THE OHIO STATE UNIVERSITY
WEXNER MEDICAL CENTER

Sleep Symposium 2019

Non-invasive Ventilation- Practical applications in CRF

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Conflicts?

NOTHING TO DISCLOSE

Objectives

Discuss practical and evidence based state-of- the-art Applications of NPPV for Chronic Respiratory Failure

Diagnosis Based Format

1) Coverage Criteria
2) Supporting Evidence
3) How to make sense and get the job done

Introduction

- CPAP side bar
  - Adding oxygen to CPAP
  - Moving to a RAD from CPAP
- Selected Diagnostic Categories
  - ALS Titration Protocol
  - COPD- the Case for the Backup Rate
  - Hypoventilation
- When all else fails- HMV horrors

Frequently Asked Questions:

Oxygen Use in Beneficiaries with OSA

Question #1

- A beneficiary has OSA with oxygen desaturation during a titration (PSG) but, the beneficiary is not tolerant to PAP therapy during the titration PSG. The physician prescribes oxygen therapy alone.
- Is the home oxygen covered?

No, home oxygen is not covered. Oxygen is not the primary treatment for OSA. The Oxygen LCD requires that the beneficiary is optimally treated with respect to their OSA. Question #1

Frequently Asked Questions:

Oxygen Use in Beneficiaries with OSA

Question #2

- A beneficiary has a diagnosis of OSA and COPD and a titration PSG >2 hours, the beneficiary was titrated with PAP to an AHI/RDI of <10/hour, yet continued to desaturate below 88% for >5 total minutes. The physician has prescribed oxygen for use with the PAP.
- In this instance, is home oxygen covered?

Yes, home oxygen would be covered. The question restates the titration PSG requirements described in the LCDs. A titration PSG meeting these requirements can (must) be used for qualification of home oxygen.

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Frequently Asked Questions:

Oxygen Use in Beneficiaries with OSA

Question #3

- A beneficiary with OSA and desaturation during a titration (PSG) met criteria for CPAP and O2 but on follow-up, the beneficiary is not using the PAP device (refused the device, is non-compliant, etc.) but the physician has prescribed oxygen for use during sleep.

- In this instance, is the home oxygen covered?

  Yes, home oxygen is covered. For beneficiaries with OSA, the titration PSG is used to assure that the OSA is optimally treated

  Beneficiary compliance with CPAP treatment after testing is not a factor for payment of home oxygen.

Bilevel Devices

Sanders, Chest 1990

Obstructive Sleep Apnea Treated by Independently Adjusted Inspiratory and Expiratory Positive Airway Pressures via Nasal Mask*

Physiologic and Clinical Implications

Mark H. Sanders, M.D., F.C.C.P.;† and Nancy Kern, C.R.T.T., R.PSG.T.

Treatment of obstructive sleep apnea with nasal continuous positive airway pressure mandates simultaneous increases of both inspiratory and expiratory positive airway pressures to eliminate apneas as well as nonapneic oxyhemoglobin desaturation events. We hypothesized that the forces acting to collapse the upper airway during inspiration and expiration are of different magnitudes and that obstructive sleep-disordered breathing events (including apneas, hypopneas and nonapneic desaturation events) could be eliminated at lower levels of EPAP than IPAP. To test these hypotheses, a device was built that allows the independent adjustment of EPAP and IPAP (nasal BiPAP). Our data support the hypotheses that expiratory phase events are important in the pathogenesis of OSA and that there are differences in the magnitudes of the forces destabilizing the upper airway during inspiration and expiration. Finally,

applying these concep
device that permits inc
IPAP, obstructive sleep
nated at lower levels
pared with convention
reduce the adverse e
therapy and improve lo

OSA = obstructive sleep
airway pressure; IPAP =
EPAP = expiratory
PSG = polysomnogra
DEF = desaturation eve
CA = central apnea; MA
popneas; CH = central h

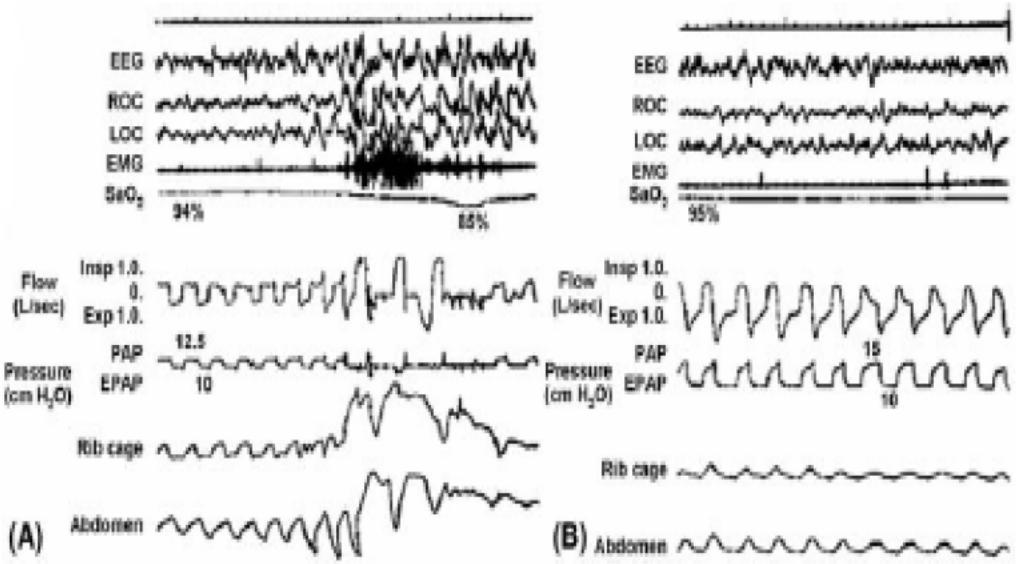


FIGURE 1 Representative tracing demonstrating elimination of apnea in the same patient by increasing inspiratory positive airway pressure (IPAP) during nasal bilevel positive airway pressure (BiPAP) therapy. (A) Obstructive apnea during nasal BiPAP (IPAP = 12.5 cm H_2O, expiratory positive airway pressure = 10 cm H_2O). (B) Elimination of obstructive apnea after increasing IPAP to 15 cm H_2O. *Abbreviations*: EEG, electroencephalogram; EMG, electromyogram; ROC and LOC, right and left outer canthi (eye movements), respectively; SaO_2, oxygen saturation. *Source*: From Ref. 9.

RAD for Failed CPAP

Local Coverage Determination (LCD): L33718

Positive Airway Pressure Devices for the Treatment of Obstructive Sleep Apnea

II. An E0470 device is covered for those beneficiaries with OSA who meet criteria A-C above, in addition to criterion D:

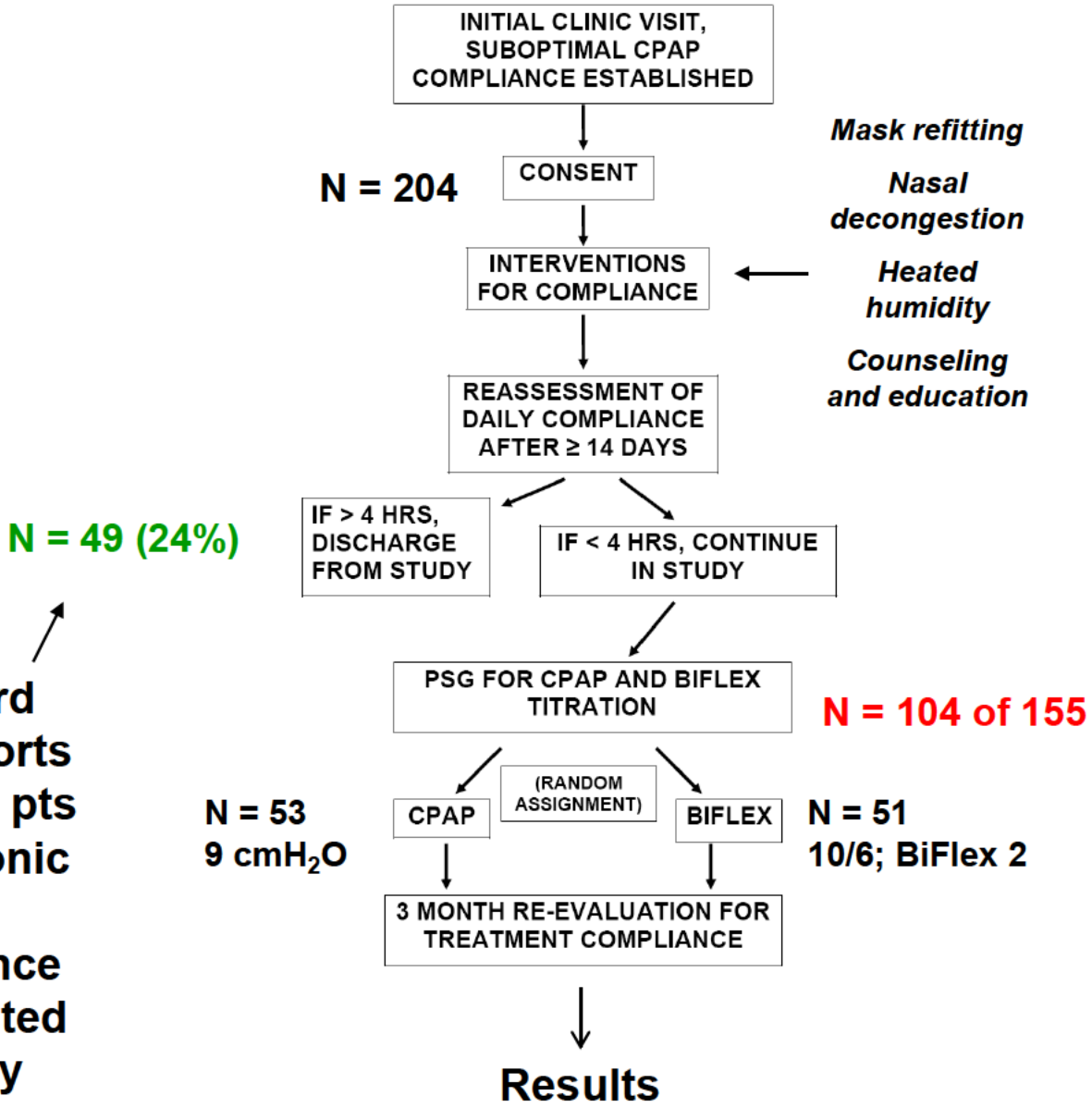
D. An E0601 has been tried and proven ineffective based on a therapeutic trial conducted in either a facility or in a home setting.

Ineffective is defined as documented failure to meet therapeutic goals using an E0601 during the titration portion of a facility-based study or during home use despite optimal therapy (i.e., proper mask selection and fitting and appropriate pressure settings).

Efficacy Targets

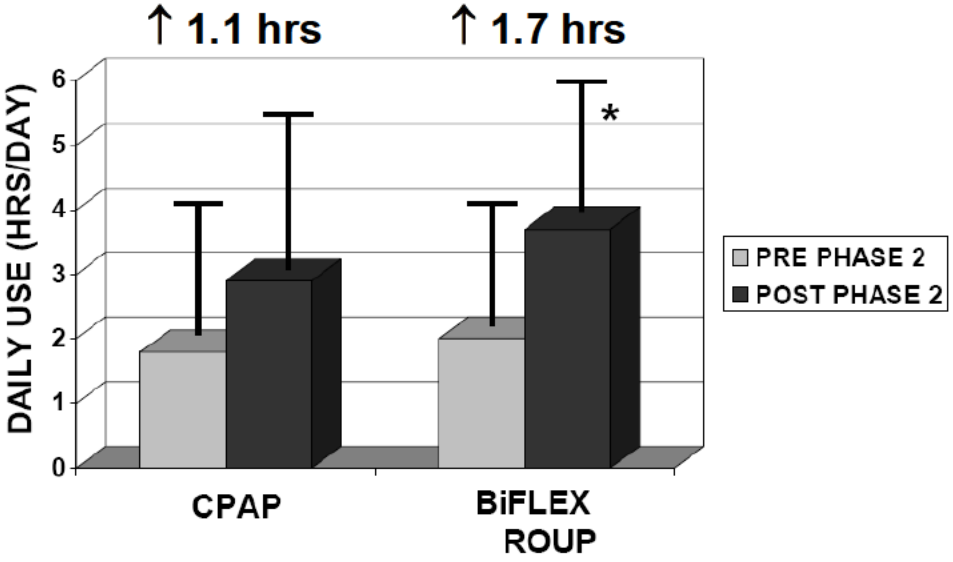
- Reduced Arousals/Residual Hypopneas
- Compliance
  - Increased comfort
  - Better patient-device synchrony
- Gas Exchange
  - Higher minute ventilation
  - Reduced daytime hypercapnia

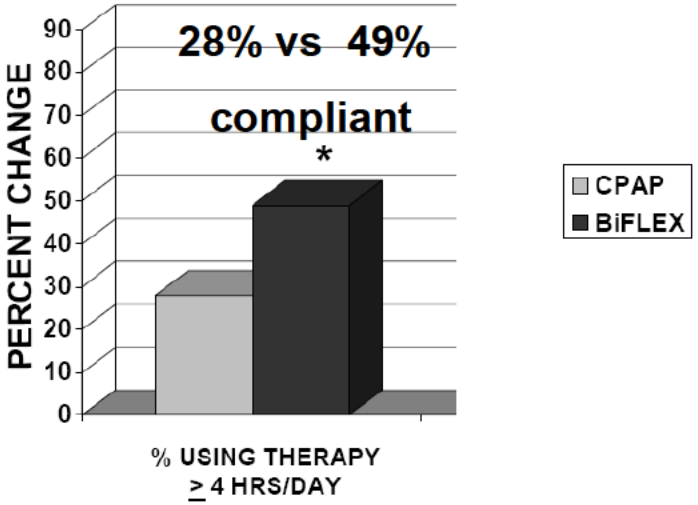
Bi-Level PAP with BiFlex as "Rescue" for CPAP Non-Compliant OSA Pts



Standard initial efforts to rescue pts with chronic poor compliance have limited efficacy

Ballard, Strollo, Gay. J Clin Sleep Med 2007;3:706-12





Bi-Level PAP with BiFlex will "rescue" some non-compliant OSA Pts

BiFlex Rescue Therapy

- **Conclusions:**
  - Standard initial efforts to ‘rescue’ patients from longer-standing poor patient compliance have limited efficacy
  - Subsequent change to flexible bi-level PAP can achieve improved compliance in this group of patients

RAD for Failed CPAP- Timing

Local Coverage Determination (LCD): L33718

- Substitution of CPAP (E0601) with BPAP S (E0470) does NOT require new face-to-face evaluation or sleep test
- If >30 days trial remain, re-evaluation still between 31-91st day after initiation of CPAP
- If <30 days trial remain, re-evaluation must occur before the 120th day after initiation of CPAP.
- If CPAP used >3 months, a switch to BPAP S requires a new face-to-face visit and re-evaluation occurs 61-91st day after initiation of BPAP and pt must have met CPAP adherence criteria or needs repeat sleep study

https://www.noridianmedicareportal.com/Supplier Q&A- Noridian.htm May 2012

Summary

- **CMS criteria provide BPAP *due to ineffective therapy while on CPAP either during a PSG or in the home setting.***
- **Some limited RCT evidence for BPAP efficacy as a rescue therapy technique**
- **Initial BPAP use offers no advantage for compliance with PAP therapy to naïve pts**

A pilot study assessing adherence to auto-bilevel following a poor initial encounter with CPAP. Powell ED; Gay PC et al. JCSM 2012; 8(1): 43-47

Improved adherence with PAP therapy after switching from CPAP to bilevel for non-compliant OSA patients et al. Adam Benjafield, Atul Malhotra, ERJ 2018

NIV in ALS

Bourke, et al. Lancet Neurol 2006; 5:140–47

- RCT Design
  - Pts assessed every 2 months and randomly assigned to NIV (n=22) or standard care (n=19) when they developed either orthopnea with MIP <60% pred or symptomatic hypercapnia

NIV in ALS: Benefits

- **Survival**

Median survival benefit of 205 days (p=0·006)

- **NIV improved survival but not for those with severe bulbar disease.**
- **NIV survival is greater than with Riluzole**
- **Quality of life with NIV maintained above 75% of baseline for most of this follow-up**

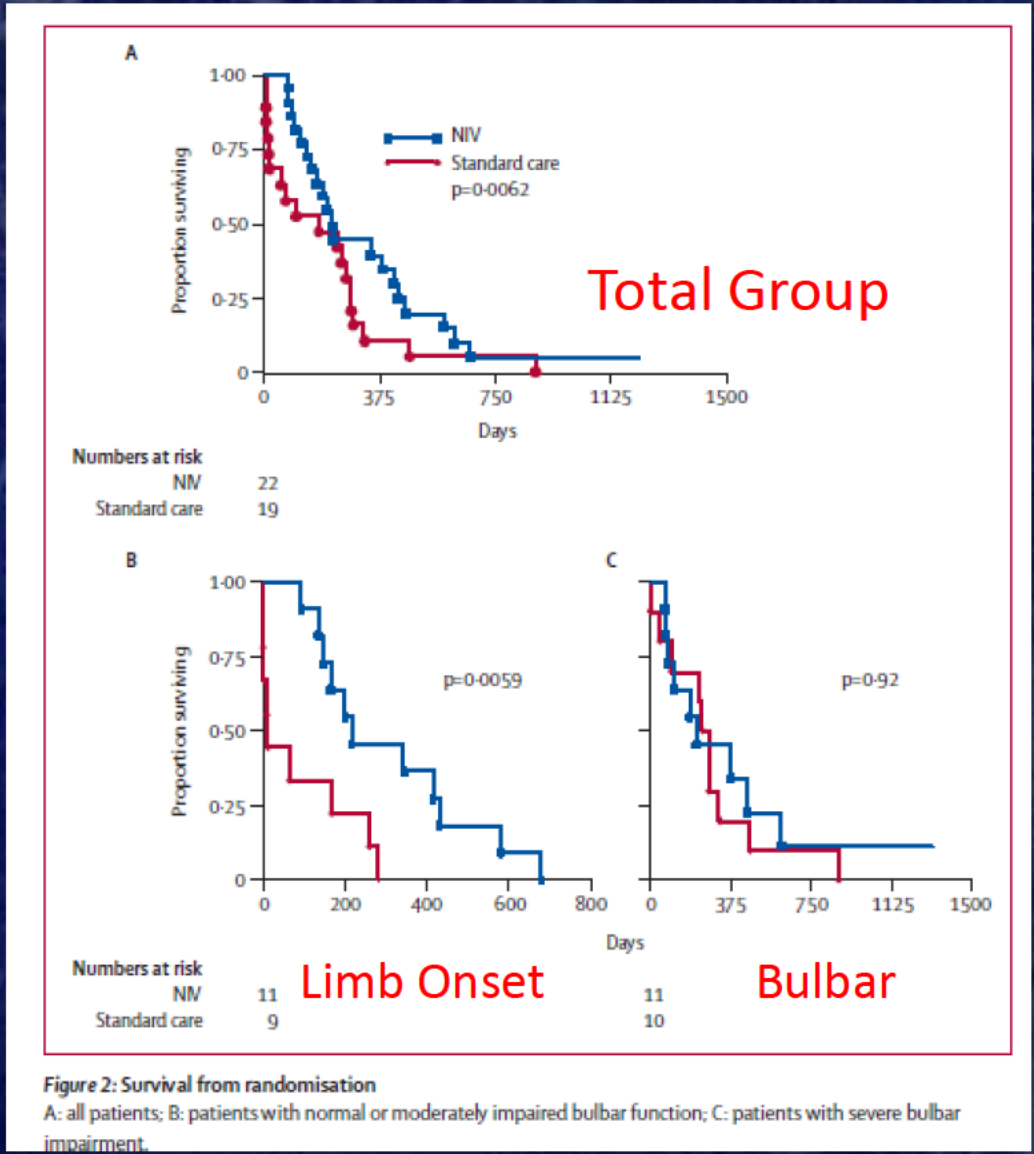


Figure 2: **Survival from randomisation**
A: all patients; B: patients with normal or moderately impaired bulbar function; C: patients with severe bulbar impairment.

Bourke, SC Lancet Neurol 2006; 5: 140–47

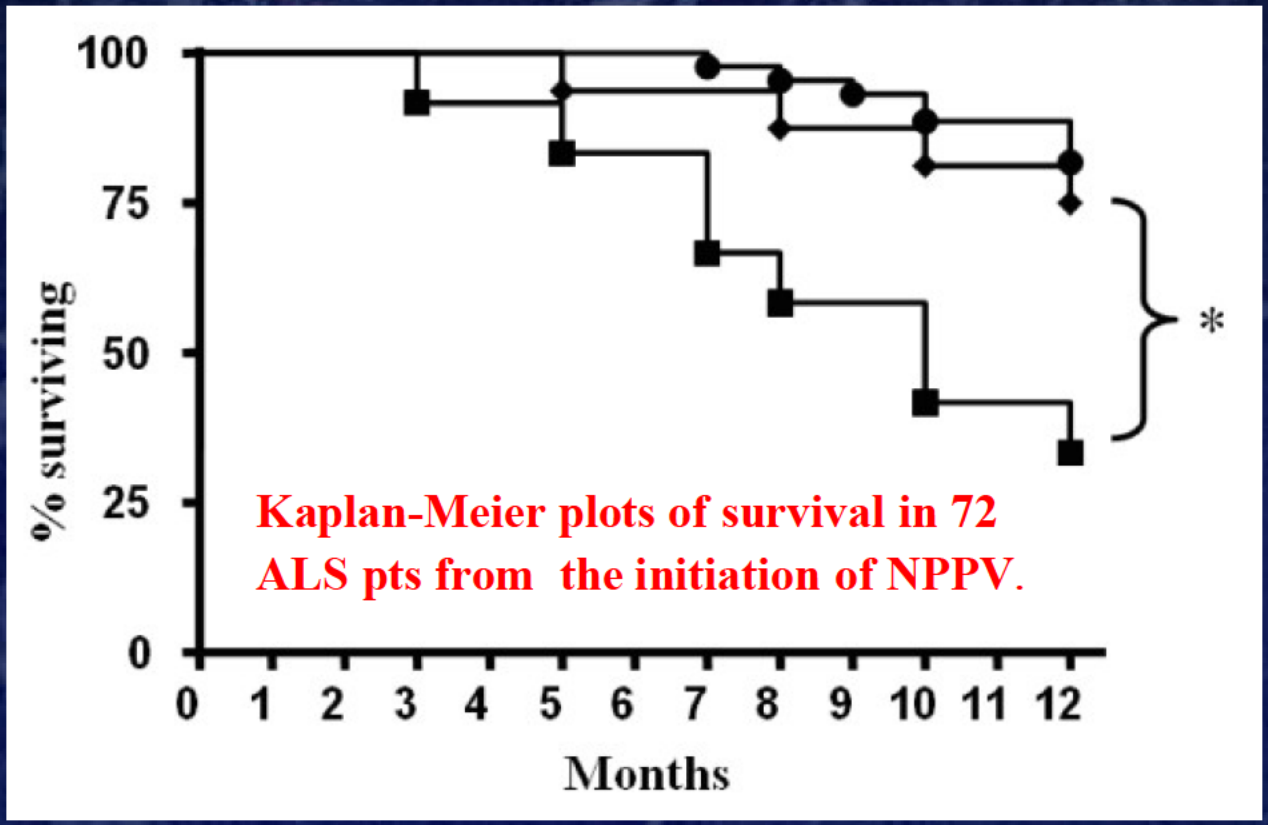
Early treatment with NPPV prolongs survival in ALS pts

Methods:

- 72 consecutive ALS patients who underwent pulmonary function tests.
- Control group- 44 presented with an FVC >75%
- 28 patients presented with an FVC <75% AND showed nocturnal respiratory insufficiency during PSG and were prescribed NPPV;
  - 16 were treated with NPPV
  - 12 refused or were intolerant

Pierluigi Carratù et al. Early treatment with noninvasive positive pressure ventilation prolongs survival in ALS patients with nocturnal respiratory insufficiency *Journal of Rare Diseases* **2009, 4:10**

Early Treatment with NPPV Prolongs Survival in ALS pts



- 44 ALS pts FVC>75% (Black circle) vs. 16 ALS pts FVC<75% treated with NPPV (Black triangle) :p = 0.5.
- 44 ALS pts ALS with FVC>75% vs. 12 ALS pts with ALS with FVC<75% not treated with NPPV (Black square) : $p < 0.0001$.

"CMS Coverage Law"
I. Restrictive Thoracic Disorders

- A. Documentation of a progressive NMD (e.g., ALS) or a severe thoracic cage
- B. 1. $PaCO_2$, awake on pt's usual FIO_2, is $\geq$ 45mmHg, or

  2. Sleep oximetry demonstrates SpO_2 $\leq$88% for 5 total min. on pt's usual FIO_2, or

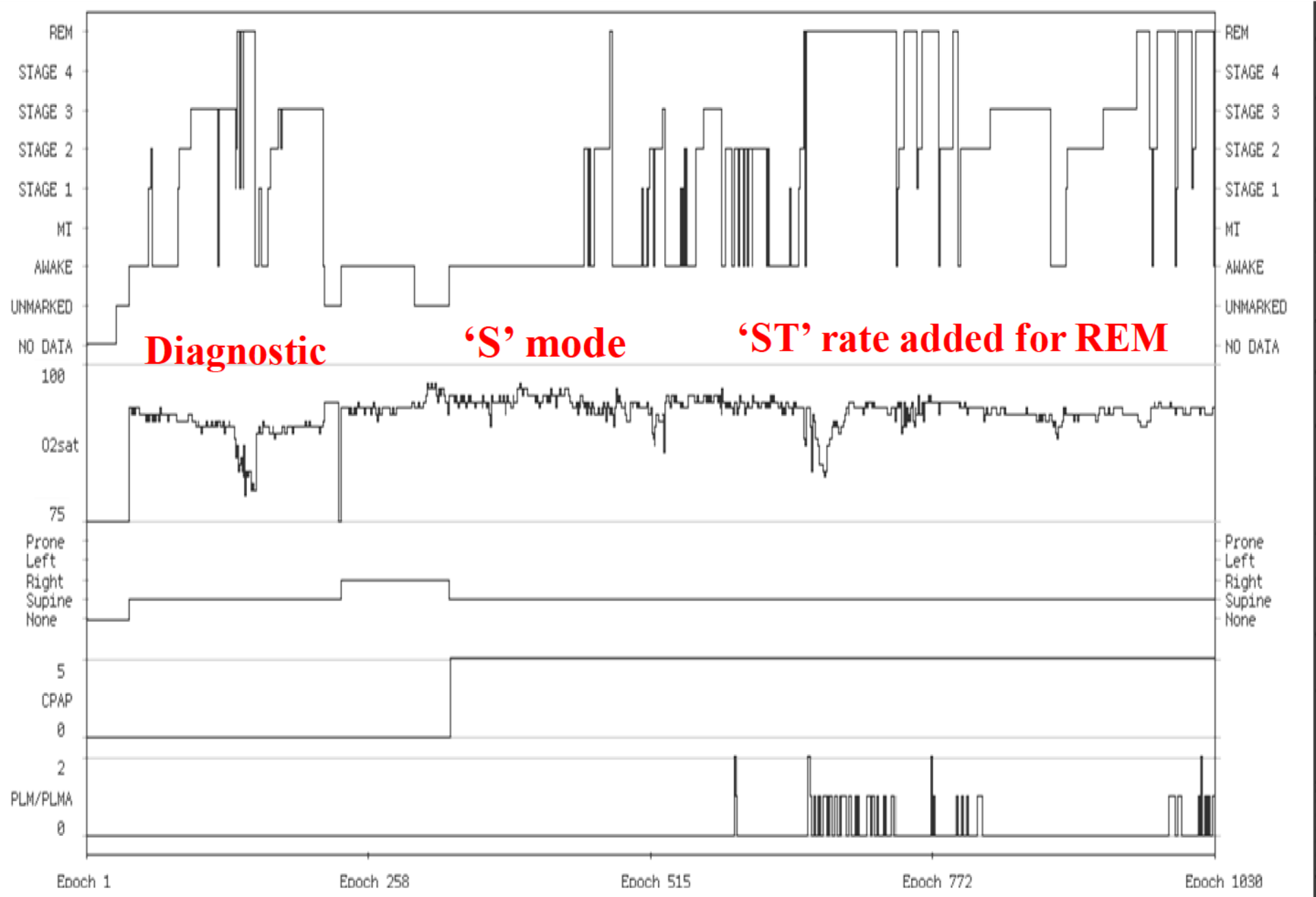
  3. For a progressive NMD only,

  PiMax <60cm H_2O or FVC < 50% pred,
- C. COPD does not contribute significantly to the pt's pulmonary limitation.

Playing the Game

Setting up the PSG

- Short diagnostic study to desensitize and then assess degree of REM sleep disordered breathing
- Move to Bi-level starting at a low IPAP (6-8 cmH_2O) and min EPAP
- Increase IPAP as tolerated target (10-12cmH2O) add backup rate (10-12 BPM) to support REM sleep ventilation


REM
STAGE 4
STAGE 3
STAGE 2
STAGE 1
MT
AWAKE
UNMARKED
NO DATA
Diagnostic
'S' mode
'ST' rate added for REM
100
O2sat
75
Prone
Left
Right
Supine
None
5
CPAP
0
2
PLM/PLMA
0
Epoch 1
Epoch 258
Epoch 515
Epoch 772
Epoch 1030

Practical Implementation of a Single-Night Split-Titration Protocol With BPAP-ST and AVAPS in Patients With Neuromuscular Disease

Salma I. Patel, MD, MPH[1]; Peter Gay, MD[1]; Timothy I. Morgenthaler, MD[1]; Eric J. Olson, MD[1]; Fadi E. Shamoun, MD[2]; Rahul Kashyap, MBBS[3]; Daniel Herold, RPSGT[1]; Sarah McNamara, RPSGT[1]; Bernardo Selim, MD[1]

J Clin Sleep Med. 2018;14(12):2031–2035.

Study Objectives: Noninvasive positive pressure ventilation titration protocols in pts with neuromuscular disease (NMD) are based on devices in a spontaneous/timed mode (BPAP-ST). Experience integrating protocols on average volume-assured pressure support (AVAPS) mode is limited, prompting development of a practical single-night titration protocol that helps decide between BPAP-ST and AVAPS modes.

Methods: Sequential titration protocol of BPAP-ST followed by AVAPS during a single-night PSG with NMD with report of PSG and clinical metrics.

Results: 27 pts completed the protocol: 14 (52%) were male with median 64 years of age and body mass index of 29.6 kg/m2. They had median %predicted maximal inspiratory and expiratory pressures, and vital capacity of 33, 34 and 60, respectively. At final titration, average tidal volume (Vt) and nadir NREM SpO2 were higher and RR/Vt, transcutaneous CO2, and arousal index were lower on AVAPS ($P < .05$) in comparison with BPAP-ST. Full face mask was used in 23 patients (85%). None of the other ventilatory or sleep parameters differed significantly between BPAP-ST and AVAPS ($P > .05$).

Conclusions: A practical single-night split-titration protocol with BPAP-ST and AVAPS can successfully be implemented in patients with NMD, assisting clinicians and patients with the decision on initial treatment modalities and settings.

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Protocol

J Clin Sleep Med. 2018;14(12):2031–2035.

- Mask fitting, 30’ awake desensitization BPAP session 6/4 cmH2O, rate 8
- BPAP-ST initiated with EPAP- 4 and IPAP increased to maintain mean SpO2 ≥ 90% with min delta 5 and an IPAP- 10 cmH2O ultimately targeted
- During the first REM period, rate is increased to 10 and then adjusted for comfort to max of pt’s spontaneous non-REM rate.

Protocol

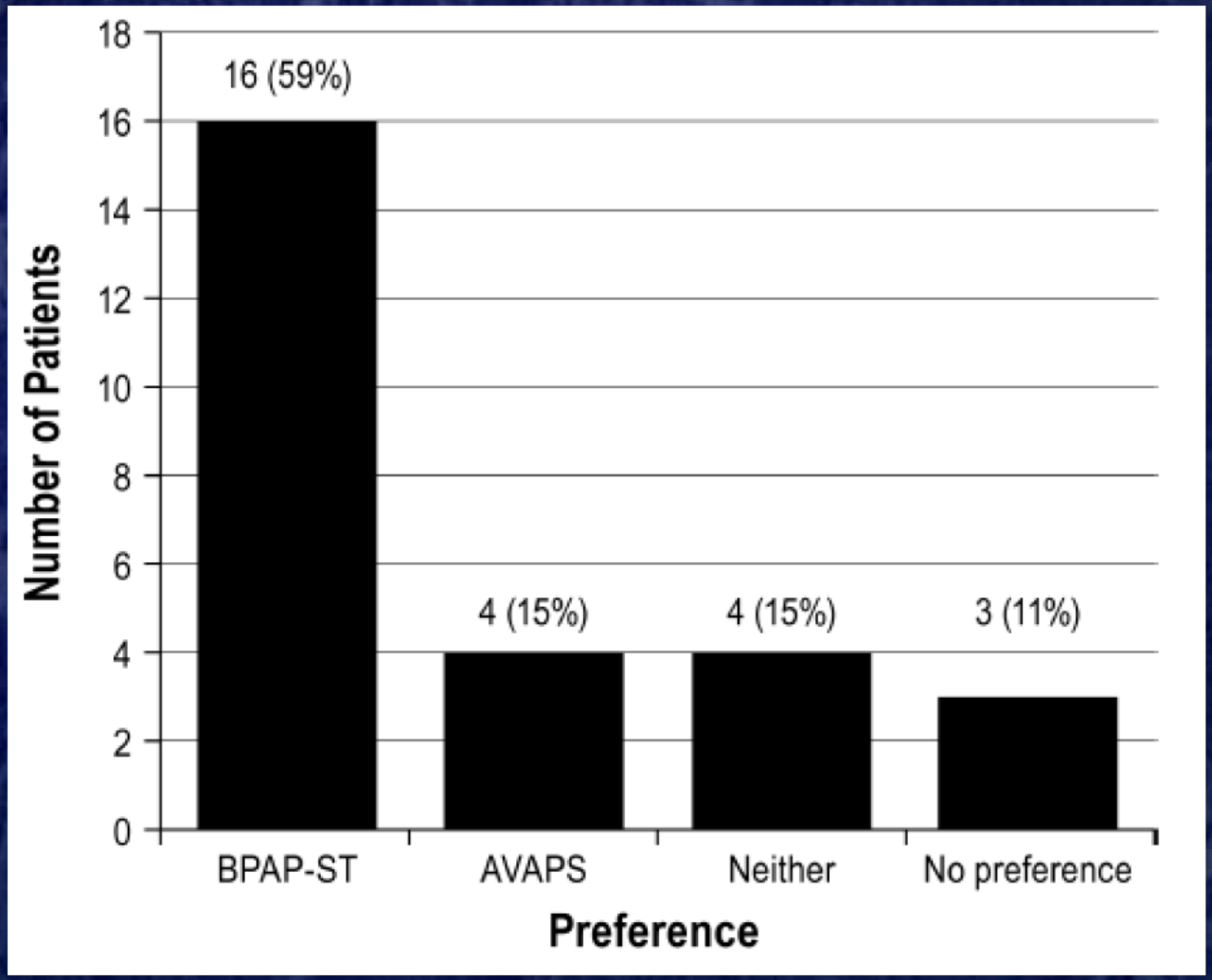
- If mean SpO2 ≥90% is achieved during REM pts are switched to AVAPS.
- For AVAPS titration in ST mode, initial IPAP, EPAP, rate and estimated average Vt are identical to the values during the BPAP-ST
- Remaining AVAPS settings are: min PS- 4, max PS- 20, max IPAP- 25 cmH2O, rate as during BPAP-ST titration, Ti- 1.5 seconds, rise time 2-3ms and AVAPS rate of 5.

Protocol

- If AVAPS Vt still <8 mL/kg IBW, Vt is increased by 30 mL q 30' as tolerated to the final target Vt or highest tidal volume tolerated by pt, whichever less
- Assessed respiratory parameters, sleep quality, and pt preferences

Results and Conclusions

J Clin Sleep Med. 2018;14(12):2031–2035.



Results and Conclusions

Table 2—Ventilation and polysomnography parameters on BPAP-ST versus AVAPS.

Variable	BPAP-ST	AVAPS	*P*
Inspiratory pressure (cmH_2O)*	12 (10, 15)	15 (13, 19)	.001
Expiratory pressure (cmH_2O)*	4 (4, 7)		
Tidal volume (mL)*	362 ± 94	481 ± 121	< .001†
$tcCO_2$ (mmHg)*	46 (43.5–59.5)	44 (43–48.5)	.012†
Respiratory rate (breaths per minutes)*	12 (10, 14)	12 (10, 14)	.730‡
Respiratory rate/tidal volume* (n = 25)	0.033 (0.027–0.046)	0.024 (0.019–0.036)	< .001†
Nadir SpO_2 NREM sleep (%)	85 (78, 89)	88 (85, 91)	.037‡
Nadir SpO_2 REM sleep (%)	87 ± 5	88 ± 4	.546†
Sleep efficiency (%)	67 ± 16	73 ± 18	.284†
Arousal index (events/h)	24.6 (13.3, 30.6)	14.1 (10.9, 20.1)	.045‡

Conclusions: A practical single-night split-titration protocol with BPAP-ST and AVAPS can be used in patients with NMD, and assist with the decision on initial Rx modalities and settings.

"It's the Law"
II. Severe COPD

A) 1. $PaCO_2 \geq 52$ mm Hg, on pt's usual FIO_2 and,

2. Sleep oximetry demonstrates O_2 Sat $\leq 88\%$ for <5 total minutes, done on oxygen at 2 LPM or the pt's usual FIO_2 (whichever is higher) and,

B) OSA (and CPAP therapy) considered and ruled out

If all of the above criteria for COPD pts are met, a E0470 device (no backup rate) is covered for first 3 months of therapy and thereafter pending successful 61-90 day reassessment

Management

- Pt was prescribed a E0470 (no backup rate) for severe hypercapnic COPD, otherwise optimally treated
- Vendor claimed requirements for COPD not met without oximetry on oxygen
- <u>Crucial to meet all requirements</u>

  Keep oximetry documentation

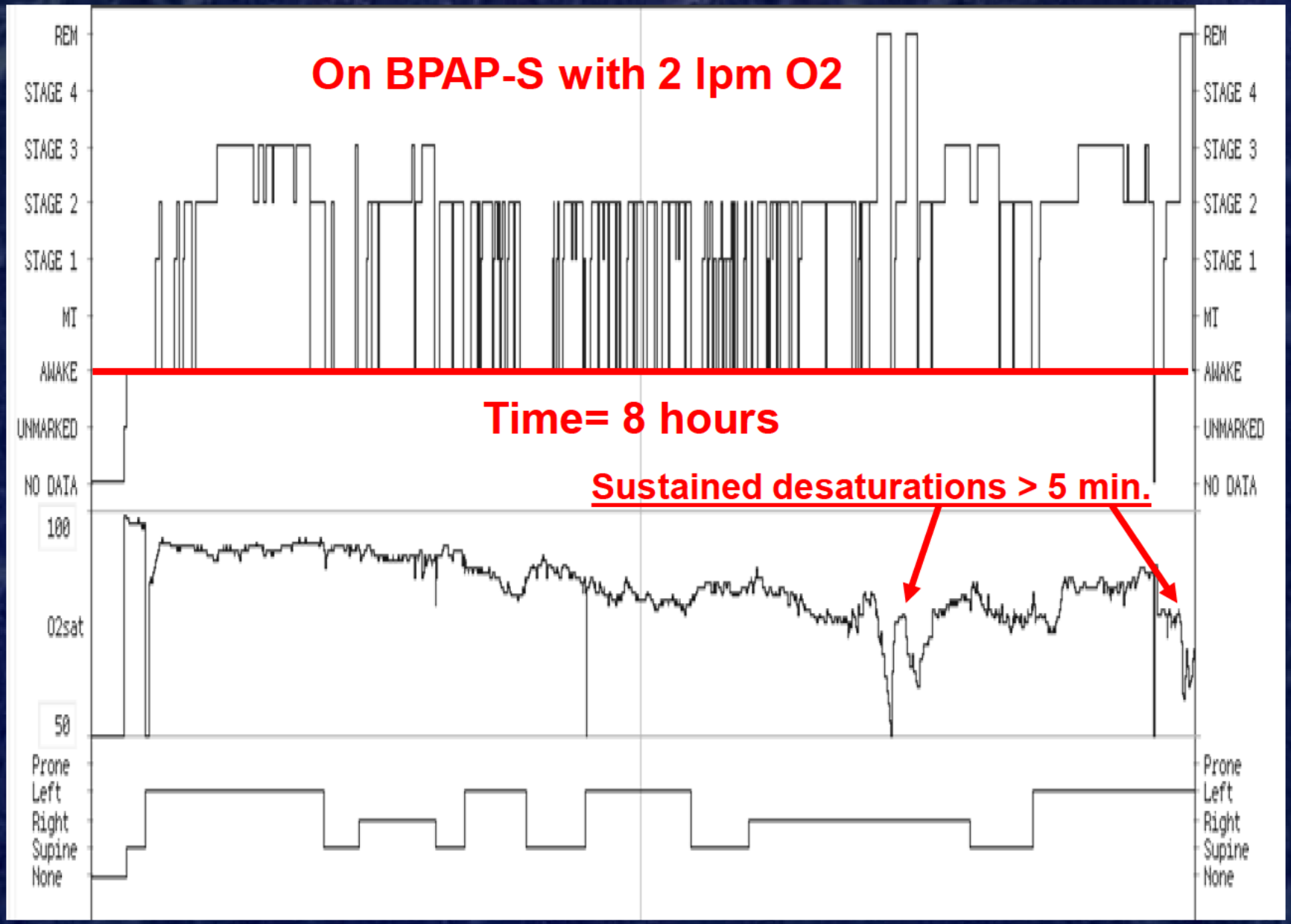
Management
Follow-up

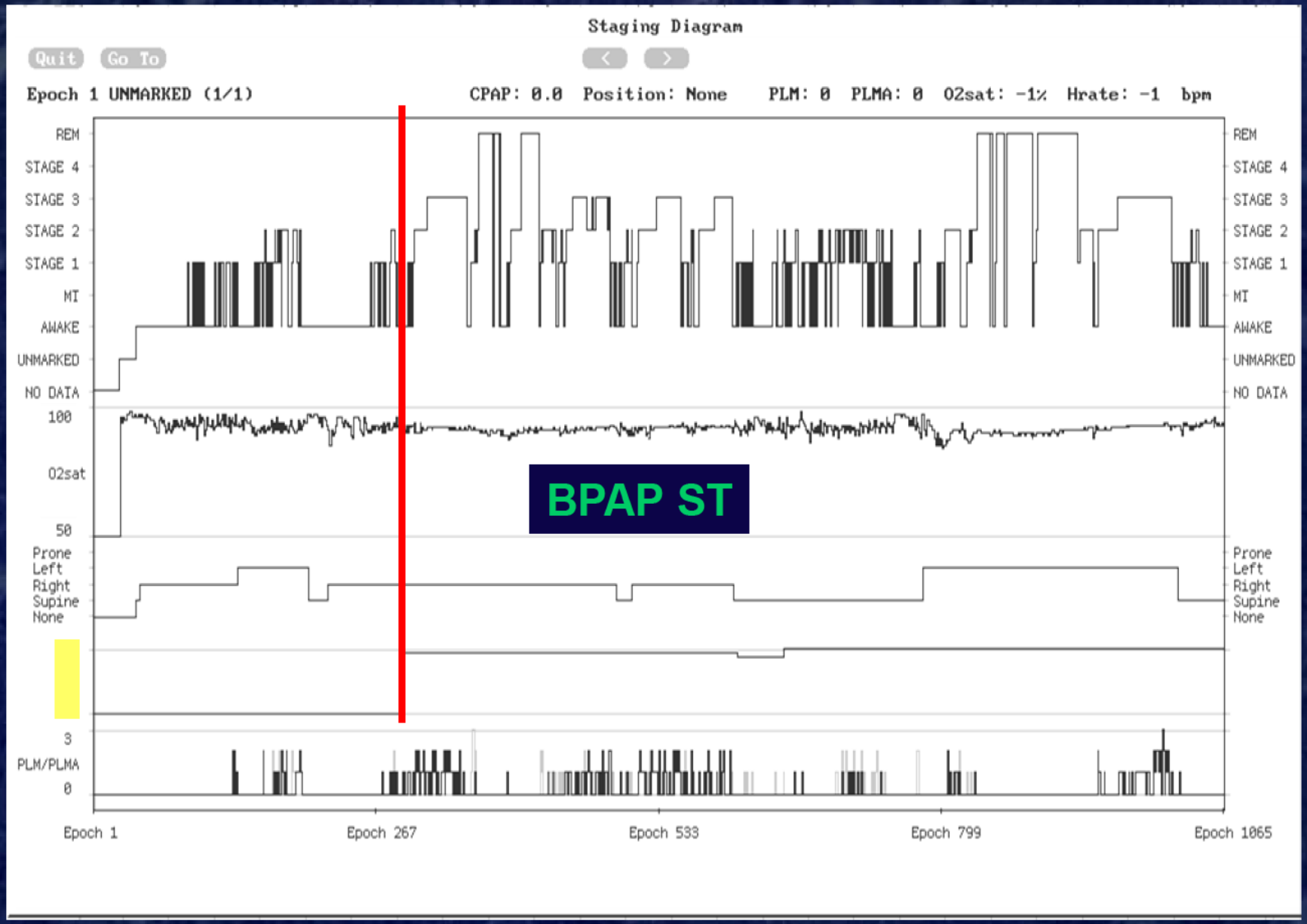
- Pt returned after 3 months of therapy
  - Compliant using nearly 8 hours/ night
    - Still fatigued, sleep better but fitful
      - ABGs on 2 lpm, $PaCO_2$= 70
- *Can anything else be done?*
- *Do I need a sleep study?*
- *What's the prognosis?*

Severe COPD
Situation 2 for Backup Rate

For COPD pts who qualified for a E0470 device, no sooner than 61 days after initial issue while compliant with a E0470 device, a E0471 device will be covered if:

1) $PaCO_2 \geq 52$ mm Hg, breathing the pt's usual FIO_2, and
2) Sleep oximetry at the same time period demonstrates $SpO_2 \leq 88\%$ <5 minutes, breathing with the E0470 device and on O_2 at 2 LPM or the pt's usual FIO_2 (whichever is higher) and
3) A signed and dated statement from the treating physician, declaring that the pt has been compliant with the E0470 device (average of 4 hrs. per 24 hour period) but pt is NOT benefiting from its use


On BPAP-S with 2 lpm O2
Time= 8 hours
Sustained desaturations > 5 min.
REM
STAGE 4
STAGE 3
STAGE 2
STAGE 1
MT
AWAKE
UNMARKED
NO DATA
100
O2sat
50
Prone
Left
Right
Supine
None


Staging Diagram
Quit
Go To
Epoch 1 UNMARKED (1/1)
CPAP: 0.0 Position: None PLM: 0 PLMA: 0 O2sat: -1% Hrate: -1 bpm
REM
STAGE 4
STAGE 3
STAGE 2
STAGE 1
MT
AWAKE
UNMARKED
NO DATA
100
O2sat
50
Prone
Left
Right
Supine
None
3
PLM/PLMA
0
BPAP ST
Epoch 1
Epoch 267
Epoch 533
Epoch 799
Epoch 1065

NIPPV for the Treatment of Severe Stable COPD: A Prospective, Multicenter, RCT.

Kohnlein et al. Lancet Resp Med 2014; 2: 698-705.

Background and Pt Population

- Sentinel prospective multicenter RCT of survival benefit with NPPV in pts with chronic stable hypercapnic COPD 2-4 wks post admission for acute exacerbation.
- Pts had stage IV COPD with rest $PaCO_2$ of 51.9 mmHg or higher and pH > 7.35.

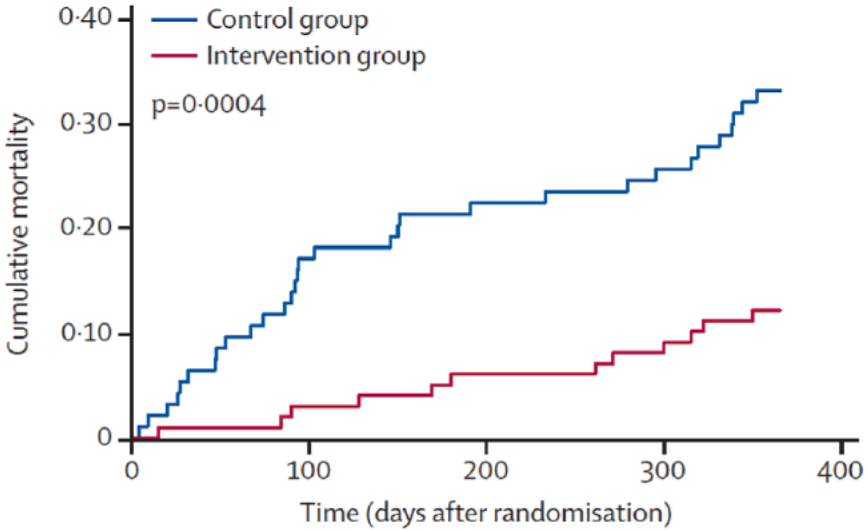
Survival with High Intensity NPPV for Severe COPD

Methods

- NPPV was targeted to reduce baseline $PaCO_2$ by at least 20%, or to achieve $PaCO_2$ < 48 mmHg.
- Mean IPAP was 21.6 cmH_2O; mean EPAP was 4.8 cm H_2O and the mean back up rate was 16.1 bpm (range 2-24).
- Mean NPPV usage was 5.6 hrs/day.

Survival with High Intensity NPPV for Severe COPD

Figure 1. Effect of NPPV with Back up rate on Survival in Stable Severe Hypercapneic COPD



Number at risk				
Control group	93	77	72	69
Intervention group	102	95	92	90

- The primary outcome, 1-year all-cause mortality
- 12% in the NPPV group and 33% in the controls

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

Murphy et al

***Murphy et al. JAMA*. 2017; 317(21):2177 - 86**

DESIGN, SETTING, AND PARTICIPANTS A randomized clinical trial of patients with persistent hypercapnia ($PaCO_2$ >53 mm Hg) 2 weeks to 4 weeks after resolution of respiratory acidemia who were recruited from 13 UK centers between 2010 and 2015. Exclusion criteria included obesity (body mass index [BMI] >35), obstructive sleep apnea syndrome, or other causes of respiratory failure. Of 2021 patients screened, 124 were eligible.

INTERVENTIONS There were 59 patients randomized to home oxygen alone (median oxygen flow rate, 1.0 L/min [interquartile range {IQR}, 0.5-2.0 L/min]) and 57 patients to home oxygen plus home NIV (median oxygen flow rate, 1.0 L/min [IQR, 0.5-1.5 L/min]). The median home ventilator settings were an inspiratory positive airway pressure of 24 (IQR, 22-26) cm H_2O, an expiratory positive airway pressure of 4 (IQR, 4-5) cm H_2O, and a backup rate of 14 (IQR, 14-16) breaths/minute.

MAIN OUTCOMES AND MEASURES Time to readmission or death within 12 months adjusted for the number of previous COPD admissions, previous use of long-term oxygen, age, and BMI.

RESULTS A total of 116 patients (mean [SD] age of 67 [10] years, 53% female, mean BMI of 21.6 [IQR, 18.2-26.1], mean [SD] forced expiratory volume in the first second of expiration of 0.6 L [0.2 L], and mean [SD] $PaCO_2$ while breathing room air of 59 [7] mm Hg) were randomized. Sixty-four patients (28 in home oxygen alone and 36 in home oxygen plus home NIV) completed the 12-month study period. The median time to readmission or death was 4.3 months (IQR, 1.3-13.8 months) in the home oxygen plus home NIV group vs 1.4 months (IQR, 0.5-3.9 months) in the home oxygen alone group, adjusted hazard ratio of 0.49 (95% CI, 0.31-0.77; P = .002). The 12-month risk of readmission or death was 63.4% in the home oxygen plus home NIV group vs 80.4% in the home oxygen alone group, absolute risk reduction of 17.0% (95% CI, 0.1%-34.0%). At 12 months, 16 patients had died in the home oxygen plus home NIV group vs 19 in the home oxygen alone group.

CONCLUSIONS AND RELEVANCE Among patients with persistent hypercapnia following an acute exacerbation of COPD, adding home noninvasive ventilation to home oxygen therapy prolonged the time to readmission or death within 12 months.

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

Table 1. Baseline Characteristics

	Home Oxygen Therapy Plus NIV (n = 57)	Home Oxygen Therapy Alone (n = 59)	Total (N = 116)
Age, mean (SD), y[a]	66.4 (10.2)	67.1 (9.0)	66.7 (9.6)
Body mass index, median (IQR)[a,b]	21.5 (18.8-24.5)	22.2 (17.9-26.9)	21.6 (18.2-26.1)
Prior use of long-term oxygen therapy, No. (%)[a]	40 (70)	40 (68)	80 (69)
≥3 COPD-related readmissions within past year, No. (%)[a]	30 (53)	31 (53)	61 (53)
Female sex, No. (%)	29 (51)	32 (54)	61 (53)
Smoking history, median (IQR), pack-years	42.0 (30.5-60.0)	45.0 (31.0-55.0)	44.0 (31.0-60.0)
Apnea Hypopnea Index, median (IQR), /h[c]	2.4 (0.9-6.2)	2.0 (0.8-3.9)	2.2 (0.8-5.1)
Neck circumference, median (IQR), cm	36.3 (33.0-40.0)	38.6 (35.3-41.0)	37.0 (34.5-40.0)
Waist circumference, median (IQR), cm	90.0 (78.0-100.5)	87.5 (78.0-106.0)	88.0 (78.0-102.0)
FEV_1, mean (SD), L	0.6 (0.2)	0.6 (0.2)	0.6 (0.2)

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

Methods

- RCT with 15 hr target O2 with PaO2~ 60 mmHg vs added 6 hr/nt NIV with a Harmony 2 or VPAP III ST
  - Primary outcome target was time to death or rehospitalization for COPD
  - Secondary outcomes included all-cause mortality, exacerbations, ABGs, 4% ODI, mean nocturnal SaO2, total sleep time with SaO2<90% ,mean and max nocturnal tcPCO2, and max nocturnal, breathlessness, health-related QOL at each follow-up assessment.

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

Results

- 116 pts mean age 67 yrs, 53% female, mean BMI 21.6, mean FEV1 of 0.6 L, and mean PaCO2 59 mmHg
- 64 pts (28 O2 vs 36 O2 plus NIV) completed the 12-mos trial.
- Median time to readmission or death in the O2 plus NIV vs O2 alone was 4.3 vs 1.4 mos., adjusted hazard ratio of 0.49 with a 12-month risk of readmission or death of 63.4% vs 80.4%, (-17%)
- At 12 months, 16 vs 19 pts died in the O2 plus NIV vs O2 alone

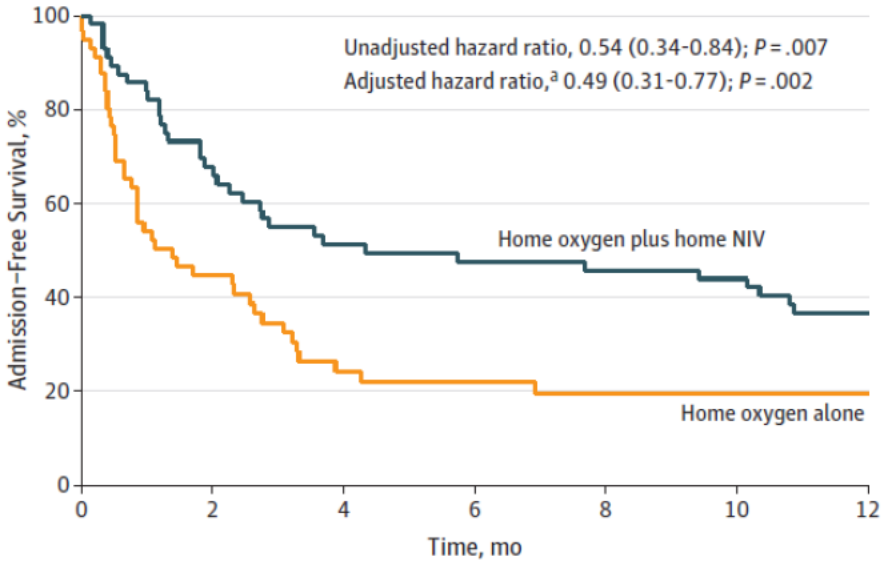
CONCLUSIONS AND RELEVANCE

Adding home noninvasive ventilation to home oxygen therapy in pts with persistent hypercapnia following acute exacerbation of COPD, prolonged time to readmission or death within 12 months.

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

Effect of Home NIV on Outcomes After Acute COPD Exacerbation

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



No. at risk							
Home oxygen plus home NIV	57	37	28	26	25	24	16
Home oxygen alone	59	23	11	10	8	8	6

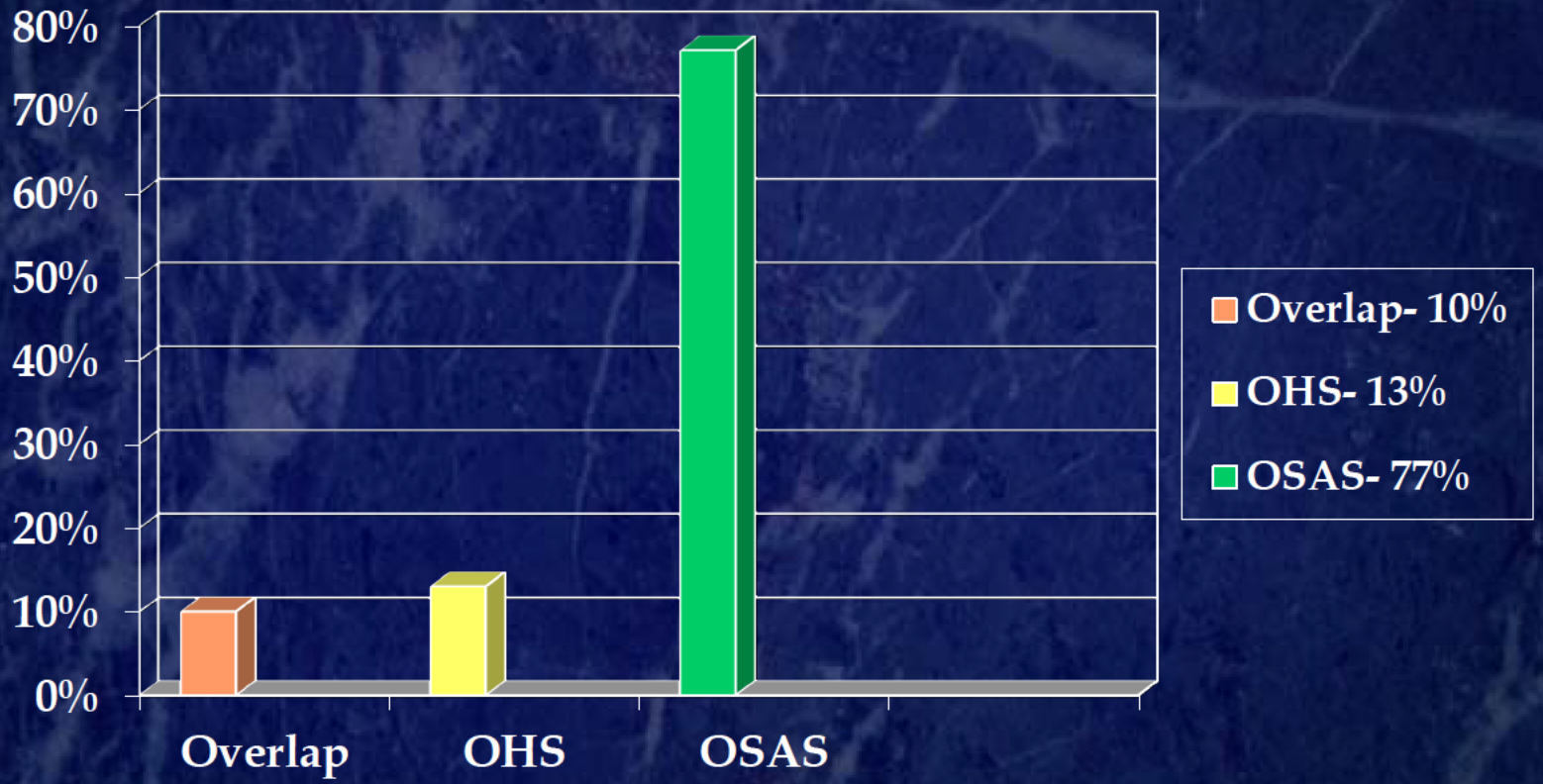
Severe COPD
Situation 1 for Backup Rate

Anytime after initial E0470 device:

- Awake $PaCO_2$, on the pt's prescribed FIO_2, shows $PaCO_2$ worsens $\geq$7 mm HG compared to ABG done to qualify for an E0470
- PSG demonstrates SpO_2 $\leq$88% for 5 total minutes of nocturnal recording time (minimum recording time of 2 hours) not caused by OSA – AHI <5 while using an E0470 device.

Hypercapnia in OSA

Diagnostic Groups of hypercapnic pts.



MAYO CLINIC

Resta O. Neth J Med; 56(6):215-22, 2000

Hypercapnia in OSA

Resta O. Neth J Med. 56(6):215-22, 2000

Distinguishing Features

OSAS

- AHI was not a distinguishing feature
- Response to CPAP alone

Overlap

- More obstruction
- Hypercapnia correlates with obstruction

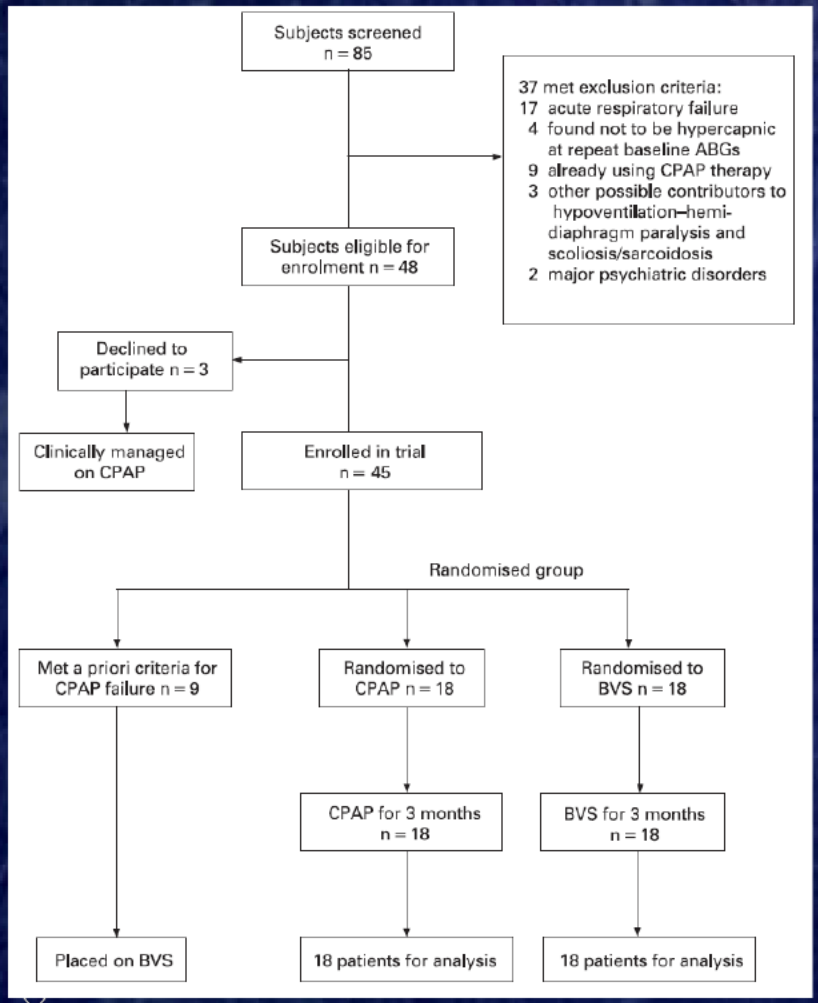
OHS

- Younger, heavier, most hypercapnic
- Hypercapnia correlates with restriction

Randomised trial of CPAP vs bilevel support in the treatment of obesity hypoventilation syndrome without severe nocturnal desaturation

A J Piper,[1,2,3] D Wang,[1,2] B J Yee,[1,2,3] D J Barnes,[1] R R Grunstein[1,2,3]

Thorax 2008;**63**:395–401.



- **Aim: Determine what type of PAP is best for OHS**
- **Inclusion:**
  - **RCT in new OHS pts on optimal CPAP**
    - **BMI >30 kg/m2; (2)**
    - **PaCO2) >45 mm Hg; pH >7.34**
    - **Absence of other respiratory disorder**
- **Primary outcome**
  - **Change in PaCO2**
  - **Compliance**

Randomised trial of CPAP vs bilevel support in the treatment of obesity hypoventilation syndrome without severe nocturnal desaturation

A J Piper,[1,2,3] D Wang,[1,2] B J Yee,[1,2,3] D J Barnes,[1] R R Grunstein[1,2,3]

Thorax 2008;**63**:395–401.

- Subjective sleep quality and psychomotor vigilance performance were better with BVS. Nothing else……

Table 3 Effect of initial CPAP therapy on overnight sleep parameters in patients allocated to longer term CPAP or BVS therapy

	CPAP group	BVS group	p Value
Effective CPAP level (cm H_2O)	14 (3)	13 (2)	0.65
Min Spo_2 (%)	70 (12)	74 (10)	0.27
%TST <90 (%)	39 (16–80)	57 (14–86)	0.66
AHI (events/h)	22 (29)	13 (12)	0.22
Sleep efficiency (%)	73 (18)	80 (12)	0.18
% REM	23 (12)	22 (12)	0.75
Change $Tcco_2$ NREM-REM (mm Hg)	5 (3)*	4 (2)†	0.25

Table 4 Change in daytime gas exchange, weight and subjective sleep quality following 3 months of positive pressure in the three treatment groups

Outcome	Change in CPAP group Mean (SD)	Change in BVS group Mean (SD)	Mean difference between treatments (95% CI)	p Value†
PSQI	−1.93 (3.5)	−5.6 (3.9)**	3.67 (0.82 to 6.5)	0.013

Average Volume Assured Pressure Support (AVAPS)

- RCT with crossover design of OHS who failed CPAP
  - CPAP failure defined as RDI>10 and $TcCO_2$ >45 mm Hg
- N=10
  - Mean age: 53.5; BMI: 41.6; $PaCO_2$ 47.4; RDI 74
- Randomized to Bilevel PAP-S/T (with a back up rate) or AVAPS and after 6 weeks patients were crossed over to the other arm

Storre JH et al. Chest 2006; 130:815

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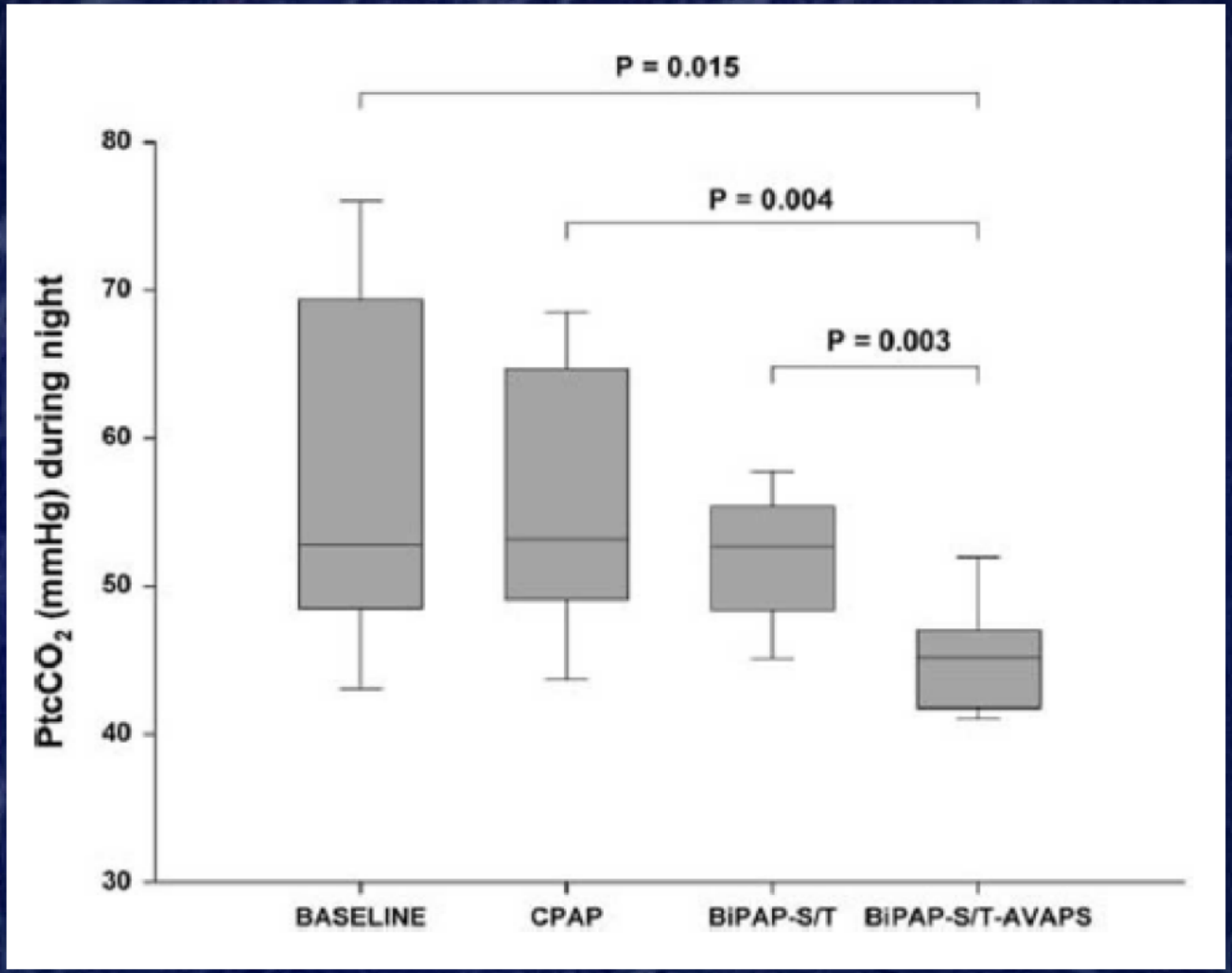
Average Volume Assured Pressure Support (AVAPS)

Variables	Baseline	CPAP	Bilevel PAP-S/T	AVAPS
RDI	74±25	25±21	21±15	31±21
Apnea index	21±17	2±3	0	0
SaO_2 nadir	88±5	92±2	92±2	92±1
Desat index	78±26	29±18	27±15	33±17
$PtCO_2$	58±12	56±9	52±4	45±3
$PaCO_2$	47.4±2	48±5	45.9±3.7	42±5.2
PaO_2	73±6	70±7	76±12	73±9
CPAP/PEEP		8.9±1	6.1±1.1	5.4±1.2
PIP			14.7±2.4	16.4±3.9

Storre JH et al. Chest 2006; 130:815

AVAPS


P = 0.015
P = 0.004
P = 0.003
80
70
60
50
40
30
PtcCO2 (mmHg) during night
BASELINE
CPAP
BiPAP-S/T
BiPAP-S/T-AVAPS

Impact of Different Backup Respiratory Rates on the Efficacy of Noninvasive Positive Pressure Ventilation in Obesity Hypoventilation Syndrome. Optimization of Noninvasive Ventilation Setting: A Randomized Trial. Contal et al. C*HEST*.2013;143(1):37-46.

Objective:

- Investigate BackUp Respiratory Rate (BURR) settings effect on ventilation, sleep, and respiratory events in OHS pts

Methods:

- 10 stable pts with OHS established with long-term NPPV underwent 3 consecutive random PSG recordings with tcPCO2 with 3 settings for BURR: spontaneous (S) mode, low BURR, and high BURR. No other ventilator parameter was modified

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RCT of Different Backup Respiratory Rates for NPPV in Obesity Hypoventilation

Results:

- The S mode was associated with highly significant increase in respiratory events, mainly of central and mixed origin, when compared with BURR modes.
- The SpO2 was higher in S mode than the S/T modes
- The TcPCO2 (mean value and time spent with $TcCO_2$ > 50 mm Hg) were similar over the three consecutive nocturnal recordings
- Quality of sleep was perceived as slightly better, and the number of perceived arousals as lower with the low- vs high-BURR (S/T) mode.

Backup Rate for OHS

Sleep Parameters	S Mode	Low BURR	High BURR	*P* Value
Sleep data				
TST, min	413 (345, 478)	445 (420, 511)	425 (284, 464)	.273
Sleep eff %	73 (60, 82)	83 (73, 87)	71 (67, 142)	.273
Event data				
AHI, /h	60 (44, 77)	19 (9, 40)	12 (3, 26)	.006
Central AHI, /h	17.7 (13.7, 37.6)	0.8 (0.1, 4.1)	0.2 (0, 4.4)	< .001
Mixed AHI, /h	9.5 (4.7, 13.2)	0.1 (0, 1.7)	0 (0, 0.6)[d]	< .001
Obstr AHI, /h	22 (15.3, 37.3)	17.2 (4.1, 36.5)	8.6 (1.8, 21.6)	.067
$Ptcco_2$, mm Hg	44 (40, 47)	44 (41, 50)	47 (38, 52)	.117
Average Spo_2	92 (91, 94)	92 (91, 93)	92 (91, 94)	.575
Minimal Spo_2	79 (73, 85)	82 (79, 86)	83 (77, 86)	.590
ODI ≥ 4%, /h	59 (52, 71)[a]	26 (15, 39)	19 (7, 36)[c]	.002

Backup Rate for OHS

Conclusions:

In established OHS Pts treated with long-term NPPV:

- Changing BURR from an S/T mode with a high or low BURR to an S mode was associated with the occurrence of a highly significant increase in respiratory events, of mainly central and mixed origin.

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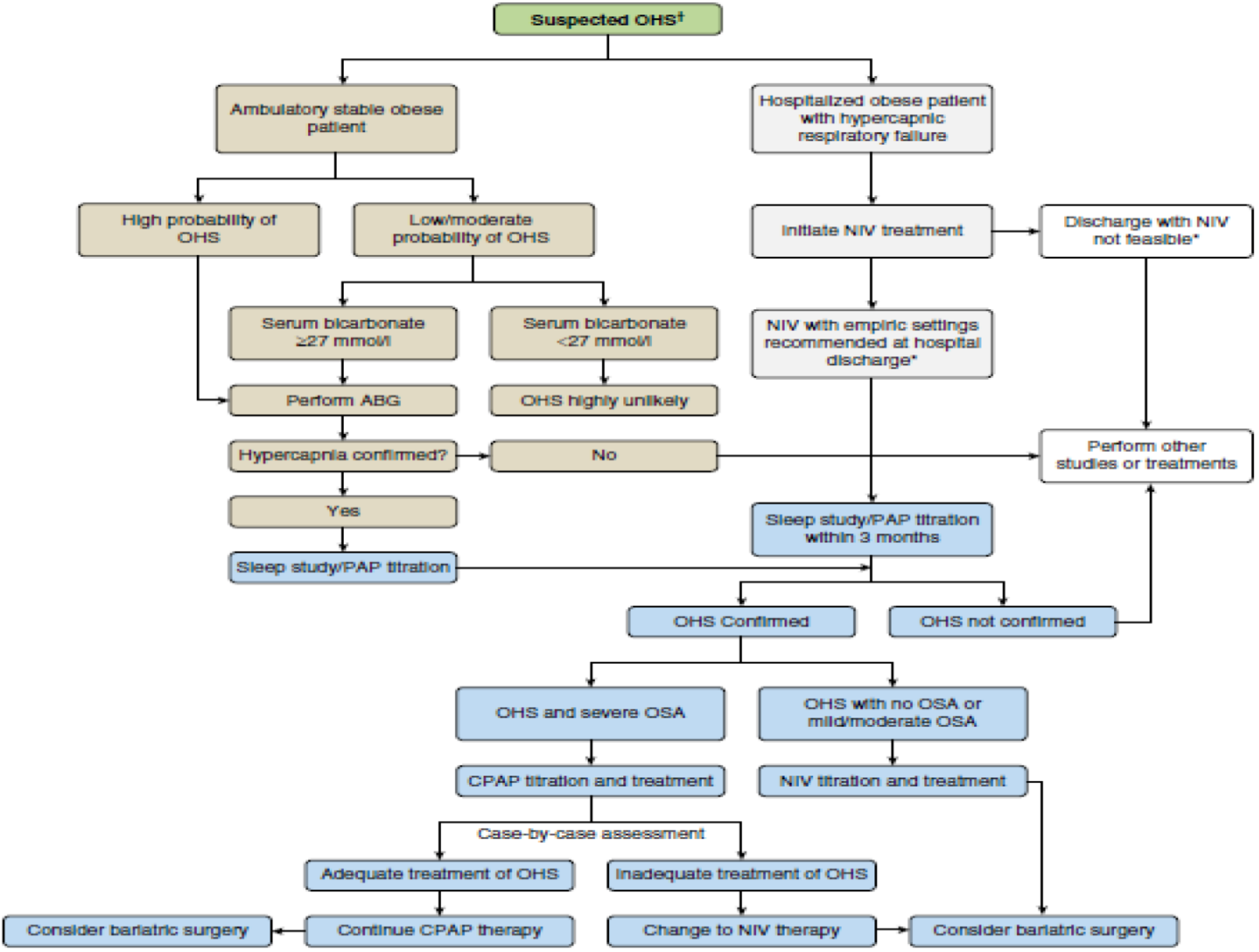
Evaluation and Management of Obesity Hypoventilation Syndrome

An Official American Thoracic Society Clinical Practice Guideline

AJRCCM 200(3): August 1 2019

http://www.atsjournals.org/doi/suppl/10.1164/rccm.201905-1071ST

- To exclude the diagnosis of OHS in patients with obesity and sleep-disordered breathing, clinicians should use a serum bicarbonate level of less than 27 mmol/L when suspicion for OHS is less than 20% but to measure arterial blood gases in patients strongly suspected of having OHS,
- Clinicians should administer positive airway pressure to stable ambulatory patients with OHS,
- Clinicians should administer continuous positive airway pressure, rather than noninvasive ventilation, as the first-line treatment to stable ambulatory patients with OHS and coexistent severe obstructive sleep apnea,
- Clinicians should prescribe noninvasive ventilation to patients hospitalized with respiratory failure and suspected of having OHS until they undergo outpatient diagnostic procedures and positive airway pressure titration in the sleep laboratory within 2 to 3 months, and
- Clinicians should prescribe weight-loss interventions that result in sustained weight loss of 25% to 30% of body weight to achieve resolution of OHS (which is more likely to be obtained with bariatric surgery).


Suspected OHS†
Ambulatory stable obese patient
Hospitalized obese patient with hypercapnic respiratory failure
High probability of OHS
Low/moderate probability of OHS
Initiate NIV treatment
Discharge with NIV not feasible*
Serum bicarbonate ≥27 mmol/l
Serum bicarbonate <27 mmol/l
NIV with empiric settings recommended at hospital discharge*
Perform ABG
OHS highly unlikely
Hypercapnia confirmed?
No
Perform other studies or treatments
Yes
Sleep study/PAP titration within 3 months
Sleep study/PAP titration
OHS Confirmed
OHS not confirmed
OHS and severe OSA
OHS with no OSA or mild/moderate OSA
CPAP titration and treatment
NIV titration and treatment
Case-by-case assessment
Adequate treatment of OHS
Inadequate treatment of OHS
Consider bariatric surgery
Continue CPAP therapy
Change to NIV therapy
Consider bariatric surgery

WHEN ALL ELSE FAILS
Use of a Portable Home Vent

VENTILATOR WITH NOINVASIVE INTERFACES covered for following:

"Neuromuscular diseases, thoracic restrictive diseases, and chronic respiratory failure consequent to chronic obstructive pulmonary disease" are comprised of conditions vary from severe and life-threatening to less serious forms

Choice of an appropriate device i.e., a ventilator versus a bi-level PAP device is made based upon the severity of the condition.

- National Coverage Analysis Decision Memo (CAG-00052N) in June 2001 stated that a RAD is "distinguished from ventilation in a patient for whom interruption or failure of respiratory support leads to death."
- Claims for ventilators used for the treatment of conditions described in the RAD LCD will be denied as not reasonable and necessary.

The Real Problem

Region	HCPCS	2010		2011		2012	
		Allowed Units	Allowed Charges	Allowed Units	Allowed Charges	Allowed Units	Allowed Charges
[E0461] Volume control ventilator		***3,090***	***$ 3,021,166.12***	***3,106***	***$ 3,043,945.66***	***3,008***	***$ 3,021,605.49***
DME MAC A	E0461	1,795	$ 1,797,828.07	1,820	$ 1,815,000.21	1,720	$ 1,753,038.98
DME MAC B	E0461	228	$ 212,698.92	225	$ 212,946.57	256	$ 251,171.43
DME MAC C	E0461	744	$ 720,740.23	739	$ 724,687.97	737	$ 745,600.72
DME MAC D	E0461	323	$ 289,898.90	322	$ 291,310.91	295	$ 271,794.36
[E0464] Pressure support ventilator		***6,203***	***$ 9,122,706.73***	***11,500***	***$ 16,916,853.89***	***23,264***	***$ 35,090,247.22***
DME MAC A	E0464	327	$ 477,660.55	667	$ 971,114.54	952	$ 1,427,543.67
DME MAC B	E0464	243	$ 358,205.23	682	$ 996,732.75	1,086	$ 1,631,834.43
DME MAC C	E0464	3,692	$ 5,441,412.20	6,280	$ 9,253,329.74	13,104	$ 19,784,499.87
DME MAC D	E0464	1,941	$ 2,845,428.75	3,871	$ 5,695,676.86	8,122	$ 12,246,369.25
[E0470] RAD without back up rate		***539,155***	***$ 100,357,300.84***	***518,608***	***$ 94,485,109.76***	***542,138***	***$ 99,667,127.12***
DME MAC A	E0470	88,516	$ 15,629,360.70	85,307	$ 14,878,592.21	91,210	$ 16,110,898.42
DME MAC B	E0470	120,932	$ 22,557,937.74	116,154	$ 21,132,450.53	123,838	$ 22,675,413.33
DME MAC C	E0470	213,501	$ 40,363,395.11	205,342	$ 37,894,047.74	212,261	$ 39,472,062.78
DME MAC D	E0470	116,206	$ 21,806,607.29	111,805	$ 20,580,019.28	114,829	$ 21,408,752.59
[E0471] RAD, with back up rate		***107,317***	***$ 48,199,294.46***	***115,182***	***$ 51,220,534.12***	***137,272***	***$ 61,696,853.97***
DME MAC A	E0471	10,325	$ 4,676,811.02	12,358	$ 5,660,222.07	18,628	$ 8,644,127.81
DME MAC B	E0471	26,825	$ 12,060,114.76	28,022	$ 12,517,384.43	33,041	$ 15,000,813.03
DME MAC C	E0471	40,251	$ 17,550,658.54	43,073	$ 18,424,856.73	46,166	$ 19,514,239.91
DME MAC D	E0471	29,916	$ 13,911,710.14	31,729	$ 14,618,070.89	39,437	$ 18,537,673.22

E0464 Pressure Support Ventilators (non-invasive) **Charges 2014 $181,181,791** **Charges 2013 $34,933,471**

LCD ID- L33800 in 2015
Original ICD-9 LCD ID- L11504
LCD Title= Respiratory Assist Devices

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
10/01/2015	R1	**Revision Effective Date: 10/01/2015** COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Revised: Definitions of Central Sleep Apnea and Complex Sleep Apnea to include a CAHI index and expands signs and symptoms that describe the conditions Revised: Severe COPD to clarify that definitive testing is not necessary to exclude OSA when the clinical picture is sufficient Revised: Severe COPD to clarify that nocturnal oximetry is a cumulative 5 minutes of testing Revised: Hypoventilation Syndromes to remove FEV1 Revised: PSG testing to also include HST testing when used in the in-patient hospital setting to establish or rule out the diagnosis of OSA Added: Ventilator section based upon NCD and April 2014 coding and coverage article Added: Sleep Test coverage and payment rules	• Provider Education/Guidance • Reconsideration Request

Conclusions

- Evidence based data supports the use of newer modes of outpatient NPPV in selected patient populations
- Clinicians must understand the specific design and practical application of PAP devices for effective and successful use
- Treating physicians must also have a strong working knowledge of coverage criteria to successfully govern treatment