Respiratory Guard System: New Technology

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DISCLOSURES

None
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

- Under-Inflated Cuff
- Over-Inflated Cuff

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

- 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:

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

The Control Unit

The multi lumen ETT

Cuff Inflation Line

Dual Suction Lines

Vent / Rinse /CO2 Line
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
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
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

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Study Group</th>
<th>Control Group</th>
<th>P-Value</th>
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<tbody>
<tr>
<td><strong>General Parameters</strong></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>N</td>
<td>34</td>
<td>30</td>
<td>NA</td>
</tr>
<tr>
<td>Gender</td>
<td>----</td>
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<tr>
<td>Male</td>
<td>23 (67.6%)</td>
<td>18 (60.0%)</td>
<td>0.606</td>
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<tr>
<td>Female</td>
<td>11 (32.4%)</td>
<td>12 (40.0%)</td>
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<tr>
<td>Age (years)</td>
<td>65.0 (±18.8)</td>
<td>66.7 (±11.2)</td>
<td>0.658</td>
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<tr>
<td>Weight (kg)</td>
<td>78.6 (±12.6)</td>
<td>77.5 (±17.7)</td>
<td>0.772</td>
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<tr>
<td>Height (cm)</td>
<td>167.3 (±10.4)</td>
<td>165.3 (±9.3)</td>
<td>0.424</td>
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<tr>
<td>BMI (kg/m²)</td>
<td>28.0 (±4.1)</td>
<td>28.5 (±6.6)</td>
<td>0.761</td>
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</tbody>
</table>
Leaks around the Endotracheal tube CUFF

A Prospective Randomized Study

Study Results - AUC

Total CO2 leakage over time (AUC)

- Study: 0.09
- Control: 0.22

Normalized AUC

Primary Endpoint
P<0.001

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

- Study: 0.056
- Control: 0.628

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)

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<th>Control</th>
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<tbody>
<tr>
<td>% of readings within the safety range</td>
<td>97.7%</td>
<td>48.2%</td>
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</table>

Secondary Endpoint
P<0.001

X 2.03
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