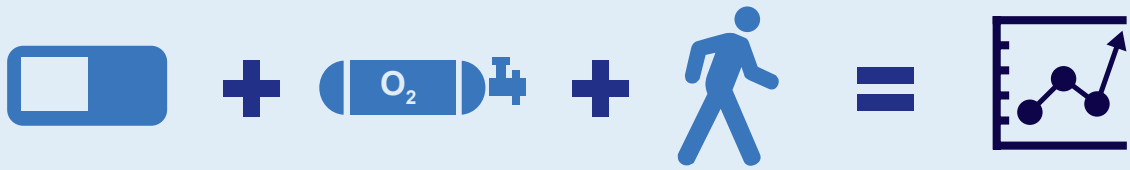
Hillrom™

Key Clinical Research Summaries:

The Benefits of Open Ventilation and Increased Ambulation for COPD

AMBULATORY VENTILATION IMPROVES OUTCOMES



VENTILATION
- Reduce WOB[1]
- Reduce Dyspnea[2]
- Improve $PaCO_2$[3]

OXYGENATION
- Increase & maintain SpO_2 levels at rest and during activity[2]

AMBULATION
- Increase exercise tolerance[2]
- Increase pulmonary rehab[4]
- Increase ADLs[5]

BETTER OUTCOMES
- Improve Quality of Life[6]
- Reduce CAT & mMRC[6]
- Reduce healthcare utilization and costs[7]

COPD is a leading cause of morbidity and mortality throughout the globe today. Within the US, it is the third leading cause of death, and costs the US healthcare system approximately $36 billion annually.[8] In 2012, over one million COPD patients were hospitalized for an acute exacerbation, at a mean cost of $11,195 per event.[9] To further compound the issue, approximately 21% of Medicare-aged COPD patients have a hospital readmission within 30 days of initial discharge,[10] and upwards of 49% have a readmission within 60 days.[11]

In terms of treatment options, noninvasive ventilation (NIV) is commonly a part of the standard of care within the hospital for treatment of patients experiencing an acute exacerbation. Long-term NIV usage in the home has increased in the past several years, as physicians and hospitals look to reduce COPD-related readmissions. A recent study showed a 76% decrease in one-year mortality in COPD patients by utilizing home NIV.[12]

THE ROLE OF ACTIVITY IN COPD READMISSION REDUCTIONS

Activity outcomes in COPD have been studied for over two decades. Studies have shown that two hours of activity per week reduces hospital admissions and respiratory mortality by 30–40%, and for every additional 1000 daily steps taken, COPD hospitalization risk is reduced by 20%.[13, 14] Attempts to combine activity and exercise with NIV have been challenging to date, as often times, the NIV devices are deemed by patients to be too uncomfortable and heavy for ambulatory use.

Hillrom (Life2000® and NIOV) ventilators address many of these therapy challenges. Our 1-lb, wearable ventilators provide patients the opportunity to resume activities of daily living while reducing their dyspnea, work of breathing (WOB), and other COPD symptoms.[1] Each wearable ventilator is connected to a lightweight, low-profile Breathe Pillows Interface that is both comfortable for long-term use and allows the patient to talk while on therapy.

The following pages highlight some of the key positive clinical outcomes and healthcare utilization savings that Hillrom ventilators can provide to patients and healthcare systems, when incorporated into treatment protocols for COPD.

HEALTH CARE UTILIZATION AND RESPIRATORY STATUS FOLLOWING THE ADDITION OF A PORTABLE NON-INVASIVE OPEN VENTILATOR (NIOV) TO THE TREATMENT REGIMEN

Morishige, R[a]; Farberow, K[b]; MacIntyre, N[c]

PRESENTED AT CHEST 2015

Methods

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

- 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).

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.

HEALTHCARE UTILIZATION

	Before Open Ventilation (1 year)				After Open Ventilation (1 year)			
Type of Service	Estimated Cost Per Service	Mean Number of Events	Mean Cost per Patient	Mean Total Cost (16 patients)	Mean Number of Events	Mean Cost per Patient	"Mean Total Cost (16 patients)"	Mean Total Cost Change (%)
Office Visit[15]	$305	5.4	$1,647	$26,352	5.9	$1,800	$28,792	9%
Emergency Room Visits[16,17]	$800	1.9	$1,520	$24,320	0.6	$480	$7,680	– 68%
Hospital Days[15, 16, 18]	$1,500	7.6	$11,400	$182,400	1.3	$1,950	$31,200	– 83%
Hospital ICU Days[16, 19]	$3,000	2.6	$7,800	$124,800	0.3	$900	$14,400	– 88%
Mechanical Ventilations[20]	$800	2.6	$2,080	$33,820	0.1	$80	$1,280	– 96%
			Total	**$391,152**		**Total**	**$83,352**	**– 79%**

[a] Clinical Research Consulting, Castro Valley, CA
[b] SCIO Health Analytics, West Hartford, CT
[c] Duke University Medical Center, Durham, NC

IMPROVEMENTS IN THE HEALTH STATUS OF PATIENTS WITH RESPIRATORY INSUFFICIENCY WITH THE USE OF A NON-INVASIVE OPEN VENTILATION SYSTEM (NIOV)

Carlin, BW[a]; Casey, L[b]; Faberow, K[c]

PRESENTED AS A LATE-BREAKING ABSTRACT AT CHEST 2014

Methods

- 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

MORE THAN 50% reduction CAT and mMRC scores

	Pre-NIOV	Post-NIOV
Average CAT score	**26.71**	**12.33**
Average mMRC dyspnea score	**3.38**	**1.43**

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).[21] 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.[22] The minimum clinically important difference (MCID) of the CAT is estimated to be ≥ 2 points.[23]

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.[24]

[a] Drexel University School of Medicine, Pittsburgh, PA
[b] Mayo Clinic Health System, Franciscan Healthcare, La Crosse, WI
[c] SCIO Health Analytics, West Hartford, CT
* 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

EFFECTS OF A HIGHLY PORTABLE NONINVASIVE OPEN VENTILATION SYSTEM ON ACTIVITIES OF DAILY LIVING IN PATIENTS WITH COPD

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Toni Brennan, RRT,[b] Dan Easley, BS,[b] Richard J. Morishige, MS, RRT[d]

CARLIN BW, ET AL. JCOPDF, JAN 2015 ABSTRACT

Background

For patients with chronic obstructive pulmonary disease (COPD), an increase in exercise tolerance and ability to perform activities of daily living (ADLs) can mean an improved quality of life with fewer exacerbations and lower health care expenses. We evaluated a wearable, noninvasive open ventilation (NIOV) system designed to enhance exercise capacity and increase mobility.

Methods

Patients with stable, oxygen-dependent COPD were recruited for this prospective, open-label, crossover study. Inclusion criteria included supplemental oxygen use, elevated dyspnea score, and the ability to perform ADLs. Patients performed a selected ADL for as long as tolerable while using standard oxygen therapy. Following a rest period, the same ADL was repeated using the NIOV system. ADL endurance time, oxyhemoglobin saturation measured by pulse oximeter (SpO_2), dyspnea, fatigue, and discomfort scores were recorded.

Results

Thirty patients were enrolled and 29 patients completed the study. Mean ADL endurance increased by 85% (13.4 vs. 7.2 min) using NIOV compared with oxygen therapy ($p < 0.0001$). Mean SpO_2 was significantly higher during ADLs using NIOV versus oxygen therapy ($p < 0.0001$). Median dyspnea, fatigue, and discomfort scores were significantly lower using NIOV during ADLs compared to oxygen therapy ($p < 0.01$). No device-related adverse events were observed.

Conclusions

This study demonstrated that a novel, portable noninvasive open ventilation system can improve ADL performance in the home setting. Compared to standard oxygen therapy, the NIOV system provided statistically and clinically significant increases in ADL endurance time and oxygenation, while decreasing dyspnea, fatigue, and discomfort. The NIOV system appears to offer a practical option for increasing activity and exercise tolerance in oxygen-dependent patients with COPD.

ACTIVITY OF DAILY LIVING PERFORMANCE USING STANDARD OXYGEN THERAPY VERSUS NONINVASIVE OPEN VENTILATION (N=29)

Variable	Standard Oxygen Therapy	NIOV System	p Value
ADL Endurance (minutes)	7.24 ± 5.21	13.38 ± 7.50	p<0.0001*
SpO_2%	90.65 ± 4.87	94.78 ± 1.99	p<0.0001*
Borg	3.00	1.00	p<0.0001†
Borg (95% CI)	2.80 – 4.07	1.16 – 2.40	
Fatigue	5.00	2.00	p=0.0005†
Fatigue (95% CI)	2.56 – 5.15	2.03 – 3.77	
Discomfort	4.50	2.00	p=0.0105†
Discomfort (95% CI)	3.17 – 4.86	1.96 – 3.63	

[a] Drexel University School of Medicine, Pittsburgh, Pennsylvania
[b] Klingensmith HealthCare, Ford City, Pennsylvania
[c] Valley Inspired Products, Apple Valley, Minnesota
[d] Clinical Research Consulting, Castro Valley, California

PHYSIOLOGIC EFFECTS OF AN AMBULATORY VENTILATION SYSTEM IN CHRONIC OBSTRUCTIVE PULMONARY DISEASE.

Porszasz J[a], Cao R[a], Morishige R[b], van Eykern LA[c], Stenzler A[d], Casaburi R[a]

PORSZASZ J, ET AL. AJRCCM, AUG 2013

Background

Exercise intolerance limits the ability of patients with chronic obstructive pulmonary disease (COPD) to perform daily living activities. Noninvasive ventilation reduces dyspnea and improves exercise performance, but current systems are unsuitable for ambulatory use.

In patients with COPD experiencing exercise-induced desaturation, we evaluated improvements in exercise tolerance facilitated by a wearable, 1-lb, noninvasive open ventilation (NIOV) system featuring a nasal pillow interface during constant work rate (CWR) cycle ergometer exercise and associated effects on dyspnea, respiratory muscle activation, and pulmonary gas exchange efficiency.

Methods

Fifteen men with COPD (FEV1 = 32.2 ± 12.0% predicted; FEV1/FVC = 31.6 ± 7.1%; exercise oxygen saturation as measured by pulse oximetry [SpO_2] = 86.5 ± 2.9%) participated. After incremental testing establishing peak work rate, subjects completed three visits in which they performed CWR exercise to tolerance at 80% peak work rate: (1) unencumbered breathing room air, (2) using NIOV + compressed air, (3) using NIOV + compressed O_2, or (4) using O_2 via nasal cannula. Assessments included exercise duration, surface inspiratory muscle EMG, SpO_2, transcutaneous PCO_2, and Borg dyspnea scores.

Results

Exercise endurance was 17.6 ± 5.7 minutes using NIOV + O_2, greatly prolonged compared with unencumbered (5.6 ± 1.9 min), nasal O_2 (11.4 ± 6.8 min), and NIOV + Air (6.3 ± 4.1 min). Isotime SpO_2 was higher and intercostal, scalene, and diaphragmatic EMG activity was reduced using NIOV + O_2 compared with unencumbered, nasal O_2, and NIOV + Air, signifying respiratory muscle unloading. Isotime dyspnea reduction correlated with isotime EMG reduction (r = 0.42, p = 0.0053). There were no significant differences in isotime Vd / Vt or transcutaneous PCO_2 among treatments.

54%

INCREASE IN EXERCISE ENDURANCE

from 11.4 to 17.5 minutes (P < .001)

Conclusions

NIOV + O_2 yielded substantial exercise endurance improvements accompanied by respiratory muscle unloading and dyspnea reductions in patients with severe hypoxemic COPD.

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[b] Breathe Technologies Inc., Irvine, California
[c] Inbiolab, Groningen, The Netherlands
[d] 12th Man Technologies, Garden Grove, California

ADDITIONAL CONFERENCE POSTERS AND ABSTRACT PRESENTATIONS

Study	Title	Key Findings
Scasserra J, et al. COPD9USA, 2015	Incorporating Noninvasive Open Ventilation (NIOV™) System into a Pulmonary Rehabilitation Program: Effect on Exercise Endurance	The subjects in the NIOV group demonstrated a significantly greater improvement in mean exercise time versus the control group.
Hill N, et al. CHEST, 2013	Evaluation of Effect of Breathe Ventilation System on Work Of Breathing in COPD Patients	NIOV System significantly: ▪ Increased Vt ▪ Decreased Respiratory Rate ▪ Decreased CO_2
Hilling L, et al. Abstract, ATS, 2010	Improved 6MWT Distance with a Highly Portable Non-Invasive Ventilator	Compared to O_2, patients on NIOV: ▪ Improved 6MWT distance by 37 m ▪ 35–54 m improvement in 6MWT for subset of COPD patients
Garvey C, et al. Abstract, ATS, 2011	Open, Noninvasive Ventilation Using a 1-lb Ventilator, Oxygen, and a Low Profile Mask Improves 6MWT Distances In Advanced COPD	Compared to traditional O_2 therapy, patients on NIOV: ▪ Mean improved 6MWT distance by 34.1 m ▪ Patients with low baseline 6MWT (<300 m) increased their 6MWT distance by 73.3 m

INVESTIGATOR-INITIATED POSTER PRESENTATIONS

Study	Title	Key Findings
Breiburg A, et al. Palo Alto VA and Stanford University Medical Center, ATS, 2016	Impact of Non Invasive Open Ventilation on Dyspnea and Quality of Life in Patients with COPD and IPF	Reduction of Borg Dyspnea Score from 7.8 to 3.5 and continuous statistically significant reduction of mMRC and CAT scores at 1, 30, 180 days.
Lam K, et al. Palo Alto VA and Stanford University Medical Center, ATS, 2017	Long-term Impact of Non Invasive Open Ventilation (NIOV™) on Dyspnea in Patients with Chronic Obstructive Disease (COPD) and Idiopathic Pulmonary Fibrosis (IPF)	Results of one-year follow up shows significant, sustained reductions in mMRC and CAT scores.

BENCH STUDIES

Study	Title	Key Findings
Siobal et al. AARC Congress, 2015	Work of Breathing using NIOV in a Low Compliance High Minute Ventilation Lung Model	Up to 70% reduction in WOB using the NIOV System.
McCoy R, et al. Abstract, ATS, 2014	Volume Assist Ventilation Using Non-Invasive Open Ventilation	NIOV delivered higher inspiratory flows to meet simulated inspiratory demand, thus providing increased Vt in each test condition.
McCoy R, et al. Abstract, COPD8, 2013	Bench Comparison of Non-Invasive Open Ventilation to High Flow Therapy in Various Test Scenarios	▪ NIOV System provided positive pressure between 7–12 cmH_2O vs. HFT (1 cmH_2O) ▪ NIOV augmented Vt by 200 mL vs. HFT by 0 mL"
McCoy R, et al. Abstract, COPD8, 2013	Bench Comparison of Non-Invasive Open Ventilation to Home and Bilevel Ventilation in Non-Invasive Conditions	NIOV System provided similar positive pressure (avg. 9 cmH_2O) and Vt (avg. 709 mL) to bilevel and critical care ventilation devices.

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For more information or to place an order, please contact your local please contact your Hillrom sales representative or call Hillrom Customer Service at 1-800-426-4224.

respiratorycare.hill-rom.com/Life2000

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