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SCOPOLAMINE DOES NOT PREVENT POST-OPERATIVE EMESIS AFTER PEDIATRIC EYE SURGERY

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Introduction: Up to 85% of pediatric eye surgery patients undergoing eye muscle surgery exhibit post— operative nausea and vomiting. Although the etiology of the vomiting is unclear, a form of motion sickness resulting from acute eye muscle imbalance may occur. We designed the present study to evaluate transdermal scopolamine (Transderm) for the prophylaxis of emesis in these children.

Methods: The study was approved by our institutional human studies committee and an FDA IND number issued. All healthy children between the ages of one and twelve years were eligible for inclusion. One of the investigators interviewed the parents and obtained informed consent. A randomized double blind protocol was employed. Placebo dots identical in formulation were provided by the manufacturer. A numbered adhesive dot was placed by the parent at 8 pm the evening before surgery. The dot was removed 36 hours later. Parents were surveyed pre and post operatively regarding side effects. The administration of antiemetics was guided by continued vomiting. If unacceptable side effects required removal of the dot or reversal with physostigmine the code was broken to ascertain that scopolamine was in use.

Our anesthesia protocol was not varied from our usual management which included oral premedication with valium, demerol and atropine, a halothane induction and maintenance with a nondepolarizing muscle relaxant plus halothane.

We enrolled 31 children in the initial study using whole dots and an additional 17 children in a second phase using half dots to minimize side effects. Vomiting episodes, need for antiemetics, arousal times, and side effects were tabulated.

Results: There was no significant difference between the groups in age (mean 3.5 years), weight (mean 17 kg) or arousal time. All children spent one hour in the recovery room, our minimum duration.

The children receiving the half-dots could not be distinguished from the children receiving whole dots and the data were therefore pooled. (Table)

Although there appears to be a tendency for treated children to vomit less, none of the results approached statistical significance (p>.30, Chi square).

	PLACEBO		SCOPOLAMINE	
Number pt.	24		24	
No vomiting	5/24	21%	8/23	35%
Severe vomit (> 2 times)	9/24	38%	6/23	26%
Antiemetics	7/24	29%	5/23	22%
Total # vomiting episodes	66 2.	8/pt	29 2.0	5/pt.
side effects requiring dot removal	0		5/24	21%

Parents of children who received whole dots of scopolamine were able to identify subtle preoperative behavioral changes, while placebo children were characterized as "normal". Five children required removal of the dot for side effects of hallucinations or extreme agitation. In 4 children this occurred postoperatively (4-12 hours) with prompt reversal of side effects within an hour of dot removal. These children could not be distinguished by age or weight from the entire group. None required antiemetic or vomited more than twice.

One 5 year old 16 kg. child arrived preoperatively 12 hours after dot application febrile and combative with active hallucinations. The dot was removed with some improvement (recognition of parents, fever resolved) although hallucinations persisted. She was given physostigmine 0.5 mg IM with further improvement although she remained disoriented. Surgery was cancelled. Drug effects persisted for 8 hours following dot removal.

No children who received placebo dots exhibited behavior which required dot removal.

<u>Discussion</u>: Our results indicate an insignificant benefit in reduction of vomiting using transdermal scopolamine preoperatively. Further, an unacceptable incidence of behavioral side effects was noted. These side effects were typical of those seen with bella donna alkaloids. We do not recommend the routine use of scopolamine as a transdermal preparation for the prophylaxis of vomiting in pediatric eye surgery patients.