Tracheal pressure and endotracheal tube obstruction can be detected by continuous cuff pressure monitoring: in vitro pilot study

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Abstract
Purpose: To evaluate whether the degree of endotracheal tube (ETT) obstruction can be predicted by changes of ETT cuff pressure ($P_c$) as a function of peak inspiratory pressure. Methods: The study was conducted in three phases: phase I evaluated the correlation between peak tracheal pressure ($P_{tr}$) and $P_c$; phase II evaluated the relation between $P_c$ versus ventilator pressure ($P_v$) and ETT obstruction (range of obstruction 0–58%). In phase III the analytical model developed in phase II was used to predict the degree of obstruction of five ETTs removed from intensive care unit (ICU) patients. All measurements were conducted on a tracheal–lung simulator. Results: In phases I and II it was found that $P_c$ correlates significantly with $P_{tr}$. The gradient ($dP_c/dP_v$) reflects the degree of ETT obstruction according to the formula:

$$ \text{obstruction (\%) } = -553 \times \left( \frac{dP_c}{dP_v} \right)^2 + 672.5 \times \left( \frac{dP_c}{dP_v} \right) - 142.81. $$

Using this formula, the degree of obstruction of the ETTs could be predicted in ICU patients during controlled mechanical ventilation ($r^2 = 0.98, p < 0.001$). Conclusions: This study proposes a new method to predict the degree of ETT obstruction based on differences between $P_c$ and $P_v$. The method was proved accurate on simulator, and further studies are needed on intubated patients.

Keywords: Tracheal pressure ∙ Endotracheal tube ∙ Obstruction ∙ Cuff pressure

Introduction

Obstruction of the endotracheal tube (ETT) is a relatively common problem for patients requiring mechanical ventilation for acute respiratory failure [1, 2]. ETT occlusion represents a medical emergency among patients requiring mechanical ventilation, necessitating urgent re-establishment of a patent airway [2]. Partial occlusion or narrowing of ETTs or tracheotomy has been associated with increased patient work of breathing and delayed weaning from mechanical ventilation [3–7]. The average reduction in intraluminal ETT obstruction in ventilated patients may range from 9.8% to 15.2% [1, 2, 8, 9]. Significant volume reduction of greater than 10% may occur in 60.8% of ETTs [2]. Significant alterations in inner ETT configuration are influenced by the type of humidification device used and the duration of ventilation [1, 8].

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Several methods have been developed to determine the degree of obstruction, which can be divided into direct and indirect approaches. The direct method, the classical and the most commonly used, is based on an additional catheter inserted via the ETT and positioned above the carina to measure pressure gradients during the respiratory cycle [10]. This method has significant technical limitations that prevent it from being used extensively in daily clinical practice [9]. The indirect group includes several methods that have been proposed and aim to detect the degree of intratube obstruction [9, 11–15]. However, until now, none of these methods has been used in daily clinical practice.

This study evaluates the hypothesis that changes in ETT obstruction are reflected in changes of ETT cuff peak pressure as a function of peak inspiratory pressure.

**Materials and methods**

**Rational**

The hypothesis was based on the following physiologic-physics assumptions:

(a) During mechanical ventilation, when the ETT cuff provides foolproof sealing of the trachea (complete sealing of the lungs from the outside environment, i.e., no leak), the peak inspiratory pressure generated by the mechanical ventilator ($P_P$) significantly correlates with the maximal ETT cuff pressure ($P_C$) [16]. The pressures at the different anatomic locations are illustrated in Fig. 1 of the Electronic Supplementary Material (ESM).

(b) The deviation between the ventilator pressure ($P_P$) and tracheal pressure ($P_T$) is mainly attributed to ventilator circuit resistance. The major detrimental factor of the ventilator circuit resistance is the degree of narrowing in the ETT (obstruction) [6, 17–19]. The difference between pressures is related to the degree of ETT resistance ($P_R$) and is expressed by a pressure drop between $P_P$ and $P_T$ (Fig. 2 in the ESM).

(c) Since $P_C$ is correlated with $P_T$, the pressure drop between the ventilator and the trachea ($P_P$ versus $P_T$) correlates with the pressure drop between $P_P$ and $P_C$.

The study was conducted in three phases: in the first phase the aim was to evaluate the in vitro correlation between tracheal and cuff pressures ($P_T$ versus $P_C$). In the second phase the intent was to establish an analytical model for prediction of ETT obstruction based on the changes in $P_T$; in the third phase the analytical model was used to predict the obstruction in ETTs removed from ICU patients.

**Phase I: correlation between peak inspiratory tracheal pressure ($P_T$) and changes in peak cuff pressure ($P_C$)**

The ventilator was set to volume-controlled ventilation (VCV) with variable pressure limits. Although different pressure limits were set in order to make the methodology easier, the ventilation was maintained with constant inspiratory flow and no end inspiratory pause. Accordingly, flow continued until the end of inhalation. The maximal ventilator pressure and the maximal tracheal pressure were recorded and measured.

**Setting and equipment**

All measurements were conducted on a tracheal–lung simulator, as illustrated in Fig. 1. The ETTs that were used during all three phases of the study were polyurethane ETT with internal diameter of 8 mm (Sealguard®; Tyco Healthcare, Mallinckrodt). The ETTs were connected to the mechanical ventilator and ventilated with 5% CO₂.

In order to confirm complete sealing of the ETT cuff, maintain baseline cuff pressure, and monitor the cyclic changes in the intracuff pressures during the respiration cycle, the AnapnoGuard 100 system was used (Hospitech Respiration Ltd., Petach Tikva, Israel). In brief, the AnapnoGuard system has been developed to detect any leak around the ETT cuff during the respiratory cycle when the patient is artificially ventilated. As detailed elsewhere [20], optimal tracheal sealing by the ETT cuff is based on closed-loop control of CO₂ levels above the cuff and of cuff intrapressure. Any leakage sensed above the cuff expressed by an increase of CO₂ level indicates nonoptimal sealing of the trachea [20]. Moreover, the AnapnoGuard system provides continuous accurate recording of any changes in cuff pressure during the respiratory cycle.
The maximal tracheal pressure \( (P_{tr}) \) and maximal cuff pressure \( (P_c) \) were recorded as a function of maximal ventilator pressure \( (P_v) \) at the following discrete values:

\[
P_v(\text{mmHg}) = 22.50, 26.25, 30.00, 33.75, 37.50, 41.25,
\]
at lung compliances \( (C) \) supplied by the artificial lung of:

\[
C(\text{cc/mmHg}) = 40.00, 26.7, 20.00, 13.3.
\]

Measurements of \( P_{tr} \) and \( P_c \) were recorded for all of the above \( P_v \) and lung compliances, and for each of the following baseline cuff inflation pressures:

Baseline cuff inflation pressures \( (\text{mmHg}) \) = 15, 20, 25, 30.

Phase II: relation between maximal cuff pressure versus ventilator pressure and degree of ETT obstruction

All measurements detailed in phase I were repeated using one of the following obstruction levels:

Obstruction \( (\%) = 0, 13, 35, 58.\)

Data were first collected. Then, based on the relation between \( P_c, P_v, P_{tr} \), and the degree of ETT obstruction, data and mathematical evaluation were performed to find the best way to predict the percentage of ETT obstruction.

Phase III: prediction of the degree of ETT obstruction by changes in maximal cuff pressure

This phase of the study included five ETTs with unknown degree of obstruction that were used in patients with more than 3 days of ventilation. The ETTs were positioned in the simulator, and the algorithm developed in phase II was used to calculate the degree of intralumen obstruction. After the calculation, the tubes were cut horizontally into small pieces \( (\sim 0.5 \text{ cm each}) \), and the degree of maximal obstruction was measured as detailed in the ESM.

Statistical analysis

Statistical analysis was performed using SPSS version 16 software. In order to evaluate correlations the data were first plotted. If the variables appeared to be linearly related, a simple linear regression model was used. The correlation between the measured and calculated ETT obstruction based on the maximal cuff and ventilator gradient pressures \( (dP_c/dP_v) \) was indeed linear: \( Y = b_0 + b_1 \times t \). The goodness-of-fit measure of the linear model, the coefficient of determination \( (r) \), was calculated using a simple linear regression model in SPSS software. If the \( r \) change associated with a variable is large, the variable is a good predictor of the dependent variable. \( P \) values \(<0.05 \) were considered significant.

**Results**

Phases I and II: correlation between peak inspiratory tracheal pressure \( (P_{tr}) \) and changes in peak cuff pressure \( (P_c) \)

The correlation between \( P_v \) and \( P_{tr} \) was of first degree, where \( P_{tr} = a \times P_v + b \) (Fig. 2). As can be seen, any increase in obstruction results in a consequent increase of
the respective $b$ parameter and decrease of the respective $a$ parameter. The correlation coefficient ($r$) was $>0.99$ for all lung compliances.

The correlation between $P_c$ and $P_{tr}$ in the absence of obstruction is presented in Fig. 3. The $r$ value for linear correlation between tracheal pressure and cuff pressure was $>0.94$ for all cuff pressures.

The correlation between $P_c$ and $P_v$ in the absence of stenosis at the different baseline cuff pressures is shown in Fig. 4 ($r > 0.93$ for all lung compliances). The linear correlation between $P_c$ and $P_{tr}$ is optimal when $P_{tr}$ is greater than the inflated cuff pressure. Correlation between the gradients of $P_c$ versus $P_v$ were similar to those for gradients of $P_{tr}$ versus $P_v$. The impact of $P_{tr}$ on $P_c$ is small in the vicinity of the inflated cuff pressure (transfer zone), and increases as $P_{tr}$ rises above the baseline cuff inflate pressure. The nature of changes in $P_c$ versus $P_v$ around the transfer zone is a second-degree polynomial. It can be observed that there is no distinct difference between the gradients for the various grades of obstruction at the transfer zones.

Phase II: correlation between the gradient of maximal cuff versus ventilator pressure and the degree of ETT obstruction

The correlation between $P_c$ and $P_v$ at different baseline cuff pressures with different degrees of obstruction is presented in Fig. 5a–d (Fig. 5b, c are in the ESM). When the ventilator pressure was more than 15 mmHg greater than the baseline cuff inflated pressure, the curve is linear and can be represented by a first-degree function. The slope of this section of
the curve, \(dP_c/dP_v\), correlates with the degree of obstruction. On the other hand, the constant term of the linear equation \((b)\), in addition to being related to the degree of obstruction, is also related to the baseline characteristics of the ventilator circuit and the lungs’ compliance.

As can be observed (Fig. 5a–d in ESM), as the baseline cuff pressure increases, the linear part of the curve starts at greater ventilator pressure. Furthermore, when the baseline cuff pressure is higher, with a small degree of obstruction the distinction between various gradient levels is smaller. In all figures, the \(r\) value for linear correlation in the marked linear zone is >0.99.

Based on the above-collected data, we derived an empirical formula representing the relation between obstruction (\%) and the gradient \((dP_c/dP_v)\):

\[
\text{Obstruction (\%)} = -553 \times (dP_c/dP_v)^2 + 672.5 \times (dP_c/dP_v) - 142.81.
\]

The \(r\) value of the correlation between this formula and the known data of \(dP_c/dP_v\) is 0.949. [The obstruction (\%) formula is represented in graphical form in Fig. 4 in the ESM.]

Practical method for calculation of obstruction

In any calculation, complete sealing of the trachea by the cuff should be confirmed before starting any measurements. In order to calculate the percentage obstruction in the linear correlation zone, \(P_v\) should be at least 15 mmHg greater than the baseline cuff inflated pressure. Two points with different \(P_v\) settings and \(P_c\) readings should be taken and the gradient \((dP_c/dP_v)\) calculated. Based on this gradient and the above-detailed formula, the percentage obstruction can be calculated.

**Phase III: prediction of ETT obstruction by changes in maximal cuff pressure**

An example of calculation of the percentage obstruction is detailed in the ESM. Using this method, the calculated obstruction percentages of the ETTs were 41.3%, 0%, 33.6%, 29.3%, and 53.0%; the actual measured obstruction percentages were 37.9%, 0%, 31.25%, 25.0%, and 56.2%, respectively \((r^2 = 0.98, p < 0.001; \text{Fig. 6})\).

**Discussion**

Respiratory monitoring is usually based on pressure, volume, and flow rate at the proximal tip of the ETT. While there is no significant difference in measured volume and flow rates at the proximal and distal ends of the ET, the pressure is highly affected, mainly by the degree of obstruction of the ETT. In this study we found that, when there is no leak around the ETT cuff, the maximal cuff pressure \((P_c)\) during inspiration is significantly correlated with the maximal tracheal pressure \((P_v)\). The correlation of first degree is optimal when \(P_v\) is at least 15 mmHg greater than the baseline cuff pressure. The gradient \((dP_c/dP_v)\) reflects the degree of ETT obstruction and can be used for calculation of the obstruction based on the following formula:

\[
\text{Obstruction(\%)} = -553 \times (dP_c/dP_v)^2 + 672.5 \times (dP_c/dP_v) - 142.81.
\]

Several methods have been developed to determine the degree of ETT obstruction. The method developed by Juan et al. [12] is based on a special ETT with a miniature sound source and two sensing microphones that are placed in line between the ventilator hose and the proximal end of the ETT. The system analyzes the reflection of the acoustic pulse and estimates the percentage obstruction accordingly [12]. Visaria and Westenskow [14] based their obstruction evaluation on a five-element lumped pulmonary model of the respiratory input impedance. Guttmann et al. [11, 13, 21] have suggested three methods for detection of ETT obstruction. Their methods are based on forced pressure oscillations [13] or on the gradient between the ventilator and tracheal pressure [11, 21]. According to their method, the tracheal pressure is estimated and then the \(P_v\) versus \(P_{tr}\) gradient reflects the degree of obstruction. Calculation of the tracheal pressure is based on analysis of the passive expiratory time constant \((\tau_E)\) [11–15]. \(\tau_E\) is the product of respiratory resistance, lung compliance, and external resistance of the tubing and the ventilator. Since the resistance affects the expiratory flow, it also affects \(\tau_E\) [11]. In the current study, the cuff used as a functional component aimed to seal the trachea is also used as a sensor for tracheal...
pressure, and the differences between $P_v$ and $P_c$ are used for estimation of intratracheal obstruction. Moreover, the accuracy of the method was proved in the third phase of the study on ETTs that were removed from ICU patients with nonhomogenous tube obstruction.

Other suggested methods were to use the slowly increasing edge of the capnograph waveform as a marker of a partially obstructed tube, although a similar waveform can be caused by bronchospasm [22]. Use of the Blasius resistance formula was also suggested for evaluation of ETT stenosis [23, 24]. This formula is based on precise knowledge of the geometric, flow-independent parameter, which is one of its major limitations [23, 24].

The correlation between $P_c$ and $P_v$ was previously investigated by Wilder et al. [16]. They found that the cuff pressure can be used to predict the tracheal pressure as measured from the ETT [16]. We have confirmed their findings. However, this correlation can be used only when there is complete sealing of the trachea by the ETT cuff and when $P_v$ is greater than $P_c$. Complete sealing of the trachea by the ETT cuff was established by measuring the above-cuff CO$_2$ levels, as previously described [20]. If the ETT cuff does not completely seal the trachea, there will be leakage of CO$_2$ from the lungs around the cuff, which can be detected by monitoring the above-cuff CO$_2$ level [20].

In the current study we suggest a new method for estimation of ETT obstruction that is based on the cuff as a sensor, exploiting the gradient of $P_v$ versus $P_c$. The gradient is constant (linear correlation between $P_c$ and $P_v$), provided that $P_v$ is more than 15 mmHg greater than the baseline cuff inflate pressure. The gradient of the function at this section of the $dP_v/dP_c$ curve significantly correlates with the degree of obstruction. The constant term of the linear equation is not only related to the degree of obstruction but also to the baseline characteristics of the ventilator circuit and to the lungs’ compliance. Since the slope of the function is not related to any patient characteristics (such as lung compliance, volume, or bronchial tonus) or the tube material, it can be used in any intubated patients. As calculated in the second phase of the study, an empirical mathematical function that enables calculation of the obstruction based on the $P_c$ and $P_v$ readings was derived (Fig. 6). The accuracy of this formula was evaluated in the last phase of the study, where five used ETTs, recently removed from ICU patients, were verified by the proposed method. The obstruction was first calculated based on the $P_c$ versus $P_v$ measurements and then verified by directly measuring the occluded area. The correlation between the calculated and the directly measured obstruction was significant, with $r = 0.949$ and $p < 0.001$. The measurements were performed at different lung compliances, and it should be noted that this method is independent of any lung characteristics such as compliance or volume.

In this pilot study we used the cuff as a sensor for tracheal pressure. This sensor may be of significant importance for the new generation of ventilators. One of the major limitations of optimal performance of the new generation of the ventilators can be the pressure gradient fall between the ventilator and the lungs due to ETT obstruction [25, 26]. This pressure gradient leads to false evaluation by the ventilator of the lung/tracheal pressure, because of which: (1) the ventilator’s ability to detect the negative pressure induced by the patient for initiation of inspiration is reduced, leading to less effective assisted ventilation; and (2) the ventilator may inflate the lung with higher or lower pressure than is truly needed. It seems plausible to speculate that, once the method is directly synchronized with the new generation of ventilators, it might be possible to improve individual ventilator performance significantly. However, further clinical studies are needed in order to reach this point.

Limitations of the study

The major limitation of the study is that the method, including its mathematical algorithm, is still not fully integrated with the ventilator. Accordingly, the evaluation of ETT obstruction was performed on tracheal–lung simulators after the tubes were removed and not in vivo. The method, including the cuff pressure controller and ventilator, should be completely automatic and synchronized, since in real life there are other variables that may lead to changes in cuff pressure (e.g., change in head position, leak of gases in or out of the ETT cuff). Another possible limitation of the method is that $P_c$ is significantly correlated with $P_v$ only when $P_v$ is at least 15 mmHg greater than the baseline cuff pressure. With a smaller difference, $P_c$ may be temporally elevated for two to three respiratory cycles in order to estimate the degree of ETT obstruction.

Finally, the evaluation of ETT obstruction with this technique has been validated only for patients receiving controlled mechanical ventilation, as the presence of an actively breathing subject during partial ventilator support could alter the $P_c$ versus $P_v$ relationship.

Conclusions

The study proposes a new method for estimation of the percentage of ETT lumen obstruction during controlled mechanical ventilation. The estimation is based on the changes in cuff pressure during peak inspiratory pressure. The axioms of the method are that the trachea is completely sealed by the ETT cuff and that $P_v$ is higher than $P_c$. The method is simple, noninvasive, and independent of both patient and ventilator circuit parameters. Further
studies are needed in order to evaluate the method as part of daily clinical practice in intubated patients.

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References