AVANOS | MICROCUFF*
Subglottic Endotracheal Suctioning

SELECTED CLINICAL STUDIES UTILISING PRODUCTS FROM VARIOUS ENDOTRACHEAL TUBE MANUFACTURERS

A. GUIDELINES

1. European HAP working group
2. SHEA: *Society of Healthcare Epidemiology for America*
3. ATS: *American Thoracic society*
4. AACN: *American Association of Critical care Nurses*
5. DH: *UK Department of Health*
6. *Robert Koch Institute, Germany*

B. META ANALYSIS; LITERATURE REVIEW

1. Subglottic secretion drainage for the prevention of ventilator-associated pneumonia: a systematic review and meta-analysis.; Muscedere J et al Crit Care Med. 2011 Aug;39(8):1985-91
2. Subglottic Suction Drainage: A Literature Review ; Depew, Charlotte L., MSN, RN, CCNS and McCarthy, Mary S., MA, PhD, RN, CNSN ; AACN 2007

C. PROSPECTIVE RANDOMIZED STUDIES

1. Influence of an endotracheal tube with polyurethane cuff and subglottic secretion drainage on pneumonia.L. Lorente, M. Lecuona, A. Jimenez, M.L. Mora, A. Sierra American Journal of Respiratory and Critical Care Medicine, 2007
2. Intermittent Subglottic Secretion Drainage and Ventilator-associated Pneumonia: A Multicenter Trial Jean-Claude Lacherade et al, American Journal of Respiratory and Critical Care Medicine, Vol. 182, No. 7 (2010), pp. 910-917.
3. Polyurethane cuffed endotrcheal tubes to prevent early postoperative pneumonia after cardiac surgery: A pilot study. J Thorac Cardiovasc Surg 2008; Jan Poelaert, MD, PhD,Pieter Depuydt, MD, Annick De Wolf, MD, Stijn Van de Velde, MD, Ingrid Herck, MD, and Stijn Blot, PhD; poelaert@uzbrussels.be

D. PROSPECTIVE OBSERVATIONAL STUDY

1. Impact of polyurethane on variations in tracheal cuff pressure in critically ill patients: a prospective observational study Intensive Care Med. 2010 Jul;36(7):1156-63. Epub 2010 Apr 16. Nseir S, Zerimech F, De Jonckheere J, Alves I, Balduyck M, Durocher A. Intensive Care Unit, Calmette Hospital, University Hospital of Lille, boulevard du Pr Leclercq, 59037, Lille Cedex, France. s-nseir@chru-lille.fr

E. RETROSPECTIVE STUDIES

1. Air leakage around endotracheal tube cuffs. Eur J Anaesthesiol. 2004 Jun;21(6):448-53. Dullenkopf A, Schmitz A, Frei M, Gerber AC, Weiss M. University Children's Hospital, Department of Anaesthesia, Zurich, Switzerland. alex.dullenkopf@kispi.unizh.ch
2. A polyurethane cuffed endotracheal tube is associated with decreased rates of ventilator-associated pneumonia. J Crit Care. 2011 Jun;26(3):280-6. Epub 2010 Jul 23. Miller MA, Arndt JL, Konkle MA, Chenoweth CE, Iwashyna TJ, Flaherty KR, Hyzy RC. Division of Pulmonary and Critical Care Medicine, University of Michigan, Ann Arbor, MI, USA. melmille@umich.edu

F. BENCH STUDIES

1. Fluid leakage past tracheal tube cuffs: evaluation of the new MICROCUFF* endotracheal tube. Dullenkopf A, et al; Intensive Care Med. 2003 Oct;29(10):1849-53. Epub 2003 Aug 16.
2. Endotracheal Tubes for Critically Ill Patients: An In Vivo Analysis of Associated Tracheal Injury, Mucociliary Clearance, and Sealing Efficacy. Gianluigi Li Bassi et al; chest volume 147 #5 May 2015
3. Benchtop study of leakages across the Portex, TaperGuard, and MICROCUFF* endotracheal tubes under simulated clinical conditions. Lau et al., Hong Kong Med J. 2014;20:7-15.
4. Bench Comparison of Suction Efficiency for Endotracheal Tubes with a Subglottic Suction Lumen. David Curd, M.S., Brian McCachren, BSEE, MBA, Stephen Baratian, M.S., Claire Couch, M.S., Paul Batchelder, LRCP, RRT; SCCM 2014 Critical Care Congress, Abstract #393
5. Variables affecting leakage past endotracheal tube cuffs: a bench study. Intensive Care Med. 2010 Dec;36(12):2066-73. Epub 2010 Sep 18. Pitts R, Fisher D, Sulemanji D, Kratohvil J, Jiang Y, Kacmarek R. Department of Respiratory Care, Massachusetts General Hospital and Harvard Medical School, Boston, MA, USA.
6. Closed tracheal suction and fluid aspiration past the tracheal tube. Impact of tube cuff and airway pressure. Minerva Anestesiol. 2011 Feb;77(2):166-71. Epub 2011 Feb 1. Dave MH, Frotzler A, Weiss M. Department of Anaesthesia, University Children's Hospital, Zurich, Switzerland. mital.dave@kispi.uzh.ch

GUIDELINES

1. Defining, treating and preventing Hospital Acquired Pneumonia: European perspective

Torres A et al (for European HAP working group; Intensive Care Med (2009) 35:9-29)

INTRODUCTION: Many controversies still remain in the management of hospital acquired pneumonia (HAP), and ventilation acquired pneumonia (VAP), Three European Societies, European Respiratory Society (ERS), European Society of Clinical Microbiology and Infectious Diseases (ESCMID) and European Society of Intensive Care Medicine (ESICM), were interested in producing
a document on HAP and VAP with European perspective.

KEY MESSAGE: 20 Points which are highly consensual between the eleven European experts:
"15. Subglottic aspiration is effective in preventing VAP, but patients should not be re-intubated just for this purpose" - "Recommended measures for prevention of VAP" – "Additional measures which might be helpful in distinct settings and populations" - "Continuous aspiration of subglottic secretions"

2. Strategies to Prevent Ventilator-Associated Pneumonia in Acute Care Hospitals: 2014 Update

Michael Klompas et al; Infection Control and Hospital Epidemiology, Vol. 35, No. 8 (August 2014)

SHEA (Society for Healthcare Epidemiology of America) **updated Practical recommendations to assist acute care hospitals in implementing and prioritizing strategies to prevent ventilator-associated pneumonia (VAP) and other ventilator-associated events (VAEs) and to improve outcomes for mechanically ventilated adults, children, and neonates.**

BACKGROUND: VAP & VAE detrimental to patients and increase costs. Attributable mortality of VAP is estimated to be approximately 10%. Clinical surveys indicate 5%–15% of ventilated patients still develop nosocomial pneumonias.

EXCERPT FROM THE GUIDELINES: SHEA recommends several basic and special practices to improve outcomes based on clinical evidence and expert consensus:

Basic practices

- Use noninvasive positive pressure ventilation in selected populations
- Manage patients without sedation whenever possible
- Interrupt sedation daily, assess readiness to extubate daily
- Perform spontaneous breathing trials with sedatives turned off
- Facilitate early mobility
- Utilize endotracheal tubes with subglottic secretion drainage ports for patients expected to require greater than 48 or 72 hours of mechanical ventilation
- Change the ventilator circuit only if visibly soiled or malfunctioning
- Elevate the head of the bed to 30–45 degrees

Special approaches

- Selective oral or digestive decontamination
- Regular oral care with chlorhexidine
- Prophylactic probiotics
- Ultrathin polyurethane endotracheal tube cuffs
- Automated control of endotracheal tube cuff pressure
- Saline instillation before tracheal suctioning
- Mechanical tooth brushing

3. ATS: Guidelines for the Management of Adults with Hospital-Acquired, Ventilator-Associated, and Healthcare-Associated Pneumonia

This official statement of the American Thoracic Society and the Infectious Diseases Society of America was approved by the ATS Board of Directors, December 2004 and the IDSA Guideline Committee, October 2004.

ABOUT SUBGLOTTIC SUCTIONING - EXCERPT FROM THE GUIDELINES

Continuous aspiration of subglottic secretions can reduce the risk of early-onset VAP, and should be used, if available (Level I).

Continuous aspiration of subglottic secretions, through the use of a specially designed endotracheal tube, has significantly reduced the incidence of early-onset VAP in several studies.

4. Practice Alert; American Association of Critical Care Nurses; ISSUE 2008

http://www.aacn.org/wd/practice/docs/practicealerts/vap.pdf?menu=aboutus

ABOUT SUBGLOTTIC SUCTIONING – EXCERPT FROM THE GUIDELINES

Use an endotracheal tube (ET) with a dorsal lumen above the endotracheal cuff to allow drainage by continuous suctioning of tracheal secretions that accumulate in the subglottic area. (Level VI)

- Micro or macro aspiration of oropharyngeal and/or gastric fluids are presumed to be an essential step in the development of VAP. Pulmonary aspiration is increased by supine positioning and pooling of secretions above the ET tube cuff.
- Studies on the use of special ET tubes which remove secretions pooled above the cuff with continuous suction decrease VAP by 45 to 50 %.

5. UK Department of Health - High Impact Intervention: care bundle to reduce Ventilator-Associated Pneumonia

http://hcai.dh.gov.uk/files/2011/03/2011-03-14-HII-Ventilator-Associated-Pneumonia-FINAL.pdf

The aim of the care bundle, as set out in this high impact intervention, is to ensure appropriate and high quality patient care. Regular auditing of the care bundle actions will support cycles of review and continuous improvement in care settings.

"The use of tracheal tubes with subglottic drainage ports can reduce VAP by preventing contaminated oral secretions that accumulate above the tracheal cuff intubated patients leaking past the cuff into the lungs."

"A tracheal tube (endotracheal or tracheostomy) which has a subglottic secretion drainage port is used if the patient is expected to be intubated for >72 hrs."

"Secretions are aspirated via the subglottic secretion port 1-2 hourly."

6. Commission for recommendation Hospital Hygiene and Infection Prevention (KRINKO) at the Robert Koch Institute. Prevention of nosocomial ventilator-associated pneumonia

Bundesgesundheitsbl (2013) 56:1578–1590

KEY MESSAGE ON SUBGLOTTIC SUCTIONING:

"New technical developments like an ultrathin polyurethane tube cuff allow for a tight fit without leaks in order to maximally prevent the aspiration of secretions. To date, one randomized trial has shown a reduction in the incidence of early and late pneumonia through the combination of subglottic suctioning and ultrathin cuffs as compared to conventional endotracheal tubes."

THE COMMISSION RECOMMENDS:

"The use of a subglottic suctioning endotracheal tube to prevent pneumonia in patients who require ventilation for more than 72 hours (Cat. IA). The risk of pneumonia from reintubating the patient should be weighed against the benefits of achieving a subglottic secretion drainage by replacing a regular endotracheal tube with an endotracheal tube with subglottic suctioning. To date, no evidence has yet been provided for the type of secretion drainage - intermittent or continous - and the preventive benefit of tubes with polyurethane cuff / newly designed cuff geometry (Cat. III)."

META ANALYSIS; LITERATURE REVIEW

1. Subglottic secretion drainage for the prevention of ventilator-associated pneumonia: a systematic review and meta-analysis

Muscedere J et al Crit Care Med. 2011 Aug;39(8):1985-91

OBJECTIVE:

Updated systematic review and meta-analysis on subglottic secretion drainage as a preventive measure for ventilator-associated pneumonia.

METHODS:

13 randomized clinical trials that met the inclusion criteria with a total of 2442 randomized patients. Of the 13 studies, 12 reported a reduction in ventilator-associated pneumonia rates in the subglottic secretion drainage arm;In meta-analysis, the overall risk ratio for ventilator-associated pneumonia was 0.55 (95% confidence interval, 0.46-0.66; p < .00001) with no heterogeneity (I = 0%). The use of subglottic secretion drainage was associated with reduced intensive care unit length of stay (-1.52 days; 95% confidence interval, -2.94 to -0.11; p = .03); decreased duration of mechanically ventilated (-1.08 days; 95% confidence interval, -2.04 to -0.12; p = .03), and increased time to first episode of ventilator-associated pneumonia (2.66 days; 95% confidence interval, 1.06-4.26; p = .001).

RESULTS:

In our systematic review and meta-analysis of ETTs with SSD, there was a highly significant reduction of VAP of approximately 50% in MV patients who received this (SSD) intervention. We were also able to demonstrate a reduction in ICU LOS and duration of MV (weakened association due to heterogeneity in meta-analysis). Furthermore, in patients receiving SSD and in whom VAP occurred, there was a delay into occurrence as compared to control group.

CONCLUSION:

In those at risk for ventilator-associated pneumonia, the use of endotracheal tubes with subglottic secretion drainage is effective for the prevention of ventilator-associated pneumonia and may be associated with reduced duration of mechanical ventilation and intensive care unit length of stay.

PMID: 21478738

2. Subglottic Suction Drainage: A Literature Review

Depew, Charlotte L., MSN, RN, CCNS and McCarthy, Mary S., MA, PhD, RN, CNSN ; AACN 2007

OBJECTIVE:

To review the available evidence regarding the use of an endotracheal tube with a subglottic secretion aspiration port to prevent ventilator-associated pneumonia. Issues, cost, benefits, and research recommendations [are] also discussed.

SUMMARY:

- Continuous aspiration of subglottic secretions (CASS) is a prophylactic intervention for reducing VAP incidence, a Level 1 recommendation by ATS (American Thoracic Society).
- Meta-analysis of 5 studies, which examined subglottic secretion aspiration and VAP and met adequate research criteria for meta-analysis, summarizing that the VAP incidence was lower in the subglottic suction group in all 5 studies and by more than 50% in some of the studies.
- Highlights that subglottic secretions are copious (0-13ml/hour). The problems with the Hi-Lo Evac tubes in this study were 1. Tenacious secretions could lead to occlusion of the suction line; 2. Intermittent hissing or suction sounds can be annoying to both staff and patient; 3. Concern for mucosal and sub mucosal injury.

CONCLUSION:

The scientific evidence to support the use of CASS is evolving as more hospitals adopt this therapy, and report their experiences with it. This additional strategy to prevent the serious and costly complications associated with VAP require more clinical investigations with meticulous attention to factors that facilitate subglottic secretion removal as well as minimize tracheal mucosal effects.

PMID: 17978611

PROSPECTIVE RANDOMIZED STUDIES

1. Influence of an endotracheal tube with polyurethane cuff and subglottic secretion drainage on pneumonia

L. Lorente, M. Lecuona, A. Jimenez, M.L. Mora, A. Sierra American Journal of Respiratory and Critical Care Medicine, 2007

OBJECTIVE:

To evaluate the effect of an endotracheal tube with a polyurethane cuff combined with intermittent subglottic secretion drainage on prevention of early- and late-onset VAP.

METHODS†:

Patients were randomized to either intubation with a SealGuard Evac endotracheal tube with a polyurethane cuff and received subglottic suctioning hourly (designation ETT-PUC-SSD; n=140); or intubation with a Hi-Lo endotracheal tube with a polyvinyl cuff and no subglottic suctioning (control group, designation ETT-C; n=140).

RESULTS:

Incidence of VAP was significantly lower (p=0.001) with the ETT-PUC-SSD group compared to the ETT-C group (control): 7.9% versus 22.1%. Incidence of both early-onset and late-onset VAP were significantly lower compared to control (using Cox regression analysis and comparison of hazard ratios): Early-onset: 3.6% vs. 10.7%, p=0.02; Late-onset: 9.5% vs. 26.7%, p=0.01.

CONCLUSION:

The use of an endotracheal tube with polyurethane cuff and subglottic secretion drainage helps prevent early- and late-onset VAP.

PMID: 17872488

† Study done using Sealguard and Hi-Lo Evac ET tubes

2. Intermittent Subglottic Secretion Drainage and Ventilator-associated Pneumonia: A Multicenter Trial

Jean-Claude Lacherade et al, American Journal of Respiratory and Critical Care Medicine, Vol. 182, No. 7 (2010), pp. 910-917.

OBJECTIVE:

To determine whether SSD reduces the overall incidence of microbiologically confirmed VAP.

METHODS†:

Randomized controlled clinical trial conducted at four French centers. A total of 333 adult patients intubated with a tracheal tube allowing drainage of subglottic secretions and expected to require mechanical ventilation for ≥48 hours was included. Patients were randomly assigned to undergo intermittent SSD (n = 169) or not (n = 164).

RESULTS:

Primary outcome was the overall incidence of VAP based on quantitative culture of distal pulmonary samplings performed after each clinical suspicion. Other outcomes included incidence of early- and late-onset VAP, duration of mechanical ventilation, and hospital mortality. The Hi Lo Evac tubes were used in all patients. Microbiologically confirmed VAP occurred in 67 patients, 25 of 169 (14.8%) in the SSD group and 42 of 164 (25.6%) in the control group (P = 0.02), yielding a relative risk reduction of 42.2% (95% confidential interval, 10.4–63.1%). Using the Day 5 threshold, the beneficial effect of SSD in reducing VAP was observed in both early-onset VAP (2 of 169 [1.2%] patients undergoing SSD vs. 10 of 164 [6.1%] control patients; P = 0.02) and late-onset VAP (23 of 126 [18.6%] patients undergoing SSD vs. 32 of 97 [33.0%] control patients; P = 0.01). VAP was clinically suspected at least once in 51 of 169 (30.2%) patients undergoing SSD and 60 of 164 (36.6%) control patients (P = 0.25). No significant between-group differences were observed in duration of mechanical ventilation and hospital mortality.

CONCLUSION:

Subglottic secretion drainage during mechanical ventilation results in a significant reduction in VAP, including late-onset VAP.

PMID: 20522796

† Study done using Hi-Lo Evac tubes

3. Polyurethane cuffed endotracheal tubes to prevent early postoperative pneumonia after cardiac surgery: A pilot study

J Thorac Cardiovasc Surg 2008
Jan Poelaert, MD, PhD,Pieter Depuydt, MD, Annick De Wolf, MD, Stijn Van de Velde, MD, Ingrid Herck, MD, and Stijn Blot, PhD; poelaert@uzbrussels.be

OBJECTIVE:

To evaluate if the use of a polyurethane cuffed tube would prevent early postoperative pneumonia through this mechanism in a population of cardiac surgical patients.

MATERIALS AND METHODS[†]:

In a prospective, single-blind, randomized study, patients scheduled for cardiac surgery were allocated to intubation with a polyurethane cuffed endotracheal tube or the routinely used polyvinyl chloride cuffed endotracheal tube.

RESULTS:

A total of 134 patients were available for analysis (67 in each group). Whereas mortality was not different between the groups, the incidence of early postoperative pneumonia and empirical prescription of antibiotic therapy were significantly lower in the polyurethane group than in the polyvinyl chloride group (23% vs 42%, P < .03). Intensive care unit and hospital stays were not significantly different between the two study subsets (3 +/- 5 days vs 3 +/- 4 days and 16 +/- 9 vs 17+/-11 days, respectively). In a multivariate regression analysis, preoperative serum creatinine levels (odds ratio 1.85, confidence interval 1.02-3.37, P = .04) and perioperative transfusion (odds ratio 1.50, confidence interval 1.08-3.37, P = .015) were independently associated with increased risk of early postoperative pneumonia, whereas use of a polyurethane endotracheal tube was protective (odds ratio 0.31, confidence interval 0.13-0.77, P = .01).

CONCLUSION:

Use of a PU cuffed ET instead of a standard PVC cuffed ET during cardiac surgery could significantly decrease the occurrence of clinically suspected pneumonia in the early postoperative phase and subsequently reduce the use of empirical antibiotic therapy.

PMID: 18374755

[†] Study done using Sealguard (PU) and Mallinckrodt (PVC) cuffed ET tubes

PROSPECTIVE OBSERVATIONAL STUDY

1. Impact of polyurethane on variations in tracheal cuff pressure in critically ill patients: a prospective observational study

Intensive Care Med. 2010 Jul;36(7):1156-63. Epub 2010 Apr 16.
Nseir S, Zerimech F, De Jonckheere J, Alves I, Balduyck M, Durocher A. Intensive Care Unit, Calmette Hospital, University Hospital of Lille, boulevard du Pr Leclercq, 59037, Lille Cedex, France.
s-nseir@chru-lille.fr

OBJECTIVE:

To determine the impact of polyurethane (PU) on variations in cuff pressure (P_{cuff})

MATERIALS AND METHODS[†]:

Prospective observational before-after study performed in a ten-bed ICU. Cuff pressure was continuously recorded for 24 h in 76 intubated patients, including 26 with polyvinyl chloride (PVC), 22 with cylindrical polyurethane (CPU), and 28 with tapered polyurethane (TPU)-cuffed tracheal tubes. P_{cuff} was manually adjusted every 8 h by nurses and was maintained around 25 cmH_2O. Time spent with cuff underinflation and overinflation was continuously measured. In addition, pepsin, a proxy for microaspiration of gastric contents, was quantitatively measured in tracheal secretions at the end of recording period.

RESULTS:

A total of 1,824 h of continuous recording of cuff pressure was analyzed. Patient characteristics were similar in the three groups. No significant difference was found in percentage of time spent with underinflation (mean +/- SD, 26 +/- 22, 28 +/- 12, 30 +/- 13% in PVC, CPU, and TPU groups, respectively) and overinflation [median (IQR), 7 (2-14), 6 (3-14), 11% (5-20)] among the three groups. However, a significant difference was found in the coefficient of variation of P_{cuff} (mean +/- SD, 82 +/- 48, 92 +/- 47, 135 +/- 67, $p = 0.002$). While the coefficient of P_{cuff} variation was significantly ($p < 0.017$) higher in the TPU compared to CPU and PVC groups, no significant difference was found between the CPU and PVC groups. The pepsin level was significantly different among the three groups (408 +/- 282, 217 +/- 159, 178 +/- 126 ng/ml; $p < 0.001$). In fact, the pepsin level was significantly lower in the CPU and TPU groups compared with the PVC group.

CONCLUSION:

PU does not impact variations in P_{cuff} in critically ill patients.

PMID: 20397001

[†] Study done using Hi-Lo Mallinckrodt, Covidien Taperguard and MICROCUFF® ET tubes

RETROSPECTIVE STUDIES

1. Air leakage around endotracheal tube cuffs

Eur J Anaesthesiol. 2004 Jun;21(6):448-53. Dullenkopf A, Schmitz A, Frei M, Gerber AC, Weiss M.
University Children's Hospital, Department of Anaesthesia, Zurich, Switzerland.
alex.dullenkopf@kispi.unizh.ch

OBJECTIVE:

To compare the recently introduced MICROCUFF* endotracheal tube with conventional tubes in respect of the cuff pressures required to prevent air leakage.

MATERIALS AND METHODS†:

The following tubes (ID 7.0mm) were compared: MICROCUFF* HVLP ICU, Mallinckrodt HiLo, Portex Profile Soft Seal, Rüsch Super Safety Clear and Sheridan CF. Fifty patients undergoing endotracheal intubation with a cuffed tube of internal diameter 7.0 mm were studied. Tracheas were intubated using one of the endotracheal tubes in random order. Cuff pressure to prevent air leakage at standardized ventilator setting (peak inspiratory pressure 20 cmH_2O/PEEP 5 cmH_2O/respiratory rate 15 breaths min(-1)) was assessed by auscultation of audible sounds at the mouth. Patients characteristics and cuff pressures from each brand were compared to the MICROCUFF* group using the Mann-Whitney U-test ($P < 0.05$ was chosen as the level of statistical significance).

RESULTS:

Patients' median age (range) was 14.2 (12.0-17.1) yr, body weight 57.5 (40.0-81.9) kg and length 164.9 (146.5-190.0) cm. No significant differences in patients' characteristics were found between groups. Mean cuff pressure (all tubes) required for air sealing was 19.1 (8-42) cmH_2O. The MICROCUFF* tube required significantly lower sealing pressures (9.5 (8-12) cmH_2O) compared to the other brands of endotracheal tube ($P < 0.05$, Mann-Whitney U-test).

CONCLUSION:

The MICROCUFF* endotracheal tube with its ultra-thin polyurethane cuff membrane required the lowest sealing pressure to prevent air leakage. These features are potentially of interest for long-term intubated patients and for cuffed endotracheal tubes in children, allowing tracheal sealing at lower cuff pressures implying less damage to the trachea.

PMID: 15248624

† Study done using MICROCUFF*, Malinckrodt HiLo, Portex Profile soft seal, Rusch Suoer Safety Clear and Sheridian CF ET tubes

2. A polyurethane cuffed endotracheal tube is associated with decreased rates of ventilator-associated pneumonia

J Crit Care. 2011 Jun;26(3):280-6. Epub 2010 Jul 23.
Miller MA, Arndt JL, Konkle MA, Chenoweth CE, Iwashyna TJ, Flaherty KR, Hyzy RC.
Division of Pulmonary and Critical Care Medicine, University of Michigan, Ann Arbor, MI, USA. melmille@umich.edu

OBJECTIVE:

the study was intended to determine if using a polyurethane-cuffed endo tracheal (ET) tube would result in a decrease in rate of ventilator-associated pneumonia.

MATERIALS AND METHODS[†]:

A polyurethane-cuff endotracheal tube (MICROCUFF*, Avanos Medical, Alpharetta, Ga) was used to replace the traditional endo tracheal tube in all adult mechanically ventilated patients systematically in all ventilated patients from July 2007 to June 2008. The rates of ventilator-associated pneumonia (VAP) before, during, and after the intervention year were compared by interrupted time series analysis.

RESULTS:

The VAP rates decreased from 5.3 per 1000 ventilator days before the use of the polyurethane-cuffed endotracheal tube to 2.8 per 1000 ventilator days during the intervention year (P = .0138). After incorporating conventional ET tubes again in practice the VAP rate rose to 3.5/1000 ventilator days, already during the first 3- months. Use of the polyurethane-cuffed endotracheal tube was associated with an incidence risk ratio of ventilator-associated pneumonia of 0.572 (95% confidence interval, 0.340-0.963). In statistical regression analysis controlling for other possible alterations in the hospital environment, as measured by rate of tracheostomy ventilator-associated pneumonia, the incidence risk ratio of ventilator-associated pneumonia in patients intubated with polyurethane-cuffed endotracheal tube was 0.565 (P = .032; 95% confidence interval, 0.335-0.953). Control intervention was 7.8/1000 days during PVC year & 5.9/1000 days for PU year (p = NS).

CONCLUSION:

The study concluded that incorporating the use of polyurethane cuffed ET tubes seemed to decrease the VAP rate in this specific study.

PMID: 20655698

[†] Study done using MICROCUFF* ET tubes

BENCH STUDIES

1. Fluid leakage past tracheal tube cuffs: evaluation of the new MICROCUFF* endotracheal tube

Dullenkopf A, et al; Intensive Care Med. 2003 Oct;29(10):1849-53. Epub 2003 Aug 16.

OBJECTIVE:

In vitro setup study compared the recently introduced MICROCUFF* endotracheal tube HVLP ICU featuring an ultrathin (7-microm) polyurethane cuff membrane with endotracheal tubes from different manufacturers regarding fluid leakage past the tube cuff.

MEASUREMENTS AND RESULTS†:

The following endotracheal tubes (ID 7.5 mm) were compared: Mallinckrodt HiLo, MICROCUFF* HVLP ICU, Portex Profile Soft Seal, Rüsch Super Safety Clear, and Sheridan CF. A vertical PVC trachea model (ID 20 mm) was intubated, and cuffs were inflated to 10, 15, 20, 25, 30, and 60 cmH_2O. Colored water (5 ml) was added to the top of the cuff. The amount of leaked fluid past the tube cuff within 5, 10, and 60 min was recorded. Experiments were performed four times using two examples of each tube brand. Fluid leakage past tube cuffs occurred in all conventional endotracheal tubes at cuff pressures from 10 to 60 cmH_2O. In the MICROCUFF* tube cuff pressure fluid leakage was observed within
10 min only at 10 cmH_2O. Results with the MICROCUFF* tube were significantly better than all other tube brands at cuff pressures of 10-30 cmH_2O.

CONCLUSION:

Within the acceptable upper limit for tracheal cuff pressure (25-30 cmH_2O) the MICROCUFF* endotracheal tube was the only one of the tested tubes to prevent fluid leakage in our in vitro setup. In vivo studies are required to confirm these findings.

PMID: 12923620

† Study done using MICROCUFF*, Malinckrodt HiLo, Portex Profile soft seal, Rusch Suoer Safety Clear and Sheridian CF ET tubes

2. Endotracheal Tubes for Critically Ill Patients: An In Vivo Analysis of Associated Tracheal Injury, Mucociliary Clearance, and Sealing Efficacy

Gianluigi Li Bassi et al; chest volume 147 #5 May 2015

OBJECTIVE AND BACKGROUND:

Improvements in the design of the endotracheal tube (ETT) have been achieved in recent years. We evaluated tracheal injury associated with ETTs with novel high-volume low-pressure (HVLP) cuffs and subglottic secretions aspiration (SSA) and the effects on mucociliary clearance (MCC).

MATERIALS AND METHODS†:

Twenty-nine pigs were intubated with ETTs comprising cylindrical or tapered cuffs and made of polyvinylchloride (PVC) or polyurethane. In specific ETTs, SSA was performed every 2 h. Following 76 h of mechanical ventilation, pigs were weaned and extubated. Images of the tracheal wall were recorded before intubation, at extubation, and 24 and 96 h thereafter through a fluorescence bronchoscope. We calculated the red-to-green intensity ratio (RIG), an index of tracheal injury, and the green-plus-blue (G+ B) intensity, an index of normalcy, of the most injured tracheal regions. MCC was assessed through fluoroscopic tracking of radiopaque markers. After 96 h from extubation, pigs were killed, and a pathologist scored injury.

RESULTS:

Cylindrical cuffs presented a smaller increase in RIG vs tapered cuffs (P = .011). Additionally, cuffs made of polyurethane produced a minor increase in RIG (P = .012) and less G+ B intensity decline (P .022) vs PVC cuffs. Particularly, a cuff made of polyurethane and with a smaller outer diameter outperformed all cuffs. SSA-related histologic injury ranged from cilia loss to subepithelial inflammation. MCC was 0.9 ± 1.8 and 0.4 ± 0.9 mml min for polyurethane and PVC cuffs, respectively (P< .001).

CONCLUSION:

HVLP cuffs and SSA produce tracheal injury, and the recovery is incomplete up to 96 h following extubation. Small, cylindrical-shaped cuffs made of polyurethane cause less injury. MCC decline is reduced with polyurethane cuffs.

PMID: 25500677

† Study done using Ruschelit Safety Clear plus, Hi Lo Evac, SACETT, Taperguard, Sheridian/HVT, MICROCUFF*, Sealguard Evac

3. Benchtop study of leakages across the Portex, TaperGuard, and MICROCUFF* endotracheal tubes under simulated clinical conditions

Lau et al., Hong Kong Med J. 2014;20:7-15.

OBJECTIVE:

To compare water leakage across respective cuffs under a comprehensive set of simulated MV situations.

MATERIALS AND METHODS†:

In vitro silicone trachea model serially intubated with three endotracheal tubes (ETs): Mallinckrodt TaperGuard (tapered PVC), MICROCUFF* (cylindrical PU), and conventional Portex (globular PVC); Simulated clinical conditions were:

- different PEEP levels
- disconnection with and without spontaneous breathing
- multiple cuff pressures
- with or without continuous suction force
- leakage measured every minute for 3 minutes.

RESULTS:

MICROCUFF* consistently provided the best protection against fluid leakage under all simulated clinical situations, followed by TaperGuard, and lastly Portex. Clinical scenarios associated with the greatest leakage were zero PEEP, circuit disconnection with spontaneous breathing efforts, application of suction, and a low cuff pressure. MICROCUFF* outperformed TaperGuard and Portex in preventing fluid leakage, which is one of the major mechanisms for ventilator-associated pneumonia.

CONCLUSION:

Although cost-effectiveness analysis is worthwhile as a basis for wider promotion of the novel ETs, taking into account the small absolute cost difference, there may be a case for just switching ETs to those with a lesser tendency to leak until evidence to the contrary appears.

PMID: 23878202

† Study done using Mallinckrodt TaperGuard, MICROCUFF*, Portex ET tubes

4. Bench Comparison of Suction Efficiency for Endotracheal Tubes with a Subglottic Suction Lumen

David Curd, M.S., Brian McCachren, BSEE, MBA, Stephen Baratian, M.S., Claire Couch, M.S., Paul Batchelder, LRCP, RRT; SCCM 2014 Critical Care Congress, Abstract #393

OBJECTIVE:

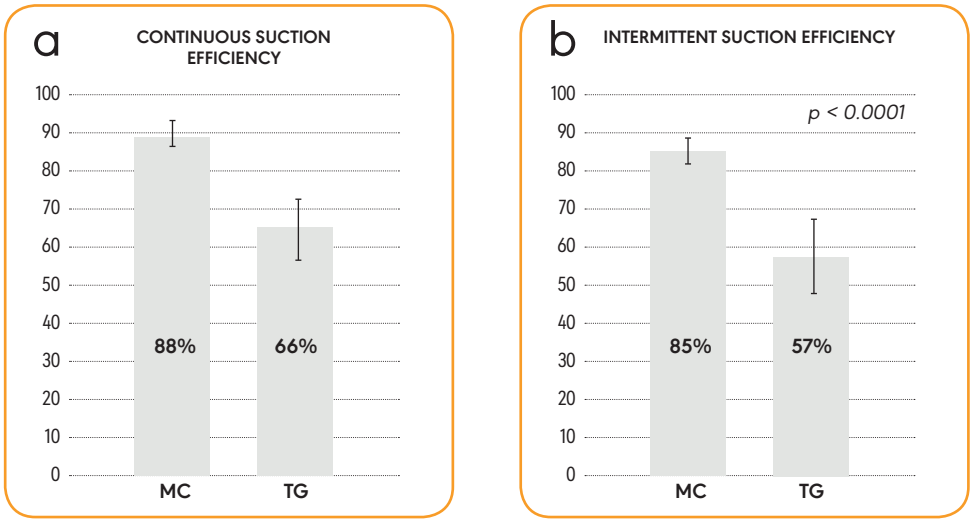
To see if ET designed with saline bolus suction ports will improve suction efficiency compared to ET designed with air bolus suction ports in simulated clinical use.

MATERIALS AND METHODS:

ET tested were the AVANOS® MICROCUFF® Subglottic Suctioning Endotracheal Tube (MC) and the Mallinckrodt TaperGuard Evac Oral Tracheal Tube (TG). A glass artificial trachea (AT) placed in an environmental chamber simulating body humidity and temperature was used for testing. Mucus simulant with similar viscosity and rheological properties to that seen in hospitalized patients was introduced into the AT above the ET tube cuff.

Tube Tested	**MC**		**TG**	
Bolus Type	**15 cc saline bolus**		**5 cc air bolus**	
Suction Type	Continuous (20 mm Hg)	Intermittent (100 mm Hg)	Continuous (20 mm Hg)	Intermittent (100 mm Hg)
Sample Size	n = 32	n = 32	n = 32	n = 32
Test Duration	4 days/tube	4 days/tube	4 days/tube	4 days/tube

Test conditions for both ET tested based on each product's indications for use.



Saline bolus design improved the suction efficiency of the ET in both the continuous (a) intermittent (b) conditions.

CONCLUSION:

In the continuous condition, 44% of the TG tubes demonstrated near or complete obstruction of the suction line (0 or <10% efficiency). In the intermittent condition, 16% of the TG tubes demonstrated near or complete obstruction of the suction. None of the MC tubes demonstrated near or complete obstruction of the suction line at either condition.

5. Variables affecting leakage past endotracheal tube cuffs: a bench study

Intensive Care Med. 2010 Dec;36(12):2066-73. Epub 2010 Sep 18.
Pitts R, Fisher D, Sulemanji D, Kratohvil J, Jiang Y, Kacmarek R. Department of Respiratory Care, Massachusetts General Hospital and Harvard Medical School, Boston, MA, USA.

OBJECTIVE:

Leakage of oral secretions past endotracheal tubes (ETT) has been implicated in ventilator-associated pneumonia. The aim of this bench study was to compare the ability of current generation ETT cuffs to prevent fluid leakage and to determine the specific mechanical ventilator settings that affect movement of fluid across an inflated ETT cuff.

MATERIALS AND METHODS†:

Using a 2.3-cm internal diameter (ID) tracheal model and simulated ventilatory support, we evaluated the impact of cuff pressure (20 and 30 cmH_2O), positive end-expiratory pressure/continuous positive airway pressure (PEEP/CPAP, 0-15 cmH_2O), peak inspiratory pressure (PIP, 15-45 cmH_2O), and mode of ventilation (volume control, volume assist/ control, pressure control, pressure assist/control, and CPAP) on leakage of fluid past the ETT cuffs of 16 ETTs. The tracheal model was configured in the vertical position with 35 ml of vitaminwater® on top of the inflated ETT cuff and mechanically ventilated. Fluid leakage past the cuff was determined by calculating the volume change in the tracheal model after each 30-min ventilation period. Initially five 8.0-mm-ID ETTs of each manufacturer type were evaluated at baseline ventilator settings. Tubes allowing a consistent leak within two SD of the mean leakage for the five tubes were numbered in consecutive order. A single tube from this group was then randomly selected for detailed evaluation.

RESULTS:

Cuff leakage varied among ETT types ($p < 0.0001$); median leak volume 6.0 ml (0.6-15.1) across all tubes under all conditions. Cuff leakage was inversely related to PEEP level, cuff pressure, and PIP except when PEEP was set at 15 cmH_2O (all $p < 0.0001$). In addition, cuff leak varied among modes ($p = 0.035$).

CONCLUSION:

Fluid leakage was significantly minimized with the use of ultra-thin walled cuffs. Among the factors affecting leakage, PEEP had the greatest effect followed by PIP, cuff pressure, and then ventilator mode.

PMID: 20852839

† Study done using SealGuard Basic, HiLO, Lo-Contour, Teleflex Sheridan/HVT, Sheridian CF, Rusch Safety Clear, Parker Flex-Tip PFHV, Portex Soft Seal Profile Clear, Portex Soft Seal Profile Ivory, Sun Medical, Bard Agento, Endoflex ETT, Endoflex Tapered cuff, Endoflex Oblong cuff, Redi Tube and MICROCUFF®

6. Closed tracheal suction and fluid aspiration past the tracheal tube. Impact of tube cuff and airway pressure

Minerva Anestesiol. 2011 Feb;77(2):166-71. Epub 2011 Feb 1.
Dave MH, Frotzler A, Weiss M. Department of Anaesthesia, University Children's Hospital, Zurich, Switzerland. mital.dave@kispi.uzh.ch

OBJECTIVE:

This study investigated the effect of different tube cuff types and airway pressures on fluid leakage past the tracheal tube cuff during suction with a closed tracheal suction system (CTSS).

METHODS†:

Unlubricated high-volume, low-pressure tracheal tube cuffs made from polyvinylchloride (PVC) and polyurethane (PU) with a size 7.5 mm internal diameter (ID) were placed in a 22 mm ID artificial trachea connected to a test lung and inflated to 25 or 50 cmH_2O of cuff pressure. Positive pressure ventilation (PPV) with peak inspiratory pressures of 15, 20 or 25 cmH_2O and positive end expiratory pressures (PEEP) of 5 or 10 cmH_2O were used. A CTSS catheter (14 Fr) was attached to the tracheal tube and suction was performed for 5, 10, 15 or 20 s with 200 or 300 cmH_2O of negative suction pressures. The volume of fluid leaking across the tube cuff at the end of the suction procedure was measured (mL), and the airway pressure was simultaneously recorded. Fluid leakage and airway pressures during different suction conditions were compared using a Kruskal Wallis test and Mann Whitney test ($p<0.05$).

RESULTS:

The airway pressure drop during suction was similar for both tube cuffs. The PU tube cuff resulted in significantly less fluid leakage (range 0.00-0.12 mL) than the PVC tube cuff ($p<0.001$). For the PVC tube cuff, fluid leakage at higher cuff pressures was significantly less ($p<0.01$).Varying PEEP and PIP did not change the fluid leakage or the drop in airway pressure.

CONCLUSION:

The use of PU tube cuffs and intermittent transient increases in cuff pressure during suction can effectively reduce fluid leakage past the tracheal tube during closed tracheal suctioning.

PMID: 21283067

† Study done using undisclosed PU and undisclosed PVC cuffed ET tubes

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For more information, please send an email to
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