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## The limits of pandemic precautions: Tympanostomy tube placement in children with cleft palate during COVID-19

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### ABSTRACT

**Purpose:** Coronavirus Disease-2019 (COVID-19) mitigation measures have led to a sustained reduction in tympanostomy tube (TT) placement in the general population. The present aim was to determine if TT placement has also decreased in children at risk for chronic otitis media with effusion (COME), such as those with cleft palate (CP).

**Materials and methods:** A cohort study with medical record review was performed including consecutive children, ages 0–17 years, undergoing primary palatoplasty at a tertiary children's hospital February 2019–January 2020 (pre-COVID) or May 2020–April 2021 (COVID). Revision palatoplasty ( $n = 29$ ) was excluded. Patient characteristics and middle ear status pre-operatively and at palatoplasty were compared between groups using logistic regression or Wilcoxon rank-sum.

**Results:** The pre-COVID and COVID cohorts included 73 and 87 patients, respectively. Seventy (44%) were female and median age at palatoplasty was 13.5 months for CP  $\pm$  cleft lip (CP  $\pm$  L) and 5.5 years for submucous cleft palate (SMCP). In patients with CP  $\pm$  L, TT were placed or in place and patent at palatoplasty in 28/38 (74%) pre-COVID and 37/50 (74%) during COVID ( $P = 0.97$ ). In patients with SMCP, these proportions were 5/35 (14%) and 6/37 (16%), respectively ( $P = 0.82$ ). Examining only patients  $<2$  years of age also revealed no difference in TT placement pre-COVID versus COVID ( $P = 0.99$ ). Finally, the prevalence and type of effusion during COVID was similar to pre-COVID.

**Conclusions:** Reduced infectious exposure has not decreased TT placement or effusion at palatoplasty. Future work could focus on non-infectious immunologic factors underlying the maintenance of COME in these children.

### 1. Introduction

SARS-CoV-2 (COVID-19) was declared a public health emergency on January 31, 2021 [1]. In response, states issued mandatory stay at home orders and day-care closures, while institutes such as the Center for Medicare and Medicaid Services (CMS) and US Centers for Disease Control (CDC) advised the deferral of elective ambulatory visits and surgical procedures starting March 2020. These measures were enacted to protect the community from perpetuating the transmission of the virus.

In the wake of this guidance, pediatric hospital utilization and

reports of infectious disease were inadvertently impacted. During the height of stay-at-home orders in April 2020, pediatric related hospital admissions were reduced by 45.5% compared with previous years [2]. Furthermore, social distancing guidelines and the closure of day care centers impacted transmission of common pediatric infections. The weekly incidence of twelve pediatric infectious diseases ranging from acute otitis media to urinary tract infections during the 2019–2020 period were significantly lower after social distancing practices were instituted [3].

Otitis media with effusion (OME) is one of the most common diseases of childhood; by the age of two nearly 80% of children will experience

**Abbreviations:** CP, cleft palate; CP  $\pm$  L, cleft palate with or without cleft lip; SMCP, submucous cleft palate; TIPP, tubes in place and patent; TT, tympanostomy tubes.

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an episode [4]. However, during the height of the COVID-19 pandemic, the field of pediatric otolaryngology witnessed a decrease in OME. In Italy, there was a dramatic decline in the prevalence of OME after the national lockdown. Specifically, OME was present in 40.6% of children ages 6 months–12 years seen for hearing or vestibular disorders in May–June 2019 compared to 2.3% in May–June 2020 [5]. In addition, there was a higher rate of disease resolution (93.3% in May–June 2020 compared to 20.7% May–June 2019) in children with chronic otitis media with effusion (COME) [5]. Furthermore, a group of otitis-prone children were among those evaluated at the end of lockdown in Italy and a complete recovery (defined as normal otoscopic findings) was detected in 90% of cases [6].

In response to the guidance of the CDC and CMS to minimize elective surgeries, the American Academy of Otolaryngology–Head and Neck Surgery released a statement endorsing their support of the recommendation [7]. In addition, specific guidance outlining how to approach management of common otolaryngologic related pediatric conditions was released in an article by Bann et al. which listed tympanostomy tube (TT) placement for otitis media with effusion as semi elective (performed within 3–6 months) [8]. As a result, the otolaryngology community did witness a decline in the number of TT placements. Interestingly though, the resumption of elective surgeries did not lead to an increase in TT placement, but rather, the number of children undergoing TT placement remained dramatically lower overall compared to previous years [9].

What has remained unclear is the impact of COVID-19 on OME and TT placement in children with cleft palate (CP). Children with CP experience inadequate eustachian tube function predisposing them to OME with studies reporting more than 90% of children being affected by one year of age [10,11]. The role of mechanics in COME in children with CP has been extensively studied [12]; however, the relationship between

inflammatory and infectious processes in the maintenance of chronic otitis media with effusion and transition from serous to mucoid effusions is less clear.

In the era of COVID-19 and the implementation of precautions such as social distancing, masking and decreases in child day-care utilization, it is possible to elucidate the role of infectious exposure in the escalation of middle ear disease in children with cleft palate. Thus, the overall aim of this study was to explore how COVID-19 has impacted the prevalence of TT placement and middle ear effusion in children with cleft palate. We hypothesized a decrease in both measures during COVID-19.

## 2. Methods

A cohort study with medical record review was performed following University of Pittsburgh Institutional Review Board Approval (STUDY20060029). Consecutive children, ages 0–17 years, undergoing primary palatoplasty at a tertiary children's hospital February 2019–January 2020 (pre-COVID) or May 2020–April 2021 (COVID) were included. Patients undergoing revision palatoplasty ( $n = 29$ ), anterior hard palate repair alone ( $n = 2$ ), cleft alveolus repair (in a patient without CP) ( $n = 1$ ), or excision of uvular cyst (in a patient without CP) ( $n = 1$ ) were excluded (Fig. 1).

Demographics (sex assigned at birth, insurance type, median household income for zip code, and distance and time to our hospital) were collected from the electronic medical record. Insurance types were dichotomized as private insurance (with or without public insurance) and public insurance only. Median household income for zip code was based on American Community Survey 2019 5-year estimates (US Census Bureau). For distance and time to hospital, the shortest estimates from Google Maps were used.

Medical history was also reviewed from the electronic medical

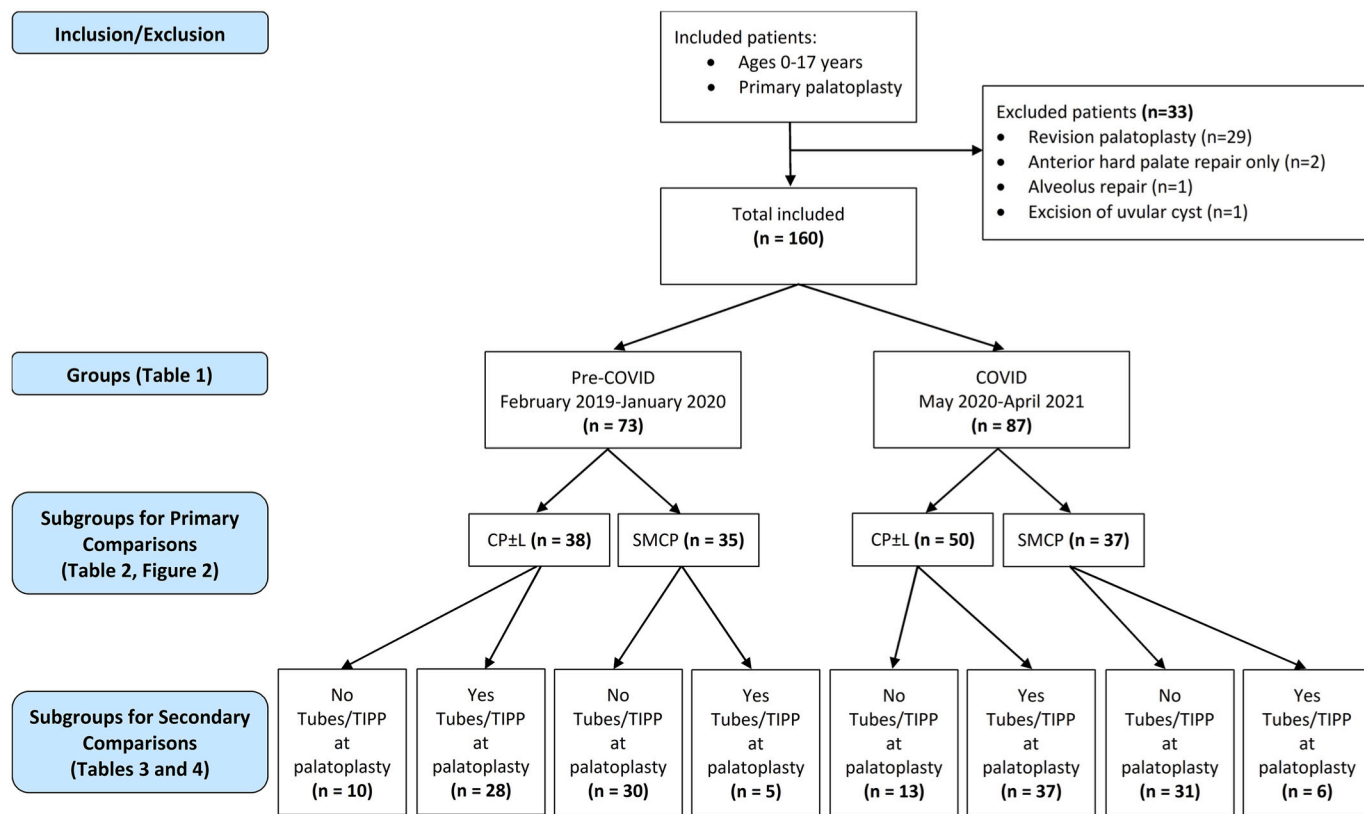


Fig. 1. Flow diagram of included and excluded patients. Sample sizes for comparison groups, and the numbers of the corresponding tables or figures, are also shown. Abbreviations: CP ± L, cleft palate with or without cleft lip; COVID, Coronavirus Disease-19; SMCP, submucous cleft palate; TIPP, (tympanostomy) tubes in place and patent.

record and parent-reported risk/protective factors for otitis media including breast milk and smoke exposure were collected. Daycare attendance was not collected since closures were inherent in the COVID group. Cleft type (submucous cleft palate, SMCP; cleft palate only, CP; unilateral cleft lip and palate, UCLP; and bilateral cleft lip and palate; BCLP), Veau classification, and comorbidities including congenital heart disease, genetic disorders, Pierre Robin Sequence, prematurity (<37 weeks gestational age at birth), and neonatal abstinence syndrome were included.

Otologic history from the otolaryngology and audiology clinic examinations immediately prior to first TT placement or palatoplasty (whichever came first) was collected. Data included middle ear effusion or retraction of the tympanic membrane observed on otoscopy, type A, B, or C tympanograms with intact tympanic membrane ( $\leq 1.2$  cc ear canal volume) [13], and age at first TT placement. Operative reports were reviewed to determine whether TT were placed or already in place and patent (TIPP) at the time of palatoplasty. In children with TT placed/TIPP, middle ear findings were reported including presence/absence of effusion and effusion type (serous, mucoid, purulent, or otorrhea).

Statistical comparisons were conducted using Stata/SE 16.1 (Stata-Corp, College Station, TX). Categorical data were summarized as frequency (%). Continuous data were evaluated for normality using the Shapiro Wilk test; all continuous data were not normally distributed (Shapiro-Wilk  $p < 0.05$ ) and are reported as median (range). Patient characteristics and middle ear status pre-operatively and at palatoplasty were compared between groups outlined in Fig. 1 using logistic regression for binary variables, Fisher's exact test for other categorical variables, and Wilcoxon rank-sum tests for continuous variables.

### 3. Results

#### 3.1. Demographics

Demographic and medical history characteristics of the 160 included patients are summarized in Table 1. Characteristics of the 87 patients with palatoplasty during COVID and 73 with palatoplasty prior to COVID were similar. Overall, 43.8% of patients were female, 42.5% had private insurance, 59.8% received some breast milk for a median of 0.5 months (range 0–36 months), and 8.6% reported smoke exposure. Median household income for zip codes was \$54,000 (range \$19,000–\$121,000). Finally, patients traveled a median of 46.9 miles (range 1.7–434 miles) or 69 min (range 10–392) to get to our hospital. Regarding medical history, SMCP, CP, UCLP, and BCLP comprised 45.0%, 33.1%, 16.9%, and 5.0% of patients, respectively. In those with cleft plate with or without cleft lip (CP  $\pm$  L), Veau classifications included I (10.2%), II (62.5%), III (20.5%), and IV (6.8%). Common comorbidities included congenital heart disease (36.3%), genetic disorders (23.1%), Pierre Robin Sequence (16.9%), prematurity (12.5%), and neonatal abstinence syndrome (5.6%). In children with CP  $\pm$  L, median age at palatoplasty was 13 months (range 10 months–2.8 years) during COVID and 13 months (range 9 months–5.3 years) pre-COVID. Three patients with CP  $\pm$  L underwent palatoplasty after 2.5 year of age. One had a small Veau 1 cleft that was not surgically repaired until the child presented with velopharyngeal insufficiency; the remaining two had other significant congenital abnormalities, including holoproccephaly in one and Nager and Treacher Collins Syndromes in the other, that delayed palatoplasty. In children with SMCP, median age at palatoplasty was 6.3 years (range 2.9 years–16.7 years) during COVID and 5.3 years (range 3.5 years–17.3 years) pre-COVID. None of these characteristics were significantly different between pre-COVID and COVID groups.

#### 3.2. Previous otologic history

Otologic history prior to palatoplasty in the pre-COVID and COVID

**Table 1**  
Demographics and medical history.

	Overall (N = 160)	Pre-COVID (N = 73)	COVID (N = 87)
	n (%)	n (%)	n (%)
Female	70/160 (43.8%)	30/73 (41.1%)	40/87 (46.0%)
Private insurance	68/160 (42.5%)	32/73 (43.8%)	36/87 (41.4%)
Breast milk (Any)	95/159 <sup>a</sup> (59.8%)	45/73 <sup>a</sup> (62.5%)	50/87 <sup>a</sup> (57.5%)
Breast milk $\geq 6$ mo	28/140 <sup>a</sup> (20.0%)	13/62 <sup>a</sup> (21.0%)	15/78 <sup>a</sup> (19.2%)
Smoke exposure	13/152 <sup>a</sup> (8.6%)	5/68 <sup>a</sup> (7.4%)	8/84 <sup>a</sup> (9.5%)
Cleft type			
Submucous cleft palate	72/160 (45.0%)	35/73 (48.0%)	37/87 (42.5%)
Cleft palate only	53/160 (33.1%)	22/73 (30.1%)	31/87 (65.6%)
Unilateral cleft lip and palate	27/160 (16.9%)	12/73 (16.4%)	15/87 (17.2%)
Bilateral cleft lip and palate	8/160 (5.0%)	4/73 (5.5%)	4/87 (4.6%)
Veau (n = 88)			
I	9/88 (10.2%)	4/38 (10.5%)	5/50 (10.0%)
II	55/88 (62.5%)	22/38 (57.9%)	33/50 (66.0%)
III	18/88 (20.5%)	10/38 (26.3%)	8/50 (16.0%)
IV	6/88 (6.8%)	2/38 (5.3%)	4/50 (8.0%)
Congenital heart disease	58/160 (36.3%)	23/73 (31.5%)	35/87 (40.2%)
Genetic disorder <sup>b</sup>	37/160 (23.1%)	14/73 (19.2%)	23/87 (26.4%)
Pierre Robin	27/160 (16.9%)	14/73 (19.2%)	13/87 (14.9%)
Prematurity	20/160 (12.5%)	7/73 (9.6%)	13/87 (14.9%)
Neonatal abstinence syndrome	9/160 (5.6%)	3/73 (4.1%)	6/87 (6.9%)
	Median (range)	Median (range)	Median (range)
Median household income (\$1000)	54 (19–121)	53 (19–111)	54 (29–121)
Distance to hospital (miles)	46.9 (1.7–434)	46.7 (3.4–195)	47.1 (1.7–434)
Time to hospital (minutes)	69 (10–392)	68 (16–215)	69 (10–392)
Breast milk (months)	0.5 (0–36)	0.6 (0–36)	0.5 (0–22)

<sup>a</sup> Number of patients for whom information regarding receipt of breast milk, duration of breast milk feeding, or smoke exposure was available from the parent questionnaire or other portion of the electronic medical record.

<sup>b</sup> Included 22q11.2 deletion (n = 6), Stickler (n = 4), Neurofibromatosis Type 1 (n = 2), Nager/acrofacial dysostosis type 1 (n = 2), Goldenhar (n = 1), Treacher Collins (n = 1), Cohen (n = 1), Kabuki (n = 1), other chromosomal anomaly (n = 19).

groups is shown in Table 2 separately for the CP  $\pm$  L and SMCP cohorts.

#### 3.2.1. Previous otologic history in children with CP $\pm$ L

In those with CP  $\pm$  L and bilateral otoscopy completed prior to palatoplasty, effusion was significantly more common in the COVID group (89.3%) compared with the pre-COVID group (65.2%) ( $P = 0.047$ ). However, retractions were documented in only one patient (pre-COVID), and the percentages of children with type B tympanograms or TT placement before palatoplasty were similar between groups. Type C tympanograms were not observed in any patients. In addition, ages at pre-operative otolaryngology or audiology clinic evaluation or first TT were not significantly different between COVID and pre-COVID cohorts.

#### 3.2.2. Previous otologic history in children with SMCP

In contrast with the CP  $\pm$  L cohort, there was no significant difference in the percentages of children with effusion in the COVID (68.4%) and pre-COVID (69.2%) groups for children with SMCP. Likewise, there

**Table 2**  
Previous otologic history.

	CP ± L			SMCP		
	Pre-COVID (n = 38)	COVID (n = 50)	OR (95% CI)	Pre-COVID (n = 35)	COVID (n = 37)	OR (95% CI)
	n (%)	n (%)		n (%)	n (%)	
Pre-op clinic with bilateral ear exam	23/38 (60.5%)	28/50 (56.0%)		26/35 (74.3%)	19/37 (51.4%)	
Pre-op during COVID	0/23 (0.0%)	17/28 (60.7%)		0/26 (0.0%)	7/19 (36.8%)	
Effusion			<b>4.44 (1.02–19.4)<sup>c</sup></b>			<b>1.04 (0.29–3.72)<sup>c</sup></b>
None	8/23 (34.8%)	3/28 (10.7%)		18/26 (69.2%)	13/19 (68.4%)	
Unilateral	4/23 (17.4%)	6/28 (21.4%)		3/26 (11.5%)	2/19 (10.5%)	
Bilateral	11/23 (47.8%)	19/28 (67.9%)		5/26 (19.2%)	4/19 (21.1%)	
Retraction			<b>0.82 (0.02–∞)</b>			<b>0.55 (0–7.29)</b>
None	23/23 (100.0%)	27/28 (96.4%)		24/26 (92.3%)	0/19 (0.0%)	
Unilateral	0/23 (0.0%)	0/28 (0.0%)		0/26 (0.0%)	0/19 (0.0%)	
Bilateral	0/23 (0.0%)	1/28 (3.6%)		2/26 (7.7%)	0/19 (0.0%)	
Pre-op tympanogram	12/38 (31.6%)	17/50 (24.0%)		15/35 (42.9%)	16/37 (43.2%)	
During COVID	0/12 (0.0%)	4/17 (23.5%)		0/35 (0.0%)	1/16 (6.3%)	
Type B			<b>1.48 (0.09–23.6)<sup>d</sup></b>			<b>1.14 (0.28–4.68)<sup>d</sup></b>
None	2/12 (16.7%)	2/17 (11.8%)		8/15 (53.3%)	8/16 (50.0%)	
Unilateral	1/12 (8.3%)	0/17 (0.0%)		4/15 (26.7%)	3/16 (18.8%)	
Bilateral	9/12 (75.0%)	15/17 (88.2%)		3/15 (20.0%)	5/16 (21.3%)	
Tube placement before palatoplasty	18/38 (47.4%) <sup>a</sup>	25/50 (50.0%) <sup>b</sup>	<b>1.11 (0.48–2.58)</b>	14/35 (40.0%)	16/37 (43.2%)	<b>1.14 (0.45–2.92)</b>
Median (range)	Median (range)	Median (range)	P	Median (range)	Median (range)	P
Age at pre-op clinic	11 m (2 m–3.4y)	8 m (3 m–1.5y)	0.93	4.2y (2 m–17.1y)	1.9y (25d–13.5y)	0.27
Age at pre-op audio	4 m (6d–3.4y)	3 m (17d–9 m)	0.36	3.1y (14d–16.8y)	2.2y (17d–7.3y)	0.66
Age at first tubes (years)	1.0y (3 m–3.5y)	10 m (4 m–1.5y)	0.53	1.6y (3 m–6.4y)	10 m (2 m–8.2y)	0.76

Abbreviations: Audio, audiology; COVID, Coronavirus Disease-19; CP ± L, cleft palate with or without cleft lip; d, days; m, months; Pre-Op, per-operative; SMCP, submucous cleft palate; y, years.

Bold indicates a significant difference between pre-COVID and COVID groups,  $p < 0.05$ , logistic regression.

<sup>a</sup> 8/22 of those with cleft palate only; 10/16 of those with cleft lip and palate.

<sup>b</sup> 11/31 of those with cleft palate only; 14/19 of those with cleft lip and palate.

<sup>c</sup> Any effusion (unilateral or bilateral) versus no effusion.

<sup>d</sup> Any type B tympanogram with normal volume (unilateral or bilateral) versus only type A tympanogram.

were no significant differences in the prevalence of retractions, type B tympanograms, TT placement before palatoplasty, or ages at examination or TT placement between groups (Table 2).

### 3.3. Middle ear status at palatoplasty

#### 3.3.1. Middle ear status at palatoplasty in children with CP ± L

New TT were placed at the time of palatoplasty in 62.0% of the COVID group and 68.4% of the pre-COVID group (OR: 0.75, 95% CI: 0.31–1.84) (Fig. 2A). An additional 12.0% of those in the COVID group and 5.3% of those in the pre-COVID group had TIPP at the time of palatoplasty (OR: 1.02, 95% CI: 0.39–2.65), and the total number of children with TT placed at or before palatoplasty was 90.0% for the COVID group and 97.4% for the pre-COVID group (OR: 0.24, 95% CI: 0.03–2.17). Effusion was present in 67.6% of the COVID group and 71.4% of the pre-COVID group (OR: 0.83, 95% CI: 0.29–2.43). Mucoid was the most common effusion type in both groups (COVID: 40.5%, pre-COVID: 35.7%), with no significant difference in effusion type between groups ( $P = 0.90$ ). Notably, in the subgroup of patients with palatoplasty prior to 2 years of age, 37/48 (77.1%) during COVID and 27/35 (77.1%) pre-COVID underwent TT placement at the time of palatoplasty (OR: 1.00, 95% CI: 0.35–2.81). The total percentage of patients with effusion at or before palatoplasty was calculated based on pre-operative otoscopy, audiology (type B tympanogram with normal volume), and middle ear aspiration at palatoplasty. This measure was also not significantly different between COVID and pre-COVID groups (OR: 2.93, 95% CI: 0.80–10.7).

#### 3.3.2. Middle ear status at palatoplasty in children with SMCP

In children with SMCP, new TT placement occurred in 10.8% of the COVID group and 5.7% of the pre-COVID group (OR: 2.00, 95% CI: 0.34–11.7) (Fig. 2B). An additional 5.4% of those in the COVID group and 8.6% of those in the pre-COVID group had TIPP at the time of

palatoplasty (OR: 1.16, 95% CI: 0.32–4.21), and the total number of children with TT placed at or before palatoplasty was 43.2% for the COVID group and 37.1% for the pre-COVID group (OR: 1.29, 95% CI: 0.50–3.32). In those with TT placed or TIPP, effusion was present in 33.3% of the COVID group and 0.0% of the pre-COVID group (OR: 2.29, 95% CI: 0.16–∞). Similar to the CP ± L cohort, there was no significant difference in effusion type ( $P = 1.00$ ) or the presence of effusion at or before palatoplasty (OR: 1.40, 95% CI: 0.49–3.98) between groups.

### 3.4. Factors associated with TT/TIPP at palatoplasty

The percentage of children with TT placed or TIPP at palatoplasty was the primary outcome measure in the present study. Therefore, additional comparisons were conducted to determine which patient characteristics influenced this measure. These comparisons were conducted separately for the CP ± L and SMCP cohorts and the pre-COVID and COVID groups, and there were no significant associations between patient characteristics and TT/TIPP at palatoplasty in patients with CP ± L (Table 3) or in patients with SMCP (Table 4).

## 4. Discussion

Masking, social distancing, and decreases in daycare utilization during the COVID-19 pandemic created a unique environment to study the role of infectious exposure in TT placement and middle ear effusion in children with CP and SMCP. We hypothesized that reduced infectious exposure would lead to a decrease in TT placement at the time of palatoplasty in the COVID group compared to the pre-COVID group. In those with CP ± L, effusion was significantly more common in the COVID group prior to palatoplasty compared with the pre-COVID group. The same analysis conducted for children with SMCP showed no significant difference. There was no difference in TT placement, presence of effusion, or type of effusion at the time of palatoplasty between the

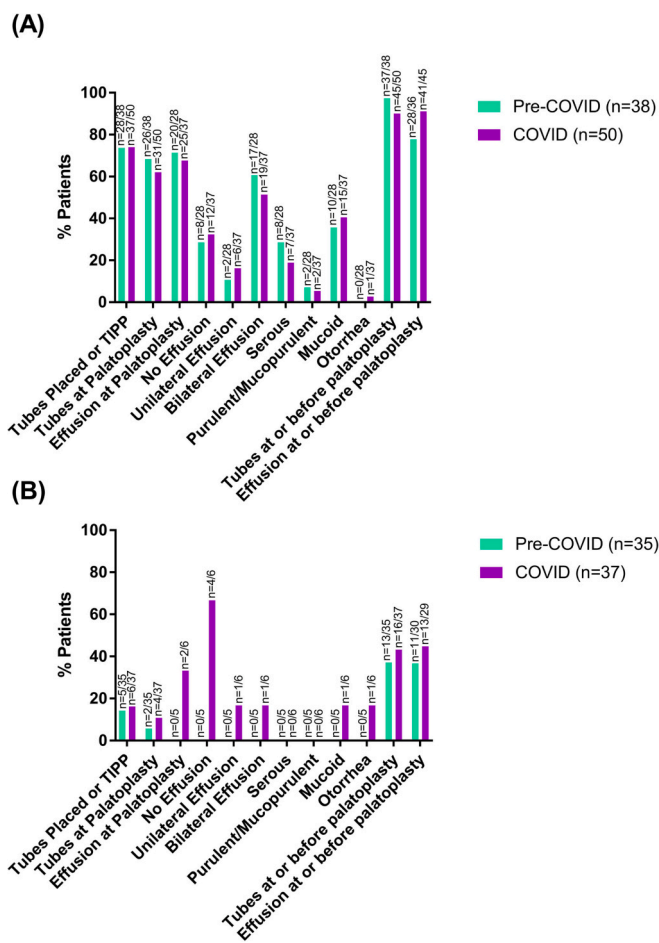


Fig. 2. Middle ear status at palatoplasty in children with (A) cleft palate with or without cleft lip or (B) submucous cleft palate. Abbreviations: COVID, Coronavirus Disease-19; TIPP, (tympanostomy) tubes in place and patent.

COVID and pre-COVID groups in both the CP ± L and SMCP cohorts. In addition, there were no significant associations between patient characteristics (biologic sex, type of insurance, smoke exposure, or receipt of breast milk) and having TT placed or TIPP at palatoplasty. These data suggest that reduced infectious exposure during COVID did not significantly impact TT placement at palatoplasty.

The two cohorts of patients (pre-COVID and COVID) were similar regarding demographics and medical history. The groups were further broken down into patients with SMCP and those with CP ± L. SMCP occurs when there is palatal muscle diastasis with intact oral and nasal mucosa, while CP is failure of the palatine shelves to fuse with the primary plate, each other, or the nasal septum [14,15]. It is hypothesized that the dysfunction of the tensor veli palatini leads to dysregulation of eustachian tube pressure and patency, predisposing patients with SMCP and CP ± L to COME [16]. However, these two groups do not have the same incidence of OME; 90% or more of patients with CP ± L experience OME, while only 49% of patients with SMCP experience OME [14,16]. This is consistent with the findings of the present study, in which 85.2% of those with CP ± L and 40.7% of those with SMCP displayed effusion during examination at or before palatoplasty.

Surprisingly, in those with CP ± L, effusion at pre-operative evaluation was significantly more common in the COVID group (89.3%) compared with the pre-COVID group (65.2%) ( $P = 0.047$ ). However, we did not find any significant difference in demographics (insurance type, smoke exposure, receipt of breast milk, or age) of the pre-COVID and COVID cohorts that could explain this finding. Additionally, when looking specifically at the 17 patients with CP ± L and pre-operative

visits during COVID, effusion was observed in 16 (94%) compared with 24/34 (70.6%) with pre-operative clinic visits before COVID. Although there was not enough power to show statistical significance, the effect was in the same direction (OR: 6.48, 95% CI: 0.780–307). There may be an underlying change in environment or the treatment protocol for these patients that was not identified in this study but increased the risk of effusion during COVID in the CP ± L, but not the SMCP, group.

Our study showed TT placement at palatoplasty in children with CP ± L was 68.4% and 62.0% in the pre-COVID and COVID groups respectively. However, 97.4% and 90.0% of patients in the pre-COVID and COVID groups had TT placed at or before palatoplasty, which is consistent with previous research conducted at our institute that demonstrated 99% of children with CP ± L had TT placed at or prior to palatoplasty [17]. The rate of TT placement prior to palatoplasty in patients with SMCP has been cited at 47% [18]. In our study only 14.3% and 16.2% of children with SMCP had TT placement prior to palatoplasty in the pre-COVID and COVID groups, respectively. The percent of children with CP ± L who had effusions at the time of palatoplasty was about 70% in our study. When analyzing children with CP ± L who were having TT placed for the first time during palatoplasty, 89.5% and 90.5% had either unilateral or bilateral effusion during the pre-COVID and COVID period, respectively. This is consistent with previous reports which showed 91–100% of children with CP ± L had effusion at the time of initial TT placement [11,19,20].

Substantial research has been conducted on risk factors and protective factors in the development of OME in children with and without CP ± L. Absence of breast feeding and exposure to smoke are known to be associated with OME [21,22]. Additionally, lower socioeconomic status (SES) and lack of private insurance has been associated with greater prevalence of COME and delayed TT placement [23,24]. However, our study showed these factors had no impact on the odds of TT placement or TIPP at palatoplasty in CP ± L and SMCP group in the pre-COVID period and during COVID. This lack of association between TT placement and classic risk factors for OME could be partially attributed to a ceiling effect in the CP ± L group, since most of these children did have tubes placed earlier in life. Previous work has suggested a protective role of breast milk feeding in the middle ear health of this population [25,26]. In addition, other measures that reflect continued eustachian tube dysfunction but were not examined in the present study, such as post-palatoplasty effusion and tube replacement, may be more sensitive to these environmental factors. However, if the non-association between these factors and TT placement is replicated in subsequent studies, it could provide further support for non-infectious nature of COME in this population.

Limitations of the study include a relatively small sample size as well as the retrospective study design. The sample size was not based on a power analysis but instead defined by the finite cohort available during the pandemic time period. Future studies exploring similar questions could improve on power and generalizability by utilizing national databases such as the Pediatric Health Information System, ACS National Surgical Quality Improvement Program, or Kids' Inpatient Database. Additionally, we had to define our pre-COVID and COVID groups using a standardized milestone (when palatoplasty was performed). This milestone made the pre-operative clinic and pre-operative audio results difficult to interpret because these events sometimes happened before and other times during COVID in the COVID group. The lack of a significant decrease in TT and effusion at palatoplasty during COVID must be interpreted with caution since it is statistically impossible to prove no difference between groups. However, this study provides additional support that anatomical variations in children with CP ± L are the underlying disease process in COME. Compared to the general pediatric population, infectious disease precautions are less likely to improve the need for TT placement and progression of COME. The results of this study support the current literature and underscore the importance of treatment programs focusing on improvement of eustachian tube

**Table 3**  
Factors associated with tubes/TIPP at palatoplasty, CP ± L.

	Pre-COVID			COVID		
	No tubes/TIPP (n = 10)	Tubes/TIPP (n = 28)	OR (95% CI)	No tubes/TIPP (n = 13)	Tubes/TIPP (n = 37)	OR (95% CI)
	n (%)	n (%)		n (%)	n (%)	
Female	3/10 (30.0%)	13/28 (46.4%)	1.99 (0.36–14.4)	5/13 (38.5%)	20/37 (54.1%)	1.86 (0.44–8.69)
Private insurance	2/10 (20.0%)	11/28 (39.3%)	2.53 (0.39–28.8)	6/13 (46.2%)	12/37 (32.4%)	0.57 (0.13–2.53)
Breast milk	5/10 (50.0%)	19/27 (70.4%)	2.32 (0.41–13.5)	8/13 (46.2%)	21/37 (56.8%)	0.82 (0.18–3.52)
Breast milk ≥6mo	2/7 (28.6%)	5/13 (38.5%)	1.53 (0.16–22.0)	1/5 (20.0%)	4/19 (21.1%)	1.06 (0.07–65.5)
Smoke exposure	1/10 (10.0%)	2/26 (7.7%)	0.76 (0.04–49.1)	1/13 (7.7%)	3/35 (8.6%)	1.12 (0.08–63.9)
Cleft type			0.36 <sup>a</sup>			0.27 <sup>a</sup>
CP	4/10 (40.0%)	18/28 (64.3%)		6/13 (46.2%)	25/37 (67.6%)	
UCLP	5/10 (50.0%)	7/28 (25.0%)		5/13 (38.5%)	10/37 (27.1%)	
BLCP	1/10 (10.0%)	3/28 (10.7%)		2/13 (15.4%)	2/37 (5.4%)	
Veau			0.91 (0.30–2.89)			1.88 (0.67–6.76)
I	0/10 (0.0%)	4/28 (14.3%)		3/13 (23.1%)	2/37 (5.4%)	
II	7/10 (70.0%)	15/28 (53.6%)		8/13 (61.5%)	25/37 (67.6%)	
III	3/10 (30.0%)	7/28 (25.0%)		1/13 (7.7%)	7/37 (18.9%)	
IV	0/10 (0.0%)	2/28 (7.1%)		1/13 (7.7%)	3/37 (8.1%)	
Congenital heart disease	3/10 (30.0%)	12/28 (42.9%)	1.73 (0.31–12.5)	9/13 (69.2%)	18/37 (48.7%)	0.43 (0.08–1.88)
Genetic disorder	1/10 (10.0%)	5/28 (17.9%)	1.93 (0.18–103)	5/13 (38.5%)	8/37 (21.6%)	0.45 (0.09–2.25)
Pierre Robin	3/10 (30.0%)	10/28 (35.7%)	1.29 (0.23–9.44)	4/13 (30.8%)	9/37 (24.3%)	0.73 (0.15–4.03)
Prematurity	1/10 (10.0%)	4/28 (14.3%)	1.49 (0.12–82.0)	2/13 (15.4%)	5/37 (13.5%)	0.86 (0.12–10.3)
Neonatal abstinence syndrome	0/10 (0.0%)	2/28 (7.1%)	0.88 (0.07–∞)	1/13 (7.7%)	3/37 (8.1%)	1.06 (0.08–60.2)
Median household income (\$1000)	Median (range) 63 (41–106)	Median (range) 50 (19–106)	P 0.10	Median (range) 54 (40–87)	Median (range) 51 (29–106)	P 0.31
Distance to hospital (miles)	25.9 (18.1–195)	66.2 (3.4–134)	0.95	77.9 (9.5–434)	71.0 (9.3–298)	0.71
Time to hospital (minutes)	66 (36–215)	88 (16–137)	0.49	93 (24–392)	93 (23–320)	0.93
Breast milk (months)	0.8 (0–6)	1.5 (0–12)	0.70	1.5 (0–8)	0.1 (0–12)	0.30

Abbreviations: BLCP, bilateral cleft lip and palate; COVID, Coronavirus Disease-19; CP, cleft palate only; CP ± L, cleft palate with or without cleft lip; TIPP, (tympanostomy) tubes in place and patent; UCLP, unilateral cleft lip and palate.

**Table 4**  
Factors associated with tubes/TIPP at palatoplasty, SMCP.

	Pre-COVID			COVID		
	No Tubes/TIPP (n = 30)	Tubes/TIPP (n = 5)	OR (95% CI)	No Tubes/TIPP (n = 31)	Tubes/TIPP (n = 6)	OR (95% CI)
	n (%)	n (%)		n (%)	n (%)	
Female	13/30 (43.3%)	1/5 (20.0%)	0.34 (0.01–3.96)	13/31 (41.9%)	2/6 (33.3%)	0.70 (0.06–5.77)
Private insurance	16/30 (53.3%)	3/5 (60.0%)	1.30 (0.13–17.7)	15/31 (48.4%)	3/6 (50.0%)	1.06 (0.12–9.25)
Breast milk	18/30 (60.0%)	3/5 (60.0%)	1.00 (0.10–13.7)	16/31 (51.6%)	5/6 (83.3%)	4.52 (0.43–236)
Breast milk ≥6mo	5/17 (29.4%)	1/3 (33.3%)	1.19 (0.02–28.2)	7/22 (31.8%)	3/4 (75.0%)	5.95 (0.40–359)
Smoke exposure	1/27 (3.7%)	1/5 (20.0%)	5.92 (0.07–529)	4/30 (13.3%)	0/6 (0.0%)	0.89 (0–8.31)
Congenital heart disease	5/30 (16.7%)	3/5 (60.0%)	6.92 (0.63–104)	5/31 (16.1%)	3/6 (50.0%)	4.90 (0.51–48.8)
Genetic disorder	6/30 (20.0%)	2/5 (40.0%)	2.58 (0.18–28.5)	8/31 (25.8%)	2/6 (33.3%)	1.42 (0.11–12.4)
Pierre Robin	0/30 (0.0%)	1/5 (20.0%)	6.00 (0.15–∞)	0/31 (0.0%)	0/6 (0.0%)	NA
Prematurity	2/30 (6.7%)	0/5 (0.0%)	2.49 (0–34.4)	6/31 (19.4%)	0/6 (0.0%)	0.56 (0–4.72)
Neonatal abstinence syndrome	1/30 (3.3%)	0/5 (0.0%)	6.00 (0–234)	2/31 (6.5%)	0/6 (0.0%)	2.13 (0–29.1)
Median household income (\$1000)	Median (range) 57 (42–98)	Median (range) 53 (43–111)	P 0.95	Median (range) 59 (33–86)	Median (range) 49 (43–121)	P 0.15
Distance to hospital (miles)	29.4 (3.4–136)	46.7 (13.8–115)	0.37	33.9 (1.7–158)	20.8 (7.1–132)	0.68
Time to hospital (minutes)	53 (16–158)	71 (31–137)	0.42	57 (10–188)	53 (26–125)	0.88
Breast milk (months)	0.05 (0–36)	0.7 (0–6)	0.80	0 (0–2)	4.5 (0–12)	0.16

Abbreviations: COVID, Coronavirus Disease-19; SMCP, submucous cleft palate; TIPP, (tympanostomy) tubes in place and patent.

function through soft palate exercises or middle ear microbiome rather than the role of acute infectious exposure.

**5. Conclusions**

This study underscores important differences in the underlying disease process of middle ear disease and TT placement in children with CP ± L and SMCP. Unlike the general pediatric population which witnessed a decrease in TT placement during COVID, these patients did not experience a decrease in TT placement. Clinically, management of these patients should continue to focus on improving eustachian tube dysfunction secondary to anatomical irregularity.

**CRedit authorship contribution statement**

**Alexa Kacin:** Investigation, Methodology, Writing – Original Draft, Review, and Editing; **Noel Jabbour:** Conceptualization, Methodology, Project administration, Resources, Supervision, Writing- Review, and Editing; **Matthew Ford:** Resources, Writing- Review and Editing; **Joseph Losee:** Resources, Supervision, Writing- Review and Editing; **Amber Shaffer:** Data Curation, Formal analysis, Investigation, Methodology, Supervision, Writing – Original Draft, Review, and Editing.

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None.

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