Managing COPD Patients in the Sleep Center
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Clinical Specialist ResMed
Course Objectives

- Discuss normal breathing
- Define chronic obstructive pulmonary disease (COPD) and discuss its prevalence
- Review Lung Mechanics of the COPD patient during Sleep
- Review current treatment options for COPD
- Identify features that improve NIV tolerance
- Examine appropriate means of monitoring NIV outcomes
Mechanism of Normal Breathing and Diagnostic Testing
Normal Breathing

Inhalation:
- Air enters through the nose.
- Ribcage expands.
- Lungs expand.
- Diaphragm contracts downward.

Exhalation:
- Air exits through the nose.
- Ribcage contracts.
- Lungs contract.
- Diaphragm contracts upward.
Breathing Relies on the Respiratory System

The 2 basic functions of the Respiratory System are:

1. Ventilation (air distribution)
2. Respiration (gas exchange)

Goals of respiration

Bring oxygen to the body
Remove carbon dioxide from the body
Arterial Blood Gas (ABG)

Norms:

- Partial pressure of oxygen (PaO₂): Greater than 80 mm Hg
- Partial pressure of carbon dioxide (PaCO₂): 35-45 mm Hg (indicates Respiratory failure / insufficiency status)
- pH: 7.35-7.45
- Bicarbonate (HCO₃): 22-26 mEq/L
- Oxygen saturation (O₂ Sat): 95%-100%

End Tidal CO2 (ETCO2)

Norms:

- 30-43 mmHg (correlates with PCO2 on ABG)

CO₂{carbon dioxide (BMP)}

Norms:

- 20-20 mmol/L (correlates with HCO3 serum bicarbonate level)
Spirometry

COPD

Can only be Diagnosed with PFT

FEV$_1 \geq$ 70%

Forced Vital Capacity - How much air you can Force out in 1 sec.

FEV$_1 = 1.8$L

FVC = 3.2$L

FEV$_1$/FVC = 0.56
Volume

- Tidal volume (Vt) is the lung volume representing the normal volume of air displaced between normal inhalation and exhalation when extra effort is not applied.
  - Adequate Vt assumed when there is good chest expansion; good breath sounds; acceptable arterial blood gases.
  - In a healthy, young human adult, tidal volume is approximately 500 Ml
  - Most directly determined by PIP and PEEP.

- Minute ventilation is the volume of gas inhaled (inhaled minute volume) or exhaled (exhaled minute volume) from a person's lungs per minute.
  - It is an important parameter due to its relationship with blood carbon dioxide levels.
**Spirometric Classification of COPD**

FEV$_1$/FVC<0.7 indication of airflow limitation that is not fully reversible

<table>
<thead>
<tr>
<th>Severity</th>
<th>Post bronchodilator FEV$_1$/FVC</th>
<th>FEV$_1$ % pred</th>
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<td><strong>At risk</strong></td>
<td>&gt;0.7</td>
<td>≥80</td>
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<tr>
<td>Patients who:</td>
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<tr>
<td>• smoke or have exposure to pollutants</td>
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<tr>
<td>• have cough, sputum or dyspnea</td>
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<td>• have family history of respiratory disease</td>
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<tr>
<td><strong>Mild COPD</strong></td>
<td>≤0.7</td>
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<tr>
<td><strong>Moderate COPD</strong></td>
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<td><strong>Severe COPD</strong></td>
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<td>30–50</td>
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<tr>
<td><strong>Very severe COPD</strong></td>
<td>≤0.7</td>
<td>&lt;30</td>
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</table>

ATS/ERS Standards for the diagnosis and mgt. of COPD, 2004

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Pathophysiology of COPD

- **Air trapping**
  - **Diaphragm flattening**
    - **↑ Dyspnea**
  - **↓ Elastic recoil**
    - **Muscle weakness**
  - **↑ Intrinsic PEEP**
    - **↑ Work of breathing**

- **Ventilatory muscle failure**
  - **↓ Ventilation**
  - **↑ PaCO₂**

Adapted from: ATS/ERS Standards for the diagnosis and mgt. of COPD, 2004
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COPD Hospital Readmissions are Expensive \(^1\)

When a COPD patient enters the hospital system:

- Average cost of a COPD acute exacerbation - \(\$11,195\)
- These hospitalizations are a major driver in the COPD costs to the U.S. health care system.

- COPD economic burden - \(\$49.9B\) annually

\(^1\) Perera PN et al. COPD: J chron Obstruct Pulmon Dis 2012
Studies of Readmissions\textsuperscript{1}

- 90\% of readmissions within 30 days are the result of clinical deterioration.
- 75\% of readmissions preventable, adding $12B/year to Medicare spending.
- Only half of the patients re-hospitalized within 30 days had a physician visit before readmission.
- 19\% of Medicare discharges are followed by an adverse event within 30 days.

\textsuperscript{1} Jencks SF et al. \textit{N Engl J Med} 2009
Nocturnal Ventilation: COPD

Respiratory Insufficiency
Respiratory Failure
Breathing is regulated by:

**Chemoreceptors** that monitor blood gas levels:
- CO$_2$ (primarily)
- O$_2$ (secondarily)

**Respiratory Control Center** in the brain.

* Caples SM & Somers VK. Prog Respir Res. Basel, Karger 2006

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Breathing Changes During Sleep

- Decreased respiratory drive with a small fall in ventilation and rise in carbon dioxide (CO2)
- Small reductions in tidal volume are compensated by an increase in breath rate
- Alterations in respiratory system mechanics
  - Increased upper airway resistance
  - Altered chest wall mechanics
- Depressed arousal responses to chemical stimuli
Respiratory insufficiency patients have an additional 10–15% drop in ventilation at sleep onset (SO)

- Further reduction in REM sleep (10–20%), due to falling tidal volumes not counteracted by increased respiratory rate
- Nocturnal Hypoventilation

Alveolar hypoventilation is defined as insufficient ventilation leading to **hypercapnia**, (\(\text{PaCO}_2 \geq 45\text{mmHg}\)). It may be an acute or chronic and is caused by several mechanisms

Respiratory Failure is defined as hypercapnia, (\(\text{PaCO}_2 >52\text{mmHg}\)). Defined as chronic when pH is normal and HCO3 is elevated.
Nocturnal Ventilation: Overlap Syndrome
Nocturnal Ventilation in Overlap Syndrome

- Consists of both:
  - Upper airway obstruction (OSA) during sleep
  - Nocturnal hypoventilation (COPD)
  - Approximately 10% of sleep apnea patients may have some degree of COPD*
- May demonstrate prolonged hypoxemia during sleep
- SpO$_2$ often does not recover between episodes of repetitive apnea
- If left untreated, morbidity and mortality much higher than for either disease process alone

Patient may present with:

- Symptoms compatible with OSA
- Existing oxygen therapy for COPD
- History of cardio-respiratory disease
- Inability to sleep lying down
- Full regime of pulmonary medications (inhalers, steroids, etc.) without significant improvement
- Worsening daytime blood gases

* Douglas NJ. *Sleep Disorders* 1998
Overlap patients

Patient may present with:

- Symptoms compatible with OSA
- Existing oxygen therapy for COPD
- History of cardio-respiratory disease
- Inability to sleep lying down
- Full regime of pulmonary medications (inhalers, steroids, etc.) without significant improvement
- Worsening daytime blood gases
HOT-HMV

is the first multi-center, open-label, parallel-group, randomized controlled trial to show that home mechanical ventilation (HMV) combined with home oxygen therapy (HOT) significantly reduces the risk of hospital readmission or death in severe COPD patients after an acute exacerbation requiring NIV.
Outcomes Utilizing NIV in COPD

COPD patients who use (NPPV) immediately following a hospital admission due to an acute exacerbation (AECOPD) with hypercapnic respiratory failure would have lower hospital readmissions and lower mortality.

The addition of long-term NPPV to standard treatment improves survival of patients with hypercapnic, stable COPD when NPPV is targeted to greatly reduce hypercapnia.

The addition of NIV to optimal standard therapy has beneficial effects in the HRQoL (Health-Related Quality of Life) of stable hypercapnic COPD patients, with the improvement in dyspnea (breathlessness) being the major determinant of HRQoL changes.


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Treatment of COPD Patients
NIV (Bi-level) Overview
Treatment for COPD Patients

- Smoking cessation
- Pulmonary rehabilitation
- Medication
  - Bronchodilators
  - Corticosteroids
  - Oxygen
  - Antibiotics
- Lung volume reduction surgeries
- Noninvasive ventilation –
  - Strong Concensus during 2016 GOLD conference
  - HOT – HMV Study indicates benefits of HMV
Does the Patient Need NIV (Bi-level) therapy?

Critical information that can aide in identifying the proper therapy for the patient:

- Patient on NIV (e.g., bilevel, VPAP, BiPAP) during hospital admission
- Recurring admissions for AECOPD
- Chronically high PCO$_2$ levels
- Moderate/severe COPD based on spirometry
- Low oxygen saturation (SpO$_2$/SaO$_2$)
- Changes in cognition (related to CO$_2$ retention)
- Sleep study results
- Physical weakness/shortness of breath (SOB)
- Lab Results
  - Total Protein
  - Albumin levels
Benefits of Bilevel (NIV) Therapy
How Does Bilevel (NIV) Work?*

• Prevents nocturnal hypoventilation and hypoxia
  o Cardiovascular consequences

• Improves ventilation (gas exchange)
  o Reduces nocturnal CO₂ levels
  o Increases nocturnal O₂ levels
  o Improves daytime blood gases

• Stabilizes upper airway

• Rests respiratory muscles

• Decreases daytime sleepiness by correcting sleep architecture
  o Reduces arousals due to SDB and associated sleep fragmentation

* Antonescu-Turcu A & Parthasarathy S. Respir Care 2010
EPAP, IPAP and PS

**IPAP**
- Achieve adequate tidal volume
- Get the respiratory rate (RR) below 25 bpm
- Decrease the work of breathing
- Reduce PaCO₂
- IPAP = EPAP + PS

**Pressure Support (PS)**
- PS = IPAP - EPAP
- The greater the PS the greater the ventilatory support
- Care must be taken not to over-ventilate

**EPAP**
- Overcome obstructive apneas and hypopneas
- Improve oxygenation
American Association of Sleep Medicine (AASM) Clinical Titration Guidelines

BPAP Titration Algorithm for Patients ≥ 12 years during Full- or Split-Night Titration Studies

- **Recommended maximum IPAP 30 cm H₂O**
  - “Exploration” of IPAP
- **≥ 30 min without breathing events**
- **≥ 10 min**
  - Control of breathing events and ≥ 15 min in supine REM sleep
  - IPAP ≥ 1 cm H₂O

- **≥ 5 min**
  - ≥ 2 obstructive apneas, or ≥ 3 hypopneas, or ≥ 5 RERAs, or (3 min of loud or unambiguous snoring)
  - If patient awakens and complains pressure is too high, a lower IPAP that the patient reports is comfortable enough to allow return to sleep should be chosen, and resume titration

- **≥ 5 min**
  - IPAP and EPAP ≥ 1 cm H₂O for apneas, IPAP ≥ 1 cm H₂O for other events
  - Minimum* IPAP 8 cm H₂O/EPAP 4 cm H₂O
  - Stop if re-emergence of breathing events

**Time**

**Note:** Upward titration of IPAP and EPAP ≥ 1 cm H₂O for apneas and IPAP ≥ 1 cm for other events over ≥ 5 min periods is continued until ≥ 30 min without breathing events is achieved. A decrease in IPAP or setting BPAP in spontaneous-time mode with backup rate may be helpful if treatment-emergent central apneas are observed.

* A higher starting IPAP and EPAP may be selected for patients with an elevated BMI and for retitration studies. When transitioning from CPAP to BPAP, the minimum starting EPAP should be set at 4 cm H₂O or the CPAP level at which obstructive apneas were eliminated. An optimal minimum IPAP-EPAP differential is 4 cm H₂O and an optimal maximum IPAP-EPAP differential is 10 cm H₂O.

Important to Note

- Parameters set during an awake state may not be appropriate during sleep due to:
  - Behavior of the glottis
  - Mouth leaks
  - Alterations in respiratory drive
  - Changes in respiratory system compliance
  - Upper airway obstruction

- What to look for while monitoring:
  - Chest wall movement is in sync with mask pressure tracing
  - Loss of chest wall movement
  - Inspiratory efforts that do not trigger device
  - Central apnea or upper airway obstruction caused by overventilation
Bilevel Modes of Therapy

Spontaneous (S)
- IPAP and EPAP

Spontaneous Timed (S/T)
- IPAP and EPAP
- Backup Rate

VAuto with Fixed Pressure Support (PS)
- Max IPAP and Min EPAP
- PS

Adaptive Servo-ventilation targeting recent minute ventilation
- Min and Max PS
- EPAP (Auto EPAP)

Intelligent Volume Assured Pressure Support (iVAPS)
- Min and Max PS
- EPAP
Synchrony Features and Benefits
Types of Asynchrony

- **At plateau**
  - During pressurization
    - Too fast, too slow
  - At transition to expiration
    - Premature cycle, delayed cycle
  - At transition to inspiration
    - Missed trigger, auto trigger

Gentile MA. *Respir Care* 2011

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Ti Control

Rise Time

Breath cycle
### Trigger and Cycle Sensitivities

#### Adjustable Trigger Sensitivity

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<th>Sensitivity</th>
<th>Trigger Response</th>
<th>Flow Rate</th>
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<td>Very High</td>
<td>Quick to trigger</td>
<td>2.4 L/min</td>
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<tr>
<td>High</td>
<td>More sensitive</td>
<td>4 L/min</td>
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<tr>
<td>Med</td>
<td>Default</td>
<td>6 L/min</td>
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<tr>
<td>Low</td>
<td>Less sensitive</td>
<td>10 L/min</td>
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<tr>
<td>Very Low</td>
<td>Slow to trigger</td>
<td>15 L/min</td>
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#### Adjustable Cycle Sensitivity

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<tr>
<th>Sensitivity</th>
<th>Cycle Response</th>
<th>Peak Flow %</th>
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<td>Very High</td>
<td>Quick to cycle</td>
<td>50%</td>
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<tr>
<td>High</td>
<td>More sensitive</td>
<td>35%</td>
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<tr>
<td>Med</td>
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<tr>
<td>Very Low</td>
<td>Slow to cycle</td>
<td>8%</td>
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</table>
“It is paramount to match the appropriate flow-cycling criterion with the specific underlying pathophysiology. Patients with obstructive disease require different cycling criteria than those with acute lung injury or other forms of lung impairment.”
Clinical Parameters

Subjective
- Dyspnea
- Comfort
- Mental status
- Ventilatory pattern
- Accessory muscle use
- Synchrony with VPAP

Objective
- Vitals (RR, HR, BP)
- Leak
- Tidal volume
- Oximetry
- ABGs
Qualifying Patients
Respiratory Assist Device (RAD) Qualifying Guidelines

CMS revision effective date: December 2014

I. Restrictive Thoracic Disorders

Perform one of the following:
- ABGs (done while awake and on prescribed FiO₂) \( \text{PaCO}_2 \geq 45 \text{ mm Hg} \) or
- Sleep oximetry
  - Oxygen saturation \( \leq 88\% \) for \( \geq 5 \) minutes, minimum 2 hours of recording time (on patient's prescribed FiO₂) or
  - For neuromuscular disease only:
    - Either FVC < 50\% of predicted or MIP < 60 cm H₂O

COPD does not contribute significantly to pulmonary limitation

(E0470) or (E0471)
Based on the treating physician's judgment

II. COPD

ABGs (done while awake and on prescribed FiO₂) 
\( \text{PaCO}_2 \geq 52 \text{ mm Hg} \)

Sleep oximetry
- Oxygen saturation \( \leq 88\% \) for \( \geq 5 \) cumulative minutes, minimum 2 hours nocturnal recording time (on 2 L/min \( \text{O}_2 \) or patient's prescribed FiO₂, whichever is higher)

OSA and CPAP treatment has been considered and ruled out (formal sleep testing is not required if medical record demonstrates sleep apnea is not predominate cause of awake hypoxemia or nocturnal arterial oxygen desaturation)

(E0470)

For COPD patients to qualify for a RAD with backup rate (E0471):

**Situation 1**  After period of initial use of an E0470; ABG (done while awake and on prescribed FiO₂) shows \( \text{PaCO}_2 \) worsens \( \geq 7 \text{ mm Hg} \) compared to original ABG result; facility-based PSG demonstrates oxygen saturation \( \leq 88\% \) for \( \geq 5 \) cumulative minutes, minimum 2 hours nocturnal recording time while on an E0470 and not caused by obstructive upper airway events (ie, AHI < 5).

Respiratory Assist Device (RAD) Documentation Requirements for Continued Coverage Beyond First 3 Months

Patients on an E0470 or E0471 device must be reevaluated no sooner than 61 days after initiating therapy.

Required Documentation
- Progress of relevant symptoms
- Signed and dated statement by treating physician declaring patient using average 4 hours per 24-hour period and patient benefiting from use

**Situation 2**  No sooner than 61 days after initial issue of E0470; ABG (done while awake and on prescribed FiO₂) shows \( \text{PaCO}_2 \geq 52 \text{ mm Hg} \); Sleep oximetry on an E0470 demonstrates oxygen saturation \( \leq 88\% \) for \( \geq 5 \) cumulative minutes, minimum 2 hours nocturnal recording time (on 2 L/min \( \text{O}_2 \) or patient's prescribed FiO₂, whichever is higher).

ResMed E0470 and E0471 Devices

**E0470–Bilevel without a backup rate:**
- AirCurve™ 10 VAuto
- AirCurve™ 10 S
- VPAP™ COPD

**E0471–Bilevel with a backup rate:**
- AirCurve 10 ST
- AirCurve 10 ASV
- VPAP ST-A
- Stellar™
* For invasive use, code E0472
NIV Monitoring
Making Data Available to Providers and Patients

Data for **Physicians/Clinicians** and **Providers**

View detailed data, make remote settings changes, troubleshoot remotely with Remote Assist

Automated coaching and support for **Patients**

Patient access to individualized coaching, education, and therapy data
Early monitoring helps you identify any potential issues and intervene so that patients are comfortable and are receiving the therapy they need.
## Wireless patients

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<tr>
<th>Name</th>
<th>Day</th>
<th>Compliant</th>
<th>Last 30</th>
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### Detailed report

**Astral 100: Program 1**

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</table>

- **Model:** IVAPS
- **Circuit:** SingleVented
- **Target alveolar ventilation - L/min:** 5.2
- **EPAP - cmH₂O:** 12.6
- **Pressure support (Min - Max) - cmH₂O:** 9.6 - 12.4
- **Target patient rate - bpm:** 8

#### Usage

- **12 hr 40 min**

#### Statistics: Program 1

- **Leak - L/min**
  - 5th %: 8.4
  - Median: 10.4
  - 95th %: 12.4
- **PIP pressure - cmH₂O**
  - 5th %: 40.1
  - Median: 41.1
  - 95th %: 42.1
- **EEP pressure - cmH₂O**
  - 5th %: 15.0
  - Median: 16.0
  - 95th %: 17.0

#### SpO₂: All programs (%)

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<th>90</th>
<th>80</th>
<th>70</th>
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<th>40</th>
<th>30</th>
<th>20</th>
<th>10</th>
<th>0</th>
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- **Leak**
  - All programs (L/min)
  - 50 | 40 | 30 | 20 | 10 | 0

- **Pressure**
  - All programs (cmH₂O)
  - 30 | 20 | 10 | 0

---

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New! myAir clinical evidence published*

- Patients who used myAir achieved compliance by **DAY 23**
- 75% of patients achieve compliance in **30 DAYS**
- 84% of patients achieve compliance in **90 DAYS**

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