

Acceptability and efficacy of orally disintegrating tablets (ODT)ondansetron: A preliminary report

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Introduction: Postoperative nausea and vomiting (PONV) is a major complication of general anesthesia in children. Ondansetron, in both intravenous and oral preparation, has been shown to be efficacious in treating nausea and vomiting, prophylactically and acutely.(1, 2) Unfortunately these routes of treatment are not appropriate in actively vomiting patients lacking intravenous access. Orally disintegrating tablets (ODT) is an attractive alternative. In this study we are observing the acceptability and efficacy of ondansetron in a high-risk surgical population (T&A) with intravenous access for rescue, if needed.

Methods: After obtaining informed consent 5 to 11 year old patients undergoing adenotonsillectomy were randomized to receive ondansetron ODT (4 mg) or a placebo. Patients assessed the medications for taste and sensation (4 point scales) and future use. For all patients, anesthesia was induced sevoflurane/ nitrous oxide/oxygen, maintained with desflurane/ N2O/O2 and supplemented with fentanyl 2.5 mcg/kg and dexamethasone 0.5 mg/kg. Endotracheal intubation was facilitated by mivacurium 0.25 mg/kg or deep sevoflurane anesthesia. Upon completion of surgery patients were evaluated by an observer, blinded to pre-operative treatment, for pain, emergence agitation and need for rescue medication. Assessment was made q 5 min for the first 30 minutes and q 15 until a Steward Score of 6 was achieved. Incidence of nausea and vomiting were recorded for the next 24 hrs.

Results:

Table 1 Demographics and ODT Acceptability scores

Treatment Group	n	Age (yrs)	Weight (kg)	Gender m/f	Taste (#)	Sensation (#)	Would retake
Ondansetron	11	7.4 (±1.8)	30 (±10.7)	6/11	7	11	7
Control	11	7.2 (±1.3)	34 (±10.4)	3/8	10	9	11
		ns	ns	ns	-----	-----	-----

Table 2 Postoperative Evaluation

Treatment Group	Vomiting (#)	Vomiting (multiple) (#)	Pain score ≥ 6 (#)	Severe Agitation (#)	Rescue dose (#)
Ondansetron	3	0	4	1	6
Control	8	3	5	3	6
	p = .03	-----	ns	ns	ns

Discussion: Our preliminary findings demonstrate that a majority of children found the medication acceptable to taste and sensation and would be willing to use it in the future. An early trend suggests that the presence of medicine in the ODT makes the preparation less palatable. Ondansetron in this formulation appears to be efficacious, significantly reducing the incidence of vomiting in this small sample. Ondansetron ODT should be an acceptable alternative for children with active vomiting and no intravenous access.

References:

1. Patel RI et al.: Anesth. Analg. 1997.
2. Rose JB et al. Anesth. Analg. 1996.