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# Outcomes After First Tympanostomy Tube Insertion in Children with Orofacial Cleft Pathologies



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## Introduction

Orofacial cleft (OFC) pathologies are associated with an increased risk of otitis media with effusion and hearing loss.

Best-practices as well as long-term outcomes for tympanostomy tube placement in children with OFC pathologies are not well understood.

## Objectives

Examine the prevalence of post-operative events following initial tube placement in children with orofacial cleft pathologies.

Understand the incidence of tube reinsertion in this patient population.

Assess the frequency of post-operative ENT visits in patients with cleft pathologies up to the age of 5.

## Methods

Retrospective Matched Cohort Study  
Birth Period: 2005 - 2017

Matching based on sex and date of birth +/- 30 days  
Matching 1:3

## Inclusion Criteria

**OFC:** OFC repair before 24 months of age

- Required a tube insertion
- Had follow up until at least 5<sup>th</sup> birthday

**Non-OFC:** No diagnosis of cleft repair

- Required tube insertion before age of 5 years
- Follow up for at least 18 months

## Outcomes of Interest:

Frequency of tube reinsertion

Post-operative healthcare visits

Post-operative events: otorrhea, tympanoplasty, and cholesteatoma formation.

## Statistical Analysis:

• Employed logistic regression for tube reinsertion, Poisson model for number of tube reinsertions, and Cox proportional hazards model for time to first tube reinsertion.

• Used Chi-squared tests to compare rates of OME, otorrhea, tympanic perforation, and cholesteatoma between groups.

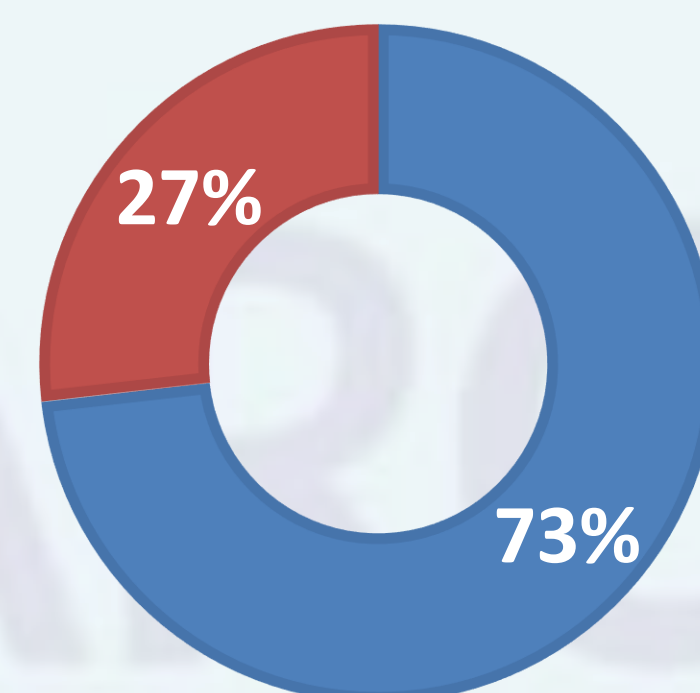
Characteristic	OFC Cohort	Non-OFC
Male; n (%)	33 (58.9)	99 (58.9)
Age at first tube insertion median (years) (IQR)	<b>1.0 (0.9, 1.7)</b>	<b>2.8 (2.0, 4.6)</b>
Cleft palate; n (%)	18 (32.1)	-
Cleft palate + cleft lip; n (%)	36 (64.3)	-
<b>Time to first tube reinsertion median (IQR)</b>	<b>937 (2.5) yrs (549.5, 1237.5)</b>	<b>720 (2 yrs) (466.5, 987.0)</b>

Table #1 Patient Characteristics

- Included 224 subjects; n=56 (OFC) matched to n=168 (non-OFC).
- 73% of OFC cohort had initial tube insertion at the time of the palatoplasty; remaining 27% underwent tube insertion afterwards.

## OFC TUBE INSERTION

- At Time of Palatoplasty
- After Palatoplasty



## Table #2 Incidence of Tube Reinsertion

Cohort	Incidence	Total tubes reinserted
Tube inserted at the time of CP repair	<b>73%</b> (30/41)	48
Tube inserted after CP repair	<b>60%</b> (9/15)	10
<b>Non-OFC cohort</b>	<b>30%</b> (51/168)	80

- Incidence of tube reinsertion was significantly lower in the non-OFC cohort.
- 51 out of 168 children (30%) required a total of 80 reinsertions
- OFC cohort was over 5 times more likely to require a tube reinsertion

	OFC MEDIAN (IQR)	OFC (N)	NON-OFC MEDIAN (IQR)	NON-OFC (N)	P-VALUE
<b>Overall number visits</b>	<b>13.0 (10.0, 17.2)</b>		<b>6.0 (3.0, 12.8)</b>		<0.001
No Reinsertions	9.0 (8.0, 11.0)	17	5.0 (3.0, 9.0)	117	<0.001
1 Reinsertion	13.0 (10.0, 15.5)	27	9.0 (5.0, 16.0)	33	0.85
2 or >2 Reinsertions	19.5 (16.8, 24.2)	12	13.5 (5.8, 19.0)		<b>0.01</b>
<b>Tube when CP repair (n=41)</b>	<b>13.0 (10.0, 19.0)</b>		--		--
No Reinsertions (n=11)	10.0 (8.5, 11.0)		--		--
1 Reinsertion (n=19)	13.0 (11.5, 16.0)		--		--
2 or >2 Reinsertions (n=11)	19.0 (16.5, 23.0)		--		--
<b>Tube after CP repair (n=15)</b>	<b>10.0 (7.5, 13.5)</b>		--		--
No Reinsertions (n=6)	7.5 (6.2, 8.8)		--		--
1 Reinsertion (n=8)	11.0 (10.0, 13.5)		--		--
2 or >2 Reinsertions (n=1)	28.0 (28.0, 28.0)		--		--

Table #3 Post-operative Healthcare Visits

In terms of post-op visits, children with cleft required more than twice the amount of post-tube insertion visits (p<0.01).

## Results

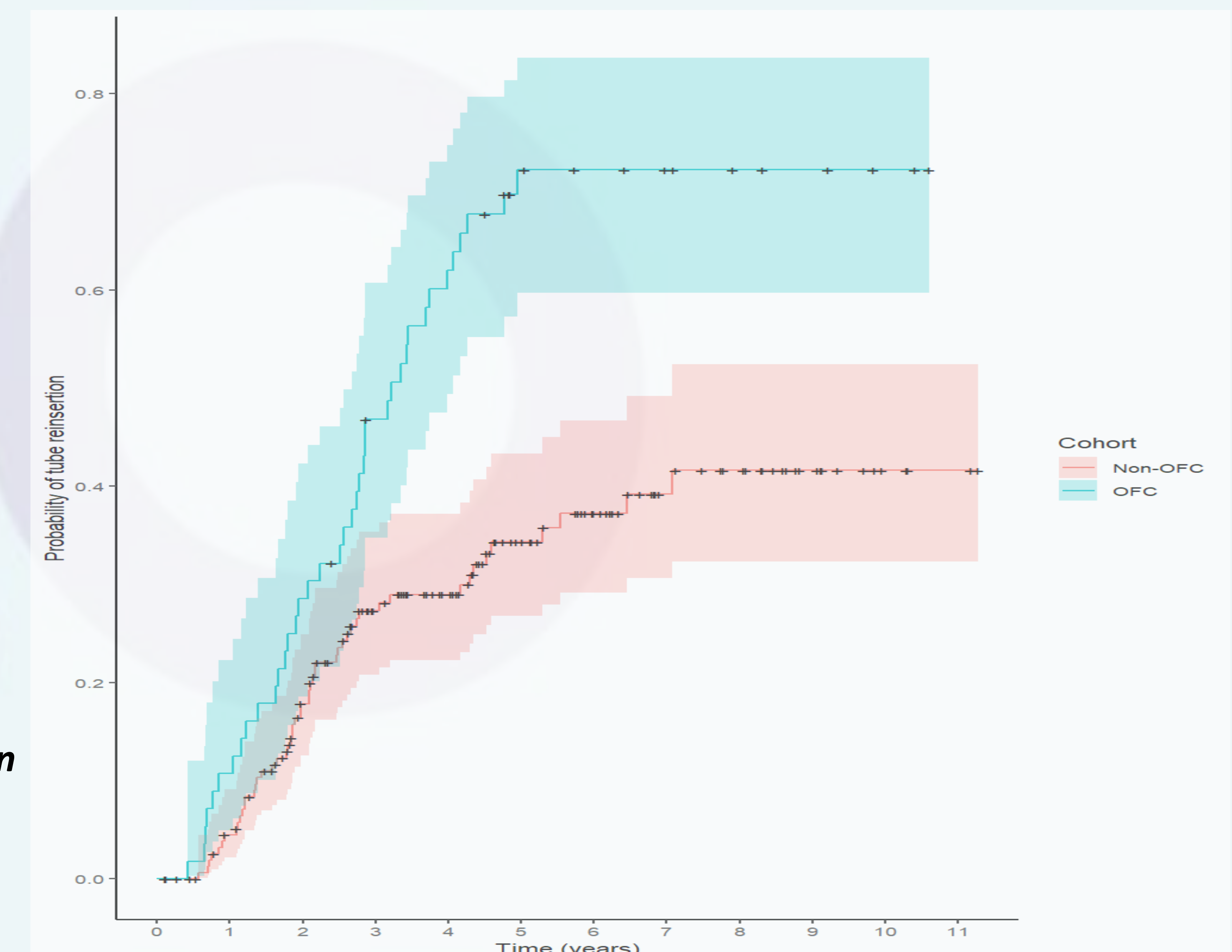


Figure #2 Risk of Tube Reinsertion

- A plateau effect was observed in the OFC cohort at the 5-year age mark.
- This implies that the risk of reinsertion is low after the age of 5 in children with OFC. In Ottawa, these data have impacted our surveillance strategy as we have now decreased the frequency of follow ups after this period.

Cohort	OME	No OME	Otorrhea	No Otorrhea	TM Perf	No TM Perf
OFC	39	17	5	51	51	102
Non-OFC	93	75	10	158	16	304

Table #4 Post-Operative Events

- There were no differences in the proportion of patients diagnosed with otorrhea, TM perforation, or cholesteatoma between the two cohorts.

## Conclusion

Children with OFC in our study had i) a 2-fold increased risk of tube reinsertion after initial operative treatment, ii) a 2-fold increase in the number of post-operative visits though no significant difference in rate of post-operative events. We observed a decreased risk of requiring tube reinsertion after 5 years, suggesting a decreased need for follow-up beyond this.