

# CUFFILL Reference Abstracts

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## Reference 1: An In Vitro and In Vivo Validation of a Novel Monitor for Intracuff Pressure in Cuffed Endotracheal Tubes<sup>1</sup>

Archana S. Ramesh, Senthil G. Krishna, William T. Denman & Joseph D. Tobias

**Background.** The clinical practice of pediatric anesthesiology has changed with increasing use of cuffed endotracheal tubes (cETTs) in infants and children. To limit the risk of tracheal mucosal damage, regular monitoring of intracuff pressure (CP) is necessary. This study evaluates the efficacy and accuracy of a novel syringe device (AG CUFFILL) that provides a digital readout of the CP.

**Methods.** The study was conducted in two phases. In phase 1, an in vitro study, cETTs of sizes 4.0, 5.0, and 6.0 mm ID were placed into polyvinylchloride tubing of appropriate sizes. The cuffs were then inflated, and the CP was measured simultaneously using the syringe device (AG CUFFILL) and a manometer. In phase 2, an in vivo study on 200 pediatric patients, the syringe device (AG CUFFILL) and the manometer were simultaneously attached to the pilot balloon to measure the CP following endotracheal intubation. Statistical analysis included linear regression analysis and Bland–Altman comparison.

**Results.** Linear regression analysis of the in vitro study demonstrated an R<sup>2</sup> value of 0.9989. Bias and precision were  $\pm 1.92 \pm 0.62$  with 95% level of agreement (LOA) ranging from  $\pm 3.13$  to  $\pm 0.72$ . For the in vivo study, the linear regression analysis demonstrated an R<sup>2</sup> value of 0.9943. The bias and precision were  $\pm 0.53 \pm 0.68$  with 95% LOA ranging from  $\pm 1.86$  to 0.81.

**Conclusion.** The study has demonstrated clinically acceptable correlation between the CPs obtained from the standard manometer and the AG CUFFILL syringe device both in vitro and in vivo. This device is a simple, reliable, portable, and affordable method to monitor CP.

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<sup>1</sup> Pediatric Anesthesia (2014) 24, 1005–1008

## Reference 2: Can the Intracuff Pressure Be Estimated by Palpation of the Pilot Balloon?<sup>2</sup>

Jason Bryant, MD, Joseph Werner, MD, Earl Moss, DO, and Joseph D. Tobias, MD

**Background.** Over the past 5 years, there has been a change in the clinical practice of pediatric anesthesiology with a transition to the use of cuffed instead of uncuffed endotracheal tubes in infants and children. However, there has been limited attention to techniques to ensure a safe intracuff pressure. We sought to determine the accuracy of estimating endotracheal tube intracuff pressure by palpation of the pilot balloon by anesthesiologists, anesthesia residents, pediatric anesthesia fellows, certified nurse anesthetists, and student nurse anesthetists.

**Methods.** A tracheal simulation model was constructed with 3 different diameters of polyvinylchloride tubing. Three different-sized endotracheal tubes (4.0, 5.0, and 6.0 mm) were then placed into the tubes and the cuffs inflated to various pressures. Each participant was given 3 different scenarios of cuff pressure for each endotracheal tube size for a total of 9 scenarios per practitioner. By feeling the pilot balloon, the anesthesia provider was asked to estimate whether the cuff pressure was greater than 30 cm H<sub>2</sub>O, 20 to 30 cm H<sub>2</sub>O, or less than 20 cm H<sub>2</sub>O. The cuff pressure was then measured using a manometer to determine whether they had correctly estimated the intracuff pressure.

**Results.** A total of 106 anesthesia providers participated in the study. Participants were able to estimate the correct intracuff pressure with palpation of the pilot balloon 45% of the time. In the remaining cases, the intracuff pressure was overestimated 29.4% of the time and underestimated 25.7% of the time. The intracuff pressure was correctly identified 44.4% of the time by attending physicians, 55.67% of the time by anesthesia residents or fellows, 50.6% of the time by certified nurse anesthetists, and 38.4% of the time by student nurse anesthetists.

**Conclusion.** Participants from all the groups were unable to reliably estimate endotracheal intracuff pressure from palpation of the pilot balloon. Given the potential injury from excessive intracuff pressures, other techniques are necessary to ensure that excessive pressures are not present.

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<sup>2</sup> ICU Director (2013) 4, 170-172

### Reference 3: Cost Analysis of Intubation-Related Tracheal Injury Using a National Database<sup>3</sup>

Nasir I. Bhatti, MD, Atta Mohyuddin, MD, Nancy Reaven, MA, Susan E. Funk, MBA, Kulsoom Laeeq, MD, Vinciya Pandian, MSN, CRNP, Marek Mirski, MD, and David Feller-Kopman, MD, Baltimore, MD; and La Canada, CA

**Objective.** To perform risk analysis of tracheal injuries caused by endotracheal intubation (ETI) and to estimate the financial impact of these sequelae.

**Study Design.** Cost analysis using a national database.

**Settings.** The Agency for Healthcare Research and Quality (AHRQ) 2006 National Inpatient Sample.

**Subjects and Methods.** We identified clinical manifestations and treatments of complications associated with endotracheal tubes and codified them into International Classification of Disease-ninth revision diagnosis and procedure codes, intentionally excluding alternative etiologies of tracheal injury. Using the AHRQ 2006 National Inpatient Sample, we then compared patients with tracheal injury coded during the medical or surgical stay for length of stay (LOS) and mean hospital cost with diagnosis-related group (DRG)-matched controls; we also examined readmissions treating tracheal injury.

**Results.** Tracheal injury presents as tracheal stenosis, tracheomalacia, tracheoesophageal fistula, laryngotracheal ulceration, and vocal cord paralysis. A total of 3232 discharge records met criteria for tracheal injury from ETI within the index hospital stay. Average LOS for patients with tracheal injury (6.3 days; 95% confidence interval [CI] 6.0-6.3) exceeded LOS in the uncomplicated sample (5.2 days; CI 5.1-5.3) by 1.1 days. The average hospital cost was \$1888 higher with tracheal injury (\$10,375 [CI \$9762-\$10,988] vs \$8487 [CI \$8266-\$8669]). LOS for procedures treating prior tracheal injury averaged 4.7 days and cost an average of \$11,025 per discharge.

**Conclusion.** Tracheal injury from ETI is associated with a significant increase in healthcare costs that accrue both during the index admission and during subsequent hospitalizations required to treat the injury.

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<sup>3</sup> Otolaryngology–Head and Neck Surgery (2010) 143, 31-36

## Reference 4: Cuff Pressure of Endotracheal Tubes after Changes in Body Position in Critically Ill Patients Treated with Mechanical Ventilation<sup>4</sup>

Christelle Lizy, RN, MNsc, Walter Swinnen, MD, Sonia Labeau, RN, MNsc, PhD, Jan Poelaert, MD, PhD, Dirk Vogelaers, MD, PhD, Koenraad Vandewoude, MD, PhD, Joel Dulhunty, MBBS, MTH, PhD, and Stijn Blot, RN, MNsc, PhD

**Background.** In order to avoid microaspiration and tracheal injury, the target for endotracheal tube cuff pressure is 20 to 30 cm H<sub>2</sub>O.

**Objective.** To assess the effect of changes in body position on cuff pressure in adult patients.

**Methods.** Twelve orally intubated and sedated patients received neuromuscular blockers and were positioned in a neutral starting position (backrest, head-of-bed elevation 30°, head in neutral position) with cuff pressure at 25 cm H<sub>2</sub>O. Then, 16 changes in position were performed: anteflexion head, hyper extension head, left and right lateral flexion of head, left and right rotation of the head, semirecumbent position (head-of-bed elevation 45°), recumbent position (head-of-bed elevation 10°), horizontal backrest, Trendelenburg position (10°), and left and right lateral positioning over 30°, 45°, and 90°. Once a patient was correctly positioned, cuff pressure was recorded during an end-expiratory ventilatory hold. The pressure observed was compared with the cuff pressure at the starting position. Values outside the target range (20-30 cm H<sub>2</sub>O) were considered clinically relevant.

**Results.** A total of 192 measurements were performed (12 subjects x 16 positions). A significant deviation in cuff pressure occurred with all 16 changes ( $P < .05$ ). No pressures were less than the lower limit (20 cm H<sub>2</sub>O). Pressures were greater than the upper limit (30 cm H<sub>2</sub>O) in 40.6% of the measurements. In each position, the upper target limit was exceeded at least once. Within-patient variability was substantial ( $P = .02$ ).

**Conclusion.** Simple changes in patients' positioning can result in potentially harmful cuff pressures.

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<sup>4</sup> American Journal of Critical Care (2014) 23, e1-e8

## Reference 5: Healthcare utilization and costs associated with *S. aureus* and *P. aeruginosa* pneumonia in the intensive care unit: a retrospective observational cohort study in a US claims database<sup>5</sup>

Moe H. Kyaw, David M. Kern, Siting Zhou, Ozgur Tunceli, Hasan S. Jafri and Judith Falloon

**Background.** Staphylococcus aureus and Pseudomonas aeruginosa are major causes of pneumonia in intensive care unit (ICU) patients. Limited data exist regarding the health economic impact of *S. aureus* and *P. aeruginosa* pneumonias in the ICU setting.

**Methods.** We conducted a retrospective observational cohort study using a 29.6 million enrollee US medical and pharmacy administrative claims database. ICU patients with *S. aureus* or *P. aeruginosa* infection per International Classification of Diseases, 9th ed. coding between 01/01/2007-8/31/2012 were compared with ICU patients without any pneumonia or infections of interest. Primary outcomes were costs in 2012 US dollars, healthcare utilization and all-cause mortality associated with hospital-acquired *S. aureus* or *P. aeruginosa* pneumonia, and the relative odds of incurring higher costs due to a comorbid condition. In other words – the research is covering the non-VAP alleged period.

**Results.** Patients with *S. aureus* or *P. aeruginosa* pneumonia had longer mean hospital (37.9 or 55.4 vs 7.2 days,  $P < .001$ ) and ICU stays (6.9 or 14.8 vs 1.1 days,  $P < .001$ ), a higher rate of mechanical ventilation (62.6 % or 62.3 % vs 7.4 %,  $P < .001$ ), higher mortality (16.0 % or 20.2 % vs 3.1 %,  $P < .001$ ), and higher total mean hospitalization costs (\$146,978 or \$213,104 vs \$33,851,  $P < .001$ ) vs controls. Pneumonia survivors had significantly increased risk of rehospitalization within 30 days (27.2 % or 31.1 % vs 15.3 %,  $P < .001$ ). Comorbid conditions were not associated with increased cost in the pneumonia cohorts.

**Conclusions.** Healthcare costs and resource utilization were high among ICU patients with *S. aureus* or *P. aeruginosa* pneumonia. Reducing the incidence of these infections could lead to substantial cost savings in the United States.

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<sup>5</sup> BMC Health Services Research (2015), 15:241

## Reference 6: Cuffed Endotracheal Tubes in Infants and Children; A Technique to Ensure an Acceptable Intracuff Pressure<sup>6</sup>

Joseph D. Tobias, MD, Senthil Gopalakrishnan, MD, Julie Rice, RN, Kris R. Jatana, MD, Charles Elmaraghy, MD, and Meredith Merz, MD

**Background.** Over the past 5 to 10 years, there has been a change in the clinical practice of pediatric anesthesiology with a transition to the use of cuffed instead of uncuffed endotracheal tubes (ETTs) in infants and children. When such tubes are used in clinical practice, it is imperative to ensure that the intracuff pressure is  $\leq 30$  cm H<sub>2</sub>O. To date, there are limited data regarding techniques to ensure this practice.

**Methods.** Following endotracheal intubation with a cuffed ETT, a stethoscope was placed in the sternal notch and continuous positive airway pressure of 20 to 25 cm H<sub>2</sub>O held. The fresh gas flow was increased as needed to achieve a gradual rise of the airway pressure. Using a syringe, air was added to the cuff until no air escape or leak was heard. The intracuff pressure was checked using a handheld manometer (Posey Cufflator Endotracheal Tube Inflator and Manometer, JT Posey Company, Arcadia, CA).

**Results.** The cohort for the study included 200 patients ranging in age from 6 months to 18 years. In 5 patients (2.5%), there was no audible air leak noted following endotracheal inflation at a continuous positive airway pressure of 20 to 25 cm H<sub>2</sub>O. In these patients, the ETT was removed and the trachea was intubated with a 0.5-mm size smaller ETT. In the entire cohort of 200 patients, the intracuff pressure was  $21 \pm 4$  cm H<sub>2</sub>O. The intracuff pressure was  $\geq 30$  cm H<sub>2</sub>O in 1 of 200 patients (0.5%).

**Conclusions.** The current study demonstrates a simple, bedside maneuver that requires no additional equipment and is effective at ensuring a safe intracuff pressure in virtually all patients.

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<sup>6</sup> International Journal of Pediatric Otorhinolaryngology (2013) 77, 1135–1138

## Reference 7: Endotracheal Cuff Pressures in Ventilated Patients in Intensive Care<sup>7</sup>

Ross C. Freebairn, Margaret Monk, Arpan Mehta, Ankia Anderson

**Aim.** To describe the endotracheal cuff pressure (Pcuff) measurements of patients receiving ventilation via endotracheal tubes in an Intensive Care Unit (ICU).

**Method.** Pcuff were measured daily using a cuff tonometer and the pressure then adjusted to <30 cmH<sub>2</sub>O in patients ventilated in the ICU, over fifteen months. Data collected were demographics, the location where intubation occurred, and airway pressures when available (PEEP, peak, and plateau). Data was analysed using Kruskal-Wallis and Dunn's Multiple Comparison Test.

**Results.** 1073 data sets were collected from 199 intubated ventilated adults. Of all Pcuff measured 15.7% (169) exceeded 30 cmH<sub>2</sub>O. The first Pcuff measurements made during ICU stay had median pressure 30 cmH<sub>2</sub>O (IQR 23.5-40) and 34.5% (68) exceeded 30 cmH<sub>2</sub>O. Median Pcuff of patients admitted following intubation in the Operating Theatre (OT) were 26 cmH<sub>2</sub>O (IQR 20-37), those via Emergency Department (ED) were 32 cmH<sub>2</sub>O (IQR 28-57), and those intubated in ICU were 28 cmH<sub>2</sub>O (IQR 22-34.25). Pcuff of patients intubated in OT differed significantly from ED patients, as did ICU patients compared to ED ( $p < 0.005$ ). ICU and OT patients did not differ.

**Conclusion.** Pcuff measurement is not routine at intubation. Described complications of elevated Pcuff include cuff herniation, vocal cord damage, tracheal mucosal ischaemia, and airway obstruction. Unrecognised elevated Pcuff is common, with a higher incidence in ED than ICU or OT. Skilled intubation assistance from anaesthetic technicians is routine in OT, common in ICU, but less frequent in ED, and may influence the initial Pcuff.

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<sup>7</sup> Critical Care & Shock (2007) 10, 142-147

## Reference 8: Experienced Emergency Medicine Physicians Cannot Safely Inflate or Estimate Endotracheal Tube Cuff Pressure Using Standard Techniques<sup>8</sup>

Robert J. Hoffman, MD, Vivek Parwani, MD, In-Hei Hahn, MD

**Objective.** Tracheal necrosis, stenosis, and rupture may result from overinflated endotracheal tube cuffs (ETTc). We sought to determine the ability of faculty emergency medicine (EM) physicians to safely inflate ETTc as well as to estimate pressure of previously inflated ETTc.

**Method.** Using a previously tested tracheal simulation model, we assessed EM physician inflation of ETTc pilot balloons. Participants also palpated the pilot balloon of 9 ETTc inflated to pressures ranging from extremely low to extremely high in a random order and reported their estimate of pressure.

**Results.** We sampled 41 faculty EM physicians from 5 EM residency programs. Using palpation, participants were only 22% sensitive detecting overinflated ETTc. The average ETTc pressure produced by inflation was more than 93 cm H<sub>2</sub>O (normal, 15-25 cm H<sub>2</sub>O).

**Conclusions.** Participants were unable to inflate ETTc to safe pressures or estimate pressure of ETTc by palpation. Clinicians should consider using devices to facilitate safe inflation and accurate measurement of ETTc pressure.

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<sup>8</sup> American Journal of Emergency Medicine (2006) 24, 139-143.

## Reference 9: The Laryngeal Mask in Infants and Children: What Is The Cuff Pressure?<sup>9</sup>

Bryan Schloss, Julie Rice, Joseph D. Tobias

**Background.** Unintended hyperinflation of the cuff of a laryngeal mask airway (LMA) has been associated with increased airway morbidity and postoperative pain. While the manufacturers recommend a cuff pressure of less than 60 cmH<sub>2</sub>O, in usual clinical practice, there is no method used to determine intracuff pressure of an LMA. The purpose of this prospective quality assurance study is to evaluate the incidence of LMA hyperinflation and excessive intracuff pressure in a busy tertiary care pediatric hospital.

**Methods.** There was no change dictated in clinical practice for these patients. Per our usual practice, the LMA was removed from the package and inserted with the cuff partially inflated. The cuff was further inflated as needed to ensure a seal during positive pressure ventilation to a peak inflating pressure of 20–25 cmH<sub>2</sub>O. During the first 30 min of the case, the pressure in the cuff of the LMA was measured using a hand held manometer. Additional data collected included the patient's demographic data (age, weight, and gender), the size of the ETT, and whether nitrous oxide was in use.

**Results.** Of the 200 subjects in the current study, 106 had an LMA cuff pressure  $\geq$  60 cmH<sub>2</sub>O (53%). Patients who were greater than 8 years of age had significantly higher average cuff pressures and significantly more LMAs with an intracuff pressure  $\geq$  60 cmH<sub>2</sub>O when compared to patients younger than 4 years of age and patients 4–8 years of age. Similarly, larger LMAs were found to have significantly higher intracuff pressures.

**Conclusions.** Using current clinical practice to inflate the cuff of the LMA, a significant percentage of pediatric patients have an intracuff pressure greater than the generally recommended upper limit of 60 cmH<sub>2</sub>O. Risk factors identified in our study included age of the patient and the size of the LMA.

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<sup>9</sup> International Journal of Pediatric Otorhinolaryngology (2012) 76, 284–286