Evaluation of a portable positive pressure device to relieve dyspnea after exercise in COPD patients: A Pilot Study

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Background

Dyspnea is the number one rated concern for patients of Chronic Obstructive Pulmonary Disease (COPD). They report that it impacts their daily lives and causes them to be less active. There is little research looking into ways of alleviating activity-related dyspnea in this patient population.

We investigated the potential impact of a novel non-invasive pressure support ventilation (NPSV) device on exercise-induced dyspnea in moderate to severe COPD patients. The aims of the study were to evaluate the recovery time after exercise and the impact of the device on exercise capacity.

Methods

A randomized, controlled, pilot study compared the impact of a portable, battery powered, hand-held NPSV device (VitaBreath, Philips Respironics, Murrysville, PA), a sham device, and pursed lip breathing (PLB) on recovery time and exercise capacity.

VitaBreath is an investigational device in the U.S. and has not been cleared by the FDA. It is contraindicated for patients with recent pneumothorax or barotrauma. The study was reviewed and approved by an independent ethics committee and participants provided written, informed consent. The study was registered with ISRCTN (ISRCTN 11274464).

Patient eligibility

- FEV1 < 55% and > 25% of predicted
- Modified Medical Research Counsel (mMRC) Dyspnea questionnaire ≥ 2
- Ability to tolerate at least mild physical activity

Interventions

- VitaBreath: NPSV device with fixed IPAP (18 cm H_2O) and EPAP (8 cm H_2O) – shown in Figure 1.
- Sham: NPSV device with fixed CPAP (~2 cm H_2O)
- Pursed lip breathing

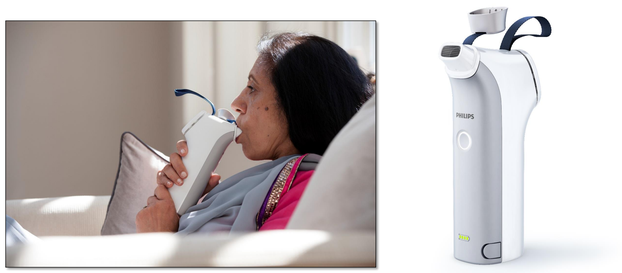


Figure 1: NPSV device - VitaBreath

To assess recovery time, patients walked on a treadmill until they reached a Borg Scale score of seven. They then sat and used, in random order, VitaBreath, sham device, or PLB until they returned to their pre-exercise BORG score. The time to recover from a Borg Scale score of seven to their at-rest baseline was recorded. There was a 30-minute rest period between tests.

To assess exercise capacity, patients performed a modified 6MWT on a treadmill as shown in Figure 2 with each of the interventions in random order. There was a 30-minute rest period between tests.

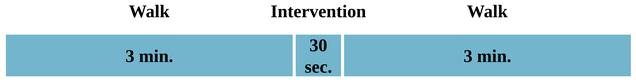


Figure 2: Modified 6-minute walk test. Total time of test: 6'30" with six minutes of walking and 30 seconds of intervention.

Statistical Analysis

Baseline variables are summarized as mean ± standard deviation. Recovery times and 6MWT distances are summarized as median (mean ± standard deviation). Due to the asymmetric distribution of the data, each endpoint was compared between the three interventions using the nonparametric Friedman Test. Bonferroni adjustment was applied to limit alpha error to 0.05.

Demographics

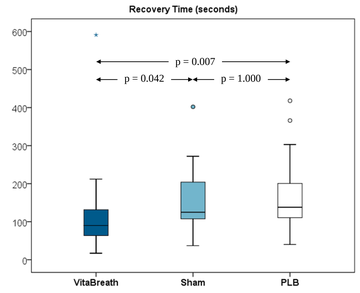
Nineteen participants (13 males (68%)) were included in the analysis. Seven participants were classified as GOLD Stage 2, nine as GOLD Stage 3, and three as GOLD Stage 4. None of the participants were involved in pulmonary rehabilitation at the time of enrollment.

Variable	Mean ± SD
Age (years)	66.9 ± 7.6
BMI (kg/m^3)	28.6 ± 4.7
FEV_1 (% predicted)	41.2 ± 9.8
SPO_2 (baseline)	94.6 ± 2.0
mMRC Dyspnea	2.7 ± 0.7

Results

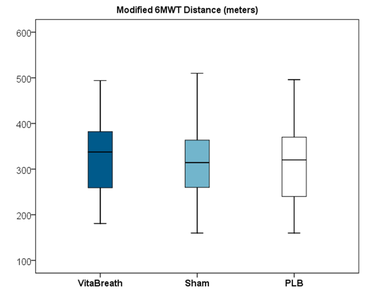
Post-exercise dyspnea recovery times are presented below. The recovery time (in seconds) when using VitaBreath was significantly lower than to the recovery times when using either the sham device or PLB.

Intervention	Median (Mean ± SD)
VitaBreath	90 (124.7 ± 125.5)
Sham	125 (157.4 ± 87.4)
Pursed lip breathing	138 (172.4 ± 103.9)



Exercise capacity, measured with the modified 6MWT as total distance walked (in meters), is presented below. Although the distance walked while using the VitaBreath was longer, no significant differences in the distances walked were detected (p =0.082, Friedman test).

Intervention	Median (Mean ± SD)
VitaBreath	337.4 (326.1 ± 85.8)
Sham	314.2 (309.6 ± 92.8)
Pursed lip breathing	320.0 (313.5 ± 91.4)



No adverse events were reported during the course of the study

Conclusions

Post-exercise, short term use of VitaBreath decreased dyspnea recovery time in stable patients with moderate to severe COPD. There is an indication that VitaBreath may also help to increase exercise capacity. These results warrant further investigation.

Commercial Support

This study was funded by Philips Respironics Inc.

Relevant Financial Interests

Ms. Nisha, Mr. Jasko and Mr. Hardy are employees of Philips Respironics

Abstract ID # 5519