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Effect of Anatomical and Developmental Factors on the Risk of Unplanned Extubation in Critically Ill Newborns

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Abstract

Objective—To quantify the daily risk of unplanned extubation (UE) in newborns based on developmental and anatomical factors.

Methods—Prospective cohort of ventilated newborns over an 18-month period in a level IV neonatal intensive care unit (NICU). We captured UEs through four data streams. We generated multivariable logistic regression models to assess the association of UE with chronological age, birth weight, and postmenstrual age.

Results—During the study, 718 infants were ventilated for 5,611 patient days with 117 UEs in 81 infants. The daily risk of UE had a significant, nonlinear relationship ($p < 0.01$) with chronological age, decreasing until day 7 (odds ratio [OR]: 0.5; 95% confidence interval [CI]: 0.17–1.47) and increasing after day 7 (day 7–28, OR: 1.36, 95% CI: 1.06–1.75; and >28 days, OR: 1.06, 95% CI: 1.0–1.14). Birth weight and postmenstrual age were not associated with UE. Adverse events occurred in 83/117 (71%) UE events. Iatrogenic causes of UE were more common in younger, smaller infants, whereas older, larger infants were more likely to self-extubate.

Conclusion—The daily risk and causes of UE change over the course of an infant's NICU hospitalization. These data can be used to identify infants at the highest risk of UE for whom targeted proactive interventions can be developed.

Keywords

unplanned extubation; patient safety; mechanical ventilation; neonates

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For infants in the neonatal intensive care unit (NICU) who require endotracheal intubation and mechanical ventilation, unplanned extubations (UEs) are a major threat to safe health care. UEs result in high rates of bradycardia, hypoxemia, chest compressions,[1] and reintubation.[2,3] Further, intubation associated adverse events are more common when intubation courses follow an UE than during intubations for other indications.[4] Since the 1970s, studies have reported high rates of UE in NICUs.[5–8] In a large, multicenter study using a NICU-specific trigger tool, UEs were the fourth most common adverse event in the NICU and the most common event specifically associated with mechanical ventilation.[9] Although the incidence and consequences of UEs are well-known, the epidemiologic factors associated with UEs in critically ill newborns, especially infants at greatest risk of UE, are poorly described making prospective evidence- based interventions difficult to determine.

Over the course of a NICU hospitalization, infants, particularly those born preterm, undergo significant developmental and anatomical changes. The impact this normal growth and development has on the daily risk of UE and the implications for respiratory care practices have not been studied. It has been shown that the daily risk of central line associated blood stream infection (CLABSI), another adverse event in the NICU, is dynamic and changes with developmental and anatomical factors including birth weight (BW) and catheter dwell time.[10,11] We hypothesized that, similar to CLABSIs, a dynamic relationship exists between the daily risk of a UE and specific developmental and anatomical factors such as patient size and age. The objective of our study was to define the associations of developmental and anatomical factors with the risk of UEs in a large cohort of mechanically ventilated infants.

Methods

Setting

We performed a prospective cohort study in the 98-bed, level IV (regional), academic NICU of the Vanderbilt University Medical Center from February 1, 2014, to July 31, 2015. More than 1,400 infants are admitted to the Vanderbilt NICU annually from the affiliated delivery service or in transport from outside facilities. All infants who require mechanical ventilation are intubated orally. Endotracheal tubes (ETTs) were secured with a standardized taping method where two pieces of 1/2-inch cloth tape are partially cut in a Y-configuration and taped to each side of the face. One leg of the Y is taped to the upper lip, while the other leg is taped to the ETT in the midline.[12] The decision to retape the ETT is at the discretion of the bedside nurse and respiratory therapist (RT) based on the condition of the existing tape. Assessment of ETT tape integrity is part of scheduled nursing and RT care performed at least every 3 to 4 hours. During the study period, no new systematic interventions to decrease UEs were implemented. Infants who are mechanically ventilated are not routinely sedated, and the decision to prescribe sedative/analgesic medications while intubated is at the discretion of the medical team. Fentanyl, morphine, and midazolam, either in bolus or continuous infusion, are the most used medications when sedation is prescribed. Neuromuscular blockers are rarely used.

Human Subjects Protection

The Vanderbilt Institutional Review Board approved the study with waiver of consent for infants and providers.

Patient Selection

Our cohort consisted of all infants who received mechanical ventilation in our NICU during the study period. The unit of observation for this study was an individual patient (ventilator) day. Infants were considered "at-risk" for the outcome (UE) on all days when they were mechanically ventilated through an ETT. Thus, "at-risk" time began when an infant was either intubated in the NICU or, if intubated outside of the NICU, was admitted to the NICU intubated. "At-risk" time ended when an infant was extubated (planned or unplanned), discharged to another unit, received a tracheostomy, or died. Infants who were extubated and then reintubated were eligible for multiple periods of "at-risk" time.

Study Outcome

The primary outcome in our study was a UE. UE was defined as any removal of an ETT that was not planned in advance by the medical team. This included ETTs dislodged by the patient and those removed inadvertently during routine nursing/medical care. ETTs that were intentionally removed during a code or a period of patient decompensation were included as a UE unless there was objective evidence that the ETT was in the trachea and patent. Our NICU has a standardized protocol to determine whether an ETT is in the trachea and patent before emergent removal. This protocol consists of auscultation for breath sounds, assessment for expiratory waveforms on the ventilator, and use of an end-tidal CO_2 detector. Direct laryngoscopy was not used to determine if the ETT was in the trachea. We only included UEs that occurred in the NICU (excluding the delivery room, operating rooms, and those occurring in transport). Four data streams were used to ascertain the occurrence of a UE, the underlying cause of the UE, and adverse events associated with the UE: (1) review of a miniroot cause analysis form completed by the bedside team immediately after a UE, (2) daily medical record review of all intubated infants in our NICU, (3) review of all reports of UEs in our hospital's voluntary incident reporting system, and (4) an ongoing list of all UEs that the NICU RTs complete after each event. Data on each UE were abstracted from the four data streams by the study primary investigator (L.D.H.) and reviewed by a multidisciplinary group that met monthly to determine if each event met the criteria for UE.

Independent Variables

We prospectively collected clinical variables on all intubated infants in our NICU. The variables chosen have either been associated with UE in previous studies or were hypothesized to be associated with UE in our NICU. These included demographic data, gestational age, BW, chronological age (CA), postmenstrual age (PMA), cumulative duration of ventilation, and illness severity using clinical risk index for babies (CRIB) scores.[13] After consideration of multiple variables, we limited the independent variables for our model to three variables that were readily available at the bedside, objective, generalizable to other NICUs, and could be prospectively used by front-line clinicians to identify infants who may be at increased risk of UE. These variables were CA, BW, and PMA at the time of intubation. CA was defined as the number of completed days since birth. PMA was defined as the gestational age in completed weeks (using the best obstetric estimate available at the time of NICU admission) plus the CA at the time of the intubation. We collected clinical data on each UE through the four data streams detailed previously.

Analysis

Demographic and clinical variables of infants with and without a UE during the study period were compared using Wilcoxon rank-sum tests for continuous nonparametric data and χ^2 tests for categorical data. Descriptive statistics were generated to assess the causes of UE and associated complications. To assess the association of our hypothesized clinical variables (CA, BW, and PMA) with the daily probability of a UE, we fit a multivariable logistic regression model with clustering at the patient level. The unit of analysis for our model was an individual patient (ventilator) day with an event defined as a UE on that day. Logistic regression allowed us to fit a discrete-time, time-to-event model that flexibly estimates the change in probability of UE over time as a function of covariates. In particular, we used restricted cubic splines (3 degrees of freedom) to allow a flexible relationship of CA, BW, and PMA with UE. Spline knot locations were chosen at clinically relevant values that corresponded to the underlying distribution of our data. As two of our variables (CA and PMA) changed together over time, we fixed PMA at the time of intubation and allowed CA to change over time. We used a robust sandwich estimator (Huber–White) clustering on subject identifier to account for repeated daily assessments of the same patient. Data were housed in the Research Electronic Data Capture program[14] hosted at the Vanderbilt University Medical Center. All analyses were performed in R version 3.1.3 using a two-sided significance level of 0.05.

Results

During the study period, 2,220 infants were hospitalized in the NICU for a total of 49,702 hospital days. A total of 718 infants received mechanical ventilation for 5,611 hospital (ventilator) days (Fig. 1). A total of 118 extubation events were submitted to the multidisciplinary team for consideration. Of these, 117 events in 81 infants met objective study criteria for UE (rate: 2.09 UE per 100 ventilator days, which remained stable throughout the study period). Medical records review was the most reliable avenue to identify UE (112/117; 96%) followed by the running list of UE in the RT office (84/117; 72%), bedside miniroot cause analysis huddle forms (75/117; 64%), and report in the hospital voluntary incident reporting system (66/117; 56%). Infant characteristics by UE status are shown in Table 1. Infants who had a UE had lower BW, were more premature at birth, older at the time of admission to our NICU, had higher CRIB scores, and had a longer duration of mechanical ventilation.

Results from our multivariable logistic regression model are shown in Table 2.We found that the daily probability of UE did not change significantly during the first week of life (adjusted odds ratio [aOR]: 0.5, 95% confidence interval [CI]: 0.17–1.47). After day 7 of life, the daily probability of a UE increased over the remainder of the NICU stay with the greatest increase from chronological day 7 to 28 (aOR: 1.36; 95% CI: 1.06–1.75). A predicted probability curve for a hypothetical infant based on our model is shown in Fig. 2. BW and PMA were not significantly associated with UE in our multivariable model.

UEs occurred at a median CA of 26 days (interquartile range [IQR]: 10–29 days), a median PMA of 34 weeks (IQR: 28–41 weeks), and a median weight of 1,755 g (IQR: 1,075– 3,027 g). About half (57/117; 49%) of the UE events occurred while an infant was either receiving a sedative/analgesic medication or had a PRN sedative/analgesic medication available. Approximately one-third of UE events (42/117; 36%) occurred in infants with a prior UE in our NICU.

We were able to ascertain the cause of the UE in 81/117 (69%) cases. The most commonly reported cause was dislodgement of the ETT due to movement by the patient (32/81; 40%). This movement was reported to be secondary to pain, agitation, poor sedation, or typical developmental activity. The second most commonly reported cause of UE was accidental extubation during retaping of the ETT (22/81; 27%) (Table 3). The cause of UE was associated with weight and maturity at the time of the extubation. Compared with infants who had their ETT dislodged during retaping, infants reported to have dislodged their own ETT were larger (median 2,685 g, IQR 1,677–3,410 vs. 975 g, IQR 620–1,600, $p < 0.001$), more mature (median PMA 41 weeks, IQR 33–44 vs. 28 weeks, IQR 26–34, $p < 0.001$), and older at extubation (median CA 56 days, IQR 25–109 vs. 16 days, IQR 10–37, $p = 0.004$).

We found that UEs were associated with significant harm (Table 3). A total of 68/117 (58%) infants were reintubated immediately after UE, 23/117 (20%) were placed on continuous positive airway pressure (CPAP), 18/117 (15%) were placed on high flow nasal cannula, 6/117 (5%) required no respiratory support, and 2/117 (2%) were placed on low flow nasal cannula. Ultimately, reintubation was performed within 24 hours after 81/117 (69%) UEs. Frequent cardiorespiratory compromise was associated with UE, including bradycardia (heart rate less than 60 bpm for >5 seconds) with 38/117 extubations (32%), chest compressions performed with 7/117 extubations (6%), and epinephrine administered for bradycardia with 3/117 extubations (3%). In 73/117 UE events, the lowest oxygen saturation associated with the UE was documented. The median lowest O_2 saturation was 31% (IQR: 9–60), and infants had oxygen saturations less than 80% in 65/73 (89%) UE events.

Discussion

This study provides the first evidence that the daily risk and causes of UE in newborns change over the course of an infant's hospitalization and are associated with CA. From the end of week 1 through week 4 of life, the odds of a UE increase by 36% per week. The causes of UE changed depending upon the age and size of the infant, with "iatrogenic" causes seen primarily in infants less than 28 weeks' PMA, representing a modifiable threat to patient safety in the smallest infants. Our study also demonstrates that more than two-thirds of UEs are associated with cardiorespiratory complications.

Our work documents for the first time a complex relationship between the causes of UE and developmental maturity. Infants in our cohort with UE generally fit into one of two categories: (1) iatrogenic, infants less than or equal to 28 weeks' PMA whose ETT was dislodged during retaping or while being moved by the healthcare team, and (2) self-extubation, infants greater than 28 weeks' PMA whose ETT was dislodged by their own movement. This finding is not unexpected given the short length of the trachea in younger, smaller infants and the increasing spontaneous and vigorous activity expected with growth and development of preterm infants. This suggests that, at least in our NICU, different interventions are needed to target these two mechanisms. For infants less than or equal to 28 weeks, respiratory care practices that promote careful attention to ETT maintenance during procedures (retaping, procedural movement) would be expected to improve the UE rate. Infants in the older group present a more challenging problem and will likely require a multifactorial intervention (i.e., nonpharmacological and pharmacological treatment of pain/agitation, evidence-based ventilation strategies, consideration of timing of tracheostomy) to balance the need for a stable airway with developmentally appropriate care.

UEs in the NICU are associated with substantial patient harm.[1,15] Two prior studies reported high rates of bradycardia and cardiopulmonary resuscitation after UE in newborns.[1,15] In these studies, bradycardia occurred after 39 (Kleiber and Hummel[15]) and 46% (Horimoto et al[1]) of UEs with cardiopulmonary resuscitation provided after 5 (Kleiber and Hummel[15]) and 12% (Horimoto et al[1]) of extubations, respectively. Our results are comparable with bradycardia in 32%, chest compressions in 6%, and epinephrine administration for bradycardia in 3% of our cohort associated with a UE event. Although the long-term consequences of UE in critically ill newborns have not been described, children with UE in a pediatric intensive care unit (ICU) have longer median ICU length of stay (10 vs. 4.5 days; $p < 0.001$), longer median hospital stay (16.5 vs. 10 days; $p < 0.001$), and higher total hospital costs compared with children without UE.[16]

Contemporary studies report that the proportion of infants who are reintubated after UE varies from 25 to 75%.[3,5] One of the largest studies to evaluate UEs in newborns included 304 patients ventilated for a total of 3,786 days over 5.5 years. In this cohort, 115 UEs occurred in 59 patients, and the reintubation rate was 66%,[2] similar to the reintubation rate of 69% in our cohort. Taken together, these observations indicate that approximately one-third of infants remained extubated following a UE. These data suggest that interventions to promote planned extubation prior to reaching periods of higher risk may substantially decrease the UE rate and subsequent complications. Objective measures of extubation readiness including spontaneous breathing trials have been tested in multiple settings including the NICU[17,18] and seem promising,[19] though their use in NICUs remains limited.[20] Nonphysician driven ventilator-weaning protocols have been shown to facilitate early extubation in adults and children.[21] Observational reports have suggested benefit in newborns[22]; however, these protocols and the optimal method of implementation have not been well assessed in the neonatal population.[23]

Our study has several limitations. First, this is a single-center study, which may limit the generalizability of our findings. Published rates and causes of UE vary widely among centers,[3,5–7] and it is possible that the age-dependent risk we observed is also center-specific. Second, we did not quantify or adjust for all possible confounders in our multivariable model. To build a clinically applicable model to identify infants at increased risk of UE, we chose to include only those infant factors that were readily available at the bedside and would not differ across centers. Other relevant factors that contribute to UE, such as sedation and analgesic medication use, pain/sedation scores, ETT fixation methods, respiratory care protocols, patterns of noninvasive ventilation/ CPAP use, and nurse/RT staffing and experience, were intentionally excluded given the anticipated variation among centers. All of these factors deserve future study to determine their role in causing or preventing UE. Finally, we chose a definition of UE that was intentionally broad to capture all possible events including those where the ETT may have been in the trachea but objective markers for intubation were not met. This broad definition could have led to misclassification of the outcome. Future studies should consider using objective criteria such as direct laryngoscopy to visualize the vocal cords and ETT to better define UE events. As others have called for, multicenter collaborative research with common definitions of UE and their causes are needed to better inform potential preventive interventions.[24]

To date, this is the largest prospective study to evaluate the epidemiological factors associated with UE in newborns in the NICU. Further strengths include the use of patient-level variables that are easily known at the bedside and are generalizable among centers, the use of restricted cubic splines in our model to better understand the dynamic relationship of increasing age on the probability of UE, and the use of a model that allows us to isolate patient variables only on the days they were intubated. We will prospectively use these data in our NICU to identify infants at the highest risk of UE and target them to test interventions such as ventilator weaning protocols,[22] extubation readiness trials,[17] ETT taping bundles,[2] and sedation/containment protocols.[25] Future work to determine the long-term consequences of UE in critically ill newborns is also needed.

Conclusion

We have shown that the daily risk and causes of UE in newborns are dynamic and associated with increasing CA, likely as a result of changing developmental activity and anatomical size. These data can be used to identify infants prospectively who are at the highest risk of UE. These findings support the idea that to mitigate the risk of UE and to provide the safest mechanical ventilation, respiratory care practices need to be tailored to an infant’s anatomical size and developmental maturity. Large-scale, collaborative research and quality improvement work is needed to confirm our findings, evaluate long-term outcomes of UE, and identify and test interventions to address this threat to safe mechanical ventilation in critically ill newborns.

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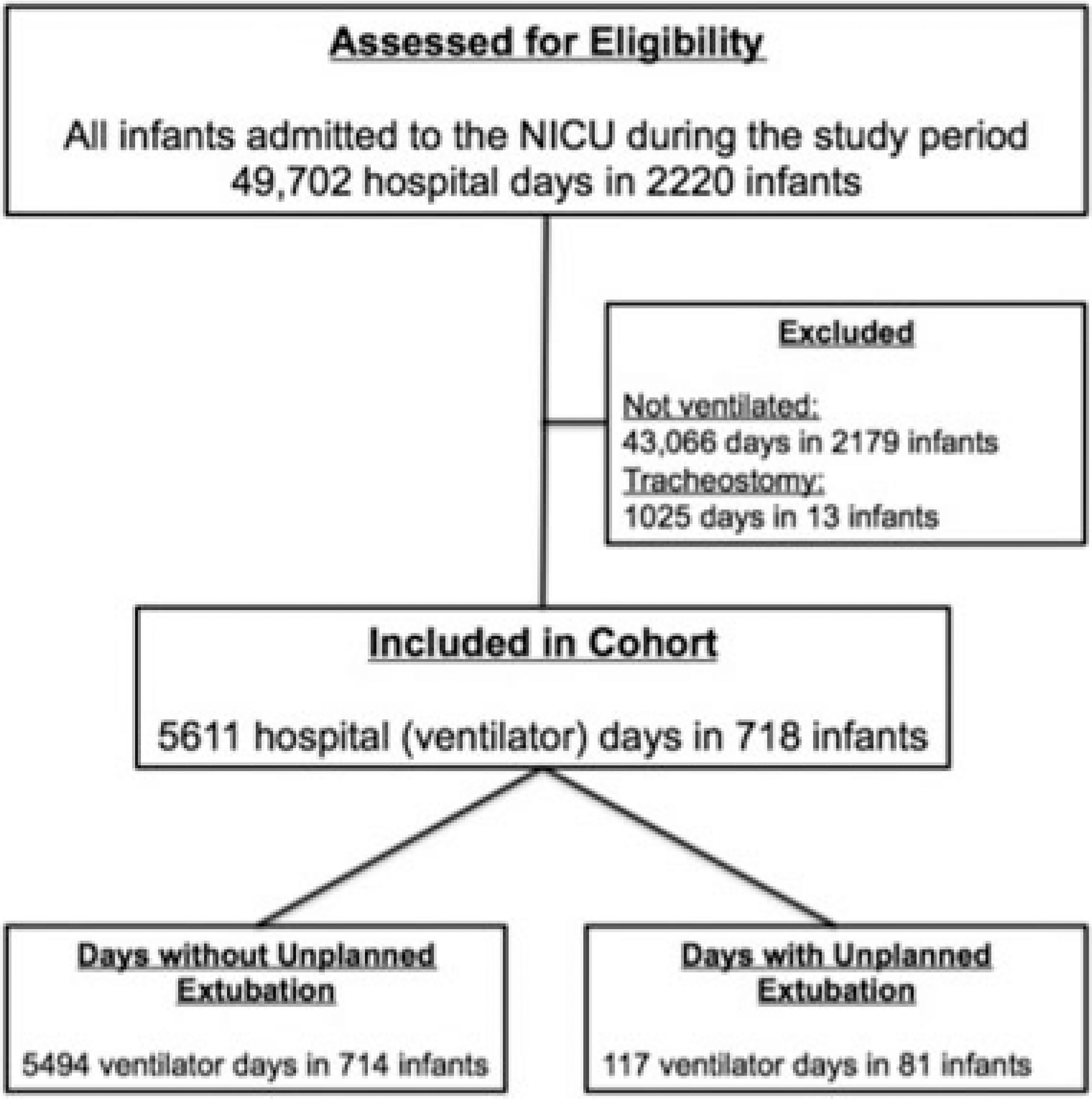

Fig. 1.
Flowchart of hospital days/infants included in the study cohort.

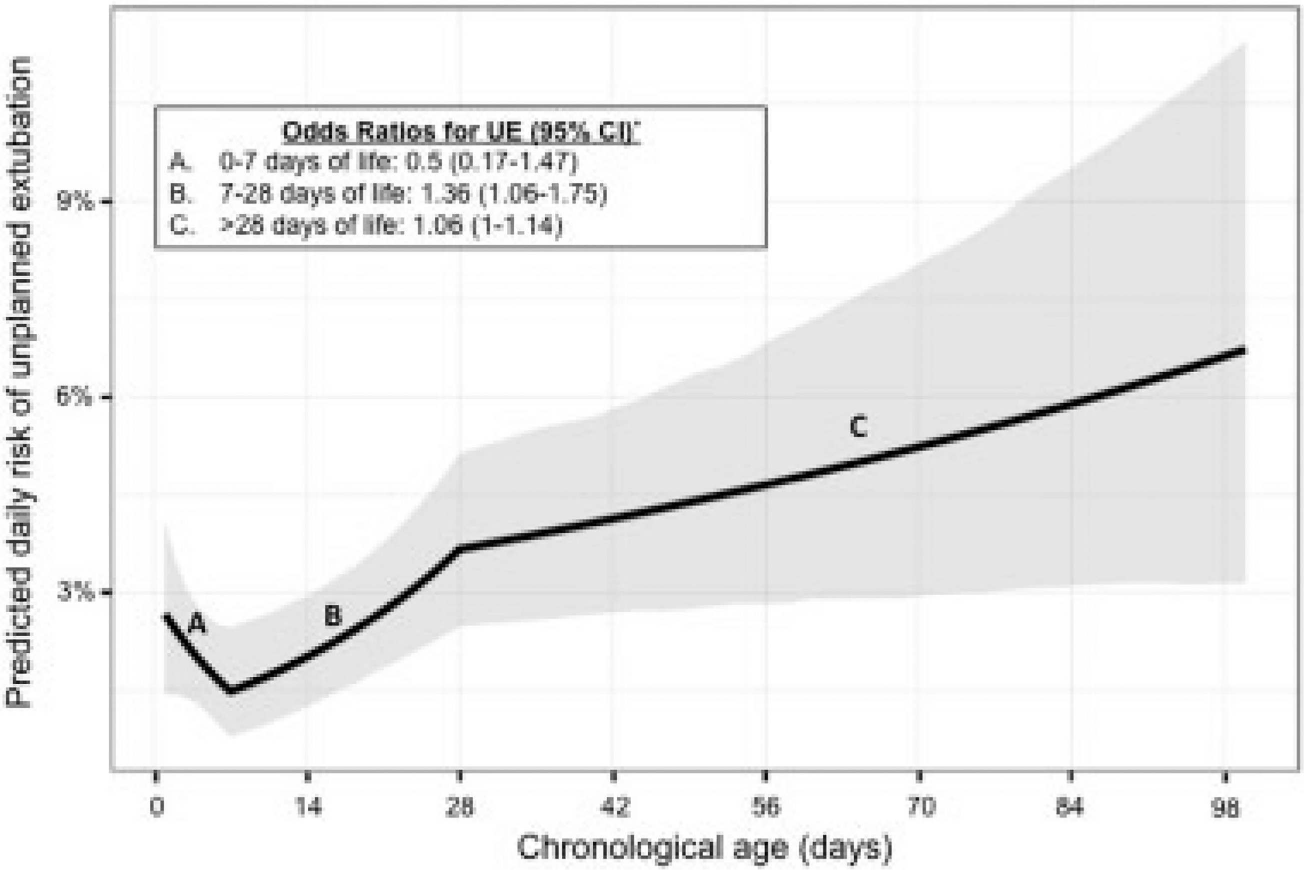

Fig. 2.
Predicted daily unplanned extubation risk (solid line) with 95% confidence intervals (shading) by chronological age adjusted for a 32-week gestation, 1,800-g birth weight infant based on ourmodel. For a newborn with different characteristics at birth, the daily predicted probability could be higher or lower, but the curve would remain the same shape. *Each odds ratio indicates the change in risk of unplanned extubation for a 7-day change in chronological age. For example, a 14-day-old infant would have a 36% higher risk of unplanned extubation than a 7-day-old infant.

Table 1

Characteristics of infants with and without unplanned extubations

Characteristic	Infants without an unplanned extubation (*n* = 637)	Infants with an unplanned extubation (*n* = 81)	*p*-Value
Male sex, *n* (%)	370 (58)	45 (56)	0.67[a]
Race			
White	528 (83)	59 (73)	0.09[a]
Black	91 (14)	19 (23)	
Other[b]	18 (3)	3 (4)	
Inborn, *n* (%)	253 (40)	38 (47)	0.2[a]
Day of life at NICU admission, median [IQR]	0 [0,1]	0 [0,5]	0.03[c]
Birth weight, median grams [IQR]	2,170 [1,170,3,060]	1,020 [694,2,320]	<0.01[c]
Gestational age at birth, median weeks [IQR]	34 [29,37]	27 [25,35]	<0.01[c]
CRIB score, median [IQR]	3 [0,4]	4 [1,7]	<0.01[c]
Total ventilator days, median [IQR]	2 [1,6]	20 [5,40]	<0.01[c]

Abbreviations: IQR, interquartile range; NICU, Neonatal Intensive Care Unit.

[a]Chi-squared test.

[b]Other races included Asian and Pacific Islander.

[c]Wilcoxon rank–sum test.

Table 2

Multivariable logistic regression model of risk of unplanned extubation

Covariate	Odds ratio [95% confidence intervals]	*p*-Value
Chronological age[a]		<0.01[b]
0–7 d	0.5 [0.17, 1.47]	
7–28 d	1.36 [1.06, 1.75]	
> 28 d	1.06 [1.0, 1.14]	
Birth weight[c]		0.07[b]
< 1,500 g	1.51 [0.96, 2.38]	
1,500–2,500 g	0.76 [0.28, 2.04]	
> 2,500 g	0.76 [0.53, 1.07]	
Postmenstrual age[d]	0.92 [0.6, 1.41]	0.69

[a]Odds change for a 7-day change in chronological age.

[b]*p*-Value for the entire covariate.

[c]Odds change for a 500-g change in birth weight.

[d]Odds change for a 50-day change in postmenstrual age.

Table 3

Reported causes, associated adverse events, and respiratory interventions after unplanned extubations

Reported causes of unplanned extubation[a]	***n* (%)**
Dislodged by the patient	32 (40)
Dislodged during retaping	22 (27)
Dislodged during movement by member of the health care team	12 (15)
Tape became soiled	9 (11)
Removed during a code situation	2 (2)
ETT plugged by mucus or blood	2 (2)
Other[b]	2 (2)
Associated adverse events	***n* (%)**
Reintubation within 24 h	81 (69)
Bradycardia (heart rate <60 bpm for >5 s)	38 (32)
Chest compressions	7 (6)
Bolus epinephrine	3 (3)
Lowest recorded oxygen saturation, median [IQR][c]	31 [9,60]
Respiratory support immediately after unplanned extubation	***n* (%)**
Immediate reintubation	68 (58)
CPAP[d]	23 (20)
High-flow nasal cannula[e]	18 (15)
Room air (no respiratory support)	6 (5)
Low-flow nasal cannula	2 (2)

Abbreviations: bpm, beats per minute; CPAP, continuous positive airway pressure; ETT, endotracheal tube; IQR, interquartile range.

[a]Available for 81 extubations.

[b]Tube dislodged during ETT suctioning; ventilator tubing was unsupported.

[c]Available for 73 extubations.

[d]Eight infants were reintubated within 24 hours.

[e]Five infants were reintubated within 24 hours.