Tracheostomy in Infants With Congenital Heart Disease: A Nationwide Population-Based Study in Taiwan

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BACKGROUND: This study aimed to use the National Health Insurance Research Database in Taiwan to examine the risk factors for tracheostomy in infants with congenital heart disease (CHD) and to evaluate the associated mortality risk in those who received a tracheostomy. METHODS: The study was conducted between 2000 and 2011 with infants assigned to either a CHD group (34,943 subjects) or an age- and sex-matched control group (136,600 subjects). We then performed descriptive, logistic regression, Kaplan-Meier, and Cox regression analyses for the investigation. RESULTS: Infants with CHD had an increased risk of tracheostomy (adjusted hazard ratio [HR], 6.67, 95% CI 4.40–10.10). Congenital airway anomaly (adjusted odds ratio [OR], 15.25, 95% CI 10.56–22.02), neuromuscular impairment (adjusted OR 6.24, 95% CI 4.35–8.94), and time (0–3 y) after CHD diagnosis (adjusted OR 3.27, 95% CI 2.19–4.89) were most highly correlated with tracheostomy placement. The mortality risk was increased in infants with CHD and a tracheostomy even after adjusting for confounders (adjusted HR 3.88, 95% CI 2.96–5.08). Mortality risk (adjusted HR and 95% CI) increased by 2.06 (1.56–2.71), 7.19 (2.42–21.38), and 14.76 (1.46–149.69) after 0–3, 4–7, and 8–11 y of follow-up, respectively. CONCLUSIONS: Infants with CHD had an increased risk of undergoing tracheostomy. The mortality risk is significantly increased in infants with CHD and tracheostomy, and the risk increases progressively with time. Further studies are warranted to clarify the mechanisms underlying the risks associated with tracheostomy. *Key words: congenital heart disease; hazard ratio; national health insurance; national health insurance research database; odds ratio; tracheostomy.* [Respir Care 2016;61(7):958–964. © 2016 Daedalus Enterprises]

Introduction

Congenital heart disease (CHD) is one of the common major congenital anomalies with a reported birth prevalence of 5–8/1,000 live births.[1-3] Progress in neonatology, intensive care, pediatric cardiology, and cardiovascular surgery means that CHD is no longer considered fatal, and favorable outcomes can often be achieved.[4] Therefore, it is crucial to explore the risk factors associated with CHD morbidity and mortality to optimize quality of life.

Tracheostomies can be lifesaving procedures following severe respiratory compromise.[5,6] Although infections have historically been the most common indication,[7] tracheos-

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Supplementary material related to this paper is available at http://www.rcjournal.com.

This study was supported by grant funding from Taipei Veterans General Hospital (V102B-047), Taiwan. The authors have disclosed no conflicts of interest.

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DOI: 10.4187/respcare.04266

tomies are increasingly indicated for prolonged ventilator dependence in children with chronic complex health conditions.[6,8-12] However, most studies have focused on the indications for tracheostomy, the subsequent outcomes, or resource utilization.[6,10-22] Data are scant regarding the epidemiological risk factors for tracheostomy in CHD, and there have been no large-scale population-based studies. Furthermore, among infants with CHD requiring a tracheostomy, previous studies have failed to investigate either the overall mortality risk or the mortality risk stratified by a follow-up period. This study aimed to use the National Health Insurance Research Database in Taiwan to examine the risk factors for tracheostomy in infants with CHD and to evaluate the associated mortality risk in those who received a tracheostomy.

QUICK LOOK

Current knowledge

Tracheostomies are increasingly indicated for prolonged ventilator dependence in children with chronic complex health conditions. Most studies have focused on the indications for tracheostomy, the subsequent outcomes, or resource utilization. Data are scant regarding the epidemiological risk factors for tracheostomy in congenital heart disease (CHD), and there have been no large-scale population-based studies.

What this paper contributes to our knowledge

We demonstrated that subjects with CHD had a 6.67 times higher risk of tracheostomy than those without CHD. Tracheostomies were more common among those with congenital airway anomaly and neuromuscular impairment and were most likely to be needed within the first 0–3 y after CHD diagnosis. Mortality risk was also elevated following tracheostomy in infants with CHD, with an adjusted hazard ratio of 3.88 after a mean 6.4-y follow-up period. Over time, there was a decrease in the risk of tracheostomy and an increase in the associated mortality risk for infants with CHD.

Methods

Ethical Statement

The institutional review board of Taipei Veterans General Hospital, Taiwan, approved this study (2014-08-005AC). Because all personal identifying information had been encrypted before the database was released, the review board waived the requirement for written informed consent.

Data Sources

This study was based on data from the National Health Insurance Research Database released by the National Health Research Institute. Enrollment in Taiwan's national health insurance program is mandatory, and data are currently available for >23 million people, representing approximately 99% of Taiwan's population.[23] The National Health Insurance Research Database includes the entire registry and original reimbursement claims data for each national health insurance enrollee in Taiwan. With extensive data for medical care reimbursement claims, the National Health Insurance Research Database provides a large and comprehensive national data set. The diagnostic codes used in the National Health Insurance Research Database are in the format of the International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM), as established by physicians and previously validated.[24-26]

All information that may identify subject information was encrypted, and confidentiality was maintained in accordance with the data regulations of the National Health Insurance Administration, the Ministry of Health and Welfare, and the National Health Research Institute. The National Health Research Institute guards the privacy of all beneficiaries and provides the National Health Insurance Research Database to researchers who have obtained ethical approval.

Infants With CHD (CHD Group)

We conducted a retrospective population-based cohort study from January 1, 2000 to December 31, 2011. Using the diagnostic codes for CHD in the National Health Insurance Research Database (ICD-9-CM 745, 746, 747.0-4), we identified 34,943 infants <1 y old born after January 1, 2000. The first date for each subject's CHD diagnosis, as recorded in the National Health Insurance Research Database, was defined as the index date. Information regarding the sex, age at CHD diagnosis, follow-up period, comorbid disease, and in-hospital mortality was collected for analysis. The age at CHD diagnosis was subclassified by neonatal (newborn up to 28 d) and infant (age >4 weeks but <12 months) periods.

Based on previous reports,[6,11,27,28] we evaluated the following comorbidities: congenital airway anomaly (ICD-9-CM 748), chromosomal anomaly (ICD-9-CM 758), prematurity (ICD-9-CM 765), neuromuscular impairment (ICD-9-CM 318, 330, 334, 335, 343, 359, 740–742, 754–756) (see the supplementary appendix at http://www.rcjournal.com), and chronic lung disease (ICD-9-CM 770.7). The comorbidities were identified using the data linkage for each infant from the National Health Insurance Research Database. Infants who received a tracheostomy were

Table 1. Demographic and Clinical Characteristics of the Congenital Heart Disease and Control Groups

Variables	CHD Group (n = 34,943)		Control Group (n = 136,600)		P
	n	%	n	%	
Age					.17
Neonate	22,147	63.4	86,040	63.0	
Infant	12,796	36.6	50,560	37.0	
Sex					.64
Male	17,507	50.1	68,246	50.0	
Female	17,436	49.9	68,354	50.0	
Follow-up, mean (SD) y	6.4 (3.5)		6.7 (3.3)		<.001
0–3 y	8,838	25.3	28,585	20.9	
4–7 y	9,177	26.3	39,090	28.6	
8–11 y	16,928	48.4	68,925	50.5	
Comorbidity					
Prematurity	9,780	28.0	11,228	8.2	<.001
NI	2,628	7.5	2,937	2.2	<.001
CAA	1,541	4.4	1,134	0.8	<.001
Chromosomal anomaly	1,161	3.3	299	0.2	<.001
Chronic lung disease	720	2.1	309	0.2	<.001
Tracheostomy	144	0.4	32	0.02	<.001
Mortality, overall	2,491	7.1	1,287	0.9	<.001

CHD = congenital heart disease
NI = neuromuscular impairment
CAA = congenital airway anomaly

identified by the procedure codes 31.1 and 31.2.[6,11] Mortality was defined according to the discharge status recorded in the National Health Insurance Research Database.

Infants Without CHD (Control Group)

Subjects without CHD were randomly selected from the same database and within the same observational period as subjects with CHD. Each subject with CHD was matched by age, sex, and index date with 4 subjects without CHD. In total, 136,600 infants met these criteria and served as the control group. The same variables were analyzed in both the control and CHD groups. All of the enrolled subjects were followed until their death or December 31, 2011, whichever occurred first.

Statistical Analysis

All data were linked by SQL server 2008 (Microsoft Corporation, Redmond, Washington) and analyzed by SPSS 19.0 for Windows (IBM Corporation, Armonk, New York). Continuous variables were described as mean and SD and were compared using independent t tests. Categorical variables were described as percentages and were compared using the chi-square or Fisher exact tests as appropriate. Cox regression analyses with crude and adjusted hazard ratios (HRs) were used to evaluate the risk for tracheostomy and the associated mortality risk among infants with CHD who received a tracheostomy. Multivariate logistic regression analyses with adjusted odds ratios (ORs) were used to assess the likelihood of tracheostomy in infants with CHD. We used Kaplan-Meier analyses and log-rank tests to estimate the cumulative incidence of mortality among infants with CHD, with and without tracheostomy. For all tests, 2-tailed P values of $<.05$ were considered statistically significant.

Results

Demographic and Clinical Characteristics of the CHD and Control Groups

We included 171,543 infants age <1 y: 34,943 with CHD and 136,600 without CHD. Most infants with CHD were diagnosed as neonates, and the most common comorbidity was prematurity, followed by neuromuscular impairment and congenital airway anomaly. Infants with CHD had significantly more comorbidities than those without CHD and underwent significantly more tracheostomies. In the CHD group, the mean follow-up period was shorter, and the mortality rate was higher (Table 1).

Table 2. Cox Regression Analysis With Hazard Ratio of the Risk of Tracheostomy in Infants With Congenital Heart Disease, Overall and Stratified by Follow-Up Period

Variables	Overall		0–3-y Follow-Up, Adjusted HR (95% CI)	4–7-y Follow-Up, Adjusted HR (95% CI)	8–11-y Follow-Up, Adjusted HR (95% CI)
	Crude HR	Adjusted HR (95% CI)			
Age					
Neonate	1.21 (0.88–1.66)	1.30 (0.92–1.84)	1.42 (0.86–2.37)	2.44 (1.17–5.09)	1.07 (0.57–2.01)
Infant	1.00	1.00	1.00	1.00	1.00
Sex					
Male	1.11 (0.83–1.50)	0.88 (0.65–1.18)	1.00 (0.65–1.54)	1.32 (0.68–2.55)	0.61 (0.35–1.06)
Female	1.00	1.00	1.00	1.00	1.00
CHD	17.87 (12.18–26.21)	6.67 (4.40–10.10)	6.86 (3.68–12.81)	6.51 (2.71–15.59)	5.82 (2.83–11.98)
CHD with comorbidity					
Prematurity	3.21 (2.33–4.42)	1.11 (0.76–1.62)	1.23 (0.70–2.14)	0.89 (0.37–2.15)	0.80 (0.39–1.64)
NI	31.37 (23.35–42.16)	6.54 (4.69–9.14)	6.15 (3.79–9.99)	6.45 (3.27–12.72)	7.84 (4.17–14.74)
CAA	77.26 (57.42–103.95)	17.77 (12.57–25.11)	10.31 (5.30–16.89)	25.71 (12.21–54.14)	18.86 (15.07–55.27)
Chromosomal anomaly	22.10 (14.67–33.30)	2.84 (1.85–4.36)	2.44 (1.34–4.41)	8.86 (4.18–18.81)	0.53 (0.13–2.22)
Chronic lung disease	18.30 (11.10–30.18)	1.99 (1.15–3.47)	2.12 (1.01–4.45)	1.72 (0.46–6.44)	1.40 (0.40–4.85)

HR = hazard ratio
CHD = congenital heart disease
NI = neuromuscular impairment
CAA = congenital airway anomaly

Risk of Tracheostomy in Infants With CHD

Infants with CHD had a significantly elevated risk of tracheostomy compared with those without CHD (HR 17.87), and this remained significant after adjusting for confounders (adjusted HR 6.67) (Table 2). When stratified by follow-up period, the risk of tracheostomy decreased gradually with time (see Table 2).

Probability of Tracheostomy in Infants With CHD

A tracheostomy was more likely for those diagnosed with CHD as neonates (adjusted OR 1.72) within the first 0–3 y after diagnosis (adjusted OR 3.27) and for those with comorbid congenital airway anomaly (adjusted OR 15.25), neuromuscular impairment (adjusted OR 6.24), chronic lung disease (adjusted OR 2.29), or a chromosomal anomaly (adjusted OR 2.10) (Table 3).

Table 3. Multivariate Logistic Regression About the Probability of Tracheostomy in Infants With Congenital Heart Disease

Variables	Adjusted OR (95% CI)
Age at CHD diagnosis	
Neonate	1.72 (1.13–2.60)
Infant	1.00
Sex	
Male	0.84 (0.60–1.19)
Female	1.00
Follow-up, y	
0–3	3.27 (2.19–4.89)
4–7	1.48 (0.91–2.42)
8–11	1.00
Comorbidity	
CAA	15.25 (10.56–22.02)
NI	6.24 (4.35–8.94)
Chronic lung disease	2.29 (1.22–4.27)
Chromosomal anomaly	2.10 (1.25–3.52)
Prematurity	0.89 (0.58–1.37)

OR = odds ratio
CHD = congenital heart disease
CAA = congenital airway anomaly
NI = neuromuscular impairment

Mortality Risk of Tracheostomy in Infants With CHD

Kaplan-Meier analysis revealed that the cumulative incidence of mortality in infants with CHD was significantly higher in those with tracheostomy than in those without (Fig. 1). The differences became rapidly prominent in the first 0–3 y after CHD diagnosis but stabilized thereafter. The mortality rate was significantly higher for CHD with tracheostomy (62 of 144; 43.1%) than without (2,429 of 34,799; 7.0%). Mortality risk was significantly elevated in infants with CHD who underwent tracheostomy compared with those who did not (HR 6.41), and this remained after adjusting for confounders (adjusted HR 3.88). When stratified by follow-up period, the mortality risk associated with tracheostomy increased with time (Table 4).

Discussion

In this large observational study, we demonstrated that subjects with CHD had a 6.67 times higher risk of tracheostomy than those without CHD. Furthermore, tracheostomies were more common among those with congenital airway anomaly and neuromuscular impairment and were most likely to be needed within the first 0–3 y after CHD diagnosis. Mortality risk was also elevated following tracheostomy in infants with CHD, with an adjusted HR of 3.88 after a mean 6.4-y follow-up period. Over time, there was a decrease in the risk of tracheostomy and an increase in the associated mortality risk for infants with CHD. The validity of our results is strengthened by the study design, which included nationwide, population-based data from multiple institutions and longitudinal follow-up.

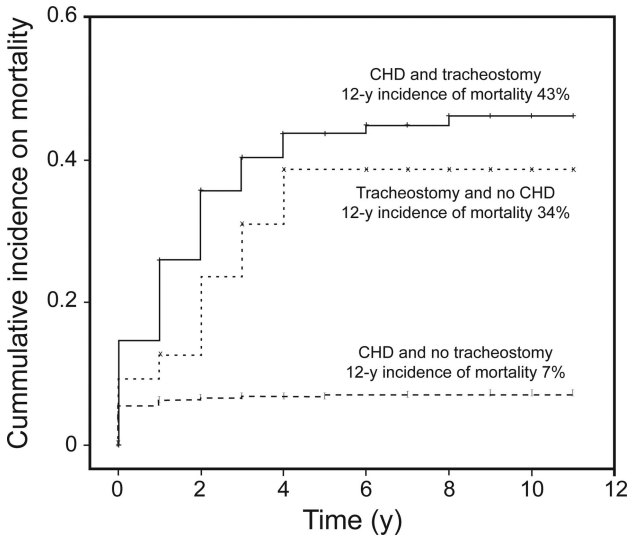

Fig. 1. Cumulative mortality incidence in infants with congenital heart disease (CHD) with and without tracheostomy (log-rank, $P < .001$).

The reported incidence of tracheostomy in children with CHD is low in the literature,[17,18,21] with a rate of 0.2% among pediatric subjects undergoing cardiovascular surgery[17] and 3.5% among pediatric admissions with CHD.[21] In this study, the rate was 0.4% among infants with CHD. Compared with our study, previous reports tended to focus on broader pediatric populations or were hospital-based, single-institution investigations with limited numbers of participants. Our extensive data set and focus on a subgroup of infants with CHD may explain the inconsistent results.

Previous studies have often failed to explore the risk for tracheostomy in infants with CHD. We demonstrated that infants with CHD had a 6.67 times higher risk of receiving a tracheostomy, after adjusting for confounders and that the greatest risk was in the first 0–3 y after CHD diagnosis (adjusted HR 6.86). We also illustrated that congenital airway anomaly (adjusted OR 15.25), neuromuscular impairment (adjusted OR 6.24), and the first 0–3 y after CHD diagnosis (adjusted OR 3.27) were most strongly correlated with tracheostomy placement. The higher probability of tracheostomy may be due to the complexity of CHD, prolonged mechanical ventilation and failed extu-

Table 4. Cox Regression Analysis With Hazard Ratios for Mortality in Infants With Congenital Heart Disease, Overall and Stratified by Follow-Up Period

Variables	Overall		0–3-y Follow-Up, Adjusted HR (95% CI)	4–7-y Follow-Up, Adjusted HR (95% CI)	8–11-y Follow-Up, Adjusted HR (95% CI)
	Crude HR	Adjusted HR (95% CI)			
Age					
Neonate	2.18 (1.98–2.41)	2.18 (1.97–2.43)	3.21 (2.88–3.57)	2.35 (1.41–3.93)	0.69 (0.19–2.48)
Infant	1.00	1.00	1.00	1.00	1.00
Sex					
Male	1.07 (0.99–1.61)	1.11 (1.02–1.20)	1.38 (1.17–1.61)	1.12 (0.70–1.78)	0.65 (0.20–2.06)
Female	1.00	1.00	1.00	1.00	1.00
CHD with tracheostomy	6.41 (4.98–8.25)	3.88 (2.96–5.08)	2.06 (1.56–2.71)	7.19 (2.42–21.38)	14.76 (1.46–149.69)
CHD with comorbidity					
Prematurity	1.37 (1.26–1.48)	1.07 (0.98–1.17)	0.75 (0.69–0.83)	0.39 (0.20–0.77)	0.90 (0.22–3.68)
NI	1.52 (1.34–1.72)	1.11 (0.97–1.27)	1.09 (0.95–1.25)	2.43 (1.34–4.39)	15.48 (4.61–52.01)
CAA	1.86 (1.61–2.16)	1.47 (1.25–1.72)	1.37 (1.17–1.61)	1.31 (0.59–2.93)	0.48 (0.05–4.83)
Chromosomal anomaly	3.91 (3.46–4.43)	3.74 (3.30–4.24)	2.21 (1.95–2.52)	6.33 (3.44–11.65)	4.01 (0.83–19.35)
Chronic lung disease	1.42 (1.12–1.80)	1.02 (0.80–1.30)	0.73 (0.57–0.94)	4.21 (1.41–12.57)	

HR = hazard ratio
CHD = congenital heart disease
NI = neuromuscular impairment
CAA = congenital airway anomaly

bation after cardiac surgery,[18,20,29,30] and comorbid chronic health conditions.[6,10] Although the effect was not significant, comorbidity with prematurity seemed to decrease the probability of tracheostomy placement (adjusted OR 0.89, 95% CI 0.58–1.37), which may be due to the co-linearity between such factors as prematurity and chronic lung disease. Further investigations into the relationships between the severity of CHD, its management, and the effects of different comorbidities by age strata may clarify these uncertainties.

Airway anomalies among pediatric patients with CHD treated with tracheostomies have been associated with mortality reductions.[6] Congenital airway anomaly is believed to be significantly associated with CHD,[4,31-34] and early identification is essential for appropriate management.[32,35] Here, we demonstrated that congenital airway anomaly was an independent risk factor for tracheostomy in infants with CHD. Tracheostomy placement may improve outcomes; therefore, timely diagnosis and optimal management of congenital airway anomaly are essential.

It has been postulated that pediatric patients with tracheostomy have an increased risk of death,[11] with a mortality rate of approximately 5–8%.[6,10,14] Reports have also indicated that the mortality rate among pediatric subjects with CHD and a tracheostomy ranges from 18.7%[6] to 52%.[20] In this study, we report a mortality rate of 43.1% for infants with CHD undergoing tracheostomy. Together, these results indicate that pediatric patients with CHD and a tracheostomy have a high mortality rate and that CHD may be an independent risk factor for increased mortality. Additional investigations are warranted to clarify the mortality risk in patients with CHD and a tracheostomy if we are to unravel the underlying mechanisms.

The critical period and prognosis for infants with CHD who have a tracheostomy have rarely been discussed. Our Kaplan-Meier analysis showed that the cumulative incidence of mortality among infants with CHD increased more steeply in the first 0–3 y after CHD diagnosis and then stabilized. This pattern was true of subjects with and without a tracheostomy, although the magnitude was different. We also showed that infants with CHD and a tracheostomy had a 3.88 times increased mortality risk compared with those without a tracheostomy. Physicians managing patients with CHD should be aware of the elevated mortality risk of those requiring a tracheostomy and that the first 0–3 y after diagnosis may be a critical period for the development of adverse events.

It has also been suggested that patients ≤1 y old with CHD have higher mortality rates following tracheostomy placement.[6] The current stratified analysis demonstrated that mortality risk increased with time among infants with CHD requiring a tracheostomy and reached 14.76 times the baseline risk during the 8–11 y after diagnosis. The progressive increase in mortality risk may be due to underlying CHD, comorbidities, or tracheostomy-related complications. As the follow-up period increased, so too did the influence of tracheostomy placement. Additional research is needed to understand the differences in mortality risk during follow-up in infants with CHD and a tracheostomy.

The major strengths of this study were the population-based design, the comprehensive coverage of CHD cases with tracheostomy in the population, and the virtual elimination of loss to follow-up. Nevertheless, several limitations are worth consideration. First, because the study was observational, it could not establish a causative link between CHD, tracheostomies, and mortality. Second, we could not clarify the phenotype, severity, and management of CHD; the presence and severity of associated pulmonary hypertension; the true indication for tracheostomy; the severity of lung disease; or the true reason for mortality from the National Health Insurance Research Database. Therefore, we could not analyze the possible relationship between these characteristics and the mortality risk. Third, because this study was conducted in Taiwan, the findings might not be valid for other populations. Additional large-scale studies, with longer follow-up periods, different age strata, and multiple countries, are needed to make definitive conclusions.

Conclusions

Infants with CHD have an increased risk of tracheostomy, particularly if they have comorbid congenital airway anomaly or neuromuscular impairment. A tracheostomy is most likely to be required during the first 0–3 y after being diagnosed with CHD. In addition, the mortality risk is significantly increased in infants with CHD and tracheostomy, and the mortality risk increases progressively with time. During the follow-up of infants with CHD, we recommend that clinicians be vigilant for the need for tracheostomy and be aware of the increased mortality risk associated with tracheostomy placement. Further studies are warranted to clarify the mechanisms underlying the risks associated with tracheostomy.

ACKNOWLEDGMENTS

This study was based, in part, on data from the National Health Insurance Research Database provided by the National Health Insurance Administration, Ministry of Health and Welfare, and managed by the National Health Research Institute. The interpretation and conclusions contained herein do not represent those of the aforementioned administration or the National Health Research Institute, Taiwan. We thank Enago for the English language review.

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