



# AIRWAY CARE, VAP, VAE, ETC

CAUSATION & PREVENTION: EVIDENCE AND LORE

The background is a gradient of blue, transitioning from a lighter shade at the top to a darker shade at the bottom. In the four corners, there are decorative white line-art elements resembling circuit traces or neural network connections, with small circles at the end of the lines.


# MARVIN C WEISS, MD, PHD

SCPMG, retired

The background is a solid teal color with a gradient from light to dark. In the corners, there are decorative white line-art patterns resembling circuit boards or neural networks, with lines and small circles.

# DISCLOSURES, CONFLICTS OF INTEREST

None



10%-20% of ventilated patients develop nosocomial pneumonia despite widespread prevention efforts.

Attributable mortality from ventilator-assisted pneumonia (VAP) is about 13%.



# VAP DEFINITIONS

- **CDC/National Healthcare Safety Network**

Pneumonia with endotracheal or tracheal tube within 48 hrs before the onset of the infection (including liberation) with a change in pulmonary secretions or impaired gas exchange with systemic signs of infection. There are associated radiographic findings of new or progressive opacities. No microbiological evidence is required.

**Table 1. Centers for Disease Control and Prevention National Healthcare Safety Network clinical definition for ventilator-associated pneumonia (PNU1)**

Patients must fulfill radiographic, systemic, and pulmonary criteria:

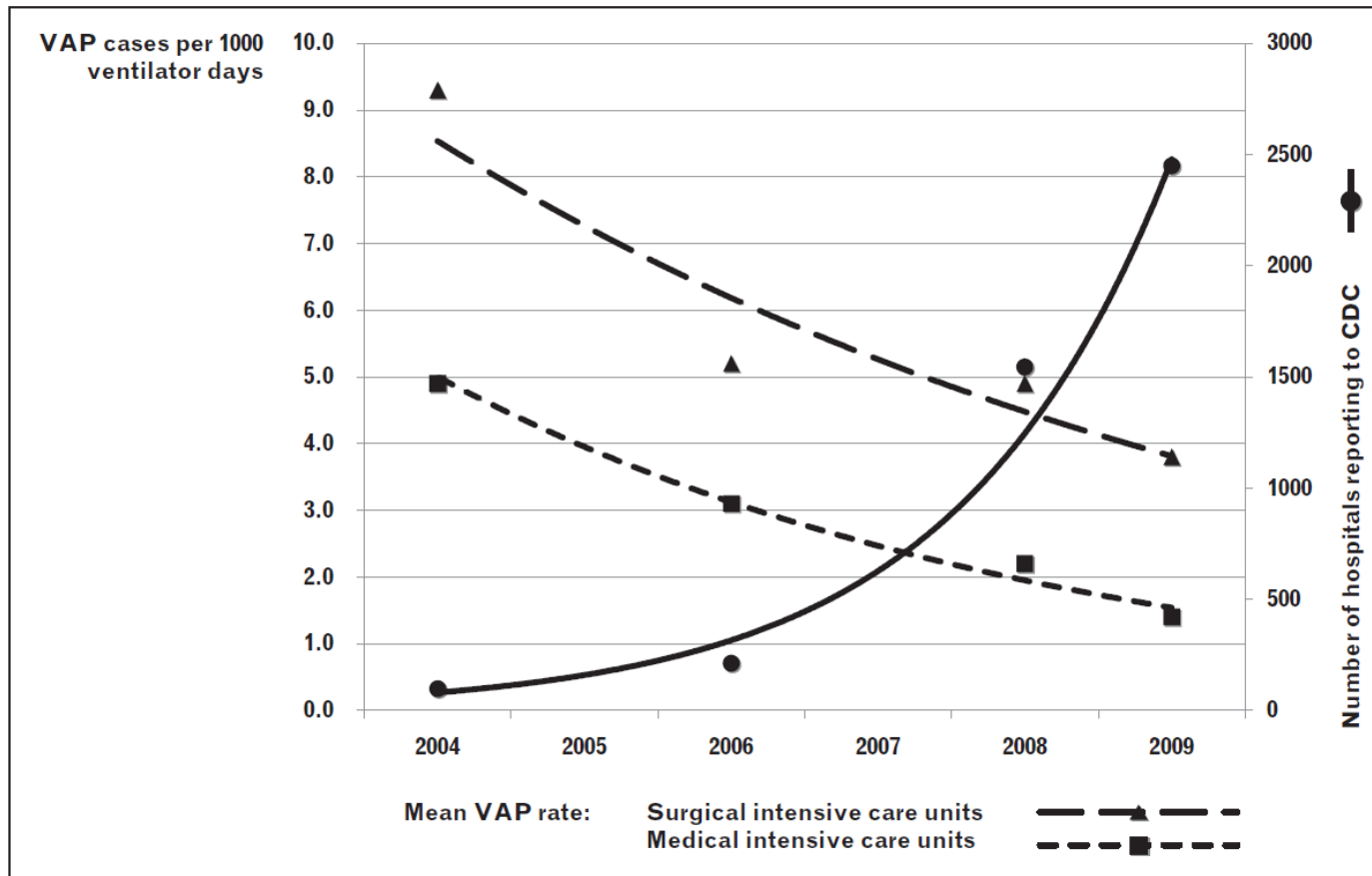
Two or more serial radiographs with at least one of the following	One of the following	Two of the following
New or progressive and persistent infiltrate	Fever ( $>38^{\circ}\text{C}$ or $>100.4^{\circ}\text{F}$ )	New onset of purulent sputum or change in character of sputum or increased respiratory secretions or increased suctioning requirements
Consolidation	Leukopenia ( $<4000$ WBC/ $\mu\text{l}$ ) or leukocytosis ( $>12000$ WBC/ $\mu\text{l}$ )	New onset or worsening cough, or dyspnea, or tachypnea
Cavitation	For adults $\geq 70$ years old, altered mental status with no other recognized cause	Rales or bronchial breath sounds
		Worsening gas exchange (e.g. oxygen desaturations, increased oxygen requirements, or increased ventilator demand)

WBC, White blood cell.

# VAP DEFINITIONS

- **ATS/IDSA**

Pneumonia that occurs within 48-72 hours of intubation with a change in pulmonary secretions or impaired gas exchange with systemic signs of infection. There are associated radiographic findings of new or progressive opacities. No microbiological evidence is required.



**FIGURE 1.** Mean ventilator-associated pneumonia (VAP) rates and counts of hospitals reporting to the Centers for Disease Control and Prevention (CDC)'s National Nosocomial Infection Surveillance system and the National Healthcare Safety Network, 2004–2009.



The background is a solid teal color with decorative white circuit-like lines in the corners. These lines consist of straight segments connected by small circles, resembling a network or data flow diagram. The lines are most prominent in the top-left, top-right, and bottom-left corners, with some extending towards the bottom-right corner.

# Centers for Disease Control and Prevention 2016 criteria for ventilator-associated events

Criteria for ventilator-associated condition (VAC) includes both

Baseline period of stability or improvement on the ventilator, defined by  $\geq 2$  calendar days of stable or decreasing daily minimum fraction of inspired oxygen ( $\text{FiO}_2$ ) or positive end-expiratory pressure (PEEP) values (baseline period defined as the 2 calendar days immediately preceding the first day of increased daily minimum PEEP or  $\text{FiO}_2$ )

AND

After a period of stability or improvement on the ventilator,  $\geq 1$  of the following indicators of worsening oxygenation:

- increase in daily minimum  $\text{FiO}_2$  of  $\geq 0.20$  (20 points) over the daily minimum  $\text{FiO}_2$  in the baseline period, sustained for  $\geq 2$  calendar days

- increase in daily minimum PEEP values of  $\geq 3$  cm H<sub>2</sub>O over the daily minimum (ZEEP to PEEP 5 cm H<sub>2</sub>O equivalent)

## Criteria for infection-related ventilator-associated condition (IVAC)

Patient meets criteria for VAC AND

On or after calendar day 3 of mechanical ventilation and within 2 calendar days before or after the onset of worsening oxygenation, patient meets both of

temperature  $> 38$  degrees C or  $< 36$  degrees C ( $> 100.4$  degrees F or  $< 96.8$  degrees F), OR white blood cell count  $\geq 12,000$  cells/mm<sup>3</sup> or  $\leq 4,000$  cells/mm<sup>3</sup>

initiation of new antimicrobial agent(s), with continuation for  $\geq 4$  calendar days

## Criteria for possible/probable ventilator-associated pneumonia

Patient meets criteria for VAC & IVAC AND

on or after calendar day 3 of mechanical ventilation and within 2 calendar days before or after the onset of worsening oxygenation, ONE of the following criteria is met

Purulent respiratory secretions (containing  $> 25$  neutrophils and  $< 10$  squamous epithelial cells per low power field) plus a positive culture of 1 of the following specimens:

sputum, endotracheal aspirate, bronchoalveolar lavage, lung tissue, protected specimen brush

Positive culture of 1 of the following specimens, meeting quantitative or semi-quantitative thresholds as outlined in protocol, without requirement for purulent respiratory secretions

endotracheal aspirate ( $\geq 10^5$  colony forming units [CFU]/mL or corresponding semi-quantitative result)



bronchoalveolar lavage ( $\geq 10^4$  CFU/mL or corresponding semi-quantitative result)

lung tissue ( $\geq 10^4$  CFU/g or corresponding semi-quantitative result)

protected specimen brush ( $\geq 10^3$  CFU/mL or corresponding semi-quantitative result)

One of the following positive tests:

pleural fluid culture, lung histopathology, diagnostic test for Legionella species, diagnostic test on respiratory secretions for influenza virus, respiratory syncytial virus (RSV), adenovirus, parainfluenza virus, rhinovirus, human metapneumovirus, or coronavirus



## Controversies in the use of ventilator-associated pneumonia as an indicator of quality and benchmarks

Diagnostic (in)accuracy

Absence of gold standards, variable bias RCTs

Difference between clinical and surveillance definitions

Different case-mix between institutions

Subjectivity of criteria








## The Clinical Impact and Preventability of Ventilator-Associated Conditions in Critically Ill Patients Who Are Mechanically Ventilated

*Muscedere, CHEST 2013; 144(5):1453–1460*

“...retrospectively applied definitions for VAC and iVAC to data from a prospective time series study in which VAP clinical practice guidelines were implemented in 11 North American ICUs. Each ICU enrolled 30 consecutive patients mechanically ventilated . 48 h during each of four study periods. Data on clinical outcomes and concordance with prevention recommendations were collected. VAC, iVAC, and VAP rates over time, the agreement (  $\kappa$  statistic) between definitions, associated morbidity/mortality, and independent risk factors for each were determined.”



**Table 1—Definitions of VACs, iVACs, and VAP**

Syndrome	Definition
VAP	New or progressive and persistent infiltrates on a chest radiograph plus 2 of the following: abnormal WBC count ( $< 4,000$ WBC/ $\mu$ L or $> 12,000$ WBC/ $\mu$ L), presence of fever or hypothermia ( $< 36^{\circ}\text{C}$ or $> 38^{\circ}\text{C}$ ), purulent sputum, and deterioration in gas exchange
VAC	An increase in daily minimum PEEP $> 3$ cm H <sub>2</sub> O or an increase of the daily minimum FIO <sub>2</sub> $> 0.20$ sustained for $\geq 2$ calendar days in a patient who had a baseline period of stability or improvement on the ventilator, defined by $\geq 2$ calendar days of stable or decreasing daily minimum FIO <sub>2</sub> or PEEP
iVAC	An episode of VAC associated with alterations in WBC count ( $\geq 12,000$ cells/ $\mu$ L or $\leq 4,000$ cells/ $\mu$ L) or temperature ( $> 38^{\circ}\text{C}$ or $< 36^{\circ}\text{C}$ ) within 2 calendar days of the start of the VAC and $\geq 4$ days of new antibiotics

iVAC = infection-related ventilator-associated complication; PEEP = positive end expiratory pressure; VAC = ventilator-associated condition; VAP = ventilator-associated pneumonia.

**Muscedere, CHEST 2013; 144(5):1453–1460**

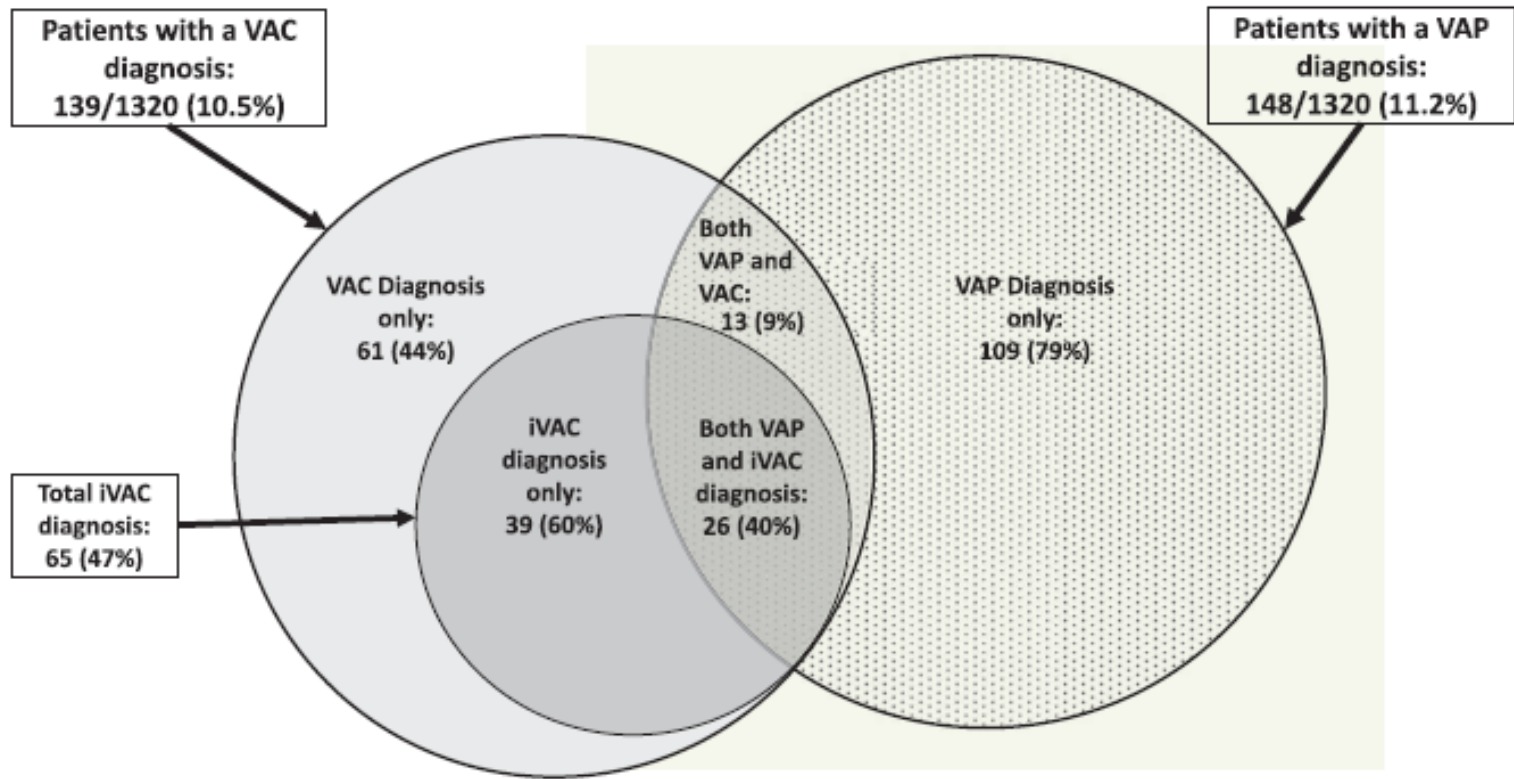


FIGURE 1. The relationship between VAP, VAC, and iVAC. iVAC = infection-related ventilator-associated complication; VAC = ventilator-associated condition; VAP = ventilator-associated pneumonia.

*Muscedere, CHEST 2013; 144(5):1453–1460*



**Table 4—Comparison Between the Patients Who Developed VAC and Those Who Did Not**

Measure	VAC (n = 139)	Non-VAC (n = 1,181)	P Value
Age, mean $\pm$ SD, y	62.2 $\pm$ 16.7	59.3 $\pm$ 17.2	.12
Women, No. (%)	52 (37.4)	476 (40.3)	.61
ICU admission diagnosis, No. (%)			.84
Medical	102 (73.4)	870 (73.7)	
Surgical: elective	14 (10.1)	90 (7.6)	
Surgical: emergency	23 (16.5)	221 (18.7)	
APACHE II, mean $\pm$ SD	22.7 $\pm$ 7.3	23.1 $\pm$ 7.6	.52
Comorbidities, mean $\pm$ SD	2.2 $\pm$ 1.8	2.2 $\pm$ 1.8	.56
SOFA on day of enrollment, mean $\pm$ SD	5.6 $\pm$ 3.0	4.4 $\pm$ 3.2	.0006
Days in hospital before ICU admission, median (q1, q3)	0.7 ( 0.2, 3.1)	0.4 (0.1, 2.2)	.64
ICU LOS, median (q1, q3), d	18.9 (12.1, 31.6)	9.0 (5.8, 14.9)	< .0001
Hospital LOS, median (q1, q3), d	31.7 (19.0, 59.9)	21.8 (12.1, 42.6)	< .0001
Duration of MV, median (q1, q3), d	15.4 (9.8, 26.6)	6.2 (3.9, 10.5)	< .0001
No. days on antibiotics	15.5 $\pm$ 7.3	9.0 $\pm$ 6.5	< .0001
Hospital mortality, No. (%)	69 (49.6)	374 (31.7)	< .0001

See Table 1 and 2 legends for expansion of abbreviations.

**Table 5—Comparison Between Patients Who Developed iVAC and Those Who Did Not**

Measure	iVAC (n = 65)	Non-iVAC (n = 1,255)	P Value
Age, mean ± SD, y	56.8 ± 18.5	59.8 ± 17.1	.08
Women, No. (%)	28 (43.1)	500 (39.8)	.59
ICU admission diagnosis			.86
Medical	49 (75.4)	923 (73.5)	
Surgical: elective	3 (4.6)	101 (8.0)	
Surgical: emergency	13 (20.0)	231 (18.4)	
APACHE II, mean ± SD	22.8 ± 7.7	23.0 ± 7.5	.76
Comorbidities, mean ± SD	1.8 ± 1.8	2.2 ± 1.8	.03
SOFA on day of enrollment, mean ± SD	5.7 ± 3.1	4.5 ± 3.2	.007
Days in hospital before ICU admission, median (q1, q3)	0.5 (0.1, 2.5)	0.4 (0.1, 2.3)	.76
ICU LOS, median (q1, q3), d	22.0 (13.7, 35.9)	9.3 (5.9, 15.6)	< .0001
Hospital LOS, median (q1, q3), d	34.6 (21.8, 59.9)	22.5 (12.4, 43.6)	.03
Duration of MV, median (q1, q3), d	16.9 (11.6, 27.7)	6.4 (4.0, 10.9)	< .0001
No. of days on antibiotics	17.8 ± 6.7	9.3 ± 6.6	< .0001
Hospital mortality, No. (%)	29 (44.6)	414 (33.0)	.07

See Table 1 and 2 legends for expansion of abbreviations.

**Table 6—Comparison Between the Patients Who Developed VAP and Those Who Did Not**

Measure	VAP (n = 148)	Non-VAP (n = 1,172)	P Value
Age, mean $\pm$ SD, y	54.3 $\pm$ 19.0	60.3 $\pm$ 16.8	.0002
Women, No. (%)	54 (36.5)	474 (40.4)	.34
ICU admission diagnosis			.03
Medical	100 (67.6)	872 (74.4)	
Surgical: elective	15 (10.1)	89 (7.6)	
Surgical: emergency	33 (22.3)	211 (18.0)	
APACHE II, mean $\pm$ SD	22.1 $\pm$ 7.8	23.1 $\pm$ 7.5	.25
Comorbidities, mean $\pm$ SD	1.8 $\pm$ 1.7	2.2 $\pm$ 1.8	.0009
SOFA on day of enrollment, mean $\pm$ SD	4.4 $\pm$ 3.0	4.5 $\pm$ 3.2	.45
Days in hospital before ICU admission, median (q1, q3)	0.2 (0.1, 1.7)	0.4 (0.1, 2.3)	.33
ICU LOS, median (q1, q3), d	17.8 (11.7, 27.9)	9.0 (5.8, 14.9)	<.0001
Hospital LOS, median (q1, q3), d	30.9 (16.0, 55.7)	22.2 (12.3, 42.4)	.01
Duration of MV, median (q1, q3), d	13.6 (8.7, 23.4)	6.2 (3.9, 10.6)	<.0001
No. of days on antibiotics	15.5 $\pm$ 7.0	9.0 $\pm$ 6.5	<.0001
Hospital mortality, No. (%)	47 (31.8)	396 (33.8)	.67

See Table 1 and 2 legends for expansion of abbreviations.

VAP, VAC, and iVAC continue to be relatively common in critically ill patients who are mechanically ventilated and are associated with adverse outcomes. There is some overlap between them, but the agreement between VAC, iVAC, and VAP is low. Given the association between VAC and iVAC and adverse outcomes, they may be useful quality indicators.

VACs and iVACs are associated with significant morbidity and mortality. Although the agreement between VAC, iVAC, and VAP is poor, a higher adoption of measures to prevent VAP was associated with lower VAP and VAC rates.

*Muscedere, CHEST 2013; 144(5):1453–1460*

# MICROBIOME

“Bacterial/fungal communities are nearly ubiquitous in the human body and the amount of microbial cells present at any given time in our organism exceeds the total number of human cells; their associated genetic pool greatly exceeds our own, while playing an important role in the determination of local and systemic inflammation and disease.”

“The microbiome has been defined by the Human Microbiome Project as the collective genetic material that belongs to all the microbial species that live in an environment – in our case the human body.”

Massimiliano, *Curr Opin Infect Dis* 2016, 29:160–166

# BIOFILMS

“Biofilms are complex, thriving microbial communities attached to surfaces and interspersed in extracellular matrix ...overall, biofilm represents a formidable adaptive response to most of the environments that bacterial life can find on Earth.”

Massimiliano, *Curr Opin Infect Dis* 2016, 29:160–166

# BIOFILMS

“The term biofilm was introduced into medicine in 1985 by J. W. Costerton...a microbial biofilm is defined as ‘an aggregate of microbial cells surrounded by a self-produced polymer matrix, and both monospecies and polyspecies biofilms exist. Biofilms may or may not adhere to surfaces, but they are predominantly situated in the tissue or in secretions, and components from the host may be found in biofilms”

➔ The term film was first used in marine microbiology in 1933, but earlier “E.C. Angst in 1922, in a report to the US Navy Department, found that slime on the ships’ bottom was caused to a large extent by bacteria when biofouling occurred on surfaces.”

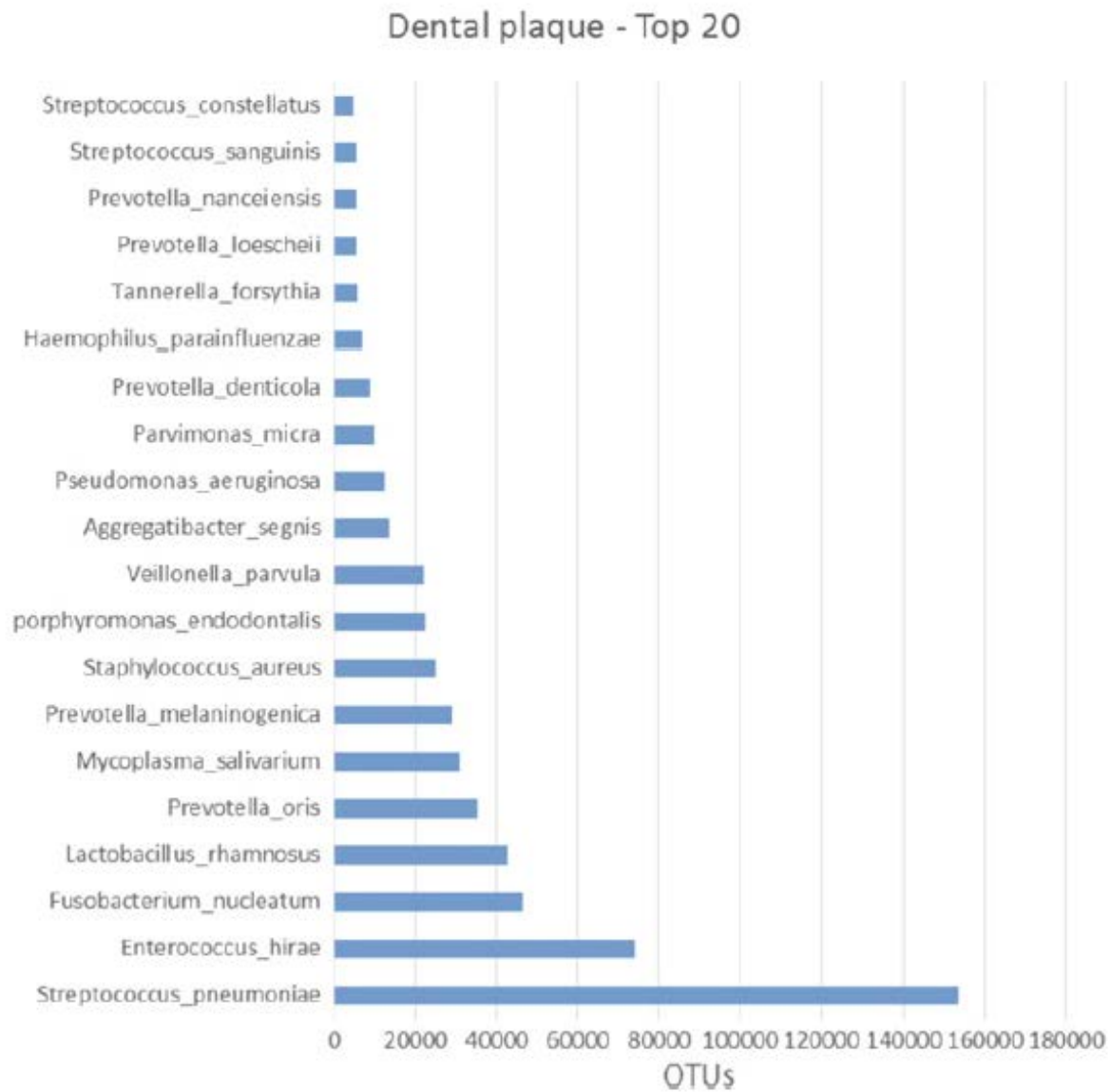
Hoiby, APMIS 2017 125:272-275

The background is a solid teal color. In the four corners, there are decorative white line-art elements that resemble circuit traces or neural network connections. These lines are thin and end in small circles, creating a modern, technical aesthetic.

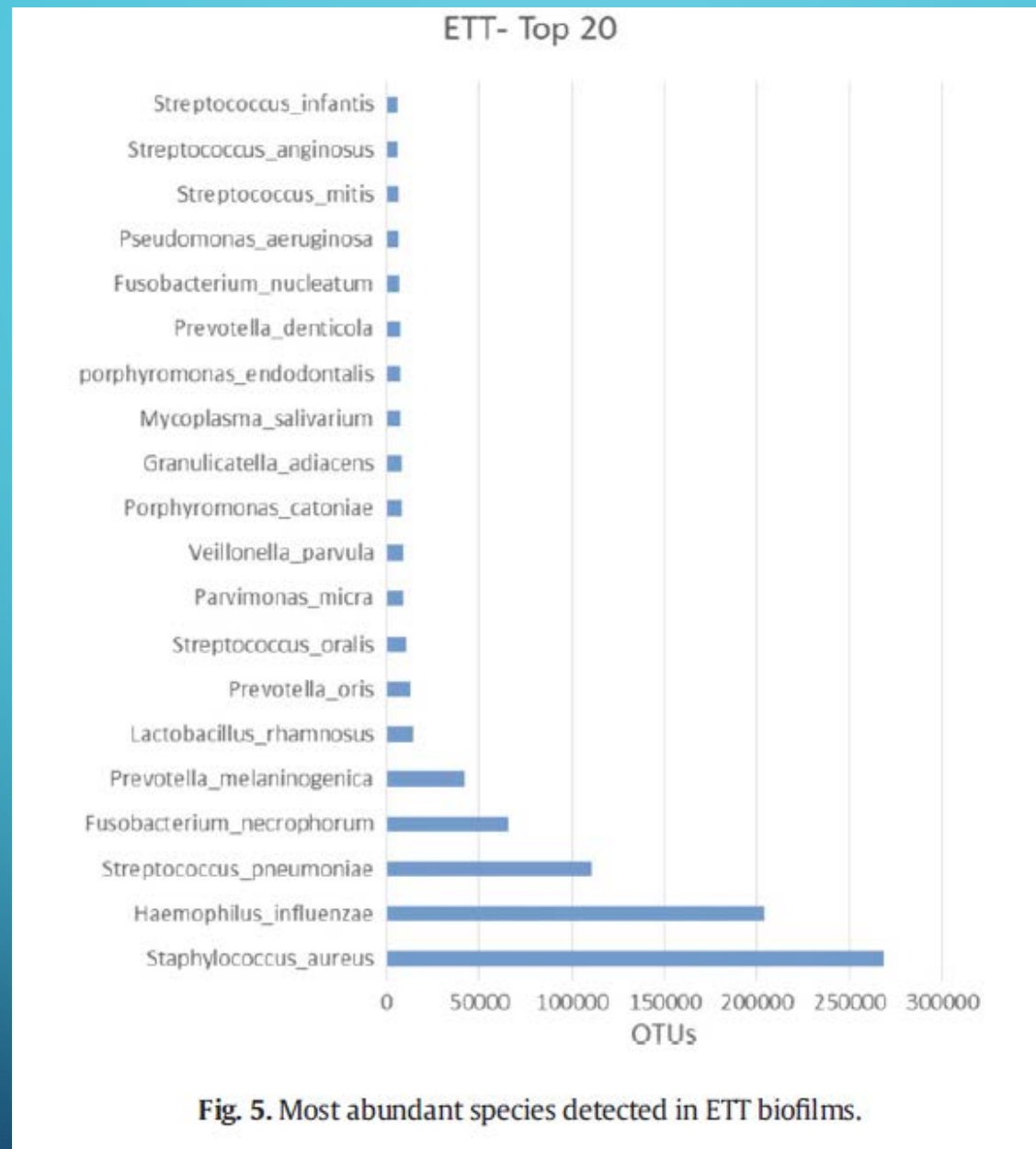
## Community analysis of dental plaque and endotracheal tube biofilms from mechanically ventilated patients

Marino, *Journal of Critical Care* 2017; 39:149-155





**Fig. 4.** Most abundant species detected in dental plaque.



**Fig. 5.** Most abundant species detected in ETT biofilms.

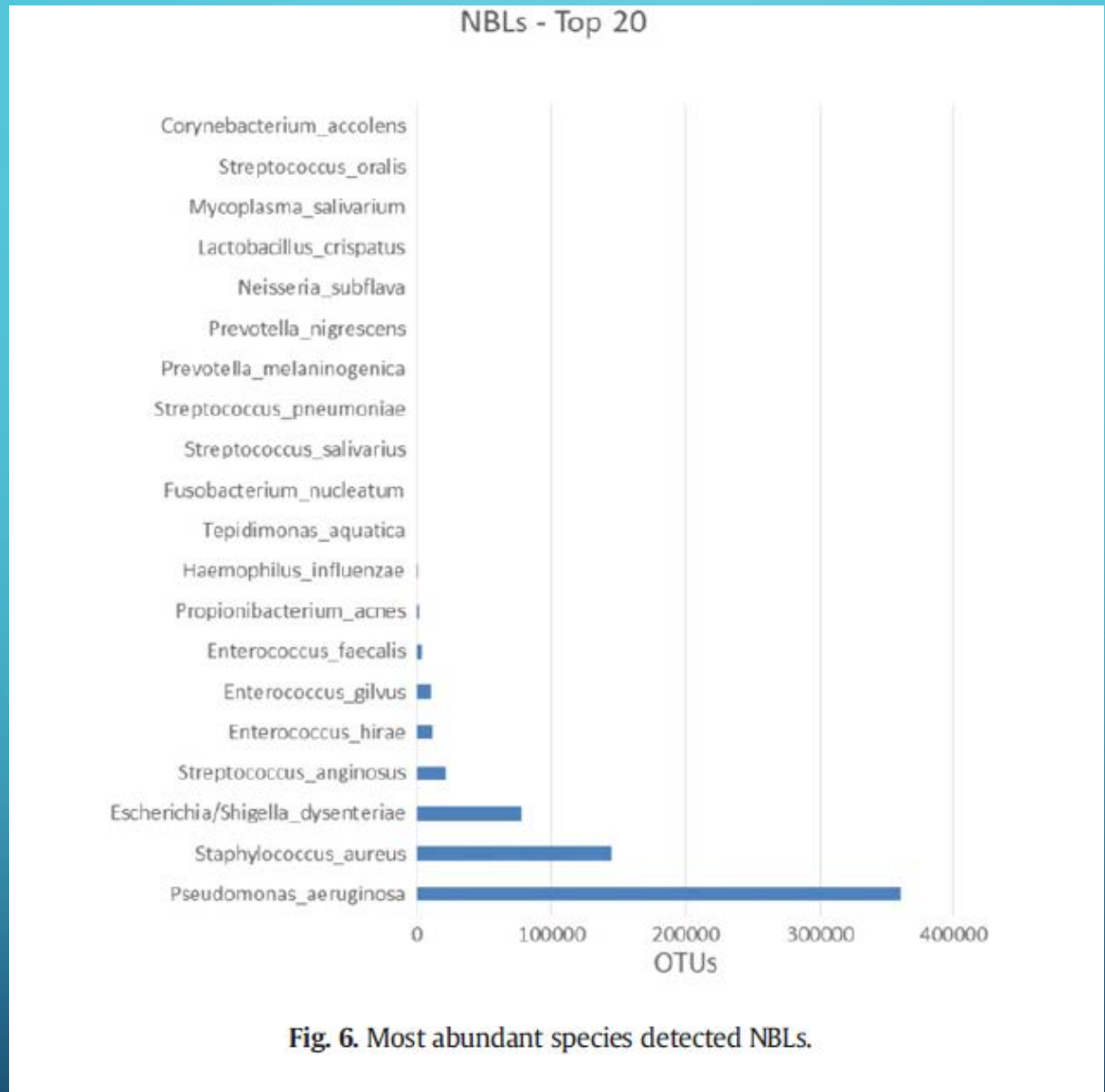
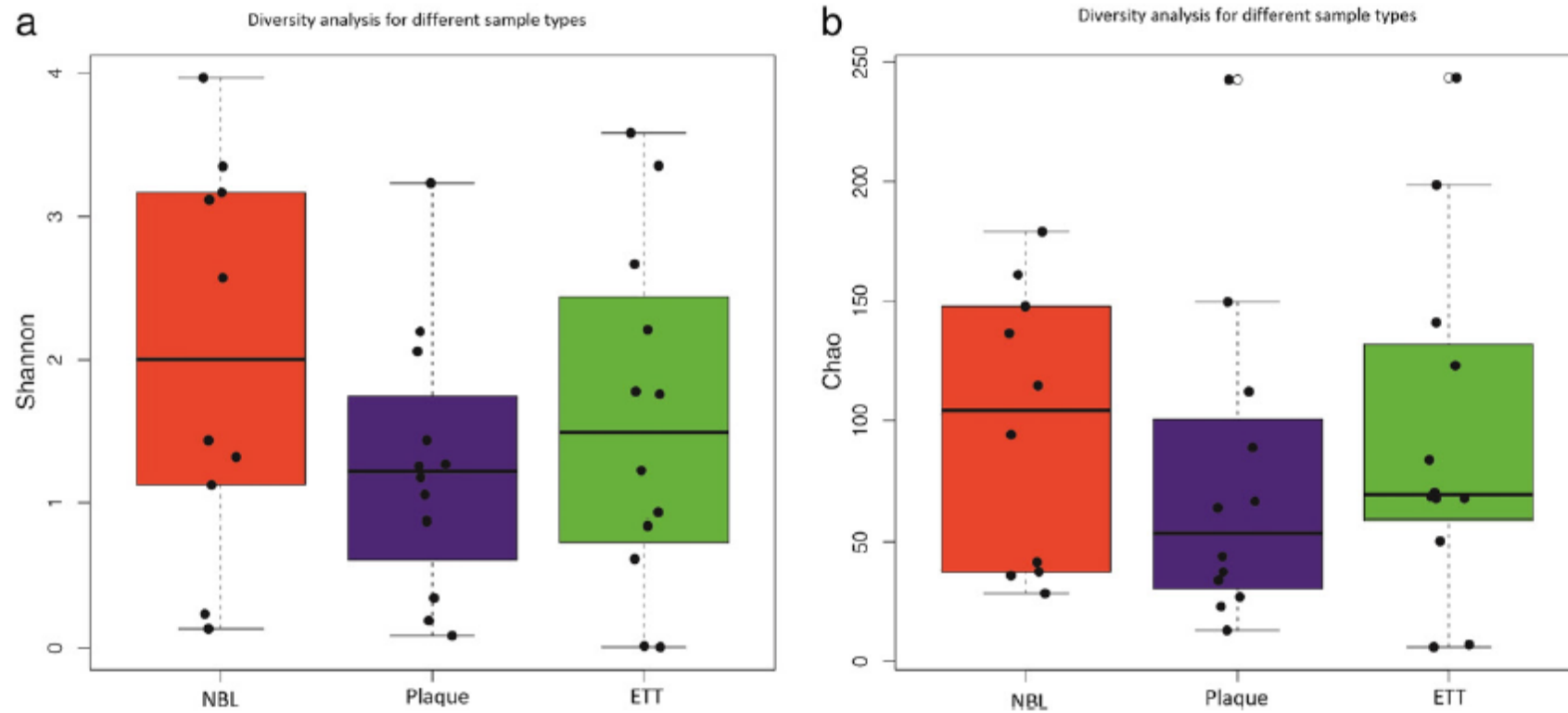


Fig. 6. Most abundant species detected NBLs.



**Fig. 1.** a, Chao analysis of similarities in the diversity of the microbiomes of dental plaque, NBLs, and ETTs. b, Shannon analysis of similarities in the diversity of the microbiomes of dental plaque, NBLs, and ETTs.

## Description and Microbiology of Endotracheal Tube Biofilm in Mechanically Ventilated Subjects

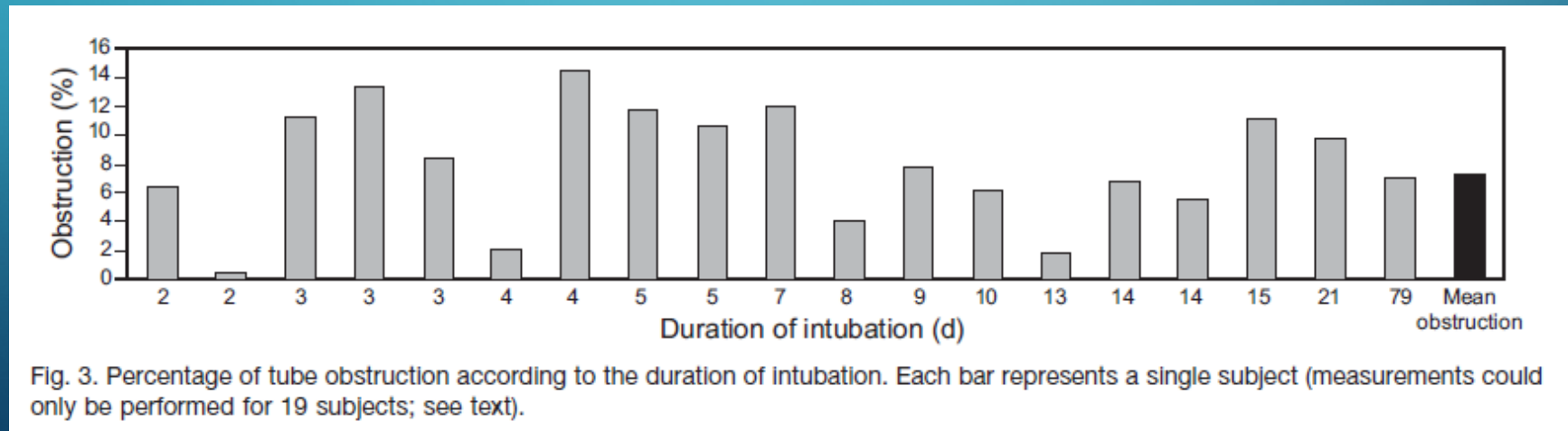
Observational study, single center.

24 patients, 2-79 days intubation.

Before extubation: measurement of ETT volume by acoustic reflection.

After extubation: biofilm analysis by optical and atomic force microscopy.

Bacteriological analysis of biofilm.



Danin, Respir Care 2015;60(1):21–29.

# Description and Microbiology of Endotracheal Tube Biofilm in Mechanically Ventilated Subjects

Table 2. Frequency of Organisms Isolated in Tracheal Tube Biofilm

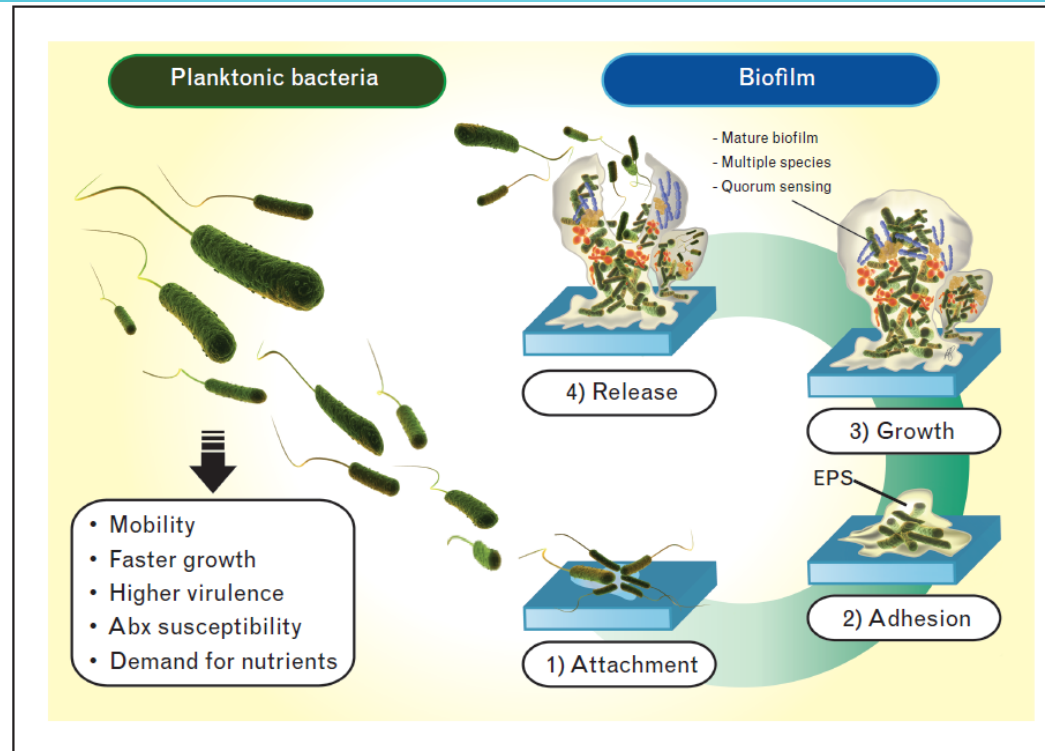
Cocci Gram-Positive	
<i>Staphylococcus aureus</i>	29
<i>Staphylococcus coagulase negative</i>	45.8
<i>Enterococcus</i> species	29
<i>Streptococcus</i> species	50
Bacilli Gram-Negative	
<i>Pseudomonas aeruginosa</i>	58.3
<i>Acinetobacter baumannii</i>	4.2
<i>Klebsiella pneumoniae</i>	12.5
<i>Proteus mirabilis</i>	8.3
<i>Enterobacter</i> species	8.3
<i>Citrobacter</i> species	8.3
<i>Morganella morganii</i>	8.3
<i>Candida albicans</i>	25

Data are given as percentage of analyzed tubes.

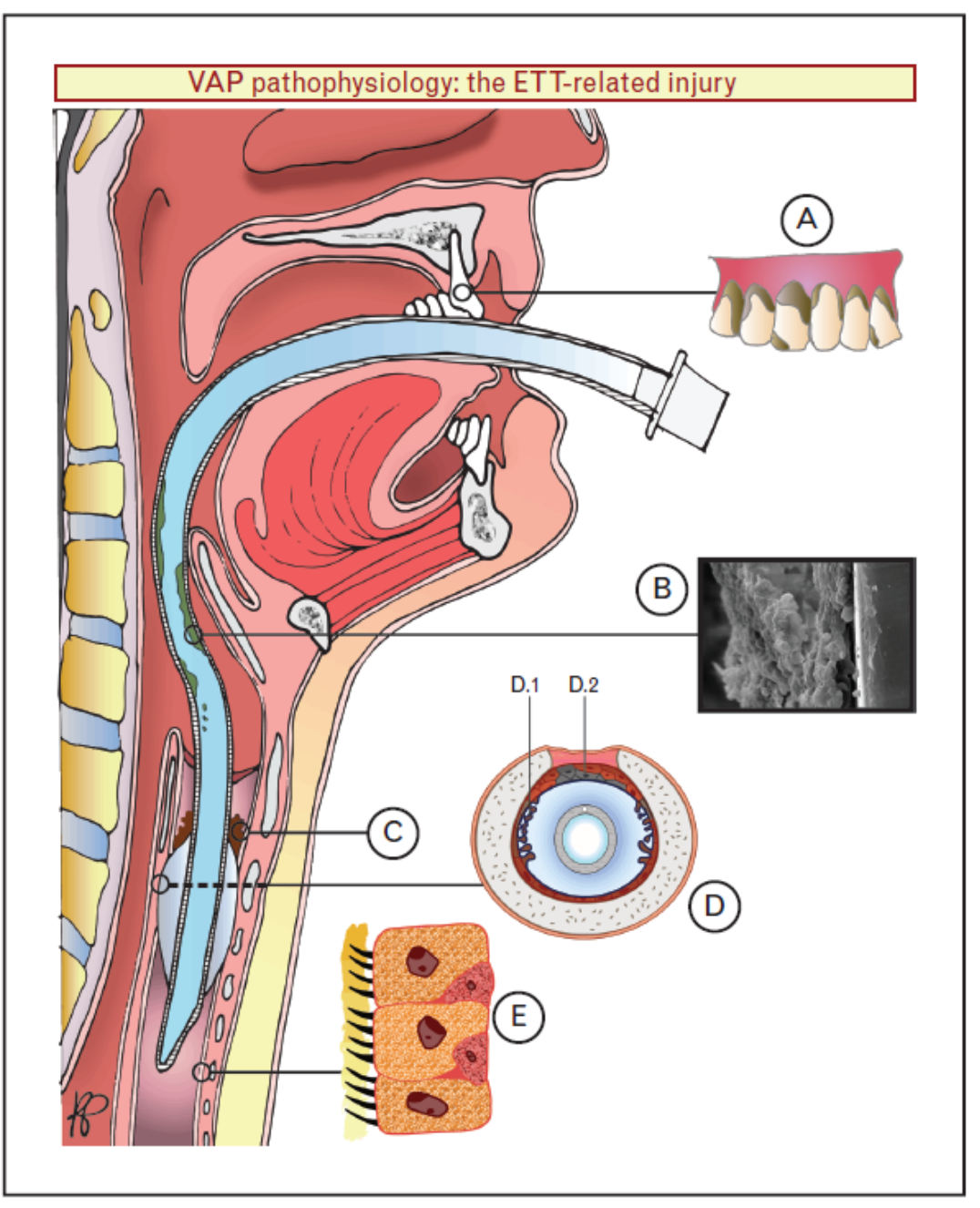
Table 3. Comparison Between Clinical Documentation (Tracheal Sample) and Bacterial Culture of Endotracheal Tube Biofilm in Subjects With Hospital (Subject 18) or Ventilator-Acquired Pneumonia (Subjects 2, 4, 10, 19, and 21)

Subject	Tracheal Aspirate	Microorganisms in Biofilm
2	<i>Pseudomonas aeruginosa</i>	<i>P. aeruginosa</i>
4	<i>Candida albicans</i>	<i>C. albicans</i>
	<i>Stenotrophomonas maltophilia</i>	<i>S. maltophilia</i>
	<i>Alcaligenes xylooxidans</i>	<i>A. xylooxidans</i>
	<i>Staphylococcus aureus</i>	NA
	<i>Proteus mirabilis</i>	NA
10	<i>Enterobacter aerogenes</i>	NA
	<i>P. aeruginosa</i>	<i>P. aeruginosa</i>
	<i>C. albicans</i>	<i>C. albicans</i>
18	<i>P. aeruginosa</i>	<i>Pseudomonas aeruginosa</i>
19	<i>P. aeruginosa</i>	<i>P. aeruginosa</i>
	<i>C. albicans</i>	<i>C. albicans</i>
21	No documentation	<i>Acinetobacter baumannii</i> , methicillin-resistant <i>S. aureus</i> , <i>S. maltophilia</i> , <i>Streptococcus mitis</i> , non- <i>albicans</i> <i>Candida</i>

Except for subject 21, the same microorganisms were found in both sites.



**FIGURE 1.** Biofilm formation. The first step of biofilm formation is the reversible attachment to a surface through aspecific interactions between the bacterial wall and the substrate. The contact triggers the microorganism into strengthening the reversible cell–substrate bonds and into synthesizing and releasing extracellular matrix components. As the colony grows and acquires a mushroom-like architecture, the matrix allows other species to attach to the developing colony. At maturity, the biofilm is capable of releasing part of its colonies into the environment, to further colonize distant surfaces.



- A. Oral microbiome, teeth and plaque
- B. Endoluminal biofilm
- C. Accumulation of secretions above inflated cuff
- D. --Dependent leak (micro-channels, positioning, cuff pressure, transport, etc.)  
--Mucosal damage
- E. Impaired mucociliary clearance

Massimiliano,  
Curr Opin Infect Dis 2016, 29:160–166



# ETT BIOFILM CONTROL/PLUMBING

Pinciroli, *Resp Care* 2016; 61:1431-1439

Mietto, *Resp Care* 2014; 59: e122-e126

Safety of endOclear™ device in maintaining ETT lumen  
No data on biofilm or colonization

Coppadoro, *Ann Intensive Care* 2015; 5:57-64

Demonstration of efficacy of a cleaning closed suction system, Airway Medix Closed Suction System™

Berra, *Crit Care Med* 2012; 40:119-125

Demonstration of Safety of Mucus Shaver™ for clearing of secretions  
Decreased colonization of treatment group by standard bacteriology

Liu, *Pediatr Crit Care Med* 2013; 14:e338-e343

Mechanical cleaning with a sterile urethral catheter reduced bacterial colonization, prevented biofilm  
Reported to have decrease in prevalence of VAP

# PREVENTION

Ref:

Society for Healthcare Epidemiology of America/Infectious Diseases Society of America (SHEA/IDSA) 2014 recommendations for prevention of VAP

Canadian Critical Care Society and Canadian Critical Care Trials Group 2008 recommendations for prevention of VAP

DynaMed Plus, 2017

- **Consider implementing practices with little risk of harm that decrease duration of mechanical ventilation, length of stay, mortality, and/or costs.**
- Avoid intubation and reintubation if possible (Strong recommendation).
- Use noninvasive ventilation whenever possible (Strong recommendation).

## • If intubation is unavoidable:

- Institute protocols to improve the use of sedation and reduce the length of mechanical ventilation (Strong recommendation), such as:
  - daily interruption of sedation
  - daily spontaneous breathing trials
  - maintenance and improvement of physical conditioning of intubated patients
- Minimize the pooling of secretions above the endotracheal tube cuff.
  - Provide endotracheal tubes with subglottic secretion drainage ports for patients likely to require greater than 48 or 72 hours of intubation (Strong recommendation).
- Elevate the head of the bed to 30-45 degrees (Strong recommendation).  
(Cochrane, 2016: “A semi-recumbent position ( $\geq 30^\circ$ ) may reduce clinically suspected VAP compared to a  $0^\circ$  to  $10^\circ$  supine position. However, the evidence is seriously limited with a high risk of bias. No adequate evidence is available to draw any definitive conclusion on other outcomes and the comparison of alternative semi-recumbent positions. Adverse events, particularly venous thromboembolism, were under-reported.”)
- Maintain ventilator circuits and change them only if visibly soiled or malfunctioning.

- **Interventions that may lower ventilator-assisted pneumonia (VAP) rates but with insufficient data to determine the impact on the duration of mechanical ventilation, length of stay, and mortality:**

- oropharyngeal decontamination and specifically oral care with chlorhexidine

Cochrane, 2017: “OHC including chlorhexidine mouthwash or gel reduces the risk of developing ventilator-associated pneumonia in critically ill patients from 25% to about 19%. However, there is no evidence of a difference in the outcomes of mortality, duration of mechanical ventilation or duration of ICU stay. There is no evidence that OHC including both antiseptics and toothbrushing is different from OHC with antiseptics alone, and some weak evidence to suggest that povidone iodine mouthrinse is more effective than saline/placebo, and saline rinse is more effective than saline swab in reducing VAP. There is insufficient evidence to determine whether powered toothbrushing or other oral care solutions are effective in reducing VAP. There is also insufficient evidence to determine whether any of the interventions evaluated in the studies are associated with adverse effects.”

**Interventions that may lower ventilator-assisted pneumonia (VAP) rates but with insufficient data to determine the impact on the duration of mechanical ventilation, length of stay, and mortality:**

- prophylactic probiotics (but not in the immunocompromised)
- ultrathin polyurethane endotracheal tube cuffs
- automated control and surveillance of endotracheal tube cuff pressure
- saline instillation before tracheal suctioning

• **Interventions that may (?) lower VAP rates without an impact on the duration of mechanical ventilation, length of stay, or mortality include:**

silver-coated endotracheal tubes (Cochrane, 2015, “review provides limited evidence that silver-coated ETT reduces the risk of VAP, especially during the first 10 days of mechanical ventilation.”)

• kinetic beds

• prone positioning

• **Interventions with no impact on VAP rates, duration of mechanical ventilation, length of stay, or mortality include:**

- stress ulcer prophylaxis
- early tracheotomy
- monitoring residual gastric volumes
- early parenteral nutrition

• **Other:**

- In-line suction catheters (commonly used)
- Aerosol delivery (MDI, mesh neb better than SVN)
- Humidification



# SUBGLOTTIC SECRETION DRAINAGE

Caroff, Crit Care Med 2016; 44:830-840

Meta-analysis: lower VAP, no change MV, LOS, VAE, mortality

Damas, Crit Care Med 2015; 43:22-30

RCT: lower VAP, lower antibiotic use, no change ICU LOS, mortality, no change in VAC

Hubbard, J Trauma Acute Care Surg 2016; 80: 218-222

Retrospective review: lower VAP, vent days, ICU LOS in trauma patients

Mao, Critical Care 2016; 20:353



Meta-analysis: lower VAP and vent days, delayed VAP, no change ICU LOS or mortality (hosp or ICU)

Frost, Australian Critical Care 2013; 26: 80-188

Meta-analysis: lower VAP, delayed VAP, may reduce vent days, no change mortality (hosp or ICU)

Muscedere, Crit Care Med 2011; 39:1985-1991

Meta-analysis: lower VAP, possible reduction vent days, ICU LOS



# **Prevention of Ventilator-Associated Pneumonia and Ventilator-Associated Conditions: A Randomized Controlled Trial With Subglottic Secretion Suctioning**

Damas, Crit Care Med 2015; 43:22–30



Damas, Crit Care Med 2015; 43:22–30

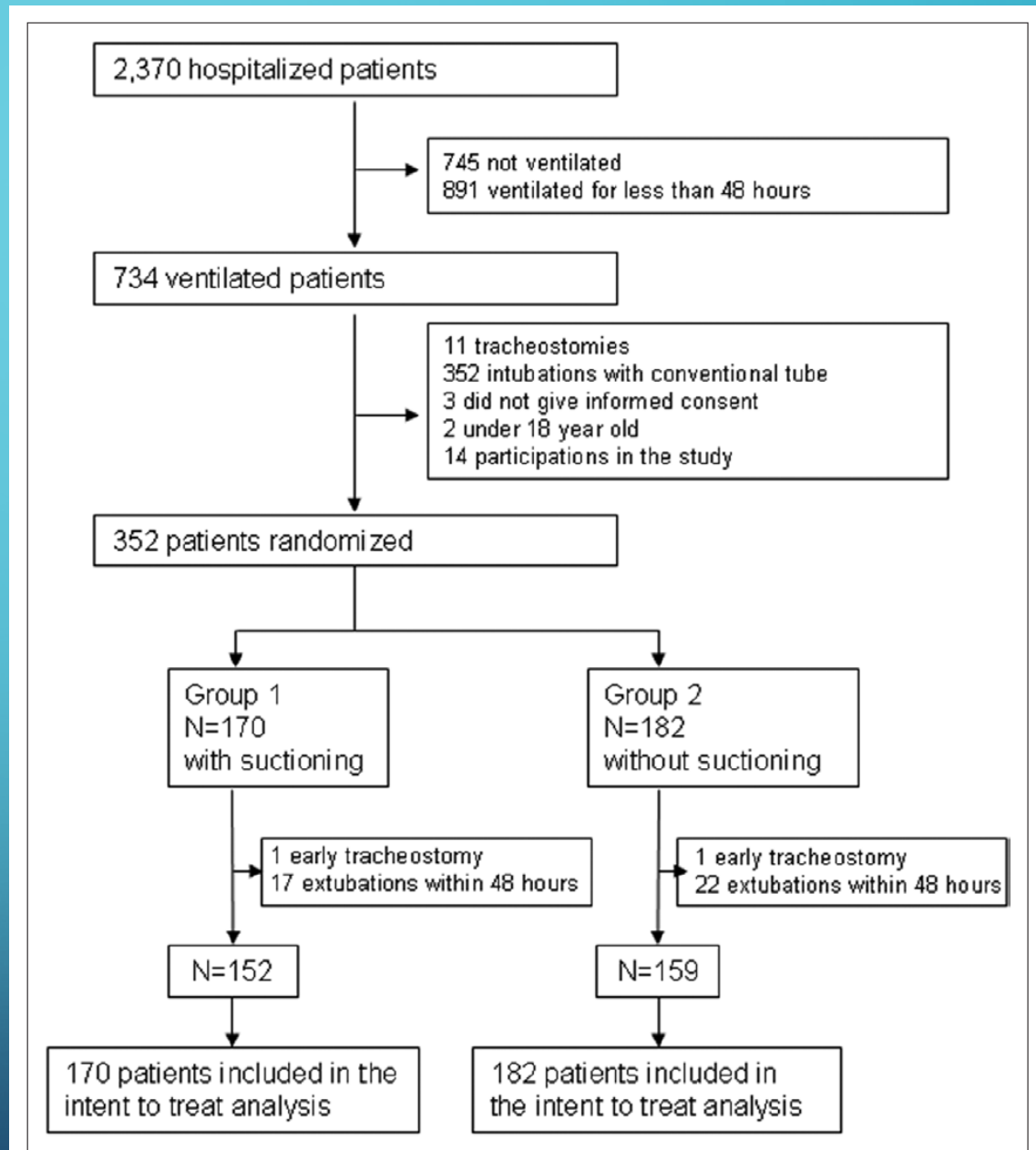
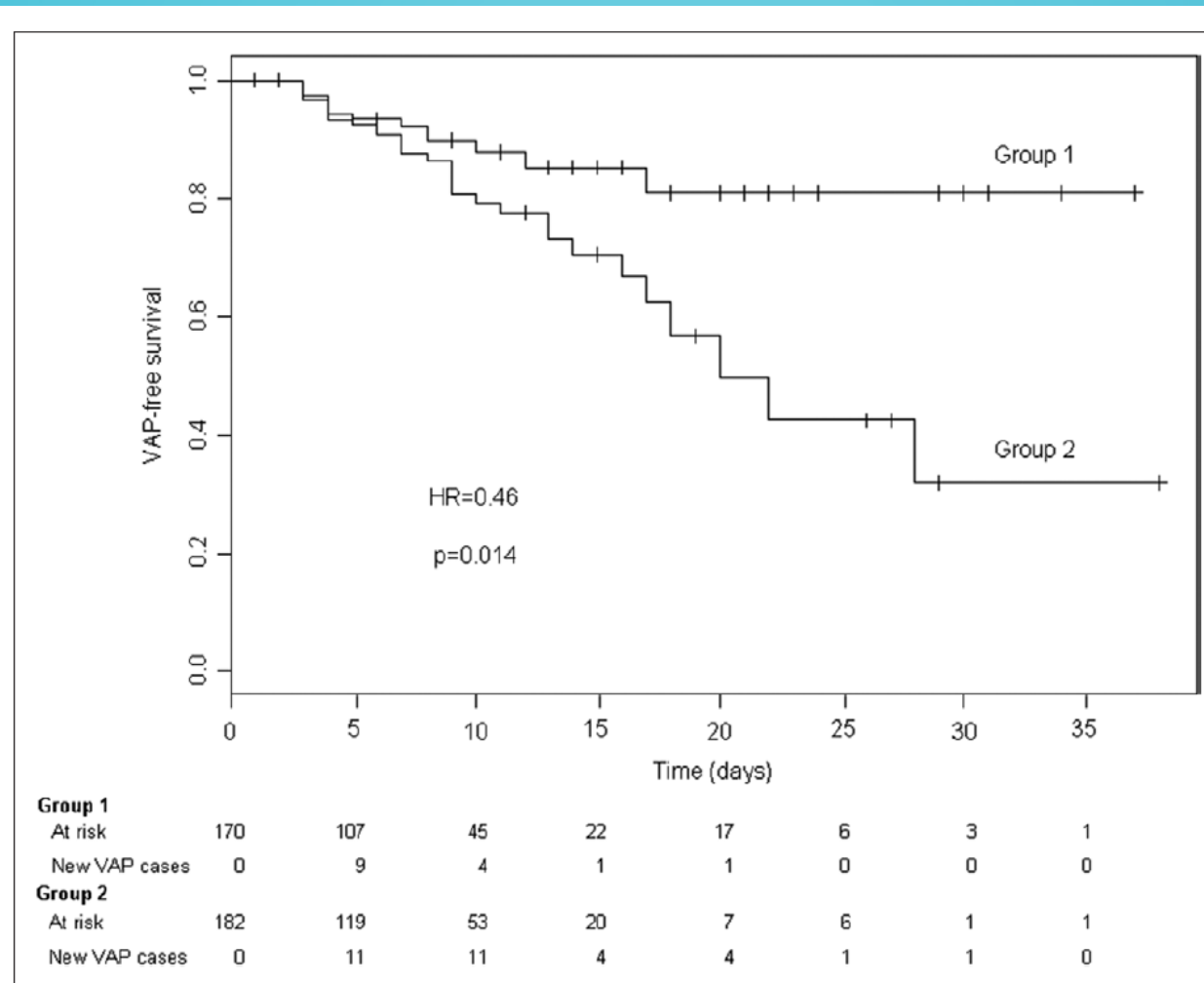


Figure 1. Flow chart of patients admitted to the ICUs between January 2012 and March 2013.



**Figure 2.** Cumulative rates of patients remaining free of ventilator-associated pneumonia (VAP) in group 1 with subglottic suctioning and control group (group 2) using the Kaplan-Meier method. HR = hazard ratio.

**TABLE 3. Primary and Secondary Outcomes**

Outcomes	Group 1	Group 2	<i>p</i>
	Experimental ( <i>n</i> = 170)	Control ( <i>n</i> = 182)	
Patients developing any kind of infection after intubation with TIET, <i>n</i> (%)	54 (34.9)	63 (39.0)	0.57
Respiratory infection at any time, <i>n</i> (%)	35 (22.4)	52 (32.7)	0.08
Early pneumonia (< 48 hr), <i>n</i> (%)	8 (5.3)	8 (5.0)	1.00
Ventilator-associated pneumonia during TIET, <i>n</i> (%)	15 (8.8)	32 (17.6)	0.016
Pneumonia after TIET withdrawal, <i>n</i> (%)	14 (7.2)	14 (7.5)	1.00
Patients with ventilator-associated condition, <i>n</i> (%)	37 (22.0)	41 (22.9)	0.84
Patients with infection-related ventilator-associated complication, <i>n</i> (%)	14 (8.2)	21 (11.5)	0.37
Duration of antibiotic treatment (d), median (IQR)	7 (3–14)	8 (5–13)	0.45
Antibiotic days during ICU stay (%)	61.6	68.5	< 0.0001
Antibiotic days during TIET ventilation (%)	68.3	75.7	0.001
ICU length of stay, median (IQR)	11 (7–21)	12 (7–19)	0.71
ICU mortality, <i>n</i> (%)	63 (37.1)	74 (40.9)	0.46
Hospital length of stay (d), median (IQR)	47 (21–148)	49 (19–96)	0.51
Hospital mortality, <i>n</i> (%)	78 (45.9)	93 (51.1)	0.33
Standardized mortality ratio	0.85	0.99	0.23

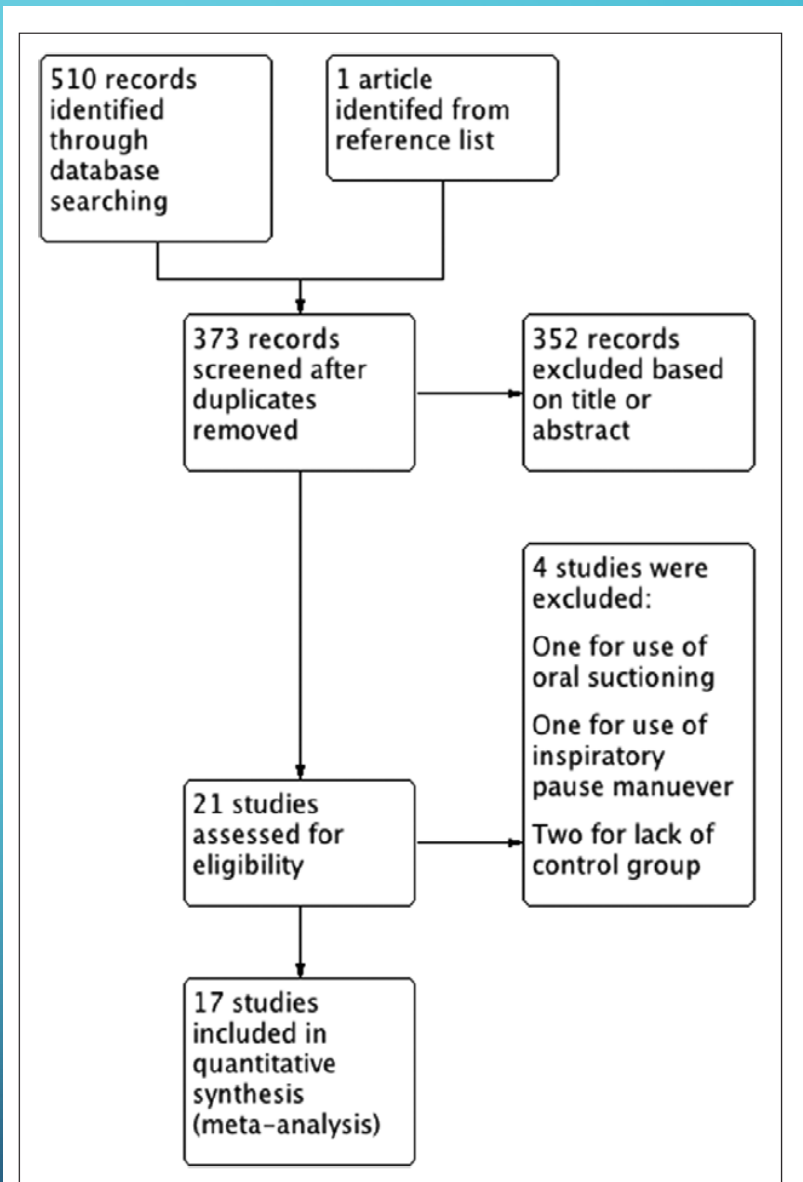
TIET = teleflex ISIS endotracheal tube, IQR = interquartile range.



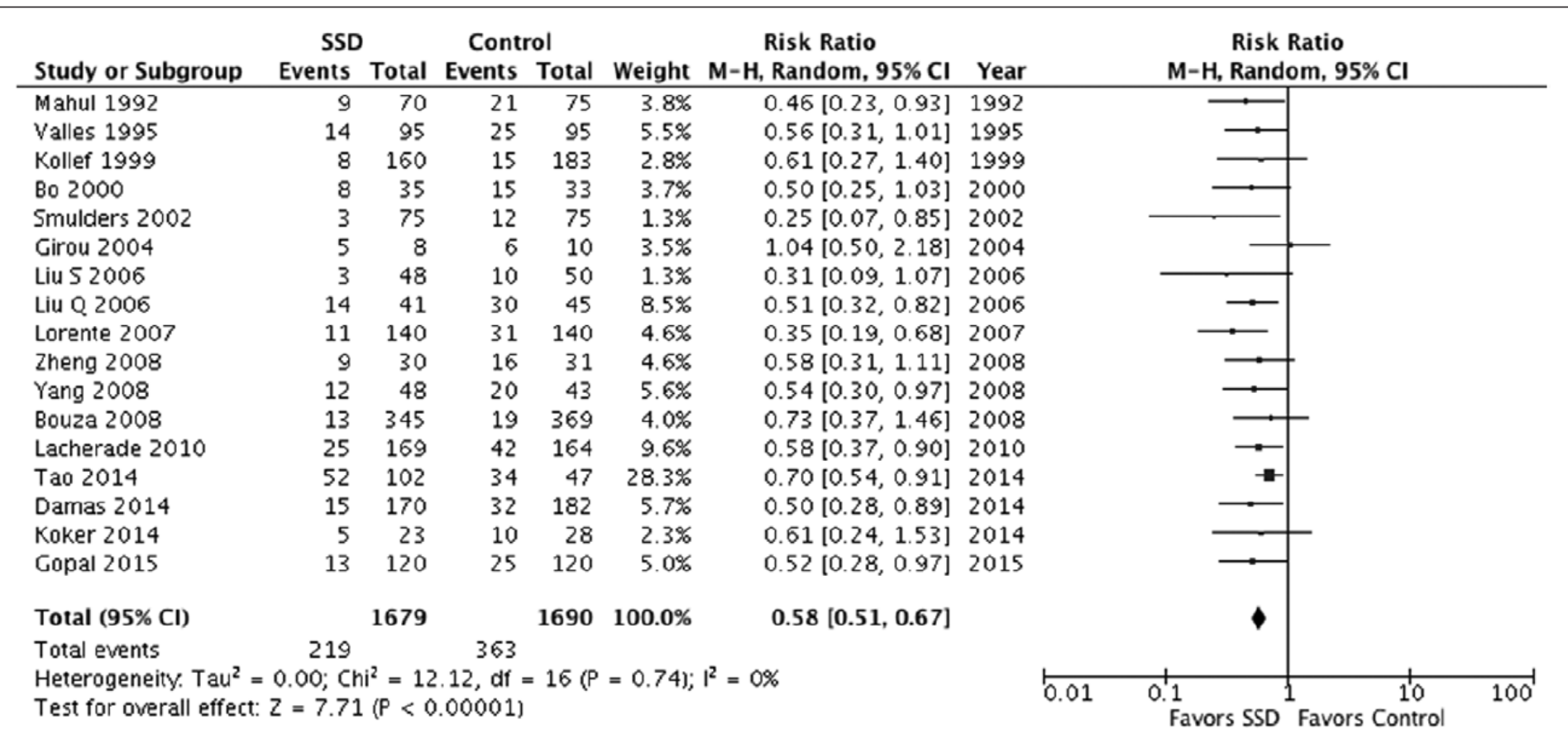
# Subglottic Secretion Drainage and Objective Outcomes: A Systematic Review and Meta-Analysis

Caroff, Crit Care Med 2016; 44:830-840



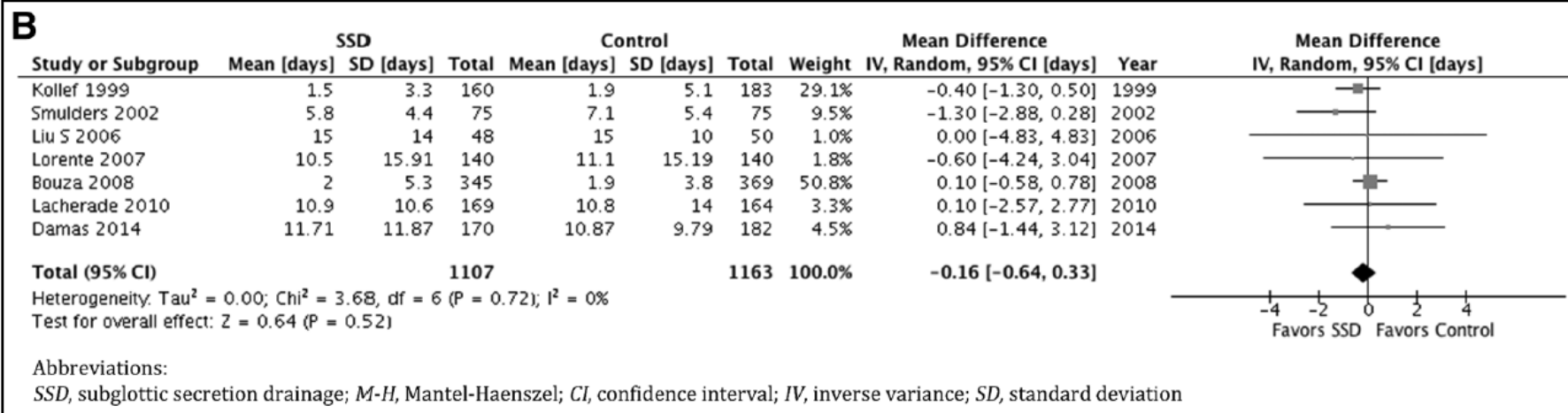
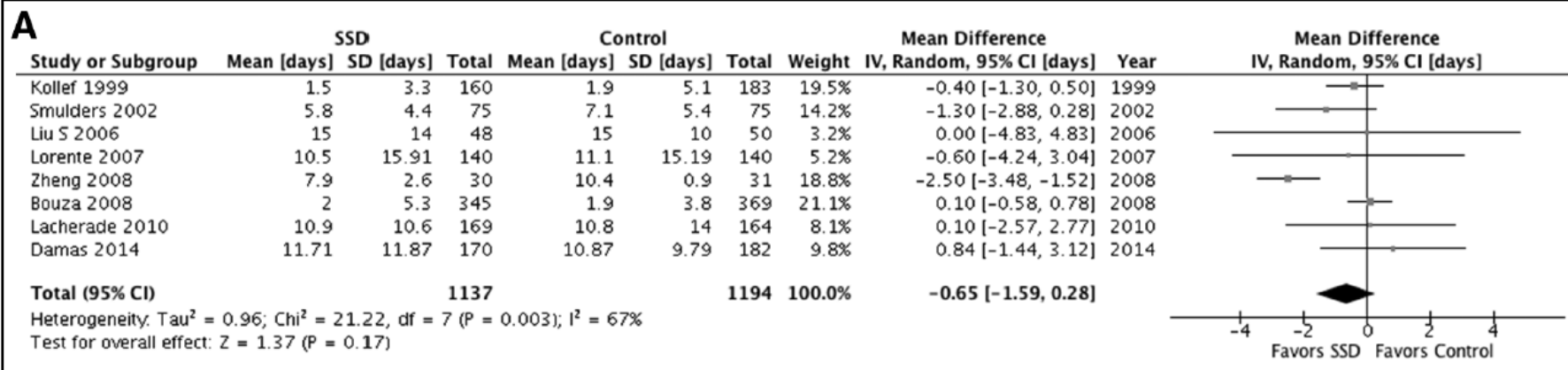


**Figure 1.** Preferred Reporting Items for Systematic Reviews and Meta-Analyses study flowchart.



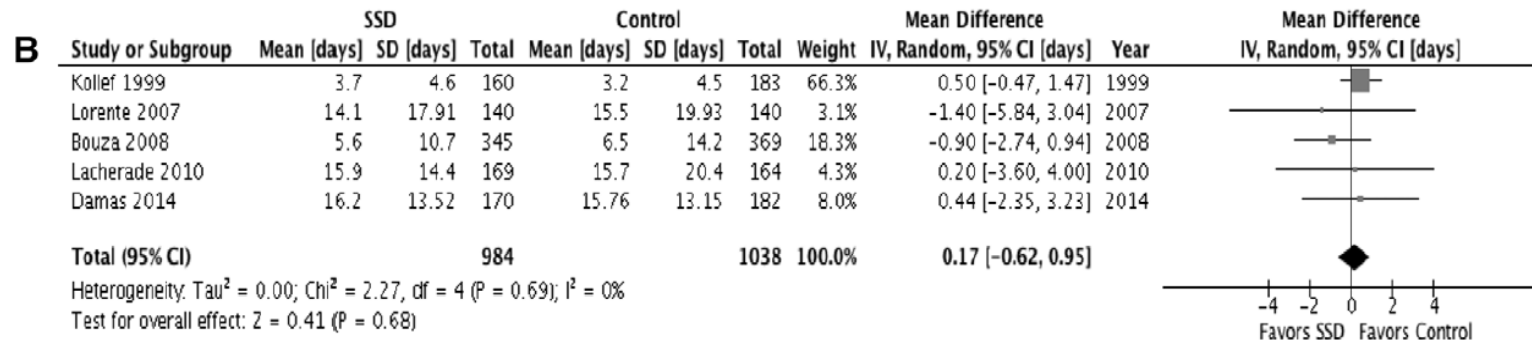
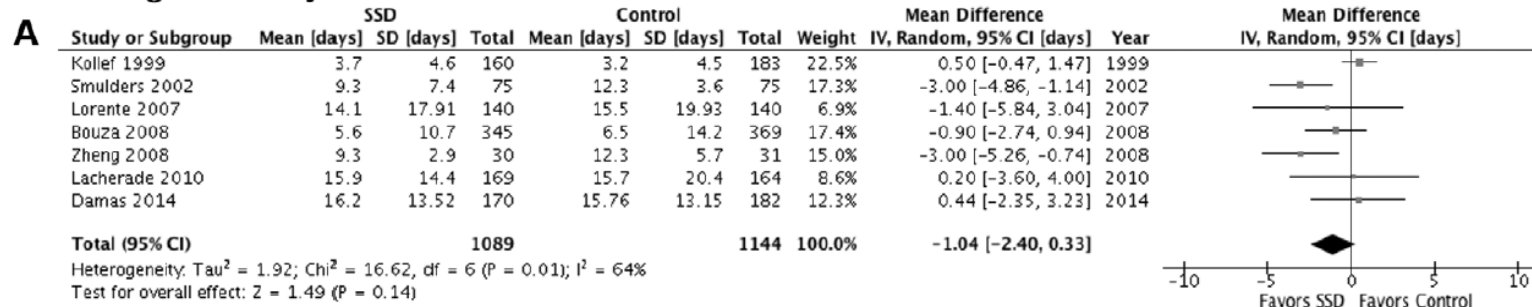
**Figure 2.** Ventilator-associated pneumonia in patients with subglottic secretion drainage (SSD) versus controls. M-H = Mantel-Haenszel.



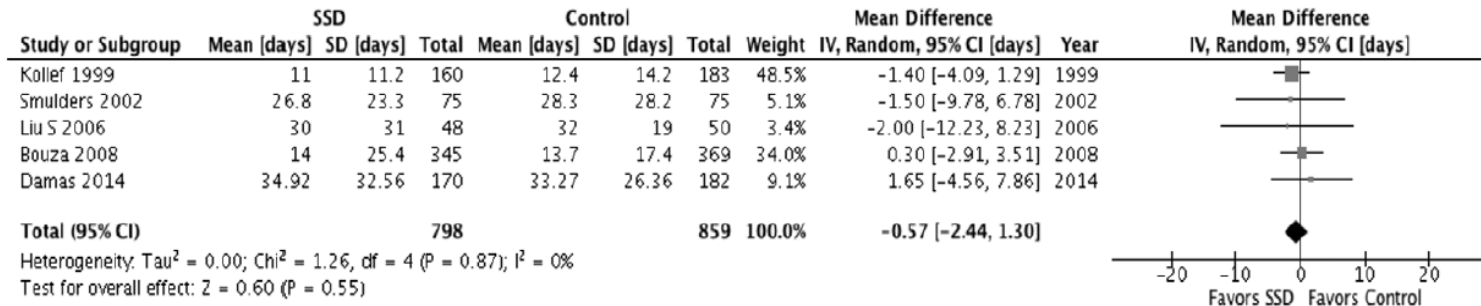


**Figure 3.** Duration of mechanical ventilation in patients with subglottic secretion drainage (SSD) versus controls. **A**, All studies with available mean and SD for duration of mechanical ventilation. One study (Zheng et al [36]) is an outlier relative to all other studies and leads to high heterogeneity on meta-analysis ( $P = 67\%$ ). **B**, Findings on meta-analysis after excluding Zheng et al (36) ( $P = 0\%$ ). M-H = Mantel-Haenszel, IV = inverse variance.

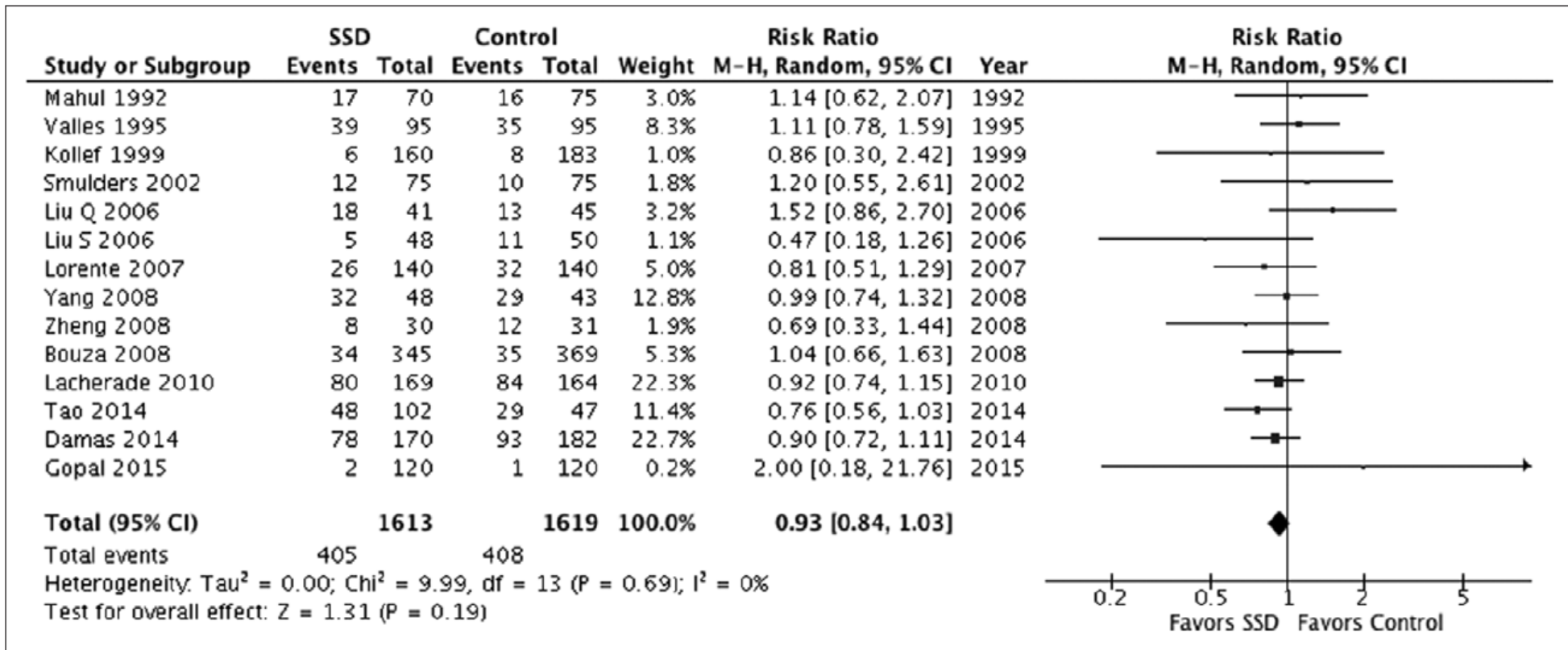
## ICU Length-of-Stay



## Hospital Length-of-Stay



**Figure 4.** Length of stay in patients with subglottic secretion drainage (SSD) versus controls. **A**, All studies with available mean and sd for intensive care length of stay. Two studies (Smulders et al [12] and Zheng et al [36]) have very small sds in the control and treatment arms, respectively, that lead to high heterogeneity on meta-analysis ( $I^2 = 64\%$ ). **B**, Findings on meta-analysis after excluding these two studies ( $I^2 = 0\%$ ). IV = inverse variance.



**Figure 5.** Mortality rates in patients with subglottic secretion drainage (SSD) versus controls. All studies that provided mortality data regardless of mortality time point were included. Analyses restricted to studies that reported ICU mortality and hospital mortality, respectively, are reported in the text. M-H = Mantel-Haenszel.

# Challenges with SSD

- Target population (>72 hours ventilation)
- Specialized tube required
- Continuous vs intermittent suction
- Wall vs manual vs automated suction
- Location of drainage port
- Numbers of ports
- Tracheal wall damage
- Mucosal dessication
- Endoluminal size restriction
- Possible drainage port occlusion
- Cross contamination wall regulator

## Potential Benefits (Automated Intermittent SSD) SIMEX™

- Intermittent aspiration reduces the risk of injury due to drying of mucous membranes or adverse pressure trauma
- Customizable to each patient's needs
- Increased patient comfort during aspiration process
- Minimized maceration of surrounding tissue due to reduction of secretion leakage
- Decreased need for frequent tracheal dressing changes due to reduction of secretion leakage
- Self-contained collection canisters help prevent cross-contamination and minimize incidence of infection

**Figure 2.** Automated Intermittent Subglottic Secretion Aspiration System.



	Traditional Approaches			Automated Approach
	<i>Continuous</i>	<i>Intermittent</i>	<i>Manual</i>	<i>Intermittent</i>
<b>Method</b>	Wall Suction or General Suction	Wall Suction or General Suction	Syringe	Specialized Suction Device
<b>Pressure</b>	-20 mmHg (may be too low to aspirate viscous secretion and increased above recommended guidelines)	-150 mmHg (high frequency aspiration – virtually continuous at a much higher pressure)	-580 to -720 mmHg (nearly 4-5 times higher than recommended)	Tailored by patient, -50 to -150 mmHg
<b>Accuracy of Pressure Delivered</b>	Not reliable	Not reliable	Always Higher than recommended Guidelines	Accurate/reliable
<b>Frequency</b>	Continuously, 24/7	Aspirating virtually continuously with short pauses (16 seconds), 24/7	Hourly (often less regularly)	Tailored by patient, Aspiration for 10 - 20 seconds and pause for 5 - 20 minutes, 24/7
<b>Daily Aspirations</b>	Non-Stop Aspiration	1,440 - 3,600 aspirations daily	24 aspirations daily	24 -144 aspirations daily
<b>Noise Level</b>	Highly Noisy	Highly Noisy	None	Quiet
<b>Staff Time (per bed per day)</b>	10 minutes	10 minutes	120 minutes	10 minutes
<b>Volume of Secretions</b>	10 - 30 ml	10 - 30 ml	30 ml	100 - 500 ml
<b>FDA Cleared</b>	No	No	No	Yes
<b>Specifically Designed for SSD</b>	No	No	No	Yes
<b>Potential for Cross Contamination</b>	Yes	Yes	Yes	Minimized

Cozean J, Benefits of automated intermittent subglottic secretion drainage. Respiratory Therapy 2015;10:4:27-28

## Determination of the amount of Negative Pressure that is generated by Syringe using various size Syringes (Bench Test)

Various size syringes 2, 5, 10 and 20 ml syringes were utilized to measure the amount of Negative Pressure that each syringe generates. A calibrated pressure sensor was used to measure the amount of negative pressure in mmHg. For each syringe the test was repeated 3 times and the results are tabulated in the following table. The photo below demonstrates how the syringe is connected via a tube to the pressure measuring device.

This bench test<sup>1</sup>, clearly demonstrates that the larger the syringe, the higher the negative pressure it generates. The most common size syringe used in hospitals for removal of secretion from respiratory airway is 10 ml syringe. As it is shown in the table below, all size syringes generate negative pressure in excess of the -770 mbar or -578mmHg which is quite high and four (4) times the AARC recommended MAXIMUM pressure range of -200 mbar or -150 mmHg. The results of this bench test are in line with other published test and data demonstrating the fact that syringes do generate higher suction pressure.<sup>2-3</sup>

### Test to measure peak vacuum pressure of syringes with different volumes

Volume of Syringe	Vacuum / Pressure [mmHg]			
	1	2	3	Average
2 ml	-578	-578	-578	-578
5 ml	-671	-671	-671	-671
10 ml	-706	-706	-706	-706
20 ml	-722	-722	-722	-722

# A Single-center, Randomized Controlled Study Comparing the Efficacy of the Simex Automated Intermittent Subglottic Aspiration System in the Prevention of Ventilator-associated Pneumonia and Ventilator-associated Events in Long-term, Tracheostomized, Mechanically-ventilated Patients

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## Introduction

Ventilator-acquired pneumonia (VAP) continues to be a significant cause of morbidity and mortality, increased hospital stays, increased antibiotic use, and increased costs. VAP is the most common and preventable nosocomial infection among mechanically ventilated patients (Davis, K., 2006). Research suggests that subglottic suctioning decreases incidence of VAP; preventing aspiration of contaminated secretions into the sterile lower airways. High mortality rates among VAP patients are primarily due to patients' comorbidities and the virulence of the colonizing bacterium. The SIMEX Automated Intermittent Subglottic Aspiration System has been utilized in Europe, in over 1000 patients, with excellent clinical outcomes.

This Randomized Control Trial (RCT), the first of its type in the world, measured the effects of the SIMEX Automated Intermittent Subglottic Aspiration System in a long-term, 40-bed ventilator unit. Working in conjunction with a 5-step VAP protocol, the SIMEX Subglottic Aspiration System yielded significant positive clinical outcomes.

## Importance of VAP Prevention

- VAP rates are important in long term ventilator units due to 45% increase in mortality rates (Ibrahim, E.H., et al, 2001).
- VAP is responsible for increased morbidity rates, decreased revenue, increased duration on mechanical ventilation, and treatment costs that may exceed \$40,000 (Guterl, G., 2013).

## RCT Methodology

- 25 patients randomized to treatment – (designated Group A, device group) See Figure 1.
- 15 patients – (designated Group B, non-device control group).
- RCT was 4 months in duration.
- Amount of aspirate recorded daily.
- Portex BlueLine subglottic tracheostomy tube – with dorsal lumen – was used for subglottic access.
- Most effective settings used in the trial was suction pressure -150 mmHg /12-second suction duration/10-minute suction intervals.

## Clinical Problems Associated with Tracheostomy Tubes

- Due to tracheostomy tube placement, normal airway defense mechanisms are compromised.
- If bacteria are introduced into the normally sterile lower airway – colonization and infection begin.
- Tracheostomy tubes disrupt the mucociliary escalator and impair the cough reflex.
- Tracheostomy tubes can cause injury to the tracheal tissue.

## Redefining Tracheal Cuff Pressures

- The tracheostomy cuff is used to seal airway to provide positive pressure mechanical ventilation.
- The cuff can provide a platform for secretions to pool and eventually leak around the cuff.
- Most Respiratory Therapists set cuff pressures to "minimally occluded volume" – between 20-25 cmH<sub>2</sub>O.
- Our research found that "minimally occluded volume" pressures are too low to prevent leakage of contaminated secretions.
- We found that cuff pressures of 30 cmH<sub>2</sub>O (+/- 5 cmH<sub>2</sub>O) are ideal for leak prevention. Results are similar to (Chendrasekhar, A. et al, 2013).
- Average cuff pressures in RCT were 28-33 cmH<sub>2</sub>O without adverse tracheal wall damage or patient discomfort.

## Respiratory Care Protocol

- Once admitted, Respiratory Therapist changes tracheostomy tube to subglottic version.
- Patient is connected to SIMEX Automated Intermittent Subglottic Aspiration System.
- Active humidification is discontinued and switched to Heat and Moisture Exchanger (HME).
- Medication nebulizers are discontinued and switch to MDIs.

- VAP Protocol allows differentiation between nosocomial and community acquired.

- If patient is admitted to the ventilator unit and spikes a temperature within 48 hours, patient is worked up for a possible VAP – considered a community-acquired VAP.
- 5-step VAP program initiated: (1) head of bed 30-45 degrees; (2) DVT prophylaxis; (3) proton pump inhibitor; (4) chlorhexidine 0.12% oral rinse; and (5) daily weaning from mechanical ventilation.

## Benchmarks Prior to Introduction of SIMEX Automated System and New VAP Protocol

- Prior to use of SIMEX subglottic devices VAP rate averaged 16.25% – with VAP protocol in place.
- Transfers to hospital with VAP averaged 50%.
- Mortality rates for transferred patients averaged 50%.
- Respiratory therapists manually aspirated subglottic ports 4x/shift – very labor intensive.
- Average manual suction volume with 20cc syringe – 30-40 ml/day.
- Suction pressures with 20cc syringe were dangerously high (~700 mmHg) – potentially causing tracheal tissue damage.
- Difficult to apply consistent and safe suction pressures.
- No way to ensure maximal aspiration of subglottic volume.

## Randomized Controlled Trial Results

- Initial subglottic secretion volumes ranged between 60-120ml/day. See Figure 3.
- After "redefining" "minimal occluded volume" – collected subglottic volumes ranged between 130-420 ml/day. This indicated leakage of subglottic secretions at lower tracheostomy cuff pressures. See Figure 3.
- Tracheostomy subglottic suction port design and position play an important role in efficiency and effectiveness of subglottic suctioning.
- Maceration of tissue surrounding the stoma decreased significantly resulting in less soiled clothing and need for frequent tracheostomy tie changes. See Figure 2.
- Conclusion of RCT – 25 patients on SIMEX device Group A resulted in VAP rate of 8% versus VAP rate of 33% in 15 patient control Group B.
- Post RCT Statistics – 40 patients on SIMEX device – past 8 months (March – October, 2016) – 2 confirmed VAP – 1 treated in-house – 1 required transfer to hospital and returned within 7 days.
- No mortality with VAP.
- Respiratory therapists report SIMEX device simple to program, maintain, and monitor.

## Conclusion

The SIMEX Automated Intermittent Subglottic Aspiration System, working in conjunction with the 5-step VAP protocol, significantly decreased the incidence of VAP in our ventilator unit. These results are important considering the 50% VAP mortality rate. We have saved significant facility resources and keep patients in beds – increasing revenue. We have also decreased the 30-day transfer rates back to feeder hospitals, improving our relationships while improving patient care. Lastly, we have decreased time on mechanical ventilation and improved quality of life.

Poster Presented at 2016 CHEST Annual Meeting, Los Angeles, California



FIGURE 1  
SIMEX Automated Intermittent Subglottic Aspiration System – setup on a patient in facility with subglottic secretions collected in the aspiration container.



FIGURE 2  
Subglottic Tracheostomy tube connected to the SIMEX Aspiration System.

FIGURE 3

Optimal Suction Settings on the SIMEX Automated Intermittent Subglottic Aspiration Device	
-150 mmHg – 12 second duration – 10 minute intervals	
Cuff Pressures	Subglottic Secretion Volume
18 – 25 cmH <sub>2</sub> O	60 – 120 ml/day
25 – 30 cmH <sub>2</sub> O	130 – 250 ml/day
30 – 35 cmH <sub>2</sub> O	250 – 420 ml/day

## References

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2. Ibrahim, E. H., Tracy, L., Hill, C., Fraser, V. J., & Kollef, M. H. (2001). The occurrence of ventilator-associated pneumonia in a community hospital: Risk factors and clinical outcomes. *Chest*, 120(2), 588-591. doi:10.1379/chest.120.2.588.
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4. Chendrasekhar, A., & Timberlake G.A., (2013). Endotracheal cuff pressure threshold for prevention of nosocomial pneumonia. *Journal of Applied Research*, 13 (3). Retrieved from <http://www.jmnappliedresearch.com/articles/Vol13Iss03/Chendrasekhar.htm> – [concluded that ETT cuff pressures of 29.5 cmH<sub>2</sub>O (+/- 3.2 cmH<sub>2</sub>O) were ideal to prevent leakage around cuff].





# The Role of Subglottic Secretion Drainage in VAP Prevention: ICU Experience with an Automated Intermittent Subglottic Secretion Drainage System

Wolf, Respiratory Therapy 2016; 11:28-33



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**Table 1.** Automated Subglottic Aspiration System Patients

Pt	M/F	Age	Condition	Pathogen(s)	Secretion/Daily	Other Observations
01	M	63	Coronary artery bypass OP. Cerebellar infarction	Morganella morganii	100 ml mucopurulent (fecal smell)	Delirium Dysphagia
02	M	85	Valve replacement. CHF. Diabetes	E.coli. Morganella morganii. Stenotrophomonas	150-250 mucopurulent	Delirium Dysphagia
03	M	67	55 day post esophagectomy for cancer. COPD		400 ml watery	Gastric regurgitation
04	M	74	Coronary artery bypass OP with aortic valve replacement. Acute persistent renal failure. Severe critical illness polyneuropathy. Slow recovery due to axonal type		150 ml mucopurulent. 1400 ml total collected within a few days	Dysphagia Depression
05	M	83	29 days post emergency coronary artery bypass OP. Severe critical illness polyneuropathy		250-350 ml mucopurulent	
06	F	79	48 hours post intubation for AECOPD	Stenotrophomonas maltophilia	50 ml mucopurulent. 600 ml total collected within a few days	Dysphagia Anxiety disorder
07	F	63	Intubated for pneumonia. MS for 20 years		400-600 ml watery	Dysphagia
08	M	75	AECOPD	Enterobacter. Serratia	50-100 ml Mucoid, hemorrhagic secretions	Delirium Dysphagia
09	M	75	AECOPD. ICU weakness. CIP. CIM.	E.coli. Pseudomonas. Klebsiella. Multi resistant against 3-4 major antibiotic classes.	500-1000 ml watery	Severe dysphagia
10	M	71	92 days post ARDS, following spondylodiscitis with sepsis and fibrotic lung	Enterococcus resistant to 4 major antibiotic classes		De-cannulated but later died not wanting further treatment
11	M	66	37 days post pneumonia. Sepsis. Multiple organ failure. Severe weakness		50-100 ml mucopurulent	Delirium Dysphagia
12	F	82	Valve replacement for endocarditis. ICU acquired weakness	Multi-resistant Klebsiella and E. coli	50 ml Mucoid, hemorrhagic secretions	Delirium
13	F	73	32 days post op for aortic dissection	Stenotrophomonas in sputum. Non-invasive ventilation		
14	F	69	AECOPD. Extreme weakness	Very resistant MRSA and Enterococcus	50-150 ml mucopurulent	Dysphagia
15	F	48	123 days post pulmonary embolism. Slightly obese	Klebsiella in sputum on non-invasive ventilation		
16	M	67	26 days intubated for pneumonia and AECOPD	Klebsiella oxytoca	500 ml watery	Dysphagia Delirium

**Figure 3.** Example of watery secretions collected (400-600ml daily) – Pat. # 7 in Table 1.

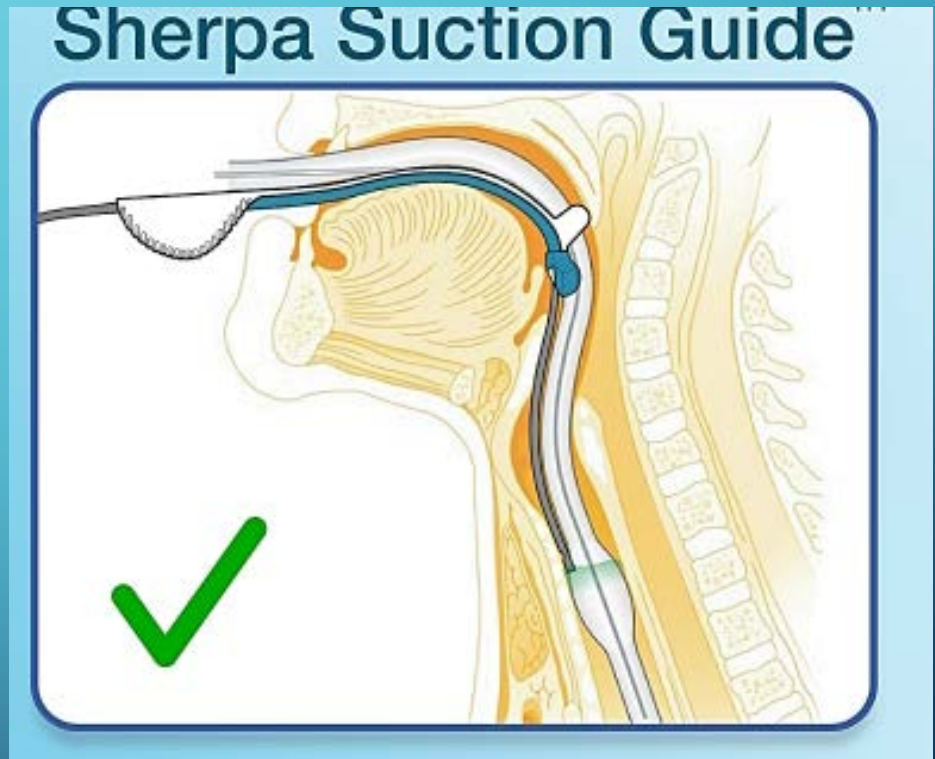


**Figure 4.** Example of watery secretions collected (500-1000ml daily) – Pat. # 9 in Table 1.



## Subglottic Automated Aspiration System

“Automated intermittent subglottic suctioning...offers a lower rate of VAP than manual and other methods, less endotracheal (bronchial) suctioning, less atelectasis, easier use of a speaking valve, shortened ICU stays, and lowers staff burden. Further studies and clinical evaluation of automated SSD are warranted.”



# Subglottic Automated Aspiration System

