

## Prevention of emesis in 1-day ophthalmic surgery: double-blind comparison of ondansetron, droperidol and placebo

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### Abstract

In a randomized, double-blind study, we compared the prophylactic efficacy of ondansetron at a dose of 0.1 mg/kg (OND) vs. droperidol at a dose of 0.075 mg/kg (DBP) vs. placebo (PLA) in 120 patients undergoing pediatric 1-day ophthalmic surgery. Results showed an incidence of emesis in 10% of the OND group, in 37.5% of the DBP group and in 65% of the PLA group. Prophylactic administration of ondansetron represents the anti-emetic agent of choice in pediatric 1-day ophthalmic surgery. © 1997 Elsevier Science Ireland Ltd.

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### 1. Introduction

Post-operative nausea and vomiting (PONV) is one of the most common complications of ophthalmic surgery. It results from stimulation of the extra-ocular muscles during general anesthesia, which triggers the oculo-gastric (also called oculo-emetic) reflex. This derives from stimulation of the chemoreceptor trigger zone in the area postrema through the labyrinth pathways or ciliary ganglion [2,9,11].

Immediate and delayed emetic post-operative manifestations, frequently difficult to treat, originate from these phenomena. A high percentage of PONV in this type of surgery is well known [1,4,12].

The aim of this study was to evaluate the incidence of emesis in ophthalmic 1-day surgery and the validity of anti-emetic agents for the prophylaxis of PONV.

### 2. Materials and methods

A total of 120 patients, aged 3-14 years, ASA score I, undergoing ambulatory ophthalmic surgical procedures (ophthalmic visit in narcosis 58 cases, lacrimal

duct probing 14 cases, strabismus 31 cases, conjunctival and palpebral trauma 17 cases) were enrolled in the study, after written informed consent by their parents. Eighteen of the 120 patients included in the study had had previous episodes of post-anesthetic emesis. Ten patients were affected by conditions predisposing to vomiting (diabetes, chetoacidosis, gastro-enteric or endocrine disorders) and were excluded from the study. Demographic patient data are reported in Table 1.

General anesthesia, preceded by premedication with atropine sulphate at a dose of 0.02 mg/kg, was induced

Table 1  
Patient characteristics and surgery data

	PLA	DBP	OND
Number	40	40	40
Sex (M/F)	18/20	21/19	20/22
Age (years)	10 ± 2	9 ± 3	9 ± 4
Weight (kg)	18 ± 1	17 ± 3	18 ± 2
Previous PONV	5	6	7
Duration (min)	19 ± 5	21 ± 4	20 ± 3
Type of surgery			
Visit in narcosis	20	19	19
Lacrimal duct probing	5	4	5
Strabismus	10	12	9
Trauma	5	7	5

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Table 2  
Results

	Emesis				Total	No emesis
	0–2 h	2–4 h	4–6 h	6–24 h		
PLA	10	7	4	5	26 (65.0%)	14 (35.0%)
DBP	8	5	2	—	15 (37.5%)*	25 (62.5%)
OND	2	1	1	—	4 (10.0%)*	36 (90.0%)
PLA <sup>a</sup>	3	1	—	1	5 (19.2%)	0 (0.0%)
DBP <sup>a</sup>	2	2	—	1	5 (33.3%)	1 (16.6%)
OND <sup>a</sup>	1	—	1	—	2 (50.0%)	5 (71.4%)

<sup>a</sup> Patients with previous emesis.

\*  $P < 0.05$  vs. other groups.

with thiopentone (3–4 mg/kg) and vecuronium bromide (0.08–0.1 mg/kg); orotracheal intubation was performed. Anesthesia was maintained with N<sub>2</sub>O + O<sub>2</sub> (60:40), fentanyl 0.0002 mg/kg and isoflurane 0.5–1.5%. Repeated doses of vecuronium bromide (1 mg every 30–45 min) were administered.

Residual neuromuscular blockade was antagonized with neostigmine and atropine sulphate. When necessary, ketorolac tromethamine (0.4 mg/kg) was administered as analgesic in the immediate post-operative period. All patients were allowed to consume small quantities of liquids (100–150 ml) up to 3 h before induction of anesthesia. Double-blinded, randomized prophylaxis of post-operative vomiting compared ondansetron (0.1 mg/kg) (OND) both to droperidol (0.075 mg/kg) (DBP) and placebo isotonic saline solution (PLA).

All agents were administered immediately before induction. We did not consider nausea as a separate event, since in our experience it always precedes emetic episodes in ophthalmic surgery.

Patients were discharged from the ward 6 h after the end of surgery. Emesis was registered at the following intervals: 0–2; 4; 4–6 and 6–24 h after discharge.

The  $\chi^2$  test was applied to the data obtained and  $P < 0.05$  was considered statistically significant.

### 3. Results

Demographic data (age, weight, duration of surgical proceedings, previous post-anesthetic episodes) regarding the three groups of patients studied demonstrated no statistically significant differences. Comparative results of the study are reported in Table 2, showing a 65% incidence of emesis in the PLA group, 37.5% in the DBP group and 10% in the OND group; in the last group, no cases of delayed emesis (6–24 h) were registered. In three cases of the PLA group and in one case of the DBP, admission to the ward for the night following surgery was necessary. Prevention of emesis

with OND was successful in 71.4% (vs. 16.6% in the DBP group and 0% in the PLA group) of patients who had had previous episodes of PONV. As regards timing, a higher incidence of emesis was observed in the first post-operative period (0–2; 2–4 h), while a decrease occurred in the late period (6–24 h), especially in the DBP and OND group. Undesirable effects are reported in Table 3.

### 4. Discussion

Anti-emetic prophylaxis with OND reduced PONV episodes by 30% vs. placebo and droperidol, decreasing both frequency and incidence of emesis. A 65% incidence of emesis in the PLA group is in agreement with the international literature, relative to this type of surgery [3,5,10].

Ophthalmic surgery is associated with a high incidence of PONV. This can be explained by the following factors: type of surgery (traction on extra-ocular muscles in strabismus surgery); anesthetic agents employed (halogenated, opioids); anxiety and post-operative pain; and particularly important in children, time of fasting; intra-operative hydration grade; time-to-drink in the post-operative period [8]. Multifactorial pathogenesis of post-anesthetic emesis and its high incidence require its systemic prevention in pediatric ophthalmic surgery.

Table 3  
Undesired side-effects

	PLA	DBP	OND
Itching	4	3	3
Muscular rigidity	2	9	—
Trigeminal pain	12	9	7
Dizziness	5	4	5
Drowsiness/sedation	3	8	3
Restlessness	2	2	1
Hypotension	—	1	—

Hirsch [7] describes a so-called 'loss of recovery time' in an ambulatory structure provoked by PONV, which can be directly correlated with an annual decrease of surgical procedures and is estimated, in economic terms, at approximately \$519 000 a year. This, correlated to the low cost of OND (0.1 mg/kg prophylaxis costs \$15) [6], confirms the validity of the drug in terms of cost–benefit.

Ondansetron is efficient in 90% of pre-treated cases and, in particular, in 71.4% of cases with a history of previous post-anesthetic emesis. These results demonstrate its significant validity vs. PLA and DBP. Results obtained in the DBP group demonstrate its minor efficacy vs. OND and a significantly higher incidence of side-effects, including muscular rigidity, which, in this study, did not prolong recovery time, but represents a potential danger in the case of early discharge.

In the group of pre-treated patients with OND, no case of delayed emesis, a potential cause of delayed release or re-admission to the hospital, was observed.

Prophylactic administration of OND at a dose of 0.1 mg/kg is highly effective in reducing the incidence of post-anesthetic emesis in ophthalmic pediatric 1-day surgery: DBP, at the dose tested, proved to be less effective and to be associated with a high incidence of side-effects. A reduction of costs and recovery time is also probable in patients pre-treated with OND.

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