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# The impact of social determinants of health and clinical comorbidities on post-tympanotomy tube otorrhea

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ABSTRACT

*Objectives:* To measure the impact of social determinants of health and clinical comorbidities on the incidence of post-tympanotomy tube otorrhea (PTTO).
*Methods:* Retrospective observational cohort study. All children between the ages of 0 and 17 having tympanotomy tube placement between 2009 and 2019. Between group comparisons entailed the calculation of odds ratios (OR) with 95% confidence intervals and associated p-values.
*Results:* Among 12,757 patients who underwent myringotomy and tube placement, 2217 (17.4%) presented with PTTO within 1 year. Race and sex did not correlate with the development of PTTO. Non-Hispanic ethnicity had a negative association with PTTO (OR: 0.80 (0.70-0.91), $p < .0001$). Insurance status correlated with incidence of PTTO with a higher rate noted among those with public insurance (OR: 1.12 (1.02–1.23), $p = .02$) and a lower rate among those with private insurance (OR: 0.84 (0.77-0.92), $p < .0001$). Craniofacial abnormalities had the strongest positive correlation with PTTO, particularly, cleft lip and/or cleft palate (OR>2.24, $p < .0001$). Immunodeficiency had similar impact on PTTO (OR: 2.38 (1.46–3.91), $p < .0001$). Asthma and prematurity did not significantly correlate with occurrence of PTTO.
*Conclusion:* Higher rates of PTTO correlated strongest with clinical factors; particularly craniofacial abnormalities and immunodeficiency. Social determinants, including private insurance and non-Hispanic ethnicity, were associated with lower rates of PTTO. Race and sex did not show significant correlations.

## 1. Introduction

Tympanotomy tubes are the most common ambulatory pediatric surgery performed in the United States [1]. More than 3 million children in the U.S. will have tubes placed each year [2]. Tube otorrhea is a common complication following tube placement. Post-tympanotomy tube otorrhea (PTTO) can negatively impact the quality of life for both patients and parents. It can be a nuisance due to its associated foul odor and discharge but can also be associated with fevers and pain, indicating an active infection, and the need for further medical treatment.

Though PTTO is a well-known complication of tube placement, its reported incidence varies greatly. A 2001 meta-analysis reported a mean incidence of 26.2%, with a range of 4%–68% from 23 analyzed studies [3]. A more recent cohort study of 1184 children reported an incidence of 52% [4]. Other studies have also looked at the incidence of PTTO as well as preventative measures, including timing and types of antibiotic drops or the use of ear plugs [3,5–8].

Predicting patients most at risk of developing PTTO may direct the use of drops, ear plugs, or close clinical follow-up to mitigate occurrence. Younger age at tube placement has been suggested to increase the risk of PTTO while BMI and sex did not impact the incidence [4]. Other potential risk factors include social determinants of health which include the impact of racism, income, education level, and geographic location of residence. Indeed, in one study socioeconomic status showed inverse correlation with PTTO [9]. In our region, profound racial

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inequality and oppression has informed the historical and present-day systemic racism that has created health disparities amongst our residents [10,11]. In recognition of this, race is utilized in this study as a social determinant impacting disproportionate health outcomes.

Our medical center is located within one of the most highly segregated cities in the United States with notable disparities in health outcomes [12]. Indeed, our previous work has shown differences in access for common otolaryngologic care in specific demographics in our region [13]. The current study sought to identify the impact of similar social determinants of health on PTTO. We also assessed clinical comorbidities and associated surgical procedures to determine whether social or clinical factors were most associated with tympanotomy tube complications.

## 2. Materials and methods

OTO Clinomics is a department-wide clinical outcomes platform to investigate determinants of disease and response to treatment (IRB# 1538127). This platform utilizes the Clinical Research Data Warehouse (CRDW), part of the Clinical and Translational Science Institute (CTSI) of Southeast Wisconsin (UL1TR001436). The CRDW extracts a mirror of the entire Children's Wisconsin electronic health record and stores this in a Jupyterhub database. Within the Jupyterhub environment we performed statistical analyses on children receiving tympanotomy tubes between 2009 and 2019.

### 2.1. Patient demographics and study design

Clinical and demographic data were extracted from the Jupyterhub for all patients seen at Children's Wisconsin who underwent tympanotomy tube placement (CPT 69436). The occurrence of post-tympanotomy tube otorrhea (PTTO) was determined by temporally linking the procedure code (CPT 69436) with the diagnostic code for otorrhea. Specifically, an encounter for a diagnosis of otorrhea (ICD9 or ICD10: H92.11, H92.12, H92.13, H95.89, or T85.890) within 12 months after tube placement was considered indicative of post-tube otorrhea.

Standard demographic data were extracted from the medical record including age, sex, race, ethnicity, and insurance status. The presence of comorbid conditions that were hypothesized to affect susceptibility to PTTO were also identified. These included a history of tonsillectomy, adenoidectomy, or both. Medical conditions assessed included asthma, cleft palate, cleft lip, cleft lip and palate, Down syndrome, immunodeficiency, and prematurity.

### 2.2. Statistical analysis

The proportion of patients within each demographic group was compared between those with PTTO and those without otorrhea. Odds ratios with 95% confidence intervals and p-values were calculated by 2-by-2 chi-square test. Independent continuous variables, such as age and body mass index (BMI), were compared between the two groups using unpaired two-tailed *t*-test. All statistical tests were performed using R language (3.6.1) within the Jupyterhub environment.

## 3. Results

There were 12,757 children who underwent tympanotomy tube placement between 2009 and 2019 [Table 1]. Of those children, 2217 (17.37%) had a diagnosis of otorrhea within 12 months of tube placement with the majority of PTTO occurring within 30 days of surgery [Fig. 1]. Demographic and socioeconomic factors were compared between patients with otorrhea and those without (n = 10,495). Patients with otorrhea had a median age of 1.20 years as compared to 1.97 years in those without otorrhea (p < .0001). Sex was similar between groups, with 57.7% of those with otorrhea being male as compared to 58.4% of those without otorrhea. BMI was also similar between those with or without PTTO.

**Table 1**
Correlations of demographics with post-tympanotomy tube otorrhea

| | All Tubes (*n* = 12,757) | Otorrhea (*n* = 2262) | No Otorrhea (*n* = 10,495) | *Odds Ratios (95% CI)* | *p-value* |
|---|---|---|---|---|---|
| Age, median (years) | 1.78 | 1.20 | 1.97 | | **p < .0001** |
| BMI, mean | 17.10 | 17.18 | 17.12 | | p = .183 |
| Sex | | | | | |
| Male, % (no.) | 58.5 (7457) | 57.7 (1306) | 58.4 (6125) | 0.97 (0.889, 1.069) | p = .58 |
| Female, % (no.) | 41.6 (5300) | 40.3 (911) | 41.6 (4370) | 0.95 (0.862, 1.037) | p = .23 |
| Race, % (no.) | | | | | |
| White | 75.6 (9649) | 73.8 (1669) | 75.7 (7947) | 0.90 (.813, 1.001) | p = .05 |
| Black | 15.6 (1988) | 16.2 (366) | 15.4 (1617) | 1.06 (.936, 1.200) | p = .36 |
| Asian | 1.8 (228) | 1.9 (43) | 1.8 (184) | 1.09 (.777,1.518) | p = .63 |
| Other | 3.3 (417) | 3.1 (69) | 3.3 (346) | .92 (.71, 1.200) | p = .55 |
| Unknown | 3.7 (475) | 3.2 (70) | 3.8 (401) | .80 (.621, 1.041) | p = .10 |
| Ethnicity, % (no.) | | | | | |
| Hispanic | 11.84 (1511) | 12.7 (287) | 11.6 (1215) | 1.11 (0.797,1.274) | p = .14 |
| Not Hispanic | 86.8 (11,071) | 84.2 (1905) | 87.0 (9130) | 0.80 (0.703,0.905) | **p < .001** |
| Unknown | 1.4 (175) | 1.1 (25) | 1.4 (150) | 0.77 (0.503,1.18) | p = .23 |
| Insurance, % (no.) | | | | | |
| Private | 61.9 (7895) | 58.3 (1319) | 62.4 (6549) | 0.84 (.768,0.924) | **p < .001** |
| Public | 36.5 (4659) | 38.5 (871) | 35.9 (3770) | 1.12 (1.017,1.227) | **p = .02** |
| Other | 0.07 (9) | 0.1 (2) | 0.1 (7) | 1.33 (0.275,6.387) | p = .72 |
| Self-Pay | 1.52 (194) | 1.1 (25) | 1.6 (169) | .68 (0.448,1.042) | p = .08 |

Statistically significant differences are highlighted in bold.

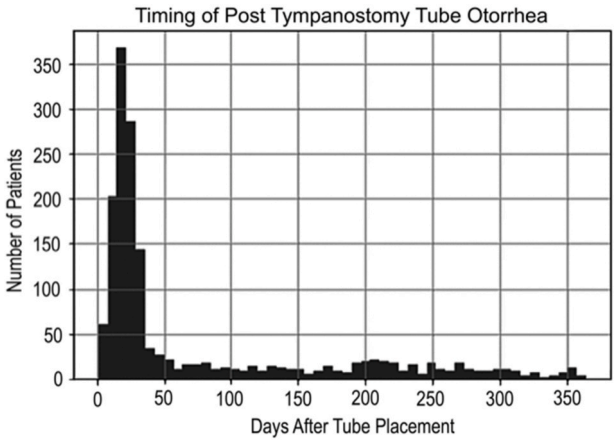


**Fig. 1.** Histogram demonstrating the timing of otorrhea after tube placement.

### 3.1. Race and PTTO

Race did not correlate with PTTO [Table 1]. Overall, 75.6% (n = 9649) of all patients were White and 15.6% Black (1,988). For those with PTTO, 73.8% were White and 16.2% were Black which compares

similarly to 75.7% White and 15.4% Black among those without PTTO. A small subset of the total patient population (1.8%, n = 228) was Asian, with similar proportions in the otorrhea (1.9%) and non-otorrhea (1.8%) groups. Calculations of PTTO rate demonstrated that White patients had a rate of 17.3% which was not statistically different than the rate of 18.4% among Black patients.

### 3.2. Ethnicity and PTTO

In contrast to race, ethnicity showed a weak correlation with outcomes. Most patients were non-Hispanic, 86.8%, with only 11.8% identifying as Hispanic. Lower rates of PTTO correlated with being non-Hispanic/Latino (OR 0.80, (0.703–0.905, p < .0001). That is, those of non-Hispanic ethnicity developed PTTO 17.2% of the time while those of Hispanic ethnicity had a slightly higher otorrhea rate of 19.0%.

### 3.3. Insurance status and PTTO

Having public or private insurance status was found to significantly affect the incidence of PTTO. Most patients undergoing myringotomy with tube placement had private insurance, 61.9% (n = 7895). However, a lower proportion of those having PTTO were privately insured, 58.3% (OR 0.84 (0.768–0.924), p < .0001). In contrast, public insurance was positively correlated with the development of PTTO (OR 1.12 (1.017–1.227), p = .02). Specifically, 38.5% of the children with PTTO were under public insurance, compared to only 35.9% of their non-otorrhea counterparts.

### 3.4. Tonsillectomy and adenoidectomy and PTTO

We assessed whether the need for additional upper aerodigestive procedures correlated with the development of PTTO (Table 2). Having an adenoidectomy alone was the only procedure significantly associated with the development of PTTO (OR 1.25 (1.132–1.391), p < .0001). The rate of PTTO was 20.2% in those having had an adenoidectomy compared with a rate of 16.9% in those not having adenoidectomy surgery. Having had a tonsillectomy or a combined tonsillectomy with adenoidectomy had no significant relationship with PTTO.

### 3.5. Medical Co-Morbidities and PTTO

Medical comorbidities were identified to further identify risk factors for otorrhea **[Table 3]**. Craniofacial anomalies, such as cleft palate and/or cleft lip, were significantly associated with higher likelihood of otorrhea, with cleft lip posing the highest aggregate risk (OR 2.64 (1.863–3.748), p < .001). Isolated cleft lip was seen in 2.2% of PTTO patients, compared to 0.8% of those without PTTO. Put another way, 35.7% of patients with cleft lip developed PTTO as compared to 17.5% of those without cleft lip. Similar increased incidence of PTTO was seen in isolated cleft palate (OR 2.24 (1.814–2.754), p < .0001) as well as both cleft palate and lip (OR 2.39 (1.855–3.079), p < .0001). The rate of PTTO in those with isolated cleft palate was 31.6% and in those with both cleft palate and lip was 33.0%.

A diagnosis of immunodeficiency was found to significantly increase the odds of the development of PTTO (OR 2.38 (1.455–3.906), p < .0001) with 32.8% of those with immunodeficiency having otorrhea. Similarly, 3.1% of those with otorrhea had Down syndrome compared to only 1.9% of those without otorrhea having Down syndrome (OR 1.64 (1.249–2.161), p < .0001). This translates into a rate of otorrhea in those with Down syndrome of 25.7%. Prematurity and a diagnosis of asthma were not significantly associated with PTTO with similar rates of otorrhea to the entire cohort.

## 4. Discussion

Our study investigated the impact of social determinants of health and clinical comorbidities on the incidence of post-tympanotomy tube otorrhea (PTTO). The overall incidence of PTTO in our study was 17.7%. This is similar to the mean incidence reported in a meta-analysis by Kay and colleagues: 17.0% in 13,760 aggregate ears and 26.2% in 5491 aggregate patients [3]. Other studies have reported much higher incidences of PTTO. Ah-tye et al. reported an incidence of 74.8% within one year and 83.0% by 18 months [9]. That study had only 230 ears in 173 patients and included randomization of patients into immediate tube placement or a 3-month observation period. van Dongen et al., reported an incidence of 52.0% in 1184 patients [4]. This, however, was based on parental diagnosis rather than provider diagnosis and may account for the difference from our study. The large size of our study cohort, 12,461 patients, suggests that an expected incidence of PTTO of under 20% is reasonable in patients without significant comorbidities.

Van Dongen et al. found that young age was a predictor of parental reported otorrhea, while sex and BMI were not [4]. Our study similarly found younger age to be a risk factor for diagnosed PTTO, while sex and BMI were not. Their study, however, had a much higher rate of PTTO compared to our outcomes, 52% versus 17.7%. The median age for patients in our study was under 2 for all groups, while the mean age for their population was 4.4 years. This may suggest differing thresholds for tube placement, and perhaps a more severe or lengthy inflammatory burden in their cohort.

We were able to identify correlations between several medical comorbidities and PTTO.

Craniofacial comorbidities are often associated with the need for tympanotomy tubes due to associated eustachian tube dysfunction (ETD) [14]. Cleft lip and palate had the highest aggregate risk for post-tube otorrhea in our patient population. Downs syndrome was also a risk factor for PTTO. This suggests that skull base abnormalities and associated ETD not only predispose to the need for tubes but also predispose to PTTO. Similarly, immunodeficiency was also positively correlated with PTTO as it can be associated with increased risk of infection.

Social determinants of health, specifically race and ethnicity, have been evaluated regarding having a diagnosis of otitis media and having the placement of ear tubes. There is little direct research, however, evaluating the effects of social determinants on PTTO. For example,

**Table 2**
Correlation of tonsillectomy and/or adenoidectomy with the occurrence of post-tympanotomy tube otorrhea.

| | All Tubes (*n* = 12,757) | Otorrhea (*n* = 2262) | No Otorrhea (*n* = 10,495) | *Odds Ratios (95% CI)* | *p-value* |
|---|---|---|---|---|---|
| Tonsillectomy | | | | | |
| Yes, % (no.) | 2.0 (251) | 2.4 (54) | 1.9 (197) | 1.28 (0.943,1.734) | p = .11 |
| No, % (no.) | 98.0 (12,506) | 97.6 (2208) | 98.1 (10,298) | .78 (0.577,1.061) | p = .11 |
| Adenoidectomy, % (no.) | | | | | |
| Yes, % (no.) | 23.8 (3042) | 27.2 (616) | 23.0 (2411) | 1.25 (1.132,1.391) | **p < .0001** |
| No, % (no.) | 76.2 (9715) | 72.8 (1646) | 77.0 (8084) | .80 (.719,.884) | **p < .0001** |
| T&A, % (no.) | | | | | |
| Yes, % (no.) | 13.5 (1719) | 13.4 (303) | 13.4 (1410) | 1.00 (.872,1.139) | p = .96 |
| No, % (no.) | 86.5 (11,038) | 86.6 (1959) | 86.6 (9085) | 1.00 (.878,1.147) | p = .96 |

Statistically significant differences are highlighted in bold.

**Table 3**
Correlation of comorbidities with the occurrence of post-tympanotomy tube otorrhea

| | All Tubes ($n$ = 12,757) | Otorrhea ($n$ = 2262) | No Otorrhea ($n$ = 10,495) | *Odds Ratios (95% CI)* | *p-value* |
|---|---|---|---|---|---|
| Asthma, % | 18.1 | 18.6 | 17.9 | 1.05 (0.933,1.179) | p = .43 |
| Cleft Palate, % | 3.4 | 6.0 | 2.8 | 2.24 (1.814,2.754) | **p < .0001** |
| Cleft Lip, % | 1.1 | 2.2 | 0.8 | 2.64 (1.863,3.748) | **p < .0001** |
| Cleft Lip and Palate, % | 2.2 | 4.1 | 1.8 | 2.39 (1.855,3.079) | **p < .0001** |
| Down Syndrome, % | 2.2 | 3.1 | 1.9 | 1.64 (1.249,2.161) | **p < .0001** |
| Immunodeficiency, % | .6 | 1.1 | .4 | 2.38 (1.455,3.906) | **p < .0001** |
| Prematurity, % | 4.0 | 4.0 | 4.0 | 1.00 (0.79,1.257) | p = .98 |

Statistically significant differences are highlighted in bold.

Chang et al. found that race and ethnicity did not impact the rate of patients undergoing placement of tubes, but they did not report on the sequela of tubes [15]. Similarly, Nieman and colleagues suggested that race influences indications for tube placement (e.g., RAOM vs. OME) but the sequelae of tube placement were also not evaluated [16].

In 2001, Ah-Tye found that patients in urban settings, where there was a higher Black population, were more likely were to develop PTTO but the explicit risk of race or ethnicity was not evaluated [9]. Our research did not find race to be correlated with the development of PTTO, but there was a statistically significant association with ethnicity. Hispanic patients were found to have a slight, but statistically significant, increased rate of PTTO, 19%, when compared to those of non-Hispanic ethnicity, 17.2%

Insurance status has been evaluated by previous studies. Insurance status was used as a proxy for socioeconomic status in Ah-Tye's 2001 patient population, which showed that children living in urban settings, majority under public insurance, had increased incidence of otorrhea compared to rural children [9]. In their study, the urban population correlated with lower socioeconomic status. Our study also found a statistically significant correlation between insurance type and PTTO, although direct correlations with regional socioeconomic status was not performed.

In this study, a history of adenoidectomy was the only procedure significantly associated with otorrhea. The 2004 American Academy of Otolaryngology Head and Neck Surgery (AAO-HNS) clinical practice guideline for OME stated that adenoidectomy should be performed with repeated tympanotomy tube insertions, while tonsillectomy or myringotomy alone should not be performed [17]. This guidance was in effect until 2013 when the revised guidelines suggested adenoidectomy if the child was older than 4 years [18]. As such, a substantial portion of the cohort in this study was cared for under the original AAO-HNSF guideline. This would suggest that those having an adenoidectomy likely had a larger burden of aerodigestive inflammatory disease which may increase the incidence of PTTO.

There are several potential limitations to this study. First, data extracted for this study was collected from patients cared for by pediatric otolaryngologists at Children's Wisconsin. Though a significant amount of care for children in the Milwaukee area is provided through our hospital system, there is an unknown cohort of children cared for outside of the system whose data was not included in the study. Another limitation is that the impact of timing of tonsillectomy and/or adenoidectomy on PTTO is not known. We did not analyze those that underwent tonsil and/or adenoid procedures at the time of ear tube placement relative to those with such procedures at another time.

In addition, while the diagnostic codes for otorrhea were used to identify patients, there is the possibility that some patients presenting with otorrhea did not receive the correct code thus underestimating the rate or PTTO. However, we feel this would have occurred across all demographic and clinical groups and would not impact the relative rates shown by the data. We were also unable to determine triggers for PTTO such as upper respiratory infection beyond the association with the comorbidities studied.

## 5. Conclusions

Higher rates of PTTO correlated strongest with clinical factors, particularly craniofacial abnormalities and immunodeficiency. Social determinants and demographic variables, including private insurance and non-Hispanic ethnicity, as well as older age, were associated with lower rates of PTTO. Race and sex did not show significant correlations with PTTO.

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## Declaration of competing interest

The authors note no competing interests relevant to this study.

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