High-volume, Low-pressure Cuffs*
Are They Always Low Pressure?

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Ischemic tracheal complications due to the ETT cuff occur in approximately 10 percent of mechanically ventilated critically ill patients despite the use of high-volume, low-pressure ETT cuffs. Using a laboratory model, we studied the effects of airway pressure on three different ETT cuff designs, including two “low pressure” designs. Positive airway pressure acted on the “low pressure” cuffs to create a “self-sealing” effect that maintained tracheal occlusion despite airway pressures that exceeded cuff inflation pressure. Increases in airway pressure caused by decreased lung compliance resulted in higher cuff inflation pressures in all three groups, with the smallest increase occurring in the design that had the longest tracheal contact length. We conclude that the current high-volume, low-pressure ETT cuff design currently used does not guarantee low cuff pressure when high airway pressures occur, and an alternative design should be developed.

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In the 1960s, ischemic tracheal complications such as tracheal stenosis and tracheoesophageal fistula occurred in up to 20 percent of intubated and mechanically ventilated patients. Endotracheal tubes were typically constructed with low-volume cuffs which had little or no resting volume and a diameter smaller than tracheal diameter. Such cuffs frequently required inflation pressures of 160 to 300 mm Hg to seal the tracheal and deformed the trachea from its normal “C” shape into an expanded circular shape. The pressure exerted upon the tracheal mucosa (CT pressure) by inflating a low-volume, high-pressure cuff was impossible to estimate; however, directly measured CT pressures ranged up to 200 mm Hg or more. Furthermore, small increments (1 to 3 ml) in cuff volume beyond the MOV produced increases in the CT pressure of up to 100 mm Hg or more. Such high CT pressures severely restricted tracheal wall blood flow and caused mucosal ulceration, tracheomalacia with tracheal dilation, perforation and tracheal stenosis as scar formation occurred with healing.

In the early 1970s, large volume cuffs with a diameter greater than that of the trachea largely replaced the low-volume, high-pressure cuffs. When used properly, these large cuffs sealed the trachea by draping themselves freely along the contours of the tracheal wall without altering the normal “C” shape of the trachea. As a result, these cuffs did not need to be inflated beyond their resting diameter and required lower inflation pressures than the earlier low-volume, high-pressure design. Furthermore, cuff inflation pressures approximately equalled CT pressure because no pressure was generated by stretching the cuff to fill the trachea. Thus, the high-volume, low-pressure design operated with less CT pressure and reduced the overall incidence of ischemic tracheal complications.

In 1981, Stauffer et al reported findings in a group of 150 patients who were mechanically ventilated with tracheal intubation in a SICU. Despite the use of high-volume, low-pressure endotracheal cuffs, at follow-up 11 percent (3 of 27) had tomographic evidence of tracheal stenosis at the cuff site, an incidence strikingly similar to previous reports involving low-volume, high-pressure cuffs. They also found that 19 percent of the 150 SICU patients required excessive cuff pressure (>25 mm Hg) to seal the trachea, while an inability to seal the airway was noted in 11 percent despite intracuff pressures up to 60 mm Hg. The reasons for the excessive intracuff pressure requirements were not clear.

Recently we had occasion to review two cases in which patients with ARDS sustained ischemic tracheal complications following a prolonged period of mechanical ventilation with high PIP above 50 cm H2O. One of these patients developed a tracheoesophageal fistula requiring tracheal reconstruction and prolonged hospitalization. The other patient suffered massive tracheal dilation before succumbing to multiple organ failure. In both cases, ETTs with high-volume, low-pressure cuffs had been continuously employed. Proper cuff inflation (minimal leak) techniques had been utilized, together with appropriate humidifica-

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tion, tidal volume and minute ventilation. As in the report of Stauffer et al, we were unable to explain the extensive tracheal damage associated with the use of high-volume, low-pressure ETT cuffs and created a laboratory model to examine intracuff pressure and volume characteristics.

METHODS

We studied the effects of airway pressure on the performance of current ETT cuff designs by using a laboratory model to simulate the extremes of clinically employed positive pressure mechanical ventilation, i.e., under conditions of high Cl with low PIP vs markedly reduced Cl with high PIP.

Three ETT cuff designs, LO, MED and HI were evaluated using 7.0- and 8.0-mm ID ETTs (Fig 1). Resting cuff volumes (the performed just inflated volume) were measured using a calibrated syringe. A mechanical lung (Vent Aid TTL, Michigan Instruments, Inc), which was connected to a lubricated (lightweight household oil, WD-40) 19 x 22-mm model trachea (Imatrac, Mallinckrodt) was used to simulate changes in Cl from 100 to 15 mL/cm H2O. A volume-cycled ventilator (Bear 2) delivered a tidal volume (VT) of 1,000 mL; inspiratory and expiratory volumes were measured with two rotating vane-type spirometers (Wright) connected in series just proximal to the ETT. Ten ETTs of each size (7.0- and 8.0-mm ID) and cuff type (LO, MED, HI) were inflated in the trachea at 21°C using a calibrated syringe until a “minimal” leak of 10 percent (100 mL) and then 5 percent (50 mL) of the 1,000 mL VT occurred (American National Standards Institute defines a minimal leak as 5 percent of the delivered volume) 19 Airway and ETT intracuff pressures were measured at both the 10 and 5 leak volumes using pressure transducers (Gould-Statham P50) and a multichannel polygraph recorder (Grass model 7B). Leak volume was ascertained by the difference between the inspiratory and expiratory volumes. Complete occlusion of the trachea was demonstrated by lack of bubble formation in a soap solution coating the proximal trachea-cuff interface and showed this method of leak measurement to be accurate ± 2 percent.

Intracuff pressure measurements were divided into four groups according to leak volume and Cl, i.e., 10 percent, high Cl; 5 percent, high Cl; 10 percent, decreased Cl; and 5 percent, decreased Cl. Within each group, the pressure readings for each ETT cuff type were compared using ANOVA and a Duncan’s multiple comparisons test. Alpha was set at 0.05 for statistical significance.

RESULTS

Resting cuff volumes ranged from 5.2 ml for the 7.0-mm ID LO, to 20.6 mL for the 8.0-mm ID HI ETT cuff (Table 1). When Cl was 100 mL/cm H2O, a PIP of approximately 15 cm H2O (11 mm Hg) was generated; reducing Cl to 15 mL/cm H2O resulted in a PIP of approximately 80 cm H2O (60 mm Hg). After cuff inflation to the predetermined leak volumes we noticed that the airway pressure was transmitted to the cuff, causing intracuff pressure to rise and fall with inspiration and exhalation (Fig 3). The intracuff pressure measurements presented in Figure 2 were recorded at end-exhalation their lowest point (referred to as the baseline cuff inflation pressure).

Figure 2A shows that in the highly compliant lung (CL = 100 mL/cm H2O) there is little difference be-
between the baseline cuff inflation pressures of the MED and HI cuff groups with either a 10 or 5 percent leak. The 7.0 LO cuffed ETT required markedly high baseline cuff inflation pressures, whereas the 8.0 LO which had a resting diameter slightly larger than that of the trachea required baseline inflation pressures closer to those of the MED and HI groups. When CL decreased to 15 ml/cm H2O (Fig 2B), every cuff required higher baseline inflation pressures, and differences among the three cuff groups became evident. To achieve identical performance, especially under conditions of reduced CL, the 7.0 LO required the highest pressures, the MED cuffs required intermediate pressures and the HI cuffs required the lowest pressures (p<0.05). Differences in performance also were discernible between the 7.0 and 8.0 HI cuffs.

Figure 3 shows a typical pressure tracing from the testing of a 7.0-mm ID ETT with a HI cuff. In the highly compliant lung (CL = 100 ml/cm H2O), the cuff had to be inflated to approximately 20 mm Hg in order to seal with a 5 percent Vr leak. Intracuff pressure exhibited little change with ventilation, sometimes rising slightly during inspiration. Under conditions of decreased compliance, the cuff had to be inflated to a baseline of approximately 40 mm Hg in order to seal with a 5 percent leak. Intracuff pressure was now greatly affected by ventilation, increasing by 50 percent during inspiration. Intracuff pressure remained constant at 40 mm Hg as the airway pressure rose from zero to 40 mm Hg. Intracuff pressure began to increase as the airway pressure exceeded the baseline cuff inflation pressure. Thereafter, intracuff pressure equaled airway pressure as both rose simultaneously to the PIP of 60 mm Hg.

**DISCUSSION**

This *in vitro* experiment utilized a plastic tracheal model specifically recommended by the American National Standards Institute for the testing of ETT cuffs designed for prolonged intubation.10 Plastic tracheal models avoid the problems of rapid deterioration of freshly excised tracheas and poor correlation between animal species.11 While our mechanical model

<table>
<thead>
<tr>
<th>ETT Type</th>
<th>LO</th>
<th>MED</th>
<th>HI</th>
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<tr>
<td>7.0 mm</td>
<td>5.2 ± 0.27</td>
<td>10.2 ± 0.26</td>
<td>15.5 ± 0.73</td>
</tr>
<tr>
<td>8.0 mm</td>
<td>9.4 ± 0.31</td>
<td>12.9 ± 0.32</td>
<td>20.6 ± 0.92</td>
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*See Figure 1.*
allowed strict control of test conditions, the absolute pressures reported may not accurately reflect in vi
vo results. Unlike the poorly compliant tracheal model, the human trachea can expand significantly with increases in airway pressure, impacting negatively on ETT cuff seal. When softened by warmth and humidity ETT cuffs are more likely to collapse as airway pressure increases, further jeopardizing tracheal occlusion. Therefore, the absolute in vivo intra-
cuff pressures were likely to be underestimated by our model, but the values obtained in this study are reasonable estimates of in vivo pressures. Apart from its in vivo relevance, the model certainly is accurate enough to establish the relative performance of one cuff design to another under similar conditions, especially when using three cuff designs from a single manufacturer that possess similar physical characteristics.

Although we designated 25 mm Hg as a reference point for safe cuff pressures, the limits of safe CT pressures have not been firmly established. In the early 1970s many investigators reported reductions in tracheal damage when CT pressure was limited to approximately 30 mm Hg, the estimated capillary perfusion pressure. Measurements by radioactive microsphere and micropuncture techniques have confirmed tracheal capillary pressure to lie between 20 and 30 mm Hg. Endoscopic studies have shown impaired tracheal blood flow at 22 mm Hg and total obstruction at 37 mm Hg, suggesting that CT pressures should not exceed a critical value of 20 mm Hg.

This study demonstrates several different properties of ETT cuff design: (1) the influence of cuff diameter to tracheal diameter on intracuff pressure, (2) the dependence of cuff inflation pressure on airway pressure, (3) the self-sealing action of large diameter cuffs and (4) the differences in performance between different high-volume, low-pressure designs.

Cuff vs Tracheal Diameter

Although designed to operate in similar fashion to the 7.0-mm LO cuff (a high pressure design), the 8.0-
mm LO cuff actually possessed pressure characteristics more like the MED and HI cuffs. This unexpected low pressure performance is attributable to the fact that the 8.0 LO cuff resting diameter was slightly larger than that of the tracheal model and did not have to be stretched to fill the trachea, instead passively assuming tracheal contour as it was inflated. The 7.0 LO cuff has the same shape as the 8.0 LO cuff, but is slightly smaller in diameter than the tracheal model. Consequently, the 7.0 LO cuff had to be stretched in order to occlude the trachea, leading to high intracuff pressures and alteration of normal tracheal contour. The marked difference in 7.0 and 8.0 LO intracuff pressures results from slight differences in cuff vs tracheal diameter. This example shows that the relationship of CT diameter has been the key principle to the reduction of intracuff (hence CT) pressures in the change from low-volume, small-diameter cuffs to high-volume, large-diameter cuffs.

The Effect of Airway Pressure on Cuff Inflation Pressure

Regardless of cuff design, raising the PIP by reducing CT necessitated additional cuff inflation and resulted in higher intracuff pressure to maintain the same level of ventilation. This in turn increases CT pressure that interferes with tracheal wall blood flow and predisposes to ischemic necrosis. The magnitude of the increase in cuff inflation pressure varied with the cuff design. In the less compliant lung (Fig 2B), the MED cuff design consistently required higher pressures than the HI cuff, and both designs required pressures bordering on or exceeding the upper limit of "safe" cuff pressure. In no case did the 7.0 LO design function within the range of "safe" pressure (the 8.0 LO is considered to be a unique example of ideal CT diameter, as discussed previously).

The absolute intracuff pressures reported in this study are estimates and are subject to error; however, the fact that cuff inflation pressure must be increased in order to seal the trachea against high PIPs is clear. Nonetheless, it is not generally appreciated that current high-volume, low-pressure cuff designs cannot effectively seal the trachea with low pressures when the PIP is high. The problem does not revolve around improper cuff inflation techniques but is instead an inherent limitation of cuff design as outlined in the next two sections.

Self-Sealing Action

When sealing the trachea during positive pressure ventilation, the ETT cuff is suspended between atmospheric pressure on one side and airway pressure on the other. The cuff resists leakage of gas from the airway by pressing itself outward into the tracheal mucosa (the CT pressure). Because the CT pressure is equal to the intracuff pressure in large diameter cuffs, a leak can develop whenever airway pressure exceeds intracuff pressure. However, our experiment showed that in such cuffs intracuff pressure begins to rise as the airway pressure exceeds the baseline cuff inflation pressure (Fig 5). By increasing its intracuff (hence CT) pressure, the cuff is automatically compensating for the increases in airway pressure without additional inflation. This self-sealing action was described by Carroll et al who wrote "...we discovered in 1968 that any large diameter, large residual volume cuff can be inflated to a baseline pressure just adequate to prevent aspiration, and that this resting intracuff pressure then rises in synchrony with the airway pressure."
The self-sealing nature of large volume cuffs is explained by the dynamic effects of airway pressure on cuff size and shape. Increasing airway pressure is freely transmitted to the cuff across the flexible cuff wall, equalizing intracuff pressure and airway pressure. As airway pressure continues to rise, the gas contained within the cuff moves away from the area of high pressure (the distal cuff) and toward an area of lower pressure (the proximal cuff). Thus, the gas within the cuff is redistributed, or “milked” from the distal end of the cuff to fill the proximal end, resulting in a cone-shaped cuff (Fig 3) as the cuff collapses distally and bulges proximally. In 1971 Lomholt described “...this transformation of the cuff shape from cylindrical to conical during the inspiratory phase ...” and estimated the extent to which such cuffs could compensate for volume changes while maintaining their seal.

Differences between High-Volume, Low-Pressure Designs

This study examines the performance of two different large-diameter cuff designs, both of which claim to be low pressure. While no differences are apparent at low PIPs, significant differences appear as the PIP increases (Fig 2). It is obvious from the difference in cuff inflation pressures shown in Figure 2 for the MED and HI cuff designs that all high-volume, low-pressure designs are not created equal. A reconsideration of the principles governing the self-sealing nature of these cuffs will expose their operational differences.

As airway pressure increases, tracheal diameter increases. In order to maintain tracheal occlusion at the lowest possible CT pressure, the resting cuff diameter must be greater than the tracheal diameter at the point of maximal expansion (at the PIP). As the trachea is expanded by rising airway pressure, gas within the cuff is compressed into a conical shape as described previously. A leak will develop when the gas within the cuff is compressed to the point that the diameter of the proximal end of the cuff is smaller than the diameter of the expanded trachea. At that point, providing more gas to the proximal end of the compressed cuff will abolish the leak. Unfortunately, additional cuff inflation will elevate the baseline cuff inflation pressure. Providing a larger reservoir of gas within the cuff allows additional gas to be “milked” into the proximal end of the cuff without increasing baseline cuff inflation pressure (Fig 4). Thus, the self-sealing action of the cuff is improved while maintaining the lowest possible CT pressure and preserving tracheal mucosal blood flow.

Because cuff inflation is limited by the tracheal diameter when cuff diameter is greater than tracheal diameter, further increases in cuff diameter will not change operational cuff volume. In practice, the only means of increasing cuff volume without additional inflation is construction of a longer cuff. The improvement in performance gained by an increase in cuff length is exemplified in our experiment. The 8.0 MED cuff dimensions have been measured as 28.4 (diameter) $\times$ 33.5 mm (length), and the 8.0 HI cuff as 29.5 $\times$ 43.3 mm. The two cuffs have nearly identical diameters, both of which exceed the 19 $\times$ 22-mm internal diameter of the model trachea. The HI cuff is about 1 cm longer and provides a larger volume of gas that can be “milked” to fill the proximal end during inspiration. The result is an improvement in the 8.0 HI cuff’s self-sealing action that is manifested by achieving tracheal occlusion with a 5 percent leak at a lower baseline cuff inflation pressure than the 8.0 MED cuff (Fig 2B). From the foregoing discussion it follows that as long as resting cuff diameter is greater than that of the trachea at maximal expansion, cuff length is the primary factor in maintaining a self-sealing effect in the face of rising airway pressure (or, all else being equal, the longer cuff wins).

Conclusion

The confounding problem of excessive intracuff pressure, which damages the trachea but is necessary to provide a seal at high PIP, has not been resolved. We recently determined that 55 percent of a group of mechanically ventilated SICU patients required cuff inflation pressures in excess of 25 mm Hg despite the
use of high-volume, low-pressure cuffs (unpublished data, E.A. Radson, T.E. Banner, M.J. Banner, et al). This observation and the report of Stauffer et al. suggest that current cuff design is inadequate. When high PIP is necessary during mechanical ventilation, tracheal damage is predictable, even with meticulous attention to cuff inflation. Such requirements are incompatible with maintenance of low intracuff and CT pressures if satisfactory ventilation is to be maintained. Intermittent cuff inflation synchronized with the ventilator’s inspiratory phase, with partial deflation during exhalation, can resolve some of these problems. The ultimate solution awaits a new cuff design.

REFERENCES