

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)”

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On behalf of
The American Thoracic Society





Dr. Owens Personal COI Disclosures

- ResMed, a maker of positive airway pressure devices, gave a donation to the UCSD Sleep Center
- 2016: honorarium and travel reimbursement (<\$2,500) from ResMed
- 2017: Site PI (no salary) for ResMed sponsored multi-site research study.

ATS Information



- American Thoracic Society (ATS) - More than 16,000 physicians, research scientists, and nurses and other allied healthcare professionals working to improve health worldwide by advancing research, clinical care, and public health in respiratory disease, critical illness, and sleep disorders.
- Dr. Owens Chair, forthcoming Clinical Practice Guideline “Long-term non-invasive ventilation in chronic stable hypercapnic chronic obstructive pulmonary disease: An Official American Thoracic Society Guideline.”

Voting Questions

- **Patient selection criteria** that will improve outcomes with any NPPV device
- **NIPPV equipment parameters** necessary to improve patient reported outcomes
- Improvements can be attributed to the use of **NIPPV equipment alone**
- **Patient usage parameters** that will improve outcomes

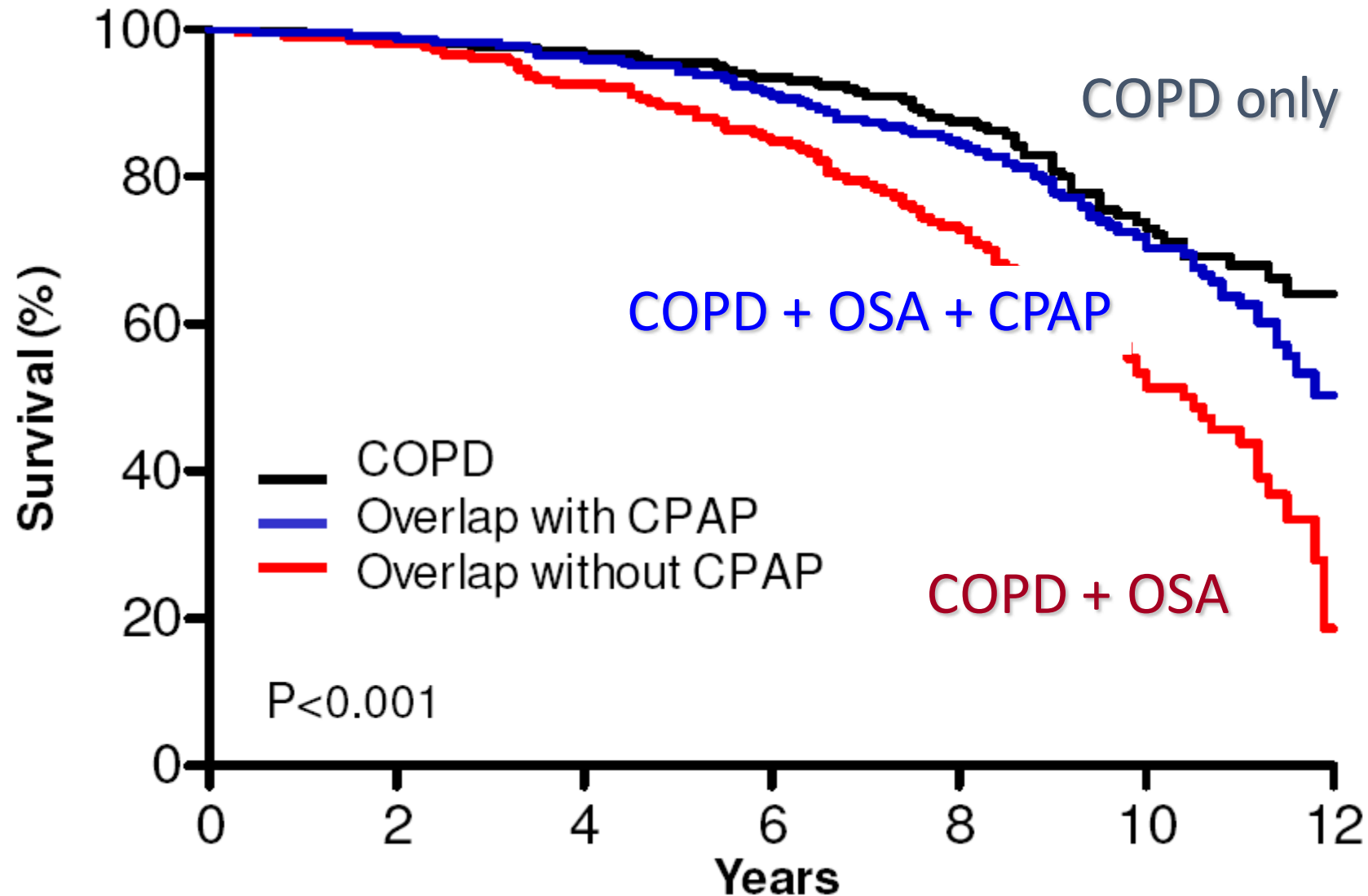
COPD + OSA

Chronic Stable Hypercapnic COPD

COPD and Obstructive Sleep Apnea (OSA)

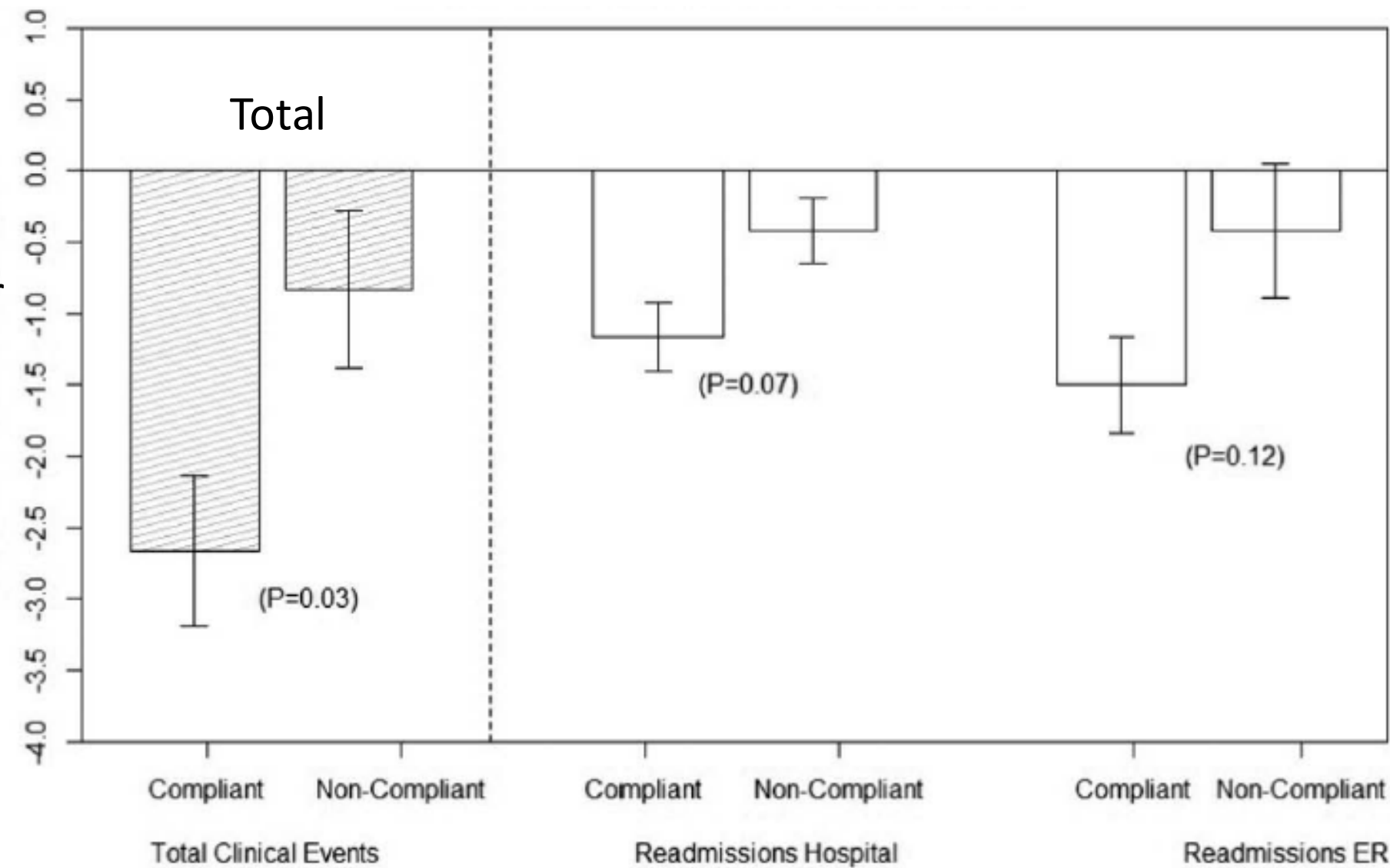
- This “Overlap Syndrome” is common
- **In absence of hypercapnia (high PaCO₂)**, continuous positive airway pressure (CPAP) can be used
- Application of **CPAP** is associated with: improved mortality, reduced ER and hospital admission.
- More use is better, **but 4 hours per night is not a magic number**

Overlap Syndrome has high mortality, CPAP use ameliorates

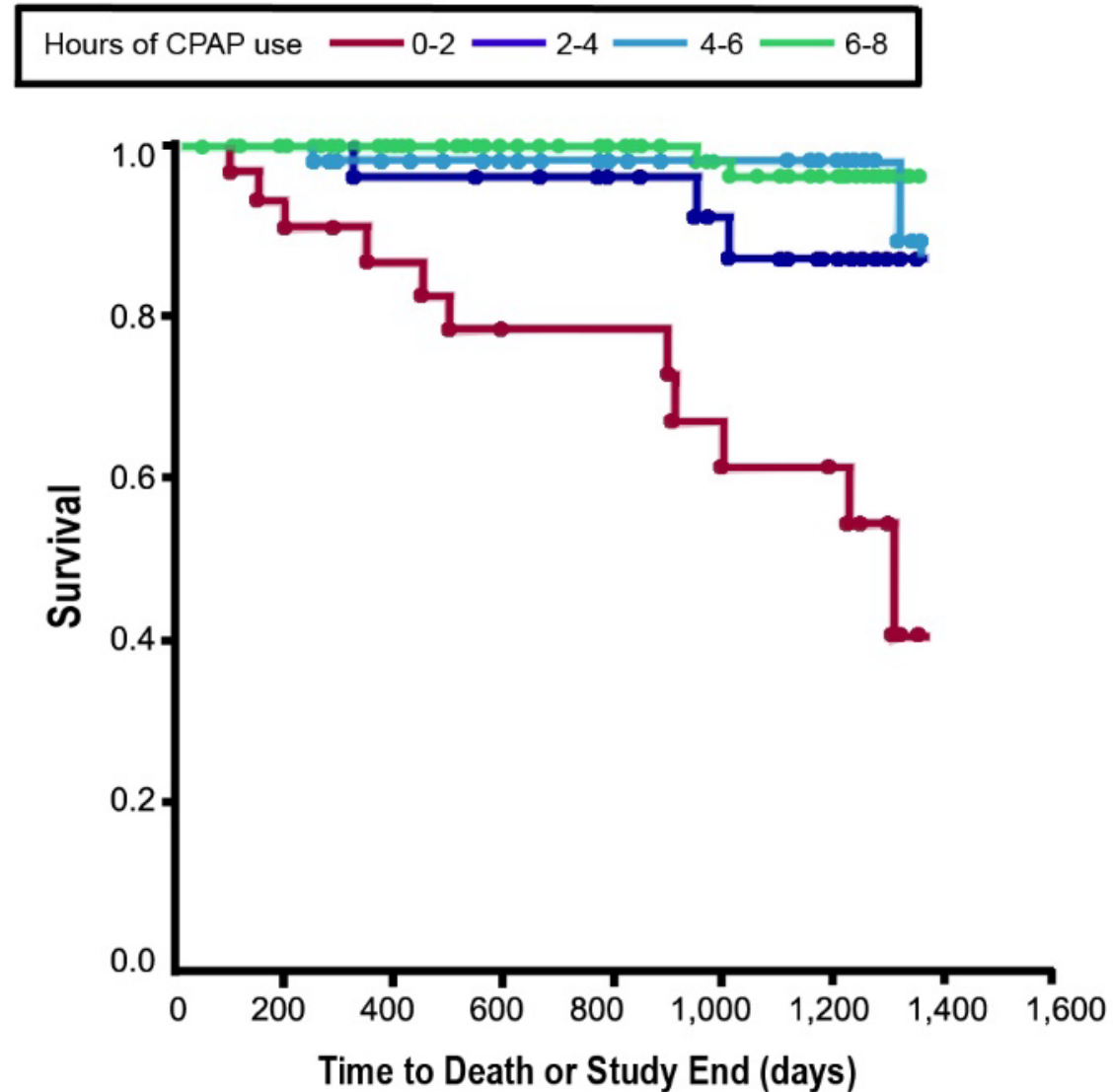


Patients with COPD on CPAP, have reduced ER visits/admissions

Change in number
of ER visits and
Admissions



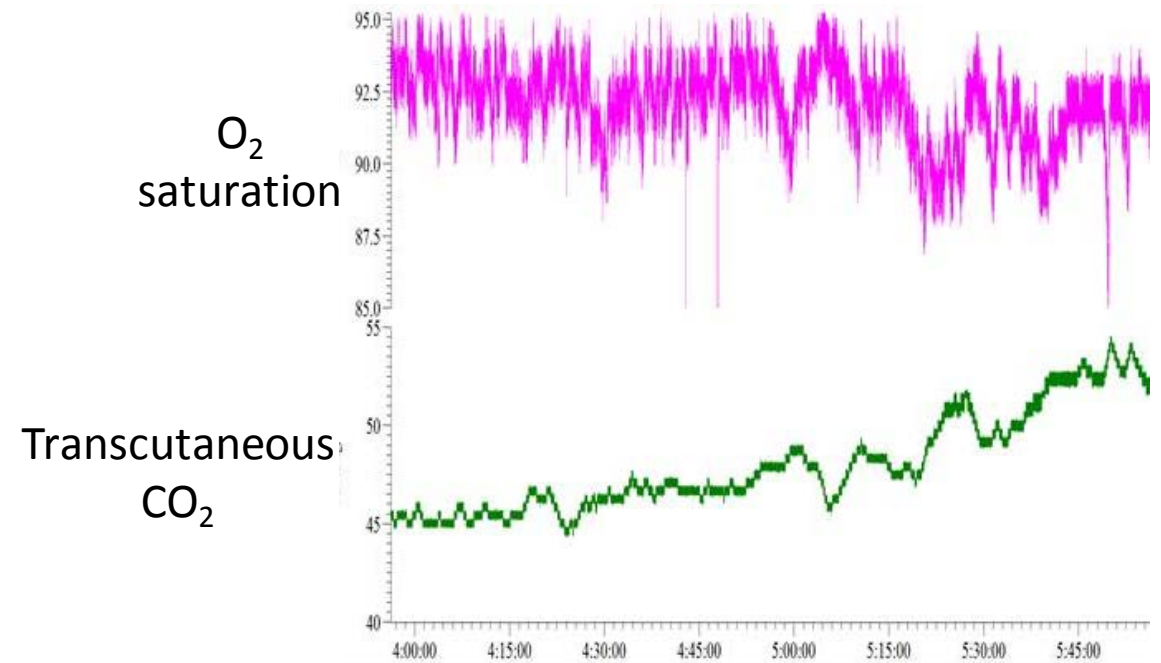
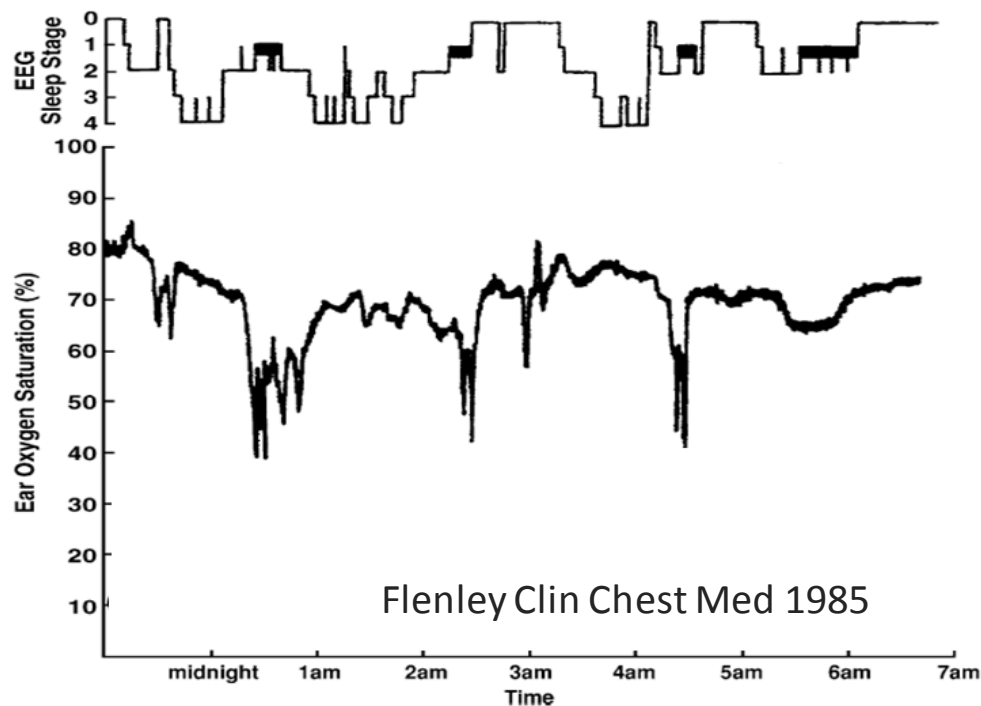
More CPAP use associated with improved survival



↓
Less CPAP use

COPD with stable hypercapnic respiratory failure

- A group with high morbidity and mortality, **with few treatments shown to improve outcomes** (smoking cessation, O₂ therapy)
- Both oxygenation **and ventilation (rarely measured)** are problems



Non-invasive positive pressure ventilation for the treatment of severe stable chronic obstructive pulmonary disease: a prospective, multicentre, randomised, controlled clinical trial

Thomas Köhnlein, Wolfram Windisch, Dieter Köhler, Anna Drabik, Jens Geiseler, Sylvia Hartl, Ortrud Karg, Gerhard Laier-Groeneveld, Stefano Nava, Bernd Schönhofer, Bernd Schucher, Karl Wegscheider, Carl P Criée, Tobias Welte

- Inclusion: GOLD IV, $\text{PCO}_2 > 51$ with $\text{pH} > 7.35$, no recent exacerbation
- Exclusion: BMI > 35 , other lung or heart disease
- Control: Medical COPD treatment, NPPV OK during exacerbation
- Intervention: Addition of NPPV 6+ hrs/day, **PS mode with high back up** targeting 20% reduction in PCO_2

- 33% of controls and 12% of NIV patients dead at 1 year (HR 0.24)
- **QOL improved** with NIV
- Intervention included scheduled hospitalizations and extensive follow-up

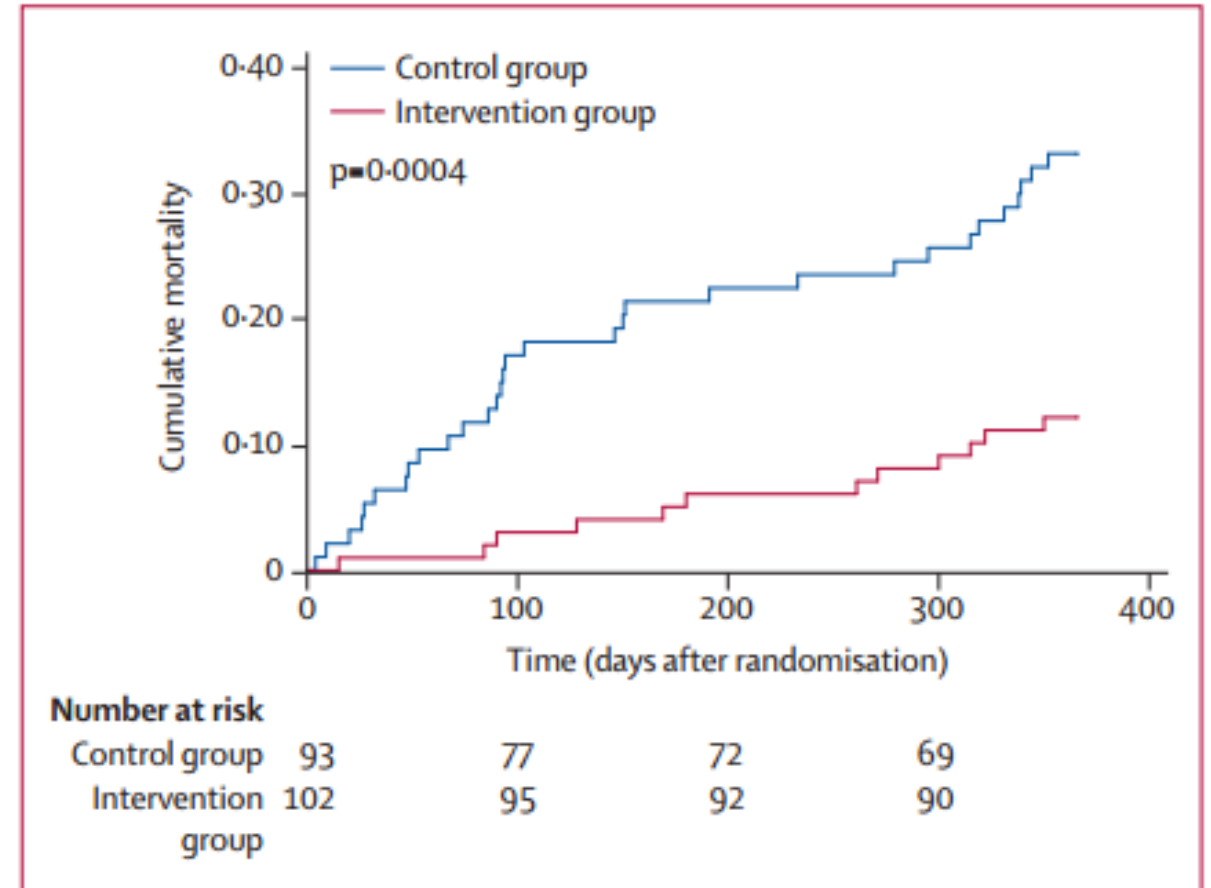


Figure 2: Kaplan-Meier estimate of cumulative all-cause mortality during the first year after randomisation (primary outcome)
The p value results from a log-rank test of the between-group difference.

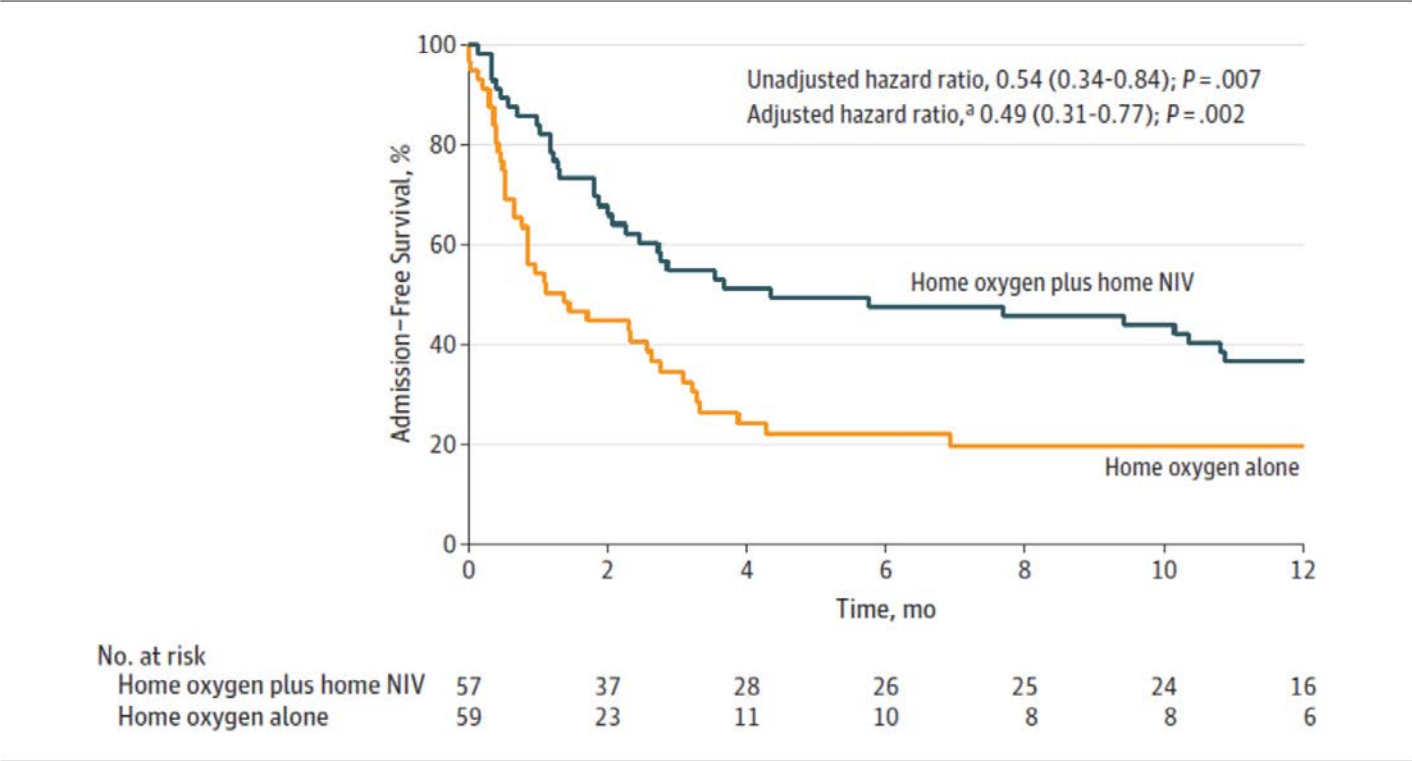
Effect of Home Noninvasive Ventilation With Oxygen Therapy vs Oxygen Therapy Alone on Hospital Readmission or Death After an Acute COPD Exacerbation

A Randomized Clinical Trial


Patrick B. Murphy, PhD; Sunita Rehal, MSc; Gill Arbane, BSc (Hons); Stephen Bourke, PhD; Peter M. A. Calverley, PhD; Angela M. Crook, PhD; Lee Dowson, MD; Nicholas Duffy, MD; G. John Gibson, MD; Philip D. Hughes, MD; John R. Hurst, PhD; Keir E. Lewis, MD; Rahul Mukherjee, MD; Annabel Nickol, PhD; Nicholas Oscroft, MD; Maxime Patout, MD; Justin Pepperell, MD; Ian Smith, MD; John R. Stradling, PhD; Jadwiga A. Wedzicha, PhD; Michael I. Polkey, PhD; Mark W. Elliott, MD; Nicholas Hart, PhD

2017

Figure 2. Kaplan-Meier Survival Plot of Time to Readmission or Death From Randomization to the End of Trial Follow-up at 1 Year



Home initiation of chronic non-invasive ventilation in COPD patients with chronic hypercapnic respiratory failure: a randomised controlled trial

Marieke L Duiverman ^{1,2}, Judith M Vonk,^{2,3} Gerrie Bladder,^{1,2} Joost P van Melle,⁴ Jellie Nieuwenhuis,^{1,2} Anda Hazenberg,^{1,2} Huib A M Kerstjens,^{1,2} Job F M van Boven,^{2,5} Peter J Wijkstra^{1,2}

What is the key question?

- Is home initiation of non-invasive ventilation (NIV) in stable hypercapnic COPD non-inferior to in-hospital NIV initiation?

What is the bottom line?

- Home initiation of chronic NIV in stable hypercapnic COPD patients is non-inferior to in-hospital initiation, safe and saves over 50% of the costs.

Voting Questions

- **Patient selection criteria** that will improve outcomes with any NPPV device
 - COPD + OSA
 - COPD + chronic hypercapnia
- **NIPPV equipment parameters** necessary to improve patient reported outcomes
 - CPAP
 - BPAP with back up rate
- Improvements can be attributed to the use of **NIPPV equipment alone**
 - Yes, but ancillary services clearly help, too
- **Patient usage parameters** that will improve outcomes
 - 4 hours/night is not a magic number
 - More is better

Additional Comments

- **BPAP with back up rate** has shown improvement for those with hypercapnic COPD, but it can be easier to satisfy requirements to get a home mechanical ventilator (HMV)
- Modifying requirements to obtain BPAP with back up rate will impact HMV utilization