### **Risk Factors and In-Hospital Outcomes following Tracheostomy in Infants**

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**Objective** To describe the epidemiology, risk factors, and in-hospital outcomes of tracheostomy in infants in the neonatal intensive care unit.

**Study design** We analyzed electronic medical records from 348 neonatal intensive care units for the period 1997 to 2012, and evaluated the associations among infant demographics, diagnoses, and pretracheostomy cardiopulmonary support with in-hospital mortality. We also determined the trends in use of infant tracheostomy over time.

**Results** We identified 885 of 887 910 infants (0.1%) who underwent tracheostomy at a median postnatal age of 72 days (IQR, 27-119 days) and a median postmenstrual age of 42 weeks (IQR, 39-46 weeks). The most common diagnoses associated with tracheostomy were bronchopulmonary dysplasia (396 of 885; 45%), other upper airway anomalies (202 of 885; 23%), and laryngeal anomalies (115 of 885; 13%). In-hospital mortality after tracheostomy was 14% (125 of 885). On adjusted analysis, near-term gestational age (GA), small for GA status, pulmonary diagnoses, number of days of forced fraction of inspired oxygen >0.4, and inotropic support before tracheostomy were associated with increased in-hospital mortality. The proportion of infants requiring tracheostomy increased from 0.01% in 1997 to 0.1% in 2005 (P < .001), but has remained stable since.

**Conclusion** Tracheostomy is not commonly performed in hospitalized infants, but the associated mortality is high. Risk factors for increased in-hospital mortality after tracheostomy include near-term GA, small for GA status, and pulmonary diagnoses. (*J Pediatr 2016;173:39-44*).

See related articles p 17, p 45, and p 50

racheostomy may be required in infants with lung disease, airway anomalies, or neurologic, cardiac, or other diseases. With improving survival of extremely preterm infants, the number of infant tracheostomies is expected to increase, although this trend has not yet been demonstrated in the literature.<sup>1,2</sup>

Epidemiologic data on infant tracheostomy are mostly limited to single-center studies focusing on premature infants,<sup>3,4</sup> with particular emphasis on those with bronchopulmonary dysplasia (BPD).<sup>4-6</sup> Data on tracheostomy and outcomes in other infant

populations are limited, as are data on risk factors associated with outcomes following tracheostomy. The few existing studies evaluating risk factors have included predominantly older children, focused on the postnatal age at tracheostomy, and reported different clinical outcomes. One study found that tracheostomy performed later in life was associated with the need for home ventilation and gastrostomy tube placement,<sup>7</sup> and another study reported an increased associated with poor outcomes specifically in infants have not been completely reported.

The objectives of this retrospective multicenter study were to describe the epidemiology of tracheostomy in infants admitted to neonatal intensive care units (NICUs), and to identify risk factors associated with in-hospital mortality following tracheostomy.

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### Methods

We used electronic medical records from a clinical data warehouse that prospectively captures information on infants cared for by the Pediatrix Medical Group in 348 NICUs throughout North America. Data on multiple aspects of care are entered into a shared electronic record to generate admission and daily progress notes, as well as discharge summaries. Information on maternal history, demographics, medications, laboratory results, diagnoses, and procedures is then transferred to the data warehouse for quality improvement and research purposes.<sup>9</sup>

We included all infants who underwent tracheostomy during their initial hospitalization at one of 348 NICUs managed by the Pediatrix Medical Group between 1997 and 2012. Infants with missing information on postnatal age at tracheostomy and those with unknown discharge status were excluded. We extracted data on all days of hospitalization in the NICU. This study was approved by Duke University's Institutional Review Board without the need for written informed consent, because the data were collected without identifiers.

#### Definitions

We reviewed all infant diagnoses associated with tracheostomy to identify possible indications for tracheostomy. We grouped diagnoses of interest into airway, pulmonary, neuromuscular, and central nervous system (CNS) categories. Airway diagnoses included vocal cord paralysis, laryngeal anomalies (atresia, webs, stenosis, or malacia), subglottic stenosis, tracheobronchomalacia, or other upper airway anomalies (macrognathia or micrognathia, macroglossia, choanal stenosis or atresia, nasal atresia, or other upper airway obstruction).

Pulmonary diagnoses included pulmonary hypoplasia, BPD, chronic aspiration, congenital diaphragmatic hernia, tracheoesophageal fistula, or other pulmonary anomalies. Given the association between BPD and several of the diagnoses considered as possible tracheostomy indications, BPD was considered a possible indication for tracheostomy only if another possible indication for tracheostomy was not present. In those cases with another possible indication, BPD was only considered a comorbidity and not listed as a possible indication. We classified infants born at <32 weeks gestational age (GA) as having BPD if they received supplemental oxygen or respiratory support (nasal cannula, continuous positive airway pressure, or mechanical ventilation) continuously from a postmenstrual age of 36 0/7-36 6/7 weeks. We classified infants born at  $\geq$  32 weeks GA as having BPD if they received supplemental oxygen or respiratory support (nasal cannula, continuous positive airway pressure, or mechanical ventilation) continuously from a postnatal age of 28-34 days.<sup>10</sup>

Neuromuscular diagnoses included spinal muscular atrophy type 1, congenital muscular dystrophy, myasthenia gravis (including congenital), and other musculoskeletal anomalies. CNS diagnoses included hypoxic ischemic encephalopathy and congenital CNS malformations. Because the database does not include a primary indication for tracheostomy, each indication variable listed above was coded as a binary (yes/no) variable, so an infant could have more than 1 possible diagnosis associated with tracheostomy. Congenital heart disease (CHD) was defined as any cardiac malformation except patent ductus arteriosus and biscupid aortic valve (Table I; available at www.jpeds.com). Genetic syndromes were defined as any of the following diagnoses: trisomies (eg, trisomy 21, 18, 13), genetic associations (eg, CHARGE, VACTERL), deletion syndromes (eg, 13q-, 5p-), and clinically relevant syndromes (eg, DiGeorge syndrome, Treacher-Collins syndrome). Retinopathy of prematurity (ROP) was defined as stage III or IV ROP, intraventricular hemorrhage as grade III or IV intraventricular hemorrhage, the need for supplemental oxygen as a fraction of inspired oxygen  $(FiO_2) > 0.4$ , and mechanical ventilation as conventional ventilation or high-frequency ventilation (HFV).

Our primary outcome of interest was in-hospital mortality. Secondary outcomes included duration of mechanical ventilation, time to wean to  $FiO_2 < 0.4$ , and supplemental  $FiO_2 > 0.21$  after tracheostomy, defined as the time from tracheostomy to the first day off mechanical ventilation and to the first day with an  $FiO_2$  of 0.21, respectively.

#### **Statistical Analyses**

We summarized continuous and categorical variables as median (IQR) and counts with proportions, respectively. We used Wilcoxon rank-sum, Kruskal-Wallis,  $\chi^2$ , and Fisher exact tests to compare the study variables across groups, as appropriate. We evaluated trends in proportion of tracheostomies over time using the Cochran-Armitage test for trend. For the risk factor analysis, we performed univariable logistic regression analyses for GA, birth weight, small for GA (SGA) status, male sex, ethnicity, presence of genetic syndromes, presence of CHD, BPD diagnosis, categories of possible indications for tracheostomy, postmenstrual age, postnatal age, and number of days on mechanical ventilation, HFV, inotropic support, and FiO<sub>2</sub> >0.4 before tracheostomy as predictors of in-hospital mortality. We classified GA into 5 a priori defined categories-≤25, 26-28, 29-32, 33-36, and ≥37 weeks-and birth weight into 3 a priori defined categories-<1000, 1000-1500, and >1500 g.

All variables found to be significant on univariable analysis (P < .05) were considered candidates for inclusion in the full model, and forward addition (P = .15) and backward elimination (P = .2) techniques were used to identify a reduced model. This reduced model was then inspected, and clinically relevant covariates that had been removed in the reduction steps were added back into the model. Following standard model assumption diagnostics, including assessment of collinearity using variance inflating factors, the following variables remained in the final model: GA, SGA, male sex, postnatal age at tracheostomy, number of days requiring FiO<sub>2</sub> >0.4, number of days requiring inotropic support

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