Use of a Portable Noninvasive Ventilation System during Pulmonary Rehabilitation and Activities of Daily Living in Patients with Severe COPD

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Background

COPD remains a major public health issue and has become the third leading cause of death in the United States. According to the National Heart, Lung, and Blood Institute (NHLBI), the number of Americans diagnosed with COPD is approximately 15 million, with an estimated 12 million persons currently undiagnosed. Statistics on COPD's financial burden are also alarming, with direct costs estimated to be more than $30 billion in the US. In addition to direct costs, which include hospital stays, emergency room visits, and physician office visits, indirect costs related to lost productivity are estimated to top $10 billion annually. On average, employed patients with COPD miss 9 work days per year.

The social burden of COPD is an equally important aspect of the disease. As COPD progresses from early to more severe stages, patients notice changes in their quality of life. Performance of routine activities of daily living (ADLs) often become too difficult and patients become dependent on others to do their daily chores. This lack of activity and exercise intolerance may lead to a reduced health-related quality of life (HRQoL) and may also have psychological consequences such as depression. Increasing activity, such as with pulmonary rehabilitation, can enhance daily functions and restore a higher level of independence.

Oxygen therapy and noninvasive ventilation (NIV) are two of the treatments recommended by the Global Initiative for Chronic Obstructive Lung Disease (GOLD). Delivering supplemental oxygen while receiving augmented ventilation has the potential to improve patient mobility, enhance the rehabilitation process, and increase activities of daily living (ADLs), with the end result being more independence and a better quality of life. Unfortunately, the use of NIV systems designed for bedside use can reduce or negate any beneficial effects and providing a portable system suitable for use during exercise and ambulation has been a major obstacle. Recently, however, a portable noninvasive open ventilation (NIOV) system has been introduced by Breathe Technologies, Inc. The NIOV system consists of a wearable 1 lb ventilator capable of delivering oxygen-enriched augmentation volumes from 50-250 mL, a non-sealing "open" nasal pillow interface, and a high-pressure oxygen source (Figure 1). In addition, the nasal pillow interface incorporates dual Venturi ports to entrain ambient air so that total augmentation volumes may exceed 450 mL with FiO2s in the range of 0.35-0.45.

In two prior clinical trials, the NIOV system has demonstrated improvements in 6-minute walk tests (6MWT) in subjects with severe COPD and other forms of respiratory insufficiency. In the first study, conducted at two pulmonary rehabilitation centers, NIOV increased 6MWT distance in 25 of 30 subjects compared to standard oxygen therapy via nasal cannula. Mean improvement in 6MWT using NIOV was 57 ± 54 meters. In the second clinical trial, completed at four pulmonary rehabilitation centers, there was a mean improvement of 36 ± 34.1 meters while using NIOV. In a subset of subjects with baseline 6MWT distances of less than 300 meters, the mean improvement was 73 meters. In both clinical trials, the NIOV system was well-tolerated and subjects reported that it was comfortable to wear.

Methods

In this study, we evaluated the NIOV system in subjects with severe but stable, oxygen-dependent COPD, in an open-label study at three pulmonary rehabilitation centers. Inclusion criteria included supplemental oxygen use during rest and exercise, notable dyspnea upon exertion, and current or recent participation in a pulmonary rehab program. The primary objective was to evaluate the NIOV system with regard to acceptability, comfort, and usability. Subjects completed five consecutive, 6-hour clinic days in which the NIOV system was worn continuously while at rest, while exercising, and during simulated ADLs, including vacuuming, folding laundry, carrying a bag of groceries, and gardening (Figure 2).

Throughout the study, subjects were able to self-select from three volume augmentation levels (low, medium, high),...
depending on their activity level and perceived needs. Each day, subjects were asked to record their responses to questions related to a self-assessment of performance paired with comfort, comparing each answer with the previous day’s experience. Subjects were also asked to rate whether the NIOV system was comfortable and would be acceptable for prolonged use. Further, subjects were asked to indicate whether they preferred the NIOV system over their standard oxygen therapy. Upon acclimation to the NIOV, baseline assessments were taken. After each activity, subjects were asked to rate their shortness of breath using the modified Borg Dyspnea Scale, and to record their emotions. At the end of the day, subjects were asked to self-assess their overall experience. Subjects were asked whether or not their performance improved through the days of the trial. The first day of using the NIOV system was compared to each subject’s perception of his/her normal performance ability and each subsequent day was compared to the day before.

Results

Nineteen subjects were screened and enrolled and 18 subjects (9 male, 9 female), aged 60-85 years, completed the study. Mean FVC % pred was 54% ± 16 and mean FEV1 % pred was 33% ± 11. Mean NIOV augmentation volumes were 100, 130, and 180 mL for low, medium, and high activity levels, respectively.

Regarding their perception of normal performance ability, 17 of the 18 subjects indicated improvement and ended the trial at a greater level of perceived performance ability than at baseline (Figure 3). When comparing their performance ability to the day before, 5 of 18 reported continuous improvement each day from the first day of use to the last. Only one subject reported a “flat” performance ability equal to standard oxygen therapy over the study’s course.

Regarding their feelings while using NIOV, the subject’s emotional state followed a similar trend to that of performance ability (Figure 4). Sixteen of 18 subjects indicated an improvement in mood during the 5 study days, ending the study at a better emotional state than at baseline. Five subjects indicated a steady improvement, indicating that their feelings improved each subsequent day of the trial. Only 2 subjects indicated no change in emotional state over the study’s course. None of the study subjects reported feeling worse at the end of the study compared to baseline.

When asked to describe their experience using the NIOV system, subjects reported that using NIOV was a positive experience and that the reduction in work of breathing was noticeable. One subject described NIOV’s volume augmentation by stating, “When I’m on the ventilator, I feel like my lungs are expanding. I feel like I can breathe better, and I feel like I have much more energy.” Another subject noted that, “the main thing we [subjects] seemed to share was that we all felt so much better. We would exercise, and the first day we had to rest in between. The second day we did a little more. Third day we did a little more. Pretty soon we weren’t resting. We were just exercising and having a great time.” Finally, subjects indicated a strong preference (median Likert scores of 5/5) for using the NIOV.
system over their standard oxygen systems with regard to performing errands, household tasks, and exercise (Table 1).

**Discussion**

Subjects’ comments during this study support that a perceived improvement in physical ability may be intrinsically linked to an improved emotional state.16,17 Study subjects who perceived a lower improvement in physical ability also experienced comparably smaller gains in their perceived emotional state. With each subsequent day of use, all but one subject reported physical ability improvement. In interviews, the perception of most subjects was that the NIOV system provided “much better breathing efficiency,” and that this improvement in breathing allowed them to regain stamina lost because of low activity levels. This improvement in perceived physical ability directly correlated to an enhanced outlook by the subjects.

During the study, it was apparent that the NIOV engendered a strong response from the subjects, although it is difficult to assess how much actual benefit would differ from perceived benefit. The nature of this trial allowed subjects to be social and active for an extended period of time each day for several consecutive days. In this way, the trial may have affected other aspects of COPD that were not directly evaluated, such as the social and psychological burden of COPD, ie, the social isolation and resultant depression of this isolation.18 The difference between the everyday behavior and routine of the subjects compared to the study’s social group environment at the pulmonary rehabilitation centers and physical demands is unknown. It is certainly possible that some of the positive emotional response could be attributed to the social aspects of the study, including interaction with fellow COPD subjects in the study and the clinical staff, while the sense of physical

<table>
<thead>
<tr>
<th>When walking or exercising with the NIOV device compared to oxygen therapy my feeling of being out of breath is:</th>
<th>When walking or exercising with the NIOV device compared to oxygen therapy my energy level is:</th>
<th>I would prefer to use this device (NIOV) instead of oxygen therapy when exercising</th>
<th>I would prefer to use this device (NIOV) instead of oxygen therapy for errands, socializing</th>
<th>I would prefer to use this device (NIOV) instead of oxygen therapy for performing household tasks</th>
<th>The (NIOV) nasal pillows were comfortable in my nose</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 = much less out of breath</td>
<td>4 = somewhat more energetic</td>
<td>4 = somewhat less dryness</td>
<td>5 = completely agree</td>
<td>5 = completely agree</td>
<td>5 = completely agree</td>
</tr>
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</table>

**Table 1. NIOV study exit questionnaire responses, (5-point Likert scale, median, n=18)**
improvement could be partly due to the nature of the study: continuous, prolonged activity conducted over consecutive days.

Conclusions
Patients with COPD face many challenges and it is widely accepted that dyspnea plays a major role in limiting a patient's ability to perform physical activity.19 Physical inactivity due to exercise intolerance often results in a downward health spiral, as progressive inactivity leads to increased disability, more frequent pulmonary exacerbations, and eventually early mortality.20

In this study, the NIOV system was used for 6-hours per day over 5 consecutive days. Subjects with severe COPD showed an improvement in self-assessed physical ability as well as emotional state. In most subjects, the preference for the NIOV system increased as the study progressed. Based on these data and previous clinical studies, the NIOV system appears capable of improving mobility and activity levels in patients with severe COPD or respiratory insufficiency. The NIOV system is very portable, was well-tolerated when worn over long periods, and was perceived as a positive experience when used during rest, ADLs, and exercise. The NIOV system appears to offer a practical method for promoting increased physical activities, improved independence, and the ability to perform everyday activities in patients with chronic respiratory insufficiency.

References