

Abstract

Tympanostomy tube (TT) placement is performed on patients with cleft palate to reduce sequelae from chronic otitis media with effusion (OME). TT are placed either before, the same day, or after palatoplasty with evidence that earlier TT placement increases risk of otorrhea but may lead to better long-term outcomes. Our objective is to assess differences in short and long-term outcomes of children with cleft palate who receive early vs late TT placement.

A retrospective review was conducted of all patients born with cleft palate from 2012-2017 and had TT placed at Children's Hospital of Wisconsin. These patients were split into two groups: those with TT placed before palatoplasty (Early) and those with TT placed simultaneously/after palatoplasty (Late). We analyzed post-op and lifetime otologic, speech, and audiology outcomes. Odds ratios (OR) and 95% confidence intervals (CI) were calculated and compared.

There were 235 children in the study: 157 in the Early group and 78 in the Late group. The Early group had higher odds of post-operative otorrhea (OR 4.42, CI 1.63-11.95), ever being cultured (OR 3.86, CI 1.11-13.37), having a VPI (OR 2.87, CI 1.53-5.36) and entering into an individualized education plan (IEP) (OR 1.91, CI 1.02-3.56). This group also had a greater number of lifetime tubes ($p < 0.001$). There was no difference in VFAS, GFTA, or pure tone averages between groups.

Placing TT before palatoplasty resulted in higher odds of postoperative otorrhea and impacted speech and hearing outcomes in several ways. However, many variables affect these differences, including type of cleft, other comorbid conditions, selection bias, and limited sample size. A larger sample size with multiple longitudinal outcomes controlling for these variables is necessary to determine which practice is most beneficial.

Introduction

- Chronic OME occurs in 91-100% of children with cleft palate due to abnormal attachment of the tensor veli palatini causing eustachian tube dysfunction¹
- Causes high risk for conductive hearing loss and results in speech, language, and developmental delays without early intervention²
- TT placement is the gold standard treatment for OME, but timing of TT placement in these patients remains controversial^{3,4,5}
- Studies show that late TT placement reduces complications, including otorrhea, perforation, premature tube extrusion, and increased number of tubes placed^{1,4,6}
- Studies also show that aggressive early TT placement shows improvement in long-term hearing, speech, and language outcomes^{2,7,8,9}
- Using this evidence, the Cleft Lip and Palate Team at Children's Hospital of Wisconsin has employed judicious use of early TT placement from 2012-2015 and switched to late TT placement following that, experiencing both successes and challenges with both approaches
- Purpose:** to determine the differences in hearing, speech, language, and middle ear outcomes between children with cleft palate receiving early vs late TT placement for chronic OME

Methods and Materials

- All children with cleft palate treated with TT placement at the Children's Hospital of Wisconsin were analyzed
- Patients with TT placed before palate repair were designated to the Early group while patients with TT placed at the time of or after repair were in the Late group
- Otologic data collected: intraoperative and postoperative (within 90 days) ear exam findings, number of lifetime TT placed, ever having OME cultured, ever having TM perforation
- Speech data collected: presence of speech disorder, type of speech disorder, presence of velopharyngeal insufficiency (VPI), initiation of individualized education plan (IEP) and Birth to Three program, and velopharyngeal functional assessment scores (VFAS) and Goldman-Fristoe test of articulation (GFTA) scores at ages 3, 4, and 5
- Audiologic data collected: pure tone averages at ages 3, 4, and 5
- 95% CI's were calculated for each outcome and compared

Results

Otologic Findings

- Intraoperatively, mucoid effusion was the most common finding for both groups, followed by serous effusion (**Figure 1**)
- Postoperatively, most tubes were healthy in both groups. Otorrhea was the most common finding in patients with early TT (**Figure 2**)
- Both the odds of having an unhealthy postoperative exam and the odds of having postoperative otorrhea were higher among those with early TT (**Figure 3**)
- With respect to long-term otologic outcomes, the odds of ever having OME that required culture was higher among those with early TT (**Figure 3**). They also had a statistically significant higher number of lifetime tube placements (Early mean = 3.42, Late mean = 2.24, $p < 0.001$)
- Only one patient in the study had cholesteatoma, and its cause was congenital

Speech Findings

- Of the cleft patients who were seen by speech, 98.97% had a speech disorder
- Most patients had an expressive speech disorder. The odds of having specific speech disorders (**Figure 4**) were not statistically different
- The odds of being diagnosed with a VPI was higher among those with early TT, as were the odds of being entered into an IEP (**Figure 5**)
- There were no differences in VFAS or GFTA scores between the ages of 3-5 (**Table 2**)

Audiology Findings

- No statistical difference in PTA at ages 3, 4, and 5 (**Table 2**)
- Hearing improved from age 3 to 5 in both groups

Demographics

4)	Sex - # (%)		Race - # (%)					Ethnicity - # (%)		Type of Cleft - # (%)		Age - Yrs (SD)		
	Count	Male	Female	White	Black or African American	Asian	American Indian or Alaskan Native	Refused or Not reported	Non-Hispanic or Latino	Hispanic or Latino	Incomplete	Complete	At first tube placement	At palate repair
Late	78	38 (48.72%)	40 (51.28%)	51 (65.38%)	4 (5.13%)	17 (21.79%)	1 (1.28%)	5 (6.41%)	72 (91.33%)	6 (8.77%)	41 (52.56%)	37 (47.44%)	1.42 (0.795)	1.19 (0.373)
Early	157	86 (54.78%)	71 (45.22%)	111 (47.23%)	23 (14.65%)	13 (8.28%)	3 (1.91%)	7 (4.46%)	143 (91.08%)	14 (8.92%)	63 (40.13%)	94 (59.87%)	0.49 (0.337)	1.15 (0.329)
Total	235	124	111	162	27	30	4	12	215	20	2	131		

Table 1. Study demographics of patients who received TT prior to palate repair (Early) vs at the time of or after palate repair (Late)

Otologic Findings

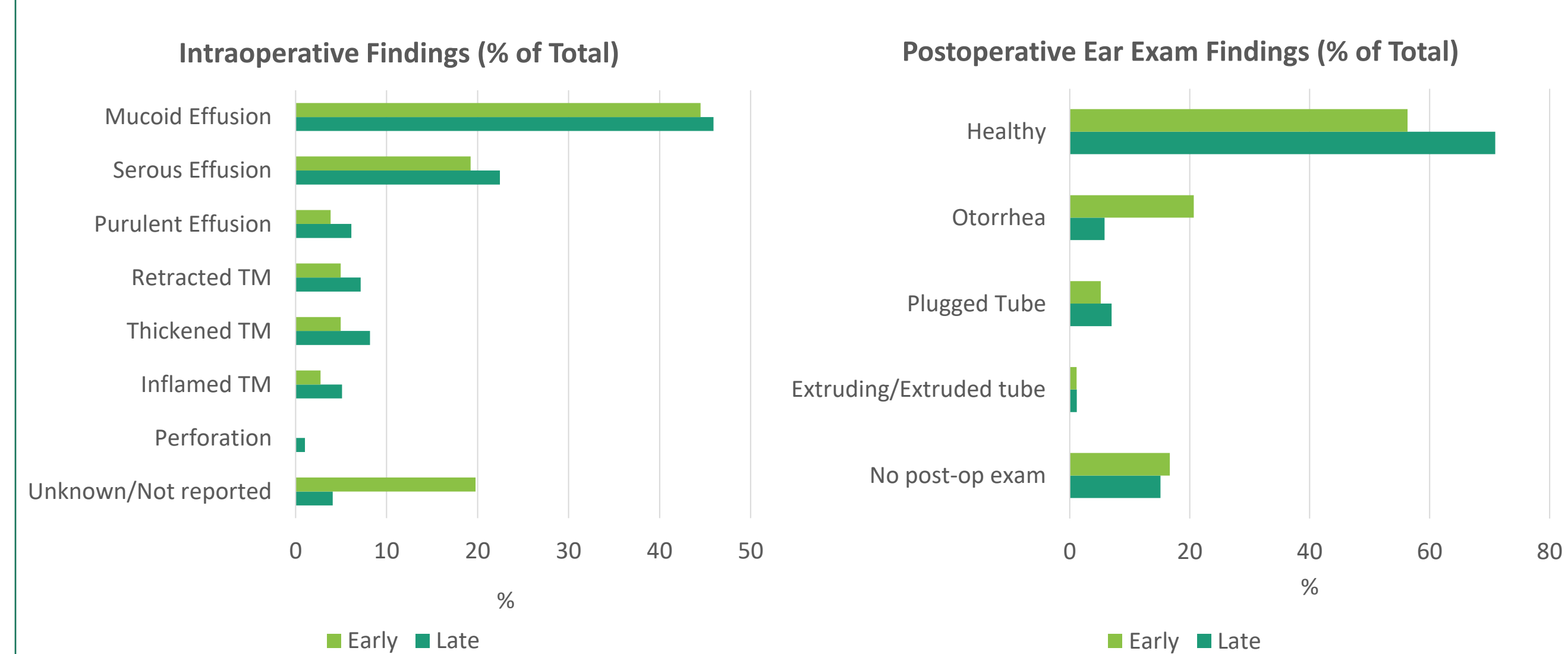


Figure 1. Intraoperative otologic exam findings of patients with cleft palate as a percent of total: early vs late tube placement

Figure 2. Postoperative otologic exam findings of patients with cleft palate as a percent of total: early vs late tube placement

Odds Ratios and 95% CIs for Otologic Outcomes: Early vs Late

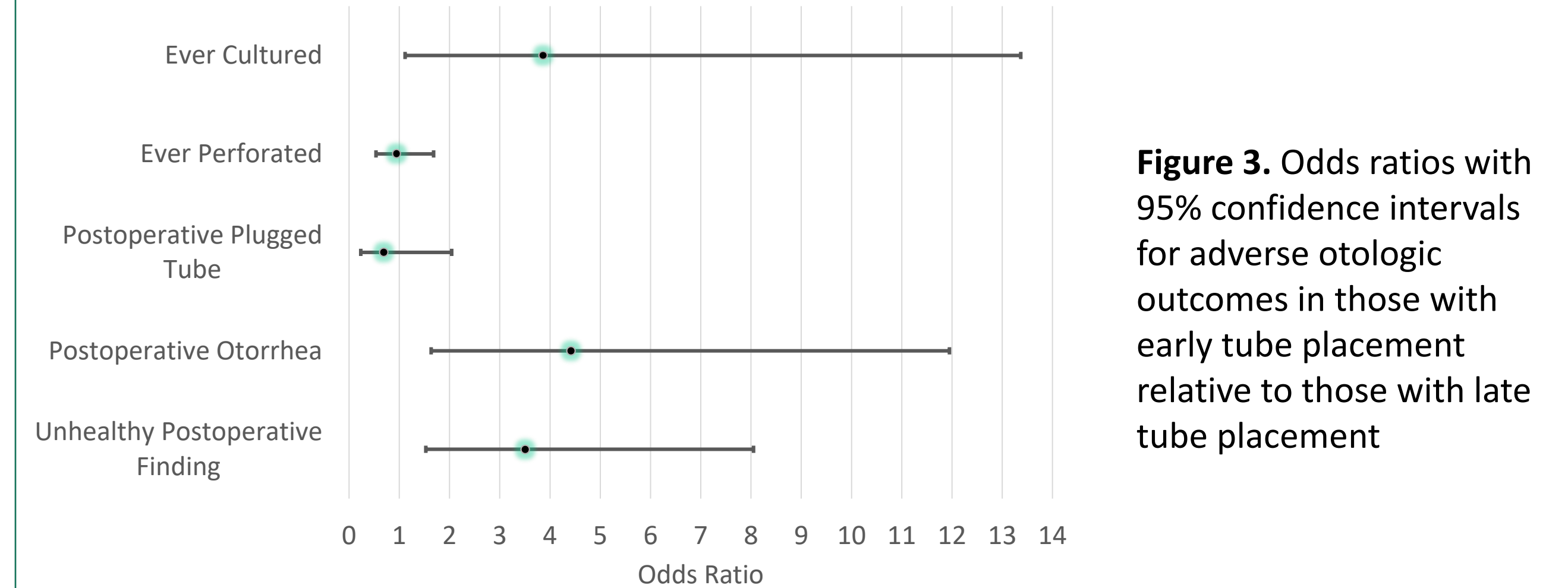


Figure 3. Odds ratios with 95% confidence intervals for adverse otologic outcomes in those with early tube placement relative to those with late tube placement

Speech and Audiologic Findings

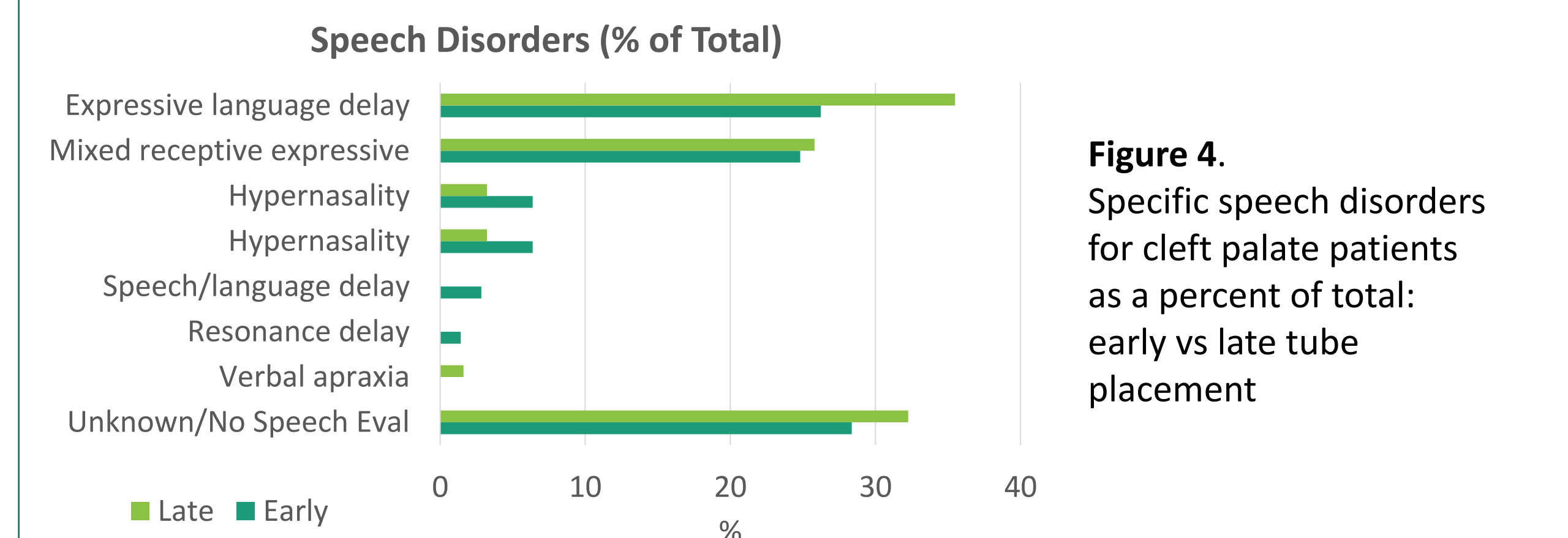


Figure 4. Specific speech disorders for cleft palate patients as a percent of total: early vs late tube placement

Odds Ratios and 95% CIs for Speech Outcomes: Early vs Late

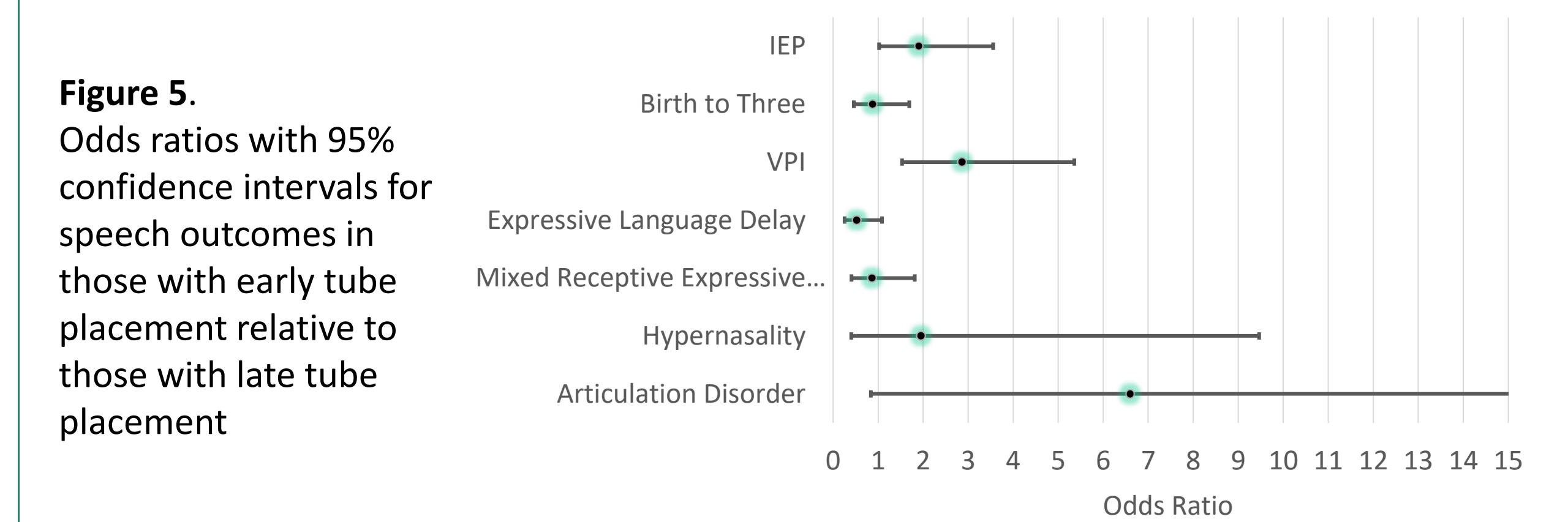


Figure 5. Odds ratios with 95% confidence intervals for speech outcomes in those with early tube placement relative to those with late tube placement

	VFAS Score Mean (95% CI)			GFTA Score Mean (95% CI)			Pure Tone Average Mean (95% CI)		
	Age 3	Age 4	Age 5	Age 3	Age 4	Age 5	Age 3	Age 4	Age 5
Late	3.20 (2.16 - 4.24)	3.40 (2.30-4.51)	3.14 (2.20, 4.08)	82 (67.13, 96.87)	70.95 (61.82, 80.08)	68.5 (59.15, 77.85)	19.38 (18.00, 20.76)	18.58 (16.76, 20.40)	17.45 (15.58, 19.32)
Early	3.44 (2.74 - 4.13)	2.98 (2.46, 3.50)	3.79 (1.85, 5.73)	90.44 (82.22, 98.65)	83.87 (76.96, 90.76)	73.97 (66.24, 81.71)	20.68 (19.36, 22.01)	18.83 (17.36, 20.30)	16.09 (14.39, 17.80)

Table 2. Means and 95% confidence intervals for VFAS, GFTA, and PTA at ages 3, 4, and 5 compared between early vs late TT placement

Discussion

- Early TT placement resulted in higher odds of having an unhealthy postoperative ear exam, having postoperative otorrhea, ever having OME that required culture, having a VPI, and initiating an IEP. This group also had a higher number of total lifetime tubes
- There were no differences in odds of ever having a perforation, having a plugged tube postoperatively, being diagnosed with a speech disorder, or any differences in specific speech disorders
- There were also no statistical differences in VFAS, GFTA, and PTA scores at ages 3, 4, and 5
- These results show that late TT in cleft palate patients reduces rates of otologic complications and may reduce rates of VPI without having other long-term ramifications on speech, language, and hearing
- The higher odds of post-operative otorrhea and higher number of tubes for early TT is consistent with the literature^{1,2,5,6,8}
- These hearing outcomes are supported by multiple studies. One study specifies these findings at ages 1-2.¹⁰ Our paper adds to this by extending this to ages 3 to 5.
- Our VPI findings are supported by two studies showing an association between the number of tubes and risk of VPI.^{9,11}
- One study found that early TT placement did not mitigate speech impairments better than late placement, further supported by our study.⁹
- Limitations include small sample size, lack of routine or consistent data collection, lack of follow-up, and not adjusting for type of cleft or comorbid conditions.

Conclusions

Placing TT before palatoplasty resulted in higher odds of postoperative otorrhea and impacted speech and hearing outcomes in several ways. However, many variables affect these differences, including type of cleft, other comorbid conditions, selection bias, and limited sample size. A larger sample size with multiple longitudinal outcomes controlling for these variables is necessary to determine which practice is most beneficial.

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