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A7

TITLE: EFFECT OF ONDANSETRON ON RECOVERY TIME, SEDATION LEVEL AND DISCHARGE FROM AMBULATORY SURGERY

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Ondansetron (OND (Glaxo)) is a new selective serotonin 3 (5HT-3) receptor antagonist effective in preventing cisplatin induced nausea and vomiting. Many antiemetic drugs produce side effects such as sedation, which may delay recovery. Purpose of study: To examine the effect of 3 different IV doses of OND on sedation level, fine, gross, and psychomotor functions, recovery and discharge times from ambulatory surgery.

Following IRB approval, written informed consent was obtained from 95 ASA I-II female patients scheduled for laparoscopy under general anesthesia.

Patients received either placebo (normal saline), OND 1, 4, or 8 mg diluted to 20 ml and infused over 2-5 min in a double-blind, randomized manner 5 min prior to anesthesia induction with alfentanyl (ALF), thiopental, and succinylcholine. Post intubation, anesthesia was maintained with N_2O/O_2, isoflurane, ALF and vecuronium. In post-anesthesia care unit (PACU), fentanyl was used to treat pain and droperidol or compazine for rescue antiemetic therapy. Awakening time was measured from time of N_2O off until patient responded. Total time from end of surgery to discharge was measured from time in PACU plus ambulatory stepdown unit (ASU). Sedation score (noted independently by patient and observer on a scale of 0 to 10: 0=awake; 10=sedated), Trieger dot test, gross motor (finger to nose) and fine motor (thumb to finger) were tested preop, 30 and 90 min postop. Balance and straight line walk were tested on admit to ASU. ANOVA and T tests were used to analyze data. Statistical significance was defined as $p<0.05$.

Regarding age, weight, height, and narcotic requirements, there was no significant difference between groups. Table values are non antiemetic rescue patients (n=72). Awakening time, PACU, ASU, and total times were not significantly different when compared to placebo (Table I). Sedation scores showed no significant difference between groups (Table II). Trieger dot test, gross, and fine motor, balance test and straight line walk were not significantly different when compared to placebo.

Patients in all groups were equally awake and responsive postop. Compared to placebo, patients at all OND doses recovered good fine, gross, and psychomotor functions without sedation, allowing rapid recovery and discharge from ambulatory surgery.

TABLE I AWAKENING AND DISCHARGE TIMES (Mean ± SD)

	Placebo	OND 1	OND 4	OND 8
n	13	17	20	22
Awakening Time (sec)	302 ± 157	296 ± 160	276 ± 111	343 ± 284
Time in PACU (min)	65 ± 8	69 ± 10	65 ± 8	73 ± 30
Time in ASU (min)	83 ± 40	87 ± 41	94 ± 49	84 ± 48
Total Time from end of Surgery to Discharge (min)	148 ± 36	156 ± 44	159 ± 50	157 ± 63

TABLE II PACU SEDATION SCORE (0=AWAKE, 10=SEDATED) (Mean ± SD)

		Placebo	OND 1	OND 4	OND 8
Post 30 Min	n	13	17	20	22
Patient		4.3 ± 2.3	6.4 ± 2.6	5.0 ± 3	4.1 ± 3
Observer		5.0 ± 1.5	5.8 ± 2	4.8 ± 2	4.5 ± 2.3
Post 90 min	n	13	17	20	22
Patient		3.3 ± 2	3.6 ± 2	3.1 ± 2.5	2.6 ± 1.6
Observer		4.0 ± 1.8	3.8 ± 1.8	3.4 ± 1.6	3.0 ± 1.6

A8

TITLE: PSYCHOMOTOR EFFECTS OF IV ONDANSETRON IN FEMALE OUTPATIENTS

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Ondansetron (Glaxo) is a new anti-emetic agent effective against chemotherapy associated nausea and vomiting.[1] We assessed the effects of ondansetron on post-operative psychomotor function in female ambulatory surgery patients.

Following IRB approval and informed consent, 83 ASA class I/II patients were randomly assigned to receive placebo or ondansetron 1, 4 or 8 mg. diluted to 20 ml and infused intravenously over 2-5 min. just prior to induction of general anesthesia. Anesthesia was induced with alfentanil 25 ug/kg, thiopental 3-6 mg/kg, and atracurium 0.3-0.4 mg/kg, and was maintained with alfentanil, isoflurane and N_2O.

Prior to induction, each patient performed a 60 sec. Finger Tapping test, Digit Symbol test, and mood evaluation (i.e. alertness, anxiety). These tests were repeated 1 and 2 hours after surgery. Statistical analysis was repeated measures ANOVA with Tukey's test; $p<0.05$ considered significant.

Patients were similar with respect to age, body mass index, operation performed, and total anesthetic agents received. Duration of recovery room stay was similar in all groups. Number of taps and Digit Symbol scores declined significantly both 1 and 2 hrs post surgery (see Figures 1 and 2, respectively). Ondansetron did not alter performance. No drug associated change in patient mood was noted.

These results suggest that: 1) psychomotor performance is still impaired two hours after surgery (at time of discharge), extending the findings of Lessin;[2] and 2) ondansetron does not cause significant impairment in psychomotor performance, compared to placebo. Additionally, ondansetron did not significantly alter patient mood compared to placebo.

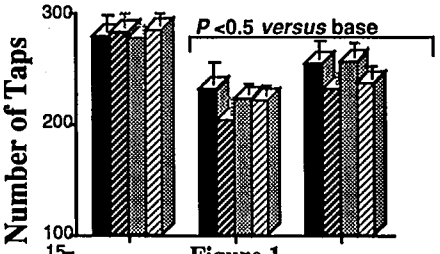

Figure 1

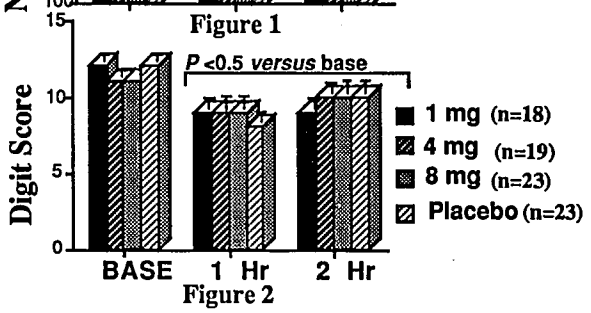

Figure 2

1. Marty M, et al. NEJM 322:816-821, 1990
2. Lessin JB, Anesth and Analg 72:S162, 1991