CALIFORNIA THORACIC SOCIETY
ANNUAL EDUCATIONAL CONFERENCE

SATURDAY, JANUARY 19, 2019

ADVANCES IN SLEEP DISORDERED BREATHING AND NONINVASIVE VENTILATION

REGISTRATION/EXHIBITS

Saturday, January 19, 2019 – 7:00 a.m. – 8:00 a.m.

PROGRAM SCHEDULE

SATURDAY, JANUARY 19, 2019

ADVANCES IN SLEEP DISORDERED BREATHING AND NONINVASIVE VENTILATION

7:00 am – 8:00 am
Registration / Exhibits

8:00 am – 8:10 am
Welcome and Introductions; Pre-Test
Michelle Cao, DO

Advances in Sleep Apnea Evaluation and Management

8:10 am – 8:50 am
KEY NOTE SPEAKER: Evidence Based OSA Management and Non-PAP Therapies
Atul Malhotra, MD

8:50 am – 9:20 am
Cardiovascular Disease and Sleep Apnea: What is the Current Evidence?
Kathleen Sarmiento, MD

9:20 am – 9:50 am
Central Sleep Apnea and Heart Failure: PAP versus Oxygen versus Phrenic Nerve Stimulation
Lisa Wolfe, MD

9:50 am – 10:10 am
BREAK / EXHIBIT HALL OPEN

10:10 am – 10:40 am
The Perioperative Management of Sleep Disordered Breathing
Janine Vintch, MD

10:40 am – 11:10 am
Using Technology to Improve Outcomes in Sleep Disordered Breathing
Shannon Sullivan, MD

11:10 am – 11:40 am
Utility of the In Lab Polysomnogram in a New Era of Home Sleep Testing
Won Lee, MD

11:40 am – 12:10 pm
Central Sleep Apnea and Chronic Opioid Use
Kathleen Sarmiento, MD

12:10 pm – 1:10 pm
LUNCH / EXHIBIT HALL OPEN

Advances in Complex Sleep Related Respiratory Disorders and Noninvasive Ventilation

1:10 pm – 1:40 pm
Sleep Disordered Breathing in Neuromuscular Disease
Won Lee, MD

1:40 pm – 2:20 pm
Respiratory Assist Devices (ST, VAPS Technology), Interpreting NIV Downloads /Mask Interface Options
Faculty: Won Lee, MD; Lisa Wolfe, MD; Shannon Sullivan, MD; Gaurav Singh, MD; Michelle Cao, DO; Kathleen Sarmiento, MD

2:20 pm – 3:00 pm
Home Ventilators, Interpreting Ventilator Downloads and Daytime use of Noninvasive Ventilation
Faculty: Won Lee, MD; Lisa Wolfe, MD; Shannon Sullivan, MD; Gaurav Singh, MD; Michelle Cao, DO; Kathleen Sarmiento, MD

3:00 pm – 3:20 pm
BREAK / EXHIBIT HALL OPEN

3:20 pm – 4:00 pm
NIPPV for the Hypercapnic COPD and Obsesity Hypoventilation Patient
Gaurav Singh, MD

4:00 pm – 4:40 pm
Daytime Use of NIPPV
Lisa Wolfe, MD

4:40 pm - 5:00 pm
Closing Remarks and Post Test
Michelle Cao, DO

WELCOME AND INTRODUCTIONS
PRE-TEST

Michelle Cao, DO
Stanford University School of Medicine
Clinical Associate Professor

Michelle Cao, DO, is a Clinical Associate Professor in the Division of Sleep Medicine and Division of Neuromuscular Medicine, at the Stanford University School of Medicine. Dr. Cao is board certified in Pulmonary, Critical Care, and Sleep Medicine. Her clinical expertise is in complex sleep related breathing disorders including central sleep apnea secondary to opioids, neuromuscular disease, and chronic respiratory failure. She manages the noninvasive ventilation program for Stanford Neuromuscular Disease Multidisciplinary Clinic.

Saturday, January 19, 2019 – 8:00 a.m. – 8:10 a.m.

EVIDENCE BASED OSA MANAGEMENT AND NON-PAP THERAPIES

Atul Malhotra, MD
UC San Diego
Professor of Medicine and Sleep Specialist

Saturday, January 19, 2019 – 8:10 a.m. – 8:50 a.m.

Atul Malhotra, MD, is a board-certified pulmonologist, intensivist and chief of Pulmonary, Critical Care and Sleep Medicine. He is active clinically in pulmonary, critical care and sleep medicine. In the sleep clinic, he provides a full spectrum of diagnostic and therapeutic services to patients with sleep-related disorders, including sleep apnea, insomnia, restless leg syndrome, narcolepsy and sleep disorders associated with medical or psychiatric conditions. He has a special interest in the treatment of sleep apnea.

Dr. Malhotra is the president of the American Thoracic Society. He has taught and presented his research on sleep-related disorders locally, regionally, nationally and internationally. He has published more than 200 original manuscripts in leading journals. He is a principal- and co-investigator on numerous projects relating to sleep apnea and serves as an ad hoc reviewer for many leading journals including the New England Journal of Medicine, Mayo Clinic Proceedings, Sleep and the Journal of American Medical Association. To view a full list of his publications, visit PubMed.

As a professor in the Department of Medicine, Dr. Malhotra is involved in training medical students, residents and fellows at UC San Diego School of Medicine.

Before joining UC San Diego Health, Dr. Malhotra practiced pulmonary, critical care and sleep medicine at Massachusetts General Hospital, Beth Israel Deaconess Medical Center and Brigham and Women's Hospital. He also served as attending physician in intensive care at King Faisal Hospital in Rwanda. He was associate professor at Harvard Medical School and medical director of the Brigham and Women's Hospital Sleep Disorders Research Program.

Dr. Malhotra completed his fellowship training in pulmonary and critical care medicine at Harvard Medical School and a residency in internal medicine at the Mayo Clinic. He completed an internship at St. Thomas Medical Center in Akron, OH and received his medical degree from the University of Alberta in Canada. Dr. Malhotra is triple board-certified in pulmonary disease, sleep medicine and critical care medicine.

Obstructive Sleep Apnea

Evidence Based Treatment

Atul Malhotra, MD

UC San Diego

Previous President ATS

Disclosures: none since 2012; Resmed provided a philanthropic gift to UCSD

Take Home Points

1. CPAP is treatment of choice for OSA and a defeatist attitude about CPAP is not justifiable
2. Alternative therapies are available which provide acceptable results for select patients
3. Individualized therapy may be viable in the future based on mechanism underlying OSA
4. Exciting time for sleep field

ORIGINAL ARTICLE

CPAP for Prevention of Cardiovascular Events in Obstructive Sleep Apnea

R. Doug McEvoy, M.D., Nick A. Antic, M.D., Ph.D., Emma Heeley, Ph.D., Yuanming Luo, M.D., Qiong Ou, M.D., Xilong Zhang, M.D., Olga Mediano, M.D., Rui Chen, M.D., Luciano F. Drager, M.D., Ph.D., Zhihong Liu, M.D., Ph.D., Guofang Chen, M.D., Baoliang Du, M.D., Nigel McArdle, M.D., Sutapa Mukherjee, M.D., Ph.D., Manjari Tripathi, M.D., Laurent Billot, M.Sc., Qiang Li, M.Biostat., Geraldo Lorenzi-Filho, M.D., Ferran Barbe, M.D., Susan Redline, M.D., M.P.H., Jiguang Wang, M.D., Ph.D., Hisatomi Arima, M.D., Ph.D., Bruce Neal, M.D., Ph.D., David P. White, M.D., Ron R. Grunstein, M.D., Ph.D., Nanshan Zhong, M.D., and Craig S. Anderson, M.D., Ph.D., for the SAVE Investigators and Coordinators*

Therapy with CPAP plus usual care, as compared with usual care alone, did not prevent cardiovascular events in patients with moderate-to-severe obstructive sleep apnea and established cardiovascular disease. (Funded by the National Health and Medical Re-

NEJM 2016

ORIGINAL ARTICLE

CPAP for Prevention of Cardiovascular Events in Obstructive Sleep Apnea

R. Doug McEvoy, M.D., Nick A. Antic, M.D., Ph.D., Emma Heeley, Ph.D., Yuanming Luo, M.D., Qiong Ou, M.D., Xilong Zhang, M.D., Olga Mediano, M.D., Rui Chen, M.D., Luciano F. Drager, M.D., Ph.D., Zhihong Liu, M.D., Ph.D., Guofang Chen, M.D., Baoliang Du, M.D., Nigel McArdle, M.D.,
Sutapa Mukherjee, M.D.,
Qiang Li, M.Biostat.,
Susan Redline,
Hisatomi Arima, M.D., P
Ron R. Grunstein, M.D., Ph.D., Nanshan Zhong, M.D.,
and Craig S. Anderson, M.D., Ph.D., for the SAVE Investigators and Coordinators*

Therapy with CPAP plus usual care, as compared with usual care alone, did not prevent cardiovascular events in patients with moderate-to-severe obstructive sleep apnea and established cardiovascular disease. (Funded by the National Health and Medical Re-

NEJM 2016

Need better therapies/adherence
Need to identify high risk patients better
Need more basic research re: mechanisms

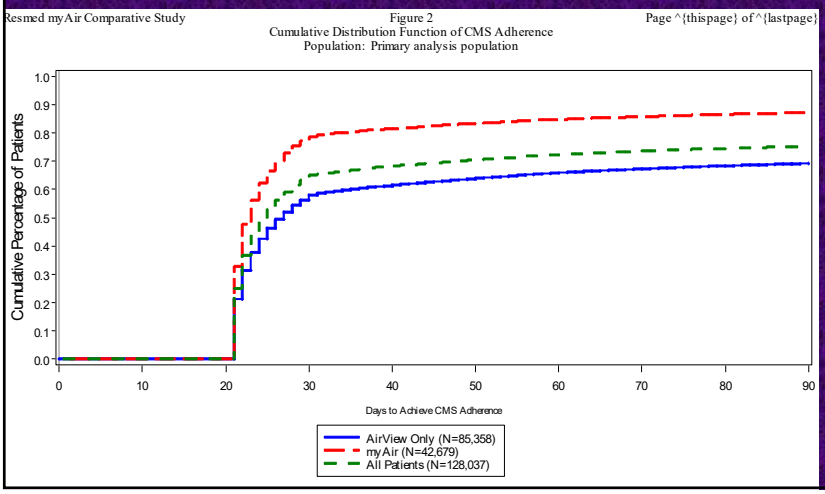
Patient Engagement Using New Technology to Improve Adherence to Positive Airway Pressure Therapy

A Retrospective Analysis

Atul Malhotra, MD; Maureen E. Crocker, BS; Leslee Willes, MS; Colleen Kelly, PhD; Sue Lynch, RN; and Adam V. Benjafield, PhD

Chest 2018

N=952,819 patients with 137,089,667 nights of recording.

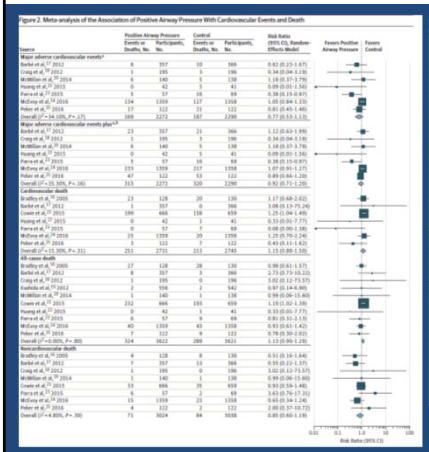


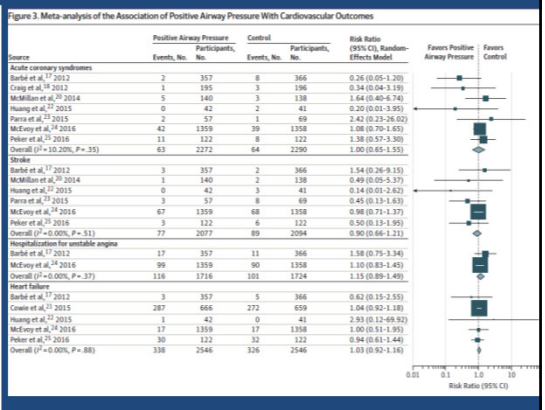
JAMA | Original Investigation

Association of Positive Airway Pressure With Cardiovascular Events and Death in Adults With Sleep Apnea

A Systematic Review and Meta-analysis

Jie Yu, MD; Zien Zhou, MD; R. Doug McEvoy, MD; Craig S. Anderson, PhD; Anthony Rodgers, PhD; Vlado Perkovic, PhD; Bruce Neal, PhD





JAMA 2017

Nasal CPAP is the Treatment of Choice

- Improves symptoms
- Improves blood pressure
- Transformative for some patients

- Need new therapies based on ongoing research

REVIEW ARTICLES

JCSM
Journal of Clinical Sleep Medicine

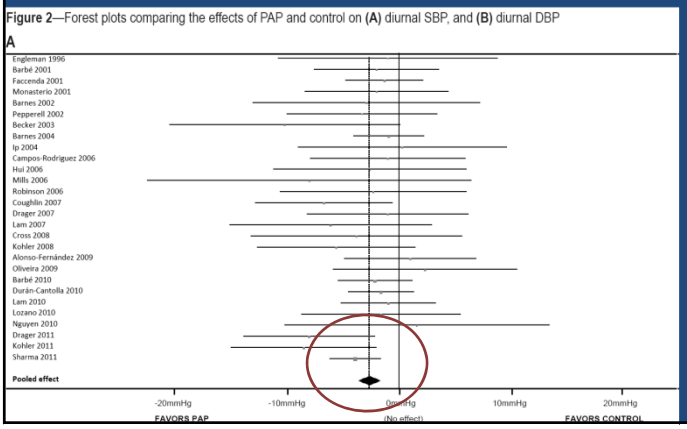
http://dx.doi.org/10.5664/xxxxxxxxxxxxxx

The Effect of Continuous Positive Airway Pressure Treatment on Blood Pressure: A Systematic Review and Meta-Analysis of Randomized Controlled Trials

Sydney B. Montesi, M.D.[1,2]; Bradley A. Edwards, Ph.D.[1]; Atul Malhotra, M.D.[1]; Jessie P. Bakker, Ph.D.[1]

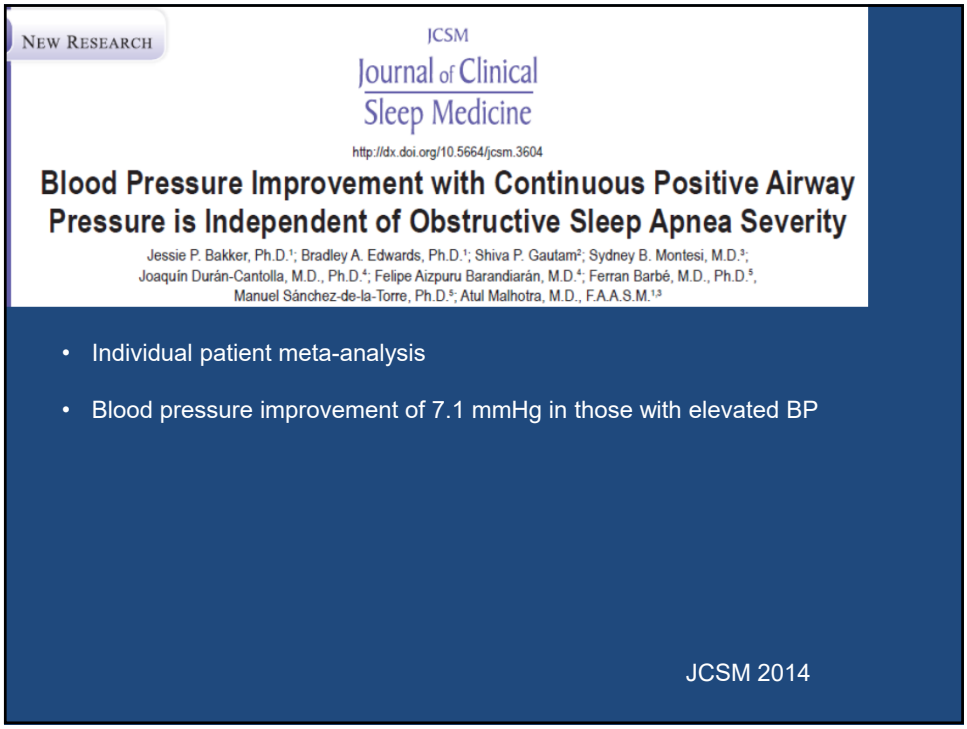
[1]*Sleep Disorders Research Program, Brigham & Women's Hospital & Harvard Medical School, Boston MA;*
[2]*Pulmonary and Critical Care Unit, Massachusetts General Hospital, Boston, MA*

Figure 2—Forest plots comparing the effects of PAP and control on **(A)** diurnal SBP, and **(B)** diurnal DBP



JCSM 2012

Maximum effect in
1. Younger
2. Higher ESS
3. More severe OSA
4. CPAP adherence



Modest Blood Pressure Improvement with OSA?

- 1. If your only reason to treat OSA is BP then there is better improvement with valsartan (AJRCCM 2010)
- 2. Some patients get marked improvements in BP
- 3. BP surges are not captured with non-invasive technology and maybe substrate for plaque rupture
- 4. Treatment of OSA helps oxidative stress and other potential causal pathways.
- 5. Adherence is critical for CPAP > other therapies

Jordan et al. Lancet 2014; Bhattacharjee et al. in press; Xue et al. AJRCMB 2017

Original Investigation

CPAP vs Mandibular Advancement Devices and Blood Pressure in Patients With Obstructive Sleep Apnea
A Systematic Review and Meta-analysis

Daniel J. Bratton, PhD; Thomas Gaisl, MD; Annette M. Wons, MD; Malcolm Kohler, MD

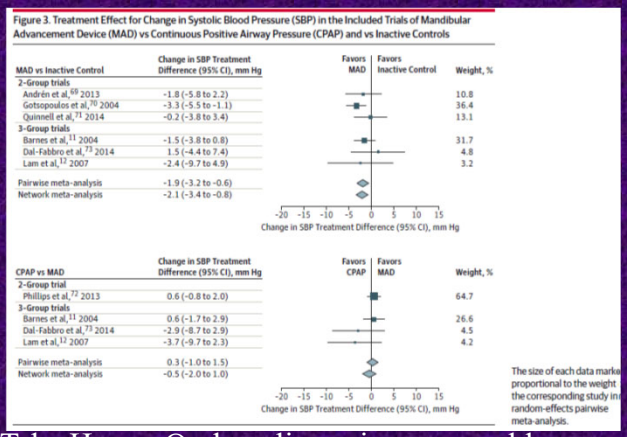


Figure 3. Treatment Effect for Change in Systolic Blood Pressure (SBP) in the Included Trials of Mandibular Advancement Device (MAD) vs Continuous Positive Airway Pressure (CPAP) and vs Inactive Controls

MAD vs Inactive Control	Change in SBP Treatment Difference (95% CI), mm Hg	Weight, %
2-Group trials		
Andrén et al,[69] 2013	-1.8 (-5.8 to 2.2)	10.8
Gotsopoulos et al,[70] 2004	-3.3 (-5.5 to -1.1)	36.4
Quinnell et al,[71] 2014	-0.2 (-3.8 to 3.4)	13.1
3-Group trials		
Barnes et al,[11] 2004	-1.5 (-3.8 to 0.8)	31.7
Dal-Fabbro et al,[72] 2014	1.5 (-4.4 to 7.4)	4.8
Lam et al,[12] 2007	-2.4 (-9.7 to 4.9)	3.2
Pairwise meta-analysis	-1.9 (-3.2 to -0.6)	
Network meta-analysis	-2.1 (-3.4 to -0.8)	

Favors MAD | Favors Inactive Control

-20 -15 -10 -5 0 5 10 15
Change in SBP Treatment Difference (95% CI), mm Hg

CPAP vs MAD	Change in SBP Treatment Difference (95% CI), mm Hg	Weight, %
2-Group trial		
Phillips et al,[72] 2013	0.6 (-0.8 to 2.0)	64.7
3-Group trials		
Barnes et al,[11] 2004	0.6 (-1.7 to 2.9)	26.6
Dal-Fabbro et al,[73] 2014	-2.9 (-8.7 to 2.9)	4.5
Lam et al,[12] 2007	-3.7 (-9.7 to 2.3)	4.2
Pairwise meta-analysis	0.3 (-1.0 to 1.5)	
Network meta-analysis	-0.5 (-2.0 to 1.0)	

Favors CPAP | Favors MAD

-20 -15 -10 -5 0 5 10 15
Change in SBP Treatment Difference (95% CI), mm Hg

The size of each data marker is proportional to the weight of the corresponding study in the random-effects pairwise meta-analysis.

Take Home: Oral appliance is a reasonable second line option for OSA, particularly mild to moderate

JAMA 2015

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

CPAP versus Oxygen in Obstructive Sleep Apnea

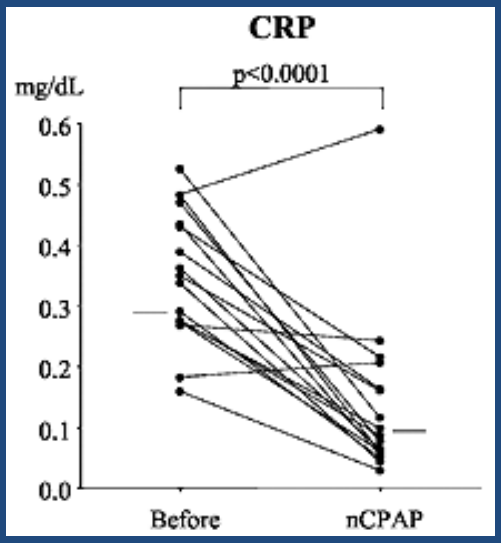
Daniel J. Gottlieb, M.D., M.P.H., Naresh M. Punjabi, M.D., Ph.D., Reena Mehra, M.D., Sanjay R. Patel, M.D., Stuart F. Quan, M.D., Denise C. Babineau, Ph.D., Russell P. Tracy, Ph.D., Michael Rueschman, M.P.H., Roger S. Blumenthal, M.D., Eldrin F. Lewis, M.D., Deepak L. Bhatt, M.D., M.P.H., and Susan Redline. M.D.. M.P.H.

Variable	CPAP (N=90)	NSO (N=94)	HLSE (N=97)	CPAP vs. HLSE	NSO vs. HLSE	CPAP vs. NSO
24-Hr mean arterial blood pressure						
Baseline	89.5±8.6	88.6±10.0	87.7±9.3			
12 Wk	87.8±8.1	90.2±11.1	89.0±11.2	−2.4 (P=0.04)	0.4 (P=0.71)	−2.8 (P=0.02)

NEJM 2014

C-Reactive Protein in Patients with OSA is Reduced by Nasal CPAP

(Yokoe et al., Circulation 107:1129, 2003)

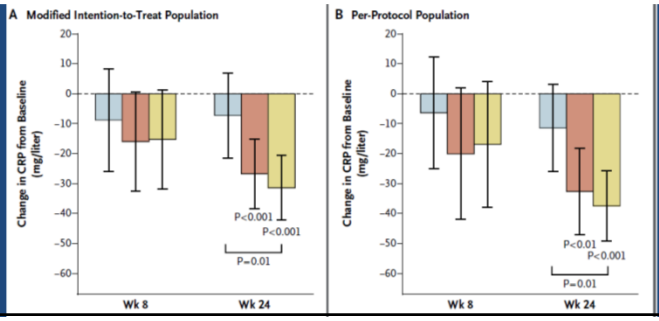


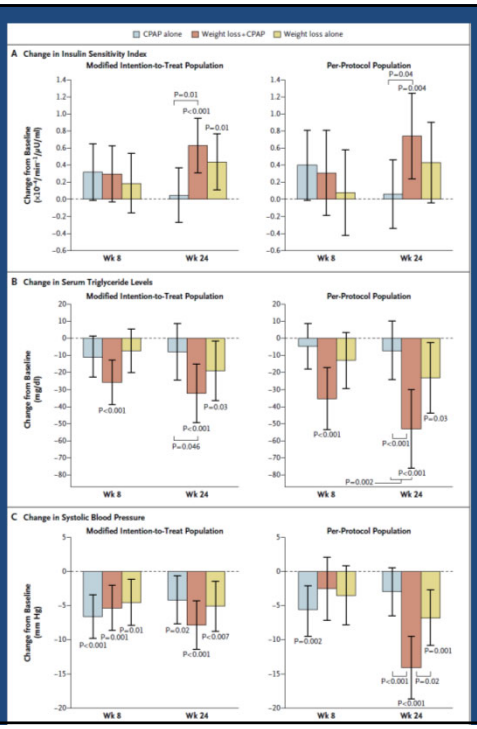
The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 JUNE 12, 2014 VOL. 370 NO. 24

CPAP, Weight Loss, or Both for Obstructive Sleep Apnea

Julio A. Chirinos, M.D., Ph.D., Indira Gurubhagavatula, M.D., Karen Teff, Ph.D., Daniel J. Rader, M.D., Thomas A. Wadden, Ph.D., Raymond Townsend, M.D., Gary D. Foster, Ph.D., Greg Maislin, M.S., M.A., Hassam Saif, M.D., Preston Broderick, M.A., Jesse Chittams, M.S., Alexandra L. Hanlon, Ph.D., and Allan I. Pack, M.B., Ch.B., Ph.D.





JAMA 2012 Sep 19;308(11):1142-9.
Surgical vs conventional therapy for weight loss treatment of obstructive sleep apnea: a randomized controlled trial.
Dixon et al.

N= 60 with BMI 35-55 kg/m2

Conventional led to 5.1 kg vs. 27.8 kg weight loss in lap band (p<0.01)

AHI decrease was 14 vs. 25.5 p=ns

CONCLUSION:
Among a group of obese patients with OSA, the use of bariatric surgery compared with conventional weight loss therapy did not result in a statistically greater reduction in AHI despite major differences in weight loss.

Interpretation: even modest weight loss works

Gastric banding surgery versus CPAP for OSA: The ABC randomized controlled trial

Bakker et al. AJRCCM in press.

N=49 randomized LGB vs. CPAP to examine impact on effective AHI

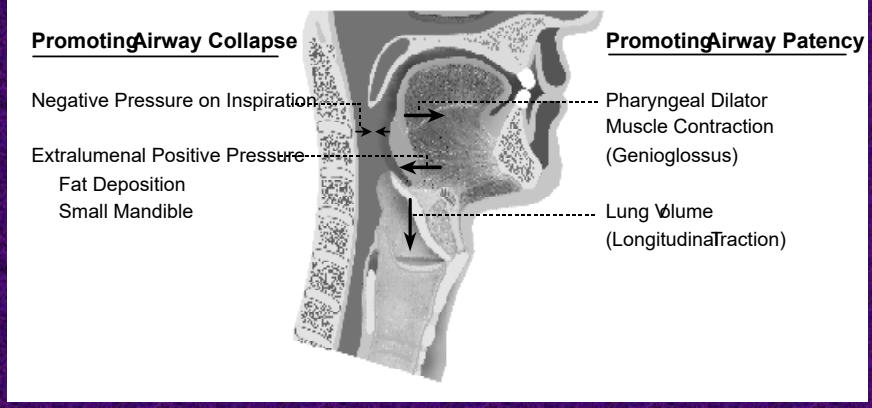
AHI=29.5 vs. 20.0 in LGB vs. CPAP at 9mos and 20.9 vs. 21.4 at 18mos.

No difference in ESS or other important symptoms

These data suggest that OSA patients should not be encouraged to pursue LGB without concurrent CPAP

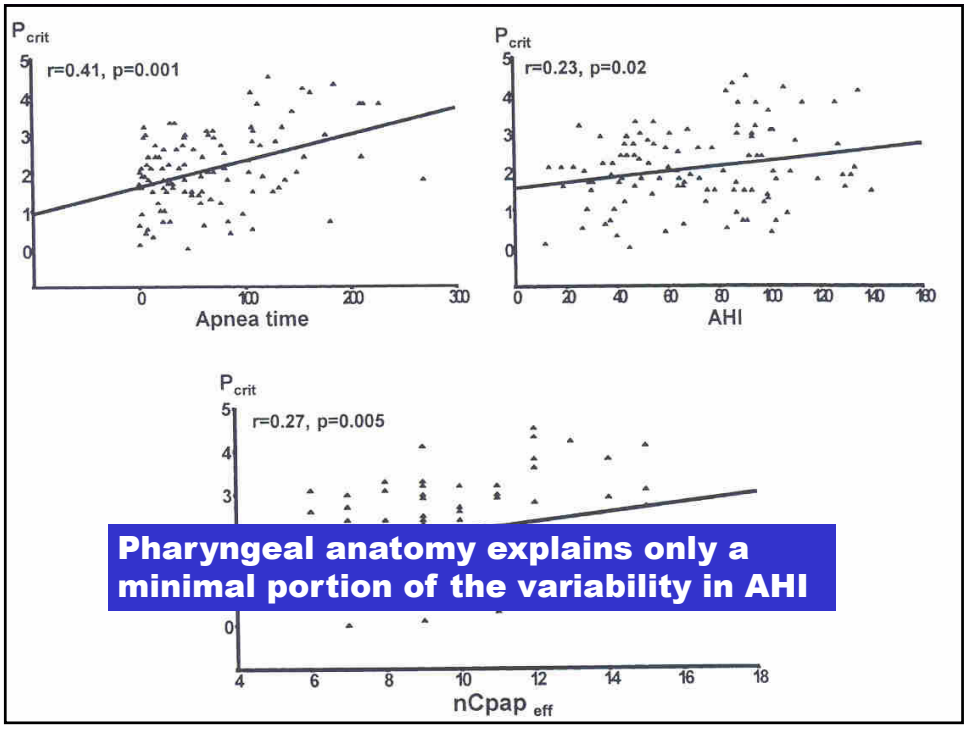
OSA Mechanisms

- **There are likely to be multiple mechanistic pathways which we need to understand and recognize**
- **Patients do not all get OSA for the same reason**



Obstructive Sleep Apnea
Underlying Mechanisms

- Anatomy
- Pharyngeal dilator muscle control asleep
- Arousal Threshold
- Loop gain
- Lung volume
- Vascular



Obstructive Sleep Apnea
Underlying Mechanisms

- Anatomy
- Pharyngeal dilator muscle control asleep
- Arousal Threshold
- Loop gain
- Lung volume
- Vascular

AIRWAY MUSCLE ACTIVITY IN OSA

Airway Dilator Muscle Activity and Lung Volume During Stable Breathing in Obstructive Sleep Apnea

Amy S. Jordan, PhD[1,2]; David P. White, MD[1,2]; Yu-Lun Lo, MD[3]; Andrew Wellman, MD[1,2]; Danny J. Eckert, PhD[1,2]; Susie Yim-Yeh, MD[1,2]; Matthias Eikermann, MD[1,2]; Scott A. Smith[1]; Karen E. Stevenson[1]; Atul Malhotra, MD[1,2]

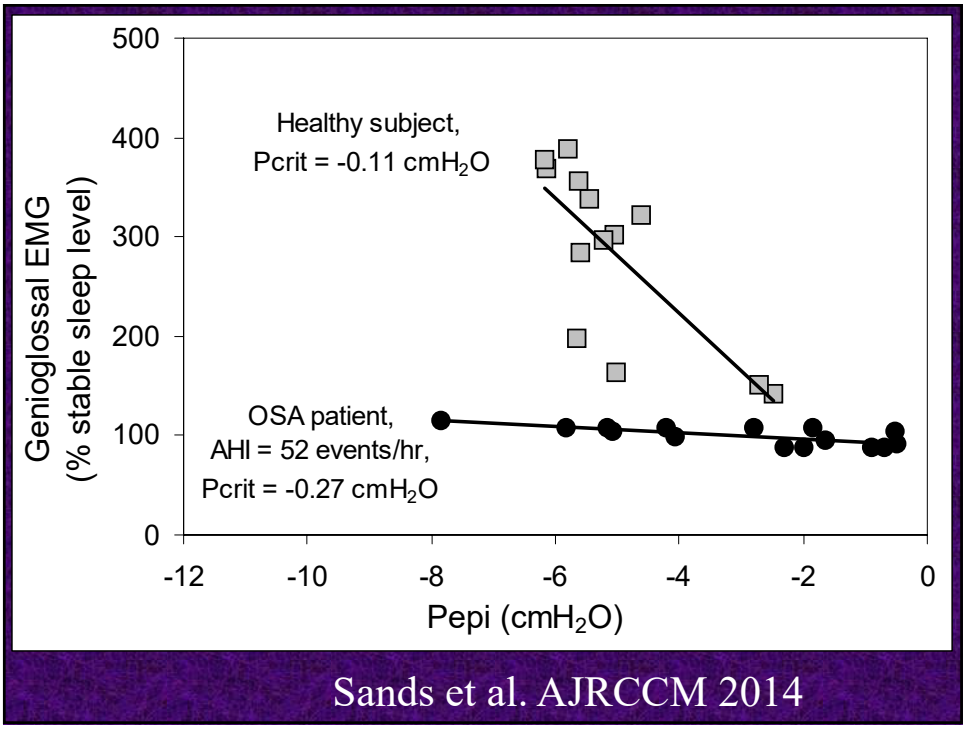
[1]Division of Sleep Medicine, Harvard Medical School, Boston, MA; [2]Sleep Disorders Research Program, Brigham and Women's Hospital, Boston, MA; [3]Department of Thoracic Medicine, Chang Gang Memorial Hospital, Taipei, Taiwan

Most OSA patients have some periods of stable breathing

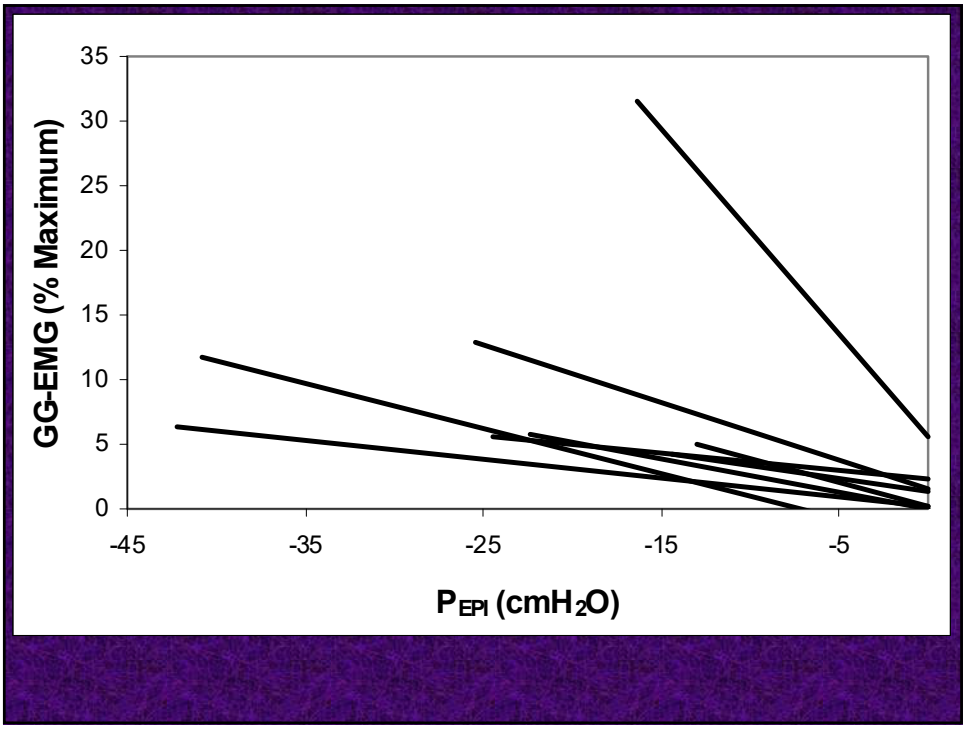
- Studied GGEMG, TPEMG, EELV etc
- Genioglossus activity was invariably high during stable breathing

- Concept: Genioglossus is necessary and sufficient to stabilize breathing spontaneously in OSA

Sleep 2009



Sands et al. AJRCCM 2014



Arousal Threshold – Double-edged Sword

- A low arousal threshold could lead to premature arousal with inadequate time to accumulate respiratory stimuli
- A high arousal threshold could lead to substantial hypoxemia and hypercapnia with end-organ impact
- Therapies to manipulate arousal threshold are likely to benefit some patients and theoretically hurt others

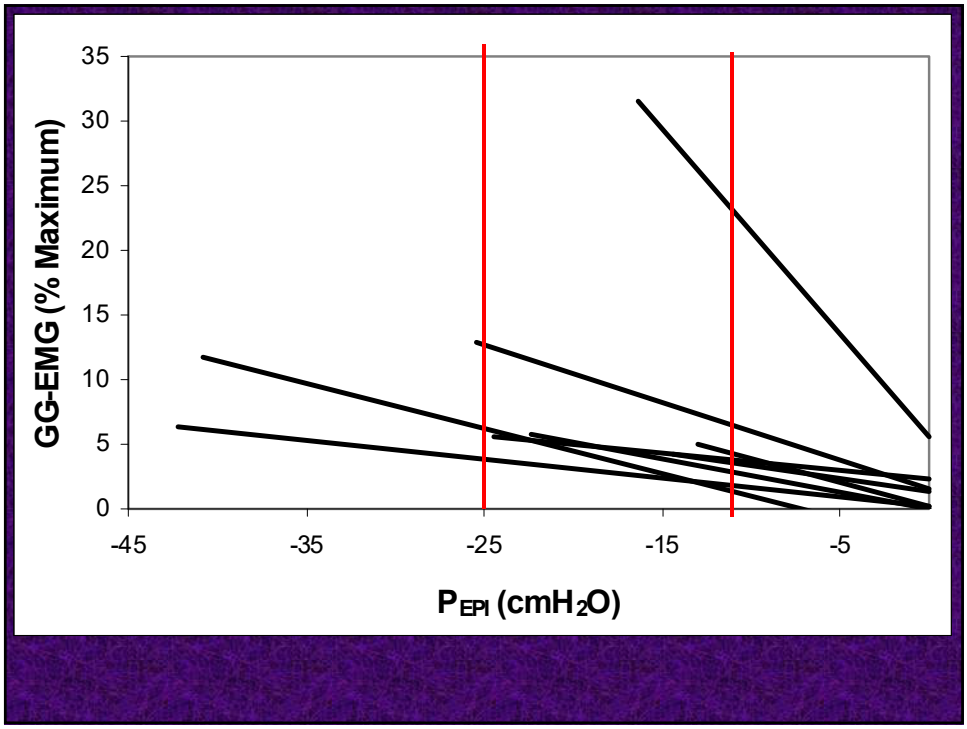
ORIGINAL RESEARCH

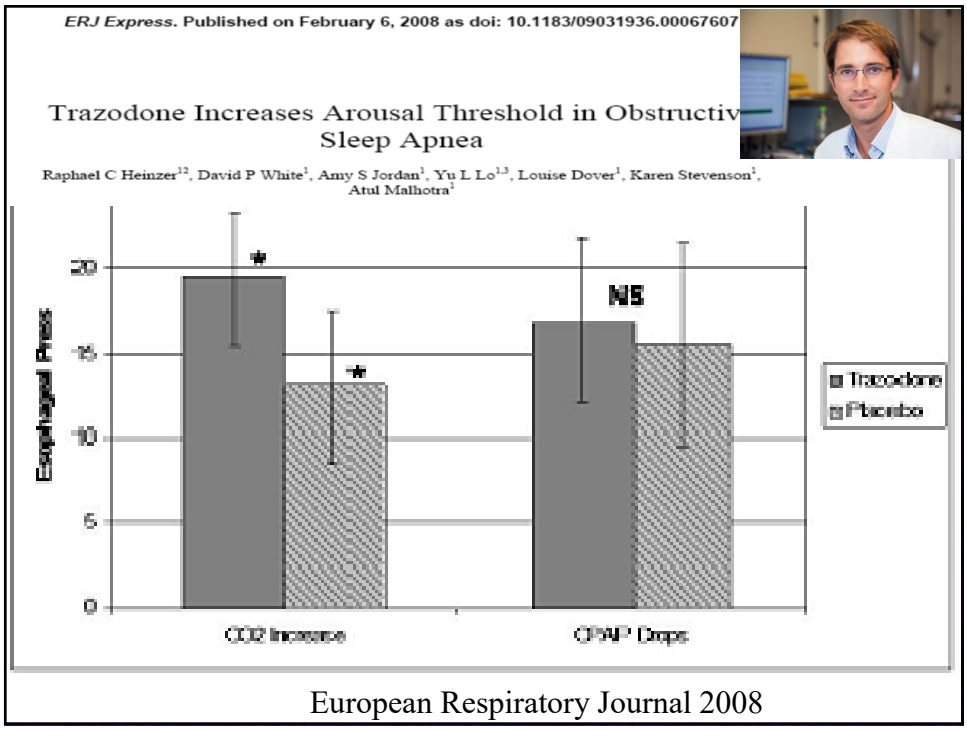
Trazodone Effects on Obstructive Sleep Apnea and Non-REM Arousal Threshold

Erik T. Smales[1,2], Bradley A. Edwards[2], Pam N. Deyoung[1,2], David G. McSharry[2], Andrew Wellman[2], Adrian Velasquez[2,3], Robert Owens[1,2], Jeremy E. Orr[1], and Atul Malhotra[1,2]

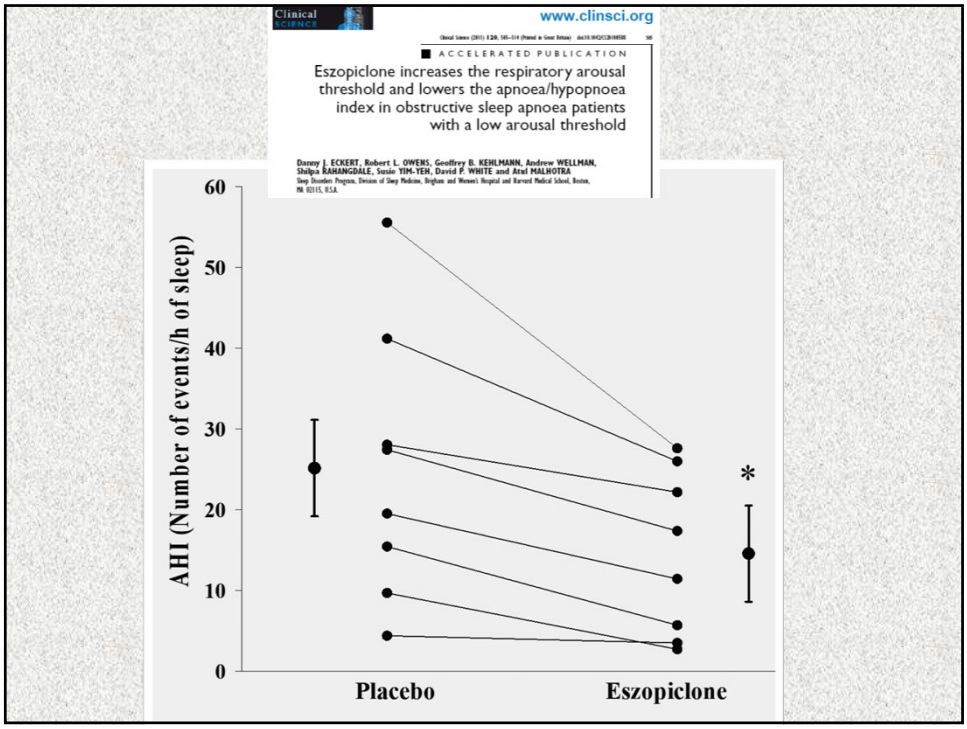
[1]Division of Pulmonary and Critical Care Medicine, University of California San Diego, La Jolla, CA; [2]Division of Sleep Medicine, Brigham and Women's Hospital and Harvard Medical School, Boston, MA; and [3]Dartmouth Hitchcock Medical Center, Lebanon, New Hampshire

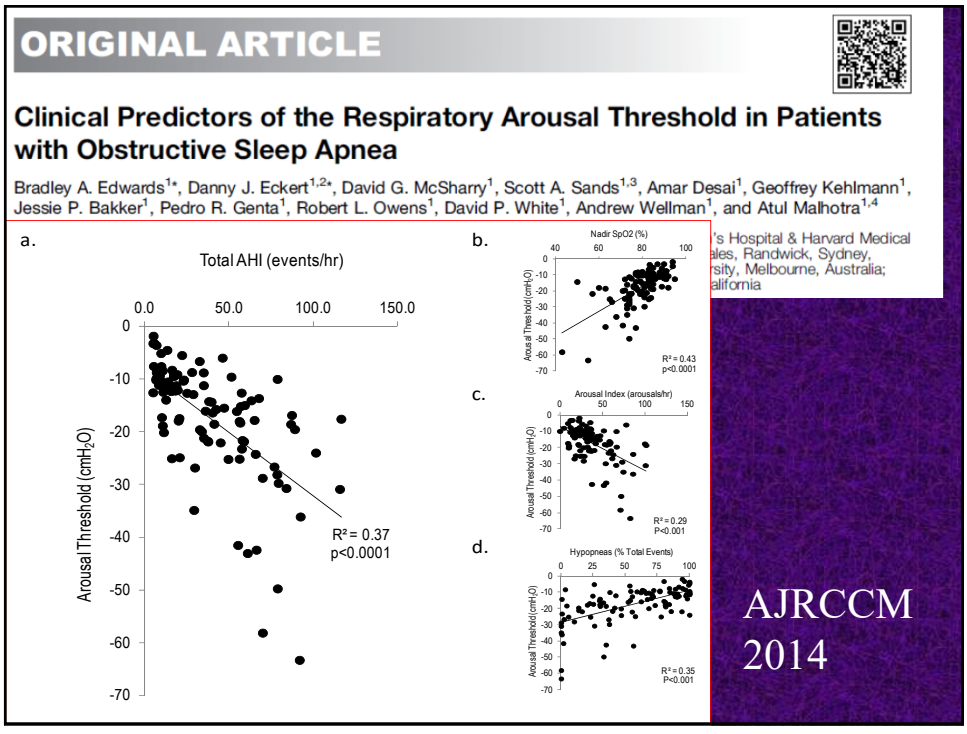
Saboisky et al. Thorax 2010; Smales et al. Annals ATS 2015





European Respiratory Journal 2008


Clinical SCIENCE
www.clinsci.org
ACCELERATED PUBLICATION
Eszopiclone increases the respiratory arousal threshold and lowers the apnoea/hypopnoea index in obstructive sleep apnoea patients with a low arousal threshold
Danny J. ECKERT, Robert L. OWENS, Geoffrey B. KEHLMANN, Andrew WELLMAN, Shilpa RAHANGDALE, Susie YIM-YEH, David P. WHITE and Atul MALHOTRA
AHI (Number of events/h of sleep)
60
50
40
30
20
10
0
*
Placebo
Eszopiclone


ORIGINAL ARTICLE
Clinical Predictors of the Respiratory Arousal Threshold in Patients with Obstructive Sleep Apnea
Bradley A. Edwards[1]*, Danny J. Eckert[1,2]*, David G. McSharry[1], Scott A. Sands[1,3], Amar Desai[1], Geoffrey Kehlmann[1], Jessie P. Bakker[1], Pedro R. Genta[1], Robert L. Owens[1], David P. White[1], Andrew Wellman[1], and Atul Malhotra[1,4]
's Hospital & Harvard Medical
ales, Randwick, Sydney,
rsity, Melbourne, Australia;
alifornia
a.
Total AHI (events/hr)
0.0
50.0
100.0
150.0
0
-10
-20
-30
-40
-50
-60
-70
Arousal Threshold (cmH2O)
R² = 0.37
p<0.0001
b.
Nadir SpO2 (%)
40
60
80
100
R² = 0.43
p<0.0001
c.
Arousal Index (arousals/hr)
0
50
100
150
R² = 0.29
P<0.001
d.
Hypopneas (% Total Events)
0
25
50
75
100
R² = 0.35
P<0.001
AJRCCM
2014

Arousal Threshold

- >60% of variance in arousal threshold is predicted with AHI, nadir saturation and % hypopneas
- Clinical prediction of arousal threshold may help to guide response to sedative/hypnotics

Editorial

Potential protective mechanism of arousal in obstructive sleep apnea

Naomi Deacon, Atul Malhotra

Editorial

The importance of arousal in obstructive sleep apnea—updates from the American Thoracic Society 2016

Atul Malhotra[1], Amy Jordan[2]

Journal Thoracic Disease 2016

Pharyngeal Muscle Control

- There are likely to be subgroups of patients who respond to efforts to augment muscle activation
- Perhaps targeting this subgroup would make sense in pharmacological studies
- Increasing upper airway muscle responsiveness may be <u>deleterious</u> in patients with unstable ventilatory control

PHYSIOLOGY IS MEDICINE

PHYSIOLOGY 29: 153–155, 2014; doi:10.1152/physiol.00013.2014

Atul Malhotra,[1] Naomi Deacon,[2] Frank Powell,[1] and Eliot S. Katz[3]
[1]University of California-San Diego, La Jolla, California; [2]University of Adelaide, Australia; and [3]Harvard Medical School, Boston, Massachussets

Adaptive Responses Using Obstructive Sleep Apnea as the Paradigm

several studies investigating pharmacological strategies, e.g., using sedative/hypnotic agents to increase arousal threshold,

Obstructive Sleep Apnea
Underlying Mechanisms

- Anatomy
- Pharyngeal dilator muscle control asleep
- Arousal Threshold
- Loop gain
- Lung volume

Loop Gain

- **measure of the stability of negative feedback control system**

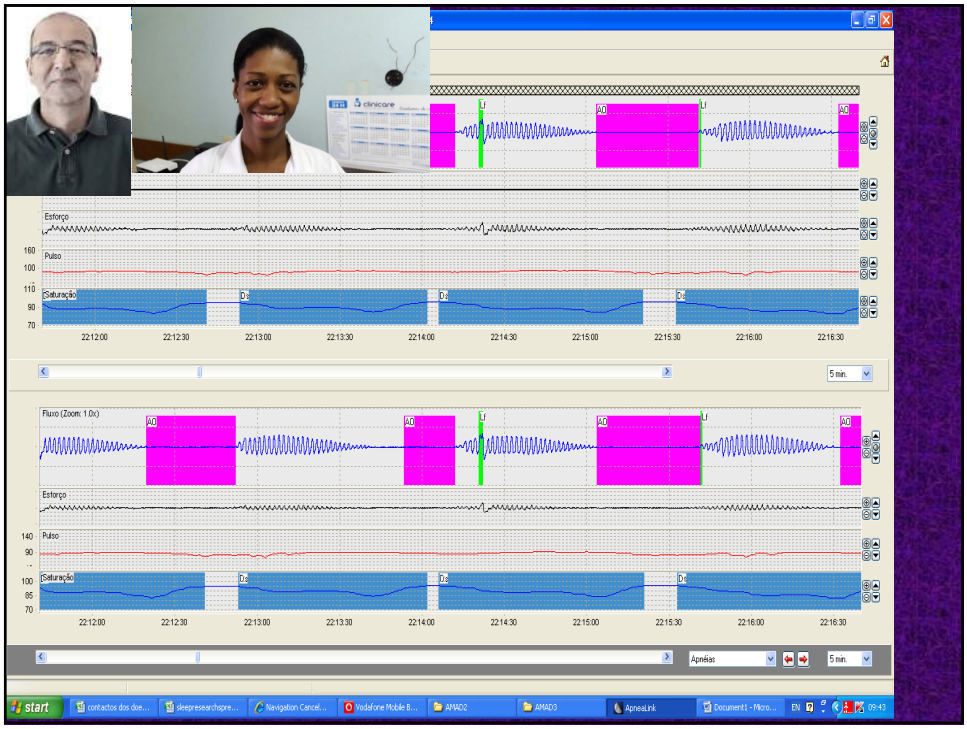
Younes AJRCCM 2001

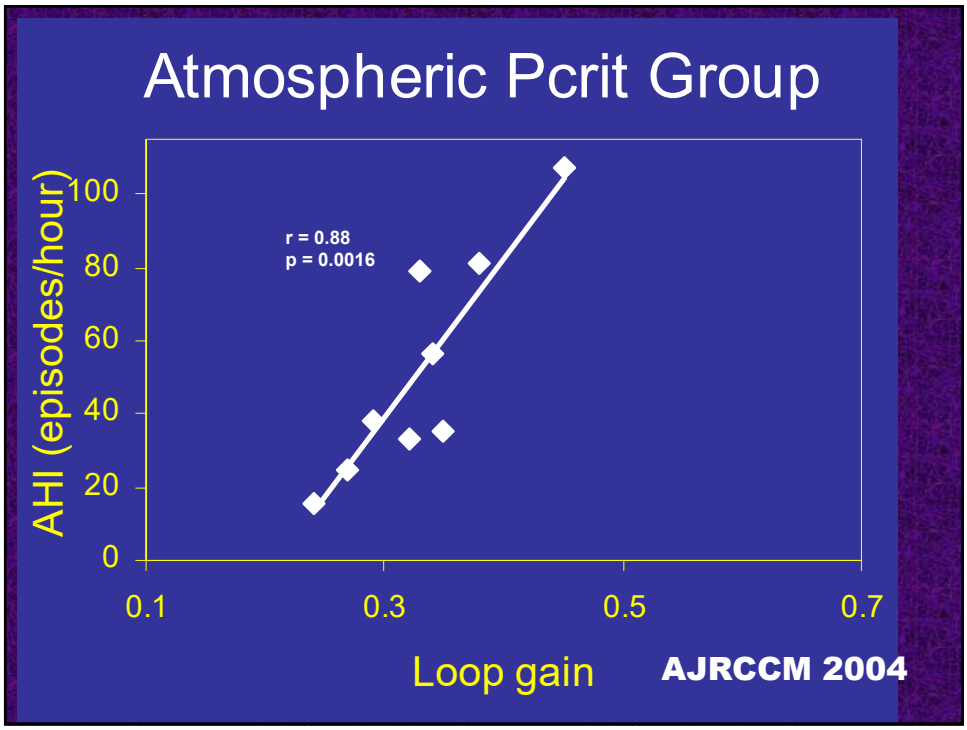
- **Thermostat analogy**

Inherent vs. Induced Loop Gain Abnormalities in Obstructive Sleep Apnea

Naomi Deacon-Diaz and Atul Malhotra*

Deacon and Malhotra Frontiers in Neurology in press; Sleep in press


Esforço
Pulso
Saturação
Fluxo (Zoom: 1.0x)
Apnéias
start


Atmospheric Pcrit Group
AHI (episodes/hour)
100
80
60
40
20
0
r = 0.88
p = 0.0016
0.1
0.3
0.5
0.7
Loop gain
AJRCCM 2004

JCSM
Journal of Clinical Sleep Medicine

SCIENTIFIC INVESTIGATIONS

Physiology-Based Modeling May Predict Surgical Treatment Outcome for Obstructive Sleep Apnea

Yanru Li, MD[1,2]; Jingying Ye, MD[1,3]; Demin Han, MD, PhD[1]; Xin Cao, MD[1]; Xiu Ding[1]; Yuhuan Zhang[1,3]; Wen Xu, MD[1]; Jeremy Orr, MD[2]; Rachel Jen, MD[2]; Scott Sands, PhD[4,5]; Atul Malhotra, MD[2]; Robert Owens, MD[2]

High LG predicts surgical failure
LG lowers after surgery suggesting is partially acquired
Low AT predicts surgical failure ? Therapeutic target

Results: Although preoperative loop gain was positively correlated with postoperative apnea-hypopnea index (AHI) ($P = .008$) and arousal threshold was negatively correlated ($P = .011$), in both model 1 and 2, the only significant variable was preoperative AHI, which explained 42% of the variance in postoperative AHI. In contrast, the physiological model (model 3), which included AHI_{REM} (anatomy term), fraction of events that were hypopnea (arousal term), the ratio of AHI_{REM} and AHI_{NREM} (muscle responsiveness term), loop gain, and central/mixed apnea index (control of breathing terms), was able to explain 61% of the variance in postoperative AHI.

Conclusions: Although loop gain and arousal threshold are associated with residual AHI after surgery, only preoperative AHI was predictive using multivariate regression modeling. Instead, incorporating selected surrogates of physiological traits on the basis of OSA pathophysiology created a model that has more association with actual residual AHI.

JCSM 2017

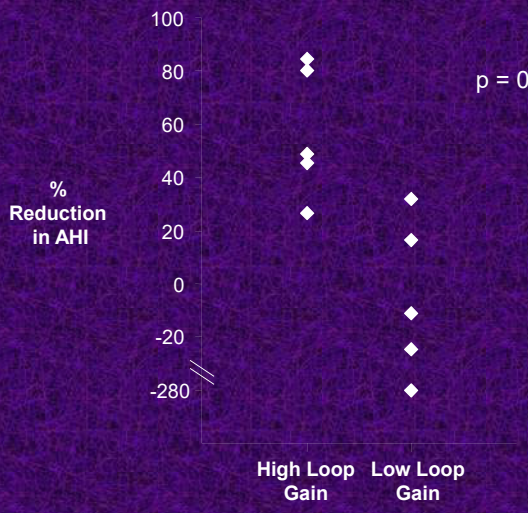
Obstructive Sleep Apnea
Underlying Mechanisms
High Loop Gain

Administer agents to reduce loop gain:

- **Oxygen** (Resp Phys 2008, ERJ 2018)
- **Acetazolamide** (Sleep 2013, J. Physiol. 2012, ATS 2019)

- **Loop gain can be manipulated pharmacologically in a subset of OSA**

Effect of Oxygen Between Groups



Resp Physiol 2008

ERJ 2018

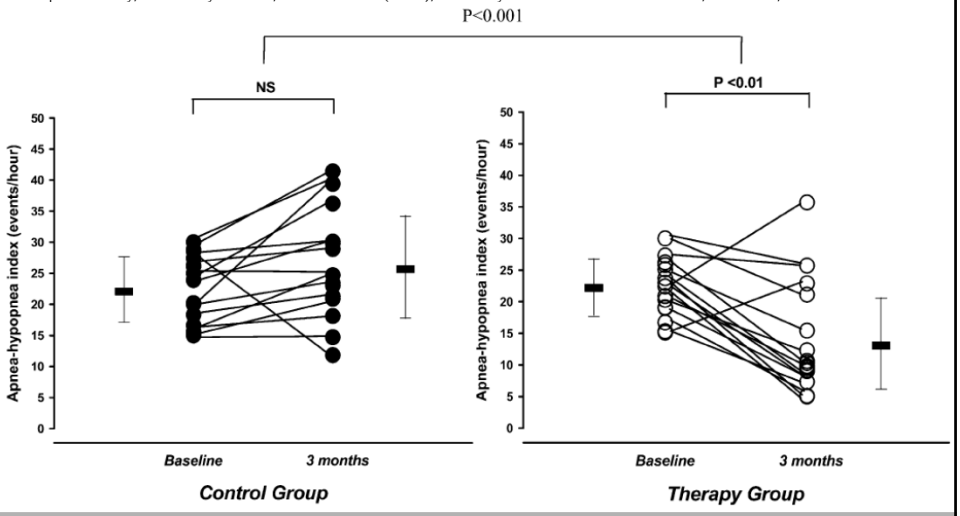
Obstructive Sleep Apnea
Potential Therapies

- Oropharyngeal exercise
- Hypoglossal nerve stimulation
- Winx
- Provent
- Postural therapy
- Bariatric surgery

Effects of Oropharyngeal Exercises on Patients with Moderate Obstructive Sleep Apnea Syndrome

Kátia C. Guimarães[1], Luciano F. Drager[1], Pedro R. Genta[1], Bianca F. Marcondes[1], and Geraldo Lorenzi-Filho[1]

[1]Sleep Laboratory, Pulmonary Division, Heart Institute (InCor), University of São Paulo Medical School, São Paulo, Brazil



AJRCCM 2009

CLINICAL RESEARCH STUDY

THE AMERICAN JOURNAL of MEDICINE®

Exercise Is Associated with a Reduced Incidence of Sleep-disordered Breathing

Karim M. Awad, MD,[a] Atul Malhotra,[a] Jodi H. Barnet,[b] Stuart F. Quan,[a,c] Paul E. Peppard[b]

[a]Division of Sleep Medicine, Brigham and Women's Hospital, Harvard Medical School, Boston, Mass; [b]Department of Population Health Sciences, University of Wisconsin School of Medicine and Public Health—Madison; [c]Arizona Respiratory Center, College of Medicine, University of Arizona, Tucson.

Table 2 Association of Exercise and Incidence of Mild and Moderate SDB*

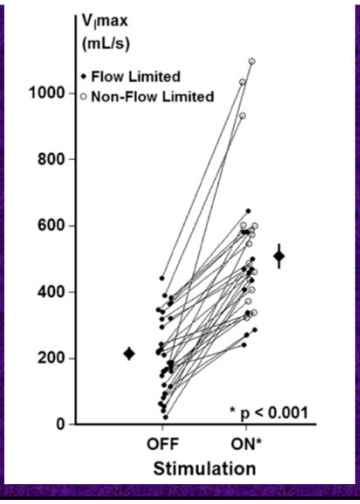
		Adjusted†	
	n	Odds Ratio (95% CI)	*P* Value
Incidence of AHI ≥5/h§			
Baseline exercise (trend)‖	763	0.76 (0.62-0.94)	.011
Baseline exercise (≥4h/week vs no exercise)	763	0.59 (0.39-0.89)	.012
Incidence of AHI ≥15/h§			
Baseline exercise (trend)‖	959	0.67 (0.51-0.87)	.002
>Baseline exercise (≥4 h/week vs no exercise)	959	0.47 (0.28-0.79)	.004

AJM 2012

Acute Upper Airway Responses to Hypoglossal Nerve Stimulation during Sleep in Obstructive Sleep Apnea

Alan R. Schwartz[1], Maree Barnes[2], David Hillman[3], Atul Malhotra[4], Eric Kezirian[5], Philip L. Smith[1], Thomas Hoegh[6], Daniel Parrish[6], and Peter R. Eastwood[3,7]

[1]Johns Hopkins School of Medicine, Baltimore, Maryland; [2]Austin Hospital, Melbourne, Australia; [3]Sir Charles Gairdner Hospital, Perth, Australia; [4]Brigham and Womens Hospital, Boston, Massachusetts; [5]University of California at San Francisco, San Francisco, California; [6]Apnex Medical, St. Paul, Minnesota; and [7]Centre for Sleep Science, School of Anatomy and Human Biology, University of Western Australia, Perth, Australia

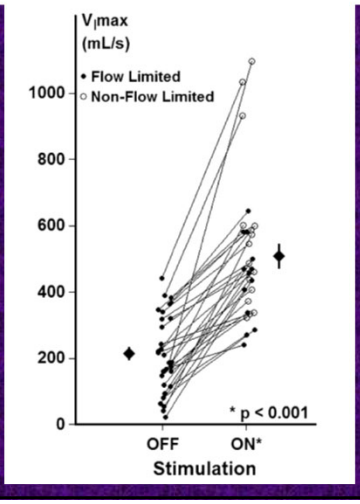


AJRCCM 2012

Acute Upper Airway Responses to Hypoglossal Nerve Stimulation during Sleep in Obstructive Sleep Apnea

Alan R. Schwartz[1], Maree Barnes[2], David Hillman[3], Atul Malhotra[4], Eric Kezirian[5], Philip L. Smith[1], Thomas Hoegh[6], Daniel Parrish[6], and Peter R. Eastwood[3,7]

[1]Johns Hopkins School of Medicine, Baltimore, Maryland; [2]Austin Hospital, Melbourne, Australia; [3]Sir Charles Gairdner Hospital, Perth, Australia; [4]Brigham and Womens Hospital, Boston, Massachusetts; [5]University of California at San Francisco, San Francisco, California; [6]Apnex Medical, St. Paul, Minnesota; and [7]Centre for Sleep Science, School of Anatomy and Human Biology, University of Western Australia, Perth, Australia



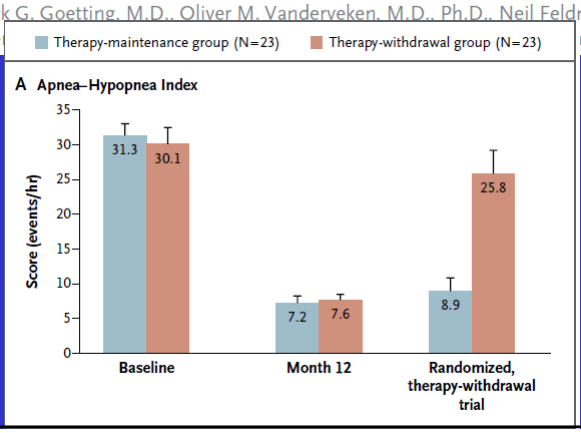
Speculation: progressive reductions in airflow may reflect UA muscle dysfunction which could be amenable to hypoglossal nerve stimulation or pharmacotherapy

AJRCCM 2012

ORIGINAL ARTICLE

Upper-Airway Stimulation for Obstructive Sleep Apnea

Patrick J. Strollo, Jr., M.D., Ryan J. Soose, M.D., Joachim T. Maurer, M.D., Nico de Vries, M.D., Jason Cornelius, M.D., Oleg Froymovich, M.D., Ronald D. Hanson, M.D., Tapan A. Padhya, M.D., David L. Steward, M.D., M. Boyd Gillespie, M.D., B. Tucker Woodson, M.D., Paul H. Van de Heyning, M.D., Ph.D., Mark G. Goetting, M.D., Oliver M. Vanderveken, M.D., Ph.D., Neil Feldman, M.D., Le... ...l Group*



NEJM 2014; OHNS 2018

The NEW ENGLAND JOURNAL of MEDICINE

Hypoglossal-Nerve Stimulation for Obstructive Sleep Apnea

Atul Malhotra, M.D.

- NEJM 2014 Strollo et al. showed potential benefit to HGNS for OSA
- Unclear which patients might respond best
- Underlying mechanism of OSA is likely to be important predictor

Stimulating therapy for obstructive sleep apnoea

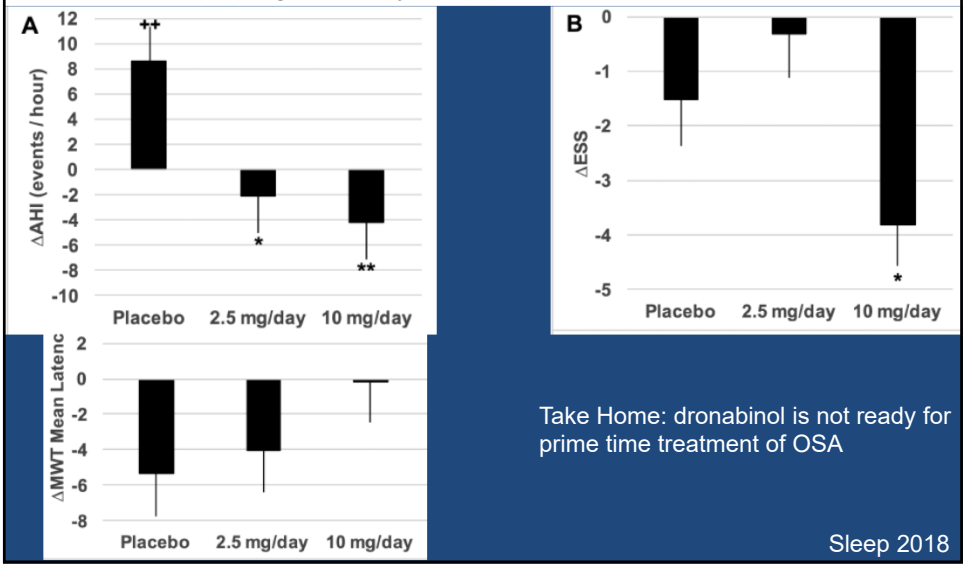
Patrick J Strollo Jr,[1] Atul Malhotra[2]

NEJM 2014; Thorax 2016

ORIGINAL ARTICLE

Pharmacotherapy of Apnea by Cannabimimetic Enhancement, the *PACE* Clinical Trial: Effects of Dronabinol in Obstructive Sleep Apnea

David W. Carley, PhD[1,2,3], Bharati Prasad, MD[2,3,4], Kathryn J. Reid, PhD[5,6], Roneil Malkani, MD[5,6], Hryar Attarian, MD[5,6], Sabra M. Abbott, MD, PhD[5,6], Boris Vern, MD, PhD[1,3,†], Hui Xie, PhD[7], Chengbo Yuan, MPH[7], Phyllis C. Zee, MD, PhD[5,6]

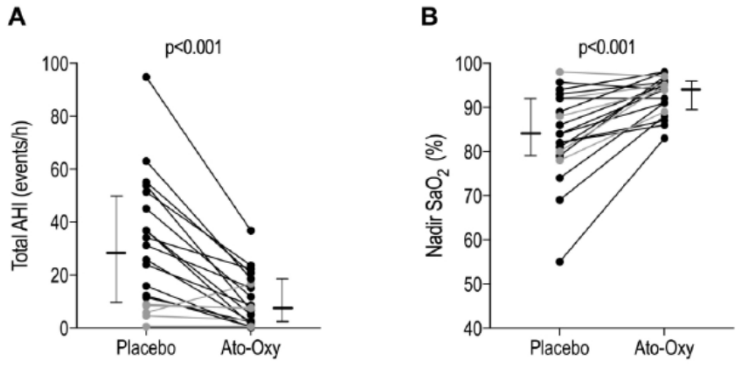


Take Home: dronabinol is not ready for prime time treatment of OSA

Sleep 2018

The Combination of Atomoxetine and Oxybutynin Greatly Reduces Obstructive Sleep Apnea Severity: A Randomized, Placebo-Controlled, Double-Blind Crossover Trial

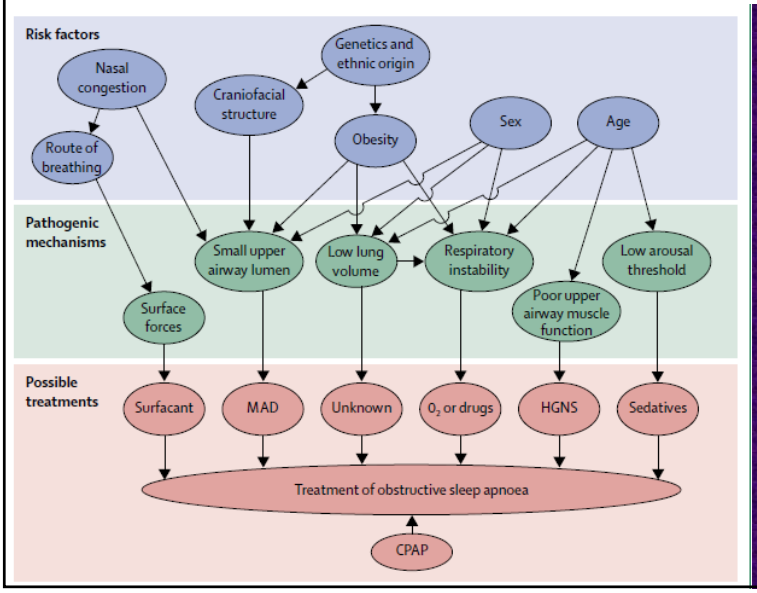
Luigi Taranto-Montemurro[1], Ludovico Messineo[1,2], Scott A Sands[1], Ali Azarbarzin[1], Melania Marques[1,3], Bradley A Edwards[4,5], Danny J Eckert[6], David P White[1] and Andrew Wellman[1].



AJRCCM in press; small numbers, one night only

Adult obstructive sleep apnoea

Amy S Jordan, David G McSharry, Atul Malhotra



Lancet 2014

Vision - Summary

To be able to assess an individual at risk of OSA using a blood test and/or simplified home recording or wearable technology to make diagnosis and WHY

To use this information to determine optimal therapy by assessing responsiveness to interventions and risk of particular complications.

To use real-time patient feedback technologies to optimize adherence and to guide interventions.

Exosomal Cargo Properties, Endothelial Function and Treatment of Obesity Hypoventilation Syndrome Bhattacharjee et al. JCSM 2018

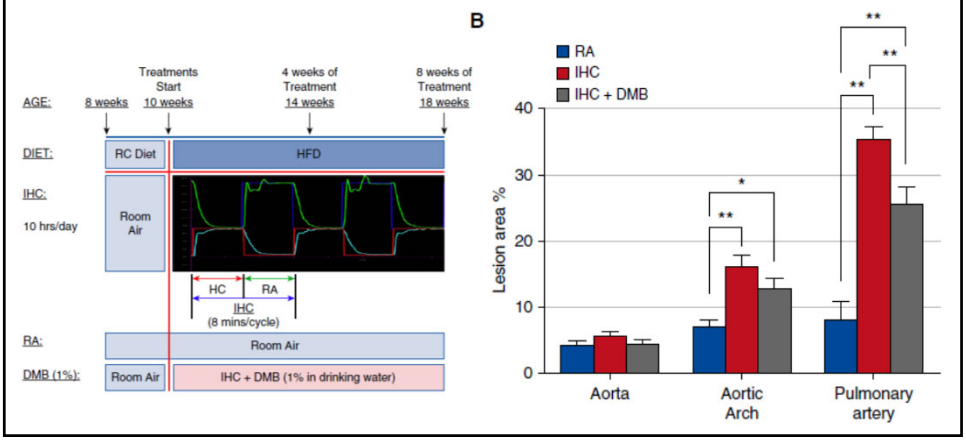
-Can isolate extracellular vesicles and miRNA from human plasma from untreated OSA
-take the exosomes and introduce into mice or cell culture systems
-assess impact on endothelial cells including monocyte adhesion, eNOS, tight junctions
-can take exosomes after CPAP treatment of OSA and reassess
-provide direct evidence of vascular benefit of CPAP

ORIGINAL RESEARCH AJRCMB 2017

Intermittent Hypoxia and Hypercapnia Accelerate Atherosclerosis, Partially via Trimethylamine-Oxide

Jin Xue[1], Dan Zhou[1], Orit Poulsen[1], Toshihiro Imamura[1], Yu-Hsin Hsiao[1], Travis H. Smith[1], Atul Malhotra[2], Pieter Dorrestein[1,3,4], Rob Knight[1,4,5], and Gabriel G. Haddad[1,3,5,6]

Departments of [1]Pediatrics, [2]Internal Medicine, and [3]Neurosciences, School of Medicine, [4]School of Pharmacy and Pharmaceutical Sciences, and [5]Department of Computer Sciences and Engineering, School of Engineering, University of California San Diego, La Jolla, California; and [6]The Rady Children's Hospital, San Diego, California



Take Home Points

1. CPAP is treatment of choice for OSA and a defeatist attitude about CPAP is not justifiable
2. Alternative therapies are available which provide acceptable results for select patients
3. Individualized therapy may be viable in the future based on mechanism underlying OSA
4. Exciting time for sleep field

CARDIOVASCULAR DISEASE AND SLEEP APNEA: WHAT IS THE CURRENT EVIDENCE?

Kathleen Sarmiento, MD
UC San Francisco
Associate Professor of Medicine

Saturday, January 19, 2019 – 8:50 a.m. – 9:20 a.m.

Kathleen (Katie) Sarmiento, MD, is an Associate Professor of Medicine at UC San Francisco, the Director of Sleep Medicine at the San Francisco VA Health Care System, and the National Lead for VA TeleSleep, an enterprise-wide initiative to build a high-performing sleep telemedicine network. She has been instrumental in building infrastructure for and leading VA Sleep operations. She has an active clinical practice in Pulmonary, Critical Care and Sleep Medicine. Her research interests are focused on health services research, including strategies to improve access to sleep care in rural areas, reduce wait times, lower cost, and de-implement low-value steps in obtaining care.

CENTRAL SLEEP APNEA AND HEART FAILURE: PAP VERSUS OXYGEN VERSUS PHRENIC NERVE STIMULATION

Lisa Wolfe, MD
Northwestern University
Associate Professor of Medicine and Neurology

Saturday, January 19, 2019 – 9:20 a.m. – 9:50 a.m.

Lisa Wolfe, MD, is originally from Ohio and did her medical school training at the Ohio State University. Her residency/ fellowship training was at Northwestern University where she has been ever since. She is an associate professor of both medicine and neurology – where she is on the faculty in pulmonary / sleep and neuromuscular medicine. She is also the medical director of respiratory care at the Shirley Ryan Ability Lab (previously known as the Rehabilitation Institute of Chicago (RIC)). Dr. Wolfe's academic focus is on the use of home based ventilation and the care of those with neuromuscular diseases. She has clinical grants for this work from the Les Turner ALS Foundation and the Muscular Dystrophy Association.

BREAK
EXHIBIT HALL OPEN

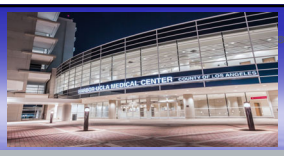
Saturday, January 19, 2019 – 9:50 a.m. – 10:10 a.m.

THE PERIOPERATIVE MANAGEMENT OF SLEEP DISORDERED BREATHING

Janine Vintch, MD
David Geffen School of Medicine at UCLA
Harbor-UCLA Medical Center
Clinical Professor of Medicine

Saturday, January 19, 2019 – 10:10 a.m. – 10:40 a.m.

Janine Vintch, MD, was born and raised in Southern California. She went to UCLA for her undergraduate training and then to USC for her medical school years. Upon graduation, she matched at Harbor-UCLA Medical Center in Torrance, California, where she has remained for her entire career. She did her Internal Medicine residency training, Chief Resident, and then Pulmonary-Critical Care fellowship at Harbor. At the end of her training years, she was jointly appointed as a faculty member to both the Division of General Internal Medicine and the Division of Pulmonary and Critical Care Medicine and is currently a full time Profession through the David Geffen School of Medicine at UCLA. In the early years of her faculty appointment, she focused on perioperative management strategies and general medicine consultations. She also had an interest in Sleep Medicine and was self-trained in this subspecialty area. She is a Diplomate of the American Board of Sleep Medicine as well as the American Board of Internal Medicine in Sleep in addition to her certification in Internal Medicine, Pulmonary Diseases, and Critical Care Medicine. In the last 10 years, she has developed an interest in the area of venous thromboembolic disease and participated in the last edition of the ACCP Guidelines on the Management of VTE. More recently, she is working on developing a PE Response Team and in one of the members of the University of California Alliance on Pulmonary Embolism (UCAPE). In addition to her clinical areas of interest, she has participated in the Medical Staff leadership at Harbor and is currently their Chief of Staff.

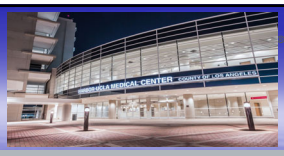


The Perioperative Management of Sleep-Disordered Breathing

Janine R. E. Vintch, MD, FCCP
Clinical Professor of Medicine
David Geffen School of Medicine at UCLA
Harbor-UCLA Medical Center
CTS 2019 Northern California Conference
January, 2019

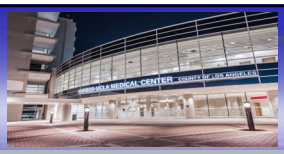
Harbor-UCLA MEDICAL CENTER

Disclosures



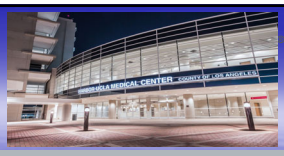
- No conflicts of interest

Learning Objectives



- Review the challenges that can be encountered in managing patients with sleep disordered breathing (SBD) in the perioperative period
- Discuss the preoperative preparation recommendations focusing on SDB
- Review management strategies for patients with SDB in the perioperative period to decrease their overall risk of complications and adverse outcomes

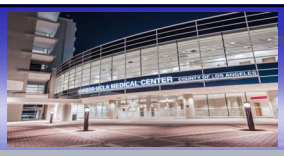
Introduction



- Every year approximately 250 million surgical procedures are performed worldwide
  - An increasing number are being performed in the ambulatory setting
- With both surgical volume and predisposing factors for SDB increasing, there is an increased interest in the impact of these disorders on perioperative outcome
  - Of note, the diagnosis of SDB including Obstructive Sleep Apnea (OSA) and Obesity Hypoventilation Syndrome (OHS) has not been established in the majority of surgical patients with these disorders

Debas HT. *JAMA Surg.* 2015;150:833-834.
Tsai A and Schumann R. *Curr Opin Anesthesiol.* 2016;29:103-108.

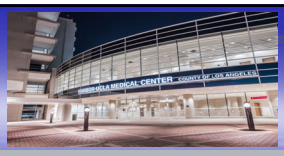
Introduction



- There are numerous variables that influence SDB in the perioperative period including:
  - Anesthesia
  - Upper airway injury after intubation
  - Fluid shifts
  - Pain medications
  - Administration of oxygen

Ayas NT et al. *Ann Am Thorac Soc.* 2018;15:117-126.

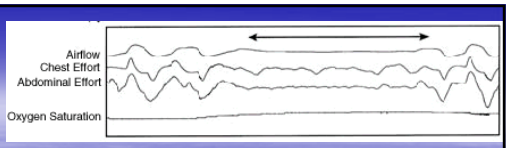
SDB in the Perioperative Period



- OSA
  - In the classic epidemiologic study by Young et al the prevalence of OSA defined as an AHI > 5 was 9% of women and 24% of men
    - Approximately 70% of patients with OSA are overweight or obese and has more than doubled in the past 40 years
  - Today, a high prevalence of OSA is noted in patients undergoing surgery with studies reporting ranges between 24 to 41%
    - Prevalence as high as 70% has been reported in bariatric surgery patients

Roesslein M and Chung F. *Eur J Anaesthesiol.* 2018;35:245-255.
Tsai A and Schumann R. *Curr Opin Anesthesiol.* 2016;29:103-108.
Young T et al. *N Engl J Med.* 1993;328:1230-1235.

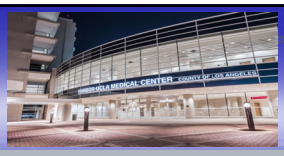
Sleep-Disordered Breathing: OSA



- OSA is characterized by repetitive partial or complete obstruction of the upper airway during sleep
  - These obstructions lead to oxygen desaturation, hypercapnia, and cortical microarousals in an attempt to restore upper airway patency
- OSA has been associated with various health-related consequences including increased rate of motor vehicle accidents, hypertension, myocardial ischemia, arrhythmias, heart failure, pulmonary hypertension, stroke, metabolic syndrome, and all-cause mortality

Adesanya AO et al. *Chest.* 2010;138:1489-1498.
Vasu TS et al. *J Clin Sleep Med.* 2012;8:199-207.

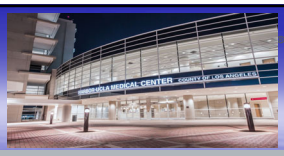
Sleep-Disordered Breathing: OSA



- The impact of OSA on postoperative pulmonary complications (PPCs) is an area of current active research
  - In 2006, the ACP guidelines suggested that PPCs may be higher among patients with OSA based on a case-control study of patients undergoing hip or knee replacement
- The importance of this was highlighted in 2008 when the Joint Commission proposed a National Patient Safety Goal focusing on preoperative screening as well as protocols for perioperative management of OSA

Bolden N et al. *J Clin Anesth.* 2009;21:286-293/
Health Leaders Media. JCAHO National Patient Safety Goals. 2011.
Smetana GW and Conde MV. *Clin Geriatr Med.* 2008;24:607-624.

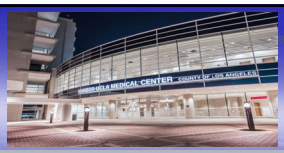
Sleep-Disordered Breathing: OSA



- A systematic review of 61 studies involving 413,304 OSA and 8,556,279 non-OSA patients to examine outcomes after procedures performed under general anesthesia, regional anesthesia, and sedation noted that OSA was associated with an increase in postoperative complications including
  - Difficult intubation
  - Pulmonary complications including need for intubation, prolonged mechanical ventilation support
  - Cardiovascular complications including atrial fibrillation, cardiac arrest
  - Delirium, agitation, confusion
  - Impaired wound healing
  - Higher resource utilization

Opperer M et al. *Anesth Analg.* 2016;122:1321-1334.

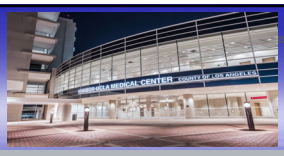
Sleep-Disordered Breathing: OHS



- OHS is a disease entity distinct from simple obesity and OSA
  - Defined as a combination of obesity with BMI > 30, daytime hypercapnia with P_aCO_2 > 45 mmHg during wakefulness with sleep-disordered breathing in the absence of an alternative neuromuscular, mechanical, or metabolic explanation for hypoventilation
  - OHS patients consume a greater level of healthcare resources than eucapnic patients with OSA
  - In contrast to OSA, new studies demonstrate a higher prevalence of OHS in women compared to men

Ayas NT et al. *Ann Am Thorac Soc.* 2018;15:117-126.
Bahammam AS. *Saudi Med J.* 2015;36:181-189.
Chau EHL et al. *Anesthesiology.* 2012;117:118-205.

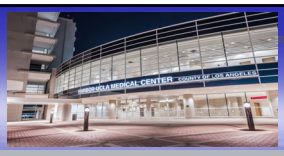
Sleep-Disordered Breathing: OHS



- The prevalence of OHS is approximately 0.15 to 0.6% of the general population and increases to 50% in patients with a BMI > 50
  - Approximately 90% of patients with OHS have concomitant OSA and is estimated to occur in 1/160 adults
    - Conversely only 10 to 20% of OSA patients have OHS
- OHS should be suspected in the following clinical scenarios:
  - Obese patients with an increased serum bicarbonate > 27 mEq/L
  - Room air hypoxemia while resting
  - Persistent hypoxemia during a sleep study

Ayas NT et al. *Ann Am Thorac Soc.* 2018;15:117-126.
Chau EHL et al. *Anesthesiology.* 2012;117:118-205.
Iftikhar IH and Roland J. *Clin Chest Med.* 2018;39:427-436.

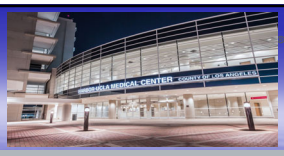
Sleep-Disordered Breathing: OHS



- Compared to eucapnic obese patients, OHS patients demonstrate
  - More severe upper airway obstruction
  - Impaired respiratory mechanics
  - Blunted central respiratory drive
  - Increased incidence of pulmonary hypertension (PH)
    - Severe PH was diagnosed in 28.6% of women and 14.3% of men in a prospective observational study of OHS patients

Priou P et al. *Chest.* 2010;138:84-90.
Iftikhar IH and Roland J. *Clin Chest Med.* 2018;39:427-436.

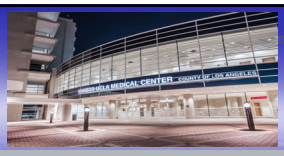
Sleep-Disordered Breathing: OHS



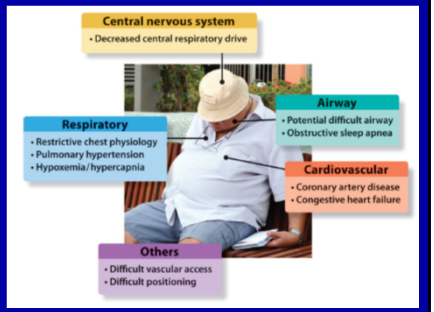
- Compared with patients who have OSA alone in the perioperative setting, patients with OHS have a increased risk of the following:
  - Respiratory failure = OR 10.9
  - Heart failure = OR 5.4
  - Prolonged intubation = OR 3.1
  - Tracheostomy = OR 3.8
  - ICU transfer = OR 10.9
    - Longer ICU stay
  - Longer hospital stay

Kaw R et al. *Chest.* 2016;149:84-91.

Sleep-Disordered Breathing: OHS and OSA

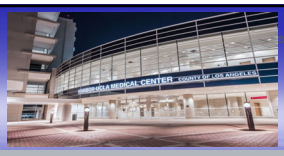


- Patients with a combination of OHS and OSA have a greater perioperative risk for cardiac and pulmonary complications as compared to patients with OSA without OHS
  - OHS was associated with 11 times increased odds for postoperative respiratory failure and ICU transfer
  - Increased incidence of postoperative heart failure (OR 5.4) and prolonged intubation (OR 3.1)
  - Longer LOS (7.3 versus 2.8 days)



Chung F et al. *Chest.* 2016;149:586-597.
Kaw R et al. *Chest.* 2016;149:84-91.

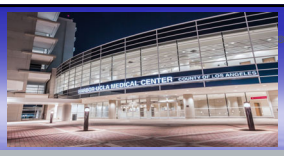
SDB in the Perioperative Period



- Several factors related to anesthesia and the operative intervention may contribute to complications in patients with underlying SDB
  - Medications such as hypnotics, opioids, muscle relaxants
  - Protracted supine position leading to decreased airway stability
  - Narrowing of the upper airway caused by pharyngeal edema following intubation
  - Perioperative discontinuation of CPAP
  - Disruption of sleep architecture
    - Sleep fragmentation with loss of REM sleep occurs initially followed by improved sleep and REM rebound seen between postop days 3 and 5

Ayas NT et al. *Ann Am Thorac Soc.* 2018;15:117-126.
Roesslein M and Chung F. *Eur J Anaesthesiol.* 2018;35:245-255.

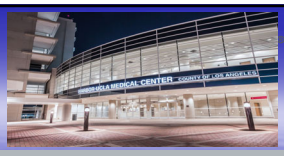
Preoperative Preparation



- The preoperative evaluation aims at gathering relevant information about the patient and formulating an anesthesia care plan
  - Diagnostic testing should be based on comorbidities and planned surgical intervention rather than on the mere presence of obesity
- Particular attention should focus on screening patients for SDB particularly obese patients
  - The 2013 Clinical Practice Guidelines for the Perioperative, Nutritional, Metabolic, and Nonsurgical Support of the Bariatric Surgery Patient recommends screening ***all*** bariatric surgery patients for OSA

Leong SM et al. *J Clin Anesth.* 2018;45:63-68.
Mechanick JI et al. *Endocrin Pract.* 2013:19:337-372.
Nightingale CE et al. *Anaesthesia.* 2015;70:859-876.

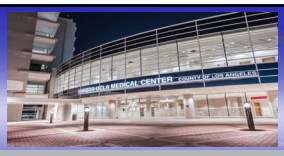
Preoperative Management



- Preoperative management should begin with a directed history and physical examination
  - Emphasis on airway examination and identifying comorbidities in order to optimize them prior to surgery with attention to identifying SDB
    - Neck circumference
    - BMI
    - Mallampati score and other airway characteristics
    - Difficulty with airway management or problems with previous anesthetics
    - Comorbidities including diabetes, hypertension, congestive heart failure, pulmonary hypertension

Adesanya AO et al. *Chest.* 2010;138:1489-1498.
Subramani Y et al. *Sleep Med Clin.* 2017;12:123-135.

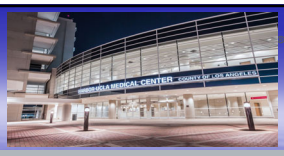
Preoperative Preparation: OSA Screening



- Many patients with underlying OSA may be undiagnosed and untreated at the time they present for surgery
- Screening for OSA in the preoperative period allows the provider to minimize postoperative complications by allowing the provider to:
  - Risk stratify the patient
  - Devise an anesthetic management plan with risk minimization
  - Plan for appropriate level and timing for postoperative monitoring

Nagappa M et al. *Anesth Analg.* 2017;125:1301-1308.

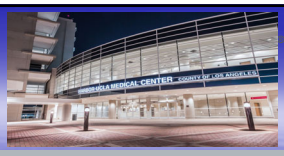
Preoperative Preparation: OSA Screening



- OSA screening tools have been developed and validated in surgical populations:
  - The STOP-Bang Questionnaire
  - The American Society of Anesthesiologists (ASA) Checklist
  - The Berlin Questionnaire
  - The Perioperative Sleep Apnea Prediction (P-SAP) Score
- These screening tools are designed to identify the presence of OSA rather than quantify the severity
- The inclusion of preoperative serum bicarbonate level may improve the predictive accuracy of the screening instrument

Rosslein M and Chung F. *Eur J Aneaesthesiol.* 2018;35:245-255.
Subramani Y et al. *Sleep Med Clin.* 2017;12:123-135.

OSA Screening: STOP-Bang Questionnaire



- The major drawback of all screening tools is their modest specificity with a high false-positive rate
  - STOP-Bang score > 3 is 93% sensitive but 43% specific for an AHI cut-off of 15
- Advantages of this tool is that it is brief, simple to administer, and requires only a fifth-grade reading level

STOP Questionnaire	BANG
Snoring	BMI >35
Tiredness	Age >50
Observed you stop breathing	Neck circumference >40 cm (>15.7")
Blood Pressure	Gender male

High risk: Yes to ≥3 items → Refer for sleep testing

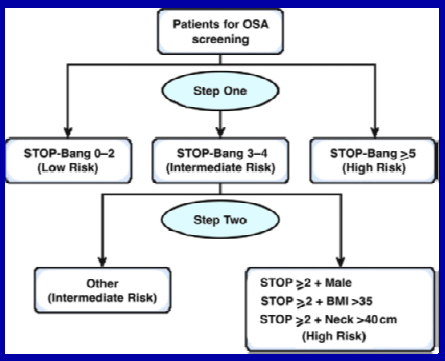
Subramani Y et al. *Sleep Med Clin.* 2017;12:123-135.

OSA Screening: STOP-Bang Questionnaire

STOP Questionnaire	BANG
Snoring	BMI >35
Tiredness	Age >50
Observed you stop breathing	Neck circumference >40 cm (>15.7")
Blood Pressure	Gender male

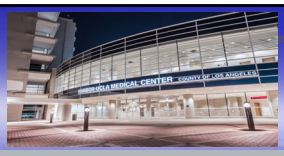
High risk: Yes to ≥3 items → Refer for sleep testing

- A new 2-step approach has recently been proposed
  - Patients with scores of 0 to 2 may be safely ruled out as low risk for moderate to severe OSA
  - Patients with scores of 5 or higher are at high risk of moderate to severe OSA
  - Among patient with scores of 3 or 4 (intermediate risk) who have 2 or the following are at higher risk as well
    - BMI > 35
    - Neck circumference > 40 cm
    - Male sex

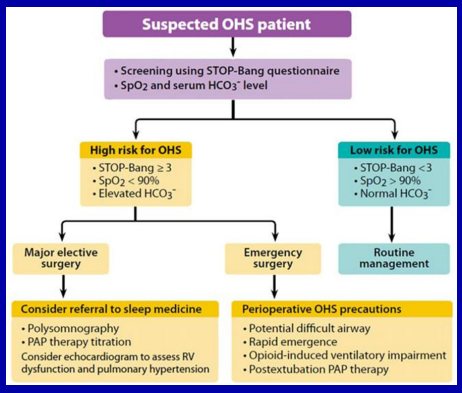


Chung F et al. *Anesthesiology.* 2008;108:812-821.
Madhusudan P et al. *Curr Opin Anesthesiol.* 2018;31:89-95.
Subramani Y et al. *Sleep Med Clin.* 2017;12:123-135.

Preoperative Preparation: OHS Screening

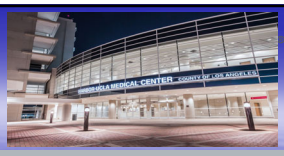


- A modified STOP-Bang Questionnaire with additional points for BMI and bicarbonate > 27 mEq/L was compared with the original STOP-Bang score for predicting OHS
  - Sensitivity 89.2% and a specificity 47.6% with a score of 6
  - Diuretics and steroid administration may lead to a primary metabolic alkalosis which may make a it to distinguish from a compensatory metabolic alkalosis



Bingol Z et a. *Sleep Breath.* 2016;20:495-500.
Chau EH et al. *Sleep Med Clin.* 2013 Mar; 8(1): 135–147.

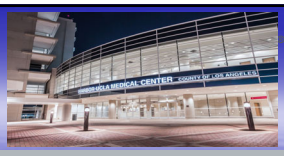
Preoperative Preparation



- Once a patient has been identified as high risk for OSA or OHS, the decision to proceed directly to surgery or to refer the patient for further evaluation will depend on the relative urgency of the surgery and made in consultation with the surgeon
  - If the plan is to proceed with surgery, all members of the healthcare team should be made aware of the patient's high-risk status in order to follow risk reduction strategies as outlined in guidelines such as the Society of Anesthesia and Sleep Medicine (SASM) and ASA

Adesanya AO et al. *Chest.* 2010;138:1489-1498.
Madhusudan P et al. *Curr Opin Anesthesiol.* 2018;31:89-95.

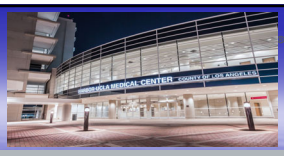
Preoperative Preparation: OSA Diagnosis



- Full-night, attended, in-laboratory polysomnography (PSG) is regarded as the gold standard in the diagnosis of OSA
  - PSG can provide the diagnosis, severity, and phenotype of OSA
  - However, the logistical issues associated with getting a PSG done timely can delay scheduled surgery
    - For non-bariatric procedures, there appears to be insufficient evidence in the current literature to support canceling or delaying surgery for a formal diagnosis unless there is evidence of associated significant uncontrolled disease or additional problems with ventilation or gas exchange

Memtsoudis SG et al. *Anesth Analg.* 2018;June 25.
Roesslein M and Chung F. *Eur J Anaesthesiol.* 2018;35:245-255.

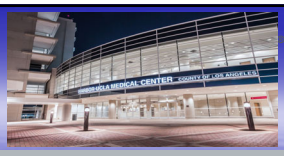
Preoperative Preparation: OSA Diagnosis



- Home sleep testing or other forms of testing such as pulse oximetry may be an alternative for patients with underlying high pre-test probability
  - Nocturnal pulse oximetry has been used as a surrogate to PSG for screening for OSA but is not accepted by CMS
    - Sensitivity can be as high as 98% for moderately severe OSA but specificity can be as low as 40% depending on how the data is interpreted

Park JG et al. *Mayo Clin Proc.* 2011;86:549-555.
Roesslein M and Chung F. *Eur J Anaesthesiol.* 2018;35:245-255.

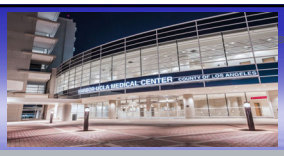
Nocturnal Pulse Oximetry



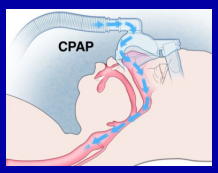
- Data from one study assessing pulse oximetry demonstrated that an oxygen desaturation index (ODI) > 5 had a higher rate of postoperative complications including respiratory and cardiac events
  - ODI = number of oxygen desaturation >4% events per hour of monitoring
- In another study comparing overnight oximetry with home sleep testing in 68 bariatric surgery patients found an ODI 3% had a negative predictive value of 95% to rule out OSA and a positive predictive value of 73%

Hwang D et al. *Chest.* 2008;133:1128-1134.
Malbois M et al. *Obes Surg.* 2010;20:326-331.

Preoperative Preparation: PAP Therapy

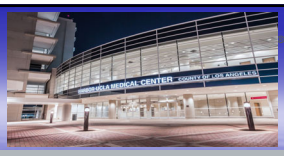


- Pneumatic splinting of the airway by applying CPAP is regarded as the gold standard treatment for OSA
  - It improves daytime sleepiness, accident risk, and quality of life
  - Several studies have also shown that it decreases the risks of several adverse cardiovascular outcomes such as hypertension and atrial fibrillation
  - CPAP use prior to surgery to prevent postoperative complications is not unequivocally confirmed in the literature
    - Because of its known benefits outside of the surgical arena, many guidelines do recommend its initiation in the perioperative period



Roesslein M and Chung F. *Eur J Anaesthesiol.* 2018;35:245-255.

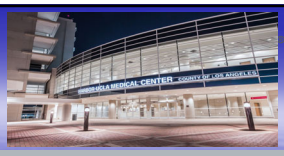
Preoperative Preparation: PAP Therapy



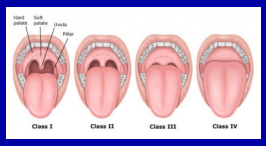
- The 2014 ASA Practice Guidelines strongly recommends considering the initiation of CPAP in the perioperative period in patients with OSA
  - Particularly for patients with severe OSA
  - It remains unclear what duration of preoperative CPAP is needed prior to elective surgery that leads to a positive impact
- For patients with OHS, PAP therapy should be also considered and if possible started during the few days or weeks before surgery
  - In a period as short as 5 days, gas exchange and SDB can improve significantly using either CPAP or NIV

ASA Task Force. *Anesthesiology.* 2014;120:268-286.
Chau EHL et al. *Anesthesiology.* 2012;117:188-205.

Preoperative Preparation: Airway Assessment

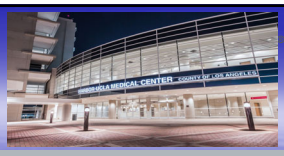


- Obesity alone is associated with up to a 30% greater chance of a difficult airway or failed intubation
  - Bag-mask ventilation is also known to be more difficult in the obese with reports as high as 79%
- Risk factors beyond BMI predictive of a difficult intubation include:
  - Reduced mobility of the lower jaw
  - Male sex
  - Large neck circumference
  - OSA: Risk appears independent from Mallampati score and BMI
    - In a case-control retrospective study of 253 patients, difficult intubation was found to occur 8 times more often in OSA patients than controls



Hillman DR and Chung F. *Respirology.* 2017;22:230-239.
Nightingale CE et al. *Anaesthesia.* 2015;70:859-876.

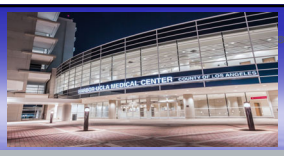
Intraoperative Care: Regional Anesthesia



- Many reviews and guidelines recommend regional as preferred to general anesthesia when possible as it offers distinct advantages
  - Minimal airway manipulation
  - Avoidance of anesthetic drugs with cardiopulmonary depression
  - Reduced postoperative nausea and vomiting
  - Reduced perioperative opioid requirements
- There is a higher risk of failure of regional techniques in the obese
  - An airway management plan should always be in place
- Sedation, if required, the should be kept to a minimum

Nightingale CE et al. *Anaesthesia.* 2015;70:859-876.
Raveendran R et al. *Curr Opin Anesthesiol.* 2017;30:146-155.

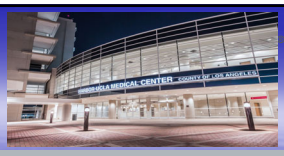
Intraoperative Care: Regional Anesthesia



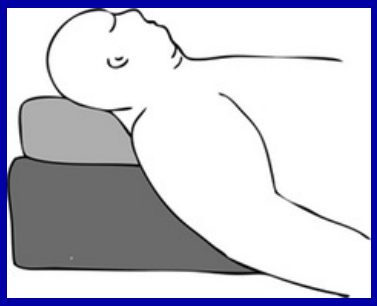
- In a study of 40,316 OSA patients undergoing hip and knee arthroplasty, the use of neuraxial anesthesia versus general anesthesia were compared
  - Neuraxial anesthesia was associated with
    - Decreased odds for the need for mechanical ventilation
    - Decreased admissions to the ICU postoperatively
    - Shorter length of stay
    - Decreased cost

Memtsoudis SG et al. *Reg Anesth Pain Med.* 2013;38:274-281.

Intraoperative Care: Induction of Anesthesia

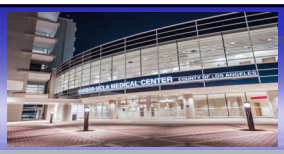


- Easily reversible drugs, with fast onset and offset, are the agents of choice for patients with SDB
- For obese patients, since their work of breathing is increased, tracheal intubation with controlled ventilation is the airway management technique of choice
  - During induction, the patient should be positioned in a ramped position with the tragus of the ear at the level of the sternum and the arms away the chest
    - HELP = Head Elevated Laryngoscopy Position
    - Sniffing position



Nightingale CE et al. *Anaesthesia.* 2015;70:859-876.

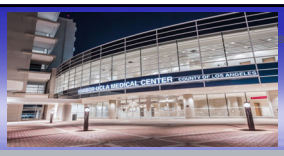
Intraoperative Care: Induction of Anesthesia



- Minimizing the time from induction to intubation will reduce the risk of oxygen desaturation should bag-mask ventilation prove difficult
  - Preoxygenation for more than 3 minutes with a tightly fitted mask can increase apnea tolerance time
    - Application of CPAP or PEEP can achieve a higher oxygen tension and longer time to desaturation
- One needs to be prepared and avail all specialized anesthesiology instruments and assistance
  - In extreme cases use of awake fiberoptic intubation be necessary

Iftikhar IH and Roland J. *Clin Chest Med.* 2018;39:427-436.
Nightingale CE et al. *Anaesthesia.* 2015;70:859-876.

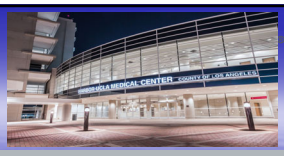
Intraoperative Care: Ventilatory Support



- Observational studies suggest that obese patients are at higher risk of being ventilated with large, potentially injurious tidal volumes
  - In a study of patient undergoing major abdominal surgery, intraoperative ventilation with low tidal volumes (6 to 8 ml/kg predicted body weight) as well as PEEP and recruitment maneuvers impart outcome benefits
    - Composite end points of pneumonia, respiratory failure, sepsis, and death
  - In a small study of 30 gastric bypass surgery patient, it was found that PEEP and recruitment maneuvers combined reduced atelectasis and improved oxygenation in morbidly obese patients whereas PEEP or recruitment maneuvers alone did not

PROVE Network Investigators. *Lancet.* 2014;384:495-503.
Reinius H et al. *Anesthesiology.* 2009;111:979-987.

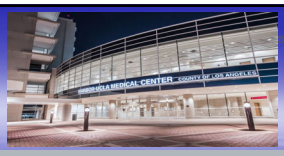
Intraoperative Care: Ventilatory Support



- The Protective Ventilation with Higher versus Lower PEEP during General Anesthesia for Surgery in Obese Patients (PROBESE) trial seeks to answer the question of PEEP in obese patients by comparing intraoperative ventilation strategies
- While awaiting additional studies to guide ventilatory strategies, some authors recommend the following intraoperative ventilator settings
  - Low tidal volume: 6 to 8 mL/kg predicted body weight
  - Higher PEEP: 8 to 15 cm H_2O
  - Peak airway pressure limit: 30 to 35 cm H_2O
  - Recruitment maneuvers

PROBESE. Bluth T et al. *Trials.* 2017;18:202.
Tsai A and Schumann R. *Curr Opin Anesthesiol.* 2016;29:103-108.

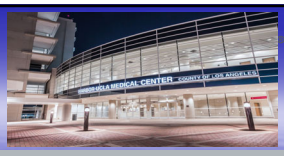
Postoperative Management: Extubation Plan



- Extubation should be performed in a similar manner to intubation
  - Patients should be in a sitting position or with the upper body elevated
  - Assure return of stable protective arousal responses is key
  - Neuromuscular blockade should be reversed if necessary
    - Patient should be able to sustain a head lift for > 5 seconds
    - Use of suggamadex or other reversal agent can be given if needed
  - Supplemental oxygen should be provided until baseline oxygenation status is achieved
    - This measure has recently been found to improve oxygenation and decrease AHI in OSA patient without increasing the duration of apnea or hypopnea events

Liao P et al. *Chest.* 2017;151:597-611.
Huschak G et al. *Best Pract Res Clin Endocrinol Metab.* 2013;27:247-260.

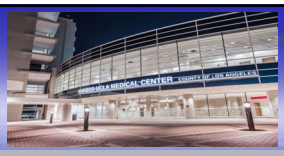
Postoperative Management: Monitoring



- Close and continuous monitoring can take place in the Post-Anesthesia Care Unit (PACU) to identify behaviors that indicate particular vulnerability to UA obstruction and/or hypoventilation in at-risk patients
  - Such patients are monitored for a longer period of time in this environment so that observations can be made well beyond the immediate emergence from anesthesia
    - Exact amount of time is controversial with some suggesting 90 minutes

Chau EHL et al. *Anesthesiology.* 2012;117:188-205.
Hillman DR and Chung F. *Respirology.* 2017;22:230-239.

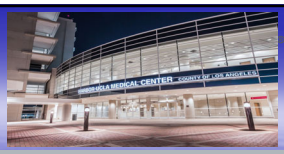
Postoperative Management: Monitoring



- The presence of the following may highlight vulnerability to ventilatory problems beyond the PACU
  - Recurrent bradypnea (RR < 8 breaths/minute)
  - Witnessed obstructive events (apneas lasting longer than 10 seconds)
  - Persistent hypoxemia requiring oxygen therapy
    - Desaturations < 90%
  - Other indices of hypoventilation such as elevated bicarbonate levels or hypercapnia
  - Mismatch between complaints of pain and levels of sedation
- If these are noted, further continuous oximetry and monitoring of ventilation should be considered

Hillman DR and Chung F. *Respirology.* 2017;22:230-239.
Raveendran R et al. *Curr Opin Anesthesiol.* 2017;30:146-155.

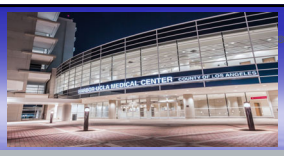
Postoperative Management: PAP Therapy



- Resumption of CPAP therapy, if feasible, should occur in the immediate postoperative period
  - Many guidelines recommend that the patient bring in their own machine and mask to ensure compliance and comfort with this interface
- Consider initiation of CPAP in individuals at risk for SDB who have recurring respiratory events while monitored in the PACU
  - A single fixed CPAP setting may not be effective in this setting likely related to fluid shifts, supine positioning, residual sedative effects
  - Use of autotitrating PAP (APAP) has shown significant reduction in postoperative AHI and improved oxygen saturations
    - Use with caution in patients at risk for OHS and opioid-induced hypoventilation

Chung F et al. *Chest.* 2016;149:586-597.
Rosslein M and Chung F. *Eur J Anaesthesiol.* 2018;35:245-255.

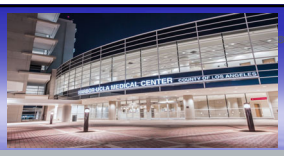
Postoperative Management: PAP Therapy



- A meta-analysis of 6 studies including 904 patients examined the effectiveness of CPAP therapy on postoperative outcomes, postoperative AHI, and length of stay in surgical patients with OSA plus CPAP versus patients with OSA without CPAP therapy
  - No significant difference in postoperative adverse events between the two groups
  - Patients who used CPAP either preoperatively and/or postoperatively compared with no CPAP had a risk ratio of 0.88 (0.73-1.06) and a 12% risk reduction of postoperative adverse events with a corresponding NNT to benefit of 45
  - The CPAP group had a significantly reduced postoperative AHI and a trend towards a shorter LOS

Chung F et al. *Chest.* 2016;149:586-597.
Nagappa N et al. *Anesth Analg.* 2015;120:1013-1023.

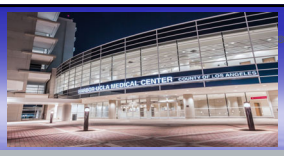
Postoperative Management: PAP Therapy



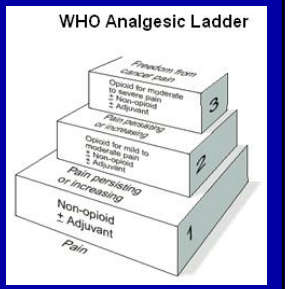
- Data collected from the Michigan Surgical Quality Collaborative of 52 community and academic hospitals compared postoperative 30-day cardiopulmonary complications between treated and untreated patients with OSA
  - Of 26,842 patients 2,646 (9.9%) had a diagnosis or suspicion of OSA and 55% of them were untreated
  - Documented OSA without therapy or suspicion of OSA was associated with higher cardiopulmonary complications (6.7% vs 4%; OR 1.8)
    - Myocardial infarction (adjusted OR 2.6) and reintubations (adjusted 2.5) were significantly higher in untreated OSA patients

Abdelsattar ZM et al. *Sleep.* 2015;38:1205-1210.
Chung F et al. *Chest.* 2016;149:586-597.

Postoperative Management: Analgesia

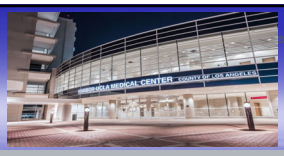


- Pain control is essential to allow patients to participate in deep breathing and coughing strategies postoperatively
- A multimodal approach to pain management should be applied and can include a combination of any of the following
  - Nonopioid adjuncts including acetaminophen, NSAIDs
  - Steroids
  - Ketamine
  - α_2 adrenergic agonists
    - Dexmedetomidine has sedative, amnestic, and analgesic properties and shown to decrease postoperative opioid without respiratory depression
  - Regional analgesia with local infiltration, epidural anesthesia, or peripheral nerve blockade



Hillman DR and Chung F. *Respirology.* 2017;22;230-239.
De Raaff CAL et al. *Curr Opin Anesthesiol.* 2018;31:104-109.

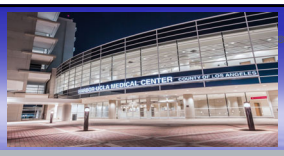
Special Considerations: Ambulatory Surgery



- The Society for Ambulatory Anesthesia has provided guidelines for the selection of OSA patients for ambulatory surgery
- STOP-Bang for screening should be performed prior to surgery
- Patients with OSA can be considered for ambulatory surgery if they have the following conditions met
  - Compliant on a stable PAP setting and able to use it upon discharge home
  - Comorbid conditions are optimized
  - Postoperative analgesia plan can be predominantly non-opioid
- Schedule the patient for the first case of the day to enable a longer monitoring time in the postanesthesia period

Joshi G et al. *Anesth Analg.* 2012;115:1160-1168.
Nightingale CE et al. *Anaesthesia.* 2015;70:859-876.

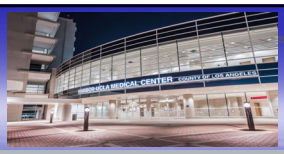
Future Directions



- **Risk stratification based on OSA phenotype**
  - An understanding of the predominant pathophysiology of OSA, known as the endotype and the identifiable morphological characteristics of an individual, known as the phenotype will give us more insight to guide screening, monitoring, and management strategies
  - Areas that play an important role in the pathogenesis of OSA include:
    - Upper airway anatomy
    - Tone of the upper airway dilator muscles
    - Arousal response of an individual
    - Stability of the respiratory system control

Madhusudan P et al. *Curr Opin Anesthesiol.* 2018;31:89-95.

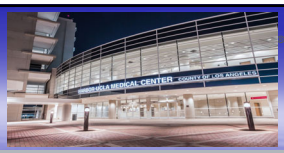
Future Directions



- **Areas for improvement include**
  - Development of better perioperative risk stratification with wider use of portable monitoring
  - Use of other metrics of OSA severity besides AHI
  - Closer regard for the possibility of coexistent hypoventilation
  - Development of cost-effective methods to continuously monitor ventilation outside high dependency areas such as the PACU and ICU
  - Use of telemetered data particularly for patients not being managed in a high dependency area
  - Increase use of PAP therapies postoperatively

Hillman DR and Chung F. *Respirology.* 2017;22:230-239.

Conclusions



- It is important to recognize obese patients with suspected sleep-disordered breathing including OSA and OHS preoperatively as many remain undiagnosed prior to this encounter with the healthcare system
  - There is growing evidence that patients with OHS have worse outcomes than patients with OSA alone
- A multidisciplinary care pathway is necessary to manage these high-risk patients to decrease their perioperative risk

USING TECHNOLOGY TO IMPROVE OUTCOMES IN SLEEP DISORDERED BREATHING

Shannon Sullivan, MD
Stanford University
Clinical Associate Professor

Saturday, January 19, 2019 – 10:40 a.m. – 11:10 a.m.

Shannon S. Sullivan, MD, is a Clinical Associate Professor at the Stanford University Department of Psychiatry and Behavioral Sciences, Center for Sleep Sciences, and is board certified in pediatrics, pediatric pulmonology, and sleep medicine. She is the Director of the Center's ACGME Sleep Medicine Fellowship program, and her interests include medical education as well as developmental aspects of familial OSA in childhood. She has served as an appointed member of the American Academy of Sleep Medicine Transportation and Safety Task Force, the Presidential Committee on Occupational Health, and the Sleep Public Safety Committee, on which she is serving at present.

Using Technology to Improve Outcomes in Sleep Disordered Breathing

Shannon S. Sullivan MD
Clinical Associate Professor
Sleep Medicine

STANFORD UNIVERSITY

January 19, 2018

Conflict of Interest Statement

I do not have any relationships with any entities producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients.

Due to the nature of the talk, commercial products are discussed; no endorsement is made.

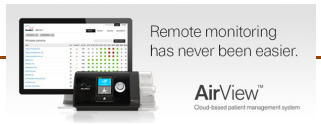
Learning Objectives

- Review outcomes-related data with respect to use of technologies to enhance the treatment of sleep disordered breathing
- Review newer delivery models such as telemedicine
- A look towards the future of consumer facing devices

The Landscape

- Sleep medicine is a poster child for dramatic change in models of care delivery and technology
- In recent years, home sleep testing has replaced a portion of laboratory sleep studies for the diagnosis of obstructive sleep apnea
- Consumer wearables and trackers, mobile applications, and health interfaces abound
- Remote device monitoring has advanced and is widely available on newer and a broader range of devices

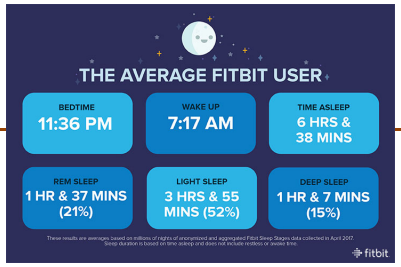
Opportunities

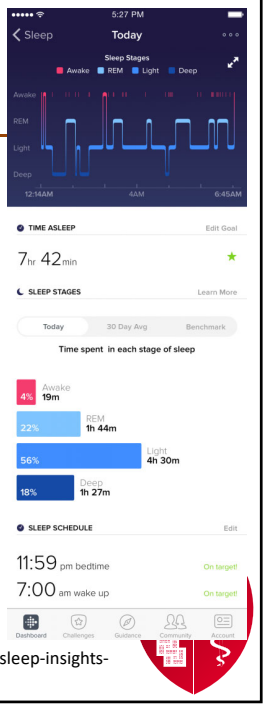


- New Treatments
  - Devices more adaptive than in the past
  - NIPPV for complicated or advanced respiratory disorders exist – patients with higher risk profile
  - Use of such devices often requires more proactive, nimble management
    - Patients highly reliant on devices
    - More rapid disease state change

- New superhighways of patient-derived data
  - Patient assessments and HST data can be remotely and securely scored and routed
  - Advent of usage data on cloud-based portals augments ability to manage patients remotely
    - Preset triggers to detect who might be struggling
    - Not just for CPAP/ BL any longer; ST, IVAPS, AVAPS, Trilogy, Astral available
  - Websites & mobile applications aimed at increased patient-facing information, tracking, and engagement
- New models of sleep center proximity, access
  - Remote in-home testing
  - Increasing interest and use of telehealth platforms, remote provider access, etc
  - Value based alternative payment models

Approach





- Remote Data collection
  - What/ which? And from where?
- Telemonitoring vs telemedicine: principles
  - Data provided to what/ whom?
  - *What happens next?*
  - Outcomes?
- Diagnostics and tracking: Consumer health vs medical tool?

"New Fitbit Features Deliver Data Previously Only Available Through a Sleep Lab", https://blog.fitbit.com/sleep-stages-and-sleep-insights-announcement/

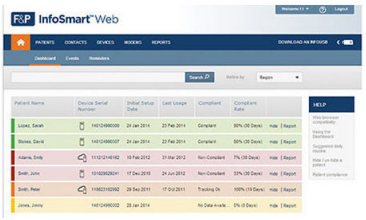
Remote PAP Monitoring: "The Cloud"

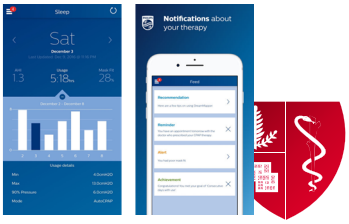
Industry-sponsored Portals

- Latest devices have wireless access to remote device data
- Most of the data available from a traditional "download" in clinic:
  - Hours of usage
  - Device-calculated proxies of AHI, leak, ventilation measures, patient-triggered breaths
  - In some scenarios, breath-to-breath data, leak, and event scoring
- Caution: different manufacturers detect and report differently
  - *Stay tuned for sessions at 1:40 and 2:20 today!*
- Patients can have access to some/ most of this data via smartphone apps or internet portals
- Also potential for alerts to patient or clinician if problems detected
- *Independent* outcomes data demonstrating consistent benefits of using patient-facing informatics on adherence to therapy largely absent until recently; also assessed by industry

Industry-sponsored Portals

- Resmed: AirView (web-based; for provider); MyAir (patient; web-based and/or mobile)
- Phillips Respironics: EncoreEverywhere (web-based; for provider; transitioning to CareOrchestrator in 2019) DreamMapper (patient; web-based and/or mobile)
- Fisher and Paykel: Infosmart Web (web-based)

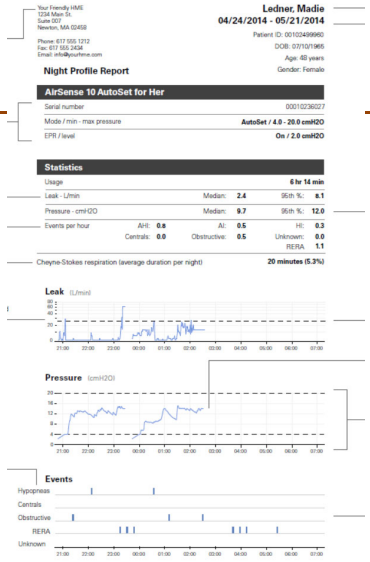




Encore is transitioning to Care Orchestrator

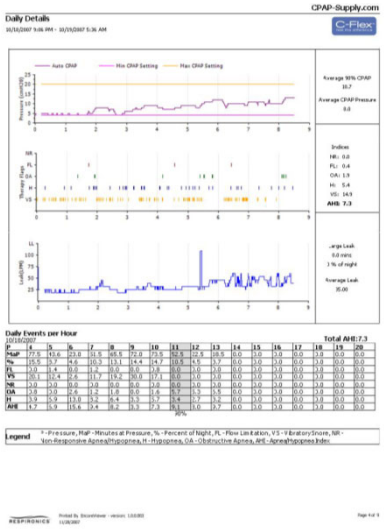
Resmed AirView

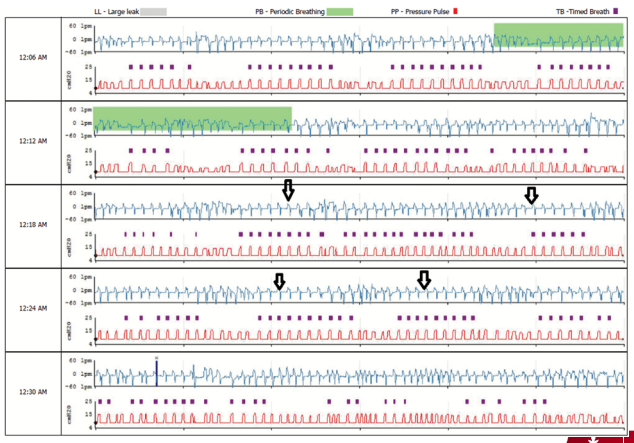
https://airview.resmed.com/resources/welcome-page/pdf/1018991_airview-report-guide_usa_eng.pdf



https://airview.resmed.com/resources/welcome-page/pdf/1018991_airview-report-guide_usa_eng.pdf

Phillips Encore Anywhere

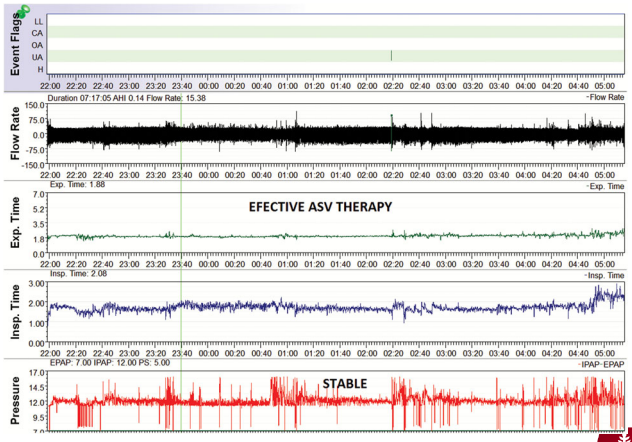




Estimation of adaptive ventilation success and failure using polysomnogram and outpatient therapy biomarkers. Sleep. 2018;41(9).

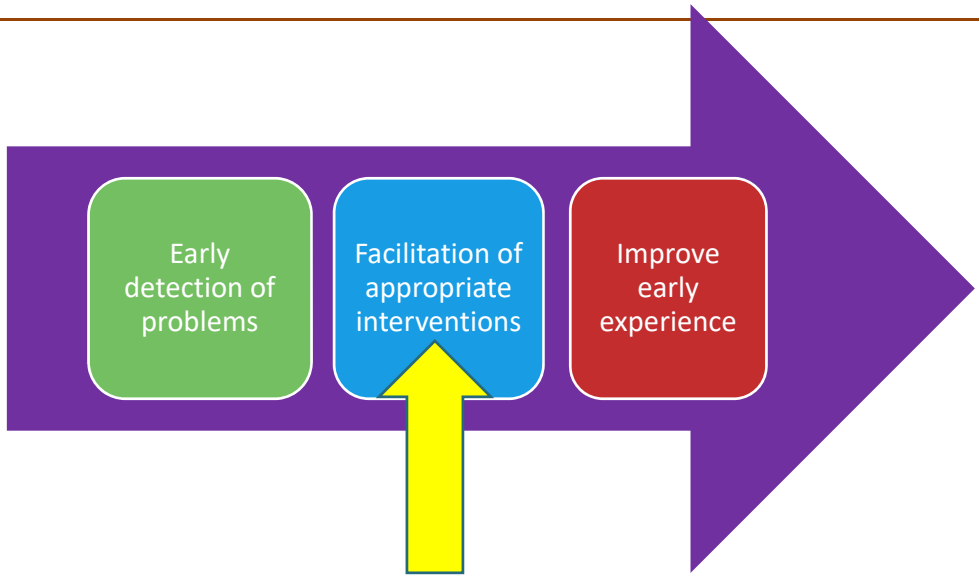
Sleepyhead

- https://sleepyhead.jedimark.net
- freeware enables review of data on SD cards
- flow, pressure, leak, inspiratory and expiratory times, and mean and median of respiratory rate, tidal volume, and minute ventilation



Thomas RJ et al. Urgent need to improve PAP management: the devil is in two (fixable) details. J Clin Sleep Med . 2017;13(5):657–664.

Remote PAP monitoring: "telemonitoring"



Early studies of remote PAP monitoring: depends what happens with the data…

Table 1 Remote monitoring of Positive Airway Pressure Therapy in OSA: published studies

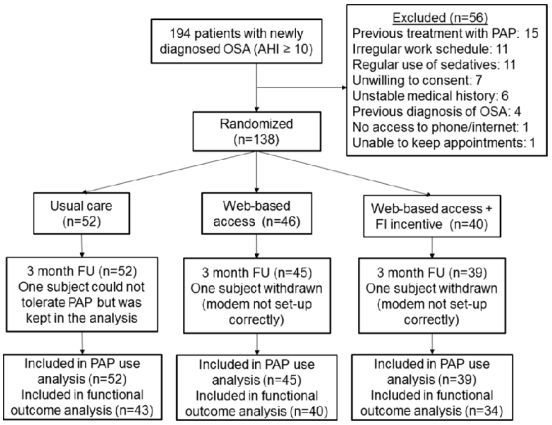
Author [reference]	Study design/ number of patients	Age (years)	Apnoea–hypopnoea index (number/hour)	Impact of TM on CPAP adherence	Functional outcomes	Patient's perception of TM	Labour/ cost-effectiveness
Stepnowsky CJ[19]	Pilot RCT/45	59 ± 14.3	39 ± 16.8	4.1 ± 1.8 (TM) vs 2.8 ± 2.2 (UC) hours, $P < 0.07$	No between groups differences for ESS, QOL (FOSQ)	No concern about being wirelessly monitored; wireless transmition data	NA
Fox N[24]							
Anttalainen U[24]							
Turino C[25]							
Munafo D[21]	RCT/140	52.3 ± 10.6 (TM); 50.0 ± 11.7 (UC)	34.3 ± 24.5 (TM); 27.4 ± 18.0 (UC)	No difference in 3 months CPAP adherence	NA	privacy aspects Program acceptance was high and similar in the two groups	Labour time for coaching was reduced in the TM arm

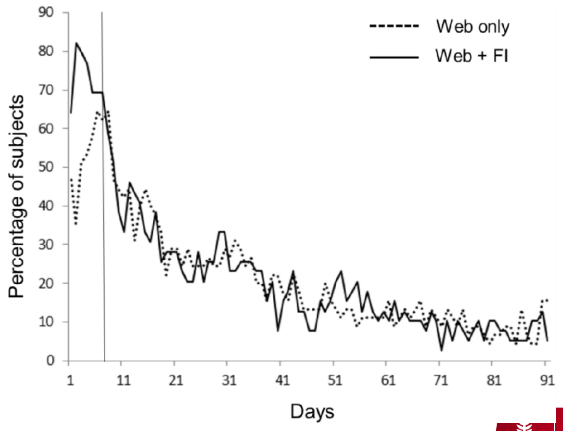
CPAP, continuous positive airway pressure; ESS, Epworth Sleepiness Scale; NA, not applicable; QOL (FOSQ), quality of life (Functional Outcomes of Sleep Questionnaire); RCT, randomized controlled trial; TM, telemonitoring; UC: usual care

The impact of telemonitoring on CPAP adherence is dependent on pre-existing 'usual care' in the control arm as well as what type of intervention is employed based on TM data

Pepin et al. Does remote monitoring change OSA management and CPAP adherence? Respirology. 2017 Nov;22(8):1508-1517. doi: 10.1111/resp.13183.

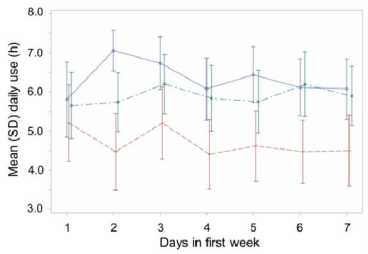
Empowering PAP adherence through patient-facing telemonitoring data?

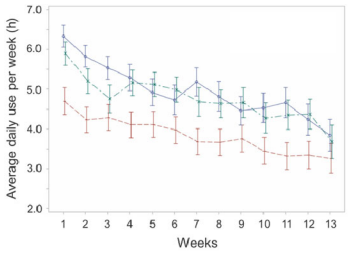


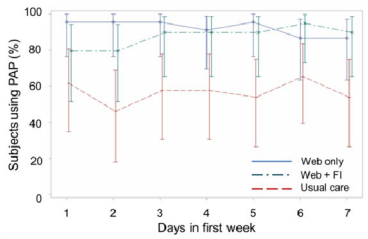


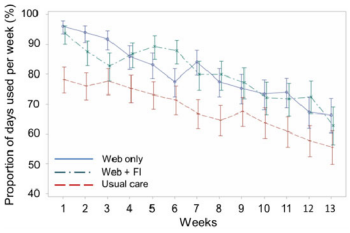
Kuna et al. Web-Based Access to Positive Airway Pressure Usage with or without an Initial Financial Incentive Improves Treatment Use in Patients with Obstructive Sleep Apnea. Sleep. 2015;38(8):1229-1236.

Improved adherence when given access to website-based PAP usage data









Kuna et al. Web-Based Access to Positive Airway Pressure Usage with or without an Initial Financial Incentive Improves Treatment Use in Patients with Obstructive Sleep Apnea Sleep. 2015;38(8):1229-1236.

Pairing Telemonitoring and Telemedicine in chronic conditions

Telemedicine

- "Delivery of health care services at a distance", using information and communication technology.
  - Telehealth: Electronic exchange of medical information to improve a patient's health status. Broader concept than telemedicine.
  - Telemedicine: A legal patient/clinician encounter using electronic communication.
- Major rationales for introduction: decreased costs, improved efficiency; increased access in health care delivery; potential for improved outcomes
- Sleep-specific rationales:
  - Increased opportunities to increase adherence rates in sleep disorder treatment management;
  - OSA – HST; PAP data downloads and feedback
  - Evaluation of home environment - assessing sleep dysfunction such as equipment problems, aspects of poor sleep hygiene, lighting, etc.

Methodologies of TM

- Asynchronous telemedicine
  - Patient and provider are separated by distance and time; information flows in one direction at a time
  - AKA **"store and forward"** (remote interpretation)
  - Common: eg, patient use of email and/or weblogs
  - May be patient self-directed; access to apps and online programs
- Synchronous telemedicine
  - Real-time interaction between provider and patient, eg by telephone or video.
  - Applications in both acute decision-making and intermittent, lower-level management of chronic illnesses
  - Increases access for patients who are either geographically isolated or find local travel challenging; improved specialist access

Kelly JM, Schwamm LH, Bianchi MT. Sleep Telemedicine: A Survey Study of Patient Preferences. ISRN Neurology. 2012;2012:135329. Dixon RF, Stahl JE. Virtual visits in a general medicine practice: a pilot study. Telemedicine and e-Health. 2008;14(6):525–530.

AASM Telemedicine Position Paper

Patient Education

"The Taskforce *endorses the use of telemedicine applications for education of patients with regard to all aspects of sleep care, including diagnostic tests and treatment.*"

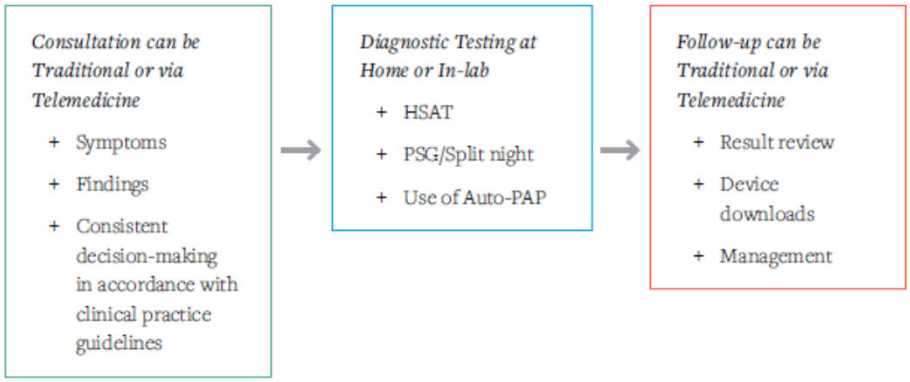
Follow-up Visits of Sleep Disorders

"Documentation of therapeutic adherence will be the responsibility of the provider who prescribes the initial therapy."

"In the case of PAP therapies, *sleep providers are encouraged to … monitor and improve PAP adherence as well as be available for follow-up visits as per current clinical standards…*"

Singh J, Badr MS, Diebert W, et al. American Academy of Sleep Medicine (AASM) position paper for the use of telemedicine for the diagnosis and treatment of sleep disorders. J Clin Sleep Med 2015;11(10):1187–1198.

Sample TM Workflow for Patients with OSA



Singh, J, et al. Sleep Telemedicine Implementation Guide. Darien, IL: AASM; 2017; https://aasm.org/download-the-sleep-telemedicine-implementation-guide-a-free-resource-from-aasm/

Potential For Growth in Telemedicine

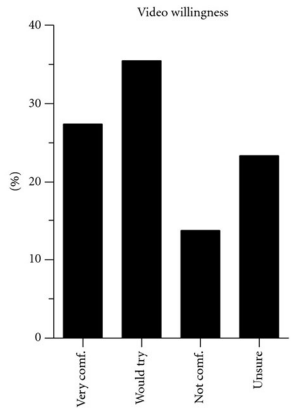
Telemedicine/ telehealth market remains one of the fastest growing sectors in the overall healthcare market.

Market estimated in last 2 years to be valued at $2.8-25 billion; with a compound annual growth rate (CAGR) of 17.85 – 27.5 percent.

While 47.7% of consumers not familiar with the term "telemedicine," 51.4% have received an email of text message from a doctor or clinician.

"The Brandigo State of Telemedicine Report: Reassessed for 2018;" accessed 5/31/18; http://brandigo.com/brandigo-pr-telemedicine-white-paper/
Cohen, J. The Growth of Telehealth: 20 Things to know. Accessed 5/31/18; https://www.beckershospitalreview.com/healthcare-information-technology/the-growth-of-telehealth-20-things-to-know.html

Majority of Sleep Patients Willing to Try TM



Kelly JM et al. Sleep telemedicine: a survey study of patient preferences. ISRN Neurol. 2012;2012:135329.

Acceptance using Telemedicine Platforms for OSA Management

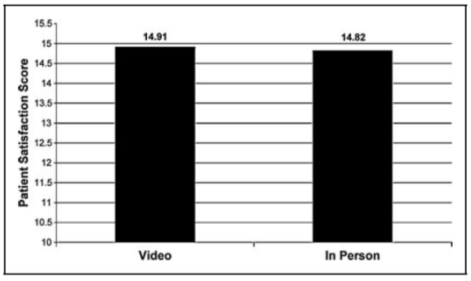


Fig. 1. Patient satisfaction score comparison.

Single center;
Initial appt in person or via TM

Table 1. Descriptive Statistics—Patient Satisfaction

	IN PERSON	VIDEOCONFERENCE
Number of patients (n=90)	56	34
Sex		
Male (%)	25 (44.64%)	14 (42.42%)
Female (%)	31 (55.36%)	19 (57.58%)
Not reported		1
Age		
Mean (standard deviation)	53.70 (15.15)	49.21 (13.62)
Median	56	47.5
Minimum	23	24
Maximum	85	79
Ethnicity		
White (%)	49 (100%)	24 (92.30%)
Asian (%)	0 (0%)	1 (3.85%)
Hispanic (%)	0 (0%)	1 (3.85%)
Not reported	7	8

Parikh R et al. Sleep telemedicine: patient satisfaction and treatment adherence. Telemed J E Health. 2011 Oct;17(8):609-14.

Equivalent PAP Adherence Using Telemedicine Platforms

Table 4. Mann–Whitney Test—Treatment Adherence (Percentage of Nights Use ≥4 h)

	IN PERSON (N=111)	VIDEOCONFERENCE (N=61)
Percentage of nights with use ≥4 h	0.71	0.65
Standard deviation	0.33	0.33
Minimum	0.00	0.00
Maximum	1.00	1.00
Mann–Whitney test		
p-Value	0.198	

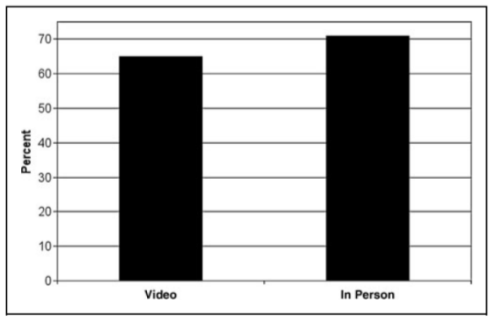
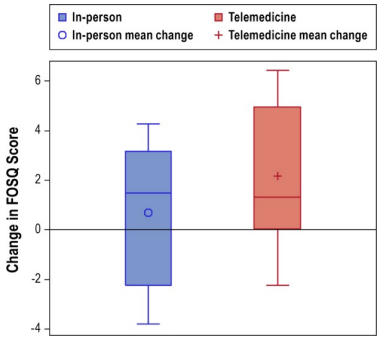


Fig. 2. Percentage of nights continuous positive airway pressure (CPAP) was used ≥4 h.

Parikh R et al. Sleep telemedicine: patient satisfaction and treatment adherence. Telemed J E Health. 2011 Oct;17(8):609-14.

Feasibility and Acceptance

- Prospective, parallel-group randomized pilot study
- Assessed feasibility of telemedicine for OSA evaluation and management vs. traditional, in-person care
- 60 Veterans at 3 affiliated VA locations
- Video vs in-person visit; HST; APAP; phone follow up at 1w; phone (w download) vs. in- person at 1m, and 3m
- PAP adherence NS between groups
- ESS improvement NS between groups
- TM highly accepted in this population



Fields BG et al. Remote Ambulatory Management of Veterans with Obstructive Sleep Apnea. Sleep. 2016 Mar 1;39(3):501-9.

Access

- Study at a single VA hospital found telemedicine resulted in an average travel savings of 145 miles and 142 minutes per visit;
- Patients to take less time off from work, associated with high levels of patient satisfaction

Watson NF. Expanding Patient Access to Quality Sleep Health Care through Telemedicine.
J Clin Sleep Med. 2016 Feb;12(2):155-6. Russo JE, McCool RR, Davies L, authors. VA telemedicine: an analysis of cost and time savings. Telemed J E Health. 2015.
Markwick L, McConnochie K, Wood N, authors. Expanding telemedicine to include primary care for the urban adult. J Health Care Poor Underserved. 2015;26:771–6

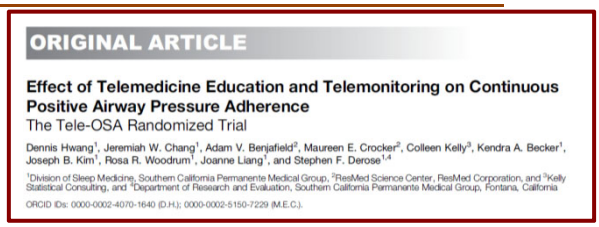
REVAMP Trial

- VA-sponsored trial, goal 350 participants
- Randomized, open label
- Access to interactive website Veterans complete intake and follow-up questionnaires on the REVAMP website and perform an unattended home sleep test (HST) without in-person instructions.
- Sleep specialists review the findings with the patient during an initial phone clinic.
- REVAMP auto-populates the Veteran's questionnaire responses into templated progress notes that are exported to CPRS, the electronic medical record.
- Veterans diagnosed with OSA are treated with APAP
- Data wirelessly transmitted to the website where treatment use and its effectiveness can be monitored by both Veterans and practitioners, thereby promoting patient self-management and productive patient-practitioner interactions.
- Designed to improve access to care, reduce patient wait times, and allow Veterans to receive care without travelling to a sleep center. End point is non-inferior care

clinicaltrials.gov; ClinicalTrials.gov Identifier: NCT03007745

Telemonitoring and Telemedicine in OSA

- N= 1455, mean age 49 ± 12.5 years, RCT
  - 956 underwent HST
  - 556 prescribed CPAP
- 2 telemedicine interventions were tested:
  - Web-based OSA education (Tel-Ed)
  - PAP telemonitoring with automated patient feedback (Tel-TM)
- 4-arm randomized trial
  - Usual care
  - Tel-Ed
  - Tel-TM
  - Tel-Ed + Tel-TM



ORIGINAL ARTICLE

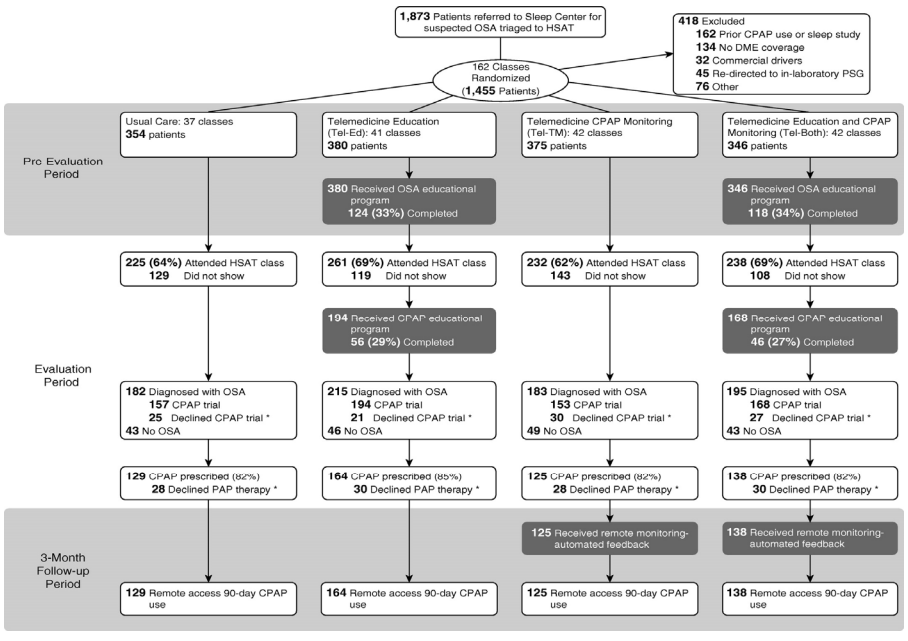
Effect of Telemedicine Education and Telemonitoring on Continuous Positive Airway Pressure Adherence
The Tele-OSA Randomized Trial

Dennis Hwang[1], Jeremiah W. Chang[1], Adam V. Benjafield[2], Maureen E. Crocker[2], Colleen Kelly[3], Kendra A. Becker[1], Joseph B. Kim[1], Rosa R. Woodrum[1], Joanne Liang[1], and Stephen F. Derose[1,4]

[1]Division of Sleep Medicine, Southern California Permanente Medical Group, [2]ResMed Science Center, ResMed Corporation, and [3]Kelly Statistical Consulting, and [4]Department of Research and Evaluation, Southern California Permanente Medical Group, Fontana, California

ORCID IDs: 0000-0002-4070-1640 (D.H.); 0000-0002-5150-7229 (M.E.C.).

Hwang D, Chang JW, Benjafield AV, Crocker ME, Kelly C, Becker KA, Kim JB, Woodrum RR, Liang J, Derose SF. Effect of Telemedicine Education and Telemonitoring on Continuous Positive Airway Pressure Adherence. The Tele-OSA Randomized Trial. Am J Respir Crit Care Med. 2018 Jan 1;197(1):117-126.

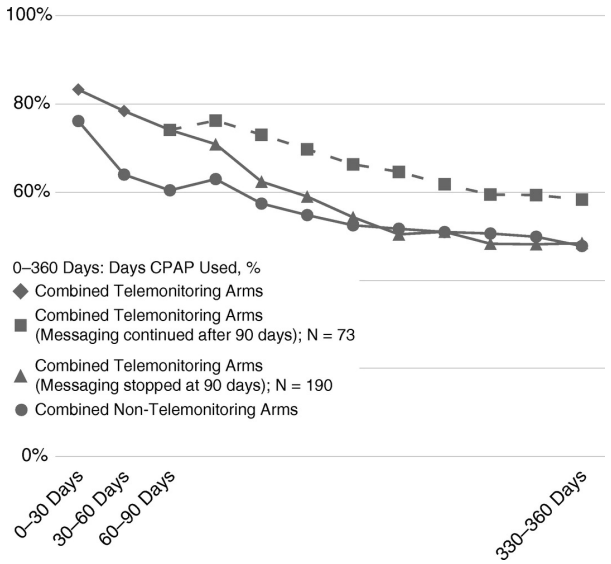


Hwang D, Chang JW, Benjafield AV, Crocker ME, Kelly C, Becker KA, Kim JB, Woodrum RR, Liang J, Derose SF. Effect of Telemedicine Education and Telemonitoring on Continuous Positive Airway Pressure Adherence. The Tele-OSA Randomized Trial. Am J Respir Crit Care Med. 2018 Jan 1;197(1):117-126.

Table 3. CPAP Use and Subjective Outcomes 90 Days after CPAP Dispensation

	Usual Care	Tel-Ed	Tel-TM	Tel-Both	Tel-Ed Effect (95% CI), *P* Value	Tel-TM Effect (95% CI), *P* Value	Tel-Both Effect (95% CI), *P* Value
	n = 129	*n* = 163	*n* = 125	*n* = 138			
Days used, %	64.8 ± 34.2	68.6 ± 31.3	76.6 ± 28.3	78.3 ± 28.3	2.8 (−2.3 to 7.9), 0.28	10.6 (5.5 to 15.7), <0.0001	13.4 (6.1 to 20.8), 0.0004
Average usage on all days, h	3.8 ± 2.5	4.0 ± 2.4	4.4 ± 2.2	4.8 ± 2.3	0.3 (−0.1 to 0.7), 0.10	0.8 (0.4 to 1.15), 0.0002	1.1 (0.5 to 1.7), 0.0002
Average usage on days used, h	5.2 ± 1.8	5.2 ± 1.8	5.3 ± 1.7	5.8 ± 1.6	0.2 (−0.1 to 0.5), 0.13	0.4 (0.1 to 0.7), 0.006	0.6 (0.2 to 1.0), 0.003
Medicare adherence, *n* (%)	69 (53.5)	100 (61.0)	82 (65.6)	101 (73.2)	1.4* (1.0 to 2.0), 0.07	1.7* (1.2 to 2.4), 0.003	2.4* (1.4 to 3.9), 0.001
	n = 83	*n* = 113	*n* = 90	*n* = 93			
Change in ESS score†	−3.7 ± 4.7	−2.8 ± 6.4	−3.7 ± 5.2	−3.0 ± 3.7	0.8 (−0.2 to 1.9), 0.13	−0.14 (−1.2 to 0.9), 0.80	0.7 (−0.9 to 2.3), 0.38
Change in FOSQ-10 score†	−14.2 ± 10.3	−9.9 ± 12.9	−10.9 ± 11.2	−11.3 ± 12.8	1.9 (−0.8 to 4.5), 0.16	0.6 (−2.0 to 3.3), 0.64	2.5 (−1.3 to 6.4), 0.20

Hwang D, Chang JW, Benjafield AV, Crocker ME, Kelly C, Becker KA, Kim JB, Woodrum RR, Liang J, Derose SF. Effect of Telemedicine Education and Telemonitoring on Continuous Positive Airway Pressure Adherence. The Tele-OSA Randomized Trial. Am J Respir Crit Care Med. 2018 Jan 1;197(1):117-126.



Hwang D, Chang JW, Benjafield AV, Crocker ME, Kelly C, Becker KA, Kim JB, Woodrum RR, Liang J, Derose SF. Effect of Telemedicine Education and Telemonitoring on Continuous Positive Airway Pressure Adherence. The Tele-OSA Randomized Trial. Am J Respir Crit Care Med. 2018 Jan 1;197(1):117-126.

Results

- Usage was significantly higher in the Tel-TM and Tel-both groups versus usual care (P = 0.0002 for both) but not for Tel-Ed (P = 0.10)
- CPAP telemonitoring with automated feedback messaging improved 90-day adherence in patients with OSA. Telemedicine-based education did not significantly improve CPAP adherence but did increase clinic attendance for OSA evaluation.
- *The improvement was observed without requiring additional provider intervention.*

Enhancement of TM using patient-facing apps

- Retrospective study funded by Resmed
- Patients initiated PAP therapy between 2009-2014
- Managed either using telemedicine (AirView™; "proactive care" group) or telemedicine + patient engagement app (AirView™ + myAir™; "patient engagement")
- Proactive care: homecare provider telephoned patients if compliance during the first 2 weeks of PAP therapy fell below the required level (<4 h/day).
  - 2 weeks - 6 months: patients were telephoned again if continued periods of no or low usage were identified from telemonitoring data.
  - 6 months+: patients were notified via telephone call or letter if telemonitoring data showed that PAP device usage dropped significantly or did not reach the required threshold (average of 4 h/night).
  - When contacted, patients were provided with detailed information on use of their PAP therapy device and management of side effects (eg, upper airway dryness, pressure, etc).

Woehrle H, Arzt M, Graml A, Fietze I, Young P, Teschler H, Ficker JH. Effect of a patient engagement tool on positive airway pressure adherence: analysis of a German healthcare provider database. Sleep Med. 2018 Jan;41:20-26.

Data at 180 days of therapy

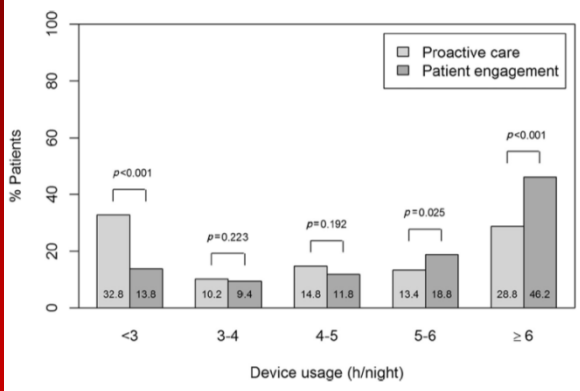


Table 4
Sleep apnea parameters.

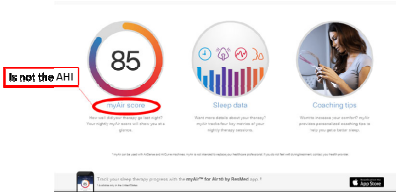
	Proactive care ($n = 500$)	Patient engagement ($n = 500$)	Difference	p
Apnea-hypopnea index, /hour				
Mean ± SD	3.1 ± 3.6	2.8 ± 3.3	−0.3 ± 4.9	0.181
Median (IQR)	1.9 (0.9, 3.5)	1.7 (0.9, 3.2)		
Apnea index, /hour				
Mean ± SD	2.1 ± 2.9	1.9 ± 2.7	−0.2 ± 3.9	0.161
Median (IQR)	1.1 (0.6, 2.4)	1.1 (0.4, 2.1)		
Hypopnea index, /hour				
Mean ± SD	0.9 ± 1.2	0.8 ± 1.2	−0.1 ± 1.8	0.460
Median (IQR)	0.5 (0.2, 1.0)	0.4 (0.2, 1.0)		
Leak, L/minute				
Mean ± SD	4.1 ± 5.3	2.7 ± 4.0	−1.4 ± 6.7	<0.001
Median (IQR)	2.3 (0.6, 5.7)	1.3 (0.3, 3.5)		

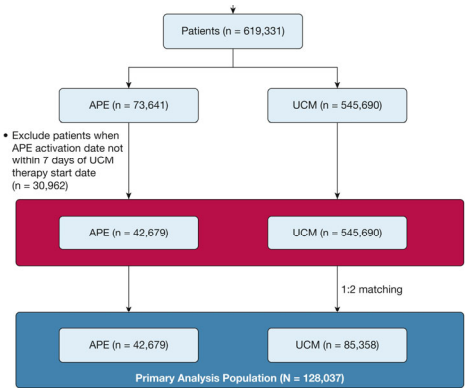
Woehrle H, Arzt M, Graml A, Fietze I, Young P, Teschler H, Ficker JH. Effect of a patient engagement tool on positive airway pressure adherence: analysis of a German healthcare provider database. Sleep Med. 2018 Jan;41:20-26.

Patient-facing interventions alone?

Resmed Active Patient Engagement

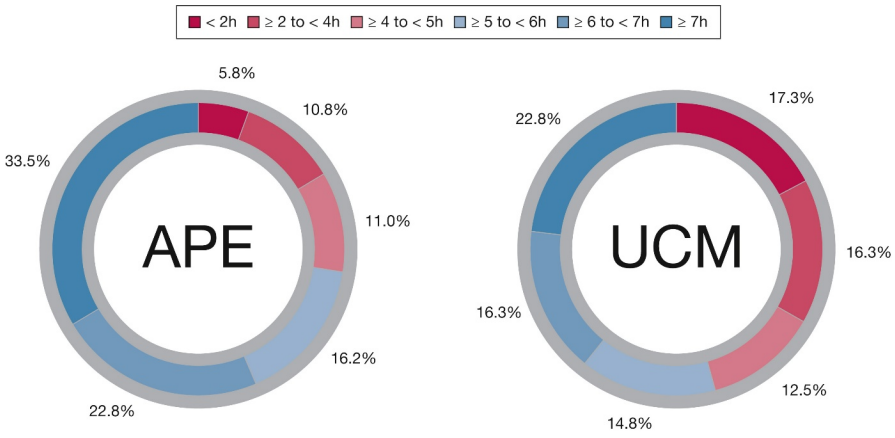
- Retrospective; 128,037 pts analyzed
- APE = MyAir
- MyAir score, usage based praise, badges, etc
- Tips on making PAP more comfortable
- Personalized coaching and reinforcement sent via email
- Increase self management reward success, resolve basic issues
- Primary outcome: % compliance in first 90 days





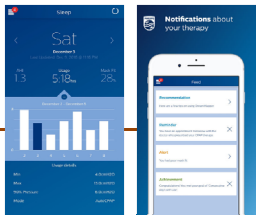
Malhotra A et al. Patient Engagement Using New Technology to Improve Adherence to Positive Airway Pressure Therapy: A Retrospective Analysis. Chest. 2018 Apr;153(4):843-850.

Adherence: APE 87.3% vs UC 70.4%



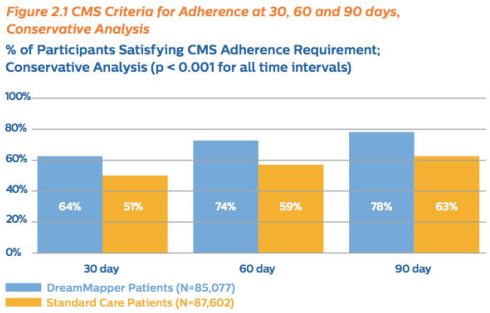
Malhotra A et al. Patient Engagement Using New Technology to Improve Adherence to Positive Airway Pressure Therapy: A Retrospective Analysis. Chest. 2018 Apr;153(4):843-850.

DreamMapper



N ~ 173,000 pts

- PAP with DreamMapper vs not
- 90-day compliance 78% (vs 63%)
- Average usage 1.1 hours longer



Hardy et al. A Mobile Application and website to engage sleep apnea patients in PAP therapy and improve adherence to treatment. Phillips Respironics White Paper, 2016.

Consumer health space and diagnostics?

Is the future of medicine a smartphone?

THE WALL STREET JOURNAL

The Saturday Essay

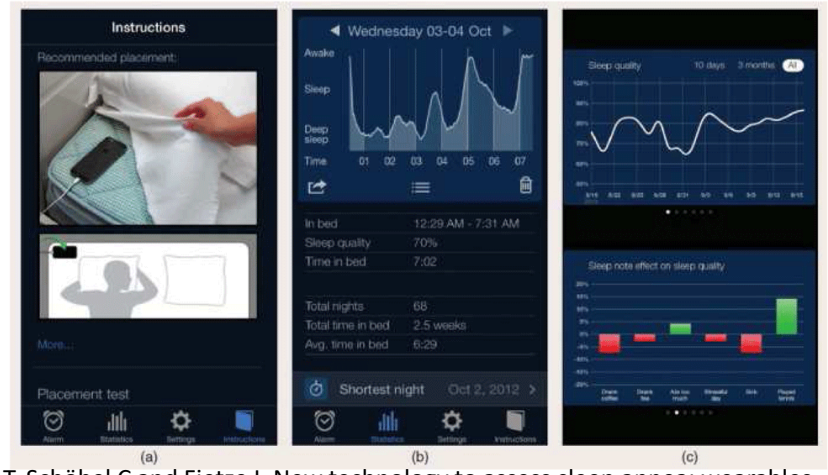
The Future of Medicine Is in Your Smartphone: New tools are tilting health-care control from doctors to patients By Eric J. Topol Jan. 9, 2015

Advancement of Consumer-facing tools

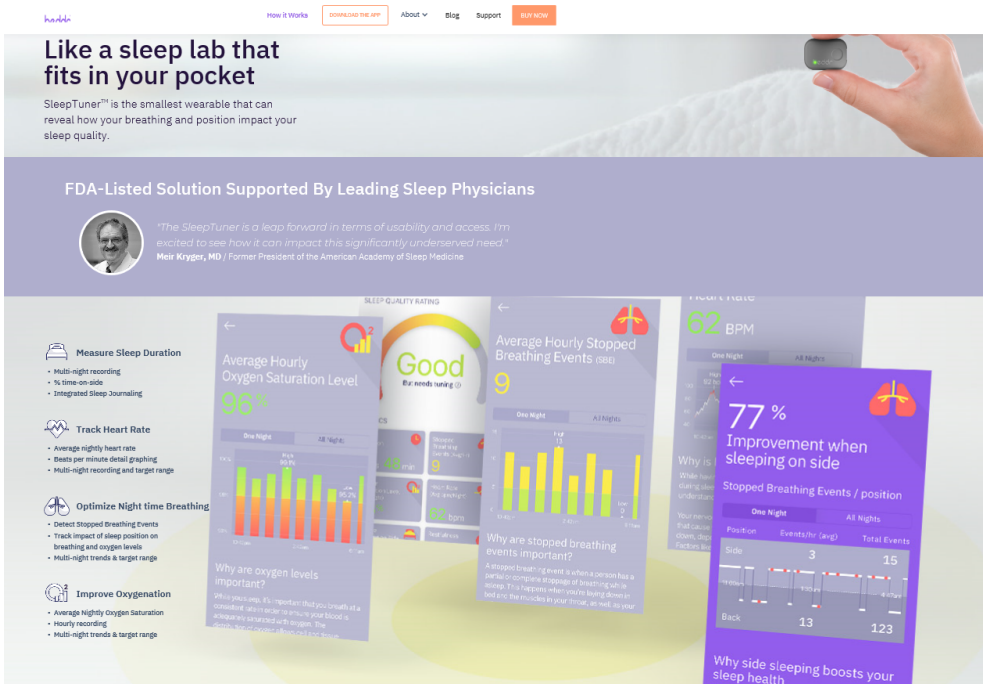
- Use of smartphone to detect OSA for almost 15 years
- Ever-growing number of consumer devices in the sleep space
- Smartphones: fast processing, ability to monitor ambient light and noise, accelerometery, low cost oximetry probes (HR and O2 sat) – requires beat to beat processing

Ishida R, Yonezawa Y, Maki H, et al.: A wearable, mobile phone-based respiration monitoring system for sleep apnea syndrome detection. Biomed Sci Instrum. 2005; 41: 289–93.

Ex: Smartphone applications to track sleep without external sensors: gimmicks?



Penzel T, Schöbel C and Fietze I. New technology to assess sleep apnea: wearables, smartphones, and accessories [version 1]. F1000Research 2018, 7:413.



Day or night, in the gym or while you sleep, the wearable watch style **BodiMetrics™ O_2 Vibe™** Sleep & Fitness Monitor helps you keep track of oxygen (SpO_2) levels, pulse rate and motion, during sleep and counts steps during exercise. If the **O_2 Vibe**'s built-in sensor detects a drop in oxygen levels while you sleep, an adjustable vibration function stimulates you to change positions. You can record up to 10 hours during sleep and 5 hours during activity, and download the data to your Android or iOS device.

Small, lightweight but packed with features

- Built-in sensor to track and analyze oxygen levels and sleep quality
- Vibrates when it detects a drop of oxygen saturation in the blood
- Two modes: sleep mode monitors SpO_2 levels, heart rate and motion during sleep; fitness mode monitors SpO_2 levels, heart rate and counts steps during light exercise.
- Customizable settings, alerts and vibration level.
- Pairs with device via available free app and Bluetooth
- Includes one soft thumb ring sensor and USB charging cable
- Rechargeable via USB and included cable
- So light you'll hardly notice it – just 1.6 oz.

The **BodiMetrics O_2 Vibe** fits on your wrist and has a thumb sensor to track heart rate and motion, and detect drops in oxygen levels. In sleep mode, the monitor vibrates when your oxygen level drops to stimulate you to change position, which can be helpful for people who snore. The quiet, adjustable vibration setting gently wakes you when your SpO_2 falls below the threshold you set, without disturbing your partner.

In the morning, you can see when and how often your blood oxygen levels dropped. With our **FREE mobile app**, you can preserve data and trends, see full color graphs and reports on your nightly oxygen levels, heart rate, and motion, including averages, lowest levels, duration, and overall score. You can share these with your health care provider via a secure cloud service.

*See the link below to download the complete **Quick Start Guide***

JCSM
Journal of Clinical Sleep Medicine

SPECIAL ARTICLES

Clinical Use of a Home Sleep Apnea Test: An Updated American Academy of Sleep Medicine Position Statement

Ilene M. Rosen, MD, MS[1]; Douglas B. Kirsch, MD[2]; Kelly A. Carden, MD[3]; Raman K. Malhotra, MD[4]; Kannan Ramar, MD[5]; R. Nisha Aurora, MD[6]; David A. Kristo, MD[7]; Jennifer L. Martin, PhD[8,9]; Eric J. Olson, MD[5]; Carol L. Rosen, MD[10]; James A. Rowley, MD[11]; Anita V. Shelgikar, MD, MHPE[12]; American Academy of Sleep Medicine Board of Directors

[1]Division of Sleep Medicine, Perelman School of Medicine, University of Pennsylvania, Philadelphia, Pennsylvania; [2]Carolinas Healthcare Medical Group Sleep Services, Charlotte, North Carolina; [3]Saint Thomas Medical Partners - Sleep Specialists, Nashville, Tennessee; [4]Washington University Sleep Center, St. Louis, Missouri; [5]Division of Pulmonary and Critical Care Medicine, Center for Sleep Medicine, Mayo Clinic, Rochester, Minnesota; [6]Johns Hopkins University, School of Medicine, Baltimore, Maryland; [7]University of Pittsburgh, Pittsburgh, Pennsylvania; [8]Veteran Affairs Greater Los Angeles Healthcare System, North Hills, California; [9]David Geffen School of Medicine at the University of California, Los Angeles, California; [10]Department of Pediatrics, Case Western Reserve University, University Hospitals - Cleveland Medical Center, Cleveland, Ohio; [11]Wayne State University, Detroit, Michigan; [12]University of Michigan Sleep Disorders Center, University of Michigan, Ann Arbor, Michigan

The diagnosis and effective treatment of obstructive sleep apnea (OSA) in adults is an urgent health priority. It is the position of the American Academy of Sleep Medicine (AASM) that only a medical provider can diagnose medical conditions such as OSA and primary snoring. Throughout this statement, the term "medical provider" refers to a licensed physician and any other health care professional who is licensed to practice medicine in accordance with state licensing laws and regulations. A home sleep apnea test (HSAT) is an alternative to polysomnography for the diagnosis of OSA in uncomplicated adults presenting with signs and symptoms that indicate an increased risk of moderate to severe OSA. It is also the position of the AASM that: the need for, and appropriateness of, an HSAT must be based on the patient's medical history and a face-to-face examination by a medical provider, either in person or via telemedicine; an HSAT is a medical assessment that must be ordered by a medical provider to diagnose OSA or evaluate treatment efficacy; an HSAT should not be used for general screening of asymptomatic populations; diagnosis, assessment of treatment efficacy, and treatment decisions must not be based solely on automatically scored HSAT data, which could lead to sub-optimal care that jeopardizes patient health and safety; and the raw data from the HSAT device must be reviewed and interpreted by a physician who is either board-certified in sleep medicine or overseen by a board-certified sleep medicine physician.

Keywords: home sleep apnea test, HSAT, obstructive sleep apnea, OSA
Citation: Rosen IM, Kirsch DB, Carden KA, Malhotra RK, Ramar K, Aurora RN, Kristo DA, Martin JL, Olson EJ, Rosen CL, Rowley JA, Shelgikar AV; American Academy of Sleep Medicine Board of Directors. Clinical use of a home sleep apnea test: an updated American Academy of Sleep Medicine position statement. *J Clin Sleep Med.* 2018;14(12):2075–2077.

Maintains:

- Only a license practitioner can diagnose a medical condition
- HSTs should not be used for screening the asymptomatic
- Diagnosis should not be made solely on automatically scored HST; raw data must be reviewed by BC sleep MD

Rosen IM, Kirsch DB, Carden KA, Malhotra RK, Ramar K, Aurora RN, Kristo DA, Martin JL, Olson EJ, Rosen CL, Rowley JA, Shelgikar AV; American Academy of Sleep Medicine Board of Directors. Clinical use of a home sleep apnea test: an updated American Academy of Sleep Medicine position statement. J Clin Sleep Med. 2018;14(12):2075–2077.

Integrating new tools into a Patient-Centered Approach

Pepin et al. Does remote monitoring change OSA management and CPAP adherence? Respirology. 2017 Nov;22(8):1508-1517. doi: 10.1111/resp.13183.

Summary

"It is ironic that the least complex and most healthy individuals get the maximum oversight – CPAP compliance is vigorously tracked in OSA patients, with a pathologically obsessive fixation on four hours of use per night regardless of severity, comorbid illnesses, or native sleep times, and the device "taken away" if adequate use is not demonstrable. Biological and clinical efficacies are nearly irrelevant. Patients in respiratory failure can obtain a bilevel ventilator with no polysomnographic data or long-term tracking requirements... In this day and age, our management should be data driven – clinical and device, of the highest quality and resolution, and dynamically tracked (over time). Blind assumptions of device efficacy raise the likelihood of harm. Once we try to manipulate respiratory drive and rhythm, adaptive and maladaptive outcomes are possible and readily recognizable, if the raw data are reviewed and analyzed."

Thomas R., Sleep Medicine 16 (2015) 1582–1583

Thank you!

UTILITY OF THE IN LAB POLYSOMOGRAM IN A NEW ERA OF HOME SLEEP TESTING

Won Lee, MD
University of Texas Southwestern Medical Center
Associate Professor

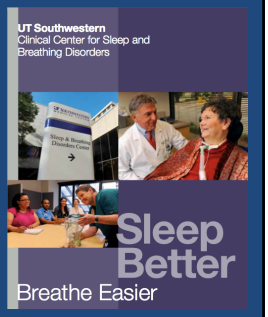
Saturday, January 19, 2019 – 11:10 a.m. – 11:40 a.m.

Won Lee, MD, is an associate professor in pulmonary, critical care and sleep medicine at the University of Texas Southwestern Medical Center in Dallas, Texas. He serves as medical director of the Sleep and Breathing Disorders Center. His primary clinical interests include sleep disordered breathing and neuromuscular pulmonary disorders.

Utility of the In Lab Polysomnogram in a New Era of Home Sleep Testing

California Thoracic Society – 2019

Won Y. Lee, MD
Associate Professor, Division of Pulmonary and Critical Care Medicine
Medical Director – Clinical Center for Sleep and Breathing Disorders Center
University of Texas Southwestern Medical Center
Dallas, Texas



UT Southwestern Medical Center

I have no financial disclosures to declare.

Topics to cover

- The past
  - The history of home sleep apnea testing
- The present
  - How home sleep apnea testing affects clinical practice
- The future
  - What will happen to the sleep laboratory?

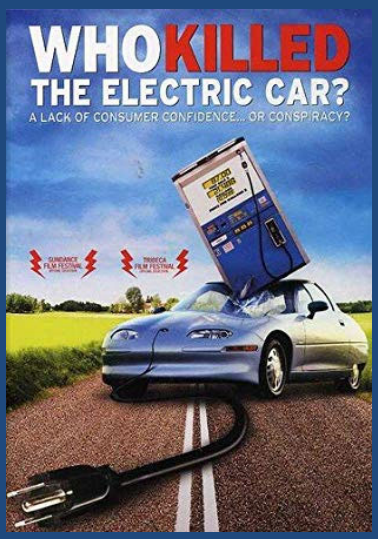
Topics to cover

- The past
  - The history of home sleep apnea testing
- The present
  - How home sleep apnea testing affects clinical practice
- The future
  - What will happen to the sleep laboratory?

How is a home sleep study, similar to a Tesla?

How is a home sleep study, similar to a Tesla?

- CARB (California Air-Resources Board)
  - 1990
  - Zero-emissions vehicle (ZEV) mandate
    - Required major automobile suppliers to offer electric vehicles in order to continue gasoline powered vehicles
    - General Motors – EV1
- CARB was subsequently REVERSED
  - WHY?
    - Practical reasons
      - American consumers
      - Batteries
    - Relentless pressure
      - Automobile manufacturers
      - Oil industry
      - Political pressure
      - Financial ?



Sony Pictures Classics. 2006.

How is a home sleep study, similar to a Tesla?

TABLE 1
Population-based studies reporting the prevalence of OSA and OSA syndrom

Study	Number of subjects	AHI ≥ 5	AHI ≥ 15	OSA syndrome	Methodology	Hypopnea Definition†
Wisconsin, U.S.A.‡ 1993 [20]	Men: 352 Women: 250 (age 30–60)	Men: 24% Women: 9%	Men: 9% Women: 4%	Men: 4% Women:2%	Attended PSG (oronasal airflow and respiratory inductance plethysmography)	Discernable reduction in airflow plus ≥ 4% oxygen desaturation ‡
Pennsylvania, U.S.A.¶ 1998, 2001 [22,23]	Men: 741 Women: 1000 (age 20–100)	Men: 17% Women: 5%	Men: 7% Women: 2%	Men: 3.3% Women:1.2%	Attended PSG (oronasal thermocouple)	Discernable reduction in airflow and ≥ 4% oxygen desaturation ‡
Spain ¶ 2001 [21]	Men: 325 Women: 235 (age 30–70)	Men: 26% Women:28%	Men: 14% Women:7%	Men: 3.4% Women:3%	Attended PSG (oronasal thermister)	50% airflow reduction Accompanied by either ≥ 4% oxygen desaturation or an EEG arousal
Australia ‡ 1995 [24]	294 men (age 40–65)	Men: 25.9%	Men: 10% (AI[illegible] 10)		MESAM IV portable monitoring (snoring and oximetry)	≥ 3% oxygen desaturation along with increased heart rate of 10 beats/minute or burst of snoring ‡
Hong Kong, China ‡ 2001, 2004 [25,26]	Men: 153 Women:106 (age 30–60)	Men: 8.8% Women: 3.7%	Men:5.3% Women: 1.2%	Men: 4.1% Women:2.1%	Attended PSG (oronasal thermister, thoracic and abdominal impedance belts)	Discernable reduction in airflow and ≥ 4% oxygen desaturation ‡
Korea ‡ 2004 [27]	Men: 309 Women: 148 (age 40–69)	Men: 27% Women: 16%	Men: 10.1% Women: 4.7%	Men: 4.5% Women:3.2%	In laboratory or home PSG (oronasal thermister)	Discernable reduction in airflow and ≥ oxygen 4% desaturation ‡
India ‡ 2004 [28]	250 men (age 35–65)	Men: 19.5%	Men: 8.4%	[illegible]	Home PSG (oronasal thermister)	Discernable 50% reduction in airflow and ≥ 4% oxygen desaturation ‡
India ‡ 2006 [29]	Men: 88 Women: 63 (age 30–60)	Men: 19.7% Women: 7.4%	n/a	Men: 4.9% Women:2.1%	Attended in laboratory PSG	Discernable 50% reduction in airflow and ≥ 4% oxygen desaturation ‡

Lee WY et al. Expert Rev Respir Med. 2008 June 1; 2(3): 349–364

History of sleep testing

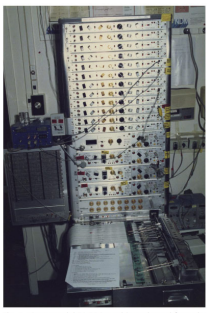


Fig. 1. Grass model 78 EEG machine adapted for polysomnographic recording.

Hirshkowitz

Fig. 2. Sleep laboratory control room, circa 1979.

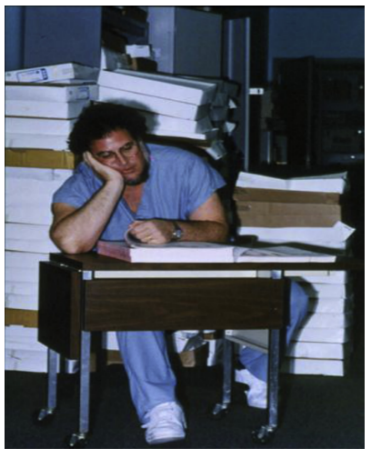
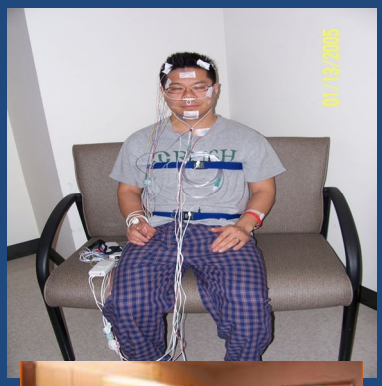


Fig. 4. Author surrounded by a sea of paper polysomnograms.

Hirshkowitz, M. Polysomnography Challenges. Sleep Med Clin 11 (2016) 403-411.

Home sleep testing



Lightweight and compact for comfortable sleeping.

www.healthcare.philips.com

Management of Obstructive Sleep Apnea Syndrome in the Home*

The Role of Portable Sleep Apnea Recording

Michael P. Coppola, M.D., F.C.C.P.;† and Michael Lawee, B.S., R.R.T.

1993

Unattended four-channel sleep apnea recording has been shown to be an accurate tool in the diagnosis of moderate to severe obstructive sleep apnea. We selected 11 patients

Table 1—*Patient Characteristics

Patient	Height, m	Mass, kg	BMI, kg/m²	Sex/ Age, yr
1	1.65	98	47.6	M/41
2	1.63	91	46.4	M/48
3	1.63	97	48	F/62
4	1.85	117	49	M/49
5	1.85	117	49	M/40
6	1.55	102	51.8	M/76
7	1.88	113	47.1	M/48
8	1.6	79	43.2	F/41
9	1.65	108	50.1	M/24
10	1.73	82	41.7	M/58
11	1.78	122	51.3	M/55
Mean, ±SD	1.71, 0.11	102, 13.8	49.5, 1.9	9M,2F 49, 13
Median	1.65	102	48	48

*BMI = body mass index.

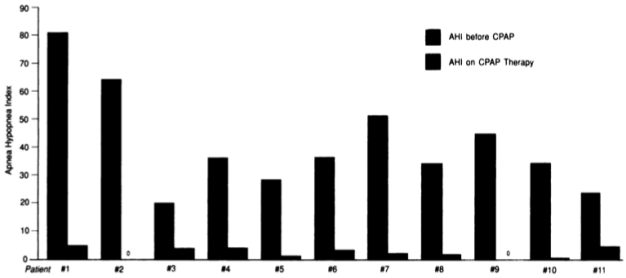


FIGURE 2. Apnea-hypopnea index (AHI) before and after home self-titration of nasal continuous positive airway pressure (CPAP). The AHI in each patient returned to normal (≤5) on treatment at home. Two patients had an AHI equal to 0 (patients 2 and 9) on NCPAP at the time of follow-up recording.

Cost Analysis

The cost for unattended sleep apnea recording in our area is $600, which includes professional interpretation fees. This fee covers the technician time to set up and retrieve the recorder, hand scoring of full disclosure tracings, and preparation of the reports. A standard overnight inpatient polysomnogram in our region ranges from $1,200 to more than $1,800 with additional professional interpretation fees in some instances.

Chest 1993;104:19-25.

1992 and 2003

CLINICAL PRACTICE

Clinical value of polysomnography

NEIL J. DOUGLAS STEPHEN THOMAS MOHAMMED A. JAN

Polysomnography is used increasingly to investigate patients with possible sleep apnoea/hypopnoea syndrome (SAHS), but it has not been assessed critically. We thus examined prospectively the value of electrophysiological and respiratory monitoring in 200 consecutive adults (163 men, 37 women; mean [SD] age 50 [13] years) having polysomnography.

At polysomnography, 91 patients had SAHS (>15 apnoeas+hypopnoeas [A+H] per h asleep) and 11 had periodic limb-movement disorder. Recording sleep electrophysiologically was of no diagnostic value and SAHS could be as accurately defined by A+H per time in bed as by A+H per time asleep. 66% of patients with SAHS could be diagnosed with oximetry alone, but many of the undiagnosed patients had moderately severe SAHS and benefited from treatment.

Neurophysiological sleep recording is unnecessary and oximetry alone is of limited value in the overnight investigation of patients suspected of having SAHS.

Lancet 1992; **339**: 347–50.

Introduction

Laboratories that use polysomnography to diagnose the sleep apnoea/hypopnoea syndrome (SAHS),[1,2] which occurs in at least 0·3% of adult men,[3] have proliferated in the past decade. However, it is unclear whether such complex and expensive investigation is appropriate. Therefore, we have done a prospective trial to see whether full polysomnography is necessary in SAHS patients and to determine which monitoring techniques help establish firm diagnoses or provide useful non-diagnostic pointers.

Methods

One-night polysomnography was done on 200 consecutive adults (163 men, 37 women; mean [SD] age 50 [13] years) referred to the Scottish National Sleep Laboratory and deemed by one of us (N. J. D.) to require further study. Presenting features included snoring (166 patients), falling asleep at least once a day when not in bed (154), witnessed apnoeas (100), and nocturnal choking (51). All patients who snored and who had polysomnography had either coexisting sleepiness or two additional features[4] of SAHS.

ADDRESS: Respiratory Medicine Unit, Department of Medicine (RIE), City Hospital, Edinburgh EH10 5SB, UK (N. J. Douglas, MD, S. Thomas, MB, M. A. Jan, MB) Correspondence to Dr N. J. Douglas

Sleep Medicine Reviews, Vol. 7, No. 1, pp 53–59, 2003
doi:10.1053/smrv.2001.0205

SLEEP MEDICINE reviews

CLINICAL REVIEW

Home diagnosis of the obstructive sleep apnoea/hypopnoea syndrome

Neil J. Douglas

Professor of Respiratory & Sleep Medicine, The University of Edinburgh, Respiratory Medicine Unit, Department of Medicine, Royal Infirmary, Edinburgh, EH3 9YW, Scotland, UK

KEYWORDS
polysomnography, hypopnoea, arousal

Summary Polysomnography has been accepted by many as a "gold standard" for the diagnosis of the Obstructive Sleep Apnoea/Hypopnoea Syndrome (OSAHS). Although polysomnography is a good method for diagnosing OSAHS, there is no evidence that the results of polysomnography more accurately identify patients with the syndrome than more simple investigations which may be done at lower cost in the patient's home. This article examines the evidence for and against home sleep studies and concludes that home sleep studies have a role. Precisely what that role is will depend on financial and organisational aspects for each sleep centre.

AASM - 2007

JCSM
Journal of Clinical Sleep Medicine

SPECIAL ARTICLE

Clinical Guidelines for the Use of Unattended Portable Monitors in the Diagnosis of Obstructive Sleep Apnea in Adult Patients

Portable Monitoring Task Force of the American Academy of Sleep Medicine

Task Force Members: Nancy A. Collop, M.D.[1] (Chair); W. McDowell Anderson, M.D.[2]; Brian Boehlecke, M.D., M.S.P.H.[3]; David Claman, M.D.[4]; Rochelle Goldberg, M.D.[5]; Daniel J. Gottlieb, M.D., M.P.H.[6]; David Hudgel, M.D.[7]; Michael Sateia, M.D.[8]; Richard Schwab, M.D.[9]

[1]*Division of Pulmonary and Critical Care Medicine, Johns Hopkins University, Baltimore, MD;* [2]*James A. Haley VA Hospital, Tampa, FL;* [3]*University of North Carolina, Chapel Hill, NC;* [4]*Department of Medicine, University of California, San Francisco, San Francisco, CA;* [5]*Sleep Medicine, Lankenau Hospital, Wynnewood, PA;* [6]*The Pulmonary Center, Boston University School of Medicine, and VA Boston Healthcare System, Boston, MA;* [7]*Henry Ford Sleep Disorders Center, Detroit, MI;* [8]*Section of Sleep Medicine, Dartmouth-Hitchcock Medical Center, Hanover, NH;* [9]*Division of Sleep Medicine, University of Pennsylvania, Philadelphia, PA*

Based on a review of literature and consensus, the Portable Monitoring Task Force of the American Academy of Sleep Medicine (AASM) makes the following recommendations: unattended portable monitoring (PM) for the diagnosis of obstructive sleep apnea (OSA) should be performed only in conjunction with a comprehensive sleep evaluation. Clinical sleep evaluations using PM must be supervised by a practitioner with board certification in sleep medicine or an individual who fulfills the eligibility criteria for the sleep medicine certification examination. PM may be used as an alternative to polysomnography (PSG) for the diagnosis of OSA in patients with a high pretest probability of moderate to severe OSA. PM is not appropriate for the diagnosis of OSA in patients with significant comorbid medical conditions that may degrade the accuracy of PM. PM is not appropriate for the diagnostic evaluation of patients suspected of having comorbid sleep disorders. PM is not appropriate for general screening of asymptomatic populations. PM may be indicated for the diagnosis of OSA in patients for whom in-laboratory PSG is not possible by virtue of immobility, safety, or critical illness. PM may also be indicated to monitor the response to non-CPAP treatments for sleep apnea.

At a minimum, PM must record airflow, respiratory effort, and blood oxygenation. The airflow, effort, and oximetric biosensors conventionally used for in-laboratory PSG should be used in PM.

The Task Force recommends that PM testing be performed under the auspices of an AASM-accredited comprehensive sleep medicine program with written policies and procedures. An experienced sleep technologist/technician must apply the sensors or directly educate patients in sensor application. The PM device must allow for display of raw data with the capability of manual scoring or editing of automated scoring by a qualified sleep technician/technologist. A board certified sleep specialist, or an individual who fulfills the eligibility criteria for the sleep medicine certification examination, must review the raw data from PM using scoring criteria consistent with current published AASM standards.

Under the conditions specified above, PM may be used for unattended studies in the patient's home. A follow-up visit to review test results should be performed for all patients undergoing PM. Negative or technically inadequate PM tests in patients with a high pretest probability of moderate to severe OSA should prompt in-laboratory polysomnography.

Keywords: Clinical guidelines, portable monitoring, home study, obstructive sleep apnea, comprehensive evaluation

Citation: Collop NA; Anderson WM; Boehlecke B; Claman D; Goldberg R; Gottlieb DJ; Hudgel D; Sateia M; Schwab R. Clinical guidelines for the use of unattended portable monitors in the diagnosis of obstructive sleep apnea in adult patients. *J Clin Sleep Med 2007;3(7):737-747.*

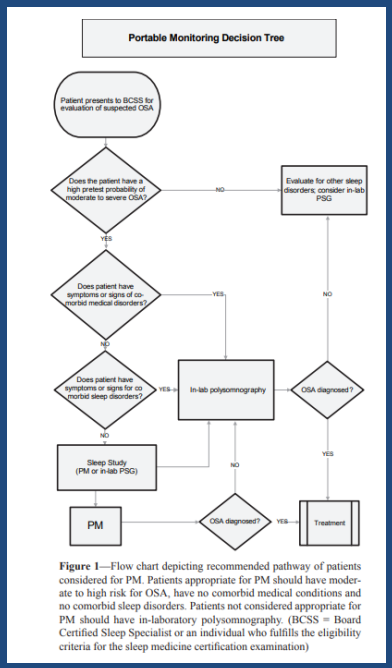


Figure 1—Flow chart depicting recommended pathway of patients considered for PM. Patients appropriate for PM should have moderate to high risk for OSA, have no comorbid medical conditions and no comorbid sleep disorders. Patients not considered appropriate for PM should have in-laboratory polysomnography. (BCSS = Board Certified Sleep Specialist or an individual who fulfills the eligibility criteria for the sleep medicine certification examination)

STEP 1
High Pretest Probability for moderate to severe OSA

YES → Portable Monitoring

STEP 2
"Other diagnosis?"
Other sleep disorders
Other medical problems

YES → In-lab PSG

2007

Annals of Internal Medicine | ARTICLE

Diagnosis and Initial Management of Obstructive Sleep Apnea without Polysomnography

A Randomized Validation Study

Alan T. Mulgrew, MB; Nurit Fox, MSc, CCRP; Najib T. Ayas, MD, MPH; and C. Frank Ryan, MB

Background: Polysomnography (PSG), despite limited availability and high cost, is currently recommended for diagnosis of obstructive sleep apnea and titration of effective continuous positive airway pressure (CPAP).

Objective: To test the utility of a diagnostic algorithm in conjunction with ambulatory CPAP titration in initial management of obstructive sleep apnea.

Design: A randomized, controlled, open-label trial that compared standard PSG with ambulatory CPAP titration in high-risk patients identified by a diagnostic algorithm.

Setting: A tertiary referral sleep disorders program in Vancouver, British Columbia, Canada.

Patients: 68 patients with a high pretest probability of moderate to severe obstructive sleep apnea (apnea–hypopnea index [AHI] >15 episodes/h) identified by sequential application of the Epworth Sleepiness Scale (ESS) score, Sleep Apnea Clinical Score, and overnight oximetry.

Intervention: Patients were randomly assigned to PSG or ambulatory titration by using a combination of auto-CPAP and overnight oximetry. They were observed for 3 months.

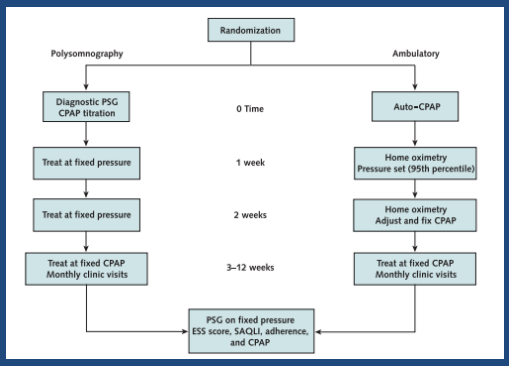
Measurements: Apnea–hypopnea index on CPAP, ESS score, quality of life, and CPAP adherence.

Results: The PSG and ambulatory groups had similar median BMI (38 kg/m^2), age (55 years), ESS score (14 points), and respiratory disturbance index (31 episodes of respiratory disturbance/h). Each episode is determined by a computer algorithm based on analysis of oxygen saturation measured by pulse oximetry. After 3 months, there were no differences in the primary outcome, AHI on CPAP (median, 3.2 vs. 2.5; difference, 0.8/h [95% CI, −0.9 to 2.3]) (P = 0.31), between the PSG and ambulatory groups, or in the secondary outcomes, ESS score, Sleep Apnea Quality of Life Index, and CPAP. Adherence to CPAP therapy was better in the ambulatory group than in the PSG group (median, 5.4 vs. 6.0; difference, −1.12 h/night [CI, −2.0 to 0.2]) (P = 0.021).

Conclusions: In the initial management of patients with a high probability of obstructive sleep apnea, PSG confers no advantage over the ambulatory approach in terms of diagnosis and CPAP titration. The ambulatory approach may improve adherence to treatment. When access to PSG is inadequate, the ambulatory approach can be used to expedite management of patients most in need of treatment.

Ann Intern Med. 2007;146:157-166. www.annals.org
For author affiliations, see end of text.
ClinicalTrials.gov identifier: NCT00254059.

- High pretest probability
  - Group 1: PSG
  - Group 2: AUTO CPAP (no diagnostic)
  - Similar PAP adherence rates

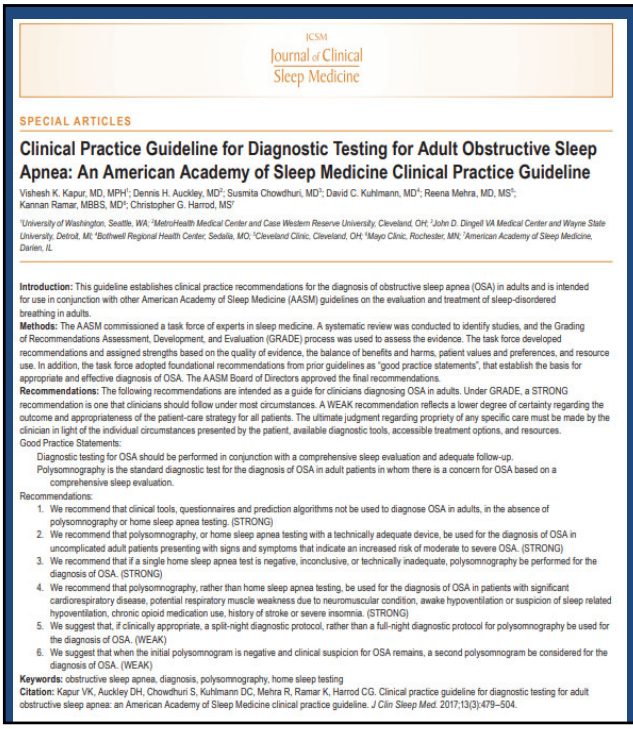


Trials comparing home vs. lab testing

Study Study design	Number of patients	Exclusion	Methods	Outcomes Time points
Berry RB et al Sleep. 2008 31(10): 1423-1431. Randomized, prospective Single center – VA Medical Center University of Florida	53 patients – LAB 53 patients – HOME * High likelihood	CHF (moderate-severe) COPD (moderate-severe) Oxygen therapy Neuromuscular disease Logistical limitations Uncontrolled psychiatric disorder	LAB - attended diagnostic and CPAP titration studies HOME – level 3 device – WatchPAT100 (peripheral arterial tone, heart rate, pulse oximetry, actigraphy)	No difference in nightly CPAP adherence, sleepiness severity, quality of life, CPAP satisfaction at 6 weeks
Skomro RP et al Chest 2010 138(2): 257-263. Randomized, prospective Single center University of Saskatchewan	51 patients – LAB 51 patients – HOME * High likelihood	Respiratory or heart failure Oxygen therapy Another suspected sleep disorder Safety sensitive occupation Pregnancy	LAB – attended diagnostic and CPAP titration study, split study if indicated HOME – level 3 home test, Embletta, followed by 1 week of auto CPAP	No difference in sleepiness scores, quality of life, blood pressure, or CPAP adherence at 4 weeks
Kuna ST et al AJRCCM. 2011. 183(9): 1238-1244 Randomized, prospective 2 centers – VA Medical Centers	148 patients – LAB 148 patients – HOME * High likelihood	Less restrictive approach	LAB – attended diagnostic and CPAP titration study, split study if indicated HOME – level 3 home test, Embletta, followed by AUTO CPAP then fixed CPAP	No difference in functional outcomes of sleep questionnaire, CPAP adherence at 3 months
Rosen CL et al. SLEEP. 2012;35(6):757-767 Randomized, open-label, parallel group, unblinded, multicenter trial 7 sleep centers – Academic Centers	186 patients - LAB 187 patients-HOME * High likelihood	Respiratory or heart failure Oxygen therapy Neuromuscular diseases Uncontrolled psychiatric disorder	LAB – attended diagnostic study and CPAP titration study HOME – home sleep testing and home auto CPAP titration	No difference - acceptance of PAP therapy, titration pressures, effective titrations, time to treatment 3 month PAP adherence was higher in the HOME arm

Topics to cover

- The past
  - The history of home sleep apnea testing
- The present
  - How home sleep apnea testing affects clinical practice
- The future
  - What will happen to the sleep laboratory?



JCSM
Journal of Clinical Sleep Medicine

SPECIAL ARTICLES

Clinical Practice Guideline for Diagnostic Testing for Adult Obstructive Sleep Apnea: An American Academy of Sleep Medicine Clinical Practice Guideline

Vishesh K. Kapur, MD, MPH[1]; Dennis H. Auckley, MD[2]; Susmita Chowdhuri, MD[3]; David C. Kuhlmann, MD[4]; Reena Mehra, MD, MS[5]; Kannan Ramar, MBBS, MD[6]; Christopher G. Harrod, MS[7]

[1]University of Washington, Seattle, WA; [2]MetroHealth Medical Center and Case Western Reserve University, Cleveland, OH; [3]John D. Dingell VA Medical Center and Wayne State University, Detroit, MI; [4]Bothwell Regional Health Center, Sedalia, MO; [5]Cleveland Clinic, Cleveland, OH; [6]Mayo Clinic, Rochester, MN; [7]American Academy of Sleep Medicine, Darien, IL

Introduction: This guideline establishes clinical practice recommendations for the diagnosis of obstructive sleep apnea (OSA) in adults and is intended for use in conjunction with other American Academy of Sleep Medicine (AASM) guidelines on the evaluation and treatment of sleep-disordered breathing in adults.
Methods: The AASM commissioned a task force of experts in sleep medicine. A systematic review was conducted to identify studies, and the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) process was used to assess the evidence. The task force developed recommendations and assigned strengths based on the quality of evidence, the balance of benefits and harms, patient values and preferences, and resource use. In addition, the task force adopted foundational recommendations from prior guidelines as "good practice statements", that establish the basis for appropriate and effective diagnosis of OSA. The AASM Board of Directors approved the final recommendations.
Recommendations: The following recommendations are intended as a guide for clinicians diagnosing OSA in adults. Under GRADE, a STRONG recommendation is one that clinicians should follow under most circumstances. A WEAK recommendation reflects a lower degree of certainty regarding the outcome and appropriateness of the patient-care strategy for all patients. The ultimate judgment regarding propriety of any specific care must be made by the clinician in light of the individual circumstances presented by the patient, available diagnostic tools, accessible treatment options, and resources.
Good Practice Statements:
Diagnostic testing for OSA should be performed in conjunction with a comprehensive sleep evaluation and adequate follow-up.
Polysomnography is the standard diagnostic test for the diagnosis of OSA in adult patients in whom there is a concern for OSA based on a comprehensive sleep evaluation.
Recommendations:
1. We recommend that clinical tools, questionnaires and prediction algorithms not be used to diagnose OSA in adults, in the absence of polysomnography or home sleep apnea testing. (STRONG)
2. We recommend that polysomnography, or home sleep apnea testing with a technically adequate device, be used for the diagnosis of OSA in uncomplicated adult patients presenting with signs and symptoms that indicate an increased risk of moderate to severe OSA. (STRONG)
3. We recommend that if a single home sleep apnea test is negative, inconclusive, or technically inadequate, polysomnography be performed for the diagnosis of OSA. (STRONG)
4. We recommend that polysomnography, rather than home sleep apnea testing, be used for the diagnosis of OSA in patients with significant cardiorespiratory disease, potential respiratory muscle weakness due to neuromuscular condition, awake hypoventilation or suspicion of sleep related hypoventilation, chronic opioid medication use, history of stroke or severe insomnia. (STRONG)
5. We suggest that, if clinically appropriate, a split-night diagnostic protocol, rather than a full-night diagnostic protocol for polysomnography be used for the diagnosis of OSA. (WEAK)
6. We suggest that when the initial polysomnogram is negative and clinical suspicion for OSA remains, a second polysomnogram be considered for the diagnosis of OSA. (WEAK)

Keywords: obstructive sleep apnea, diagnosis, polysomnography, home sleep testing
Citation: Kapur VK, Auckley DH, Chowdhuri S, Kuhlmann DC, Mehra R, Ramar K, Harrod CG. Clinical practice guideline for diagnostic testing for adult obstructive sleep apnea: an American Academy of Sleep Medicine clinical practice guideline. *J Clin Sleep Med.* 2017;13(3):479–504.

The Present – AASM - 2017

- Updated Clinical Practice Guideline
  - Task Force, good practice for appropriate and effective diagnosis of OSA
  - Uncomplicated adults with signs and symptoms of moderate to severe OSA → PSG or HSAT
  - If HST is negative, inconclusive, technically inadequate, PSG should be performed
  - Attended PSG recommended:
    - Significant cardiopulmonary disease
    - Respiratory muscle weakness due to neuromuscular condition
    - Sleep related hypoventilation
    - Chronic opioid usage
    - History of stroke
    - Severe insomnia

SPECIAL ARTICLES

Clinical Use of a Home Sleep Apnea Test: An Updated American Academy of Sleep Medicine Position Statement

Ilene M. Rosen, MD, MS[1]; Douglas B. Kirsch, MD[2]; Kelly A. Carden, MD[3]; Raman K. Malhotra, MD[4]; Kannan Ramar, MD[5]; R. Nisha Aurora, MD[6]; David A. Kristo, MD[7]; Jennifer L. Martin, PhD[8,9]; Eric J. Olson, MD[5]; Carol L. Rosen, MD[10]; James A. Rowley, MD[11]; Anita V. Shelgikar, MD, MHPE[11]
American Academy of Sleep Medicine Board of Directors

In November 2017, the American Medical Association (AMA) House of Delegates adopted a policy that emphasizes that a licensed physician must be involved in determining the need for, and appropriateness of, ordering objective tests to diagnose OSA or evaluating treatment efficacy in patients with OSA. In addition, the AMA policy recognizes that objective tests for diagnosing OSA are medical assessments that must be ordered and interpreted by a licensed physician.[9] The AASM supports this policy specifically as it relates to the use of HSATs by licensed medical providers for diagnosing OSA as well as assessing treatment efficacy in patients treated for OSA in the manner further delineated in the statements that follow.

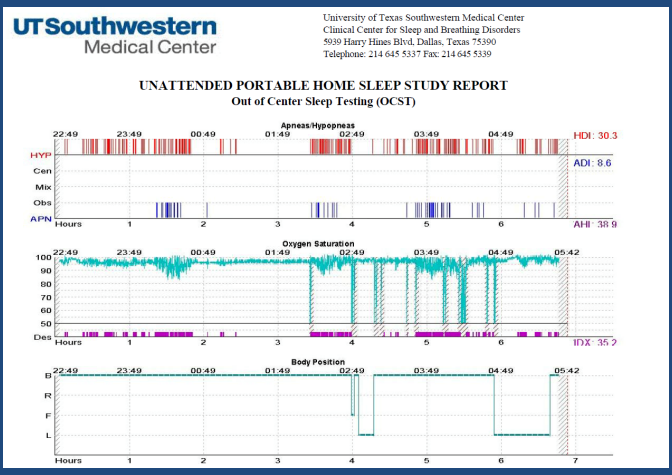
Citation: Rosen IM, Kirsch DB, Carden KA, Malhotra RK, Ramar K, Aurora RN, Kristo DA, Martin JL, Olson EJ, Rosen CL, Rowley JA, Shelgikar AV; American Academy of Sleep Medicine Board of Directors. Clinical use of a home sleep apnea test: an updated American Academy of Sleep Medicine position statement. *J Clin Sleep Med.* 2018;14(12):2075–2077.

POSITION

It is the position of the AASM that:

- Only a medical provider can diagnose medical conditions such as OSA and primary snoring.
- The need for, and appropriateness of, an HSAT must be based on the patient's medical history and a face-to-face examination by a medical provider, either in person or via telemedicine.
- An HSAT is a medical assessment that must be ordered by a medical provider to diagnose OSA or evaluate treatment efficacy.
- An HSAT should not be used for general screening of asymptomatic clinical populations.
- Diagnosis, assessment of treatment efficacy, and treatment decisions must not be based solely on automatically scored HSAT data, which could lead to sub-optimal care that jeopardizes patient health and safety.
- The raw data from the HSAT device must be reviewed and interpreted by a physician who is either board-certified in sleep medicine or overseen by a board-certified sleep medicine physician.

Patient CN – August 2018



UT Southwestern Medical Center

University of Texas Southwestern Medical Center
Clinical Center for Sleep and Breathing Disorders
5939 Harry Hines Blvd, Dallas, Texas 75390
Telephone: 214 645 5337 Fax: 214 645 5339

UNATTENDED PORTABLE HOME SLEEP STUDY REPORT
Out of Center Sleep Testing (OCST)

Apneas/Hypopneas
22:49 23:49 00:49 01:49 02:49 03:49 04:49
HDI: 30.3
HYP
Cen
Mix
Obs
APN
ADI: 8.6
Hours 1 2 3 4 5 6
AHI: 38.9

Oxygen Saturation
22:49 23:49 00:49 01:49 02:49 03:49 04:49 05:42
100 90 80 70 60 50
Des
Hours 1 2 3 4 5 6
IDX: 35.2

Body Position
22:49 23:49 00:49 01:49 02:49 03:49 04:49 05:42
B
R
F
L
Hours 1 2 3 4 5 6 7

- 55 year old female
  - BMI 35
  - Snoring, chronic rhinosinusitis
- HST
  - AHI 39, LOS – 82%
  - Time < 88% for 9.4 minutes
- What's the next best treatment approach?

  A) AUTO CPAP prescription
  B) PAP titration in the sleep laboratory?

Letter – denial from insurance

- Your doctor is requesting a sleep study in a sleep facility to determine the pressure settings on a CPAP machine to treat your sleep condition.
- Based on available information sent in, you do NOT have any medical conditions that prevent you from having this sleep study in your home.
  - These conditions include significant or unstable heart or lung disease, special nerve or muscle disease
- Therefore the request for a study (95811) does NOT meet your health plan's coverage criteria.
  - This service is NOT medically necessary, so it is NOT covered by your plan.
- Sleep testing can be done in a home setting using an auto-adjusting sleep breathing machine.
  - Please speak to your doctor who can arrange a home sleep auto PAP study.

COVERAGE for in-facility PSG (95810)

In-Facility Polysomnography (PSG)-Full-Night:

Cigna covers full night in-facility polysomnography (PSG) (CPT codes 95808, 95810) as medically necessary in an adult (age 18 or older) when BOTH of the following criteria are met:

- medical necessity criteria for a sleep study for suspected obstructive sleep apnea (OSA) as outlined above have been met
- **ANY** of the following:
  - significant comorbid condition that would be expected to degrade the accuracy of a home/portable study such as any of the following:
    - moderate to severe pulmonary disease, such as chronic obstructive pulmonary disease (COPD)
    - moderate to severe neuromuscular/neurodegenerative disorder causing restrictive lung diseases (e.g., kyphoscoliosis, myasthenia gravis, amyotropic lateral sclerosis (ALS), post-polio syndrome, polymyositis, Guillian Barre syndrome)
    - congestive heart failure (moderate to severe) NYHA Class III or IV (LVEF ≤ 45%)
    - obesity hypoventilation syndrome, previously documented (defined as $pCO2 > 45$ mmHg and $pO2 < 60$ mmHg on arterial blood gas)
    - pulmonary hypertension (defined as mPAP ≥ 25 mmHg)
  - sleep disorder other than OSA is suspected (e.g., central sleep apnea, periodic limb movement disorder, complex; potentially injurious of violent parasomnias, narcolepsy, REM behavior sleep disorder, nocturnal seizures) that is corroborated by the clinical documentation
  - recent home/portable testing proved to be technically inadequate or failed to establish the diagnosis of OSA in an individual with high pretest likelihood of OSA
  - individual and caregiver/companion incapable of operating home testing equipment

Cigna covers full night in-facility polysomnography (PSG) (CPT codes 95808, 95810) as medically necessary prior to a planned multiple sleep latency test (MSLT) in an adult (age 18 or older) with suspected narcolepsy.

http://help.carecentrix.com/ProviderResources/Cigna%20Medical%20Coverage%20Policy.pdf

Cigna – COVERAGE for in-facility SPLIT (95811)

Cigna covers split-night in-facility polysomnography (PSG) (CPT code 95811), in which the initial diagnostic portion of the PSG is followed by positive airway pressure (PAP) titration, as medically necessary in an adult (age 18 or older) when ALL of the following criteria are met:

- medical necessity criteria for a sleep study for suspected obstructive sleep apnea (OSA) as outlined above have been met
- apnea/hypopnea index (AHI) or respiratory disturbance index (RDI) of 15 or higher during initial diagnostic portion of split-night study, or AHI or RDI ≥ 5 with symptoms indicative of significant OSA (e.g., repetitive obstructions, significant oxygen desaturation [i.e. oxygen saturation < 80% for >1% of sleep time or < 90% for > 30% of sleep time during a diagnostic facility based PSG])
- **ANY** of the following:
  - significant comorbid condition that would be expected to degrade the accuracy of a home/portable study such as any of the following
    - moderate to severe pulmonary disease, such as chronic obstructive pulmonary disease (COPD), documented on pulmonary function studies (PFTs)
    - moderate to severe neuromuscular/neurodegenerative disorder causing restrictive lung diseases (e.g., kyphoscoliosis, myasthenia gravis, amyotropic lateral sclerosis (ALS), post-polio syndrome, polymyositis, Guillian Barre syndrome)
    - congestive heart failure (moderate to severe), NYHA Class III or IV (LVEF ≤ 45%)
    - obesity hypoventilation syndrome, previously documented (defined as pCO2 > 45 mmHg and pO2 < 60 mmHg on arterial blood gas)
    - pulmonary hypertension (defined as mPAP ≥ 25 mmHg)
  - sleep disorder other than OSA is suspected (e.g., central sleep apnea, periodic limb movement disorder, complex; potentially injurious of violent parasomnias, narcolepsy, REM behavior sleep disorder, nocturnal seizures) and is corroborated by the clinical documentation
  - recent home/portable testing proved to be technically inadequate or failed to establish the diagnosis of OSA in an individual with high pretest likelihood of OSA
  - individual and caregiver/companion incapable of operating home testing equipment

http://help.carecentrix.com/ProviderResources/Cigna%20Medical%20Coverage%20Policy.pdf

Cigna – COVERAGE PAP titration (95811)

In-Facility Polysomnography (PSG)-Positive Airway Pressure (PAP) Titration:

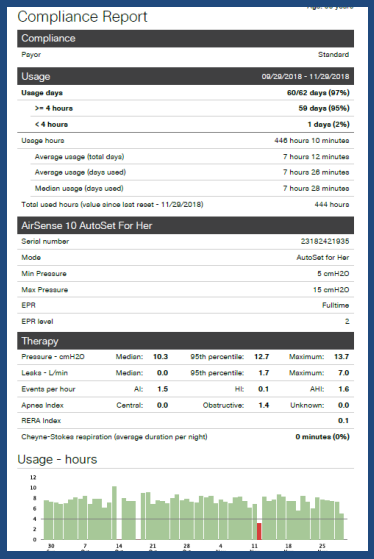
Cigna covers in-facility PSG (CPT code 95811) for PAP titration, following a prior diagnostic study as medically necessary in an adult (age 18 or older) when ALL of the following criteria are met:

- AHI or RDI or Respiratory Event Index (REI) ≥ 15 documented on prior PSG or home/portable study, or AHI or RDI or REI ≥ 5 and < 15, with symptoms of OSA (e.g., excessive daytime sleepiness, impaired cognition, mood disorders or insomnia), or with hypertension, ischemic heart disease or history of stroke
- AHI or RDI or REI was calculated based on at least two hours of continuous recorded sleep or, if calculated based on less than two hours of sleep, the total number of recorded events to calculate the AHI or RDI was, at a minimum, the number of events that would have been required in a two-hour period.
- ANY of the following:
  - a comorbid sleep disorder (e.g., significant central sleep apnea [i.e., central sleep apneas/hypopneas > 50% of total apneas/hypopneas, or ≥ 5 central apneas/hypopneas per hour], periodic limb movement disorder [> 15 periodic limb movements per hour resulting in arousal], complex; potentially injurious of violent parasomnias, narcolepsy, REM behavior sleep disorder, nocturnal seizures) corroborated by the clinical documentation
  - a significant comorbid condition that would be expected to degrade the accuracy of a home/portable study, such as any of the following
    - moderate to severe pulmonary disease, such as chronic obstructive pulmonary disease (COPD), as documented on pulmonary function studies (PFTs)
    - moderate to severe neuromuscular/neurodegenerative disorder causing restrictive lung diseases (e.g., kyphoscoliosis, myasthenia gravis, amyotropic lateral sclerosis (ALS), post-polio, polymyositis, Guillian Barre syndrome)
    - congestive heart failure (moderate to severe), NYHA Class III or IV (LVEF ≤ 45%)
    - obesity hypoventilation syndrome, previously documented (defined as pCO2 > 45 mmHg and pO2 < 60 mmHg on arterial blood gas)
    - pulmonary hypertension (defined as mPAP ≥ 25 mmHg)
    - individuals with significant oxygen desaturation described as O_2 saturation < 80% for > 1% of sleep time or < 90% for > 30% of sleep time during prior diagnostic facility-based study

http://help.carecentrix.com/ProviderResources/Cigna%20Medical%20Coverage%20Policy.pdf

Clinic Follow Up – November 2018

- 55 year old female
  - HST
    - AHI 39
    - Desats to 88% for 9.4 minutes
  - Denied PAP titration study
    - AUTO CPAP ordered
- Clinic follow up
  - Feels less fatigued
  - Resolved daytime sleepiness
  - Tolerating nasal pillows well (despite rhinosinusitis)



Compliance Report

Compliance	
Payor	Standard

Usage	09/29/2018 - 11/29/2018
Usage days	60/62 days (97%)
>= 4 hours	59 days (95%)
< 4 hours	1 days (2%)
Usage hours	446 hours 10 minutes
Average usage (total days)	7 hours 12 minutes
Average usage (days used)	7 hours 26 minutes
Median usage (days used)	7 hours 28 minutes
Total used hours (value since last reset - 11/29/2018)	444 hours

AirSense 10 AutoSet For Her	
Serial number	23182421935
Mode	AutoSet for Her
Min Pressure	5 cmH2O
Max Pressure	15 cmH2O
EPR	Fulltime
EPR level	2

Therapy						
Pressure - cmH2O	Median:	10.3	95th percentile:	12.7	Maximum:	13.7
Leaks - L/min	Median:	0.0	95th percentile:	1.7	Maximum:	7.0
Events per hour	AI:	1.5	HI:	0.1	AHI:	1.6
Apnea Index	Central:	0.0	Obstructive:	1.4	Unknown:	0.0
RERA Index						0.1
Cheyne-Stokes respiration (average duration per night)						0 minutes (0%)

Usage - hours

Sleep. 2002 Mar 15;25(2):148-73.

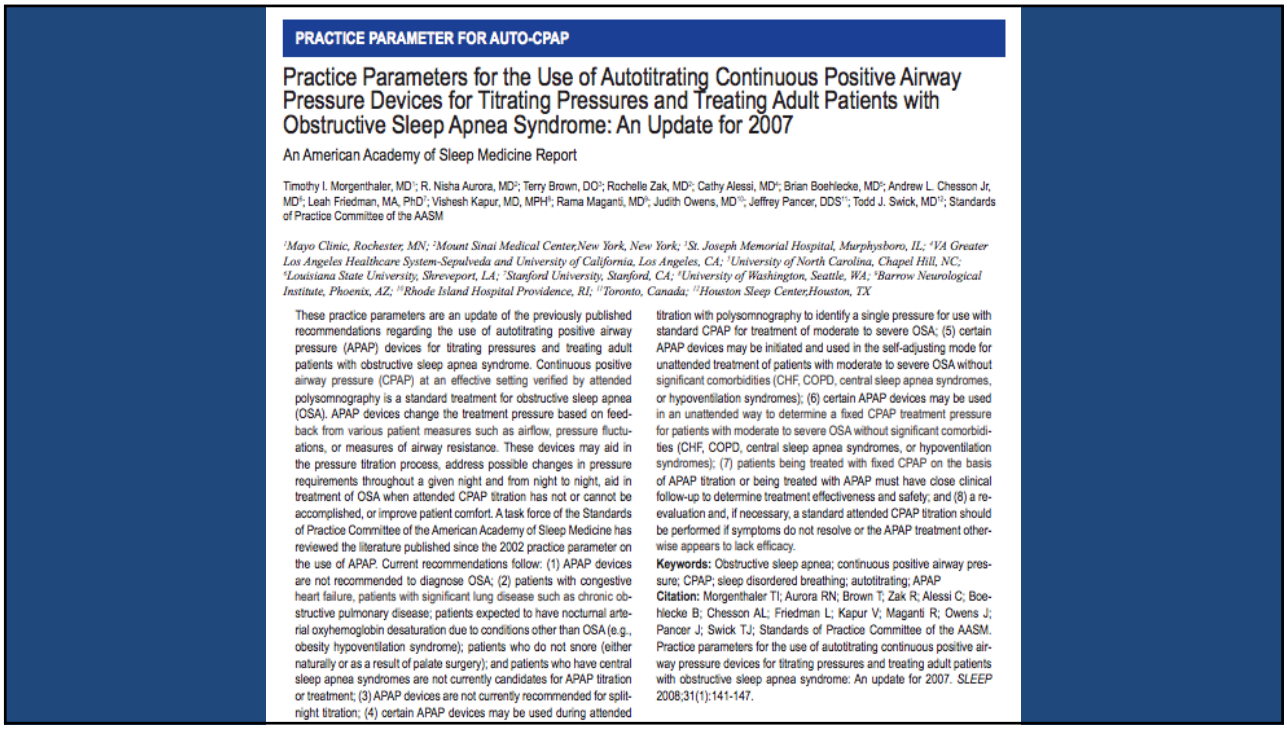
The use of auto-titrating continuous positive airway pressure for treatment of adult obstructive sleep apnea. An American Academy of Sleep Medicine review.

Berry RB[1], Parish JM, Hartse KM.

⊕ **Author information**

Abstract

This paper reviews the efficacy of auto-titrating continuous positive airway pressure (APAP) for treatment of obstructive sleep apnea. It is based on a review of 30 articles published in peer review journals conducted by a task force appointed by the American Academy of Sleep Medicine to develop practice parameters for use of APAP devices for treatment of obstructive sleep apnea (OSA). The data indicate that APAP can be used to treat many patients with OSA (auto-adjusting) or to identify an effective optimal fixed level of continuous positive airway pressure (CPAP) for treatment (auto-titration). Patients with significant congestive heart failure, chronic obstructive pulmonary disease (COPD), or significant amounts of central apnea were excluded from many treatment trials and there is insufficient evidence that APAP can be used to treat these patients. Many clinical trials have been performed in patients already on CPAP or with the initial APAP night in a laboratory setting. At this time only a few studies have evaluated initial titration with APAP in CPAP-naïve patients in an unattended setting. Further studies of APAP in this circumstance are needed. No studies have systematically compared the efficacy of one APAP technology with another. Devices using different technology may not give the same results in a given patient. Devices solely dependent on vibration may not work in non-snorers or patient who have undergone upper-airway surgery. High mask or mouth leaks may prevent adequate titration in devices monitoring snoring, flow, or impedance (forced oscillation technique). Review of the raw data to identify periods of high leak was performed in several of the APAP titration studies, to identify a pressure for fixed CPAP treatment or to determine if the titration was adequate. There is conflicting evidence for and against the premise that treatment with APAP increases acceptance and adherence compared to fixed CPAP. In studies demonstrating an increase in adherence with APAP, there was similar improvement in measures of daytime sleepiness as with fixed CPAP treatment. Further studies are needed to determine if APAP can increase acceptance or adherence with positive pressure treatment in patients with OSA.



PRACTICE PARAMETER FOR AUTO-CPAP

Practice Parameters for the Use of Autotitrating Continuous Positive Airway Pressure Devices for Titrating Pressures and Treating Adult Patients with Obstructive Sleep Apnea Syndrome: An Update for 2007

An American Academy of Sleep Medicine Report

Timothy I. Morgenthaler, MD[1]; R. Nisha Aurora, MD[2]; Terry Brown, DO[3]; Rochelle Zak, MD[2]; Cathy Alessi, MD[4]; Brian Boehlecke, MD[5]; Andrew L. Chesson Jr, MD[6]; Leah Friedman, MA, PhD[7]; Vishesh Kapur, MD, MPH[8]; Rama Maganti, MD[9]; Judith Owens, MD[10]; Jeffrey Pancer, DDS[11]; Todd J. Swick, MD[12]; Standards of Practice Committee of the AASM

[1]Mayo Clinic, Rochester, MN; [2]Mount Sinai Medical Center,New York, New York; [3]St. Joseph Memorial Hospital, Murphysboro, IL; [4]VA Greater Los Angeles Healthcare System-Sepulveda and University of California, Los Angeles, CA; [5]University of North Carolina, Chapel Hill, NC; [6]Louisiana State University, Shreveport, LA; [7]Stanford University, Stanford, CA; [8]University of Washington, Seattle, WA; [9]Barrow Neurological Institute, Phoenix, AZ; [10]Rhode Island Hospital Providence, RI; [11]Toronto, Canada; [12]Houston Sleep Center,Houston, TX

These practice parameters are an update of the previously published recommendations regarding the use of autotitrating positive airway pressure (APAP) devices for titrating pressures and treating adult patients with obstructive sleep apnea syndrome. Continuous positive airway pressure (CPAP) at an effective setting verified by attended polysomnography is a standard treatment for obstructive sleep apnea (OSA). APAP devices change the treatment pressure based on feedback from various patient measures such as airflow, pressure fluctuations, or measures of airway resistance. These devices may aid in the pressure titration process, address possible changes in pressure requirements throughout a given night and from night to night, aid in treatment of OSA when attended CPAP titration has not or cannot be accomplished, or improve patient comfort. A task force of the Standards of Practice Committee of the American Academy of Sleep Medicine has reviewed the literature published since the 2002 practice parameter on the use of APAP. Current recommendations follow: (1) APAP devices are not recommended to diagnose OSA; (2) patients with congestive heart failure, patients with significant lung disease such as chronic obstructive pulmonary disease, patients expected to have nocturnal arterial oxyhemoglobin desaturation due to conditions other than OSA (e.g., obesity hypoventilation syndrome); patients who do not snore (either naturally or as a result of palate surgery); and patients who have central sleep apnea syndromes are not currently candidates for APAP titration or treatment; (3) APAP devices are not currently recommended for split-night titration; (4) certain APAP devices may be used during attended titration with polysomnography to identify a single pressure for use with standard CPAP for treatment of moderate to severe OSA; (5) certain APAP devices may be initiated and used in the self-adjusting mode for unattended treatment of patients with moderate to severe OSA without significant comorbidities (CHF, COPD, central sleep apnea syndromes, or hypoventilation syndromes); (6) certain APAP devices may be used in an unattended way to determine a fixed CPAP treatment pressure for patients with moderate to severe OSA without significant comorbidities (CHF, COPD, central sleep apnea syndromes, or hypoventilation syndromes); (7) patients being treated with fixed CPAP on the basis of APAP titration or being treated with APAP must have close clinical follow-up to determine treatment effectiveness and safety; and (8) a re-evaluation and, if necessary, a standard attended CPAP titration should be performed if symptoms do not resolve or the APAP treatment otherwise appears to lack efficacy.

Keywords: Obstructive sleep apnea; continuous positive airway pressure; CPAP; sleep disordered breathing; autotitrating; APAP

Citation: Morgenthaler TI; Aurora RN; Brown T; Zak R; Alessi C; Boehlecke B; Chesson AL; Friedman L; Kapur V; Maganti R; Owens J; Pancer J; Swick TJ; Standards of Practice Committee of the AASM. Practice parameters for the use of autotitrating continuous positive airway pressure devices for titrating pressures and treating adult patients with obstructive sleep apnea syndrome: An update for 2007. *SLEEP* 2008;31(1):141-147.

Trends – 2018 versus 2015

- HST volume has markedly increased
  - 47% increase
- In lab sleep volume has stayed the same, but with more complicated patients
  - LVAD, PD, PH, Neuromuscular
  - Training for complex cardiopulmonary disorders must be emphasized
- Clinic
  - Increase by 40%
- More FTE allocated day staff
  - More time with insurance companies
  - Appeals and denials of PSGs
  - More staff for set ups of HSTs
- DME companies
  - More dependence on their care for set ups of AUT titrating devices and appropriate mask interfaces
- Clinical care
  - Marked INCREASE in AUTO titrating devices
  - Clinicians
    - Fingers crossed approach
    - Marked increase in oximetry testing
  - CPAP adherence rates in this new model, likely similar but "to be determined"

UT Southwestern Medical Center

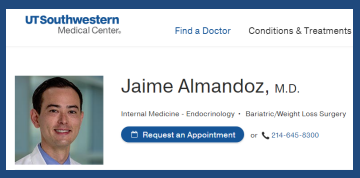
The case for HST
Weight loss/bariatric surgery clinic referrals
70% "positive" rate


UTSouthwestern Medical Center

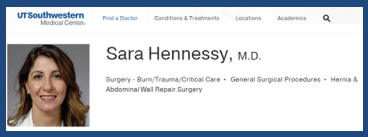
University of Texas Southwestern Medical Center
Clinical Center for Sleep and Breathing Disorders
5939 Harry Hines Blvd, Dallas, Texas 75390
Telephone: 214 645 5337 Fax: 214 645 5339

UNATTENDED PORTABLE HOME SLEEP STUDY REPORT
Out of Center Sleep Testing (OCST)

Apneas/Hypopneas
Oxygen Saturation
Body Position


UTSouthwestern Medical Center. Find a Doctor Conditions & Treatments

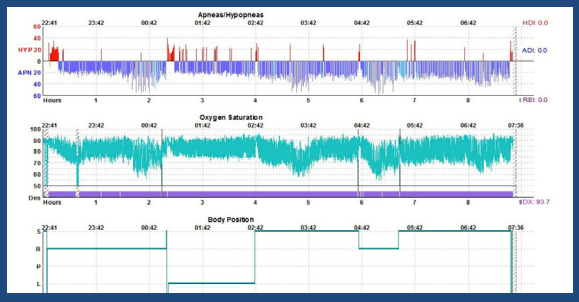
Jaime Almandoz, M.D.
Internal Medicine - Endocrinology • Bariatric/Weight Loss Surgery
Request an Appointment or 214-645-8300


UTSouthwestern Medical Center. Find a Doctor Conditions & Treatments Locations Academics

Sara Hennessy, M.D.
Surgery - Burn/Trauma/Critical Care • General Surgical Procedures • Hernia & Abdominal Wall Repair Surgery

Ravesloot MJ et a. Eur Arch Otorhinlaryngol. 2012; 269 (7):1865-1871

Severe OSA


Apneas/Hypopneas
Oxygen Saturation
Body Position

- 51 year old man
  - Obesity, Hyperlipidemia, Diabetes
- HST
  - AHI of 96
  - Time < 88% for 433 minutes
- Question
  - A) AUTO CPAP
  - B) PAP titration in the sleep lab

PAP in lab titration study

History/Indication: A positive airway titration study was performed to determine optimal level of treament for obstructive sleep hypersomnolence). UTSW HST on November 7, 2018 - very severe OSA with an AHI of 96 and time < 88% for 433 minutes.

Current Medications: ergocalciferol, vitamin D2, famotidine, fluticasone, herbal complex, L-desoxyephedrine, oregano oil, vitami

ICD CODES: Obstructive Sleep Apnea, Adult (G47.33-1)

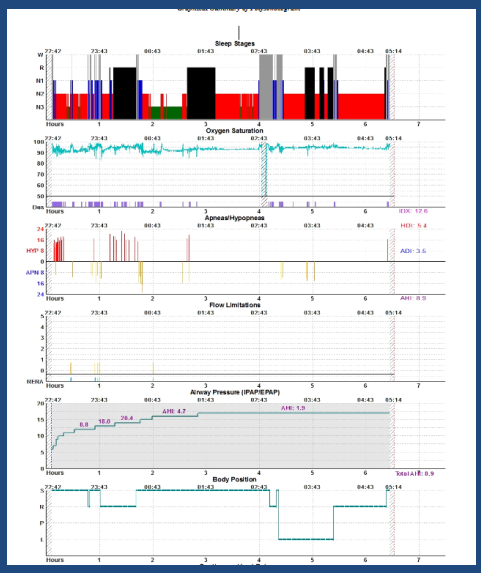
INTERPRETATION:

* Sleep efficiency is 89.8 % which is normal. Sleep architecture is abnormal.
* Positive pressure titration was successful. CPAP was well tolerated.
* The optimal treatment pressure is determined to be **16 or 17 cm water**. The AHI is less than 5 at this pressure. Supine REM
* Time below 88% was 3.2 minutes.
* Heart rhythm is sinus rhythm with mean heart rate 54.
* No periodic limb movements or other abnormal motor activity is noted. PLM Index 0.0, PLM Arousal Index 0.0
* No EEG abnormality is noted.

RECOMMENDATIONS:

Prescription:

* **AUTO CPAP = 12 cm H2O and max 18 cm H2O.**
* **ResMed F30 size Small** or fit to comfort with nasal, nasal pillows, or full-face mask.
* Humidifier: Heated humidification. Heated humidifier will help reduce nasal resistance and decrease mouth leaks.
* Ramp time = 20 minutes.
* Chin strap: Yes.



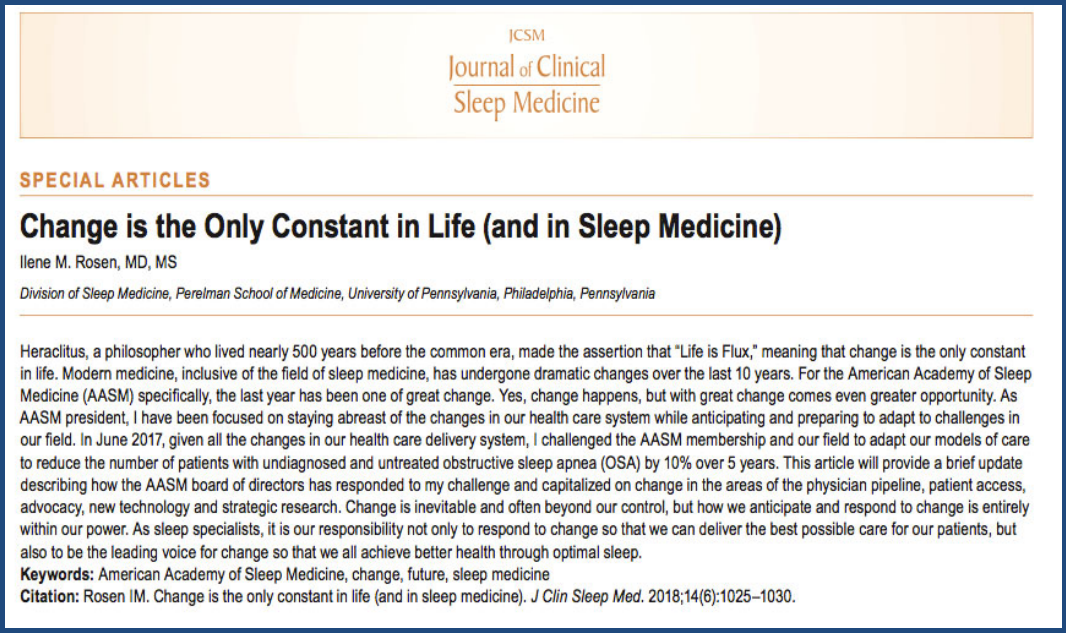
Compliance Summary

Compliance Summary	
Date Range	11/13/2018 - 12/10/2018 (28 days)
Days with Device Usage	27 days
Days without Device Usage	1 day
Percent Days with Device Usage	96.4%
Cumulative Usage	7 days 3 hrs. 43 mins. 39 secs.
Maximum Usage (1 Day)	10 hrs. 15 mins. 57 secs.
Average Usage (All Days)	6 hrs. 7 mins. 59 secs.
Average Usage (Days Used)	6 hrs. 21 mins. 37 secs.
Minimum Usage (1 Day)	3 hrs. 48 mins. 31 secs.
Percent of Days with Usage >= 4 Hours	92.9%
Percent of Days with Usage < 4 Hours	7.1%
Total Blower Time	7 days 3 hrs. 43 mins. 39 secs.
Auto-CPAP Summary (Philips Respironics)	
Auto-CPAP Mean Pressure	9.7 cmH2O
Auto-CPAP Peak Average Pressure	11.9 cmH2O
Average Device Pressure <= 90% of Time	11.6 cmH2O
Average Time in Large Leak Per Day	7 mins. 13 secs.
Average AHI	4.7
Device Settings as of	12/10/2018

- 96% usage
- 6 hours and 21 minutes
- 90% pressure
  - 12 cm H2O
- Residual AHI of 4.7

Topics to cover

- The past
  - The history of home sleep apnea testing
- The present
  - How home sleep apnea testing affects clinical practice
- The future
  - What will happen to the sleep laboratory?



JCSM
Journal of Clinical Sleep Medicine

SPECIAL ARTICLES

Change is the Only Constant in Life (and in Sleep Medicine)

Ilene M. Rosen, MD, MS

Division of Sleep Medicine, Perelman School of Medicine, University of Pennsylvania, Philadelphia, Pennsylvania

Heraclitus, a philosopher who lived nearly 500 years before the common era, made the assertion that "Life is Flux," meaning that change is the only constant in life. Modern medicine, inclusive of the field of sleep medicine, has undergone dramatic changes over the last 10 years. For the American Academy of Sleep Medicine (AASM) specifically, the last year has been one of great change. Yes, change happens, but with great change comes even greater opportunity. As AASM president, I have been focused on staying abreast of the changes in our health care system while anticipating and preparing to adapt to challenges in our field. In June 2017, given all the changes in our health care delivery system, I challenged the AASM membership and our field to adapt our models of care to reduce the number of patients with undiagnosed and untreated obstructive sleep apnea (OSA) by 10% over 5 years. This article will provide a brief update describing how the AASM board of directors has responded to my challenge and capitalized on change in the areas of the physician pipeline, patient access, advocacy, new technology and strategic research. Change is inevitable and often beyond our control, but how we anticipate and respond to change is entirely within our power. As sleep specialists, it is our responsibility not only to respond to change so that we can deliver the best possible care for our patients, but also to be the leading voice for change so that we all achieve better health through optimal sleep.

Keywords: American Academy of Sleep Medicine, change, future, sleep medicine
Citation: Rosen IM. Change is the only constant in life (and in sleep medicine). *J Clin Sleep Med*. 2018;14(6):1025–1030.

The Future?

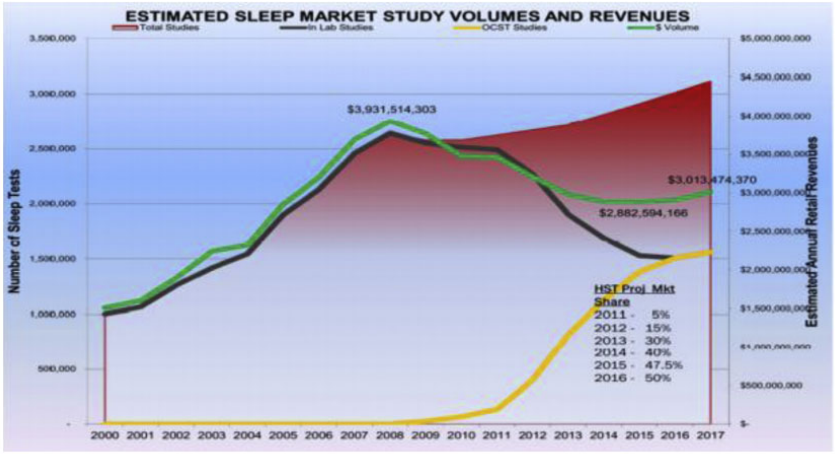


Fig. 6. Changes in the clinical use of polysomnography and predicted trends from T. Crabtree of Health Strategy Partners. (*From* Crabtree T. Sleep 2014 what to expect – how to prepare. Presented at The Business of Sleep October 29 & 30, 2014, Bear Mountain, NY. Health Strategy Partners. Available at: foocus.com/power-point/Sleep-in-2014-and-beyond.pdf. Accessed June 6, 2016; with permission.)

Hirshkowitz, M. Polysomnography Challenges. Sleep Med Clin 11 (2016) 403-411.

Reality of sleep testing

- "The vast majority of clinical PSG recordings were made to either diagnose sleep disordered breathing disorders or titrate positive airway pressure."

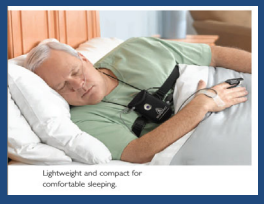
- Clinic diagnosis
  - Circadian disorders
  - Insomnia disorders
  - Narcolepsy with/without cataplexy *** MSLT
  - Parasomnias
  - Restless legs syndrome/ PLMS *** PSG

HST
No OSA, hypoxemia

- 66 year old man, BMI 40, suspected OSA, polycythemia
- HST
  - AHI 2.55
  - 325 minutes → time less than 88%, average SpO2 86%
- Attended PSG
  - AHI was 3
  - Hypoxemia was confirmed
- Diagnosis: emphysema, secondary polycythemia, Tx: supplemental oxygen

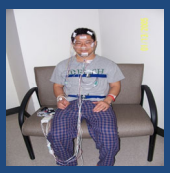
The Future of Sleep Apnea Care

1. HST is here to stay and the technology will only get better.
   - "Home sleep testing cannot be replaced into Pandora's box."
     - Doug Kirsch, MD – JCSM 2013.
   - Advancements in technology to simplify diagnostic testing will emerge
     - Wireless technology, less intrusive monitoring, biomedical sensors



2. The biggest challenge will be maintaining QUALITY of care
   - Quality of diagnostic testing, review of raw data
   - Who will differentiate a "true test" from a "false test?"
   - Who will make sure of TECHNICAL failures?
3. AUTO titrating devices are here to stay
   - Technology will improve
   - MORE DME involvement
   - Oximetry testing will markedly increase (incorporate with AUTO devices?)

The Future of Sleep Apnea Care



4. A diagnostic attended PSG is really needed for…
   - Physically or mentally impaired patients who CAN'T do an HST
   - Patients with advanced cardiopulmonary diseases where oxygenation is an issue
   - Narcolepsy evaluation, combined with MSLT
   - Parasomnias – RBD or pseudo RBD
   - Insomnia – psychophysiologic insomnia, paradoxical insomnia, an alternative diagnosis

5. A PAP attended titration study is really needed for…
   - Complicated cardiopulmonary patients (oxygen, high levels of PAP, tracheostomy, hypoventilation)
   - Inadequate response to AUTO PAP therapy
   - Hypoglossal nerve titrations
   - Neuromuscular patients – titrations

The Future of Sleep Apnea Care

6. Who will serve as the stewards of sleep care?

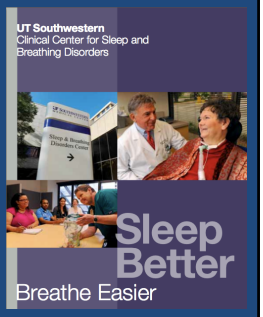
   - Beyond sleep apnea
     - Narcolepsy, circadian disorders, insomnia, RLS, parasomnias
   - Sleep trained clinicians → FELLOWSHIPs
     - Internal medicine/sleep
     - Family medicine/sleep
     - Pediatrics/sleep
     - Medicine Pediatrics/sleep
     - Psychiatry/sleep
     - Pulmonary/sleep – adult and pediatrics
     - Neurology/sleep
   - Advanced practice providers

Utility of the In Lab Polysomnogram in a New Era of Home Sleep Testing

California Thoracic Society – 2019

Won Y. Lee, MD
Associate Professor, Division of Pulmonary and Critical Care Medicine
Medical Director – Clinical Center for Sleep and Breathing Disorders Center
University of Texas Southwestern Medical Center
Dallas, Texas

I have no disclosures to declare.



Question

- Which of the following cases is MOST LIKELY to be declined by insurance for an attended diagnostic sleep study?
  - A. 65 year old man with advanced COPD on 3 LPM supplemental oxygen
  - B. 54 year old female with neuromuscular disease leading to restrictive physiology
  - C. 59 year old man with early onset dementia
  - D. 59 year old female with advanced pulmonary hypertension on supplemental oxygen therapy
  - E. 35 year old female with non-ischemic cardiomyopathy with an ejection fraction of 28%

Question

- A 55 year old female undergoes a home sleep study revealing an AHI of 39, lowest oxygen saturation of 82% and time < 88% for 9.4 minutes.

- Which of the following is the next best treatment approach?

- A. AUTO CPAP prescription and clinic follow up
- B. PAP titration in the sleep laboratory and clinic follow up

CENTRAL SLEEP APNEA AND CHRONIC OPIOD USE

Kathleen Sarmiento, MD
UC San Francisco
Associate Professor of Medicine

Saturday, January 19, 2019 – 11:40 a.m. – 12:10 p.m.

Kathleen (Katie) Sarmiento, MD, is an Associate Professor of Medicine at UC San Francisco, the Director of Sleep Medicine at the San Francisco VA Health Care System, and the National Lead for VA TeleSleep, an enterprise-wide initiative to build a high-performing sleep telemedicine network. She has been instrumental in building infrastructure for and leading VA Sleep operations. She has an active clinical practice in Pulmonary, Critical Care and Sleep Medicine. Her research interests are focused on health services research, including strategies to improve access to sleep care in rural areas, reduce wait times, lower cost, and de-implement low-value steps in obtaining care.

LUNCH
EXHIBIT HALL OPEN

Saturday, January 19, 2019 – 12:10 p.m. – 1:10 p.m.

SLEEP DISORDERED BREATHING IN NEUROMUSCULAR DISEASE

Won Lee, MD
University of Texas Southwestern Medical Center
Associate Professor

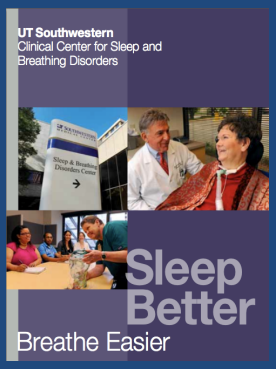
Saturday, January 19, 2019 – 1:10 p.m. – 1:40 p.m.

Won Lee, MD, is an associate professor in pulmonary, critical care and sleep medicine at the University of Texas Southwestern Medical Center in Dallas, Texas. He serves as medical director of the Sleep and Breathing Disorders Center. His primary clinical interests include sleep disordered breathing and neuromuscular pulmonary disorders.

Sleep Disordered Breathing in Neuromuscular Disease

Won Y. Lee, M.D.

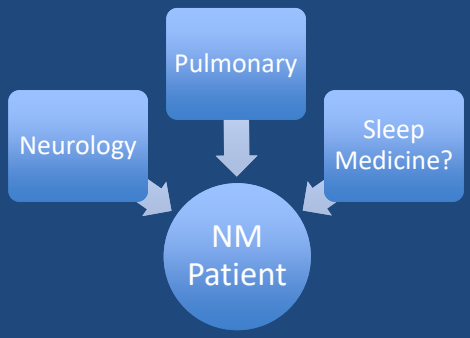
Associate Professor, Division of Pulmonary and Critical Care Medicine
University of Texas Southwestern Medical Center
Dallas, Texas



UT Southwestern Medical Center

I have no financial disclosures to declare.

Traditional Management of Patients with Neuromuscular Diseases



- Sleep medicine specialists
  - have expertise to IMPROVE quality of life
  - can also make mistakes to WORSEN quality of life

Outline

Neuromuscular Disorders (NMD)

- Overview of neuromuscular diseases
- Physiologic testing
  - Restrictive physiology and impaired forces

Noninvasive Ventilation (NIV)

- How to qualify for a respiratory assist device?
- The Polysomnogram – Friend or Foe?
  - The double edged sword

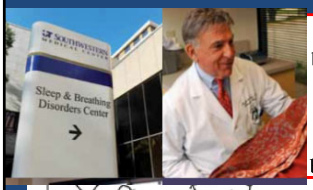
Longitudinal Management

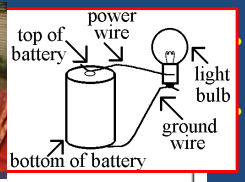
- Practical pearls and lessons learned
  - "With great power, comes great responsibility"

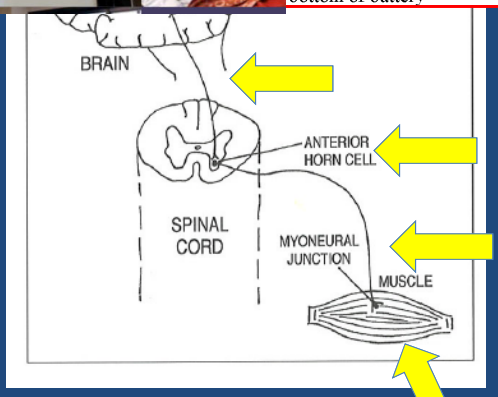
Outline

Neuromuscular Disorders (NMD)	• Overview of neuromuscular diseases • Physiologic testing • Restrictive physiology and impaired forces
Noninvasive Ventilation (NIV)	• How to qualify for a respiratory assist device? • The Polysomnogram – Friend or Foe? • The double edged sword
Longitudinal Management	• Practical pearls and lessons learned • "With great power, comes great responsibility"

The Nerves and Muscles in NMD

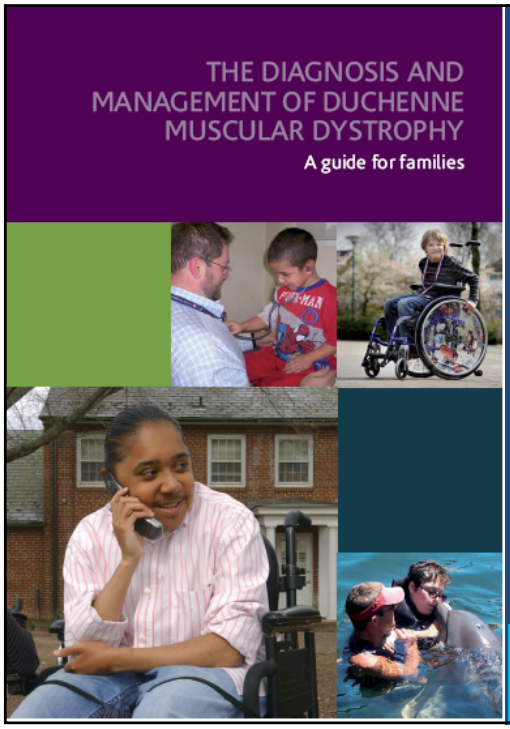






- Motor, not sensory dysfunction
- Neuropathies
  - Guillain-Barre syndrome
    - Acute inflammatory demyelinating polyneuropathy
    - Molecular mimicry/autoimmune
    - Injury/loss of myelin sheath
      - Myelin → coils around nerve
- Anterior horn cell
  - Poliomyelitis (infection)
- Myoneural junction
  - Myasthenia gravis (antibodies)
- Myopathies
  - Muscular dystrophy

Bach JR. Guide to the Evaluation and Management of Neuromuscular Disease. 1999.

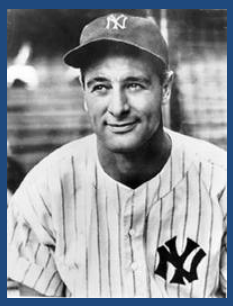


Muscular Dystrophy

- Duchenne muscular dystrophy
  - X-linked.
  - 1 in 3600-6000 live male births.
  - Mutation leading to absence of dystrophin protein
- Proximal muscle weakness
  - Age 5→ initial symptoms
  - Age 13 → Most require wheelchair before their teenage years
  - Late teens/early 20's → Respiratory failure
  - Cardiomyopathies

Bushby K et al. Lancet Neurol 2009; published online Nov 30. DOI:10.1016/S1474-4422(09)70271-6.
http://www.cdc.gov/ncbddd/musculardystrophy/

Amyotrophic Lateral Sclerosis (ALS) Lou Gehrig's Disease

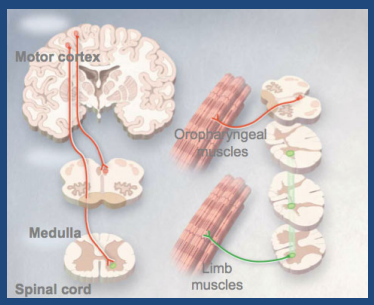


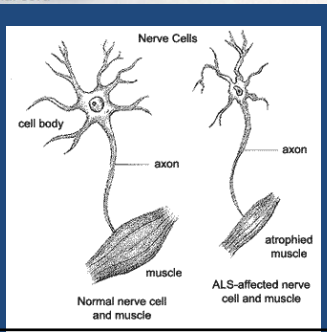
- Lou Gehrig
  - 17 seasons –NY Yankees
  - 2130 consecutive games
- 1938/1939 season
  - Tired, decreased coordination, lack of power, muscle atrophy, batting average (.143)
- Went to Mayo Clinic in 1939
  - Diagnosed with ALS
  - July 4, 1939 → retired/speech
    - "Fans, for the past two weeks you have been reading about the bad break I got. Yet today I consider myself the luckiest man on the face of the earth"
- Died in 1941, at age 37 from ALS

Brennan F. Am J Hosp Palliat Care. 2012: 29(7): 512-4

Amyotrophic Lateral Sclerosis

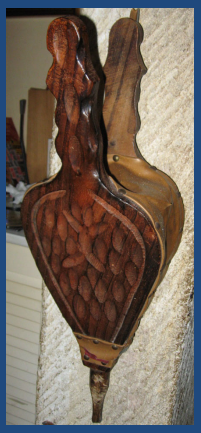
- Most cases are sporadic (90%)
  - 10% are familial
  - Median survival of 3 to 5 years
    - Relentless, progressive, and incurable
- All races, age 40-75, Men > women
  - Adult onset, progressive
  - Incidence → 1 to 3 cases/100,000 persons
  - Prevalence → 2.7 to 7.4 persons/100,000
- Idiopathic degeneration of cells of
  - motor cortex
  - anterior horn
  - corticospinal tracts
  - corticobulbar tracts
    - Pathologic inclusions
- UMN
  - Slowness, hyperreflexia, spasticity
  - Degeneration of frontal motor neurons
- LMN
  - Progressive muscle weakness and muscle wasting
  - Fasciculations





Why pulmonologists need to know…

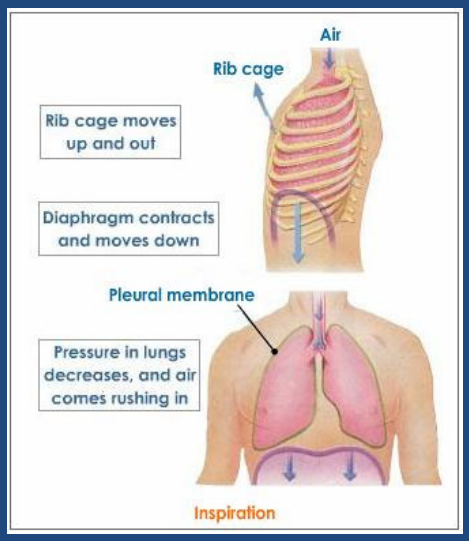
- Severe restrictive physiology
  - Progressive dyspnea
- Need for ventilatory support
  - Acute Guillain Barre Syndrome
    - 20-30 %
  - Myasthenia gravis
    - 15-28 %
  - ALS
    - most will die from progressive respiratory failure



Sharshar T et al. Crit Care Med. 2003:31:278.
Mehta S. Respir Care. 2006;51:1016.
Durand MC et al. Lancet Neurol. 2006;5:1012.

NMD → Weakened Inspiratory Muscles

- Diaphragm, external intercostels, scalene, sternocleidomastoid, trapezii
  - Dyspnea, orthopnea, rapid shallow breathing
    - Low Vt and increased RR to maintain alveolar ventilation
  - Use of accessory muscles
    - Abdominal paradox (inward motion of abdomen during inspiration)
  - Hypercarbia, hypoxemia
    - Alveolar hypoventilation
    - Atelectasis
  - Nocturnal hypoventilation
    - Fatigue, impaired cognition, choking



West JB. Respiratory physiology: the essentials. 5th Ed. Williams & Wilkins, 1995.

ALS and Respiratory System

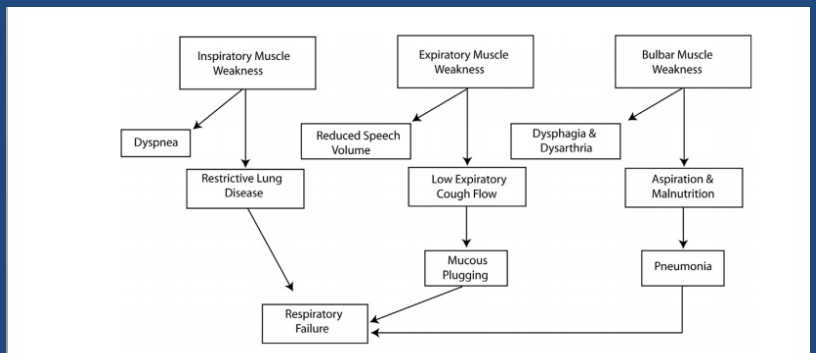
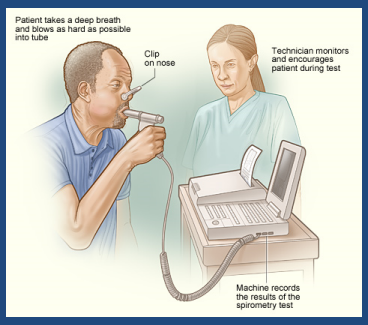


Fig. 1. The major respiratory abnormalities that develop in ALS.

Braun AT, Caballero-Eraso C, Lechtzin N. Clin Chest Med 39 (2018) 391-400.

Physiologic Evaluation In NMD

- Reason?
  - Quantify respiratory muscle weakness
  - Evaluate cough effectiveness
  - Identify those who need ventilatory support



- Tools
  - FVC and MIPs/MEPs

ATS/ERS Statement on Respiratory Muscle Testing. 2002

Why restrictive physiology on PFTs?

- IRV is reduced → due to weak inspiratory muscles
- ERV is reduced → due to weak expiratory muscles
  - Therefore VC is reduced (VC = IRV + TV + ERV)
  - RV is ELEVATED
- FVC in the supine position is ~ 10% lower than upright
  - Can drop between 12 and 65% in NM disease patients.

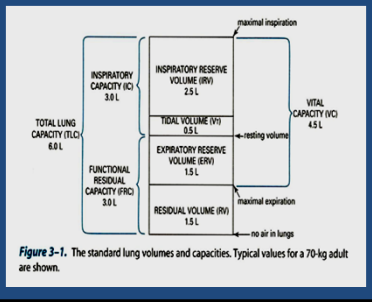
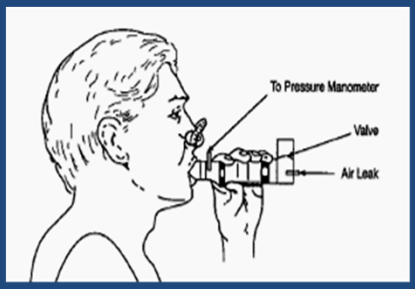
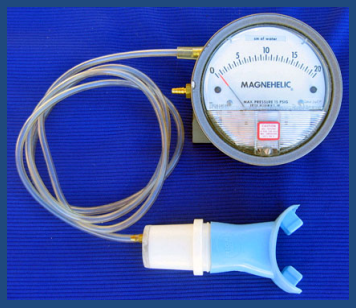


Figure 3–1. The standard lung volumes and capacities. Typical values for a 70-kg adult are shown.

MIP/MEPs





- Mechanical pressure gauge connected to a mouthpiece
- Electronic devices available

- Should have a small hole (1mm diameter and 20-30 mm in length) which allows an air leak.
  - Prevents patient from generating pressure by using cheek muscles

ATS/ERS Statement on Respiratory Muscle Testing. 2002

Reference Ranges for MIP/MEP

Maximal inspiratory pressure (MIP) and maximal expiratory pressure (MEP) reference ranges derived from population-based studies with good reference equations

	MIP*	MEP*
Children (ages 7 to 13)[1]	Male: 77 to 114	99 to 161
	Female: 71 to 108	74 to 126
Adolescents (ages 13 to 35)[2]	Male: 114 to 121	131 to 161
	Female: 65 to 85	92 to 95
Adults (ages 18 to 65)[3]	Male: 92 to 121	140•
	Female: 68 to 79	95•
Older adults (ages 65 to 85)[4]	Male: 65 to 90	140 to 190
	Female: 45 to 60	90 to 130

* Mean values in cm H_2O.

• These mean MEP values from another study[5]. They are underestimates because the mouthpiece was used between the teeth instead of against the lips and teeth.

Data from:

1. Gaultier C, Zinman R. Maximal static pressures in healthy children. Respir Physiol 1983; 51:45.
2. Leech JA, Ghezzo H, Stevens D, Becklake MR. Respiratory pressures and function in young adults. Am Rev Respir Dis 1983; 128:17.
3. Harik-Khan RI, Wise RA, Fozard JL. Determinants of maximal inspiratory pressure: the Baltimore Longitudinal Study of Aging. Am J Respir Crit Care Med 1998; 158:1459.
4. Enright PL, Kronmal RA, Manolino TA, et al. Respiratory muscle strength in the elderly. Correlates and reference values. Am J Respir Crit Care Med 1994; 149:430.
5. Bruschi C, Cerveri I, Zoia MC, et al. Reference values of maximal respiratory mouth pressures: a population-based study. Am Rev Respir Dis 1992; 146:790.

UpToDate

Outline

Neuromuscular Disorders (NMD)

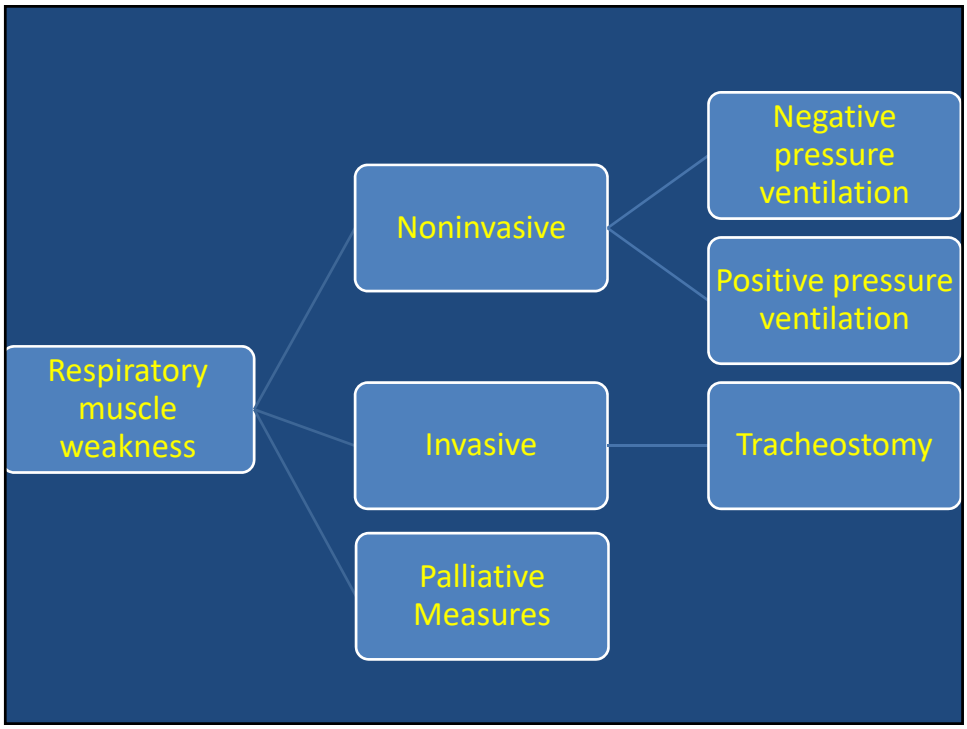
- Overview of neuromuscular diseases
- Physiologic testing
  - Restrictive physiology and impaired forces

Noninvasive Ventilation (NIV)

- How to qualify for a respiratory assist device?
- The Polysomnogram – Friend or Foe?
  - The double edged sword

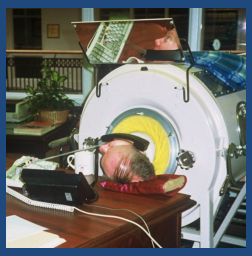
Longitudinal Management

- Practical pearls and lessons learned
  - "With great power, comes great responsibility"



Negative Pressure Ventilation (NPV) The Iron Lung

- Replicates and augments normal spontaneous breathing
  - Negative (subatmospheric) pressure
  - Rotary pumps placed
    - Causes thoracic expansion, pressure gradient

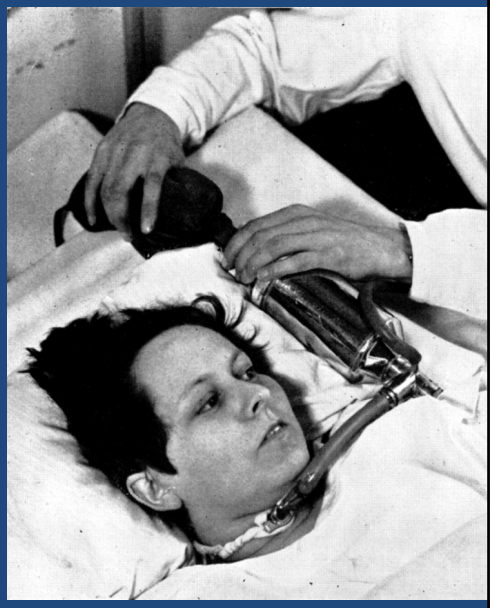


- Poliomyelitis epidemic
  - Copenhagen in 1952
    - Paralysis, of the legs, arms and respiratory muscles
  - 31 patients, 27 died
    - Within 3 days *despite negative pressure ventilation*.

West JB. J Appl Physiol 2005;99:424-432

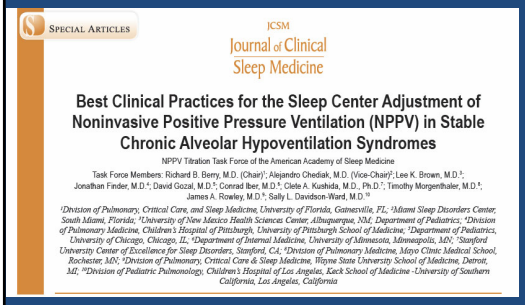
Positive Pressure Ventilation

- Patient 32 (12 year girl)
  - Dr. Bjorn Ibsen
    - tracheostomy
    - positive pressure ventilation
    - manual pressure from a rubber bag
- Up to 1500 medical and dental students
    - 6-8 hour shifts around the clock to deliver positive pressure ventilation



West JB. J Appl Physiol 2005;99:424-432

Noninvasive Positive Pressure Ventilation (NPPV)


SPECIAL ARTICLES

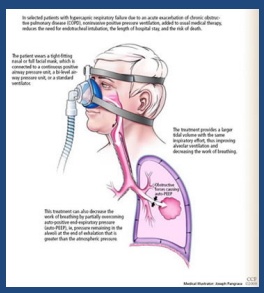
JCSM
Journal of Clinical Sleep Medicine

Best Clinical Practices for the Sleep Center Adjustment of Noninvasive Positive Pressure Ventilation (NPPV) in Stable Chronic Alveolar Hypoventilation Syndromes

NPPV Titration Task Force of the American Academy of Sleep Medicine

Task Force Members: Richard B. Berry, M.D. (Chair)[1]; Alejandro Chediak, M.D. (Vice-Chair)[2]; Lee K. Brown, M.D.[3]; Jonathan Finder, M.D.[4]; David Gozal, M.D.[5]; Conrad Iber, M.D.[6]; Clete A. Kushida, M.D., Ph.D.[7]; Timothy Morgenthaler, M.D.[8]; James A. Rowley, M.D.[9]; Sally L. Davidson-Ward, M.D.[10]

[1]Division of Pulmonary, Critical Care, and Sleep Medicine, University of Florida, Gainesville, FL; [2]Miami Sleep Disorders Center, South Miami, Florida; [3]University of New Mexico Health Sciences Center ,Albuquerque, NM; Department of Pediatrics, [4]Division of Pulmonary Medicine, Children's Hospital of Pittsburgh, University of Pittsburgh School of Medicine; [5]Department of Pediatrics, University of Chicago, Chicago, IL, [6]Department of Internal Medicine, University of Minnesota, Minneapolis, MN; [7]Stanford University Center of Excellence for Sleep Disorders, Stanford, CA; [8]Division of Pulmonary Medicine, Mayo Clinic Medical School, Rochester, MN; [9]Division of Pulmonary, Critical Care & Sleep Medicine, Wayne State University School of Medicine, Detroit, MI; [10]Division of Pediatric Pulmonology, Children's Hospital of Los Angeles, Keck School of Medicine -University of Southern California, Los Angeles, California



- Task Force → evidence and consensus-based standardized NPPV titration guidelines
- Chronic Alveolar Hypoventilation syndromes secondary :
  - central respiratory control disturbances (CRCD)
  - restrictive thoracic cage disorders (RTCD) → scoliosis
  - neuromuscular diseases (NMD)
  - obesity hypoventilation syndrome (OHS)

Berry, RB et al. J Clin Sleep Med 2010;6(5):491-509.

Survival Benefit for use of NIPPV in ALS

Table 1. Studies demonstrating survival benefit for ALS patients using NIV.

Author, year	Study design	NIV device	NIV started	Participants & treatments	Findings
Pinto, 1995	NCT	Bi-level PAP	Daytime hypercapnia or hypoxia	10 NIV 10 standard	3-year survival higher with NIV (87.5% vs 22.2%, $P < .004$)
Aboussouan, 1997	Obs	BiPAP®; ST mode or PLV-100	Daytime orthopnea, hypercapnia or both	21 NIV ≥4h nocturnal 18 intolerant	Median survival 2 months in those NIV intolerant, 15 months NIV tolerant ($P < 0.001$)
Kleopa, 1999	Obs	Bi-level PAP	Respiratory symptoms, FVC <50% predicted, or FVC drop >15% in 3 months	38 NIV>4h/d 32 NIV<4h/d 52 refused NIV	Mean survival 14.2 mo >4h/d(p<0.001), 7.0 mo <4 h/d ($P = 0.038$), 4.6 mo refused NIV
Gruis, 2006	Obs	Bi-level PAP; S mode	Respiratory symptoms and FVC <50% or MIF <−60 cm water	18 NIV ≥4 h/nocturnal 19 intolerant	NIV tolerant decreased risk of death (HR 0.23) 95% CI (0.10,0.54)
Bourke, 2006	RCT	VPAP® STIl; ST mode	Orthopnea & MIP <60% or hypercapnia	22 NIV 19 standard	Median survival benefit 205 days with NIV ($P = .006$).

NCT, nonrandomized controlled clinical trial; Obs, observational study; RCT, randomized controlled clinical trial; NIV, noninvasive positive-pressure ventilation; PAP, positive airway pressure; FVC, forced vital capacity; MIP, maximum inspiratory pressure; MIF, maximum inspiratory force (MIP, MIF, or negative inspiratory force are often used interchangeably); PLV-100, volume-controlled portable ventilator in assist-control mode (Life Care Products, Lafayette, CO); BiPAP® (Respironics, Inc., Murrysville, PA); VPAP® STIl (ResMed, UK Ltd, Abingdon, UK); ST, spontaneous timed mode; S, spontaneous mode; HR, hazard ratio; CI, confidence interval; cm, centimeters; h, hours; mo, months.

Muscle Nerve. 2012; 46: 313–331.

NIV improves ALS survival in those with preserved bulbar function

Effects of non-invasive ventilation on survival and quality of life in patients with amyotrophic lateral sclerosis: a randomised controlled trial

Stephen C Bourke, Mark Tomlinson, Tim L Williams, Robert E Bullock, Pamela J Shaw, G John Gibson

- ALS patients
  - Randomized
    - NIV (22 patients) vs. no ventilation (19)
  - Orthopnea, MIP < - 60, or symptomatic hypercapnia
  - NIV improved quality of life, sleep quality, and survival mostly in ALS patients without bulbar disease
    - Increased survival by 205 days
  - Good bulbar function → 9.3 hours per day
  - Poor bulbar function → 3.8 hours per day
  - Settings?
    - Average IPAP of 15 cm H2O
    - Average EPAP of 4 cm H2O

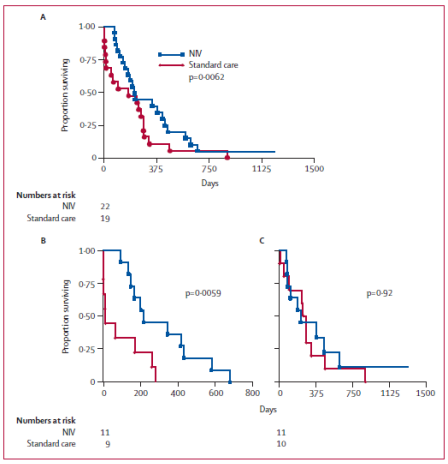


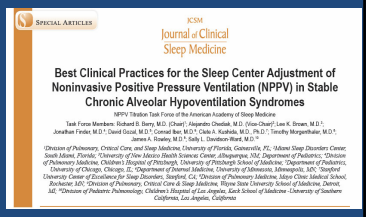
Figure 2: **Survival from randomisation**
A: all patients; B: patients with normal or moderately impaired bulbar function; C: patients with severe bulbar impairment.

Bourke SC et al. Lancet Neurol. 2006;5:140-7.

Why does optimal NIPPV titration matter?

4.1.8 Attended NPPV titration with polysomnography allows definitive identification of an adequate level of ventilatory support for patients with NMD in whom NPPV treatment is planned. (Level A - Consensus)

- Preserve quality of life
  - Maintain ability to communicate
  - Improve sleep quality
- Reduce morbidity
  - Decrease carbon dioxide
  - Avoids morbidity involved with tracheostomy
- Reduce mortality
  - Extend duration of life



Berry, RB et al. J Clin Sleep Med 2010;6(5):491-509.

Do we need a DIAGNOSTIC sleep study to facilitate initiating a RAD for NMD?

- Common phone call
  - "I have a patient with a diagnosis of a NMD (ALS, muscular dystrophy, etc…) and hypercapnic respiratory failure."
  - "The patient has done GREAT on bilevel PAP in the hospital."
  - "I am told that the patient needs a diagnostic attended polysomnogram to get his bilevel PAP device."
  - True or **False**?

Bilevel PAP Devices

Coding

- **E0470** – Respiratory Assist Device, Bi-Level Pressure, Without Backup Rate Feature
  - Delivers adjustable, variable levels of positive air (during single respiratory cycle) and supplements volume of air into the lungs
- **E0471** – Respiratory Assist Device, Bi-Level Pressure, With Backup Rate Feature
  - Has the same features as E0470, with the addition of timed backup feature to deliver air when insufficient inspiratory efforts fail

www.medicare.gov

Why is a sleep study NOT needed to initiate NIV?

Initial Coverage Criteria

- **Restrictive Thoracic Disorders**

A	**Documentation of progressive neuromuscular disease, or severe thoracic cage abnormality**
B	**1. Arterial blood gas (while awake) ≥ 45 mm Hg or** **2. O2 saturation ≤ 88% for at least 5 continuous minutes** **3. For progressive neuromuscular disease (only) maximal inspiratory pressure is < 60 cm H2O or Forced vital capacity is %50 predicted and**
C	**Chronic Obstructive pulmonary disease does not contribute significantly to beneficiary's pulmonary limitations**

- **If criteria A-C are met, either E0470 or E0471 will be covered for the first three months.**

www.medicare.gov

Survival Benefit for use of NIPPV in ALS

Table 1. Studies demonstrating survival benefit for ALS patients using NIV.

Author, year	Study design	NIV device	NIV started	Participants & treatments	Findings
Pinto, 1995	NCT	Bi-level PAP	Daytime hypercapnia or hypoxia	10 NIV 10 standard	3-year survival higher with NIV (87.5% vs 22.2%, $P < .004$)
Aboussouan, 1997	Obs	BiPAP®; ST mode or PLV-100	Daytime orthopnea, hypercapnia or both	21 NIV ≥4h nocturnal 18 intolerant	Median survival 2 months in those NIV intolerant, 15 months NIV tolerant ($P < 0.001$)
Kleopa, 1999	Obs	Bi-level PAP	Respiratory symptoms, FVC <50% predicted, or FVC drop >15% in 3 months	38 NIV>4h/d 32 NIV<4h/d 52 refused NIV	Mean survival 14.2 mo >4h/d(p<0.001), 7.0 mo <4 h/d ($P = 0.038$), 4.6 mo refused NIV
Gruis, 2006	Obs	Bi-level PAP; S mode	Respiratory symptoms and FVC <50% or MIF <−60 cm water	18 NIV ≥4 h/nocturnal 19 intolerant	NIV tolerant decreased risk of death (HR 0.23) 95% CI (0.10,0.54)
Bourke, 2006	RCT	VPAP® STII; ST mode	Orthopnea & MIP <60% or hypercapnia	22 NIV 19 standard	Median survival benefit 205 days with NIV ($P = .006$).

NCT, nonrandomized controlled clinical trial; Obs, observational study; RCT, randomized controlled clinical trial; NIV, noninvasive positive-pressure ventilation; PAP, positive airway pressure; FVC, forced vital capacity; MIP, maximum inspiratory pressure; MIF, maximum inspiratory force (MIP, MIF, or negative inspiratory force are often used interchangeably); PLV-100, volume-controlled portable ventilator in assist-control mode (Life Care Products, Lafayette, CO); BiPAP® (Respironics, Inc., Murrysville, PA); VPAP® STII (ResMed, UK Ltd, Abingdon, UK); ST, spontaneous timed mode; S, spontaneous mode; HR, hazard ratio; CI, confidence interval; cm, centimeters; h, hours; mo, months.

Muscle Nerve. 2012; 46: 313–331.

Eur Respir J 2002; 19: 1194–1201
DOI: 10.1183/09031936.02.01302001a
Printed in UK – all rights reserved

European Respiratory Journal
ISSN 0903-1936

REVIEW

Sleep and breathing in neuromuscular disease

S.C. Bourke, G.J. Gibson

NORMAL SUBJECTS

Changes in minute ventilation, tidal volume,
and respiratory rate in:

- NREM
- REM
- Tonic REM
- Phasic Rem

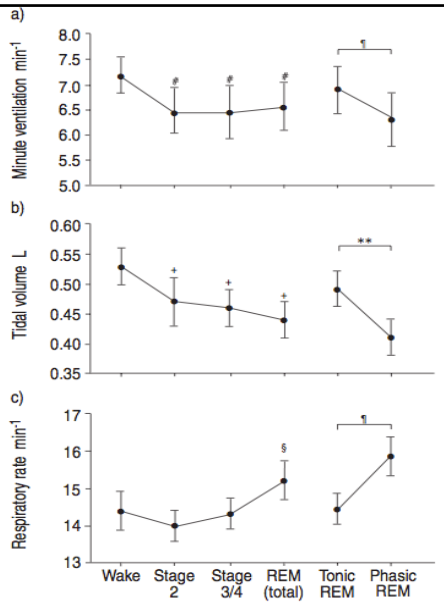


Fig. 1.–a) Minute ventilation, b) tidal volume and c) respiratory rate during wakefulness and sleep in 10 normal adult subjects. Data are presented as mean±SEM. #: Ventilation lower during sleep compared to wake $p<0.02$; ": $p=0.01$; +: tidal volume lower during sleep compared to wake $p<0.05$; **: $p<0.01$; §: respiratory rate higher in rapid eye movement (REM) compared to nonrapid eye movement sleep (NREM) or wake $p<0.05$. Data from GOULD *et al.* [26].

Eur Respir J 2002; 19: 1194–1201
DOI: 10.1183/09031936.02.01302001a
Printed in UK – all rights reserved
Copyright ©ERS Journals Ltd 2002
European Respiratory Journal
ISSN 0903-1936
REVIEW
Sleep and breathing in neuromuscular disease
S.C. Bourke, G.J. Gibson

Screening sleep studies have been recommended in patients with neuromuscular disease, often guided by serial daytime respiratory function tests (typically spirometry plus/minus blood gases) [9, 10, 39, 40]. However in comparison to daytime lung function, nocturnal measurements, including oxygen saturation, are surprisingly weak predictors of survival [4, 44]. In amyotrophic lateral sclerosis orthopnoea (due to respiratory muscle weakness) is a more sensitive predictor of benefit from noninvasive ventilation than either nocturnal desaturation or daytime hypercapnia and the apnoea/hypopnoea index is unhelpful [45]. The studies available cast doubt on the need for routine polysomnography or nocturnal oximetry in assessing such patients for noninvasive ventilation, although polysomnography may identify the occasional patient with coexistent obstructive sleep apnoea. There is a need for further studies evaluating the optimal criteria for and timing of initiating noninvasive ventilation in patients with neuromuscular disease. Currently there is no evidence that sleep studies improve the selection of subjects for noninvasive ventilation over and above evaluation of symptoms and daytime respiratory function.

Is a sleep study needed?

- "…daytime respiratory function has greater prognostic value than nocturnal measurements."
- In comparison to daytime lung function [and symptoms],
  - nocturnal measurements are surprisingly WEAK predictors of survival.
- There is NO evidence that sleep studies improve the selection of subjects for NIV over and above symptoms and daytime respiratory function.

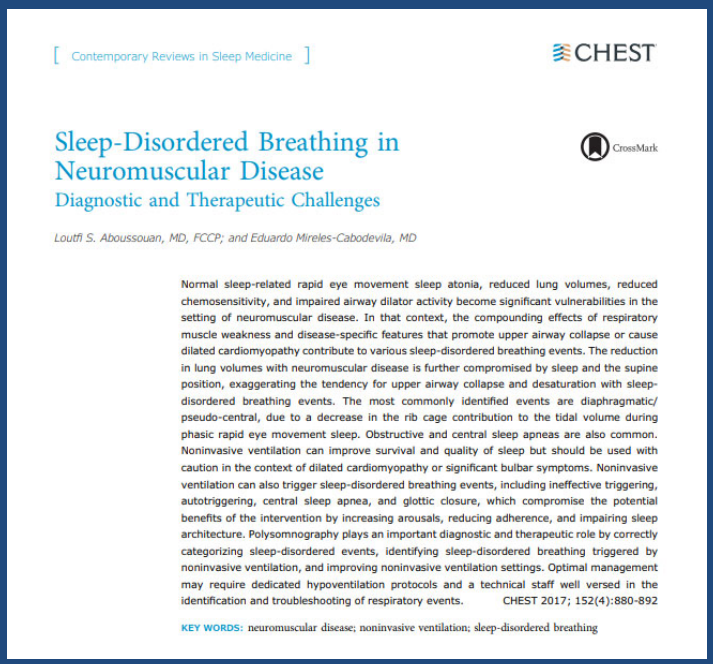
A diagnostic sleep study is NOT needed to initiate NIV therapy

- "…daytime respiratory function has greater prognostic value than nocturnal measurements."

Bourke SC and Gibson, GJ. Eur Respir J. 2002; 19:1194-1201.

- Confirmed NMD Diagnosis AND one of the following…
  - PaCO2 > 45 mm Hg
  - SpO2 < 88% for 5 consecutive minutes (min 2 hour recording)
  - FVC < 50%
  - MIP < - 60

- These patients can EITHER:
  - DIRECTLY obtain a respiratory assist device
  - Go DIRECTLY to the sleep laboratory or hospital for optimal titration



[Contemporary Reviews in Sleep Medicine]

CHEST

Sleep-Disordered Breathing in Neuromuscular Disease

Diagnostic and Therapeutic Challenges

Loutfi S. Aboussouan, MD, FCCP; and Eduardo Mireles-Cabodevila, MD

Normal sleep-related rapid eye movement sleep atonia, reduced lung volumes, reduced chemosensitivity, and impaired airway dilator activity become significant vulnerabilities in the setting of neuromuscular disease. In that context, the compounding effects of respiratory muscle weakness and disease-specific features that promote upper airway collapse or cause dilated cardiomyopathy contribute to various sleep-disordered breathing events. The reduction in lung volumes with neuromuscular disease is further compromised by sleep and the supine position, exaggerating the tendency for upper airway collapse and desaturation with sleep-disordered breathing events. The most commonly identified events are diaphragmatic/pseudo-central, due to a decrease in the rib cage contribution to the tidal volume during phasic rapid eye movement sleep. Obstructive and central sleep apneas are also common. Noninvasive ventilation can improve survival and quality of sleep but should be used with caution in the context of dilated cardiomyopathy or significant bulbar symptoms. Noninvasive ventilation can also trigger sleep-disordered breathing events, including ineffective triggering, autotriggering, central sleep apnea, and glottic closure, which compromise the potential benefits of the intervention by increasing arousals, reducing adherence, and impairing sleep architecture. Polysomnography plays an important diagnostic and therapeutic role by correctly categorizing sleep-disordered events, identifying sleep-disordered breathing triggered by noninvasive ventilation, and improving noninvasive ventilation settings. Optimal management may require dedicated hypoventilation protocols and a technical staff well versed in the identification and troubleshooting of respiratory events. CHEST 2017; 152(4):880-892

KEY WORDS: neuromuscular disease; noninvasive ventilation; sleep-disordered breathing

Clinical Case #1

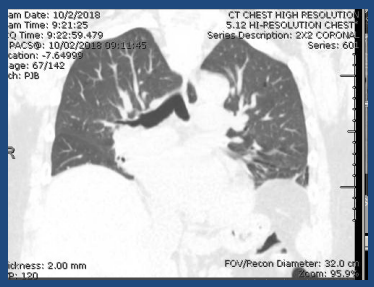
- 37 F with limb girdle muscular dystrophy.
  - Wheelchair limited. Marked dyspnea.
  - FVC 19% and MIP – 17
- Evaluated by a pulmonary/sleep specialist
  - Diagnosed with mild sleep apnea (AHI 5.1)
  - Titrated, then retitrated to CPAP 19 cm H2O
    - Choking, suffocating, dyspnea is markedly worse.
- We switched her from CPAP to NIV during nighttime and daytime mode ventilation
  - Marked improvement in quality of life

Clinical Case #2

- 35 F, diagnosed with bulbar ALS early this year and referred to discuss ventilation options.
  - She is getting more dyspneic and rapidly weakening.
- Spirometry and forces
  - FVC 45%
  - MIP -20
- ABG
  - pH 7.32, PaCO2 55mm Hg, and PaO2 of 62 mm Hg
- She had a diagnostic sleep study 8/1/17
  - "poor sleep efficiency, AHI of 1.5, no sleep related breathing disorder" so unfortunately it wasn't super helpful.
- Can you help?

Clinical Case #3

- 51 year old female
- Shrinking lung syndrome, SLE
- Gradual dyspnea
  - FVC 27%
  - MIPs -42
  - 2 diagnostic PSGs
    - Both showed an AHI < 5



- Which of the following is the next appropriate step?
  - A. Repeat a 3rd diagnostic sleep study
  - B. Order oxygen, she is not a candidate for noninvasive ventilation (NIV)
  - C. Order a bilevel PAP with back up rate at settings of 8/4 cm H2O with a rate of 10 and gradually increase as tolerated
  - D. Order a bilevel PAP in AVAPS mode
  - E. Perform a titration sleep study using bilevel PAP with back up rate to meet patients' respiratory needs

A diagnostic sleep study is NOT needed to initiate NIV therapy for NMD

- "…daytime respiratory function has greater prognostic value than nocturnal measurements."

Bourke SC and Gibson, GJ. Eur Respir J. 2002; 19:1194-1201.

- Confirmed NMD Diagnosis AND one of the following…
  - PaCO2 > 45 mm Hg
  - SpO2 < 88% for 5 consecutive minutes (min 2 hour recording)
  - FVC < 50%
  - MIP < - 60

- These patients can EITHER:
  - DIRECTLY obtain a respiratory assist device
  - Go DIRECTLY to the sleep laboratory or hospital for optimal titration

NMD and Sleep Medicine

- Strengths
  - Expertise in noninvasive ventilation
    - Synchrony to optimize sleep quality, ventilation, and oxygenation
  - Expertise in mask interfaces
  - Compliance monitoring
- Pitfalls of sleep medicine
  - The current state of sleep medicine training, does not focus on NMD patient population
    - Excess focus on OSA
  - Complexities of respiratory physiology

Lessons Learned

Protocols and equipment to accommodate for NM patients in the sleep lab

- Hospital bed
  - 2 of our beds
- Hoyer lift
- Suction
- Supplemental O2
- Call system
- Accommodations for a care giver
- Technical expertise
  - RRT and RPSGT
  - 1:1 if needed

Goals of NIV

1. Decrease work of breathing
2. Optimize ventilation and oxygenation
3. Tolerance to NIPPV
   - Minimize mask leakage
   - Good sleep quality

4.9.4.3 THE RESPIRATORY FUNCTION OF PATIENTS ON CHRONIC NPPV TREATMENT SHOULD BE ASSESSED WITH MEASURES OF OXYGENATION AND VENTILATION (ARTERIAL BLOOD GAS, END-TIDAL CO_2, TRANSCUTANEOUS PCO_2) ON A REGULAR FOLLOW-UP BASIS OR IF SIGNS OF CLINICAL DETERIORATION ARE PRESENT. (LEVEL A - CONSENSUS)

4.9.1.1 THE NPPV DEVICE SETTINGS USED FOR TREATMENT SHOULD IDEALLY REFLECT THE FOLLOWING TREATMENT GOALS: CONTROL OF AIRWAY OBSTRUCTION AS DEFINED BY A RESPIRATORY DISTURBANCE INDEX (RDI) < 5/HOUR, ABSENCE OF SNORING, A MINIMUM SPO_2 > 90% AT SEA LEVEL, NORMALIZATION/IMPROVEMENT OF VENTILATION WITH A PCO_2 (IF MEASURED) NO GREATER THAN 10 MM HG ABOVE THE TREATMENT GOAL, REDUCTION IN EXCESSIVE RESPIRATORY MUSCLE ACTIVITY, AND A MASK LEAK WITHIN ACCEPTABLE PARAMETERS FOR THE SELECTED PRESSURES AND MASK INTERFACE. IN THIS WORK RDI REFERS TO THE NUMBER OF APNEAS + HYPOPNEAS + RERAS AND THE HOURS OF SLEEP. (LEVEL A - CONSENSUS)

4.9.1.2 AN OPTIMAL TITRATION MEETS THE ABOVE TREATMENT GOALS AT THE SELECTED NPPV SETTINGS FOR AT LEAST A 15-MINUTE PERIOD THAT INCLUDES REM SLEEP IN THE SUPINE POSITION (UNLESS THIS POSITION IS CONTRAINDICATED) THAT IS NOT CONTINUALLY INTERRUPTED BY AROUSALS. (LEVEL A - CONSENSUS)

4.9.1.3 A GOOD TITRATION MEETS THE ABOVE TREATMENT GOALS AT THE SELECTED NPPV SETTINGS FOR AT LEAST A 15-MINUTE PERIOD THAT INCLUDES NREM SLEEP IN THE SUPINE POSITION (UNLESS THIS POSITION IS CONTRAINDICATED) AND REM SLEEP IN ANY POSITION AT THE SELECTED SETTINGS. (CONSENSUS B)

4.9.1.4 AN ADEQUATE TITRATION MEETS THE ABOVE TREATMENT GOALS, EXCEPT THAT THE RDI MUST BE LESS THAN 10/HOUR AT THE SELECTED NPPV SETTINGS FOR AT LEAST A 15-MINUTE PERIOD THAT INCLUDES NREM SLEEP IN THE SUPINE POSITION (UNLESS THIS POSITION IS CONTRAINDICATED) AND REM SLEEP IN ANY POSITION AT THE SELECTED SETTINGS. (LEVEL A - CONSENSUS)

Berry, RB et al. J Clin Sleep Med 2010;6(5):491-509.

- Start 8/4 cm H2O
- Increase IPAP to augment tidal volume
- Goal tidal volume of 8-10 mL/kg
  - Ideal body weight
- Example
  - 15/5 cm H2O
  - TV ~600 mL

4.3 Recommendations for Initial and Maximum Pressures during NPPV Titration

4.3.1. The recommended minimum starting IPAP and EPAP should be 8 cm H_2O and 4 cm H_2O, respectively. (Level A - Consensus).

4.4.2 Recommendations for adjusting pressure support for low tidal volume or hypoventilation during sleep

4.4.2.1 THE PS SHOULD BE INCREASED EVERY 5 MINUTES IF THE TIDAL VOLUME IS BELOW THE ACCEPTABLE GOAL. AN ACCEPTABLE TIDAL VOLUME GOAL FOR MOST PATIENTS RANGES FROM 6 TO 8 ML/KG USING IDEAL BODY WEIGHT (**FIGURE 3**). (LEVEL A - CONSENSUS).

4.3.5 The minimum and maximum incremental changes in PS during NPPV titration should be 1 and 2 cm H_2O, respectively. (Level A - Consensus).

4.3.4 The recommended maximum IPAP should be 20 cm H_2O for patients < 12 years and 30 cm H_2O for patients ≥ 12 years. (Level A - Consensus)

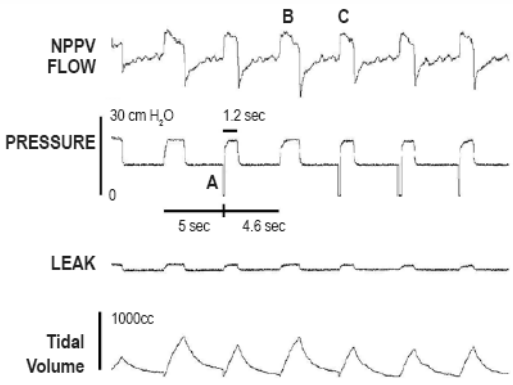
Berry, RB et al. J Clin Sleep Med 2010;6(5):491-509.

BPAP ST Mode

- BPAP S
  - Spontaneous mode
- BPAP ST
  - NPPV in the spontaneous-timed (ST) mode provides a backup rate to ensure a minimum respiratory rate
  - For example, if the back-up rate is 10 bpm, the time window following the previous breath is 6 seconds.
  - If a spontaneous breath does not occur, the device provides a machine triggered breath.

NPPV Titration Task Force

Figure 1—Tracing of NPPV flow, pressure, leak, and tidal volume in a patient receiving BPAP in the ST mode

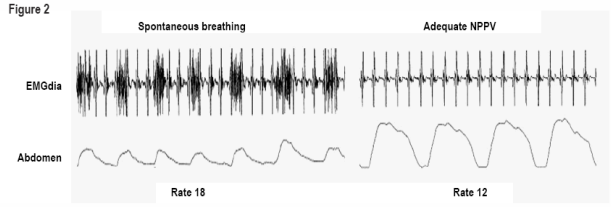


The backup rate is 12, and as the patient did not trigger a breath for 5 seconds, a machine triggered breath was provided (A). Note that spontaneous and machine triggered breaths have similar peak flows (B, C) but different durations and different tidal volumes. The negative pressure spike (A) is an artifact generated by the NPPV device to denote a machine triggered breath.

Achieve Muscle Rest

Best Clinical Practices for the Sleep Center Adjustment of NPPV

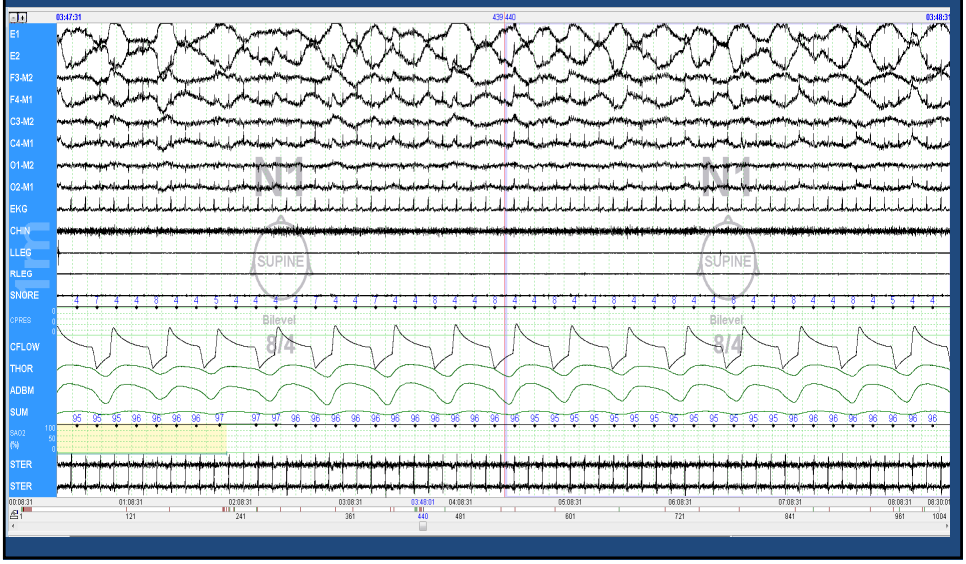
Figure 2



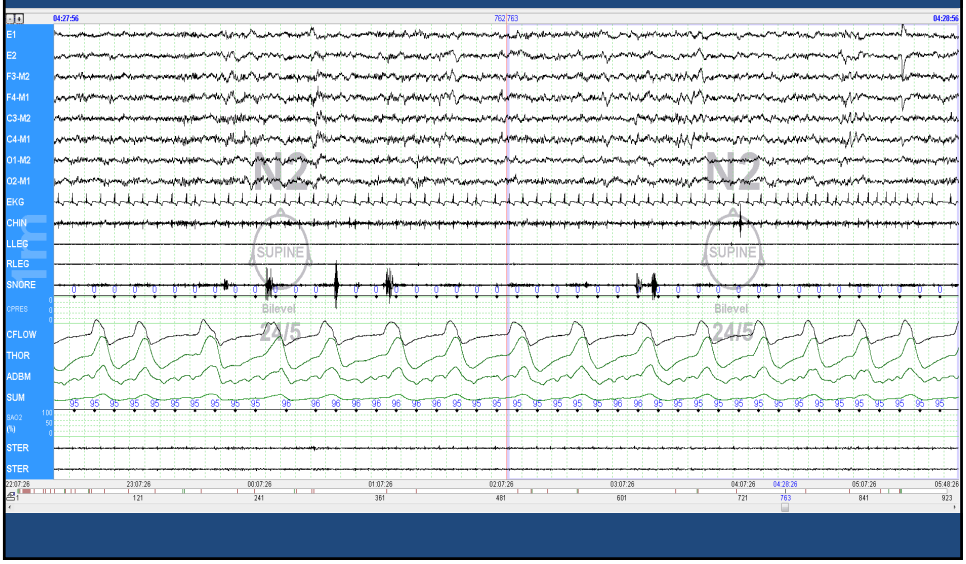
When adequate NPPV was provided to this patient the diaphragmatic EMG (EMGdia) decreased as did the respiratory rate. Note the EKG artifact superimposed on the diaphragmatic EMG (figure courtesy of Conrad Iber).

- Bipolar electrodes
  - Surface diaphragm electrodes
    - 2 electrodes, 2 cm apart horizontally in 7-8th intercostal spaces in right anterior axillary line (reduce EKG artifact)
  - Sternocleidomastoid muscles
  - Right parasternal intercostal muscles
    - 2nd and 3rd intercostal spaces in mid-clavicular line

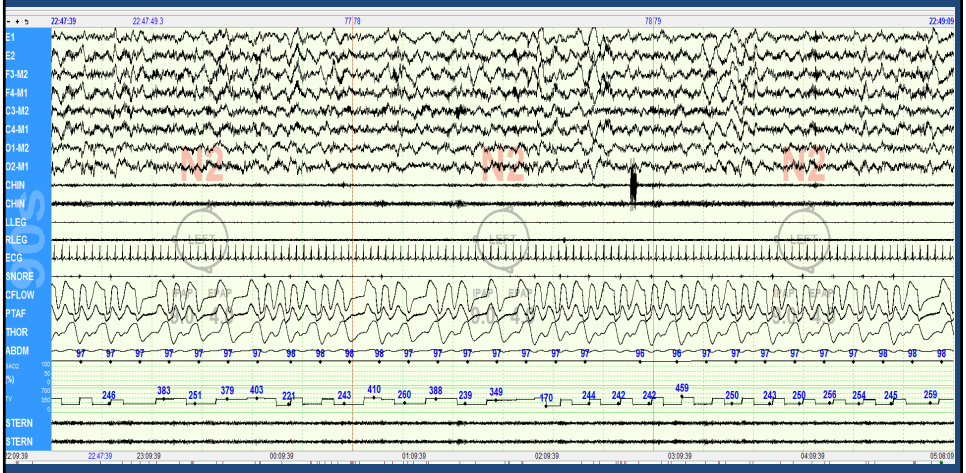
Initial settings
Bilevel PAP 8/4 cm H2O with rate 16



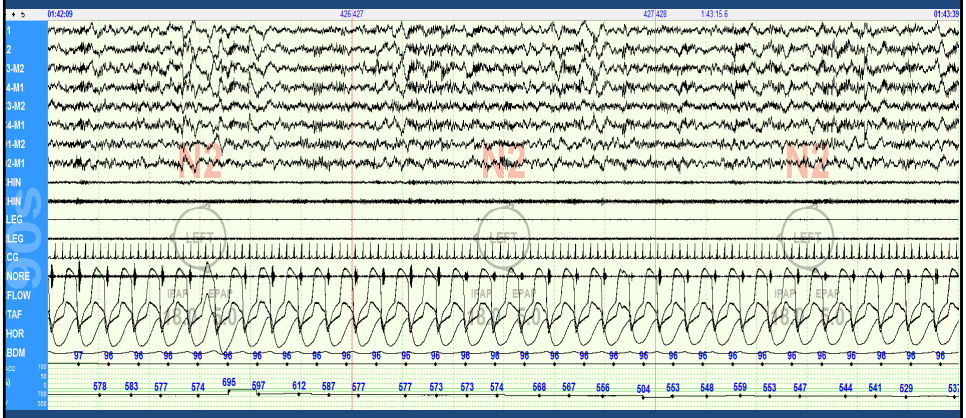
Better settings
Reduction in accessory muscle use



Suboptimal – Bilevel 8/4 with rate 10
Irregular breathing, low tidal volumes…



Optimal – bilevel 16/5 rate 20
Regular breathing and better tidal volumes…



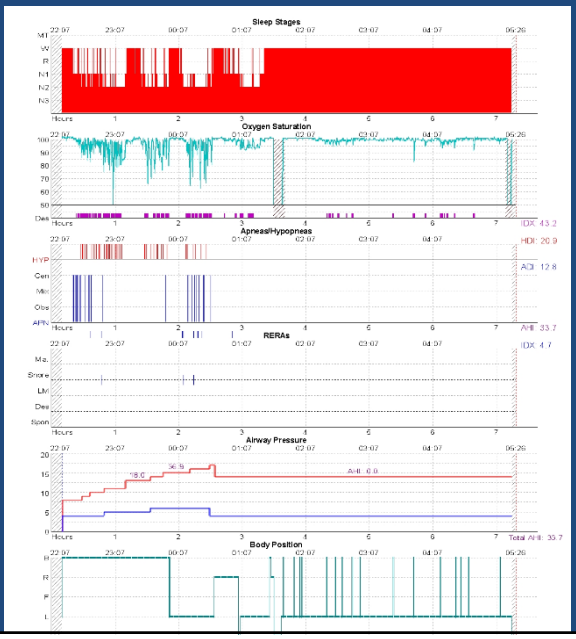
Pearl

Not all NMD can tolerate NIPPV

- Bulbar disease
  - May trigger vocal cord spasm
  - Sialorrhea
  - Suboptimal mask fit, poor seal
- Claustrophobia
  - Myotonic dystrophy
  - Weakened upper extremity strength, inability to remove mask

Benditt JO. Semin Respir Crit Care Med 2002;23:239-47.

Clinical Case



- 32 year man
- Myotonic dystrophy
- FVC 82%
- MIP - 54
- Poorly tolerated bilevel PAP
  - Poor sleep efficiency
  - Severe desaturations
  - No REM

Pearl

NM patients may require several interfaces

- Interface needs
  - Daytime
  - Nighttime
  - Chin straps may be necessary
- Sleep clinics/labs have access to a wide variety of interfaces
  - "creativity"

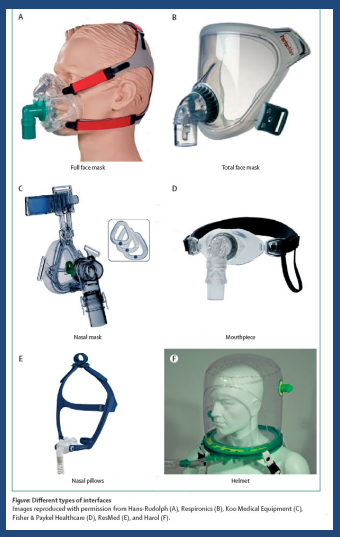
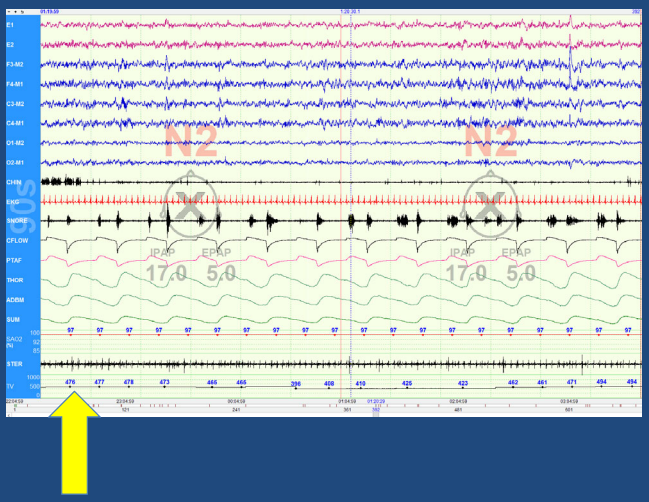


Figure: Different types of interfaces
Images reproduced with permission from Hans-Rudolph (A), Respironics (B), Koo Medical Equipment (C), Fisher & Paykel Healthcare (D), ResMed (E), and Harol (F).

Nava S and Hill N. Lancet. 2009;374:250-259

Why I like the sleep lab for NM titrations?

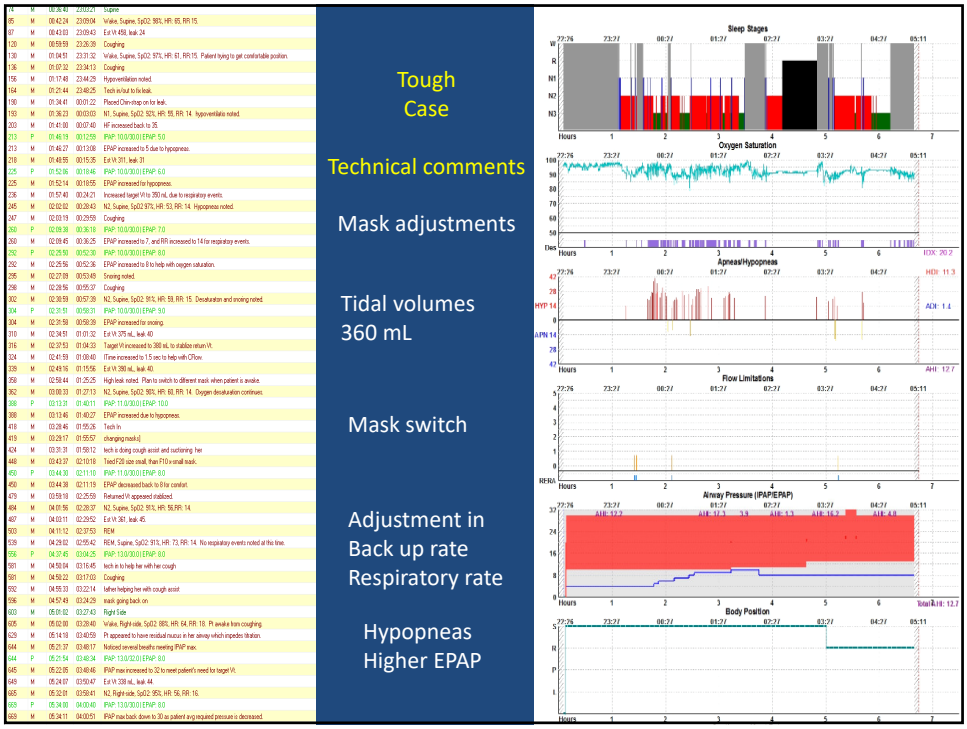


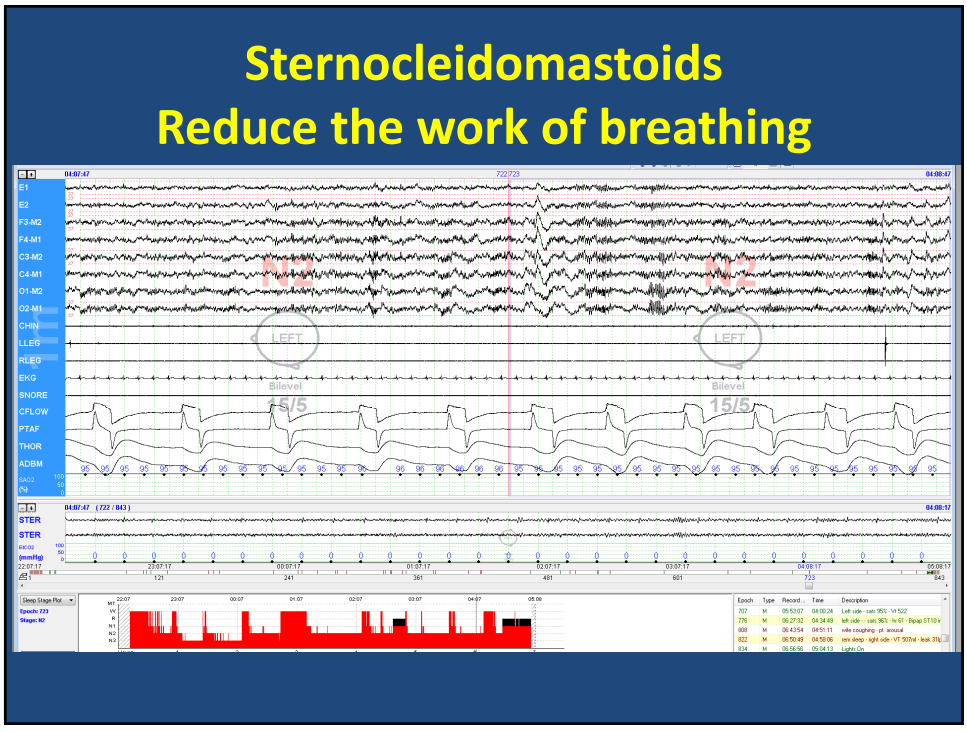
52 year old man
ALS
FVC 28%
MIP – 8 cm H2O

On BIPAP at settings of 10/5 with a rate of 10

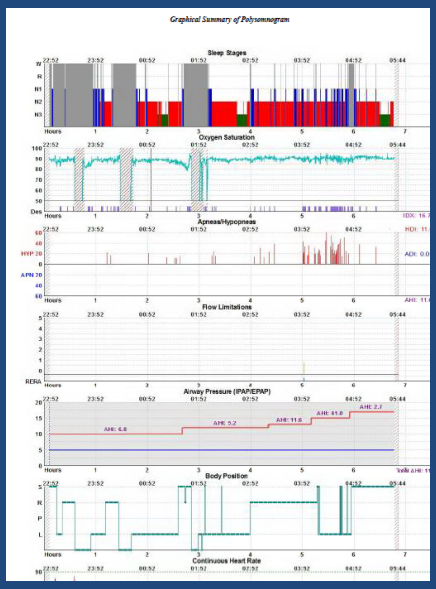
Sleep stages
IPAP
EPAP
Rate
Sternocleidomastoids
Tidal volumes

Height 69 inches
Male
8 cc/kg = 566 mL


Tough Case
Technical comments
Mask adjustments
Tidal volumes 360 mL
Mask switch
Adjustment in Back up rate Respiratory rate
Hypopneas Higher EPAP
Sleep Stages
Oxygen Saturation
Apneas/Hypopneas
Flow Limitations
Airway Pressure (IPAP/EPAP)
Body Position


Sternocleidomastoids
Reduce the work of breathing
E1
E2
F3-M2
F4-M1
C3-M2
C4-M1
O1-M2
O2-M1
CHIN
LLEG
RLEG
EKG
SNORE
CFLOW
PTAF
THOR
ABDM
LEFT
LEFT
Bilevel
15/5
Bilevel
15/5

Another Challenging Case



- Bilevel PAP 17 / 5 cm H2O
  - Rate of 12
  - Tidal volumes of 260-320 mL
- Hypoxemic
  - Needed 2 LPM oxygen

Outline

Neuromuscular Disorders (NMD)

- Overview of neuromuscular diseases
- Physiologic testing
  - Restrictive physiology and impaired forces

Noninvasive Ventilation (NIV)

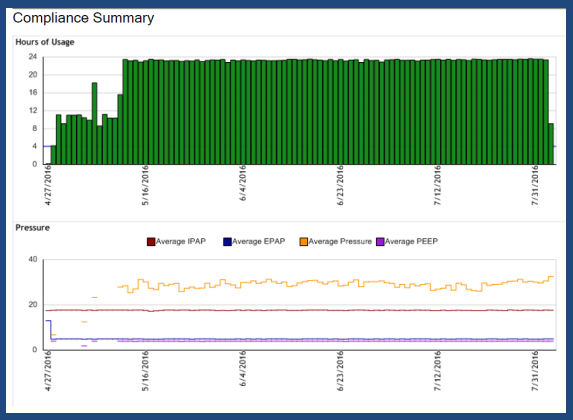
- How to qualify for a respiratory assist device?
- The Polysomnogram – Friend or Foe?
  - The double edged sword

Longitudinal Management

- Practical pearls and lessons learned
  - "With great power, comes great responsibility"

Lessons Learned

Assessment of compliance data is important



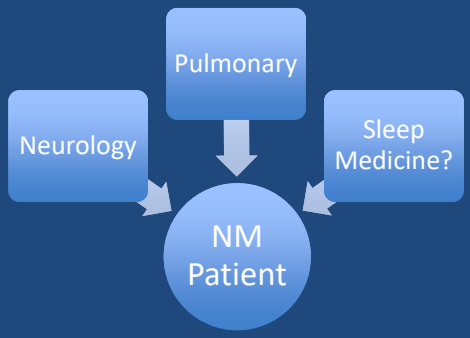
- Hours of usage
- Physiologic data
  - Respiratory rate
  - Tidal volume
  - Patient triggered breaths
- Sleep clinics have expertise in obtaining this data

Last Case

We have work to do….

- 31 year old female with muscular dystrophy, scoliosis
  - Seen in our sleep and breathing clinic for a 2nd opinion
    - 4 months ago prior – outside hospital
      - Dyspnea, ABG: pH 7.25, PaCO2 of 87, SpO2 70%.
      - Treated with NIV, improved
    - Discharged with a ResMed ASTRAL device on iVAPS mode
  - She used iVAPS consistently, until she saw a neurologist who decided to perform a diagnostic sleep study
    - Diagnosed with mild OSA and switched to an auto CPAP
      - Last 3 weeks and her 95th percentile pressure is ~ 16.7 cm H2O.
  - FVC of only 37% and an MIP of only -42

Traditional Management of Patients with Neuromuscular Diseases

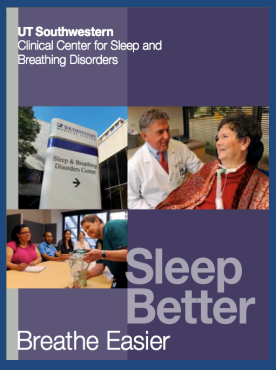


- Sleep medicine specialists
  - have expertise to IMPROVE quality of life
  - can also make mistakes to WORSEN quality of life

Sleep Disordered Breathing in Neuromuscular Disease

Won Y. Lee, M.D.

Associate Professor, Division of Pulmonary and Critical Care Medicine
University of Texas Southwestern Medical Center
Dallas, Texas



UT Southwestern Medical Center

RESPIRATORY ASSIST DEVICES (ST, VAPS TECHNOLOGY) INTERPRETING NIV DOWNLOADS/ MASK INTERFACE OPTIONS

Saturday, January 19, 2019 – 1:40 p.m. – 2:20 p.m.

FACULTY:

Won Lee, MD
University of Texas Southwestern Medical Center
Associate Professor

Won Lee, MD, is an associate professor in pulmonary, critical care and sleep medicine at the University of Texas Southwestern Medical Center in Dallas, Texas. He serves as medical director of the Sleep and Breathing Disorders Center. His primary clinical interests include sleep disordered breathing and neuromuscular pulmonary disorders.

Lisa Wolfe, MD
Northwestern University
Associate Professor of Medicine and Neurology

Lisa Wolfe, MD, is originally from Ohio and did her medical school training at the Ohio State University. Her residency/ fellowship training was at Northwestern University where she has been ever since. She is an associate professor of both medicine and neurology – where she is on the faculty in pulmonary / sleep and neuromuscular medicine. She is also the medical director of respiratory care at the Shirley Ryan Ability Lab (previously known as the Rehabilitation Institute of Chicago (RIC)). Dr. Wolfe's academic focus is on the use of home based ventilation and the care of those with neuromuscular diseases. She has clinical grants for this work from the Les Turner ALS Foundation and the Muscular Dystrophy Association.

Shannon Sullivan, MD
Stanford University
Clinical Associate Professor

Shannon S. Sullivan, MD, is a Clinical Associate Professor at the Stanford University Department of Psychiatry and Behavioral Sciences, Center for Sleep Sciences, and is board certified in pediatrics, pediatric pulmonology, and sleep medicine. She is the Director of the Center's ACGME Sleep Medicine Fellowship program, and her interests include medical education as well as developmental aspects of familial OSA in childhood. She has served as an appointed member of the American Academy of Sleep Medicine Transportation and Safety Task Force, the Presidential Committee on Occupational Health, and the Sleep Public Safety Committee, on which she is serving at present.

Gaurav Singh, MD
Stanford University
Associate Professor

Gaurav Singh, MD, completed all of his medical education and training locally. He attended UC Berkeley for undergraduate studies and UCSF for medical school. He also went on to complete a Masters of Public Health at UC Berkeley. He completed residency training in Internal Medicine at Stanford University, followed by Pulmonary and Critical Care fellowship as well as Sleep Medicine fellowship at Stanford University. He joined the Stanford faculty in Pulmonary, Critical Care, and Sleep Medicine after his medical training. He has recently transitioned his career to VA Palo Alto Healthcare System.

Kathleen Sarmiento, MD
UC San Francisco
Associate Professor of Medicine

Kathleen (Katie) Sarmiento, MD, is an Associate Professor of Medicine at UC San Francisco, the Director of Sleep Medicine at the San Francisco VA Health Care System, and the National Lead for VA TeleSleep, an enterprise-wide initiative to build a high-performing sleep telemedicine network. She has been instrumental in building infrastructure for and leading VA Sleep operations. She has an active clinical practice in Pulmonary, Critical Care and Sleep Medicine. Her research interests are focused on health services research, including strategies to improve access to sleep care in rural areas, reduce wait times, lower cost, and de-implement low-value steps in obtaining care.

Michelle Cao, DO
Stanford University

HOME VENTILATORS, INTERPRETING VENTILATOR DOWNLOADS, AND DAYTIME USE OF NONINVASIVE VENTILATION

Saturday, January 19, 2019 – 2:20 p.m. – 3:00 p.m.

FACULTY:

Won Lee, MD
University of Texas Southwestern Medical Center
Associate Professor

Won Lee, MD, is an associate professor in pulmonary, critical care and sleep medicine at the University of Texas Southwestern Medical Center in Dallas, Texas. He serves as medical director of the Sleep and Breathing Disorders Center. His primary clinical interests include sleep disordered breathing and neuromuscular pulmonary disorders.

Lisa Wolfe, MD
Northwestern University
Associate Professor of Medicine and Neurology

Lisa Wolfe, MD, is originally from Ohio and did her medical school training at the Ohio State University. Her residency/ fellowship training was at Northwestern University where she has been ever since. She is an associate professor of both medicine and neurology – where she is on the faculty in pulmonary / sleep and neuromuscular medicine. She is also the medical director of respiratory care at the Shirley Ryan Ability Lab (previously known as the Rehabilitation Institute of Chicago (RIC)). Dr. Wolfe's academic focus is on the use of home based ventilation and the care of those with neuromuscular diseases. She has clinical grants for this work from the Les Turner ALS Foundation and the Muscular Dystrophy Association.

Shannon Sullivan, MD
Stanford University
Clinical Associate Professor

Shannon S. Sullivan, MD, is a Clinical Associate Professor at the Stanford University Department of Psychiatry and Behavioral Sciences, Center for Sleep Sciences, and is board certified in pediatrics, pediatric pulmonology, and sleep medicine. She is the Director of the Center's ACGME Sleep Medicine Fellowship program, and her interests include medical education as well as developmental aspects of familial OSA in childhood. She has served as an appointed member of the American Academy of Sleep Medicine Transportation and Safety Task Force, the Presidential Committee on Occupational Health, and the Sleep Public Safety Committee, on which she is serving at present.

Gaurav Singh, MD
Stanford University
Associate Professor

Gaurav Singh, MD, completed all of his medical education and training locally. He attended UC Berkeley for undergraduate studies and UCSF for medical school. He also went on to complete a Masters of Public Health at UC Berkeley. He completed residency training in Internal Medicine at Stanford University, followed by Pulmonary and Critical Care fellowship as well as Sleep Medicine fellowship at Stanford University. He joined the Stanford faculty in Pulmonary, Critical Care, and Sleep Medicine after his medical training. He has recently transitioned his career to VA Palo Alto Healthcare System.

Kathleen Sarmiento, MD
UC San Francisco
Associate Professor of Medicine

Kathleen (Katie) Sarmiento, MD, is an Associate Professor of Medicine at UC San Francisco, the Director of Sleep Medicine at the San Francisco VA Health Care System, and the National Lead for VA TeleSleep, an enterprise-wide initiative to build a high-performing sleep telemedicine network. She has been instrumental in building infrastructure for and leading VA Sleep operations. She has an active clinical practice in Pulmonary, Critical Care and Sleep Medicine. Her research interests are focused on health services research, including strategies to improve access to sleep care in rural areas, reduce wait times, lower cost, and de-implement low-value steps in obtaining care.

Michelle Cao, DO
Stanford University

BREAK
EXHIBIT HALL OPEN

Saturday, January 19, 2019 – 3:00 p.m. – 3:20 p.m.

NIPPV FOR THE HYPERCAPNIC COPD AND OBSESITY HYPOVENTILATION PATIENT

Gaurav Singh, MD
Stanford University
Associate Professor

Saturday, January 19, 2019 – 3:20 p.m. – 4:00 p.m.

Gaurav Singh, MD, completed all of his medical education and training locally. He attended UC Berkeley for undergraduate studies and UCSF for medical school. He also went on to complete a Masters of Public Health at UC Berkeley. He completed residency training in Internal Medicine at Stanford University, followed by Pulmonary and Critical Care fellowship as well as Sleep Medicine fellowship at Stanford University. He joined the Stanford faculty in Pulmonary, Critical Care, and Sleep Medicine after his medical training. He has recently transitioned his career to VA Palo Alto Healthcare System.

NIPPV FOR THE HYPERCAPNIC COPD AND OBESITY HYPOVENTILATION SYNDROME PATIENT

Gaurav Singh, MD, MPH
Clinical Assistant Professor
Pulmonary, Critical Care, and Sleep Medicine
VA Palo Alto Health Care System
Stanford Health Care

Disclosures

- No conflicts of interest

Learning Objectives

1. Recognize when to consider NIPPV over CPAP for hypercapnic COPD and obesity hypoventilation syndrome
2. Identify the appropriate NIPPV modality and settings to select for hypercapnic COPD and obesity hypoventilation syndrome
3. Understand the health outcomes associated with NIPPV use among patients with hypercapnic COPD and obesity hypoventilation syndrome

Outline

- Relevant pathophysiology
- Rationale and mechanism of NIPPV
- Clinical evidence supporting use of NIPPV
- Patient selection for NIPPV
- NIPPV initiation and titration
- Qualification criteria for NIPPV

Review Question: COPD

1. Which non-invasive ventilation modality has been demonstrated to prolong the time to hospital readmission or death in patients with hypercapnic COPD?

A) Bilevel

B) Bilevel-S/T

C) Volume Assured Pressure Support

D) Adaptive Servo Ventilation

Review Question: OHS

2. What clinical outcome has demonstrated improvement with bilevel compared to continuous positive airway pressure in patients with obesity hypoventilation syndrome?

A) Daytime hypercapnia

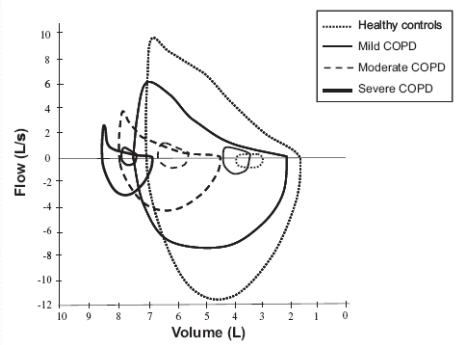
B) Quality of life

C) Daytime sleepiness

D) Pulmonary hypertension

Hypercapnic COPD: Definitions

- GOLD definition of COPD: post-bronchodilator $FEV_1/FVC < 70\%$
- Hypercapnia: $PaCO_2 > 45$ mmHg



www.goldcopd.org

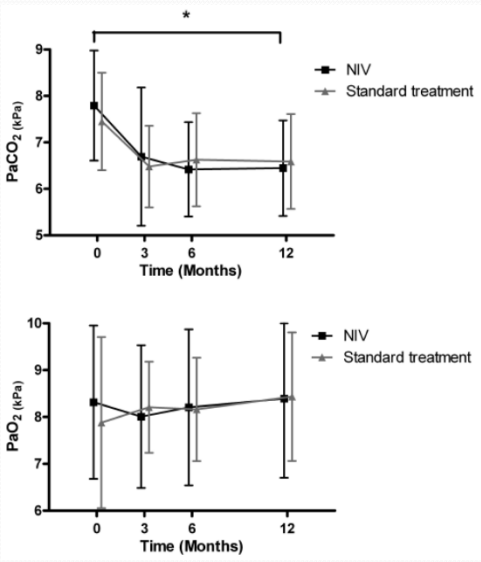
Hypercapnic COPD: Pathophysiology

- Lung parenchyma and airway destruction
  - Poor matching of ventilation to perfusion (i.e., V/Q mismatch or dead space ventilation)
- Imbalance between inspiratory muscle capacity and load placed on respiratory system
  - Hyperinflation changes configuration of diaphragm and shortens inspiratory muscles (mechanical disadvantage, atrophy, respiratory muscle weakness)
  - Excessive resistive load on respiratory muscles due to increased airway resistance and intrinsic positive end-expiratory pressure (iPEEP), inspiratory threshold

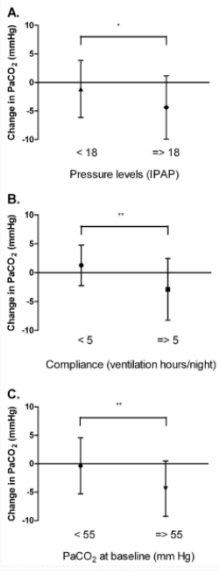
NIPPV Rationale/Mechanism in COPD

- Relief of ventilatory muscle fatigue
- Reduction in respiratory load
  - Decrease in lung hyperinflation with improvement in lung volumes
  - Decrease in iPEEP
- Augment alveolar ventilation
- Correcting CO_2 responsiveness (i.e., change in central chemosensitivity)
- Treating sleep-disordered breathing
- Benefits: improvements in dyspnea, nocturnal and daytime respiratory function, gas exchange, sleep quality, and functional status

Effective NIPPV Reduces PaCO2



Struik et al. Thorax. 2014;69:826-34

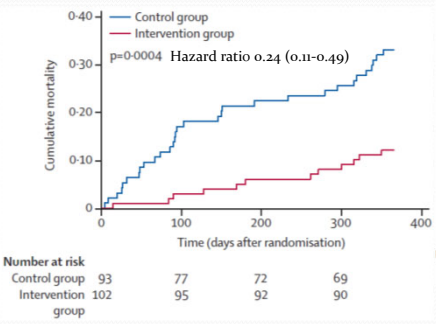


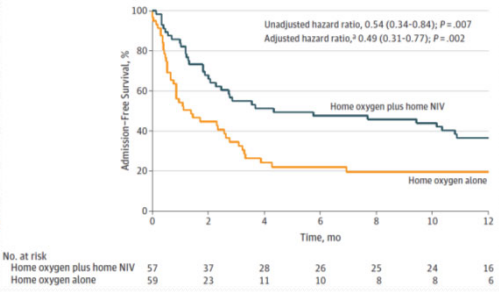
Struik et al. Respir Med. 2014;108:329-37

Factors that augment reduction in $PaCO_2$

- Higher IPAP
- Better adherence
- Higher baseline $PaCO_2$

NIPPV Improves Mortality/Readmission





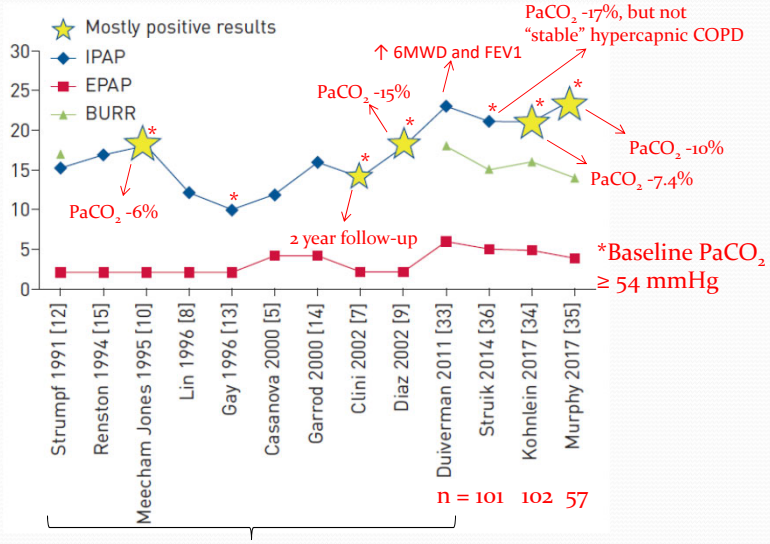
- Baseline $PaCO_2$ ≥ 51.9 mmHg (mean 58.5 mmHg)
- No exacerbation within 4 weeks
- NIPPV targeted to reduce $PaCO_2$ by at least 20% or < 48 mmHg
- Mean IPAP 21.6 cmH_2O, EPAP 4.8 cmH_2O, backup rate 16.1 breaths/min
- 1-year mortality 12% in NIPPV group vs 33% in control group

Kohnlein Lancet Respir Med. 2014;2:698-705

- Baseline $PaCO_2$ > 53 mmHg (mean 59.0 mmHg)
- Persistent hypercapnia after acute COPD exacerbation (2-4 weeks after resolution of respiratory acidemia)
- NIPPV targeted to reduce $PaCO_2$ by 3.75 – 7.5 mmHg overnight
- mMean IPAP 24 cmH_2O, EPAP 4 cmH_2O, backup rate 14 breaths/min
- Mean time to readmission or death 4.3 months in NIPPV group vs 1.4 months in control group

Murphy et al. JAMA. 2017;317:2177-2186

Overview of Randomized Controlled Trials

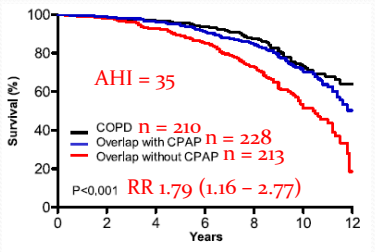


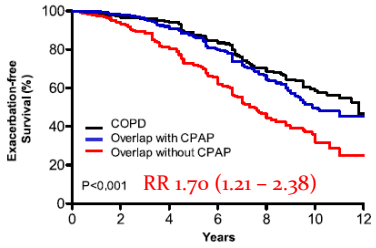
Duiverman. ERJ Open Res. 2018;4

Reasons for Heterogeneity

- Underpowered studies
- Patient selection and poorly characterized patient populations
  - Severity of COPD and degree of baseline hypercapnia
- NIPPV pressures capable of achieving adequate ventilation and reduction in $PaCO_2$
- Adherence with NIPPV therapy
- Duration of therapy and follow-up
- Underlying OSA

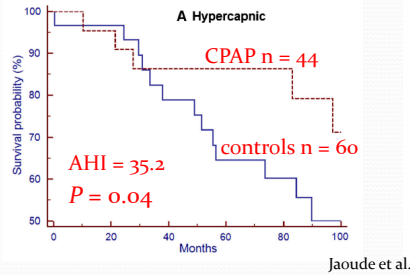
The Overlap Syndrome

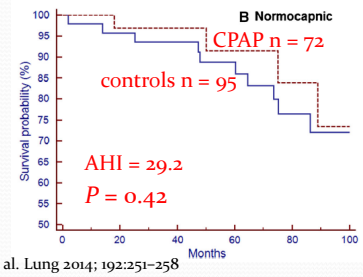




Adjust for age, sex, BMI, smoking, EtOH, comorbidities, COPD severity, AHI, daytime sleepiness

Marin et al. Am J Respir Crit Care Med 2010; 182:325-31





$PaCO_2 \geq 45$ mmHg (average 51.6 mmHg)

Jaoude et al. Lung 2014; 192:251–258

Selecting COPD Patients for NIPPV

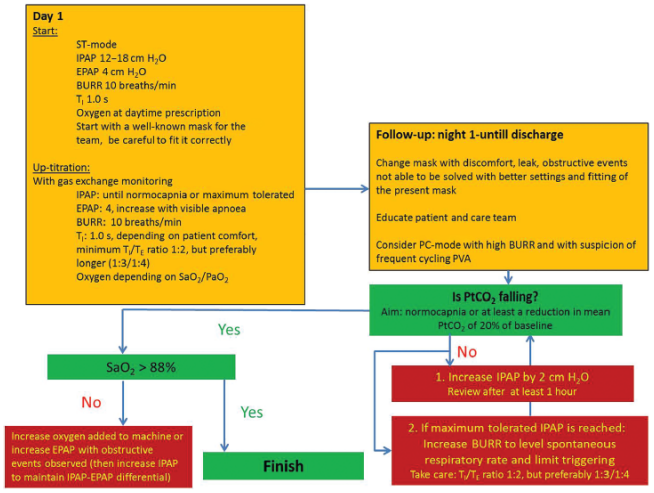
- Patients most likely to derive a benefit are those with most severe and advanced disease
- Daytime $PaCO_2$ ≥ 52 mmHg and O2 desaturation during sleep (i.e., SpO_2 ≤ 88% for ≥ 5 minutes) despite use of supplemental O_2 at ≥ 2 L/min
- History of hospitalization for acute respiratory failure with persistent, severe hypercapnia
- Others recovering from acute exacerbation that necessitated use of continuous NIPPV during hospitalization

Initiation of NIPPV for COPD

- Optimal approach has not been determined
- Typically start bilevel with EPAP of 5 cmH_2O and IPAP of 10 cmH_2O and gradually increase
  - Final IPAP near 15 cmH_2O (range 12-20 cmH_2O)
    - Adjust IPAP for pressure support (PS) that achieves goal tidal volume (~8 ml/kg ideal body weight), as tolerated
  - Final EPAP at least 5 cmH_2O below IPAP
    - Adjust EPAP to eliminate obstructive apneas
    - If ineffective trigger, adjust EPAP to overcome high iPEEP

"High Intensity" NIPPV

- Specific NIPPV settings to achieve normocapnia or lowest $PaCO_2$ levels possible
- Often requires high IPAP ± backup rate



van der Leest and Duiverman. Respirology. 2018 Nov 30

Other NIPPV Options for COPD

- AVAPS/iVAPS
  - Volume-assured pressure support
    - No proven clinical benefit of switching from high intensity NIPPV; possible physiological advantages in breathing pattern
- AVAPS AE
  - Includes auto-titrating EPAP
    - Optimize EPAP to maintain airway patency
- Mouth Piece Ventilation (MPV)
  - Prevents deterioration of gas exchange as well as NIPPV in COPD exacerbations with mild to moderate acidosis, and it is better tolerated
- Ventilation before oxygenation

Challenges

- Patient comfort and tolerance of high pressures
  - Concern for hyperinflation with high backup rate
  - Important to titrate stepwise (usually over several days)
- Cardiovascular side effects
  - High IPAP may reduce cardiac output in patients with cardiac failure
- Initiation of NIPPV in the hospital or ventilator facility
  - Not mandatory for success
- Reimbursement for devices with backup rate
  - Standard bilevel devices only allow for PS of 10 cmH_2O

Qualifying for NIPPV: COPD

ABG with $PaCO_2 \geq 52$ mmHg (awake and on prescribed FiO_2)

AND

Sleep oximetry with oxygen saturation ≤ 88% for ≥ 5 cumulative minutes on 2 L/min O_2 or prescribed FiO_2 (whichever is higher)

AND

OSA and CPAP treatment have been considered and ruled out (formal sleep testing not required)

E470 = Bilevel S

Conversion from S to ST

Situation 1 (after period of initial use of E0470):

ABG with $PaCO_2$ worsening ≥ 7 mmHg vs original ABG (awake and on prescribed FiO_2)

AND

Facility-based PSG on E470 with oxygen saturation ≤ 88% for ≥ 5 cumulative minutes (not caused by OSA – AHI < 5)

E471 = Bilevel ST

Situation 2 (no sooner than 61 days after initial use of E0470):

ABG with $PaCO_2 \geq 52$ mmHg (awake and on prescribed FiO_2)

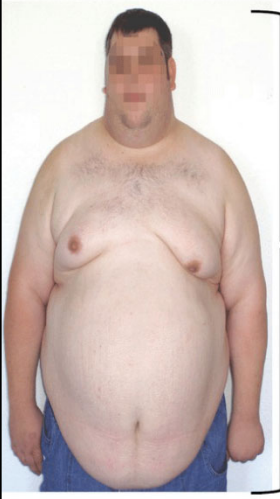
AND

Sleep oximetry on E470 with oxygen saturation ≤ 88% for ≥ 5 cumulative minutes on 2 L/min O_2 or prescribed FiO_2 (whichever is higher)

OHS: Definition and Consequences

- OHS definition: awake alveolar hypoventilation ($PaCO_2$ > 45 mmHg) in obese (BMI > 30 mg/kg^2) patients which cannot be attributed to other causes (i.e., neuromuscular, metabolic, lung, or chest wall diseases)
- OHS will progress if not treated with PAP, and it is associated with significantly worse cardiovascular morbidity, mortality, and healthcare utilization vs eucapnic OSA and eucapnic obese patients
- Can lead to pulmonary hypertension, right heart failure, and increased risk of hospitalization due to acute-on-chronic hypercapnic respiratory failure

OHS: Pathophysiology



Altered upper airway mechanics; ↑ upper-airway resistance, OSA

Impaired respiratory mechanics; ↓FRC, ↓ ERV, ↓ compliance, ↑ resistance, ↑ mechanical load

Gas exchange deterioration; V/Q mismatch, ↑VD/VT

Respiratory muscles weakness

Neurohumoral influences leptin resistance

↑ Sleep $PaCO_2$, ↓ sleep PaO_2, ↑ serum bicarbonate

↑ Work of breathing

Blunted ventilatory drive; ↓ CO_2 response

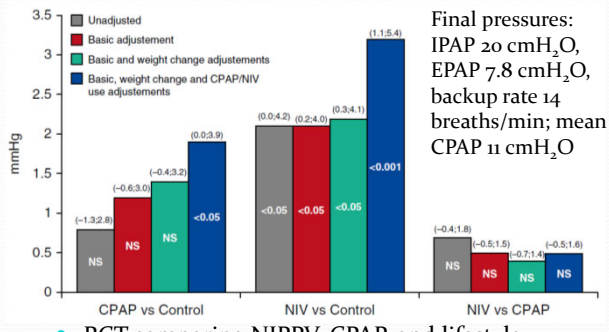
Chronic daytime hypercapnia

Boing et al. J Thorac Dis. 2015;7:1273-85

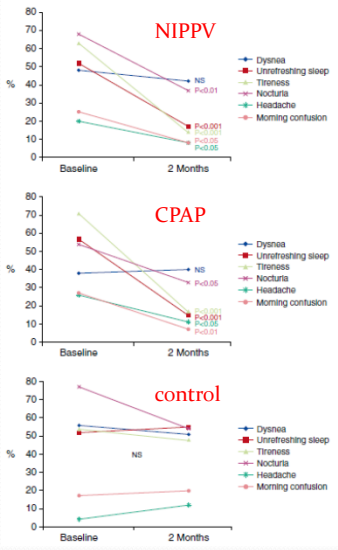
NIPPV Rationale/Mechanism in OHS

- Controversy remains as to the preferred modality of positive airway therapy
- Conceptually, NIPPV should be more effective than CPAP, as it addresses the various complex pathophysiological disturbances that result in OHS:
  - EPAP for upper airway resistance, chest wall and abdominal resistance, and atelectasis
  - IPAP for altered ventilatory drive, worsened hypoventilation during sleep, and rest of respiratory muscles

Pickwick Study



Final pressures: IPAP 20 cmH_2O, EPAP 7.8 cmH_2O, backup rate 14 breaths/min; mean CPAP 11 cmH_2O

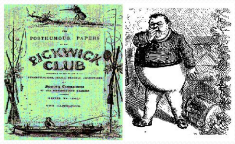


- RCT comparing NIPPV, CPAP, and lifestyle modification in OHS patients with severe OSA
- Main outcome: daytime $PaCO_2$
- Total n = 221, follow-up = 2 months
- Greatest reduction in $PaCO_2$ and bicarbonate in NIPPV group, but not significant vs CPAP
- FEV_1 and 6MWD improved more with NIPPV than CPAP

Masa et al. Am J Respir Crit Care Med. 2015;192:86-95

Pickwick Study: Update

- RCT of CPAP vs NIPPV for OHS with severe OSA
- Primary outcome: hospitalization days
- Secondary outcomes: hospital resource utilization, mortality, cardiovascular events, compliance, side effects
- Total n = 215
- Median follow-up = 5.42 years
- Hospital days/yr was 2.19 ± 5.65 for CPAP and 1.44 ± 3.07 for NIV (adjusted P = 0.12)
- No difference in secondary outcomes



Quiroga et al. European Respiratory Journal 2018 52: Suppl. 62, OA5414

Cardiovascular Effects of NIPPV

- Secondary analysis of Pickwick Study
- Conventional transthoracic 2D and doppler echo performed at baseline and after 2 months
- At baseline 55% of patients had pulmonary hypertension (PH), 51% with left ventricular hypertrophy LVH)
- NIPPV lowered systolic pulmonary artery pressure, but CPAP did not (–3.4 mmHg, –5.3 to –1.5; adjusted P = 0.025 vs control and P = 0.033 vs CPAP)
  - Greater reduction with NIPPV in those with PH at baseline (–6.4 mm Hg, –9 to –3.8)
- NIPPV reduced left ventricular mass and improved 6MWD (32 m; 19 to 46)

Corral et al. Thorax. 2018;73:361-368

Selecting OHS Patients for NIPPV

- ~90% of patients with OHS have coexisting OSA → CPAP is appropriate initial modality
- Bilevel is appropriate for patients with OHS and sleep-related hypoventilation (i.e., few obstructive events during sleep)
  - Patients with OHS and OSA who fail or do not tolerate CPAP should be treated with bilevel
  - Patients who fail or do not tolerate bilevel should be treated with average volume-assured pressure support
- Features that suggest bilevel may be more appropriate than CPAP:
  - Lower AHI on PSG
  - More restrictive physiology on PFTs
  - More severe and persist O_2 desaturation during PSG

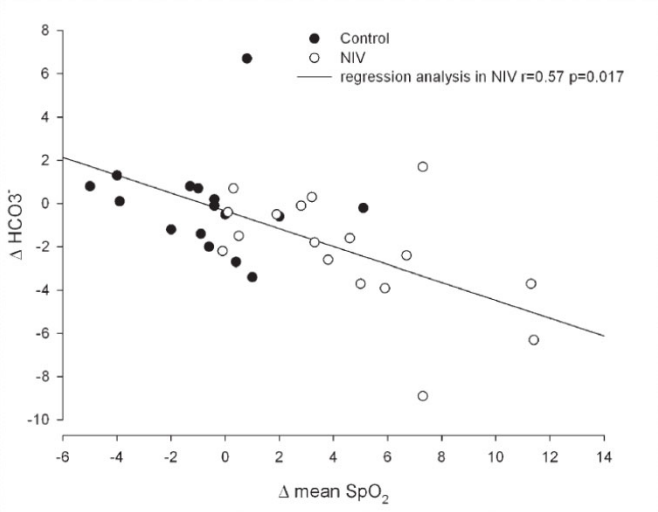
Initiation of NIPPV for OHS

- At a minimum, set EPAP at 4 cmH_2O and IPAP at 8 cmH_2O
- EPAP should be adjusted for obstructive apneas
  - Some studies have adjusted EPAP for all obstructive events (obstructive apneas, hypopneas, flow limitation, and snoring) → results in higher EPAP
  - Increase IPAP simultaneously to maintain pressure difference between EPAP and IPAP
- IPAP should be adjusted for hypoventilation (which may be manifested by persistent O_2 desaturation unrelated to obstructive events) and hypopneas

Monitoring/Goals of NIPPV in OHS

- Normalize $PaCO_2$ (< 45 mmHg) during wakefulness and sleep
- Eliminate O_2 desaturation during wakefulness and sleep
- Treat sleep disordered breathing (obstructive apneas, hypopneas, and hypoventilation)
- Improve sleep architecture and quality
- Relieve symptoms (daytime hypersomnolence, morning headache)
- Prevent complications (erythrocytosis, pulmonary hypertension, right heart failure, mortality)

NIPPV Improvement in SpO_2 During Sleep Correlates with Reduction in Bicarbonate



- Total n = 35
- 1-month follow-up
- Mean IPAP 18 cmH_2O, EPAP 11 cmH_2O, backup rate 13 breaths/min

Borel et al. Chest. 2012;141:692-702

Other NIPPV Options for OHS

- AVAPS/iVAPS
  - Residual airway obstruction on bilevel (but EPAP fixed)
  - Sufficient alveolar ventilation cannot be achieved with bilevel (due to decreased respiratory system compliance)
  - Can achieve higher PS vs bilevel (which has maximum of 10 cmH_2O) and higher overall pressure (30 vs 25 cmH_2O)
  - Similar improvement in daytime $PaCO_2$ as bilevel
- AVAPS AE
  - Likely better for obstructive events and maintaining airway patency
  - Can achieve even higher maximal pressures (i.e., 50 cmH_2O)

Qualifying for NIPPV: OHS

ABG with $PaCO_2 \geq 45$ mmHg (awake and on prescribed FiO_2)

AND

Spirometry with $FEV_1/FVC \geq 70\%$

AND

ABG with $PaCO_2$ worsening ≥ 7 mmHg vs original ABG (done during sleep or immediately upon awakening on prescribed FiO_2)

OR

PSG or HST with oxygen saturation ≤ 88% for ≥ 5 minutes (not caused by OSA – AHI < 5)

E470 = Bilevel S

Conversion from S to ST

Covered E0470 is being used

AND

Spirometry with $FEV_1/FVC \geq 70\%$

AND

ABG with $PaCO_2$ worsening ≥ 7 mmHg vs ABG used to qualify for E0470 (done during sleep or immediately upon awakening on prescribed FiO_2)

OR

PSG or HST on E0470 with oxygen saturation ≤ 88% for ≥ 5 minutes (not caused by OSA – AHI < 5)

E471 = Bilevel ST

TABLE 5] Matching NIV Settings to Patient's Respiratory Mechanics

Pathophysiology/ Device Settings	Chronic OHS (Compensated)	Chronic COPD (Compensated)	Chronic NMD (Compensated)
Respiratory mechanics	↑ Muscle load (↑ UA resistance, 90% OHS) Increased resistance from chest and abdominal wall ↓ FRC due to obesity (expiratory flow limitation, airway closure, V/Q mismatch) ↓ Respiratory drive (leptin resistance, 10% OHS)	↑ Muscle load (↑ Lower airway resistance in COPD) ↓ Muscle capacity (diaphragm atrophy, mechanical disadvantage)	↓ Muscle capacity ↑ Chest wall resistance
Target volume (cc)	Target tidal volume 8 cc/kg ideal body weight	Target tidal volume 8 cc/kg ideal body weight	Target tidal volume 8 cc/kg ideal body weight
	To adjust PS (BPAP-ST), expiratory tidal volume (AVAPS), or Va (iVAPS) based on ABG (pH, $Paco_2$), $TcCO_2$, or a combination		
IPAP (cm H_2O)	High IPAP BPAP-ST: adjust IPAP to a PS for goal tidal volume (average PS, 8-10 cm H_2O) VAPS: allow a large IPAP max/IPAP min difference to reach target expiratory tidal volume or Va	High IPAP (or best tolerated) BPAP: adjust IPAP to a PS for goal tidal volume (or best tolerated) Allow large IPAP max/IPAP min difference to reach target expiratory tidal volume or Va as tolerated	Intermediate IPAP (or best tolerated) Adjust IPAP to a PS for tidal volume goal in BPAP-ST. (average PS, 6 cm H_2O) Allow IPAP min at a higher baseline
EPAP (cm H_2O)	High EPAP in OHS/OSA Adjust to eliminate obstructive apneas (average 8-12 cm H_2O) or snoring	Adjust to eliminate obstructive apneas if present If ineffective trigger, increase EPAP to overcome high iPEEP (first-line therapy)	Low EPAP to reduce work of breathing and improve triggering
Respiration rate (bpm)	To adjust to goal minute ventilation based on ABGs or $TcCO_2$, or both		
Trigger sensitivity[a]	Respironics: Auto-Trak or flow trigger 2-3 L/min ResMed: trigger from medium to low	Respironics: Auto-Trak or flow trigger 4-5 L/min ResMed: trigger medium	High trigger sensitivity to support a weak respiratory muscular effort Respironics: flow trigger at 1-3 L/min ResMed: trigger high or very high
Rise time (ms)	Default or slow rise time Respironics: 3 (300 ms)-6 (600 ms) ResMed: 500-900 ms	Fast rise time	Default or slow rise time Respironics: 3 (300 ms)-6 (600 ms) ResMed: 500-900 ms
Ti (ms)	Long Ti or long Ti min to maximize tidal volume and gas exchange by (↑ I:E) Ti/Ttot 50%	Short Ti or short Ti max to increase expiratory time and minimize iPEEP (↓ I:E) Ti/Ttot 25% in patients with BMI > 30	Long Ti or long Ti min to maximize tidal volume and gas exchange (↑I:E) Ti/Ttot 50%
Cycle Sensitivity[a]	Default or low cycle sensitivity Respironics: Auto-Trak or manual at 10%-15% of peak flow ResMed: Cycle medium to low	Default or high cycle sensitivity (early cycle) to provide a longer exhalation time (↓ I:E) Respironics: Auto-Trak or manual at 30%-50% of peak flow ResMed: Cycle sensitivity medium to high	Default or low cycle sensitivity (late cycle) to provide a longer inhalation time (maximize tidal volume and gas exchange by high I:E) Respironics: Auto-Trak or manual at 10%-15% of peak flow ResMed: Cycle low

Selim et al. Chest. 2018;153:251-265

Key Points

- NIPPV addresses the underlying pathophysiology of hypercapnic COPD and OHS, manifest as reduction in $PaCO_2$
- High intensity NIPPV has demonstrated physiological and clinical benefit in hypercapnic COPD (reduction in mortality and readmissions)
- NIPPV improves lung function, exercise capacity, pulmonary hypertension, pulmonary hypertension, and left ventricular hypertrophy vs CPAP in OHS patients
- Appropriate patient selection for NIPPV is essential

References

- Borel JC, Tamisier R, Gonzalez-Bermejo J, et al. Noninvasive ventilation in mild obesity hypoventilation syndrome: a randomized controlled trial. Chest. 2012 Mar;141(3):692-702.
- Corral J, Mogollon MV, Sánchez-Quiroga MÁ, et al. Echocardiographic changes with non-invasive ventilation and CPAP in obesity hypoventilation syndrome. Thorax. 2018 Apr;73(4):361-368.
- Duiverman ML. Noninvasive ventilation in stable hypercapnic COPD: what is the evidence? ERJ Open Res. 2018 Apr 9;4(2).
- Duiverman ML, Windisch W, Storre JH, et al. The role of NIV in chronic hypercapnic COPD following an acute exacerbation: the importance of patient selection? Ther Adv Respir Dis. 2016 Apr;10(2):149-57.
- Jaoude P, El-Solh AA. Survival benefit of CPAP favors hypercapnic patients with the overlap syndrome. Lung. 2014 Oct;192(5):633-4.
- Köhnlein T, Windisch W, Köhler D, et al. Non-invasive positive pressure ventilation for the treatment of severe stable chronic obstructive pulmonary disease: a prospective, multicentre, randomised, controlled clinical trial. Lancet Respir Med. 2014 Sep;2(9):698-705.
- Marin JM, Soriano JB, Carrizo SJ, et al. Outcomes in patients with chronic obstructive pulmonary disease and obstructive sleep apnea: the overlap syndrome. Am J Respir Crit Care Med. 2010 Aug 1;182(3):325-31.
- Masa JF, Corral J, Alonso ML, et al. Efficacy of Different Treatment Alternatives for Obesity Hypoventilation Syndrome. Pickwick Study. Am J Respir Crit Care Med. 2015 Jul 1;192(1):86-95.
- Murphy PB, Rehal S, Arbane G, et al. 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. JAMA. 2017 Jun 6;317(21):2177-2186.
- Nicolini A, Santo M, Ferrari-Bravo M, et al. Open-mouthpiece ventilation versus nasal mask ventilation in subjects with COPD exacerbation and mild to moderate acidosis: a randomized trial. Respir Care. 2014 Dec;59(12):1825-31.
- Quiroga AS, Mokhlesi B, Peñafiel JC, et al. Long term positive airway pressure effectiveness in obesity hypoventilation syndrome. Pickwick study results. European Respiratory Journal 2018 52: Suppl. 62, OA5414.
- Selim BJ, Wolfe L, Coleman JM 3rd, et al. Initiation of Noninvasive Ventilation for Sleep Related Hypoventilation Disorders: Advanced Modes and Devices. Chest. 2018 Jan;153(1):251-265.
- Storre JH, Matrosovich E, Ekkernkamp E, et al. Home mechanical ventilation for COPD: high-intensity versus target volume noninvasive ventilation. Respir Care. 2014 Sep;59(9):1389-97.
- Struik FM, Lacasse Y, Goldstein RS, et al. Nocturnal noninvasive positive pressure ventilation in stable COPD: a systematic review and individual patient data meta-analysis. Respir Med. 2014 Feb;108(2):329-37.
- Struik FM, Sprooten RT, Kerstjens HA, et al. Nocturnal non-invasive ventilation in COPD patients with prolonged hypercapnia after ventilatory support for acute respiratory failure: a randomised, controlled, parallel-group study. Thorax. 2014 Sep;69(9):826-34.
- van der Leest S, Duiverman ML. High-intensity non-invasive ventilation in stable hypercapnic COPD: Evidence of efficacy and practical advice. Respirology. 2018 Nov 30.

Thank You!

- gsingh8@stanford.edu

DAYTIME USE OF NIPPV

Lisa Wolfe, MD
Northwestern University
Associate Professor of Medicine and Neurology

Saturday, January 19, 2019 – 4:00 p.m. – 4:40 p.m.

Lisa Wolfe, MD, is originally from Ohio and did her medical school training at the Ohio State University. Her residency/ fellowship training was at Northwestern University where she has been ever since. She is an associate professor of both medicine and neurology – where she is on the faculty in pulmonary / sleep and neuromuscular medicine. She is also the medical director of respiratory care at the Shirley Ryan Ability Lab (previously known as the Rehabilitation Institute of Chicago (RIC)). Dr. Wolfe's academic focus is on the use of home based ventilation and the care of those with neuromuscular diseases. She has clinical grants for this work from the Les Turner ALS Foundation and the Muscular Dystrophy Association.

CLOSING REMARKS AND POST TEST

Michelle Cao, DO
Stanford University School of Medicine
Clinical Associate Professor

Michelle Cao, DO, is a Clinical Associate Professor in the Division of Sleep Medicine and Division of Neuromuscular Medicine, at the Stanford University School of Medicine. Dr. Cao is board certified in Pulmonary, Critical Care, and Sleep Medicine. Her clinical expertise is in complex sleep related breathing disorders including central sleep apnea secondary to opioids, neuromuscular disease, and chronic respiratory failure. She manages the noninvasive ventilation program for Stanford Neuromuscular Disease Multidisciplinary Clinic.

Saturday, January 19, 2019 – 4:40 p.m. –5:00 p.m.