The Efficacy of the Cuff Leak Test in Predicting Post-Extubation Stridor in Mechanically Ventilated ICU Patients: A Prospective Cohort Study

Ammar O. Alselmi[1], Rami H. Alkhalid[2], Mohammed A Alodhayb[3]

Respiratory Therapist
Health affairs at the ministry of National Guard

Abstract:
This prospective cohort study aimed to evaluate the effectiveness of the cuff leak test (CLT) in predicting post-extubation stridor (PES) in mechanically ventilated ICU patients. A total of 100 patients underwent the CLT, with a positive test (cuff leak volume < 110 mL) showing a sensitivity of 80% and specificity of 90.6% for predicting PES. Multivariate analysis identified a positive CLT and longer duration of intubation as significant predictors of PES. Our findings highlight the utility of the CLT as a valuable tool in extubation decisions but emphasize the need for a multimodal approach to patient management.

Keywords: Cuff leak test, post-extubation stridor, mechanically ventilated patients, intensive care unit, predictive value.

Introduction

Background:

Post-extubation stridor (PES) is a significant complication encountered in mechanically ventilated patients within Intensive Care Units (ICUs). It is characterized by a high-pitched wheezing sound resulting from upper airway obstruction, which can lead to severe respiratory distress and necessitate re-intubation in some cases (Tanaka et al, 2021). The incidence of PES has been reported to range from 2% to 15% among extubated patients (Jaber et al., 2005). Identifying patients at risk for PES is crucial for implementing preventive strategies and ensuring patient safety.

The process of extubation, which involves removing a patient's endotracheal tube, represents a critical transition where airway patency must be assured. While successful extubation marks a step towards recovery, complications like PES can significantly impact outcomes, prolong ICU stay, and increase healthcare costs (Epstein, 2002).

The cuff leak test (CLT) is a diagnostic procedure used to predict the likelihood of PES before extubation. It involves deflating the cuff of an endotracheal tube and measuring the volume of air that 'leaks' around the tube during positive pressure ventilation. A reduced or absent cuff leak is indicative of potential airway edema or obstruction, suggesting a higher risk for PES (Nicod, 2006). Despite its widespread use, the efficacy of the CLT in reliably predicting PES remains a topic of debate, with varying sensitivity and specificity reported across studies (Lewis et al., 2022).

Rationale:
Given the mixed evidence regarding the predictive value of the cuff leak test, there is a need for further research to ascertain its reliability and clinical utility in different patient populations. This study aims to contribute to the existing body of knowledge by evaluating the efficacy of the CLT in predicting PES specifically in a cohort of mechanically ventilated ICU patients.

Objective:
The primary objective of this prospective cohort study is to assess the efficacy of the cuff leak test in predicting the occurrence of post-extubation stridor in mechanically ventilated ICU patients. This research seeks to determine whether the CLT can be a dependable tool for clinicians to identify patients at risk for PES and to make informed decisions about extubation readiness.

Literature Review

Post-Extubation Stridor and Its Clinical Implications:

Post-extubation stridor is primarily caused by laryngeal edema resulting from prolonged intubation (Pluijms, 2015). The presence of stridor indicates a substantial risk of airway obstruction, which can lead to respiratory failure and necessitate reintubation. PES has been shown to increase ICU stay and healthcare costs while posing a risk of morbidity and mortality (Epstein, 2002).

Cuff Leak Test as a Predictive Tool:

The cuff leak test has been proposed as a simple bedside method to assess the risk of PES. The test involves deflating the endotracheal tube cuff and measuring the volume or presence of air leaking around the tube during positive pressure ventilation. Several studies have investigated the utility of the CLT with varying results.

Sensitivity and Specificity of the Cuff Leak Test:

In a landmark study, Jaber et al. (2005) evaluated the CLT in 128 ICU patients and found that a cuff leak volume (CLV) below 110 mL predicted PES with a sensitivity of 75% and a specificity of 85%. However, subsequent studies have reported inconsistent sensitivity and specificity values. Jaber et al. (2003) reported a sensitivity of 59% and specificity of 88% in a mixed ICU population, indicating a need for further validation.

Factors Influencing the Outcome of the Cuff Leak Test:

The performance of the CLT can be influenced by various factors, including the method of leak measurement, patient positioning, and underlying respiratory conditions. Nicod (2006) highlighted that the presence of copious secretions or bronchospasm might affect the accuracy of leak measurements, thus leading to false-negative results. Additionally, the timing of the CLT relative to the patient's clinical status plays a crucial role. Ochoa et al. (2009) emphasized the importance of considering factors such as sedation level, fluid balance, and steroid use when interpreting CLT results.

Comparison with Other Predictive Methods:

Several alternative methods to predict PES have been explored, including direct laryngoscopy, laryngeal ultrasound, and biomarkers of inflammation. Valentin et al. (2009) conducted a comparative study and found that while laryngeal ultrasound could visualize airway edema, combining it with the CLT improved the prediction of PES. However, ultrasound requires specialized skills and equipment, which may limit its use in all ICU settings.

Meta-Analyses and Systematic Reviews:

Recent meta-analyses and systematic reviews have consolidated the findings of individual studies to provide more robust conclusions. A meta-analysis by Patel, et al. (2015) synthesized data from 13 studies, concluding that the CLT has moderate sensitivity and high specificity for predicting PES. The authors suggested that while the CLT alone should not be the sole criterion for extubation decisions, it remains a valuable tool when used alongside clinical judgment and other assessment methods.

Gaps in Current Knowledge and Future Directions:

Despite considerable research, the variability in study designs and patient populations makes it challenging to draw definitive conclusions about the universal applicability of the CLT. There is a need for large-scale, multicenter prospective studies to standardize the CLT procedure and validate its predictive accuracy across diverse ICU settings. Furthermore, exploring adjunctive methods and integrating them with the CLT could enhance predictive accuracy and improve patient outcomes (Rose and Presneill, 2011).

Methodology

Study Design:

This study was designed as a prospective cohort study aimed at evaluating the efficacy of the cuff leak test (CLT) in predicting post-extubation stridor (PES) in a cohort of mechanically ventilated ICU patients.

Setting:

The study was conducted in the Intensive Care Unit (ICU) of Military Hospital.

Participants :

A total of 100 mechanically ventilated patients who were deemed ready for extubation by their attending physicians were enrolled in the study. Inclusion criteria were: (1) adults aged 18 years or older, (2) intubated for more than 24 hours, and (3) scheduled for elective extubation. Exclusion criteria included: (1) patients with preexisting upper airway abnormalities, (2) tracheostomized patients, and (3) patients who were moribund or had orders for withdrawal of life-sustaining treatment.

Ethical Considerations:

The study protocol was approved by ethics committee. Informed consent was obtained from all participants or their legally authorized representatives prior to inclusion in the study.

Procedure:

Cuff Leak Test
1. Pre-extubation Assessment: All participants underwent a routine pre-extubation assessment including arterial blood gas analysis, spontaneous breathing trials, and clinical evaluation.

2. Performing the Cuff Leak Test:
- The endotracheal tube cuff was fully deflated.
- A volume-controlled ventilation mode was used with a constant tidal volume of 8 mL/kg of predicted body weight.

- The expired tidal volume was measured over six consecutive breaths and the cuff leak volume (CLV) was calculated as the difference between the inspiratory tidal volume and mean expired tidal volume.
- A CLV of less than 110 mL was considered a positive test indicating a higher risk of PES.

Extubation and Monitoring:
- Following the CLT, all patients were extubated if they met the extubation readiness criteria.
- Patients were monitored for signs of stridor, which included clinical observation and auscultation of the neck.

Outcome Measures:
- Primary Outcome: Incidence of post-extubation stridor within 24 hours of extubation.
- Secondary Outcomes: Necessity of reintubation due to stridor, ICU length of stay, and in-hospital mortality.

Data Collection and Analysis:
- Data Collection: Patient demographics, clinical characteristics, CLT results, and outcomes were recorded using a standardized data collection form.
- Statistical Analysis:
  - Descriptive statistics were used to summarize patient characteristics.
  - The sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of the CLT were calculated.
  - Chi-square tests and t-tests were used to compare categorical and continuous variables, respectively.
  - Multivariate logistic regression was performed to identify independent predictors of PES.
  - All statistical analyses were conducted using SPSS version 26.0 (IBM Corp., Armonk, NY). A p-value < 0.05 was considered statistically significant.

Findings

Participant Characteristics:

The study included 100 mechanically ventilated ICU patients. The demographic and clinical characteristics are summarized in Table 1.

Table 1. Demographic and Clinical Characteristics

Characteristic	All Patients (n = 100)
Age, mean (SD), years	58.4 (14.7)
Gender, n (%)	
- Male	56 (56%)
- Female	44 (44%)
Duration of intubation, mean (SD), days	8.6 (3.1)
Underlying conditions, n (%)	
- COPD	22 (22%)
- Heart failure	18 (18%)
- Neurological disorders	30 (30%)
- Others	30 (30%)

Cuff Leak Test Results:

The cuff leak test (CLT) was performed on all patients. The distribution of CLT results and the incidence of post-extubation stridor (PES) are shown in Table 2.

Table 2. Cuff Leak Test Results and Post-Extubation Stridor

Cuff Leak Volume (CLV)	Patients (n)	PES (n)	No PES (n)
< 110 mL (Positive CLT)	20	12	8
≥ 110 mL (Negative CLT)	80	3	77
Total	100	15	85

Predictive Values of the Cuff Leak Test:

The sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) for the CLT are presented in Table 3.

Table 3. Predictive Values of the Cuff Leak Test

Metric	Value
Sensitivity	80% (12/15)
Specificity	90.6% (77/85)
Positive Predictive Value (PPV)	60% (12/20)
Negative Predictive Value (NPV)	96.3% (77/80)

Multivariate Logistic Regression Analysis:

Significant predictors of PES were identified through multivariate logistic regression analysis, as depicted in Table .

Table 4. Multivariate Logistic Regression Analysis for Predicting Post-Extubation Stridor

Variable	Odds Ratio (95% CI)	p-value
Positive CLT (CLV < 110 mL)	12.3 (3.7 - 40.8)	< 0.001
Duration of intubation (days)	1.8 (1.3 - 2.6)	0.01
Age	0.95 (0.88 - 1.02)	0.18
Underlying COPD	1.5 (0.5 - 4.7)	0.45

Discussion

Principal Findings:

Our prospective cohort study assessed the efficacy of the cuff leak test (CLT) in predicting post-extubation stridor (PES) in mechanically ventilated ICU patients. We found that a positive CLT (cuff leak volume < 110 mL) had a sensitivity of 80% and a specificity of 90.6% for predicting PES. Furthermore, multivariate logistic regression analysis revealed that a positive CLT and increased duration of intubation were significant independent predictors of PES. These findings suggest that while the CLT is a valuable tool, it should ideally be used in conjunction with other clinical factors to guide extubation decisions.

Comparison with Existing Literature:

Our findings align with earlier studies on the efficacy of the CLT. Jaber et al. (2005) reported similar sensitivity (75%) and specificity (85%) values in their study, indicating that our threshold for a positive CLT

is consistent with previous research. However, the variation in predictive values across studies highlights the need for context-specific interpretation of CLT results.

Previous studies have noted the wide variability in the sensitivity and specificity of the CLT. For instance, Patel et al. (2015) reported a lower sensitivity of 59%, suggesting that patient population differences and methodological variations could impact the test's performance. Our study contributes to this body of knowledge by providing further validation in a cohort of ICU patients with varied underlying conditions.

Factors Influencing the Outcome:

The predictive accuracy of the CLT can be influenced by several factors, including the method of leak measurement, patient positioning during the test, and the duration of intubation. Nicod (2006) emphasized that conditions such as copious secretions and bronchospasm could lead to false-negative results. Consistent with these observations, our findings showed that duration of intubation was a significant predictor of PES, underscoring the need to consider patient-specific factors when interpreting CLT results.

Clinical Implications:

The strong negative predictive value (96.3%) observed in our study indicates that a negative CLT (cuff leak volume ≥ 110 mL) reliably identifies patients at low risk for PES, potentially facilitating safe extubation decisions. Conversely, the positive predictive value (60%) suggests that while a positive CLT indicates increased risk, it may not be definitive on its own. Clinicians should, therefore, consider additional factors such as the duration of intubation, the presence of clinical signs of airway edema, and other diagnostic tools such as laryngeal ultrasound (Valentin et al., 2009).

Our study supports the incorporation of the CLT into extubation protocols but advocates for a multimodal approach to decision-making. By using the CLT alongside other assessments, clinicians can make more informed decisions, potentially reducing the incidence of PES and its associated complications.
Strengths and Limitations

One of the strengths of our study is the prospective design, which allows for a more accurate assessment of the CLT's predictive value. Additionally, our sample size of 100 patients provides a robust dataset for analysis. However, there are limitations to consider. The study was conducted in a single tertiary care ICU, which may limit the generalizability of our findings to other settings. Moreover, variations in CLT methodology and the subjective nature of clinical assessment for stridor could introduce bias.

Future Research:

Future research should focus on multicenter studies to validate our findings across different ICU settings and patient populations. Additionally, exploring adjunctive diagnostic tools and incorporating machine learning algorithms to predict PES could enhance the predictive accuracy and practical utility of extubation readiness assessments. Rose and Presneill (2011) has suggested that integrating respiratory mechanics and biomarkers of inflammation may provide further insights into extubation outcomes.

Conclusion

In conclusion, the cuff leak test is a valuable tool for predicting post-extubation stridor in mechanically ventilated ICU patients, demonstrating high specificity and strong negative predictive value. While a positive CLT indicates increased risk for PES, it should be used in combination with other clinical assessments to guide extubation decisions. Our findings contribute to the growing body of evidence supporting the use of the CLT in ICU practice and highlight the importance of a comprehensive and multimodal approach to patient management.

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