Ambulatory Augmented Ventilation – An Unmet Need: Breathe Technologies - Non-Invasive Open Ventilation (NIOV) Evaluation

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Overview

The progression of chronic respiratory disease eventually produces respiratory insufficiency and limits a patient's mobility. Portable oxygen systems are essential for patients who exhibit hypoxemia with activity, and these systems have evolved to provide light-weight, long lasting devices that can increase FiO2.[1] Yet, these oxygen systems cannot compensate for reduced ventilatory capacity.

In order to maintain cardiovascular status, respiratory status, secretion clearance, and most importantly, a positive mental attitude, patients with chronic lung disease need to remain active and mobile for as long as possible. The lack of an effective portable method of ventilation and oxygenation for patients with chronic lung disease encourages a pattern of reduced activity, decreased clearance of secretions, infections, exacerbations, and hospitalizations. Unfortunately, these "frequent flyer" patients are well known to hospitals and caregivers, and attempts to prevent re-hospitalization are often unsuccessful. Patients return to their homes and the vicious downward pattern begins again.[2]

Oxygen therapy, even when effectively prescribed and applied, does not address the need for augmented ventilation. Yet, the combination of augmented ventilation and oxygen therapy during ambulation has not been available. The recent development of a novel Non-invasive OPEN Ventilation (NIOV) System that provides both oxygenation and ventilation in a lightweight system (1lb), portable enough to be worn by a patient, may change the playing field. The ventilator is light enough to be carried by a patient and uses a proprietary "open" nasal pillow interface. Because of its portability and comfortable nasal pillows interface, the NIOV System is uniquely positioned to provide patients with a means of receiving truly ambulatory supplemental oxygen plus augmented ventilation.

Patient Case Study

An evaluation of the NIOV System was conducted in an outpatient setting on oxygen dependent patients with a primary diagnosis of chronic obstruction pulmonary disease (COPD). After acclimating the patient to the NIOV System, the patients were walked on the NIOV System at various distances in an attempt to titrate the patients augmented volume settings to all 3 levels of activity (mild, moderate, high). When exerting these patients continuous SpO2, HR, and RR were recorded in addition to a Borg Scale reading as a measurement tool for assessing dyspnea. The low activity setting was titrated for comfort and stable SpO2 readings at rest, the medium activity titration was approached in a similar fashion but during an exertional walk, and the high activity titration during a brisk walk (if tolerated).

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Summary of Data

Patient #1: 66 y/o female diagnosed with emphysema with a history of multiple hospitalizations for acute COPD exacerbation. She is a former smoker with a pack-year history of 9 and is on continuous oxygen at 3 lpm. She has dyspnea with heavy exertion when climbing flights of stairs, walking up hills or inclines. Her symptoms are moderate. While continuing her current medication regimen her degree of exercise limitation is moderate.

Pulmonary function testing reveals:

Spirometry at BTPS	Actual	Predicted	% Pred.
FVC	0.88	2.59	33
FEV1	0.30	1.84	16
FEV1/FVC	34	73	46
PEFR	1.82	5.21	34

Spirometry impression: very severe obstructive lung disease. DLCO is severely reduced.

	3 lpm O_2 via N/C	NIOV Low Activity Setting at 120 mL during rest	NIOV Medium Activity Setting at 190 mL during walk	NIOV High Activity Setting at 230 mL during brisk walk
SpO_2	94	95	95	92
HR	90	89	110	120
RR	14	17	19	20
Borg	1	0.5	3	3

Patient's final augmentation volumes on low, medium, high activity levels were titrated to 120mL / 190mL / 230mL. Trigger sensitivity set at 6 with a 30% delivery percent time. This patient walked a total of 3 rounds at distances of 176ft the first round, 176ft the second round and 230ft the third round. Initial volume settings of 100mL/130mL/170mL were inadequate as suggested by Borg scale reading, SpO_2, HR, and RR during activity. Low activity augmentation volume (120mL) was titrated at rest. The medium augmentation volume (190mL) was titrated during a

mild exertional walk. This particular patient had the capacity to perform a brisk walk for a distance of 230ft which the high augmentation volume (230mL) was titrated too. Overall, when using the NIOV System the patient observed an improvement in her exercise tolerance, oxygen saturation, and walking distance, with a reduction in dyspnea respectively during mild to moderate exertional activity compared to her traditional oxygen therapy. The patient also noted that her recovery time after exerting herself was noticeably short.

Patient #2: 67 y/o female patient diagnosed with COPD. As a former smoker she has a documented 22 pack-year history. She has dyspnea with heavy exertion with moderate exercise limitations. She is currently using oxygen at 2lpm at rest, and adjusts her liter flow consumption with activity to high as 4lpm.

Pulmonary function testing reveals:

Spirometry at BTPS	Actual	Predicted	% Pred.
FVC	1.35	2.34	57
FEV1	0.43	1.64	26
FEV1/FVC	32	72	44
PEFR	1.16	4.94	23

Spirometry impression: moderate-to-severe obstructive lung disease.

	2 lpm O_2 via N/C	NIOV Low Activity Setting at 110 mL during rest	NIOV Medium Activity Setting at 150 mL during walk	NIOV High Activity Setting at 190 mL during brisk walk
SpO_2	90	94	94	92
HR	87	83	88	96
RR	20	18	24	26
Borg	0.5	0.5	4	5

Patient's final augmentation volumes on low, medium, high activity levels were titrated to 110mL / 150mL / 190mL. This patient walked a total of two rounds at distances of 176ft the first round, and 176ft the second round. Initial volume settings of 80mL/110mL/150mL were inadequate as suggested by Borg scale reading, SpO_2, HR, and RR during activity. The patient's low activity augmentation volume (110mL) setting was titrated to at rest. The medium augmentation volume (150mL) setting was titrated during a mild exertional walk. With this patient's limited exercise capacity we encouraged her to increase her walking pace on the last walk which the high augmentation volume (190mL) was titrated too. She walked a total distance of 88ft at a brisk pace. The patient's trigger sensitivity was set at 5 with the delivery percent time set at 25%. Overall, the patient observed a significant gain in her exercise tolerance, and improved oxygen saturation, with a reduction in dyspnea respectively during rest and at mild to moderate activity compared to her traditional oxygen therapy. While using the NIOV System we also found the patient to be "full of color." She ended the evaluation with a good understanding of when appropriate levels of activity were to be selected and was quite fascinated with ease of use.

Patient #3: 53 y/o female diagnosed with COPD and moderate pulmonary hypertension. She currently uses a portable liquid oxygen system with 6lpm continuous flow. She is a current smoker and has a documented 40 pack-year history. With mild exertion she has moderate dyspnea with acrocyanosis. While continuing her current medication regimen her degree of exercise limitation is severe.

Pulmonary function testing reveals:

Spirometry at BTPS	Actual	Predicted	% Pred.
FVC	2.61	3.35	77
FEV1	1.59	2.52	63
FEV1/FVC	61	75	81
PEFR	5.88	6.03	97

Spirometry impression: mild obstructive lung disease. Reduced DLCO with actual reading of 9.11 mL/min/mmHg which is 39% of predicted.

	6 lpm O_2 via N/C	NIOV Low Activity Setting at 220 mL during rest	NIOV Medium and High Activity Setting at 250 mL during walk
SpO_2	90	92	95
HR	88	92	99
RR	18	16	15
Borg	2	2	3

Patient's final augmentation volumes on low, medium, high activity levels were titrated to 220mL / 250mL / 250mL. Trigger sensitivity was set to 8 with a 35% delivery time. With her particular disease process she required aggressive settings to maintain acceptable SpO2 readings. That being said, her low activity augmentation volume (220mL) was titrated at rest and then proceeded to walk this patient at the 250mL augmentation volume. During this first attempt to walk the patient, the patient found such a dramatic improvement in her exercise tolerance and oxygenation she walked a total of 1,232 feet. During the walk the patient maintained SpO_2 >88%, and commented that she didn't experience the "blackout feeling" she normally experiences when she performs in any mild to moderate activity. Overall, the patient observed a dramatic increase in her exercise tolerance capacity, with improved oxygen saturation, and a reduction in dyspnea respectively during any level of activity compared to her traditional oxygen therapy. While using the NIOV System we also found the patient to be "full of color," and quite enthusiastic with the level of improvement she gained.

Conclusion

Augmented ventilation for patients with respiratory insufficiency may provide the necessary ventilatory assistance to allow patients to participate more fully in life and to perform the ADLs in and outside their homes in an attempt to improve conditioning and prevent complications associated with a sedentary life-style. The Breathe NIOV System has proven to address an unmet need for many patients with chronic respiratory insufficiency. This case study, along with prior clinical trials[3,4] using the NIOV System, support the premise that a truly portable ventilator can provide utility in improving mobility and exercise tolerance. As with LTOT, further research and education will create a solid foundation and scientific bases for using NIOV to improve the outcomes of patients requiring continued treatment of their chronic respiratory disease.

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New Treatment Approach

In July 2009, MT, weighing 225 lbs, continued to present with loud snoring, daytime sleepiness and inability to tolerate earlier treatment alternatives. She inquired about new options. She was prescribed Provent Sleep Apnea Therapy and underwent home sleep testing with a Watch-PAT 100 Polysomnography System to immediately confirm treatment efficacy. (See Figure 2.)

MT experienced a nearly complete resolution of respiratory events and snoring while non-supine and a marked improvement in sleep continuity. She also reported feeling more energized.

She continues to use Provent Therapy on a nightly basis. She believes that it fits her home life as well as her active lifestyle which includes travel, dog-sledding, zip-lining and other adventures.

Summary

This study highlights an example of Provent Therapy becoming the mainstay treatment for a patient who has failed traditional OSA treatment options. Efficacy with the Provent Device was demonstrated immediately after trial of the device using home monitoring with the Watch-PAT 100 System and patient's subjective response. Her initial AHI of 26.6 was reduced to 6.9 and the fatigue and snoring were resolved. Adjunctive diet and exercise programs continue to be recommended as well as non-supine positioning.

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