Respiratory Guard System: New Technology

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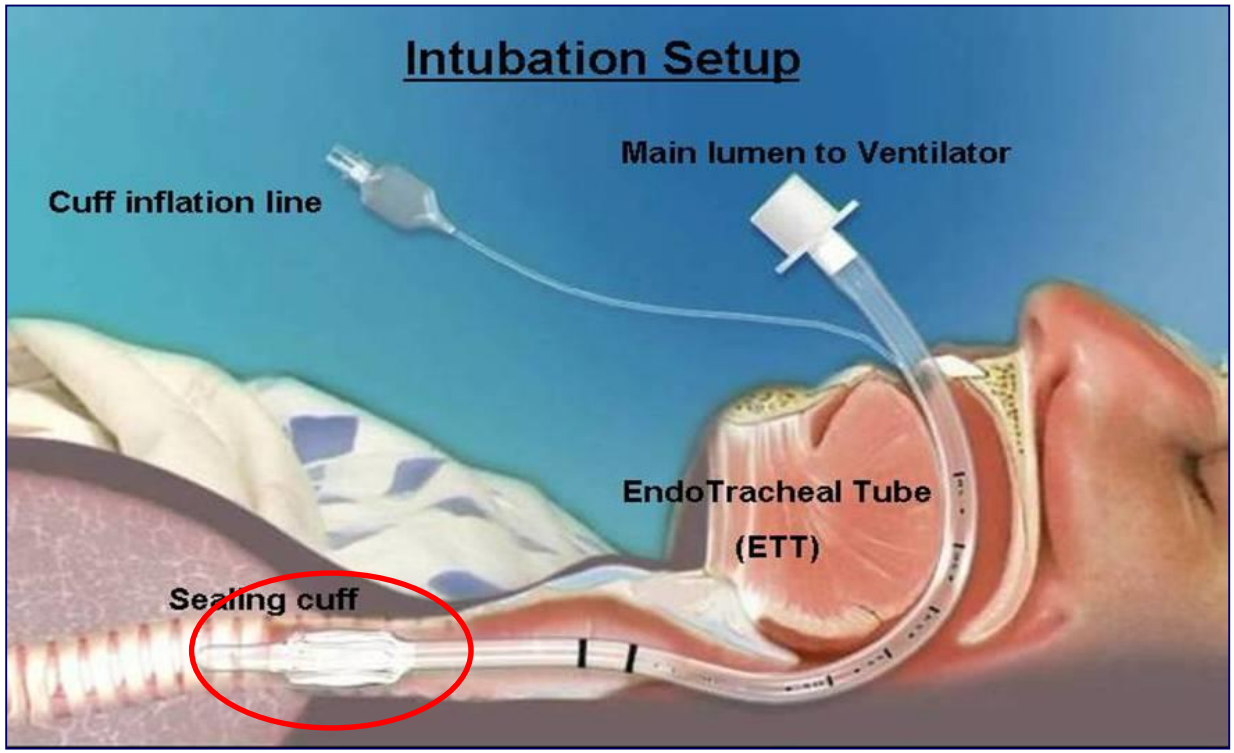
DISCLOSURES

None

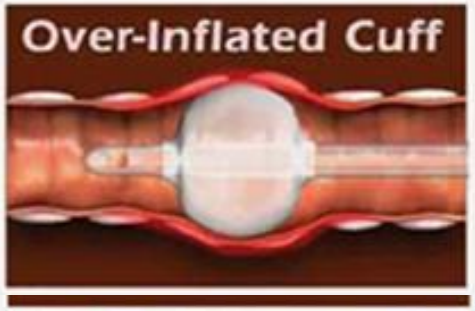
Ventilation Associated Pneumonia(VAP) – Aspiration



- The main reasons for inflammatory complications:
  - Improper management of the upper airway
  - Improper management of cuff pressure
  - Insufficient evacuation of subglottic secretions

Improper management of cuff pressure

Causes



Inappropriate ventilation pressure & tube resistance

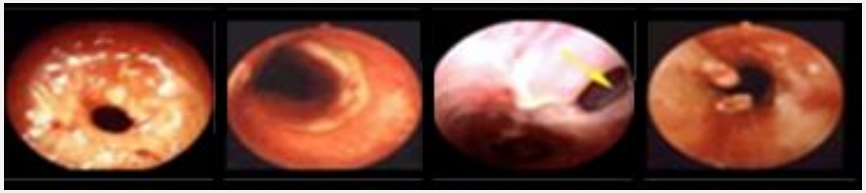
Complications

Secretion leakage into the lungs

> Ventilator-Associated Pneumonia (VAP)

Uncontrolled pressure on tissue

> Injury to the trachea & vocal cords



Tracheal Stenosis | Ulceration | Fistula | Tracheal Granulomas

Increased Work of Breathing

> Longer weaning process

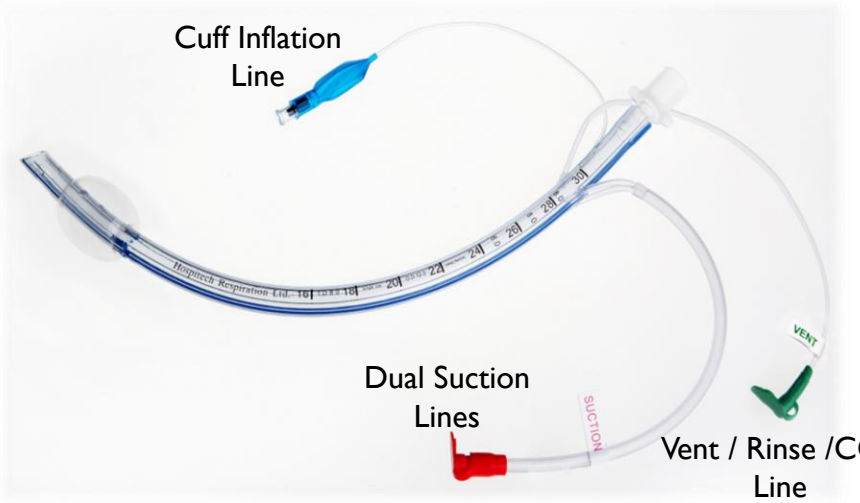
>ARDS (Acute Respiratory Distress Syndrome)

The AnapnoGuard Solution

- The AnapnoGuard system *(Hospitech Respiration Ltd.)* is an innovative device that reduces Ventilator Associated Complications by:

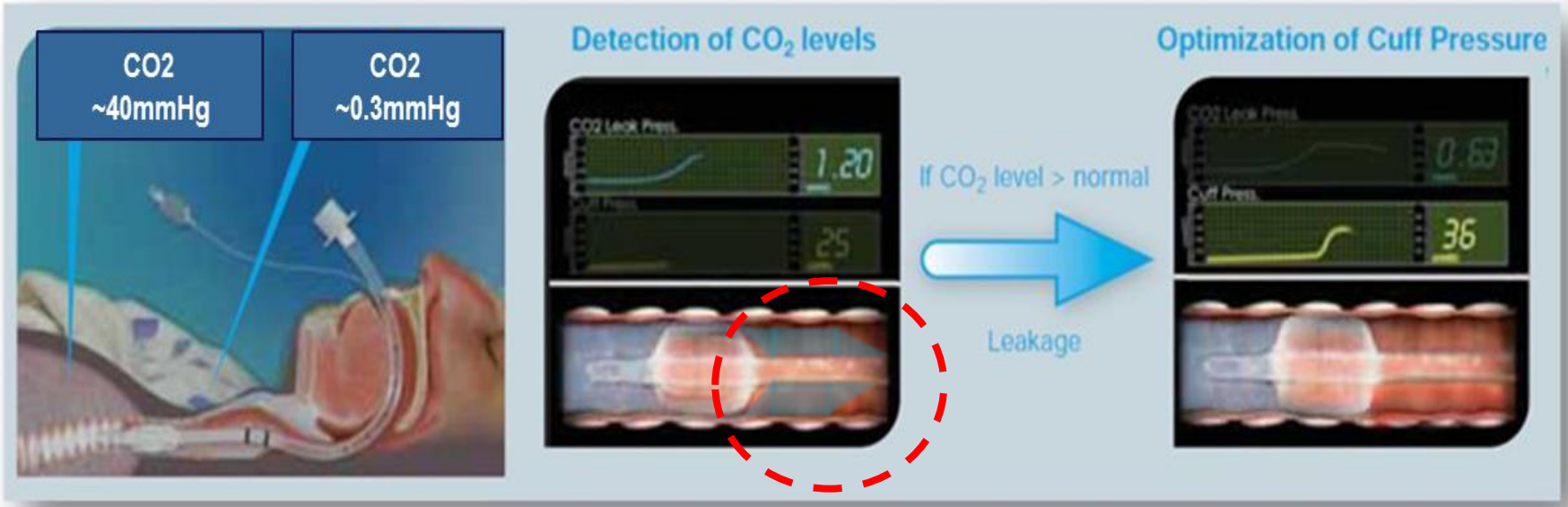
The Control Unit

The multi lumen ETT



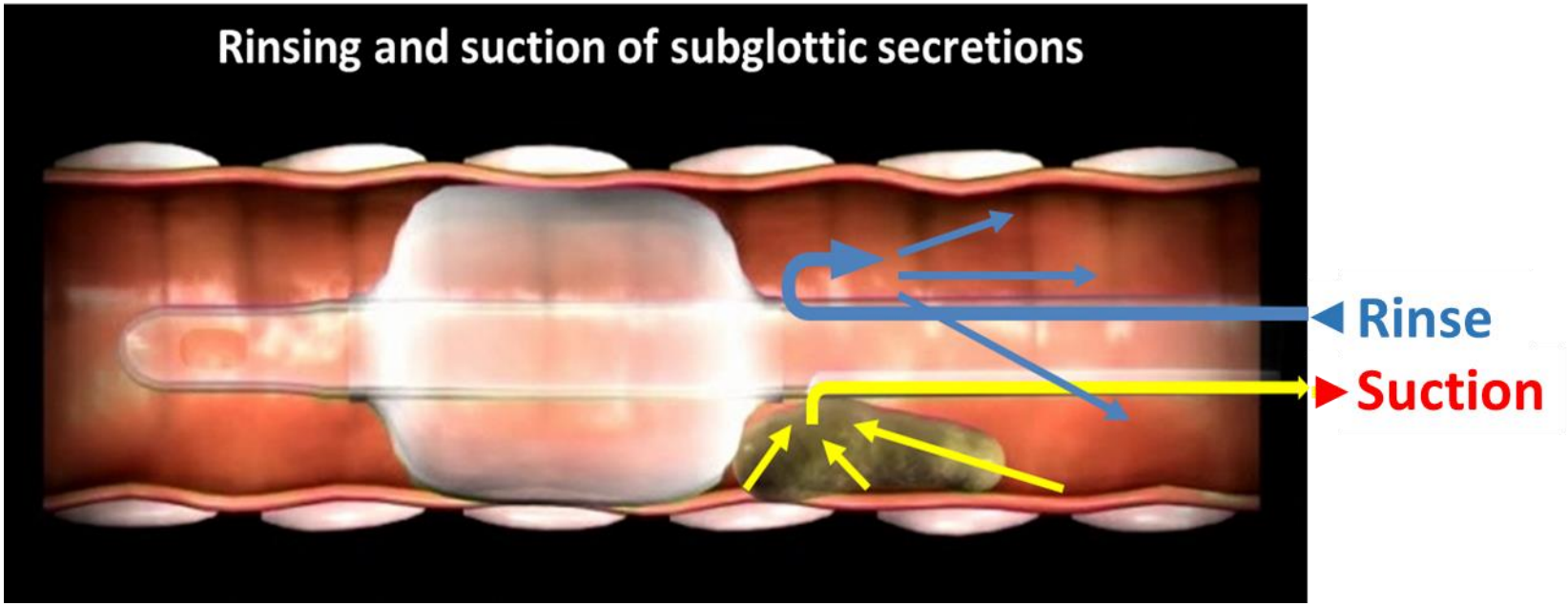
- Continuous monitoring of CO2 leaks and adjustment of ETT cuff pressure
- Effective rinsing and evacuation of subglottic secretions

Cuff Pressure Optimization

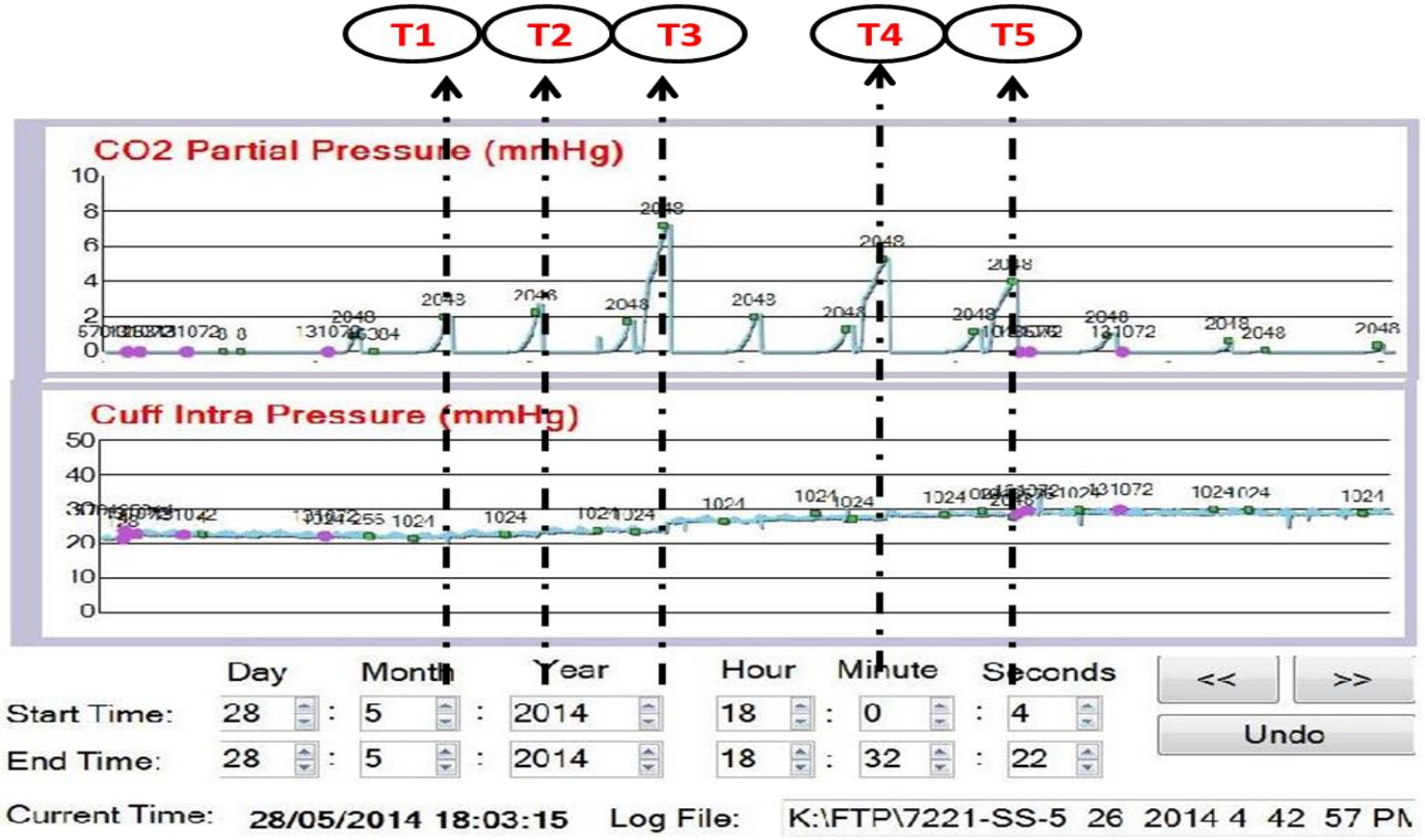


- Detects leaks around the ETT cuff based on the CO2 level above the cuff
- Automatic closed loop adjustment of cuff pressure to ensure effective sealing at minimal pressure

Effective Rinsing and Evacuation of Secretions



- Simultaneous intermittent rinsing and suctioning


T1
T2
T3
T4
T5
CO2 Partial Pressure (mmHg)
Cuff Intra Pressure (mmHg)
Day
Month
Year
Hour
Minute
Seconds
Start Time:
28
5
2014
18
0
4
End Time:
28
5
2014
18
32
22
<<
>>
Undo
Current Time:
28/05/2014 18:03:15
Log File:
K:\FTP\7221-SS-5 26 2014 4 42 57 PM

STUDY TO EVALUATE THE EFFICACY OF THE ANAPNOGUARD 100 SYSTEM IN PREVENTION OF AIR LEAK AROUND THE ENDOTRACHEAL TUBE CUFF IN INTUBATED PATIENTS

A Prospective Randomized multi center Study

Study Group (34)

-Anapnoguard system and ETT
-Automatic suction
-**Automatic** cuff pressure control

Control Group (30)

-Anapnoguard system and ETT
-Automatic suction
-**Manual** cuff pressure control

Leaks around the Endotracheal tube CUFF

A Prospective Randomized Study

Inclusion Criteria

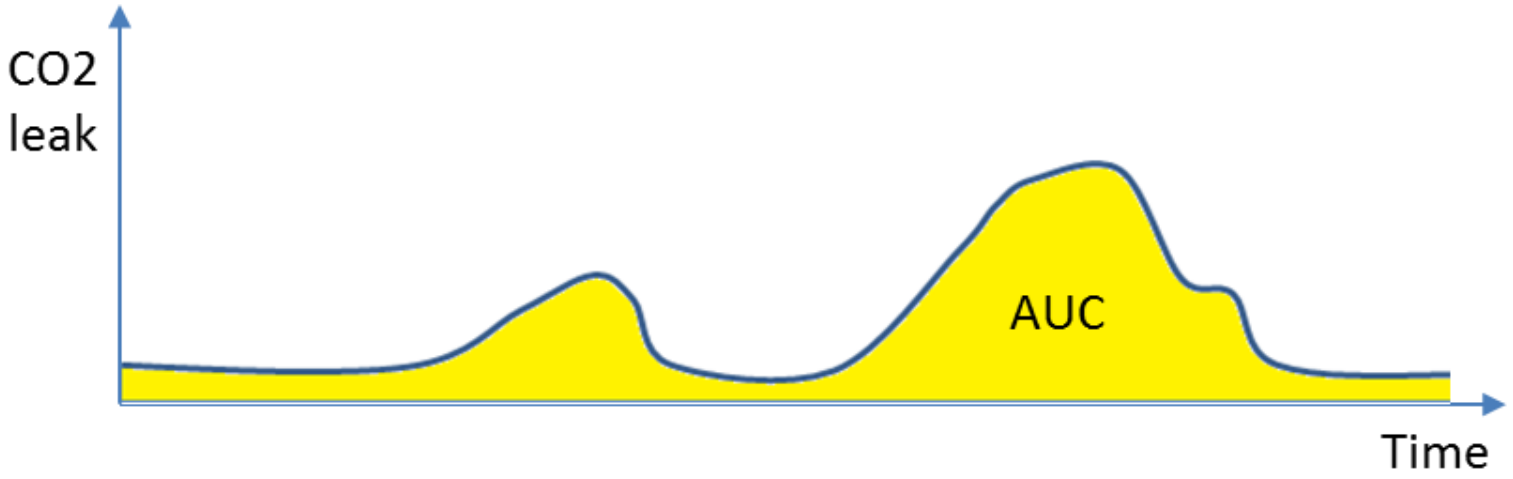
- Age above 18 years
- Subject expected to receive MV for more than 12 hours;
- Connection of the ETT to the AnapnoGuard system within 12 hours from intubation initiation;
- Subject or subject's legally acceptable representative signed the Informed Consent Form

Exclusion Criteria

- Subjects with facial, oropharyngeal or neck trauma
- BMI>40
- Difficult intubation (defined as more than 3 intubation attempts)

Primary Endpoint

Overall duration and level of CO2 leakage, as assessed by the **Area Under the Curve** (AUC) of CO2 leakage over time



Secondary Confirmatory Endpoints

- Number of CO2 leakage readings at or above 2 mmHg
- Number of the cuff pressure measurements within the safety accepted range (24 and 40cmH2O)

Baseline Characteristics

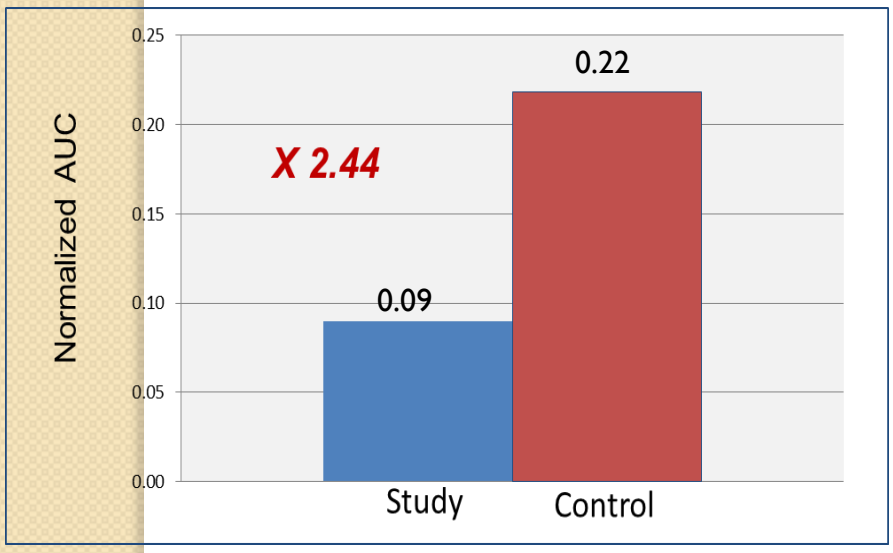
Parameter	Study Group	Control Group	P-Value
General Parameters			
N	**34**	**30**	**NA**
Gender	**----**	**----**	**----**
Male	23 (67.6%)	18 (60.0%)	0.606
Female	11 (32.4%)	12 (40.0%)	
Age (years)	65.0 (±18.8)	66.7 (±11.2)	0.658
Weight (kg)	78.6 (±12.6)	77.5 (±17.7)	0.772
Height (cm)	167.3 (±10.4)	165.3 (±9.3)	0.424
BMI (kg/m2)	28.0 (±4.1)	28.5 (±6.6)	0.761

Leaks around the Endotracheal tube CUFF

A Prospective Randomized Study

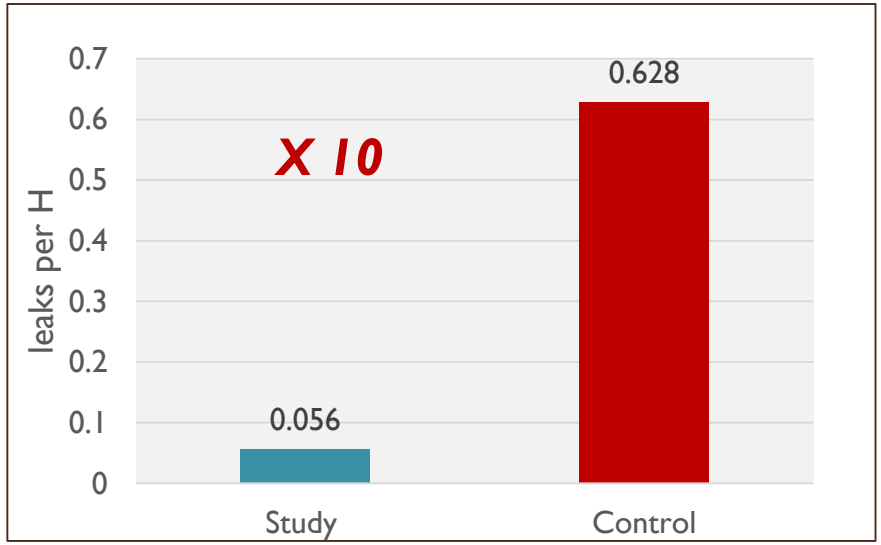
Study Results - AUC

Total CO2 leakage over time (AUC)



Primary Endpoint
P<0.001

# of Large CO2 leaks above 2mmHg (per h)



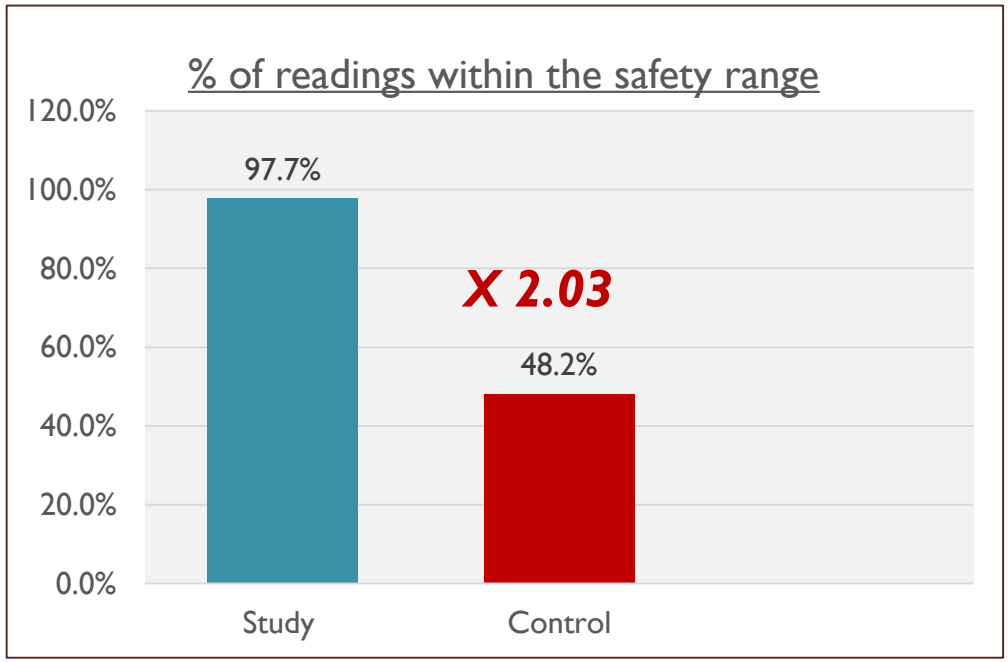
Secondary Endpoint
P<0.001

Leaks around the Endotracheal tube CUFF

A Prospective Randomized Study

Study Results – cuff pressure within range

of cuff pressure measurements within range (24-40cmH2O)



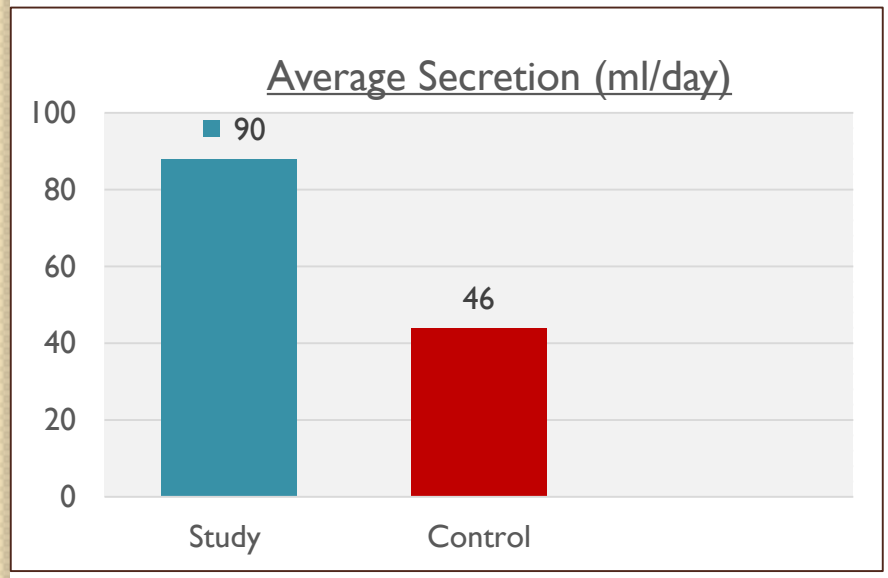
Secondary Endpoint

P<0.001

Leaks around the Endotracheal tube CUFF

A Prospective Randomized Study

Other observations – Evacuation of Subglottic Secretions



Rinse and suction - Both Groups
Cuff control – Study group only

Summary

- Automatic management of the cuff helps prevent leaks around the ETT cuff, especially significant leaks (>2mmHg) over time
- CO2 monitoring helped maintaining the cuff pressure within desired range of 24-40 cmH2O
- Better sealing of the trachea – less aspired secretion while maintaining minimal pressure on the surrounding tissue thus preventing injury.
- Following this study - FDA approval

Thank you