

"Clearer Airways, Fewer Ventilator Days"

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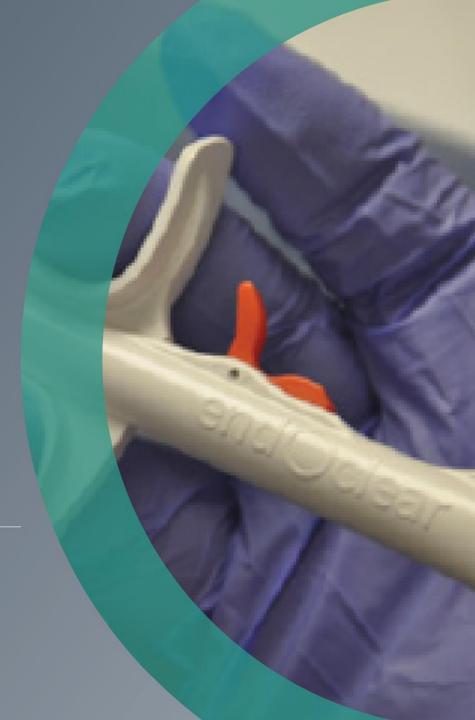
"Cleaner Airways, Fewer Ventilator Days"

- Current standard of care closed suction does not keep the ETT patent or free of bacterial and fungal colonization.
- The build-up of biofilm is harmful and can lead to infection and increased duration of ventilation and ICU length of stay.
- Using an ETT cleaner addresses retained secretions and colonization in a positive way.
- Effective cleaning of the ETT results in improved outcomes when used in both PRN and protocol fashion.
- 5 Alternatives to standard of care?



Current standard of care closed suction does not keep the ETT patent or free of bacterial and fungal colonization.

Suction catheters (closed systems and open) have been the standard of care for clearing endotracheal tubes since the inception of intubation and mechanical ventilation, yet the consensus is that suction is generally ineffective in cleaning the endotracheal tube.



Current Standard of Care Closed Suction.....





Quantifying the Opportunity:

- ≈100,000 ICU Beds in the US¹
- Occupancy range 57.4% to 82.1% (Mean of 69,750)²
- Mechanically ventilated patients range 20.7% to 38.9% (Mean of 21,909)²
- Estimated annual ventilator days 7.99M (21,909 x 365)
- Spending for hospital care was \$937B for 2013⁴
- ICU costs account for 17-39% of hospital care (Mean of 262B)⁵
- Day 3 on the ventilator in the ICU 32B (\$3,968 x 7.99M)⁶
- Process Improvement opportunity:
 - Quality or outcome improvement (reduce time on ventilator)
 - ✓ Cost reduction (decrease length of stay)



Current Standard of Care Closed Suction..



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Original Research

CRITICAL CARE MEDICINE

Increases in Endotracheal Tube Resistance Are Unpredictable Relative to Duration of Intubation

Alison M. Wilson, MD; Dana M. Gray; and John G. Thomas, PhD

Background: Accumulated secretions after intubation can affect the resistance of an endotracheal tube (ETT). Our objective was to measure extubated patient tubes and size-matched controls to evaluate differences in resistance.

Methods: New ETIs, with internal diameters of 7.0 through 8.5 mm, were tested as controls to establish the resistance of each size group as measured by pressure drop. Measurements were obtained using a mass flowmeter and pressure transducer. Pressure drop was measured at three flow rates. Seventy-one patient ETI's were evaluated after extubation by an identical method and compared with controls.

Results: In each control group, pressure drop was tightly clustered with low variation and no overlap between sizes. A total of 73 to 75% of the patient ETTs had a pressure drop of > 3 SDs of size-matched controls at all flow rates, Pressure drop in 48 to 56% (across three flow rates) of extubated tubes was equivalent to the next smaller size of controls. At 60 and 90 L/min, 10% and 15% of patient tubes, respectively, had the pressure drop of a control tube three sizes smaller. The pressure drop was unpredictable relative to the duration of intubation.

Conclusions: Organized secretions can significantly increase resistance as measured by the pressure drop of ETTs. The degree of change was highly variable, occurs in all sizes, and was unrelated to the duration of intubation. The performance of an ETT may be comparable to new tubes one to four sizes smaller. This may impact the tolerance of ventilator weaning. (CHEST 2009; 136:1006–1013)

Abbreviations: ETT = endotracheal tube; HEPA = high-efficiency particulate air; IID = internal diameter; SBT = spontaneous breathing trial

D uration of mechanical ventilation in a critically ill patient is affected by many factors, including underlying illness, comorbidities, presence of pneumonia, and ability to wean from the ventilator.^{1,2} Airway resistance can significantly impact required

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Affiliations: From the Departments of Surgery (Dr. Wilson) and Pathology (Ms. Gray and Dr. Thomas), West Virginia University, Morgantown, WV.

Morgantown, WV.
The study was performed at West Virginia University, School of
Medicine and West Virginia University Hospitals, Morgantown, WV.
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ventilator settings, ability to wean, patient comfort, and synchrony with the ventilator.³⁻⁵ Multiple factors influence the resistance of endotracheal tubes (ETTs),

For editorial comment see page 957

including airway humidification, secretions, and bacterial colonization.^{6–11} Inflammatory reactions in the lung secondary to bacterial infection may cause increased production of secretions within the first 24 h of intubation, leading to increased resistance and possible occlusion of ETTs.^{15–16}

Very strict industry standards regulate length and diameter specifications for ETT production. ¹⁵ Regulations mandate that for ETTs with internal diameters (IDs) of ≥ 6.5 mm, the variation in ID cannot exceed ± 0.20 mm. Regulation prohibits the overlap of tube ID between adjacent tube sizes. ¹⁶ For each size, there is a predictable amount of resistance that

Original Research

Secretion build-up in ETT:

- Occurred in <u>all</u> patients
- 48% had pressure drop equivalent to next smaller size tube
- 10% to 15% of patient tubes had a pressure drop of a tube three sizes smaller
- Independent of duration of ventilation
- Cannot predict which patients will have high volume of secretions



Current Standard of Care Closed Suction.....

Endotracheal tube intraluminal volume loss among mechanically ventilated patients

Shah, Chirag MD; Kollef, Marin H. MD Critical Care Medicine: January 2004 - Volume 32 - Issue 1 - pp 120-125 doi: 10.1097/01.CCM.0000104205.96219.D6 Clinical Investigations

Abstract

Objective: To measure endotracheal tube intraluminal volume loss among mechanically ventilated patients.

Design: Prospective observational study.

Setting: Medical intensive care unit (19 beds) of an urban university-affiliated teaching hospital.

Patients: A total of 101 patients with acute respiratory failure requiring >24 hrs of mechanical ventilation.

Interventions: None.

Measurements and Main Results: Acoustic reflectometry was employed to measure the intraluminal volume of 13-cm endotracheal tube segments. The endotracheal tube segment volumes were statistically smaller among endotracheal tubes used in patients compared with unused endotracheal tubes (5.4 \pm 0.7 vs. 6.0 \pm 0.6 mL, p < .001). The average percentage

difference in endotracheal tube segment volumes, between the unused endotracheal tubes and the endotracheal tubes used in patients, was 9.8% (range, 0–45.5%). The percentage difference in the endotracheal tube segment volumes increased significantly with increasing duration of tracheal intubation (r2 = .766, p < .001). The minimum diameter of the endotracheal tube segments was also statistically smaller among endotracheal tubes used in patients compared with the unused endotracheal tubes (7.5 ± 0.4 vs. 6.7 ± 1.2 mm, p < .001).

Conclusions:

Endotracheal tube intraluminal volume loss is common among patients with acute respiratory failure requiring mechanical ventilation and increases with prolonged tracheal intubation.



Current Standard of Care Closed Suction....



High-Resolution Computer Tomography in Assessing Endotracheal Tube Obstruction



Cristina Mietto¹, Riccardo Pinciroli¹, Annop Piriyapatsom¹, John G. Thomas², Lynn Bry³, Mary L. Delaney³, Andrea Du Bois³, Jessica Truelove⁴, Gregory R. Wojtkiewicz⁴, Matthias Nahrendorf⁴, Robert M. Kacmarek^{1,5}, Lorenzo Berra¹

1, Department of Anesthesia, Critical Care and Pain Medicine, Massachusetts General Hospital, Boston, MA; 2, School of Dentistry, West Virginia University, Morgantown, WV;
3, Center for Clinical and Translational Metagenomics, Department of Pathology, Brigham and Women's Hospital, Boston, MA; 4, Center for System Biology, Massachusetts General Hospital, Boston, MA;
5, Department of Respiratory Care, Massachusetts General Hospital, Boston, MA.

Introduction

The reduction in ETT lu

increased airflow resist

The two parts of this s

use of High-Resolution

(HR-CT) in measuring

obstruction and B) deter

between volume loss

resistance in the ETT.

of breathing.2

The presence of the endotracheal to physiological homeostasis of mucus cledett becomes covered in a thick layer of preventable by the use of commer catheters (Fig. 1).



Fig. 1. ETT in mucus layer.

Part A. Methods

From Nov-Dec 2012, we collected 2 intensive care units at MGH. Patient study group if they required mech.

more than 48 hours. Immediately after extubation, these study ETTs were sealed and cut at 24 cm from the Murphy Eye (lung end).

The control group (n=24) consisted of new adult ETTs matched with the study group by size and brand. All the ETTs underwent HR-CT scanning within 48 hours after extubation. HR-CT was performed with an isotopic spatial resolution of 110µm (Siemens Inveon system).

The entire 24cm ETT

was scanned.

However, three

4.4cm long sections

of each tube were

used for the analysis

(Fig. 2)

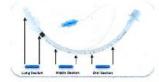


Fig. 2. Scheme of ETT sections for HR-CT scan analysis

On the CT images, the luminal space open to ventilation (air)
Hounsfield
as chosen to
or mucus

"In summary, standard methods for ETT cleaning are insufficient to prevent ETT narrowing, leading to an increase in patient work of breathing."

Part A.
ETTs from 20 patient (average time on ventilato)
Study group ETT analysis: HR average reduction of 8.2±7.1% or ranging from 0.0% to 23.7% (p=0.013)
Minimum CSA reduction was 24.9±3.9%

Fig. 4. Distribution of CSA reduction of used ETT group along the tube length.

Tal Art Volume Reddschon (S

Fig. 5. Correlation between grade of ETT occlusion and days of intubation.

The grade of occlusion was weakly correlated with the length of intubation (R²=0.352, p=0.006) (Fig. 5).

The mean internal diameters (ID) free of secretions were reduced from initial IDs of 7.0mm to 6.74 ± 0.24 mm (p=0.026), of

7.5mm to 7.10±0.52mm (p=0.007), and of 8.0mm to 7.63±0.43mm (p=0.038).

Part B.

oges of a used ed ETT (B).

filled with

retions. The

the ETT was

ween HR-CT

68±14 years, BMI 26±6

re than 48 hours

vsis showed an

air volume,

trol group).

n control

iced

vere collected.

Cross sech

progressively

section) (Fig. 4).

from oral to lung b

section 4.7±5.5%,

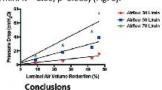
section 7.8±8.0% and lun

section 12.6±14.4%;

p=0.031 for oral vs. lung

Pressure drop (a surrogate of airflow resistance) strongly correlated with an increase in volume loss from the ETT silicone filling. This correlation is maintained at different airflows. (Airflow 30 I/min: R²= 0.87, p=0.021; 50 I/min: R²= 0.91, p=0.013; 70 I/min: R²= 0.90, p=0.015) (Fig. 6).





Part A. In a group of 20 prolonged mechanically ventilated adult patients, the CSA of the ETT was reduced by about 25%.

Part B. Volume loss determined an increase in airflow resistance.

In summary, standard methods for ETT cleaning are insufficient to prevent ETT narrowing, leading to an increase in patient work of breathing.

References

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Current Standard of Care Closed Suction.....

The primary goal of mechanical ventilation is to reduce the "work of breathing." Work of breathing is both the effort to inspire air into the lungs and the effort to exhale. This effort depends on compliance (How elastic the lung is) and resistance (How much obstruction exists in the airway).

The total work of breathing in the mechanically ventilated patient consists of:

- 1. the patient's own physiologic work of breathing,
- 2. the disease process that the patient is suffering from, and,
- 3. the resistance offered by the ventilator circuit and endotracheal tube (known as the "imposed work of breathing").



Current Standard of Care Closed Suction....

Airway resistance and lumen radius are exponentially related to the fourth power. This means any change in the radius causes a tremendous change in the airway resistance.

For example, if the radius is cut in half airway resistance doesn't just double. It increases by a factor of $2 \times 2 \times 2 \times 2 = 16$ (Poiseuille's equation).

If the radius increases 2 times, airway resistance decreases by the same factor of 16.

Because of this relationship any small amount of bronchospasm, secretion accumulation in the endotracheal tube, water in the ventilator tubing, or other obstruction considerably increases airway resistance.



Suction does <u>not</u> effectively clean endotracheal tubes and can be harmful!

AARC Clinical Practice Guidelines



Endotracheal suctioning of mechanically ventilated patients with artificial airways (2010):

Although the internal lumen of an ETT decreases substantially after a few days of intubation, due to formation of biofilm, suctioning should be performed *only* when clinically indicated in order to maintain the patency of the artificial airway used. Special consideration should be given to the potential complications associated with the procedure.



The build-up of biofilm is harmful and can lead to infection and increased duration of ventilation and ICU length of stay.

Endoluminal narrowing is generally under-appreciated for it's severe impact on pressure and resistance.



The Build-up of Biofilm is Harmful

Tracheal Tube Biofilm as a Source of Bacterial Colonization of the Lung

TIMOTHY J. J. INGLIS,1* MICHAEL R. MILLAR,2 J. GARETH JONES,3 AND DAVID A. ROBINSON4

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Biofilm formation in tracheal tubes, its bacterial content, and its interaction with ventilator gas flow were investigated. At least 50 mg (dry weight) of biofilm was found in 30 of 40 tracheal tubes used in intensive care patients for 2 h to 10 days. Electron microscopy showed bacteria in this layer, and quantitative studies showed that bacterial counts could reach up to 106/cm of tube length. Bacteria were cultured from the patient side 18' of 78 heat and moisture exchanger-microbiological units removed from ventilator circuits. Particles were nown to detach from tracheal tube luminal biofilm and were projected up to 45 cm from the tracheal tube tip. Following contamination of the tracheal tube biofilm with a patient's own gastrointestinal flora, entrainment of bacteria in the inspiratory gas flow provides a mechanism for initial and repeated lung colonization.

"Following contamination of the tracheal tube biofilm with a patient's own gastrointestinal flora, entrainment of bacteria in the inspiratory gas flow provides a mechanism for initial and repeated lung colonization."



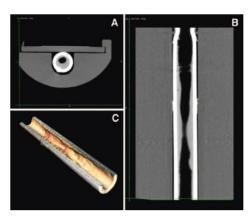
The Build-up of Biofilm is Harmful

Hugh C. Herrinings, Jr., M.D., Ph.D., Editor Alan Jay Sobwartz, M.D., M.S. Ed., Associate Editor

Use of High-definition Computed Tomography to Assess Endotracheal Tube Luminal Narrowing after **Mechanical Ventilation**

Riccardo Pinciroli, M.D., Cristina Mietto, M.D., Lorenzo Berra, M.D.*

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RODUCTION and clearance of mucus are key mechanisms in the physiology of the respiratory system. Their regulation is often impaired in intubated patients who show superabundant production and inefficient clearance. As a result, a variably thick layer of mucus ultimately adheres to the inner surface of the endotracheal tube (ETT), reducing its original cross-sectional area. This luminal narrowing significantly impacts airflow resistance that varies inversely to the fourth power of the conduit's radius according to the Poiseuille's equation $(\Delta P = 8 \mu L Q(\pi r^4)^{-1})$. Patient's work of breathing may consequently increase.1 However, the importance of ETT progress luminal narrowing during tion is still wine. used suctioning systems are un

tain the ETT function.2 To study the magnitude of this adverse event,

we developed an innovative approach to visualize the accretion of mucus in extubated ETTs

with high-definition computed tomography. The ETT is collected on extubation and sealed. Scanning is performed on a positron emission tomography-computed tomography scanner (Siemens, Malvern, PA), with resolution down to 15 µm. Multiplanar images of the ETT, particularly its lung end (terminal 10 cm), show the reduced inner diameter on coronal (fig. A) and transverse (fig. B) sections. 3D-volume rendering reconstructions of the lumen can also be obtained (fig. C). This technique precisely visualizes the morphology of the lumen and quantifies the existing amount of mucus. Measurements such as volume of secretions/air or minimum cross-sectional area can be collected, all of which may have exerted significant effects by vivo. High-definition computed tomography may also be useful to study the efficacy of devices for the maintenance of the ETT function.

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- 3. Berra L, Coppadoro A, Bittner EA, Kolobow T, Laquerniere P, Pohlmann JR, Bramati S, Moss J, Pesenti A: A clinical assessment of the Mucus Shaver: A device to keep the endotracheal tube free from secretions. Crit Care Med 2012; 40:119-24

"However, the importance ETT progressive luminal narrowing during mechanical ventilation is still widely unrecognized, and currently used suction systems are unable to maintain the function1"

Financial support: endOclear, LIC. (Petosley, MC) covered the costs of high-definition computed to mography and provided study supplies. Oppright © 2013, the American Society of Ameshosiologists, Inc. Eppincott Williams & Wilkims Ameshosiology 2013, XXX XXX



The Build-up of Biofilm is Harmful

Advanced endotracheal tube biofilm stage, not duration of intubation, is related to pneumonia

Wilson, Alison MD, FACS; Gray, Dana; Karakiozis, Jacqueline BS; Thomas, John PhD

Journal of Trauma and Acute Care Surgery: April 2012 - Volume 72 - Issue 4 - p 916–923 doi: 10.1097/TA.0b013e3182493a10 Original Articles

Abstract

BACKGROUND: Biofilms are complex communities of living bacteria surrounded by a protective glycocalyx. Biofilms have been implicated in the development of infections such as dental caries and hardware infections. Biofilms form on endotracheal tubes (ETT) and can impact airway resistance. The lifecycle of a biofilm has four stages. We hypothesize that there is a relationship between the stage of biofilm on the ETT and development of pneumonia.

METHODS: Thirty-two ETT were analyzed for biofilms and staged. Staging was performed by a microbiologist blinded to all patient information. Data included development of pneumonia, duration of intubation, comorbidities, and microbiology. Pneumonia was defined as presence of fever, WBC >12 K or <4 K, infiltrate on chest X-ray, and purulent sputum with +lower airway culture (bronchoalveolar lavage or brush). Statistics were performed by a biostatistician; p < 0.05 defined significance.

RESULTS: There were 11 women and 21 men with a mean age of 50 years. Mean intensive care unit days were 13 (standard deviation \pm 9.9) and mean length of intubation was 7.4 days (standard deviation \pm 5.0). Half (16 of 32) the patients developed pneumonia while intubated. Eight of 10 patients with a stage IV biofilm had pneumonia. There was a relationship between increasing biofilm stage with the incidence of pneumonia (p < 0.05). Stage IV biofilms were associated with pneumonia (p < 0.02). There was no relationship to duration of intubation, patient age or hospital stay and biofilm stage.

CONCLUSIONS:

"Advanced biofilm stage (stage IV) is associated with pneumonia. Duration of intubation does not predict biofilm stage."



The Build-up of Biofilm is Harmful

Implications of endotracheal tube biofilm in ventilatorassociated pneumonia response: a state of concept

Critical Care 2012, 16:R93 doi:10.1186/cc11357

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Results:

Eighty-seven percent of the patients were colonized based on ETA cultures. Biofilm was found in 95% of the ETTs. In 56% of the cases, the same microorganism grew in ETA and biofilm. In both samples the most frequent bacteria isolated were Acinetobacter baumannii and Pseudomonas aeruginosa. Nineteen percent of the patients developed VAP (N=14), and aetiology was predicted by ETA in 100% of the cases. Despite appropriate antibiotic treatment, bacteria involved in VAP were found in biofilm (50%). In this situation, microbial persistence and impaired response to treatment (treatment failure and relapse) were more frequent (100% vs 29%, P=0.021; 57% vs 14%, P=0.133).

Conclusions:

"Airway bacterial colonization and biofilm formation on ETTs are early and frequent events in ventilated patients. There is microbiological continuity between airway colonization, biofilm formation and VAP development. Biofilm stands as a pathogenic mechanism for microbial persistence, and impaired response to treatment in VAP.

In summary, our study supports the idea of a dynamic relationship between airway colonization, biofilm, and VAP development. The idea of bacterial survival on ETT biofilm as a pathogenic mechanism for microbial persistence and impaired response to antibiotic therapy highlights the importance of discovering new strategies focused in the removal of biofilm from the ETT."*



Description and Microbiology of Endotracheal Tube Biofiln in Mechanically Ventilated Subjects

Pierre-Eric Danin MD, Emmanuelle Girou PharmD, Patrick Legrand MD, Bruno Louis PhD, Redouane Fodil PhD, Christo Christov MD, Jérôme Devaquet MI Daniel Isabey PhD, and Laurent Brochard MD

BACKGROUND: A biofilm is found on the inner side of endotracheal tubes (ETT) in mechanically ventilated patients, but its features and role in pneumonia remain unclear. METHODS: Thi prospective, observational, monocentric study included critically ill ventilated subjects. Measure ment of the ETT inner volume was first performed before extubation using the acoustic reflection method. After extubation, the biofilm was studied by means of optical and atomic force microscopy Bacteriological analysis was then performed and compared with clinical documentation. RESULTS Twenty-four subjects were included. Duration of intubation lasted from 2 to 79 d (mean \pm SD) 11 \pm 15 d). The mean percentage of ETT volume loss evaluated in situ (n = 21) was 7.1% ap not linked with the duration of intubation. Analyses with atomic force microscopy (n = f)a full coverage of the inner part of the tube with biofilm, even after saline rinse. Its this from 0.8 to 5 μ m. Bacteriological cultures of the biofilm (n = 22) often showed as in tracheal secretions, especially for pathogenic organisms. Pseudomonas albicans were among the most frequent microorganisms. In subjects y cessfully treated episode of ventilator-associated pneumonia (n = 5still present in the biofilm. CONCLUSIONS: ETT biofilm is whatever the duration of intubation and appears quickly aver intubation. Even after soft rinse, small but measurable part of biofilm remains always present, and seems strongly adherent to th ETT lumen. It contains potentially pathogenic bacteria for the lung. Key words: biofilm; endotrached tube; ventilator-associated pneumonia. [Respir Care 2015;60(1):21–29. © 2015 Daedalus Enterprises]

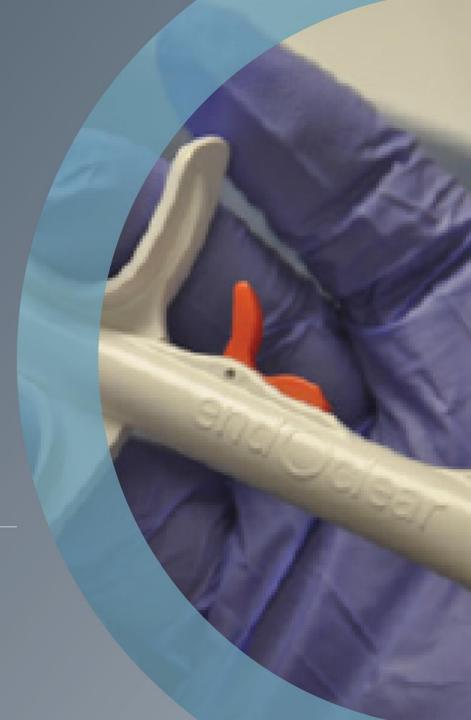
Biofilm build-up in ETT Respiratory Care 2015

- Biofilm is always
 present whatever the
 duration of intubation
 and appears quickly.
- Biofilm is strongly adherent and remains after rinse.
- Average total volume loss was 7.1% which is equivalent to 1 – 1.5 cc of material in tubes ranged 7 – 9 mm.



Using an ETT cleaner addresses retained secretions and colonization in a positive way.

Current indications for endotracheal tube suctioning are to use as minimally as possible



Using an ETT Cleaner Addresses....



Quantifying the Benefit of an Optically Directed Endotracheal Tube **Clearing Device Using Bioluminescent Bacteria**

John G. Thomas, PhD1; Hamed M. Motlagh, MPH1; Christopher Waters, MS1; Sarah L. McLaughlin, BS2 West Virginia University, Department of Pathology; West Virginia University, Animal Models and Imaging Facility

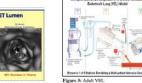


INTRODUCTION:

Previously, we had optimized the use of 1) our Adult Ventilator-Endotrach-Lung Simulator (A-VEL) (Fig. 3) combined with 2) bioluminescent (BL) bacteria Staphylococcus aureus (Sa) (Xen 036) or Pseudomonas aeruginosa (Pa) (Xen 05) (Fig. 4a & 4b) to measure the efficacy of an endotracheal tube (ETT) luminal clearing device. (Fig. 2a)



500 cross sections emphasizing ETT luminal restriction of intubation @4 hours (A) and @48





HYPOTHESIS:

Here, we wanted to evaluate the device, integrating quantitative BL photonic assessment addressing three ETT regions (A- Oral, B- Middle, C- Lung,) (Fig. 2b) while visualizing the distribution of labeled biofilm-accretion, Pre and Post clearing

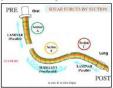
METHODS:

The A-VEL is composed of three integrated systems: Puritan-Bennett Ventilator 720, anatomically designed head position, and a compliant bi-lobed Michigan Lung; model settings were those used for a COPD patient, Extubated ETTs were received within two hours after extubation, and placed on the A-VEL with a

nebulized broth/ glucose mixture for 12 hours Bioluminescent mixture of Sa and Pa, were grown independently overnight, and nebulized for 6 hours at the ETT-Lung interface, combined or independently, at a concentration of 1x106 CFU's/ml. The ETT was placed in an anatomically correct head, and cleared in approximately 10 seconds from Murphy's eye, backward to the Oral end, recovering biofilm accretion material utilizing the EndoClear device. IVIS (Fig. 4a & 4b) (Caliper Life Sciences) Photonic Intensity measurements were taken Pre cleaning for each ETT zone, and Post cleaning three times.



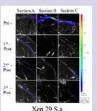
detracheal tube clearing device (ECCD) composed Activating handle 4) Fiberoptic cable 5) Camera and displaincluding touchscreen monitor for still image/movie capture for simultaneous visualization of device placement and potential obstruction viewing.

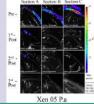


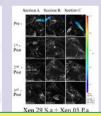
RESULTS:

For Pre samples, Pa labeled ETT accretion alone with Region C having greatest intensity and or in combination with Sa produce the greatest intensity (p/sec / cm2/sec), with each sector different: A (2.1-6.1), B (2.2-5.5), C (5.1-7.0). Visualization highlighted differences in distribution, imprint but intensity.

near occlusion. Post clearing for all section detected zero labeled ETT accretion, independent of times cleared. Sa. alone, gave similar visual





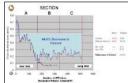


CONCLUSION

The combination of the IVIS technique and the A-VEL simulator provided a method which demonstrated the clearing device eliminated photonic labeled ETT accretion after one pass. This was independent of luminal endotrach location (A, B, C).

DISCUSSION:

The impact of occulusion is highlighted by our previouse experiments, where with the use of CT radiography the endotrach-biofilm occulusion reduced airway volume by 44%. (Poster ASM 578/038) (Fig. 1) Figure 8: (See Fig. 1)



CLINICAL APPLICATION:

The application of IVIS and engineered bioluminescent bacteria, particularly bio-film associated, is an unrecognized tool for clinical microbiologists; it's application here, particularly quantification, clearly highlighted the benefit of the clearing

The clearing device could be part of routine ETT suctioning that has the potential of reducing 1) BF occlusion and 2) nidus of infection without the use of anti-

ICES:

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andolph Cancer Center and NIH grants P20 nd P30 RR032138/ GM103488.

"The clearing device could be part of routine ETT suctioning that has the potential of reducing 1) BF occlusion and 2) nidus of infection without the use of antibiotics."



Using an ETT Cleaner Addresses......

WVU, IVIS Imaging. Freshly suctioned ETT, pre and post endOclear® use Florescence Key: Blue = Low, Green/Yellow = Medium, Red = High bacteria counts

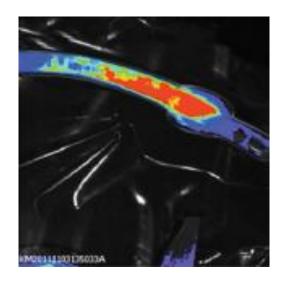
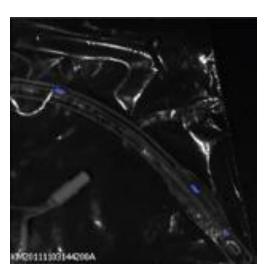


Figure 1

Bioluminescence from pseudomonas bacteria within in an ET Tube after suctioning



Near absence of bioluminescence after one cleaning with the endOclear® device

Figure 2



Amount of mucous and secretions removed from the ET Tube in Figure 1

Figure 3



Using an ETT Cleaner Addresses....

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A clinical assessment of the Mucus Shaver: A device to keep the endotracheal tube free from secretions

Lorenzo Berra, MD: Andrea Coppadoro, MD: Edward A. Bittner, MD. PhD: Theodor Kolobow, MD: Patrice Laguerriere, PhD; Joshua R. Pohlmann, BS; Simone Bramati, MD; Joel Moss, MD, PhD; Antonio Pesenti, MD

Objective: We evaluated a new device designed to clean the endotracheal tube in mechanically ventilated patients, the Mucus

Design: Prospective, randomized trial,

Setting: University hospital intensive care unit.

Patients: We enrolled 24 patients expected to remain ventilated for >72 hrs.

Interventions: The Mucus Shaver is a concentric inflatable catheter for the removal of mucus and secretions from the interior surface of the endotracheal tube. The Mucus Shaver is advanced to the distal endotracheal tube tip, inflated, and subsequently withdrawn over a period of 3-5 secs. Patients were prospectively randomized within 2 hrs of intubation to receive standard endotracheal tube suctioning treatment or standard suctioning plus Mucus Shaver use until extubation.

Measurements and Main Results: During the study period, demographic data, recent medical history, adverse events, and staff evaluation of the Mucus Shaver were recorded. At extubation, each endotracheal tube was removed, cultured, and analyzed by scanning electron microscopy. Twelve patients were assigned to the study group and 12 were assigned to the control group. No adverse events related to the use of the Mucus Shaver were observed. At extubation, only one endotracheal tube from the Mucus Shaver group was colonized, whereas in the control group ten endotracheal tubes were colonized (8% vs. 83%; p < .001). Scanning electron microscopy showed little secretions on the endotracheal tubes from the study group, whereas thick bacterial deposits were present on all the endotracheal tubes from the control group (p < .001 by Fisher exact test, using a maximum biofilm thickness of 30 µm as cut-off). The nursing staff was satisfied by the overall safety, feasibility, and efficacy of the Mucus Shaver.

Conclusions: The Mucus Shaver is a safe, feasible, and efficient device for endotracheal tube cleaning in the clinical setting. The Mucus Shaver is helpful in preventing endotracheal tube colonization by potentially harmful microorganisms. (Crit Care Med 2012; 40:000-000)

KEY WORDS: bacterial biofilm; endotracheal tube; endotracheal tube occlusion; endotracheal tube suctioning; mechanical ventilation; Mucus Shaver; secretion removal; ventilator-associated pneumonia



management of critically ill

n endotracheal tube (ETT) is maintained by using suctioning cathegenerally required for the ters. Nevertheless, it has been shown that intraluminal volume loss attribut-

vented by standard suctioning treatment or by optimal humidification (1-4). This vicious process of secretion mechanically ventilated na- able to the accumulation of secretions accumulation can lead to life-threaten-

- Bacterial colonization:
 - Control group 83%
 - Study group 8%
- Biofilm by SEM > 30um thickness:
 - Present in all control group
 - Minimal in study group

"In conclusion, we propose the Mucus Shaver as a device able to improve care of mechanically ventilated patients by reducing bacterial colonization of the inner ETT lumen, suggesting a potential role in infection prevention, and reducing secretion deposits, preventing possible partial or complete ETT occlusion and leading to increased airway resistance and work of breathing."



Using an ETT Cleaner Addresses......

The Impact of a Unique Airway Clearance System on Airway Mechanics in Ventilated Patients

Schofield, L.¹, Shorr, A.F.², Washington, J. ¹, Carlson, M. ¹, Wagner, W. ¹ ¹ McLaren Northern Michigan Hospital, Petoskey, MI, ² Washington Hospital Center, Washington, DC

* Work completed at: McLaren Northern Michigan Petoskey, Michigan ((231) 387-3042

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reduces

Abstract

Background: The adherence of secretions along the endotracheal tube (ETT) lumen in mechanically ventilated (MV) patients' results in airway narrowing and concomitantly may increase patients' work of breathing. Biofilm accumulation may also promote the development of ventilator-associated pneumonia. Routine suctioning does not address the potential risks associated with secretions and biofilm that collect within the ETT lumen. A unique mucus shaver system (endOclear®) facilitates

The purpose of this study is to determine the effectiveness of reducing peak airway pressures and resistance in ventilated patients who have their ETT cleared with a mucus shaver system. The hypothesis is: Application of a mucus shaver system in addition to routine suctioning prior to spontaneous breathing trials (SBTs) lowers both peak airway pressures and airway resistance

Methods: This study retrospectively identified all subjects having their ETTs cleared at a single institution prior to beginning a SBT between Jan 2012-Jul 2013. All subjects had received at least 24 hrs of MV prior to the SBT and all underwent routine suctioning with a closed in-line system prior to use of the mucus shaver. Peak airway pressures before and after the additional use of the mucus shaver along with changes in airway resistance served as our co-primary endpoints. The study also compared changes in these variables as function of the ETT lumen size.

Results: The median peak airway pressure measured 29 cmH₂0 before use of the mucus clearance system and fell to 23 cm H,0 (p<0.001). There was a similar decline in the median airway resistance (27 cm H₃0/Lps to 15 cm H₃0/Lps, p < 0.001). The average percent decline in peak airway pressure equaled 17.6±13.3% while the mean drop in airway resistance was greater, 33.3±18.9%. Seventy-five percent of subjects experienced a greater than 10% and 19% fall in peak airway pressure and airway resistance, respectively. Differences in ETT lumen size did not alter the magnitude of the fall seen in either of the co-primary endpoints

Conclusions: The addition of a unique mucus shaving and tube cleaning system to routine suction prior to an SBT significantly reduces both peak airway pressure and airway resistance in persons undergoing

- Current standard of care closed suction systems do not completely clean the inside of the endotracheal
- Secretions and biofilm accumulation may lead to decreased liberation from the ventilator^{7,8} and increased ventilator associated pneumonia (VAP).6
- Recent protocol use of an endotracheal tube cleaning device prior to spontaneous breathing trials at one center was associated with improved patient outcome (decreased length of intubation and decreased length of ICU and hospital stay) and decreased hospital cost.2
- Physiologic implications of this new secretion management tool have not yet been described

Study Objective

To describe the effect of routine, protocolized use of endOclear® device on physiologic measures of airway resistance and peak pressures during efforts to liberate patients from the ventilator

Methods

Design: Prospective, observational quality assurance study, January 2012 through July 2013

Setting: Community hospital mixed medical-surgical ICU

Subjects: Mechanically ventilated patients on the ventilator over 24 hours

- Prior to SBT the patient undergoes standard closed suctioning
- peak-airway-pressure (PAP) and resistance are measured while the patient is still on the vent in ventilated
- endOclear® (Figure 1) is used and measurements on the same settings are repeated
- patient undergoes SBT

Endpoints: PAP and airway resistance

Statistics:

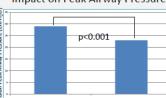
- Endpoints from before and after period compared with either Student's t test (paired)
- p < 0.05 assumed to represent statistical significance

Results

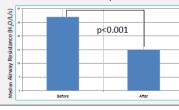
Cohort

- n = 109 patients, 18 bed mixed surgical / medical ICU
- In 2011, prior to use of endOclear® the mean duration of MV was 4.3 days Mean duration of MV in current population 3.4 days
- Median airway resistance declined from 27 cm H₂0/Lps to 15 cm H₂0/Lps (p < 0.001).
- The average percent decline in peak airway pressure equaled 17.6+13.3%
- The mean drop in airway resistance was greater, 33.3+18.9%.
- Seventy-five percent of subjects experienced a greater than 10% and 19% fall in peak airway pressure and airway resistance, respectively
- Differences in ETT lumen size (e.g., whether 8.0 mm vs. smaller) did not alter the magnitude of the fall seen in either of the co-primary endpoints

Results: Impact on Peak Airway Pressure







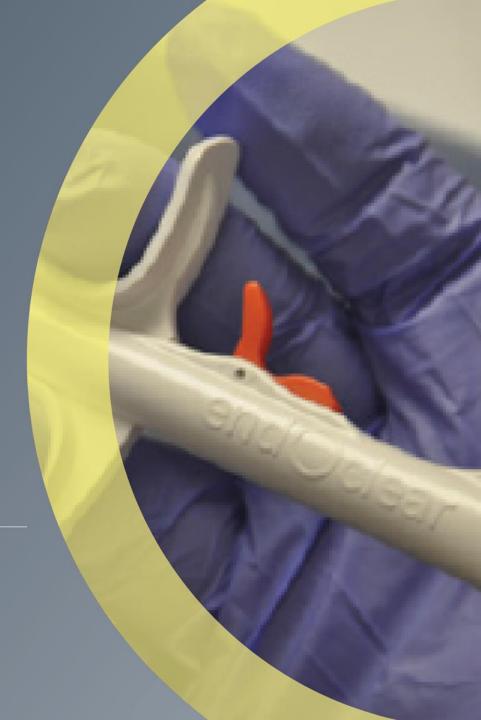
Conclusions

- Addition of a unique mucus shaving and tube cleaning s (endOclear®) to rou prior to an SBT sign both peak airway pr airway resistance
- "Addition of a unique mucus shaving and tube cleaning system (endOclear®) to routine suctioning prior to an SBT significantly reduces both peak airway pressure and airway resistance"



Effective cleaning of the ETT results in improved outcomes when used in both PRN and protocol fashion.

The build-up of biofilm is harmful and can lead to infection and increased duration of ventilation and ICU length of stay



Effective cleaning of the ETT results



Efficacy Study of a Novel Device to Clean the Endotracheal Tube

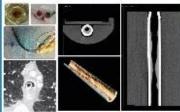
Massimiliano Pirrone^{1,3}, Riccardo Pinciroli¹, Cristina Mietto^{1,3}, David Imber¹, Christopher Chenelle², Robert M Kacmarek², Lorenzo Berra¹



Department of Anesthesia, Critical Care and Pain Medicine, Mossachusetts General Hospital, Boston, MA; Z. Department of Respiratory Care, Massachusetts General Hospital, Boston, MA;
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 Dipartment of Anesthesia Critical Care and Pain Medicine, Mossachusetts General Hospital, Boston, MA;
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Background

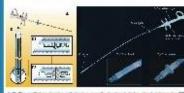
The Endotrachael Tube (ETT) is a life-serving device for respiratory support and airway protection. However, its austimated presence in the traches disrupts the physicological mechanisms that maintain success homeostasis. The process of mucus buildup and luminous increwing leaded to an increased ventilatory effort and neight delay liberation from mechanical ventilation. In addition, potential lung attraction from mechanical ventilation, in addition, potential lung pathogens often colonize the ETT lumen in the form of complex blottless, with the plastic surface offering the ideal environment for their proliferation. Nevertheless, in everyley practice the extent of ETT blottlin formation and the degree of sociation are generally not investigated. Bled trachest suctioning, the standard procedure adopted to clear secretors from the ETT and the sinvey, is poorly effective.



Signer labb. Section of an ETT immediately after exclusion. Obstruction and cross-sectional one sections are visible. The exclusion of volume exclusive to efficie to review make their consequently exclusionly effect, users labb. ETT obstruction class to secretion accumulation in white on a standard CT sheet soon. States and EST of the interest companies from on ETT after exclusions reviewed colorably significant obstruction and interest interest colorably.

Rational

Different new medical devices have been recently developed specifically for ETT cleaning. Among them, the endicities catheter (Endoclear, LLC, Petrokey, MI) has been recently asported to be an effective tool in relieving 89-threatening ETT obstruction. We designed a rendomized clinical trial to test the hypothesis that the implementation of routine ETT cleaning with endicities prevents ETT luminal occlusion and reduces birdim accumulation.



Left. The entrollater descring contents in a recently developed clother strong of improving ET interrupt procedure and indices ETT pattering in case of notice ETT clotheration. The clother behavior an endercollete made in the sp. After materials of the statement recent the ETT, the clother grape is pushed under extraction made transfers of our began of the ETT of parting patting is achieve and of the table, assentions accordinate details the ETT are reconciled both the clother graph. Actually pattern of the entrollater deviale, with addies of the closest and deployed repre-

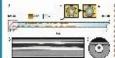
Methodo

We enrolled in the study adult intubated patients expected to be ventilisted for more than 48 hours. Random silocation to either treatment or control arm was performed with a 1-1 ratio. Control group consisted in institutional standard of care (suctioning every 4 hours or as needed), while treatment group received standard or care pius a single pass of the endOctear catheter, three times per day every 8 hours.



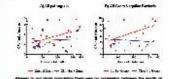
dotracheal tube ensiysis.

ETTs were collected at the bedside, sealed and rapidly processed. High-Resolution Computed (Tonography (HRCT) was obtained for the terminal 22 cm of each ETT. Rew imaging date of mucus and air volumes were acquired and subsequently elaborated as volume percentages. "Overall occlusion" was defined as the swenge ratio of mucus volume vs total ETT volume throughout all the scan slices. "Reactinum collaide" was defined as the maximum ratio within each ETT scan. Cross-sectional area (CSA) was estimated for each table by taking into consideration the nanowest conduit available to flow. By assuming the measured CSA was circle-shaped, we estimated for each table or virtual instrument.



Microbiology

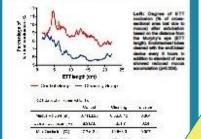
After HRCT scan, we processed each table in order to collect microbiological samples from the inner layer. On these samples we performed microbiological identification and quantitation of becteria and fungi.



Result

526 pittents were screened across different intensive Care Units. 74 patients mat enrollment criteria and were mendomized. 37 ETTs were collected from the cleaning group and 40 ETTs from the centrol group. ETTs from the cleaning group showed record recorded when mucus volume was calculated as "Overall collected when mucus volume was calculated as "Overall collected when mucus volume was calculated as "Overall between the best groups (p=0.007). Although ETTs from both groups showed variable degrees of reduction of liner dismeter (D), only in the most numerous subgroup of ID size 7.5mm we were able to detect a significant difference (p=0.001). The degree of ETT occlusion did not correlate with the length of industrian.

Pathogenic bacteria were isolated in ETTs from both groups and no difference in antibiotic susceptibility was noted. However, there was a trend towards reduction of total microbial load in ETT biofilm.



Above illuminary table of HRCT results, lightfurst differences in STT shattacks recorded with all the techniques adapted for insure obstacles. The HRCT size attentional controlled in the techniques agreemed spillated was controlled in table techniques and traverses subgroup (ETT size 7.5), contains an investment through their Mini-vanishment of the controlling state of the Controlled spillates are received for ETT file of the 7.0 or sections in the controlling state of the controlling state

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Preservation of ETT patency is a feasible goal pursued when caring for mechanically vertilate trial, endoburniant neurosing was safely implementation of a cleaning protocol with subsequent reduction in sirvery resistance to the cleaning protocol with subsequent reduction in sirvery resistance to the patent. Regular error cleaning might also discupt the biofilm formation process at the ETT unrined surface, having the content to cardinating reduce besterial

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In our trial, endoluminal narrowing was safely prevented by the implementation of a cleaning protocol with a novel device. The subsequent reduction in airway resistance might be beneficial in terms of reduced ventilatory effort by the patient. Regular ETT cleaning might also disrupt the biofilm formation process at the ETT luminal surface, having the potential to significantly reduce bacterial colonization.



4 Effective cleaning of the ETT results

Removal of Endotracheal Tube Debris Obstruction by a Clearing Secretion Device.

Cristina Mietto1 MD, Kevin Foley2 RRT, Lindsay Salerno2 RRT, Jenna Oleksak2 RRT, Riccardo Pinciroli1 MD, Jeremy Governan3 MD, Lorenzo Berra1 MD

- 1 Department of Anesthesia, Critical Care and Pain Medicine, Massachusetts General Hospital, Boston MA, USA
- 2 Department of Respiratory Care, Massachusetts General Hospital, Boston MA, USA
- 3 Department of Surgery, Burn Service, Massachusetts General Hospital, Boston MA, USA

RESPIRATORY CARE Paper in Press. Published on December 24, 2013 as DOI: 10.4187/respcare.02995 Copyright (C) 2013 Daedalus Enterprises

ABSTRACT

Accumulation of secretions may suddenly occlude the endotracheal tube (ETT) requiring immediate medical attention. The endOclear® catheter (EndOclear LLC, Petoskey, MI) is a novel device designed to clean the ETT from mucus debris and restore the luminal patency. We present a series of three subsequent cases of life-threatening partial ETT-occlusion recorded over a period of six months at Massachusetts General Hospital.

After the failure of conventional methods, standard tracheal suctioning and bronchoscopy, the endOclear® device was implemented with successful restoration of the airways in all three cases. The three patients rapidly improved their respiratory conditions and tolerate well the ETT-clearing maneuver.

"These observations showed that such device is (I) safe, (II) easy to use during an emergent-airway situation, and (III) efficient to rapidly remove secretions in the setting of ETT obstruction by the respiratory therapist personnel."



Effective cleaning of the ETT results

The Use of a Unique Mucus Shaver Clearing Device to Improve Ventilator Weaning

Linda Schofield PhD, RN • Gary W Saur, MBA, RRT • Jeffrey Washington, M.D.

PURPOSE

Routine endotracheal suctioning techniques are unable to remove adherent secretions and biofilm from within the endotracheal (ET) tube. resulting in a narrowed airway, increased work of breathing, and colonization by ventilator associated pneumonia (VAP) organisms. The purpose of this study is to compare the efficacy of removing adherent endotracheal tube secretions with the use of a mucus shaver clearing device prior to weaning trials with the efficacy of routine suctioning alone prior to weaning trials.

References

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- Boque et al. Intensive Care Med, No 30 2004
- 4. Wilson, Thomas, et al. CHEST, Oct 2009
- The Mucus Shaver is helpful in preventing endotracheal tube colonization by potentially harmful microorganisms. Berra, Crit Care Med 2012; 40:000-000"Wilson et al, EAST Meeting, 2011

BACKGROUND

Ventilator-associated pneumonia (VAP) is a frequently occurring nosocomial infection associated with increased morbidity and mortality. Bacteria that colonize the oropharyngeal area, including dental plaque, can aspirate into the lungs and cause nosocomial respiratory disease. Oral care does not address the potential risk of VAP associated with secretions and biofilm that collect within the ET tube. Partial occlusion or narrowing of the endotracheal tube has been associated with increased patient work of breathing and delayed extubation. Caring for ventilated patients in an ICU is substantially more expensive than caring for non-ventilated patients. A unique mucus shaver clearing device can be used to decrease airway resistance, expedite weaning and remove bacteria that cause VAP. The mucus shaver clearing device restores the ET tube to optimal weaning conditions by confirming ET Tube patency. The main indications for use of the mucus shaver clearing device include:

Prior to spontaneous breathing trials

Thick Secretions

Difficulty suctioning/weaning

Acute change in patient condition

Hemoptysis

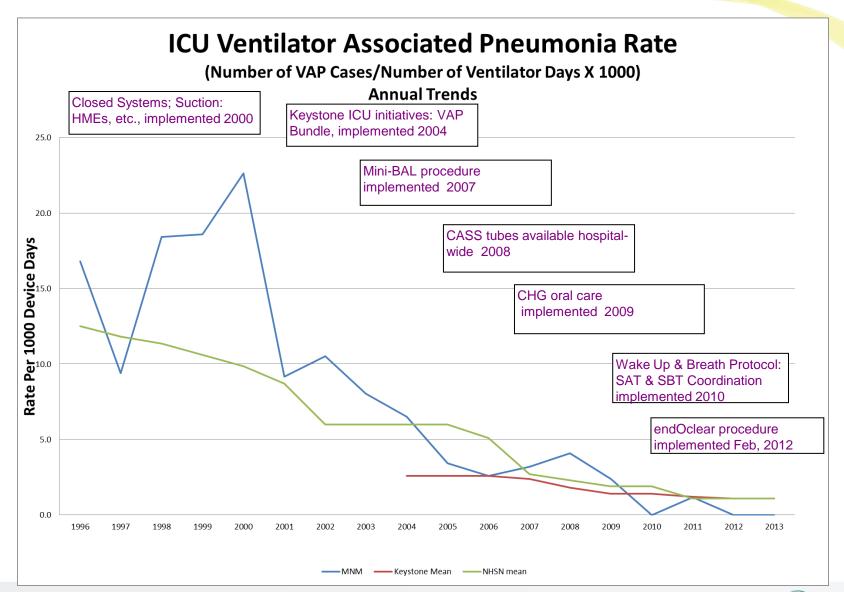
Prior to Bronchoscopy/tube exchange/tracheostomy





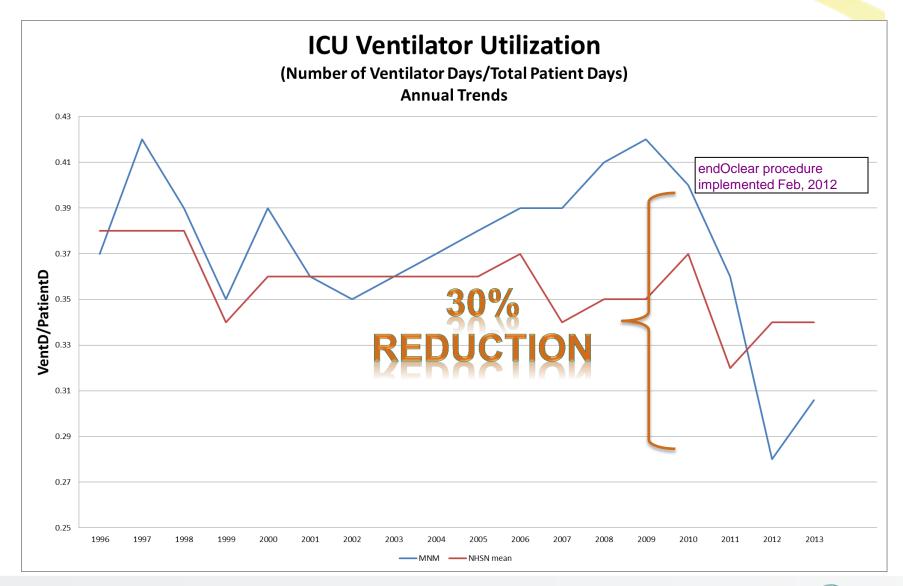


Effective cleaning of the ETT results





Effective cleaning of the ETT results





Effective cleaning of the ETT results ..

The Use of a Unique Mucus Shaver Clearing Device to Improve Ventilator Weaning

PURPOSE	BACKGROUND			
Routine endotracheal suctioning techniques are unable to remove adherent secretions and biofilm from within the endotracheal (ET) tube, resulting in a narrowed airway, increased work of breathing, and colonization by ventilator associated pneumonia	Ventilator-associated pneumonia (VAP) is a frequently occurring nosocomial infection associated with increased morbidity and mortality. Bacteria that colonize the oropharyngeal area, including dental plaque, can aspirate into the lungs and cause nosocomial respiratory disease. Oral care does not address the potential risk of VAP associated with secretions and biofilm that collect within the ET tube. Partial occlusion or narrowing			
(VAP adhe prior trials	McLaren Northern Michigan			g for ventilated patients in can be used to decrease the LT tube to optimal nclude:
uras	Twelve Months Ending			
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This patie Inten	Pre endOclear	Post end	Post endOclear Post endOclear	
were met i Ventilator Days per Case	4.3	3.4	3.2	
stay ICU Days per Case	5.2	4.6	3.7	100 100 100 100 100 100 100 100 100 100
Hospital ALOS per Case	9.7	9.0	8.0	
Direct Cost per Case	\$ 18,802	\$ 17,680	\$ 15,590	
Annual Savings (Direct Costs)		\$ 578,952	\$1,383,580	
Number of Cases	583	516	662	MAGNET STORES

References:

1. Shah et al. Critical Care Med, Vol 32 2004

2. Glass et al. American Journal of Critical Care, Vol 8, March 1999

3. Boque et al. Intensive Care Med, No 30 2004

4. Wilson, Thomas, et al. CHEST, Oct 2009.

5. The Mucus Shaver is helpful in preventing endotracheal tube colonization by potentially harmful microorganisms. Berra, Crit Care Med 2012; 40:000–000"Wilson et al, EAST



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Alternatives to standard of care?

SThe standard of care does not effectively clean the endotracheal tube and the AARC guidelines recommend limiting it's use. Is this the best we can do? Is there an alternative?



- Research and experience teaches that endotracheal tube biofilms, secretion build-up and narrowing occur in as many as 95% (Gil-Perotin¹⁴) to 100% (Danin¹⁵) of endotracheal tubes and is unpredictable in its progression (Wilson¹³).
- Biofilms, bacteria and fungus in the ETT repeatedly colonize the lung (Inglis¹¹) and are associated with pneumonia (Wilson¹³).
- AARC guidelines promote a minimalist approach to suctioning to avoid complications.
- Are we then accepting that "this is the best we can do" in clearing endotracheal tubes?

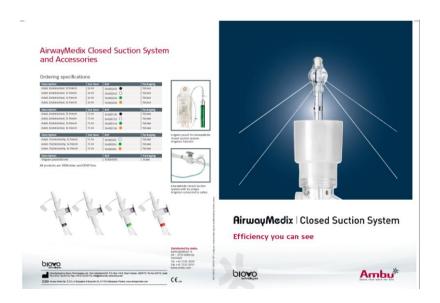


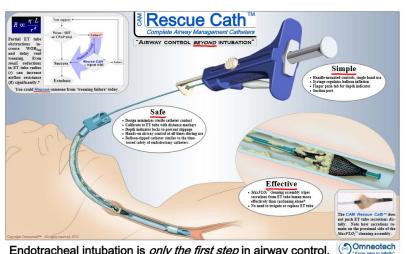
Complex patients, numerous variables!





Alternatives to standard of care?





Endotracheal intubation is only the first step in airway control.



Novel devices for cleaning endotracheal tubes:

- Mucus Shaver™ (not shown)
- endOclear®
- Biovo Airwaymedix
- Rescue Cath®



Conclusion - Summary

- 1. Biofilm, mucus, secretions and fungus represent an under-recognized cause of serious complications in mechanically ventilated patients and current standards of care (closed and open suction) do not adequately address biofilm, bacterial and fungal growth and intraluminal narrowing. The AARC recommends minimizing suction (confounding for trying to clear the ETT).
- 2. Biofilm, mucus, secretions and fungus are increasingly linked to prolonged length of ventilation, VAP, ICU and hospital stay.
- 3. The impact of endotracheal tube narrowing and subsequent clearing can have a profound impact on patient status.
- 4. Effective cleaning of the ETT has the potential to assist in improved outcomes when used in both a PRN and protocol fashion.
- 5. Alternatives may help us do better.

Contact: gsaur@endoclearllc.com



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