Minimal Occlusive Pressure with Cuffed Endotracheal Tubes: A Comparison of Two Different Techniques to Ensure a Tracheal Seal

THESIS

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By

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Abstract

Introduction: There has been an increased use of cuffed endotracheal tubes in the pediatric population among pediatric anesthesiologists, dentist anesthesiologists, and pediatric critical care physicians. The biggest concern with the use of cuffed endotracheal tubes in this population is the potential for compromising tracheal mucosal blood flow resulting from pressure transmitted from the cuff to the tracheal wall. To date there are several techniques employed to guide cuff inflation in order to establish a tracheal seal and avoid generating intracuff pressures exceeding mean tracheal mucosal perfusion pressures. There are, however, few reports in the literature of actual cuff pressures generated from this routine practice, and even fewer comparative studies. This in vitro study compares intracuff pressures generated from a commonly used inflation technique, the air leak test, to a less commonly used technique involving tidal volume analysis.

Methods: A 1-liter test lung apparatus was used to simulate a human lung with normal compliance (Respironics California, Inc, 2271 Cosmos Court, Carlsbad, CA. 92011 USA). An appropriately sized endotracheal tube based on the internal diameter of the simulated trachea was used for the primary experimental settings. The tidal volume delivered during mechanical ventilation was selected based on a normal expected percentage of total lung capacity in a clinical scenario. The two cuff inflation techniques were
performed and the intracuff pressures produced from each technique were measured directly using a standard invasive pressure monitoring system. Additional experimental variables included endotracheal tube size and delivered tidal volume. The difference between the intracuff pressures was evaluated using a paired t-test. A repeated-measures ANOVA was used to determine whether the difference in intracuff pressure following the application of each sealing technique varied across different experimental settings. Analyses were performed in Stata/IC 13.1 (College Station, TX: StataCorp, LP) and p<0.05 was considered statistically significant.

Results: Ten trials were performed for each combination of cuffed endotracheal tube size (4.0 and 5.0) and delivered tidal volumes (100 mL and 200 mL) for a total of forty trials. The primary experimental settings of interest included using a 5.0 cuffed endotracheal tube and a delivered tidal volume of 100 ml based on the appropriate clinical parameters for the testing apparatus used. Using these settings, and establishing a clinically relevant target TVexp/TVinsp ratio of 0.9 to guide cuff inflation, the test group cuff pressure averaged 11.7 ± 8.9 mmHg compared to the air leak test group at 21.8 ± 11.1 mmHg. This difference was significant (p=0.006) with a 95% confidence interval ranging from 3.7 to 16.5 mmHg.

Conclusion: The purpose of the in vitro portion of this study was to determine if further testing in the human subject model was both appropriate and necessary. The data suggests the tidal volume ratio technique to guide cuff inflation may produce lower mean intracuff pressures than when an air leak test is performed. Further testing of the tidal volume ratio technique as a guide to cuff inflation in the pediatric population is both safe,
resulting in consistently lower cuff pressures, and warranted in the human population.
Dedication

This work is dedicated to my mother and father who have always supported me and never once questioned any path that I took throughout my educational journey. In addition, I would like to dedicate this project to my incredible wife, Ahalya, who has continually set the bar so high during her own pursuit to become a physician that it has been impossible for me to feel sorry for my own challenges along the way. Ahalya, you have been an inspiration to me and you continue to be the biggest reason that this lengthy educational process has been not just tolerable, but enjoyable.
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In addition, I would like to thank Dr. Senthil Krishna and Dr. Joseph Tobias for providing me with the opportunity to take part in this project at Nationwide Children’s Hospital. I feel incredibly lucky to have had the opportunity to work alongside both of you, and I am extremely grateful for your knowledge and support.

Lastly, I would like to thank Mumin Hakim and Dimitry Tumin for their help with collecting and analyzing the experimental data. You both have been fantastic to work with, and I appreciate the contributions you both made to this project.
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Fields of Study

Major Field: Dentistry
Specialization: Anesthesiology
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Introduction

One of the more recent changes that has taken place within the clinical practice of pediatric anesthesia has been the transition from the routine use of uncuffed to cuffed endotracheal tubes. While the use of cuffed endotracheal tubes has been a mainstay in airway management among adults receiving general anesthesia for many years, anesthesiologists historically favored the use of uncuffed endotracheal tubes in children under eight to ten years of age largely due to differences in pediatric and adult airway anatomy [1]. Adherence to the traditional approach favoring the use of uncuffed tracheal tubes was prompted by two major considerations. First, the presence of a cuff invariably increases the external diameter of an endotracheal tube, and mandates the use of a smaller sized endotracheal tube with a narrower than ideal internal diameter. For example, compared to a similar uncuffed endotracheal tube, the addition of a polyvinylchloride (PVC) cuff requires the tube to be sized down by one-half size to accommodate the increase in external diameter from the bulk of the cuff [2]. As a result, patients may be subjected to less than optimal pulmonary flow dynamics. More specifically, the increased resistance to flow that is produced from this reduction in internal diameter will increase work of breathing (WOB) during spontaneous ventilation [2]. Secondly, while the shape of an endotracheal tube is conventionally circular in horizontal cross section,
the narrowest portion of the adult airway (the glottis) is often not circular. Consequently, an endotracheal tube that passes through the glottis without causing injury will not sufficiently seal the trachea. On the contrary, it was previously thought that the narrowest portion of the pediatric airway was at the cricoid cartilage, which is circular in nature. Therefore, it was the belief of many anesthesiologists and intensivists that an endotracheal tube with an external diameter that approximates the internal diameter of the cricoid cartilage would presumably permit an adequate tracheal seal and avoid the need of an inflatable cuff. For these reasons, the use of cuffed endotracheal tubes in the pediatric population historically had been reserved for select clinical situations.

Current literature, however, now supports that pediatric airway anatomy does not significantly differ from that of an adult. Recent studies using imaging or direct bronchoscopy have demonstrated that the anatomical dimensions of the airway do not significantly change with age [3]. This finding, coupled with the introduction of polyurethane high-volume, low-pressure cuff designs, has led to a reconsideration among many anesthesiologists regarding the clinical use of cuffed endotracheal tubes in children. Consequently, it is now recognized that cuffed endotracheal tubes may offer several advantages. One such advantage is reducing the rate of reintubation due to an excessive air leak that would otherwise compromise the clinician’s ability to deliver positive pressure ventilation if needed. In a study comparing cuffed and uncuffed endotracheal tubes in the pediatric population, Khine et al. demonstrated a significantly higher rate of reintubation in the uncuffed group when compared to the cuffed group, most frequently
due to unacceptable air leaks [3]. Cuffed endotracheal tubes also maintain adequate lung ventilation at lower fresh gas flows compared to uncuffed endotracheal tubes, thereby reducing total medical gas consumption, potential operating room pollution, and anesthetic costs [4]. In addition, cuffed endotracheal tubes allow for more accurate monitoring of ventilation, including end-tidal carbon dioxide concentration, a marker used to guide the mechanical ventilation settings applied by the clinician. The latter is important in general and critical care situations but also useful in the spontaneously ventilating patient to help accurately guide titrated opioid doses for the imminent postoperative care situation. As one may expect, cuffed endotracheal tubes also appear to reduce the incidence and severity of aspiration events both intraoperatively and postoperatively among patients who remain intubated following surgery. In a study performed by Gopalareddy et al. measuring the prevalence of gastric pepsin in tracheal aspirates, children on ventilators in the pediatric intensive care unit (PICU) who had cuffed endotracheal tubes demonstrated significantly less pepsin positive aspirates than those with uncuffed endotracheal tubes [5].

It is worth noting that recent advancements made to modern anesthesia machines now readily permit the use of several newer ventilator modes, e.g. pressure support ventilation. While there are still many anesthesia machines being used today that do not feature the pressure support ventilation (PSV) mode, most newer models of mechanical ventilators include this mode of spontaneous ventilation as a standard feature. If available, and used routinely by clinicians, the concern for increased work of breathing
during spontaneous ventilation incurred by the use of narrower endotracheal tubes may
be nullified. Nevertheless, the major concern surrounding the use of an inflatable cuff in
the pediatric population today is the potential risk of tracheal mucosal ischemia due to
cuff hyperinflation. If intracuff pressure exceeds tracheal mucosal perfusion pressure,
cellular injury from tissue hypoperfusion may result. Depending on the extent and
duration of the insult, outcomes from this injury can range from sore throat, to loss of
cilia in tracheal rings, to tracheal mucosa pressure necrosis, scarring, and subglottic
stenosis (SGS) [6] [7]. Subglottic stenosis is becoming more widely recognized as a
significant sequela following intubation in the pediatric population, possibly ranging
from 0.9%-3%, and it remains one of the most common causes of post-extubation upper
airway obstruction [6]. Although SGS may be congenital, it is estimated that at least 90%
of SGS cases are acquired, with intubation being the main cause. In a retrospective study
by Rodríguez et al., of 71 patients with post-intubation SGS, only 5 had evidence of
congenital SGS [6].

The primary goal of endotracheal cuff inflation is to create an adequate tracheal seal
allowing positive pressure ventilation when needed and minimizing the risk of gastric
aspiration without exerting excessive pressure on the tracheal wall. In adults, the tracheal
mucosal mean capillary perfusion pressure is about 20 mmHg (~27 cmH₂O) [7].
Different techniques described in the literature have been employed with the aim of
maintaining intracuff pressure below this threshold to avoid the risk of ischemic injury.
One of the more commonly used techniques is the air leak test. With this technique, the
anesthesia provider partially closes the adjustable pressure limiting-valve in order to maintain continuous pressure within the circuit of approximately 20-25 cm H₂O. Air is then slowly injected into the pilot balloon in order to inflate the cuff until a leak can no longer be heard via auscultation over the suprasternal notch. In addition, a leak should be audible between 25 and 30 cm H₂O, implying that the true intracuff pressure falls somewhere within the 20-25 cm H₂O range. While there is no scientific data regarding mucosal perfusion pressures in the pediatric population, it is speculated that the average capillary pressure of tracheal mucosa is lower in children than in adults; as a result, an upper limit of 20 cm H₂O for pediatric intracuff pressures has been recommended. As simple and reliable as this method appears, Ong et al. demonstrated that it may still fail to avoid cuff hyperinflation [8]. An alternative method more recently introduced to guide cuff inflation involves the use of calibrated spirometers available on modern anesthesia machines. Using simple spirometry, a ratio of expired to inspired tidal volume (TVexp/TVinsp) is continuously assessed, and the endotracheal tube cuff is incrementally inflated until the desired TVexp/TVinsp ratio is achieved.

For the purpose of this study, we selected a ratio of 0.9 (TVexp/TVinsp) as the target of interest. The presence of a minimal leak implies that there is enough intracuff pressure to create a nearly closed system permitting positive pressure ventilation without cuff hyperinflation. This study compared the intracuff pressures that resulted from the application of the air leak test and the spirometry assisted technique for cuff inflation in an in vitro experimental design. Intracuff pressures were measured using the previously
described and validated technique by Krishna et al. whereby a standard pressure transducer more routinely used for the measurement of intravascular pressures was attached to the pilot balloon to continuously measure intracuff pressure after implementing each inflation technique to attain a tracheal seal [9]. Following data analysis, a comparison of the two techniques was made to determine if one of these techniques used to seal the trachea produced lower intracuff pressures.

This picture illustrates how even minor inflammation in the pediatric population can lead to dramatic changes in respiratory mechanics and airway resistance. If we consider Pouseille’s (pwah-zuhee’s) Law relating resistance to the radius of a tube, if inflammation resulting from cuff-induced cellular injury cuts the radius of the tracheal lumen in half, the airway resistance will increase by a factor of 16. So even minor insults leading to small inflammatory changes can have a significant clinical effect with regards to airway resistance and work of breathing following extubation.
Methods

This first phase of the study did not involve direct patient care. This was in vitro experimental design conducted in a hospital operating room at Nationwide Children’s Hospital, Columbus, Ohio using a regular anesthesia machine. Size 4.0 and 5.0 internal diameter (ID) cuffed endotracheal tubes (Kimberly Clark Microcuff ETT, Kimberly Clark Organization, Rosewell, Georgia) were used for this study. A 1-liter capacity ventilator test lung apparatus with 0.02 L/cm H₂O compliance was used to simulate a single human lung with normal compliance (Respironics California, Inc, 2271 Cosmos Court, Carlsbad, CA. 92011 USA). The proximal airway tubing was cut from a size 5 LMA (Ambu AuraOnce™, Ballerup, Denmark) and connected to the test lung apparatus to simulate the trachea. This section of simulated trachea allowed for the development of intracuff pressure following cuff inflation using the two techniques to be tested. The inflating port of the endotracheal tube cuff was connected using a 3-way stopcock to a standard invasive pressure monitoring setup (IPMS) used by itself without a fluid interface (Transpac IV Monitoring Kit, ICU Medical, Inc, San Clemente, California and Philips Medizin Systems, Boblingen Gmbh, Boeblingen, Germany). A fluid-filled transducer system was deemed not necessary since the pilot balloon was filled with air. The experimental set up is depicted below (Fig. 4).
Immediately prior to the experiment, an automatic machine leak test was performed on the anesthesia machine (GE Datex-Ohmeda Avance S5, San Diego, CA) to ensure that there were no detectable leaks. The pressure transducer of the IPMS was zeroed to atmospheric pressure. An unused, 5.0 mm ID cuffed endotracheal tube was placed in the simulated tracheal apparatus so that the cuff was centered at a marked distance, and the endotracheal tube connector was connected to the anesthesia circuit. With the anesthesia machine on manual mode, an air leak test was performed with the fresh gas flow rate at 6 L/min of 100% oxygen and the airway pressure release valve adjusted in order to achieve a continuous positive airway pressure of 20 cmH₂O. Using a 1 mL syringe (BD™, Franklin Lakes, NJ) attached to the 3-way stopcock and connected to the pilot balloon, the cuff was gradually inflated until no audible air-leak was heard. The anesthesia machine was then switched from manual to automatic ventilation with the following ventilation settings applied: volume controlled ventilation mode, tidal volume 100 mL, respiratory rate 16 breaths/min, inspiratory-to-expiratory time ratio (I:E) 1:2, and positive end-expiratory pressure (PEEP) 5 H₂O. A fresh gas flow rate of 6 L/min of 100% oxygen was maintained throughout each trial. After 5 consecutive breaths in which the set tidal volume was achieved, the intracuff pressure was recorded. In addition, the TVexp/TVinsp ratio was also noted. Then, using the 1-mL syringe, air was either injected into or removed from the cuff via the pilot balloon in order to achieve a target TVexp/TVinsp ratio of 0.9 as explained previously. Once this volume ratio was maintained for 5 consecutive breaths, the associated intracuff pressure was recorded. The
primary experimental design using a 5.0 cuffed endotracheal tube and a delivered tidal volume of 100 mL was selected to simulate a typical clinical scenario. The average human tidal volume is approximately one tenth of total lung capacity in a normal state [10]. Since we used a 1-liter capacity lung, a 100 mL tidal volume was chosen as the primary experimental setting of interest. A 5.0 mm cuffed endotracheal tube was selected based on a study performed by Dullenkopf A et al., which approximated the appropriate tube size based on the external diameter of the endotracheal tube and the average anterior-posterior and transverse internal diameters of pediatric trachea [11]. The internal diameter of the simulated trachea was 11 mm. Alternative experimental settings included using a smaller cuffed endotracheal tube (size 4.0 mm) and a greater inspired tidal volume (200 mL). A new endotracheal tube was used for each individual trial. Between each trial, the pressure transducer that was used to measure intracuff pressure was zeroed. The intracuff pressure was recorded following the application of each technique. If the TVexp/TVinsp was 0.9 following the application of the air leak test, the measured intracuff pressure was recorded for both techniques.

The difference between the intracuff pressures was evaluated using a paired t-test. A repeated-measures ANOVA was used to determine whether the difference in intracuff pressure following the application of each sealing technique varied across different experimental settings. Analyses were performed in Stata/IC 13.1 (College Station, TX: StataCorp, LP) and p<0.05 was considered statistically significant.
Results

Ten trials were performed for each combination of cuffed endotracheal tube size (4.0 and 5.0) and delivered tidal volumes (100 mL and 200 mL) for a total of forty trials. The results of all of the experimental settings are outlined in Table 1. Of primary interest was the difference in intracuff pressures in the 5.0 mm endotracheal tube and 100 ml tidal volume group, as these were the selected experimental settings based on a clinically appropriate tube size and tidal volume for the simulated airway and lung apparatus used. With these settings, using a target TVexp/TVinsp of 0.9 to guide cuff inflation, we observed a decrease in average cuff pressure from 21.8 ± 11.1 seen in the air leak test group, to 11.7 ± 8.9 mmHg. This difference was statistically significant (p=0.006) with a 95% confidence interval ranging from 3.7 to 16.5 mmHg. Of note, the air leak test led to TVexp/TVinsp ratios >0.9 in 8 out of 10 experimental trials after mechanical ventilation was initiated. However, repeated-measures ANOVA found that there was significant variability in the change in cuff pressure when alternative experimental settings were used (p=0.006). With a smaller diameter tube (4.0 mm), the difference in cuff pressure observed between the two techniques demonstrated greater variability, with a mean difference of 9.3 mmHg and a 95% confidence interval ranging from -0.84 to 19.4 mmHg. However, the change in cuff pressure for this group was not statistically
significant (p=0.068). When the inspired tidal volume was increased to 200 ml for both the 4.0 and 5.0 tube sizes, using the target volume ratio of 0.9 to guide cuff inflation did not significantly affect the resulting cuff pressure when compared to the air leak test results (Table 1).
Discussion

Unintentional cuff hyperinflation when establishing a tracheal seal has been a longstanding concern among pediatric anesthesiologists, dentist anesthesiologists, and pediatric critical care physicians. The primary concern continues to be the cuff’s potential to jeopardize mucosal perfusion at the contact site between the cuff and the trachea. This is likely to occur if intracuff pressure exceeds the mean tracheal mucosal perfusion pressure in a given patient. Furthermore, because neonates, infants, and young children have a lower baseline mean arterial pressure and therefore lower mucosal perfusion pressures, the margin of safety for the range of acceptable intracuff pressures is likely narrowed in this group [9]. Nevertheless, the use of cuffed endotracheal tubes in the pediatric population using individual clinical judgement of cuff filling volumes continues to increase, perhaps encouraged by the introduction of microthin polyurethane cuffs. [14] [15]. Polyurethane cuffs are high volume low pressure cuffs that have been marketed towards the pediatric population suggesting an effective seal can be established without achieving clinically relevant increases in intracuff pressure. Consequently, because polyurethane cuffs are thought to be safer, pediatric anesthesiologists, dentist anesthesiologists, and critical care physicians have begun to favor the use of cuffed endotracheal tubes to uncuffed tubes for the potential advantages associated with
attaining a tracheal seal.

Despite this increase in the use of cuffed endotracheal tubes in pediatric patients, an ideal method to guide cuff inflation remains unknown. Stewart et al. demonstrated in a study comparing four different inflation techniques (minimal occlusive volume technique, predetermined volume technique, minimum leak technique, and finger palpation technique) that no technique was able to reliably create both an adequate tracheal seal and a physiologically safe intracuff pressure on a consistent basis, although the results were limited due to sample size [16]. Among the numerous inflation techniques practiced, the audible air leak test remains the most commonly practiced technique at our institution. This technique, however, requires a clinician to perform several steps, during which multiple opportunities for operator error are present. In addition, there is, without question, significant variability between providers regarding the point at which an air leak can no longer be appreciated by auscultation. Furthermore, the speed at which the cuff is gradually inflated and the volume of air that is incrementally added throughout cuff inflation is highly variable. Our study aimed to see if minimizing this potential for operator variability, by using measurements produced from most modern anesthesia machine spirometers, could provide a more consistent technique for establishing a reliable tracheal seal at minimal and consistent intracuff pressures.

Our in vitro comparison of these two techniques was performed to determine if the use of spirometry-guided cuff inflation to a TVexp/TVinsp ratio of 0.9 might be beneficial by
avoiding producing potentially harmful intracuff pressures and therefore be a technique that warrants further clinical investigation. Our results in vitro demonstrate that inflating the cuff to achieve a TVexp/TVinsp ratio of 0.9 appears to result in lower mean intracuff pressures than after performing a standard air leak test, and that this technique is unlikely to cause higher intracuff pressures. Based on these results, we are of the opinion that an in vivo model is of clinical interest and warranted at this time.

It is important at this stage to note the mean cuff pressures that were observed when a size 4.0 endotracheal tube was used in this experimental design. With the application of either inflation technique, the mean intracuff pressures ranged from approximately 55 to 65 mmHg, a range well above what is thought to be physiologically safe. This may have been due to the plastic approaching its limit of plasticity, which could dramatically alter the observed pressure; however, the tidal volume ratio technique ensures a leak at peak inspiratory pressure, permitting the assumption that the observed pressure was a reflection of the contact pressure between the simulated trachea and the cuff. This assumption could not have been made with auscultation alone. While the 5.0 endotracheal tube was a more appropriate size based on the internal diameter of the simulated trachea used, the results reinforce the importance of using an appropriately sized tube regardless if the tube has a cuff or not. This contests one of the reported advantages of cuffed versus uncuffed tubes in that multiple intubation attempts may still be necessary if a tracheal seal can only be established when high intracuff pressures are created, and will also be dependent on manufactured total volume of the microcuff.
While there are many formulas used by anesthesiologists to approximate the appropriate tube size for a given patient, none of them are foolproof. However, the presence of a cuff should not encourage the practitioner to routinely choose an undersized tube. For procedures requiring nasal intubation this cannot always be avoided as the diameter of the nasal passage is often the limiting factor that dictates the tracheal tube size used. Thus, for those cases in which nasal intubation is performed, it may be wise to consider direct intracuff pressure monitoring.

Throughout the air leak test group, there were some cases in which the recorded expired tidal volume was greater than the recorded inspired volume for the same delivered breath. This finding was not anticipated prior to conducting the experimental trials. Previously, we believed that in the absence of any leaks the measured expired volume would approximately equal the measured inspired volume (a TVexp/TVinsp ratio of 1.0). However, in all trials, we were able to continually inflate the cuff to achieve a measured expired volume that was roughly 7-10 mL greater than the measured inspired volume. In every circumstance, this situation was attainable when the volume of air injected into the cuff created high intracuff pressures (hyperinflation). After investigation, it appears that this finding can be expected due to a compliance factor within the inspiratory limb of the circuit, as well as the position of the inspired and expired flow sensors being used to compute the respective volumes. During inspiration, the delivered volume will be marginally less than the actual volume within the inspiratory circuit due to circuit distensibility. During a machine checkout test, the machine will calculate the compliance
of the circuit and compensate for the ‘lost’ volume attributed to this compliance factor in order to deliver the set tidal volume. The breathing circuit compliance factor is defined as the compliance of just the breathing circuit external to the anesthesia machine components, specifically between the inspiratory and expiratory valves. The greater the compliance of the breathing system, the greater the reduction in volume that actually reaches the patient from the ventilator; furthermore, the expired volume sensor will overestimate tidal volume due to the release of gas that is compressed within the circuit during inspiration [17]. In addition, fresh gas flow, which continues throughout the respiratory cycle, may also contribute to tidal volumes that deviate from set values.

While the same anesthesia machine was used for the entirety of this study, as a result of this unexpected observation, the measured expired and inspired volumes from multiple anesthesia machines were assessed and it was confirmed that this volume discrepancy was a function of the system being used and not an incidental finding unique to the anesthesia machine used in this study.

There are recognizable limitations with this in vitro model, emphasizing the importance of retrieving in vivo data to draw more clinically accurate conclusions about these two inflation techniques. For one, unlike our simulated trachea that was perfectly cylindrical in shape, the human trachea often exhibits different anterior-posterior (AP) and transverse diameters [17]. As a result, the cuff is more likely to maintain its natural cylindrical shape throughout the inflation process, thereby establishing a larger area of contact with the simulated trachea than what we may expect to see clinically. In this scenario, the
forces applied to the cuff following inflation may be more evenly distributed across a larger surface area in the in vitro model and possibly lowering the average intracuff pressure. In addition to the diametric differences between the AP and transverse tracheal dimensions, the internal anatomy of the trachea adds to the complexity of the interaction between the cuff and tracheal mucosa. It has been demonstrated in vivo that tracheal wall pressures are not evenly distributed circumferentially around the cuff; rather, they decrease gradually from the anterior to posterior position [18]. The reason for this can be attributed to the fact that the posterior membranous wall is more distensible than the cartilaginous framework that comprises the anterolateral walls [18]. This study also made no account of differences in intracuff pressure during spontaneous ventilation versus positive pressure ventilation. The negative intrathoracic pressure generated during spontaneous ventilation may in fact partially protect against cuff-induced ischemia. In contrast, positive pressure ventilation increases intrathoracic pressure and may worsen tracheal mucosal perfusion due to the increase in pressure transmitted to the cuff. Further investigation pertaining to patient-related factors and their influence on intracuff pressure and mucosal perfusion pressure seem warranted.

It is also worth noting that in this experimental design, the same clinician performed the air leak test for each individual trial. As a result, it is likely that the intracuff pressures we observed following the application of the air leak test revealed less variability than what we may expect to see if multiple providers performed the air leak test. This is worth analyzing in vivo to highlight the potential clinical benefit to introducing a method to
guide cuff inflation that eliminates human variation.

In future studies, it may also be of interest to investigate what an ideal TVexp/TVinsp ratio may be. We selected 0.9 for this study as a starting point based on the conjectural notion that if only a minimal amount of the delivered gas failed to reach the expired flow sensor then it would be likely that a minimally adequate, low pressure seal was present. The goal for cuff inflation is to establish a tracheal seal while producing the lowest intracuff pressure possible and thereby avoid potential compromise of blood flow to the tracheal mucosa. To this goal we arbitrarily chose a TVexp/TVinsp ratio of 0.9 instead of 1.0 hypothesizing that if no volume was lost during ventilation (TVexp = TVinsp), the pressure within the cuff could potentially be very high. More research is needed to examine the tracheal seal characteristics and the intracuff pressures produced at different TVexp/TVinsp ratios.
Conclusion

The purpose of the in vitro portion of this study was to determine if further testing in the human subject model was both appropriate and necessary. Based on the results of the in vitro data, it does appear that there may be a benefit to using tidal volume analysis as a guide for cuff inflation. While we did not expect using a TVexp/TVinsp ratio of 0.9 as a guide for cuff inflation to create high and potentially harmful intracuff pressures, the results of this preliminary study demonstrate that the application of this technique is not likely to create intracuff pressures exceeding those that would otherwise be created by the air leak test; therefore this technique, that may promise a more consistent tracheal tissue perfusion could safely be studied in vivo. In fact, our data already suggests using the tidal volume ratio technique to guide cuff inflation may produce lower mean intracuff pressures than the conventional air leak test, and achieve a more consistent mucosal:cuff pressure interface. In addition, there appears to be less intracuff pressure variability in the tidal volume ratio group compared to the air leak test group. These findings support our initial thought that the elimination of the subjective component inherent to the air leak test may be of significant clinical benefit. In conclusion, further investigation of the tidal volume ratio technique as a guide to cuff inflation is both safe and warranted in the human population.
<table>
<thead>
<tr>
<th>Experimental setting (inspired TV, CETT size)</th>
<th>TV ratio achieved with air leak test (n)</th>
<th>Intracuff pressure (mmHg, mean ± SD)</th>
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<tr>
<td></td>
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<tr>
<td>200ml, 4mm</td>
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*Table 1: Tidal Volumes and Intracuff Pressures.*

a Ten trials were performed for each experimental setting.

b Target expired to inspired TV ratio was 0.9.

c Paired t-test probability values.

CETT - cuffed endotracheal tube, CI - confidence interval, SD - standard deviation, TV - tidal volume
Figure 1: Intracuff Pressures and Tidal Volume Ratios – Air Leak Test vs 0.9 TVexp/TVinsp

Measured cuff pressure and TV ratio achieved for the 5.0 mm ID ETT and 100 mL TV group using both inflation techniques. Air leak test labeled red. Target TV ratio of 0.9 labeled blue.

ALT = Air Leak Test

TVR = Tidal Volume Ratio
Figure 2: Intracuff Pressures During Testing

Cuff pressures following application of tidal volume (TV) ratio and air leak test for cuff inflation using primary experimental settings (5.0 mm ID ETT & 100 mL).

ALT = Air Leak Test

TVR = Tidal Volume Ratio
Figure 3 - Intracuff Pressures – 4.0 vs 5.0 ETT

5.0 mm ETT was an appropriate tube size for the tracheal apparatus used. 4.0 mm ETT was an inappropriately small tube size for the same apparatus. Data depicts cuff pressures using air leak test.

*ID = Internal Diameter*

*ETT = Endotracheal Tube*
Figure 4: Experimental Setup

Experimental setup demonstrating simulated lung and trachea apparatus. The pilot balloon is directly connected via a 3-way stopcock to a pressure transducer for direct pressure measuring.
References


