Laboratory Evaluation of 4 Brands of Endotracheal Tube Cuff Inflator

Paul B Blanch RRT

INTRODUCTION: Routine measurement of endotracheal tube (ETT) cuff pressure is a standard in respiratory care, and several devices are available for measuring ETT cuff pressure. Yet an informed choice in the buying process is hindered by the present paucity of unbiased, comparative data. METHODS: Four brands of cuff inflator were tested: Posey Cufflator, DHD Cuff-Mate 2, Rüsch Endotest, and SIMS-Portex Cuff Pressure Indicator. Ten randomly selected 8.0-mm-inner-diameter ETTs were modified and tested in a trachea model. The cuffs were gradually inflated and deflated. After each sequential change in cuff volume, cuff pressure measurements were simultaneously recorded with the cuff inflator and with a calibration analyzer. These data were compared using limits-of-agreement analysis. Then, with each of the 10 ETTs, each cuff inflator was used to measure 3 known (ie, measured with the calibration analyzer) cuff pressures: 20, 40, and 60 cm H₂O. Cuff pressure measurements were averaged, by brand, and compared to the respective baseline cuff pressure. Finally, using the 10 ETTs and trachea model, the ETT cuffs were inflated, in 0.25-mL increments, using only a syringe and the calibration analyzer. The cuff pressure and cuff volume data from that procedure were plotted and the best-fit regression line was determined. RESULTS: There were differences in bias and precision among the tested cuff inflators. The Cuff-Mate 2 had the smallest bias and best precision. None of the cuff inflator brands accurately measured cuff pressure. In each case the Cuff-Mate 2 measured cuff pressures closest to actual. The Cuff-Mate 2 contains about half the compressible volume of that in the Endotest and Cufflator and < 20% of that in the Cuff Pressure Indicator. Regarding the relationship between cuff pressure and intracuff volume, the best-fit linear regression equation was: cuff volume = 0.05 × CP – 0.39 (r² = 0.96). CONCLUSIONS: The 4 cuff inflators tested differ in bias and precision and none of the devices accurately measure cuff pressure. Cuff inflator manufacturers should design an accurate yet reasonably priced device to inflate ETT cuffs, and ideally that device should allow cuff-pressure checks without decreasing cuff pressure. In the meanwhile clinicians may opt to use my proposed cuff-pressure measurement technique, which minimizes the loss of cuff pressure during cuff-pressure checks and provides more accurate cuff-pressure measurements. Key words: endotracheal tube, cuff, pressure, monitoring, mechanical ventilation. [Respir Care 2004;49(2):166–173. © 2004 Daedalus Enterprises]

Introduction

The notion of attaching a balloon-like cuff onto an endotracheal tube (ETT) to reduce leaks during positive-pressure mechanical ventilation is not new; cuffed artificial airways can be traced back to the mid-1800s. ETT cuffs, although conceptually simple, must be inflated carefully—until they just fill the trachea—if they are to function safely. Determining precisely when to stop inflating, however, is not easy. If we underinflate, some or all of the ventilator-delivered tidal volume will be lost. In the other direction, even slightly overinflated cuffs exert too much pressure against the trachea, impede mucosal blood flow.

Paul B Blanch RRT is affiliated with the Department of Anesthesiology, University of Florida College of Medicine, and with Respiratory Care Services, Shands Hospital at the University of Florida, Gainesville, Florida.

Correspondence: Paul B Blanch RRT, Respiratory Care Services, Shands Hospital at the University of Florida, PO Box 100373, Gainesville FL 32610-0254. E-mail: blancpb@shands.ufl.edu.
and eventually predispose to ischemic complications. Not surprisingly, a debate over the best inflation technique arose early; by 1904 clinicians were already experimenting with “self-inflating” cuffs, presumably to avoid errors secondary to filling technique. Today, 100 years later, most cuffs are still inflated by hand, and the debate over the optimal filling strategy rages on.

Devastating, even fatal, tracheal complications secondary to overinflated cuffs began appearing in the literature as early as the 1930s. Yet it wasn’t until the 1980s that endoscopic studies conclusively demonstrated impaired tracheal mucosal blood flow at cuff-to-tracheal wall pressures (CTWP) of 28–34 cm H_2 O and complete blocking of blood flow at CTWP ≥ 50 cm H_2 O. Based on those data it seems obvious that whenever possible CTWP should be maintained at or below 34 cm H_2 O. However, it is difficult to directly measure CTWP, so clinicians operate under the assumption that with a high-volume, low-pressure ETT cuff the CTWP is lower than cuff pressure (CP). If that assumption is accurate, then maintaining CP below 34 cm H_2 O should avoid excessive CTWP.

Unfortunately, clinicians cannot simply use the lowest CP that effectively seals the trachea, because too low a CP can allow silent aspiration of pharyngeal secretions. Bernhard et al first studied this issue and found that silent aspiration was likely unless CP was maintained at or above 25–27 cm H_2 O. More recently a study clearly linked low CP to silent aspiration and nosocomial pneumonia. Ideally then, to be safe, CP must be at least 25 cm H_2 O but not more than 34 cm H_2 O. That is a very narrow range—one that cannot always be maintained. A report by Stauffer et al in 1981 underscored that point. Although they used modern ETTs and optimal inflation techniques, at follow-up 11% (3 of 27) exhibited tomographic evidence of tracheal stenosis at the cuff site—though not unexpectedly, since each of the patients required a CP > 34 cm H_2 O to adequately seal the trachea during positive-pressure ventilation.

The possibility of cuff-induced tracheal ischemia led to an early call for routine CP measurements. Other compelling reasons to routinely monitor CP are:

1. Gradual pressure loss due to leaks in either the cuff or the check valve in the pilot line.
2. Cuffs absorb certain gases (eg, nitrous oxide) and gradually expand.
3. Mismanaged CP can gradually dilate the trachea.
4. CP may need frequent adjustment when patient conditions change. Thus, routine CP measurements are now an established standard in respiratory care practice.

The practice of using a bedside mercury manometer (modified with oxygen tubing and a stopcock) to fill ETT cuffs or check CP, though practical and economical, was abandoned after it was found to be flawed. One report stated that if a 4-way stopcock is not used in the appropriate manner when filling the cuff or checking CP, the measurement will be erroneous, due to gases lost from the cuff during compression of the oxygen tubing between the stopcock and the mercury manometer and between the cuff and the manometer. Several medical equipment manufacturers sell devices designed for inflating ETT cuffs and, presumably, for checking CP. Though most cuff inflators obviate additional tubing and stopcocks, they all rely on aneroid manometers; since all manometers contain at least some compressible volume, it is reasonable to wonder how much compressible volume is contained in today’s commonly-used cuff inflators and how much that compressible volume affects the CP measurement. That and other questions involving cuff inflators remain unanswered. The present study evaluated the hypothesis that 4 brands of cuff inflator are not different.

Methods

This study was conducted in 3 phases, and 4 brands of cuff inflator were tested (Fig. 1): Cufflator (JT Posey Company, Arcadia, California), Endotest (Rüsch, Duluth, Georgia), Cuff Pressure Indicator (SIMS-Portex, Keene, New Hampshire), and Cuff-Mate 2 (DHD Healthcare, Canastota, New York). In phase 1, which simulated using a cuff inflator to fill an ETT cuff, each cuff inflator brand was tested for bias and precision. I tested 2 Cufflators, 2 Endotests, and 2 Cuff Pressure Indicators, and, because it is no longer being marketed, 1 Cuff-Mate 2. Before testing, 10 randomly selected 8.0-mm-inner-diameter ETTs (Hi-Lo, Puritan Bennett, St Louis, Missouri) were modified by cutting and then reconnecting the pilot line with a tiny, in-line, plastic T-piece (Industrial Specialties, Englewood, Colorado), and by placing a 3-way stopcock into the check valve at the end of each pilot line.

During testing, each cuff inflator was, in turn, attached (via the stopcock in the ETT pilot line) to each ETT and

Fig. 1. Four brands of cuff inflator were tested. A: Cuff-Mate 2. B: Cufflator. C: Cuff Pressure Indicator. D: Endotest.
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For the purposes of this study that additional compressible volume was considered inconsequential, for 2 reasons: (1) it introduces only a very small systematic error that would equally influence measurements from each of the 4 cuff inflator brands and (2) with the 10 ETT cuffs studied (when in the trachea model) the mean ± SD volume required to create a CP of 10 cm H₂O was 12.42 ± 0.61 mL, and the mean ± SD volume required to create a CP of 60 cm H₂O was 15.14 ± 0.60 mL, and the additional 0.33 mL represents, respectively, only 2.6% and 2.2% of the total volume of the system (ETT cuff, pilot tubing, T-piece, tubing, and transducer).

Phase 2 of the study was designed to simulate a series of routine CP measurements. The same equipment setup was used as in phase 1, except the cuff inflator was removed from the stopcock during pre-pressurization of each ETT cuff. Each cuff was first inflated to 60 cm H₂O, as measured with the calibration analyzer, using only the syringe and stopcock. After inflating to a CP slightly greater than 60 cm H₂O, CP was allowed to equilibrate for 1 minute, after which air was added or subtracted until CP was stable at 60 ± 0.1 cm H₂O for at least 1 minute. At that point, with the stopcock positioned to maintain CP, a cuff inflator was firmly attached to the open port of the stopcock. The stopcock was then rotated to the position that simultaneously connects the ETT cuff, calibration analyzer, and cuff inflator. After 1–2 minutes, to allow the temperature and pressure in the cuff to equilibrate, I recorded the resultant CP measured by the calibration analyzer.

During the measurement CP was simultaneously displayed on both the cuff inflator and the calibration analyzer (see Fig. 2), but, because the baseline CP was established with the calibration analyzer and to avoid intradevice measurement errors, the CP measurements were taken only from the calibration analyzer. This step-by-step process was then repeated, using each of the cuff inflators of each studied brand, and again with each of the 10 ETTs. Then the entire procedure was conducted again at CP of 40 and 20 cm H₂O. This produced 20 CP measurements for each tested cuff inflator brand at each of the 3 CPs (20, 40, and 60 cm H₂O), except for the Cuff-Mate 2 which had only 10 measurements because only 1 Cuff-Mate 2 was tested.

In phase 3 of the study each of the 10 ETTs was, in turn, placed into the trachea model and pre-inflated to 10 cm H₂O (as measured by the calibration analyzer) using the syringe and stopcock. (The cuff inflators were not required during this phase.) Then, using a 1-mL syringe, the cuff was incrementally inflated, 0.25 mL per increment, until CP reached approximately 60 cm H₂O. After adding each 0.25-mL aliquot of air the stopcock was rotated, thereby trapping the air in the ETT cuff. While the stopcock was rotated, the syringe was removed and refilled, as necessary. After turning the stopcock CP was allowed to equilibrate for about 30 s before recording the total volume of

![Fig. 2. Test setup used to measure intracuff pressure (CP) simultaneously with a cuff inflator and a calibration analyzer. A small, plastic T-piece was placed into the pilot line of an 8.0-mm-inner-diameter endotracheal tube (ETT) and connected directly to the pressure transducer inside the calibration analyzer (insert, upper left corner). A syringe and cuff inflator was attached to the ETT via a stopcock in the check valve at the end of the pilot tube. The ETT was placed into the trachea model.](image-url)
Statistical Analysis

The phase 1 data were analyzed using limits of agreement analysis. The 4 studied brands were analyzed separately. Bias was taken as the mean difference between the CP measurement from the calibration analyzer and that from the cuff inflator. Precision was taken as the range included between ± 2 SD from the mean difference.

In phase 2 the CP measurements were averaged, by brand, and compared to the respective actual CP (20, 40, or 60 cm H₂O, measured with the calibration analyzer) using a 1-sample t test. The cuff inflators were then compared, by brand, at each of the 3 CPs (20, 40, or 60 cm H₂O) using a 1-way, repeated-measures analysis of variance. Post-hoc multiple comparisons were made using Tukey’s honest significant difference test. Differences were considered statistically significant when p < 0.05.

The data from phase 3 (total cuff volume versus CP data) were used to create a scatter plot (Fig. 3), which shows a distinctly linear pattern. The best-fit linear equation was determined using the technique of least squares, and the regression line appears as a straight line among the data points in Figure 3. The prediction equation was then solved twice: first for the cuff volume at the pre-existing (ie, calibration-analysis) CP and then again for the CP measurement from the cuff inflator. This process was repeated for each of the 3 CPs tested, with each cuff inflator brand. Cuff volume predicted at the measured CP was then subtracted from the volume predicted at the pre-existing CP; the difference provides a reasonable estimate of the volume of gas lost to compression during a routine CP check, by brand and by pre-existing CP. Boyle’s law indicates that these cuff volume differences are directly proportional to the empty volume contained within a particular cuff inflator brand, or, alternatively, that the magnitude of the difference between a pre-existing and measured CP is inversely proportional to the magnitude of the empty volume within the cuff inflator.

All descriptive statistics, regression modeling, and hypothesis testing were performed with commercially available software (Statistica AX, version 6.0, Stat-Soft, Tulsa, Oklahoma). The regression models were solved at various CPs (using Mathcad 2000, MathSoft, Cambridge, Massachusetts).

Results

There were differences in bias and precision between the cuff inflator brands. The mean ± SD bias and precision were: Cuff-Mate 0.1 ± 1.2 cm H₂O; Cufflator 0.7 ± 1.9 cm H₂O; Cuff Pressure Indicator −0.9 ± 1.2 cm H₂O; Endotest −0.9 ± 1.3 cm H₂O (Fig. 4). Interestingly, all of the tested cuff inflators had at least some systematic error, most noticeably at higher CPs; that is, they either gradually trended up or down, compared to the calibration analyzer. The 2 Cufflators I tested trended in opposite directions. The Cuff-Mate 2 systematically trended upward, whereas the Endotests and Cuff Pressure Indicators all trended downward. The 2 Endotests performed the most comparably, but Endotest was also the only brand to exhibit hysteresis—slightly different pressures during inflation versus deflation (see Fig. 4).

When used to perform the 3 routine, simulated CP checks, each of the tested brands significantly lowered the pre-existing CP (Fig. 5). Under all 3 of the tested conditions, the Cuff-Mate 2 reduced the pre-existing CP significantly less than the other 3 brands. The Endotest and Cufflator were not different in this regard, but both reduced the CP significantly less than the Cuff Pressure Indicator (see Fig. 5).

Using the data gathered in phase 3, the best-fit linear regression model predicting cuff volume was: cuff volume = 0.05 × CP − 0.39. The coefficient of determination (r²) for that equation was 0.96. At a pre-existing CP of 60 cm H₂O, 0.3 mL was lost to compression with the Cuff-Mate 2; approximately 0.5 mL was lost with either the Endotest or Cufflator; and 1.5 mL were lost with the Cuff Pressure Indicator. The results from the other 2 CP levels were nearly identical. From those data it appears that Cuff-Mate 2 has about half the internal, compressible volume of the Bourdon gauges used by the Endotest and Cufflator devices. It can be further inferred that the Cuff-Mate 2 contains < 20% of the compressible volume in the Cuff Pressure Indicator’s tubing, check valve, and manometer.

Discussion

The primary findings of the present study are:

1. There are measurable differences in bias and precision between the 4 tested cuff inflator brands.
2. All of the tested cuff inflators exhibited some form of systematic error, most noticeably at high CPs.
3. None of the tested devices can measure an existing CP without significantly reducing the pre-existing CP, and the higher the pre-existing CP, the greater the CP loss. The Cuff-Mate 2 reduced CP the least.
4. The Cufflator and Endotest contain approximately the same compressible volume, whereas the other cuff inflators have different compressible volumes.

It is important to note that these bias and precision differences may or may not represent clinically relevant information; that distinction must be decided by the individual clinician in the context of the requirements and expectations of his or her facility. For the vast majority of patients, the differences are probably moot, particularly if 90% of patients do not require a high CP to adequately seal the trachea, as Stauffer suggests. That is, if we consider only the CPs within the normal range (25–34 cm H₂O), the differences are probably clinically irrelevant.
H₂O), then it appears that each of the tested brands offers a clinically acceptable degree of accuracy. Outside of the normal range, however, each of the tested cuff inflators suffered a noticeable degradation in agreement, which was not the result of a change in precision (which stayed relatively unchanged), but rather a systematic increase or decrease in bias (see Fig. 4). With regard to the accuracy of medical record-keeping, this finding may cause some concern. Pragmatically though, CP < 25 cm H₂O is seldom used (because of the risk of aspiration and resulting pneumonia), and when a CP > 34 cm H₂O is required, the cuff is generally filled so as to minimize leak around the ETT cuff during mechanical ventilation (regardless of the risk to the trachea), not by filling the cuff to a specific CP value. These data also suggest that with some brands (possibly any brand) there can be measurable intradevice variability. For instance, CPs measured by the 2 Cufflators I tested began to separate at about 30 cm H₂O, and from there exhibited systematic errors of about the same magnitude but in opposite directions. Also, the Endotest devices showed noticeable hysteresis above 30 cm H₂O; unfortunately, it is not possible to distinguish from the data which leg of the loop is inflation and which is deflation (see Fig. 4).

Cox and Schatz recommend measuring CP with a syringe, 4-way stopcock, and manometer.¹⁰ That configuration allows for simultaneous filling of the ETT cuff, tubing, and manometer. Manufactured cuff inflators are also recommended, because they provide the same functionality in a self-contained package. Unfortunately, the present study’s data demonstrate that, with the cuff inflator brands tested, the ETT cuff can be filled accurately, but the recommended types of equipment do not permit measuring pre-existing CP without substantially lowering the CP in the process of measuring it. In light of that, it is unclear how clinicians are supposed to perform routine CP measurements. Depressurizing the ETT cuff and

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Fig. 3. Intracuff pressure (CP) versus total intracuff volume with 10 randomly selected 8.0-mm-inner-diameter endotracheal tubes, which were, in turn, positioned within the trachea model and incrementally inflated, using aliquots of 0.25 mL of air. Total intracuff volume at 10 cm H₂O was considered zero. CP measurements (data points represented by triangles) were taken after allowing each aliquot time for thermal equilibration. The best-fit linear regression (solid line), determined with the technique of least squares, was: cuff volume = 0.05 × CP – 0.39. The coefficient of determination (r²) was 0.96.
then refilling it to the desired CP is certainly not a safe practice. Deflating an ETT cuff, even for a moment, risks silent aspiration of any secretions that may have accumulated above the cuff. Even if the oropharynx is thoroughly suctioned before deflating the cuff, secretions can still remain pooled above an ETT cuff. Simply adding or releasing air until a minimum leak, minimum occlusion, or the desired CP is obtained also has shortcomings. If the CP is decreased far enough (as the Cuff Pressure Indicator brand might), secretions accumulated above the ETT cuff may leak past the partially deflated cuff before it can be restored to the proper CP. The instructions available for using ETT cuff inflators do not discuss this important issue but instead are limited to step-by-step procedures for filling the ETT cuff.

There is no question that routine CP checks are a standard of care, yet it is unclear whether clinicians should (1) measure and chart the pre-existing CP before re-establishing CP, (2) measure and chart CP only following adjustment, or (3) both. This confusion makes the phrase “routine CP measurement” a potential misnomer; it might be equally appropriate to refer to the procedure as a “routine CP adjustment.” Unquestionably, a routine pressure adjustment restores optimal CP, but it also poses a risk for silent aspiration while ignoring potentially important information that would be revealed by sequentially measuring and charting the pre-existing CP. Theoretically, the safest and most informative approach to routine CP check would be to measure and report both the pre-existing CP and the CP following adjustment.
Cuff inflators (including the “home-made” syringe, stopcock, tubing, and manometer setup) can be categorized into 2 basic groups:

1. Bourdon gauge types (such as the Cufflator, Endotest, and Cuff Pressure Indicator)

2. Electronic pressure transducer type (such as Cuff-Mate 2)

A Bourdon gauge (aneroid manometer) contains a hollow, metal bellows that expands or contracts when exposed to internal changes in pressure; the expansion or contraction is transmitted to a series of gears that move the gauge’s pressure-indicator needle. All Bourdon gauges contain volume, even when not pressurized. In comparison, miniature pressure transducers have very little internal volume; the present data suggest that the transducer inside the Cuff-Mate 2 contains much less volume than the other tested devices (which contain Bourdon gauges). Based on the average CP change during the simulated CP checks and the regression model developed in phase 3, it appears that the transducer-operated Cuff-Mate 2 contains about half the internal volume of the Cufflator and Endotest and less than one fifth of the volume inside the tubing and gauge of the Cuff Pressure Indicator.

There are several potential solutions to the CP-measurement problem. First, an interested manufacturer could take note of these data and design a more accurate cuff inflator—one with very little internal volume. Considering the fact that a small, ballpoint-pen-shaped laser pointer can be purchased for under $10, a similarly priced and shaped cuff inflator doesn’t seem out of the question. Unfortunately, industry is moving in the opposite direction: most of the transducer-operated devices, including the Cuff-Mate 2, have been removed from the market. Possibly the industry was simply responding to clinicians, who, unaware of the performance differences, allowed pricing rather than accuracy to determine which device they purchased.
There is a strategy to reduce the amount of gas lost to compression during CP check and thereby improve the accuracy of CP measurements. This technique involves placing a stopcock into the check valve of the ETT’s pilot line. With the stopcock’s lever set to the closed-in-all-directions position (midway between vertical and horizontal on either side of the center port), the cuff inflator and a syringe (if needed; for devices such as the Cufflator and Endotest the bulb on the device can be used in place of a syringe) are attached to the 2 open ports. The stopcock is then positioned to allow the syringe to pre-pressurize the cuff inflator; if the cuff inflator has a built-in inflator bulb, the stopcock can remain in the closed-in-all-directions position. The syringe or bulb is then used to pre-pressurize the inflator’s internal manometer to 25 cm H2O. Once the cuff inflator is properly pressurized, the stopcock is rotated to the position connecting the cuff inflator to the ETT cuff. If the existing CP is in the normal range, then the pre-pressurized cuff inflator manometer should remain nearly unaffected by the opening of the stopcock. If the existing CP is not near 25 cm H2O, the effect will be slightly larger but still much less than it would be otherwise.

It is difficult to compare the present data, because there are no similar studies that I am aware of. As with any bench study, the present study has several limitations, probably the most important of which is the trachea model, which was designed to model a “C-shaped” adult trachea. “C-shaped” refers to the shape of the cross-sectional area. The C shape is the most common shape, according to one study.16 The trachea model used in the present study has a coronal (side-to-side) internal dimension of 22 mm and a sagittal (front-to-back) dimension of 26 mm. Those dimensions fall within the normal range but are somewhat larger than that reported for the average adult male (approximately 19 × 20 mm) and average adult female (approximately 16 × 17 mm) trachea.17 Furthermore, the trachea model is constructed of rigid plastic, whereas the normal human trachea is somewhat elastic, particularly the membranous posterior aspect. Finally, the human trachea is both wet and warm, and the model is not; certainly, these factors combine to influence the behavior of the thin plastic that forms the ETT cuff. Considering all of these factors, the CP measurements in the present study can be considered only representative of those a clinician might actually encounter. Even if all of these factors were inconsequential, if the patient’s trachea is larger than the model, it would increase the slope of the CP-versus-cuff-volume relationship, which would reduce the magnitude of the CP changes during a routine CP measurement. On the other hand, if the patient’s trachea is smaller than the model, the CP-versus-cuff-volume slope would decrease (move toward horizontal), thereby increasing the CP change during a routine CP check.

Conclusions

Routine ETT CP measurements are an acknowledged and important standard in respiratory care. It is somewhat disturbing that currently available CP-measurement equipment substantially lowers the existing CP. Hopefully, the present data will convince manufacturers and clinicians that we need a better cuff inflator—one that allows clinicians to measure and report both the pre-existing CP and the post-adjustment CP—without risking silent aspiration. Until then I hope that this report helps clinicians and respiratory therapists better understand the advantages and limitations of today’s available cuff inflators, which should assist in deciding which brand to buy. Finally, the easy-to-perform, bedside CP measurement technique suggested above will help clinicians provide the safest, most accurate CP measurements possible with the equipment currently available.

REFERENCES