Continuing Medical Education Article

The endotracheal tube air leak test does not predict extubation outcome in critically ill pediatric patients

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LEARNING OBJECTIVES

On completion of this article, the reader should be able to:

1. Explain factors associated with extubation success and critically ill pediatric patients.
2. Identify the relationship between various approaches to postextubation support and extubation success in the pediatric intensive care unit.
3. Identify the controversies associated with air leak testing and extubation success or failure in pediatric patients.

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Objective: Endotracheal tube air leak pressures are used to predict postextubation upper airway compromise such as stridor, upper airway obstruction, or risk of reintubation. To determine whether the absence of an endotracheal tube air leak (air leak test ≥30 cm H_2O) measured during the course of mechanical ventilation predicts extubation failure in infants and children.

Design: Prospective, blinded cohort.

Setting: Multidisciplinary pediatric intensive care unit of a university hospital.

Patients: Patients younger than or equal to 18 yrs and intubated ≥24 hrs.

Interventions: The pressure required to produce an audible endotracheal tube air leak was measured within 12 hrs of intubation and extubation. Unless prescribed by the medical care team, patients did not receive neuromuscular blocking agents during air leak test measurements.

Measurements and Main Results: The need for reintubation (i.e., extubation failure) was recorded during the 24-hr postextubation period. Seventy-four patients were enrolled resulting in 59 observed extubation trials. The extubation failure rate was 15.3% (9 of 59). Seven patients

were treated for postextubation stridor. Extubation failure was associated with a longer median length of ventilation, 177 vs. 78 hrs, *p* = 0.03. Extubation success was associated with the use of postextubation noninvasive ventilation (*p* = 0.04). The air leak was absent for the duration of mechanical ventilation (i.e., ≥30 cm H_2O at intubation and extubation) in ten patients. Absence of the air leak did not predict extubation failure (negative predictive value 27%, 95% confidence interval 6–60). The air leak test was ≥30 cm H_2O before extubation in 47% (28 of 59) of patients yet 23 patients extubated successfully (negative predictive value 18%).

Conclusions: An endotracheal tube air leak pressure ≥30 cm H_2O measured in the nonparalyzed patient before extubation or for the duration of mechanical ventilation was common and did not predict an increased risk for extubation failure. Pediatric patients who are clinically identified as candidates for an extubation trial but do not have an endotracheal tube air leak may successfully tolerate removal of the endotracheal tube. (Pediatr Crit Care Med 2008; 9:490–496)

KEY WORDS: air leak test; cuff leak test; predictor variables; extubation; mechanical ventilation; endotracheal tube leak; respiratory failure; pediatric; neonate; stridor; noninvasive ventilation

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The extubation failure rate in the pediatric intensive care unit (PICU) ranges from 5% to 29% (1–13). The need for reintubation significantly increases morbidity and mortality among critically ill patients (4, 13). Extubation failure results in a prolonged length of ventilation (LOV) and intensive care stay, and may lead to repeated extubation failures (4, 5, 12–14). Extubation failure is independently associated with a five-fold increased risk of death in pediatric patients (4, 5, 15). The primary etiology of extubation failure in the pediatric population is upper airway obstruction.

The endotracheal tube (ETT) air leak test (ALT) is often measured before extubation to predict postextubation upper airway obstruction. The ALT identifies the pressure required to produce an audible leak of air between the ETT and the tracheal wall when auscultated with a stethoscope placed over the larynx (16). If the pressure required to produce an air leak is "high" (i.e., ALT $\geq$30 cm H_2O), the clinician may infer that the ETT is "tight" within the upper airway secondary to acquired upper airway edema and/or the presence of a larger than appropriate ETT size (8–20). In a small case series evaluating the predictive value of the ALT measured before extubation in patients who are mechanically ventilated and pharmacologically paralyzed after laryngotracheal reconstruction or cricoid split surgery, an ALT <20 cm H_2O was 100% sensitive in those patients with a successful extubation, whereas an ALT $\geq$30 cm H_2O was 100% predictive of postextubation stridor or the need for reintubation (9).

Furthermore, preextubation ALT measurements are used to modify clinical decision making. In a survey, Foland et al. (21) found that 76% of pediatric intensivists reported routinely measuring the ALT before extubation. When the ALT is $\geq$30 cm H_2O, clinicians reported the test changed their clinical judgment: 95% of respondents would delay extubation; 60% would administer systemic corticosteroids to reduce airway swelling; whereas 42% would reintubate the patient to place a smaller sized ETT.

It is not currently standard practice to measure the ALT at intubation or to monitor the air leak pressure during the course of mechanical ventilation in intubated PICU patients. When measured at intubation, an ALT <20 cm H_2O is reported in the anesthesia literature as a method to select an appropriately sized ETT that prevents tracheal compression injury and facilitates extubation without postextubation airway compromise (22–26). However, in critically ill patients a significant ETT air leak may result in ineffective ventilation particularly when pulmonary compliance is low. We hypothesized PICU patients may be intubated with larger ETTs which could result in the loss of the ETT air leak for the duration of mechanical ventilation. Therefore, we conducted the first prospective, blinded study to evaluate the ALT as a predictor of extubation failure in critically ill infants and children.

MATERIALS AND METHODS

Study Population. Mechanically ventilated PICU patients were prospectively enrolled from October 2003 to April 2005 if they met the following inclusion criteria: 1) $\geq$37 wks gestational age to $\leq$18 yrs of age; 2) PICU admission within 12 hrs of intubation; and 3) expected duration of mechanical ventilation $\geq$24 hrs. Patients were excluded for: 1) receiving mechanical ventilation via a tracheostomy; 2) known vocal cord paralysis; 3) limitations of medical care in place; and 4) high frequency ventilation, inhaled nitric oxide, or extracorporeal membrane oxygenation support within 24 hrs of intubation. The study was approved by the Duke University Institutional Review Board and informed consent was obtained for all patients before enrollment.

Research Protocol and Data Collection. Demographic data were collected including literature-based risk factors previously associated with extubation failure (1, 3–7, 12, 14, 27, 28) such as: 1) patient factors (age, gender, race, weight, admission diagnosis, pediatric risk of mortality II score); 2) airway factors (presence of known airway anomalies such as previous airway surgery, trisomy 21, laryngo- or tracheomalacia); 3) intubation factors (history of recent intubation within prior 7 days, history of recent systemic corticosteroid use within prior 7 days, number of intubation attempts, ETT size, presence or absence of an ETT cuff, nasal vs. orotracheal placement, and hospital location where intubation was performed); and 4) mechanical ventilation factors (systemic steroid use during mechanical ventilation and duration of mechanical ventilation). The size of the ETT placed for intubation was compared with the age-appropriate cuffed and uncuffed ETT size recommended by the pediatric advanced life support (PALS) guidelines (29). The ETT size was documented as: too large if >PALS + 0.5 mm; too small if >PALS − 0.5 mm; and as appropriate if within PALS ± 0.5 mm.

The ALT was performed in all patients within 12 hrs of a planned extubation trial. For the first consecutive 50 patients, the ALT was also measured within 12 hrs of intubation.

One of two study investigators not directly involved in the patient's care performed the ALT using a standardized process (10, 25). The ALT was performed with the patient supine, head midline, and chin in the neutral position. Unless prescribed by the medical care team, patients did not receive neuromuscular blocking agents during ALT measurements. For a cuffed ETT, air was completely extracted from the cuff with a syringe and complete deflation was confirmed with a cuff pressure manometer. An Ambu bag with an in-line manometer was connected to the proximal end of the ETT. A stethoscope bell was placed over the larynx while manual pressure was applied to achieve sequential pressures of 20, 25, and 30 cm H_2O. An audible air leak was recorded as present or absent at each of the three pressures tested. The air leak was categorized as "present" if the air leak pressure was <30 cm H_2O and "absent" if $\geq$30 cm H_2O pressure was required. An air leak pressure measured as $\geq$30 cm H_2O at both intubation and extubation defined the air leak as absent for the duration of mechanical ventilation.

Extubation. During the study period, the standardized use of a spontaneous breathing trial or extubation readiness protocols were not in place. Extubation timing and all postextubation interventions were determined by the care team based on an assessment of the available clinical data. The patient care team, including all respiratory therapists, remained blinded to the ALT results. All study patients were followed for 24 hrs postextubation and the use of noninvasive respiratory support and reintubation were recorded. Postextubation airway support was defined as the use of any one or more of the following: nasal trumpet, helium-oxygen mixtures (heliox), racemic epinephrine, intravenous steroid initiation, or noninvasive ventilation with continuous positive airway pressure or bilevel positive airway pressure ventilation. Extubation failure was defined as the need for reintubation within 24 hrs of a planned extubation. When reintubation occurred, the medical team attributed a presumed etiology for reintubation to one of the following categories: upper airway obstruction/stridor, hypoventilation/oversedation, lower respiratory failure, or other (e.g., acidosis, systemic deterioration, or a combination of etiologies).

Statistical Analyses. Continuous variables were reported as medians and ranges whereas percentages were reported as discrete variables. Categorical variables were compared using either a chi-square or the Fisher's exact test where appropriate. Each predictor was independently tested for its association with extubation failure. Predictors previously shown to be associated with extubation outcome were tested: male gender, age <24 months, trisomy 21, known medical or surgical airway pathology, and LOV $\geq$48 hrs. Evaluation of the ALT as a predictor of extubation outcome was determined by sensitivity, specificity, positive and negative predictive values,

Table 1. Study population characteristics (n = 59)

Patient Features	Frequency	%
Gender, male (female)	42 (17)	71.2 (28.8)
Age distribution (months)		
≤6	29	49.2
7 to <24	15	25.4
≥24	15	25.4
Underlying primary condition		
Cardiac	30	50.9
Respiratory	13	22.0
Neurologic	4	6.7
Oncologic	6	10.2
Other[a]	6	10.2
PRISM II range (median)	1.0–40.0 (12.0)	—
Airway features		
Airway anomalies[b]	17	28.8
Malacia	6	10.2
Airway surgery	10	17.0
Trisomy 21	7	11.9
Other[c]	3	5.1
None	42	71.2
Prior intubation[d] vs.	22	37.3
None	37	62.7
Steroid exposure[d] vs.	24	40.7
None	35	59.3
Endotracheal tube features		
Location of intubation, PICU vs.	23	39.0
OR	33	56.0
Other[e]	3	5.0
ETT size[f]		
Appropriate (PALS ± 0.5 mm)	51	86.4
Too small (>PALS − 0.5 mm)	4	6.8
Too large (>PALS + 0.5 mm)	4	6.8
Cuffed ETT vs.	11	18.6
Uncuffed	48	81.4
Intubation attempts range (median)	1–6 (1)	—
Air leak test		
Intubation ALT ≥30 cm H_2O	33	66.0
Intubation ALT <30 cm H_2O	17	34.0
Extubation ALT ≥30 cm H_2O	28	47.6
Extubation ALT <30 cm H_2O	31	52.4
Absent for duration MV[g]	10	20.0
Mechanical ventilation		
LOV, hrs range (median)	17.8–765.5 (96.5)	

Factors included in this table are risk factors for extubation failure.

PRISM II, pediatric risk of mortality; PICU, pediatric intensive care unit; OR, operating room; ETT, endotracheal tube; PALS, pediatric advanced life support; ALT, air leak test; MV, mechanical ventilation; LOV, length of mechanical ventilation.

[a]Other: trauma, plastic surgery, intestinal surgery/disorder; [b]Seven patients had more than one airway anomaly; [c]Other airway history includes history of intermittent noninvasive positive airway pressure use (n = 1), postdiaphragm plication (n = 1), and angioedema (n = 1); [d]≤7 days before intubation; [e]Other location: ER, wards, and outside hospital; [f]Comparison of size of ETT placed vs. pediatric advanced life support recommendations = (Age in yrs/4 + 4) for uncuffed ETT and for cuffed ETT = (Age in yrs/3 + 4); [g]ALT ≥30 cm H_2O at both intubation and extubation.

and positive and negative likelihood ratios (LRs). Analyses were performed using STATA version 9 (College Station, TX). A p value ≤0.05 was considered statistically significant for all analyses.

RESULTS

Seventy-four patients were prospectively enrolled resulting in 59 observed extubation trials. The 15 patients excluded did not undergo a full extubation trial because three patients died; two underwent a tracheostomy procedure; one withdrew consent; two were extubated but electively reintubated within 24 hrs for operative procedures; two self-extubated; and five were extubated before measurement of the ALT.

The median age for the study cohort was 6.3 months (range 0 days–17.6 yrs) and the median LOV was 96.5 hrs (range 17.8–765.5 hrs). The prevalence of other risk factors for extubation failure included male gender (71%); age <24 months (74.6%); airway anomalies (28.8%); LOV ≥48 hrs in 74.6%. ETT sizes were within 0.5 mm of the PALS-recommended size in 51 of 59 patients (86.4%). Only four patients had an ETT >0.5 mm larger than the PALS-recommended ETT size. Characteristics of the study cohort are summarized in Table 1.

Fifty of 59 (84.7%) extubation trials were successful. The extubation failure rate was 15.3% (9 of 59 patients). The causes of extubation failure were upper airway obstruction (n = 3), lower airway failure (n = 2), hypoventilation (n = 1), or other etiologies (n = 3). Interventions attempted before reintubation included continuous positive airway pressure (n = 5) and a combination of racemic epinephrine and intravenous dexamethasone (n = 1). The median time from extubation to reintubation was 3.0 hrs (range 10 mins–19.5 hrs). Postextubation stridor occurred in seven patients (11.9%). Of these seven patients, five patients received racemic epinephrine, each patient received an average of five doses of intravenous dexamethasone, and one patient was ultimately reintubated. No patient received heliox postextubation.

Extubation outcome was not associated with patient age, gender, airway anomalies, location of intubation, number of intubation attempts, or primary admitting diagnosis (Table 2). There was no significant association between a higher pediatric risk of mortality score and extubation failure ($p = 0.09$). Patients who failed extubation had a statistically longer median duration of mechanical ventilation before extubation than those patients who successfully extubated (177 vs. 78 hrs; $p = 0.03$). The receiver operating characteristic curve identified the threshold value of LOV of 97 hrs as a discriminator between successful and failed extubation with 78% sensitivity and 67% specificity. As the LOV increased, the proportion of failed extubations also increased although this was not statistically significant ($p = 0.3$) (Fig. 1). The use of continuous positive airway pressure for postextubation support was significantly associated with extubation success ($p = 0.04$). Systemic corticosteroid exposure within 7 days before intubation was associated with extubation success ($p = 0.006$).

The air leak was absent (≥30 cm H_2O) within 12 hrs of intubation in 33 of 50 patients (66%). Twenty-three of these patients recovered an air leak before extu-

Table 2. Predictors of extubation failure vs. success

	Success (n = 50)	Failure (n = 9)	OR	p
Airway features				
Airway anomaly vs.	13	4	0.4	NS
None	37	5		
Airway surgery vs.	8	2	0.7	NS
None	42	7		
Trisomy 21 vs.	5	2	0.4	NS
None	45	7		
Prior intubation[a] vs.	20	2	2.3	NS
None	30	7		
Steroid exposure[a] vs.	24	0	—	0.006
None	26	9		
ETT features				
Extubation ALT $\geq$30 cm H_2O	23	5	1.5	NS
Extubation ALT <30 cm H_2O	27	4		
ALT absent for duration MV[b]	7	3	0.3	NS
ALT present during MV[c]	43	6		
Cuffed ETT vs.	10	1	2.0	NS
Uncuffed	40	8		
Postextubation support				
CPAP vs.	11	5	0.2	0.04
None	39	4		
Noninvasive bilevel positive pressure ventilation vs.	5	0	—	NS
None	45	9		
Nasal trumpet vs.	3	0	—	NS
None	47	9		
Racemic epinephrine treatments vs.	5	1	0.9	NS
None	45	8		
Dexamethasone vs.	4	1	0.7	NS
None	46	8		

OR, odds ratio; ETT, endotracheal tube; ALT, air leak test; MV, mechanical ventilation; LOV, length of mechanical ventilation; CPAP, continuous positive airway pressure; NS, not significant.

[a]$\leq$7 days before intubation; [b]ALT $\geq$30 cm H_2O at both intubation and extubation; [c]ALT <30 cm H_2O at either intubation or extubation.
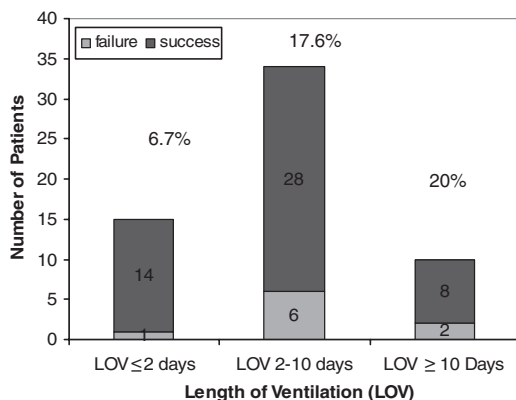

Figure 1. Length of mechanical ventilation (LOV) is divided into three known risk groups LOV $\leq$2 days, LOV between 2 and 10 days, and LOV $\geq$10 days. The percentage of patients who failed extubation (i.e., were reintubated within 24 hrs) increases as the LOV increases ($p = 0.3$).

bation. For ten patients (20%), the air leak remained absent for the duration of mechanical ventilation ($\geq$30 cm H_2O at intubation and extubation). The extubation failure rate in this subgroup was 30% (3 of 10) with reintubation attributed to upper airway obstruction in two patients and to other causes in the third patient. The absence of an ETT air leak for the duration of mechanical ventilation was not associated with larger ETT size, as the ETT size was appropriate in eight patients; too small in one patient; and too large in one patient. Absence of the ETT leak for the duration of mechanical ventilation did not predict extubation outcome: specificity 43%, negative predictive value (NPV) 30%, and the ratio for

Table 3. The pre-extubation air leak test does not aid clinical decision-making

	$\leq$20 cm H_2O	25 cm H_2O	$\geq$30 cm H_2O
Patients, success vs. failure	15 2	12 2	23 5
Sensitivity (%)	30.0	24.0	46.0
Specificity (%)	77.8	77.8	44.4
Positive predictive value (%)	88.3	85.7	82.1
Negative predictive value (%)	16.7	15.6	12.9
Positive likelihood ratio	1.4	1.1	0.8
Negative likelihood ratio	0.9	1.0	1.2
Accuracy (%)	37.3	32.2	45.8

An air leak test (ALT) recorded as 25 cm H_2O includes ALT that are between >20 cm H_2O and <30 cm H_2O. The ALT did not accurately discriminate between the group of patients who would fail extubation and those who would extubate successfully. Likelihood ratios <2 indicate that the ALT adds little information to alter clinical determination of extubation readiness.

the likelihood that such a patient would require reintubation was 0.38. If the ALT was present at any one point during mechanical ventilation (i.e., <30 cm H_2O at either intubation or extubation) this predicted extubation success with a sensitivity of 46%, positive predictive value 82%, and LR 0.83. Therefore, the air leak measurement at intubation did not correlate with extubation outcome ($p = 0.47$). Also, the change in the air leak measurement during the course of mechanical ventilation, whether present, improved, worsened or absent for the duration of mechanical ventilation did not correlate with extubation outcome ($p = 0.16, 0.65, 0.46,$ and $0.16,$ respectively).

More commonly, the preextubation ALT is used as a predictor of extubation outcome (Table 3). The air leak was absent in 28 of 59 patients (47.4%) before extubation. Despite an absent air leak, 23 of 28 patients (82.1%) successfully extubated. A preextubation ALT >20 cm H_2O did not predict extubation failure (NPV 16.7%) nor did an ALT $\geq$30 cm H_2O increase the likelihood of postextubation reintubation (LR 1.2). The preextubation ALT did not statistically predict extubation success or failure (LR 0.8–1.4). Nor was the ALT a predictor of the combined outcome of either need for postextubation respiratory support or reintubation ($p = 0.84$). The ALT results before extubation in the seven patients with postextubation stridor were 20 cm H_2O in three pa-

tients, 25 cm H_2O in one patient, and equal to 30 cm H_2O in three patients.

DISCUSSION

Predicting extubation outcome is of significant clinical importance because both extubation delay and extubation failure are associated with increased patient morbidity and mortality (12–15, 30–32). Extubation criteria that accurately discriminate between those patients who will successfully extubate and those who will fail extubation may help to modify clinical determinations of extubation readiness (33–35). Despite its prevalent use, the accuracy of the ALT in predicting postextubation upper airway compromise such as stridor, upper airway obstruction, or the need for reintubation is debated (8–10, 36–40). This study was the first prospective evaluation of the ALT as a predictor of extubation outcome in mechanically ventilated PICU patients.

Two important findings emerge from our study. First, our hypothesis that PICU patients may be intubated with larger than recommended ETT size was false. The absence of an ETT air leak before extubation in these study patients was not related to the placement of larger-sized ETTs. Second, the preextubation ALT is not an accurate discriminator of patients likely to extubate successfully or likely to have significant postextubation airway compromise and, therefore, adds little data to modify clinical decision making regarding extubation readiness in the mechanically ventilated PICU patient.

The predictive capacity of the ALT may depend on the patient cohort studied and the definition of extubation failure. For intubated patients with known upper airway pathology, including intubation after upper airway surgical reconstruction, burns, or laryngotracheobronchitis, the ALT may be an accurate predictor of extubation outcome (8, 9). Small, single-center retrospective studies measuring the ALT in pharmacologically paralyzed patients found that an ALT <20 cm H_2O before extubation was associated with a 100% extubation success rate whereas an ALT >30 H_2O was 100% predictive of postextubation stridor and/or reintubation (8–10). The authors concluded that the ALT should determine extubation timing, recommending extubation be delayed in patients with an ALT >20 cm H_2O until airway swelling decreased. However, for the patient without known upper airway disease or the nonpharma-

cologically paralyzed patient, such as most intubated PICU patients, only one recent retrospective study and this prospective study have evaluated the predictive capacity of the ALT. Mhanna et al. (10) performed a retrospective review of 105 PICU patients who had an ALT performed before extubation. Postextubation stridor occurred in 42 patients and four patients were reintubated within 48 hrs of extubation. The authors found the ALT to be a more sensitive predictor of postextubation stridor in older patients (≥7 yrs) than in younger patients (<7 yrs). In this study, we found an air leak ≥30 cm H_2O was no more predictive of extubation outcome in patients older than or equal to 7 yrs (NPV 0%) than in patients younger than 7 yrs (NPV 20%).

The value of the ALT measurement will vary considerably based on testing conditions. For a given patient, the ALT measurement will vary if midline head positioning is not maintained, if the patient is not pharmacologically paralyzed, and if testing is performed by more than one observer (9, 17, 36). Finholt et al. (17) provided the original description of ALT measurements performed in the setting of complete pharmacologic paralysis with the patient's head supine and midline. When these conditions were not maintained, the air leak pressures required to produce an audible air leak were generally higher and more interobserver variability was noted. Finholt et al. (17) noted that the air leak pressure increased progressively from 16.9 ± 1.3 cm H_2O with complete neuromuscular blockade to an average of 30.6 ± 1.4 cm H_2O after full recovery from neuromuscular blockade. In a similar study on nonparalyzed patients, Schwartz et al. (36) found an average variance of 38% at both high and low air leak pressure measurements between two trained observers. In this study cohort of nonparalyzed patients, we found 28 of 59 (47.4%) patients had an ALT ≥30 cm H_2O before extubation. Despite an absent air leak, 23 of 28 (82.1%) patients successfully extubated. We did not administer a neuromuscular blocking agent to patients to obtain the ALT, therefore, higher ALT pressures may be associated with the lack of complete muscle paralysis (16, 36–40). This may explain why higher ALT pressures in this cohort did not correlate with a greater risk for postextubation stridor, airway compromise or the need for reintubation.

No single test is likely to predict extubation outcome for an individual patient

with absolute certainty. However, a useful predictive tool must be able to accurately discriminate between patients who will extubate successfully and those who will require reintubation (41–43). The discriminatory power of a diagnostic test is expressed in terms of its sensitivity, specificity, positive predictive value, and NPV. We found the ALT did not accurately predict extubation outcome. Low air leak pressures (ALT <20 cm H_2O) may be a reassuring preextubation result (positive predictive value 88.3%), but high air leak pressures (ALT ≥30 cm H_2O) do not predict extubation failure (NPV 12.9%). LRs are calculated to express how significantly a predictive tool may modify clinical judgment (43). LR >10 or <0.1 indicate predictive tools which significantly modify clinical assessment. Experienced clinicians estimate the probability of extubation success or failure for each patient (i.e., pretest probability) using an assimilation of laboratory and radiologic data plus a subjective interpretation of the patients' ability to resume effective gas exchange and airway control once mechanical ventilation is discontinued. The LR for the predictive tool adds objective data to change the direction and magnitude of the pre- to the posttest probability of extubation outcome. We found the LR+ and LR− for all ALT results were between 0.8 and 1.4 indicating the ALT does not enhance clinical judgment of experienced providers to determine extubation readiness. Therefore, the ALT measured before extubation cannot be used as the sole criterion to determine extubation timing. Instead, the clinician must weigh clinical determination of extubation readiness along with an objective assessment of the likelihood for upper airway compromise (known upper airway disease or surgical condition or acquired airway edema) to determine the optimal extubation management and timing.

The ideal extubation failure rate for the PICU population is unknown. Thus, extubation timing is often a balance between the unknown risks of reintubation vs. prolonging the length of mechanical ventilation. The extubation failure rate in our cohort was 15.3%. Previous authors have reported similar rates of reintubation, ranging from 2.7% to 22%, when extubation readiness is determined by clinical judgment of experienced clinicians without standardized assessments of spontaneous breathing capacity (2, 4, 6–12). The extubation failure rate among

PICU patients is much higher when the patient has had prior airway surgery (29%) or a longer LOV (failure rate of 8% if LOV >48 hrs and of 17.5% if LOV >10 days) (4, 12). The extubation failure rate in our cohort may reflect the relative prevalence of these risk factors associated with extubation failure risk in our study population.

A limitation of this study is the small sample size which may have contributed to the inability to find a true association between the ALT and extubation outcome (type II error). A sample size calculation using a two-sample proportion (assuming $\alpha = 0.05$ and $\beta = 0.2$) indicated that 141 patients in each group were needed to detect a 10% reduction in postextubation airway compromise (given an adverse event rate of 5% in patients with an ALT <30 cm H_2O and of 15% in patients with an air leak ALT $\geq$30 cm H_2O). Thus, a larger study would be required to thoroughly assess the ALT in the context of other systematic evaluations of extubation readiness. However, the prospective, blinded study design maximized our potential to capture the population at risk for extubation failure and to accurately record patient, intubation, and mechanical ventilation characteristics to characterize the mechanically ventilated PICU population.

It is important to state the ALT when performed at intubation still remains a valuable tool to select an appropriately sized ETT, to monitor ETT cuff inflation pressure, and to serve as an indicator of the potential for tracheal wall injury. When measured at the time of intubation, an ALT $\geq$30 cm H_2O has been associated with compromised mucosal capillary blood flow and a higher incidence of postextubation adverse events (25). Thus, some pediatric institutions may elect to maintain the patient's mean arterial pressure higher than the air leak pressure, to reintubate these patients with a smaller ETT size, or to place a cuffed ETT and adjust the ETT cuff to maintain a suitable leak pressure (21, 25, 26). Unfortunately, reintubations and multiple intubation attempts to place a correctly sized ETT can also lead to tracheal injury and a greater risk for postextubation compromise (14). The benefits of a cuffed ETT for children undergoing general anesthesia has been documented, but has not yet been validated for the PICU patient with a longer LOV (25). We measured the ALT within 12 hrs of intubation which may have allowed time for postintubation airway

edema to occur and thus may account for the high prevalence of ALT $\geq$30 cm H_2O in our study cohort despite intubation with an appropriately sized ETT.

In the mechanically ventilated, critically ill pediatric patient it is likely that no single criterion can predict extubation failure. Extubation failure in the PICU population may be multifactorial and not isolated to a single etiology such as upper airway edema. An endotracheal tube air leak $\geq$30 cm H_2O was common in this population before extubation and was not associated with a greater likelihood for postextubation stridor, airway compromise, or need for reintubation. When the preextubation ALT is measured in the nonpharmacologically paralyzed patient, ALT $\geq$30 cm H_2O may reflect a recovery of laryngeal and hypopharyngeal muscle tone rather than the presence of laryngotracheal edema. Therefore, the preextubation ALT should not be used as a sole criterion of extubation timing. Measurement of the ALT at intubation remains an important tool to select an appropriately sized ETT and ETT cuff inflation pressure which minimize the potential risk for tracheal wall injury. Further research is needed to determine accurate predictors of extubation failure in mechanically ventilated pediatric intensive care unit patients.

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