Optimization of Endotracheal Tube Cuff Filling by Continuous Upper Airway Carbon Dioxide Monitoring

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Inappropriate cuff filling is responsible for various complications related to the use of an endotracheal tube (ETT). In this study, we evaluated an objective, noninvasive method for continuous assessment of leak around the ETT cuff by monitoring carbon dioxide pressure (P\textsubscript{CO2}) in the upper airway. P\textsubscript{CO2} levels were measured by capnography simultaneously between the ETT cuff and the vocal cords, at the oropharynx, and in the nares of the nose. Cuff filling was regulated by an electronic controller to achieve the minimal pressure needed to prevent CO\textsubscript{2} leak. Feasibility of the method was assessed in a human simulator and in a porcine model. Clinical function was evaluated in 60 patients undergoing surgery, comparing the method to the standard anesthesiologist evaluation. Linear correlations were observed between the ETT cuff pressure and P\textsubscript{CO2} level in the human simulator (R\textsuperscript{2} = 0.954, P < 0.0001) and in the porcine model (R\textsuperscript{2} > 0.98, P < 0.0001). Iodine leak around the ETT cuff, in the porcine model, occurred only when P\textsubscript{CO2} levels were >2 mm Hg. In the surgery patients, the mean ETT cuff pressure determined clinically by the anesthesiologist was significantly higher than the optimal cuff pressure assessed by P\textsubscript{CO2} (25.2 ± 3.6 versus 18.2 ± 7.8 mm Hg, respectively; P < 0.001). According to these findings, optimal ETT cuff filling pressure can be identified by monitoring P\textsubscript{CO2} at the nares or the oropharynx.


A critical aspect in management of mechanically ventilated patients is to avoid complications related to inappropriate endotracheal tube (ETT) cuff filling (1–8). An appropriately inflated ETT cuff should achieve isolation of the lower airways, thus reducing the risk of aspiration around the cuff and possible ventilator-associated pneumonia (VAP), which occurs in up to 25% of intensive care unit (ICU) patients (5–9). However, an over-inflated cuff may cause local mechanical complications such as mucosal ulcerations, granulomas, tracheal stenosis, and tracheoesophageal fistulae (1–4).

Optimal ETT cuff filling is defined as the minimal pressure required for airway isolation. It is influenced by airway anatomy, cuff location, cuff compliance, size and volume, and by peak inspiratory pressure (10,11). The common clinical practice of optimizing cuff filling by auscultation or by assessing inhaled-exhaled volume difference is imprecise, and evaluating leak by dye infusion is impractical (12–14).

Capnographic measurement of carbon dioxide pressure (P\textsubscript{CO2}) based on infrared absorption has evolved into a commonly used procedure (15). Cyclic changes of P\textsubscript{CO2} measured proximal to the ETT cuff can be used to identify gas leakage around the cuff. The purpose of this study was to establish an accurate, objective, noninvasive bedside method for assessment of a leak around the ETT cuff by continuous monitoring of P\textsubscript{CO2} at the upper airways. Initially, the feasibility of the method was investigated in a human simulator. Later, leaks at various cuff pressures were evaluated by iodine leak test in a porcine model simulating human airway mucosa. Finally, the feasibility of the method was evaluated in 60 patients undergoing elective surgery, comparing the new method to the standard clinical evaluation used today.

Methods

To find the best feasible place for CO\textsubscript{2} measurements, we evaluated 3 anatomic locations: 1. between the ETT...
with high-volume, low-pressure cuffs with an external side-attached mini-guide lumen which opens 1 cm above the cuff (Hi-Lo® Evac, Mallinckrodt). The proximal end of the suction mini-guide was connected to the capnograph (Fig. 1). Figure 2 shows a photograph of the PC display including a graph of the ETT cuff pressure controller and a graph of Pco2 readings in the upper airways of the human simulator.

**Phase 1: Human Simulator Model**

We used a human simulator of a 70-kg man (Medical Education Technologies, Inc. [METI], Sarasota, FL) located in the Israel Sheba Simulation Center. A Hi-Lo® Evac ETT no. 8 was inserted into the human simulator trachea. The tracheal diameter at the location of the ETT cuff was 25 mm. Exhaled air end-tidal CO2 of 40 mm Hg was simulated by adjusting a continuous CO2 stream into the simulator lungs.

While ventilating the human simulator, we sequentially inflated the cuff, 2 mm Hg at a time and measured Pco2 leak level at the 3 anatomic sites (Fig. 1). After each cuff pressure change, we suctioned the oropharynx to avoid any CO2 remnants.

**Phase 2: Porcine Model**

Experiments were conducted with permission from and according to the National Institutes of Health Guidelines for the Care and Use of Laboratory Animals. Two pigs, weight 10 and 13 kg, underwent general anesthesia with a no.7 ETT. CO2 leak was assessed by a 4-mm-diameter catheter inserted directly through a small incision into the trachea 1 cm above the ETT cuff and below the vocal cords. The ETT cuff pressure was increased sequentially, 2 mm Hg at a time and Pco2 was measured through the catheter. After each measurement, we suctioned the upper airway to avoid any CO2 remnants.

After reaching a steady cuff pressure that gave no Pco2 readings at the upper airway, we surgically opened a tracheal “window” below the ETT cuff. Iodine solution (5 mL) was injected above the cuff and rested there for 60 min while we evaluated through the tracheal window any iodine leak below the cuff at different cuff pressure levels. Throughout the experiment (including the period of iodine leak measurements), animals were maintained on the same positive pressure ventilation and the ETT location and animal head and neck positions were not changed.

**Phase 3: Human Subjects**

Sixty consecutive adult patients undergoing elective surgery with balanced generalized anesthesia (NO2/O2) were included in our study. To obtain a homogeneous group of patients regarding mechanical ventilation volumes and pressures, patients with a history of...
cigarette smoking or dyspnea were preassessed by pulmonary function tests. Nine patients were excluded because of forced expiratory volume per second (FEV₁) or vital capacity (VC) <50% of predicted. The study protocol was approved by the local ethics committee and patients signed an informed consent.

In all patients, the tracheal intubation was performed by an anesthesiologist and the ETT position inside the trachea was determined according to the height of the patient, using the following formula: the length from the distal tip of the ETT to the right mouth angle (cm) = [body height (cm)/5] – 13 (16). After intubation, the anesthesiologist was requested to set the minimal ETT cuff pressure required to prevent leak according to exhalation-inhalation volume difference and air leak heard with the stethoscope around the cuff. The cuff pressure was considered optimal by the anesthesiologist when there was no exhalation-inhalation volume difference and no air leak heard with the stethoscope using the minimal cuff pressure for 5 min. Once cuff pressure level was considered optimal by the anesthesiologist, we started measuring P

\[ P_{CO_2} \]

at the 3 locations: proximal to the ETT cuff via the external mini-guide lumen of the Hi-Lo® Evac ETT, at the oropharynx via a plastic oropharyngeal airway, and at the nares via a nasal cannula (Fig. 1). Based on the findings in the porcine model, optimal cuff filling was defined as the minimal cuff pressure required to avoid a P

\[ P_{CO_2} \]

leak of >2 mm Hg proximal to the ETT cuff via the external mini-guide lumen of the Hi-Lo® Evac ETT. Suction was performed through the plastic airway as needed and 2 min before each P

\[ P_{CO_2} \]

measurement. Continuous monitoring of P

\[ P_{CO_2} \]

from the 3 anatomic locations was performed throughout the operation.

### Statistical Analysis

The statistical SPSS software (version 10.0; SPSS Inc., Chicago, IL) was used for all analyses performed. Categorical data were expressed in numbers and percentages. Continuous data were expressed as means ± standard deviations and compared by a paired t-test. Regression coefficient (R) was calculated as a measurement of correlation between ETT cuff pressure and P

\[ P_{CO_2} \]

in the upper airways and expressed as R². P values < 0.05 were considered significant.

### Results

#### Phase 1: Human Simulator Model

Figure 2 illustrates an example of the exhaled P

\[ P_{CO_2} \]

waveform in accordance with ETT cuff pressure as displayed on the PC monitor in the human simulator model. A linear correlation was observed between the ETT cuff pressure and the P

\[ P_{CO_2} \]

measured above the cuff in all 3 anatomic locations: 1. between the cuff and the vocal cords, R² = 0.954, P < 0.0001; 2. at the oropharynx above the epiglottis, R² = 0.923, P < 0.0001; 3. at the nares of the nose, R² = 0.911, P < 0.0001. Figure 3 demonstrates the correlation between ETT cuff pressures and CO₂ levels measured between the cuff and the vocal cords. At an ETT cuff pressure of ≥26 mm Hg, no P

\[ P_{CO_2} \]

was recorded at any of the 3 anatomic locations (Fig. 1). At an ETT cuff pressure of 25 mm Hg, P

\[ P_{CO_2} \]

was detected only between the cuff and the vocal cords. Once ETT cuff pressure reached 24 mm Hg, CO₂ leak was measured at all locations. At all levels of cuff pressures, the maximal difference in P

\[ P_{CO_2} \]

readings between the various anatomic locations was <2 mm Hg.
Phase 2: Porcine Model

In animal “A,” the minimal cuff pressure needed to prevent CO₂ leak around the ETT cuff was 28 mm Hg whereas the minimal cuff pressure needed to prevent iodine solution leak around the cuff was 24 mm Hg, a pressure at which we already measured a Pc₀₂ leak of 2–3 mm Hg. There was a linear correlation between ETT cuff pressure and Pc₀₂ leak above the cuff (R² = 0.984, P < 0.0001) (Fig. 4a).

In animal “B,” the minimal cuff pressure needed to prevent CO₂ leak around the ETT cuff was 30 mm Hg whereas the minimal cuff pressure needed to prevent iodine solution leak around the cuff was 25 mm Hg, a pressure at which we measured a Pc₀₂ leak of 3–4 mm Hg. There was a linear correlation between the ETT cuff pressure and Pc₀₂ leak above the cuff (R² = 0.988, P < 0.0001) (Fig. 4b).

Phase 3: Human Subjects

Baseline characteristics of the patients are summarized in Table 1. The mean age of the patients was 58.5 ± 16.2 yr. The mean peak inspiratory pressure was 21.2 ± 0.6 mm Hg. Although patients with severe pulmonary diseases were excluded from the study (FEV₁ or VC <50% of predicted), 6 patients (10%) had mild obstructive lung disease and 1 patient had mild restrictive lung disease.

The results from the human simulator and the porcine model demonstrated a linear correlation between Pc₀₂ leak measurements and ETT cuff pressures. The fact that iodine solution leak occurred only when the Pc₀₂ leak readings were >2 mm Hg induced us to consider a Pc₀₂ leak measurement clinically significant only if it was >2 mm Hg proximal to the ETT cuff via the external mini-guide lumen of the Hi-Lo® Evac ETT.

The mean initial ETT cuff pressure of all of the study population, determined clinically by the anesthesiologist, was significantly higher than the mean optimal cuff pressure determined by upper airway Pc₀₂ leak monitoring proximal to the ETT cuff (25.2 ± 3.6 versus 18.2 ± 7.8 mm Hg, respectively; P < 0.001) (Fig. 5). In 43 patients (72%), the clinically determined ETT cuff pressure was significantly higher than the optimal cuff pressure determined by CO₂ leak, with a mean change of 10.2 mm Hg in cuff pressure (25.4 ± 3.9 versus 15.2 ± 4.7 mm Hg, P < 0.0001) (Fig. 6). In 8 patients (13%) the initial ETT cuff pressures were significantly lower than the optimal cuff pressure. Nine patients (15%) had an initial ETT cuff pressure similar to the optimal cuff pressure (Fig. 6).
In 3 patients, CO2 leak continued despite the exceptionally high cuff pressure, up to 35 mm Hg. The pressures determined by the anesthesiologist in these patients were 30, 32, and 33 mm Hg. After distal repositioning of the ETT, the cuff pressures needed to prevent CO2 leak were reduced to $30$ mm Hg, similar to the remainder of the study population. Because cuff pressures required for complete sealing were reduced dramatically after distal reposition, we assumed that the primary incomplete sealing was probably the result of a very high proximal airway position causing poor contact between the ETT cuff and the patient airway anatomy (e.g., direct contact between the cuff and the vocal cords).

During surgery, a new leak of CO2 around the ETT cuff developed in 16 patients (27%) attributable to variable causes such as increased peak inspiratory pressure by $>5$ mm Hg caused by laparoscopic surgery with abdominal gas inflation, light anesthesia or inadequate neuromuscular blockade, change of head position because of surgical requirements, and ETT movement during surgery (Table 2).

During surgery, CO2 recordings were obtained at all 3 anatomic locations (Fig. 1) and differences in $P_{CO2}$ readings were $2$ mm Hg. After a mean of $9.4$ measurements through the suction mini-guide catheter attached to the ETT, no further readings could be obtained because of obstruction by secretions and thus further $P_{CO2}$ readings were obtained only from the plastic airway (hypopharynx) and from the nares.

### Table 1. Baseline Patient Characteristics

<table>
<thead>
<tr>
<th></th>
<th>n = 60</th>
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<tbody>
<tr>
<td>Age (yr)</td>
<td>$58.5 \pm 16.2$</td>
</tr>
<tr>
<td>Sex (male/female)</td>
<td>44/16</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>$79.4 \pm 14.9$</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>$168.9 \pm 10.1$</td>
</tr>
<tr>
<td>Patients with mild obstructive lung disease</td>
<td>6 (10)</td>
</tr>
<tr>
<td>Patients with mild restrictive lung disease</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Tube size (mm ID)</td>
<td></td>
</tr>
<tr>
<td>7.5</td>
<td>20 (33)</td>
</tr>
<tr>
<td>8</td>
<td>16 (27)</td>
</tr>
<tr>
<td>8.5</td>
<td>24 (40)</td>
</tr>
<tr>
<td>Peak inspiratory pressure (mm Hg)</td>
<td>$21.2 \pm 0.6$</td>
</tr>
<tr>
<td>End-tidal CO2 (mm Hg)</td>
<td>$36.3 \pm 2.4$</td>
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<tr>
<td>Type of operation</td>
<td></td>
</tr>
<tr>
<td>Abdominal laparoscopic surgery</td>
<td>4 (7)</td>
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<tr>
<td>Open abdominal surgery</td>
<td>22 (37)</td>
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<tr>
<td>Orthopedic</td>
<td>22 (37)</td>
</tr>
<tr>
<td>Urologic</td>
<td>2 (3)</td>
</tr>
<tr>
<td>Other</td>
<td>10 (17)</td>
</tr>
</tbody>
</table>

Data are expressed as means ± standard deviations or number of patients (percentage).

**Figure 5.** Comparison between the initial mean endotracheal tube cuff pressure, determined clinically by the anesthesiologist using the audible leak test and exhalation-inhalation volume difference, to the mean optimal cuff pressure determined by CO2 leak monitoring ($n = 60$).

**Figure 6.** Percentage of patients with initial endotracheal tube cuff pressure significantly higher, lower, or accurate compared with the optimal cuff pressure determined by $P_{CO2}$ leak monitoring ($n = 60$).

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**Discussion**

Methods used today to determine adequate cuff filling are either inaccurate or cumbersome (13,14). An underfilled cuff may cause aspiration of nasopharyngeal content whereas an overfilled cuff may cause local mechanical injury (1–9). The ETT bypasses normal upper airway reflexes preventing effective cough, thus facilitating pooling of nasopharyngeal secretions above the cuff which tend to “trickle” down the airway and cause VAP. Kollef et al. (17) have shown that, in patients undergoing cardiac surgery with mechanical ventilation, reducing aspiration around the ETT cuff by continuous suctioning proximal to the cuff delayed the occurrence of VAP from $2.9 \pm 1.2$ to $5.6 \pm 2.3$ days ($P = 0.006$). The independent risk of the ETT in ventilated patients may be deduced from studies of noninvasive ventilations (NIV). In a matched case-control study, Girou et al. (18) found that, among ICU patients, NIV reduced nosocomial pneumonia from 60% to 18% ($P < 0.001$). Similarly, in a large survey, 42 ICU patients receiving NIV were less likely to develop pneumonia, even after adjustment for severity of illness (19). The findings of these studies support the
suggesting that the P area allows for continuous CO2 leaks, whereas, at high cuff pressures, there is still considerable space which remains un sealed at the beginning and at the end of the curve, with lower cuff pressures needed to prevent CO2 leak and that needed to prevent iodine leak would be sufficient to prevent secretion leak around the ETT cuff. In this model, using sequential increases of 2 mm Hg, an over-inflated cuff increases the risk of mucosal ulcerations, granulomas, tracheal stenosis, and tracheoesophageal fistulae (1–4). The consequences of these complications are of significant clinical importance because surgical corrections are not always successful (1–4). The mechanisms are related to direct pressure necrosis by over-inflated ETT cuff duration of intubation, macro- and microtrauma during intubation, the specific technique of endotracheal intubation, severity of respiratory failure, infection, and poor tissue perfusion caused by hemodynamic instability (1–4,20). These mechanical complications are less common in elective surgical patients, and are seen mostly in patients with prolonged mechanical ventilation, such as ICU patients (1,2,4,20). The proposed PCO2 method helps determine the minimal initial cuff pressure needed to prevent a leak. However, after the initial setting, another regulatory problem, not yet solved, is the need to deflate the cuff in order to evaluate the possibility of pressure reduction (required, for example, after decreasing respiratory pressures) and then inflate it again according to the new CO2 readings. A further study is needed to evaluate the regulatory of an over-inflated cuff.

Although the general tendency of the anesthesiologists was to “overshoot” the initial cuff pressure, we found, in 13% of the cases, lower than optimal initial cuff pressures. Moreover, during surgery, a new leak developed in 27% of the patients, potentially exposing them to aspiration risk. This variability in cuff pressure, observed even in stable elective surgery patients, emphasizes the need for an accurate, continuous bedside method to determine the appropriate cuff pressure.

An important problem encountered during the study was obstruction by secretions of the mini-guide lumen of the Hi-Lo® Evac ETT after several aspirations for PCO2 measurements, despite suctioning of the upper airways. In contrast, PCO2 readings through nasal cannula, or from the oropharynx through the plastic airway, were easily obtained after secretion clearance by oral suctioning. The obstruction of the mini-guide catheter lumen, with its tip located in the

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**Table 2. Causes of a New Leak Around the Endotracheal Tube Cuff During Operation**

<table>
<thead>
<tr>
<th>Cause</th>
<th>Frequency</th>
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<tbody>
<tr>
<td>Increase in peak inspiratory pressure</td>
<td>10/11</td>
</tr>
<tr>
<td>Gas inflation of the abdomen</td>
<td>4/4</td>
</tr>
<tr>
<td>Inadequate neuromuscular block</td>
<td>3/4</td>
</tr>
<tr>
<td>Light anesthesia</td>
<td>3/3</td>
</tr>
<tr>
<td>Change of patient’s head position</td>
<td>5/9</td>
</tr>
<tr>
<td>Change of tube position</td>
<td>1/2</td>
</tr>
</tbody>
</table>

Data are expressed as ratio of patients with new leak/total number of patients who underwent the specific procedure.
CO2 leak in the trachea, by secretions, prevents its use for monitoring CO2 leakage. However, because the maximal difference in PCO2 readings between the 3 anatomic locations was <2 mm Hg (a pressure not causing iodine leak), we suggest the nares of the nose or the oropharynx as the locations of choice for CO2 sampling. However, we must emphasize that these findings are based on a one-size human simulator model and only 60 adult anesthetized patients. It is possible that, in patients with diverse anatomic variations, differences in PCO2 readings between the trachea and the oropharynx or the nares will be >2 mm Hg. Further study is needed to evaluate the optimal place for CO2 sampling in a larger study population with a variety of airway anatomies.

Another important issue is the position of the ETT. A malpositioned ETT is hazardous for tracheally intubated patients. Insertion of an ETT too distally leads to endobronchial intubation, which may cause collapse of the contralateral lung, whereas proximal insertion may lead to accidental extubation or vocal cord trauma (20,21). Several formulae and other methods have been proposed to estimate the optimal length for ETT insertion; however, none is always satisfactory (22–25). In the current study, 3 patients had a CO2 leak despite exceptionally high (>35 mm Hg) cuff pressures. However, pressure decreased to <30 mm Hg (as in the remainder of the study population) after distal repositioning of the ETT. Although it was not the aim of the study, continuous CO2 leak around an appropriately inflated cuff can be used as a marker for malpositioned ETT. Incessant CO2 leak around the ETT cuff can occur when there is incomplete sealing caused by poor contact with the vocal cords, endobronchial intubation (CO2 from the contralateral lung), or intubation above the vocal cords.

Regarding comparisons between the above cuff CO2 measurement and the audible leak test, several differences should be noted. Although both methods evaluate air leak around the ETT cuff, the CO2 method is an objective, accurate technique that could be automated and used as a standard in clinical trials and later as a standard of care for intubated patients, aiming to reduce complications related to the ETT tube. However, the CO2 method has several important limitations: 1. the technique requires adequate equipment, including a second capnograph (besides the capnograph used for measurements of intra-ETT CO2) and a cuff pressure controller device; 2. the need for oropharynx suctioning between samples of CO2 measurements at different cuff pressures is cumbersome and prolongs the time needed to achieve optimal cuff filling. We hope that we will soon be able to supply an automatic device capable of synchronizing the CO2 measurements, the cuff pressure controller, and the suction.

The study has several limitations: 1. the study did not include ICU patients who required prolonged mechanical ventilation. 2. The experiment was performed only during positive pressure ventilation whereas the CO2 method may not be as reliable in spontaneously breathing patients. 3. Patients with moderate-to-severe pulmonary disease were not included in the study. However, there is a real need for a simple, noninvasive method that can be used as an objective standard in clinical practice and in studies addressing the important issue of leak around the cuff. This standard may be applied not only to short-term over-inflation of ETT cuffs in the operating room, which has less significant clinical importance, but also to more complicated conditions, such as in neonates, children, patients with pulmonary diseases or anatomic malformations, and ICU patients. However, before using this new method in more complicated conditions, we evaluated the method in optimal conditions.

In this study, we evaluated a new, objective method for optimizing ETT cuff filling by monitoring CO2 levels in the upper airways. The method is simple, noninvasive, and can be used in any tracheally intubated patient. Continuous CO2 monitoring in the upper airway can be used to identify the minimal cuff pressure needed to prevent an air leak around the ETT cuff. Data obtained in two pigs suggest that this method may also be useful for identifying the cuff pressure that would prevent aspiration of secretions around the cuff. Before the CO2-based cuff inflation method can be used as a standard of care for all tracheally intubated patients, further studies comparing the clinical relevance of the differences between the audible leak test to the CO2 method are needed for patients more prone to ETT complications, such as those with pulmonary diseases, ICU patients, and children.

References


