Title: Tracheostomy after Surgery for Congenital Heart Disease: An Analysis of the Society of Thoracic Surgeons Congenital Heart Surgery Database

Running Head: Tracheostomy after Surgery for CHD

Authors:
[1,2]Christopher W. Mastropietro, MD; [1,2]Brian D. Benneyworth, MD; [1,3]Mark Turrentine, MD; [4]Amelia S. Wallace MS; [4]Christoph P. Hornik, MD MPH; [5,6]Jeffery P. Jacobs, MD; [5]Marshall L. Jacobs, MD

Institutions and Affiliations:
[1] Riley Hospital for Children, Indianapolis, IN, 46202

[2] Division of Critical Care, Department of Pediatrics, Indiana University School of Medicine, Indianapolis, IN

[3] Department of Cardiovascular Surgery, Indiana University School of Medicine, Indianapolis, IN

[4] Duke Clinical Research Institute, Duke University, Durham, NC

[5] Division of Cardiac Surgery, Department of Surgery, Johns Hopkins University School of Medicine, Baltimore, Maryland

[6] Division of Cardiovascular Surgery, Department of Surgery, Johns Hopkins All Children's Heart Institute, All Children's Hospital and Florida Hospital for Children, Saint Petersburg, Tampa, and Orlando, Florida

Meeting Presentation: Accepted for presentation at STS 52nd Annual Meeting, January 2016, Phoenix, AZ

Funding source: None

Key Words: congenital heart disease, CHD; tracheostomy; epidemiology; outcomes; surgery, complications

Word Count: 4228

Corresponding Author:
Christopher Mastropietro, MD
Associate Professor in Pediatrics
Division of Critical Care Medicine, Department of Pediatrics
Indiana University School of Medicine
Riley Hospital for Children
705 Riley Hospital Drive, RI 4119C
Indianapolis, IN 46202
Phone #: 317-944-5165
Fax #: 317-944-3442
cmastrop@iupui.edu

This is the author's manuscript of the article published in final edited form as:
Mastropietro, C. W., Benneyworth, B. D., Turrentine, M., Wallace, A. S., Hornik, C. P., Jacobs, J. P., & Jacobs, M. L. (2016). Tracheostomy After Operations for Congenital Heart Disease: An Analysis of the Society of Thoracic Surgeons Congenital Heart Surgery Database. The Annals of Thoracic Surgery, 101(6), 2285–2292. http://dx.doi.org/10.1016/j.athoracsur.2016.01.046

Abstract

Background: Information concerning tracheostomy after surgery for congenital heart disease has come primarily from single center reports. We aimed to describe the epidemiology and outcomes associated with postoperative tracheostomy in a multi-institutional registry.

Methods: The Society of Thoracic Surgeons Congenital Heart Database (2000-2014) was queried for all index operations with the complication "postoperative tracheostomy" or "respiratory failure, requiring tracheostomy." Patients with preoperative tracheostomy or less than 2.5 kg undergoing isolated closure of patent ductus arteriosus were excluded. Trends in tracheostomy incidence over time from 1/2000 to 6/2014 were analyzed using a Cochran-Armitage test. Patient characteristics associated with operative mortality were analyzed for 1/2010 to 6/2014, which includes deaths occurring up to 6 months after transfer to chronic care facilities.

Results: From 2000-2014, tracheostomy incidence following surgery for congenital heart disease increased from 0.11% in 2000 to a high of 0.76% in 2012, $p<0.0001$. From 2010-2014, 648 patients underwent tracheostomy. Median age at surgery was 2.5 months (25^{th}, 75^{th} percentile: 0.4-7). Prematurity (n=165, 26%), genetic abnormalities (n=298, 46%), and preoperative mechanical ventilation (n=275, 43%) were common. Postoperative complications were also common including cardiac arrest (n=131, 20%), extracorporeal support (n=87, 13%), phrenic or laryngeal nerve injury (n=114, 18%), and neurological deficit (n=51, 8%). Operative mortality was 25% (n=153).

Conclusions: Tracheostomy as a complication of surgery for congenital heart disease remains rare but has been increasingly utilized over the past 15 years. This trend and the considerable mortality risk among patients requiring postoperative tracheostomy support the need for further research in this complex population.

Word Count: 250

Introduction

As the field of pediatric cardiovascular surgery has evolved, surgical repair or palliation of patients with complex underlying cardiac lesions who often have co-existent non-cardiac co-morbidities has become commonplace at most centers. Many of these patients have prolonged postoperative courses, including prolonged need for mechanical ventilation. In some cases, liberation from mechanical ventilation is not possible and tracheostomy is considered. Several institutions have reported their experiences with pediatric patients requiring tracheostomy following cardiac surgery.[1-5] The incidence of tracheostomy after pediatric cardiac surgery in these reviews ranged from 0.2-2.7%. In-hospital mortality was much more variable, ranging from 0-40% [1-5]. In the two most contemporary reports (published in 2011 and 2014), in-hospital mortality rates were 22% and 11%.[4,5] In a study by Berry and colleagues reporting data from a large multi-institutional database, children with congenital heart disease who underwent tracheostomies had the highest in-hospital mortality when compared to children who underwent tracheostomies in association with other underlying illnesses.[6] A more recent single center study by Rosner et al reported survival at 2 years after tracheostomy to be just 28% in patients with a history of prior cardiac surgery as compared to 75% in patients with no history of cardiac surgery [5]. Tracheostomy after cardiac surgery therefore appears to be relatively infrequent but associated with high mortality.

Single center reports, though very important additions to the literature, have included a relatively small number of subjects, ranging from 4 to 59 cardiac surgical patients who underwent tracheostomy.[1-5] In order to better understand the epidemiology of patients who undergo tracheostomy after surgery for congenital heart disease, analysis of a larger cohort of patients from multiple centers is needed. To our knowledge, no such

multi-center study related specifically to patients who undergo tracheostomy after surgery for congenital heart disease has been conducted. We therefore aimed to utilize the Society of Thoracic Surgeons Congenital Heart Surgery Database (STS-CHSD) to explore the epidemiology and outcomes of patients who undergo tracheostomy after surgery for congenital and/or pediatric heart disease.

Patients and Methods

Data Source

As of June 2014, the STS-CHSD contains de-identified data on more than 320000 surgeries conducted since 2000 at 119 centers in North America. It is estimated that the database currently represents greater than 95% of all US centers that perform congenital heart surgery and greater than 98% of all congenital and pediatric cardiac operations [7]. Preoperative, operative, and outcomes data are collected on all patients undergoing pediatric and congenital heart surgery at participating centers. Coding for this database is accomplished by clinicians and ancillary support staff using the International Pediatric and Congenital Cardiac Code [8,9] and is entered into the contemporary version of the STS-CHSD data collection form (DCF).[10] The Duke Clinical Research Institute serves as the data warehouse and analytic center for all STS National Databases. Evaluation of data quality includes the intrinsic verification of data, along with a formal process of in-person site visits and data audits conducted by a panel of independent data quality personnel and pediatric cardiac surgeons at approximately 10% of participating institutions each year.[7] Approval for the study was obtained from the Duke University Medical Center Institutional Review Board as well as the Access and Publications Task Force of the STS Workforce on Research Development and was not considered human subjects research in accordance with the Common Rule (45 CFR 46.102(f)).

Study Population

The STS-CHSD was queried for all index operations between 1/2000 - 6/2014 with the complication “postoperative tracheostomy” or “respiratory failure, requiring tracheostomy.” Patients who had tracheostomy already in place prior to cardiac surgery and patients less than 2.5 kg undergoing isolated closure of patent ductus arteriosus were excluded.

Data Collection and Definitions

All instances of tracheostomy after cardiac surgery coded in the STS CHSD between 1/2000 - 6/2014 were identified and are reported as cumulative occurrence rate, center-specific occurrence rate, and annual occurrence rate. In January 2010, the STS-CHSD began analyzing operative mortality based on a definition that includes (1) mortality occurring before discharge from the hospital where the index cardiac operation took place or any secondary acute care facility, (2) any out-of-hospital deaths occurring within 30 days of the index cardiac operation, and (3) any deaths occurring in a secondary chronic care facility (or rehabilitation facility) within 180 days following the index cardiac operation. This definition of operative mortality is particularly relevant to our study population, since patients with tracheostomy after cardiac surgery often are transferred for ongoing care to either secondary acute care or rehabilitation facilities.[6,11]. We therefore explored the occurrence of postoperative tracheostomy across the entire period (2000 - 2014), but limited the analyses including preoperative risk factors, diagnostic and operative variables, and outcomes data as currently defined in the STS-CHSD to the time period of 1/2010 - 6/2014.

Statistical Analysis

To determine if there has been any change in the use of tracheostomy over the study time period 1/2000 - 6/2014, annual incidences of tracheostomy, defined as the occurrence rates of tracheostomy each year (with the 95% Clopper-Pearson confidence interval for the proportions), were calculated. Annual incidence of tracheostomy for each year was calculated as follows: number of index operations with a complication of tracheostomy divided by the number of index operations performed. To determine if the occurrence rate of tracheostomy differed in relation to center surgical volume during the same time period, we calculated the occurrence rate for the following surgical volume categories: <150 cases per year, 150-349 cases per year, and >350 cases per year, consistent with previous analyses.[12] Trends in tracheostomy occurrence over time and across centers were analyzed using Cochran-Armitage tests.

Descriptive statistics were used for patient characteristics and outcomes of those patients reported to have required tracheostomy during 1/2010 - 6/2014. Absolute counts and percentages are used for categorical variables and median and interquartile ranges (25th and 75th percentiles) are provided for continuous variables. Study patients who died (i.e. operative mortality) were compared to study patients who survived using χ^2 tests or Wilcoxon Rank-sum tests as appropriate for individual variables. Patients missing data on operative mortality were not included in this analysis. All analyses were performed using SAS version 9.4 (SAS Institute, Inc., Cary, NC) and R 3.2.1 software (R Foundation for Statistical Computing, Vienna, Austria). A probability value of less than 0.05 was considered statistically significant.

Results

From 1/2000 - 6/2014, 211,408 index cardiovascular operations without the presence of tracheostomy preoperatively occurred at the 119 centers participating in the STS-CHSD. The incidence of tracheostomy over time is illustrated in Figure 1. The rate of tracheostomy increased from 3 of 2625 patients (0.11%; 95% CI's: 0 - 0.24) in 2000 to a peak of 173 of 22798 patients in 2012 (0.76%; 95% CI's: 0.65-0.88) followed by 150 of 2339**0** patients in 2013 (0.64%; 95% CI's: 0.54 - 0.74). The overall tracheostomy rate for the period 1/2000 - 6/2014 for each center in the context of their average annual surgical center volume is provided in Figure 2. Higher volume centers (i.e. > 350 cases per year) had significantly lower rates of tracheostomy.

From 1/2010 to 6/2014, 648 patients within the STS-CHSD underwent postoperative tracheostomy. Patient demographics, anthropometric measurements, and pre-, peri- and postoperative characteristics are summarized in Table 1, and the 10 most common primary cardiac diagnoses and index cardiac surgical procedures performed are listed in Table 2. Median age was 2.5 months (range: 0 - 79.3 years, interquartile range: 0.4 - 7 months). Forty-six patients were adults with congenital or pediatric heart disease, i.e. greater than or equal to 18 years of age. Patients frequently had premature birth, and genetic and chromosomal abnormalities were especially prevalent (47.5%). Preoperative mechanical ventilation was also very common. Postoperative complications in addition to the need for tracheostomy, were seen nearly all cases (96.0%), with the most common being delayed sternal closure, sepsis, cardiac arrest, chylothorax, mechanical circulatory support, phrenic or laryngeal nerve injury, and neurologic deficit persistent at discharge. The percentages of operative mortality and postoperative complications in patients with tracheostomies are illustrated in Figure 3 along with the percentages of postoperative complications in the 98298 patients in the

STS-CHSD database who did not require tracheostomy during the same time period. There was wide range of diagnoses and procedures in this cohort. Hypoplastic left heart syndrome and other single ventricle lesions comprised the largest portion of the cohort (16.6%) and, accordingly, the Norwood procedure was the most common index cardiac surgical procedure performed.

Operative mortality for the 606 patients for which these data were available was 25.2% (n=153). Outcome data including location where death occurred are summarized in Figure 4. The annual mortality rate was relatively consistent over time (2010-2013), ranging from 24.5% - 27.5%. Patients with hypoplastic left heart syndrome had significantly higher mortality (25 of 57 patients, 44%) as compared to the rest of the cohort (p=0.0007), while patients with ventricular septal defects-type 2 had significantly lower mortality (2 of 28 patients, 7%) than the rest of the cohort (p=0.024). No other underlying diagnoses were associated with higher or lower mortality in relation to the rest of the patients, including other single ventricle lesions (13 of 49 patients, 26.5%, p=0.829). Patient characteristics of those who survived are compared to patients who died in Table 3. In regards to pre- or perioperative characteristics, patients who died were more likely to require preoperative mechanical ventilator support. Otherwise, there were no other differences observed in preoperative characteristics including STAT mortality category of the index procedure. Postoperatively however, several major complications occurred more frequently in those patients with tracheostomy who ultimately died as compared to those who survived, including mechanical circulatory support, cardiac arrest, sepsis, and chylothorax. Patients who died were also likely to require additional cardiovascular procedures within their admission following their index cardiovascular procedure (Table 4). On the other hand, the presence of recurrent

laryngeal nerve injury was significantly more common in survivors, and a similar trend was observed with respect to phrenic nerve injury.

Comment

This study represents the largest cohort to date of patients who received tracheostomy following surgery for congenital heart disease. Foremost, the incidence of tracheostomy following cardiac surgery has steadily increased over the past decade. An earlier multi-center report from the Kids' Inpatient Database similarly reported a significant increase from 1997 to 2006 in the number of patients with congenital heart disease who underwent tracheostomy as a proportion of all children undergoing tracheostomy.[6] These trends underscore the importance of the descriptive data from STS-CHSD provided in this report, which should provide clinicians with a better understanding of contemporary practice in regards to this complex patient population.

It can also be surmised from the data in this report that patients who require tracheostomy following surgery for congenital heart disease, for the most part, are high-acuity patients with complicated postoperative courses, as evidenced by the considerable prevalence of postoperative delayed sternal closure, cardiac arrest, mechanical circulatory support, and sepsis. Not surprisingly, in-hospital mortality was high, especially in patients who experienced the aforementioned postoperative morbidities. In comparison, in a retrospective analysis of 917 children with any diagnoses undergoing tracheostomy from 36 children's hospitals, Berry and colleagues reported an in-hospital mortality of only 7.7%.[13] Additionally, in-hospital mortality of our cohort was also higher than reported in the majority of the available single center studies.[1,3-5] This finding possibly reflects the inclusion of deaths that occur in patients discharged to chronic care or rehabilitation facilities. Indeed, in the study by Berry and

colleagues, 19% of all patients who had tracheostomies had been discharged to a post-acute care facility after at least one admission and 9.6% had only been discharged to such a facility.[13] The in-hospital mortality rate of 25% in this report is therefore likely more indicative of the proportion of deaths that are suffered by these patients prior to being discharged home.

In most cases, one of the goals of tracheostomy is to facilitate the safe discharge of patients with airway abnormalities or the persistent need for mechanical ventilation to home. Examining our data from this standpoint, this goal was not achieved in 25% of all cases and nearly half (44%) of all patients with hypoplastic left heart syndrome. In contrast, in the Single Ventricle Reconstruction Trial, a prospective trial of 549 infants undergoing stage I palliation for hypoplastic left heart syndrome, in-hospital mortality was 16%.[14] Follow-up data on the 75% of our study patients who were ultimately discharged to home is not available in the STS-CHSD. Available long-term follow-up data from other studies, however, are not encouraging, especially in regards to patients with hypoplastic left heart syndrome and those requiring long-term ventilation. In a study of 35 children with congenital heart disease enrolled in a home mechanical ventilation program, 5 year survival in the entire cohort was 68% but only 12% in patients with Risk Adjusted Classification for Congenital Heart Surgery score (RACHS-1) ≥ 4 (only 1 of 9 patients survived).[15,16] Moreover, only 1 of 6 patients with single ventricle anatomy completed the three stages of surgical palliation - a child with a single functional left ventricle. Cotts and colleagues similarly reported only 1 of 13 patients with single ventricle anatomy who required long-term ventilation survived through the three surgical stages.[4] Lastly, in the aforementioned study by Rosner et al, 17 of 18 patients with tracheostomy in association with cardiac surgery were discharged to home with the need for long-term ventilation. Two year survival in this study was only 28%, and all of

the 4 patients with single ventricle anatomy died prior to the second stage of their palliation.[5] Based on these data along with the data in our study, the need for tracheostomy and long-term ventilation likely signifies the presence of considerable concomitant lower airway or lung pathology in these fragile patients, increasing their risk for poor outcomes. Both short and long-term prognoses in patients with complex cardiac lesions and single ventricle anatomy who require tracheostomy and long-term ventilation could therefore be considered guarded at best, and this information should be made clear to the families of these patients prior to undertaking the procedure. More long-term follow-up data from this population are sorely needed.

On the other hand, our data suggest that prognoses in certain sub-groups may be more optimistic. For example, all but 2 patients in our cohort with ventricular septal defect type 2 as their primary diagnosis survived. Edwards and colleagues reported a 5 year survival rate of 90% in patients with RACHS-1 score of ≤ 3 who require tracheostomy and long-term mechanical ventilation.[15] We speculate that a relatively lower cumulative burden of disease is likely present in these lower complexity patients, giving them this apparent survival advantage. Patients in our report with recurrent laryngeal nerve palsy also seemed to have lower in-hospital mortality. Berry and colleagues reported a similar finding: in 883 patients with congenital heart disease who underwent tracheostomy in 2006, in-hospital mortality in patients with an upper airway anomaly was 7.3% as compared to 27.2% in patients without an upper airway anomaly.[6] Data from the report from Cotts et al also corroborates these findings: all six patients with single ventricle anatomy and isolated vocal cord paralysis who required tracheostomy for airway protection (i.e. no need for long-term ventilation) survived through all three stages of their surgical palliation.[4] For many of the children in these subgroups, tracheostomy

is likely a valuable and potentially life-sustaining therapy without which hospital discharge and long-term survival could not occur.

This study has some limitations, most importantly of which is the inability to assess intermediate and long-term outcomes. In the current iteration of the STS-CHSD, data can only support inferences concerning mortality status and peri- and postoperative complications. In addition, we did not perform a multivariable analysis due to concerns of confounders not accounted for within the available dataset. It is also difficult, based on the STS-CHSD data, to make definitive conclusions regarding relationship between occurrence rate of tracheostomy and individual centers. Though center-to-center variations in indication for tracheostomy, timing of tracheostomy, and post-tracheostomy care could potentially influence outcomes, these data are not explicitly reported to the STS-CHSD database. Further, the number of centers participating in the STS-CHSD increased considerably during the period of study, therefore confounding the center experience analysis. The number of cases per center is influenced not only by the pattern of practice but also by the longevity of database participation.

In conclusion, the incidence of tracheostomy as a complication of surgery for congenital heart disease has consistently increased since 2000. Tracheostomy is being utilized in patients at all levels of surgical complexity and most prevalent in patients with complicated postoperative courses. Use of tracheostomy may not be of equivalent benefit in all types of patients, and warrants careful consideration in certain patient populations such as infants with hypoplastic left heart syndrome likely to require chronic mechanical ventilation. Long-term follow-up data in a large cohort of these patients are therefore needed to evaluate further the role of tracheostomy following cardiovascular surgery.

Conflicts of Interest: The authors have no conflicts of interest to disclose.

Acknowledgements: None

References

1. LoTempo MM, Shapiro NL. Tracheostomy Tube Placement in Children Following Cardiothoracic Surgery: Indications and Outcomes. Am J Otolaryngol. 2002;23:337.340.
2. Rossi AF, Fishberger S, Hannan RL, et al. Frequency and indications for tracheostomy and gastrostomy after congenital heart surgery. Pediatr Cardiol 2009;30:225.231.
3. Hoskote A, Cohen G, Goldman A, Shekerdemian L. Tracheostomy in infants and children after cardiothoracic surgery: Indications, associated risk factors, and timing. J Thorac Cardiovasc Surg 2005;130:1086.1093
4. Cotts T, Hirsch J, Thorne M, Gajarski R. Tracheostomy after pediatric cardiac surgery: Frequency, indications, and outcomes J Thorac Cardiovasc Surg 2011;141:413.418.
5. Rosner E, Mastropietro CW. Prior cardiac surgery is independently associated with decreased survival following infant tracheostomy. Respir Care 2015;60:47.55.
6. Berry J, Graham R, Roberson D, et al. Patient characteristics associated with in-hospital mortality in children following tracheotomy. Arch Dis Child 2010;95:703.710.
7. Jacobs ML, Mavroudis C, Jacobs JP, Tchervenkov CI, Pelletier GJ. Report of the 2005 STS Congenital Heart Surgery Practice and Manpower Survey. Ann Thorac Surg 2006; 82:1152.1159.
8. Franklin RC, Jacobs JP, Krogmann ON, et al. Nomenclature for congenital and paediatric cardiac disease: historical perspectives and The International Pediatric and Congenital Cardiac Code. Cardiol Young 2008; 18:70.80.

9. International Paediatric and Congenital Cardiac Code. Available at: http://www.ipccc.net/.
10. STS Congenital Heart Surgery Database v3.0. Available at: http://www.sts.org/sites/default/files/documents/pdf/CongenitalDataSpecificationsV3_0_20090904.pdf.
11. Benneyworth BD, Gebremariam A, Clark SJ, Shanley TP, Davis MM. Inpatient health care utilization for children dependent on long-term mechanical ventilation. Pediatrics. 2011;127:e1533.e1541.
12. Welke KF, O'Brien SM, Peterson ED, Ungerleider RM, Jacobs ML, Jacobs JP. The complex relationship between pediatric cardiac surgical case volumes and mortality rates in a national clinical database. J Thorac Cardiovasc Surg. 2009; 137:1133.1140.
13. Berry JG, Graham DA, Graham RJ, Zhou J, Putney HL, O'Brien JE, Roberson DW, Goldmann DA. Predictors of clinical outcomes and hospital resource use of children after tracheotomy. Pediatrics. 2009; 124:563.572.
14. Tabutt S, Ghanayem N, Ravishankar C, et al. Risk factors for hospital morbidity and mortality after the Norwood Procedure: A report from the Pediatric Heart Network Single Ventricle Reconstruction trial. J Thorac Cardiovasc Surg 2012;144:882.895.
15. Edwards JD, Kun SS, Keens TG, Khemani RG, Moromisato DY. Children with corrected or palliated congenital heart disease on home mechanical ventilation. Pediatr Pulmonol. 2010;45:645.649.
16. Jenkins KJ. Risk Adjustment for congenital heart surgery: the RACHS-1 method. Semin Thorac Cardiovasc Surg Pediatr Card Surg Annu 2004;7:180.184.

Tables

Table 1. Characteristics of Patients Requiring Tracheostomy after Surgery for Congenital Heart Disease, 1/2010 – 6/2014 (*N*=648)

Preoperative Data	
Age at Surgery (months)	2.5 (0.4, 7)
Gender	
Male	348 (53.7%)
Female	298 (46%)
Ambiguous	1 (0.2%)
Weight at Surgery (kg)	4.0 (3.0, 6.5)
Prematurity (<37 weeks completed gestation)	165 (25.5%)
Preoperative Mechanical Ventilatory Support	275 (42.4%)
Neurological Deficit	53 (8.2%)
Down Syndrome (Trisomy 21)	56 (8.6%)
DiGeorge Syndrome (22q11 Deletion)	51 (7.9%)
Any other genetic / chromosomal abnormality	201 (31.0%)
Peri- and Postoperative Data	
STAT Mortality Category	
1	68 (10.5%)
2	118 (18.2%)
3	90 (13.9%)
4	271 (41.8%)
5	82 (12.7%)
Uncategorized	19 (2.9%)
CPB Time (minutes)	137.0 (91.0, 189.0)
Circulatory Arrest Used	130 (20.1%)
Delayed sternal closure	178 (27.5%)
Mechanical circulatory support	87 (13.4%)
Cardiac arrest	131 (20.2%)
Chylothorax	102 (15.7%)
Recurrent laryngeal nerve injury	60 (9.3%)
Phrenic nerve injury / paralyzed diaphragm	62 (9.6%)
Neurological deficit persisting at hospital discharge	51 (7.9%)
Septicemia	143 (22.1%)
Mediastinitis	17 (2.6%)
Additional cardiovascular procedures prior to discharge	293 (45.2%)

Continuous data represented as median (25^{th} percentile, 75^{th} percentile) and categorical data are represented as absolute counts (percentages)

Table 2. Most Common Primary Diagnoses and Procedures for Patients Requiring Tracheostomy after Surgery for Congenital Heart Disease, 1/2010 – 6/2014

	n [a]	Mortality [b]
Primary Diagnosis		
Hypoplastic left heart syndrome	62 (9.6%)	25 (44%)
Other Single Ventricle Lesions	50 (7.7%)	13 (26%)
Atrioventricular septal defect, complete	44 (6.8%)	8 (19%)
Ventricular septal defect, Type 2	29 (4.5%)	2 (7%)
Patent ductus arteriosus	25 (3.9%)	6 (24%)
Pulmonary atresia, ventricular septal defect	20 (3.1%)	6 (32%)
Tetralogy of Fallot, absent pulmonary valve	20 (3.1%)	6 (33%)
Truncus arteriosus	19 (2.9%)	3 (17%)
Coarctation of aorta	17 (2.6%)	1 (7%)
Tetralogy of Fallot	14 (2.2%)	2 (14%)
Primary Procedure		
Norwood procedure	47 (7.3%)	15 (33%)
Pulmonary artery banding	33 (5.1%)	7 (23%)
Atrial septal defect creation / enlargement	30 (4.6%)	5 (17%)
Ventricular septal defect repair, patch	30 (4.6%)	9 (32%)
Atrioventricular septal defect repair, complete	29 (4.5%)	4 (14%)
Patent ductus arteriosus closure, surgical	25 (3.9%)	5 (21%)
Aortic arch repair	21 (3.2%)	3 (16%)
Transplant, Heart	20 (3.1%)	4 (22%)
Modified Blalock-Taussig Shunt	19 (2.9%)	4 (24%)
Pulmonary atresia, reconstruction	17 (2.6%)	3 (18%)

[a] Data represented as absolute counts with percentages of total patients in study, *N*=648
[b] Data represented as absolute counts with percentages of patients with mortality data available, *N*=606

Table 3. Comparison of Preoperative Characteristics between Patients Who Died and Survived after Tracheostomy following Surgery for Congenital Heart Disease

Preoperative Data	Survived N=453	Died N=153	*p*-value
Age at Surgery (months)	2.6 (0.5, 7.0)	2.0 (0.3, 7.4)	0.2370
Gender			
Male	242 (53.4%)	85 (55.6%)	0.2006
Female	210 (46.4%)	67 (43.8%)	
Ambiguous	0 (0%)	1 (0.7%)	
Weight at Surgery (kg)	4.0 (3.1, 6.8)	3.9 (3.0, 6.1)	0.3426
Prematurity (<37 weeks completed gestation)	120 (26.5%)	33 (21.6%)	0.3013
Mechanical Ventilator Support[a]	183 (40.4%)	76 (49.7%)	0.0247
Neurological Deficit	40 (8.8%)	11 (7.2%)	0.5730
Down Syndrome (Trisomy 21)	41 (9.1%)	11 (7.2%)	0.4669
DiGeorge Syndrome (22q11 Deletion)	36 (7.9%)	8 (5.2%)	0.2563
Any other genetic / chromosomal abnormality	140 (30.9%)	50 (32.7%)	0.7077
STAT Mortality Category[b]			
1	53 (11.7%)	9 (5.9%)	0.1314
2	81 (17.9%)	29 (19%)	
3	68 (15%)	20 (13.1%)	
4	188 (41.5%)	60 (39.2%)	
5	54 (11.9%)	27 (17.6%)	
Unclassified	9 (2.0%)	8 (5.2%)	

Continuous data represented as median (25th percentile, 75th percentile) and categorical data are represented as absolute counts (percentages)

[a] Mechanical ventilator support is coded as a preoperative factor when a patient is "supported with mechanical ventilation to treat cardiorespiratory failure during the hospitalization of his or her operation and prior to operating room entry date and time

[b] STAT: Society of Thoracic Surgeons-European Association of Cardio-Thoracic Surgery Congenital Heart Surgery Mortality Categories

Table 4. Comparison of Peri- and Postoperative Characteristics between Patients Who Died and Survived after Tracheostomy following Surgery for Congenital Heart Disease

Peri- and Postoperative Data	Survived N=453	Died N=153	*p*-value
CPB Time (minutes)	136 (89,193)	153 (94,195)	0.1913
Circulatory Arrest Used	85 (18.8%)	34 (22.2%)	0.3522
Norwood Procedure	31 (6.8%)	15 (9.8%)	0.2323
Delayed sternal closure	107 (23.6%)	61 (39.9%)	0.0001
Mechanical circulatory support	49 (10.8%)	35 (22.9%)	0.0002
Cardiac arrest	71 (15.7%)	55 (35.9%)	<.0001
Chylothorax	55 (12.1%)	40 (26.1%)	<.0001
Recurrent laryngeal nerve injury	48 (10.6%)	8 (5.2%)	0.0477
Phrenic nerve injury / paralyzed diaphragm	51 (11.3%)	9 (5.9%)	0.0544
Neurological deficit at discharge	33 (7.3%)	17 (11.1%)	0.1373
Septicemia	83 (18.3%)	51 (33.3%)	0.0001
Wound infection	12 (2.6%)	5 (3.3%)	0.6888
Mediastinitis	14 (3.1%)	3 (2.0%)	0.4647
Additional cardiovascular procedures	189 (41.7%)	89 (58.2%)	0.0004

Data are represented as absolute counts (percentages).

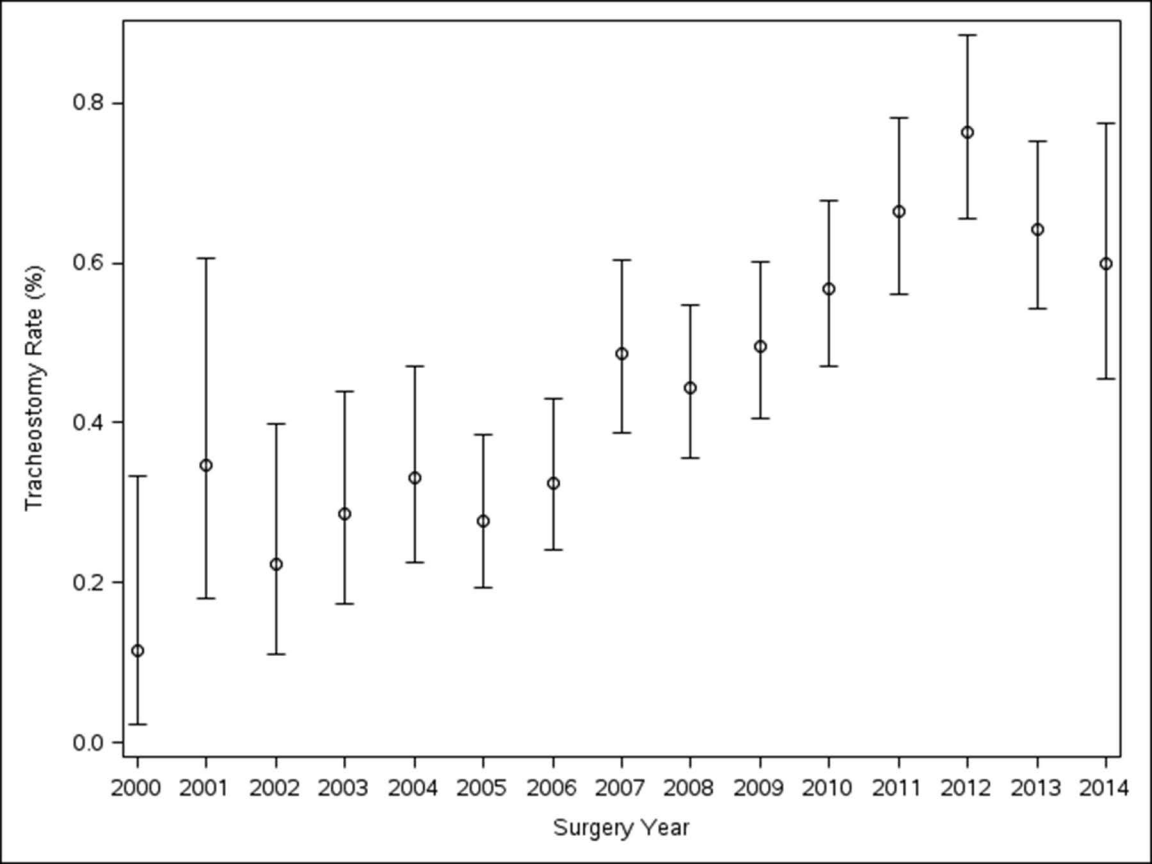
Figure Legends

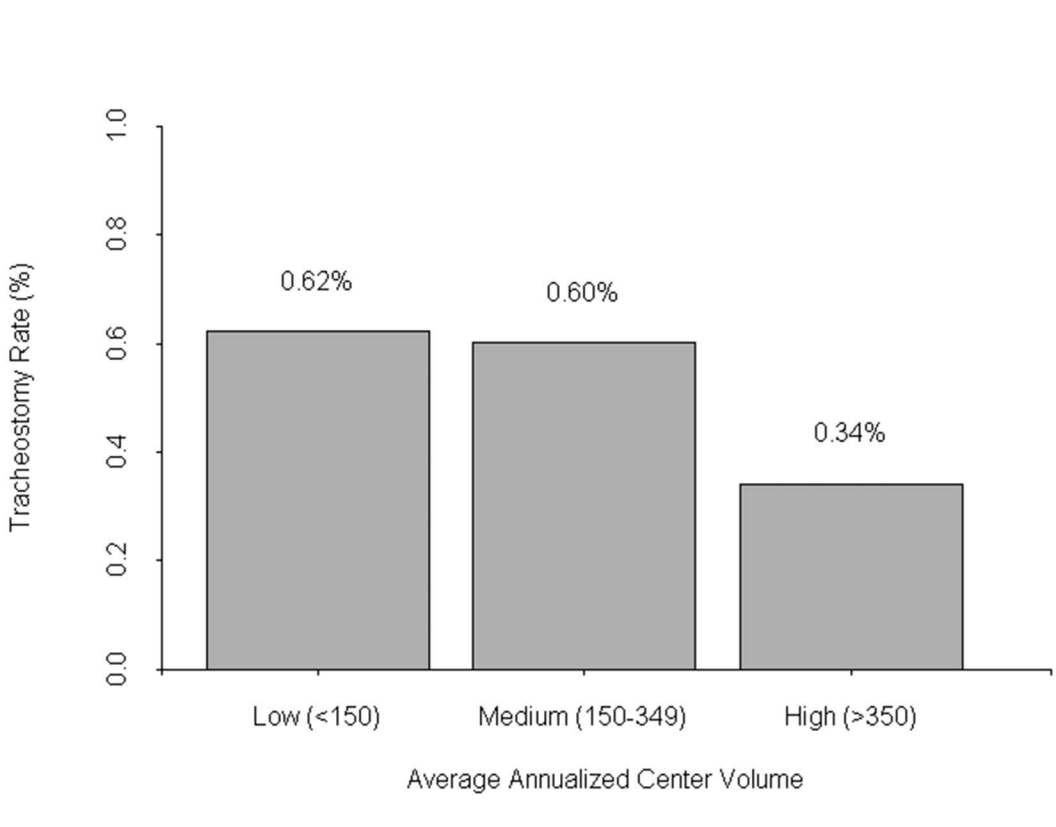
Figure 1. Incidence of tracheostomy over time. The incidence of tracheostomy increased over time, from 0.11% in 2000 to a peak of 0.76% in 2012. Note that 2014 represents partial year data (January - June).

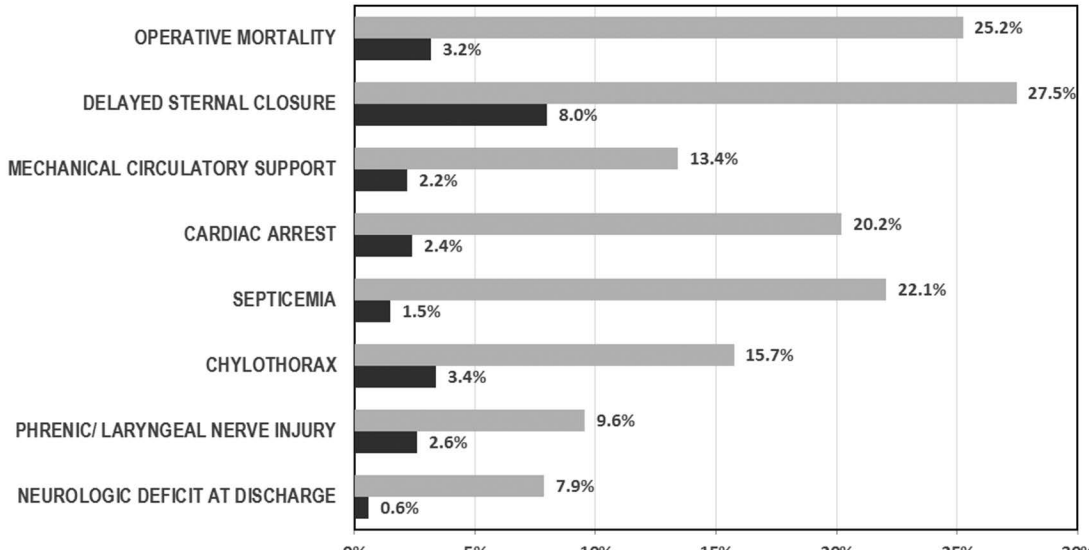
Figure 2. Center level occurrence rate of tracheostomy graphed by average annual surgical volume, 1/2000 – 6/2014. Higher volume centers had significantly lower rates of tracheostomy utilization (Cochrane-Armitage Test for trend: $Z=7.31$, $p<0.0001$).

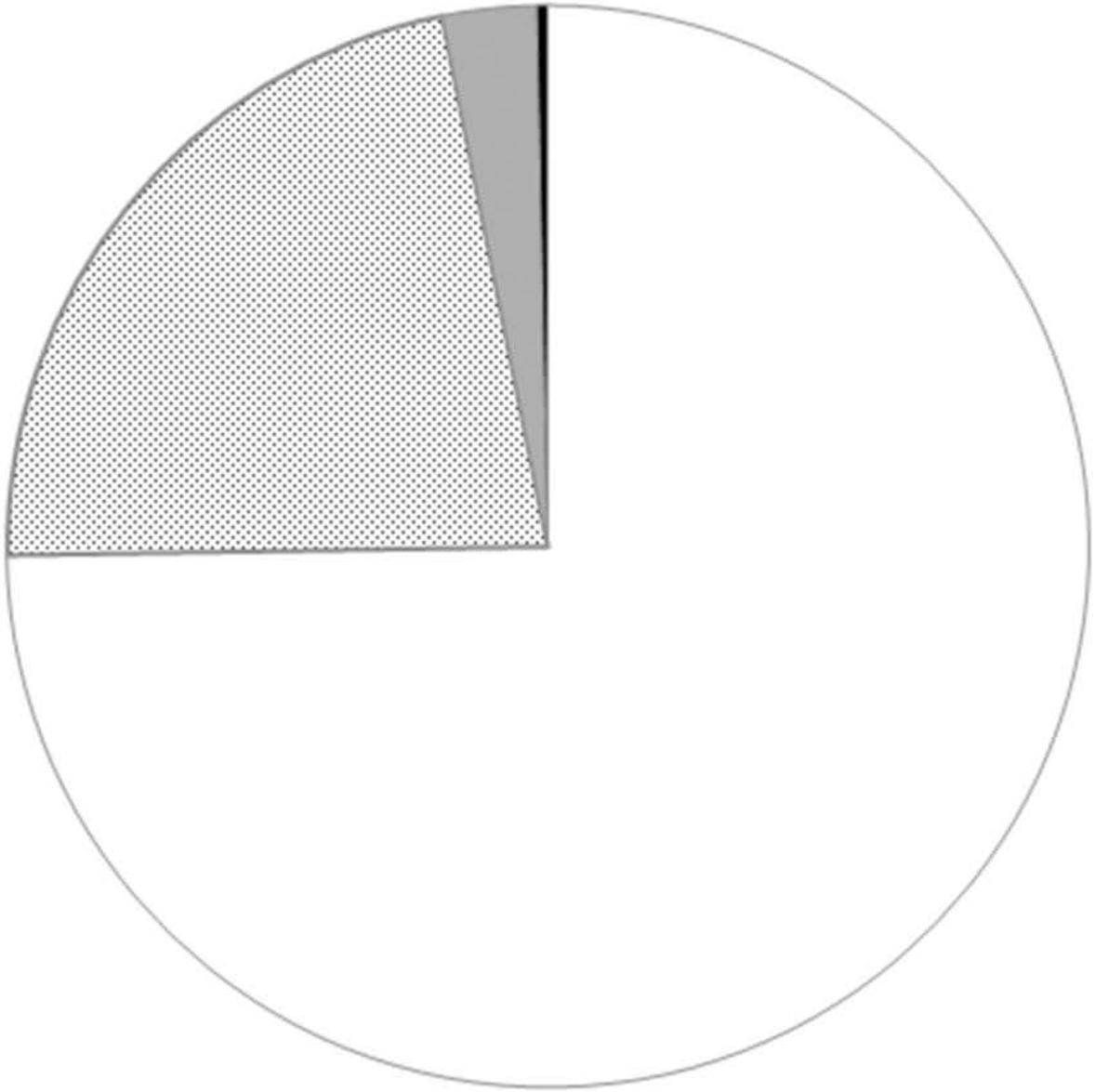
Figure 3. Operative mortality and complications in patients who required tracheostomy after cardiac surgery (gray bars) and patients who did not (black bars), 2010-2014.

Figure 4. Outcomes for patients who underwent tracheostomy between 2010-2014 and had mortality data available (*N*=606). Of these patients, 453 survived (white), 134 died prior to hospital discharge (dotted), 17 died at outside facilities prior to discharge home, and 2 patients died outside of a medical facility but within 30 days of surgery (black).


Tracheostomy Rate (%)
0.0
0.2
0.4
0.6
0.8
2000
2001
2002
2003
2004
2005
2006
2007
2008
2009
2010
2011
2012
2013
2014
Surgery Year


Tracheostomy Rate (%)
0.0
0.2
0.4
0.6
0.8
1.0
0.62%
0.60%
0.34%
Low (<150)
Medium (150-349)
High (>350)
Average Annualized Center Volume


OPERATIVE MORTALITY
25.2%
3.2%
DELAYED STERNAL CLOSURE
27.5%
8.0%
MECHANICAL CIRCULATORY SUPPORT
13.4%
2.2%
CARDIAC ARREST
20.2%
2.4%
SEPTICEMIA
22.1%
1.5%
CHYLOTHORAX
15.7%
3.4%
PHRENIC/ LARYNGEAL NERVE INJURY
9.6%
2.6%
NEUROLOGIC DEFICIT AT DISCHARGE
7.9%
0.6%
0%
5%
10%
15%
20%
25%
30%


Survived
Died in-hospital
Died in subacute care facility
Died outside of medical facility