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Can we control upper airway secretions and reduce their impact on the incidence of Ventilator-associated pneumonia?

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Introduction

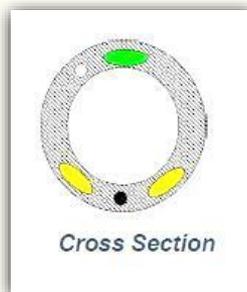
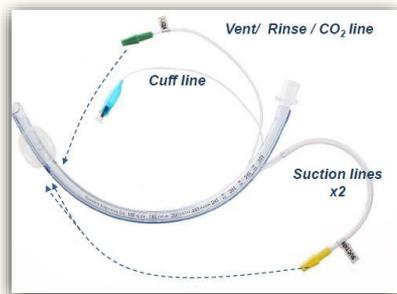
- Daily standard endotracheal tube (ETT) care in ICU includes frequent monitoring of cuff pressure, oral and endotracheal suctioning of secretions, and confirmation of ETT position.
- Minimum pressure of 20 cmH₂O is recommended to prevent aspiration of airway secretions and VAP.
- Cuff pressure > 30 cmH₂O is associated with hoarseness, subglottic stenosis, nerve damage, fistulas, and tracheal wall necrosis.

Study Purpose

- To assess the performance of the **AnapnoGuard system** in critically ill patients requiring mechanical ventilation (FDA approved device which automatically adjusts cuff pressure and suctions subglottic secretions).
- Primary endpoint:
Measure frequency of adverse events (AEs) and serious adverse events (SAEs) related to over-inflation of ETT cuff.
- Secondary endpoint:
Quantify amount of airway secretions evacuated.

AnapnoGuard™ System: Components

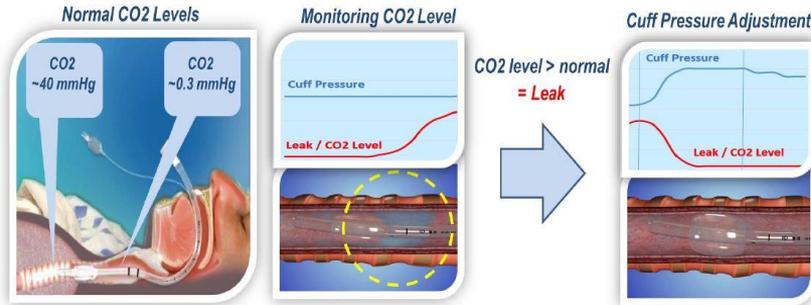
- PVC ETT with thin wall PU cuff, two suction lines and an extra CO2/venting line.
- Connection kit
- Control Unit (AG100s).



AnapnoGuard™ System (AG100s)

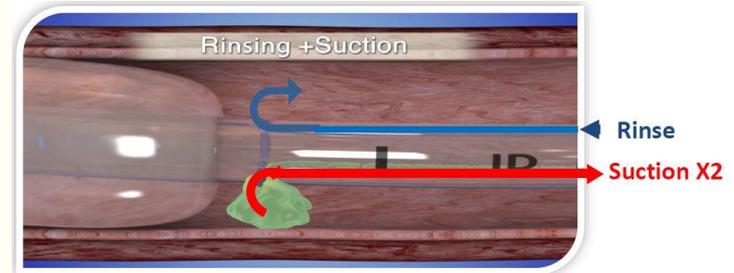
Cuff Pressure Control & Optimization

- **Automatic leak detection** around the cuff, based on the CO₂ level in the subglottic space.
- **Automatic feedback loop** to ensure effective sealing with minimal ETT cuff



Effective Evacuation of Secretions

Automatically performs programmable subglottic suction of secretions by synchronized, simultaneous rinsing with saline and suction.



Methods

- Pilot, prospective, observational design utilizing AG™ 100s in patients admitted to the ICU at Mayo Clinic FL, who require intubation and mechanical ventilation in 2019.
- **Patient Variables**
 - Demographics and reason for endotracheal intubation.
- **Device's variables**
 - Total duration of intubation and connection to the AG
 - Cuff pressure measurements
 - Frequency of CO₂ leaks detected, and respective cuff pressure adjustments.
 - Quantification of suctioned subglottic secretions

Results

We analyzed 39/40 patients who were intubated with the AG ETT and connected to the AG 100s System from April to December 2019 (Excluded patients connected to the system less than 6 hours).

Table No1. Demographics

Age	Mean: 60 ± 14.9 years (Min 21-Max 83)	
	n	%
Gender		
Female	19	49.7%
Male	20	51.3%
Race		
White/Caucasian	32	82.3%
African American	4	10.1%
Asian	1	2.5%
Hispanic	2	5.1%

Table No2. Indication for intubation

Unit	Diagnosis	n	%
MICU n: 22 (56.4%)	-Respiratory failure	16	73%
	-COPD Exacerbation	2	9%
	-Pneumonia	1	4.5%
	-Altered mental status	2	9%
	-Cardiogenic Shock	1	4.5%
SICU n: 17 (43.6%)	-Post-lung transplant	11	65%
	-Post-heart transplant	1	5.8%
	-Post-liver transplant	1	5.8%
	-Post-AAA Repair	1	5.8%
	-Post-CABG	1	5.8%
	-NeuroSurgery	2	11.8%

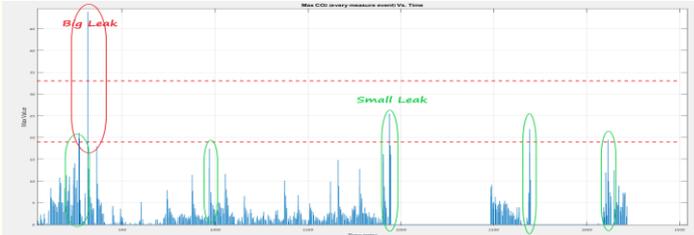
Results

Table No3. AnapnoGuard™ 100s System Variables

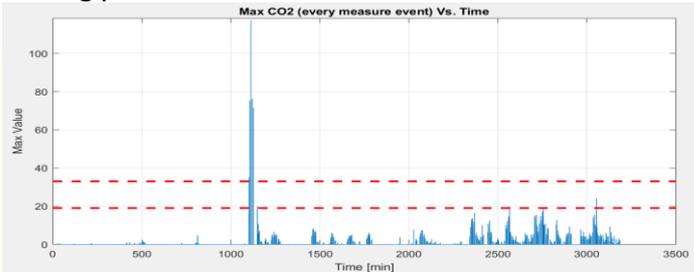
Variable	Mean ± SD	(Min – Max)
Time connected to the system - Automatic Mode: 87.2% - Maintaining Mode: 33.3%	68.1 hours ± 52.5	6hrs - 205hrs
Cuff Pressure Limits Lower pressure Predominance pressure Higher pressure	24.27 cmH ₂ O ± 2.6 26.46 cmH ₂ O ± 1.8 29 cmH ₂ O ± 3	20 – 35 cmH ₂ O
# Leaks (during entire monitoring)	8 events ± 5	0 - 36 events
Net Secretions	60 ml ± 68	0 - 264 ml

Some remarkable cases

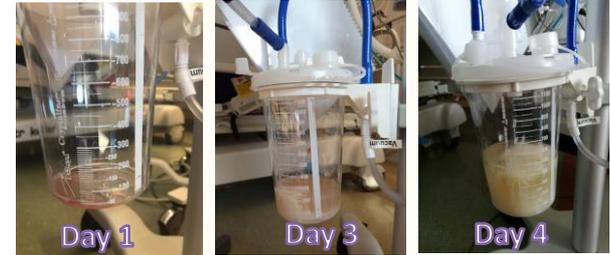
CASE #1: Detection of displacement of ETT with major CO₂ leak.



CASE #9: All “big” leaks are related to the NG being placed in the trachea.

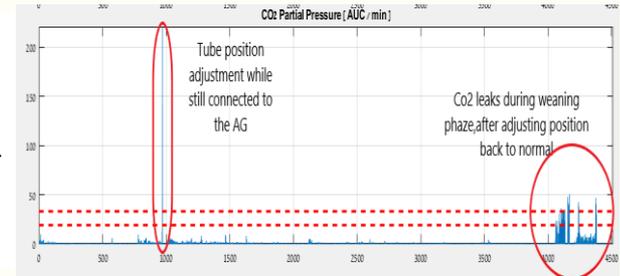


CASE #11: 20 small leaks and 16 big leaks fixed in the presence of major purulent subglottic secretions.



Total Secretions - 350cc (Net 264 ml)

CASE #18: CO₂ leaks detected during weaning trial due to the ETT being higher than initial position (27 to 29cm).



- No adverse events or serious adverse events were reported.
- There was no diagnosis of VAP in the patients connected to the system.

Conclusions

- The AG 100s system appears to be an effective tool to maintain the appropriate ETT cuff pressure and to clear secretions.
- Its use can effectively and continuously monitor and optimize ETT cuff pressure.
- This innovative device may be effective at reducing the risk of VAP and airway injury.
- Future studies, using larger samples are needed to evaluate the effect of the AG on VAP occurrence.