Preventing Secondary Lung Infections in COVID 19 Patients: Implementing Evidence Based Practices to Save Lives

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Disclosures

- Consultant-Michigan Hospital Association Keystone Center
- Subject matter expert on CAUTI, CLABSI, HAPI, Sepsis, Safety culture for HRET/AHA
- Consultant and speaker bureau
 - \triangle Stryker's Sage business
 - \triangle LaJolla Pharmaceutical
 - \triangle Potrero Medical
 - △ Practical Hospital Services
- Baxter Advisory Board

Session Objectives

- Outline the problem of secondary bacterial infections in the COVID patient population
- Discuss key evidence based clinical intervention to prevent ventilator associated pneumonia
- Demonstrate the impact of new technology in reducing significant risk factors

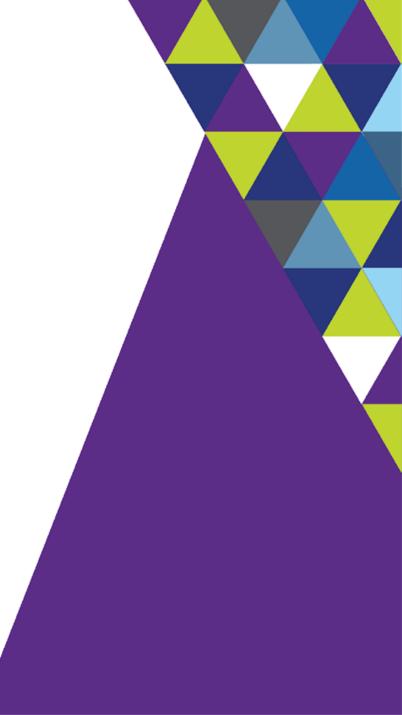


Notes on Hospitals: 1859

"It may seem a strange principle to enunciate as the very first requirement in a Hospital that it should do the sick no harm."

- Florence Nightingale





The Why







Ventilator Associated Pneumonia: Pre-Pandemic

- Rates in US: 1-2.5 cases per 1000 vent days
- Premier Database 2012-2019:
 - △ Ventilator hospital acquire ventilator pneumonia 25.6% (HAP requiring vent)
 - △ Ventilator associated bacterial pneumonia 47.9%
- VAP is associated with 个 MV days and 个 ICU & hospital LOS
- Attributable mortality estimated to be 4.0–13.5% (driven by underlying condition)
- Financial cost of a VAP \$19,325-\$80,013



TABLE 3.	Costs in a Matched Cohort of 2,144 Patients with Ventilator-Associated Pneumonia (VAP)
and 2,144	Patients without VAP	

	Cost, dollars,	mean \pm SD [*]			
Outcome type	With VAP	Without VAP	Р	Difference in dollars (%)	
Hospitalization	99,598 ± 86,359	59,770 ± 58,278	<.0001	39,828 (40.0)	
Nursing time	$3,369 \pm 16,487$	$2,980 \pm 14,109$.568	389 (11.5)	
Pharmacy	$14,345 \pm 16,992$	8,547 ± 14,497	<.0001	5,798 (40.4)	
Antibiotic	$1,947 \pm 4,095$	$1,011 \pm 2,039$	<.0001	936 (48.1)	
Vancomycin	$327~\pm~564$	$248~\pm~420$	<.0001	79 (24.2)	
Propofol for sedation	947 ± 1,768	585 ± 1,202	<.0001	362 (38.2)	
Ventilator	4,710 ± 6,251	2,184 ± 2,807	<.0001	2,526 (53.6)	
Ventilator in ICU	3,716 ± 4,479	$1,909 \pm 2,304$	<.0001	1,807 (48.6)	
Respiratory therapy	$2,650 \pm 4,007$	$1,496 \pm 2,539$	<.0001	1,154 (43.5)	
Chest x-rays	$1,762 \pm 1,594$	1,009 \pm 958	<.0001	753 (42.7)	

Cost, dollars, mean ± SD^a

NOTE. ICU, intensive care unit; SD, standard deviation.

^a Costs represent medical direct and indirect costs (not Medicare charges). Costs were not additive (eg, antibiotic and propofol costs were a subset of pharmacy costs).



Relationship Between COVID 19 infection & Incidence of Ventilator Associated Lower Respiratory Tract Infections

- Multicenter retrospective cohort/36 ICUs
- All patients MV > 48hrs, if had COVID 19 pneumonia, influenza pneumonia or no viral infection on admission
- Measured ventilator-lower respiratory tract infections (VA-LRTI) (VAT & VAP)
- 1576 patients: COVID 19: VA-LRTI 50%, Influenza; 30.3%, No viral: 25.3%

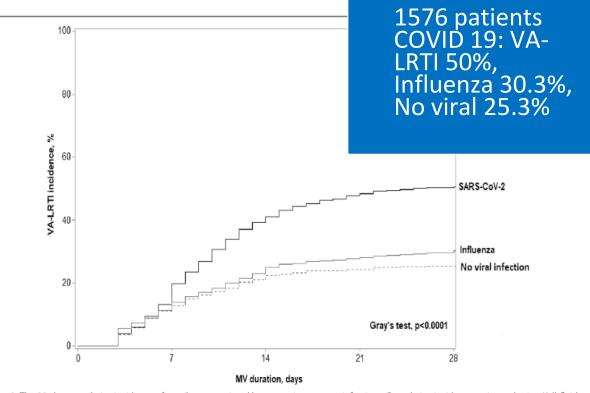
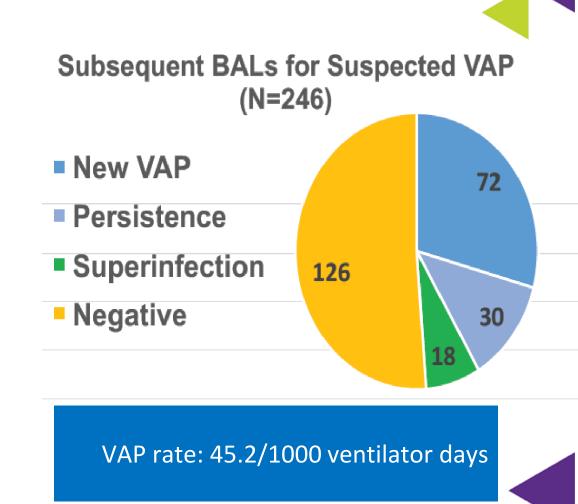


Fig. 1 The 28-day cumulative incidence of ventilator-associated lower respiratory tract infections. Cumulative incidence estimated using Kalbfleish and Prentice method, considering extubation (dead or alive) within 28 days as competing event. VA-LRTI ventilator-associated respiratory tract infection, MV mechanical ventilation

Bacterial Superinfection Pneumonia in COVID 19 Respiratory Failure

- Examined BAL samples from patients with COVID 19 pneumonia requiring mechanical ventilation
 - Sampled at time of intubation & identified episodes of VAP
- 179 ventilated patients (June 2020)
 - △ 90% 1 BAL procedure, 74.3% 48 hrs post intubation,
 62.6% at least 1 during hospitalization
- Results:
 - $\bigtriangleup~$ 44.4% of patients developed at least 1 VAP
 - \triangle 20.8% of initial VAP multidrug resistant pathogens



Significance of VAP in COVID Patients: A Systematic Review and Case Series

- Case series & systematic review (5 studies)
- COVID and Non COVID studies that measured VAP using the same methodology
- Outcome measures
 - △ Mortality during hospitalization
 - \triangle Secondary
 - Mortality at ICU
 - LOS
 - VAP
- Results: Mortality at 28 days

	COVID	-10	Non-COVII	D-19		Odds Ratio	Odds Ratio
Study or Subgroup	Events		Events	Total	Weight	M-H, Random, 95% CI	M-H, Random, 95% Cl
Hue 2020	13	38	4	36	17.1%	4.16 [1.21, 14.33]	_
Razazi 2020	36	82	25	82	34.1%	1.78 [0.94, 3.39]	
Rouze 2021	166	568	132	482	48.8%	1.09 [0.84, 1.43]	+
Total (95% CI)		688		600	100.0%	1.63 [0.87, 3.02]	P=.12
Total events	215		161				
Heterogeneity: Tau ²	= 0.19; C	hi ² = 5.	74, df = 2 (F	P = 0.06	$i); I^2 = 65$	%	
Test for overall effect	: Z = 1.5	4 (P = 0)).12)				0.1 0.2 0.5 1 2 5 10 Non-COVID-19 COVID-19

	COVID	-19	Non-COV	D-19		Odds Ratio	Odds Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% CI	M-H, Random, 95% CI
Hue 2020	29	38	15	36	13.9%	4.51 [1.66, 12.25]	
Luyt 2020	43	50	28	45	13.9%	3.73 [1.37, 10.14]	
Maes 2021	39	81	19	144	20.8%	6.11 [3.19, 11.71]	
Razazi 2020	58	90	36	82	21.7%	2.32 [1.25, 4.28]	P=.0001
Rouze 2021	205	568	107	482	29.7%	1.98 [1.50, 2.60]	- P0001
Total (95% CI)		827		789	100.0%	3.17 [1.94, 5.18]	•
Total events	374		205				
Heterogeneity: Tau ²	= 0.19; Cl	$hi^2 = 13$	2.04, df = 4	(P = 0.0)	(2); $I^2 = 6$	7%	
Test for overall effect	t: Z = 4.60	0 (P < 0	0.00001)				0.1 0.2 0.5 1 2 5 10 Non-COVID-19 COVID-19

26%

45%

VAP Rates

ICU Mortality

COVID	-19	Non-COVI	D-19		Odds Ratio	Odd	Is Ratio
Events	Total	Events	Total	Weight	M-H, Fixed, 95% Cl	M-H, Fiz	xed, 95% CI
14	38	7	36	3.2%	2.42 [0.84, 6.95]		+ · · ·
17	50	18	45	8.8%	0.77 [0.34, 1.78]		
31	81	30	144	9.4%	2.36 [1.29, 4.30]		
37	82	27	82	10.5%	1.67 [0.89, 3.16]		P=.0
164	568	125	482	68.0%	1.16 [0.88, 1.52]		+
	819		789	100.0%	1.33 [1.07, 1.66]		•
263		207					
7.80, df	= 4 (P)	= 0.10); I ² =	= 49%				
Z = 2.59	9 (P = 0	0.010)				Non-COVID-19	1 2 5 10 COVID-19
						26.3%	32.1%
	Events 14 17 31 37 164 263 7.80, df	Events Total 14 38 17 50 31 81 37 82 164 568 819 263 7.80, df = 4 (P	Events Total Events 14 38 7 17 50 18 31 81 30 37 82 27 164 568 125 819 207	Events Total Events Total 14 38 7 36 17 50 18 45 31 81 30 144 37 82 27 82 164 568 125 482 819 709 789 263 207 7.80, df = 4 (P = 0.10); l ² = 49% 49% 49%	Events Total Events Total Weight 14 38 7 36 3.2% 17 50 18 45 8.8% 31 81 30 144 9.4% 37 82 27 82 10.5% 164 568 125 482 68.0% 263 207 789 100.0% 263 207 7.80, df = 4 (P = 0.10); l ² = 49% 500	Events Total Events Total Weight M-H, Fixed, 95% CI 14 38 7 36 3.2% 2.42 [0.84, 6.95] 17 50 18 45 8.8% 0.77 [0.34, 1.78] 31 81 30 144 9.4% 2.36 [1.29, 4.30] 37 82 27 82 10.5% 1.67 [0.89, 3.16] 164 568 125 482 68.0% 1.16 [0.88, 1.52] 819 789 789 100.0% 1.33 [1.07, 1.66] 263 207 249% 1.33 [1.07, 1.66]	Events Total Events Total Weight M-H, Fixed, 95% Cl M-H, Fixed, 95% Cl 14 38 7 36 3.2% 2.42 [0.84 , 6.95] 1 17 50 18 45 8.8% 0.77 [0.34 , 1.78]

Lukasz L, et al in press

Impact of COVID on HAI's in 2020 Compared to 2019: Data from NHSN

	2020 Q1	2020 Q2	2020 Q3	2020 Q4
CLABSI	-11.8%	27.9%	16.4%	47.0%
CAUTI	-21.3%	No Change ¹	12.7%	18.8%
VAE	11.3%	1 33.7%	1 29.0%	44.8%
SSI: Colon surgery	-9.1%	No Change ¹	-6.9%	-8.3%
SSI: Abdominal hysterectomy	-16.0%	No Change ¹	No Change ¹	-13.1%
Laboratory-identified MRSA bacteremia	-7.2%	12.2%	22.5%	133.8%
Laboratory-identified CDI	-17.5%	-10.3%	-8.8%	-5.5%

Weiner-Lastinger LM, Pattabiraman V, Konnor RY, et al. The impact of coronavirus disease 2019 (COVID-19) on healthcare-associated infections in 2020: A summary of data reported to the National Healthcare Safety Network. *Infection Control & Hospital Epidemiology*. 2021:1-14. doi:10.1017/ice.2021.362

What to Remember

- All patients with SARS-CoV-2 are at increased risk of bacterial infections
- 2. Infections in COVID-19 patients are often antibiotic resistant
- 3. The risk of bacterial infections is concentrated in the critically ill and mechanically ventilated population.
- 50% of mechanically ventilated COVID-19 patients contract Ventilator-Associated Pneumonia (VAP)
- 2. COVID-19 + VAP = Increased Mortality
- Thus VAP prevention in COVID-19 patients = decreased mortality



Risk Factor Categories for Hospital Acquired Pneumonia

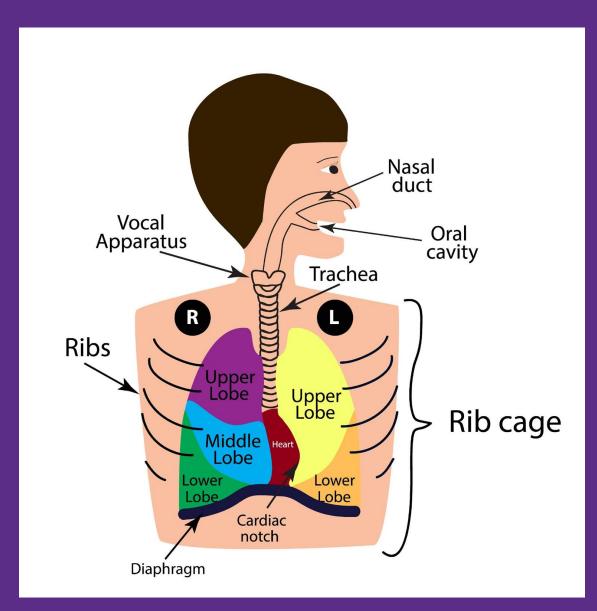
- Factors that increase bacterial burden or colonization
- Factors that increase risk of aspiration



Single Ecosystem

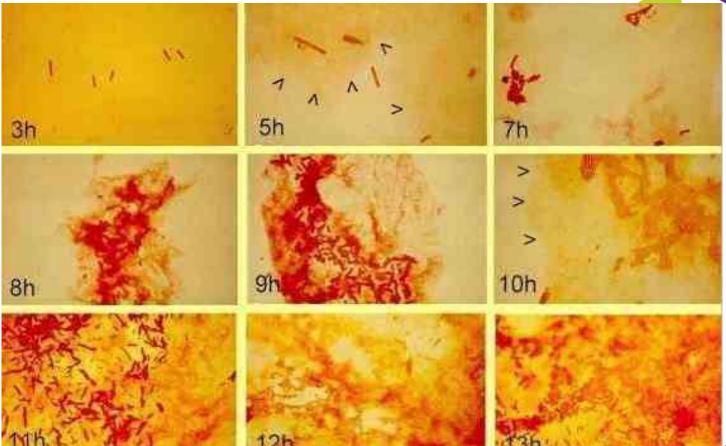
- Entire respiratory tract is one ecosystem
 - △ Upper-nasal and oral cavities
 - \triangle Lower-alveoli
- Not sterile environment
- Oral flora changes in hospitalized patients
- Relationship between dental plaque and pulmonary lavage fluid

Huffnagle GB, et al. Mucosal Immunol. 2017 Mar;10(2):299-306 Johanson WG, et al. N Engl J Med. 1969 Nov 20;281(21):1137-40 Heo SM, et al. Clin Infect Dis. 2008 Dec 15;47(12):1562-70.

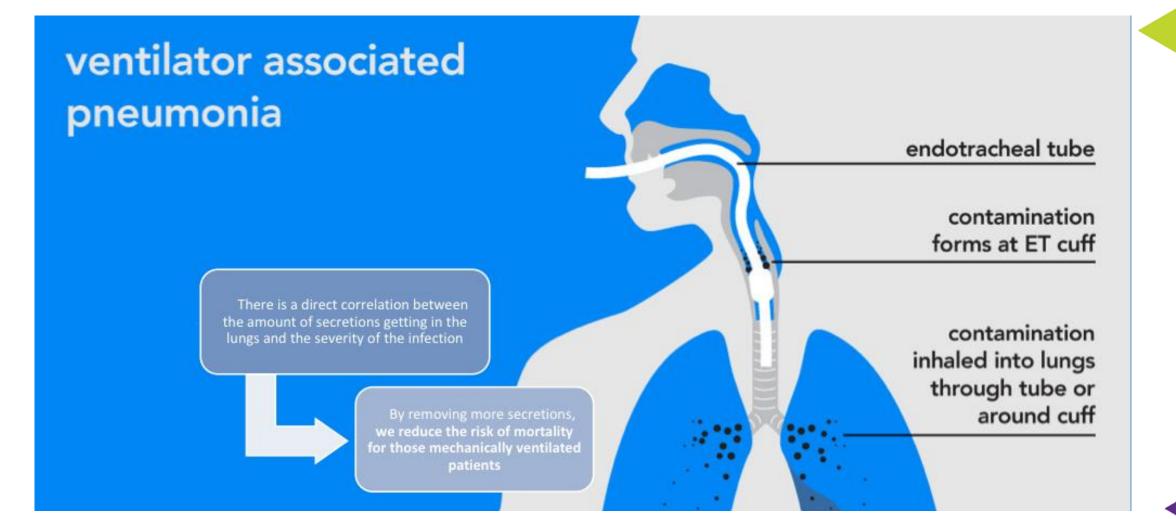


Where does Pneumonia Start: Oral Bacteria during Hospitalization & Illness

- Oral cavity
 - \triangle > 1 billion oral microbes
 - △ 700-1000 species
 - \triangle Replicate's 5 x in 24hr period
- Disruption of Microbiome
 - △ Plaque, gingivitis, tooth decay
 - △ Reduced salivary flow/change in pH
- 24-48 hours for HAP pathogens in mouth
- If aspirated =100,000,000 bacteria/ml saliva into lungs



What to Remember





Building Blocks to Best Practice in Caring for Mechanically Ventilated Patients

Ventilator Bundle: HOB 30, Deep Vein Thrombosis (DVT) prophylaxis, Peptic Ulcer Disease (PUD) prophylaxis, Sedation interruption, Spontaneous breathing trial, daily care with chlorhexidine





VAP Bundle: HOB 30, Sedation interruption, Spontaneous breathing trial, oral care 6x per day, CHG rinse 2x per day, subglottic secretions drainage if expected to be ventilated > 72hrs



Micro Aspiration during Sleep in Healthy Subjects

- Prospective duplicate full-night studies
- 10 normal male's 22-55 years of age
- Methods:
 - Radioactive 99 mTc tracer inserted into the nasopharynx
 - Lung scans following final awakening
 - No difference in sleep efficacy between 2 study nights
- Results:



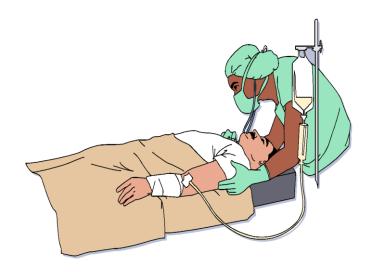
In the lung parenchyma



Body Position: Supine versus Semi-recumbent (30-45 degrees)

Methodology

- 19 mechanically ventilated patients
- 2 period crossover trial
- Study supine and semirecumbent positions over 2 days
- Labeled gastric contents (Tc 99m sulphur colloid)
- Measured q 30 min content of gastric secretions in endobronchial tree in each position
- Sampled ET secretions, gastric juice & pharyngeal contents for bacteria





Body Position: Supine versus Semi-recumbent

Results:

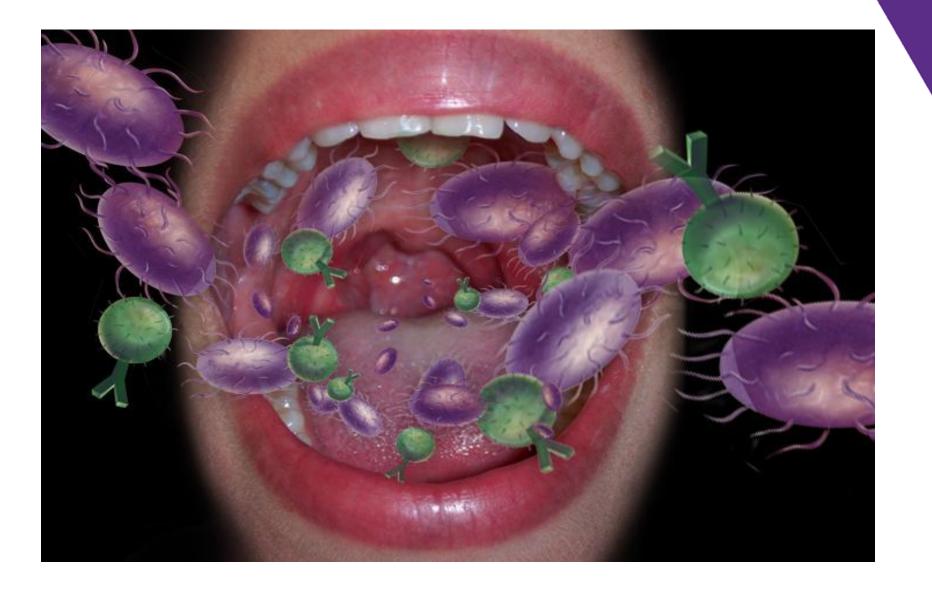
- Radioactive contents higher in endobronchial secretions in supine patients
- Time dependent:
 - Supine: 298cpm/30min vs.
 2592cpm/300min
 - HOB: 103cpm/30min vs.
 216cpm/300min



Same microbes cultured in all 3 areas

- HOB: 32%
- Supine: 68%

Oral Hygeine





What Does the Evidence Tell Us?

Brush CHG rinse alone CHG rinse in Combination Swab/Clean/Moisturize Suction

All of the above

Comprehensive Oral Care Program

Literature Review: Oral Care Impact of VAP

Comprehensive Oral Care:

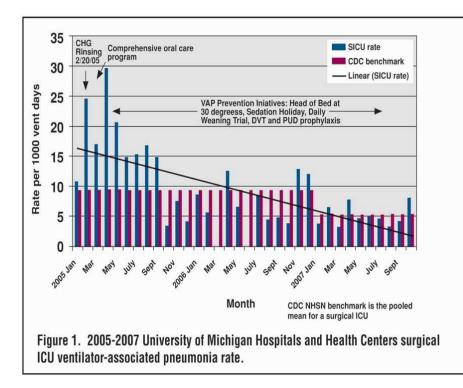
- Reduction in VAP from 5.6 to 2.2 (Schleder B. et al. J Advocate Health 2002;4(1):27-30)
- Reduction in VAP from 4.10 (2005) to (2.15) in 2006 with addition of CPC & comprehensive oral care. Vent bundle & rotational therapy already being performed
- Reduction in VAP from 12.0 to 8.0 (p=.060) with 80% compliance, vent bundle already being preformed, 1538 patients randomized to control or study group, Additional outcomes; vent days (p=.05), ICU LOS (p=.05) time to VAP (p= <.001) & reduction in mortality (p=.05) (Garcia R et al AJCC, 2009;18:523-534)



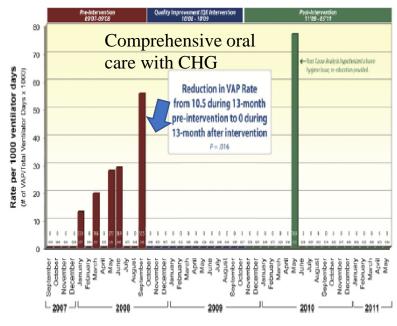
Literature Review: Oral Care Impact of VAP

Comprehensive Oral Care & CHG:

• Reduction in VAP to zero for 2 years, vent bundle, mobility, oral care & CHG with comprehensive education preformed (Murray TM et al. AACN Advanced Critical Care. 2007;18(2):190-199)



Dickinson S et al. SCCM Critical Connections, 02/2008



Ventilator-Associated Pneumonia

Heck K, et al. American Journal of Infection Control 40 (2012) 877-9

Does CHG Oral Care Impact VAP and Mortality

- Klompas Study-Retrospective review
 - \triangle Single center
 - △ Impact of vent bundle (5536 patients)
 - △ Connection of CHG with increase mortality on patients vented > 3 days

- Deschepper study: Retrospective Review
 - △ Hospital wide retrospective cohort (82,274 patients)
 - △ 11,133 patients received CHG oral care
 - △ Divided into low exposure-cumulative dose < 300 mg (8080 pts)
 - \triangle High exposure > 300 mg (3053 pts)
 - △ 300 mg CHG is equivalent to 1 bottle of 250ml of oral care soln at .12%-covers 5-6 days at 3 times a day)
- In the sickest group CHG low or high exposure was not a risk for increased mortality
- Showed improvement on mortality in ICU patients ventilated < 96hrs and not harm if vented > 96 hrs
- Greatest risk for mortality increase is use in non-ICU patients.

Cochrane Meta-Analysis 2020 of RCT's

NNT

12

Analysis 1.1. Comparison 1: Chlorhexidine versus placebo/usual care, Outcome 1: Incidence of VAP

	CHIOTHE	xidine	Placebo/Us	ual care		Risk Ratio	Risk Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% CI	M-H, Random, 95% CI
1.1.1 Chlorhexidine solution	versus placel	oo (no tool	hbrushing in	either gro	1p)		
Fu 2019	7	40	37	40	9.0%	0.19 [0.10 , 0.37]	_ _
Meidani 2018	6	50	15	50	7.6%	0.40 [0.17, 0.95]	
Grap 2011 (1)	7	21	10	18	8.6%	0.60 [0.29 , 1.25]	
Ozcaka 2012	12	29	22	32	10.6%	0.60 [0.37, 0.98]	
Bellissimo-Rodrigues 2009	16	64	17	69	9.7%	1.01 [0.56 , 1.83]	
Tuon 2017	4	8	2	8	4.5%	2.00 [0.50 , 8.00]	
Subtotal (95% CI)		212		217	50.0%	0.57 [0.33, 1.00]	
Total events:	52		103				•
Heterogeneity: Tau ² = 0.33; Cl	hi² = 17.96, df	= 5 (P = 0	.003); I ² = 72 ⁴	16			
Test for overall effect: Z = 1.9	7 (P = 0.05)						
1.1.2 Chlorhexidine gel versu	as placebo (no	o toothbru	shing in eith	er group)			
Cabov 2010	1	17	6	23	2.6%	0.23 [0.03 , 1.70]	
Koeman 2006	13	127	23	130	9.4%	0.58 [0.31, 1.09]	
Subtotal (95% CI)		144		153	12.0%	0.53 [0.29, 0.97]	•
Total events:	14		29				•
Heterogeneity: Tau ² = 0.00; Cl	hi² = 0.77, df =	= 1 (P = 0.3	8); I ² = 0%				
Test for overall effect: Z = 2.0	4 (P = 0.04)						
1.1.3 Chlorhexidine solution	versus placel	oo (toothb:	rushing both	groups)			
Tantipong 2008	5	58	10	52	6.6%	0.45 [0.16 , 1.23]	
Scannapieco 2009 (2)	14	97	12	49	8.9%	0.59 [0.30 , 1.18]	
Beny 2011 (3)	4						
	4	33	1	43	2.4%	5.21 [0.61 , 44.47]	-
	4	33 188	1	43 144	2.4% 17.8%	- 1 -	
Subtotal (95% CI) Total events:	4 23		1 23			5.21 [0.61 , 44.47]	•
Subtotal (95% CI) Total events:	23	188	23			5.21 [0.61 , 44.47]	•
Subtotal (95% CI) Total events: Heterogeneity: Tau ² = 0.36; Cl	23 hi ^z = 4.30, df =	188	23			5.21 [0.61 , 44.47]	•
Subtotal (95% CI) Total events: Heterogeneity: Tau ² = 0.36; CI Test for overall effect: Z = 0.6	23 hi ^z = 4.30, df = 4 (P = 0.53)	188 = 2 (P = 0.1	23 2); I² = 53%	144		5.21 [0.61 , 44.47]	
Subtotal (95% CI) Total events: Heterogeneity: Tau ² = 0.36; CI Test for overall effect: Z = 0.6 1.1.4 Chlorhexidine gel versu	23 hi ^z = 4.30, df = 4 (P = 0.53)	188 = 2 (P = 0.1	23 2); I² = 53%	144		5.21 [0.61 , 44.47]	
Sublotal (95% CI) Total events: Heterogeneity: Tau ² = 0.36; CI Test for overall effect: Z = 0.6 1.1.4 Chlorhexidine gel versu Kusahara 2012a (4)	23 hi² = 4.30, df = 4 (P = 0.53) us placebo (to	188 = 2 (P = 0.1 othbrushi	23 2); I ² = 53% ng both grou	144 ps)	17.8%	5.21 [0.61 , 44,47] 0.74 [0.29 , 1.89] 1.02 [0.57 , 1.82]	
Subiotal (95% CI) Total events: Heterogeneity: Tau ² = 0.36; Cl Test for overall effect: Z = 0.6 1.1.4 Chlorhexidine gel versu Kusahara 2012a (4) Meinberg 2012	23 hi ^z = 4.30, df = 4 (P = 0.53) us placebo (to 15	188 = 2 (P = 0.1 othbrushi 46	23 2); I ² = 53% ng both grou 16	144 ps) 50	17.8% 9.8%	5.21 [0.61, 44,47] 0.74 [0.29, 1.89] 1.02 [0.57, 1.82] 1.40 [0.84, 2.35]	
Subiotal (95% CI) Total events: Heterogeneity: Tau ² = 0.36; Cl Test for overall effect: Z = 0.6 1.1.4 Chlorhexidine gel versu Kusshara 2012a (4) Meinberg 2012 Subiotal (95% CI)	23 hi ^z = 4.30, df = 4 (P = 0.53) us placebo (to 15	188 = 2 (P = 0.1 othbrushi 46 28	23 2); I ² = 53% ng both grou 16	144 ps) 50 24	17.8% 9.8% 10.4%	5.21 [0.61 , 44,47] 0.74 [0.29 , 1.89] 1.02 [0.57 , 1.82]	
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Subtotal (95% CI) Total events: Heterogeneity: Tau ² = 0.36; CI Test for overall effect: Z = 0.6	23 hi ^z = 4.30, df = 4 (P = 0.53) us placebo (to 15 18 33 hi ^z = 0.67, df =	188 = 2 (P = 0.1 othbrushi 46 28 74	23 2); I ² = 53% ng both grou 16 11 27	144 ps) 50 24	17.8% 9.8% 10.4%	5.21 [0.61, 44,47] 0.74 [0.29, 1.89] 1.02 [0.57, 1.82] 1.40 [0.84, 2.35]	
Subtotal (95% CI) Total events: Heterogeneity: Tau ² = 0.36; CI Test for overall effect: Z = 0.6 1.1.4 Chlorhexidine gel versi Kusahara 2012a (4) Meinberg 2012 Subtotal (95% CI) Total events: Heterogeneity: Tau ² = 0.00; CI	23 hi ^z = 4.30, df = 4 (P = 0.53) us placebo (to 15 18 33 hi ^z = 0.67, df =	188 = 2 (P = 0.1 othbrushi 46 28 74	23 2); I ² = 53% ng both grou 16 11 27	144 ps) 50 24 74	17.8% 9.8% 10.4%	5.21 [0.61, 44,47] 0.74 [0.29, 1.89] 1.02 [0.57, 1.82] 1.40 [0.84, 2.35]	
Subiotal (95% CI) Total events: Heterogeneity: Tau ² = 0.36; CI Test for overall effect: Z = 0.6 1.1.4 Chlorthexidine gel versu Kusahara 2012a (4) Meinberg 2012 Subiotal (95% CI) Total events: Heterogeneity: Tau ² = 0.00; CI Test for overall effect: Z = 1.0	23 hi ^z = 4.30, df = 4 (P = 0.53) us placebo (to 15 18 33 hi ^z = 0.67, df =	188 = 2 (P = 0.1 othbrushi 46 28 74 = 1 (P = 0.4	23 2); I ² = 53% ng both grou 16 11 27	144 ps) 50 24 74	9.8% 10.4% 20.2%	5.21 [0.61, 44,47] 0.74 [0.29, 1.89] 1.02 [0.57, 1.82] 1.40 [0.84, 2.35] 1.22 [0.83, 1.79]	
Subiotal (95% CI) Total events: Heterogeneity: Tau ² = 0.36; CI Test for overall effect: Z = 0.6 1.1.4 Chlorhexidine gel versu Kusahara 2012a (4) Meinberg 2012 Subtotal (95% CI) Total events: Heterogeneity: Tau ² = 0.00; CI Test for overall effect: Z = 1.0 Total (95% CI) Total events:	23 hi ² = 4.30, df = 4 (P = 0.53) us placebo (to 15 18 hi ² = 0.67, df = 0 (P = 0.32) 122	188 = 2 (P = 0.1 othbrushi 46 28 74 = 1 (P = 0.4 618	23 2); T ² = 53% ng both grou 16 11 :1); T ² = 0% 182	144 ps) 50 24 74 588	9.8% 10.4% 20.2%	5.21 [0.61, 44,47] 0.74 [0.29, 1.89] 1.02 [0.57, 1.82] 1.40 [0.84, 2.35] 1.22 [0.83, 1.79]	
Subiotal (95% CI) Total events: Heterogeneity: Tau ² = 0.36; CI Test for overall effect: Z = 0.6 1.1.4 Chlorthexidine gel versu Kusahara 2012a (4) Meinberg 2012 Subtotal (95% CI) Total events: Heterogeneity: Tau ² = 0.00; CI Test for overall effect: Z = 1.0 Total (95% CI)	23 hi ² = 4.30, df = 4 (P = 0.53) 15 18 hi ² = 0.67, df = 0 (P = 0.32) 122 hi ² = 35.29, df	188 = 2 (P = 0.1 othbrushi 46 28 74 = 1 (P = 0.4 618	23 2); T ² = 53% ng both grou 16 11 :1); T ² = 0% 182	144 ps) 50 24 74 588	9.8% 10.4% 20.2%	5.21 [0.61, 44,47] 0.74 [0.29, 1.89] 1.02 [0.57, 1.82] 1.40 [0.84, 2.35] 1.22 [0.83, 1.79] 0.67 [0.47, 0.97]	0.02 0.1 Favours placebo'u c

Analysis 3.1. Comparison 3: Toothbrushing versus no toothbrushing, Outcome 1: Incidence of VAP

	Toothbr	ushing	No toothb:	rushing		Risk Ratio	Risk Ratio
tudy or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% CI	M-H, Random, 95% CI
.1.1 Powered toothbru	ısh + usual	care (± CI	IX) versus u	isual care ((± CHX)		
obo 2009 (1)	15	74	18	73	23.5%	0.82 [0.45 , 1.50]	-
ao 2011 (2)	4	28	14	25	12.7%	0.26 [0.10 , 0.67]	
ubtotal (95% CI)		102		98	36.2%	0.49 [0.16 , 1.53]	-
otal events:	19		32				•
leterogeneity: Tau ² = 0.	52; Chi ² = 4	1.05, df = 1	(P = 0.04); I	² = 75%			
est for overall effect: Z	= 1.23 (P =	0.22)					
.1.2 Toothbrush + CH	X versus C	HX alone					
orente 2012	21	217	24	219	25.7%	0.88 [0.51 , 1.54]	-
e Lacerda 2017	17	105	28	108	26.4%	0.62 [0.36 , 1.07]	
ubtotal (95% CI)		322		327	52.1%	0.74 [0.50 , 1.09]	•
otal events:	38		52				•
eterogeneity: Tau ² = 0.	.00; Chi ² = 0).77, df = 1	(P = 0.38); I	² = 0%			
est for overall effect: Z	= 1.53 (P =	0.13)					
.1.3 Toothbrush + pov	idone iodin	ie versus p	ovidone iodi	ne alone			
ong 2012	4	31	11	30	11.6%	0.35 [0.13 , 0.98]	
ubtotal (95% CI)		31		30	11.6%	0.35 [0.13, 0.98]	-
otal events:	4		11				-
leterogeneity: Not appl	icable						
est for overall effect: Z	= 1.99 (P =	0.05)					
otal (95% CI)		455		455	100.0%	0.61 [0.41 , 0.91]	
otal events:	61		95				
leterogeneity: Tau ² = 0.	.08; Chi ² = 6	5.71, df = 4	(P = 0.15); I	² = 40%			0.01 0.1 1 10
est for overall effect: Z	= 2.44 (P =	0.01)					Toothbrushing No toothbru
est for subgroup differe	ances: Chi ² :	= 2 03 df =	= 2 (P = 0.36)	P = 1.5%			

Analysis 1.2. Comparison 1: Chlorhexidine versus placebo/usual care, Outcome 2: Mortality

	Chlorhe	xidine	Placebo/us	ual care		Risk Ratio	Risk Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% (CI M-H, Random, 95% CI
1.2.1 Chlorhexidine solution	versus placel	bo (no tool	thbrushing in	either gro	up)		
Bellissimo-Rodrigues 2009	. 34	64	32	69	30.1%	1.15 [0.81 , 1.	61]
Ozcaka 2012	17	29	19	32	20.1%	0.99 [0.65, 1.	50]
Meidani 2018	4	50	5	50	2.2%	0.80 [0.23 , 2.	81]
Fu 2019	3	40	7	40	2.2%	0.43 [0.12, 1.	54]
Subtotal (95% CI)		183		191	54.6%	1.03 [0.80 , 1.	33]
Total events:	58		63				
Heterogeneity: Tau ² = 0.00; Ch	ni² = 2.46, df =	= 3 (P = 0.4	48); I ² = 0%				
Test for overall effect: Z = 0.21	l (P = 0.83)						
1.2.2 Chlorhexidine gel versu	is placebo (ni	o toothbru	shing in eith	er group)			
Cabov 2010	0	17	0	23		Not estima	ble
Subtotal (95% CI)		17		23		Not estima	ble
Total events:	0		0				
Heterogeneity: Not applicable							
Test for overall effect: Not app	licable						
1.2.3 Chlorhexidine solution	versus placel	be (toothb	rushing both	groups)			
Tantipong 2008	36	102	37	105	25.9%	1.00 [0.69 , 1.	45] _
Scannapieco 2009	16	116	8	59	5.7%		-
Subtotal (95% CI)		218		164	31.6%	1.00 [0.72 , 1.	40] 🔶
Total events:	52		45				
Heterogeneity: Tau ² = 0.00; Ch		= 1 (P = 0.9)	97); I² = 0%				
Test for overall effect: $Z = 0.03$	3 (P = 0.98)						
1.2.4 Chlorhexidine gel versu	• •	othbrushi	ng both grou	ips)			
Kusahara 2012a (1)	8	46	12	50	5.5%	0.72 [0.33 , 1.	61]
Meinberg 2012	13	28	9	24	8.3%	1.24 [0.65 , 2.	38]
Subtotal (95% CI)		74		74	13.8%	1.00 [0.59 , 1.	68] 🔶
Total events:	21		21				
Heterogeneity: Tau ² = 0.01; Ch		= 1 (P = 0.3)	30); I ² = 6%				
Test for overall effect: Z = 0.01	1 (P = 0.99)						
Total (95% CI)		492		452	100.0%	1.02 [0.84 , 1.	23]
Total events:	131		129				
Heterogeneity: Tau ² = 0.00; Ch	ni² = 3.50, df :	= 7 (P = 0.8	34); I ² = 0%				0.002 0.1 1 10 500
Test for overall effect: Z = 0.17	7 (P = 0.86)					:	Favours chlorhexidine Favours placebo/u
Test for subgroup differences:	Chi ² = 0.02, d	if = 2 (P =)	0.99), I ² = 0%				

Impact on Mortality

It is More than CHG

- .12% CHG application 2x daily is a small part of the oral care equation
- It is the comprehensive and frequent delivery of oral hygiene, including toothbrushing and cleansing



SUP: Impact on Bleeding Risk

Comparison		Odds Ratio (95% CI)
H2RA vs Placebo Direct Indirect Network		0.53 (0.23, 1.19) 1.36 (0.29, 6.51) 0.64 (0.32, 1.30)
PPI vs H2RA Direct Indirect Network	▶ ▶ - 8 - 1 ▶ ▶ - 8 - 1	0.35 (0.18, 0.69) 0.86 (0.11, 7.02) 0.38 (0.20, 0.73)
H2RA vs Sucralifate Direct Indirect Network	►	0.86 (0.48, 1.55) 0.32 (0.04, 2.67) 0.80 (0.46, 1.40)
PPI vs Placebo Direct Indirect Network		0.66 (0.12, 3.74) 0.17 (0.06, 0.49) 0.24 (0.10, 0.60)
Sucralfate vs Placebo Direct Indirect Network		1.15 (0.41, 3.23) 0.48 (0.14, 1.64) 0.80 (0.37, 1.73)
PPI vs Sucraifate Direct Indirect Network		0.23 (0.02, 2.30) 0.32 (0.13, 0.76) 0.30 (0.13, 0.69)
	0.01 0.05 0.1 0.5 1 5	

Alhazzani W, et al. Intensive Care Med (2018) 44:1–11

SUP: Impact on Risk of Pneumonia

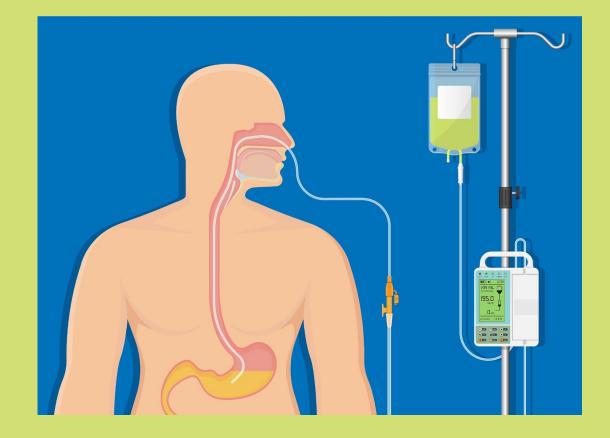
Comparison		Odds Ratio (95% CI)
H2RA vs Placebo Direct Indirect Network	┝────₽────┤ ┝────₽───┤	1.09 (0.70, 1.71) 1.94 (0.73, 5.20) 1.19 (0.80, 1.78)
PPI vs H2RA Direct Indirect Network	┝╌╼╌┙ ┝──╼╌┙	1.15 (0.85, 1.57) 2.10 (1.04, 4.21) 1.27 (0.96, 1.68)
H2RA vs Sucralifate Direct Indirect Network		1.32 (0.98, 1.77) 1.35 (0.64, 2.86) 1.30 (1.08, 1.58)
PPI vs Placebo Direct Indirect Network		1.48 (0.55, 3.99) 1.53 (0.90, 2.59) 1.52 (0.95, 2.42)
Placebo vs Sucralfate Direct Indirect Network		0.67 (0.34, 1.32) 1.54 (0.84, 2.80) 1.09 (0.72, 1.66)
PPI vs Sucralifate Direct Indirect Network		2.16 (1.24, 3.77) 1.44 (0.97, 2.14) 1.65 (1.20, 2.27)
	0.5 1	5

Alhazzani W, et al. Intensive Care Med (2018) 44:1–11



Treat patients at high risk of stress bleed?

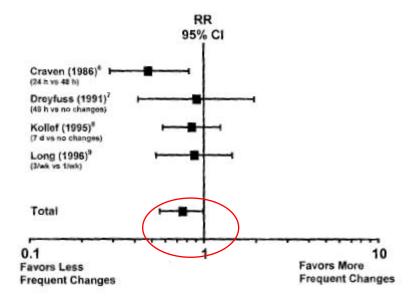
Huang HB, e tal. Crit Care. 2018;22:20 This Photo by Unknown Author is licensed under <u>CC BY-SA</u>



Receiving EN, pharmacologic SUP offered no beneficial effect GI bleeding and other clinically important outcomes.

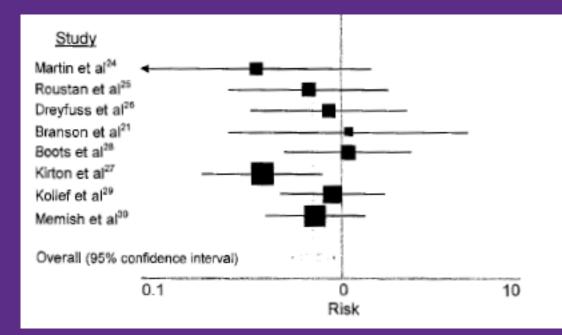
Strategies to Reduce VAP

Heat Wire Exchange vs Humidifier



Kola A. Intensive Care Med, 2005;31(1):5-11. Gillies D, et al. Cochrane Database Systematic Review 2017;9:CD004711 Hess DR et al, Respir Care 2003;48(9):869-879

Ventilator Circuit Change

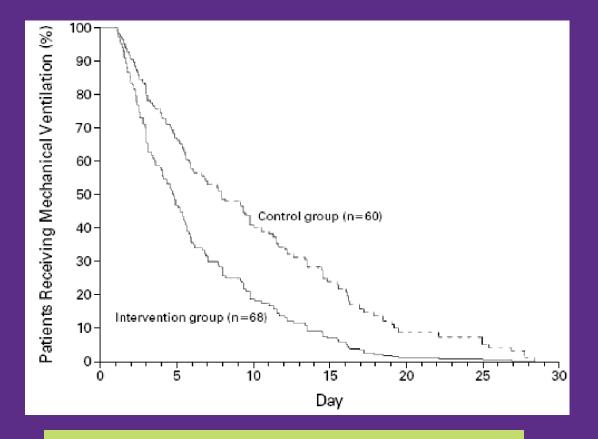


Some benefit on pneumonia prevention/no difference in airway occlusion

Daily Sedation Interruption Decreases Duration of Mechanical Ventilation

- Hold sedation infusion until patient ٠ awake, then restart at 50% of prior dose
- "Awake" defined as any 3 of the following:
 - Open eyes in response to voice

Use eyes to follow investigator on request Squeeze hand on request Stick out tongue on request



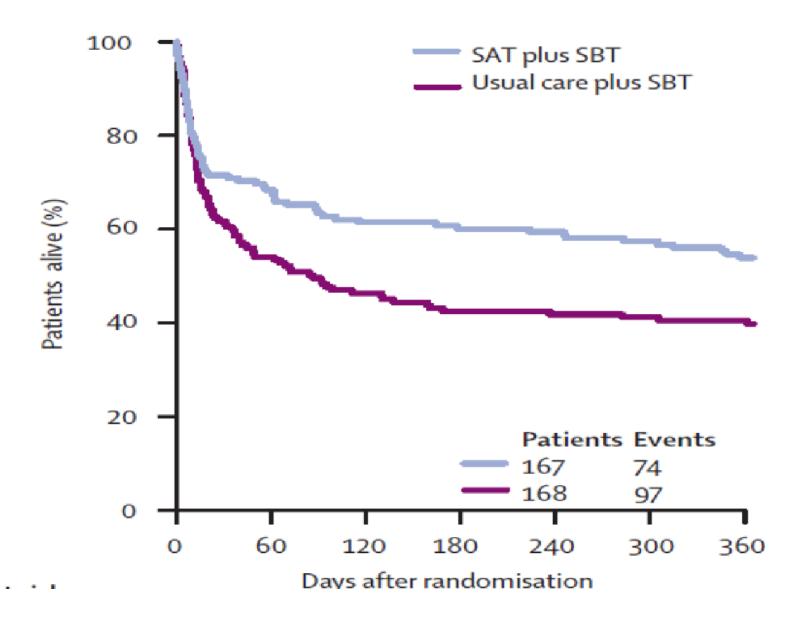
- Length of MV 4.9 vs. 7.3 days (P=0.004) lacksquare
- ICU LOS 6.4 vs. 9.9 days (P=0.02)
- Fewer diagnostic tests to assess changes in ۲ mental status
- No increase in rate of agitated-related ۲ complications or episodes of patientinitiated device removal
- No increase in PTSD or cardiac ischemia •

ABC Trial (RCT Paired Sedation & Vent Weaning Protocols)

Outcome*	SBT	SAT+SBT	P value
Ventilator-free days	12	15	0.02
Time-to-event, days			
Successful extubation, days	7.0	5	0.05
ICU discharge, days	13	9	0.02
Hospital discharge, days	19	15	0.04
Death at 1 year, n (%)	97 (58%)	74 (44%)	0.01
Days of brain dysfunction			
Coma	3.0	2.0	0.002
Delirium	2.0	2.0	0.50
*Median, except as noted			

Girard, et al, Lancet. 2008;371:126-34

ABC Trail: Mortality at 1 Year

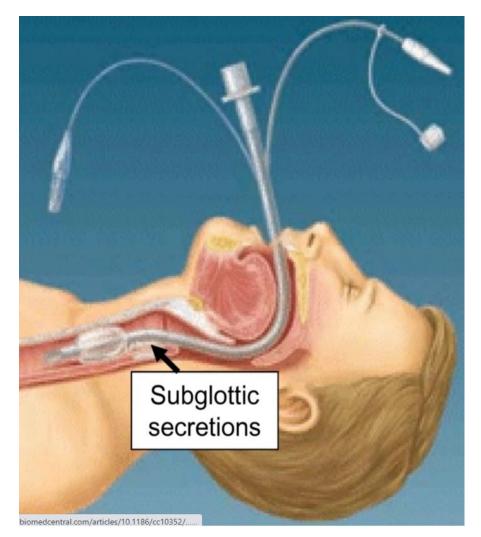




Endotracheal / Nasogastric Tube/ Sinusitis

- Carriage of oropharyngeal bacteria during intubation
- If cuff pressure < 20 cm 4x 🛛 risk VAP
 - △ Cuff pressure range btwn 25-40cm (JBI-Level A) with maintenance at 25cm-30cm of H2O pressure.
 - △ No difference between freq & infrequent measurement
 - \bigtriangleup Continuous monitoring resulted in a lower portion of out-of-range cuff pressure (11% vs. 51.7% p< 0.001) and $\downarrow in$ VAP
- Use oral ET versus nasal (CDC-Cat IB)
 - \triangle NGT increases risk of sinusitis/gastric reflux & increases or pharyngeal colonization
 - \triangle Sinusitis increases the risk of nosocomial pneumonia by 3-fold

Current Subglottic Suctioning Endotracheal Tubes



Subglottic suctioning ETTs in patients mechanically ventilated for >72 hours

Results of Subglottic Suctioning Study

	Suction Group 1 (n=170)	No Suction Group 2 (n=182)
VAP	8.8%, 15 patients	17.6%, 32 patients
VAP by vent days	9.6 of 1000 days	19.8 of 1000 days
VAC	21.8%	22.5%
Antibiotic days	61% 1696 of 2754 days	68.5% 1965 of 2868 days

Damas P, et al. Crit Care Med. 2015 Jan;43(1):22-30.

Subglottic Secretion Drainage: Meta-analysis

- Results
 - Shorten vent days
 1.55
 - Prolonged VAP by 4 days
 - ISSD may result in less mucosal injury

	SSD		Contr			Risk Ratio	Risk Ratio
Study or Subgroup		Total	Events	Total	Weight	M-H, Fixed, 95% CI	M-H, Fixed, 95% Cl
1.1.1 intermittent SSE)						
Lacherade 2010	25	169	42	164	23.1%	0.58 [0.37, 0.90]	
Mahul 1992	9	70	21	75	11.0%	0.46 [0.23, 0.93]	
Smulders 2002	3	75	12	75	6.5%	0.25 [0.07, 0.85]	
Subtotal (95% CI)		314		314	40.6%	0.49 [0.34, 0.71]	
Total events	37		75				
Heterogeneity: Chi ² = 1	1.71, df = 2	? (P = 0).43); I² =	0%			
Test for overall effect: 2	Z = 3.85 (F	P = 0.0	001)				
1.1.2 continuous SSD)						
Bo 2000	8	35	15	33	8.4%	0.50 [0.25, 1.03]	
Bouza 2008	13	345	19	369	10.0%	0.73 [0.37, 1.46]	
Kollef 1999	8	160	15	183	7.6%	0.61 [0.27, 1.40]	+
Valles 1995	16	95	25	95	13.6%	0.64 [0.37, 1.12]	
Yang 2008	12	53	20	48	11.4%	0.54 [0.30, 0.99]	
Zheng 2008	9	30	16	31	8.5%	0.58 [0.31, 1.11]	
Subtotal (95% CI)		718		759	59.4%	0.61 [0.46, 0.79]	
Total events	66		110				
Heterogeneity: Chi ² = ().73, df = 5	5 (P = 0).98); ² =	0%			
Test for overall effect:	Z = 3.63 (F	P = 0.0	003)				
Total (95% CI)		1032		1073	100.0%	0.56 [0.45, 0.69]	
Total events	103		185				
Heterogeneity: Chi ² = 2	2.93, df = 8	8 (P = 0).94); ² =	0%			
Test for overall effect:	Z = 5.26 (F	< 0.0	0001)				0.02 0.1 1 10 50 Favours SSD Favours Control
Test for subaroup diffe	rences: Ch	ni² = 0.8	80. df = 1	(P = 0.)	.37). l ² = 0	%	Favours 55D Favours Colluon

Update: Subglottic Secretion Drainage Meta-Analysis 20 RCT's, studies from 1992-2017, 3684 Patients

VAP Incidence

Mortality

First author,		SD	Co	ntrol					Weight										
year	VAP	Total	VAP	Total			RR (95%	6 CI)	%	First author,	S	SD		ntrol					Weight
MAHMOODPOOR, 2017	30	138	46	138			0.65 (0.4	4-0.97)	8.16	year	Events	Total	Events	Total				RR (95% CI)	%
DEEM, 2016	10	34	14	36			0.76 (0.3	9-1.47)	1.97	MAHMOODPOOR, 2017	36	138	48	138	_ _			0.75 (0.52-1.08)	9.36
JENA, 2016	11	25	13	25			0.85 (0.4)	7-1.51)	2.11	Deem, 2016	9	34	9	36				1.06 (0.48-2.35)	0.82
GOPAL, 2015	13	120	25	120			0.52 (0.2)	B-0.97)	4.84	GOPAL, 2015	2	120	1	120			>	2.00 (0.18-21.76)	0.01
Damas, 2015	15	170	32	182			0.50 (0.2)	8-0.89)	6.12	DAMAS, 2015 (ICU)	63	170	74	182		-		0.91 (0.70-1.19)	12.25
TAO, 2014	52	102	34	47			0.70 (0.5	4-0.91)	16.68	DAMAS, 2015 (hospital)	78	170	93	182	i			0.90 (0.72-1.12)	18.76
SEYFI, 2013	4	40	7	40			- 0.57 (0.1)	8-1.80)	0.87	TAO, 2014	48	102	29	47	_			0.76 (0.56-1.03)	12.88
LACHERADE, 2010	25	169	42	164			0.58 (0.3)	7-0.90)	8.07	Lacherade, 2010	80	169	84	164				0.92 (0.74-1.15)	17.40
ZHENG, 2008	9	30	16	31			0.58 (0.3	1-1.11)	3.55	ZHENG, 2008	8	30	12	31				0.69 (0.33-1.45)	2.31
Yang, 2008	12	48	20	43			0.54 (0.3)	D-0.96)	5.15	Yang, 2008	32	48	29	43				0.99 (0.74-1.32)	8.63
BOUZA, 2008	12	331	19	359			0.69 (0.3	4-1.39)	2.07	Bouza, 2008	23	331	26	359				0.96 (0.56-1.65)	2.43
LORENTE, 2007	11	140	31	140			0.45 (0.1)	9-0.68)	9.47	LORENTE, 2007	26	140	32	140				0.81 (0.51-1.29)	4.77
Liu QH, 2006	14	41	30	45			0.51 (0.3)	2-0.82)	9.02	Liu QH, 2006	18	41	13	45				1.52 (0.86-2.70)	0.85
Liu SH, 2006	3	48	10	50		—	0.31 (0.0	9-1.07)	2.40	Liu SH, 2006	5	48	11	50				0.47 (0.18-1.26)	2.45
GIROU, 2004	5	8	6	10	-	•	1.04 (0.5	0-2.18)	0.81	SMULDERS, 2002	12	75	10	75				1.20 (0.55-2.61)	0.68
SMULDERS, 2002	3	75	12	75			0.25 (0.0)	7-0.85)	3.79	KOLLEF, 1999	6	160	8	183				0.86 (0.30-2.42)	0.64
Bo, 2000	8	35	15	33		-	0.50 (0.2	5-1.03)	3.74	VALLES, 1995	39	95	35	95				1.11 (0.78-1.59)	4.37
KOLLEF, 1999	8	160	15	183			0.61 (0.2	7–1.40)	1.77	MAHUL, 1992	17	70	16	75				1.14 (0.63-2.07)	1.37
VALLES, 1995	14	76	25	77		•	0.57 (0.3	2–1.01)	4.85	Overall (12=0.0%, p=0.888	8)							0.88 (0.80-0.97)	100.00
MAHUL, 1992	9	70	21	75			0.46 (0.2)	3-0.93)	4.56						¥.			,	
Overall (I ² =0.0%, p=0	.841)				\diamond		0.56 (0.4)	8-0.63)	100.00					ò	0.5 1	1.5	2 2.5		
				ó	0.5 1	1.5	2 2.5			FIGURE 3 Forest plot con	nparing su	bglottic sea	retion drain	nage (SSD)) <i>versus</i> non-SSD o	on mortality. R	R: risk ratio; l	CU: intensive care uni	t.

Guideline Recommendations: Subglottic Secretion Drainage

- HIPAC Pneumonia Guidelines 2003
- ATS pneumonia prevention & treatment 2005
- Spanish Guidelines
- Ireland VAP Guidelines 2011
- SHEA Pneumonia Prevention Guidelines 2014
- VAP Bundle (National Delphi Study)

ATS/IDSA 2016 Clinical Practice Guidelines

AARC 2010 Clinical Practice Guidelines. Endotracheal suctioning of mechanically ventilated patients with artificial airways

AACN VAP Practice Alert

APIC 2009 Guide to the Elimination of VAP

SHEA 2008 Strategies to Prevent VAP in Acute Care Hospitals



So Why is SGD not being used?



Subglottic ETT

*** Challenges: Current Suctioning

- Intermittent suction q 1hr for SGD with a syringe/labor intensive & difficult to achieve
- Intermittent suction by machine or syringe-exerts 2 to 5x more pressure than AARC recommends
- A high variability in the volume of secretions suctioned between patients and, for each individual patient, during the period of MV
- Continuous suction continues even if clogged grabbing the subglottic wall-keeps on going
- Back flow leading to potential vector for infection
 - \triangle 470 regulators/11 facilities/5 states
 - ightarrow 37% found to be colonized
 - △ Pathogens can disseminate throughout the circuit (antegrade & retrograde)



Challenges: Current Suctioning

- Poor removal of pathogenic fluid
- Increased rates of complications
- Increased workflow
- Increased Costs of SSETTs



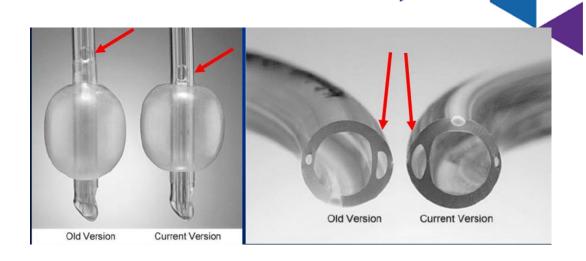


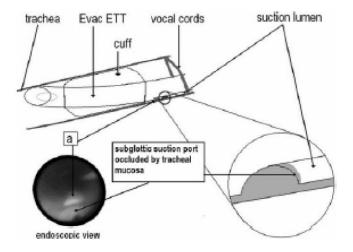
Challenges: Suction Apparatus

		Automated Approach		
	Continuous	Intermittent	Manual	Intermittent
Method	Wall Suction or General Suction	Wall Suction or General Suction	Syringe	Specialized Suction Device
Pressure	-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
Accuracy of Pressure Delivered	Not reliable	Not reliable	Always Higher than recommended Guidelines	Accurate/reliable
Frequency	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
Daily Aspirations	Non-Stop Aspiration	1,440 - 3,600 aspirations daily	24 aspirations daily	24 - 144 aspirations daily
Noise Level	Highly Noisy	Highly Noisy	None	Quiet
Staff Time (per bed per day)	10 minutes	10 minutes	120 minutes	10 minutes
Volume of Secretions	10 - 30 ml	10 - 30 ml	30 ml	100 - 500 ml
FDA Cleared	No	No	No	Yes
Specifically Designed for SSD	No	No	No	Yes
Potential for Cross Contamination	Yes	Yes	Yes	Minimized

Challenges: SGD ET Tube

- Configuration of the tube
- Suction blockage
 - \triangle 40 intubated patients/SGD
 - 48% blockage
 - 43% caused by suctioned tracheal mucosa
- Safety of the tube with continuous or intermittent suction and mucosal tissue damage
- 40% laryngeal edema



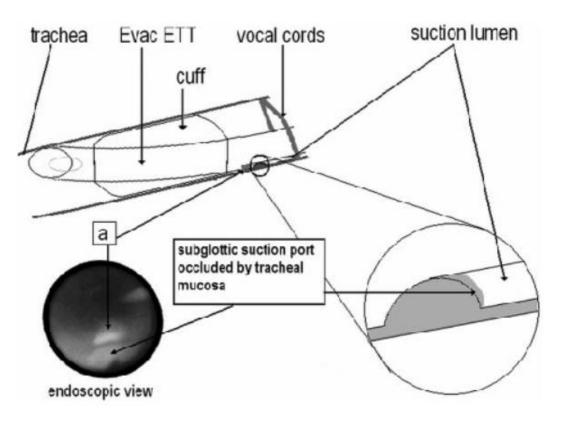


Lacherade JC, Ann Transl Med. 2018;6(21):422. Dragoumanis CK, et.al. Anesthia & Analgesia. 2007;105(4):1083-1085 Girou E, et al. Intesive Care Med. 2004;30:225-233.

Challenges: SGD ET Tube



Investigating the Failure to Aspirate Subglottic Secretions with the Evac Endotracheal Tube



DISCUSSION

The observed incidence of Evac ETT suction lumen dysfunction in our study was high, 48% (95% CI: 32%–63%). Moreover, it appears that the dominant cause of suction lumen dysfunction was occlusion of the subglottic suction port by suctioned tracheal mucosa (Fig. 1). This finding raises significant questions concerning the safety of evacuation of subglottic secretions with subglottic suction using the Evac ETT.

• 40% laryngeal edema

Subglottic Suction Endotracheal Tube: A Better Way

Tissue Spacer

△ Multiple Ports, smooth, soft,

- When it does a better job*
 - \triangle Reduces Risk of VAP
 - \triangle Reduces Respiratory Needs
 - △ Reduces Time on Ventilation
 - △ Reduces Antibiotics Use

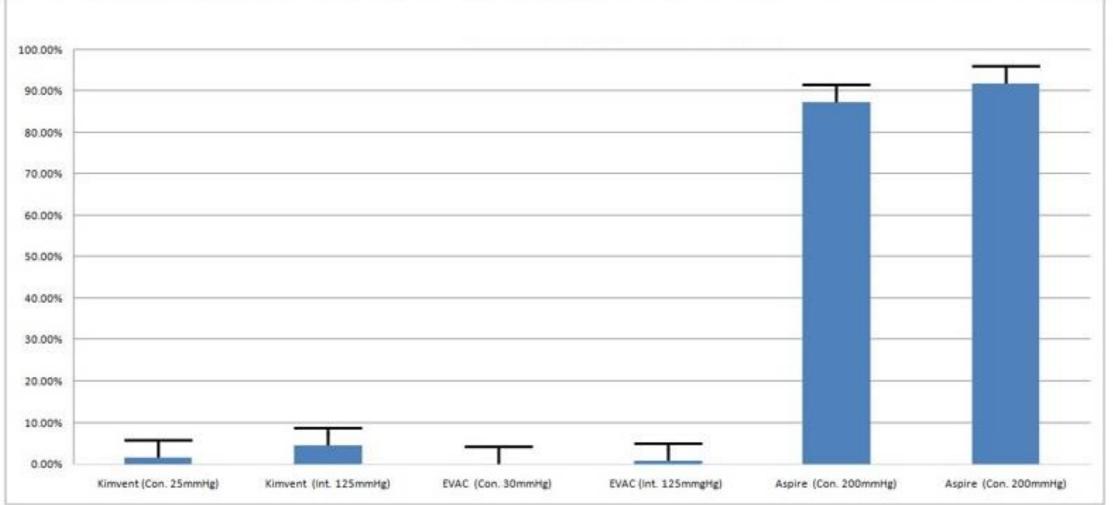


Comparison of Single and Multi-Port SGD tubes

- 7 porcine trachea/set up to simulate 30° HOB
- Controlled model without SG tube
- 1033 cc of simulate oral secretions were dripped over 52 hrs.
 - △ Regular ET tube: 95% leaked past cuff
 - △ Single port SG tube: All experience suction failure due to tissue
 - △ Multi-Port SG tube: Rapidly removed fluid/preventing leakage (0 % leakage)

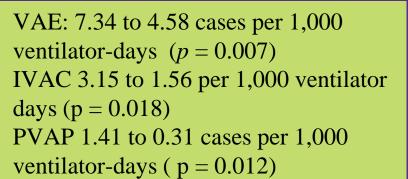


Comparison of Single and Multi-Port SGD tubes



Impact of a New Bundle/2 State Collaborative

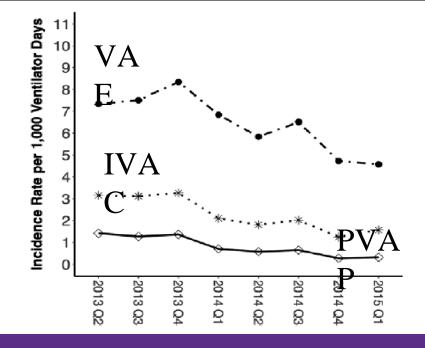
- 38 hospitals, 56 ICU's in 2 states from October 2012 to March 2015
- Evidence based interventions, teamwork & safety culture
- Head-of-bed elevation, use of subglottic secretion drainage endotracheal tubes, oral care, chlorhexidine mouth care, and daily spontaneous awakening and breathing trials.



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