Clinical Evidence Summary

Endotracheal Tube Cuff Pressure Monitoring and AG Cuffill®

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The AnapnoGuard CUFFILL Manometer is manufactured by Hospitech Respiration and distributed by Medline Industries, Inc.

Section 1

Cuff pressure regulation and complications

- Airway management of patients in trauma is complicated.[1]
- Duration of intubation, patient repositioning, and suction procedures can cause cuff pressures to deviate outside of therapeutic range.
  - If cuff pressure is **too high,** it can result in **tracheal injuries.**[2]
  - If cuff pressure is **too low,** it can cause secretions to leak past the endotracheal tube (ETT) into the lungs and can be a risk factor for **ventilator-associated pneumonia (VAP).**[3]
- Clinical evidence suggests that maintaining optimal cuff pressure, between 20 and 30 cm H_2O, can aid in lowering risk factors for VAP and tracheal injuries.

Patients with intracuff pressure less than 20 cm H_2O and not receiving antibiotics are at a higher risk for VAP[4]

Background

- VAP is a form of nosocomial infection occurring in patients receiving mechanical ventilation for longer than 48 hours.
- Leakage of colonized subglottic secretions around the ETT cuff is a risk factor for pneumonia in intubated patients.
- Intubated patients undergoing continuous aspiration of subglottic secretions (CASS) have lower incidence of VAP as compared to patients not undergoing CASS, due to reduction in inoculum of organisms that leak around the ETT cuff.
- **The investigators sought to assess potential risk factors for VAP in patients within the first eight days of ventilation, with regards to intracuff pressure and CASS.**

Method

- This was a prospective observational study which involved 83 patients undergoing CASS.
- Intracuff pressure was monitored every four hours using an aneroid manometer (109-01; Mallinckrodt Laboratories, Neunkirchen-Seelscheid, Germany)

Results

2.4X	Risk factor for pneumonia in patients with intracuff pressure <20 cm H_2O and not receiving antibiotics was 2.4 times higher than in patients with optimal intracuff pressure (20-30 cm H_2O)
5X	Risk factor for pneumonia in patients with failure of CASS and not receiving antibiotics was 5 times higher than in patients who were on antibiotics.

Conclusion

Optimal intracuff pressure and effective aspiration of subglottic secretions are important in preventing VAP in intubated patients who are not receiving antibiotic treatment.

Rello J, Soñora R, Jubert P, Artigas A, Rué M, Vallés J. Pneumonia in intubated patients: role of respiratory airway care. Am J Respir Crit Care Med. 1996 Jul; 154(1):111-5. PMID: 8680665, https://www.ncbi.nlm.nih.gov/pubmed/8680665

Endotracheal intubation at mean cuff pressure greater than 30 cm H_2O can be potentially harmful[2]

Background

- Treatment of acute respiratory failure requires tracheal intubation using either an ETT or a tracheostomy tube.
- Tracheal intubation can result in severe complications such as laryngotracheal injuries, tracheal stenosis, ulcers, etc., resulting from various factors including changes in cuff pressure.
- **The investigators sought to determine various factors influencing the development of complications and consequences of endotracheal intubation in critically ill patients.**

Methods

- This study involved 150 adult patients who required artificial airways for more than 24 hours.
- Patients were examined daily for cuff pressure measurement, movement and frequency of tube changes, and type of ventilation.
- Autopsies were performed on patients who died, and laryngeal and tracheal injuries were evaluated.

Results

- In this study, endotracheal intubation required cuff pressure > 30 cm H_2O to achieve seal of the airway.

Complications due to endotracheal intubation and cuff pressure >30 cm H_2O	Laryngotracheal injury	Mucosal ulcers	Tracheal stenosis	Hoarseness, sore throat, cough, sputum production, hemoptysis
Patients experiencing complications (%)	39 of 41(95%)	6 of 41(15%)	5 of 27(19%)	59 of 69 (86%)

Conclusion

Cuff pressures > 30 cm H_2O in patients undergoing endotracheal intubation can lead to various complications such as laryngotracheal injury, ulcers and tracheal stenosis as well as hoarseness, sore throat, cough, sputum production and hemoptysis.

Stauffer JL, Olson DE, Petty TL. Complications and consequences of endotracheal intubation and tracheotomy. A prospective study of 150 critically ill adult patients. Am J Med. 1981 Jan; 70(1):65-76. PMID: 7457492, https://www.ncbi.nlm.nih.gov/pubmed/7457492

Changes in patient's body positions can lead to cuff pressures greater than 30 cm H_2O[5]

Background

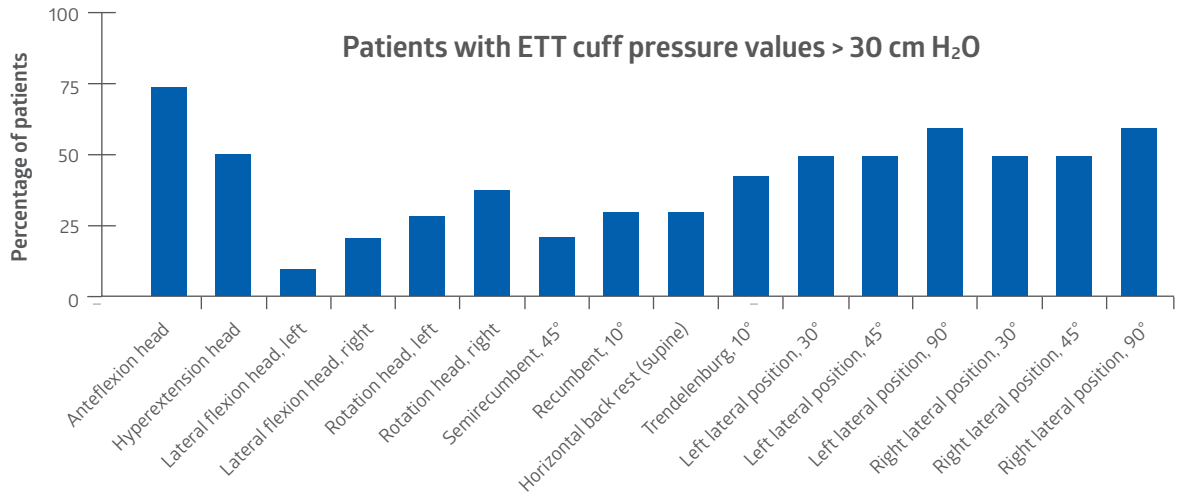
- In patients with prolonged intubation, overinflation may lead to complications such as tracheal stenosis or formation of a fistula, and cuff pressures greater than 50 cm H_2O may cause total obstruction of tracheal blood flow.
- Numerous factors may increase cuff pressure, yet it is unknown how changes in body position interact with cuff pressure levels.
- **The authors sought to investigate the effect of a variety of changes in body positions on ETT cuff pressure in sedated patients receiving mechanical ventilation.**

Methods

- This study carried out a total of 192 measurements utilizing 12 orally intubated and sedated patients who were positioned in a neutral starting position (backrest, head-of-bed elevation 30° and head in neutral position) with cuff pressure at 25 cm H_2O.
- Each patient was brought into 16 different body positions and cuff pressures were recorded at each changed body position.
- Values outside the target range (20-30 cm H_2O) were considered clinically relevant.

Results

- ETT cuff pressures were > 30 cm H_2O in 40.6% of the measurements.



Conclusion

Strict monitoring of cuff pressures is important, as simple and frequent changes in patient's body position may lead to overinflation and potentially harmful cuff pressures

Lizy C, Swinnen W, Labeau S, Poelaert J, Vogelaers D, Vandewoude K, Dulhunty J, Blot S. Cuff pressure of endotracheal tubes after changes in body position in critically ill patients treated with mechanical ventilation. Am J Crit Care. 2014 Jan; 23(1):e1-8. PMID: 24382623, https://www.ncbi.nlm.nih.gov/pubmed/24382623.

Section 2

Benefits of maintaining optimal cuff pressure through monitoring

- Variations in endotracheal tube (ETT) cuff pressures are common in Intensive Care Units (ICU), operating rooms, and during transport, and can result in cuff pressure being too low or too high.[6]

- Underinflation and overinflation are associated with complications such as aspiration and tracheal wall damage, but maintaining optimal cuff pressure can minimize these risks.[6]

- Devices that monitor cuff pressure may help in maintaining optimal intracuff pressure.[7]

Section 3

Intracuff pressure monitoring with AG Cuffill®

- The AG Cuffill is a portable syringe manometry device that provides a measurement and digital reading of the intracuff pressure of an ETT.[7]
- The AG Cuffill device can help regularly monitor intracuff pressure.
- The AG Cuffill device can be reused up to 100 times and does not require routine calibration.[8]

Intracuff pressure monitoring can reduce postoperative airway complications[8]

Background

- As many as 50% of postoperative patients experience postoperative sore throat (POST) after general anesthesia procedures that require manipulation of the airway.
- Objective measurements of ETT cuff pressures can maintain the clinically acceptable range for cuff pressures and significantly reduce postoperative airway complications.
- This quality improvement study, conducted by Fritz et al. and published in the BMC Anesthesiology journal, evaluated the incidence of post-operative airway complications associated with the use of cuffed airway devices.
- The study sought to improve the incidence of postoperative airway complications with the implementation of a cuff pressure manometer device that monitors intracuff pressure.

Methods

- 215 pre-intervention surveys were included in the study from postoperative patients at a single center who had undergone general anesthesia.
    - Prior to intervention, clinicians at the center did not routinely monitor objective intracuff pressure measurements. Clinicians commonly monitor intracuff pressure by subjective means, such as palpating the pilot balloon.
    - The pre-intervention surveys determined the baseline incidence of postoperative airway complications such as POST, hoarseness, and dysphagia (difficulty swallowing).
- Education was provided to anesthesia providers regarding the clinically acceptable intracuff pressure range, and instructions were provided regarding the use of the cuff pressure manometer device.
- The cuff pressure manometer device was then used in the facility as the sole means of routinely monitoring intracuff pressure. 299 post-intervention surveys describing postoperative airway complications were included in the study from patients who had undergone general anesthesia.

Results

- Monitoring objective intracuff pressure measurements using a cuff pressure manometer device reduced the incidence of moderate to severe POST, postoperative hoarseness, and postoperative dysphagia.

Conclusion

- The routine monitoring of cuff pressure measurements using a cuff pressure manometer device can be feasible to implement in clinical practice.
- Monitoring the intracuff pressure of ETTs can help reduce postoperative airway complications.

In vitro and *in vivo* data shows clinically acceptable intracuff pressure measurements with the use of AG Cuffill®[7]

Background

- Changes in cuff pressure after endotracheal intubation pose safety concerns for intubated patients.
- The study, published in the Journal of Pediatric Anesthesia and conducted by Ramesh et al., evaluated the efficacy of the AG Cuffill syringe device compared to a standard manometer for monitoring the intracuff pressures of cuffed ETTs.

Method

- The study was conducted in separate *in vitro* and *in vivo* phases.
  - —In the *in vitro* phase, 4.0 mm, 5.0 mm, and 6.0 mm cuffed ETTs were placed in polyvinylchloride tubes. The cuffs were then inflated to various intracuff pressures. 100 pressure readings for each ETT size were obtained using the AG Cuffill device and a standard manometer.
  - —In the *in vivo* phase conducted in a cohort of 200 pediatric patients, the AG Cuffill device and a standard monometer were simultaneously attached to a pilot balloon to measure the intracuff pressure after endotracheal intubation.

Results

- Statistical analysis of the *in vitro* and *in vivo* study data showed no difference in the reading accuracy of the intracuff pressures between the AG Cuffill device and a standard manometer.

Conclusion

- The study demonstrated a clinically acceptable correlation between the intracuff pressure measurements obtained from the AG Cuffill device and a standard manometer.
- The AG Cuffill is a portable, reliable, and affordable device for accurately monitoring intracuff pressure.

Section 4

Conclusions

- Endotracheal tube cuff pressure between 20 and 30 cm H_2O is recommended to help minimize risks for complications such as tracheal injuries and VAP.
- Manometry devices such as the AG Cuffill device can help ensure intracuff pressures are within the clinically acceptable range.

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Medline Industries, Inc.
Three Lakes Drive, Northfield, IL 60093
Medline United States | 1-800-MEDLINE (633-5463)
medline.com | info@medline.com

Medline Canada
1-800-268-2848 | medline.ca | canada@medline.com
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