Introduction

Patients with chronic lung disease frequently have dramatically reduced capacity for exertion, which limits their ability to complete activities of daily living and eventually results in a loss of functional independence (1). Although exercise tolerance can be improved in the research setting with positive pressure ventilation (e.g., bilevel mask-based ventilation) (2, 3), poor portability and cumbersome patient interfaces have limited the adoption of ambulatory non-invasive ventilatory support in chronic lung disease. A portable ventilatory support system with a comfortable, unobtrusive patient interface could play a valuable role as an adjunct therapy for chronic lung disease by improving exercise tolerance, thus facilitating patient activity.

As an initial step in addressing this important unmet need, we conducted a non-significant risk trial using a small, wearable ventilator with a non-invasive interface (Breathe Technologies, Figure 1). The ventilator weighs less than 5 kg and requires an external pressurized oxygen source. This ventilator and mask system, which are not yet commercially available, have performance characteristics in bench tests that indicate function within a range where traditional mask-based ventilators provide benefit to patients (Figure 2). We hypothesized that this ventilator would be well tolerated by patients in a pulmonary rehabilitation setting and would improve 6MWT distances. Here we present our results from a 30-patient, first-in-human, non-significant risk feasibility trial.

Experimental Ventilator with Prototype Interface

Study Description

Non-invasive open ventilator (NOVEL) study: A non-significant risk (NSR) study to establish feasibility

Purpose

- Evaluate portable, non-invasive ventilator system with respect to patient comfort and device function during rest and exercise over a several hour period at a pulmonary rehabilitation facility.

Hypotheses

- Ventilator system will be well-tolerated for 1 hr of use.
- Use of ventilator will improve exercise capacity

Study features

- Two community pulmonary rehabilitation centers
- Total of 30 patients with previous enrollment in a pulmonary rehabilitation program
- Protocols, non-optimized open mask-based interface in conjunction with wearable 5 kg ventilator (Breathe Technologies) and oxygen canister

Study Design and Endpoints

- Determine tolerance and device function at rest and with exertion
- Compare exertional (6MWT or cycle ergometry) with and without ventilator
- Oxygen use to be matched if possible to within 1 lpm between control and experimental exertions

Key Inclusion/Exclusion Criteria

- Chronic lung disease patient with home oxygen prescription at ≥2 lpm
- Diagnosis of obstructive or restrictive lung disease
- Able to participate in some form of physical activity
- No signs of acute illness

Flowchart of Study Procedure

Experimental Ventilator Function in Lung Model

Achieving the Goals of Pressure Support

- Improved work of breathing
- Improved volumes

Inspiratory parameters

- Pressure: PIP, PEEP
- Flow: backpressure

Expiration parameters

- Pressure: CPAP
- Flow: expired flow

6 min walk test

- Maximal incremental test
- 5 min walk test with and without NOVEL

6MWT Distance with a Highly Portable Non-Invasive Ventilator

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Results 1: Test ventilator and mask system was well tolerated

Table 1: Results of change in walk distance for all patients

<table>
<thead>
<tr>
<th>Change in 6MWT After Exercise</th>
<th>Test Ventilator</th>
<th>Control Ventilator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change in Maximal 6MWT</td>
<td>63.0</td>
<td>15.0</td>
</tr>
<tr>
<td>Change in 6MWT on cycle ergometry</td>
<td>50.0</td>
<td>20.0</td>
</tr>
</tbody>
</table>

Results 3: Substantial 6MWT improvement in COPD patient subset

Figure 4

- 6 min walk test with and without NOVEL
- Maximal incremental test
- 5 min walk test with and without NOVEL

References