Published in final edited form as:

Pediatr Pulmonol. 2018 April ; 53(4): 498–504. doi:10.1002/ppul.23925.

A Multi-institutional Analysis of Children on Long-Term Non-Invasive Ventilation and Their Outcomes

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Abstract

Objectives—To characterize a multi-institutional cohort of children with chronic respiratory failure that use long-term, non-invasive respiratory support, perform a time-to-event analysis of transitions to transtracheal ventilation and identify factors associated with earlier transition to transtracheal ventilation.

Study Design—A retrospective cohort study of patients less than 21 years of age with diagnoses associated with chronic respiratory failure and discharged on non-invasive respiratory support was performed using data from the Pediatric Health Information System (PHIS) between 2007 and 2015. Demographic and clinical characteristics, as well as times from index discharge on non-invasive support to transtracheal ventilation were presented. A competing risk regression model was fitted to estimate factors associated with earlier transition to transtracheal ventilation.

Results—A total of 3802 patients were identified. Their median age at index discharge was 10.4 years (interquartile range [IQR] 4.1-14.9). Of these patients, 337 (8.9%) transitioned to transtracheal ventilation and transitioned at a median of 11.5 months (IQR 4.6-26) post-index discharge, or a median age of 9.3 years (IQR 4.2-14.5). Competing risk modeling demonstrated that patients who were older or whose discharge occurred later in the study period had lower hazards of earlier transition to transtracheal ventilation, whereas patients with anoxia/encephalopathy and quadriplegia had higher hazards of earlier transitioning.

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Prior Presentations: An abstract analyzing subset of this cohort was accepted to the Society of Critical Care Medicine 46th Critical Care Congress, Honolulu HI; January, 2017

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The authors have no financial or potential conflicts of interest to disclose.

Conclusions—Most patients on long-term, non-invasive respiratory support who progress to transtracheal ventilation transition do so within a few years of support initiation. Various characteristics were associated with earlier risk of transitioning to transtracheal ventilation. This information may enhance anticipatory guidance for this population.

Keywords

Pediatrics; Continuous Positive Airway Pressure; Intermittent Positive-Pressure Ventilation; Respiratory Insufficiency

Introduction

Over the last few decades, the use of long-term, non-invasive respiratory support has increased in children with chronic respiratory failure and may be outpacing the use of invasive, transtracheal ventilation.^{1,2} Non-invasive respiratory support includes continuous positive airway pressure (CPAP) and bi-level positive airway pressure (BPAP) delivered through a non-invasive interface that increases proximal airway pressure.³ Anecdotally and from a few single-center studies,^{4,5} it is known that some patients initiated on non-invasive respiratory support with severe or progressive conditions ultimately cannot be supported by it and need to be transitioned to transtracheal ventilation. However, multi-institutional data on how often, when, and which patients transition from non-invasive support to transtracheal ventilation are lacking.

The lack of this data describing transitions to transtracheal ventilation is an obstacle to appropriate care planning and to realistic anticipatory guidance for patients and families. To address this gap in knowledge, we sought to characterize a multi-institutional cohort of children using long-term, non-invasive respiratory support and to perform a time-to-event analysis of those who transition to transtracheal ventilation.

Methods

A retrospective cohort study of pediatric patients using long-term, non-invasive respiratory support, hospitalized between January 1, 2007 and September 30, 2015, was performed to investigate their outcomes. Data for this study were obtained from PHIS, an administrative data base that contains inpatient, emergency department, ambulatory surgery, and observation encounter-level data from 48 not-for-profit, tertiary care pediatric hospitals in the United States. These hospitals are affiliated with the Children's Hospital Association (Lenexa, KS, www.childrenshospitals.org). Data quality and reliability are assured through a joint effort between the Children's Hospital Association and participating hospitals. Portions of the data submission and data quality processes for the PHIS database are managed by Truven Health Analytics (Ann Arbor, MI). For the purposes of external benchmarking, participating hospitals provide discharge/encounter data including demographics, diagnoses, and procedures. Data are converted to clinical transaction codes (CTC) for easy comparison. Data are de-identified at the time of data submission, and data are subjected to a number of reliability and validity checks before being included in the database. For this study, data were used from 46 hospitals that contributed data during the study period.

Patients were included in this study if they had one or more inpatient admissions during the study period, had a chronic condition that is associated with chronic respiratory failure, and were discharged using non-invasive respiratory support to home or to an on-acute care facility (eg, chronic care facility). Chronic conditions associated with chronic respiratory failure were identified using International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9) codes (Supplementary Table S1) based on previous literature and by consensus of study investigators.⁶ Because our population of interest was patients with chronic respiratory failure, patients were excluded if they had an ICD-9 code for obstructive sleep apnea or upper airway obstruction in the absence of a chronic respiratory failure diagnosis.⁷ “Index discharge” was defined as the first inpatient hospitalization during the study period that the patient used non-invasive respiratory support on the day before and day of discharge. Hospitalizations resulting in a patient discharged on non-invasive support to another acute care hospital were not considered as index discharges because the ventilatory requirements could have changed following transfer. Patients whose index discharge was after their 21st birthday were excluded. Admittedly, this index discharge may not have been when some patients were initiated on long-term, non-invasive respiratory support, as some patients may have been initiated during a hospitalization prior to the study period, at another hospital, or at home.^{4,8}

Non-invasive respiratory support use was ascertained with CTC codes (eg, continuous positive airway pressure [CPAP]; bilevel positive airway pressure [BPAP], Supplementary Table S1). Patients with an ICD-9 diagnosis or procedure code associated with tracheostomy, tracheostomy complications, or tracheostomy placement preceding index discharge were excluded (Supplementary Table S1). Patients were also excluded if they had a CTC code for mechanical ventilation on the day of or day preceding discharge (Supplementary Table S1) to exclude patients for whom support via tracheostomy was inadvertently coded as mechanical ventilation. These exclusions also reduced the likelihood of including patients who received chronic CPAP or BPAP invasively via tracheostomy. Inpatient sleep studies during index hospitalization were also discerned using CTC codes (Supplementary Table S1).

Transition to transtracheal ventilation was determined using ICD-9 or CTC codes associated with tracheotomy, tracheostomy complications, or tracheostomy placement following the index discharge (Supplementary Table S1). Date of transition was determined using the earliest date that these CTC codes or ICD-9 codes were present. Cumulative incidences of transitioning at 2 and 5 years were reported.

Demographic and clinical characteristics of patients at index discharge were described. Demographic characteristics included age, gender, race, ethnicity, and insurance status. Chronic, comorbid conditions were discerned using ICD-9 codes and reported. Other clinical characteristics included whether the hospitalization was elective, length of stay, and year of index discharge. Hospital size and region where index discharges occurred were also described. Categorical variables were reported as proportions, and continuous variables were reported as medians with IQRs. A Kernel density plot was created to illustrate the overall distribution pattern of age at index discharge. Times from index discharge to tracheotomy or

death were presented in the aggregate, by chronic condition categories, and by specific, prevalent chronic conditions.

Using transition to transtracheal ventilation as the primary outcome, cumulative incidence function (CIF) curves for major diagnostic categories (eg, neuromuscular, pulmonary, etc.) were created and a competing risk regression model was fitted to estimate the subdistribution hazard ratio (SHR) of factors associated with earlier transition. Competing risks were death while using non-invasive respiratory support or reaching the age of 21. Age 21 was included as a competing risk as some of these patients may have transitioned to adult programs. Conditions associated with chronic respiratory failure were included in the final regression model if they were prevalent in >10% of our cohort. Other characteristics were included if their P value was <0.2 or were thought to be clinically relevant. Hospital site was treated as a random effect to account for correlation of subjects within hospitals. Temporal trends in incidence of index discharges and transition to transtracheal ventilation were described. Because new hospitals joined PHIS during the study period, data for temporal trends came just from the 32 PHIS hospitals that contributed data from 2009 to 2015. Only 32 hospitals were used so that any trends in incidence would be reflective of true changes in patient numbers and not of additional patients from new hospitals; 2007 and 2008 were excluded due to the limited number of participating hospitals then.

Statistical analysis was performed using Stata 14 (StataCorp LLC, College Station, TX). A P-value of <0.05 was considered statistically significant. The Institutional Review Board of Columbia University Medical Center approved this study.

Results

There were 3802 patients who met inclusion criteria. This cohort contributed 8628.5 patient-years of data, assuming that these patients were followed until age 21 at the same hospital as their index discharge, and had 10 339 discharges on non-invasive respiratory support.

Additional patient demographic characteristics are presented in Table 1. The median age at index discharge was 10.4 years (IQR 4.1-14.9). Age at index discharge had bimodal peaks occurring during infancy/toddler years and adolescence (Supplementary Figure S1). The majority of patients were of white race (60%) and non-Hispanic/Latino background (73%). Most patients had government insurance (56%). Twenty-nine percent of index hospitalizations were elective. A total of 11% of patients had an inpatient sleep study some time during their index hospitalization, with 1.4% having a sleep study within the first three days of an index hospitalization. Patients had a median of one chronic, comorbid condition (IQR 1-2), most frequently neurologic disorders (46%) and cardiac disorders (36%) (Supplementary Table S2). Detailed data for specific comorbid conditions of the cohort are shown in Supplementary Tables S2-S5. At index discharge, 48% of patients required CPAP while 52% required BPAP. Four hundred fifty-seven (12%) patients were admitted on respiratory support (eg, CPAP, BPAP, or mechanical ventilation) during their index hospitalization.

Three hundred thirty-seven children (8.9%) transitioned to transtracheal ventilation. These patients' index discharges were at younger ages than the overall cohort (7.8 years, IQR 2.6-12.5). These patients transitioned to transtracheal ventilation at a median age of 9.3 years (IQR 4.2-14.5) and at a median time of 11.5 months (IQR 4.6-26.0) post-index discharge. Accounting for competing risks, the 2- and 5-year cumulative incidences of transition to transtracheal ventilation were 6.3% (95% confidence interval [CI] 5.6-7.1%) and 8.5% (95%CI 7.7-9.4%), respectively. Neurologic (58%) and neuromuscular disorders (39%) were most common in this group (Supplementary Table S2). Cumulative incidence function curves for transition to transtracheal ventilation for all patients and by comorbidity categories are depicted in Supplementary Figure S2. Median time to tracheostomy and median time to death were less than 2 years for most comorbidity categories (Table 2, Supplementary Table S5 for specific comorbidities). Temporal trends in number of index discharges and transitions to transtracheal ventilation at 32 PHIS hospitals are depicted in Figure 1. Index discharges on non-invasive respiratory support increased annually since 2010.

Competing risk regression modeling showed various characteristics and conditions independently associated with earlier transition to transtracheal ventilation (Table 3). Controlling for age, ethnicity, insurance, mode of support, year of index discharge on non-invasive respiratory support, hospital size, census region, total number of comorbid conditions, and various individual comorbid conditions, older age at index discharge was associated with later transitioning to transtracheal ventilation. For every year older a child was at index discharge, there was a 6% lower hazard of transitioning. For each year later in the study period that non-invasive respiratory support was initiated, there was a 29% lower hazard of transitioning. Patients of Hispanic/Latino ethnicity had a lower risk of earlier transition to transtracheal ventilation (SHR 0.72, 95%CI 0.54-0.94, $P = 0.020$) compared to patients of non-Hispanic ethnicity. Patients from the Western census region had the lowest hazard of transitioning to transtracheal ventilation (SHR 0.62, 95%CI 0.37-1.05, $P = 0.029$) compared to patients from the other regions. Disorders of anoxia/encephalopathy (SHR 1.83, 95%CI 1.36-2.46, $P < 0.001$) and quadriplegia (SHR 1.47, 95%CI 1.05-2.05, $P = 0.021$) had a higher hazard of earlier transition to transtracheal ventilation. Initial mode of support, number of comorbid conditions, other comorbid conditions (eg, complex and non-complex congenital heart disease, congenital neurologic disorder, cerebral palsy, and anterior horn disorders), insurance type, and hospital size were not associated with time to transition to transtracheal ventilation.

One hundred thirty-six patients (3.6%) died while using noninvasive respiratory support. These patients initiated non-invasive respiratory support earlier than the overall cohort (9.0 years, IQR 3.0-15.0 years). Death while using long-term, non-invasive respiratory support occurred at a median 11.5 months (IQR 4.5-28.7) post-index discharge. Cardiac (49%) and neurologic (43%) disorders were most common in this group. Temporal trends of the number of deaths while using non-invasive respiratory support are depicted in Figure 1.

Ages, times to events of interest, and number of patients that experienced each event by specific comorbidities are presented in Supplementary Tables S4 and S5. Two hundred

twenty-three patients (5.7%) reached age 21 years using non-invasive respiratory support by the end of the study period.

Discussion

Over the last decade, the use of long-term, non-invasive respiratory support has increased in children with chronic respiratory failure, likely due to its increased acceptance for certain populations, such as those with neurologic and neuromuscular conditions, as well as the increased availability of portable, high-efficiency positive pressure devices and non-invasive interfaces. Single-site studies suggest that over 75% of children are initiated on non-invasive respiratory support in the inpatient setting^{9,10} often non-electively.¹¹ Despite the increased use of non-invasive respiratory support, some patients with severe or progressive conditions ultimately cannot be supported without transtracheal ventilation. This multi-institutional study characterizes the largest reported cohort of patients who used long-term, noninvasive respiratory support and is the first to perform a time-to-event analysis of their transitions to transtracheal ventilation.

We found that a small, but noteworthy, proportion (9%) of long-term, non-invasive respiratory support patients ultimately transition to transtracheal ventilation. Most children who transitioned to transtracheal ventilation did so within a relatively short time frame, measurable in months rather than years. After adjusting for multiple demographic and clinical characteristics, regression analysis suggests that younger age, initiation earlier in the study period, and disorders of anoxia, encephalopathy, and quadriplegia confer a greater risk of earlier transition to transtracheal ventilation. Patients had a 6% lower hazard of transitioning to transtracheal ventilation for every year older they were at index discharge, suggesting that younger patients with chronic respiratory failure who are initially managed with non-invasive respiratory support are at higher risk of failing non-invasive support. Two findings may reflect overall improvements in managing patients on long-term, non-invasive respiratory support. First, for every year later in the study period, patients had a 29% lower hazard of transitioning to transtracheal ventilation. Second, when looking at the 32 hospitals that contributed data throughout the study period, the number of children that transitioned to transtracheal ventilation stayed within a relatively narrow range, but the number of index discharges on non-invasive support grew substantially. These findings may be related to improvements in technology (eg, new home ventilators) and other supportive care (eg, mechanical insufflation-exsufflation), better selection of appropriate candidates for long-term, non-invasive respiratory support, and/or greater provider expertise caring for these patients over the last decade. It is conceivable that the Affordable Care Act, enacted in 2010, had an impact on the rise in the number of index discharges on non-invasive support. Finally, the finding that patients followed in the Western region had a statistically lower hazard of transitioning to transtracheal ventilation may suggest regional variations in practice.

Previous single-centered studies of children using long-term, noninvasive respiratory support reported comparable findings to this study. Cancelhina et al¹² reported that 7.4% of non-invasive patients transitioned to transtracheal ventilation, and Amin et al⁴ reported that 7.6% of patients requiring transtracheal ventilation had previously required non-invasive respiratory support. The median age of index discharge and bimodal distribution of ages of

our cohort was similar to that reported in Edwards et al,⁶ Chatwin et al,⁹ and Amin et al⁴ and is consistent with the pathophysiology of chronic respiratory failure.¹³ This study augments previous ones by being multi-institutional, concentrating on transitions to transtracheal ventilation (as opposed to mortality), and providing granular data on multiple disorders associated with chronic respiratory failure.

These data can improve clinicians' ability to provide anticipatory guidance to families on the likelihood and timing of possible outcomes of children who are initiated on long-term, non-invasive respiratory support for chronic respiratory failure.¹⁴ For example, families of younger children or those with static encephalopathy should have more intensive counseling about their likely higher risk of eventually not being able to be supported non-invasively. Notably, this study focuses on children initiated as inpatients or, at least, needing inpatient care; thus, this cohort likely reflects children with more complex conditions, which is the population most in need of anticipatory guidance.

This study has several limitations. First, it is an observational, retrospective study using administrative data. Second, while single-site data suggest long-term, non-invasive respiratory support is often initiated in the inpatient setting, we cannot ensure that our index hospitalizations were when long-term, non-invasive support was initiated. Because some patients may have been initiated at home or at non-PHIS hospitals, it is possible that time-to-events are actually longer and ages of initiation younger. Third, we could not assess outcomes outside of PHIS hospitals, including death at home or at non-PHIS facilities or tracheotomy at non-PHIS facilities. Therefore, we may have underestimated the frequency of these events. Like other longitudinal studies of children using medical technologies,¹⁵ we assumed patients continued to receive their care at their index institution. However, many complex patients tend to receive their on-going care in their respective regional, tertiary center.¹⁶ Fourth, the age at which PHIS hospitals transition their patients to adult programs is not known and likely varies. Therefore, some study patients may have transitioned out before 21 years of age and were not appropriately censored. Given that older complex patients frequently use pediatric services and few pediatric home ventilation programs have formalized transition processes, we felt that an upper age limit of 21 years was reasonable.^{17,18} Fifth, we did not have access to some information that are worthy of study, namely reasons for (and reasons for not) transitioning to transtracheal ventilation and causes of death. Similarly, we did not have access to clinical variables that could be relevant to risk of transitioning to transtracheal ventilation, such as degree of chronic respiratory failure (eg, if non-invasive respiratory support was used at night-time only or during daytime as well, and how this may have changed over time), use of outpatient sleep studies, and presence of a home ventilator program.

Conclusion

The use of long-term, non-invasive respiratory support in children with chronic respiratory failure is increasing. While we may be becoming more successful managing these children, some of these children ultimately cannot be supported non-invasively, forcing a decision of whether to transition to transtracheal ventilation. This situation demands that patients and families be aware of the possibility of this outcome; clinicians need robust data to inform

and guide their decision-making and advance care planning. As long-term, noninvasive respiratory support use continues to increase and to be used for more complex patients, further study of the outcomes of children with chronic respiratory failure using non-invasive support will be needed to guide care, counseling, and decision-making.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

We would like to thank the following for their contributions: Katherine Biagas, MD FCCM FAA, Andrei Constantinescu, MD PhD, Steve Cichowski, Cody Chiuhan, PhD, Jay Berry, MD MPH, Jeffrey Silber, MD PhD, and Stephanie Kjelleren Conner, MHSA.

Funding/Support: Dr. Edwards is supported by a National Institutes of Health K23 grant (K23 HD 082361)

Abbreviated Terms

NIV	non-invasive ventilation
PHIS	Pediatric Health Information System
SHR	subdistribution hazard ratio
IQR	interquartile range
CTC	Clinical Transaction Code
ICD-9	International Classification of Diseases, Ninth Revision, Clinical Modification
CPAP	continuous positive airway pressure
BiPAP	bilevel positive airway pressure
CIF	cumulative incidence function

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Figure 1.

Temporal trends in incidence of index NIV discharges, transition to transtracheal ventilation and deaths on NIV. Data for temporal trends from the 32 PHIS hospitals that contributed data from 2009 to 2015

Table 1

Demographic Characteristics at Index NIV Hospitalization/Discharge

Characteristic (n, %)	All Patients (n=3802)	Transitioned to Transtracheal Ventilation (n=337)	Died While Using NIV (n=136)
Modality			
CPAP	1831 (48.2)	152 (45.1)	56 (41.2)
BiPAP	1971 (51.8)	185 (54.9)	80 (58.8)
Age (median years, IQR)	10.4 (4.1-14.9)	7.8 (2.6-12.5)	9.0 (3.0-15.0)
Gender			
Male	998 (26.3)	143 (42.4)	94 (69.1)
Female	840 (22.1)	126 (37.4)	41 (30.2)
Unknown	1964 (51.7)	68 (20.2)	1 (0.7)
Race			
White	2274 (59.8)	202 (59.9)	81 (59.6)
Black	681 (17.9)	58 (17.2)	27 (19.9)
Asian	92 (2.4)	5 (1.5)	5 (3.7)
Pacific Islander	21 (0.6)	3 (0.9)	0
American Indian	35 (0.9)	4 (1.2)	0
Other/Unknown	699 (18.4)	65 (19.3)	23 (16.9)
Ethnicity			
Non-Hispanic/Latino	2787 (73.3)	254 (75.4)	104 (76.5)
Hispanic/Latino	714 (18.8)	55 (16.3)	26 (19.1)
Other/Unknown	301 (7.9)	28 (8.3)	6 (4.4)
Insurance			
Government	2126 (55.9)	196 (58.2)	92 (67.7)
Commercial	1451 (38.2)	116 (34.4)	40 (29.4)
Other/Unknown	225 (5.9)	25 (7.7)	4 (2.9)
Elective Admission	1118 (29.4)	53 (15.7)	3 (16.9)
Length of Stay (median days, IQR)	7 (3-15)	8 (4-18)	10 (5-22)
Year			
2007	47 (1.2)	14 (4.2)	1 (0.7)
2008	55 (1.4)	10 (3.0)	1 (0.7)
2009	202 (5.3)	56 (16.6)	4 (2.9)
2010	223 (5.9)	43 (12.8)	12 (8.8)
2011	309 (8.1)	62 (18.4)	19 (14.0)
2012	390 (10.3)	51 (15.1)	29 (21.3)
2013	855 (22.5)	56 (16.6)	35 (25.7)
2014	940 (24.7)	33 (9.8)	30 (22.1)
2015 ^a	781 (20.5)	12 (3.6)	5 (3.7)
Hospital Size (beds)			
<200	322 (8.5)	37 (11.0)	6 (4.4)

Characteristic (n, %)	All Patients (n=3802)	Transitioned to Transtracheal Ventilation (n=337)	Died While Using NIV (n=136)
200-399	2183 (57.4)	183 (54.3)	72 (53.0)
400	1297 (34.1)	117 (34.7)	58 (42.7)
Region			
Midwest	1161 (30.5)	99 (29.4)	33 (24.3)
Northeast	835 (22.0)	80 (23.7)	31 (22.8)
South	1039 (27.3)	110 (32.6)	43 (31.6)
West	767 (20.2)	48 (14.2)	29 (21.3)

BiPAP=bilevel positive airway pressure; CPAP=continuous BPAP, bilevel positive airway pressure; CPAP, continuous positive airway pressure; IQR, interquartile range.

^aDoes not include entire year, data ends 9/30/15

Table 2

Interval time from index NIV discharge to event

Comorbidity Category ^a (median months, IQR)	Time to Tracheostomy (n=337)	Time to Death (all patients) (n=164)	Time to Death (without transition to transtracheal ventilation) (n=136)
All Patients	11.5 (4.6-26.0)	12.8 (4.8-29.4)	11.5 (4.5-28.7)
Cardiac	10.8 (4.6-30.6)	11.9 (4.8-29.1)	11.5 (4.8-30.9)
Pulmonary	14.8 (3.7-33.7)	11.5 (2.0-25.8)	13.4 (2.0-25.8)
Neuromuscular	12.7 (5.5-27.4)	13.5 (5.0-28.8)	8.3 (3.3-25.8)
Neurologic	10.9 (4.2-24.8)	16.8 (7.0-32.7)	16.8 (6.5-30.3)
Other Disorders	5.3 (2.4-23.4)	8.2 (4.2-20.3)	8.2 (3.5-21.7)

IQR = interquartile range

^aSpecific conditions within each category can be found in E-Tables 3, 6-8

Table 3

Competing Risk Regression Model of Factors Associated with Earlier Transition to Transtracheal Ventilation

Characteristic	Subdistribution Hazard Ratio (95% CI)	p value
Age (years)	0.94 (0.91-0.97)	<0.001
Ethnicity		
Non-Hispanic/Non-Latino	Reference	
Hispanic/Latino	0.72 (0.54-0.94)	0.020
Year of Index Discharge on Non-Invasive Respiratory Support	0.71 (0.67-0.74)	<0.001
Co-morbidity Condition		
Anoxia/Encephalopathy	1.83 (1.36-2.46)	<0.001
Quadriplegia	1.47 (1.05-2.05)	0.021
Region		
Midwest	Reference	
Northeast	0.75 (0.50-1.14)	0.183
South	0.95 (0.63-1.44)	0.826
West	0.62 (0.37-1.05)	0.029

CI=confidence interval; NIV=noninvasive ventilation; Ref=reference.

Statistically significant results presented. Also controlled for insurance status, mode of support, hospital size, number of comorbidities, and other comorbid conditions (complex congenital heart disease, non-complex congenital heart disease, anterior horn disease, congenital neurologic disorders, cerebral palsy).

These characteristics did not reach statistical significance. References provided for categorical variables.