Long-term outcomes of a single institution's tympanostomy tube protocol in children with cleft palate

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BACKGROUND

- Tympanostomy tube insertion for children with cleft lip and/or palate is often utilized as a prophylactic measure for otitis media with effusion in this at-risk group during a critical time of speech and language development.
- Although eustachian tube dysfunction and susceptibility to middle ear effusion is well established in this pediatric population, controversy exists regarding the impact of early and routine versus selective tympanostomy tube placement on long-term hearing and language development.
- The rationale behind offering tympanostomy tubes early and routinely is to minimize the potential detrimental effect of a persistent conductive hearing loss on the child's development, by improving drainage and ventilation of the middle ear. Previous data has shown support for routine early tympanostomy tube insertion in improving functional outcomes like hearing and speech, with lower reported rates of adverse sequelae, like perforation of the ear drum or otorrhea, either self-resolving or easily managed with antibiotic drops.[1,2]

AIMS

- The purpose of this study is to provide long-term otologic results from our institution's protocol for the placement of routine and early short-term tympanostomy tubes followed by subsequent placement of long-term tympanostomy tubes in children with cleft palate.

METHODS

- Ninety-four children with cleft palate, who were born between 2003 and 2007 and treated by the University of California, Davis Cleft and Craniofacial Team using the same institutional protocol, were included in this retrospective cohort study.
- Our institutional protocol entails early routine short-term ear ventilation tube placement between 3 to 6 months of age, followed by long-term ear ventilation tube placement at the time of cleft palate repair around 12 months of age, and any subsequent replacement of ear ventilation tubes as indicated at follow-up visits.
- Surgical and long-term otologic complications, including the rate of chronic perforation and cholesteatoma and the need for myringoplasty or tympanoplasty, were measured over a ten-year period.

RESULTS

Table 1. Baseline Characteristics

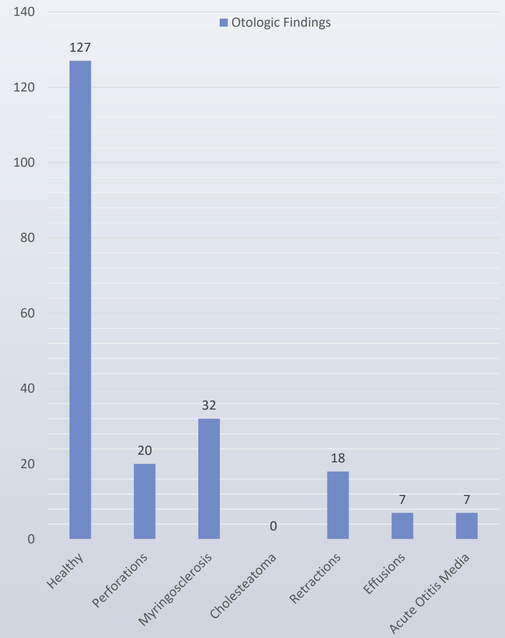
	N (%/SD)
Age at palate repair, years	1.14 (SD 0.47)
Male (%)	47 (50)
Cleft lip (%)	53 (56)
Ethnicity	
Latino	32
White	51
Asian	3
Black	2
Insurance type	
California Children's Services	53
Sacramento Medi-Cal (GMC)	29
HMO	6
PPO	3
Other	17
Genetic anomaly	24
Stickler syndrome	2
Pierre Robin sequence	17
22q deletion syndrome	2
Speech surgeries	
Furlow (%)	16 (17)
Pharyngeal flap (%)	32 (34)
Sphincter pharyngoplasty (%)	3 (3)

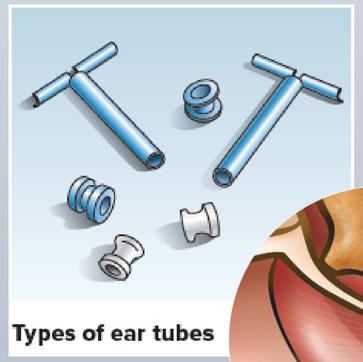
Table 2. Ten-Year Outcomes

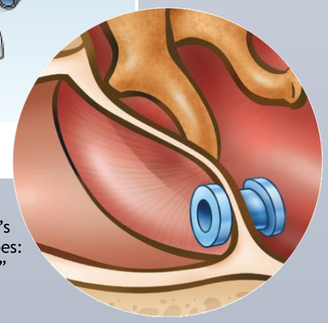
	N (%/SD)
Length of follow-up, years	9.65 (SD 3.50)
Tubes	
1/unilateral tube still in place (%)	34 (36)
2/bilateral tubes in place (%)	19 (20)
Number of sets of tubes	2.97 (SD 1.47)
Perforations, number of patients (%)	19 (20)
Single-sided	18
Bilateral	1
Fat myringoplasty/tympanoplasty for chronic perforation (%)	19 (20)
Conductive hearing loss (>20 dB thresholds)	
Unilateral	14
Bilateral	9
Mean air bone gap	9.7

RESULTS

Figure 1. Summary of Findings by Ears at Ten-Year Follow-Up







Figures 2 and **3.** Images from the UC Davis Children's Hospital pamphlet "Ear Tubes: A Patient and Family Guide"

CONCLUSIONS

- Otologic complications at ten-year follow-up included 32 cases of myringosclerosis and 20 chronic perforations, but there were zero cases of cholesteatoma, a potential complication associated with tympanostomy tube insertion in which cyst-like growths of epithelial tissue invade and dissolve ossicles in the middle ear or erode through the skull base and affect the brain. This reflects the success of the surgeries at our institution in preventing this feared complication of recurrent acute otitis media.
- However, our institution's protocol of routine short-term ear tube placement followed by replacement with long-term ear tubes at the time of palate repair and any subsequent ear tube placement was associated with a high rate of chronic tympanic membrane perforation and surgical intervention for treatment of chronic tympanic membrane perforation. In fact, our institution's complication rate of chronic perforations (20%) in children with cleft palate having early tympanostomy tube insertion is higher than the average rates reported in the literature (6%).[1]
- One possible confounding factor is the performance of prophylactic fat myringoplasty for some patients, which may have yielded a higher than expected number of perforations at ten-year follow-up. Other possible confounders include insurance type and the necessity for secondary speech surgeries, perhaps contributing to more adverse outcomes or reflecting more severe disease phenotypes, respectively.
- Since the discovery of these findings in 2017, we have altered our protocol to use short-term tympanostomy tubes as deemed necessary per AAO-HNS Clinical Practice Guidelines at follow-up every 3-6 months after palate repair.

	At time of lip repair (3 months)	**At time of palate repair** (9-12 months)	**Follow-up***
Previous Protocol	Short (Armstrong)	Long (T-tube)	Long (T-tube)
Revised Protocol	Short (Armstrong)	Long (T-tube)	Short (Sheehy)

* As indicated (e.g., retraction, hearing loss on audiogram, effusion, multiple ear infections, when the previous tube falls out)

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2. Zielnik-Jurkiewicz B, Olszewska-Sosinska O, Rakowska M. Results of treatment with tympanostomy tubes in children with otitis media with effusion. *Otolaryngol Pol*. 2006;60:181-185.

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