

Medicare Evidence Development Coverage
Advisory Committee (MEDCAC) meeting:

**“Home Use of Noninvasive Positive
Pressure Ventilation in Patients with
Chronic Respiratory Failure (CRF)
Consequent to Chronic Obstructive
Pulmonary Disease (COPD)”**

Comments from:

CHEST - The American College of Chest Physicians:
Representing 15,000 US physicians, surgeons and
healthcare providers focused on respiratory
health.

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CHEST - Health Policy and Advocacy Committee
Associate Professor of Medicine and Neurology
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COI:

No Financial Conflicts to Disclose

Patient Selection Criteria

OSA COPD Overlap Syndrome

These patients have:

- OSA as determined by PSG
- COPD as determined clinically
- Daytime PCO₂ and Oxygen saturation are normal
- Nighttime O₂ saturation is very low even after appropriate therapy for OSA.

Severe COPD

These patients have:

- COPD as determined clinically
- Stable daytime hypercapnia (↑PCO₂).
- Hospitalizations

Obesity Hypoventilation – COPD Overlap

These patients have:

- Obesity with a BMI >35
- COPD as determined clinically
- Daytime hypercapnia (↑PCO₂).
- Hospitalizations

NIPPV Equipment Parameters

OSA COPD Overlap Syndrome

- These patients are treated when stable outpatients
- **CPAP** therapy is appropriate
- In lab PSG is often needed to add / titrate oxygen bleed into CPAP therapy

Severe COPD

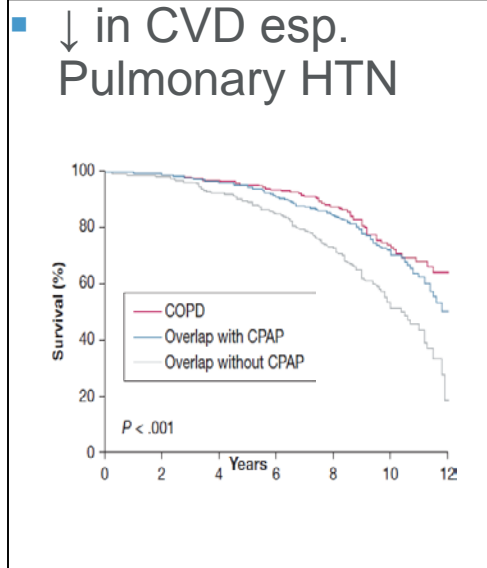
- These patients should be treated as stable outpatients
- High Intensity PS support therapy:
 - **BPAP with back up rate**
- Extras are often needed requiring **HMV**
 - High O2 with blender
 - Back up battery
 - Daytime portability

Obesity Hypoventilation – COPD Overlap

- These patients should be treated at the time of hospital discharge
- **HMV** is appropriate
 - Need for VAPS mode with Auto – EPAP
 - Need for higher pressures

WHY treat? Is the evidence sufficient?

OSA COPD Overlap Syndrome



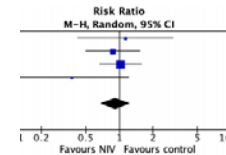
Walter T. McNicholas *Chest*
Yr 2017 Vol 152, Is 6, P 1318-1326

Severe COPD

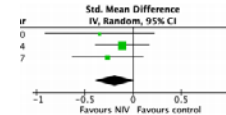
The European Respiratory Society:

■ “This ERS Task Force suggests the application of long-term home non-invasive ventilation to improve health outcomes by targeting a reduction in carbon dioxide in COPD patients with persistent hypercapnic respiratory failure.”

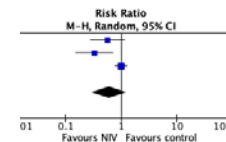
Ergan B et al ERS Guideline on Long-term Home NIV for Management of COPD. *Eur Respir J* 2019; in press



Mortality

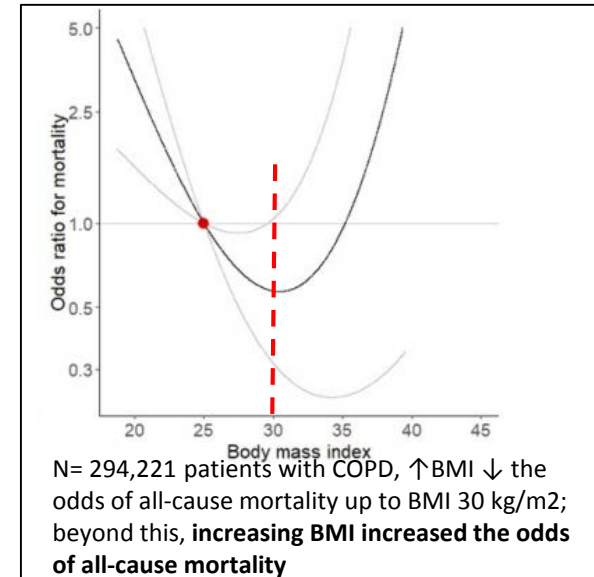


Exacerbations



Hospitalizations

Obesity Hypoventilation – COPD Overlap



Mine, S et al *Am J Respir Crit Care Med*
2020;201:A4580

Equipment VS Other Support Services

OSA COPD Overlap Syndrome

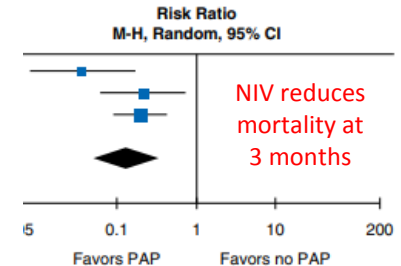
- These patients do not seem to need additional support services
- The patients are much less impaired

Severe COPD

- There appears to be a need for a full respiratory care team
- Struik Vs Galli
 - Struik
 - ✓European - both sides had homecare
 - ✓ICU enrollment for domiciliary NIV
 - ✓FAILED
 - Galli
 - ✓US – Only NIV pt had home care
 - ✓ICU enrollment for domiciliary NIV
 - ✓SUCCESS

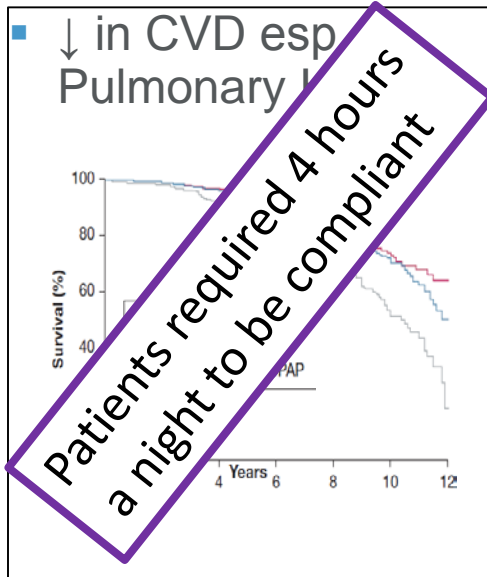
Obesity Hypoventilation – COPD Overlap

- The data on this group is limited but the obesity group getting NIV + homecare



When is the PAP use sufficient?

OSA COPD Overlap Syndrome



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Severe COPD

Kholein - Usage time was less than 3 hr in 18.8% of patients (23.8% of periods). Mean NPPV usage was 5.9 hr per day.

Murphy— the longer in the study the higher the use

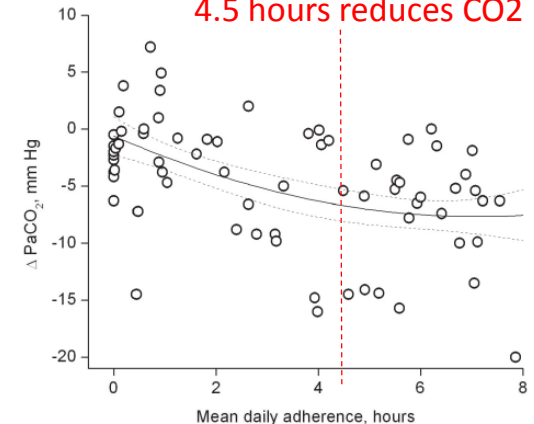
Visit	Number of patients attended	Number of patients with adherence data	Median usage ^a (25 th to 75 th percentile) hours/night
6 weeks	45	38	4.73 (2.50 to 5.6)
3 months	40	34	6.02 (4.0 to 7.4)
6 months	40	30	5.37 (3.48 to 7.1)
12 months	36	26	7.61 (3.55 to 8.37)

Obesity Hypoventilation – COPD Overlap

2 examples

Mokhlesi, B J Clin Sleep Med 2006;2(1):57-62.

4.5 hours reduces CO₂



Priou, P. *CHEST* 2010; 138(1):84–90

Increased survival with >5 hours/day

Summary

1. Do we feel that we know best **“patient selection criteria”**
 - The COPD patients need to be divided into groups and daytime PCO₂ is the most important marker
2. Do we feel that we know best **“NIPPV equipment parameters”**
 - The COPD phenotypes allow us to best assign appropriate PAP therapy
3. Do we feel that we know if the benefit is due to NIV or **“the use of the equipment alone as opposed to the concomitant provision of other support services”**
 - The presence of Daytime Hypercapnia is a hallmark for the need of more aggressive homecare
4. Do we feel that **“the evidence is sufficient to provide the patient usage parameters”**
 - The time cut offs are not specific but the greater the use the greater the effect

Final Thoughts

- There is no doubt that the system for assigning and managing domiciliary PAP needs to be modernized and better integrated across the board including ALL disease states and pathologies
- Attempts to correct the NCD and policies around HMV use for COPD will be most effective if the BPAP (RAD) criterion are fixed at the same time
- More research is needed to best assess the role of these devices in the US population