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

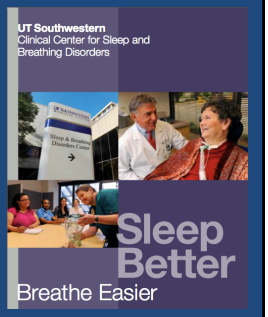
Saturday, January 19, 2019 – 11:10 a.m. – 11:40 a.m.

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.

Objectives

- 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 and sleep medicine?

Objectives

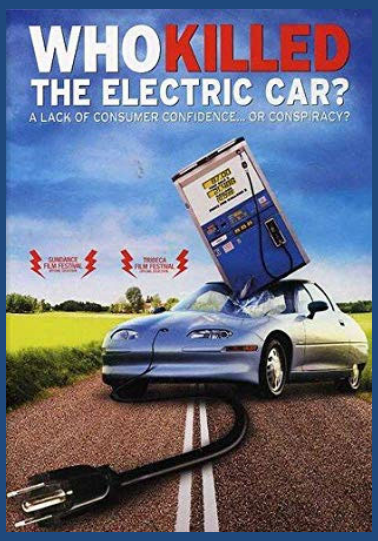
- The past
  - The history of home sleep apnea testing
- The present
  - How home sleep apnea testing affects clinical practice
- The future
  - What will happen to the sleep laboratory and sleep medicine?

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

Electric car – charging station

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 syndrome

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]	[illegible]	[illegible]	[illegible]	[illegible]	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]	[illegible]	[illegible]	[illegible]	[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

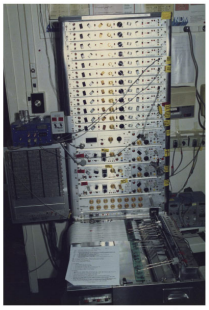


Fig. 1. Grass model 78 EEG machine adapted for polysomnographic recording.

Hirshkowitz

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

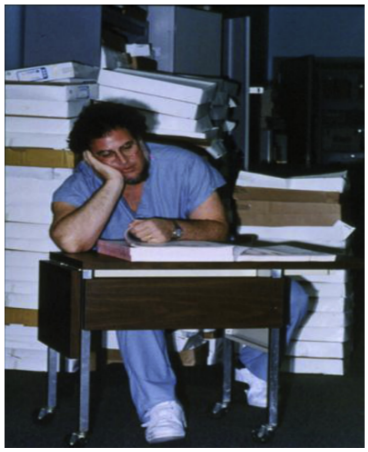
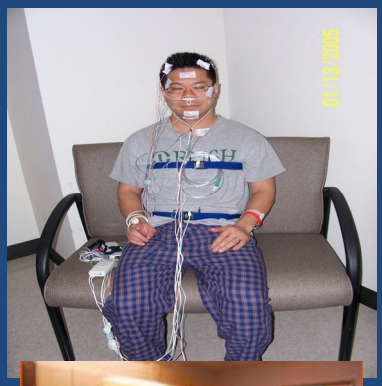
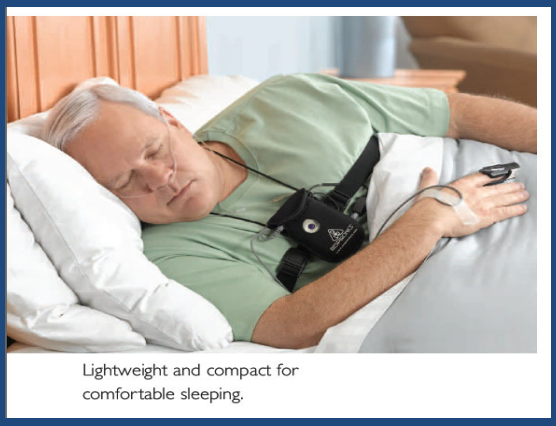


Fig. 4. Author surrounded by a sea of paper polysomnograms.

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.

Unattended four-channel sleep apnea shown to be an accurate tool in the di to severe obstructive sleep apnea. We with severe obstructive sleep apnea hypopnea index (AHI) determined b apnea recording. The mean AHI wa began nasal continuous positive airwa at home empirically with 5 cm to 7.5

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.

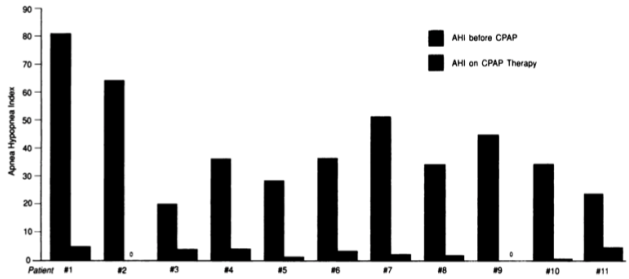


FIGURE 2. Apnea-hypopnea index (AHI) before and after home self-titration of nasal continuous positive airway pressure (CPAP). The AHI in each patient returned to normal (≤5) on treatment at home. Two patients had an AHI equal to 0 (patients 2 and 9) on NCPAP at the time of follow-up recording.

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.

1993

HST - $600
PSG - $1800

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[2] 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.

- "Although polysmonography is a good method for diagnosing OSA, there is NO evidence that it is more accurate than simple investigations done at lower costs in the patient's home."

2007 – Do we need a diagnostic test?

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.

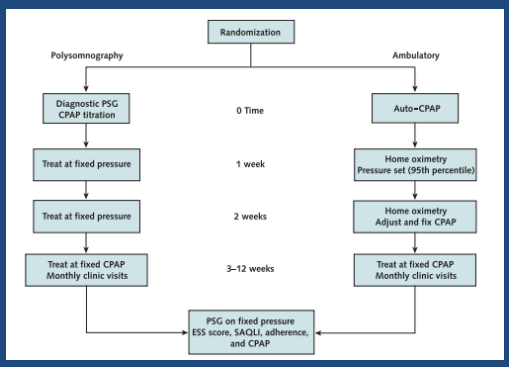
Measurements: Apnea–hypopnea index on CPAP, ESS score, quality of life, and CPAP adherence.

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: Attended PSG/CPAP titration
  - Group 2: AUTO CPAP (no diagnostic)
  - Similar PAP adherence rates



AASM - 2007

ICSM
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.*

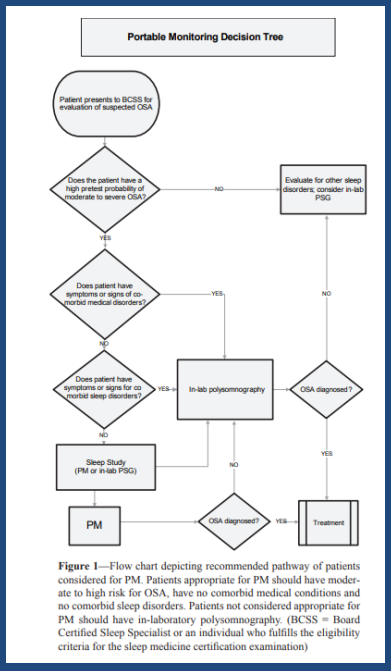


Figure 1—Flow chart depicting recommended pathway of patients considered for PM. Patients appropriate for PM should have moderate to high risk for OSA, have no comorbid medical conditions and no comorbid sleep disorders. Patients not considered appropriate for PM should have in-laboratory polysomnography. (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

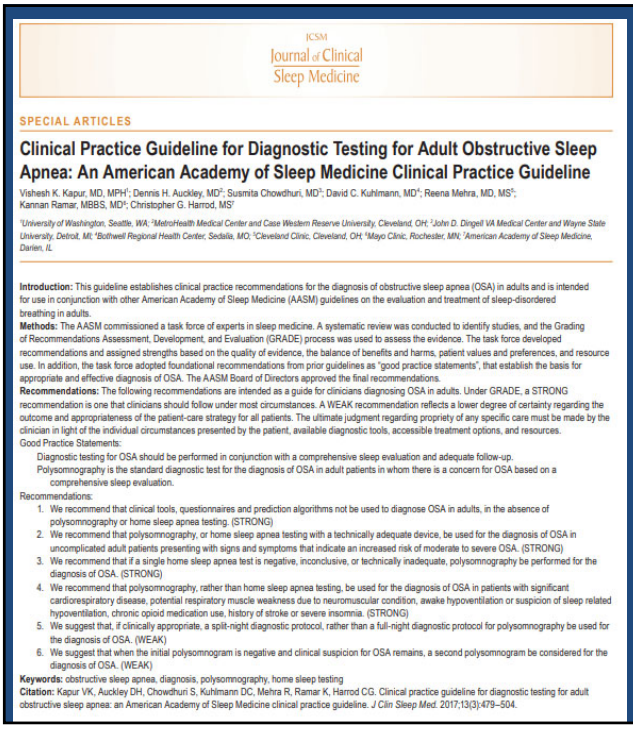
YES → In-lab PSG

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

Objectives

- 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 and sleep medicine?



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.

2017 - Updated Clinical Practice Guidelines

1. Uncomplicated adults with signs and symptoms of moderate to severe OSA
   - PSG or HSAT
2. If HST is negative, inconclusive, technically inadequate…
   - PSG should be performed
1. 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.

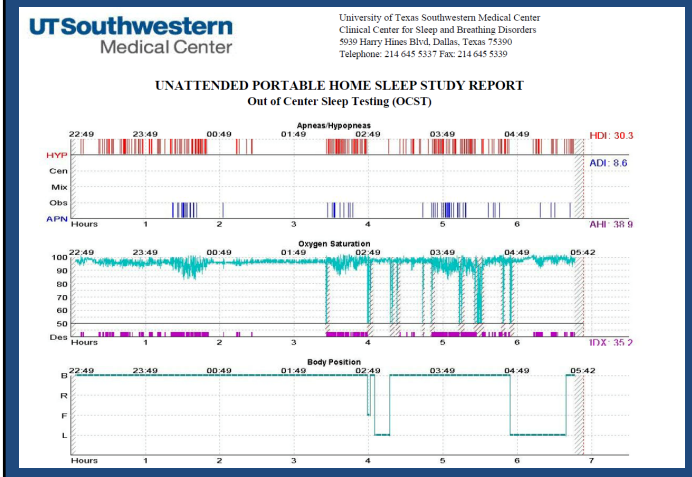
Citation: Rosen IM, Kirsch DB, Carden KA, Malhotra RK, Ramar K, Aurora RN, Kristo DA, Martin JL, Olson EJ, Rosen CL, Rowley JA, Shelgikar AV; American Academy of Sleep Medicine Board of Directors. Clinical use of a home sleep apnea test: an updated American Academy of Sleep Medicine po statement. *J 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 — HDI: 30.3 — ADI: 8.6 — AHI: 38.9
Oxygen Saturation — IDX: 35.2
Body Position

- 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

Denial of PAP titration lab study (95811)

- 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 PAP titration (95811)

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

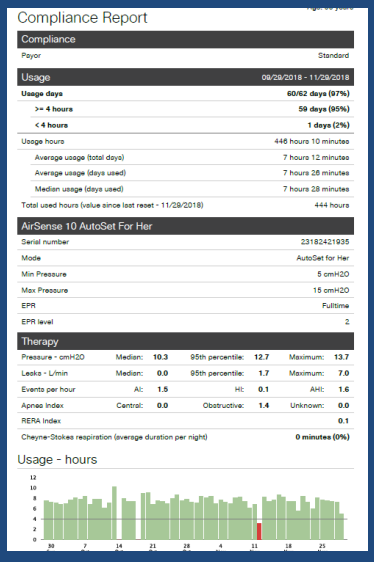
Cigna covers in-facility PSG (CPT code 95811) for PAP titration, following a prior diagnostic study as medically necessary in an adult (age 18 or older) when ALL of the following criteria are met:

- 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 (2%/night)
  - 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	58 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 28 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 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

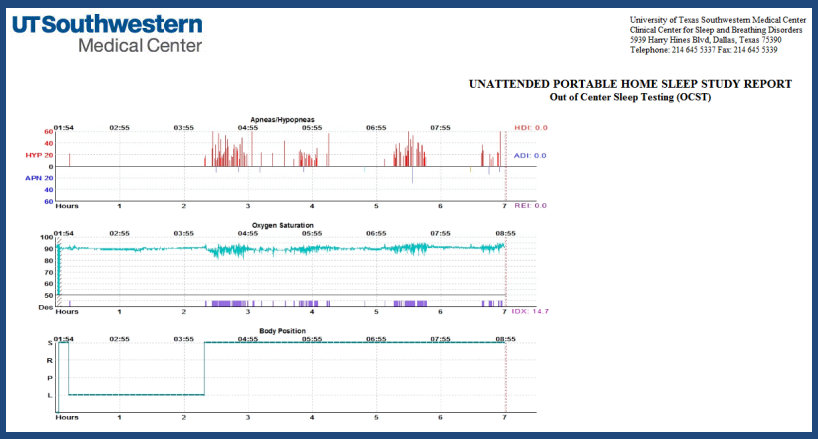
Citation: Morgenthaler TI; Aurora RN; Brown T; Zak R; Alessi C; Boehlecke B; Chesson AL; Friedman L; Kapur V; Maganti R; Owens J; Pancer J; Swick TJ; Standards of Practice Committee of the AASM. Practice parameters for the use of autotitrating continuous positive airway pressure devices for titrating 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
  - CHF/LVAD, PH, Advanced lung disease, peritoneal dialysis
  - 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 AUTO 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 b "to be determined"

UT Southwestern Medical Center

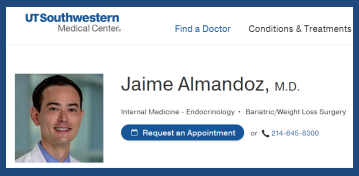
The case for HST
Weight loss/bariatric surgery clinic referrals
70% "positive" rate

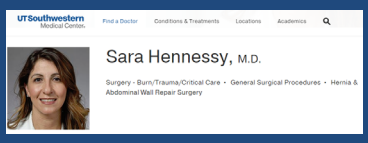

UT Southwestern Medical Center

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)

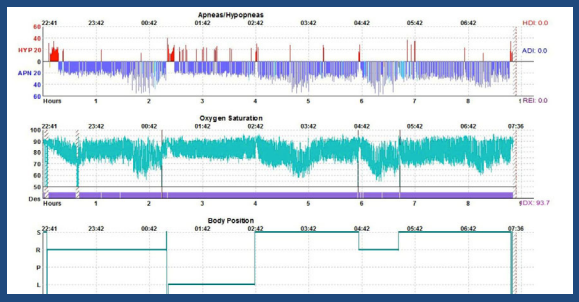
Apneas/Hypopneas
Oxygen Saturation
Body Position





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

Severe OSA - Hypoxemia



- 51 year old man
  - Obesity, Hyperlipidemia, Diabetes
- HST
  - AHI of 96
  - Time < 88% for 433 minutes (90% night)
- 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, vitamin

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

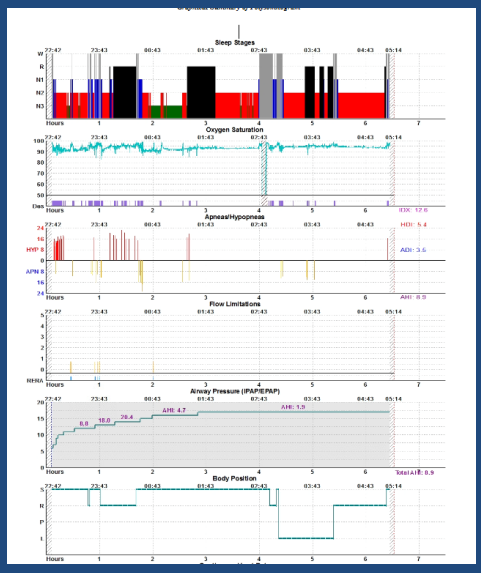
INTERPRETATION:

* 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

HST → Review The Raw Data

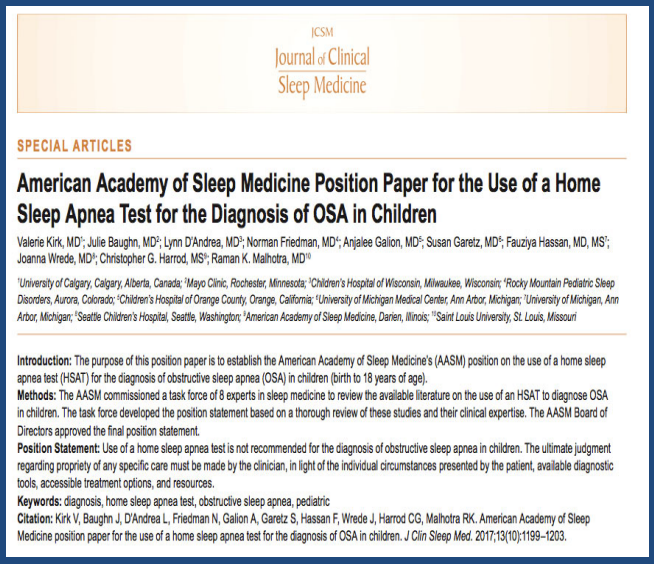
- 66 year old man, BMI 40, suspected OSA, polycythemia
- HST
  - AHI 2.55
  - 325 minutes → time less than 88%, average SpO2 86%
- Are we finished?
- Attended PSG
  - AHI was 3
  - Hypoxemia was confirmed
- Diagnosis: emphysema, secondary polycythemia, Tx: supplemental oxygen

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.

HST → Not recommended for pediatrics



JCSM
Journal of Clinical Sleep Medicine

SPECIAL ARTICLES

American Academy of Sleep Medicine Position Paper for the Use of a Home Sleep Apnea Test for the Diagnosis of OSA in Children

Valerie Kirk, MD[1]; Julie Baughn, MD[2]; Lynn D'Andrea, MD[3]; Norman Friedman, MD[4]; Anjalee Galion, MD[5]; Susan Garetz, MD[6]; Fauziya Hassan, MD, MS[7]; Joanna Wrede, MD[8]; Christopher G. Harrod, MS[9]; Raman K. Malhotra, MD[10]

[1]University of Calgary, Calgary, Alberta, Canada; [2]Mayo Clinic, Rochester, Minnesota; [3]Children's Hospital of Wisconsin, Milwaukee, Wisconsin; [4]Rocky Mountain Pediatric Sleep Disorders, Aurora, Colorado; [5]Children's Hospital of Orange County, Orange, California; [6]University of Michigan Medical Center, Ann Arbor, Michigan; [7]University of Michigan, Ann Arbor, Michigan; [8]Seattle Children's Hospital, Seattle, Washington; [9]American Academy of Sleep Medicine, Darien, Illinois; [10]Saint Louis University, St. Louis, Missouri

Introduction: The purpose of this position paper is to establish the American Academy of Sleep Medicine's (AASM) position on the use of a home sleep apnea test (HSAT) for the diagnosis of obstructive sleep apnea (OSA) in children (birth to 18 years of age).
Methods: The AASM commissioned a task force of 8 experts in sleep medicine to review the available literature on the use of an HSAT to diagnose OSA in children. The task force developed the position statement based on a thorough review of these studies and their clinical expertise. The AASM Board of Directors approved the final position statement.
Position Statement: Use of a home sleep apnea test is not recommended for the diagnosis of obstructive sleep apnea in children. 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.
Keywords: diagnosis, home sleep apnea test, obstructive sleep apnea, pediatric
Citation: Kirk V, Baughn J, D'Andrea L, Friedman N, Galion A, Garetz S, Hassan F, Wrede J, Harrod CG, Malhotra RK. American Academy of Sleep Medicine position paper for the use of a home sleep apnea test for the diagnosis of OSA in children. *J Clin Sleep Med.* 2017;13(10):1199–1203.

- 2017
  - Position Paper – AASM

Reasons:

1. Insufficient evidence, currently
2. Technical feasibility concerns
   - TUCASA study, hooks up by technologists at home
   - 90 % success rate, caregivers?
3. Lack of ability to score arousals and hypoventilation

Objectives

- 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 and sleep medicine?

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?

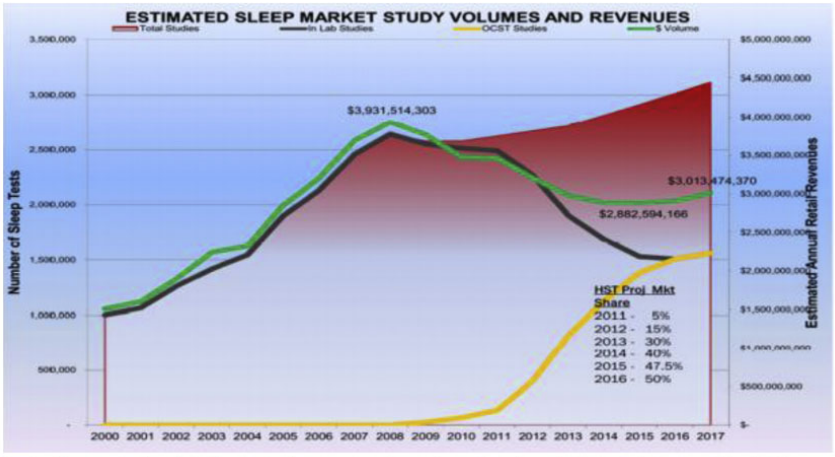


Fig. 6. Changes in the clinical use of polysomnography and predicted trends from T. Crabtree of Health Strategy Partners. (*From* Crabtree T. Sleep 2014 what to expect – how to prepare. Presented at The Business of Sleep October 29 & 30, 2014, Bear Mountain, NY. Health Strategy Partners. Available at: 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.

Is the attended PSG truly the gold standard?

JCSM
Journal of Clinical Sleep Medicine

SCIENTIFIC INVESTIGATIONS

Predictors of Obstructive Sleep Apnea on a Home Sleep A Negative Attended Polysomnography

Katie Lipatov, MD; Adam Hayek, DO; Shekhar Ghamande, MD; Carl Boethel, MD; Wencong Chen, PhD; Shirley Jone

Baylor Scott and White Health, Central Division, Temple, Texas

Study Objectives: A home sleep apnea test (HSAT) is an acceptable alternative to polysomnography (PSG) for the diagnosis of obstructive sleep apn (OSA) in patients with high pretest probability without certain comorbidities, such as severe pulmonary disease, congestive heart failure, or neuromusc weakness. Current guidelines recommend repeat in-laboratoary PSG in those with an initial negative PSG and high clinical suspicion for OSA. This retrospective study evaluated predictors of OSA on HSAT in patients who had a negative PSG.

Methods: Electronic medical records were reviewed on 206 patients who underwent an in-laboratory PSG followed by HSAT at the Baylor Scott and W Sleep Institute. Of these patients, 141 were included in the study. Clinical patient characteristics, PSG data, and HSAT data were obtained.

Results: A total of 141 patients had a negative PSG and underwent a subsequent HSAT. Of these patients, 83.7% had a positive diagnosis on HSAT, a defined by respiratory event index greater than or equal to 5 events/h, using the 4% oxygen desaturation criteria, (64.5% mild, 17.7% moderate, 1.4% se and 16.3% had a negative HSAT. Older age and hypertension predicted the diagnosis of OSA made on HSAT in patients with an initial negative PSG.

Conclusions: This retrospective study illustrates that there are patients for whom PSG gave a false-negative study. Patients who had negative PSG ar positive HSAT are more likely to be older and have the diagnosis of hypertension. Sleep physicians may consider repeat testing with HSAT in patients v negative PSG and clinical symptoms of OSA.

Commentary: A commentary on this article appears in this issue on page 1839.

Keywords: home sleep apnea test, obstructive sleep apnea, polysomnography

Citation: Lipatov K, Hayek A, Ghamande S, Boethel C, Chen W, Jones S. Predictors of obstructive sleep apnea on home sleep apnea test after a nega attended polysomnography. *J Clin Sleep Med*. 2018;14(11):1889–1894.

JCSM
Journal of Clinical Sleep Medicine

COMMENTARY

Physics and Alchemy

Comment on Lipatov et al. Predictors of obstructive sleep apnea on home sleep apnea test after a negative attended polysomnography. *J Clin Sleep Med*. 2018;14(11):1889–1894.

Michael P. Coppola, MD

NovaSom Inc., Glen Burnie, Maryland

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.

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 with severe obstructive sleep apnea who had an apnea-hypopnea index (AHI) determined by unattended sleep apnea recording. The mean AHI was 41 (SD, 17.5). We began nasal continuous positive airway pressure (NCPAP) at home empirically with 5 cm to 7.5 cm of pressure for several nights. We then adjusted the level of NCPAP after telephone interview with the patients and their significant others. The level of NCPAP was increased by 2.5-cm increments until the patients reported cessation of snoring and symptom improvement. The mean NCPAP was 8.0 cm (SD, 1.4). We repeated the overnight sleep apnea recording while on NCPAP in all patients at home to determine their response to therapy. All 11 patients had documented return of their AHI to normal (mean AHI, 2.4; SD, 1.6). Statistically significant improvement was noted in the number of obstructive apneas, hypopneas, total respiratory events, and the AHI. Follow-up data confirmed that patients had improvement in their symptoms and remained compliant with therapy (mean follow-up = 18 months; SD, 10.2). No serious complications were encountered when NCPAP was introduced in an unattended setting. We were able to diagnose and treat these patients in an entirely outpatient setting.

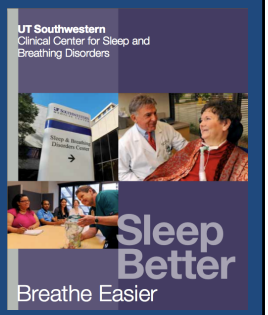
(Chest 1993; 104:19-25)

AHI = apnea-hypopnea index; OSAS = obstructive sleep apnea syndrome; NCPAP = nasal continuous positive airway pressure; RDI = respiratory disturbance index; REM = rapid eye movement

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

Home Sleep Testing and Telemedicine
Kaiser and the Veterans Affairs

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.).

Abstract

Rationale: Automated telemedicine interventions could potentially improve adherence to continuous positive airway pressure (CPAP) therapy.

Objectives: Examining the effects of telemedicine-delivered obstructive sleep apnea (OSA) education and CPAP telemonitoring with automated patient feedback messaging on CPAP adherence.

Methods: This four-arm, randomized, factorial design clinical trial enrolled 1,455 patients (51.0% women; age, 49.1 ± 12.5 yr [mean ± SD]) referred for suspected OSA. Nine hundred and fifty-six underwent home sleep apnea testing, and 556 were prescribed CPAP. Two telemedicine interventions were implemented: *1)* web-based OSA education (Tel-Ed) and *2)* CPAP telemonitoring with automated patient feedback (Tel-TM). Patients were randomized to *1)* usual care, *2)* Tel-Ed added, *3)* Tel-TM added, or *4)* Tel-Ed and Tel-TM added (Tel-both).

Measurements and Main Results: The primary endpoint was 90-day CPAP usage. Secondary endpoints included attendance to OSA evaluation, and change in Epworth Sleepiness Scale score. CPAP average daily use at 90 days was 3.8 ± 2.5, 4.0 ± 2.4, 4.4 ± 2.2, and 4.8 ± 2.3 hours in usual care, Tel-Ed, Tel-TM, and Tel-both groups. 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 ($P = 0.10$). Medicare adherence rates were 53.5, 61.0, 65.6, and 73.2% in usual care, Tel-Ed, Tel-TM, and Tel-both groups (Tel-both vs. usual care, $P = 0.001$; Tel-TM vs. usual care, $P = 0.003$; Tel-Ed vs. usual care, $P = 0.07$), respectively. Telemedicine education improved clinic attendance compared with no telemedicine education (show rate, 68.5 vs. 62.7%; $P = 0.02$).

Conclusions: The use of 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.

Clinical trial registered with www.clinicaltrials.gov (NCT02279901).

Keywords: disease management; patient compliance; telehealth

SLEEP DISORDERED BREATHING

Remote Ambulatory Management of Veterans with Obstructive Sleep Apnea

Barry G. Fields, MD, MSEd[1,2]; Pratima Pathak Behari, MD[3,4,5]; Susan McCloskey, CRNP[3]; Gala True, PhD[3]; Diane Richardson, PhD[3]; Arwin Thomasson, PhD[3,6]; Danijela Korom-Djakovic, PhD[1,7]; Keith Davies, BSEE[8]; Samuel T. Kuna, MD[3,4,5]

[1]Division of Pulmonary, Allergy, Critical Care, and Sleep Medicine, Emory University, Atlanta, GA; [2]Atlanta Veterans Affairs Medical Center, Decatur, GA; [3]Philadelphia Veterans Affairs Medical Center, Philadelphia, PA; [4]Division of Sleep Medicine, Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA; [5]Center for Sleep and Circadian Neurobiology, Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA; [6]Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA; [7]Independent Researcher, Philadelphia, PA

Study Objectives: Despite significant medical sequelae of obstructive sleep apnea (OSA), the condition remains undiagnosed and untreated in many affected individuals. We explored the feasibility of a comprehensive, telemedicine-based OSA management pathway in a community-based Veteran cohort.

Methods: This prospective, parallel-group randomized pilot study assessed feasibility of a telemedicine-based pathway for OSA evaluation and management in comparison to a more traditional, in-person care model. The study included 60 Veterans at the Philadelphia Veterans Affairs Medical Center and two affiliated community-based outpatient clinics. Telemedicine pathway feasibility, acceptability, and outcomes were assessed through a variety of quantitative (Functional Outcomes of Sleep Questionnaire, dropout rates, positive airway pressure [PAP] adherence rates, participant satisfaction ratings) and qualitative (verbal feedback) metrics.

Results: There was no significant difference in functional outcome changes, patient satisfaction, dropout rates, or objectively measured PAP adherence between groups after 3 months of treatment. Telemedicine participants showed greater improvement in mental health scores, and their feedback was overwhelmingly positive.

Conclusions: Our pilot study suggests that telemedicine-based management of OSA patients is feasible in terms of patient functional outcomes and overall satisfaction with care. Future studies should include larger populations to further elucidate these findings while assessing provider- and patient-related cost effectiveness.

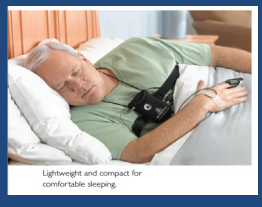
Keywords: obstructive sleep apnea, telemedicine, home sleep testing, auto-titrating positive airway pressure

Citation: Fields BG, Behari PP, McCloskey S, True G, Richardson D, Thomasson A, Korom-Djakovic D, Davies K, Kuna ST. Remote ambulatory management of veterans with obstructive sleep apnea. *SLEEP* 2016;39(3):501–509.

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 Attended Polysomnogram will always be needed…

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 ***
   - Training sleep staff

Sleep Medicine = Beyond Sleep Apnea…

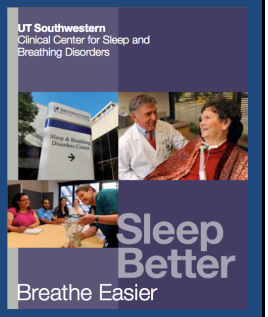
6. Who will serve as the stewards of sleep care?

   - 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, pediatrics, neuromuscular disorders
     - Neurology/sleep
   - Allied health
     - Advanced practice providers
     - Sleep technologists – education
     - Respiratory therapists

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

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