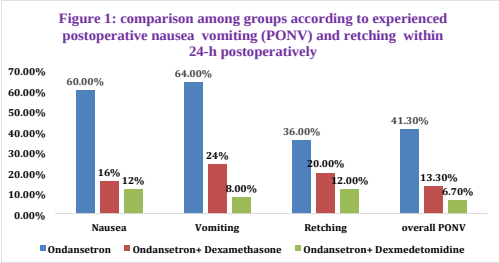
| | Ondansetron Alone | Ondan+ Dexamethasone | Ondan+ Dexmed | P value |
|---|---|---|---|---|
| **Age(year)** | **37.2±13.2** | **37.1±12.3** | **33.7±10.5** | **0.507** |
| **Weight(kg)** | **58.9±10.5** | **56.8±11.1** | **58.3±11.5** | **0.77** |
| **SEX (male/female)** | **11/14** | **11/14** | **16/9** | **0.263** |
| **Duration of anesthesia(min.)** | **76.2±5.9** | **74.7±4.9** | **76.5±6.3** | **0.522** |
| **Duration of surgery(min.)** | **66.4±4.8** | **65.1±4.7** | **66.6±5.9** | **0.548** |
| **ASA 1 / 2** | **12/13** | **9/16** | **11/14** | **0.682** |

Data are presented as mean±SD or numbers of patients. ANOVA, analysis of variance; PONV, postoperative nausea and vomiting. aANOVA test. bχ2-test

**Experienced postoperative nausea and vomiting incidence within 24-h postoperatively in relation to the study medications**

There were non-significant differences between the three groups regarding the incidence of PONV during the 24 h postoperatively, with a slight difference in the ondan–dexmed group in relation to the other groups. Regarding the incidence of nausea, it was less in the ondan–dexmed group, with three (12.0%) episodes of nausea in comparison with fifteen (60.0%) episodes in the ondan group and four (16.0%) episodes in the ondan–dexameth group. Regarding the incidence of retching, it was 3 (12.0%) episodes in the on dan–dexmed group versus 9(36.0%) episodes in ondan group and 5 (20.0%) episodes in the ondan–dexa group (P=0.118). Regarding the incidence of vomiting, it was 2 (8.0%) episodes in the ondan–dexmed group versus 16-episode (64.0%) in the ondan group and 6 (24.0%) episodes in the ondan–dexmed group (P=0.00007).

Table 2 and Fig. 1 demonstrate the difference among all groups according to incidence of nausea, retching, vomiting, and overall PONV during the 24 h postoperatively




Data are presented as mean±SD or numbers of patients. ANOVA, analysis of variance; PONV, postoperative nausea and vomiting. aANOVA test. bχ2-test

Table 2 Comparison among groups according to experienced postoperative nausea and vomiting within 24-h postoperatively (N=25)

| | Ondansetron alone | Ondan+ Dexamethasone | Ondan+ Dexmetomidine | P value |
|---|---|---|---|---|
| Nausea | 15(60) | 4(16) | 3(12) | 0.00019 |
| vomiting | 16(64) | 6(24) | 2(8) | 0.00007 |
| Retching | 9(36) | 5(20) | 3(12) | 0.118 |

Data expressed as number of patients (%). χ2-test. PONV, postoperative nausea and vomiting

**Postoperative nausea and vomiting incidence in relation to intraoperative and postoperative medications**

maximum participant 5(20%) from group ondansetron had required rescue antiemetic drugs within 2-6 hours postoperatively followed by 2(8%) participants from ondansetron+dexamethasone group. None of the participant from ondansetron+ dexmedetomidine group had required rescue antiemetic drugs within 26 hours postoperatively. Difference between three group for requirement of antiemetic rescue

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treatments within 2-6 hours postoperatively was statistical difference($p<0.05$).
maximum 17(68%) participants from group ondansetron+ dexmedetomidine had got complete response within 0-2 hours postoperatively followed by 12(48%) & 8(32%) participants from group ondansetron+dexamethasone and group ondansetron respectively. Similar increase trend of complete response was found from 3 groups within 2-6,6-12 & 12-24 hours postoperatively but it wasn't significant ($p>0.05$)

**Experienced postoperative complication developed within 24 hours postoperatively.**
2(8%) participants from group of ondansetron+ dexamethasone was developed headache complication within 24 hours postoperatively followed by 1(4%) participant from both remaining groups. Participants from group ondansetron (8%) & group ondansetron+ dexmedetomidine (8%) had developed complication of dizziness. Only one participant from all three group had developed complication of constipation. Difference between three group for developing complication within 24 hours postoperatively was not significant ($p>0.05$).

## IV. DISCUSSION

Postoperative nausea and vomiting (PONV) are the most common annoying events and complications following general anesthesia and surgery. Anesthesia is provided worldwide to more than 75 million patients every year. If it is not performed appropriately, one third of patients will experience postoperative vomiting, nausea or both PONV (1).

The primary objective of the study is to analyses how effective ondansetron, ondansetron–dexamethasone and ondansetron–dexmedetomidine are to alleviate post-operative nausea and vomiting in elective laparoscopic surgeries under general anaesthesia.

In our study, mean age of total participants was 36±12.1, out of which mean age of participant of group A(ondansetron) and group B (ondansetron+dexamethasone) were 37.2±13.2 & 37.1±12.3 respectively followed by group C ondansetron+dexmedetomidine (33.7±10.5) & not significantly difference ($p>0.05$)

In present study, more than half of participants from group A (56%) and group B (56%) were female. only around one third participants from group C (36%) were female., mean weight of total participants was 58.1±10.9 kg, out of which mean weight of participant of group A and group C were 58.9±10.5 & 58.3±11.5 kg respectively followed by group C (56.8±11.1) ($p>0.05$). More than half of participants (64%) had ASA status II from group B followed by group C (56%) & group A (52%) ($p>0.05$) mean duration of surgery from participant of group C and group A were 66.6±5.9 & 66.4±4.8 minutes respectively followed by group B (65.1±4.7) ($p>0.05$). Mean duration of anaesthesia of group C and group A were 76.5±6.3 & 76.2±5.9 minutes respectively followed by group B (74.7±4.9) ($p>0.05$) (Table 4). majority episode of nausea (28%) was experienced by group ondansetron within 0-2 & 2-6 hour postoperatively. Only 14% & 7% episodes of nausea was experienced by group ondansetron+dexamethasone within 0-2 & 2-6hours postoperative respectively. Only single episode (4%) of nausea occurred from group ondansetron+dexmedetomidine($p<0.05$). Overall episodes of nausea within 0-2 & 2-6 hours postoperatively in three comparison groups had statistically significant difference($p<0.05$). In our study, we found that majority of vomiting episodes (32% & 28%) occurred in group ondansetron within 0-2 & 2-6 hour postoperatively. Only 12% & 8% episodes of vomiting had occurred in group ondansetron+dexamethasone within 0-2 & 2-6 hour postoperative respectively. Only single episode (4%) of vomiting had occurred in group ondansetron+dexmedetomidine($p<0.05$). Overall majority of episodes of vomiting was experienced by group ondansetron (64%), followed by ondansetron+dexamethasone (24%) &ondansetron+dexmedetomidine (8%)

we found that overall majority of episodes of retching had experienced by group ondansetron (36%) within 24 hours postoperatively followed by ondansetron+dexamethasone (20%) &ondansetron+dexmedetomidine (12%) and the difference between three groups was not significant($p>0.05$). In our study, 20% of participants from group ondansetron had required rescue antiemetic drugs within 2-6 hours postoperatively followed by 8% of participants from ondansetron+dexamethasone group. None of the participant from ondansetron+ dexmedetomidine group had required rescue antiemetic drugs within 2-6 hours postoperatively and it was statistically significant($p<0.05$). Difference between three group for requirement of antiemetic drugs within 0-2, 6-12,12-24 hours postoperatively was not statistically significant ($p>0.05$).

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## V. CONCLUSION

On the basis of this study finding, dexmedetomidine has a superior antiemetic effect when combined with ondansetron in comparison with both ondansetron alone and dexamethasone combined with ondansetron in reducing the incidence of PONV during the first 24 hours after surgery, without any major adverse effects. They also provide higher incidence of complete response. Furthermore, the need for rescue antiemetic drugs in dexmedetomidine+ondansetron was lower as compared to other remaining two group. We therefore conclude that a single dose of dexmedetomidine +ondansetron is appropriate for preventing PONV in patients undergoing laparoscopic surgery under general anaesthesia.

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