# Effusion Prevalence at Tympanostomy During COVID-19: Follow-Up

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## Abstract

**Objective:** We previously reported pandemic year (2020) intraoperative middle ear effusion (MEE) **rate** at time of bilateral myringotomy tube (BMT) placement was 18% lower compared to pre-pandemic year (2019). After mandatory stay at home orders (MSHO) and pandemic social distancing precautions were relaxed, we aimed to assess the impact of a persistent pandemic with new COVID-19 variants on MEE presence during BMT. **Methods:** This study is a retrospective chart summary exempted by Nemours institutional review board at a single tertiary children's hospital. Children < 18 years who underwent BMT during March 1, 2019–June 31, 2019 (pre-COVID), March 1, 2020–June 31, 2020 (PY1), and March 1, 2021–June 31, 2021 (PY2) were included. Statistical analysis included chi-squared and KruskalWallis. **Results:** A total of 1069 BMTs were reviewed: 551 (52%) during pre-COVID, 227 (21%) during PY1, and 291 (27%) during PY2. There were no significant differences in age, sex, or BMI across comparison groups. Intraoperative MEE was significantly higher pre-COVID (83%) compared to PY1 (65%) and PY2 (69%) (P < .001) despite a small rebound in PY2. **Conclusion:** Intraoperative MEE remains lower in subsequent pandemic years despite relaxed public health measures and may be impacted by persistent public health measures like masking, lower return to daycare, variable social distancing, and/or change to access to health care.

Level of evidence: Level 3 prevalence study

#### Keywords

otitis media effusion, middle ear effusion, myringotomy, COVID-19

# Introduction

Acute otitis media (AOM) and otitis media with effusion (OME) commonly affect more than 80% of children by the age of 10.<sup>2,3</sup> With 3% of OME patients annually undergoing bilateral myringotomy tube placement (BMT),<sup>4</sup> it has become the most frequently performed pediatric ambulatory surgical procedure in the United States (USA).<sup>5</sup> However, throughout the COVID-19 pandemic, numerous studies have elucidated a decrease in various measures of AOM/OME including incidence,<sup>6,7</sup> prevalence,<sup>8</sup> mean number of AOM episodes and hospitalizations,<sup>9,10</sup> number of BMT procedures,<sup>5</sup> intraoperative presence of middle ear effusion (MEE),<sup>11</sup> and AOM/OME consultations<sup>12</sup> in multiple countries worldwide such as the Netherlands, Italy, Brazil, and USA. The pandemic has also influenced known risk factors of AOM/OME such as

daycare attendance,<sup>13</sup> causing clinicians and healthcare systems to shift toward telemedicine encounters.<sup>14-17</sup>

While there are many reasons that could contribute to the decline in OME prevalence, a few studies assert that this

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decline in prevalence is in part due to lockdown restrictions and social distancing measures.<sup>6,9,18</sup> However, these restrictions and social-distancing measures started relaxing as early as April 2020 in Alaska, USA<sup>19</sup> with many states following suit soon thereafter-as evidenced by an increase in workplace cellphone activity and correlative rise in COVID-19 infections.<sup>20</sup> To our knowledge, there are no studies on the prevalence of intraoperative MEE after the relaxation of lockdown restrictions within the USA. If MEE prevalence returned to pre-COVID levels, this would significantly support the hypothesis that social distancing and lockdown precautions contributed to the decline of MEE prevalence and vice-versa. However, if MEE prevalence is persistently lower compared to pre-COVID levels despite the relaxation of restrictions and precautions, other reasons for the decline in MEE prevalence would need to be investigated.

Thus, the objectives of our study were to identify whether MEE prevalence differed significantly between pre-pandemic year and the 2 consecutive years with ongoing pandemic and various surges. We aimed to identify any significant associated factors that may have contributed to potential shifts in MEE prevalence. We compared the incidence of intraoperative MEE findings for children undergoing BMT before the COVID-19 pandemic (March 1, 2019–June 31, 2019) vs the first year of the pandemic (PY1) of COVID-19 (March 1, 2020–June 31, 2020) then against the second year of the pandemic (PY2) during the Delta variant (March 1, 2021–June 31, 2021). These 8-month windows were selected to account for seasonality as a potential factor in influencing risk of AOM/ROM or chronic OME (COME) in our region and climate.

# **Materials and Methods**

## Selection Criteria

This study was approved by the Nemours Institutional Review Board as exempt. All children aged 18 or younger seen by the Division of Otolaryngology (6 surgeons) at a tertiary children's hospital that underwent BMT (CPT code 69436) for recurrent otitis media (ROM), COME, conductive hearing loss, eustachian tube dysfunction (ETD), with or without concomitant adenoid/tonsillar hypertrophy (ATH), obstructive sleep apnea (OSA), or sleep-disordered breathing (SDB) were included. Exclusion criteria included patients with complex otology diagnoses including cholesteatoma, acute mastoiditis, cerebellar subdural phlegmon, coalescent mastoiditis with postauricular abscess, or sigmoid sinus thrombosis. Patients were also excluded if no pre-operative or operative note was identified.

At our institution, both physical exam specific to middle ear and presence of MEE, as well as tympanometry results were utilized in the diagnosis of ROM and COME. For any discrepancies, physical exam was prioritized over tympanometry results as at times children were not cooperative. Despite exam

findings of MEE, if the patient had normal or type A tympanometry, ENT surgeons and advanced practitioners practiced in standardized fashion and offered scheduled follow-up visit before recommendation of BMT based on clinical practice guidelines and best practice. Decisions for BMT were made if there were confounding factors such as speech delay diagnosed by evaluation, presence of craniofacial and other medical comorbidities, or allergies to multiple oral antibiotics with severe persistent clinical symptoms. If conductive hearing loss was evident on audiogram along with history of RAOM/COME, the patients were offered BMT as an option. If the patient only had unilateral MEE at the time of surgery, the patient was categorized as having MEE. Only patients that had no MEE bilaterally intraoperatively were categorized as having no MEE and did not undergo BMT surgery. Elective surgeries were canceled from March 15, 2020, to April 15, 2020, and rescheduled if patients had persistent symptoms. During that same period, many were evaluated by telehealth for RAOM/COME as chief complaint and best decisions were made based for either in person follow up or BMT depending on history and comorbidities.

## Data Extraction

Data collected included patient age, BMI, ethnicity, sex, prematurity, antibiotic exposure within 3 months of BMT procedure, insurance type, surgical indication, pre-operative audiogram (completed, results, and date), post-operative audiogram (completed, results, and date), medical complexity (defined as any subject with a significant past medical history of cardiac, neurologic, cerebral palsy, genetic disorder, or radiation/chemotherapy treatment), daycare attendance, secondhand smoke-exposure, history of speech delay, speech therapy, Early Step program enrollment, reported IM Rocephin use within 3 months of BMT procedure, nasal steroid use, antihistamine use, tympanogram classification, pre-operative and intraoperative presence of MEE, surgical procedure, days between pre-operative ENT visit and BMT surgery, and telehealth encounter for ROM/COME. Two authors (DN, YG) independently reviewed all patient EMRs for data collection, and discrepancies were corrected cooperatively with unanimous agreement.

# Statistical Analysis

Statistical analysis was conducted using SPSS 27.0 (IBM; Chicago, IL). Categorical and continuous variables were reported as medians and interquartile ranges. There were 3 groups of comparison: patients undergoing BMT before the COVID-19 pandemic (March 1, 2019–June 31, 2019) those undergoing BMT during PY1 (March 1, 2020–June 31, 2020), and patients undergoing BMT during PY2 (March 1, 2021–June 31, 2021). Patients seen by telehealth who were scheduled for BMT were categorized as "undefined/unable to visualize middle ear" and were not included in the statistical

N = 1069	White, Caucasian	Black, African American, %	American Indian, Alaskan Native, Other, Unidentified, %	Asian, Asian-Indian, Hawaiian, Pacific Islander, %	Hispanic, Latino, Spanish Origin
Pre-COVID	58%ª	11	9.1	1.5	20% <sup>a</sup>
PYI	45% <sup>a</sup>	10	12	0.4	33% <sup>a</sup>
PY2	48%	11	11	1.0	28%

Table 1. Ethnicity Distributions and Adjusted Residuals for Pre-COVID, PY1, and PY2 Groups During March–June of Their RespectiveYears. Frequencies Not Totaling 100% are Due to Rounding Errors.

<sup>a</sup>indicates a statistical difference from the estimated frequency for each cell using the standardized residual.

analysis of presence of MEE. Kolmogorov–Smirnov testing for normality revealed that the data was not normally distributed for age, BMI, or days between pre-operative ENT visit and surgery for all comparison groups, and nonparametric testing was chosen for analysis. Chi-squared and Kruskal–Wallis tests were used to compare groups, as appropriate. For chi-square tests where expected counts where more than 20% of cells had expected counts of less than 5, the Fisher–Freeman–Halton exact test was utilized to determine significance; otherwise, the Pearson chi-square test was utilized. Post hoc testing with Bonferroni corrections for 3 comparisons was applied toward adjusted residuals. Statistical significance for all tests was tested at P < .05.

# Results

A total of 1069 BMTs were reviewed: 551 (52%) during pre-COVID, 227 (21%) during PY1, and 291 (27%) during PY2. Patient demographics for all 3 groups are presented in Table 1 for each time frame, respectively. The median age and BMI of all patients is 34 months (IQR 38) and 17.1 (IQR 2.6) There were 642 male (60%) and 427 (40%) female patients across all groups.

# Demographics

There were no statistically significant differences in BMI distribution between groups. PY2 patients were significantly younger than PY1 patients (26 months vs 34 months, P < .01) and pre-COVID patients (34 months, P < .001). While there were no differences in sex proportions between groups, there were more Caucasian patients and less Hispanic/Latino patients pre-COVID compared to the other time periods (P < .01). Distributions of ethnicities can be viewed in Table 1. There were also no significant differences between insurance types across comparison groups.

# Middle Ear Effusion

Incidence and differences between children who underwent BMT pre-pandemic vs during PY1 vs during PY2 was of primary interest for this study. The prevalence of intraoperative effusion was statistically significantly different between pre-COVID (83%), PY1 (65%) and PY2 (69%) from March to June, respectively (P < .01). Pre-operative effusion concordantly revealed a similar trend (92%  $\rightarrow$  71%  $\rightarrow$  78%, P < .001). The small 7% and 4% increase in preoperative and intraoperative prevalence between PY1 and PY2 was statistically significant (P < .01, respectively). The PY2 group saw a significantly decreased time between ENT pre-operative visit and surgery (25 days) compared to the prior 2 years (35 days pre-COVID and 44 days PY1, P < .001).

# Secondary Objectives

Primary surgical indication for patients undergoing BMT is shown in Table 2, and distributions of the tympanometry classifications can be viewed in Table 3. There were no statistically significant differences across groups and time periods for either primary surgical indication or tympanometry classification.

Table 4 displays the distributions of secondary objectives collected in this study. For the PY2 group, patients were significantly younger and were more likely to have been born prematurely, reported more usage of systemic antibiotics, and had fewer abnormal pre-operative audiogram results, (P < .05 for all comparisons). The PY1 group had significantly more telemedicine encounters for COME/OME or RAOM (P < .05) compared to the other years. The Pre-COVID group had significantly greater post-operative audiogram completion rates compared to the other comparison groups (P < .05 for all comparisons).

# Discussion

The primary objective of this study was to compare intraoperative presence of MEE pre-pandemic, during onset and year 1 of pandemic, and year 2 with Sars-CoV-2 variants such as Delta. The decreased surgical BMT volume over the 3 years reflect multiple factors. First, during PY1 and PY2, the division was reduced by 1 surgeon, 1 physician assistant, and 2 audiologists, and reduction in force must be acknowledged as the primary cause for reduced patient access after the MSHO. This is compounded with recent literature supporting that MEE rates and upper respiratory infection (URI) rates were decreased during these time periods, which likely led to a decreased demand for BMT.

The decline in MEE prevalence compared to pre-COVID is reflected with a statistically significant and concordant decline

Table 2.	Distribution	of Surgical	Indications a	s Listed in	Operative
Note.					

	Mar–Jun (n = 1065)				
	COME/OME, %	ROM, %	ETD, %	HL, %	ATH, %
Pre-COVID	80	13	1.3	0.5	5.5
PYI	82	11	2.6	1.3	3.5
PY2	86	9.1	2.2	1.1	1.8

(C)OME – (chronic) otitis media with effusion; ROM: recurrent otitis media; ETD: eustachian tube dysfunction; HL: hearing loss; ATH: adenotonsillar hypertrophy. Pre-COVID, PY1, and PY2 indicate patients who underwent BMT from March through June 2019, 2020, and 2021, respectively.

<sup>a</sup>indicates a statistical difference (P < .05) from the estimated frequency for each cell using the standardized residual. Distributions not totaling 100% for each group are a result of rounding errors.

in abnormal pre-operative tympanometry and audiograms. In our study, there were no significant differences in daycare attendance across comparison groups. While daycare is a wellknown risk factor for developing OME.<sup>21-24</sup> PY1 davcare attendance numbers may be overestimated during the MSHO periods due to lack of updated patient information. We observed a 10% increase in systemic antibiotic use during this period, which could contribute to the decreased prevalence of OME. However, reported IM Rocephin administration rates remained unchanged, and overall decreased use of antibiotics is a desired outcome for treatment of AOM/COME in avoidance of both adverse events and promoting bacterial resistances.<sup>25</sup> There was a statistically significant decrease in time to surgery for PY2 compared to PY1 and pre-COVID years (25 days vs 44 days and 35 days, respectively, P < .01). A decrease in time to surgery would favor an increase in MEE since watchful waiting is a strong recommendation for managing OME, which could potentially help explain the increased effusion rates for PY2 compared to PY1. However, this would not help explain the disparity in MEE prevalence between PY2 and pre-COVID.<sup>25</sup> There was a statistically significant increase in proportion of patients born prematurely in PY2 compared to other comparison groups, which likely attributed to the slight increase in MEE prevalence.

Multiple papers have asserted that MSHOs, selfquarantining, social distancing, and overall increase in health-conscious behaviors are factors for this decline.<sup>8-10,18</sup> Once MSHOs and social distancing precautions were relaxed throughout the United States,<sup>19</sup> MEE prevalence was expected to rebound. Our data matched this prediction and showed a small rebound from PY1 with a decreased prevalence of intraoperative findings of MEE in comparison to pre-COVID. Additionally, since there was a 59% and 47% volume reduction in BMT surgeries during PY1 and PY2 compared to pre-COVID, respectively, our results may overestimate the actual prevalence of MEE.

Throughout the initiation of the 2020–2021 school year, mask mandates were placed on teachers, staff, as well as

**Table 3.** Right and Left Ear Tympanometry Classification

 Distribution between Comparison Groups.

I			
Tympanometry Classification	A, %	B, %	C, %
Right ear (n = 814)			
Pre-COVID	16	70	14
PYI	13	76	12
PY2	19	72	9.9
Left ear (n = 805)			
Pre-COVID	17	70	13
PYI	17	72	11
PY2	22	66	13

Pre-COVID, PY1, and PY2 indicate patients who underwent BMT from March through June 2019, 2020, and 2021, respectively.

<sup>a</sup>indicates a statistical difference (P < .05) from the estimated frequency for each cell using the standardized residual. Distributions not totaling 100% are a consequence of rounding errors.

children of all ages.<sup>26,27</sup> Combined with an overall increase in health-conscious behaviors such as utilizing hand sanitizers, this increased protection against the spread of URIs, a known risk-factor for OME, may indeed have played a role to the overall decreased prevalence described in our study from pre-COVID. The statistically significant rebound in PY2 compared to PY1 may be accounted for by the reversal of MSHO restrictions and non-standardized social distancing precautions throughout 2021. Several papers have illustrated correlations between increases in cell-phone activity in the workplace and lower activity in residential spaces with higher COVID case rates in the same time periods and those after.<sup>20,28,29</sup> This idea correlates with a recent ecological study conducted by Budzyn et al that showed 62% of 520 counties within the US did not have a school masking requirement from July 1 to September 4, 2021.<sup>30</sup> Another study by Boutzoukas revealed that approximately 25% of K-12 districts across 9 states had optional or partial masking policies and increased COVID-19 transmission rates from July 2021 to December 2021.<sup>31</sup> Collectively, these findings support a rebound in OME and consequently BMT volume, which this study's findings support.

Presence or absence of preoperative and intraoperative findings of MEE is influenced by multiple factors including individual patient factors and those established to increase risk of AOM such as daycare attendance. The COVID-19 pandemic has challenged the ability to identify any association or causal relationships between public health mandates and societal behavioral variations in the course of clinical illnesses and exam findings such as persistent MEE before BMT is performed. Natural resolution of MEE over time without intervention has been well established. Our study supports this as pandemic year 1 had the longest waiting period but smallest prevalence of intraoperative MEE while pandemic year 2 saw the shortest waiting period to BMT and second highest intraoperative MEE finding. Pre-COVID baseline had the **Table 4.** Between Group Comparisons for March–June Patients, Respectively. Comparison Groups Include Pre-COVID, PY1, and PY2 Patients as Defined in the Methods Section. All Quantitative Data are Reported in Medians and Iqrs, Whereas All Qualitative Data are Reported in Frequencies. PY1: Pandemic Year 1; PY2: Pandemic Year 2.

Mar-Jun Comparisons

Total N = 1069

	2019 Pre-COVID	2020 PY I	2021 PY2
Total patients (n)	551	227	291
Age <sup>a</sup>	34 (38)	34 (40)	26 (25)
Body mass index	17 (2.6)	17 (2.8)	17 (2.7)
Male sex	61%	60%	59%
Days between pre-operative visit and surgery <sup>a</sup>	35 (22)	44 (67)	25 (14) <sup>b</sup>
Pre-operative effusion <sup>a</sup>	92% <sup>b</sup>	71 <sup>%b</sup>	78% <sup>b</sup>
Intraoperative effusion <sup>a</sup>	83% <sup>b</sup>	65%	<b>69</b> %
Prematurity <sup>a</sup>	5.3% <sup>b</sup>	5.7%	۱2.7% <sup>b</sup>
Telemedicine <sup>a</sup>	0 <sup>b</sup>	20.7% <sup>b</sup>	۱.4% <sup>b</sup>
Medical complexity	14%	10.1%	9.6%
Daycare attendance	61%	55%	58%
Passive and/or parental smoking	5.1%	3.5%	6.9%
History of speech delay	25%	25%	20%
In speech therapy	13%	12%	8.2%
In early steps	3.6%	2.6%	2.7%
Antibiotic exposure <sup>a</sup>	72% <sup>b</sup>	75%	82% <sup>b</sup>
Received IM rocephin	14%	9.7%	10.3%
Intranasal steroid use	30%	28%	24%
Antihistamine use <sup>a</sup>	37%	43%	47%
Pre-operative audiogram	76%	74%	72%
Pre-operative audiogram results <sup>a</sup>	82%	84%	73% <sup>b</sup>
Post-operative audiogram <sup>a</sup>	68% <sup>b</sup>	46% <sup>b</sup>	58%
Post-operative audiogram results	12%	14%	7.6%

<sup>a</sup>indicates a statistical difference (P < .05) from the estimated frequency for each cell using the standardized residual.

<sup>b</sup>indicated that the chi-square distribution for the Bonferroni-corrected adjusted residual is P < .05.

second longest waiting period to BMT but greatest prevalence of intraoperative MEE reflecting pre-pandemic common pediatric viral URIs associated with daycare attendance and high volume of pediatric otolaryngology practice resulting often in families waiting for few weeks until BMT is scheduled from clinic appointment and decision.

The length of time between plan for BMT to actual procedure date is highly variable based on patient and non-patient-related factors, including testing COVID positive resulting in rescheduling, current OR nurse staffing shortage, decreased access to OR time for surgeons, and decreased access to ambulatory care and appointments for practices experiencing loss of any otolaryngology providers secondary to financial impact and reduction in force. At the time, this study's primary goal was to extend upon our initial findings to identify changes in public health mandate and social behaviors as the pandemic evolved. Various surges of omicron variants and pandemic impacts on pediatric otolaryngology clinics and surgical volumes are highly complex. Our findings confirm unclear associations between the length of "time" between planned BMT prevalence of MEE as documented intraoperatively during BMT.

Risk factors for developing OME include prior AOM or URIs both of which declined in parallel during sharp decline in the incidence of influenza and RSV during the onset of the COVID-19 pandemic.<sup>32-34</sup> Despite loosening of social distancing precautions and MSHOs, 40%-75% of counties and districts across the United States have strictly enforced mask mandates for students and for teachers from July 2021 to December 2021,<sup>30,31</sup> which have been shown to reduce the number of COVID-19 cases.<sup>35</sup> Mask mandates in schools in pandemic years 1 and 2 are no longer in place, nor is social distancing, MSHOs, and self-quarantine practices are now voluntary. During the first 2 years of pandemic, reduction in overall URI incidence in children may likely key be a factor for decreased intraoperative MEE findings. However, as the pandemic has become endemic, and more children have returned to daycare and preschool now without masking, demand for pediatric otolaryngology ambulatory appointments for AOM have risen since fall of pandemic year 2.

This study has several limitations. While this study can attest to correlative factors, we cannot demonstrate causality. Moreover, our observations that MSHOs, self-quarantining practices, and mask mandates in schools contributed to the decrease in URIs and consequently MEE prevalence remain extremely difficult to test in randomized controlled trials. Given the inherent dangers of acquiring Sars-CoV-2 in children, especially prior to FDA approval for vaccination in phases with preschool children as the last group approved, it is not possible to test these specific factors safely and ethically. Moreover, while this study specifically did not include cold and flu season, our previous study highlighted the decrease in prevalence was persistent from December through July for pre-COVID and PY1. It is likely that with the increased rates of viral URIs typically seen through cold and flu season, the prevalence of MEE pre-operatively and intraoperatively would be elevated in PY2 compared to PY1.

Our study highlights associated factors that may contribute to the reduced prevalence of MEE as well as extrapolating findings regarding validated risk factors to support our conclusions. As the pandemic continues to evolve alongside booster options, return to near baseline "normal" as far as no masking mandates and children returning to pre-pandemic socialization in school and other activities, presence of MEE at time of ambulatory visit without language delay and/or audiologic test finding of hearing loss, may be less of an indicator for recommendation of BMT. The ongoing intermittent surge of COVID-19 variants also impacts our observations. We specified seasonal periods in attempts to minimize variations but exact dates of Delta and Omicron surges specific to our geographic regions are not precisely known. The study was also limited by our binary classification of MEE. Lastly, our study is limited to BMTs performed in ambulatory setting of a single hospital and geographic region. Future research on AOM, OME, and MEE prevalence should include patient's history of COVID infection, vaccination, and booster status, along with daycare attendance and other pre pandemic factors as the pandemic has influenced and reshaped prior knowledge about common pediatric viral URIs and related clinical symptoms and diseases.

# Conclusion

There remains a persistent decrease in intraoperative MEE during the second year of the pandemic compared to prepandemic year, although prevalence is rebounding. Associated factors include decrease in time between pre-operative visit and surgery, documented usage of systemic antibiotics, and increase in patients born prematurely. Significant decrease in URIs and school mask mandates may have a significant impact on the overall decreased MEE prevalence when compared to pre-COVID times. Given variations in MEE duration for pediatric patients, consideration for longer watchful observation periods for those without decreased hearing or additional risk factors is reasonable.

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#### **Data Accessibility**

The data that support the findings are available from the corresponding author, XX, upon reasonable request.

#### Ethical Approval

This study was approved by the Institutional Review Board at Nemours' Children's Hospital as Exempt.

#### Statement of Human and Animal Rights

This article does not contain any studies with human or animal subjects.

### **Statement of Informed Consent**

There are no human subjects in this article and informed consent is not applicable.

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