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Long Term Otitis Media Outcomes in Infants with Early Tympanostomy Tubes

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Abstract

Objective: to review the otologic outcomes of infants who failed the newborn hearing screen and received early tympanostomy tubes for otitis media with effusion (OME).

Study Design: retrospective case series

Setting: tertiary care pediatric hospital

Subjects and Methods: Consecutive patients (2007–2018) who failed a NBHS and required tympanostomy tubes before 6 months of age were included. Variables including hearing loss and otitis media risk factors, episodes of acute otitis media (AOM), number of subsequent tympanostomy tubes, and post-tympanostomy tube audiogram results were recorded.

Results: The cohort included 171 patients. Median age at referral to otolaryngology was 2.7 months. Sensorineural hearing loss (SNHL) was subsequently identified in 22 (12.9%) of infants after resolution of the effusion. The peak incidence of AOM was during the second year of life (1–1.9 years), with a median of 1 episode. Ninety-five patients (55.6%) had replacement of tubes, 41/171 (24.0%) had 2 or more additional sets of tubes, and long-term tubes were eventually placed in 8/95 (8.4%) patients. Craniofacial anomalies were identified in 43.3% of patients. Tube replacement (HR:3.00, 95% CI:1.95–4.63, $p<0.01$, log-rank) and AOM (β:1.04, 95% CI:0.43–1.65, $p=0.04$, ordered logistic regression) were more common, and SNHL less common (OR:0.17, 95% CI:0.031–0.61, $p<0.01$, logistic regression), in children with craniofacial anomalies.

Conclusion: OME is a common cause of failed NBHS. A notable proportion were subsequently found to have SNHL, reiterating the need for postoperative hearing assessments. Infants meeting indication for early tympanostomy tubes for resolution of OME have a high incidence of recurrent AOM and require subsequent tubes.

Introduction

The Joint Committee on Infant Hearing (JCIH) recommends universal newborn hearing screening (NHS) prior to discharge from the hospital for all infants[1]. Between two to four percent of infants who undergo NHS fail the test, with otitis media with effusion found in

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55% of these infants[2,3]. OME is most commonly diagnosed in infants and children between the ages of six months and four years, and it may contribute to a mild conductive hearing loss (CHL) of approximately 20dB[4,5,6]. OME is initially managed with watchful waiting. However, when OME persists past three months, the placement of bilateral tympanostomy tubes (BMT) is indicated as prolonged hearing loss can negatively impact the development of speech and language skills[7]. The literature reports approximately 35% of children who were initially diagnosed with OME undergo BMT[3].

Despite such a high prevalence of newborns who failed NHS and requiring BMT for chronic OME (COME), there is a paucity of data on the long-term middle ear status of this population. Thus, it is not known whether early tympanostomy tubes increased the risk of recurrent acute otitis media (RAOM) or COME requiring multiple sets of tympanostomy tubes. Additionally, it is important to assess the hearing status of the infant after resolution of OME. More data are needed to determine the incidence of underlying sensorineural hearing loss (SNHL) or CHL after the resolution of OME.

This study aimed to characterize the middle ear status of infants who failed the newborn hearing screen and subsequently underwent tympanostomy tube placement for early COME. Middle ear status is characterized by number of episodes of AOM, total number of tympanostomy tubes, and incidence of underlying hearing loss.

Methods

After University of Pittsburgh institutional board review approval, a retrospective chart review of electronic medical records (EMR) from all consecutive patients with ear tubes placed between July 12, 2007 and July 8, 2018 at a tertiary care children's hospital was performed. Inclusion criteria consisted of failed NHS and tympanostomy tube placement before 6 months of age. Indication for initial tympanostomy tubes followed the Clinical Practice Guidelines for tympanostomy tubes in Children[8]. Indication for subsequent tympanostomy tubes followed the same guidelines.

Patients were identified through surgical schedules and through a search of the EMR for the ICD-9, ICD-10, and CPT codes for BMT. Demographic data and presence of hearing loss risk factors was collected. The parameters assessed were status of the middle ear at the time of tympanostomy tube placement, number of subsequent tubes placed, number of AOM episodes after placement of tubes, and post tube placement audiogram results.

Normality of continuous variables was evaluated by Shapiro-Wilk tests; all continuous variables were not normally distributed and were therefore summarized as median (range). Categorical variables were summarized as n (%). The impact of demographics, medical history, risk factors, and effusion at first tubes on long-term outcomes (tube replacement, long-term tube placement, future AOM episodes, and hearing loss in otologically clear ears) were evaluated. The length of follow-up (time from first tube placement to the date of data collection) differed between patients; therefore, log-rank tests were used to compare the prevalence of tube replacement over time between patients with and without each characteristic (demographic, medical history, risk factor, or effusion). Cox proportional

hazards regression was used to examine the impact of age at first tube placement on tube replacement. In the subgroup of patients who were at least 5 years of age at the time of data collection, the proportion who eventually received long-term tubes was compared between patients with and without these patient characteristics using exact or standard logistic regression. The relationship between patient characteristics and number of AOM episodes per year was examined through ordered logistic regression. The prevalence of CHL, SNHL, and mixed hearing loss after tubes was compared between patients with and without each characteristic using exact or standard logistic regression. Hearing loss pre- and post-tube placement was compared using McNemar's test. Age at first tubes was compared between patients with and without hearing loss after tubes using Wilcoxon rank-sum tests. All comparisons were performed using Stata/SE 16.0 (StataCorp, College Station, TX). $P<0.05$ was considered significant.

Results

Demographics and risk factors

One hundred and seventy-one patients met inclusion criteria. Demographic characteristics of these patients are summarized in Table 1. Most children were white (90.1%) and male (56.7%). Median age at first visit to the otolaryngology clinic was 2.7 months (range 7 days-5.2 months), and median age at the time of data collection was 6.2 years (range 9 months-12.0 years).

The risk factors for hearing loss and otitis media that were examined in the study are summarized in Table 2. Most notably, a large proportion of our population were not breast fed, 108/171 (63.2%), had noted craniofacial anomalies, 74/171 (43.3%) and were born premature 35/171 (20.5%) or had NICU-related risk factors, 35/171 (20.5%).

Audiology

Audiogram and tympanogram results before and after tubes are summarized in Table 3. Of the 149 patients with audiograms before first tube placement, 148 (99.3%) had hearing loss, with 127 cases being bilateral. The 1 patient without hearing loss pre-operatively underwent an examination of the ears under anesthesia, performed as a combined case with removal of mandibular hardware. When fluid was seen on exam, a decision to place tubes was made based on a limited preoperative ABR and parental concern.

Of the 157 patients with tympanograms before first tube placement, 153 (97.5%) were abnormal (type B or C), and 141 cases were bilateral. After first tubes, 163 patients had audiograms in the presence of patent tubes or with type A tympanograms. Thirty-eight (23.3%) patients had hearing loss (24 bilateral). Twenty-two patients were diagnosed with sensorineural hearing loss, 10 with conductive hearing loss, and 6 with mixed hearing loss. The etiology was identified in 11 of the 28 patients with sensorineural or mixed hearing loss (Table 3).

Initial Tympanostomy Tube Placement

Table 4 displays information related to tympanostomy tube history. Median age at first tube placement was 3.9 months (range 1.6 months-5.7 months). Tympanostomy tubes were placed for COME in 168/171 (98.2%) patients. One patient had 3 ear infections prior to tubes; however, primary care records documenting clearing of the middle ears between episodes were not available in the EMR. The remaining 2 (1.2%) patients had tubes placed because of facial paresis during their first or second AOM episode. The majority of patients had fluid confirmed at the time of first tube placement, 146/153 (95.4%).

Future Tympanostomy Tubes

Ninety-five patients (55.6%) had replacement of tubes, 41/171 (24.0%) had 2 or more additional sets of tubes, and long-term tubes were eventually placed in 8/95 (8.4%) patients. Tube replacement was more common over time in preterm infants ($p=0.02$), children with secondhand smoke exposure ($p=0.04$), and children with craniofacial anomalies ($p<0.01$) (Table 5). Specifically, 53/74 (71.6%) of children with craniofacial anomalies underwent additional tube placement compared with 42/97 (43.3%) of those without a craniofacial anomaly; this included 31/74 (41.9%) of those in the craniofacial group with 2 or more additional sets of tubes compared with 10/97 (10.3%) of those in the non-craniofacial group. Tube replacement was less common over time in children with a history of breastfeeding ($p=0.01$) and with serous effusions at first tubes ($p=0.04$) (Table 5). Age at first tubes did not have a significant impact on undergoing tube replacement over time. No factors were significantly associated with receiving long-term tubes.

Acute Otitis Media

The peak incidence of AOM was during the second year of life (1–1.9 years), with a median of 1 episode. All other years had a median of 0 episodes. Being female was associated with 0.69 fewer episodes of AOM during the second year of life ($p=0.04$) (Table 6). Craniofacial anomalies were associated with 1.04 more episodes of AOM during the first year of life ($p<0.01$; 38/70 (54.3%) of patients with craniofacial anomalies had at least one episode of AOM during the first year of life compared with 30/94 (31.9%) of those without a craniofacial anomaly). Having no NICU-related risk factors was associated with 1.50 fewer episodes of AOM during the fifth year of life ($p=0.02$) and 1.62 fewer episodes of AOM during the sixth year of life ($p=0.048$). Finally, being born prior to 37 weeks gestation was associated with 2.00 more episodes of AOM during the sixth year of life ($p=0.03$) (Table 6).

Hearing Loss after Tubes

Results from hearing tests both before and after tubes were available for 143 patients. Only 1 child had no hearing loss before tubes. This child continued to have no hearing loss after tubes. 109 children had resolution of hearing loss after tubes (in the presence of patent tympanostomy tubes or type A tympanograms). The remaining 33 patients continued to have hearing loss after tubes, even with dry middle ears. The majority of patients had resolution of hearing loss, Figure 1. No demographic, medical history, or risk factors were significantly associated with CHL or mixed hearing loss in dry (patent tubes or type A tympanogram) ears. However, SNHL was significantly less common in children with craniofacial anomalies

compared with those without craniofacial anomalies (OR: 0.17, 95% CI: 0.03–0.61, p<0.01, Figure 2). Specifically, of the 90 patients with no craniofacial anomaly and audiogram completed after ears were otologically clear, 5 (5.6%) had CHL, 3 (3.3%) had mixed hearing loss, and 19 (21.1%) had SNHL. Of the 70 patients with craniofacial anomalies, 5 (7.1%) had CHL, 3 (4.3%) had mixed HL, and 3 (4.3%) had SNHL. (All patient characteristics shown in Tables 1 and 2 were evaluated, but only demographic and medical history/risk factors with at least 5% prevalence were included in this figure.)

Discussion

The majority of children who fail newborn hearing screening are found to have otitis media with effusion. Many of these children go on to eventually require placement of tympanostomy tubes for chronic otitis media with effusion. Although tympanostomy tube placement is well studied, there is limited published data on this specific population.

The majority, 55%, of our population required at least 1 additional set of tympanostomy tubes. This is significantly higher than expected from the general tympanostomy tube population. Chi et al identified a second BMT rate of 15% of children with recurrent AOM population[9]. In the general pediatric population, rates of second BMT range from 19.9% – 29.3%[10,11]. Both of these studies identified that younger age at the time of tube placement was associated with undergoing a second tube procedure. Padia et al. observed a total of 14.4% of patients who underwent BMT placement at between zero and three years of age received a second set of tubes within the five-year follow-up, and 4.6% overall received a third tube[12].

These results may introduce the hypothesis that this particular subset is more otitis prone. Given that otitis media peaks between ages 6 to 36 months, children who undergo BMT at a young age should be expected to remain in this age range after extruding their first set of tubes. Unsurprisingly, other factors were found to increase the risk of requiring multiple tympanostomy tubes. We found subsequent BMT was more common in patients with secondhand smoking exposure, preterm infants, and non-breastfed infants. This is consistent with well-established and published risk factors for otitis media[2,13]. Adenoidectomy at the time of first BMT has been shown to decrease the need for subsequent BMT[11,14]. However, the mean age of BMT was 3.9 months in our population, too young for adenoidectomy to be considered.

Our study population included 43% of patients who had a craniofacial abnormality, with cleft palate as the most common. Cleft palate has been well documented as a risk factor for COME due to anatomical factors that lead to eustachian tube dysfunction. The overwhelming majority (98.6%) of cleft palate patients undergo BMT, often before the age of 1 year[15]. Additionally, the majority of these patients, 55.3% – 67.4%, receive at least 1 subsequent set of tubes[15,16]. The rate of subsequent BMT in our study population is closer to the rate in cleft palate patients than the general population. When patients with and without craniofacial anomalies were examined separately, the proportions with tube replacement (71.6% of the craniofacial group and 43.3% of the non-craniofacial group) were still higher than that previously reported in the literature. This analysis is of patients in an academic

tertiary care center and although it services a large catchment area, it may still not be entirely representative of the general community.

It is recommended that patients who fail the newborn hearing screen be evaluated in an outpatient setting within the first 30 days of life[17]. The target is to diagnose hearing loss within the first 3 months and intervene by 6 months of age[18,19]. The mean age at first otolaryngology clinic visit in our group was 2.7 months, and the mean age at first BMT of 3.9 months. Following this, all patients underwent post procedure audiograms, and we identified 12.9% with underlying SNHL. This is slightly higher but close to the reported range of 0–11% in other studies[3,6]. Having COME delays the identification and subsequently treatment of underlying SNHL. This finding reiterates the need for timely postoperative hearing assessments to ensure completion of the NHS.

In addition to the limitations inherent within a retrospective review, many of the patients included in this study had a cleft palate. Future studies either excluding this population, or with the objective of comparing the two populations, may provide results that are more generalizable. Data regarding risk factors, including smoke exposure and absence of breastfeeding, relied on caregiver-completed clinic intake forms, which may not always be accurate. Due to the number of years captured in this study, the follow up period was variable and ranged from two to seven years. Continuing to collect data on those patients in the lower end of the follow up spectrum would provide more comprehensive data. Finally, episodes of acute otitis media were captured through documentation of patient reports and episodes of otorrhea. Although it is not uncommon practice for caregivers to self-diagnose and treat with antibacterial otic drops, ideally, episodes of otorrhea would be accurately associated with a physicians' assessment. Using more objective data in future studies would provide a more accurate assessment of otitis media outcomes.

Conclusion

Examination of our patients who fail the newborn hearing screen and require early tympanostomy tubes shows that the majority of this cohort will require at least 1 additional set of tubes. Underlying sensorineural hearing loss was seen in 12.9% of patients, highlighting the importance of expeditious resolution of OME to complete the newborn hearing evaluation.

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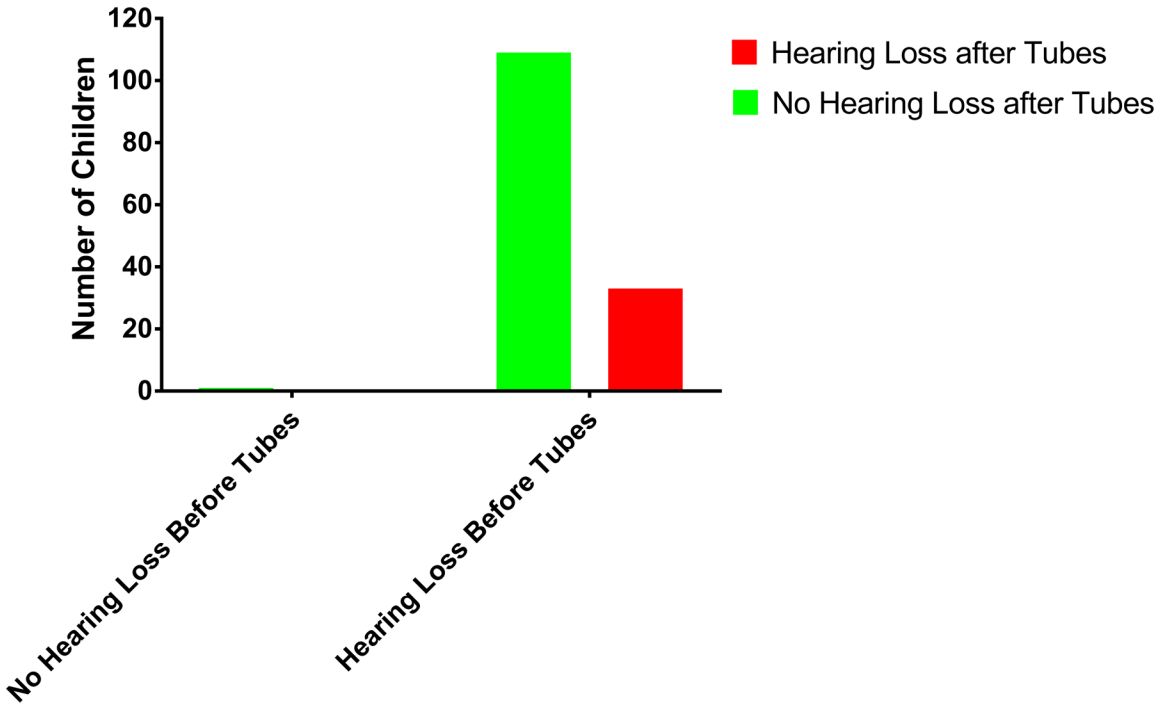

Figure 1.

The percentage of children with hearing loss was significantly reduced after tympanostomy tube placement, *p<0.01, Exact McNemar significance probability.

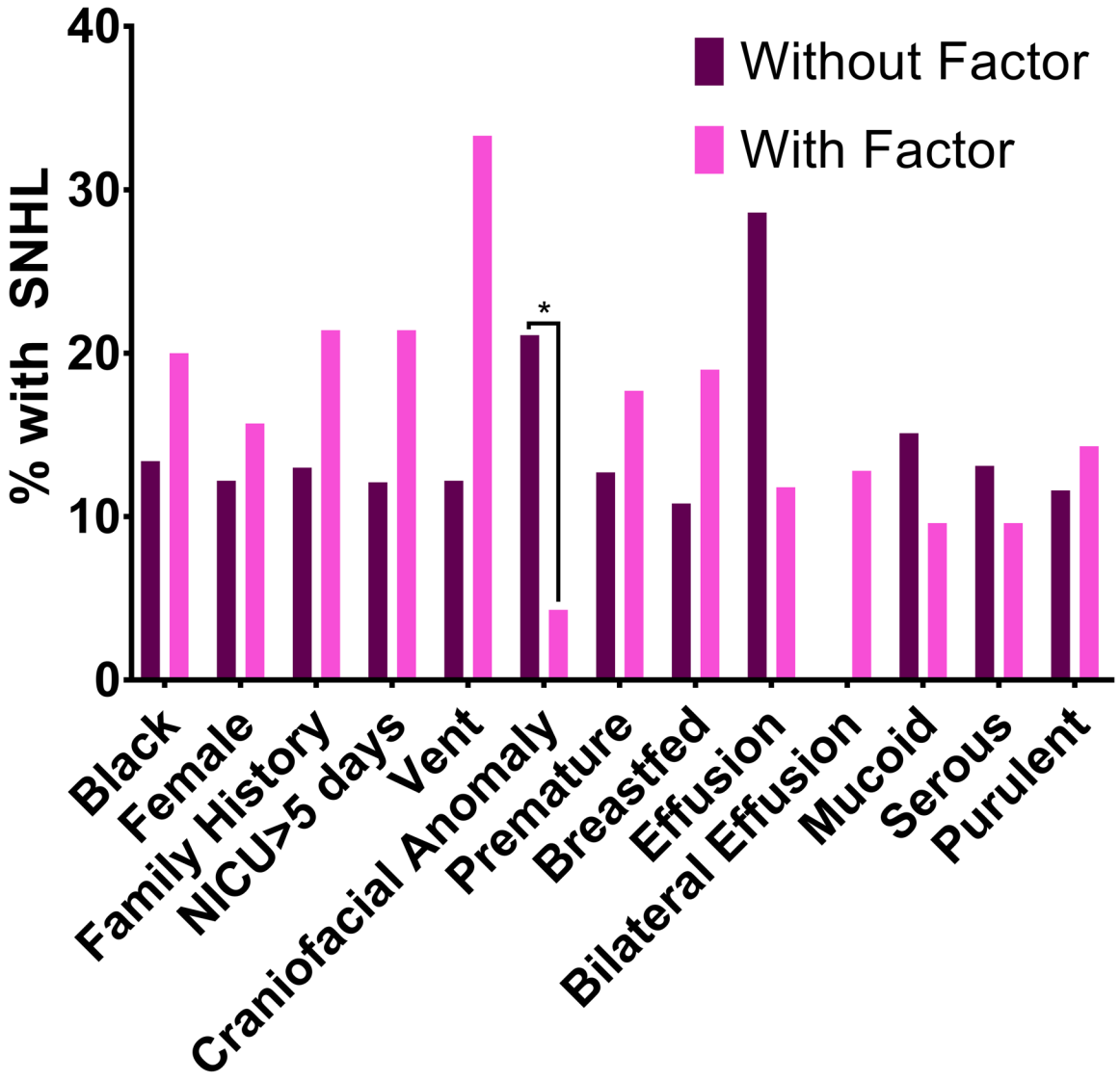

Figure 2.

Sensorineural hearing loss was significantly less common in children with craniofacial anomalies compared with those without craniofacial anomalies, *p<0.01, exact logistic regression.

Table 1.

Demographics (N=171)

Categorical	**n**	**%**
Race		
White	154	90.1
Black	12	7.0
Asian	2	1.2
Not Reported	3	1.8
Female	74	43.3
Continuous	Median	Range
Age at Data Collection	6.2 years	9 months-12.0 years
Age at First ENT Clinic Visit	2.7 months	7 days-5.2 months

Table 2.

Risk Factors (N=171)

Categorical	n	%
Family History of Hearing Loss	16	9.4
NICU-Related		
NICU >5 Days	32	18.7
Assisted Ventilation	14	8.2
Hyperbilirubinemia Requiring Exchange	3	1.8
Ototoxic Medication	1	0.6
ECMO	0	0
None	136	79.5
Medical History		
Craniofacial Anomalies	74	43.3
Cleft Palate	67	39.2
Born Before 37 Weeks	35	20.5
Down Syndrome	6	3.5
Congenital Cytomegalovirus	4	2.3
Head Trauma	1	0.6
Myotubular Myopathy	1	0.6
Meningitis	0	0
Environmental		
History of Breastfeeding	63	36.8
Secondhand Smoke Exposure	6	3.5

Abbreviations: ECMO, Extracorporeal Membrane Oxygenation; NICU, Neonatal Intensive Care Unit

Table 3.

Audiology

Categorical	n	%
Audiologic Testing Before Tubes	149/171	87.1
Auditory Brainstem Response	102/149	68.5
Otoacoustic Emissions Only	47/149	31.5
Hearing Loss Before Tubes	148/149	99.3
Bilateral	127/148	85.8
Tympanogram Before Tubes	157/171	91.8
Abnormal	153/157	97.5
Bilateral	141/153	92.2
Audiologic Testing after Tubes	163/171	95.3
Pure Tone Audiometry	92/163	56.4
Otoacoustic Emissions Only	37/163	22.7
Auditory Brainstem Response	34/163	20.9
Hearing Loss with Patent Tubes or Type A Tympanogram	38/163	23.3
Bilateral	24/37*	64.9
Severity of Hearing Loss		
Mild (20–40dB)	8/38	21.1
Moderate (40–55dB)	11/38	28.9
Moderate-Severe (55–70dB)	1/38	2.6
Severe (70–90dB)	3/38	7.9
Profound (>90dB)	12/38	31.6
Otoacoustic Emissions Only	3/38	7.9
Hearing Loss Type with Patent Tubes or Type A Tympanogram		
Sensorineural Hearing Loss+	22/38	57.9
Conductive Hearing Loss	10/38	26.3
Mixed Hearing Loss	6/38	15.8

*One patient with hearing loss only had testing completed on one ear when ontologically cleared (patent tubes or type A tympanograms).

+Etiologies included congenital cytomegalovirus (n=2), Kniest Skeletal Dysplasia and Pierre Robin Sequence (n=1), Down syndrome (n=2), hypoplastic cochlea with enlarged vestibular aqueduct and semicircular canal malformation (n=1), an absent 8th nerve on the left ear and hypoplastic 8th nerve on the right ear (n=1), connexin gene mutation (n=1), and 1 each of 7q32.3q36, 5q11, and 2q12 microdeletions. Other cases did not have an infectious or syndromic etiology.

Table 4.

Tympanostomy Tubes

Categorical		**n**	**%**
Indication for Initial Tube Placement			
COME		169/171	98.8
AOM with Facial Paresis		2/171	1.2
Effusion at Initial Tube Placement			
Dry		7/153	4.6
Effusion		146/153	95.4
Bilateral Effusion		134/146	91.8
No Comment *		18	
Consistency of Effusion			
Mucoid		90/146	61.6
Serous		56/146	38.4
Purulent		8/146	5.5
Unknown		5/146	3.4
Additional Tubes			
	0	76/171	44.4
	1	54/171	31.6
	2	25/171	14.6
	3	9/171	5.3
	4	6/171	3.5
	5	1/171	0.6
Long-Term Tube		8/95	8.4
Continuous		Median	Range
Age at First Tubes		3.9 months	1.6 months-5.7 months

Abbreviations: COME, Chronic Otitis Media with Effusion; RAOM, Recurrent Acute Otitis Media

* No comment regarding presence or absence of middle ear effusion in the operative note.

Table 5.

Factors Associated with Tube Replacement

	HR	95% CI	p*
Born Before 37 Weeks	1.97	1.13–3.46	0.02
Secondhand Smoke Exposure	3.52	1.05–11.8	0.04
Craniofacial Anomalies	3.00	1.95–4.63	<0.01
History of Breastfeeding	0.58	0.38–0.87	0.01
Serous Effusion at First Tubes	0.63	0.41–0.98	0.04

Abbreviations: CI, Confidence Interval; HR, Hazard Ratio

* Log-rank test

Table 6.

Factors Associated with Acute Otitis Media Episodes

	Age	β	95% CI	p*
Female	1–1.9 years	−0.69	−1.35-(−0.02)	0.04
Craniofacial Anomalies	0–0.9 years	1.04	0.43–1.65	<0.01
No NICU	4–4.9 years	−1.50	−2.80-(−0.21)	0.02
	5–5.9 years	−1.62	−3.22-(−0.02)	0.048
Born Before 37 Weeks	5–5.9 years	2.00	0.16–3.84	0.03

Abbreviations: CI, Confidence Interval; NICU, Neonatal Intensive Care Unit

* Ordered logistic regression