Evaluation of Effect of Breathe Ventilation System on Work of Breathing in COPD patients

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• Personal financial relationships with commercial interests relevant to this presentation during the past 12 months:  
  – No relationships to disclose

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• Relevant institutional financial interests:  
  – No relationships to disclose

• Personal financial relationships with tobacco industry entities within the past 3 years:  
  – No relationships to disclose
Background

• Severe COPD limits functional capacity partly via increases in work of breathing, placing an increased load on the inspiratory muscles

Background

Background

O'Donnell DE et al. Dynamic Hyperinflation and Exercise Intolerance in Chronic Obstructive Pulmonary Disease. AJRCCM 2001(164); 770-777.
• The combination of inspiratory pressure support and PEEP reduces work of breathing in patients with severe COPD
  • Extrinsic PEEP counterbalances intrinsic PEEP
  • Inspiratory pressure support assists inhalation
• CPAP, PSV, and PAV can augment exercise capacity in rehabilitation settings
  • Use for everyday activities in patients with severe COPD is limited by size and weight of the devices
The Breathe Non-Invasive Open Ventilation (NIOV) System is a small, lightweight FDA-approved device designed to optimize portability:

- Battery powered
- Weighs less than 2lbs (without oxygen source)
- Delivers three different volumes which can be set according to level of exertion
- Utilizes a specially-designed nasal mask which incorporates ambient air via the Bernoulli Principle to augment airflow
Breathe NIOV Ventilator

Recorded Tidal Volume (mL) - 20BPM, Vt 600

<table>
<thead>
<tr>
<th>Volume (mL)</th>
<th>Tidal Volume (mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Open Nose</td>
<td>599</td>
</tr>
<tr>
<td>100 mL</td>
<td>607</td>
</tr>
<tr>
<td>150 mL</td>
<td>679</td>
</tr>
<tr>
<td>200 mL</td>
<td>812</td>
</tr>
<tr>
<td>250 mL</td>
<td>934</td>
</tr>
</tbody>
</table>

Bench Comparison of Non-Invasive Open Ventilation to Home and Bilevel Ventilation in Non-Invasive Conditions” R, McCoy, RRT, FAARC: R. Diesem, BS; COPD8USA June 2013
Study Design

• **Inclusion Criteria**
  - Age > 18
  - Severe COPD (GOLD III or IV)
  - Increased work of breathing evidenced by SCM contraction during inspiration

• **Exclusion Criteria**
  - AECOPD with hospitalization within last month
  - Requires supplemental oxygen > 5L to maintain 90% saturation
  - Severe dyspnea at rest
Study Design

• Nasal catheters with balloons inserted into the stomach and esophagus
  • Pdi measured as difference between Pga and Pes
• Respiratory inductive plethysmography using thoracic and abdominal bands applied to measure TV
• Transcutaneous probe applied to the ear to measure oxygen saturation and serum CO2
Study Design

• Measurements taken at the following conditions:
  • Baseline (with or without O2)
  • Baseline with nasal mask mask
  • NIOV at 100mL
  • NIOV at 180mL
  • NIOV at 250mL
  • NIV at 4cm H2O
  • NIV at 8/4cm H2O
  • NIV at 12/4cm H2O

• Subjective measures recorded for mask comfort and breathing comfort
## Patient Demographics

<table>
<thead>
<tr>
<th>Patient</th>
<th>Age</th>
<th>Gender</th>
<th>FEV1</th>
<th>FEV1 % Predicted</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>63</td>
<td>Female</td>
<td>0.5L</td>
<td>23%</td>
</tr>
<tr>
<td>2</td>
<td>62</td>
<td>Male</td>
<td>1.62L</td>
<td>41%</td>
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<tr>
<td>3</td>
<td>54</td>
<td>Female</td>
<td>0.61L</td>
<td>24%</td>
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<tr>
<td>4</td>
<td>76</td>
<td>Male</td>
<td>1.79L</td>
<td>41%</td>
</tr>
<tr>
<td>5</td>
<td>55</td>
<td>Male</td>
<td>1.96L</td>
<td>35%</td>
</tr>
<tr>
<td>6</td>
<td>56</td>
<td>Male</td>
<td>0.84L</td>
<td>18%</td>
</tr>
<tr>
<td>7</td>
<td>64</td>
<td>Male</td>
<td>0.69L</td>
<td>20%</td>
</tr>
<tr>
<td>8</td>
<td>65</td>
<td>Female</td>
<td>0.43L</td>
<td>20%</td>
</tr>
<tr>
<td>AVERAGE</td>
<td>62</td>
<td>F=3, M=5</td>
<td>1.06L</td>
<td>27.8%</td>
</tr>
</tbody>
</table>
Results - Respiratory Rate

F(2.590, 10.361)=6.219, p=0.013
Results-paCO2

![Bar chart showing pCO2 (mmHg) levels for different conditions: Baseline, Breathe 100, Breathe 180, Breathe 250, CPAP 4, Bipap 8/4, Bipap 12/4. The chart includes statistical results: F(1.245, 7.469), p=0.046 (Baseline vs. Breathe) and F(1.302, 6.683), p=0.013 (Baseline versus NIV).]
Results - Tidal Volume

F(2.344, 9.378) = 4.631, p = 0.036
Conclusions

• Breathe NIOV system showed the following statistically significant changes:
  • Decreased RR
  • Decreased CO2
  • Increased tidal volume
Limitations

• Despite differences in individual variables, we were unable to show a statistically significant effect on minute ventilation or trans-diaphragmatic pressure.

• Subjects were evaluated at rest
  – More study is needed to determine the effect on minute ventilation and work of breathing with exercise.
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