An in vitro characterization of endotracheal tube cuff performance

CHUCK BIDDLE, CRNA, MS
Kansas City, Kansas

Knowledge of design characteristics and performance of tracheal tube cuffs is essential in minimizing morbidity and ensuring efficacy. Using helium and nitrous oxide in several in vitro models, Mallinckrodt Hi-lo® and Shiley Low Pressure® tracheal tube cuffs were studied. Significant differences were found between the devices with regard to intubated and non-intubated compliance, diffusion of gas across the cuff membrane, and other relevant physical characteristics. Clinical implications of the findings are discussed, and a gaseous diffusion retardant model is tested and found promising.

Complications attend advances in the management of the patient requiring intubation and mechanical ventilation. Knowledge of the design characteristics of endotracheal tubes aids clinicians caring for patients with such devices in situ. Given the contemporary tendency to monitor cuff pressure and assess tracheal mucosal integrity, an in vitro experimental design was developed to elucidate factors operative in the clinical performance of tracheal tubes.

Diffusion is concerned with the rate of migration of molecules. Gaseous diffusion through living membranes occurs in biological processes. In the intact organism, factors such as gas solubility, membrane thickness, permeability, and viscosity interact to govern diffusion. Diffusion through inert (non-living) substances is dependent upon the porosity of the material, temperature, size/weight of the molecules, and the solubility of the gas in the inert substance. The laws of Graham, Fick and Dalton serve to describe these phenomena. Such principles have important clinical applications, one of which is the management of the patient with a cuffed tracheal tube in situ. Diffusion of gases across the pulmonary membrane takes place with ease. Contemporary designs of tracheal tube cuffs mimic this quality, often to the frustration of the clinician. Tracheal tubes have subtle design variations which account for differential clinical performance. The Mallinckrodt Intermediate Hi-lo Tracheal Tube® (MTT) and the Shiley Low Pressure Endotracheal Tube (SET), devices commonly used in operating rooms and intensive care units nationwide, were selected for study.

Materials and methods

Seven MTT and seven SET devices, all sized 8.0 mm internal diameter, were studied. An artificial trachea (a 20 cc glass syringe barrel with an internal diameter of 20 mm) was utilized in the measurement of each characteristic. Three simple apparatuses were designed to quantify compliance, diffusion time, and diffusion rate. The technique and setup of each design is explained in Figures 1, 2 and 3.

Experimental design I. Compliance of the non-
intubated cuff ($C_{int}$) was measured as ml/20 cm H$_2$O, that is, the volume of air delivered from the nonintubated cuff when the cuff pressure was reduced from 40 to 20 cm H$_2$O. The compliance is reflected by the cuff volume change secondary to decreasing the cuff pressure by 20 cm H$_2$O (Figure 1).

Compliance of the intubated cuff ($C_{int}$) was measured as ml/20 cm H$_2$O, that is, the volume of air delivered for the intubated cuff when the cuff pressure was reduced from 40 to 20 cm H$_2$O (Figure 1).

Volume of air aspirated from the intubated cuff at 20 cm H$_2$O cuff pressure ($VA$) was measured as ml, determined following measurement of $C_{int}$ (Figure 1).

Residual volume ($RV$) was measured as ml, that is, the volume of air aspirated from the nonintubated cuff at a cuff pressure of 2 cm H$_2$O (Figure 1).

Experimental design II. Diffusion time ($DT$) was measured in minutes, that is, the time required to increase the intubated cuff pressure from 20 to 40 cm H$_2$O following the insufflation of 100% nitrous oxide or 100% helium to the cuff. A 37°C ($\pm$ 0.25°) water bath enveloped the tracheal tube cuff area and apparatus (Penn Plax Thermal Flow Aquarium Heater®, 8", 100 watts) (Figure 2).

Experimental design III. Cuffs were dissected carefully from all tubes and suspended over the transected inner 20 cc syringe barrel (cuff area = 3.14 cm$^2$). Diffusion rate ($DR$) was ml/3.14 cm/hr, that is, the volume of gas that diffused through the 3.14 cm$^2$ area of the cuff following insufflation of 100% nitrous oxide or 100% helium for one hour. A 37°C ($\pm$ 0.25°) water bath enveloped the tracheal tube cuff area and apparatus (Figure 3).

Experimental design IV. $DR$ was determined for all cuffs and for both gases as described in Design III after the application of a 2 mm film of silicone sealant (Radio Shack Silicone Seal 64-2314®) to the inner, non-gas-exposed surface of the barrel-suspended cuff membrane. This design was hampered by the inability to reproduce consistently a uniform thickness of the silicone in the 14 cuff preparations. A 37°C ($\pm$ 0.25°) water bath enveloped the transected inner 20 cc syringe barrel (cuff area = 3.14 cm$^2$). Diffusion rate ($DR$) was ml/3.14 cm/hr, that is, the volume of gas that diffused through the 3.14 cm$^2$ area of the cuff following insufflation of 100% nitrous oxide or 100% helium for one hour. A 37°C ($\pm$ 0.25°) water bath enveloped the tracheal tube cuff area and apparatus (Figure 3).

Experimental design IV. $DR$ was determined for all cuffs and for both gases as described in Design III after the application of a 2 mm film of silicone sealant (Radio Shack Silicone Seal 64-2314®) to the inner, non-gas-exposed surface of the barrel-suspended cuff membrane. This design was hampered by the inability to reproduce consistently a uniform thickness of the silicone in the 14 cuff preparations. A 37°C ($\pm$ 0.25°) water bath enveloped the transected inner 20 cc syringe barrel (cuff area = 3.14 cm$^2$). Diffusion rate ($DR$) was ml/3.14 cm/hr, that is, the volume of gas that diffused through the 3.14 cm$^2$ area of the cuff following insufflation of 100% nitrous oxide or 100% helium for one hour. A 37°C ($\pm$ 0.25°) water bath enveloped the tracheal tube cuff area and apparatus (Figure 3).
oped the tracheal tube cuff area and apparatus (Figure 3). Multiple paired t-tests were performed on each parameter to test for significance between the cuff groups; p < 0.05 was considered significant.

Results

Data is summarized in Table I for all studies performed. The measured/derived characteristics of each tracheal tube cuff are described as follows:

The MTT cuff design had a higher static compliance ($C_1 = 2.5 \text{ ml/20 cm } H_2O$) than the SET; however, upon placement into the artificial trachea, compliance fell precipitously ($C_1 = 0.32 \text{ ml/20 cm } H_2O$). The VA was less than the RV, indicating that increases in cuff pressure transmit directly to the tracheal wall. DT was shorter and DR greater than in the SET design.

For the SET, $C_{n-1}$ was lower ($C_{n-1} = 1.7 \text{ ml/20 cm } H_2O$), but $C_1$ was more than twice that of the MTT ($C_1 = 0.7$ versus $0.3 \text{ ml/20 cm } H_2O$). VA was greater than RV, suggesting that tracheal wall pressure is less than cuff pressure. DT was longer, and DR was less than in the MTT design.

The silicone film blunted the diffusion of nitrous oxide by 23.8% and 27.8% respectively in the MTT and SET designs (results from experimental design III served as control).

Discussion

Nitrous oxide and helium represent excellent gases to establish inert membrane characteristics. Nitrous oxide's differential solubility with respect to nitrogen (about 34 times more soluble) will cause it to expand any closed space containing air. Helium is monatomic; its molecular weight is 4.002, and it is the second lightest element (density of 0.177 gm/liter). It is the least soluble of the elemental gases. Its clinical utility is based upon its lightness, resulting in its ability to facilitate gas flow in patients with respiratory disease by reducing the work of breathing. It is only $\frac{1}{6}$ as heavy as oxygen and diffuses 2.8 times faster (Graham's Law). A mixture of 79% helium and 21% oxygen weighs only about one-third as much as an equal volume of air. As predicted, helium readily traversed cuff membranes.

---

Figure 2
Measurement of diffusion time (Minutes to raise cuff pressure from 20-40 cm H$_2$O)

One hundred percent helium or nitrous oxide was supplied via gas inlet (5) at 1 L/min. The proximal opening of the tracheal tube was plugged with a stopper (6). 3 side holes were punched just above the cuff (4). A tracheal tube was intubated into the mock trachea (3), and the cuff was inflated with air via a 3-way stopcock (9) until the H$_2$O column of the manometer (8) descended to 20 cm H$_2$O, that is, cuff pressure of 20 cm H$_2$O. Arrows indicate the pathway of gas flow. As cuff pressure increased, the H$_2$O column in the manometer descended. When meniscus was formed at the distal opening of the manometer, a cuff pressure of 40 cm H$_2$O had been achieved. Time from the initiation of flow to the achievement of a pressure of 40 cm H$_2$O was considered the diffusion time.

Key:
1. H$_2$O bath vessel
2. tubing to gas source
3. mock trachea
4. side holes
5. gas inlet
6. stopper
7. IV extension tubing
8. manometer
9. 3-way stopcock
10. H$_2$O reservoir
11. Penn Plax Aquarium Heater
The diffusion of gas into an air-inflated tracheal tube cuff is dependent upon the partial pressure gradient, available surface area for diffusion, membrane thickness, membrane porosity, and the size and weight of the gaseous molecules. Temperature is also a factor; for this reason, it was carefully controlled at 37°C.

Comparison of the MTT with the SET revealed certain conspicuous differences. The MTT has an RV approximately twice that of the SET, a larger cuff surface area, and a narrower cuff membrane (0.033 mm versus 0.20 mm). Compliance upon intubation depends on cuff expansion into areas not limited by physical barriers, such as the trachea. When placed into the in vitro trachea, a large area of the cuff communicates with the glass barrel, resulting in a fallen compliance. The tapered design of the SET cuff provides for more free surface area, explaining the greater compliance for the SET design.

The floppy design of the MTT helps predict a clinically shorter DT. When floppy cuffs are inflated within the trachea, wrinkling occurs. Wrinkling could increase surface area, providing more area for diffusion. DR is greater in the MTT, at least in part, because of a thinner cuff membrane (Fick's Law). Conversely, the SET resists development of high pressure because of its more favorable compliance quality in the intubated setting and the cuff's tendency to retard diffusion.

Given a situation where similarly designed cuffs are inflated with an equal volume of air, pressure within the non-intubated cuff will be less than within the intubated cuff; a relationship described by:

\[ P_i = P_n + P_t \]

Where

- \( P_i \) = Pressure of the intubated cuff for the given volume
- \( P_n \) = Pressure of the non-intubated cuff for the given volume
- \( P_t \) = Tracheal wall pressure

---

**Figure 3**

**Measurement of diffusion rate (ml/3.14 cm²/hr)**

One hundred percent helium or nitrous oxide was supplied via gas inlet (8) at 1 L/min, insufflating the area of the cuff membrane 3.14 cm² (2). Diffusion of gas increased the volume, which was transferred to the collecting syringe barrel 3 ml (12), which was prefilled with H₂O. The volume of H₂O displaced by the expanding gas volume was measured at the end of an hour. An H₂O bath was maintained by 37°C.

In Experimental Design IV, a thin film of silicone sealant was applied to the inner, non-gas-exposed surface of the cuff membrane suspended over the barrel of the inner syringe barrel (14).

(1) tubing to gas source
(2) cuff membrane area = 3.14 cm²
(3) rubber band wrapping
(4) Penrose* tubing pad
(5) syringe barrel 20 ml, 2 cm internal diameter transected at the 10 ml mark
(6) syringe barrel 50 ml
(7) H₂O bath vessel
(8) gas inlet
(9) Penn Plax Aquarium Heater®
(10) IV extension tubing
(11) 3-way stopcock
(12) collecting syringe barrel 3 ml
(13) H₂O reservoir
Residual volume was that volume of the non-intubated cuff which produced negligible cuff pressure (a function of the individual design of the cuff). If RV is greater than cuff volume at \( P_1 \), then \( P_1 = P_r \), that is, the cuff transmits all its pressure to the tracheal wall. Conversely, if RV is less than cuff volume at \( P_1 \), then the difference between \( P_i \) and \( P_r \) will equal the \( P_t \), and the entire cuff pressure does not transmit to the tracheal wall.

These factors help explain the findings of this study regarding the observed differences between the MTT and SET with respect to the \( C \). The RV of the MTT was larger than the VA, so virtually all the cuff pressure was transmitted to the tracheal wall. In the case of the SET, the RV was less than the VA, so tracheal wall pressure was less than cuff pressure.

It is clear that contemporary designs of tracheal cuffs are far from optimal. A tracheal tube placed in a patient receiving helium or nitrous oxide will undergo cuff expansion. Certain designs may not produce a seal sufficient to provide for adequate positive pressure ventilation. For instance, pressure to an area of tracheal mucosa may produce injury, large cuff surface areas enhance gaseous diffusion, and the wrinkles of a floppy cuff might produce uneven tracheal pressure or serve as conduits for aspiration. The capacity of an industrial grade silicone compound to retard gaseous diffusion across a cuff membrane deserves further investigation. The imaginative designer could utilize silicone, Teflon®, epoxy, flexible metals, or any number of substances on the inside of the cuff to provide a barrier to gaseous diffusion. Such a retardant could be incorporated easily into the manufacturing process of the tracheal tube.

The tendency for manufacturers to incorporate descriptive terminology for their product names such as, “hilo,” “low pressure,” “intermediate hilo”, and the like, may be misleading. Supplying the clinician with more relevant information, such as residual volume, intubated compliance, and diffusion rate, would prove more profitable in terms of patient care. Designers should continue to search for improved tracheal cuff designs that will attenuate diffusion of gases, maximize compliance, and minimize physiological trespass.

It is unclear at this time how best to equate the findings of in vitro with an in vivo setting.

### Table I

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>MTT (n = 7)</th>
<th>SET (n = 7)</th>
<th>Gas</th>
</tr>
</thead>
<tbody>
<tr>
<td>( C_{n-i} ) (ml/20 cm H2O)</td>
<td>2.40 ± 0.2</td>
<td>1.80 ± 0.2</td>
<td>100% N2O</td>
</tr>
<tr>
<td>( C_{i} ) (ml/20 cm H2O)</td>
<td>0.40 ± 0.2</td>
<td>0.80 ± 0.2</td>
<td>100% He</td>
</tr>
<tr>
<td>VA (ml)</td>
<td>8.80 ± 0.2</td>
<td>8.40 ± 0.2</td>
<td></td>
</tr>
<tr>
<td>RV (ml)</td>
<td>16.20 ± 0.8</td>
<td>7.80 ± 0.8</td>
<td></td>
</tr>
<tr>
<td>DT (mins)</td>
<td>6.80 ± 1.6</td>
<td>21.80 ± 1.8</td>
<td></td>
</tr>
<tr>
<td>DT (mins)</td>
<td>4.60 ± 1.8</td>
<td>14.60 ± 1.6</td>
<td>100% He</td>
</tr>
<tr>
<td>DR (ml/3.14 cm²/hr)</td>
<td>2.10 ± 0.4</td>
<td>1.80 ± 0.4</td>
<td>100% N2O</td>
</tr>
<tr>
<td>DR (ml/3.14 cm²/hr)</td>
<td>1.40 ± 0.8</td>
<td>1.20 ± 0.8</td>
<td>100% He</td>
</tr>
<tr>
<td>DR silicone seal (ml/3.14 cm²/hr)</td>
<td>1.60 ± 0.6</td>
<td>1.20 ± 0.6</td>
<td>100% N2O</td>
</tr>
</tbody>
</table>

All values are mean ± standard deviation

All values were statistically significant; \( p < 0.05 \)

\( C_{n-i} \) = compliance in the non-intubated cuff

\( C_{i} \) = compliance in the intubated cuff

VA = volume of aspiration

RV = residual volume

DT = diffusion time

DR = diffusion rate
What is clear is that cuff geometry, floppiness, thickness, and chemical constituency all serve to modify significantly the clinical performance of the device. While contemporary designs for cuffs are far from optimal, care should be planned around the limitations of the devices. Knowledge of their design and performance provides anesthesia practitioners with data to assess reliably in situ tracheal tubes, attenuate mucosal damage, minimize aspiration risk, and ensure ventilatory integrity in the mechanically ventilated patient.

**REFERENCES**


**AUTHOR**

Chuck Biddle, CRNA, MS, is a graduate of the School of Anesthesia, Norfolk General Hospital/Old Dominion University, Norfolk, Virginia. He is an assistant professor with the Department of Nurse Anesthesia Education at the University of Kansas Medical Center, Kansas City, Kansas.