Health Care Utilization and Respiratory Status Following the Addition of a Portable Non-Invasive Open Ventilator (NIOV) to the Treatment Regimen

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STUDY DESIGN
Retrospective analysis of 16 stable oxygen-dependent patients with moderate to severe chronic lung disease

COLLECTED DATA
• Diagnosis, demographic/clinical characteristics
• Respiratory function
• Physician visits, ER visits, hospital and ICU admissions
• Inpatient and ICU days, mechanical ventilation days
• 2 patient-reported measures of respiratory status (CAT and mMRC)

RESULTS
• Statistically significant health care utilization across four of five health care utilization measures: emergency room visits, hospital days, hospital ICU days and mechanical ventilations.
• Estimated total cost reductions across the study population of between 68 and 96 percent. Office visits were the only measure that did not achieve significant decreases in frequency or cost.
• COPD Assessment Test (CAT) and modified Medical Research Council (mMRC) scores improved significantly in the post-NIOV implementation period (p < 0.0001 and p = 0.0001, respectively).

HEALTH CARE UTILIZATION & PROJECT COST DATA PRE- AND POST-NIOV SYSTEM USE

<table>
<thead>
<tr>
<th>Type of Service</th>
<th>Assumed Cost Per Service (USD)</th>
<th>Pre-NIOV Mean</th>
<th>Pre-NIOV Mean Cost (USD)</th>
<th>Post-NIOV Mean</th>
<th>Post-NIOV Mean Cost (USD)</th>
<th>Pre-NIOV Mean Total Cost (16 patients)</th>
<th>Post-NIOV Mean Total Cost (16 patients)</th>
<th>Mean Total Cost Reduction (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Office Visit</td>
<td>305</td>
<td>5.4</td>
<td>1,647</td>
<td>5.9</td>
<td>1,800</td>
<td>26,352</td>
<td>28,792</td>
<td>9%</td>
</tr>
<tr>
<td>Emergency Room Visits</td>
<td>800</td>
<td>1.9</td>
<td>1,520</td>
<td>0.6</td>
<td>480</td>
<td>24,320</td>
<td>7,680</td>
<td>-68%</td>
</tr>
<tr>
<td>Hospital Days</td>
<td>1,500</td>
<td>7.6</td>
<td>11,400</td>
<td>1.3</td>
<td>1,950</td>
<td>182,400</td>
<td>31,200</td>
<td>-83%</td>
</tr>
<tr>
<td>Hospital ICU Days</td>
<td>3,000</td>
<td>2.6</td>
<td>7,800</td>
<td>0.3</td>
<td>900</td>
<td>124,800</td>
<td>14,400</td>
<td>-88%</td>
</tr>
<tr>
<td>Mechanical Ventilations</td>
<td>800</td>
<td>2.6</td>
<td>2,080</td>
<td>0.1</td>
<td>80</td>
<td>33,820</td>
<td>1,280</td>
<td>-96%</td>
</tr>
</tbody>
</table>

CONCLUSIONS
In this group of ambulatory patients with chronic respiratory insufficiency, introduction of the NIOV System was associated with significantly decreased utilization of inpatient health care services and improved self-reported respiratory status.

Improvements in the Health Status of Patients with Respiratory Insufficiency with the Use of a Non-Invasive Open Ventilation System (NIOV)

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STUDY DESIGN
- Retrospective analysis of 21 patients with chronic lung disease*
- Comparison of CAT and mMRC dyspnea scores pre- and post-NIOV System use
- Patients used standard therapy** plus the NIOV System for 10.2 months

RESULTS

<table>
<thead>
<tr>
<th></th>
<th>Pre-NIOV</th>
<th>Post-NIOV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average CAT score</td>
<td>26.71</td>
<td>12.33</td>
</tr>
<tr>
<td>Average mMRC dyspnea score</td>
<td>3.38</td>
<td>1.43</td>
</tr>
</tbody>
</table>

ABOUT CAT & mMRC
COPD Assessment Test (CAT) is a short, simple, patient-completed health status tool developed to assist patients and their clinicians to quantify the impact of COPD on patients' health. The CAT is validated via scientific development process as well as clinical research studies and has properties very similar to much more complex health status questionnaires such as the St. George Respiratory Questionnaire (SGRQ). A CAT score can range between 0-40 with a score of 10-20 representing medium, 20-30 high, and 30-40 representing very high impact level. The CAT score has also been shown to provide a reliable score of exacerbation severity—the higher CAT scores resulted in higher exacerbation severity. The minimum clinically important difference (MCID) of the CAT is estimated to be ≥ 2 points.

The Medical Research Council (MRC) and the modified Medical Research Council (mMRC) scales are well established and frequently used clinical tools for determination of dyspnea. The mMRC and MRC are very similar in format and outcomes when used to measure severity of dyspnea. Variations of 1 point in the MRC scale have been shown to signify a perceived clinical improvement.

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* A group of 21 patients had a variety of chronic lung diseases including COPD, alpha-1 antitrypsin, bronchiolitis obliterans and pulmonary hypertension
** Standard therapy included prescription medications, oxygen and other equipment as prescribed by a physician

1 Jones et al. 2009
2 MacKay et al. 2009
3 Kon et al. 2014
4 Crisafulli et al. 2010