Trisomy 21 and Outcomes of Tympanostomy with Tube Insertion

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Abstract

Background: Tympanostomy with tube insertion is a common procedure within the Trisomy 21 (Down Syndrome) population used to treat chronic otitis media effusion (COME) or recurrent acute otitis media (RAOM). While often viewed as a benign procedure, we set out to determine the rate of complications in the Down Syndrome population compared to those without Down Syndrome.

Methods: A retrospective analysis using TriNetX datasets from 2014 to present compared the outcomes of two cohorts: Cohort 1 (120) named Tympanostomy with Trisomy 21 ≤ 18 years old and Cohort 2 (5,120) named Tympanostomy without Trisomy 21 ≤ 18 years old. The following outcomes were measured: Development of cholesteatoma, hearing loss, tympanic membrane (TM) perforation, and requiring multiple sets of tubes.

Results: Results presented as risk odd ratio with 95% confidence interval (OR [95%CI]). We found Cohort 1 to have an increased risk of hearing loss [RR]: 3.626, [2.47, 5.323], TM perforation [OR]:2.188, [1.45, 3.301], and requiring multiple sets of tubes [OR]: 3.438, [2.332, 5.07]. We found no increased risk of cholesteatoma formation.

Conclusion: We found that while tympanostomy with tube insertion is often viewed as a benign procedure, within the Down Syndrome population, we found there to be an increased risk of hearing loss, TM perforation, and requiring multiple sets of tubes. Further research should be conducted as to ways of reducing the negative outcomes observed.

Introduction

Trisomy 21 (Down Syndrome) is one of the most common genetic disorders affecting 1 in 700 births [1]. Down Syndrome (DS) patients are predisposed to a wide variety of otolaryngologic problems, including chronic ear infections and chronic middle ear effusions associated with hearing loss, airway obstruction, and sleep apnea [2]. Tympanostomy with tube insertion (TT) is a frequently performed procedure in the Trisomy 21 (Down Syndrome) population to manage chronic otitis media effusion (COME) or recurrent acute otitis media (RAOM). Despite often being perceived as a benign procedure, there can be complications associated with TT including hearing loss, Tympanic membrane (TM) perforation, and non resolution of the problem requiring multiple sets of tube.

Our study is aimed at thoroughly examining and understanding the rates of complications within the Down Syndrome (DS) population. By conducting this research, we aim to provide a more comprehensive and detailed insight into the prevalence and nature of these complications.

Methods and Materials

Study Design:
- This study is a retrospective cohort study.

Ethics Approval:
- Ethical approval was granted by the Institutional Review Board (IRB) at The University of Tennessee Health and Science Center, under protocol number 23-09356-NHSR, ensuring adherence to ethical guidelines and principles.

TriNetx:
- TriNetx utilizes Electronic Health Records to provide clinical data and analytical tools to generate real-world evidence (RWE) localized to a single healthcare center, The University of Tennessee Health Science Center. The queries are federated, and only aggregated results are visible on the TriNetX platform. We utilized ICD10 and CPT codes to determine the rates of outcomes within our populations.

Inclusion Criteria:
- Age ≤ 18 years old
- Underwent Tympanostomy with Tube insertion
- Cohort 1 Inclusion Criteria:
  - Presence of trisomy 21
- Cohort 2 Inclusion Criteria:
  - Absence of trisomy 21

Outcome Measures:
- Presence of cholesteatoma (ICD10: H71)
- Hearing loss (ICD10: H90, H91)
- Perforation (ICD10: H72)
- Multiple sets of tubes. (CPT: 69436, 69433)

Data Collection and Analysis:
- Patient data, including demographic characteristics and clinical parameters, were extracted from electronic health records in the TriNetX Database.
- Rates of the mentioned outcome measures were gathered anytime following initial surgery.
- Odds Ratios were used to compare postoperative outcomes between the two groups.
- Significance was determined using 95% Confidence Intervals (CIs).

Results

The study population was divided into two cohorts: Cohort 1, consisting of 120 patients, and Cohort 2, comprising 5,120 patients. Patients with Down Syndrome had documented hearing loss post operatively at a rate of 66.7% compared to the 35.5% of the control population. This gave them an OR: 3.626 [2.47,5.32]. Additionally, the rate of perforation in this population was 16.7% compared to 7.6%, which produced an OR of 2.188 [1.45 - 3.301]. Lastly, 33.3% of the Down Syndrome cohort required multiple sets of tube, compared to the 12.7% of our control group, producing an OR 3.438 [2.332 - 5.07]. There was no statistically significant difference in the development of Cholesteatoma with a <1% occurrence rate in both populations. **See Table 1.**

Discussion

In Down Syndrome (DS), craniofacial abnormalities such as mid-face hypoplasia and Eustachian tube dysfunction predispose individuals to chronic otitis media [3-4]. Our research underscores an increased risk of complications post-initial tube placement (33%), with Chi et al. reporting an even higher rate (61.4%) [5]. Hearing loss, is prevalent in DS, affecting 67% after tube insertion in our study. Shott et al. found that 81% of DS patients had pre-existing SNHL hearing loss, and Tanaka et al. noted mild-moderate hearing loss in some DS children even after tube insertion [6-7]. Additionally, Tympanic membrane (TM) perforation is a notable complication, and our determined rate of 16.7% is consistent with Shott et al.'s rate of 17% [6].

While this study has uses a robust database and uses comprehensive analysis it does have its limitations, including a single-organization scope, potential misclassification bias, and reliance on ICD codes.

Table 1

	Cohort 1 (120)	Cohort 2 (5,120)	Odds Ratio	95% Confidence Interval
Cholesteatoma	1 (.83%)	50 (.98%)	0.61	(0.08 , 4.46)
Hearing Loss	80 (66.7%)	1,820 (35.5%)	3.626	(2.47,5.323)**
Perforation	20 (16.7%)	390 (7.6%)	2.188	(1.45,3.301)**
Multiple sets of Tubes	40 (33.3%)	650 (12.7)	3.438	(2.332,5.07)**

**** indicates statistical significance**

Conclusions

We found that while tympanostomy with tube insertion is often viewed as a benign procedure, within the Down Syndrome population, we found there to be an increased risk of hearing loss, TM perforation, and requiring multiple sets of tubes. Further research should be conducted as to ways of reducing the negative outcomes observed.

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