Remote measurement of the leak around the uncuffed tracheal tube: objective measurement and physical characteristics

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Editor’s key points

- Incorrectly sized tracheal tubes (TTs) can cause problems especially in neonatal or paediatric intensive care.
- This study defines a new variable, $Q_{10}$, to quantify leak conductance (LC).
- $Q_{10}$ is a function of the interface between the TT and the tracheal wall and is unaffected by changes in inflation pressure.
- LC might be more objective than conventional measurements of loss of tidal volume.

Background. We have developed a technique for measuring a characteristic of the tracheal tube (TT)–trachea interface: the leak conductance (LC). This study aimed to validate the technique in the laboratory and to compare LC with measurements of fractional volume loss (FVL) in neonates undergoing mechanical ventilation.

Methods. LC, expressed as leak flow at a lung pressure of 10 cm H₂O, was derived remotely from ventilator pressure and flow signals. Validation was by simulating breathing circuits for 10 models in which LC was measured directly. LC was compared with FVL for different settings of PEEP, inspired pressure, and time at plateau pressure. Clinically, LC was measured for 135 infants admitted to paediatric intensive care after cardiac surgery and compared with FVL.

Results. No significant differences were found between direct and remote laboratory measurements of LC ($P > 0.05$). FVL varied with PEEP, plateau pressure, and time at plateau ($P < 0.05$) but LC did not ($P > 0.05$). The between-patient standard deviation ($\sigma$) of LC ($0.4$ litre min$^{-1}$) exceeded the within-patient $\sigma$ of LC ($0.05$ litre min$^{-1}$; $P < 0.05$); the between-patient $\sigma$ of FVL ($22.1\%$) exceeded the within-patient $\sigma$ of FVL ($1.3\%$; $P < 0.05$). The median LC was $0.38$ (inter-quartile range $0.29–0.46$) litre min$^{-1}$. LC was correlated with FVL ($r = 0.82$; $95\%$ confidence interval $0.76–0.88$) but wide ranges of FVL were observed for patients with similar LC.

Conclusions. LC can be derived remotely and was correlated with FVL, a conventional proxy for tube fit. It may be a better measure of TT fit than FVL.

Keywords: intensive care units, neonatal; intensive care units, paediatric; mechanical ventilation; positive pressure ventilation; respiratory function tests; respiratory mechanics, child; tracheal intubation

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While there are guidelines for choosing the correct size of tracheal tubes (TTs) in infants and children based on age, a leak test is recommended in each case because there is significant variation in airway size between individuals of similar age. Despite this being established practice, there is a 3% incidence of tracheostomy in the invasively ventilated paediatric intensive care unit (PICU) population in the UK, and in a recent multicentre study, Weiss and colleagues noted post-extubation stridor in 4.4% of patients with cuffed tubes and 4.7% with uncuffed tubes. Adherence to the guidelines does not obviate the need for changing tubes. Exchange rates of 23% and 30.8% have been reported in large studies with uncuffed tubes.

The leak test was confirmed as a poor predictor of extubation outcome by Wratney and colleagues but the reasons remain unclear and the physics of the leak phenomenon has not been studied extensively. Physically, the leak is a conduction path which allows the escape of ventilatory gas. Remote measurement of this conduction may provide more objective information than subjective assessment of the leak by a physician.

In this study, we aim to show first that a characteristic of the TT–tracheal interface [leak conductance (LC)] can be measured remotely and non-invasively using pressure and flow signals from a ventilator by laboratory validation. Secondly, we aim to compare the characteristic (LC) with fractional volume loss (FVL) in the laboratory and in neonates undergoing mechanical ventilation.

Methods

Favourable ethical opinion was received from the Northumberland and Tyne and Wear Local Research Ethics Committee
and the Gateshead and South Tyneside Local Research Ethics Committee (Ref: 05/Q0901/71). The Newcastle upon Tyne Hospitals NHS Foundation Trust acted as a sponsor for the project under UK Department of Health Guidelines for research in health and social care. Before taking measurements, written informed consent was obtained from the parents of all subjects.

Theory

Figure 1 shows a schematic of a ventilator, breathing circuit, and respiratory system. The spaces between a TT and the mucosa allow ventilatory gases to escape and are modelled by an additional leak. The theory of remote measurement of this leak, as assessed in this study, is described in the Appendix section and introduces two variables, \(a'\) and \(b'\) which are characteristics of the constriction but are unfamiliar in clinical practice. We introduce a quantity called \(Q_{10}\) which is the flow (in litre min\(^{-1}\)) through a leak when the lung pressure is 10 cm H\(_2\)O. The quantity \(Q_{10}\), which can be calculated from \(a'\) and \(b'\) using the Prony equation, is proportional to the conductance of the leak. Larger values of \(Q_{10}\) are associated with larger leaks and vice versa.

Laboratory measurements

We procured and built 10 physical models of the interface between a TT and the trachea. These included parabolic resistors used for ventilator testing (PneuFlo\textsuperscript{®}, Michigan Instruments, Grand Rapids, MI, USA), a custom-made parabolic resistor (orifice diameter 0.6 mm), and a series of uncut uncuffed TTs inside larger diameter TTs (Portex\textsuperscript{TM}, Smiths Medical, Kent, UK). In order of increasing conductance, the 10 models were: (1) custom resistor, Michigan models Rp500 and Rp200 in series; (2) custom resistor; (3) 5.5 mm outer diameter (OD) within 6.0 mm inner diameter (ID) TT; (4) 4.4 mm OD within 5.0 mm ID TT; (5) 4.8 mm OD within 5.5 mm ID TT; (6) 5.1 mm OD within 6.0 mm ID TT; (7) 4.2 mm OD within 5.5 mm ID TT; (8) 4.4 mm OD within 6.0 mm ID TT; (9) 4.2 mm OD within 6.0 mm ID TT; (10) Michigan model Rp50.

We measured the conductance of each model using steady flows. A cylinder of medical air, with a regulator, was connected via a tube (internal diameter 7.0 mm, length 1.5 m) to a flow laminiser (Intersurgical\textsuperscript{®} Clear Guard II Breathing Filter) in series with: a flow sensor (AWM720P1, Honeywell, Golden Valley, MN, USA), a T-piece connected to an electronic pressure gauge (FM321, Regional Medical Physics Department), the model under test, a second flow sensor (AWM720P1), and a second flow laminiser left open to atmosphere. Both flow sensors and the pressure sensor were calibrated using secondary standards. Laminar flow was confirmed by checking for a stable voltage output from the sensors according to manufacturer’s recommendations. The pressure decrease across each model was measured for steady flows in the range 0–12 litre min\(^{-1}\). For each model, variables \(a'\) and \(b'\) were calculated using a quadratic best fit (Matlab, Mathworks Ltd, Cambridge, UK).
The model was introduced to the breathing circuit as a leak and signals were recorded for 100 contiguous breaths in BIPAP mode ($T_{insp}=0.7$ s, $P_{insp}=25$ cm H$_2$O, frequency=20 bpm, PEEP=5 cm H$_2$O). Optimal values of $a'$ and $b'$ were calculated with equation (5) using an iterative technique. Values of $Q_{10}$ were calculated from $a'$ and $b'$ coefficients. The mean FVL was calculated from the mean difference between the integrated inspired and expired flows. Flow through the leak was measured using a flow sensor placed after the leak.

Using one of the models (custom made parabolic resistor) in the simulated breathing circuit, contiguous sequences of 100 breaths were captured for different ventilator settings. PEEP, time spent at plateau, and plateau pressure were varied independently. For each setting, pressure and flow signals were used to calculate $a'$, $b'$, $Q_{10}$, and the FVL.

**Clinical measurements**

We studied 135 children after surgery for cardiac defects whose tracheas were intubated with uncuffed TTs (Portex™). Once they had been admitted to the ICU and were clinically stable, a nurse initiated the collection of signals from the ventilator for 100 contiguous breaths. The first recording for each subject was used to calculate $a'$, $b'$, and $Q_{10}$ using the algorithm described earlier. The FVL was calculated from inspired and expired flow signals. Individual breaths were identified from the recordings using an algorithm written in Matlab. For each recording, 10 values of $Q_{10}$ were calculated for each series of consecutive breaths.

No data were analysed until the patient had been discharged from ICU; the study did not influence clinical management. Three ventilators were used in the study (one Evita XL, two Evita 4, Dräger). In the laboratory, pressures and flows from the calibrated sensors were used to calculate correction factors for the internal sensors of each ventilator.

**Statistics**

For the laboratory measurements, the method of Bland and Altman$^9$ was used to compare the values of $Q_{10}$ for each model by direct measurement and remote measurement. Values for bias, 95% confidence interval of bias (95% CI) and 95% limits of agreement (95% LA) are given for each comparison. Analysis of variance was used to assess the variation of $Q_{10}$ and FVL with ventilator settings and to calculate the between- and within-subject variations of clinical measurements. Correlations were tested using Pearson’s product moment coefficient. Minitab (State College, PA, USA) and Matlab were used for statistical calculations and the null hypothesis was rejected for $P<0.05$.

**Results**

**Laboratory measurements**

We found no significant difference between the internal pressure sensor of the ventilator and the calibrated pressure gauge with bias 0.09 (95% CI: −0.02 to 0.21; 95% LA: −1.19

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**Table 1** Coefficients ($a'$ and $b'$) of the Prony equation and characteristic $Q_{10}$ for 10 physical models of the trachea–TT interface measured directly using steady flows and estimated using the algorithm described in the Methods section.

<table>
<thead>
<tr>
<th>Model</th>
<th>Direct measurements with steady flows</th>
<th>Remote ventilator measurements</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$b'$ (kg m$^{-2}$)</td>
<td>$a'$ (kg m$^{-4}$ s$^{-1}$)</td>
</tr>
<tr>
<td>1</td>
<td>$2.40 \times 10^{12}$</td>
<td>$9.16 \times 10^{7}$</td>
</tr>
<tr>
<td>2</td>
<td>$2.32 \times 10^{12}$</td>
<td>$7.30 \times 10^{7}$</td>
</tr>
<tr>
<td>3</td>
<td>$2.74 \times 10^{11}$</td>
<td>$3.03 \times 10^{7}$</td>
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<td>4</td>
<td>$1.73 \times 10^{11}$</td>
<td>$1.91 \times 10^{7}$</td>
</tr>
<tr>
<td>5</td>
<td>$9.44 \times 10^{10}$</td>
<td>$7.39 \times 10^{6}$</td>
</tr>
<tr>
<td>6</td>
<td>$6.43 \times 10^{10}$</td>
<td>$7.55 \times 10^{6}$</td>
</tr>
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<td>$5.46 \times 10^{10}$</td>
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<td>8</td>
<td>$4.88 \times 10^{10}$</td>
<td>$3.37 \times 10^{6}$</td>
</tr>
<tr>
<td>9</td>
<td>$3.58 \times 10^{10}$</td>
<td>$2.63 \times 10^{6}$</td>
</tr>
<tr>
<td>10</td>
<td>$1.38 \times 10^{10}$</td>
<td>$4.24 \times 10^{5}$</td>
</tr>
</tbody>
</table>
to 1.37) cm H$_2$O or between the inspired flow sensor of the ventilator and the calibrated flow meter with bias 0.02 (95% CI: −0.01 to 0.05; 95% LA: −0.10 to 0.14) litre min$^{-1}$. A bias of 0.14 (95% CI: 0.13–0.15; 95% LA: 0.04–0.25) litre min$^{-1}$ was detected between the ventilator flow expired sensor and the calibrated flow sensor and was corrected for in all subsequent analysis.

Pressure–flow characteristics for all 10 leak models are shown in Figure 2. Coefficients $a'$ and $b'$, and LC characteristic $Q_{10}$ calculated by both methods for each model are given in Table 1. There was no significant difference between the two methods for calculating $Q_{10}$ with a mean difference (direct measurement–remote measurement) of 0.08 (95% CI: −0.46 to 0.63; 95% LA: −1.88 to 2.04) litre min$^{-1}$.

For variation of PEEP, from an analysis of variance with five groups (i.e. five values of PEEP) each of 10 repeat measurements of $Q_{10}$, we found no significant differences between groups. From a similar analysis, we found significant differences in FVL ($P<0.05$) between settings of PEEP. Similar results were found for different settings of inspired pressure and time at plateau. The FVL changes (increases) with increasing PEEP, peak pressure, and time at plateau, but $Q_{10}$ remains invariant (Fig.3).

Clinical measurements

Of the recordings taken from 135 patients, 130 (96%) were suitable for analysis. Recordings were rejected due to excessive noise. Of the 130 patients studied, the mean (range) age was 208 days (2–1800 days) and the mean (range) weight was 5.8 kg (2.5–16.8 kg).

We found no significant differences between internal pressure sensors of the three ventilators and the calibrated pressure sensor with biases (95% CI; 95% LA) of 0.09 (−0.02 to 0.21; −1.19 to 1.37), 0.05 (−0.02 to 0.13; −0.68 to 0.79), and 0.00 (−0.03 to 0.03; −1.22 to 1.22) cm H$_2$O or between internal ventilator inspired flow sensors and the calibrated flow sensor with biases (95% CI; 95% LA) of 0.02 (−0.01 to 0.05; −0.10 to 0.14), 0.04 (−0.02 to 0.09; −0.33 to 0.42), and 0.04 (−0.03 to 0.10; −0.55 to 0.62) litre min$^{-1}$. There were small but significant differences between internal ventilator expired flow sensors and the calibrated sensor with biases (95% CI; 95% LA) of 0.14 (0.13–0.15; 0.04–0.25), 0.17 (0.12–0.22; −0.30 to 0.65), and 0.16 (0.11–0.21; −0.47 to 0.79) litre min$^{-1}$ which were corrected for in all subsequent analysis.

Consecutive sequences of breaths were used to calculate 10 separate estimates of $Q_{10}$ for each patient. Analysis of variance was calculated for 130 groups of 10 values of $Q_{10}$.
The between-group standard deviation (SD 0.40 litre min⁻¹) significantly exceeded the within-group SD (0.05 litre min⁻¹), P<0.01. We conclude that the within-subject repeatability, at least for measurements taken within a few minutes, is sufficiently small to permit differences between subjects to be detectable. For FVL, the between-subject SD (22.1%) exceeded the within-subject SD (1.3%) with P<0.01.

The median value of $Q_{10}$ was 0.38 litre min⁻¹ (range 0.18–2.46 litre min⁻¹, inter-quartile range 0.29–0.46 litre min⁻¹). LC was positively correlated with FVL (Pearson’s $r$ coefficient 0.82, 95% CI 0.76–0.88), but wide ranges of fractional losses were observed for patients with similar values of $Q_{10}$ (Fig. 4).

Figure 5 shows the relationship between the volume lost to the leak and the time integral of lung pressure (TILP)—that is, the degree of pressure difference and its duration of action, for two different $Q_{10}$ ranges corresponding to small and moderate leaks. For each range of $Q_{10}$, there was an increase in the volume lost to leak in response to increases in TILP. The slope of the best fit was greater for larger values of $Q_{10}$.

**Discussion**

By constructing a series of different models of the leak between a TT and the tracheal wall, we found that the pressure vs flow relationship is adequately described by a quadratic relationship consistent with the Prony equation. We have developed an algorithm to calculate the Prony coefficients of a leak constriction in a breathing circuit by analysis of pressure and flow signals measured at the ventilator and have validated this algorithm using a simulated breathing circuit in the laboratory. The quantity $Q_{10}$ has been introduced to represent the conductance of the leak as a single number with clinical meaning, which is calculated from the Prony coefficients.

Remote measurements of $Q_{10}$ are invariant to changes in ventilator settings (PEEP, plateau pressure, time at plateau) while the conventional measure of leak—FVL—varied significantly. In measurements of $Q_{10}$ and FVL from 130 subjects, we found that $Q_{10}$ was positively correlated with FVL, but that different patients with similar measurements of $Q_{10}$ were found to have different FVLs. This is consistent with $Q_{10}$ being a characteristic of the TT–trachea interface while FVL depends on the pressure at the distal end of the TT and the characteristics of the interface. We observed a large range of FVLs, with up to 90% in some cases. This is consistent with the results of other studies: Mahmoud and colleagues reported a range of leaks of 6–97% on the day on which the leak was first noted and Main and colleagues reported leaks exceeding 90% before tube change.

Characterization of the leak has usually been by measuring the volume loss. The largest series previously reported was by Main and colleagues who found that volume lost through the leak confounds the measurement of pulmonary mechanics and recommended that leak volume should be clearly displayed by ventilators to improve clinical decisions. The flow characteristics of the leak were first analysed by Bijaou and colleagues. That clinical series was small and
the authors assumed a linear relationship between pressure and flow through the leak constriction.

We consider $Q_{10}$ to be a better descriptor of the TT subglottis interaction as it remains invariant to changes in inflation pressure or duration of inflation as illustrated in Figure 3 (laboratory) and Figure 5 (clinical environment). Thus, it describes a space between the external surface of the TT and the subglottis which might get smaller with fluid loss or steroid therapy. Although the same space might permit the loss of a larger fraction of the tidal volume around the TT should the pressures exerted around it be different. This study is particularly relevant to the neonatal intensive care unit and PICU setting, where TTs are in place for longer than during anaesthesia and surgery and the safety of cuffed tubes has not yet been established.\(^{14}\)

This study did not aim to establish an acceptable range for LC. To do so would require further research to test its association with clinical outcome measures such as incidence of reintubation and post-extubation stridor compared with conventional measures of leak such as FVL. The shape of the leakage ring around the TT is not constant and pressure-related damage may arise even in the presence of a leak due to asymmetric positioning of the tube. This is an inherent limitation in the concept of the leak test and does not diminish the relevance of this study in its aim to validate a more objective assessment of the interface. Although the Prony equation includes linear and quadratic components, it is not optimal in describing flow in the transitional region between laminar and turbulent flow (the ‘knee’ regions in Figure 2, for example). An improved empirical or theoretical relationship between pressure and flow through the leak in the transitional region may yield better fit to in vitro measurements.

Further clinical research is needed to establish whether or not LC is a better measure of TT fit than FVL, by testing relative association with incidence of tracheal injury and incidence of reintubation.

LC may be a more useful quantity than volume loss to describe the fit of a TT in the glottis of an infant. It is an objective measure of the interaction between the TT and the child’s trachea. We have shown that it can be derived remotely and could be calculated by an algorithm within the software of a ventilator which would provide real-time measurements of LC. It promises a more objective analysis of TT fit and may help prevent the recurrent under sizing of TTs in infants.

**Supplementary material**

Supplementary material is available at British Journal of Anaesthesia online.

**Declaration of interest**

None declared.

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**Appendix**

**Theory of non-invasive measurement of LC**

The empirical Prony equation\(^{15}\) is used to estimate the head pressure decrease, $h_t$, due to a constriction with characteristic length $L$ and diameter $D$ for a fluid flowing with mean velocity $V$. The coefficients $a$ and $b$ depend on the shape of the constriction, the roughness of the boundaries, and the viscosity of the fluid.

$$h_t = \frac{L}{D}(aV + bV^2) \tag{1}$$

For pressure decrease, $P$, and volumetric flow rate, $Q$, the Prony equation becomes

$$P = a'Q + b'Q^2 \tag{2}$$

Coefficients $a'$ and $b'$ combine $a$, $b$, acceleration due to gravity, gas density, and geometrical factors associated with the constriction and have units of kg m$^{-4}$ s$^{-1}$ and kg m$^{-7}$, respectively. They are normally calculated empirically from a quadratic fit to the pressure–flow curve of a flow constriction. It is impracticable to measure pressure and flow at the distal end of a TT in vivo and we estimated $a'$ and $b'$ using an indirect technique.

When the distal pressure of the TT, $P_L$, exceeds atmospheric pressure, there will be a leak. $P_L$ is equal to the pressure at the ventilator, $P_V$, minus the pressure decrease due to the TT, $P_{TT}$. Jarreau and colleagues\(^{16}\) measured the relationship between $P_{TT}$, tube diameter ($d_{TT}$), length ($l_{TT}$), and volumetric flow rate, $Q_V$, at the ventilator.

$$P_{TT} = l_{TT}(0.0203d_{TT}^{4.25}Q_V^{1.5}) + (0.0319d_{TT}^{-4}Q_V) \tag{3}$$

The Prony equation relates $P_L$ to the volumetric flow rate through the leak, $Q_L$.

$$b'Q_L^2 + a'Q_L - P_L = 0 \tag{4}$$

Signal $Q_L$ is not known, but over each breath, its time integral is equal to the volume loss, $V_L$, which is known. For a breath of duration $\tau$, equation (4) leads to the following expression for $V_L$.

$$V_L = -\frac{a'}{2b'} \tau + \frac{1}{2b'} \left[ \sqrt{\frac{a'^2}{4b'^2} + 4b'P_L} \right] \tag{5}$$

In this study, we estimated values for coefficients $a'$ and $b'$ from signal $P_L$ and volume loss $V_L$ for a series of breaths, using equation (5) and a numerical two-variable fitting technique.
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