TITLE: RANDOMIZED, DOUBLE-BLIND COMPARISON OF ONDANSETRON AND PLACEBO IN THE TREATMENT OF POSTOPERATIVE NAUSEA AND VOMITING.

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Postop nausea (N) and vomiting (V) are common sequelae of general anesthesia. Ondansetron (O; Glaxo Inc.) a serotonin type 3 ($5\text{-}HT_3$) receptor antagonist, has been shown to be effective in the control of acute cisplatin-induced emesis. This study was designed to evaluate the antiemetic effect and the safety of O in patients suffering from postop N and V. Informed consents were obtained from ASA I-III patients scheduled for elective surgery under general anesthesia to participate in this IRB approved study. No patient with clinical or laboratory evidence of hematologic, hepatic or renal diseases was included. Premedication consisted of morphine and scopolamine or atropine 1-2 hr prior to induction of anesthesia with thiopental. Anesthesia was maintained with N_2O/O_2 (70/30) and narcotic. The choice of the narcotic and muscle relaxant was left to the discretion of the anesthesiologist. Patients who complained of N or V within 2 hr of arriving in the PACU and requested antiemetic therapy were given either a single dose of O (8 mg) or placebo (P) IV over 2-5 min in a randomized double-blind manner. Vital signs were recorded frequently for 30 min after O or P administration. A rescue antiemetic (Compazine® 5-10 mg IV) was provided in case of continued V or at patient's request during the 4 hr observation period. Antiemetic efficacy was defined as no request for Compazine® and no V episode during the 4 hr period. Data was analyzed by unpaired student t-test and Mantel-Haenszel Chi-square test. Thirty-six patients (34 female) requested antiemetic within 2 hr postop and received either O (mean age = 35 years, N=18) or P (mean age = 37 years, N=18). There was no significant difference in the demographic data between the groups. The majority of the patients in each group had undergone either a gynecologic or an orthopedic surgical procedure. Administration of O or P did not have any significant effect on blood pressure or heart rate. Twenty four hour post treatment blood studies did not show any sign of hematologic, hepatic or renal alterations. O was an effective antiemetic in 78% of the patients (14/18) while P was effective in 28% of the patients (5/18). O was significantly better than P in the treatment of postop N and V ($P < 0.01$, 95% CI = 22 to 78%). We conclude that O (8 mg, IV) is a safe and effective antiemetic drug for the treatment of postop N and V.

Title: DROPERIDOL DOSE-RESPONSE IN OUTPATIENTS FOLLOWING ALFENTANIL-N_2O ANESTHESIA

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Introduction: Alfentanil (A), is commonly used in ambulatory surgery; but may cause nausea, vomiting, and oversedation, which may delay discharge and lead to unanticipated admission. The purpose of this study was to establish an appropriate dose of droperidol (D) as an antiemetic agent for $A/N_2O/O_2$ anesthesia by facemask or endotracheal tube.

Methods: With informed consent and IRB approval 123 patients, ASA 1 or 2 scheduled for outpatient surgery on the lower extremity, were randomly assigned to one of three treatment groups: I-no D, II-D 10 mcg/kg or III-D 20 mcg/kg. All patients received midazolam 1-2 mg, d-tubocurarine 3 mg, or vecuronium 0.01 mg/kg, and thiamylal. Anesthesia was maintained with A 0.5 - 1.5 mcg/kg/min, with 5 mcg/kg boluses as needed; and N_2O 70% in O_2. In Phase I, 63 patients, anesthesia was maintained by facemask and ventilation was spontaneous or assisted as needed. In Phase II, 60 patients were intubated with vecuronium. A was discontinued at the completion of skin closure and N_2O, when the dressing was applied. Postoperative data were recorded: times to awakening, command, orientation, ambulation and discharge. Emetic symptoms (ESx) were graded on a 3-point scale with 1 = nausea. 2 = retching, and 3 = vomiting. Data were analyzed by Kruskal-Wallis, t-test, and ANOVA, with $p < 0.05$ considered significant.

Results: There were no differences in demographics, times to verbal commands, orientation, ambulation or discharge. In Phase I there was no difference with regard to nausea or retching. However, the incidence of vomiting (Group III only) and overall ESx (Groups II and III) was significantly reduced. In Phase II the overall incidence of ESx was equivalent in both groups I and II and significantly less in Group III versus I or II. Intubation did not decrease the incidence of overall ESx compared to mask.

Discussion: In Phase I, D-20 ug/kg significantly decreased the incidence of vomiting and in Phase II, D-20 ug/kg significantly decreased the incidence of ESx. In Phase I,D-10 significantly decreased ESx but not in Phase II. D-20 appears to be more effective than D-10 in decreasing both vomiting and ESx.

Phase I - Mask (%)				Phase II - ETT (%)			
Group	I	II	III	Group	I	II	III
Vomiting	33	10*	0*	Vomiting	30	25	15
Overall ESx	62	31*	33*	Overall ESx	45	55	25*+
n = 21, all groups				n = 20, all groups			

*Different from Group I ($p<0.05$); +Different from Group II ($p<0.05$)

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