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# Evaluation of a **portable positive pressure device** to relieve dyspnea during exercise in COPD patients

## Philips VitaBreath dyspnea relief device

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## Background

**Chronic Obstructive Pulmonary Disease (COPD)** is a disease with inflammation and fibrosis of the small airways leading to airflow limitation and loss of lung parenchyma causing the loss of lung elasticity. The increased airway resistance and lack of lung recoil leads to impaired airflow, increased work of breathing, and abnormal gas exchange.

A primary measure of lung function is the forced expiratory volume at one second (FEV<sub>1</sub>). The FEV<sub>1</sub> is one of the common measurements for defining the severity of COPD. Symptoms also contribute to the severity of the disease and are the basis of treatment. Breathlessness and exercise intolerance are common symptoms in COPD and are present in all severity stages, either at rest or with exercise. As breathlessness can also occur while doing everyday activities, such as climbing a flight of stairs and showering or bathing, the patient's ability to participate in activities of daily living becomes compromised. These symptoms progress as the disease advances, leading to inactivity and muscle deconditioning. This can continue in a cycle leading to further inactivity, social isolation, and fear of undertaking any activities that could result in dyspnea. Finally, given that exercise is a recommendation in patients with COPD, dyspnea can interfere with the best treatment regimen<sup>1</sup>.

### **Exertional dsypnea in COPD**

Pathophysiological factors known to contribute to exertional dyspnea in COPD include increased intrinsic mechanical loading of inspiratory muscles from air trapping (PEEPi), inspiratory muscle weakness, increased ventilatory demand relative to capacity, gas exchange abnormalities, dynamic airway compression, and cardiovascular factors, or any combination of the above<sup>2,3</sup>. In addition to lung function, peripheral muscle strength is an important determinant of exercise capacity in COPD. By gaining muscle mass and strength through exercise training, there would be an improvement in peripheral muscle function, which could be a reasonable therapeutic target for patients with COPD undergoing exercise training.

Well-designed exercise training programs are essential for patients with COPD to achieve a physiological training effect. Substantial improvements in exercise tolerance and overall improvements in the disease can be obtained from a properly designed exercise training program. The improvements in exercise tolerance have been found to be linked with physiological changes such as improved muscle function, altered breathing pattern (higher tidal volume), and lower breathing frequency that leads to a reduced dead space to tidal volume ratio and thus to a lower ventilatory requirement for exercise<sup>4,5</sup>.

In order to enhance exercise training programs, patients with COPD need to feel relief from their dyspnea. Interventions that reduce airflow obstruction or dynamic hyperinflation and subsequently dyspnea include pursed lip breathing (PLB)<sup>6,7</sup>, the administration of anti-inflammatory drugs<sup>8</sup>, helium-oxygen mixtures<sup>9,10</sup>, or bronchodilators<sup>8,10</sup>, and surgical placement of endobronchial valves<sup>11,12</sup>, or lung volume reduction surgery<sup>13,14</sup>.

Increased respiratory muscle effort associated with high ventilatory demand relative to respiratory muscle capacity may contribute to dyspnea in many patients with COPD. The administration of continuous positive pressure (CPAP) or pressure support ventilation (PSV) by noninvasive mechanical ventilation (NIV) devices can improve exercise tolerance and breathlessness in stable COPD patients<sup>15</sup>.

### Research on the effect of NIV on dyspnea

There are multiple studies that have evaluated the effect of NIV on dyspnea but only a few have considered it as an endpoint measure. One study of COPD patients in pulmonary rehabilitation found that short-term administration of NIV during exercise training significantly improved dyspnea and exercise endurance<sup>16</sup>. This was supported by a review of studies<sup>17</sup> suggesting that NIV support during exercise may acutely reduce exertional dyspnea and improve exercise endurance in patients with COPD<sup>18</sup>. Another study compared two different levels of inspiratory pressure support, 5 and 10 cm H<sub>2</sub>O, and found statistically significant improvements in exercise performance and dyspnea relief when using 10 cm H<sub>2</sub>O over 5 cm H<sub>2</sub>O<sup>17</sup>. Two studies examining long-term nocturnal use of NIV in patients with severe COPD reported significant improvements in dyspnea ratings<sup>19,20</sup>. Two other studies found that the use of NIV or CPAP during exercise decreased dyspnea and increased exercise tolerance<sup>21,22</sup> which may facilitate patients' participation in pulmonary rehabilitation.

In the existing research, NIV is typically applied using a face mask which can be cumbersome. NIV devices need to be connected to a power source, limiting portability and creating an obstacle to their use during exercise. In the comparative study referenced above<sup>17</sup>, NIV was applied via a mouthpiece interface with additional benefits of independent usage by patients and portability.

Although there has been research involving the benefit of providing NIV during exercise to increase tolerance overall, there is little research specifically looking at shortening dyspnea recovery times associated with exercise.

In this study, we examined the effect of providing intermittent noninvasive positive pressure therapy (NIPPV) to COPD patients during exercise to relieve dyspnea. The aim of the study was to evaluate the time it takes COPD patients to recover from shortness of breath using intermittent positive pressure and to evaluate the impact of NIPPV on exercise capacity.

Well-designed exercise training programs are essential for patients with COPD to achieve a physiological training effect.

## Methods

A randomized controlled clinical trial was undertaken to compare the impact of a portable, battery powered, hand-held NIPPV device (VitaBreath) on recovery time (the time to return to a baseline dyspnea level after exercise) and exercise capacity (distance walked in a six-minute walk test [6MWT]).

The study was reviewed and approved by an independent ethics committee and all participants provided written, informed consent.

There were three interventions. The VitaBreath device provided a pressure of 8 cm H<sub>2</sub>O during exhalation and 18 cm H<sub>2</sub>O during inhalation in synchrony with breathing. A pressure support (difference between the inspiratory and expiratory pressures) of 10 cm H<sub>2</sub>O was previously shown to increase exercise performance<sup>24</sup>. A sham device, having the same appearance as the VitaBreath device but delivering a constant pressure of approximately 2 cm H<sub>2</sub>O, was a second intervention. Pursed lip breathing (PLB), restricting expiratory airflow through the lips, was the third intervention. Prior to exercising and using the portable devices (active and sham), participants practiced breathing with them at rest.

The Borg scale was used to assess dyspnea<sup>25,26,27</sup>. The 10-point Borg scale is a subjective scoring system in which a patient rates his or her level of dyspnea while performing a particular activity; the higher the number, the greater the perceived degree of dyspnea. The modified Borg scaling most often used to measure dyspnea in COPD literature is the 0-10 scale<sup>27,28</sup>.

Eligible participants underwent a screening visit to collect baseline and anthropometric data and to undergo an evaluation of oxygen saturation during exercise. Participants who persistently desaturated below 88% were excluded from the study.

On the next visit, participants underwent incline treadmill tests. Participants were instructed to take their short acting bronchodilator medication at the beginning of the visit. Fifteen minutes after taking their short acting bronchodilator, participants were asked for their pre-exercise Borg Scale score. They then began the treadmill test at a speed of 1 mph and a grade of 0. Participants were monitored with 6 lead ECG to monitor heart rate and arrhythmias and continuous pulse oximetry. Participants rated their Borg score every 30 seconds during exercise. The treadmill speed was increased gradually until the participant felt they reached their maximum walking speed or they reached the target Borg Scale score of 7. If the participant did not reach a score of 7, the incline of the treadmill was increased gradually at the discretion of the site clinician until the patient reached their maximum incline walking level or the participant reached the target score of 7. If the participant did not reach a target score of 7 within fifteen minutes, the test was stopped. The time it took the participant to achieve a Borg scale rating of 7 was recorded.

Once a Borg Scale score of 7 was reported, participants immediately sat and used the intervention they were randomly assigned to for post-test recovery. Post-test, using the intervention, Borg was assessed every 30 seconds until the participant reached their pre-exercise Borg Scale score or 10 minutes elapsed.

Participants rested for approximately 30 minutes between each treadmill test.

Participants returned for a final visit to complete 6MWT assessments. Participants were instructed to take their short acting bronchodilator medication prior to exercising. Fifteen minutes after their bronchodilator administration, participants initiated the 6MWT assessments.

Participants performed three 6MWT tests in which they were randomly assigned to use either a VitaBreath device, a sham device, or PLB.

Participants were asked for their pre-exercise Borg Scale score prior to each of the three tests. After walking for three minutes, the test was stopped and the participant used the assigned intervention for 30 seconds to help relieve shortness of breath. After the 30 second pause, participants completed the remaining three minutes of the walk test with Borg assessments made every 30 seconds. At the end of the 6MWT, participants sat down and Borg assessments were made every 30 seconds until they returned to their baseline Borg.

Participants rested 20-30 minutes between 6MWT tests.

### **Statistical Analysis**

Baseline variables are summarized with descriptive statistics. Recovery time and 6MWT distance were each compared between the three conditions (active, sham, and PLB) using a repeated-measures analysis of variance (ANOVA). Bonferroni adjustment was applied to limit alpha error to 0.05.



## Results

A total of ten participants (7 males) were evaluated. Demographic data (mean  $\pm$  SD) are presented in **Table 1**. The mean age of the participants was  $67.1 \pm 9.6$ , the mean BMI was  $27.8 \pm 2.9$  Kg/m<sup>2</sup>, and the mean FEV<sub>1</sub> was  $43.3 \pm 5.1$  %. At rest, the mean SPO<sub>2</sub> was  $93.9 \pm 1.9$  and dyspnea was rated at  $3.2 \pm 0.6$  using the MMRC Dyspnea scale.

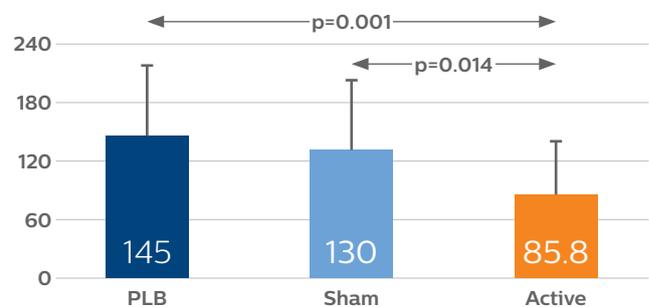
**Table 1. Demographic Data**

Variable	Mean ( $\pm$ SD)
Age (years)	$67.1 \pm 9.6$
BMI (Kg/m <sup>2</sup> )	$27.8 \pm 2.9$
FEV <sub>1</sub> (% predicted)	$43.3 \pm 5.1$
SPO <sub>2</sub> (Baseline)	$93.9 \pm 1.9$
MMRC Dyspnea	$3.2 \pm 0.6$

Recovery times to baseline Borg Scale for each arm of the study are presented in **Figure 1**. The recovery time when using the VitaBreath device ( $85.8 \pm 54.3$  sec.) was significantly lower compared to recovery time when using both the sham device ( $130 \pm 72.8$ ) and PLB ( $145 \pm 72.2$ ).

**Figure 1. Exercise Recovery Times**

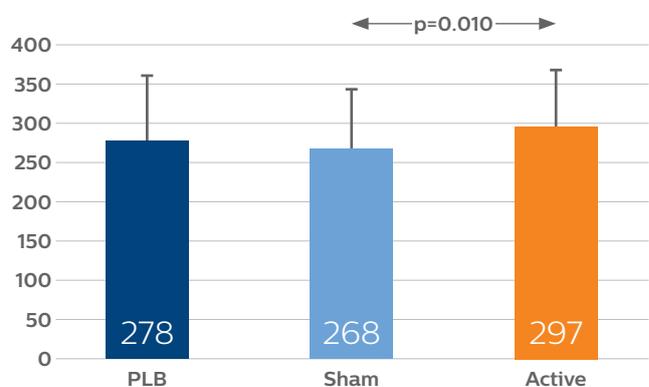
Borg recovery time (seconds)



Distance walked in the 6MWT described above are in **Figure 2**. The distance walked using the VitaBreath portable hand-held device ( $297 \pm 69.9$  m) was significantly greater than the distance walked using the sham device ( $268 \pm 75.5$  m,  $p = 0.01$ ). There were no other significant differences detected.

**Figure 2. 6MWT Results**

Six-minute walk test distance (meters)



The VitaBreath portable hand-held positive pressure device shortened dyspnea recovery time and increased exercise tolerance acutely during exercise.

## Discussion

When using the VitaBreath device in this randomized, controlled pilot study, patients with severe COPD (mean FEV<sub>1</sub> 43%) had a shorter average recovery time from breathlessness compared to both SHAM and PLB. The benefits of portable intermittent positive pressure therapy delivered by the VitaBreath device were also evident in the 6MWT. Participants using the active portable hand-held device walked an average of 29 ± 23.4 meters farther than when using the hand-held SHAM device (p = 0.01).

Noninvasive positive airway pressure has been reported to be beneficial in patients with COPD. CPAP has been reported to relieve dyspnea and reduce intrinsic PEEP<sup>28,29</sup>. Inspiratory pressure support was found to improve dyspnea, increase exercise capacity and improve oxygenation during exercise<sup>22</sup>. A systematic review also confirmed a benefit in reducing dyspnea and improving exercise tolerance for COPD patients using NIV during exercise<sup>16</sup>.

In one study, NIV was reported to reduce intrinsic PEEP and inspiratory workloads<sup>30</sup>. Acutely, NIV improves oxygen consumption<sup>31</sup>.

Exercise is an important component of pulmonary rehabilitation and increasing the duration or intensity of exercise could have a positive effect on the benefits of a rehabilitation program and improve the quality of life for COPD patients<sup>32</sup>.

The VitaBreath device is portable and could be used to relieve dyspnea during supervised or unsupervised exercise or during other activities of daily living where dyspnea is experienced. Having a readily available, non-pharmacological adjunct available could encourage COPD patients to maintain or increase exercise and remain active. Long term physical activity has been shown to reduce the frequency of hospitalizations<sup>33</sup> and exacerbations<sup>34</sup>.

One limitation of this study is the small sample size. However, study participants fell into the severe category based on 2015 GOLD<sup>1</sup> (Global Initiative for Obstructive Lung Disease) criteria. Long term outcomes, which were beyond the scope of this study, were not evaluated.

### Conclusion

In conclusion, the VitaBreath portable hand-held positive pressure device shortened dyspnea recovery time and increased exercise tolerance acutely during exercise. This novel, non-pharmacological tool could benefit patients with exertional dyspnea in exercise programs and with activities of daily living.



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