NIOV: Non-Invasive Open Volume Augmentation for Rehab

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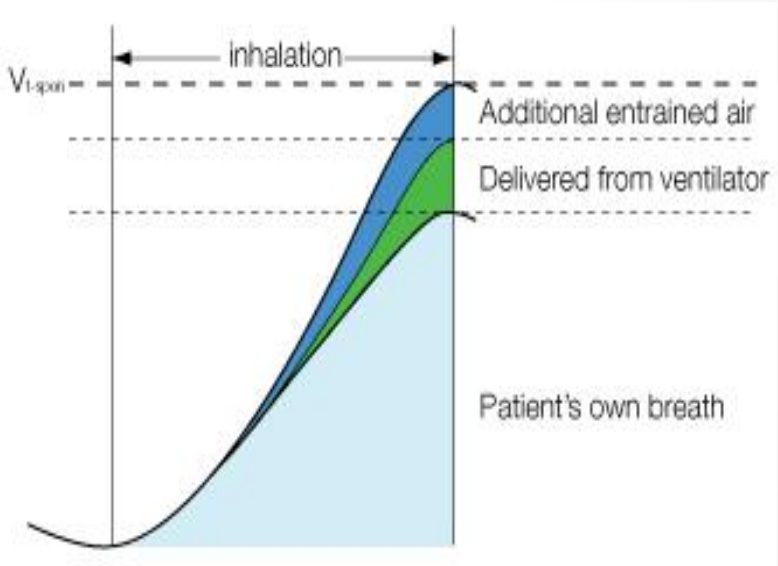
What is NIOV?

- A new device that provides pressurized gas to augment ventilation to improve capabilities of patients that have ventilatory impairment:
  - Dyspnea that prevents activity
  - Hypoventilation that prevents adequate gas exchange
  - Mobility restrictions due to stationary therapy equipment
  - Hypoxemia due to ventilation and perfusion issues
- Ambulatory to encourage mobility
  - Home activities of daily living
  - Early mobility within the hospital
  - Pulmonary rehabilitation

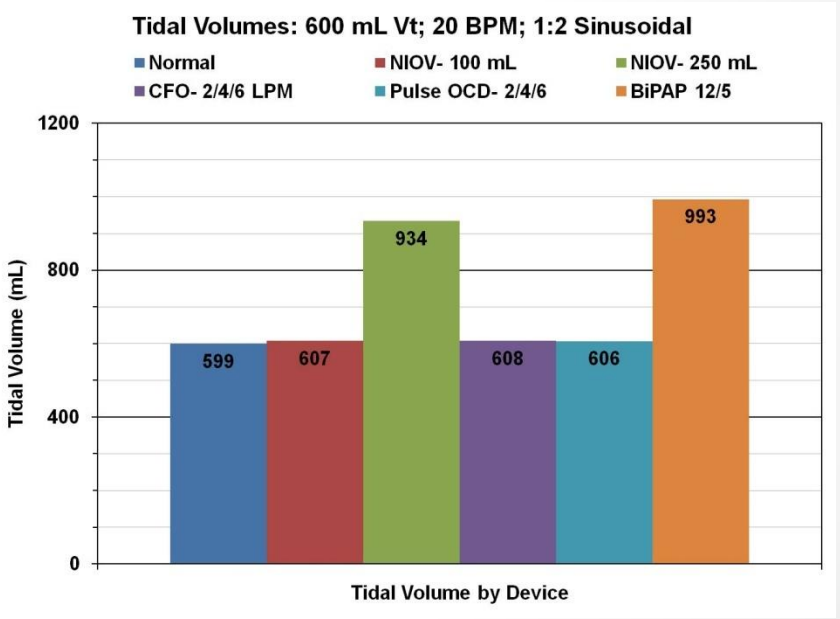
Non-Invasive Open Ventilation

- Non-Invasive: Not entering the body
- Open: Comfortable interface does not seal the system from the atmosphere allowing the patient to breathe around the system if needed
- Ventilation: Adds to ventilation with positive pressure augmenting the patients normal breathing



Why is NIOV Unique

- Allows for ambulation with augmented ventilation
  - Ambulation is the most critical part of home respiratory care
- Small and light enough to gain patient compliance
- Addresses an un-met need in home ventilation



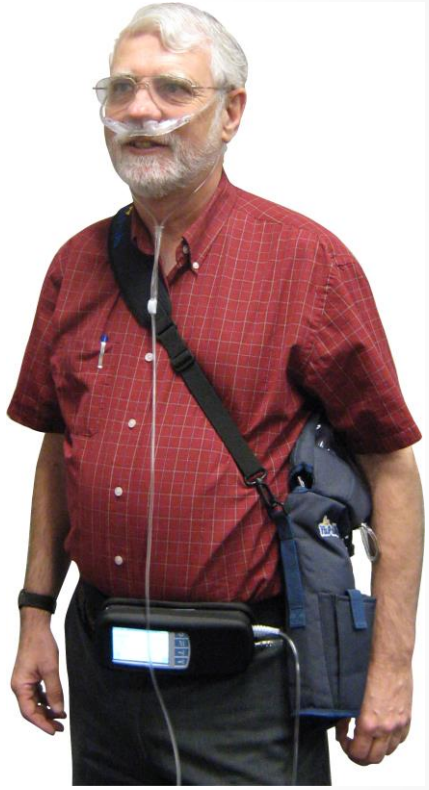
Why Use NIOV

- Early ambulation within the hospital to prevent pneumonia
- Use with pulmonary rehabilitation to allow patient with severe dyspnea to begin exercise
- Home use to encourage mobility
  - Continue exercise at home
  - Encourage normal home activities
  - Prevent exacerbations due to hypoventilation
- Reduce work of breathing for patients recovering from an exacerbation
- As an option for patients using Bi-level devices in their home to "catch their breath"

Current Environment

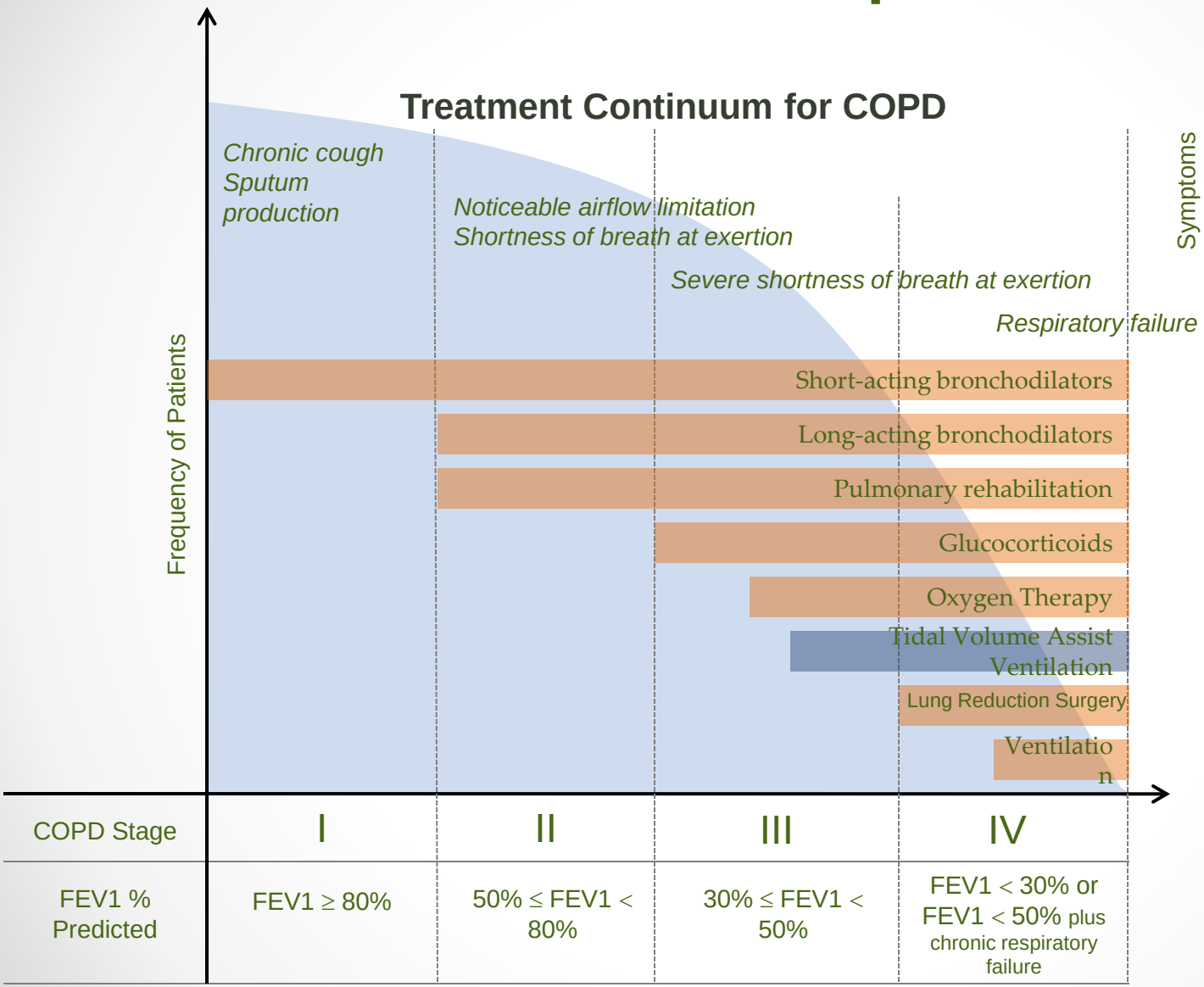
- Two million patients on LTOT in the US
  - How many have respiratory insufficiency?
  - How many are "frequent flyers" returning g to the hospital with an exacerbation?
- Hospitals incentivized to have patients stay home after discharge for greater than 30 days
  - Education and medications will not address respiratory insufficiency
  - The current home equipment model does not address therapy
- Patients are interested and encouraged to take responsibility for their health needs
  - They know what they can't do, they don't know options
  - Patient education is a key focus for hospitals

NIOV System



- 1 lb. tidal-volume assist ventilator
- Touch screen
- Three activity level settings
- Pillows-style nasal interface
- *510(k)* for homecare and institutional use

The Treatment Gap for COPD

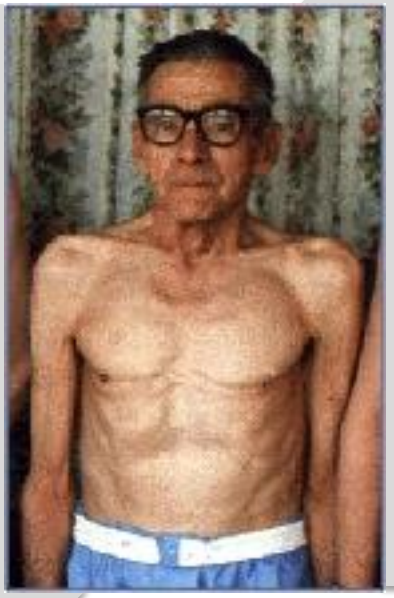


Clinical Problem – A Decline in Physiological Condition

Despite current standards of care, many COPD patients still experience a rapid decline in their physical condition.

Decreased QoL

- Depression
- Loss of social contact
- Loss of independence
- Inability to perform ADLs
- Increased breathlessness
- Increased hospital utilization



High number of co-morbidities

COPD patients have, on average, **nearly three other chronic medical conditions**[1,2]

- Cardiovascular diseases
- Lung cancer
- Respiratory failure
- Pulmonary hypertension
- Depression (40% of COPD patients)[7]

High levels of healthcare utilization

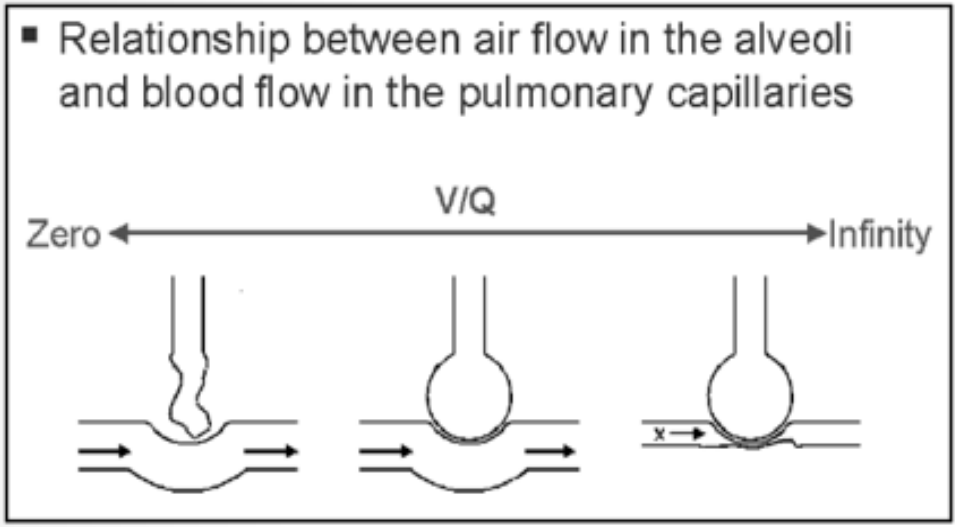
Nearly **15% of all COPD patients have an inpatient hospital stay each year**[3]**,** at an estimated average cost of **$6,500 per stay.** [4]

Mortality

- 3th leading cause of death in the US[5]
- ~130,000 die each year[6]
- 1/3 of COPD patients on long-term oxygen therapy die from respiratory failure [1]

1 Role of Comorbidities. European Respiratory Journal 2006; 28: 1245-1257
2 Global Initiative for COPD 2009
3 Adapted from SRBI, "Confronting COPD in America" (2000)
4 Per Breathe independent 3rd party research; EMR data of COPD patients using oxygen
5 Minino, A. Deaths: Preliminary Data for 2008. National Vital Statistics Reports. Vol. 59, #2. December 9, 2010
6 http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5745a4.htm (126,000 COPD patients in 2005)
7 Yohannes, AM. *Depression and COPD in older people: a review and discussion.* Br J Community Nurs. January 10, 2005. 42-6.

Ventilation Perfusion V/Q



V/Q matching is an important balance for ventilation and oxygenation

Oxygen therapy without adequate ventilation is minimally effective

Acute or chronic episodes of hypoventilation prevents patients from adequate gas exchange

For home bound patients, poor ventilation/oxygenation is the beginning of an exacerbation

NIOV provides both augmented ventilation and oxygenation in an ambulatory system

Physical Activity and COPD Outcomes

- **Positive outcomes are associated with higher levels of physical activity**
  - Physically active COPD patients show better functional status in terms of DLCO, PEmax, 6MWD, VO2 peak, and systemic inflammation.
  - Patients with higher activity levels had a lower hospitalization risk than those with a low activity levels.
  - Out-patient pulmonary rehabilitation was able to improve health outcomes for patients with COPD. Hospital utilization and health costs were reduced as well.
- **Low levels of physical activity result in decline in health status and poor outcomes**
  - Time until first admission due to COPD exacerbation was shorter for the patients with lower activity levels.
  - Patients hospitalized for an acute exacerbation (AE) in the prior year had lower activity levels compared to those without a recent hospitalization.
  - Patients with a low activity level at 1 month after discharge were more likely to be readmitted in the following year.
  - Patients with COPD are markedly inactive during and after hospitalization for an AE.
  - COPD patients that maintain a low activity level have impaired HRQoL, whereas an increase in physical activity can improve HRQoL parameters.

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Physical Activity Improves COPD Outcomes

"This 20 year follow-up study of 2386 subjects with COPD shows that, for these subjects, a level of physical activity equivalent to walking or cycling 2 hours/week or more was associated with a 30-40% reduction in the risk of both hospital admission due to COPD and respiratory mortality."[1]

"Patients with COPD receiving long term oxygen had a 4-year survival of 35% if they reported regular outdoor activity, while survival was 18% if they had no regular outdoor activity."[2]

"Physical activity is a strong predictor of mortality in patients with COPD. For every 0.14 decrease in physical activity level, the relative risk of death more than doubled."[3]

1. J Garcia-Aymerich et al "Regular physical activity reduces hospital admission and mortality in chronic obstructive pulmonary disease: a population based cohort study. Thorax 2006;61:772-778
2. Ringback et al "Outdoor activity and performance status as predictors of survival in hypoxaemic chronic obstructive pulmoanry disease." Clin Rehabil2005:19331-338
3. Waschki et al "Physical Activity Is the Strongest Predictor of All-Cause Mortality in Patients With COPD." Chest:140 August 2011

Non-invasive Positive Pressure Ventilation Improves Exercise Tolerance

Key Findings:

- Exercise training is an essential component of pulmonary rehabilitation
- Non-invasive positive pressure ventilation (NPPV) provides benefit by unloading overtaxed ventilatory muscles, thus allowing increased exercise tolerance
- Out of 22 trials, 20 reported positive effects of NPPV on exercise tolerance and related outcome measures

- **Positive effects of NPPV on exercise tolerance include:**
  - Reduction of dyspnea
  - Improvement in exercise time and/or maximum workload
  - Improvement in oxygen saturation or PaO2
  - Improvement in walking distance
  - Improvement in maximal oxygen uptake
  - Improvement in leg muscle oxygenation & fatigue
  - Improvement in breathing pattern, FEV1, and lung hyperinflation
  - Improvement in Chronic Respiratory Disease Questionnaire

Literature Review bibliography included in Appendix

Pride Clinical Study

Patients reported less dyspnea, reduced work of breathing, greater mobility, and improved exercise endurance using NIOV compared to their current oxygen systems.

Klingensmith Clinical Study

NIOV significantly improved all primary endpoints.

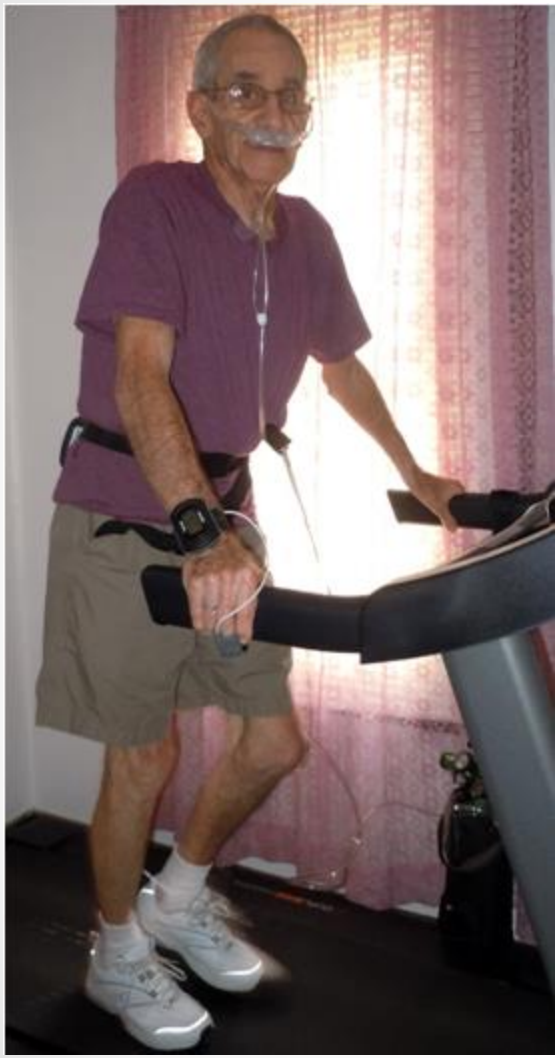
Table 1 Study subject characteristics

Variable	Subjects (n=30)	Range
Gender, F/M	18/12	
Age (years)	72 ± 6.3	(57 - 81)
Height (in)	66 ± 4.2	(60 - 76)
Weight (lbs)	175 ± 49.3	(89 - 300)
BMI (lbs/in^2)	28.2 ± 7.1	(17.4 - 44.9)
Mean O_2 Use, Rest (lpm)	2.6	(2 - 4)
Mean O_2 Use, Exertion (lpm)	2.8	(2 - 5)
Median MMRC	3	(1 - 4)

Table 2 Activity of daily living performance using standard oxygen therapy versus NIOV (n=29)

Variable	Standard Oxygen Therapy	NIOV System	*P Value*
ADL Endurance (min)	7.2	13.4	$P < 0.0001$[1]
SpO_2%	90.7	94.8	$P < 0.0001$[1]
Borg	3.0	1.0	$P < 0.0001$[2]
Comfort	4.5	2.0	$P = 0.0105$[2]
Fatigue	5.0	2.0	$P = 0.0005$[2]

[1] Means, paired t test, two-tailed. [2] Medians, Wilcoxon matched-pairs signed-ranks test, two-tailed.



Klingensmith HealthCare – Case Study – Kim Wiles BS RRT

- **Study objective:** To evaluate the effects of NIOV on performance of activities of daily living in the home setting for 46 days compared with standard oxygen use
- **Measures:** ADL activity, SpO2, Dyspnea (Borg), Fatigue (FRS), Comfort (CRS), Respiratory rates
- **Patients enrolled:** Subject 1
- **Completion date:** March 2012

@ 46th Day	O2 Only	NIOV
ADL (Treadmill)	<1 min	16 min
Dyspnea	3	1
SpO2	94-95%	95-98%

- **Comments:** Subject 1 now uses his treadmill 15 min/day, has achieved motivational goal of taking walks and driving his car where on day 1 on oxygen, was never able to leave home or exercise.

- Abstract submitted to AARC (American Association of Respiratory Care) November 2012

Novel 2 Clinical Study

Open, Noninvasive Ventilation Using a 1-lb Ventilator, Oxygen, and a Low Profile Mask Improves 6 MWT Distances in Advanced COPD

C. Garvey[1], L. Hilling[2], C. Cayou[2], R. Escobar[1], G. Heron[3], L. McCabe[4]

[1]Seton Medical Center - Daly City, CA; [2]John Muir Health - Concord, CA; [3]Intermountain McKay-Dee Hospital, Ogden, UT; [4]Sharp Memorial Hospital, San Diego, CA

Introduction: Loss of mobility occurs with advanced COPD and heralds reduced quality of life and increased health care utilization[1]. The current standard of care for treating activity limitation caused by COPD is pulmonary rehabilitation, which is effective in improving mobility and exertional tolerance[2]. However, pulmonary rehabilitation may not restore normal exercise tolerance in advanced COPD, and disease progression eventually leads to worsening functional limitation. Available ventilation systems either dramatically reduce quality of life, or are not suitable for ambulatory use, and thus are not a practical solution to treat activity limiting dyspnea in COPD. There is an urgent need for research on additional therapeutic options that minimize functional impairment in advanced COPD.

To address this important unmet need, we previously conducted a non-significant risk trial with a pre-commercial, prototype mask and wearable ventilator system. In that trial, use of the ventilator system was comfortable for most patients. In addition, patients using the test ventilation system showed a mean increase in 6MWT distance of 24 meters, while patients with a baseline walk distance of < 300 meters improved 44 meters on average. These trial results were reported at the 2010 ATS conference[3].

Here we report on a follow-up trial where we studied the same wearable 1-lb ventilator system featuring a refined mask designed for regular ambulatory use (Figure 1). The noninvasive open ventilation (NIOV™) mask and ventilator system (Breathe Technologies, San Ramon, CA) have received FDA clearance for home and institutional use. The ventilator requires an external, pressurized oxygen source and utilizes proprietary NIOV™ technology. We hypothesized that this ventilator system would be well tolerated by patients in a pulmonary rehabilitation setting and would improve 6MWT distances to a similar extent as the previously tested prototype.

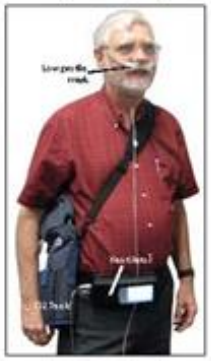


Figure 1. Test Ventilator System

NIOV™ Test System Compared to Alternative Therapies Using a Lung Simulation Model

In bench tests using an IngMar Medical ASL 5000 simulator, the NIOV™ system provides substantial augmentation of tidal volumes and oxygen concentration using lung test conditions that model COPD (Figures 2 & 3).

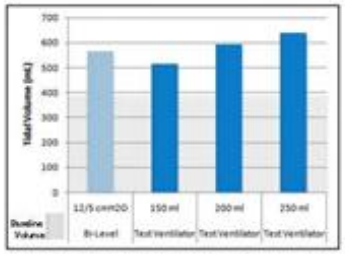


Figure 2: Tidal Volume Augmentation in Lung Simulation Model

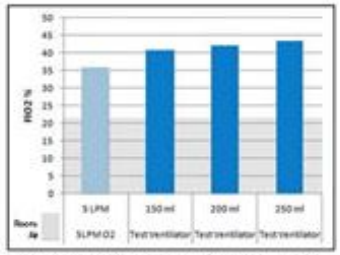


Figure 3: FIO_2 Augmentation in Lung Simulation Model

These results are comparable to augmentation achieved with traditional Bi-level ventilation set at 12/5 cmH_2O of IPAP/EPAP, while standard oxygen therapy provides no augmentation of test lung volumes.

Non-invasive Open Ventilation (NOVEL 2) Study Overview:

Study Hypothesis: The ventilator system will be well-tolerated for 1 hour of use.

Study Design: Open-label, cross over in 34 patients previously enrolled in a pulmonary rehab program. Four pulmonary rehab centers. Use of a low-profile, open mask-based interface in conjunction with a wearable 1-lb ventilator (Breathe Technologies) and oxygen tank. For the control walk, oxygen use was 5 lpm, or the patient's oxygen Rx for exertion - which ever was greater.

Key Inclusion/Exclusion Criteria: COPD patients with FEV_1 < 60% of predicted. Oxygen prescription of ≥ 2 lpm and <8 lpm at exertion. Able to complete 6MWT on standard oxygen therapy. No signs of acute illness.

Study Endpoints: Patient tolerance and device function while at rest, and with exertion.

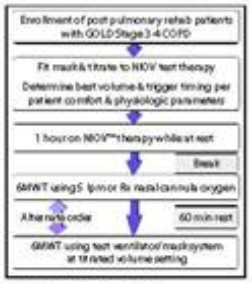


Figure 4. Study Flowchart

Table 1: Patient Characteristics in NOVEL 2 Trial

Patient Characteristic	Mean	SD	Range
Age (yrs)	66.8	9.6	55 - 79
Body Mass Index (BMI)	27.7	6.1	15.7 - 39.6
FEV_1 % Predicted	33.9	11.7	17.0 - 60.0
RV % Predicted[1]	163.5	60.1	77.0 - 290.0
FEV_1/FVC Ratio % Predicted[2]	46.4	13.7	23.0 - 68.0
O_2 Rx at Rest (lpm)	2.35	0.97	0.00 - 4.00
O_2 Rx during Exertion (lpm)	3.21	1.23	2.00 - 6.00
Male/Female %	59 / 41		

(1) n=15. Data unavailable for all 34 subjects.
(2) n=21. Data unavailable for all 34 subjects.

Results 1: Patient Reaction to Test Ventilator Indicates Long-term Use Potential

Among study participants, 2/3 of the subjects reported improved or equivalent comfort over their nasal cannula during their 6MWTs.

Results 2: Test NIOV™ System Improves 6MWT Distance without Changing Other Metrics

Metric	n[1]	Baseline Walk Mean	Baseline Walk SD	Test Walk Mean	Test Walk SD	Change from Baseline Mean	Change from Baseline SD	P Value*
6MWT Distance (m)	34	323.7	97.6	357.7	84.5	34.1	50.0	0.0004
Respiratory Rate (bpm)[2]	22	22.8	4.5	21.9	3.8	-0.8	2.1	0.0787
Heart Rate (bpm)[2]	26	100.6	13.1	101.1	14.2	0.5	7.2	0.7877
Change in Borg Dyspnea Score	34	2.7	2.0	2.6	2.2	-0.1	1.8	0.7460
Change in SpO_2	25	-4.6	3.6	-4.4	4.5	0.1	5.2	0.9094

(1) Data not available for all subjects for all metrics (2) Reported as averages for each walk
* Two-tailed P value calculated using paired t test

Results 3: Substantial Increase in 6MWT Distance in Patients Walking < 300 m at Baseline

Sample	Sample Size	Mean Change from Baseline (m)	SD
All Patients	34	34.1	50.0
Patients' Baseline 6MWD < 300 m	13	73.3	55.5
Patients' Baseline 6MWD > 300 m	21	9.8	25.5

Conclusions: Study results show that the NIOV™ system was well tolerated on patients at both rest and exertion. No adverse events were reported.

- Mean 6MW distance across the full study population (n=34) improved by 34.1 meters using NIOV™ therapy.
- Patients with low baseline 6MW distances < 300 meters (n=13) showed a substantially higher mean improvement of 73.3 meters. This is well above generally accepted MCID values.[4-6]
- Patients with baseline 6MW distances ≥ 300 meters (n=21) showed a mean improvement of 9.8 meters.

Future Directions: Given that the majority of study subjects tolerated NIOV™ therapy for at least one hour of continuous use, future studies should test patient tolerance for longer periods of exposure. Additionally, there is much promise for this therapy to improve exercise capacity. Future studies with NIOV™ therapy should measure the effect on patients in other key patient outcomes, such as in performing activities of daily living (ADLs) or in quality of life measurements. Finally, the system has shown promise, in both this study and a prior study, for patients with COPD. There is a potential to study increased exercise tolerance with NIOV™ therapy in patients with other types of lung disease, such as ILD.

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The authors thank would like to thank the following individuals for their hard work and efforts in conducting this study: Thomas Hazlehurst, MD, Richard Kops, MD, Kathleen Kennady, RRT, RCP, Susan Mann, RRT, RCP, Lynne Schneider, RCP, Michele Wadsworth, Colette O'Bitz, and Danielle Nielsen, B.S.

This Study was sponsored by Breathe Technologies, Inc. San Ramon, CA

Presented at the American Thoracic Society 2011 International Conference Denver, CO May 13-18, 2011

Presented at ATS 2012

Pride Clinical Study

Use of a Novel Non-invasive Open Ventilation System During Rest, Activities of Daily Living, and Exercise in Patients with Severe COPD

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Introduction: In patients with severe COPD, the ability to perform activities of daily living (ADLs) or to exercise may be severely impacted. For patients recovering from an exacerbation, ambulation can exceed respiratory reserves and hamper rehabilitation efforts. A portable device that augments ventilation while supplying supplemental oxygen could improve patient mobility, enhance rehabilitation, and offset some of the functional impairment associated with advanced COPD. Here we report the results of a study in which a novel, lightweight (1-lb), wearable, 510(k) cleared, non-invasive open ventilation (NIOV) system was evaluated in subjects with severe COPD.

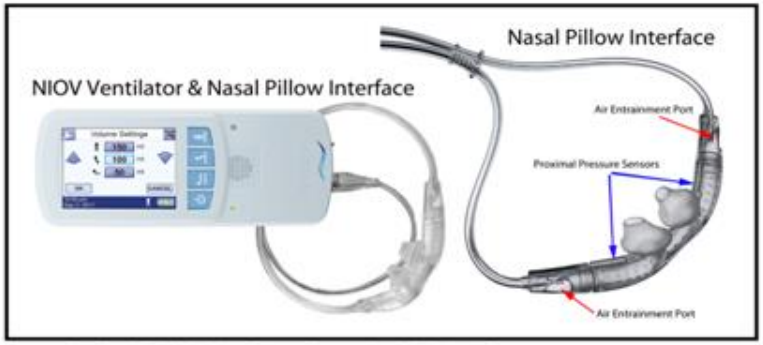

***Figure 1**: The Breathe Technologies NIOV ventilator and nasal pillow interface.*

The Breathe NIOV system provides synchronized, volume-augmented ventilation to adult patients with respiratory insufficiency. The system consists of a wearable, volume-assist, non-life-supporting ventilator and a non-sealing, non-invasive nasal interface (Fig 1). The ventilator is connected to a medical grade oxygen cylinder or hospital wall oxygen, and can deliver volumes of oxygen ranging from 50-250 ml during the inspiratory phase of the breathing cycle. The NIOV system is described as "open" rather than sealed, meaning that the user's respiratory tract retains immediate access to ambient air. This "openness" is possible because of a unique nasal pillow interface which does not require sealing-off the nose as do conventional nasal/face masks used with other noninvasive ventilation systems. Two air-entrainment ports located on the nasal interface allow for the delivery of total augmentation volumes in excess of 450 mL and FiO_2s in the range of 0.35 - 0.45.[1]

Presented at the American Thoracic Society 2012 International Conference San Francisco, CA May 18-23, 2012

Methods: This was a non-randomized, open-label study conducted at three pulmonary rehabilitation centers, with an objective to evaluate the NIOV ventilator 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, during ADLs, and while exercising. 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.

Results: Eighteen subjects, aged 60-85 years, completed the study. Mean (SD) FVC % Predicted was 54% (16). Mean (SD) FEV_1% Predicted was 33% (11). Mean NIOV augmentation volumes were 100, 130, and 180 mL for low, medium, and high activity levels, respectively. Based on questionnaire responses, subjects reported that the NIOV system was comfortable and easy to use. Additionally, subjects indicated a strong preference (median Likert scores of 5/5) for using the NIOV system over their standard oxygen systems for performing errands, household tasks, and exercise. No serious adverse events or adverse events related to the study device were reported.

Table 1. Subject Characteristics

Age	Gender	Height (in)	Weight (lbs)	BMI	Smoking Hx (pk/yrs)	FVC % Predicted	FEV_1 % Predicted	Oxygen Use	
								Rest	Exer.
68.6 (6.3)	9 M 9 F	65.4 (4.4)	178.0 (40.4)	28.7 (5.0)	53.0 (30.5)	54.0 (16.0)	33.0 (11.0)	2.7 (1.1)	3.6 (1.5)

Mean (SD), n=18

Table 2. Study Exit Questionnaire Responses*

Compared to oxygen therapy:					
When walking or exercising with NIOV, my feeling of being out of breath is:	When walking or exercising with NIOV, my energy level is:	When walking or exercising with NIOV, dryness in my nose and throat is:	I would prefer to use NIOV when exercising.	I would prefer to use NIOV for errands & socializing.	I would prefer to use NIOV for performing household tasks.
5	4	4	5	5	5
5 = much less out of breath	4 = somewhat more energetic	4 = somewhat less dryness	5 = completely agree	5 = completely agree	5 = completely agree

* 5-point Likert scale, median scores, n=18

Conclusions: In two prior clinical trials, patients using the NIOV system showed increases in mean 6MW distances of 57 (± 54) meters[2] and 36 (± 34) meters[3], respectively. In this follow up study, the lightweight NIOV ventilator system was worn for prolonged periods over five consecutive days, and was found to be comfortable and well-accepted by all subjects. Subjects reported that using the study device would result in less dyspnea, reduced work of breathing, and greater mobility and exercise endurance compared to their current oxygen systems. Further clinical evaluations of this portable ventilator system to assess its effects on the work of breathing, pulmonary mechanics and gas exchange, and its application in the home and acute-care institutional setting are warranted, and are currently planned or under way.

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2. Hilling L, Cayou C, Garvey C, Wondka T, Kops RS. Improved 6MWT Distance with a Highly Portable Non-Invasive Ventilator. Presented at the Annual American Thoracic Society International Conference; May 14-19, 2010; New Orleans, Louisiana.

3. Garvey C, Hilling L, Cayou C, Escobar R, Heron G, McCabe L. Open, Noninvasive Ventilation Using a 1-lb Ventilator, Oxygen, and a Low Profile Mask Improves 6 MWT Distances in Advanced COPD. Presented at the Annual American Thoracic Society International Conference; May 13-18, 2011; Denver, Colorado.

The authors thank would like to thank the study patients and the following individuals for their contributions and efforts in this study: *Michele Wadsworth, Lynne Schneider RCP, Lonni Ocampo RCP, James Harrell RCP, Thomas Lawrie MD, Darlene Syme, and Holly Arave, RRT.*

This Study was sponsored by Breathe Technologies, Inc. Irvine, CA., USA

Presented at ATS May 2012

NIOV Is Not

- NIOV is not continuous flow: It is volume delivery under pressure, efficient oxygen delivery
- NIOV is not an oxygen conserving device: It is volume delivery under pressure, greater FiO2 potential
- NIOV is not NIV: It is open ventilation providing more patient flexibility and is ambulatory

Device Comparison of Capabilities

Therapy Comparison

	Technology	Patient Population	Primary Use Case
	Oxygen	Stage III / Stage IV COPD patients	During both rest and exertion
	**Bi-Level[1] (RADs)**	COPD patients who desaturate during sleep & CPAP failure for OSA	During sleep
	**Breathe (Volume Assist)**	Stage III / IV COPD patients needing additional assistance during exertion and other forms of respiratory insufficiency	During rest & ambulation
	**Ventilators[1] (Volume Control)**	Respiratory failure	24/7 for life support, emergencies

High Flow Clinical Summary

High Flow is intended to be used for adding warm moisture to breathing gases such as oxygen

Potential mechanisms of action include[1]

- Washout of anatomical (nasopharyngeal) dead space
- Reduction of inspiratory resistance associated with gas flow through nasopharynx
- Improvement in respiratory mechanics associated with gas temperature and humidification
- Reduction in metabolic work associated with gas conditioning
- Provision of mild distending pressure
- Optimized mucociliary clearance
- Effective oxygen delivery

Crossover trial in 10 COPD patients comparing Low Flow Oxygen (LFO) and High Flow Oxygen (HFO) in exercise[2]

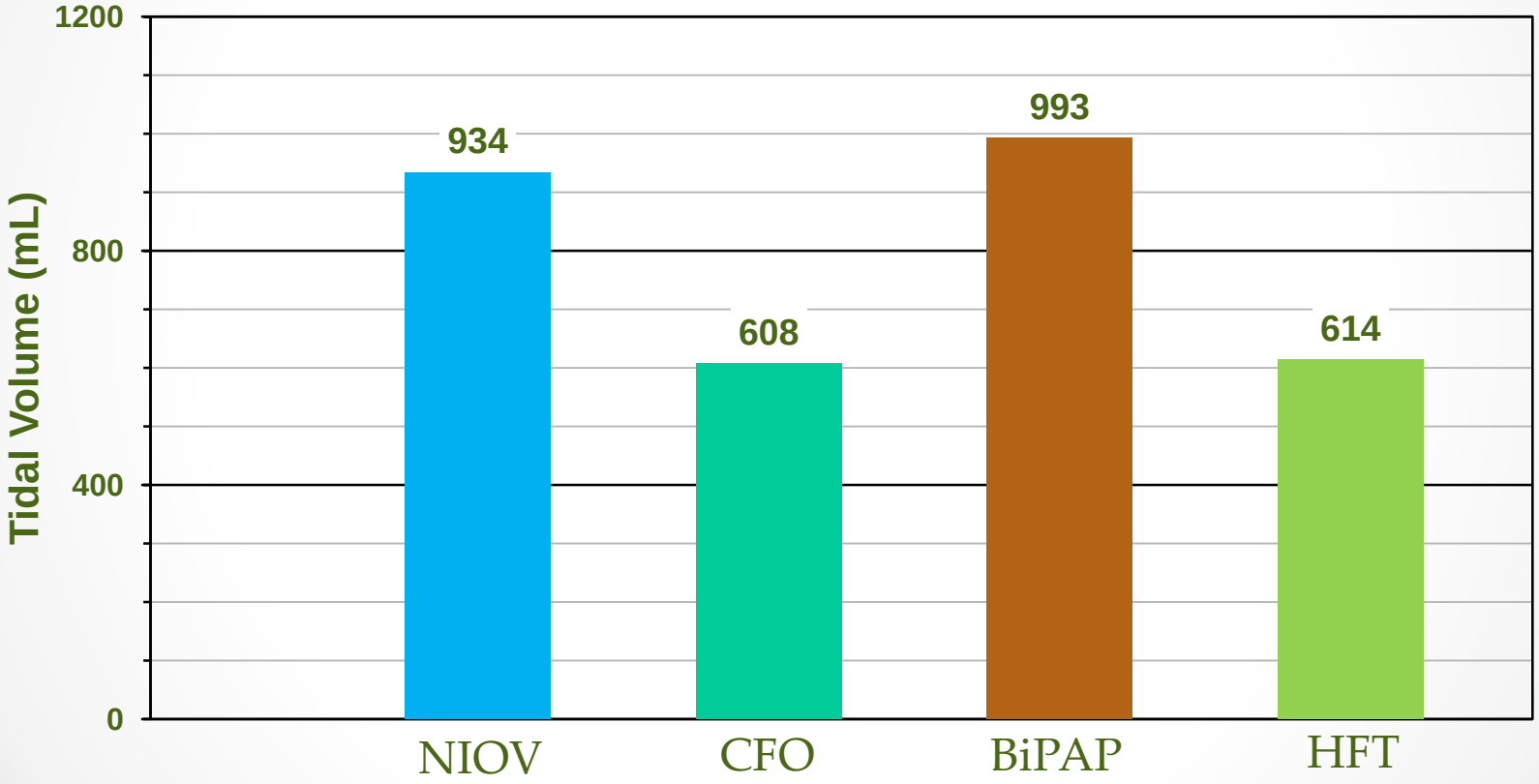
- Ages 54 ± 6 years, FEV1 23 ± 6% predicted
- Exercise time 10.0 ± 2.4 minutes on HFO versus to 8.2 ± 4.3 minutes on LFO
- Patients reported less dyspnea
- SpO2 was 98 ± 2 versus 95 ± 3% for LFO
- No difference in VE, VT, or WOB
- RR, RR/VT, Ti/TTOT were lower with HFO compared to LFO

1. Dysart K, et al. “Research in high flow therapy:mechanisms of action” Respiratory Medicine 2009;103.1400-5
2. Chatila W. et al “The Effects of High-Flow Versus Low-Flow Oxygen on Exercise in Advanced Obstructive Airways Disease” Chest 2004;126:1108-15

NIOV Comparison – Tidal Volume Augmentation

NIOV, Continuous Flow Oxygen (CFO), Oxygen Conserving Device (OCD), BiPap, High Flow Therapy (HFT)

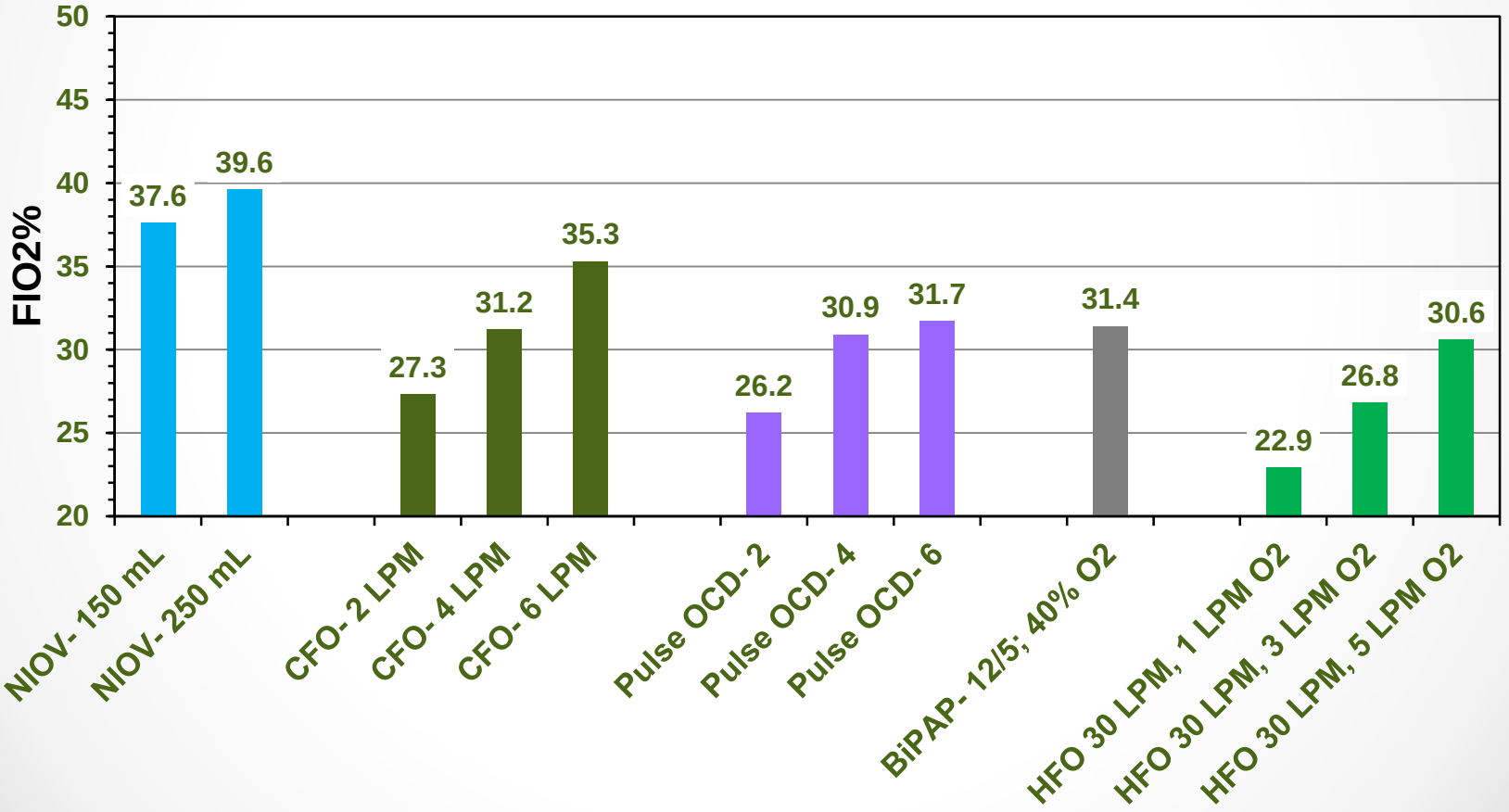
Tidal Volumes: 600 mL Vt; 20 BPM; 1:2 Sinusoidal



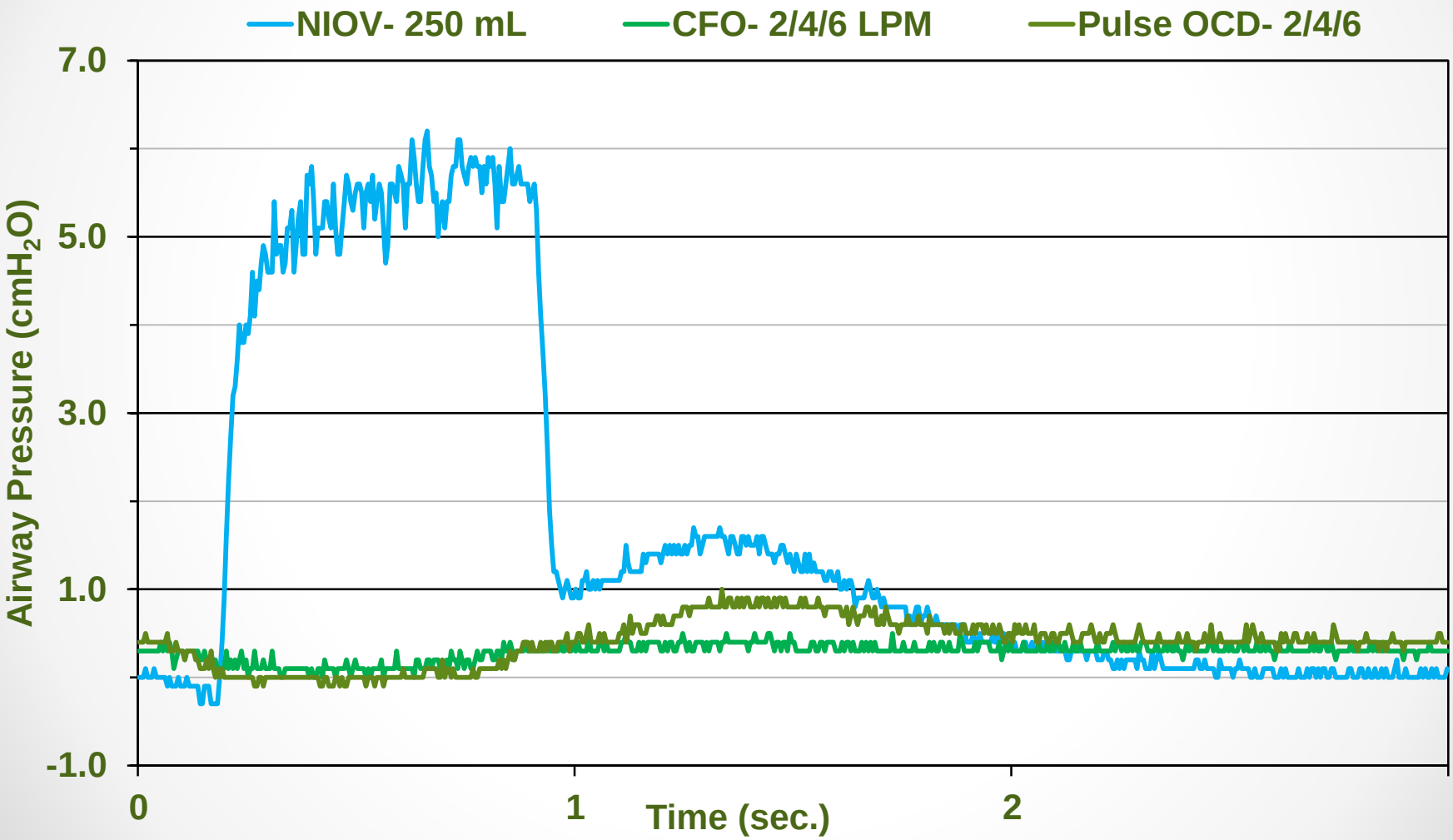
NIOV Comparison – FiO_2

NIOV, Continuous Flow Oxygen (CFO), Oxygen Conserving Device (OCD), BiPAP, High Flow Therapy (HFT)

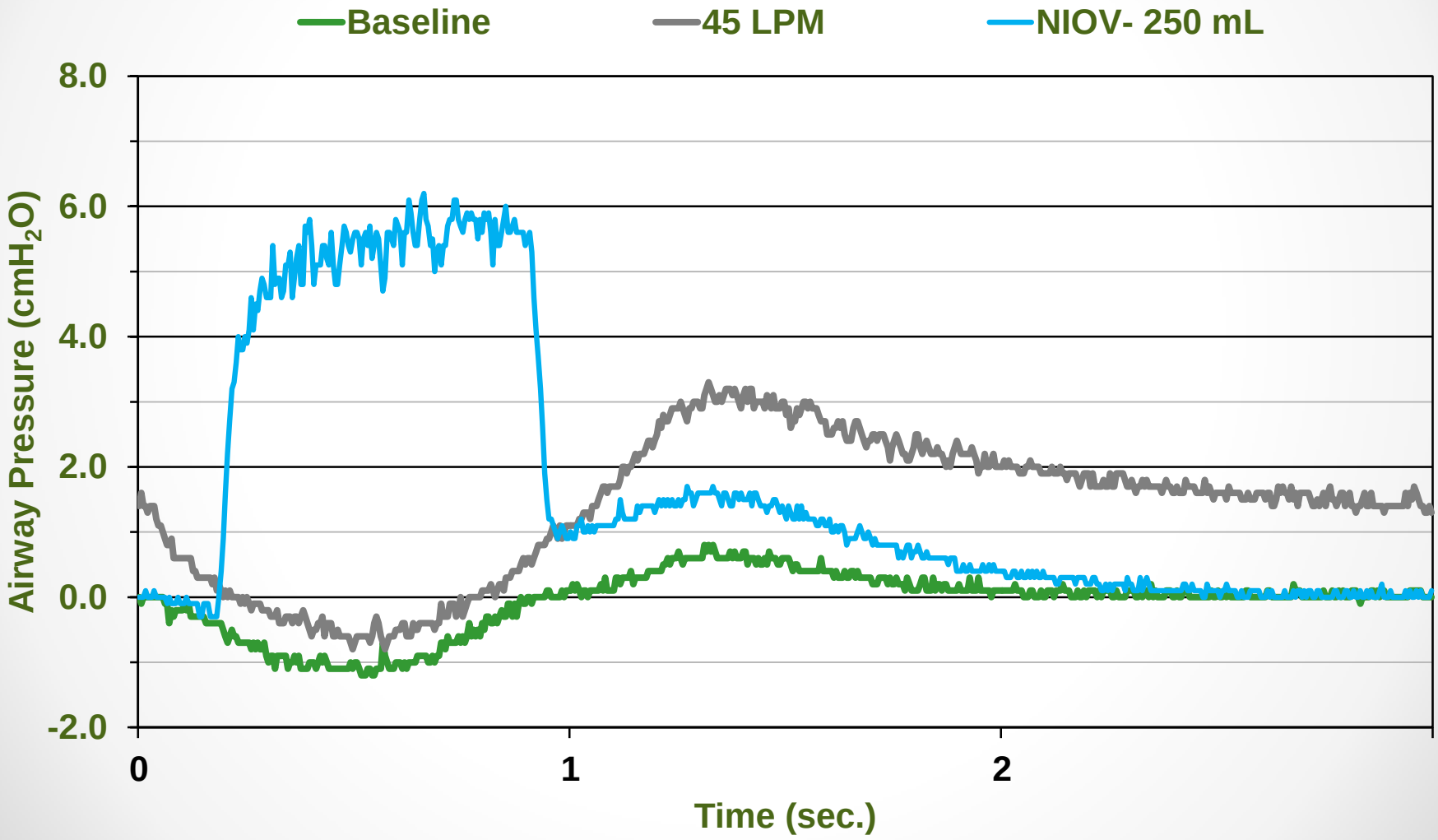
FIO2%: 600 mL Vt; 20 BPM; 1:2 Sinusoidal

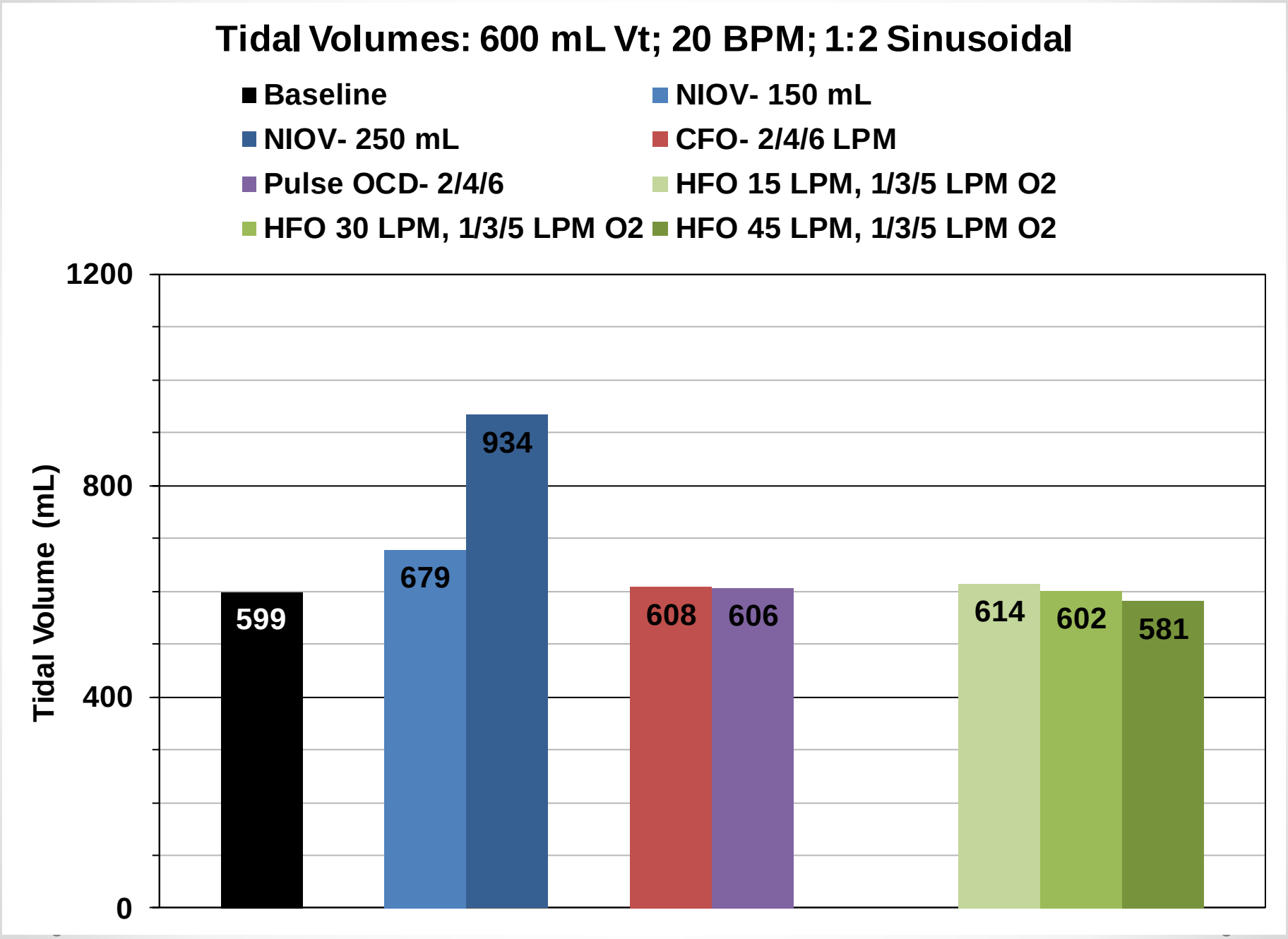


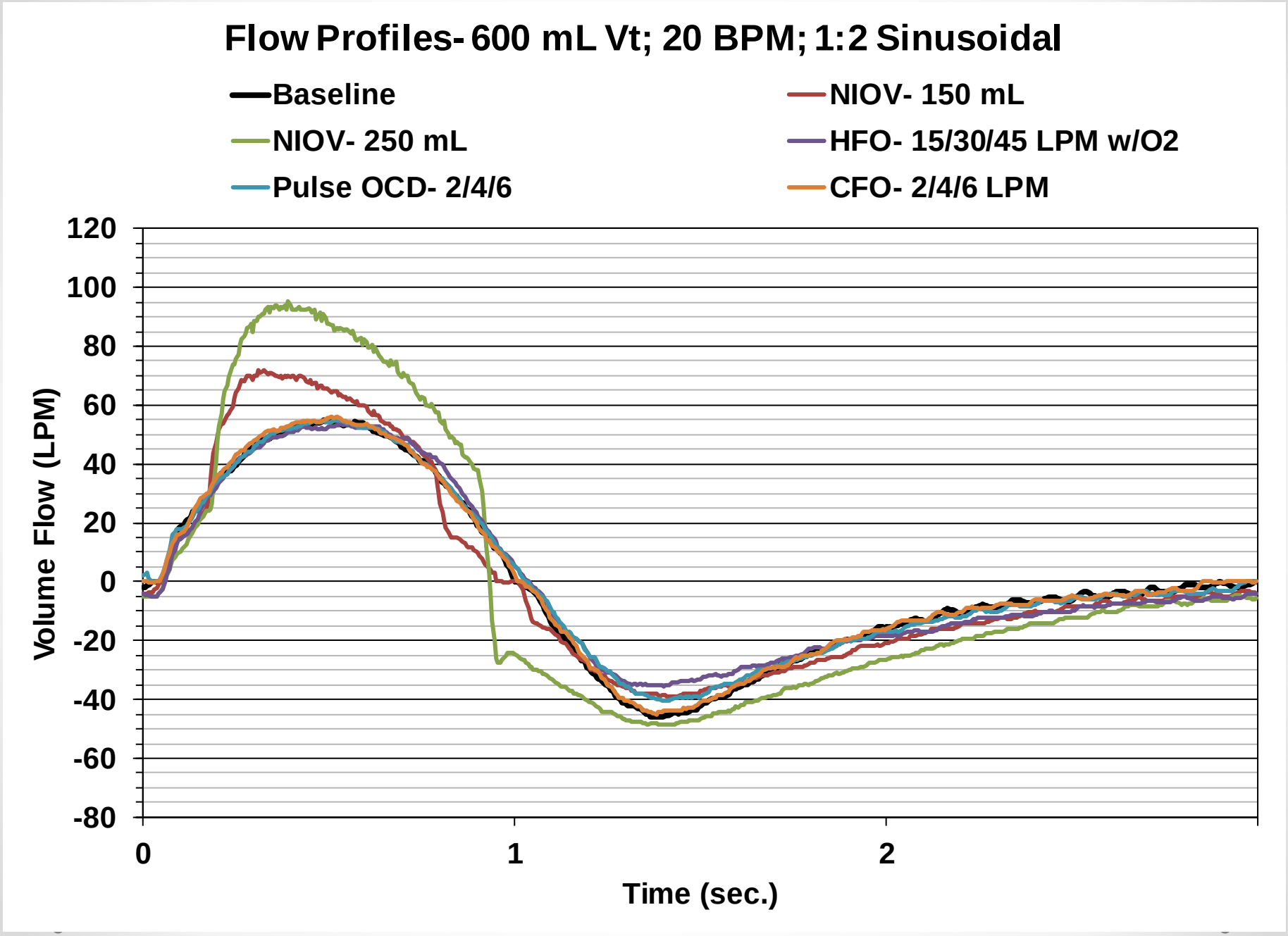
Pressure Profile Comparison of NIOV and Low Flow



Pressure Profile Comparison of NIOV and High Flow




Tidal Volumes: 600 mL Vt; 20 BPM; 1:2 Sinusoidal
Baseline
NIOV- 150 mL
NIOV- 250 mL
CFO- 2/4/6 LPM
Pulse OCD- 2/4/6
HFO 15 LPM, 1/3/5 LPM O2
HFO 30 LPM, 1/3/5 LPM O2
HFO 45 LPM, 1/3/5 LPM O2
Tidal Volume (mL)
1200
800
400
0
599
679
934
608
606
614
602
581


Flow Profiles- 600 mL Vt; 20 BPM; 1:2 Sinusoidal
Baseline
NIOV- 150 mL
NIOV- 250 mL
HFO- 15/30/45 LPM w/O2
Pulse OCD- 2/4/6
CFO- 2/4/6 LPM
120
100
80
60
40
20
0
-20
-40
-60
-80
Volume Flow (LPM)
0
1
2
Time (sec.)

Gary's Story

- Toxic shock to his respiratory system
- Difficult diagnosis
  - Local hospital
  - University hospital
  - Mayo clinic
- Not a lung transplant candidate
- Introduced to NIOV
  - Able to do ADLs
  - Able to work
  - Disease progression has plateaued
  - Assisting with educating healthcare providers

Conclusion

- NIOV is a unique device that can address respiratory insufficiency to support mobility
- NIOV has the potential to increase activity to maintain conditioning
- NIOV has the potential to improve ventilation to prevent exacerbations
- NIOV is the first device to allow augmented ventilation for an ambulatory patient

Thank You

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