Tracheostomy in Very Low Birth Weight Infants: A Prospective Multicenter Study

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abstract

OBJECTIVES: In this study, we benchmark outcomes and identify factors associated with tracheostomy placement in infants of very low birth weight (VLBW).

METHODS: Data were prospectively collected on infants of VLBW (401–1500 g or gestational age of 22–29 weeks) born between 2006 and 2016 and admitted to 796 North American centers. Length of stay (LOS), mortality, associated surgical procedures, and comorbidities were assessed, and infants who received tracheostomy were compared with those who did not. Multivariable logistic regressions were performed to identify risk factors for tracheostomy placement and for mortality in those receiving tracheostomy.

RESULTS: Of 458 624 infants of VLBW studied, 3442 (0.75%) received tracheostomy. Infants with tracheostomy had a median (interquartile range) LOS of 226 (168–304) days and a mortality rate of 18.8%, compared with 58 (39–86) days and 8.3% for infants without tracheostomy. Independent risk factors associated with tracheostomy placement included male sex, birth weight <1001 g, African American non-Hispanic maternal race, chronic lung disease (CLD), intraventricular hemorrhage, patent ductus arteriosus ligation, and congenital neurologic, cardiac, and chromosomal anomalies. Among infants who received tracheostomy, male sex, birth weight <751 g, CLD, and congenital anomalies were independent predictors of mortality.

CONCLUSIONS: Infants of VLBW receiving tracheostomy had twice the risk of mortality and nearly 4 times the initial LOS of those without tracheostomy. CLD and congenital anomalies were the strongest predictors of tracheostomy placement and mortality. These benchmark data on tracheostomy in infants of VLBW should guide discussions with patient families and inform future studies and interventions.

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WHAT'S KNOWN ON THIS SUBJECT: With medical advancement and increased survival of preterm infants, indications for tracheostomy have shifted, with severe pulmonary disease and congenital anomalies becoming major contributors. Data from multicenter studies on incidence, mortality, and risk factors for tracheostomy placement remain sparse.

WHAT THIS STUDY ADDS: In this prospective, multi-institutional analysis, we describe the incidence and outcomes of tracheostomy placement in infants of very low birth weight. These data should help guide clinicians in their multidisciplinary approach to proceeding with tracheostomy placement in preterm infants.

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The decision to place a tracheostomy in preterm infants remains challenging. With medical advancement over the last decade and increased survival of preterm infants, most tracheostomies placed in children are now done at <12 months of age.[1,2] In addition, indications for tracheostomy placement in infants have shifted over the last decade, with severe pulmonary disease requiring prolonged ventilation, neurologic conditions, and cardiac anomalies becoming major contributors.[3–5]

The reported incidence of tracheostomy placement in infant populations ranges from 0.55% to 2.7%,[6,7] albeit within single-center retrospective studies. Similarly, authors of single-center studies have described mortality in infants receiving tracheostomy as between 13% and 19%. Data from large multicenter population-based studies[1,8,9] on the incidence, mortality, and risk factors for tracheostomy placement are sparse. This is especially true in the case of preterm infants.[2]

The decision to proceed with tracheostomy placement may be difficult for both families and health care providers. The ability to provide families with robust data regarding infants receiving tracheostomy may better guide this decision-making process. In this study, we use a multicenter prospective cohort to evaluate infants of very low birth weight (VLBW) who underwent tracheostomy placement over an 11-year period. The purpose of the study was to test the hypothesis that infants of VLBW undergoing tracheostomy would have significantly higher mortality than their counterparts. Additional aims of the study included to benchmark the incidence of tracheostomy placement in this patient population and to leverage this large data set to describe risk factors for tracheostomy placement and independent predictors of mortality in this complex patient cohort.

METHODS

Vermont Oxford Network (VON) is a nonprofit, voluntary worldwide community of practice dedicated to improving the quality, safety, and value of care through a coordinated program of data-driven quality improvement, education, and research. This study was performed as an ongoing collaboration between VON and the Boston Children's Hospital Department of Surgery. The Committee on Human Research at the University of Vermont determined that the use of the VON Research Repository (15–143) for this study was not human subjects research, and the Boston Children's Hospital Institutional Review Board (P00002185) exempted the study on the basis of use of deidentified data.

For this cohort study, data were prospectively collected on infants of VLBW born from January 1, 2006, to December 31, 2016, in 796 participating North American centers. Infants receiving tracheostomy were identified on the basis of a specific procedure code in the VON database. Characteristics and outcomes for infants who underwent tracheostomy placement were compared with those for infants who did not receive tracheostomy placement during their initial hospitalization.

Members prospectively collected data on infants of birth weight 401 to 1500 g or infants 22 to 29 completed weeks' gestational age born at participating institutions (inborn) or transferred to those institutions within 28 days of birth (outborn). Deidentified data were collected and submitted by local staff using standardized definitions outlined in the VON Manual of Operations.[10] Records were subject to automated checks and returned for correction to ensure data quality. Data on infants were accrued until neonates were discharged, died, or reached 1 year of age in the hospital.

Data collected included gestational age, birth weight, delivery characteristics, associated congenital anomalies, hospital course, and morbidity during the initial hospitalization. Infants were divided into 5 categories on the basis of birth weight: 401 to 500, 501 to 750, 751 to 1000, 1001 to 1250, and 1251 to 1500 g. The primary outcome was mortality, whereas secondary outcomes included total length of stay (LOS), supplemental oxygen requirement, and cardiorespiratory monitoring on discharge. Surgical procedures other than tracheostomy performed on infants during their initial hospital course were assessed.

Small for gestational age was defined within categories of sex, race, and ethnicity as a birth weight below the 10th percentile by using smoothed curves constructed from the US natality data set.[11] Neurologic, cardiac, gastrointestinal, chromosomal, and pulmonary anomaly groups were based on the VON congenital anomaly codes.[10] Cardiac anomalies only included major defects listed in the VON Manual of Operations[10] and did not include atrial or ventricular septal defects. Initial resuscitation refers to oxygen, face mask ventilation, endotracheal tube ventilation, surfactant delivery, epinephrine, or cardiac compression performed in the delivery room immediately after birth and before admission to a NICU. Chronic lung disease (CLD) was diagnosed if an infant continued to have oxygen requirement at 36 weeks' postmenstrual age or was discharged on oxygen at 34 or 35 weeks' postmenstrual age. A diagnosis of necrotizing enterocolitis was based on direct visualization of the intestines during an operation or at least 1 clinical finding (bilious gastric aspirate or emesis, abdominal distention, or blood in stool) in addition to at least 1 radiographic

finding (pneumatosis intestinalis, portal venous gas, or pneumoperitoneum). Sepsis was categorized as culture-confirmed bacterial or fungal infection after day 3 from birth. Definitions for all items can be found in the VON Manual of Operations.[10]

LOS was defined by the number of days from the date the infant was admitted to the hospital to the date of discharge from the hospital, death, or when the patient reached 1 year of age. Monitor at discharge was defined by apnea or cardiorespiratory monitor requirement on discharge from the hospital or transfer. Survival was defined as discharge from the hospital or being still hospitalized at 1 year of age.

Statistical analyses were conducted by using SAS version 9.4 (SAS Institute, Inc, Cary, NC). Data were presented as percentages or median (interquartile range [IQR]) when applicable. Multivariable generalized estimating equation logistic regression was performed to assess risk factors for tracheostomy placement and mortality in those infants of VLBW receiving tracheostomy while controlling for clustering of infants within hospitals. Model covariates included sex, birth weight, maternal race, CLD, intraventricular hemorrhage, patent ductus arteriosus (PDA) ligation, and the presence of neurologic, cardiac, or chromosomal anomalies. Adjusted odds ratios (aOR) with 95% confidence intervals (CIs) were calculated to compare infants receiving tracheostomy with those without tracheostomy.

RESULTS

Of 458 624 infants of VLBW studied during the 11-year period, 3442 (0.75%) received tracheostomy during their initial hospitalization. Patient demographic and obstetric characteristics, including birth weight, are shown in Table 1. The median birth weight was lower for infants receiving tracheostomy (740 vs 1100 g). When separated into birth weight categories, those weighing <751 g had a higher incidence of tracheostomy placement compared with those who weighed more (Fig 1). Other notable differences included lower 1-minute Apgar scores and a higher likelihood of being outborn in the tracheostomy group. In addition, infants of African American mothers were overrepresented in the tracheostomy group.

Infants receiving tracheostomy were more likely to have major congenital anomalies and significant morbidity during their initial hospital course (Table 2). Congenital anomalies were diagnosed in 15.8% of infants with tracheostomy, compared with 3.2% in

TABLE 1 Demographic and Obstetric Characteristics of Infants of VLBW With and Without Tracheostomy Placement in the 796 Participating US Centers Between 2006 and 2016

	Tracheostomy, *n* = 3442	No Tracheostomy, *n* = 455 182
Male sex, %	57.8	50.5
Birth wt, g, median (IQR)	740 (605–960)	1100 (830–1330)
401–500, %	6.6	1.8
501–750, %	44.4	16.1
751–1000, %	25.8	22.4
1001–1250, %	12.0	25.6
1251–1500, %	8.8	31.6
Small for gestational age, %	20.9	21.2
Maternal race, %		
White	44.9	45.9
African American	36.2	29.0
Hispanic	14.1	18.1
Other	4.9	6.9
Apgar score, min, median (IQR)		
1	4 (2–6)	6 (4–8)
5	7 (5–8)	8 (7–9)
Mode of delivery, %		
Vaginal	26.3	27.1
Cesarean	73.7	72.9
Outborn, %	25.8	15.4

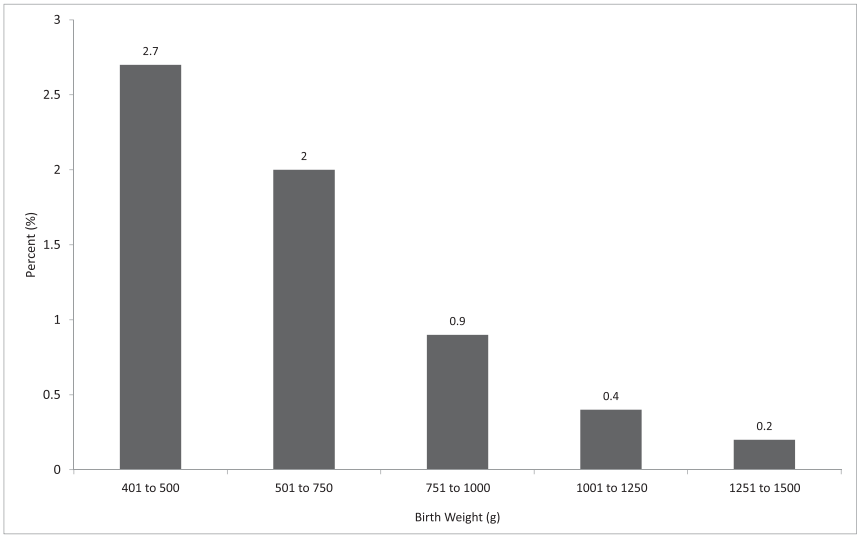

FIGURE 1
Percentage of infants of VLBW receiving tracheostomy by birth weight categories.

TABLE 2 Associated Congenital Anomalies and Hospital Course for Infants of VLBW With and Without Tracheostomy

	Tracheostomy, *n* = 3442	No Tracheostomy, *n* = 455 182
	%	%
Congenital malformations (any of below)	15.8	3.2
Neurologic	1.9	0.5
Cardiac	4.9	1.0
Gastrointestinal	7.1	1.2
Chromosomal	5.3	0.9
CDH, CCAM, or other pulmonary abnormalities	2.1	0.1
Hospital course		
CLD	92.2	26.7
PDA	71.2	34.1
Intraventricular hemorrhage	37.9	25.1
Necrotizing enterocolitis	11.5	6.2
Late sepsis	44.3	13.9
Retinopathy of prematurity	73.5	34.9

CCAM, congenital cystic adenomatoid malformation; CDH, congenital diaphragmatic hernia.

those without tracheostomy. Individual rates of neurologic, cardiac, gastrointestinal, chromosomal, and pulmonary anomalies were greater in the tracheostomy group compared with their counterparts without tracheostomy. An overwhelming majority of infants receiving tracheostomy had CLD (92.2%). All other significant hospital morbidity diagnoses evaluated were higher in infants receiving tracheostomy.

The overall mortality for infants undergoing tracheostomy was 18.8%, starkly higher than for those who did not receive tracheostomy (8.3%) (Table 3). Although mortality decreased as birth weight increased in infants without tracheostomy, the mortality percentage for the tracheostomy group remained relatively stable (range 14.5%–23.7%) when evaluated by birth weight categories (Fig 2).

The median (IQR) LOS for the initial hospitalization was 226 (168 304) days for those receiving tracheostomy and 58 (39–86) days for infants who did not require tracheostomy placement (Table 3). A majority of infants in the tracheostomy group required supplemental oxygen at discharge (82.2%). Overall, 87.5% of infants of VLBW receiving tracheostomy required either an apnea or cardiorespiratory monitor at discharge, compared with 25.2% in infants without tracheostomy. Additionally, 68.4% of infants receiving tracheostomy also received feeding tube (gastrostomy or jejunostomy) placement, compared with 2.2% of those without tracheostomy (Table 4). PDA ligation (35.0%) and fundoplication (23.7%) were the next 2 commonly associated procedures for infants receiving tracheostomy; however, other abdominal surgeries (15.8%), ventriculoperitoneal shunt placement (4.3%), and open heart surgery (3.1%) were all more commonly performed on the tracheostomy group.

A multivariable analysis was performed to assess factors associated with tracheostomy placement in infants of VLBW (Fig 3). Infants with CLD had the highest odds of receiving tracheostomy with an aOR of 17 (95% CI 13.6–21.2), strikingly higher than all other predictors assessed. Congenital anomalies were also independently associated with a higher risk of tracheostomy placement. The aORs for these predictors were as follows: chromosomal anomaly: 5.8 (95% CI 4.8–7.1); major cardiac anomalies: 4.4 (95% CI 3.5–5.6); and neurologic anomalies: 3.6 (95% CI 2.8–4.8). Other notable factors independently associated with tracheostomy placement included birth weight <1001 g, male sex, African American maternal race, and PDA ligation.

A multivariable analysis in which risk factors for mortality in the tracheostomy group were assessed revealed that male sex, birth weight <751 g, CLD, and congenital anomalies were each independently associated with 1-year mortality (Fig 4). Again, a diagnosis of CLD was associated with the highest odds for mortality with an aOR of 3.2 (95% CI 1.9–5.5). Similar to predictors for tracheostomy placement, congenital anomalies were also associated with a higher independent risk for mortality in infants receiving tracheostomy: chromosomal anomaly: 1.7 (95% CI 1.1– 2.9); major cardiac anomaly: 2.5 (95% CI 1.7–3.7); and neurologic anomaly: 2.5 (95% CI 1.3–4.9). Maternal race, birth weight categories >751 g, intraventricular hemorrhage, and PDA ligation were not associated with mortality in infants receiving tracheostomy.

TABLE 3 Outcomes Comparing Infants With and Without Tracheostomy

	Tracheostomy, *n* = 3442	No Tracheostomy, *n* = 455 182
Total LOS, d, median (IQR)	226 (168–304)	58 (39–86)
Oxygen at discharge from the hospital, %	82.2	14.6
Monitor at discharge from the hospital, %	87.5	25.2
Final disposition, %		
Home	66.6	91.6
Still hospitalized as of 1 y of age	14.6	0.2
Died	18.8	8.3

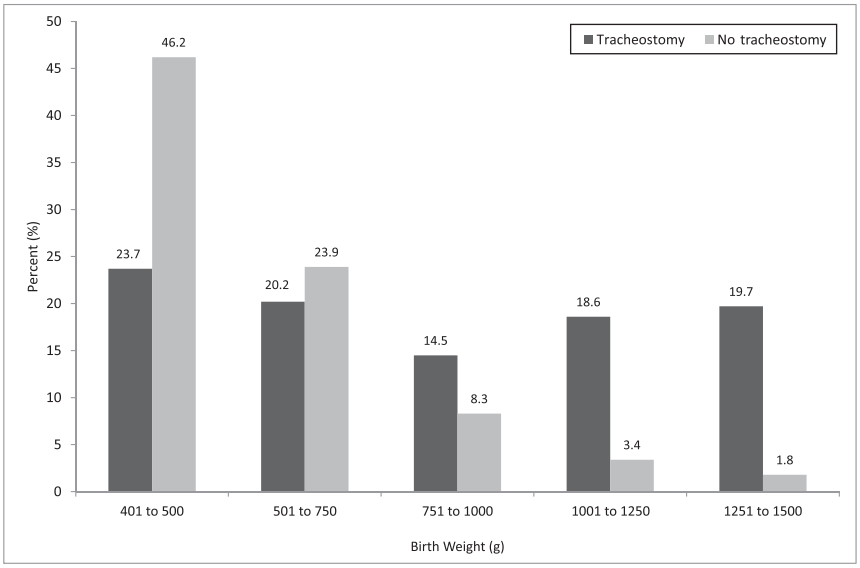

FIGURE 2
Mortality percentage of infants of VLBW with and without tracheostomy placement by birth weight categories.

DISCUSSION

The decision to proceed with tracheostomy in infants of VLBW and the care of these infants after tracheostomy is complex and involves a multidisciplinary approach with many pediatric specialties. Data on tracheostomy placement in infants have been limited mostly to single-center studies. With the majority of pediatric tracheostomies in the United States being performed in children <1 year of age, it is important to identify predictors for tracheostomy placement and risk factors for adverse outcomes to provide providers with benchmark data to inform decision-making and counseling of patient families.[1,2]

The VON database encompassed ~85% of infants of VLBW born in the United States over the 11-year period of this study. In this national, nearly population-level cohort, 3442 (0.75%) of 458 624 infants of VLBW received a tracheostomy. Overall tracheostomy rates in infants have been reported as between 0.1% and 3.5%.[2,12,13] Previous studies have included all infants rather than limiting to the VLBW population. The authors of one study observing all infants born before 30 weeks' gestation in 16 centers participating in the National Child Health and Human Development Neonatal Research Network reported a tracheostomy rate of 3.5%.[2] However, the VON database represents a broad range of NICUs, including academic centers and community hospitals, and may be a more accurate representation of infants treated in NICUs across the country. This rate of tracheostomy placement is specific to infants who are <1500 g birth weight or 22 to 29 weeks' gestation and is the largest study for this group of infants to date.

In this study, receipt of tracheostomy was inversely related to the birth weight in infants of VLBW (Fig 1). Whereas previous studies in infants of VLBW have revealed a stratification slightly more skewed toward infants at 1001 to 1500 g birth weight, with only 58% of tracheostomy placements in the extremely low birth weight category, this study revealed that nearly 77% of tracheostomy placements in infants of VLBW occurred in the patients at <1001 g birth weight.[13] The higher rate of tracheostomy placement in infants of lower birth weight in this study may be indicative of overall trends toward higher survival of infants of lower birth weight with improvements in neonatal care over time and subsequent higher rates of prolonged ventilation and CLD.[14]

Mortality rates in infants receiving tracheostomy were higher in this cohort than previously suggested. Given its size and scope, this study can serve as a benchmark for expected outcomes with data from a national, nearly population-level sample. Berry et al[15] reported a mortality range of 10.2% to 13.1% in children <1 year receiving tracheostomy in a 10-year study period using the Kids' Inpatient Database. Authors of another study, using the Pediatrix database, reported a mortality of 14% in infants receiving tracheostomy,

TABLE 4 Percentage of Infants of VLBW With and Without Tracheostomy at Their Initial Hospitalization Who Require Other Surgical Procedures

	Tracheostomy, n = 3442		No Tracheostomy, n = 455 182	
	Cases	%	Cases	%
Gastrostomy or jejunostomy tube placement	2355	68.4	9967	2.2
PDA ligation	1206	35.0	32 525	7.1
Fundoplication	815	23.7	3289	0.7
Other abdominal surgery	544	15.8	18 914	4.2
VP shunt placement	147	4.3	4699	1.0
Other open heart surgery	105	3.1	1309	0.3

VP, ventriculoperitoneal.

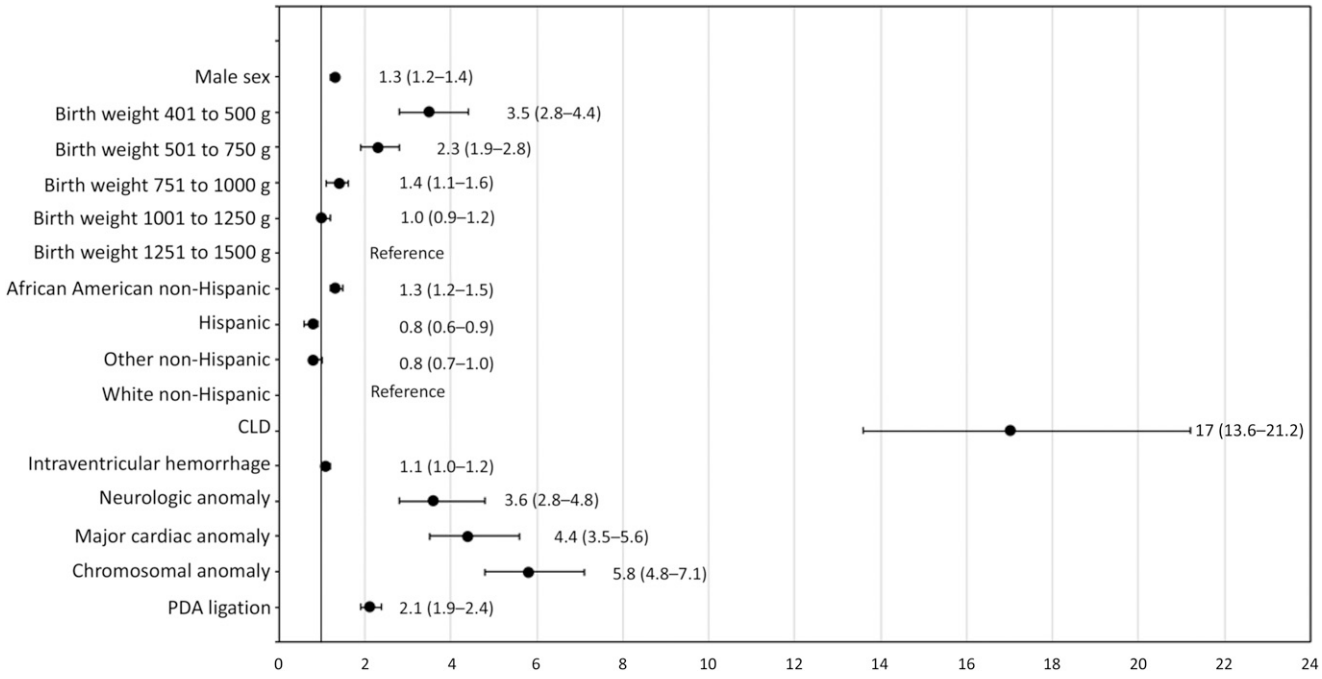

FIGURE 3
Forest plot of the aORs (95% CIs) associated with tracheostomy placement in infants of VLBW.

compared with 2.5% in all infants who were hospitalized.[12,15] In the present cohort, infants of VLBW receiving tracheostomy had 18.8% mortality, compared with 8.3% in infants without tracheostomy, during their initial hospitalization. CLD and the presence of neurologic, cardiac, or chromosomal anomalies were the strongest predictors of mortality, similar to previous findings.[15–17]

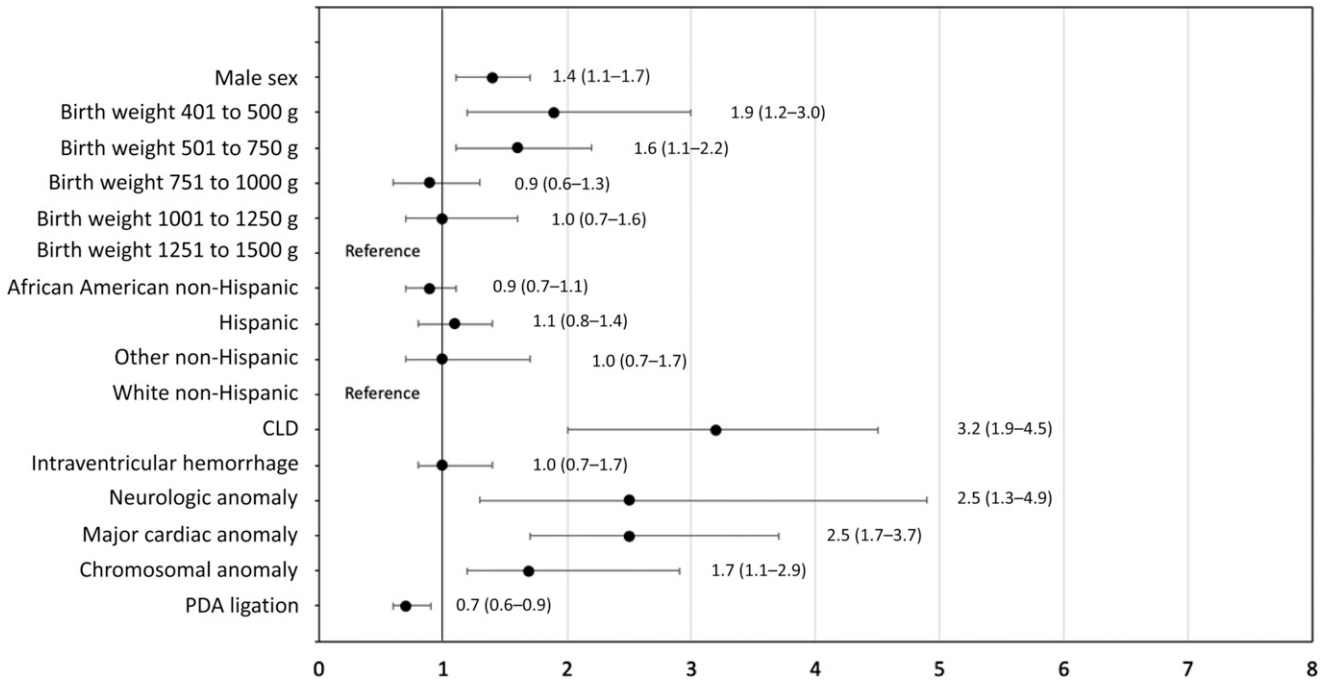

FIGURE 4
Forest plot of the aORs (95% CIs) for 1-year mortality in infants of VLBW receiving tracheostomy.

Given the size of the cohort, we were able to illustrate rates of mortality in infants receiving tracheostomy stratified by birth weight categories. Most interestingly, the overall rate of mortality among infants with tracheostomy was relatively stable throughout the birth weight categories, whereas mortality rates by birth weight categories decreased for infants without tracheostomy. Although one might postulate that the smaller infants are sicker, it is also possible that the very smallest patients who survive to tracheostomy would be more robust. One limitation of the current data set is a lack of data on the timing of tracheostomy, making a judgment in this regard impossible. This trend (or lack thereof) in mortality based on birth weight category among infants receiving tracheostomy merits further investigation, which could elicit relationships to timing of tracheostomy and help guide future management.

In this report, we also identify a higher median LOS (226 days [IQR 168–304]) for infants receiving tracheostomy than previous studies. Overman et al[13] reported a median LOS of 186 days for infants <1000 g and 130 days in those >1000 g receiving tracheostomy placement, whereas others have reported a median LOS between 50 and 99 days.[18,19] These remarkable LOS data highlight the large and complicated medical burden these infants and their families face. Associated with this burden are also the other surgical needs these patients require. In this cohort, 68.4% of infants receiving tracheostomy also had a feeding tube placed before their initial discharge, compared with only 2.2% in infants without tracheostomy. Rates of PDA ligation, fundoplication, and major abdominal surgeries were higher in infants receiving tracheostomy as well. There have not been other large multicenter studies evaluating the surgical burden of infants receiving tracheostomy. However, in an analysis of 556 infants with CLD, 24% went on to need gastrostomy insertion, and another 11% received fundoplication.[20] These data are important for neonatologists, surgeons, and other care providers in both counseling families and planning the treatment course for these patients.

In recent studies, congenital neurologic anomalies, cardiac anomalies, and CLD have been closely associated with the need for tracheostomy placement in infants.[7,12,21] These data seem to be in contrast to those of older studies that revealed airway obstruction and infection as being some of the primary risk factors for tracheostomy placement.[7,16,22] This study's findings are concordant with those of recent studies and suggest that rates of CLD and congenital anomalies, including neurologic and cardiac disease, are significantly higher in the tracheostomy group compared with infants of VLBW without tracheostomy.

Along with CLD and congenital heart disease, male sex and African American maternal race were also independently associated with tracheostomy placement. Authors of previous studies have reported male sex as a risk factor for tracheostomy placement[23]; however, the overrepresentation of African American ethnicity in the tracheostomy cohort is interesting. In adults, literature suggests that minority patients, including African American patients, are less likely than white patients to receive a variety of surgical procedures.[24–26] These data suggest otherwise, instead revealing that infants of VLBW of African American maternal race have an aOR of 1.3 (95% CI 1.2–1.5) for receiving tracheostomy during their NICU course. The National Vital Statistics Report by the Centers for Disease Control and Prevention reported that African American women experience nearly 3 times the rate of preterm birth at <32 weeks' gestational age.[27] Although it has been understood that African American infants have lower rates of bronchopulmonary dysplasia, a recent study of 835 infants born at 23 to 28 weeks' gestational age revealed that African American infants were more likely to have post-prematurity respiratory disease, defined by the increased use of inhaled bronchodilators or steroids, increased hospitalizations for cardiopulmonary causes, and higher rates of supplemental oxygen use, ventilator dependence, and tracheostomy after 36 weeks' postmenstrual age.[28] The disparities seen in preterm births in the United States and rates of post-prematurity respiratory disease may explain the increased rate of tracheostomy in African American infants. These data, however, cannot account for potential cultural, religious, and socioeconomic factors that could contribute to the disparity seen in this tracheostomy cohort, warranting further investigation.

A key strength of this study lies in the use of a prospectively collected data set that contains reliable clinical data and a large sample size. However, there are limitations to consider. The mortality reflected in the nontracheostomy group was 8.3%, compared with 18.8% in the tracheostomy group. It must be acknowledged, however, that the mortality in the nontracheostomy group may include patients who died before receipt of a tracheostomy. This limitation could skew the comparison toward a higher-than-actual mortality in the nontracheostomy group because of cases in which underlying severity of disease would have eventually led to a tracheostomy. Also, VON participation is voluntary, and centers are not chosen at random or with strict criteria. Therefore, although it represents 85% of the infants of VLBW in the United States during the study period, the cohort is

not strictly population based. In addition, specific information on timing of tracheostomy placement or other surgical procedures is not available, making the ramifications of such data difficult to determine. Finally, as with almost all database-driven studies, specific indications and clinician discussions regarding tracheostomy placement were not reported.

CONCLUSIONS

Infants of VLBW requiring tracheostomy placement during initial hospitalization are at a high risk for morbidity and mortality. CLD, congenital anomalies, and birth weight were among the strongest factors associated with tracheostomy placement and mortality among those with tracheostomy. These data provide vital benchmarks for neonatologists, pediatricians, surgeons, and other health care providers to understand the risk factors and outcomes associated with tracheostomy in infants of VLBW. They can also inform discussions with families and help guide management. Future studies are needed to guide the timing of tracheostomy placement and identify long-term neurologic outcomes and other morbidity in this patient population.

ABBREVIATIONS

aOR: adjusted odds ratio
CI: confidence interval
CLD: chronic lung disease
IQR: interquartile range
LOS: length of stay
PDA: patent ductus arteriosus
VLBW: very low birth weight
VON: Vermont Oxford Network

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