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### Decisional regret following ventilation tube insertion

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#### ABSTRACT

Objective: The purpose of this study was to see if parental regret following ventilation tube (VT) insertion was related to non-resolution of ear infections and thus ongoing need for otolaryngological care and VT reinsertion

*Materials and methods:* All consecutive parents presenting with children who had VT in place were given a validated regret survey and asked the reason for their visit. Chart review was used for medical history. *Results:* Two hundred and ten respondents were included. The children involved had a mean age of 5.2 years, 63.3% were male, and mean number of years since first VT insertion was 1.12 with a range of 0.04 -9.28 years. 70.5% had a regret score of 0, with mean score 6.98 (95%CI 5.11–8.85). Scores were significantly higher for parents who presented their child with an ear complaint such as otorrhea (15.52, 95%CI 7.67–23.37, p = 0.004). Parents whose children had a history of reflux had significantly lower regret scores than parents whose children did not have a history of reflux (3.33 versus 7.89, p = 0.007). Parental regret was unrelated to patient age, other comorbidities, indication for initial tube insertion, hearing status on the day of inquiry, number of sets of tubes, visits for otorrhea, prescriptions given for eardrops, clinic visits, or length of follow-up.

Conclusion: Transient factors may influence decisional regret at any given time. For parents whose children receive VT, regret is not related to prolonged specialized ear care and need for VT reinsertion.

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#### 1. Introduction

The opportunity for decisional regret (DR), remorse or distress regarding a healthcare decision, has increased in recent years because patients and families have become more involved in healthcare decisions [1]. The decision to have a child undergo ventilation tube (VT) insertion can be problematic for parents. This is an elective procedure, with the potential for the instigating factor - middle ear effusions and recurrent otitis media - to resolve spontaneously. There are proven benefits including a reduction in the incidence of symptomatic otitis media and improvement in hearing in the short-term [2]. However, surgery can be followed by persistent healthcare needs, such as visits for otorrhea, non-resolution of hearing loss, and even ongoing specialist check-ups for those who do well.

The purpose of this study is to evaluate DR in parents who made the decision to have VT placed in their children's ears and to look

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for evidence of increase in DR for parents whose children undergo multiple sets of tubes, have many specialist visits, have complications, or who have prolonged follow-up.

#### 2. Materials and methods

The participants of this study were parents or legal guardians of patients 18 years of age or younger who presented at the Pediatric Otolaryngology outpatient clinic following VT insertion at the Penn State Hershey Medical Center. Consent was obtained for surgery by one of a team of physician assistants and surgeons. Risks discussed were identical, although the discussion was customized depending on the child's situation. Parents who required a translator were not included in this study.

At a scheduled clinic visit, an experienced research assistant obtained consent from participants and guided completion of the questionnaire. The research assistant confirmed the guardian's relationship to the patient, verified the total number of tube surgeries the patient had undergone, and asked the reason for the clinic visit. The attending surgeons were not involved in enrollment

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or data collection.

Data collected from the medical record included: current age of the child, gender, indication for surgery, date and number of sets of VT placed, co-morbidities, number of clinic visits, number of episodes of otorrhea, and number or prescriptions for ototopicals given.

#### 2.1. Decisional regret scale

The DR scale is a 5-item questionnaire using a Likert scale for responses, with reverse coding on 2 items that is used to assess remorse after a health care decision [3]. The following items were included: "It was the right decision," "I regret the choice that was made," "I would go for the same choice if I had to do it over again," "The choice did my child a lot of harm," and "The choice was a good one." Each choice is scored on a scale of 0–100 so that a higher number indicates a higher level of regret. The total score is obtained by averaging the score of all 5 questions. A respondent was considered to have moderate regret if their total score was  $\geq 26$  [4].

#### 2.2. Data analysis

Data was imported into SPSS 22 (IBM Corp) and analyzed using non-parametric methods. Kruskal-Wallis and Mann Whitney U tests were used as appropriate.

#### 3. Results

There were 210 respondents included. Respondents were mothers in 83.3%, fathers in 12.9% and grandmothers/greatgrandmothers in 3.8%. Demographic information appears in Table 1. Information about the patients' ears appears below:

- Indication for tube insertion
  - 111 OME (52.9%)
  - 99 Recurrent otitis media (47.1%)
- Reason for visit on day of DR score
  - 174 Routine tube check (82.8%)
  - 29 Ear problem (13.8%)
  - 7 Other otolaryngological concern (3.3%)

**Table 1**Patient demographics & comorbidities.

Characteristic	n (%)			
Gender	77 Female (36.7)			
	133 Male (63.3)			
Age	Mean 5.2 years (Range 0.5-17 years)			
Developmental delay	19 (9.1)			
Trisomy 21	7 (3.3)			
Cleft palate	14 (6.7)			
Reflux	42 (20)			
Asthma	38 (18.1)			

- Number of years since first tube insertion
  - Mean 1.12 years (Range 0.004–9.28 years)
- Number of tube sets inserted
  - Mean 1.86 (Range 1 to 8)
- Type of tube currently in place
- 191 Armstrong grommets (91%)
- 11 T-tubes (9.2%)
- 8 Other (3.8%)
- Hearing status
- 108 Normal (51.4%)
- 78 Mild hearing loss or worse in at least one ear or failed otacoustic emissions screening (35.2%)
- 28 Unknown (could not test, not tested) (13.3%)

Seventy point five percent had a regret score of 0 (n = 148); scores ranged up to 90.

Scores of 26 or higher, indicating at least moderate regret, were present in 16 cases (7.6%). Score distribution is seen in Table 2 and Fig. 1.

There was no significant difference (p > 0.05) in regret score between groups based on age of the patient, comorbidities including asthma, developmental delay, trisomy 21, cleft palate, hearing loss or respondent. There was no significant difference in regret score based on total number of sets of tubes placed, years since first tube insertion, age of the patient, indication for tube insertion, type of tube placed, number of clinic visits since tubes were placed, number of visits for otorrhea, number of antibiotic prescriptions for otorrhea, or hearing status on the day of evaluation.

There was a significant difference (p = 0.004, see Fig. 2) in regret scores between groups based on the reason for the visit at which

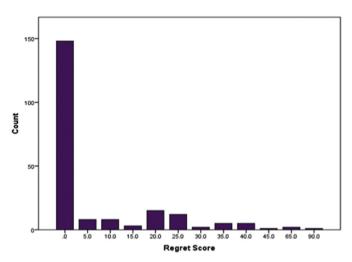


Fig. 1. Regret scores following ventilation tube insertion.

**Table 2**Regret scores — subgroups with significant differences.

	n	Mean	Mode	% with Mode	Standard deviation	95% CI
Whole group	210	6.98	0	70.5	13.739	5.11-8.85
Reason For Visit on Day of Survey						
Routine tube check	174	5.63	0	74.7	11.98	3.84-7.46
Ear complaint	29	15.52	0	48.3	20.63	7.67-23.37
Other otolaryngological concern	7	5.00	0	57.1	6.46	-0.97 - 10.97
Reflux History						
Reflux history	42	3.33	0	83.3	7.78	0.91 - 5.76
No reflux history	168	7.89	0	67.3	14.74	5.64-10.13

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