Tracheostomy Following Surgery for Congenital Heart Disease: 14-year Institutional Experience

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Abstract (Word Count 243/250)**:**

Background: Tracheostomy following congenital heart disease (CHD) surgery is a rare event and associated with significant mortality. Hospital survival has been reported from 20-40%. Late mortality for these patients is not well characterized.

Methods: We performed a retrospective observational study of patients who had a tracheostomy following CHD surgery (excluding isolated patent ductus arteriosus ligation) between 01/2000 and 12/2013. Patients were categorized into single ventricle or biventricular physiology groups. Demographics, genetic syndromes, pulmonary disease, and comorbidities were collected. Outcomes including hospital survival, long-term survival, and weaning from positive pressure ventilation are reported. Bivariate and time to even models were used.

Results: Over a 14-year period, 61 children (0.9% incidence) had a tracheostomy placed following CHD surgery. There were 12 single ventricle patients and 49 biventricular patients. Prematurity, genetic syndromes, lung/airway disease, and other comorbidities were common in both CHD groups. Gastrostomy tubes were used more frequently in biventricular physiology patients (91.8%) versus single ventricle patients (66.7%, p=0.04). Survival to hospital discharge was 50% in the single ventricle group compared to 86% in biventricular patients (p=0.01). Long-term survival continued to be poor in the single ventricle group comparatively (3-year 27.8% vs 64.8%, p=0.01). Gastrostomy tube placement was independently associated with survival in both groups (p=0.002).

Conclusion: Tracheostomy is performed following many types of surgery for CHD and is commonly associated with other comorbidities. Both hospital and long-term survival are substantially lower in children with single ventricle physiology as compared to patients with biventricular physiology.

Introduction:

Outcomes following surgery for pediatric congenital heart disease (CHD) have improved in the last decade with a current overall survival of 96.6%. [1] The majority of patients recover from surgery and are weaned from mechanical ventilation post-operatively. A small number of patients require prolonged respiratory support, necessitating consideration of placement of a tracheostomy. Published reports of patients requiring tracheostomy have ranged from 0.2-2.7%. [2-6] Data from the Society for Thoracic Surgeons (STS) Registry demonstrates that only 0.7% of patients who required a Norwood operation, had a subsequent tracheostomy. [7]

The indication for tracheostomy in pediatric patients is often multifactorial and only performed after prolonged periods of invasive positive pressure ventilation. Genetic syndromes associated with CHD (such as 22q11, Trisomy 21, CHARGE, and VATER) can predispose affected children to airway problems. Surgical complications including recurrent laryngeal nerve injury, diaphragmatic paralysis, and persistent chylothorax have been associated with tracheostomy. [8-12] In the CHD population, there is often residual cardiac disease that exacerbates an underlying pulmonary process. [9] Without a clear indication for tracheostomy, prolonged mechanical ventilation and multiple extubation failures usually occur. The timing of tracheostomy is highly variable among studies. [3, 5, 13, 14] This practice variation may be due in part to perceived high mortality associated with tracheostomy and the difficulty in separating the numerous cardiopulmonary interactions that occur in CHD patients.

Hospital survival following CHD surgery and tracheostomy are reported at approximately 65-80%. [2, 3, 5, 15, 16] Hospital survival of more complicated lesions and single ventricle patients after tracheostomy has been reported at 50-75%. [2, 16] Other groups of pediatric patients who require tracheostomy (including infants with prolonged intensive care unit stays for

prematurity and related complications) have an 80-90% survival and 30-70% chance of weaning from positive pressure ventilation. [17-20] While patients with tracheostomy and CHD are likely at higher risk of death than other pediatric patients, precise comparisons are unknown.

The objective of this retrospective review of a single center's experience with tracheostomy following surgery for CHD was to compare associated comorbidities and outcomes for patients with single and biventricular physiological repairs who required tracheostomy following surgery. The authors hypothesize that most CHD patients who require tracheostomy will have significant comorbid illnesses and other complications. Single ventricle repairs are likely at greater risk for diminished short and long-term survival and weaning from positive pressure ventilation.

Materials and Methods:

A retrospective observational study of all children <18 years of age requiring tracheostomy following surgery for CHD at Riley Hospital for Children at Indiana University Health between January 1, 2000 and December 31, 2013 was performed. Premature infants who required an isolated PDA ligation with no other CHD were excluded. Patient follow-up was included until March 2015. The hospital clinical information system was queried for all patients who had surgery for CHD and then limited to those with subsequent tracheostomy using the International Classification of Disease Version 9, Clinical Modification (ICD-9-CM) procedure codes (31.1 and 31.2). This list was compared against a registry of cardiac surgical patients and a database of patients maintained by the home mechanical ventilation program. The study was approved and exempted by the Indiana University School of Medicine Institutional Review Board.

Riley Hospital has over 3 decades of experience in both the medical and surgical management of CHD. The modern surgical program performs over 600 procedures annually on approximately 360 patients. The chronic mechanical ventilation program has managed over 700 patients since its inception in 1984. It adds approximately 25 new patients each year with a variety of pediatric respiratory disease. Patients are seen regularly by a multidisciplinary team from the time of tracheostomy until they are weaned from positive pressure ventilation.

Medical records were reviewed for baseline demographics, cardiac diagnosis, congenital heart procedures, and comorbidities. The most hemodynamically significant congenital heart lesion was characterized. The first operation for CHD during the hospitalization when the tracheostomy occurred was used as the index operation. Secondary operations were noted, both during and subsequent to that hospitalization. The primary diagnosis, ensuing surgical repairs, and in limited cases echocardiography reports were used to group CHD patients into single ventricle and biventricular physiology groups. [2] The subset of biventricular physiology patients with conotruncal disease were listed separately in Table 1, but their characteristics and outcomes mirrored those of the other biventricular groups so were combined for analysis.

Comorbidities were common in this population and categorized for descriptive purposes after reviewing the medical record. Genetic syndromes including DiGeorge, Charge, VACTERAL/VATER, Trisomy 21, and Heterotaxy were recorded if present. Prematurity for infants born less than 37 weeks was documented. Pulmonary complications, either congenital or acquired, included upper airway anatomic abnormalities, lower airway malacia (of the trachea or bronchi), and chronic lung disease. These categories were often part of the indication for tracheostomy. In many patients, pulmonary disease was present in multiple categories. Pulmonary hypertension was documented on echocardiography or heart catheterization. Because

of the complex interaction of acquired/congenital respiratory disease, pulmonary hypertension, and residual cardiac disease, no attempt was made to identify a primary indication for tracheostomy. Patients with gastrointestinal, neurological, other comorbidities and/or complications were noted. Complications were included with comorbidities as they may have influenced decision making regarding placement of tracheostomy. The timing of the decision for tracheostomy was often impossible to determine from the medical record.

Outcomes were determined from medical record review and through query of the outpatient records/database of the chronic mechanical ventilation program. The time in days from the index CHD surgical operation to tracheostomy was recorded. The proportions of patients requiring gastrostomy or a subsequent CHD surgery during that admission were noted. Patient status at hospital discharge including death, alive on positive pressure ventilation, or alive with tracheostomy alone were evaluated. The time from tracheostomy to hospital discharge and total hospital length of stay (LOS) were collected. Long-term survival and weaning from positive pressure ventilation are reported based on time from the index CHD surgical operation. There were 6 surviving patients with less than 3 years of follow-up. One surviving patient had less than 1 year of follow-up data as he moved following hospital discharge, and a second moved out of state after 2 years. The remaining 4 patients have been seen in clinic in late 2014 or early 2015. Median follow-up for all surviving patients was 6.6 years (interquartile range 3.8, 9.5).

Statistical analysis was performed using STATA 12.1 (Stata Corp, College Station, TX). Patients in each physiological group were compared using Fischer's exact and Kruskal-Wallis testing. Proportions or median values with 25^{th} and 75^{th} percentiles were reported. Time to event analysis among the physiological groups for long-term survival and weaning from positive pressure ventilation were analyzed. Kaplan-Meier curves for survival were performed. Time for

weaning from positive pressure ventilation was adjusted for the competing risk of death and reported as the cumulative incidence. [21] Comorbidities and patient characteristics potentially associated with long-term outcomes were evaluated with log-rank tests. Gastrostomy tube placement and lower airway malacia were potentially statistically significant ($p<0.2$) and were included as part of Cox proportional hazard model after testing the proportional hazard assumption. Lower airway malacia was removed from the final model as it did not contribute to model fit.

Results:

Over this 14-year period an estimated 7000 surgical repairs for CHD were performed. During this period 61 of these patients (approximate incidence 0.9%) required tracheostomy following their initial cardiac surgery. The distribution of single ventricle and biventricular physiological categories are shown in Table 1. The distribution of conotruncal lesions (as a subcategory of biventricular physiology) is also described. Most patients had biventricular lesions unrelated to conotruncal defects. Atrioventricular canals and complex ventricular septal defects were the most common lesions.

Detailed demographic characteristics are highlighted in Table 2. Overall, patients were 55.7% (34) female and most had CHD surgery during the first 6 months of life; 37.3% (23) in the first month and 39.3% (24) in the next 1-6 months. The age distribution between physiological categories was not statistically different. Among single ventricle patients 41.7% (5) had CHD surgery <1 month of age, but 3 patients (25.0%) had CHD surgery at >12 months of age. These patients included a complex single ventricle patient with tricuspid atresia who initially had a coarctation repair with pulmonary artery band, but developed congestive heart failure around a

year of age. She had mitral valve repair and central shunt prior to her tracheostomy. The other 2 complex single ventricle patients had tracheostomy following the Fontan procedure.

Comorbidities and complications were common among patients requiring tracheostomy following CHD surgery as shown in Table 2. An identified genetic syndrome occurred in 60.7% of patients (37), with Trisomy 21 being the most common. Specific syndromes such as DiGeorge or Heterotaxy, while commonly associated with specific CHD diagnoses, were found in both physiologic groups. Pulmonary disease including upper airway obstruction, lower airway malacia, and chronic lung disease were common in both groups. Diaphragmatic paralysis was documented in a patient with single ventricle physiology. Vocal cord paralysis was documented in a patient with truncus arteriosus and DiGeorge Syndrome and in another patient with a balanced atrioventricular canal and Trisomy 21. Pulmonary hypertension occurred in 59.0% (36) of all patients. Gastrointestinal comorbidities including necrotizing entercolitis, feeding intolerance, omphalocele, and visceral malposition were common. Neurological comorbidities including hypoxic ischemic encephalopathy, stroke, hydrocephalus, and interventricular hemorrhage were less common. Approximately half of all patients had other comorbidities including failure to thrive, renal disease, intrauterine growth impairment, metabolic disease, etc. Among patients in either the single or biventricular physiology groups 31.2% (19) required a subsequent CHD surgical procedure prior to discharge. Gastrostomy placement was common in both groups but occurred less commonly (66.7%, 8 patients) in single ventricle patients (p=0.04).

Overall outcomes for these patients are presented in Table 3. Tracheostomy occurred at a median of 70 days (38, 95) following the index CHD repair and was not different among the groups. Hospital survival was substantially less in single ventricle patients 50% (6) versus 85.7% (42) in biventricular patients (p=0.01). Only 22.9% (11) of hospital survivors were discharged

home without positive pressure ventilation in either group. The median time from tracheostomy to discharge (90 days (53, 144)) and total hospital LOS (195 days (151, 251)) were not different between groups.

Long-term survival is significantly less in single ventricle patients than in biventricular physiology patients (p=0.01, Figure 1). Survival at 1-year is 37% in single ventricle patients versus 77.6% in biventricular patients. Survival at 3-years continued to decline to 27.8% and 64.8% respectively but was stable out to 5 years. Of the 4 surviving single ventricle patients: 2 were able to complete the Fontan palliation (1 tricuspid atresia and 1 heterotaxy, unbalanced AVSD (the only single ventricle patient discharged home off positive pressure ventilation)), 1 survives with a central shunt after 14 years, and the other had a tracheostomy following his Fontan (subsequently lost to follow-up). The three patients with follow-up have been decannulated. Of the demographic characteristics, comorbidities, or complications assessed in both study groups, only gastrostomy tube placement was independently associated with improved survival (Hazard Ratio 0.22, p=0.002) in all patients using a multivariable Cox Proportional Hazard model. The cumulative incidence of weaning from positive pressure ventilation was not statistically different, but may be lower in single ventricle patients. (Figure 2) None of the comorbidities impacted weaning from positive pressure ventilation.

Among those patients who died, the cause of death was most frequently attributed to withdrawal of care (57.7%, 15). Withdrawal occurred both during and following the initial hospitalization. Cardiac arrests including tracheostomy events occurred in 30.8% (8) of patients. Sepsis or multi-system organ failure rarely occurred in 11.5% (3) of patients. There were no differences in the causes of death between single and biventricular physiology patients.

Comment:

This series of patients with tracheostomy following surgery for CHD represents one of the largest single institution studies to date with a long period of follow-up. This study compared patients with complex single and biventricular physiology, and it demonstrates substantially lower hospital (50.0% vs 85.7%) and long-term survival (3-year, 27.8% vs 64.8%) in single ventricle patients. These findings are similar to previous studies in cardiac populations. In comparison to reported outcomes for other pediatric populations, infants with chronic lung disease from prematurity or respiratory distress syndrome have 80-90% survival. While patients who require CHD repair have potentially more complicated cardiopulmonary interactions, this analysis suggests that tracheostomy may be as useful in patients with biventricular disease as it has been in premature neonates. [15,17,18,20] The reduced survival in single ventricle patients may be due in part to the complex cardiopulmonary interactions, underlying pulmonary disease, and the required low pulmonary vascular resistance need to maintain single ventricle physiology. In this cohort, single ventricle patients did not have additional comorbidities or complications that were associated with reduced survival.

This study was not designed to identify predictors of patients requiring tracheostomy after CHD surgery, but it continues to suggest that, while comorbidities are common in these complex patients, they are not as important as the underlying CHD in determining long-term outcomes. Only gastrostomy tube placement independently improved survival in all groups. While the mechanism is not clear, it has been previously suggested that improved nutrition and growth impacts survival. [22, 23] While the presence of lower airway malacia may impact

survival in a larger cohort, other comorbidities (including neurological disease, chronic lung disease, upper airway disease, and genetic syndromes) are less likely to impact this population.

These results are consistent with other studies indicating that patients with CHD who require tracheostomy have prolonged hospital stays. These prolonged stays continue to put these patients at risk for hospital acquired infections and ongoing developmental delay, which could not be evaluated in this study. [24] The analysis demonstrated a relatively consistent 3-month hospital stay post-tracheostomy across all groups. This period of time likely represents the required period of stabilization and training that must occur prior to discharge. The time from CHD surgery to tracheostomy was also just over 2 months in most patients. This study could not identify if patients received positive pressure ventilation for the entire period and how many tracheal extubation attempts were made. Other reports have indicated that patients with CHD are endotracheally intubated on mechanical ventilation for 1-2 months prior to tracheostomy placement. [2, 3, 5] There is debate in the pediatric community regarding the optimal timing of tracheostomy. There may be a benefit to earlier tracheostomy in specific conditions such as trauma or documented upper airway obstruction. [24, 25] No recommendation for the optimal timing can be made for all CHD patients. Clearer evidence on long-term outcomes may help clinicians and families balance the risks and benefits of earlier tracheostomy based on the patient's physiologic category (single versus biventricular) and the etiology of chronic respiratory failure.

This study also finds that tracheostomy related events only account for a third of deaths. Most deaths occur as a result of withdrawal of support. While this study could not evaluate the precise decision making around withdrawal, 5 of the 8 single ventricle patients who died, did so after withdrawal of support. All but 2 of these patients died during their initial hospitalization.

These were arduous decisions in complicated patients, but additional studies evaluating the long-term outcomes may facilitate these discussions in the future.

This single center retrospective study has the inherent limitations in study design and generalizability. Precise details regarding the clinical decision-making leading to tracheostomy and the attempts to avoid it were not available in the medical record. Also, complete identification of complications such as the number of post-operative infections or characterization of the post-operative course could not be identified. The results, however, are consistent with previous studies and its larger size with more complete follow-up adds to the current experience with tracheostomy and CHD. This study should encourage future multicenter analyses evaluating the excess risk of death and/or poor outcomes in CHD patients who require tracheostomy.

Tracheostomy following cardiac surgery is a rare complication that is associated with considerable mortality. Short and long-term mortality is substantially worse in the single ventricle population than patients with biventricular physiology. Most comorbidities and complications, while common, were not associated with a change in survival except gastrostomy tube placement, which improved survival. Future work should be directed towards defining the contribution of tracheostomy to long-term outcomes in specific CHD populations.

Supplementary Files:

None

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Tables:

Table 1: Underlying Congenital Heart Disease diagnosis by physiologic repair (n=61)

Single Ventricle Physiology	**12**		**19.7 %**
HLHS		3	4.9 %
Unbalanced AVSD		2	3.3 %
Complex Single Ventricle		4	6.6 %
HLHS/TAPVR		1	1.6 %
Tricuspid Atresia		2	3.3 %
Biventricular Physiology	**49**		**80.3 %**
Conotruncal Disease		**12**	**19.7 %**
Tetralogy of Fallot		4	6.6 %
Pulmonary Atresia, Tetralogy of Fallot		4	6.6 %
Interrupted Aortic Arch		1	1.6 %
Common Arterial Trunk		3	4.9 %
Other Biventricular Physiology		**37**	**60.7 %**
Atrioventricular Septal Defect (AVSD)		8	13.1 %
Ventricular Septal Defect (VSD)		8	13.1 %
Coarctation of the Aorta		2	3.3 %
Coartation of the Aorta/VSD		6	9.8 %
Anomalous Pulmonary Venous Return		4	6.6 %
Transposition of the Great Arteries		3	4.9 %
Other		6	9.8 %

CHD – Congenital Heart Disease, PDA – Patent Ductus Arteriosus,
HLHS – Hypoplastic Left Heart Syndrome, VSD – Ventricular Septal Defect
AVSD – Atrioventricular Septal Defect, ASD – Atrial Septal Defect,
TAPVR – Total Anamolous Pulmonary Venous Return

Table 2: Demographics and Comorbidities/Complications Among CHD Physiology Groups

Demographics	**All Patients (*n*=61)**		**Single Ventricle Physiology (*n*=12)**		**Biventricular Physiology (*n*=49)**		***p***
Female Gender	55.7%	(34)	58.3 %	(7)	55.1 %	(27)	0.99
Median Age at CHD Surgery	63	(16,166)	97	(11,364)	63	(21,114)	0.43
Age Categories							
<1 months	37.3 %	(23)	41.7 %	(5)	36.7 %	(18)	0.07
1-6 months	39.3 %	(24)	16.7 %	(2)	44.9 %	(22)	
6-12 months	14.8 %	(9)	16.7 %	(2)	14.3 %	(7)	
>12 months	8.2 %	(5)	25.0 %	(3)	4.1 %	(2)	
Comorbidities/Complications							
Prematuriy (<= 37 wks)	60.7 %	(51)	66.7 %	(8)	59.2 %	(29)	0.75
Genetic Syndrome							0.14
Trisomy 21	13.1 %	(8)			16.3 %	(8)	
Charge Association	4.9 %	(3)	8.3 %	(1)	4.1 %	(2)	
DiGeorge	6.6 %	(4)			8.2 %	(4)	
VACTER/VATER	8.2 %	(5)			10.2 %	(5)	
Heterotaxy	8.2 %	(5)	25.0 %	(3)	4.1 %	(2)	
Other	19.7 %	(12)	25.0 %	(3)	18.4 %	(9)	
None	39.3 %	(24)	41.7 %	(5)	38.8 %	(19)	
Pulmonary Disease							
Upper airway disease	36.1 %	(22)	33.3 %	(4)	36.7 %	(18)	0.99
Lower airway malacia	52.5 %	(32)	33.3 %	(4)	57.1 %	(28)	0.20
Chronic lung disease	41.0 %	(25)	16.7 %	(2)	46.9 %	(23)	0.10
Pulmonary Hypertension	59.0 %	(36)	66.7 %	(8)	57.1 %	(28)	0.75
Gastrointestinal Comorbidities	41.0 %	(25)	66.7 %	(8)	34.7 %	(17)	0.06
Neurological Comorbidities	23.0 %	(14)	25.0 %	(3)	22.5 %	(11)	0.99
Other Comorbidities	49.2 %	(30)	33.3 %	(4)	53.1 %	(26)	0.34
Additional CHD Surgery	31.2 %	(19)	16.7 %	(2)	34.7 %	(17)	0.31
Gastrostomy Placement	86.9 %	(53)	66.7 %	(8)	91.8 %	(45)	0.04

Median age reported in days with $25^{th}/75^{th}$ percentiles

Table 3: Hospital Outcomes Among CHD Physiology Groups

	All Patients (*n*=61)		**Single Ventricle Physiology (*n*=12)**		**Biventricular Physiology (*n*=49)**		***p***
Alive at Hospital Discharge	78.7 %	(48)	50.0 %	(6)	85.7 %	(42)	0.01
Alive and Off Positive Pressure at Hospital Discharge	22.9 %	(11)	16.7 %	(1)	23.8 %	(10)	0.99
Surgery to Tracheostomy	70	(38,95)	77	(48,128)	69	(35,93)	0.23
Tracheostomy to Discharge	90	(53,144)	59	(51,122)	97	(59,144)	0.22
Total Hospital LOS	195	(151,251)	179	(131,223)	198	(160,267)	0.38

Times in days are reported as median with $25^{th}/75^{th}$ percentiles

Figure Legends:

Figure 1 – Long-term survival for patients requiring tracheostomy following single ventricle and biventricular repairs

Figure 2 – Cumulative incidence of survival and weaning off positive pressure ventilation for patients requiring tracheostomy following single ventricle and biventricular repairs